Achieve better fixation in osteoporotic bone

White paper

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1. Executive summary

Osteoporotic patients have an increased risk to sustain a fracture even after low-energy trauma, and the treatment of such fractures may result in a complication associated with fracture fixation. The reason for this potential complication is that the underlying factors contributing to the fracture also persist during fracture fixation. Implant fixation is aggravated by the same rarefied bone structure, by a diminished network and thinned trabeculae that altogether predispose to low-energy fractures.

Fracture healing is age-dependent but is not directly linked to the degree of osteoporosis. Therefore, these fractures may undergo normal repair processes if the fragments can be stabilized throughout the normal healing time. Conventional screws exhibit a linear correlation between screw anchorage and both cortical thickness and cancellous bone density. This linear relationship leads to inferior screw anchorage in osteoporotic bone. The resulting failure mode is screw pull-out or cut-out under repeated loading. It mainly affects metaphyseal and spinal screw fixation but can also occur when diaphyseal fractures are stabilized in patients with advanced stages of osteoporosis.

To verify this biomechanical problem and to support clinical observations with reliable data, a systematic literature review focusing on randomized-controlled trials was already performed in 2008. The goal of this literature review was to a) quantify the medical need by identifying fixation problems in osteoporotic patients, and to b) quantify the development gap via limitations of current technology detected in biomechanical tests.

For this white paper, a reverse approach was used by identifying potential fixation complications first and relating them to compromised bone structure both in vivo and in vitro afterwards. However, this approach carries the risk of overassessing the number of complications attributed to impaired bone status if other factors like inadequate surgical technique cannot be ruled out.

The search had been limited to publications within the last 20 years and combined different approaches of Pubmed search using MeSH and several terms of implant failure with different descriptions of poor bone quality. Of the 852 references found in the Pubmed searches, 373 duplicates were identified and excluded. The titles of 641 references were screened for eligibility. 334 references remained for primary abstract review. During

reference list screening, few additional papers were identified. Finally, 81 articles were selected for the extraction of data.

In the selected references, clinical complications related to poor bone quality were reported for dorsal, transpedicular fixation in the osteoporotic spine, lumbo-sacral fixation, proximal and distal humerus fracture, proximal femoral fracture and ankle fracture. They not only resulted from conventional screws or screw-based implants like the proximal femoral nail but also from new fixation solutions like cement augmentation. The reports range from single observations in all indications to complication rates higher than 30%, e.g. in transpedicular stabilization or proximal humerus fracture. The failure mechanisms in screw-based fixation most commonly reported were screw perforation, loosening or cut-out. Other described mechanisms like Z-phenomenon are limited to the proximal femur only, but screw perforation and cut-out are common to all indications.

Biomechanical tests show that thresholds exist for several indications where conventional implants and even new solutions fail, e.g. at the proximal femur or vertebral body. At the same time, these tests indicate that new fixation solutions have the potential to improve implant fixation significantly. This includes improved implant design, cement augmentation, and dowel-like solutions.

Indications that might benefit from improved anchorage are transpedicular and ventral spinal stabilization, proximal and distal humerus fracture, proximal femoral fracture, proximal tibia fracture and salvage operations after failed initial screw fixation. Enhancement of implant/bone interface via a nylon cavity plug or ultrasound-based amelioration technology may serve as predicate devices.

New technologies have to respect the local biological environment. Especially, solutions targeting the implant/bone interface should not introduce a new safety risk, e.g. via material degradation or fragmentation. Local blood supply has to remain undisturbed and invasivity during insertion as well as removal has to be considered. If new material is utilized, full biological compatibility has to be ensured. Additionally, potential interactions with the combination device, e.g. screw, have to be determined.

Because clinical data based on high levels of evidence are rare in this field of research, biomechanical data are mandatory to show the efficacy with a reasonable cost-benefit ratio. If large biomechanical data are available, they may already convince clinicians to use the

new solution as a rescue tool if screw change is needed or in patients where screw failure is anticipated.

2. Introduction

2.1. The challenge: Fracture fixation in osteoporotic bone

Osteoporotic patients suffer twice. On the one hand, they have an increased risk to sustain a fracture, even after low-energy trauma. This fact is well-known and became part of the current osteoporosis definition [1]. As a consequence, the scientific community has focused on fracture prevention for decades. On the other hand, the same conditions which result resulting in a low-energy fracture may aggravate fracture fixation and potentially lead to fixation complications. The same rarefied bone structure, diminished network and thinned trabeculae that altogether predispose to low-energy fracture aggravate implant fixation [2].

Several factors were responsible for neglecting this obvious link for decades. Whereas the prevention of low-energy trauma is the domain of health care providers such as rheumatologists, gynaecologists or physiotherapists, the treatment of fractures is in the core competence of trauma surgeons and orthopaedic surgeons. While for the first entity, osteoporosis associated fractures represent an endpoint in a clinical study, they are the starting point for treatment for the other entity. Even specialty societies did not find common ground for many years. Additionally, many trauma and orthopaedic surgeons were lacking the necessary knowledge to diagnose, manage and treat the underlying osteoporosis. So, a recent survey revealed a substantial deficit concerning training and knowledge about the management of prevention, diagnosis, and treatment of osteoporosis and fragility fractures. The majority of survey participants requested educational opportunities to become qualified for a better disease control [3]. As a consequence, several initiatives like the *Bone and Joint Decade*, the *Fracture working group* of the *International Osteoporosis Foundation* but also the *Clinical Priority Program "Fracture Fixation in osteroporotic bone"* of the *AO Foundation* were initiated to close this gap.

The overarching goal of these new inititatives is the co-management of the underlying osteoporosis in parallel to adapted fragility fracture treatment. Any next fracture should be prevented by initiating an appropriate osteoporosis diagnostics and subsequent treatment. Several of these treatments are potentially beneficial for fracture fixation and healing [4]. For instance, treatment with bisphosphonate in experimental models is associated with increased callus size and mineralization, reduced callus remodeling, and improved mechanical strength. Local and systemic bisphosphonate treatment may improve implant

fixation. Extensive experimental results for teriparatide indicate increased callus formation, improved biomechanical strength, a greater external callus volume and total bone mineral content and density.

In conclusion, fragility fractures require adjusted fracture fixation but also treatment of osteoporosis as the underlying disease. The principles of this combined approach have been summarized as orthogeriatric fragility fracture treatment [5]. New solutions for fracture fixation can take advantage from this combined orthogeriatric approach. Improved diagnostics will lead to better patient selection, pharmaceutical treatment of osteoporosis may enhance fracture fixation, and fall prevention will enable uneventful fracture healing.

2.2. Biomechanics of fracture fixation in osteoporotic bone

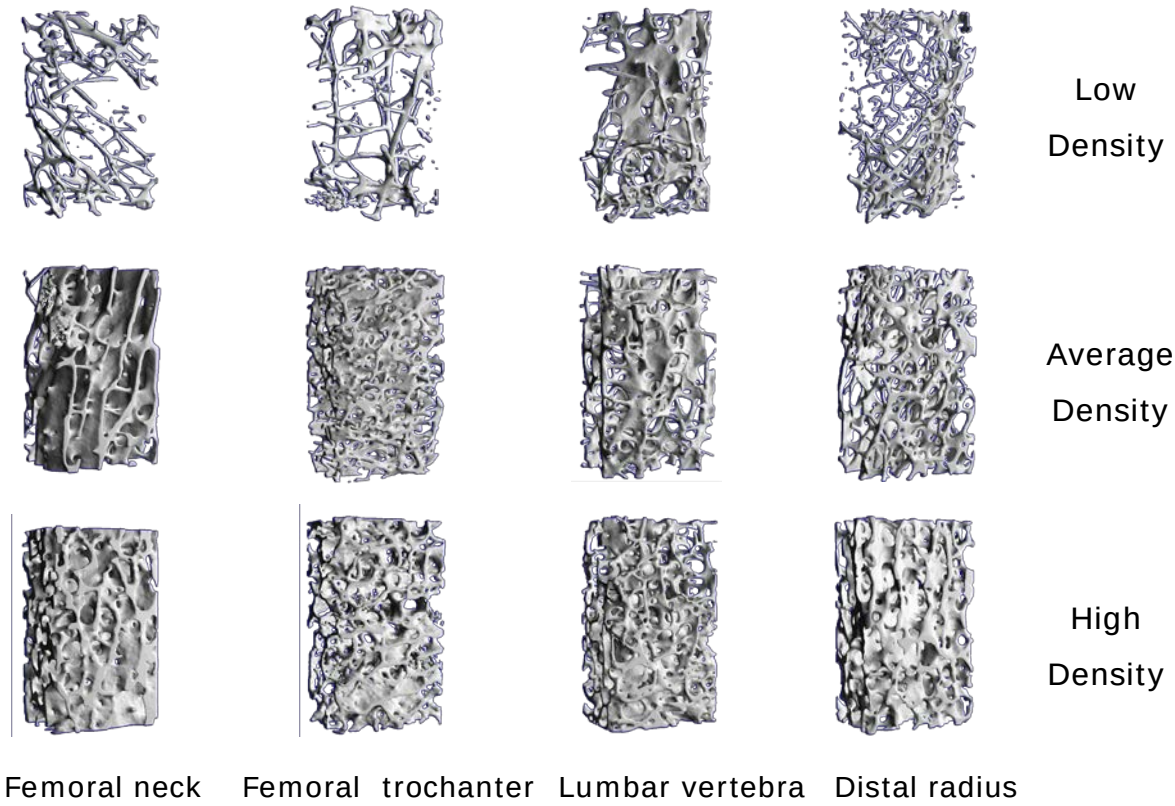
Traditional surgical fracture fixation devices which are attached to the bone, e.g. plates, rely on screws to fix the plate to the bone. These screws were developed decades ago based on generic assumptions about bone geometry [6].

At that time, neither diagnostic tools for measuring bone quality nor knowledge to adjust fracture fixation for different bone qualities were available. Screw design was adapted for two categories of bone: very dense bone, which corresponds to cortical bone, and less dense bone corresponding to trabecular bone. No further adjustements were made.

In the meantime, bone research has discovered the structural changes resulting from net bone loss caused by osteoporosis: The negative metabolic balance leads to trabecular thinning, widening of the trabecular distance, loss of connectivity and thinning of the cortex at later stages of the disease that predisposes to fragility fracture [1]. Due to the higher metabolic turnover, those structural changes first occur in the trabecular regions of the bone, especially in the metaphyseal bone and vertebrae (see figure 1).

Numerous biomechanical experiments have been performed that addressed the relation between different parameters of bone quantity and quality and implant anchorage [7]. For instance, it has been demonstrated that in regions with cortical thicknesses of less than 1.5 mm, cancellous density determines the ultimate pull-out load, while in regions with cortices of more than 1.5 mm, cortical thickness alone influences the holding capacity of a screw significantly [8].

Fig. 1: Change of bone structure at typical metaphyseal locations associated with decreasing apparent bone density (courtesy H. van Lenthe, AO CPP Fracture fixation in Osteoporotic Bone), reproduction only with agreement by author



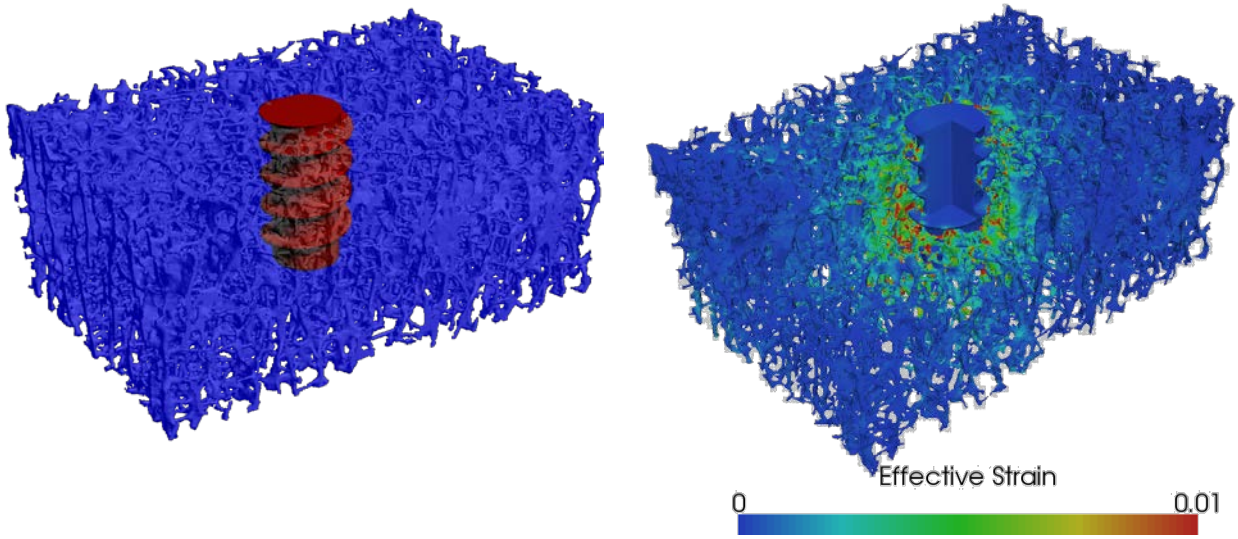
However, conventional screws exhibit a linear correlation between screw anchorage (pull-out and cut-out force) and both cortical thickness and cancellous bone density as demonstrated in parametric in vitro experiments [9]. This linear relationship leads to inferior screw anchorage in osteoporotic bone. The resulting failure mode is screw pull-out or cut-out under repeated loading. It mainly affects metaphyseal and spinal screw fixation but may also occur in diaphyseal fixation in advanced stages of osteoporosis.

Many groups have demonstrated this correlation in vitro. A significant correlation has been revealed between trabecular bone mineral density (BMD) and pull-out force at the proximal humerus [10]. It has also been shown that lumbar BMD significantly predicts failure of pedicle screws [11], and there have been several attempts to establish a threshold for failure, e.g. for instrumentation of lumbar vertebral body at an areal BMD of 0.22 g/cm^2 [12].

New investigations utilizing sophisticated methods of computersimulation have contributed to a better understanding of implant failure. With the support of the AO Foundation, a

number of parametric computer simulations have been carried out that demonstrated several principles of implant anchorage. It could be shown that **implant failure always starts in the peri-implant bone structure at the points of highest stress concentration** [13]. And it could also be demonstrated that conventional implant anchorage via screws significantly correlates with contact area (see figure 2) [14].

Fig. 2: Contact area of a screw in trabecular bone and resulting strain distribution (courtesy H. van Lenthe, AO CPP Fracture fixation in Osteoporotic Bone, reproduction only with agreement by author)

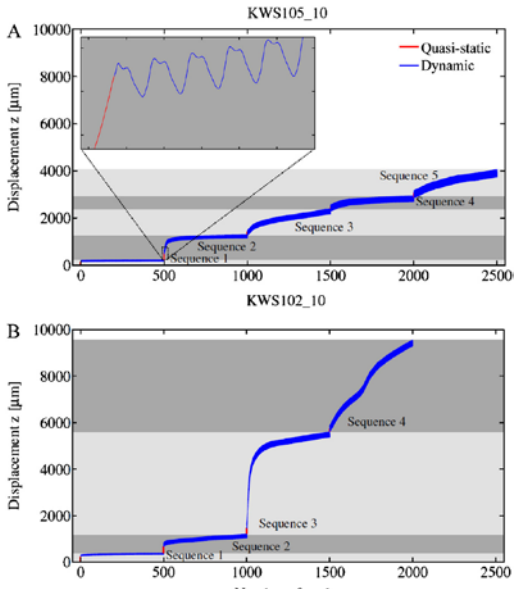


These findings explain the linear relation between anchorage of most conventional implants and bone quality. In rarefied bone structure as shown in figure 1, the contact area between implant and bone is decreased. Therefore, the remaining trabeculae have to transmit the full load resulting in higher peak stress and earlier failure. Only technical solutions that enable an equal load distribution at the implant/bone interface may counteract this linear correlation.

If a higher number of trabeculae are in contact, they withstand repeated loading, and resulting subsidence remains small. In case of only few available contact points, subsidence increases leading to macroscopic loosening and implant failure, as exemplified in a dynamic ramp test of hip screws in high- and low bone density specimens [14] (see figure 3).

Several technical solutions have been proposed to introduce new materials to enlarge this interface. They should not only increase the implant/bone interface but also reduce stress peaks, e.g. via sharp threads. The most common solution is bone augmentation with bone cement such as PMMA. It has been demonstrated that this method enhances implant anchorage thereby reducing the incidence of implant cut-out in osteoporotic bone. However, best results can be reached only in combination with a separate irrigation system [15].

Fig. 3: Displacement profiles of subsequent loading sequences for a high (A) and for a low (B) BV/TV specimen. Quasi-static displacement contributions are plotted in red, while dynamic migration is plotted in blue (Basler et al. 2013)



This approach illustrates the main challenge associated with bone augmentation. The augmentation material requires low viscosity during injection. This low viscosity contributes to distribution into spaces with least resistance. As a consequence, the augmentation material may flow into areas where it will not contribute to implant anchorage. In the worst case, it may extravasate into vessels or even the spinal canal [16]. **Controlled placement of any additional material between implant and bone may contribute to improved load transmission without increased risk for material related complication.**

Despite the described fixation problems, healing of a fracture is not directly impaired by the factor osteoporosis. The normal healing process results from the unique mammal rescue mechanism to heal a fracture by utilizing the developmental pathway of bone formation [17]. It is considered to mimic postnatal development independent of normal bone remodelling, where cartilage is formed first, replaced by unstructured bone and finally remodelled into lamellar bone [18].

Although fracture healing is age-dependent, it is not directly linked to the degree of osteoporosis [19]. Therefore, fractures may undergo normal repair processes if the fragments can be stabilized throughout the healing period.

2.3. Literature: Published patent review

A number of narrative reviews about implant fixation in osteoporotic bone have been published. Most of them focused either on technology exploration or in-vitro testing. For example, in a context-sensitive patent search 21 different fixation principles have been retrieved [20].

The three main principles identified for improved anchorage in osteoporotic bone were:

1. Improved anchorage technology
2. Optimized load sharing of the implant/bone construct
3. Augmentation of the implant/bone interface

Examples for the improved anchorage technology are **design adaptations** of the femoral head component like helical blades, implants that plastically deform during insertion, and claw-like technologies. All those technologies still have to demonstrate added value.

The most prominent example for **optimized implant/bone load sharing** is represented by the internal fixator. Since the screws act as bending beams and plates no longer have to be pressed against the cortex, less screw pull-out is observed. On top, all screws act as one anchorage unit minimizing the risk of single screw failure.

Augmentation of the **implant/bone interface** by different synthetic materials has become popular in recent years and has shown some promising results but also some caveats, which will be one topic of this white paper.

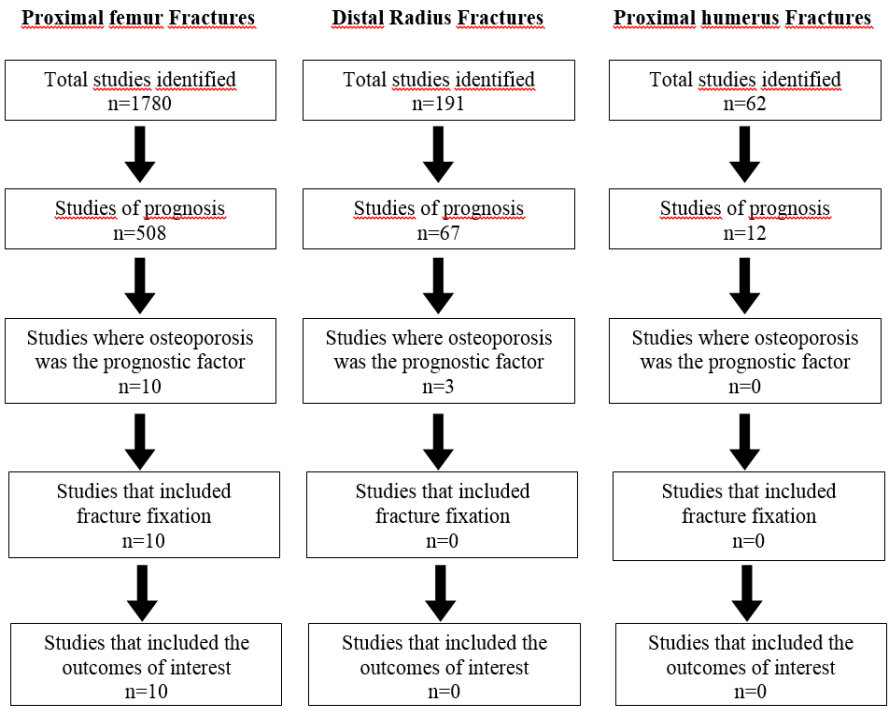
The authors of this patent-based review concluded that despite numerous patents **only a few solutions found their way into clinical testing**. It was suggested that not only biological compatibility, but also a lack of appropriate surgical instrumentation may limit clinical use. Therefore, every new approach should contain the **full surgical intervention including surgical instruments, guidance about the technique as well as appropriate teaching.**

2.4. Literature: Published review about the influence of osteoporosis on fracture fixation

The well-documented problems of implant anchorage in osteoporotic bone should be supported by clinical reports about an increased risk for implant failure in osteoporotic bone. If they are clinically relevant indeed, a number of high evidence level studies linking osteoporosis and implant failure could have been expected. Therefore, a systematic literature review has been initiated based on a AO CID led initiative as part of the AO Clinical Priority Program (AO CPP) "Fracture Fixation in osteoporotic bone" [7]. The review focused on identifying randomized controlled studies about fracture fixation at the proximal humerus, proximal femur and distal radius, where **any osteoporosis measure** was described **as a risk factor for implant associated complication**.

However, after reviewing 77 randomized controlled trials with 9504 fractures the authors had to conclude: "In contrast to biomechanical evidence that local osteoporosis affects anchorage of implants, this could not be reproduced in clinical studies, due to the lack of accurate osteoporosis assessment, missing complication definitions and heterogeneous inclusion criteria in these studies. Prospective studies are required that address specifically the correlation between local bone status and the risk of fixation failure." Those studies have been initiated, and first results have been published

Fig. 4: Data reduction during the systematic search (Goldhahn J et al, 2008)



recently [21]. The described lack of randomized studies investigating the correlation between compromised bone structure and reduced anchorage strength led to a modified search structure for this white paper.

3. Methods, data sources and search strategy

A reverse approach was used by identifying potential fixation complications first and relating them afterwards to compromised bone structure. However, this approach carries the risk of overassessing the number of complications attributed to impaired bone status if other factors like inadequate surgical technique cannot be ruled out.

With respect to a meeting between Woven Orthopedic Technologies and AO CID in Boston on June 6, 2014 and a number of phone calls between the persons involved, the search characteristics for clinical data was set up as following:

Population	Intervention	Comparator	Outcome	Time
Age: 50+ Inclusion: Fragility/osteoporotic fracture Exclusion: Comminuted fx Pathological fx Defect fx Infected fractures	Surgical treatment with a medical device - Screws - Nails - Plates Exclusion: External fixators Key wires Arthroplasty	Not applicable	Complications related to fracture fixation and/or low bone quality	Not applicable

The search should only include papers published during the last 20 years (01.01.1994 - September 2014).

A number of Pubmed searches were performed between August 4 and September 8, 2014. According to the agreed study proposal between Woven Orthopedic Technologies and GCTM of July 7, 2014, the search terms (osteoporosis OR osteopenia), (osteosynthesis OR spondylolisthesis), (pullout OR pull-out OR "pull out"), (non-union OR nonunion OR "non union" OR pseudarthrosis), ("implant failure" or "screw failure") were used for a first screening search in various combinations and with adding wildcard search for the terms "loose*", "break*"; excluding terms were "arthroplasty" and "augment*". This search

retrieved 293 hits. During a title screening the lack of potentially important information was obvious. Therefore, wild card search, exclusions and the terms (osteosynthesis OR spondylolisthesis) were deleted, and the terms (cutout OR "cut out" OR cut-out) OR (cut-through OR "cut through" OR cutthrough) were added. This search retrieved 577 hits.

To cover important surgical fixation techniques without limitations, the next search was performed using the MeSH terms ("Fracture Fixation"[Mesh] OR "Surgical Fixation Devices"[Mesh] OR "Jaw Fixation Techniques"[Mesh] OR "Orthopedic Fixation Devices"[Mesh] OR "Internal Fixators"[Mesh]) in various combinations with the above mentioned complications; the term "fragility" was added.

In a next approach and with respect to the research question of interest, the term "interface" was included. During further searches and because of more than 500 results, the next searches were limited to humans and to English papers.

Finally, the results of the following searches were exported into an Endnote database:

Search (osteoporosis OR osteopenia) AND (osteosynthesis OR spondylolisthesis OR spinal fixation OR dental) AND (loose* OR pullout OR pull-out OR "pull out" OR non-union OR nonunion OR "non union" OR pseudarthrosis OR break* OR "implant failure" or "screw failure") NOT arthroplasty) NOT augment*	293
Search ("Fracture Fixation"[Mesh] OR "Surgical Fixation Devices"[Mesh] OR "Jaw Fixation Techniques"[Mesh] OR "Orthopedic Fixation Devices"[Mesh] OR "Internal Fixators"[Mesh]) AND (cutout OR cut-out OR "cut out" OR loosening OR breakage OR pullout OR pull-out OR "pull out" or "cut through") AND (osteoporosis OR osteopenia OR fragility)	245
Search (bone screw failure) AND (osteopenia OR "fragility fracture" OR osteopor*) NOT arthroplasty Filters: Humans	315
Search bone screw interface osteopor* Filters: Humans	45

Of the 852 references imported from Pubmed, 373 duplicates were found and excluded. The titles of 641 references were screened for eligibility. To further focus the search results, articles were excluded if they were:

- Older than 1980
- Single case reports
- Overview articles without clinical results
- Foreign language articles if the abstract did not contain relevant data
- References from other research areas
- References about arthroplasty
- References about techniques (in imaging, lab, simulation, testing)

- References with no association to fracture fixation, e.g. drug treatment
- About non-unions caused by reasons such as infections or bone defect
- Diagnostic studies

Finally, **334** references remained for primary abstract review.

Parallel to the Pubmed searches, a contextual search was performed using Gopubmed. The searches included the same MeSH terms and the words “loosening”, “breakage”, “pullout” (different way of typing), "cut through", “osteoporosis”, “osteopenia”, “fragility” and excluded children, adolescents and animals. The feature “Top concepts” and the “Knowledge base” were used to exclude irrelevant findings (e.g., prosthesis failure), and the hits were screened and cross checked against the findings from the Pubmed search.

In general, the following publications were excluded: Comments on articles and author replies, articles with published Errata due to scientific fraud, articles on hypotheses or opinions without data.

Articles without an abstract and a title that not clearly contained the items “osteoporosis/osteoporotic” or “fragility fractures” were excluded. Only articles in English were ordered for further review.

All relevant clinical abstracts and articles were screened regarding the type of surgical treatment, the number and type of complications, bone quality and potential cause of failure.

All relevant biomechanical abstracts and articles were screened regarding the type of implant, the indication, test setup, bone quality influence and complications.

For abstracts covering the research question on a high level, the Pubmed feature “related articles” was used to identify additional publications. If reference lists of relevant articles contained promising unidentified papers older than 20 years, these abstracts were checked as well and the inclusion period for these selectd, cited articles was extended to papers published from 1990 onwards. Finally, **354** publications were included into the database and reviewed.

The results were used to create two tables as presented in the section Results. If promising full text papers reporting about osteoporotic/fragility fractures did not contain any additional

information allowing conclusions about the influence of bone quality on fracture fixation complications, these studies were not used for the table and not mentioned in this review.

4. Results

4.1. Clinical evidence overview

While the previous systematic literature review of AO CID focusing on **osteoporosis as a predictive factor for implant complication** could not demonstrate a significant association, a **reverse approach was used for this presented review**. Clinical reports about implant failure were related to an underlying osteoporosis.

More than 8 years after the previous literature review of AOCID has been published, the evidence in this area of research is still low. Papers of high evidence levels investigating implant failure and osteoporosis/bone quality are lacking. Although more clinical reports could be identified, there is a r**isk of overestimation due to other contributing factors** such as surgical technique or specific design features. As a result of this search, most of the reports are either retrospective analyses or prospective cohort studies. Often, mandatory information regarding the assessment of bone status and the definitions and evaluation of complications is lacking. Therefore, true complication incidence cannot be calculated and pooled. The substantial heterogeneity also prevents pooling of data, and the studies were only listed but not processed into summary risk estimations. Finally, 31 clinical reports with an evidence level III and IV were included, where differences in anchorage and subsequent complications were linked to bone quality (see table 1).

Additionally, one clinical review about the role of bone substitutes in hip fracture could be identified [22]. This review includes summary tables about biomechanical tests with bone substitutes as well as clinical reports.

The second search strategy focused on biomechanical implant tests, where implant failure was associated with bone quality. This was either any type of correlation or a threshold of bone quality such as microCT or bone quantity such as bone mineral density with implant failure. Only those publications were selected where a statistical association was tested. Generalization of those tests was aggravated by significant differences in test

setup, loading mode but also in assessment of bone quantity and quality. 50 studies were included for this review to support the insufficient clinical data.

Both searches help to **identify the development gap** which a new implant could fill. The clinical failure reports help to identify and quantify remaining unmet medical need. The biomechanical tests quantify the advantages and limitations of current engineering solutions. Together, they may serve as a **benchmark for further implant development**.

4.2. Unmet medical need (clinical complications)

Results are grouped according to indications from oldest to newest.

Table 1: Clinical complications associated with bone status

Indication	Implants	Clinical complications	Bone quality	Potential cause of failure	Study type & evidence level		Reference
			SPINE				
Geriatric odontoid fracture	Anterior screw fixation	12 patients with loss of correction, delayed union, or non-union	Clinical	Local bone status of the odontoid process	Retro-spective case series	IV	Osti et al. 2011 [23]
Anterior and posterior stabilization	Screw aug-mentation with calcium apatite cement	1/16 ventral screws still loose, 4/48 dorsal screws showed leakage	Clinical	Pedicle wall damage	Pro-spective cohort study	III	Wuisman et al. 2000 [24]
Lumbo-sacral fixation	Expandable pedicle screws	Only 86% fused, 3 screw breakages, 6 removed due to discomfort	Not specified	Screw breakage	Retro-spective case series	IV	Cook et al. 2001 [25]
Trans-pedicular stabilisation	Pedicle screws	Radiolucency around 18 screws	Clinical	No influence of insertional torque	Pro-spective cohort study	III	Ozawa et al. 2005 [26]
Trans-pedicular stabilisation	Cannulated pedicle screw with PMMA aug-mentation	Asymptomatic anterior cement extra-vasation in nine patients (39%), one asymptomatic PMMA pulmonary embolus and one wound infection	Not specified	Cement extra-vasation and PMMA bolus	Pro-spective cohort study	III	Frankel et al. 2007 [27]
Spinal compression fracture	Ventral and dorsal spinal stabilization	Late implants loosening in 5, subcutaneous wound infections in 4 patients	Clinical	Implant loosening	Retro-spective case series	IV	Chotigavanich et al. 2009 [28]
Spondylo-lysthesis	ALIF with or without anterior augmentatio n	One non-union and 3 screw migrations without augmentation, less subsidence with augmentation	Clinical	Subsidenc e without augment-tation	Pro-spective cohort study	III	Kim et al. 2010 [29]

Indication	Implants	Clinical complications	Bone quality	Potential cause of failure	Study type & evidence level		Reference
Trans-pedicular stabilisation	Fenestrated screws and PMMA aug-mentation	Two cement leakages with one transitory nerve root palsy and 3 extravasations into the spinal canal	Poor bone stock (un-specified)	Cement extra-vasation	Pro-spective cohort study	III	Amendola et al. 2011 [30]
Trans-pedicular stabilisation	Expandable and normal pedicle screws	20 expandable screws loose (4.1%) and two screws (0.4%) broken, 48 normal screws loose (12.9%)	Not reported	Screw loosening	Pros-pective cohort study	III	Wu et al. 2012 [31]
Trans-pedicular stabilisation	Pedicle screws with/without PMMA	Clear zones 9.4% vs. 71.4%, loss of correction 3 vs. 7.2°	Clinical	Screw loosening	Pros-pective comp. study	III	Sawakami et al. 2012 [32]
Trans-pedicular stabilisation	Cannulated pedicle screw with PMMA aug-mentation	Persistent left thigh pain due to cement leakage at the L1 level in one patient	Not specified	Cement extra-vasation	Retro-spective case series	IV	Chang et al. 2013 [33]
Trans-pedicular stabilisation	Pedicle screws with teriparatide, risedronate or placebo	Loosening 7-13% in teriparatide, 13-26% in risedronate and 15-25% placebo	Clinical	Radio-graphically defined loosening	Pros-pective comp. study	III	Ohtori et al. 2013 [34]
TRAUMA							
Intertro-chanteric hip fracture	Com-pression screw and adjunctive PMMA in the head-neck fragment.	1/21 failure in augmented vs. 10/17 in non-augmented group	Singh classi-fication	Lack of support	Retro-spective study	IV	Bartucci et al. 1985 [35]
Undisplaced femoral neck fracture	Per-cutaneous Knowles' pinning	17.6% complications	Singh classi-fication	Singh>3 or old age	Retro-spective study	IV	Lee et al. 1996 [36]
Intertro-chanteric hip fracture	Asiatic gamma nail	6 cut-outs in 60 fractures	Singh classi-fication	Large antero-posterior deviation of the lag screw	Pro-spective cohort study	III	Kawaguchi et al. 1998 [37]
Intertro-chanteric hip fracture	Dynamic hip screw	49 cases with radiographic failure, unstable fractures demonstrated more than 50% failure	Singh-index	Unstable fracture type	Retro-spective case series	IV	Kim et al. 2001 [38]
Intertro-chanteric hip fracture	Multiple pins	Adjusted hazard ratio 7.7 for subsequent hospitalization for revision surgery due to osteoporosis	ICD-code	Poor bone quality due to osteo-porosis	Retro-spective case series	IV	Spangler et al. 2001 [39]

Indication	Implants	Clinical complications	Bone quality	Potential cause of failure	Study type & evidence level		Reference
Proximal femoral fracture	Proximal Femur Nail (PFN)	11 (8%) screw cut-outs	Singh classi-fication	Screw perforation	Pro-spective cohort study	III	Hohendorff et al. 2005 [40]
Per-trochanteric femoral fracture	Per-cutaneous compression plate (PCCP, Gotfried) vs. Dynamic hip screw	Re-operation rate: DHS 4/18 [22 %] vs. PCCP 3/29 [10 %]	Singh classi-fication	Unstable fracture type	Pro-spective cohort study	III	Knobe et al. 2008 [41]
Per-trochanteric femoral fracture	PFNA vs. PFN	PFNA showed a decrease in post-operative implant-associated complications especially in osteoporotic bone	Singh classi-fication	Unstable fracture type	Retro-spective case series	IV	Penzkofer et al. 2009 [42]
Extra-capsular hip fracture	Femoral intramedullar y nailing	3.6% cut-out	Singh classi-fication	Tip-apex distance and poor fixation quality	Case – control study	III	Lobo-Escolar et al. 2010 [43]
Intertro-chanteric hip fracture	Short proximal femoral nailing	2 with Z, 1 with reversed Z effect, 6 with superior migration with varus collaps, 2 cut-out, 10 shortening >2cm, 7 irritations due to protruding screw		Screw perforation, loosening and cut-out	Retro-spective case series	IV	Gadegone et al. 2010 [44]
Intertro-chanteric hip fracture	Proximal Femoral Nail (PFN)	Screw cut-out in 4 reverse Z-effect in 3 and Z-effect in one patient	Singh-index	No sig. correlation to Singh but to clinical result	Cohort study	III	Akan et al. 2011 [45]
Intertro-chanteric hip fracture	PFNA with helical balde and PMMA augmenta-tion	No cut-out, cut through, unexpected blade migration, implant loosening or implant breakage within the study period	Clinically defined osteo-porotic		Cohort study	III	Kammerlander et al. 2011 [46]
Pubic symphysis	Locked symphyseal plates	3 implant loosening and 3 early failure, all resulting in loss of reduction	Clinical	Inaccurate insertion	Retro-spective case series	IV	Moed et al. 2012 [47]
Ankle fracture	Screws with bone void fillers	1 augmented, 1 non-augmented screw ra-diographically loose, 2 deep wound infections after 2 resp. 6 mo	Osteo-penic bone, where normal screws have failed	Implant/ bone interface two screws, infection unclear	Pro-spective open-label study	IV	Andreassen et al. 2004 [48]
Proximal humerus fracture	PlantTan Humerus Fixator Plate	4 screw penetrations and secondary displacement	Not reported	High age, bone quality	Retro-spective case series	IV	Sadowski et al. 2003 [49]

Indication	Implants	Clinical complications	Bone quality	Potential cause of failure	Study type & evidence level		Reference
Proximal humerus fracture	PHILOS	24 (11%) screw perforations, 3 implant dislocations (1.7%) Plate dislocations in 4 (2.4%) and 14 collapses of the humeral head	Not reported	Screw perforation, loosening and cut-out	Retrospective case series	IV	Kettler et al. 2006 [50]
Proximal humerus fracture	Locking compression plate (LCP	9 early back outs within 4 week	All patients osteoporotic	Screw perforation, loosening and cut-out	Retrospective case series	IV	Micic et al 2009 [51]
Proximal humerus fracture	PHILOS	53/150 (35%) patients with mechanical failure (loss of reduction and screw perforation)	All patients osteoporotic	Screw perforation, loosening and cut-out	Prospective cohort study	III	Kralinger et al. 2014 [21]
Distal humerus	Plate fixation	Screw loosening and plate failure at the lateral column	Not reported	Screw loosening	Retrospective case series	IV	Korner et al. 2005 [52]

Implant related complications associated with poor bone quality were reported for spinal as well as metaphyseal fixation. Most of the spinal complications were reported in posterior, transpedicular fixation [24, 34]; but fixation problems are also reported for ventral stabilization [29] as well as odontoid fixation [23]. Reports about almost all other metaphyseal locations indicate that screw fixation in osteoporotic bone is a generic problem complicated by local biomechanics. It is not surprising that proximal femur fractures, which experience high repetitive loads during fracture healing, often fail at the implant/bone interface.

Fixation problems resulted not only from conventional screws or screw-based implants like the proximal femoral nail but also from new fixation solutions like cement augmentation. The reports range from single reports in all indications (not included in the table) to complication rates higher than 30%, e.g. in transpedicular stabilization or proximal humerus fractures. The most common failure mechanism in screw-based fixation was screw perforation, loosening or cut-out. Other specific mechanisms like Z-phenomenon (*two lag screw intramedullary nail designs used for fixation of intertrochanteric hip fractures, in which the inferior lag screw migrates laterally and the superior lag screw migrates medially during physiologic loading*) are limited to the proximal femur, but screw perforation [45] and cut-out are common to all indications. Screw breakage seems very uncommon and was only noticed in transpedicular fixation [25, 53].

Most of the complications did not require re-operation but specific failures like cement extravasation into the spinal canal may lead to re-operation or persistent damage [33]. This finding is supported by a clinical review [22] which identified high re-operation rates for all cements except PMMA: For instance, more than half of 11 patients augmented with Bisphenol-a-glycidyl-demethacrylate had to undergo re-operation because of complications related to healing.

Newly developed implants like the PHILOS plate for the treatment of proximal humerus fracture but also expandable screws for transpedicular screws could not eradicate fixation failures in poor bone quality. They remain high with up to 35% in metaphyseal (proximal humerus) and vertebral bone and constitute an unmet medical need so far.

In conclusion, there remains unmet medical need despite new fixation solutions especially for transpedicular spinal fixation, proximal femoral fracture, proximal humerus fracture, and other metaphyseal fractures in osteoporotic bone.

4.3. Limitation of current technical solutions (biomechanical tests)

Results are grouped according to indications from oldest to newest.

Table 2: Biomechanical testing of current solutions and association with bone quality

Indication	Implants	Test setup	Bone quality	Results	Complications/ Conclusions	Reference
			SPINE			
Ventral spinal fixation	Ventral stabilization	Static pull-out	BMD with DEXA	Pullout force is the highest predictor for pullout force.		Lim et al. 1995 [54]
Ventral spinal fixation	Spiralblade vs. VentroFix vs. MACS-TL	Dynamic cyclic loading of 100, 200 and 400 N	All vertebrae osteoporotic	VentroFix highest, Spiral-Blade better results than other implants	SpiralBlade may offer advantage in osteoporotic vertebrae	Ferguson et al. 2002 [55]
Ventral spinal fixation	Ventral vs. added dorsal stabilization	6 degree-of-freedom loading device	QCT	Sig. influence of BMD on load displacement and range of motion threshold value for use of single ventral instrumentation is a BMD >0.22 g/cm		Knoller et al. 2005 [12]
Ventral spinal fixation	MACSTL(R) Twin Screw Concept and 2 prptotypes	6 degree-of-freedom loading device	QCT	Implant stability within each implant group was influenced by BMD and load bearing cross-sectional area.		Reinhold et al. 2006 [56]
Anterior cervical fixation	Standard vs. cannulated rescues scews with cement	Insertional torque and pullout	BMD	Higher insertional toque, trend to higher pullout, effect of increased holding strength more pronounced in the presence of low bone density		Pitzen et al. 2006 [57]

Indication	Implants	Test setup	Bone quality	Results	Complications/ Conclusions	Reference
Ventral spinal salvage fixation	Revision screw with/ without augmentation	Static pullout	DEXA normalized pairs	Revision of a smaller diameter bicortical to a larger diameter bicortical screw leads to a decrease in pullout strength (4-5 mm 40.1%, 5-7 mm 63.7%).		Behrend et al. 2013 [58]
Trans-pedicular fixation	Steffee plates, AO fixateur interne, Kluger fixateur interne	Cyclic loading	BMD	Measurement of equivalent mineral density correlates with the fixation strength of the intrapedicular screws		Wittenberg et al. 1991 [59]
Trans-pedicular fixation	Pedicle screws with diff. diameter / length	Insertional torque	BMD	Removing and replacing a pedicle screw in its original hole substantially decreases its mechanical fixation.		Polly et al. 1998 [60]
Trans-pedicular fixation	Pedicle screws with and without coupling	Static pullout	BMD	Improvement of pullout strength by screw coupling significant in a test group with BMD of more than 90 mg/ml but not below		Suzuki et al. 2001 [61]
Trans-pedicular fixation	Pedicle screws with and without cement	Static pullout	BMD	PMMA-assisted vertebroplasty can significantly increase pedicle screw pullout forces to levels exceeding the strength of cortical bone.		Sarzier et al. 2002 [62]
Trans-pedicular fixation	Cemented expandable screws	Static pullout	BMD	Sig. increase in pullout force in cemented expandable screws	Anchorage in poor bone quality possible	Cook et al. 2004 [63]
Trans-pedicular fixation	Pedicle screws with and without cement	Shear test after 5000 cycles	BMD	Augmentation sig. increases shear	Anchorage better in non-osteoporotic bone	Burval et al. 2007 [64]
Trans-pedicular fixation	Screws with different types of augmentation	Static pullout	microCT	Vertebroplasty sig. improved pullout, kyphoplasty not	Several extravasations	Becker et al. 2008 [65]
Lumbo-sacral fixation	Pedicle screws with and without cement	Cyclic loading and subsidence	Three bone quality groups	For BMD>0.7 g/cm3 screw fixation o.k., between 0.6-0.7 augmentation better then screw alone, below screw loosening in both groups		Zhuang et al. 2010 [66]
Revision of trans-pedicular fixation	Augmented and non-augmented screws	Axial pullout force after revision	QCT	Augmentation sig. increases pullout in revised screws	Extravasation into spinal canal	Bullmann et al. 2010 [67]
Trans-pedicular fixation	Sublaminar wires, pedicle screws, lamina claw hooks, or pedicle screws with wires	Static pullout	BMD	Fixation strength in the osteopenic group one-fourth of good bone quality, irrespective of the instrumentation used, pedicle base fracture most common failure mechanism		Paxinos et al. 2010 [68]
Trans-pedicular fixation	Expansive or pedicle screw with-/without augmentation	Static pullout	Normal, osteopenia, osteoporosis and severe osteoporosis	Augmented screws. sig. stronger	In severe osteoporosis no system sufficient	Gao et al. 2011 [69]
Trans-pedicular fixation	Standard vs. Expandable screws	Axial pullout	BMD	Expandable titanium pedicle screws demonstrated improved screw pullout stability compared with standard titanium screws in osteopenic or osteoporotic bone.		Vishnu-bhotla et al. 2011 [70]

Indication	Implants	Test setup	Bone quality	Results	Complications/ Conclusions	Reference
Trans-pedicular fixation	Cement pre-filling vs. cement augmented	Static pullout	No influence (uniform synthetic blocks)	Cement pre-filled screws had sig. higher pullout force	Pre-filling recommended	Chen et al. 2011 [71]
Trans-pedicular fixation	Standard and fenestrated pedicle screws with PMMA	Static pullout	Osteoporotic spines only	Augmentation increases sig. pullout force without correlation to volume		Pare et al. 2011 [72]
Trans-pedicular fixation	Cement aug-mentation with diff. volumes	Static pullout	Synthetic material resembling severe osteoporosis	Sig. correlation between cement volume and pullout force	Should be limited to 4ml due to cement leakage	Folsch et al. 2012 [73]
Trans-pedicular fixation	Straight vs. end-plate screw	Cephalo-caudal toggling followed by pullout	BMD	No difference but sig. correlation to insertional torque		Higashino et al. 2012 [74]
Trans-pedicular fixation	Overlapping (doubled) threads in the proximal part	Static pullout and fatigue testing	Low-porosity foam to mimic osteoporosis	New screws moderately increase pullout and fatigue	Mechanical performance depends on porosity	Brasiliense et al. 2013 [75]
Trans-pedicular fixation	Pedicle screw vs. customized with a distal expansion mechanism	Static pullout	BMD	Trend to higher failure load of expanded pedicle screws	More vertebral fractures at the vertebral body-pedicle junction in expanded screws	Koller et al. 2013 [76]
TRAUMA						
Per-trochan-teric fracture	Hip screw with/ without PMMA augmentation after irrigation	Step-wise fatigue testing	BMD	All of the nonaugmented specimens failed during testing, where 50% of the augmented specimens did not fail.		Von der Linden et al. 2006 [15]
Per-trochan-teric fracture	DHS with TSP, PFN and TGN	New test setup for unstable trochanteric fracture	Cut-off limit at 0.6g/cm^2 measured with pQCT	Implants survived fatigue above BMD threshold	Augmentation or design change recommended below 0.6g/cm^2	Bonnaire et al. 2007 [77]
Intertro-chanteric hip fracture	TGN system with/without biopolymer augmentation	Axial compression	PU foam to reproduce osteoporotic bone	Augmentation sig. increases failure load		Paech et al. 2010 [78]
Per-trochan-teric fracture	PFNA with blade and aug-mentation	Rotational stability and pullout resistance	QCT	Sig. increased tor-sional stability and pullout force	The higher the BMD, the lower was the effect of augmentation.	Erhart et al. 2011 [79]
Per-trochan-teric fracture	Intramedullary nail	Cyclic loading if an unstable trochanteric fracture	QCT	Incidence of cut out for BMD <250 mg/cm^3 0.55 (5 of 9) and for BMD >250 mg/cm^3, 0.05 (1 of 21)	For a BMD <250 mg/cm^3, high risk of fixation failure after surgical treat-ment of per-trochanteric fractures.	Konstan-tinidis et al. 2013 [80]

Indication	Implants	Test setup	Bone quality	Results	Complications/ Conclusions	Reference
Per-trochan-teric fracture	Dynamic hip screw	Image-guided failure assessment	extremeCT	Sig. correlation between bone volume fraction and implant migration	Implants migrate on a path of least resistance	Basler et al. 2013 [14]
Femoral fracture	External fixator with/ without pre-drilling	Static pullout	BMD	Osteoporosis, bicortical pin placement but not predrilling sig. influenced holding power	Bicortical placement rendered 69% greater holding power	Oliphant et al. 2013 [81]
Distal femoral fracture	Locking compression plate with/ without augmentation	Axial sinusoidal loading	Osteoporotic vs. non-osteoporotic bone model	Augmentation significantly reduced the cut-out distance in the osteoporotic models by about 67%, no statistical reduction following augmentation in the non-osteoporotic models		Wahnert et al. 2013 [82]
Proximal tibia	Cancellous screws	Pullout and cut-out testing	QCT density profile along screw axis	If cortical thickness <1.5mm, correlation with pullout/cut-out	Basis for new implant development	Seebeck et al. 2005 [8]
Ankle fracture fibula	Locking plate with/ without augmentation	Axial cyclic loading	BMD	Significant differences between augmented and non-augmented constructs		Panchbhavi et al. 2008 [83]
Ankle fracture tibia	Locking plate with/ without augmentation	Axial cyclic loading	BMD	No significant differences between augmented and non-augmented constructs		Panchbhavi et al. 2009 [84]
Ankle fracture fibula	Conventional contoured plate vs. locking plate	Torque to failure	pQCT	Locking plate showed a higher torque to failure, angle at failure, and maximal torque compared to the conventional plate, fixation with the locking plate was independent of BMD		Zahn et al. 2012 [85]
Proximal humerus	Cancellous screws in different regions	Cyclic loading and pullout	BMD in different regions	Pullout strength was lower in the superior-anterior region	Sig. correlation of trabecular BMD and pullout strength	Tingart et al. 2006 [10]
Proximal humerus	Cannulated screws with or without augmentation	Cyclic loading in varus or rotation	BMD	Sig. higher load to failure in augmented group, only non-augmented group has correlation between BMD and load cycles		Unger et al. 2012 [86]
Proximal humerus	Locked vs. conventional plate	Torsional loading around three axes	BMD	Locking superior, typical mode of failure loss of fixation in the humeral head occurring earlier in the conventional group		Roderer et al. 2013 [87]
Proximal humerus	Screws tightened to 50%, 70%, or 90% of the T(max)	Static pullout	BMD	Tightening screws beyond 50% T(max) does not increase pullout strength of the screw and may place bone at risk for damage that might result in loss of fixation.		Tankard et al. 2013 [88]

Indication	Implants	Test setup	Bone quality	Results	Complications/ Conclusions	Reference
Distal humerus	Perpendicular vs. parallel locking plate	Stiffness, plastic deformation and failure in torsion	BMD	Parallel locking plate system provided a significantly higher stability	Stability depends on bone quality in both systems	Stoffel et al. 2008 [89]
Olecranon	5 olecranon plates: Acumed, Synthes-SS, Synthes-Ti, US Implants/ITS, and Zimmer	Physio-logical cyclic arcs of motion and failure loading	BMD	No statistical difference between the groups, catastrophic failure of the bone-implant interface rather than in gradual implant loosening		Edwards et al. 2011 [90]
Distal humerus	Locking vs. non-locking plates	Dynamic loading of posteriorly placed plates	Osteoporotic cadavers	Improved mechanical performance over nonlocking plates in torsional cyclic loading in osteoporotic bone	Locking contributes to construct stiffness	Davis et al. 2012 [91]
Distal Radius	Cancellous vs. cortical vs. rescue screw	Static pullout	BMD, cortical thickness	No significant difference in pullout strength between cortical and cancellous screw, but sig. less for rescues crew, all. sig affected by bone density		Wall et al. 2010 [92]
Distal Radius	Volar plate with locking or hybrid screws	Axial compression	Normal, osteoporotic and overdrilled	No difference in construct stiffness and load at failure between the all-locking and hybrid constructs in the normal, osteoporotic, or over-drilled osteoporotic synthetic bone model		Sokol et al. 2011 [93]
Distal Radius	Volar plates with different screw configurations	Dynamic loading of an unstable distal radius	Not reported	Using more screws increases implant/bone stiffness but promotes screw penetration	Loss of reduction seems to be more relevant	Mair et al. 2013 [94]
Diaphyseal fixation	3.5 mm titanium cortical bone screw	Static pullout	microCT	Overall bone mass, thickness and the bone mineral density of the cortical layer predict pullout		Thiele et al. 2007 [95]
Diaphyseal fixation	Biplanar vs. linear screw configuation	Static torsional loading	Osteoporotic vs. non-osteoporotic surrogate	Biplanar screw configuration improves anchorage in all bone qualities		Denard et al. 2012 [96]
Screw revision	Nylon plug	Static pullout	BMD	Nylon plug increases pullout up to 3.2 times	Potential salvage implant	Drew et al. 2002 [97]
Screw revision	Re-insertion of 4 diff. screws	Pullout and pushout	PU foam to reproduce osteoporotic bone	Holding power directly correlated to bone density, thread design and number of threads engaging the bone, reinsertion reduces the ultimate pullout strength (4-30%)		Ramas-wamy et al. 2010 [98]

Biomechanical tests are motivated by clinical need. Therefore, similar indications are mimicked with the test setup. In-vitro tests are easier to standardize, better to control and more features can be studied. Research groups have focused on a) the generic understanding of implant/bone interaction, b) limitations with current solutions and c) added value of new solutions.

The influence of bone-specific parameters like cortical thickness and cancellous density [9], but also bone mass [95] has been demonstrated in simplified test setups. Image guided failure assessment has further contributed to our understanding how implants fail at the interface to bone [14]. All biomechanical results suggest that **implant anchorage correlates with the contact area at the interface between implant and bone**. This can be provided either by rather dense cortical bone or contact points of the trabecular network. Sufficient measures are cortical thickness and trabecular bone mass [9]. It could be demonstrated that in regions with cortical thickness greater than 1.5 mm the cortical bone contributes most whereas in regions with cortical thickness below 1.5 mm the trabecular network contributes more to screw anchorage [9]. Thresholds of minimal bone mass/density for appropriate screw anchorage were determined for several anatomic regions, e.g. the proximal femur [77]. In other words, there is a high change for failure of existing implants below those tresholds.

Several groups could demonstrate that changes in screw configuration or biomechanics alone (locking vs. non-locking screws) lead to significantly increased failure loads [56, 89, 91, 96]. Specific design adaptations like blades or hollow cylinders instead of screws further improve anchorage. This has been shown for ventral spinal stabilization [55, 56] as well as for proximal femoral fracture fixation [77]. However, this approach is limited by anatomical constraints such as pedicle diameter [75] and could lead to new complications such as iatrogenic fractures at the vertebral body-pedicle junction due to screw expansion [76].

With cement augmentation, screw anchorage can be increased up to 3.2 times compared to controls in osteoporotic bone [97]. This observation applies to most locations, especially metaphyseal and vertebral bone, but has not been demonstrated in ankle fractures at the tibia [84] and can also not compensate for poor bone quality in lumbosacral fixation [66]. Those findings indicate that cement augmentation significantly improves screw anchorage in many locations but has biomechanical limitations in severely osteoporotic bone. Leakage

of material as well as low shear strength of currently available bone cements both contribute to this finding.

Scew revision has been studied and described biomechanically. Screw re-insertion reduces ultimate pullout force by 4–30% [98]. Although this can be counteracted by augmentation, it increases the risk of cement extravasation, e.g. into the spinal canal [67]. Therefore, researchers have proposed to use other materials to improve the implant/bone interface.

A nylon plug increases pullout force up to 3.2 times [97]. This technical solution indicates that controlled placement of material at the implant/bone interface seems more effective than the injection of cement, which will follow the way of least resistance in the surrounding trabecular network.

Increased initial anchorage strength without biological side effect has been demonstrated with the new Constant Amelioration Process (CAP). The CAP technology employs ultrasonic energy to liquefy 70:30 poly-(l-lactide-co-d,l-Lacide) which enters the inter-trabecular space, leading to local reinforcement of the cancellous bone structure after solidification of the copolymer. The inventing group could demonstrate in-vivo safety utilizing a sheep model [99].

Implant anchorage can be improved by screw configuration, design modification and implant augmentation. Those measures cannot fully compensate for severely osteoporotic bone structure. **Therefore, there is room for new and improved fixation solutions in severely osteoporotic bone or complex conditions such as screw revision.**

4.4. Confounding factors

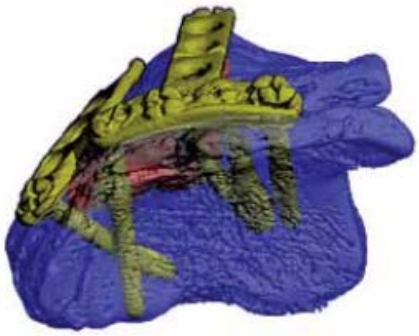
Screw position

Not only an implant's design but also the way it is implanted both influence anchorage. Influence of the screw position is well examined in hip fractures and significant predictors for screw cut-out have been established e.g. in intertrochanteric hip fracture [100]: It could be shown that the tip apex distance (TAD) measurement is reliable and patients with device cut-out have a significantly higher TAD. Additionally, poor fracture reduction was shown to be significantly related to a higher incidence of cut-out in univariate analysis. Central-inferior and anterior-inferior positions, after adjustment for tip apex distance and screw position,

can be significantly protective against cut-out. However, another study demonstrated that not the commonly used tip apex distance but a correct caudal-cranial lag screw position is the most important factor in preventing mechanical failure [101]. It has been shown that mechanical failure rates increased from 4.8% to 34.4% when the centre of lag screw was not in the second quarter of the head-neck interface line (the so-called “safe zone”). Lag screw insertion lower or higher than 11 mm of the head apex line was associated with failure rates of 5.5% and 18.6%, respectively. Multivariate logistic regression showed that lag screw insertion not within the “safe-zone” was associated with an Odds Ratio of 13.4. These results are supported by a retrospective cohort study which identified screw position as the only significant factor for hip screw cut-out [102]. Similar findings have been reported with the Asian gamma nail back in 1998 [37].

Screw alignment within an implant also plays a role in implant anchorage. Especially in osteoporotic bone, biplanar fixation of locking plates significantly increases anchorage compared to linear screw position [96]. Biplanar screw configuration improves the torsional strength of diaphyseal plate fixation relative to a planar configuration in both osteoporotic and normal bone. With biplanar fixation, unicortical screws provide the same fixation strength as bicortical screws in non-osteoporotic bone. Locked screws in angle stable constructs act as bolts. Screw pitch can therefore be reduced to a minimum (figure 5) [103].

Fig. 5: Illustration of three dimensional screw configuation at the distal radius imaged with XtremecCT, Scanco Medical AG Bassersdorf, Switzerland, reproduction only with permission of publisher (Goldhahn J et al, 2010)



Surgical technique

The best implant will not work if it is inserted in the wrong way. In a clinical study after its market introduction, the use of the new PHILOS for fractures of the proximal humerus has been investigated in 176 patients [50]. Primary screw perforations were found in 24 (11%) cases and axial deviations by more than 30 degrees in 11 (5%), and of 159 displaced tubercles, malreduction by more than 5 mm was found in 14 (9%) cases. On top, further implant dislocation was observed in 3 cases (1.7%), plate dislocation off the shaft in 4

(2.4%), and 14 collapses of the humeral head with secondary screw perforation were recorded.

Based on such results, it is mandatory to distinguish between surgery related complications and implant related complications. In many publications those two factors were not separated, leading to an overestimation of osteoporosis related failures. For the first time, such a more thorough assessment was made in an AO multicentre study about the influence of local bone density on the outcome of proximal humeral fractures treated with a locking plate [104]. The group used detailed definitions of implant failure and of appropriate surgical technique as well as independent radiological assessment. They demonstrated that the lack of medial support is the most predictive factor exceeding local bone density or other potential candidates [21].

Fracture characteristics

Several groups have shown that the underlying fracture type significantly contributes to the surgical result. Unstable intertrochanteric hip fractures associated with osteoporosis have been identified as the most predictive factor for radiographic failure [38]: The failure rate exceeded 50% when patients had been treated with a dynamic hip screw. These results are supported by another study of 103 consecutive patients with osteoporotic pertrochanteric femur fracture [41] demonstrating that mechanical complications especially occur in unstable fractures (re-operation rate: DHS 4/18 [22%], PCCP 3/29 [10%]), without correlation to the Singh index.

In proximal humerus fractures, it is known that remaining medial support is the factor of highest prognostic value [21].

Fracture biology

Although there is no evidence that fracture healing is impaired by an underlying osteroporosis, there are other biological factors that can impair the course of healing. Several factors have been identified that may delay or prevent fracture healing such as high age, smoking, metabolic diseases like diabetes and several drugs [17]. If a fracture does not heal within the anticipated time frame, repeated loading may exceed the fatigue life of the implant and will subsequently lead to either implant breakage or failure of the

implant/bone interface. Therefore, several attempts were made to accelerate fracture healing. So far, high-level human evidence for fracture healing acceleration is lacking [4].

Only screw position and surgical technique can be addressed out of the confounding factors. Fracture characteristics as well as fracture biology are predetermined. A **long-lasting sufficient primary fixation is the only logical response** to the biomechanical and biological challenges of the confounding factors.

4.5. Methodological limitations

The literature screening period included only the last 20 years. Full publications were checked only if they were written in English. This approach may exclude relevant findings from the German and French speaking community as well as from several Asian countries.

Despite the systematic approach, this literature search does not cover all potential publications. An extensive archive of biomechanical data is contrasted by only a few and low evidence clinical data. Since almost every biomechanical trauma research lab is performing mechanical tests, develops new solutions and proposes new principles, it would exceed the scope of this review and would not add additional value to include all in-vitro data into this white paper.

The clinical reports often did not focus on osteoporosis associated complications, did not report bone status and did not use standardized complication assessment. Most clinical studies focused on implant performance in a clinical cohort. Bone status associated complications were out of focus and only accidentially reported. Therefore, not all potentially relevant studies may have been be identified, and many studies found could not be used due to the lack of necessary information. As a result, studies that would contribute information may have been missed.

An additional limitation of this literature review is the lack of standardized search terms and descriptions of this field. There are no accepted mesh terms available that help to identify relevant articles in a reliable and way. As a result extensive screeing and selection by hand had to be utilized. This introduces another potential limitation of this review.

5. Discussion with focus on potential for new solution

In this chapter, we describe the development gap identified by mechanical testing and the medical need that will drive some subsequent proposals for new studies combined with necessary requirements for safety. Altogether it should serve as a base for study planning and development of a clinical strategy for the new patient solution. Biomechanical studies are required to adequately plan clinical studies and to demonstrate added value of the new solution on a mechanistic level first and on a functional level later.

5.1. Development gap

The easiest way to increase pull-out force is to increase the screw diameter [105]. Yet, this approach is often limited by anatomical constraints such as the smallest pedicle diameter and others. Avoidance of predrilling also increases screw purchase [106]. Specific thread designs may also contribute [75]. However, several authors found either bone quality thresholds where implants will fail [77] or linear relations between screw anchorage and bone density [9]. This would mean that low BMD will automatically lead to low values for screw anchorage.

Whereas bone cement augmentation may improve screw anchorage in several indications, it introduces a new safety problem. The clinical reports about cement extravasation into adjacent tissue, vessels, the spinal canal, or joints can lead to severe complications, e.g. paraplegia. Although vertebral body augmentation as well as augmentation of pedicle screws have demonstrated significant biomechanical benefit, they also come with a significant safety risk. The spatial distribution of currently available cement is hard to control during injection. The material will flow into areas with least resistance. If connections to the spinal canal or vessels exist, it will end up in these areas.

Since screw anchorage depends on the contact to the adjacent bone, this interface provides an opportunity to introduce another supporting material, which will increase the interface area and will bond the screw to the cortical bone and trabecular network. **New fixation solutions are required, which will work even in low bone quality**, ideally without correlation to BMD. A solution of **adding material at the interface between implant and bone that can be better controlled** would address an improved anchorage without increased safety risk.

Based on the identified development gap the following indications in osteoporotic bone can be addressed with a new implant solution:

1. Transpedicular spinal fixation (cervical, thoracic, lumbar)
2. Ventral spinal fixation at all levels
3. Lumbosacral fixation
4. Primary screw fixation in metaphyseal areas with poor bone stock
    a. Proximal and distal humerus
    b. Proximal and distal femur
    c. Proximal and distal tibia
5. Screw revision in all anatomic locations

5.2. Requirements for safety

Despite numerous patented approaches only a small number of new devices were introduced. Many engineering solutions are not compatible with the biological system [20]. Therefore, new technologies have to respect the local biological environment. Especially, solutions targeting the implant/bone interface **should not introduce a new safety risk**, e.g. via material degradation or fragmentation. New material should not:

1. damage the adjacent bone, e.g. via thermal reaction during hardening
2. cause local reactions, via local cytotoxicity or immunogenicity
3. systemic reactions
4. interact/crossreact with the implant
5. damage local blood supply, neither during insertion nor removal (iatrogenic)
6. change properties during the course of fracture healing, which may lead to degradation, corrosion or material fracture.

5.3. Potential predicate devices

A dowel-like concept [97], using a nylon cavity plug together with an applicator, has been described as one potential solution to improve the implant/bone interface. The developers could demonstrate increased pullout force up to 3.2 times of the controls in vitro. They recommend the device as an add-on for rescue operations in failed screws. However, no reports about clinical use could be identified.

Another potential solution [40] has recently been tested in-vivo, consisting of screws in combination with an ultrasound-based process named Constant Amelioration Process (CAP). The CAP technology employs ultrasonic energy to liquefy 70:30 poly-(l-lactide-co-d,l-Lacide) which enters the inter-trabecular space, leading to local reinforcement of the cancellous bone structure after solidification of the copolymer. A significant increase in insertion torque as well as good osseointegration could be shown. The primary application might be dental screw anchorage but also screw fixation in osteoporotic bone, according to the developers.

5.4. Biomechanical aspects

To show that the use of the new solution has added value, a pool of biomechanical data should be generated demonstating an increase of pull-out force. This could be shown in a variety of biomechanical tests including static testing, semidynamic ramp testing as well as cyclic loading and fatigue testing always with correlation to bone density or bone structure, and could be tested in combination with different screws such as pedicle screws, cancellous screws, cortical screws to better characterize the potential impact of the new solution. If this large biomechanical data is available, it may already convince clinicians to use the new solution as a rescue tool if screw failure is anticipated or screw change is needed.

5.5. Potential clinical studies

Clinical studies have to address efficacy and safety. In other words: the new solution leads to better fracture fixation without new or increased safety risk. Several key features may contribute to a successful clinical study in the field of interest:

5.5.1. Efficacy

- Clinical studies should be guided by in-vitro tests that have demonstrated biomechanical benefit in the target indication.
- Biomechanical superiority is expected to be more pronounced in poor bone stock. Therefore, local quality assessment, e.g. via pQCT or Densiprobe [107], will help to identify cases with potential for improved fixation with the new solution.

- Clear inclusion and exclusion criteria based on information about local bone quality and potential benefit of the new method will help to reduce variability in the groups and subsequently sample size.
- Pre-defined and validated endpoints, such as radiographically measured subsidence, are required to demonstrate efficacy. This may require automated image analysis or semi-quantitative rating by a group of external experts.
- Functional benefit should be measured via performance tests or patient reported outcome to quantify patient added value.
- Relevant time points for follow-up are necessary to demonstrate differences between conventional and new solutions. They have to be determined based on expected failure of conventional solutions.

5.5.2. Safety

- Anticipated complications based on the working principle should be defined prior to the study.
- Documentation should be standardized including information about potential actions taken, final outcome and assessment on top of the nature of the complication [108].
- An external, independent safety monitoring board should be established to ensure required study quality. It should generate a safety report that will be included in any publication.

5.5.3. Logistics

- Only sites with relevant case load and experience in the indication should participate.
- Participating surgeons have to standardize surgical technique throughout the trial.
- Sites need to have the necessary imaging technology and experience.

5.5.4. Potential study designs

Lumbar spinal fusion in patients with osteoporosis constitutes a valid target for a new screw fixation method. The study protocol of *Ohtori et al.* may serve as guidance for inclusion and exclusion criteria as well as for radiographic endpoints [34]:

- Key inclusion criterion
  - Patients aged 55 to 84 with diagnosed osteoporosis requiring lumbar fusion randomized to new or standard solution
- Key exclusion criterion
  - Previous spinal surgery, spondylolisthesis, tumor, infection or trauma
- Endpoints
  - Screw loosening determined by X-ray and or CT
  - Increase of insertion torque due to new solution (screw insertion first, removal and re-insertion together with new solution), determined with a torque meter
  - Change in back pain and function quantified via VAS and Oswestry Disability score
- Adverse event reporting according to pre-defined criteria and procedures
- Follow-ups at 3, 6, 9, and 12 months after surgery

Proximal humeral fracture in osteoporotic patients represents another potential indication due to the high failure rate and potential problems related to augmentation. The study protocol used by *Kralinger et al.* may serve as guidance for inclusion and exclusion criteria but modified endpoints are necessary [104]:

- Key inclusion criterion
  - Patients aged 55 to 84 with proximal humerus fracture and diagnosed osteoporosis randomized to new or standard solution
- Key exclusion criterion
  - Previous surgery, tumor, infection or trauma
- Endpoints
  - Screw loosening/penetration determined by X-ray
  - Increase of insertion torque due to new solution (screw insertion first, removal and re-insertion together with new solution)
  - Shoulder function quantified with patient reported outcome, e.g. SPADI
- Adverse event reporting according to pre-defined criteria and procedures
- Follow-ups at 3, 6, 9, and 12 months after surgery

Alternative approaches to demonstrate added value of the new screw sleeve technology are possible, especially for screw rescue or salvage procedures.

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7. List of abbreviations

µCT	Micro computed tomography
AO CID	AO Clinical Investigation and Documentation
AO CPP	AO Clinical Priority Program
BV/TV	Bone volume/trabecular volume
BMD	Bone Mineral Density
DHS	Dynamic Hip Screw
PFN	Proximal Femoral Nail
PMMA	Poly(methyl methacrylate)
pQCT	Peripheral quantitative computed tomography
QCT	Quantitative computer tomogram
SPADI	Shoulder Pain and Disability Index
TAD	Tip apex distance
TGN	Targon Gamma-Nail
TSP	Trochanter Support Plate

8. Abstracts

Abstracts of all studies cited in this review in alphabetical order.

Akan, K., et al. (2011). "Effect of osteoporosis on clinical outcomes in intertrochanteric hip fractures treated with a proximal femoral nail." J Int Med Res **39**(3): 857-865.

The effect of osteoporosis on clinical outcomes following surgical treatment of intertrochanteric hip fractures was investigated. A total of 80 patients aged 65-97 years with intertrochanteric hip fractures underwent insertion of a proximal femoral nail. Osteoporosis severity was measured using the Singh index in the unaffected hip. Screw cut-out occurred in four patients, reverse Z-effect in three patients and Z-effect in one patient. Four patients were lost to follow up. Clinical results were evaluated according to the Harris hip scoring system. The mean Harris hip score was 73.58 (range 25-100). When divided according to Singh index grade (I-II versus III-V), there were no significant differences in mean age, type of fracture, American Society of Anesthesiologists classification or frequency of technical failures between the two groups. The mean Harris hip score, however, was significantly lower in patients with grades I-II compared with grades III-V, suggesting that the **presence of osteoporosis had a negative effect on clinical outcome after hip fracture**.

Akesson, K., et al. (2013). "Capture the Fracture: a Best Practice Framework and global campaign to break the fragility fracture cycle." Osteoporos Int **24**(8): 2135-2152.

The International Osteoporosis Foundation (IOF) Capture the Fracture Campaign aims to support implementation of Fracture Liaison Services (FLS) throughout the world. INTRODUCTION: FLS have been shown to close the ubiquitous secondary fracture prevention care gap, ensuring that fragility fracture sufferers receive appropriate assessment and intervention to reduce future fracture risk. METHODS: Capture the Fracture has developed internationally endorsed standards for best practice, will facilitate change at the national level to drive adoption of FLS and increase awareness of the challenges and opportunities presented by secondary fracture prevention to key stakeholders. The Best Practice Framework (BPF) sets an international benchmark for FLS, which defines essential and aspirational elements of service delivery. RESULTS: The BPF has been reviewed by leading experts from many countries and subject to beta-testing to ensure that it is internationally relevant and fit-for-purpose. The BPF will also serve as a measurement tool for IOF to award 'Capture the Fracture Best Practice Recognition' to celebrate successful FLS worldwide and drive service development in areas of unmet need. The Capture the Fracture website will provide a suite of resources related to FLS and secondary fracture prevention, which will be updated as new materials become available. A mentoring programme will enable those in the early stages of development of FLS to learn from colleagues elsewhere that have achieved Best Practice Recognition. A grant programme is in development to aid clinical systems which require financial assistance to establish FLS in their localities. CONCLUSION: Nearly half a billion people will reach retirement age during the next 20 years. IOF has developed Capture the Fracture because this is the single most important thing that can be done to directly improve patient care, of both women and men, and reduce the spiralling fracture-related care costs worldwide.

Amendola, L., et al. (2011). "Fenestrated pedicle screws for cement-augmented purchase in patients with bone softening: a review of 21 cases." J Orthop Traumatol **12**(4): 193-199.

BACKGROUND: This prospective mixed cohort study was designed to evaluate the middle- to long-term purchase of cement-augmented pedicular screws in patients with poor bone quality. The growing number of surgical procedures performed in the spine has highlighted the problem of screws loosening in patients with poor bone stock due to osteoporosis and/or tumors. Different methods of increasing screw purchase have been reported in the literature, including polymethylmethacrylate (PMMA) augmentation. MATERIALS AND METHODS: From September 2006 to April 2008, 21 patients with a poor bone stock condition due to

osteoporosis or tumor underwent posterior stabilization by fenestrated pedicle screws and PMMA augmentation. Pain improvement and long-term clinical outcome were assessed by visual analogue scale (VAS) score and SF-36 health survey (SF-36) questionnaire. Implant stability was evaluated by plain radiography and CT scans performed three days after surgery and every three months thereafter. After the first 12 months, radiologic controls were taken once a year in all surviving patients. Complications were evaluated in all cases. RESULTS: All patients were clinically and radiographically followed up for a mean of 36 months. VAS scores and SF-36 questionnaires showed a statistically significant reduction in pain and improvement in the quality of life. No radiological loosening or pulling out of screws was observed. **In two cases, cement leakage occurred intraoperatively: one patient who suffered from a transitory nerve root palsy improved spontaneously, while the surgeon immediately removed the excess cement before setting in the other case. In three cases, the post-op CT scan revealed a small amount of cement in the canal without clinical relevance.** CONCLUSIONS: Fenestrated screws for cement augmentation provided effective and lasting purchase in patients with poor bone quality due to osteoporosis or tumors. No case of loosening was recorded after a mean follow-up of 36 months. The only clinical complication strictly related to PMMA screw augmentation did not require further surgery.

Andreassen, G. S., et al. (2004). "Use of a synthetic bone void filler to augment screws in osteopenic ankle fracture fixation." Arch Orthop Trauma Surg **124**(3): 161-165.

INTRODUCTION: Sufficiently stable constructs may be difficult to obtain with ankle fractures in patients with severe osteopenic bone. Augmentation of the osteosynthesis with a new synthetic bone void filler may help to solve this problem, and it can improve the clinical outcome. MATERIALS AND METHODS: A prospective, open-label study was performed in two surgical clinics in Norway. In 37 of 42 selected patients with Weber type B ankle fractures showing clinical and radiologic signs of osteopenic bone, at least one screw was found to be stripping during open reduction and internal fixation (ORIF). All the stripped screws were augmented with the bone void filler, and tightness was assessed clinically afterwards. All patients were followed up for 2 years. Successful healing of the fracture after 3 months and absence of radiographic movement of the augmented screws were assessed relative to the plate and the bone. Safety was assessed by recording adverse events and abnormal haematology findings. RESULTS: All 86 augmented screws were clinically tight after augmentation. After 3 months, all fractures healed, and **1 augmented and 1 non-augmented screw appeared to be radiographically loose. After 2 and 6 months, respectively, deep wound infections occurred in 2 patients (5%)**, necessitating antibiotic treatment, revision surgery and implant removal. After 2 years, all patients had resumed their normal daily activities, and none of the augmented screws showed signs of loosening. CONCLUSIONS: Augmentation of bone screws with this new synthetic bone void filler was an effective means of gaining screw anchorage. Screw stabilisation with the new synthetic bone void filler proved to be safe and effective in the ORIF of ankle fractures in patients with osteopenic bone.

Bartucci, E. J., et al. (1985). "The effect of adjunctive methylmethacrylate on failures of fixation and function in patients with intertrochanteric fractures and osteoporosis." J Bone Joint Surg Am **67**(7): 1094-1107.

In a retrospective review of eighty-two intertrochanteric fractures (twenty-nine stable and fifty-three unstable) in seventy-nine elderly, debilitated patients with associated advanced osteoporosis (Grade III or less by the system of Singh et al.), fifty-six were available for follow-up: twenty-eight that had been treated at the University of Illinois with an approximately anatomical reduction and compression-screw fixation and twenty-eight (in twenty-seven patients) that had been treated at the University of Chicago with an approximately anatomical reduction, compression-screw fixation, and adjunctive methylmethacrylate bone cement in the head-neck fragment. Follow-up analysis after an

average of thirty-four months for the group that had augmentation with cement and an average of twenty-six months for the uncemented group showed that for the eighteen stable fractures that could be followed the rates of complications of fixation were the same in the two groups, while for the thirty-eight unstable comminuted fractures that were followed the rate of complications of fixation was lower when adjunctive methylmethacrylate cement was used. Among the unstable fractures, one failure (in twenty-one fractures) in the cement-augmented group and ten failures (in seventeen fractures) in the uncemented group were due to failure of fixation (p less than 0.01). For reasons that are not clear, when the thirty-two patients with a healed fracture who could be evaluated for function were rated using the Iowa hip score, **the nineteen who were treated with adjunctive cement had significantly lower scores than did the thirteen who were treated without cement (76 +/- 16.5 compared with 92 +/- 12.1, p less than 0.01).**

Basler, S. E., et al. (2013). "Peri-implant bone microstructure determines dynamic implant cut-out." Med Eng Phys **35**(10): 1442-1449.

Dynamic implant cut-out is a frequent complication associated with surgical fracture fixation. In this in vitro study, we investigated the influence of the local trabecular bone microstructure on the rate and path of implant migration. Dynamic hip screws were implanted into six human femoral head specimens with a wide range of bone volume fractions. The specimens were subjected to image-guided failure assessment using physiological dynamic hip loading. Mechanical testing was used intermittently with high-resolution computed tomography scanning. A high correlation was found between the bone volume fraction and implant migration (R(2)=0.95). Profiles of the bone-implant interface were computed based on the positions of the screw and the femoral head. With a larger interface, the implant migration rate was smaller. The bone-implant interface was significantly smaller on the approximated screw migration path than if it had been on a straight line in loading direction. We thus hypothesize that implants migrate on a path of least resistance. This would indicate a relevant mechanism for targeted surgical intervention.

Becker, S., et al. (2008). "Assessment of different screw augmentation techniques and screw designs in osteoporotic spines." Eur Spine J **17**(11): 1462-1469.

This is an experimental study on human cadaver spines. The objective of this study is to compare the pullout forces between three screw augmentation methods and two different screw designs. Surgical interventions of patients with osteoporosis increase following the epidemiological development. Biomechanically the pedicle provides the strongest screw fixation in healthy bone, whereas in osteoporosis all areas of the vertebra are affected by the disease. This explains the high screw failure rates in those patients. Therefore PMMA augmentation of screws is often mandatory. This study involved investigation of the pullout forces of augmented transpedicular screws in five human lumbar spines (L1-L4). Each spine was treated with four different methods: non-augmented unperforated (solid) screw, perforated screw with vertebroplasty augmentation, solid screw with vertebroplasty augmentation and solid screw with balloon kyphoplasty augmentation. Screws were augmented with Polymethylmethacrylate (PMMA). The pullout forces were measured for each treatment with an Instron testing device. The bone mineral density was measured for each vertebra with Micro-CT. The statistical analysis was performed with a two-sided independent student t test. Forty screws (10 per group and level) were inserted. The vertebroplasty-augmented screws showed a significant higher pullout force (mean 918.5 N, P = 0.001) than control (mean 51 N), the balloon kyphoplasty group did not improve the pullout force significantly (mean 781 N, P > 0.05). **However, leakage occurred in some cases treated with perforated screws**. All spines showed osteoporosis on Micro-CT. Vertebroplasty-augmented screws, augmentation of perforated screws and balloon kyphoplasty augmented screws show higher pullout resistance than non-augmented screws. Significant higher pullout forces were only reached in the vertebroplasty augmented vertebra. The perforated screw design led to epidural leakage due to the position of the

perforation in the screw. The position of the most proximal perforation is critical, depending on screw design and proper insertion depth. Nevertheless, using a properly designed perforated screw will facilitate augmentation and instrumentation in osteoporotic spines.

Behrend, C., et al. (2013). "Biomechanical evaluation of anterior thoracic salvage screws in the osteoporotic thoracic spine." J Spinal Disord Tech **26**(6): E235-239.

STUDY DESIGN: Controlled, cadaveric implantation trial. OBJECTIVE: Evaluation of revision thoracic screw fixation: with revision from unicortical screws to bicortical screws, to larger diameter screws, and the addition of bone cement. SUMMARY OF BACKGROUND DATA: Limited data is available regarding the effect of salvage screws on fixation quality in the anterior thoracic spine. Biomechanical studies in the cervical spine and the lumbar spine demonstrate dramatic decreases in fixation in salvage situations. METHODS: Seventy-two cadaveric thoracic vertebrae from 6 specimens were DEXA scanned at T1-T12. A control screw and a second identical screw were placed in each segment. One screw was then removed and replaced with a revision screw. Varying screw diameter, the number of cortices, and the addition of 1.5 cm of bone cement was evaluated in a pairwise fashion. Comparisons were made using descriptive statistical analysis and a general linear statistical model. RESULTS: Bone mineral density had a significant effect on the pullout force. Pullout force did not vary significantly with control screw diameter. **Revision of a smaller diameter bicortical to a larger diameter bicortical screw resulted in a decrease in pullout strength for 4-5 mm screws by 40.1% (P=0.02) and 5-7 mm screws by 63.7% (P=0.05). When a 4 mm bicortical screw is revised to a 5 mm unicortical screw, the pullout force decreases by 67.7% (P<0.001).** There was a nonsignificant increase (44%) in pullout with revision of a unicortical 4 mm screw to a bicortical 4 mm screw. If a bicortical screw is revised to a unicortical screw with 1.5 cm of cement, the pullout strength is increased by 240% (P<0.001). CONCLUSIONS: **When the use of salvage screws is required, the surgeon should anticipate a significant decrease in the holding force compared with the original screw regardless of screw size unless a unicortical screw is revised to a bicortical screw or cement is added to the construct.**

Bonnaire, F., et al. (2007). "["Cutting out" in pertrochanteric fractures--problem of osteoporosis?]." Unfallchirurg **110**(5): 425-432.

BACKGROUND: Despite the use of intramedullary fixation devices for the stabilisation of intertrochanteric fractures, the rate of complications is still high. One of the main reasons for burdensome reinterventions in 9-15% of cases is the cutting out of the fixation device through both the spongious bone and the cortical bone at the apex of the femoral head. This phenomenon is strongly connected to the reduction of the fractures achieved, the technical performance of the operation with optimal implant positioning and the resistance of the trabecular bone in the femoral head against deformation by the fixation device. The latter is very low in cases of severe osteoporosis. To prevent the complication of cutting out, it seems sensible to find the limits of load-bearing capacity of individual osteoporosis-associated features (i.e. bone mineral density) at which special additional measures or other techniques for the treatment of these patients are desired. METHODS: In a first step a new biomechanical standard test for implants stabilizing unstable trochanteric fractures was developed, which would provide predictable results depending on bone mineral density. In a second step a cut-off limit was sought for the bone density in the proximal femur that would afford stable fixation as measured by QCT (quantitative computed tomography) and DEXA (dual-energy X-ray absorptiometry). RESULTS: The developed test is realistic; it can be used to study typical cutting out phenomena on cadaver femora. In an unstable fracture model (type A 2.3 of the AO classification), the implants DHS with TSP, PFN and TGN showed a stable long-term load-bearing capacity at a bone mineral density of >0.6 g/cm3. In 5 of 32 specimens a cutting out phenomenon could be demonstrated, in 4 cases if the bone mineral density of the proximal femur was below 0.6 g/cm3 as measured by DEXA, and in one case poor performance of the implant (short screw in the femoral head) was evident.

CONCLUSIONS: **In cases of bone density of >0.6 g/cm3 in the proximal femur (DEXA), the standard implants for the fixation of unstable trochanteric fractures could guarantee fixation without cutting out.** The critical value of sufficient bone density in our few cases seems to be around 0.6 g/cm3 as measured by DEXA. Further investigation is needed to define the limits of bone mineral density for a successful osteosynthesis. An appropriate augmentation of the trabecular bone of the femoral head or a new design of the central loading device could increase the load-bearing capacity and thus help to reduce the cutting out phenomenon. Another alternative could be the primary implantation of an endoprosthesis in the treatment of these patients.

Brasiliense, L. B., et al. (2013). "Characteristics of immediate and fatigue strength of a dual-threaded pedicle screw in cadaveric spines." Spine J **13**(8): 947-956.

BACKGROUND CONTEXT: Novel dual-threaded screws are configured with overlapping (doubled) threads only in the proximal shaft to improve proximal cortical fixation. PURPOSE: Tests were run to determine whether dual-threaded pedicle screws improve pullout resistance and increase fatigue endurance compared with standard pedicle screws. STUDY DESIGN/SETTING: In vitro strength and fatigue tests were performed in human cadaveric vertebrae and in polyurethane foam test blocks. PATIENT SAMPLE: Seventeen cadaveric lumbar vertebrae (14 pedicles) and 40 test sites in foam blocks were tested. OUTCOME MEASURES: Measures for comparison between standard and dual-threaded screws were bone mineral density (BMD), screw insertion torque, ultimate pullout force, peak load at cyclic failure, and pedicular side of first cyclic failure. METHODS: For each vertebral sample, dual-threaded screws were inserted in one pedicle and single-threaded screws were inserted in the opposite pedicle while recording insertion torque. In seven vertebrae, axial pullout tests were performed. In 10 vertebrae, orthogonal loads were cycled at increasing peak values until toggle exceeded threshold for failure. Insertion torque and pullout force were also recorded for screws placed in foam blocks representing healthy or osteoporotic bone porosity. RESULTS: In bone, screw insertion torque was 183% greater with dual-threaded than with standard screws (p<.001). Standard screws pulled out at 93% of the force required to pull out dual-threaded screws (p=.42). Of 10 screws, five reached toggle failure first on the standard screw side, two screws failed first on the dual-threaded side, and three screws failed on both sides during the same round of cycling. In the high-porosity foam, screw insertion torque was 60% greater with the dual-threaded screw than with the standard screw (p=.005), but 14% less with the low-porosity foam (p=.07). Pullout force was 19% less with the dual-threaded screw than with the standard screw in the high-porosity foam (p=.115), but 6% greater with the dual-threaded screw in the low-porosity foam (p=.156). CONCLUSIONS: Although dual-threaded screws required higher insertion torque than standard screws in bone and low density foam, dual-threaded and standard pedicle screws exhibited equivalent axial pullout and cyclic fatigue endurance. Unlike single-threaded screws, the mechanical performance of dual-threaded screws in bone was relatively independent of BMD. In foam, the mechanical performance of both types of screws was highly dependent on porosity.

Bullmann, V., et al. (2010). "Revision of cannulated and perforated cement-augmented pedicle screws: a biomechanical study in human cadavers." Spine (Phila Pa 1976) **35**(19): E932-939.

STUDY DESIGN: Biomechanical investigation of primary and revised cement-augmented pedicle screws in comparison with unaugmented screws. OBJECTIVE: To evaluate revision of cannulated pedicle screws and investigate cement-augmented and nonaugmented screws biomechanically, testing the torque of primary screws and axial pullout force of revised screws in cadaver vertebrae. SUMMARY OF BACKGROUND DATA: Cement augmentation increases the pullout force and stability of pedicle screws in vertebrae with low bone mineral density, but surgeons are concerned about complications during revision. METHODS: Bone mineral density was measured using quantitative computed tomography (CT) in 23 osteoporotic thoracolumbar junction vertebrae from human cadavers. Cannulated pedicle

screws, augmented with bone cement (on right) or unaugmented (left), were inserted into each vertebra. After CT control, extraction torque was measured and the pedicles were reinstrumented with larger-diameter screws. The right screws were augmented again, with another CT control, before pullout testing. RESULTS: Mean vertebral bone density was 52.6 mg/cm. No major screw malpositioning was observed on primary CTs. Cement leakage was observed anterolaterally and into the spinal canal. Mean maximal torque in augmented screws (1.2 Nm, SD: 0.6) differed significantly from nonaugmented screws (0.8 Nm, SD: 0.6). Screw removal did not lead to vertebral destruction. No relevant changes due to positioning or leakage were observed on CT after revision procedures compared with primary findings. Maximal pullout force in revised augmented screws (713.2 N, SD: 254.6) differed significantly compared with nonaugmented screws (554.0 N, SD: 296.5). Bone damage was observed in several vertebrae during pullout force testing in augmented screws. CONCLUSION: Revision of cement-augmented pedicle screws was feasible without bone destruction, and larger-diameter screws can be used in revision procedures. The pullout force after revision was significantly better in cement-augmented screws. During pullout testing, the cement-bone interface broke before the screw-cement interface in several vertebrae, fracturing the pedicles.

Burval, D. J., et al. (2007). "Primary pedicle screw augmentation in osteoporotic lumbar vertebrae: biomechanical analysis of pedicle fixation strength." Spine (Phila Pa 1976) **32**(10): 1077-1083.

STUDY DESIGN: Pedicle screw pullout testing in osteoporotic and control human cadaveric vertebrae, comparing augmented and control vertebrae. OBJECTIVE: To compare the pullout strengths of pedicle screws fixed in osteoporotic vertebrae using polymethyl methacrylate delivered by 2 augmentation techniques, a standard transpedicular approach and kyphoplasty type approach. SUMMARY OF BACKGROUND DATA: Pedicle screw instrumentation of the osteoporotic spine carries an increased risk of screw loosening, pullout, and fixation failure. Osteoporosis is often cited as a contraindication for pedicle screw fixation. Augmentation of the vertebral pedicle and body using polymethyl methacrylate may improve fixation strength and construct survival in the osteoporotic vertebrae. While the utility of polymethyl methacrylate has been demonstrated for salvage of screws that have been pulled out, the effect of the cement technique on pullout strength in osteoporotic vertebrae has not been previously studied. METHODS: Thirteen osteoporotic and 9 healthy human lumbar vertebrae were tested. All specimens were instrumented with pedicle screws using a uniform technique. Osteoporotic pedicles were augmented with polymethyl methacrylate using either a kyphoplasty type technique or a transpedicular augmentation technique. Screws were tested in a paired testing array, randomly assigning the augmentation techniques to opposite sides of each vertebra. Pullout to failure was performed either primarily or after a 5000-cycle tangential fatigue conditioning exposure. After testing, following screw removal, specimens were cut in the axial plane through the center of the vertebral body to inspect the cement distribution. RESULTS: Pedicle screws placed in osteoporotic vertebrae had higher pullout loads when augmented with the kyphoplasty technique compared to transpedicular augmentation (1414 +/- 338 versus 756 +/- 300 N, respectively; $P < 0.001$). An unpaired t test showed that fatigued pedicle screws in osteoporotic vertebrae augmented by kyphoplasty showed higher pullout resistance than those placed in healthy control vertebrae ($P = 0.002$). Both kyphoplasty type augmentation ($P = 0.007$) and transpedicular augmentation ($P = 0.02$) increased pullout loads compared to pedicle screws placed in nonaugmented osteoporotic vertebrae when tested after fatigue cycling. CONCLUSIONS: Pedicle screw augmentation with polymethyl methacrylate improves the initial fixation strength and fatigue strength of instrumentation in osteoporotic vertebrae. Pedicle screws augmented using the kyphoplasty technique had significantly greater pullout strength than those augmented with transpedicular augmentation technique and those placed in healthy control vertebrae with no augmentation.

Chang, M. C., et al. (2013). "Polymethylmethacrylate augmentation of cannulated pedicle screws for fixation in osteoporotic spines and comparison of its clinical results and biomechanical characteristics with the needle injection method." J Spinal Disord Tech **26**(6): 305-315.

STUDY DESIGN: This is a retrospective study carried out to evaluate the clinical results of patients with osteoporosis and various spinal diseases treated surgically with polymethylmethacrylate (PMMA)-augmented cannulated pedicle screws, and to compare this method with the needle injection technique in terms of the clinical results and fixation strength. OBJECTIVES: To report a technique using PMMA-augmented cannulated pedicle screws for fixation in osteoporotic spines and to compare its clinical results and biomechanical characteristics with the needle injection technique. SUMMARY OF BACKGROUND DATA: Many studies have shown that PMMA-augmented pedicle screws can significantly increase the stiffness and strength of the screw. Various designs of cannulated screws have been used for cement augmentation in experimental studies; however, clinical reports using these screws in osteoporotic patients are rare. A practical and reliable technique and optimal screw design have not yet been established. METHODS: Forty-five patients (23 women, 22 men), mean age of 71.37 years (range, 53-94 y), with osteoporosis and various spinal diseases underwent spinal decompression and instrumentation with PMMA augmentation of cannulated pedicle screws. Preoperative and postoperative visual analog scale scores for pain and the Oswestry disability index questionnaire data were analyzed. Screw migration, which is the distance from the screw tip to the anterior cortex and the upper endplate of the vertebra, was also evaluated immediately after surgery and at the mean follow-up of 15.9 months. These clinical results were then compared with those reported for the needle injection technique. The pullout strength, insertional, and backout torque of these 2 techniques were compared using osteoporotic synthetic bone (0.12 g/cm). RESULTS: A total of 255 out of 283 cannulated screws were augmented with PMMA. The mean visual analog scale pain score of these patients improved from 9.5 to 3.1 (P<0.01) and the functional Oswestry disability index score improved from 71% to 28.9% (P<0.01). Kyphotic deformity of the compression fracture group (19 patients) was improved from an average of 9.38 to 3.27 degrees after surgery, and to 5.45 degrees at the final follow-up (P<0.01). There was no significant vertical screw migration when the screws' distances were compared just after the operation and at the final follow-up (P>0.01). However, significant horizontal screw migration was found in lesions below the L2 level (P<0.01). **There was no major neurovascular injury, except in 1 patient, who had persistent left thigh pain due to cement leakage at the L1 level, and the symptom was controlled with analgesics.** The clinical results of both techniques were satisfactory and there were no significant differences. Although the pullout strength and screw backout torque was significantly higher in the needle injection group (234.1 vs. 187.8 N, 1119.6 vs. 836.7 N mm, respectively), the operation time was shorter and the cement leakage rate was less in the cannulated pedicle screw group than that of the needle injection group (211.4 vs. 296.3 min, 14.05% vs. 26.2%, respectively). CONCLUSIONS: The technique of cannulated pedicle screws with PMMA augmentation used in this study can be an option for osteoporotic patients with various spinal diseases who require spinal instrumentation.

Chapman, J. R., et al. (1996). "Factors affecting the pullout strength of cancellous bone screws." J Biomech Eng **118**(3): 391-398.

Screws placed into cancellous bone in orthopedic surgical applications, such as fixation of fractures of the femoral neck or the lumbar spine, can be subjected to high loads. Screw pullout is a possibility, especially if low density osteoporotic bone is encountered. The overall goal of this study was to determine how screw thread geometry, tapping, and cannulation affect the holding power of screws in cancellous bone and determine whether current designs achieve maximum purchase strength. Twelve types of commercially available cannulated and noncannulated cancellous bone screws were tested for pullout strength in rigid unicellular polyurethane foams of apparent densities and shear strengths within the

range reported for human cancellous bone. The experimentally derived pullout strength was compared to a predicted shear failure force of the internal threads formed in the polyurethane foam. Screws embedded in porous materials pullout by shearing the internal threads in the porous material. Experimental pullout force was highly correlated to the predicted shear failure force (slope = 1.05, R2 = 0.947) demonstrating that it is controlled by the major diameter of the screw, the length of engagement of the thread, the shear strength of the material into which the screw is embedded, and a thread shape factor (TSF) which accounts for screw thread depth and pitch. The average TSF for cannulated screws was 17 percent lower than that of noncannulated cancellous screws, and the pullout force was correspondingly less. Increasing the TSF, a result of decreasing thread pitch or increasing thread depth, increases screw purchase strength in porous materials. Tapping was found to reduce pullout force by an average of 8 percent compared with nontapped holes (p = 0.0001). Tapping in porous materials decreases screw pullout strength because the removal of material by the tap enlarges hole volume by an average of 27 percent, in effect decreasing the depth and shear area of the internal threads in the porous material.

Chatzistergos, P. E., et al. (2010). "A parametric study of cylindrical pedicle screw design implications on the pullout performance using an experimentally validated finite-element model." Med Eng Phys **32**(2): 145-154.

The present study aims to the design of a finite-element model simulating accurately the pullout behaviour of cylindrical pedicle screws and predicting their pullout force. Three commercial pedicle screws, subjected to pure pullout from synthetic bone, were studied experimentally. The results were used for the design, calibration and validation of a finite-element model. Special attention was paid to the accurate simulation of the failure inside the host material under shear. For this purpose, a bilinear cohesive zone material model was adopted, controlling the mode-II debonding of neighbouring elements in the vicinity of the screw. Comparison between experimental and numerical results proved that the implementation of this approach can significantly enhance the accuracy of the numerical simulation of a screw's mechanical behaviour under pure pullout loads. The numerical model was used for the parametric study of various factors affecting the pullout performance of a cylindrical pedicle screw. It was concluded that the major parameter influencing the pullout force is the outer radius (increasing its value by 36% increases the pullout force by 34%). The influence of the purchase length of the screw is of similar quantitative nature. The respective dependence on the thread inclination, depth and pitch was significantly weaker.

Chen, L. H., et al. (2011). "Pullout strength of pedicle screws with cement augmentation in severe osteoporosis: a comparative study between cannulated screws with cement injection and solid screws with cement pre-filling." BMC Musculoskelet Disord **12**: 33.

BACKGROUND: Pedicle screws with PMMA cement augmentation have been shown to significantly improve the fixation strength in a severely osteoporotic spine. However, the efficacy of screw fixation for different cement augmentation techniques, namely solid screws with retrograde cement pre-filling versus cannulated screws with cement injection through perforation, remains unknown. This study aimed to determine the difference in pullout strength between conical and cylindrical screws based on the aforementioned cement augmentation techniques. The potential loss of fixation upon partial screw removal after screw insertion was also examined. METHOD: The Taguchi method with an L8 array was employed to determine the significance of design factors. Conical and cylindrical pedicle screws with solid or cannulated designs were installed using two different screw augmentation techniques: solid screws with retrograde cement pre-filling and cannulated screws with cement injection through perforation. Uniform synthetic bones (test block) simulating severe osteoporosis were used to provide a platform for each screw design and cement augmentation technique. Pedicle screws at full insertion and after a 360-degree back-out from full insertion were then tested for axial pullout failure using a mechanical testing machine. RESULTS: The results revealed the following 1) Regardless of the screw

outer geometry (conical or cylindrical), solid screws with retrograde cement pre-filling exhibited significantly higher pullout strength than did cannulated screws with cement injection through perforation (p = 0.0129 for conical screws; p = 0.005 for cylindrical screws). 2) For a given cement augmentation technique (screws without cement augmentation, cannulated screws with cement injection or solid screws with cement pre-filling), no significant difference in pullout strength was found between conical and cylindrical screws (p >0.05). 3) Cement infiltration into the open cell of the test block led to the formation of a cement/bone composite structure. Observations of the failed specimens indicated that failure occurred at the composite/bone interface, whereas the composite remained well bonded to the screws. This result implies that the screw/composite interfacial strength was much higher than the composite/bone interfacial strength. 4) The back-out of the screw by 360 degrees from full insertion did not decrease the pullout strength in any of the studied cases. 5) Generally, larger standard deviations were found for the screw back-out cases, implying that the results of full insertion cases are more repeatable than those of the back-out cases. CONCLUSIONS: Solid screws with retrograde cement pre-filling offer improved initial fixation strength when compared to that of cannulated screws with cement injection through perforation for both the conically and cylindrically shaped screw. Our results also suggest that the fixation screws can be backed out by 360 degrees for intra-operative adjustment without the loss of fixation strength.

Chotigavanich, C., et al. (2009). "The surgical treatment of the osteoporotic vertebral compression fracture in the elderly patients with the spinal instrumentation." J Med Assoc Thai **92 Suppl5**: S109-115.

The study was to present the results of the surgical treatment using the spinal instrumentation toe resolve the osteoporotic vertebral compression fracture in the elderly patients having the clinical symptoms of pain and the neurological compromise. Sixty elderly patients who underwent the surgical treatment of the osteoporotic vertebral compression fracture were retrospectively reviewed. Their average age was 72 years; the range was 60-90. The average follow-up period for these patients was 4.2 years; the range was 3-7. Twenty-four patients were performed by the posterior stabilization enhanced by the pedicle screws and rods with the transpedicular bone grafting. Thirty-two patients were performed by the anterior corpectomy with the interbody fusion and the anterior spinal instrumentation. Four patients were performed by two-step surgical treatment: firstly the posterior stabilization enhanced by pedicle screws and rods, and finally, the anterior corpectomy with the interbody fusion. The sagittal Cobb angle and the back pain were improved in all patients. The neurological deficits were improved in 14 patients out of the 16 patients. Twelve patients had the post operative complications: late implants loosening in 5 patients, subcutaneous wound infections in 4 patients, painful neuromas at thoracic cage in 2 patients and incisional hernia in one patient. Although the surgical treatment with spinal implants in the osteoporotic compression fracture was performed in the selected patients, the complication rate was still high, i.e. twenty percent. All of them, nevertheless, were not the mortal complications. The anterior column support could maintain the sagittal alignment better than the posterior spinal fusion alone in the long-term follow up period while the VAS of pain was improved in the similar results.

Consensus development conference: diagnosis, prophylaxis, and treatment of osteoporosis. (1993). Am J Med, 94(6), 646-650.

Cook, S. D., et al. (2001). "Lumbosacral fixation using expandable pedicle screws. an alternative in reoperation and osteoporosis." Spine J **1**(2): 109-114.

BACKGROUND CONTEXT: Pedicle screw fixation in osteoporotic bone and in revision of previous pedicle screw fixation cases presents a significant challenge to spine surgeons. Biomechanical tests have shown that a pedicle screw that expands within the vertebrae body can substantially improve fixation in the presence of compromised bone. PURPOSE:

To review the clinical and radiographic results with the use of expandable pedicle screws. STUDY DESIGN: One hundred forty-five patients received one or more expandable pedicle screws from the Omega21 spinal fixation system (EBI, L.P., Parsippany, NJ) to obtain thorocolumbar or lumbosacral stabilization. PATIENT SAMPLE: The indications for use of the expandable screws were osteoporosis (21 cases), reoperation of previous pedicle instrumentation (27 cases), intraoperative screw relocation (17 cases), construct reinforcement (23 cases), and sacral anchoring to avoid the necessity of anterior penetration of the sacral cortex (57 cases). OUTCOME MEASURES: The presence of radiographic fusion and complications arising from the instrumentation were reviewed at a mean follow-up period of 35 months (range, 24-72 months). METHODS: A retrospective clinical and radiographic review was performed. Fusion was evaluated based on anterior-posterior and lateral radiographs as well as dynamic radiographs in flexion and extension. RESULTS: Radiographic evidence of fusion was obtained in 125 of the 145 cases (86%). Eighty-six percent of patients with osteoporosis and 89% of reoperations fused. There were no instances of screw loosening or pullout of the expandable screws. Screw breakage occurred in four patients (2.8%), including three patients where fusion was not obtained. In six patients the expandable screws were removed without difficulty after fusion because of local discomfort. CONCLUSION: The results of this study have shown that expandable pedicle screws can be efficacious in cases in which pedicle screw fixation is difficult and adds a valuable tool to the growing armamentarium of spinal instrumentation.

Cook, S. D., et al. (2004). "Biomechanical study of pedicle screw fixation in severely osteoporotic bone." Spine J **4**(4): 402-408.

BACKGROUND CONTEXT: Obtaining adequate purchase with standard pedicle screw techniques remains a challenge in poor quality bone. The development of alternate insertion techniques and screw designs was prompted by recognition of potential fixation complications. An expandable pedicle screw design has been shown to significantly improve fixation compared to a conventional screw in poor quality bone. PURPOSE: The purpose of this study was to determine if polymethylmethacrylate (PMMA) bone cement augmentation of an expandable pedicle screw can further improve fixation strength compared to the expandable screw alone in severely osteoporotic bone. A technique for cement insertion into the pedicle by means of the cannulated central portion of the expandable screw is also described. STUDY DESIGN: The axial pullout strength, stiffness and energy absorbed of cemented and noncemented expandable pedicle screws was determined in cadaveric vertebrae. METHODS: Twenty-one fresh unembalmed vertebrae from the thoracolumbar spine were used. Radiographs and bone mineral density measurements (BMD) were used to characterize bone quality. Paired cemented and noncemented pedicle screw axial pullout strength was determined through mechanical testing. Mechanical pullout strength, stiffness and energy to failure was correlated with BMD. RESULTS: Overall, there was a 250% increase in mean pullout strength with the cemented expandable screw compared with a noncemented expandable screw including a greater than twofold increase in pullout strength in the most severely osteoporotic bone. The mean stiffness and energy absorbed to failure was also significantly increased. A cemented conventional screw achieved a pullout strength similar to the noncemented expandable screw. CONCLUSIONS: PMMA cement augmentation of the expandable pedicle screw may be a viable clinical option for achieving fixation in severely osteoporotic bone.

Curtis, R., et al. (2005). "Fixation principles in metaphyseal bone--a patent based review." Osteoporos Int **16 Suppl 2**: S54-64.

Osteoporotic changes start in cancellous bone due to the underlying pathophysiology. Consequently, the metaphyses are at a higher risk of "osteoporotic" fracture than the diaphysis. Furthermore, implant purchase to fix these fractures is also affected by the poor bone quality. In general, researchers and developers have worked on three different approaches to address the problem of fractures to osteoporotic bone: adapted anchoring

techniques, improved load distribution as well as transfer with angular stable screws, and augmentation techniques using bone substitutes. A patent-based review was performed to evaluate which ideas were utilized to improve fixation in osteoporotic, metaphyseal bone, especially in the proximal femur, and to analyze whether the concept had entered clinical use. Anchoring devices that are either extramedullary or intramedullary have a long clinical history. However, demanding surgical techniques and complications, especially in poor quality bone, are justification that such implants and their corresponding surgical techniques need to be improved upon. Expanding elements have been evaluated in the laboratory. The results are promising and the potential of this approach has yet to be fully exploited in the clinics. Internal fixators with angular stable screws open the door for many new anchorage ideas and have great potential for further optimization of load distribution and transfer. Augmentation techniques may improve anchorage in osteoporotic bone. However, the properties of bone substitute materials will need to be modified and improved upon in order to meet the demanding requirements. If we summarise the development process and the clinical use of implants to date, we have to clearly state that more factors than simply biomechanical advantage will determine the clinical success of a new fixation principle or a new implant. Instead, fracture treatment of patients with osteoporosis really needs an interdisciplinary approach!

Davis, C., et al. (2012). "Locking plates in osteoporosis: a biomechanical cadaveric study of diaphyseal humerus fractures." J Orthop Trauma **26**(4): 216-221.

OBJECTIVE: To determine whether locking plates offer an advantage in fixation of fractures in osteoporotic humeral bone. DESIGN: Biomechanical testing of 18 matched pairs of osteoporotic human cadaver humeri plated posteriorly with either all locked or all nonlocked screws. An established protocol was used to test the constructs with torque applied to a peak of ±10 Nm for 1000 cycles at 0.3 Hz or until failure. Eighteen pairs were tested for failure, 11 pairs were tested for cycles survived, and 10 pairs were tested for stiffness. SETTING: University biomechanical laboratory. MAIN OUTCOME MEASUREMENTS: Percentage surviving testing, mean cycles survived, and stiffness. RESULTS: We observed catastrophic failure of the constructs in 47% of the samples. Humeri plated with nonlocking plates failed at a higher rate than those with locking plates (67% nonlocking vs 28% locking, n = 18 pairs, P = 0.008). Locking constructs also outperformed nonlocking constructs in mean cycles survived (707 cycles locking, 345 cycles nonlocking, n = 11 pairs, P < 0.05) and stiffness at 10 cycles (0.853 Nm/degree locking vs 0.416 Nm/degree nonlocking, n = 10 pairs, P < 0.001). CONCLUSIONS: Locking plates were shown to provide improved mechanical performance over nonlocking plates in torsional cyclic loading in a osteoporotic cadaveric fracture model. Our results confirm general conclusions of previous work that used a synthetic bone model of osteoporosis, but we found a high rate of catastrophic failure, questioning the validity of the previously published synthetic model of osteoporosis (overdrilling of synthetic bone) for this application.

De Bruijn, K., et al. (2012). "Reliability of predictors for screw cutout in intertrochanteric hip fractures." J Bone Joint Surg Am **94**(14): 1266-1272.

BACKGROUND: Following internal fixation of intertrochanteric hip fractures, tip apex distance, fracture classification, position of the screw in the femoral head, and fracture reduction are known predictors for screw cutout, but the reliability of these measurements is unknown. We investigated the reliability of the tip apex distance measurement, the Cleveland femoral head dividing system, the three-grade classification system of Baumgaertner for fracture reduction, and the AO classification system as predictors for screw cutout. METHODS: All patients with an intertrochanteric hip fracture who were managed with either a dynamic hip screw or a gamma nail between January 2007 and June 2010 were evaluated from our hip trauma database. RESULTS: The tip apex distance measurement was reliable and patients with device cutout had a significantly higher tip apex distance. The agreement between observers with regard to screw position and fracture

reduction was moderately reliable. After adjustment for tip apex distance and screw position, A3 fractures were at more risk of cutout compared with A1 fractures. Poor fracture reduction was significantly related with a higher incidence of cutout in univariate analysis, but not in multivariate analysis. Central-inferior and anterior-inferior positions, after adjustment for tip apex distance and screw position, were significantly protective against cutout. CONCLUSION: To decrease probable risks of cutout, the tip apex distance needs to stay small or the screw needs to be placed central-inferiorly or anterior-inferiorly. LEVEL OF EVIDENCE: Therapeutic Level III. See Instructions for Authors for a complete description of levels of evidence.

Denard, P. J., et al. (2011). "Biplanar fixation of a locking plate in the diaphysis improves construct strength." Clin Biomech **26**(5): 484-490.

BACKGROUND: Elevation of a locking plate over the bone surface not only supports biological fixation, but also decreases the torsional strength of the fixation construct. Biplanar fixation by means of a staggered screw hole arrangement may combat this decreased torsional strength caused by plate elevation. This biomechanical study evaluated the effect of biplanar fixation on the torsional strength of locking plate fixation in the femoral diaphysis. METHODS: Custom titanium plates were manufactured with either a linear or staggered hole pattern to evaluate planar and biplanar fixation, respectively. Fixation strength under torsional loading was evaluated in surrogates of the femoral diaphysis representative of osteoporotic and non-osteoporotic bone. Furthermore, fixation strength was determined for plate fixation with unicortical or bicortical locking screws. Five specimens per configuration were loaded to failure in torsion to determine their strength, stiffness, and failure mode. FINDINGS: In osteoporotic bone, biplanar fixation was 32% stronger (P=0.01) than planar fixation when unicortical screws were used and 9% stronger (P=0.02) when bicortical screws were used. In non-osteoporotic bone, biplanar fixation was 55% stronger (P<0.001) than planar fixation when unicortical screws were used and 42% (P<0.001) stronger when bicortical screws were used. INTERPRETATION: A biplanar screw configuration improves the torsional strength of diaphyseal plate fixation relative to a planar configuration in both osteoporotic and normal bone. With biplanar fixation, unicortical screws provide the same fixation strength as bicortical screws in non-osteoporotic bone.

Dreinhofer, K. E., et al. (2004). "Orthopaedic surgeons and fragility fractures. A survey by the Bone and Joint Decade and the International Osteoporosis Foundation." J Bone Joint Surg Br **86**(7): 958-961.

Drew, T. and P. Allcock (2002). "A new method of fixation in osteoporotic bone. A preliminary report." Injury **33**(8): 685-689.

Over-tightening of cortical bone screws in osteoporotic bone results in weak fixation. Once a screw is over-tightened and the bone thread form is stripped, there are limited means at the surgeon's disposal to rescue the situation, none of them entirely satisfactory. We describe a simple device that is specifically designed to resolve this problem. It consists of a nylon cavity plug and applicator. The plug is inserted into the stripped hole and the screw re-applied and tightened in the normal manner. The plug expands and forms a load-bearing region on the inner face of the bone. Tests on osteoporotic cadavaric bone have shown that the plug effectively re-establishes screw fixation. When compared to an over-tightened screw, the plug is at least twice as resistant to loads acting to pull the screw out of the surrounding bone.

Edwards, S. G., et al. (2011). "Comparison of olecranon plate fixation in osteoporotic bone: do current technologies and designs make a difference?" J Orthop Trauma **25**(5): 306-311.

OBJECTIVES: The purpose of this study is to determine if recent innovations in olecranon plates have any advantages in stabilizing osteoporotic olecranon fractures. METHODS: Five olecranon plates (Acumed, Synthes-SS, Synthes-Ti, US Implants/ITS, and Zimmer) were

implanted to stabilize a simulated comminuted fracture pattern in 30 osteoporotic cadaveric elbows. Specimens were randomized by bone mineral density per dual-energy x-ray absorptiometry scan. Three-dimensional displacement analysis was conducted to assess fragment motion through physiological cyclic arcs of motion and failure loading, which was statistically compared using one-way analysis of variance and Tukey honestly significant difference post hoc comparisons with a critical significance level of alpha = 0.05. RESULTS: Bone mineral density ranged from 0.546 g/cm to 0.878 g/cm with an average of 0.666 g/cm. All implants limited displacement of the fragments to less than 3 mm until sudden, catastrophic failure as the bone of the proximal fragment pulled away from the implant. The maximum load sustained by all osteoporotic specimens ranged from 1.6 kg to 6.6 kg with an average of 4.4 kg. There was no statistical difference between the groups in terms of cycles survived and maximum loads sustained. CONCLUSIONS: Cyclic physiological loading of osteoporotic olecranon fracture fixation resulted in sudden, catastrophic failure of the bone-implant interface rather than in gradual implant loosening. Recent plate innovations such as locking plates and different screw designs and positions appear to offer no advantages in stabilizing osteoporotic olecranon fractures. Surgeons may be reassured that the current olecranon plates will probably adequately stabilize osteoporotic fractures for early motion in the early postoperative period, but not for heavy activities such as those that involve over 4 kg of resistance.

Einhorn, T. A. and L. C. Gerstenfeld (2014). "Fracture healing: mechanisms and interventions." Nat Rev Rheumatol.

Fractures are the most common large-organ, traumatic injuries to humans. The repair of bone fractures is a postnatal regenerative process that recapitulates many of the ontological events of embryonic skeletal development. Although fracture repair usually restores the damaged skeletal organ to its pre-injury cellular composition, structure and biomechanical function, about 10% of fractures will not heal normally. This article reviews the developmental progression of fracture healing at the tissue, cellular and molecular levels. Innate and adaptive immune processes are discussed as a component of the injury response, as are environmental factors, such as the extent of injury to the bone and surrounding tissue, fixation and the contribution of vascular tissues. We also present strategies for fracture treatment that have been tested in animal models and in clinical trials or case series. The biophysical and biological basis of the molecular actions of various therapeutic approaches, including recombinant human bone morphogenetic proteins and parathyroid hormone therapy, are also discussed.

Erhart, S., et al. (2011). "Biomechanical effect of bone cement augmentation on rotational stability and pull-out strength of the Proximal Femur Nail Antirotation." Injury **42**(11): 1322-1327.

INTRODUCTION: After surgical treatment of osteoporotic hip fractures, complications such as implant cut-out are reported to be high and implant failure often is associated with poor bone quality. As augmentation is reported to enhance implant anchorage, the aim of our study was to investigate the effect of bone cement augmentation on the rotational stability and the pull-out resistance of the Proximal Femur Nail Antirotation (PFNa) blade. MATERIALS AND METHODS: A total of 18 fresh-frozen femoral heads (mean age 68 years, standard deviation (SD) 8.2) were scanned with quantitative computed tomography (qCT) for bone mineral density (BMD) measurements and instrumented with a PFNa blade. Nine specimens were augmented with a mean volume of 4.4 ml Traumacem V+. After cement consolidation, the blade was rotated for 60 degrees for the rotational test. Subsequently, the blade was extracted from the specimens. Force, torque, displacement and angle were recorded constantly. RESULTS: In the rotational test, the mean maximum torque in the augmented group (17.2 Nm, SD 5.0) was significantly higher (p=0.017) than in the non-augmented group (11.7 Nm, SD 3.5). The pull-out test also yielded a significant difference (p=0.047) between the augmented (maximum pullout force: 2315.2N, SD 1060.6) and the non-augmented group (1180.4N, SD 1171.4). DISCUSSION: Augmentation of femoral

heads yielded a significantly superior rotational stability, as well as an enhanced pull-out resistance, compared to the non-augmented state. However, the higher the BMD of the specimens, the lower was the effect of augmentation on the rotational stability. Therefore, augmentation can be a good clinical tool to enhance implant anchorage in osteoporotic bone.

Ferguson, S. J., et al. (2002). "Anterior fixation in the osteoporotic spine: cut-out and pullout characteristics of implants." Eur Spine J **11**(6): 527-534.

A new concept for the anchorage of anterior fixation implants in the osteoporotic thoracic and lumbar spine is presented. The SpiralBlade has been proposed as a suitable device for use in the osteoporotic spine, due to its broad, flat surface, which should provide resistance against cut-out of the implant through the vertebral body under dynamic loading. The cut-out and pullout characteristics of this implant were tested. The SpiralBlade was tested with and without a supplementary insertion guide screw. Two other commercial implants were tested for comparison: the VentroFix and the MACS-TL HMA (hollow monoaxial) screw. All implants were tested in osteoporotic human cadaveric vertebrae, using a modified in vitro testing protocol which simulated a full corpectomy model. Dynamic cyclic loading of 100 N, 200 N and 400 N was applied to the implant for 1000 cycles at each load level, and the subsidence of the vertebral body relative to the implant was measured. Following cyclic testing, the pullout strength of the implant was measured. No significant differences were found in the cut-out performance between the SpiralBlade with guide screw and the VentroFix. The SpiralBlade inserted without a guide screw was prone to cutting-out and a substantial loss of angular alignment of the vertebral body. Cut-out of the HMA screw was significantly greater than with the other implants. Two HMA screws fractured during testing. The VentroFix, with an average pullout force of 1166 N, has a significantly higher resistance to pullout than the SpiralBlade with guide screw (417 N), the SpiralBlade (332 N) and the Aesculap HMA screw (298 N). The SpiralBlade may be an alternative to anterior screw fixation in the osteoporotic spine, offering the same cut-out resistance with one implant rather than two screws.

Folsch, C., et al. (2012). "Correlation of pull-out strength of cement-augmented pedicle screws with CT-volumetric measurement of cement." Biomed Tech (Berl) **57**(6): 473-480.

BACKGROUND: Cement augmentation of pedicle screws increases fixation strength in an osteoporotic spine. This study was designed to determine the cement distribution and the correlation between the pull-out strength of the augmented screw and the cement volume within polyurethane (PU) foam. METHODS: Twenty-eight cannulated pedicle screws (6x45 mm) (Peter Brehm, Erlangen, Germany) with four holes at the distal end of the screw were augmented with the acrylic Stabilit ER Bone Cement Vertebral Augmentation System (DFine Inc., San Jose, CA, USA) and implanted into open-cell rigid PU foam (Pacific Research Laboratories, Vashon Island, WA, USA) with a density of 0.12 g/cm3, resembling severe osteoporosis. Volumetric measurement of the cement with consideration of the distribution around the screws was done with multislice computed tomography scan (Somatom Definition, Siemens, Erlangen, Germany). Pull-out strength was tested with a servohydraulic system (MTS System Corporation, Eden Prairie, MN, USA), and nonaugmented screws served as control. Pearson's correlation coefficient with significance level alpha=0.05 and one-way analysis of variance test were used. RESULTS: We found a high (r=0.88) and significant ($p<0.01$) correlation between the cement volume and the pull-out strength, which increased by more than 5-fold with a volume of 3 ml. The correlation appeared linear at least up to 4 ml cement volume and failure always occurred at the cement-bone interface. The cement distribution was symmetric and circular around the most proximal hole, with a distance of 14 mm from the tip, and nearly 90% of the cement was found 6 mm distal and cranial to it. The 95% confidence interval for the relative amount of cement was 37%-41% within 2 mm of the most proximal hole. CONCLUSION: Compared with the control, a cement volume between 2.0 and 3.0 ml increased the pull-out strength significantly and is relevant

for clinical purposes, whereas a volume of 0.5 ml did not. A cement volume beyond 3.0 ml should further increase the pull-out strength because the correlation was linear at least up to 4.0 ml, but the possibility of in vivo cement leakage with increasing volume has to be considered. Pressure-controlled cement application might be a tool to avoid this complication. The cement almost completely penetrated the most proximal perforation.

Frankel, B. M., et al. (2007). "Segmental polymethylmethacrylate-augmented pedicle screw fixation in patients with bone softening caused by osteoporosis and metastatic tumor involvement: a clinical evaluation." Neurosurgery **61**(3): 531-537; discussion 537-538.

OBJECTIVE: Instrumentation of the osteoporotic spine may result in bone failure because of pedicle screw loosening and pullout. A clinical evaluation of a novel fenestrated bone tap used in pedicle screw augmentation was performed to determine the performance and safety of this technique. METHODS: Over a 2.5-year period, the clinical and radiographic results of 119 consecutive patients who underwent instrumented arthrodesis were reviewed. Of these patients, 23 had bone softening secondary to osteoporosis and/or metastatic spinal tumor involvement. These patients underwent surgical decompression and spinal instrumentation. RESULTS: Six patients (26%) had metastatic spine disease (squamous cell lung carcinoma, renal cell carcinoma, bladder carcinoma, breast, prostate, and uterine adenocarcinoma); five patients (22%) had a degenerative spondylolisthesis; and 12 patients (52%) had burst fractures, eight as a result of benign causes and four as a result of metastatic disease. Four (17%) patients underwent revision surgery of previous pedicle screw failure resulting from bone softening and pseudarthrosis. A total of 98 levels were fused using 158 polymethylmethacrylate-augmented screws. None of the patients experienced operative death, myocardial infarction, hypoxemia, intraoperative hypotension, radiculopathy, or myelopathy. **Asymptomatic anterior cement extravasation was observed in nine patients (39%). There was one asymptomatic polymethylmethacrylate pulmonary embolus and one wound infection.** There was no significant relationship between cement extravasation and the quantity used, levels augmented, or location ($P > 0.05$). There were no construct failures. CONCLUSION: Polymethylmethacrylate-augmented pedicle screw fixation reduces the likelihood of pedicle screw loosening and pullout in patients with osteoporosis requiring instrumented arthrodesis.

Gadegone, W. M. and Y. S. Salphale (2010). "Short proximal femoral nail fixation for trochanteric fractures." J Orthop Surg (Hong Kong) **18**(1): 39-44.

PURPOSE: To review outcomes of 100 patients who underwent short proximal femoral nailing for stable and unstable intertrochanteric fractures. METHODS: Records of 62 men and 38 women aged 56 to 83 (mean, 67) years who underwent short proximal femoral nailing for stable peritrochanteric A1 (n=36), unstable peritrochanteric A2 (n=40), and unstable intertrochanteric A3 (n=24) fractures were reviewed. RESULTS: 80 patients achieved anatomic reduction. At the one-year follow-up, 90% of the patients had good or excellent outcomes, and 50% had returned to their pre-injury functional level. One patient with avascular necrosis noted at 20 months and another patient with non-union/pseudarthrosis underwent a revision bipolar arthroplasty. Two patients had a Z effect and one a reverse Z effect. Six patients with osteoporosis had superior migration of the nail with varus collapse. Two patients had cutting out of the screw, but the fractures eventually healed. Ten patients had shortening of <2 cm. Seven patients had lateral thigh discomfort attributed to irritation of the protruding screws against the tensor fascia lata, and 5 of them underwent screw removal. None had fractures of the femoral shaft or trochanter or experienced nail breakage. CONCLUSION: The short proximal femoral nail is a superior implant for stable and unstable intertrochanteric fractures in terms of operating time, surgical exposure, blood loss, and complications, especially for patients with relatively small femora.

Gao, M., et al. (2011). "Biomechanical evaluation of fixation strength of conventional and expansive pedicle screws with or without calcium based cement augmentation." Clin Biomech (Bristol, Avon) **26**(3): 238-244.

BACKGROUND: The expansive pedicle screw was originally developed to be installed in the bone of compromised quality, but there are some concerns whether it can provide enough fixation strength in the spine with osteoporosis or severe osteoporosis. METHODS: Twelve fresh human cadaver spines were stratified into four levels: normal, osteopenia, osteoporosis and severe osteoporosis. The vertebra was bilaterally instrumented with pedicle screws according to four protocols, including conventional pedicle screw without augmentation, expansive pedicle screw without augmentation, conventional screw with augmentation and expansive screw with augmentation. Screw pullout tests were conducted. FINDINGS: Given the same specimen, the fixation strength of expansive screw was significantly higher than that of the conventional screw. When the same type of screw was used, the fixation strength of the calcium based cement augmented group was stronger than that of the non-augmented group. The pullout strength and stiffness of the expansive screw, augmented conventional screw and augmented expansive screw groups at the osteoporotic level were comparable to those of the conventional pedicle screw group at the osteopenic level. **However, under the severely osteoporotic bone environment, the pullout strength of pedicle screw with whatever placement protocol was significantly lower than that of the conventional screw group at the osteopenic level.** INTERPRETATION: Our results demonstrate that (i) the expansive pedicle screw appears feasible and safe in either osteopenic or osteoporotic spine; (ii) calcium based cement augmentation can offer improved initial fixation strength of pedicle screws.; and (iii) no screw placement protocol we examined is efficacious in the bone at the severely osteoporotic level.

Gerstenfeld, L. C., et al. (2003). "Fracture healing as a post-natal developmental process: molecular, spatial, and temporal aspects of its regulation." J Cell Biochem **88**(5): 873-884.

Fracture healing is a specialized post-natal repair process that recapitulates aspects of embryological skeletal development. While many of the molecular mechanisms that control cellular differentiation and growth during embryogenesis recur during fracture healing, these processes take place in a post-natal environment that is unique and distinct from those which exist during embryogenesis. This Prospect Article will highlight a number of central biological processes that are believed to be crucial in the embryonic differentiation and growth of skeletal tissues and review the functional role of these processes during fracture healing. Specific aspects of fracture healing that will be considered in relation to embryological development are: (1) the anatomic structure of the fracture callus as it evolves during healing; (2) the origins of stem cells and morphogenetic signals that facilitate the repair process; (3) the role of the biomechanical environment in controlling cellular differentiation during repair; (4) the role of three key groups of soluble factors, pro-inflammatory cytokines, the TGF-beta superfamily, and angiogenic factors, during repair; and (5) the relationship of the genetic components that control bone mass and remodeling to the mechanisms that control skeletal tissue repair in response to fracture.

Goldhahn, J., et al. (2012). "Implications for fracture healing of current and new osteoporosis treatments: an ESCEO consensus paper." Calcif Tissue Int **90**(5): 343-353.

Osteoporotic fracture healing is critical to clinical outcome in terms of functional recovery, morbidity, and quality of life. Osteoporosis treatments may affect bone repair, so insights into their impact on fracture healing are important. We reviewed the current evidence for an impact of osteoporosis treatments on bone repair. Treatment with bisphosphonate in experimental models is associated with increased callus size and mineralization, reduced callus remodeling, and improved mechanical strength. Local and systemic bisphosphonate treatment may improve implant fixation. No negative impact on fracture healing has been observed, even after major surgery or when administered immediately after fracture. Experimental data for denosumab and raloxifene suggest no negative implications for bone

repair. The extensive experimental results for teriparatide indicate increased callus formation, improved biomechanical strength, and greater external callus volume and total bone mineral content and density. Case reports and a randomized trial have produced mixed results but are consistent with a positive impact of teriparatide on clinical fracture healing. Studies with strontium ranelate in models of fracture healing indicate that it is associated with improved bone microstructure, callus volume, and biomechanical properties. Finally, there is experimental evidence for a beneficial effect of some of the agents currently being developed for osteoporosis, notably sclerostin antibody and DKK1 antibody. There is currently no evidence that osteoporosis treatments are detrimental for bone repair and some promising experimental evidence for positive effects on healing, notably for agents with a bone-forming mode of action, which may translate into therapeutic applications.

Goldhahn, J., et al. (2008). "Influence of osteoporosis on fracture fixation--a systematic literature review." Osteoporos Int **19**(6): 761-772.

The goal of our systematic literature search was to prove whether the experimentally shown influence of osteoporosis on fracture fixation could be confirmed in clinical studies. Despite significant effects in several studies, this is not supported by pooled data due to lack of accurate osteoporosis assessment and complication definitions. INTRODUCTION: The fact that osteoporosis causes fractures is well-known; the assumption that it aggravates their orthopaedic treatment has not been proven. The goal of our systematic literature search was to find out whether the experimentally proven influence of osteoporosis on fracture fixation could be confirmed in clinical studies. METHODS: A systematic electronic database search was performed identifying articles that evaluated complications after fracture fixation among patients suspected of having osteoporosis as measured by BMD or surrogates including Singh index or risk factors. To determine complications risks (relative risk within 95% confidence interval) data were pooled across studies, weighted by sample size and stratified by treatment type. RESULTS: Ten studies out of 77 randomized controlled trials (51 hip, 23 distal radius and three proximal humerus studies) and three systematic reviews finally met eligibility criteria. Despite significant differences of the relative complication risk between osteoporotic and non-osteoporotic patients in several studies, this could not be proven in the pooled data. CONCLUSIONS: In contrast to biomechanical evidence that local osteoporosis affects anchorage of implants, this could not be reproduced in clinical studies, due to the lack of accurate osteoporosis assessment, missing complication definitions and heterogeneous inclusion criteria in these studies. Prospective studies are required that address specifically the correlation between local bone status and the risk of fixation failure.

Gruber, R., et al. (2006). "Fracture healing in the elderly patient." Exp Gerontol **41**(11): 1080-1093.

Clinical experience gives rise to the impression that there are differences in fracture healing in different age groups. It is evident that fractures heal more efficiently in children than in adults. However, minimal objective knowledge exists to evaluate this assumption. Temporal, spatial, and cellular quantitative and qualitative interrelationships, as well as signaling molecules and extracellular matrix have not been comprehensively and adequately elucidated for fracture healing in the geriatric skeleton. The biological basis of fracture healing will provide a context for revealing the pathophysiology of delayed or even impaired bone regeneration in the elderly. We will summarize experimental studies on age-related changes at the cellular and molecular level that will add to the pathophysiological understanding of the compromised bone regeneration capacity believed to exist in the elderly patient. We will suggest why this understanding would be useful for therapeutics focused on bone regeneration, in particular fracture healing at an advanced age.

Guven, M., et al. (2010). "Importance of screw position in intertrochanteric femoral fractures treated by dynamic hip screw." Orthop Traumatol Surg Res **96**(1): 21-27.

BACKGROUND: Tip-apex distance greater than 25 mm is accepted as a strong predictor of screw cut-out in patients with intertrochanteric femoral fracture treated by dynamic hip

screw. The aim of this retrospective study was to evaluate the position of the screw in the femoral head and its effect on cut-out failure especially in patients with inconvenient tip-apex distance. MATERIALS AND METHODS: Sixty-five patients (42 males, 23 females; mean age of 57.6 years) operated by dynamic hip screw for intertrochanteric femoral fractures were divided in two groups taking into consideration the tip-apex distance less (group A; 14 patients) or more (group B; 51 patients) than 25 mm. Patient's age and gender, follow-up period, fracture type, degree of osteoporosis, reduction quality of the fracture, position of the screw in the femoral head, number of patients with cut-out failure and Harris hip score were compared. RESULTS: The average follow-up time was 41.7 months. The mean tip-apex distance was 17.14 mm in group A and 36.67 mm in group B. One (7.1%) patient in group A and three (5.8%) patients in group B had screw cut-out. Except the screw position, no statistical differences were observed between the two groups with regards to study data. The screw was placed in femoral head more inferiorly (p=0.045) on frontal and more posteriorly (p=0.013) on sagital planes in group B, while central placement of the screw was present in group A. The common characteristics of three patients with screw cut-out in group B was the position of the screw which was located in femoral head more superiorly and anteriorly after an acceptable fracture reduction. CONCLUSIONS: Peripheral placement of the screw in femoral head increases tip-apex distance. However posterior and inferior locations may help to support posteromedial cortex and calcar femoral in unstable intertrochanteric fractures and reduce the risk of cut-out failure. LEVEL OF EVIDENCE: IV, retrospective series.

Herman, A., et al. (2012). "Radiological evaluation of intertrochanteric fracture fixation by the proximal femoral nail." Injury **43**(6): 856-863.

BACKGROUND: Successful treatment of intertrochanteric femoral fractures was reportedly influenced by the position of the fixation devices, by reduction quality and by fracture type. METHODS: The records of 227 patients with intertrochanteric fractures treated by intramedullary hip screws were analysed retrospectively. The angle and distance from the femur head apex were transformed into Cartesian coordinates. Comparisons were performed between patients with no mechanical failure (207 patients, 90.7%), with cutouts (15 patients, 6.6%) and with secondary loss of reduction (5 patients, 2.2%). RESULTS: The standard tip apex distance (TAD) measurement above 25 mm did not predict failure (p=0.62). Mechanical failure rates increased from 4.8% to 34.4% when the centre of lag screw was not in the second quarter of the head-neck interface line (the so-called "safe zone") (p=0.001). Lag screw insertion lower or higher than 11 mm of the head apex line were associated with failure rates of 5.5% and 18.6%, respectively (p=0.004). Multivariate logistic regression showed that lag screw insertion not within the "safe-zone" was associated an Odds Ratio of 13.4 (95% CI 2.24-81) for mechanical failure (p=0.004). CONCLUSIONS: The TAD scale focuses on length measurement and lacks the vector properties of multidirectional measurements. Vector analysis revealed that the caudal-cranial correct lag screw position is the most important factor in preventing mechanical failure.

Higashino, K., et al. (2012). "A biomechanical study of two different pedicle screw methods for fixation in osteoporotic and nonosteoporotic vertebrae." J Surg Orthop Adv **21**(4): 198-203.

In reconstruction of the osteoporotic spine, patients often show poor outcome because of pedicle screw failure. This study used osteoporotic and nonosteoporotic vertebrae to determine the difference in fixation strength between pedicle screws inserted straight forward and pedicle screws inserted in an upward trajectory toward the superior end plate (i.e., end-plate screws). There is some evidence to suggest that end-plate screws have a strength advantage. The particular focus was on osteoporotic vertebrae. Thirty-three vertebrae (T10-L2) were harvested. The bone mineral density (BMD) was measured: 15 vertebrae were greater than 0.8 g/cm(2) and designated as nonosteoporotic (average BMD 1.146 +/- 0.186 g/cm(2)) and 18 vertebrae were designated as osteoporotic (average BMD 0.643 +/- 0.088 g/cm(2)). On one pedicle the screw was inserted straight forward and on the other pedicle the screw was inserted as an end-plate screw. The torque of insertion was

measured (Proto 6106 torque screwdriver). Using an MTS Mini Bionix, two types of mechanical testing were carried out on each pedicle: (a) cephalocaudad toggling was first carried out to simulate some physiological type loading: 500 cycles at 0.3 Hz, at +/-50 N; and (b) then each pedicle screw was pulled out at a displacement rate of 12.5 cm/min.There was no difference in pullout force between the pedicle screws inserted straight forward and the pedicle screws inserted as end-plate screws. This result applies whether the vertebrae were osteoporotic or nonosteoporotic. For both the straight-forward screws and the end-plate screws, a statistically significant correlation was observed between torque of insertion and pullout force. The results of this experiment indicate that pedicle screws inserted as end-plate screws do not provide a strength advantage over pedicle screws inserted straight forward, whether the vertebrae are osteoporotic or not.

Hohendorff, B., et al. (2005). "[Treatment results and complications after PFN osteosynthesis]." Unfallchirurg **108**(11): 938, 940, 941-936 passim.

Intramedullary implants, such as the proximal femur nails (PFN), are inserted for the treatment of per-, inter- and subtrochanteric fractures. The initial experiences with these PFN, carried out by AO/ASIF in 1996, have been published. PATIENTS AND METHODS: This study makes a systematic examination of the complications and clinical treatment results from 133 patients treated at our clinic from December 1997-2001 with 139 PFN in per-, inter- and subtrochanteric femur fractures. The mean age at the time of surgery was 78.4 years. All fractures were classified according to the AO system. The most frequent injuries were 31 A2.3 fractures (61.2%). All intraoperative image-converter images and all radiographs from the total period of treatment were evaluated retrospectively in accordance with 28 criteria. The degree of osteoporosis was estimated using the Singh classification. RESULTS: A total of 44 (31.7%) complications arose in 31 (23.3%) patients. On 11 occasions, hip screw cut-out was observed. Of these, two cases involved a Z-effect and one an inverted Z-effect. Two patients suffered a femoral neck fracture following removal of the hip screws. There were 38 (27.3%) reoperations required with 13 changes in procedure. In autumn 2002, clinical follow-up examinations were carried out on 65 (48.9%) patients who were assessed according to the Merle d'Aubigne score. A total of 51 (38.3%) patients had died at the time of follow-up. Normal ambulation was achieved by 33.8% of patients, while 64.6% were free of pain. CONCLUSIONS: The PFN is an appropriate implant in cases of per-, inter- and subtrochanteric femur fractures. Anatomical resetting and correct implant positioning are the keys to successful osteosynthesis. The risk of implant failure is highest in the case of multi-fragmentary per- and intertrochanteric fractures in which medial strengthening has been degraded in patients aged over 80 years. The clinical results in elderly patients are unsatisfactory.

Kammerlander, C., et al. (2011). "Standardised cement augmentation of the PFNA using a perforated blade: A new technique and preliminary clinical results. A prospective multicentre trial." Injury **42**(12): 1484-1490.

Pertrochanteric fractures are a rising major health-care problem in the elderly and their operative stabilisation techniques are still under discussion. Furthermore, complications like cut-out are reported to be high and implant failure often is associated with poor bone quality. The PFNA((R)) with perforated blade offers a possibility for standardised cement augmentation using a polymethylmethacrylate (PMMA) cement which is injected through the perforated blade to enlarge the load-bearing surface and to diminish the stresses on the trabecular bone. The current prospective multicentre study was undertaken to evaluate the technical performance and the early clinical results of this new device. In nine European clinics, 59 patients (45 female, mean age 84.5 years) suffering from an osteoporotic pertrochanteric fracture (Arbeitsgemeinschaft fur Osteosynthesefragen, AO-31) were treated with the augmented PFNA((R)). Primary objectives were assessment of operative and postoperative complications, whereas activities of daily living, pain, mobility and radiologic parameters, such as cement distribution around the blade and the cortical thickness index,

were secondary objectives. The mean follow-up time was 4 months where we observed callus healing in all cases. The surgical complication rate was 3.4% with no complication related to the cement augmentation. More than one-half of the patients reached their prefracture mobility level within the study period. A mean volume of 4.2ml of cement was injected. We did not find any cut-out, cut through, unexpected blade migration, implant loosening or implant breakage within the study period. Our findings lead us to conclude that the standardised cement augmentation using the perforated blade for pertrochanteric fracture fixation enhances the implant anchorage within the head-neck fragment and leads to good functional results.

Kawaguchi, S., et al. (1998). "Cutting-out of the lag screw after internal fixation with the Asiatic gamma nail." Injury **29**(1): 47-53.

Sixty consecutive intertrochanteric femoral fractures were treated with the Asiatic gamma nail followed by early postoperative weight bearing. Cutting-out of the lag screw from the femoral head occurred in six fractures and were analysed radiographically with regard to fracture type (Evans' classification), osteoporosis (Singh grade), accuracy of post-operative reduction (neck-shaft angle and diastasis of the fracture), and location of the lag screw in the femoral head (depth, height, and antero-postero-posterior radiograph and large antero-posterior deviation of the lag screw were significantly related to the increased incidence of the screw cutting-out. This suggests that deep insertion of the lag screw on the antero-posterior view with central placement on the lateral view is an optimal location in the femoral head. The inverted question markcut-out index' (the multiplication value of the depth and the anteroposterior deviation of the lag screw in the femoral head) is an excellent measure of the risk of the lag screw cutting-out.

Kettler, M., et al. (2006). "[Treatment of proximal humeral fractures with the PHILOS angular stable plate. Presentation of 225 cases of dislocated fractures]." Unfallchirurg **109**(12): 1032-1040.

BACKGROUND: Proximal fracture of the humeral head is the third most frequent fracture in humans. Most (70%) of those affected are over 60 years old. It is hoped that advanced locking medullary screws or plates will reduce the risk of secondary dislocation of screws or fracture segments when the bone of the humeral head is osteoporotic. METHODS: From January 2002 to August 2005, 225 displaced humeral head fractures in 223 patients aged on average 66+/-15 years were treated with a new locking proximal humeral plate. RESULTS: In 176 patients in whom follow-up was possible, the average Constant Score after 9 months was 70+/-19 points (raw data), or 81+/-22% in the normalized score. No significant difference was detected between the younger group up to 65 years of age (73% points) and those over 65 years of age (80% points). Axial deviations by more than 30 degrees were noted in 11 (5%), and of 159 displaced tubercles, malreduction by more than 5 mm was noted in 14 (9%). Two infections and two haematomas had to be treated so far. Primary screw perforations were seen in 24 (11%) cases as well as further implant dislocations in 3 (1,7%). Plate dislocations out of the shaft existed in 4 (2,4%) and 14 collapses of the humeral head with secondary screw perforations were recorded. All other complications arose out of technical faults, such as 24 screw perforations (11%) into the glenohumeral joint and 3 (1.7%) cases of secondary implant dislocation from the humeral head and 5 (3%) from the shaft, and 14 (8%) sinterings with glenohumeral screw perforation. So far, in addition to 1 case of pseudarthrosis with a broken plate, 5 (3%) cases of total and 9 (5%) of partial avascular humeral head necrosis have been observed. CONCLUSION: The new implant provides superior stability in the fixation of humeral head fragments and has proved its worth in everyday clinical practice when additional indirect fixation of the tubercle is needed, as it frequently is in elderly patients.

Kim, K. H., et al. (2010). "Anterior bone cement augmentation in anterior lumbar interbody fusion and percutaneous pedicle screw fixation in patients with osteoporosis." J Neurosurg Spine **12**(5): 525-532.

OBJECT: The purpose of the present study was to evaluate the efficacy of anterior polymethylmethacrylate (PMMA) cement augmentation in instrumented anterior lumbar interbody fusion (ALIF) for patients with osteoporosis. METHODS: Sixty-two patients with osteoporosis who had undergone single-level instrumented ALIF for spondylolisthesis and were followed for more than 2 years were included in the study. The patients were divided into 2 groups: instrumented ALIF alone (Group I) and instrumented ALIF with anterior PMMA augmentation (Group II). Sixty-one patients were interviewed to evaluate the clinical results, and plain radiographs and 3D CT scans were obtained at the last follow-up in 46 patients. RESULTS: The mean degree of cage subsidence was significantly higher in Group I (19.6%) than in Group II (5.2%) (p = 0.001). The mean decrease of vertebral body height at the index level was also significantly higher in Group I (10.7%) than in Group II (3.9%) (p = 0.001). No significant intergroup differences were observed in the incidence of radiographic adjacent-segment degeneration (ASD) or in terms of pain and functional improvement. The incidences of clinical ASD (23% in Group I and 10% in Group II) were not significantly different. There was 1 case of nonunion and 3 cases of screw migration in Group I, but none resulted in implant failure. CONCLUSIONS: Anterior PMMA augmentation during instrumented ALIF in patients with osteoporosis was useful to prevent cage subsidence and vertebral body collapse. In addition, PMMA augmentation did not increase the nonunion rate and incidence of ASD.

Kim, W. Y., et al. (2001). "Failure of intertrochanteric fracture fixation with a dynamic hip screw in relation to pre-operative fracture stability and osteoporosis." Int Orthop **25**(6): 360-362.

We have reviewed 178 intertrochanteric fractures treated by dynamic hip screw (DHS) fixation between March 1995 and December 1999 and followed for a minimum of 1 year. We used Singh's classification of the trabecular bone structure in the proximal femur as a measure of osteoporosis and also classified the fractures according to three different systems (Boyd-Griffin, Evans, AO). The postoperative radiographs were examined for loss of reduction, i.e. varus angulation >100, perforation of the femoral head, more than 20-mm extrusion of a lag screw or metal failure. We found 49 cases which showed radiographic failures. Two were stable fractures and 47 unstable fractures (Evans' classification). Unstable fractures with osteoporosis had a failure rate of more than 50%. In such cases DHS should not be the first choice for treatment.

Knobe, M., et al. (2008). "[Surgical outcome in pertrochanteric femur fracture: the impact of osteoporosis. Comparison between DHS and percutaneous compression plate]." Z Orthop Unfall **146**(1): 44-51.

AIM: The dynamic hip screw (DHS) often shows an impared outcome and a high incidence of therapeutic failure in patients with osteoporotic pertrochanteric femur fractures. This is caused predominantly by a fracture collapse and appears often in unstable fractures (31A2, 31A3). In a prospectively documented clinical study, we examined whether or not the percutaneous compression plate (PCCP, Gotfried) offers advantages following osteoporotic fractures. METHOD: From August 2003 to December 2005, 103 patients underwent internal fixation with the DHS (n = 40, age 76.1, ASA 2.9) or with the PCCP (n = 63, age 76.9, ASA 2.8). Proximal femurs were classified with the Singh grading system, which uses six grades of trabecular patterns to describe the degree of osteoporosis. Reexamination of the patients (27 DHS, 43 PCCP) was performed on average 18 months later. RESULTS: The PCCP was implanted into very osteoporotic femurs (Singh 2) in less time than the DHS (47 vs. 79 min). These patients treated with PCCP showed no difference in blood loss, but tended to have better outcomes (Merle d'Aubigne, Harris hip score) than those treated with DHS. Life quality, subjectively measured with the visual analogue score, was significantly better in the PCCP group with high-grade osteoporosis (Singh 2). The outcome after implantation of the PCCP was not correlated to the Singh index in stable or in unstable fractures. Mechanical complications occurred especially in unstable fractures (re-operation rate: DHS 4/18 [22 %], PCCP 3/29 [10 %], p = 0.266), without correlation to the Singh index. Excluding the

avoidable complication of loosening of the screw-barrel portion, the re-operation rate for the PCCP was 3 % (cut-out: 1/29, p = 0.042) in unstable fractures. CONCLUSION: Use of the minimally invasive PCCP technique in osteoporotic pertrochanteric femur fractures provides an alternative to the dynamic hip screw, especially with regard to surgical time and outcome. Advantages occurred also in the re-operation rate following fracture fixation complications. The cut-out rate was significantly lower than in the DHS group in unstable fractures.

Knoller, S. M., et al. (2005). "Range of motion in reconstruction situations following corpectomy in the lumbar spine: a question of bone mineral density?" Spine (Phila Pa 1976) **30**(9): E229-235.

STUDY DESIGN: In vitro biomechanical study to evaluate the stability of different types of instrumentation in the lumbar spine following corpectomy in relation to bone mineral density (BMD). OBJECTIVES: To investigate the relation between the stability of a spinal instrumentation and BMD. To determine a threshold value of BMD allowing a single ventral instrumentation following corpectomy in the lumbar spine. SUMMARY OF BACKGROUND DATA: Some in vitro studies determined the biomechanical properties of different spinal instrumentations in various spinal injury models. To the authors' knowledge, there are no published data available concerning stabilization in relation to BMD. A guideline for the treatment of a corpectomy depending on BMD would be helpful in order to choose the appropriate surgical method. METHODS: Twenty-four fresh frozen human lumbar cadaveric spine specimens L1-L3 were used for testing of biomechanical properties. Plain radiographs were taken. BMD was determined using quantitative computed tomography (QCT). Testing in a 6 df loading device included native specimens and specimens after corpectomy of L2, restoration of the defect with a titanium cage, and two reconstruction situations: single ventral and additional dorsal instrumentation. Load-displacement curves and range of motion parameters were recorded and correlated with BMD. RESULTS: A significant ($P < 0.05$) influence of BMD on range of motion was found. Single ventral instrumentation was critical concerning axial rotation. Combined dorsoventral instrumentation offered sufficient stability. The threshold value for use of single ventral instrumentation is a BMD > or = 0.22 g/cm. CONCLUSIONS: Single ventral instrumentation can provide sufficient stability following corpectomy in the lumbar spine under the condition of a high BMD. Determination of BMD and the use of this guideline provides a valid tool for surgical planning.

Koller, H., et al. (2013). "The impact of a distal expansion mechanism added to a standard pedicle screw on pullout resistance. A biomechanical study." Spine J **13**(5): 532-541.

BACKGROUND CONTEXT: Spinal deformity surgery in elderly patients is associated with an increased risk of implant loosening due to failure at the screw-bone interface. Several techniques can be used to increase the screw anchorage characteristics. Cement-augmented screw fixation was shown to be the most efficient method; however, this technique is associated with a risk of complications related to vertebral cement deposition and leakage. Hence, there is a need to further elaborate the alternative screw augmenting techniques to reduce the indications for bone cement. PURPOSE: To analyze surgical alternatives to cement augmentation, the present study sought to quantify the impact of a distal expansion mechanism added to a standard pedicle screw on an axial pullout resistance. STUDY DESIGN: A biomechanical laboratory study on the uniaxial pullout resistance of a standard pedicle screw versus a customized pedicle screw with a distal expansion mechanism. METHODS: A total of 40 vertebrae from seven fresh-frozen human specimens were harvested and subjected to a computed tomography scanning and an analysis of the bone mineral density (BMD). The vertebrae were instrumented with a standard 6.0-mm pedicle screw and a modified 6.0-mm pedicle screw with a distal expansion mechanism added. The actual working length of both screws inside the vertebrae was identical. The distal expansion mechanism made up one-fifth of the shaft length. The accuracy of the screw insertion was assessed using biplanar radiographs and by inspection. Analysis of resistance to pullout was performed by a coaxial alignment of the pedicle screws and attachment to an electromechanical testing machine. The pullout rate was 5 mm/min,

and the load-displacement curve was recorded until the force of the pullout resistance peaked. The peak load-to-failure was measured in Newtons and reported as the ultimate failure load. With each test, the mode of failure was noted and analyzed descriptively. RESULTS: A total of 17 vertebrae with matched pairs of standard and expansion pedicle screws were eligible for the final statistical analysis. The BMD of the vertebrae tested was 0.67+/-0.19 g/cm(3). The screw length was 50 mm, and the actual working length of both screws was 40.3+/-4.2 mm. The ultimate failure load of the standard screw was 773.8+/-529.4 N and that of the expansion screw was 910.3+/-488.3 N. Statistical analysis revealed a strong trend toward an increased failure load with the expansion screw (p=.06). The mean increase of the ultimate failure load was 136.5+/-350.4 N. Abrupt vertebral fracture at the vertebral body-pedicle junction and the pedicle occurred seven times with the expansion screw and only five times with the standard screw (p=.16). CONCLUSIONS: Our study indicates that adding a distal expansion mechanism to a standard pedicle screw increases the failure load by one-fifth. Modern expansion screws might offer an intermediate solution for the augmentation of screw-rod constructs in osteoporotic bone while reducing the need for cement-augmented screws and avoiding the related risks.

Konstantinidis, L., et al. (2013). "Failure after osteosynthesis of trochanteric fractures. Where is the limit of osteoporosis?" Osteoporos Int **24**(10): 2701-2706.

SUMMARY: The aim of this study is to identify osteoporosis values, beyond which there is a high risk of osteosynthesis failure. Bone mineral density (BMD) of 30 cadaveric femora with a pertrochanteric fracture osteotomy was correlated to the risk of cut out after osteosynthesis on a biomechanical testing approach. For a BMD less than 250 mg/cm(3), there is a high risk of fixation failure after surgical treatment of pertrochanteric fractures. This value can be regarded as a reference value for future experimental and clinical studies. INTRODUCTION: Despite continuous modification of intramedullary load carriers for the surgical stabilization of trochanteric fractures, cut out remains the most frequent complication. The aim of this experimental study was to identify threshold osteoporosis values, beyond which there is a high risk of osteosynthesis failure. METHODS: Bone mineral density (BMD) of 30 cadaveric femora was recorded for the femoral head by QCT measurement. Subsequently, a standardized osteotomy mimicking an unstable trochanteric type fracture was stabilized by intramedullary nailing. The constructs were loaded axially at a force of 2,100 N up to 20,000 cycles. Cut out at the femoral head was documented by radiograph. Statistical evaluation of the cohort group was performed by calculation of relative risk in relation to the BMD values. RESULTS: In total, there were six cases of cut out after 10,000 cycles. The incidence of cut out for BMD less than 250 mg/cm(3) was 0.55 (5 of 9) and for BMD greater than 250 mg/cm(3), it was 0.05 (1 of 21). Therefore, the relative risk of cut out for BMD <250 mg/cm(3) is 11x greater than for a BMD >250 mg/cm(3). After 20,000 cycles, an additional test caused one cut out (relative risk of cut out for a BMD <250 mg/cm(3) 5.8). CONCLUSIONS: For a BMD less than 250 mg/cm(3), there is a high risk of fixation failure after surgical treatment of pertrochanteric fractures. Although this value is based on an experimental in vitro study design with all its associated limitations, it can be regarded as a reference value for future experimental and clinical studies.

Korner, J., et al. (2005). "Distal humerus fractures in elderly patients: results after open reduction and internal fixation." Osteoporos Int **16 Suppl 2**: S73-79.

PROBLEM: Fractures of the distal humerus are difficult to treat. In elderly patients, diminished bone mineral quality and increased trauma-associated joint destruction may make stable joint reconstruction even more problematic. Furthermore, comorbidities and poor tolerance of joint immobilization might be additional factors which influence elbow function negatively. Until now, disagreement has existed on how to treat these fractures in elderly patients. Recommendations range from conservative treatment to primary total elbow replacement. So far, reports in the literature on whether or not open reduction and internal fixation in these patients is justified are very rare. AIM OF THE STUDY: To analyze fracture

patterns, surgical approach, complications, and functional results after open reduction and internal fixation in patients of age 60 years and older. PATIENTS AND METHODS: Retrospective clinical study of two university level 1 trauma centers, including 45 patients (median age 73 years; range, 61-92 years) with surgically treated distal humerus fractures. Fracture patterns were recorded according to their AO classification. All patients were treated by open reduction and internal fixation. A clinical and radiological follow-up was obtained after a minimum of 24 months following surgery (median 87 months; range, 24-121 months). Functional results were evaluated according to the Mayo Elbow Score. RESULTS: Fractures with complete joint involvement were seen most often. Taking the fracture type into consideration, functional results deteriorated with degree of joint involvement. **Postoperative complication rate was high, predominantly seen as screw loosening and/or implant failure at the lateral column.** Neverthless, functional results were preponderating good or excellent. Factors negatively influencing outcome were joint immobilization longer than 14 days and severe joint involvement. DISCUSSION: In elderly patients, distal humerus fractures, which are often considered "osteoporotic fractures," still remain one of the most demanding challenges in trauma surgery. The present study demonstrates that despite diminished bone quality and a high complication rate, open reduction and internal fixation in elderly patients is justified. CONCLUSION: Open reduction and internal fixation of distal humerus fractures in elderly patients should be the main goal, since good elbow function can be achieved in the majority of patients. Elbow immobilization longer than 14 days should be avoided. Stable implant anchorage at the lateral column remains problematic, reflecting a general potential for further implant improvements.

Kralinger, F., et al. (2014). "The Influence of Local Bone Density on the Outcome of One Hundred and Fifty Proximal Humeral Fractures Treated with a Locking Plate." J Bone Joint Surg Am **96**(12): 1026-1032.

BACKGROUND: There is biomechanical evidence that bone density predicts the mechanical failure of implants. The aim of this prospective study was to evaluate the influence of local bone mineral density on the rate of mechanical failure after locking plate fixation of proximal humeral fractures.METHODS: We enrolled 150 patients who were from fifty to ninety years old with a closed, displaced proximal humeral fracture fixed with use of a locking plate from July 2007 to April 2010. There were 118 women and thirty-two men who had a mean age of sixty-nine years. Preoperative computed tomography (CT) scans were done to assess bone mineral density of the contralateral humerus, and dual x-ray absorptiometry of the distal end of the radius of the unaffected arm was conducted within the first six weeks postoperatively. At follow-up evaluations at six weeks, three months, and one year postoperatively, pain, shoulder mobility, strength, and multiple functional and quality-of-life outcome measures (Disabilities of the Arm, Shoulder and Hand [DASH] questionnaire; Shoulder Pain and Disability Index [SPADI]; Constant score; and EuroQuol-5D [EQ-5D]) were done and standard radiographs were made. We defined mechanical failure as all complications related to bone quality experienced within one year.RESULTS: After locking plate fixation, fifty-three (35%) of 150 patients had mechanical failure; loss of reduction and secondary screw loosening with perforation were common. CT assessments of local bone mineral density showed no difference between patients with and without mechanical failure (89.82 versus 91.51 mg/cm3, respectively; p = 0.670). One-year DASH, SPADI, and Constant scores were significantly better for patients without mechanical failure (p </= 0.05).CONCLUSIONS: We did not find evidence of an association between bone mineral density and the rate of mechanical failures, which may suggest that patients with normal bone mineral density are less prone to sustain a proximal humeral fracture. Future studies should target other discriminating factors between patients with and without mechanical failure.LEVEL OF EVIDENCE: Prognostic Level III. See Instructions for Authors for a complete description of levels of evidence.

Lee, Y. H., et al. (1996). "Complications in surgical treatment of undisplaced femoral neck fracture." Zhonghua Yi Xue Za Zhi (Taipei) **58**(1): 24-28.

BACKGROUND: Percutaneous Knowles' pinning is a well accepted treatment of undisplaced femoral neck fracture, but there are some complications that have seldom been discussed. METHODS: One hundred and eighty two patients with undisplaced femoral neck fractures, at a mean age of 67 years, were treated by percutaneous Knowles' pinning between 1983 to 1989, and followed for an average of 102 months. The clinical results and complications were evaluated. The data were collected on the basis of age and bone density. Student's t-test was used to evaluate the significance of the results. RESULTS: The mean union time was 20 weeks. In all the patients, 85.8% had good results, 3.8% patients had acceptable results and 10.4% patients had poor results. Old age (> or = 65 years) and osteoporosis (Singh index < or = 3) were two factors of the poor result. Thirty-two cases (17.6%) developed complications. The incidence of nonunion or implant problems was apparently higher in the older or osteoporosis group, but avascular necrosis of femoral head correlated little with old age or osteoporosis. CONCLUSIONS: Although percutaneous Knowles' pinning is simple, safe, economic and reasonably effective for the treatment of undisplaced femoral neck fractures, we should pay more attention to the uncooperative, old, and osteoporotic patients.

Lim, T. H., et al. (1995). "Strength of anterior vertebral screw fixation in relationship to bone mineral density." J Spinal Disord **8**(2): 121-125.

A biomechanical study was performed to investigate the relationship among the pullout strength of anterior vertebral screw fixation, bone mineral density (BMD) of the vertebral body, screw insertion torque, and width of the vertebral body. BMD was measured using a dual energy x-ray absorptiometry unit. Screw insertion torque and width of the lumbar vertebrae were also measured before the pullout test. Pullout strength was significantly correlated with BMD (r = 0.85) and screw insertion torque (r = 0.47), but not with width of the vertebral body. Multiple regression analyses demonstrated better correlation between pullout strength and the other parameters (r = 0.886). A stepwise regression analysis showed that BMD is the most significant predictor of the pullout strength followed by width of the vertebral body, whereas screw insertion torque is not a significant predictor. Furthermore, the mean pullout strength of the grade I osteoporosis group was significantly greater than that of grade II or III osteoporosis group.

Lindner, T., et al. (2009). "Fractures of the hip and osteoporosis: the role of bone substitutes." J Bone Joint Surg Br **91**(3): 294-303.

Failure of fixation is a common problem in the treatment of osteoporotic fractures around the hip. The reinforcement of bone stock or of fixation of the implant may be a solution. Our study assesses the existing evidence for the use of bone substitutes in the management of these fractures in osteoporotic patients. Relevant publications were retrieved through Medline research and further scrutinised. Of 411 studies identified, 22 met the inclusion criteria, comprising 12 experimental and ten clinical reports. The clinical studies were evaluated with regard to their level of evidence. Only four were prospective and randomised. Polymethylmethacrylate and calcium-phosphate cements increased the primary stability of the implant-bone construct in all experimental and clinical studies, although there was considerable variation in the design of the studies. In randomised, controlled studies, augmentation of intracapsular fractures of the neck of the femur with calcium-phosphate cement was associated with poor long-term results. There was a lack of data on the long-term outcome for trochanteric fractures. Because there were only a few, randomised, controlled studies, there is currently poor evidence for the use of bone cement in the treatment of fractures of the hip.

Lobo-Escolar, A., et al. (2010). "Predictive factors for cutting-out in femoral intramedullary nailing." Injury **41**(12): 1312-1316.

BACKGROUND: Femoral intramedullary nailing is currently one of the most frequent surgical treatments for extracapsular hip-fracture fixation. Cutting-out of the lag screw is the main complication of this technique, but only few studies have approached the cutting-out focussed on femoral nailing. The aim of this study was to confirm in patients treated with intramedullary nailing not only with regard to previous reports about the association of cutting-out with technical factors, but also with regard to clinical factors not previously studied. METHODS: Case-control study of all patients sustaining a cut-out of the femoral nail was carried out and a control sample was randomly selected among all extracapsular hip-fracture patients during the study period (2005-2008). All clinical and technical variables were collected from medical records. Orthopaedic Trauma Association (AO/OTA) fracture classification, Singh Osteoporosis Index of the contralateral hip and the American Society of Anaesthesiology (ASA) criteria for preoperative clinical status were used. Statistical assessment included bivariant analysis and multivariant logistic regression analysis. RESULTS: A total of 916 hip-fracture cases were treated in the study period: 33 of them (3.6%) were identified as suffering cutting-out, and 315 controls fulfilling inclusion criteria were also recruited. No statistical differences were found in age, sex or other socio-demographic variables between the two groups. Bivariant analysis showed significant differences between groups in technical variables (tip-apex distance, suboptimal placement of lag screw, fracture diastasis, inadequate fixation quality and distal static locking) and in clinical variables (osteoporosis severity, right hip affected, better previous ability for walking and better preoperative ASA status). Multivariant logistic regression analysis showed significant association only for tip-apex distance and inadequate fixation quality. Differences in distal static locking were close to statistical significance. CONCLUSIONS: The strongest predictor of cutting-out in femoral nailing is tip-apex distance. This study suggests that distal static locking and other clinical conditions play an important role in this fixation failure.

Mair, S., et al. (2013). "[Stability of volar fixed-angle plating for distal radius fractures. Failure modes in osteoporotic bone]." Unfallchirurg **116**(4): 338-344.

BACKGROUND: Distal radius fractures continue to show significant complication rates after operative treatment with locked plating. Failure occurs by screw loosening or screw penetration in the distal fragment. Placement of additional screws may enhance the stiffness of fracture fixation. The aim of this study was to determine the fatigue properties of different screw configurations in distal radius plate osteosynthesis with biomechanical tests and finite element analysis (FEA). MATERIAL AND METHODS: Unstable distal radius fractures were created in 12 human cadaveric bone specimens and were fixed with volar locking plates. Group 4SC was fixed with four screws in the distal row and group 6SC with two additional screws the row below. Dynamic loading was applied physiologically. The radial shortening, the angulation of the distal fragment and the failure mechanism were determined by experimental tests and were further elucidated by FEA. RESULTS: Group 6SC showed a significantly lower radial shortening and inclination. Breakage of the screws within the plate was noted in group 4SC, while moderate screw penetration was observed in group 6SC. FEA confirmed the biomechanical tests. In group 4SC elevated von Mises strain in the locking mechanism explained the inclination of the screws and the distal fragment. The elastic strain in group 6SC was increased at the screw-bone interface which explained the resulting screw penetration. CONCLUSION: The failure mechanism in volar plating of distal radius fractures depended on the number of screws and their configuration. Using two more screws increases construct stiffness and angular stability under dynamic loading. However, increased stiffness also promoted screw penetration mainly in osteoporotic bone. Compared to screw penetration, loss of reposition and inclination of the distal fragment observed in the 4SC configuration is more likely to result in clinical complications.

Micic, I. D., et al. (2009). "Analysis of early failure of the locking compression plate in osteoporotic proximal humerus fractures." J Orthop Sci **14**(5): 596-601.

BACKGROUND: Although there has been continuous evolution in the management of fracture fixation, treatment for osteoporotic proximal humerus fractures is still challenging to trauma surgeons. The purpose of this study was to report early failure of the locking compression plate (LCP) in the treatment of osteoporotic proximal humerus fracture and characterize the mode of failure. METHODS: Nine patients, older than 65 years, underwent internal fixation with the use of a locking compression plate and had early failure within 4 weeks postoperatively. According to Neer's classification, five were included in a two-part surgical neck fracture, three in a three-part fracture, and one in a four-part fracture. RESULTS: All failures occurred with back-out of the plate-screw construct, leading to varus displacement in eight patients and plate breakage in one. Revision surgery was performed in six patients using replating and tension band wiring with a bone graft, and three patients underwent hemiarthroplasty. The average UCLA score was 25 points for the hemiarthroplasty group and 30 points for the reconstruction group. CONCLUSIONS: Early postoperative failure of the LCP developed within 4 weeks with a presentation of en bloc back-out of the plate-screw construct and plate breakage. Possible risk factors included malreduction, loss of medial support, and negligence of tension band sutures on the tuberosities.

Moed, B. R., et al. (2012). "Failure of locked design-specific plate fixation of the pubic symphysis: a report of six cases." J Orthop Trauma **26**(7): e71-75.

OBJECTIVES: Physiological pelvic motion has been known to lead to eventual loosening of screws, screw breakage, and plate breakage in conventional plate fixation of the disrupted pubic symphysis. Locked plating has been shown to have advantages for fracture fixation, especially in osteoporotic bone. Although design-specific locked symphyseal plates are now available, to our knowledge, their clinical use has not been evaluated and there exists a general concern that common modes of failure of the locked plate construct (such as pullout of the entire plate and screws) could result in complete and abrupt loss of fixation. The purpose of this study was to describe fixation failure of this implant in the acute clinical setting. DESIGN: Retrospective analysis of multicenter case series. SETTING: Multiple trauma centers. PATIENTS: Six cases with failed fixation, all stainless steel locked symphyseal plates and screws manufactured by Synthes (Paoli, PA) and specifically designed for the pubic symphysis, were obtained from requests for information sent to orthopaedic surgeons at 10 trauma centers. A four-hole plate with all screws locked was used in 5 cases. A six-hole plate with 4 screws locked (two in each pubic body) was used in one. INTERVENTION: Fixation for disruption of the pubic symphysis using an implant specifically designed for this purpose. MAIN OUTCOME MEASUREMENTS: Radiographic appearance of implant failure. RESULTS: Magnitude of failure ranged from implant loosening (3 cases), resulting in 10-mm to 12-mm gapping of the symphyseal reduction, to early failure (range, 1-12 weeks), resulting in complete loss of reduction (3 cases). **Failure mechanism included construct pullout, breakage of screws at the screw/plate interface, and loosening of the locked screws from the plate and/or bone. Backing out of the locking screws resulting from inaccurate insertion technique was also observed.** CONCLUSIONS: Failure mechanisms of locked design-specific plate fixation of the pubic symphysis include those seen with conventional uniplanar fixation as well as those common to locked plate technology. Specific indications for the use of these implants remain to be determined. LEVEL OF EVIDENCE: Therapeutic Level IV. See Instructions for Authors for a complete description of levels of evidence.

Mueller, T. L., et al. (2009). "Non-invasive bone competence analysis by high-resolution pQCT: an in vitro reproducibility study on structural and mechanical properties at the human radius." Bone **44**(2): 364-371.

Osteoporosis is defined as a skeletal disorder characterized by compromised bone strength. Bone strength depends, among others, on bone density, bone geometry and its internal architecture. With the recent introduction of a new generation high-resolution 3D peripheral

quantitative computed tomography (HR-pQCT) system, direct quantification of structural bone parameters has become feasible. Furthermore, it has recently been demonstrated that bone mechanical competence can be derived from HR-pQCT based micro-finite element modeling (microFE). However, reproducibility data for HR-pQCT-derived mechanical indices is not well-known. Therefore, the aim of this study was to quantify reproducibility of HR-pQCT-derived indices. We measured 14 distal formalin-fixed cadaveric forearms three times and analyzed three different regions for each measurement. For each region cortical and trabecular parameters were determined. Reproducibility was assessed with respect to precision error (PE) and intraclass correlation coefficient (ICC). Reproducibility values were found to be best in all three regions for the full bone compartment with an average PE of 0.79%, followed by the cortical compartment (PE=1.19%) and the trabecular compartment with an average PE of 2.31%. The mechanical parameters showed similar reproducibility (PE=0.48%-2.93% for bone strength and stiffness, respectively). ICC showed a very high reproducibility of subject-specific measurements, ranging from 0.982 to 1.000, allowing secure identification of individual donors ranging from healthy to severely osteoporotic subjects. From these in vitro results we conclude that HR-pQCT derived morphometric and mechanical parameters are highly reproducible such that differences in bone structure and strength can be detected with a reproducibility error smaller than 3%; hence, the technique has a high potential to become a tool for detecting bone quality and bone competence of individual subjects.

Myers, B. S., et al. (1996). "The role of imaging and in situ biomechanical testing in assessing pedicle screw pull-out strength." Spine (Phila Pa 1976) **21**(17): 1962-1968.

STUDY DESIGN: This study determined the predictive ability of quantitative computed tomography, dual energy x-ray absorptiometry, pedicular geometry, and mechanical testing in assessing the strength of pedicle screw fixation in an in vitro mechanical test of intra-pedicular screw fixation in the human cadaveric lumbar spine. OBJECTIVE: To test several hypotheses regarding the relative predictive value of densitometry, pedicular geometry, and mechanical testing in describing pedicle screw pull-out. SUMMARY OF BACKGROUND DATA: Previous investigations have suggested that mechanical testing, geometry, and densitometry, determined by quantitative computed tomography or dual energy x-ray absorptiometry, predict the strength of the screw-bone system. However, no study has compared the relative predictive value of these techniques. METHODS: Forty-nine pedicle screw cyclic-combined flexion-extension moment-axial pull-out tests were performed on human cadaveric lumbar vertebrae. The predictive ability of quantitative computed tomography, dual energy x-ray absorptiometry, insertional torque, in situ stiffness, and pedicular geometry was assessed using multiple regression. RESULTS: Several variables correlated to force at failure. However, multiple regression analysis showed that bone mineral density of the pedicle determined by quantitative computed tomography, insertional torque, and in situ stiffness when used in combination resulted in the strongest prediction of pull-out force. No other measures provided additional predictive ability in the presence of these measures. CONCLUSIONS: Pedicle density determined by quantitative computed tomography when used with insertional torque and in situ stiffness provides the strongest predictive ability of screw pull-out. Geometric measures of the pedicle and density determined by dual energy x-ray absorptiometry do not provide additional predictive ability in the presence of these measures.

Ohtori, S., et al. (2013). "Comparison of teriparatide and bisphosphonate treatment to reduce pedicle screw loosening after lumbar spinal fusion surgery in postmenopausal women with osteoporosis from a bone quality perspective." Spine (Phila Pa 1976) **38**(8): E487-492.

STUDY DESIGN: Prospective study. OBJECTIVE: To examine the efficacy of teriparatide or bisphosphonate treatment to reduce pedicle screw (PS) loosening after instrumented lumbar posterolateral fusion in postmenopausal women with osteoporosis. SUMMARY OF BACKGROUND DATA: Failure of fixation caused by loosening of PSs in osteoporosis is a

problem in spinal surgery. Oral administration of bisphosphonate or intermittent injection of parathyroid hormone treatment increases bone mass and reduces the risk of osteoporotic vertebral fractures. Although these treatments may be factor in improving bone quality, a clinical study of the efficacy of bisphosphonate or parathyroid hormone for reducing PS loosening that addresses the quality of the bone marrow and pedicle cortex has not yet been reported. METHODS: Sixty-two women with osteoporosis diagnosed with degenerative spondylolisthesis were divided into 3 groups: a teriparatide group (daily subcutaneous injection of 20 mug of teriparatide, n = 20), a bisphosphonate group (daily oral administration 2.5 mg of risedronate, n = 20), and a control group (without medication for osteoporosis, n = 22). All patients underwent decompression and 1- or 2-level instrumented posterolateral fusion with a local bone graft. Loosening of PSs and surgical outcome were evaluated radiographically, clinically, and by computed tomography 12 months after surgery. RESULTS: At 12-month follow-up, the incidence of PS loosening was 7% to 13% in the teriparatide group, 13% to 26% in the risedronate group, and 15% to 25% in the control group. The incidence of PS loosening in the teriparatide group was significantly lower than that in the risedronate or the control group ($P < 0.05$). In contrast, the extent of PS loosening in the risedronate group was not significantly different from that in the control group ($P > 0.05$). CONCLUSION: Our findings suggest that administration of teriparatide increased the quality of the lumbar spine bone marrow and pedicle cortex.

Oliphant, B. W., et al. (2013). "Predrilling does not improve the pullout strength of external fixator pins: a biomechanical study." J Orthop Trauma **27**(2): e25-30.

OBJECTIVES: External fixator pins are thought to have improved pullout strength if inserted into both cortices and if pilot holes are drilled. We tested these hypotheses and investigated effects of osteoporosis and pin location on pin pullout strength. METHODS: Self-drilling external fixator pins were inserted using 4 techniques: 1) predrilled bicortically inserted, 2) not predrilled bicortically inserted, 3) not predrilled unicortically inserted, and 4) technique 2 with far cortex disengaged to test holding power of near cortex in isolation. Ninety-six samples were tested from four locations in 12 matched pairs of cadaveric femora [6 pairs osteoporotic (T </= -2.5), six pairs nonosteoporotic (T > -2.5)]. Pullout force was tested on materials testing system until failure of pin-bone interface. RESULTS: Bicortical pin placement and location within femur had substantial effects on the holding power of the pins. Osteoporosis had statistically significant effect but with smaller effect size ($P = 0.05$). No significant difference in holding power was observed between predrilling and no predrilling techniques ($P = 0.27$). We observed only a trend toward "stripping effect" in near cortex with technique 4. Bicortical placement rendered 69% greater holding power than unicortical. Proximal placement rendered 56% greater holding power than distal. Osteoporotic samples had 15% less holding power than nonosteoporotic samples. CONCLUSIONS: Single-cortex pin placement, osteoporotic bone, and more distal pin location decreased pin pullout strength. We did not observe a significant mechanical advantage of predrilling for modern external fixator pins. The near cortex of a pin inserted into 2 cortices without predrilling did not exhibit substantial stripping effect.

Osti, M., et al. (2011). "Analysis of failure following anterior screw fixation of Type II odontoid fractures in geriatric patients." Eur Spine J **20**(11): 1915-1920.

Anterior screw fixation of Type II odontoid fractures has been recommended. Only few publications analyse the mechanism of failure in geriatric patients. We reviewed 18 male and 15 female patients aged 65 and above for parameters that influence the development of postoperative loss of correction, delayed union or non-union. Patients were stratified in two groups: 21 cases in Group A (union) and 12 patients in Group B (loss of correction, delayed union, non-union, revision surgery). Statistically significant correlation ($p < 0.05$) could be detected between failure to heal and: (1) degenerative changes in the atlanto-odontoid joint, (2) severity of osteoporosis in the odontoid process, (3) posterior oblique fracture type, (4) suboptimal fracture reduction, (5) suboptimal position of implant following demanding

intraoperative conditions, (6) quality of fracture compression and (7) severity of fracture comminution. The overall morbidity and mortality rates were 29.0 and 8.6%, respectively. Our results indicate that these factors should be addressed regarding the selection of the operative treatment method in the geriatric patient.

Ozawa, T., et al. (2005). "Insertional torque of the lumbar pedicle screw during surgery." J Orthop Sci **10**(2): 133-136.

The purposes of this study were to determine if the intraoperative insertional torque of pedicle screws correlates with the degree of osteoporosis and if insertional torque can be used as a predictor of screw loosening and clinical results in elderly patients. Pedicle screw fixation was performed in 25 patients. Their mean age at the time of surgery was 72.2 years (range 65-79 years). The mean follow-up period was 2.8 years (range 1.0-4.8 years). The insertional torque of the pedicle screws was measured using a Kannon-type torque wrench with a special connector. In the present study, 136 screws were evaluated. The mean insertional torque was 12.2 +/- 5.0 kgf x cm. A negative relation was found between insertional torque and the grade of osteoporosis. Roentgenograms showed the radiolucency of 18 screws in eight patients. Radiolucency appeared as early as 6 months postoperatively. However, there was no significant relation between insertional torque and the presence of screw loosening. Furthermore, there was no significant difference in the clinical results between patients with low insertional torque and those with high insertional torque. This study demonstrated that intraoperative insertional torque is not an objective predictor of screw loosening or clinical results.

Paech, A., et al. (2010). "Biopolymer augmentation of the lag screw in the treatment of femoral neck fractures--a biomechanical in-vitro study." Eur J Med Res **15**(4): 174-179.

The cut-out of the sliding screw is one of the most common complications in the treatment of intertrochanteric fractures. The reasons for the cut-out are: a suboptimal position of the hip-screw in the femoral head, the type of fracture and poor bone quality. The aim of this study was to reproduce the cut-out event biomechanically and to evaluate the possible prevention of this event by the use of a biopolymer augmentation of the hip screw. Concerning the density and compression force of osteoporotic femoral bone polyurethane foam according to the terms of the Association for Standard Testing Material (ASTMF 1839-97) was used as test material. The polyurethane foam Lumoltan 200 with a compression force of 3.3 Mpa and a density of 0.192 g/cm(3) was used to reproduce the osteoporotic bone of the femoral fragment (density 12 lbm/ft(3)). A cylinder of 50 mm of length and 50 mm of width was produced by a rotary splint raising procedure with planar contact. The axial load of the system was performed by a hydraulic force cylinder of a universal test machine type Zwick 1455, Ulm, Germany. The CCD-angle of the used TGN-System was preset at 130 degrees. The migration pattern of the hip screw in the polyurethane foam was measured and expressed as a curve of the distance in millimeter (mm) against the applied load in Newton (N) up to the cut-out point. During the tests the implants reached a critical changing point from stable to unstable with an increased load progression of steps of 50 Newton. This unstable point was characterized by an increased migration speed in millimeters and higher descending gradient in the migration curve. This peak of the migration curve served as an indicator for the change of the hip screw position in the simulated bone material. The applied load in the non-augmented implant showed that in this group for a density degree of 12 (0,192 g/cm(3)) the mean force at the failure point was 1431 Newton (+/- 52 Newton). In the augmented implant we found that the mean force at the failure point was 1987 Newton (+/- 84 Newton). This difference was statistically significant. In conclusion, the bone density is a significant factor for the stability of the hip screw implant. The osteosynthesis with screws in material with low density increases the chance for cut-out. A biopolymer augmented hip screw could significantly improve the stability of the fixation. The use of augmentation with a fast hardening bone replacement material containing polymer-ceramic changes the point of failure under axial load in the osteoporotic bone model and could significantly improve the

failure point. Our study results indicate, that a decrease of failure in terms of cut-out can be achieved with polymer augmentation of hip screws in osteoporotic bones.

Panchbhavi, V. K., et al. (2008). "The use of calcium sulfate and calcium phosphate composite graft to augment screw purchase in osteoporotic ankles." Foot Ankle Int **29**(6): 593-600.

BACKGROUND: Screws placed in the distal fibula may not have satisfactory purchase during internal fixation of an osteoporotic ankle fracture. Tibia-pro-fibula screws that extend from the fibula into the distal tibial metaphysis provide additional purchase. The purpose of this study was to investigate if purchase of these screws can be enhanced further by injecting calcium sulfate and calcium phosphate composite graft into the drill holes prior to insertion of the screws. MATERIALS AND METHODS: Bone density was quantified using a DEXA scan in paired cadaver legs. One leg from each pair was randomly selected for injection of composite graft into the screw holes before insertion of the screws. Two screws were inserted through the fibula into the distal tibial metaphysis in each leg, at the level of the syndesmosis under fluoroscopy in a standardized fashion in an MTS machine. RESULTS: After testing 4 pairs of cadaver legs, a statistically significant difference was noted in displacement ($p = 0.018$ distal, $p = 0.0093$ proximal), failure load, ($p = 0.0185$ distal, $p = 0.0238$ proximal), and failure energy ($p = 0.0071$ distal, $p = 0.0115$ proximal) between augmented and non-augmented screws, with the augmented screws being considerably stronger. CONCLUSION: Screws augmented with composite graft provide significantly greater purchase in an osteoporotic fibular fracture model. CLINICAL RELEVANCE: Composite graft augmented screws inserted into the distal tibia from the fibula may enhance the stability of internal fixation of an osteoporotic ankle fracture. This may enable earlier weightbearing and return to function which is important in elderly patients.

Pare, P. E., et al. (2011). "Biomechanical evaluation of a novel fenestrated pedicle screw augmented with bone cement in osteoporotic spines." Spine (Phila Pa 1976) **36**(18): E1210-1214.

STUDY DESIGN: Comparative biomechanical study was conducted in osteoporotic human cadaveric spines. OBJECTIVE: Determine the influence of the volume of polymethyl methacrylate injected through a fenestrated pedicle screw on the pullout strength and on the ability to safely remove the implant. SUMMARY OF BACKGROUND DATA: Pedicle screw fixation in the osteoporotic spine can be improved by the addition of bone cement. Various injection techniques have been used. While improvement has been shown for the pullout strength, the optimal volume of cement to inject has not been previously studied. METHODS: Seven osteoporotic spines were instrumented with a standard and a fenestrated pedicle screw augmented with polymethyl methacrylate at each level (T7-L5). Three volumes of bone cement were randomly injected and stratified to the thoracic (0.5 cc, 1.0 cc, and 1.5 cc) and lumbar spine (1.5 cc, 2.0 cc, and 2.5 cc). Axial pullout strength and removal torque of the pedicle screws were quantified. RESULTS: The pullout strength of the fenestrated screw was normalized with respect to its contralateral control. Student paired t tests were conducted and a statistically significant increase was noted for 1.0 cc (186 +/- 45%) and 1.5 cc (158 +/- 46%) in the thoracic spine and for 1.5 cc (264 +/- 193%), 2.0 cc (221 +/- 93%), and 2.5 cc (198 +/- 42%) in the lumbar spine. There was no significant difference with higher volumes of cement. The median removal torque was 0.34 Nm for the standard and 1.83 Nm for the augmented screws. When the augmented implants were removed, the bone cement sheared completely off at the fenestrations in 15 of the 17 cases. CONCLUSION: Significant increases in pullout strength can be accomplished by injecting a limited quantity of bone cement through a fenestrated screw while minimizing the risks associated with higher volume. The majority of implants were removed without damaging the vertebra as the bone cement sheared off at the fenestrations.

Paxinos, O., et al. (2010). "Evaluation of pullout strength and failure mechanism of posterior instrumentation in normal and osteopenic thoracic vertebrae." J Neurosurg Spine **13**(4): 469-476.

OBJECT: There is limited data on the pullout strength of spinal fixation devices in the thoracic spine among individuals with different bone quality. An in vitro biomechanical study on the thoracic spine was performed to compare the pullout strength and the mechanism of failure of 4 posterior fixation thoracic constructs in relation to bone mineral density (BMD). METHODS: A total of 80 vertebrae from 11 fresh-frozen thoracic spines (T2-12) were used. Based on the results from peripheral quantitative CT, specimens were divided into 2 groups (normal and osteopenic) according to their BMD. They were then randomly assigned to 1 of 4 different instrumentation systems (sublaminar wires, pedicle screws, lamina claw hooks, or pedicle screws with wires). The construct was completed with 2 titanium rods and 2 transverse connectors, creating a stable frame. The pullout force to failure perpendicular to the rods as well as the pattern of fixation failure was recorded. RESULTS: Mean pullout force in the osteopenic Group A (36 vertebrae) was 473.2 +/- 179.2 N and in the normal BMD Group B (44 vertebrae) was 1414.5 +/- 554.8 N. In Group A, no significant difference in pullout strength was encountered among the different implants (p = 0.96). In Group B, the hook system failed because of dislocation with significantly less force than the other 3 constructs (931.9 +/- 345.1 N vs an average of 1538.6 +/- 532.7 N; p = 0.02). In the osteopenic group, larger screws demonstrated greater resistance to pullout (p = 0.011). The most common failure mechanism in both groups was through pedicle base fracture. CONCLUSIONS: Bone quality is an important factor that influences stability of posterior thoracic implants. Fixation strength in the osteopenic group was one-fourth of the value measured in vertebrae with good bone quality, irrespective of the instrumentation used. However, in normal bone quality vertebrae, the lamina hook claw system dislocated with significantly less force when compared with other spinal implants. Further studies are needed to investigate the impact of different transpedicular screw designs on the pullout strength in normal and osteopenic thoracic spines.

Penzkofer, J., et al. (2009). "[Treatment results of pertrochanteric and subtrochanteric femoral fractures: a retrospective comparison of PFN and PFNA]." Unfallchirurg **112**(8): 699-705.

BACKGROUND: Can the helical blade in proximal femur nailing antirotation (PFNA) reach a better bony fixation than proximal femur nailing (PFN), thereby decreasing complication rates and improving clinical outcomes especially in osteoporotic bone? MATERIALS AND METHODS: In a retrospective study complications and clinical treatment results of pertrochanteric and subtrochanteric femoral fractures were analyzed. For this purpose a group of patients stabilized with PFN (n=65) were compared to a patient group treated with PFNA (n=66). Objective and subjective parameters were acquired and analyzed by clinical follow-up studies using the Merle d'Aubigne score and X-ray evaluation. Individual bone quality was analyzed radiologically by determining the Singh index. The mean follow-up time was 7 months in each group. RESULTS: The PFNA showed a decrease in postoperative implant-associated complications especially in osteoporotic bone and unstable fracture types. CONCLUSION: The philosophy of the PFNA blade with better fixation through an increased implant-bone-interface and smaller cross-section, compaction of cancellous bone as well as an antirotational fixation, seems to show advantages compared to the double screw system of the PFN.

Perren, S. M. (2002). "Evolution of the internal fixation of long bone fractures. The scientific basis of biological internal fixation: choosing a new balance between stability and biology." J Bone Joint Surg Br **84**(8): 1093-1110.

The advent of 'biological internal fixation' is an important development in the surgical management of fractures. Locked nailing has demonstrated that flexible fixation without precise reduction results in reliable healing. While external fixators are mainly used today to provide temporary fixation in fractures after severe injury, the internal fixator offers flexible fixation, maintaining the advantages of the external fixator but allowing long-term treatment. The internal fixator resembles a plate but functions differently. It is based on pure splinting rather than compression. The resulting flexible stabilisation induces the formation of callus.

With the use of locked threaded bolts, the application of the internal fixator foregoes the need of adaptation of the shape of the splint to that of the bone during surgery. Thus, it is possible to apply the internal fixator as a minimally invasive percutaneous osteosynthesis (MIPO). Minimal surgical trauma and flexible fixation allow prompt healing when the blood supply to bone is maintained or can be restored early. The scientific basis of the fixation and function of these new implants has been reviewed. The biomechanical aspects principally address the degree of instability which may be tolerated by fracture healing under different biological conditions. Fractures may heal spontaneously in spite of gross instability while minimal, even non-visible, instability may be deleterious for rigidly fixed small fracture gaps. The theory of strain offers an explanation for the maximum instability which will be tolerated and the minimal degree required for induction of callus formation. The biological aspects of damage to the blood supply, necrosis and temporary porosity explain the importance of avoiding extensive contact of the implant with bone. The phenomenon of bone loss and stress protection has a biological rather than a mechanical explanation. The same mechanism of necrosis-induced internal remodelling may explain the basic process of direct healing.

Pitzen, T. R., et al. (2006). "Effectiveness of cemented rescue screws for anterior cervical plate fixation." J Neurosurg Spine **4**(1): 60-63.

OBJECT: Among the various ways to optimize the fixation of bone implants is to use bone cement, for example, in a total hip prosthesis. No data exist, however, concerning the effectiveness of cemented rescue screws for anterior cervical plate fixation. The aim of this study was to investigate whether cemented rescue screws increase fixation strength in comparison with uncemented standard screws. METHODS: Six cervical spine segments (C4-7) were explanted during routine autopsy studies from fresh human cadavers. Bone mineral density (BMD) was measured for each vertebral body (VB) using quantitative computerized tomography scanning, and 24 VBs were dissected from the segments. Two initial pilot holes were drilled into each VB parallel to the sagittal plane. Based on their BMD, the specimens were assigned to one of two groups in which torque and pullout force were tested. The test was begun with standard screws and was repeated with cannulated slotted rescue screws into which bone cement was injected. The mean values of peak torque and pullout forces resulting from the left and right measurements were used for statistical analysis. A t-test was performed to determine the effect of screw type on peak torque and pullout force. Moment correlation coefficients were calculated to determine the effect of BMD on peak torque and pullout force for each type of screw. The mean insertional peak torque was 67.1 N/cm for the standard screw and 102.6 N/cm for the cemented screw ($p < 0.05$). The mean pullout force was 526.9 N for standard osteoporosis screws and 531.5 N for cemented screws ($p > 0.05$). The effect of increased holding strength as measured by peak torque and pullout force was more pronounced in the presence of low bone density. CONCLUSIONS: Cemented rescue screws that have been inserted into a fatigued pilot hole in the cervical VB strengthen the screw-bone interface compared with the strength initially conferred by a standard screw.

Polly, D. W., Jr., et al. (1998). "Revision pedicle screws. Bigger, longer shims--what is best?" Spine (Phila Pa 1976) **23**(12): 1374-1379.

STUDY DESIGN: To evaluate the effect of change in screw dimensions and hole augmentation in pedicle screw revisions, the insertional torque was determined, and results were compared with those in control specimens in an in vitro study using cadaveric thoracolumbar spines. OBJECTIVES: To determine the best method of salvage for failed pedicle screws, by evaluating the insertional torque after placing a larger diameter or longer screw into a stripped hole. Use of a shim and use of larger and longer screws were also investigated. Finally, the effect on insertional torque of simply removing and replacing a pedicle screw in its original hole was investigated. SUMMARY OF BACKGROUND DATA: The effects of using bigger or longer screws and shims to salvage failed pedicles have been

studied. The interaction between how much larger, how much longer, and inserting with or without shims, has not been well studied. Optimizing reinsertional torque through the use of bigger screws risks exceeding the pedicle capacity. Using longer screws risks violation of the anterior vertebral body, thereby placing the great vessels and viscera at risk. By knowing the relative contribution of increase in length and diameter, the surgeon can optimize the risk-benefit ratio. METHODS: Eight cadaveric spines from T10 to S1 were harvested. The specimens underwent radiographic screening and bone densitometry. A modified Latin square randomization was designed to evaluate the screw diameters and lengths. Each pedicle was its own control. A 35- x 6.5-mm screw was used as a control. Test screws were placed after pedicle screw hole failure was achieved and documented by stripping. For the test screws, the diameters were increased by 1 mm and 2 mm, the lengths were increased by 5 mm and 10 mm. Shims were added randomly. The peak insertional torque was measured for each control screw and test screw placement. In addition, during each screw placement, the screw was removed and replaced to determine the effect. RESULTS: Insertional torque, after the pedicle screw is removed and replaced in the same hole, was decreased by 34% ($P < 0.000005$). Increasing the diameter of the salvage screw by 2 mm caused the insertional torque to be increased by 8.4% of the original. Increasing the length of the screw did not improve the salvage screw insertional torque. There was an interaction effect for the 1-mm increase in diameter and the increase in length. At this diameter, increasing the length had a significant effect ($P = 0.009$) on the salvage torque. Using a shim created no improvement in salvage insertional torque ($P = 0.77$). There was a poor linear correlation between torque and bone mineral density ($r = 0.18$) in these osteoporotic specimens. CONCLUSIONS: Removing and replacing a pedicle screw in its original hole substantially decreases its mechanical fixation. For pedicle salvage, increasing the diameter causes the greatest restoration of strength. Shims had no effect in pedicle salvage in osteoporotic specimens.

Ramaswamy, R., et al. (2010). "Holding power of variable pitch screws in osteoporotic, osteopenic and normal bone: are all screws created equal?" Injury **41**(2): 179-183.

INTRODUCTION: Biomechanical properties of four different commercially available small fragment cannulated screws (Twin fix (Stryker, Freiburg, Germany), Herbert, (Zimmer, Warsaw, USA), Omnitech (Unimedical, Torino, Italy), Barouk (Depuy, Warsaw, USA)), with variable pitch, used for fracture fixation were compared. MATERIALS AND METHODS: Polyurethane foam blocks of three different densities with mechanical properties similar to osteoporotic, osteopenic and normal bones were used to conduct the tests. Each screw was tested for pushout and pullout holding power after a primary insertion and for pullout after a repeated insertion into the respective foam blocks. RESULTS: The mean pullout and pushout strengths of all screws correlated to the foam density, and were significantly ($p<0.001$ and <0.001, respectively) better in foam with higher density. The mean pullout strength of each screw was consistently lower after reinsertion into the osteoporotic, osteopenic and normal bone densities by 4-30%, when compared to the index insertion (Fig. 4b). Yet, this difference was not found to be statistically significant ($p=0.23$). The Barouk screw performed significantly ($p<0.0001$) better than the other screws in all three different densities of foam for both for pushout and pullout after index insertion as well as for pullout tests after reinsertion. CONCLUSION: The holding power of screws is directly correlated to bone density, thread design and number of threads engaging the bone. Reinsertion through the same hole could reduce the ultimate pullout strength. The surgeon should consider the advantages and disadvantages of each implant, depending on the clinical situation and choose accordingly.

Reinhold, M., et al. (2006). "Influence of screw positioning in a new anterior spine fixator on implant loosening in osteoporotic vertebrae." Spine **31**(4): 406-413.

STUDY DESIGN: A biomechanical study was designed to assess implant cut-out of three different angular stable anterior spinal implants. Subsidence of the implant relative to the

vertebral body was measured during an in vitro cyclic loading test. OBJECTIVES: The objective of the study was to evaluate two prototypes (Synthes) of a new anterior spine fixator with different screw angulations in comparison to the established MACSTL(R) Twin Screw Concept (Aesculap). The influence of factors like load-bearing cross-sectional area, screw angulation and bone mineral density upon implant stability should be investigated. SUMMARY OF BACKGROUND DATA: Epidemiologic data predict a growing demand for appropriate anterior spinal fixation devices especially in patients with inferior structural and mechanical bone properties. Although different concepts for anterior spinal instrumentation systems have been tried out, implant stability is still a problem. METHODS: Three angular stable, anterior spinal implants were tested using 24 human lumbar osteoporotic vertebrae (L1-L5; age 84 (73-92)): MASC TL system (Aesculap); prototype 1 (MP1) with 18 degrees and prototype 2 (MP2) with 40 degrees screw angulation (both Synthes). All implants consisted of two screws with different outer screw diameters: 7-mm polyaxial screw with 6.5-mm stabilization screw (MASC TL), two 5-mm locking-head screws each (MP1 and MP2). Bone mineral density (BMD) and vertebral body width of the three specimen groups were evenly distributed. The specimens were loaded in craniocaudal direction (1Hz) for 1000 cycles each at three consecutive load steps; 10-100 N, 10-200 N and 10-400 N. During cyclic loading subsidence of the implant relative to the vertebral body was measured in the unloaded condition. Cycle number at failure (defined as a subsidence of 2 mm) was determined for each specimen. A survival analysis (Cox Regression) was performed to detect differences between implant groups at a probability level of 95%. RESULTS: High correlations were found between BMD and number of cycles until failure (MP1; r = 0.905, P = 0.013; MP2: r = 0.640, P = 0.121; MACS TL: r = 0.904, P = 0.013) and between load bearing cross sectional area and number of cycles until failure (MP1: r = 0.849, P = 0.032;MP2: r = 0.692, P = 0.085; MACS TL: r = 0.902, P = 0.014). Both Prototypes survived significantly longer than the MACS TL implant (MP1: P = 0.012, MP2: P = 0.014). The survival behaviour of MP1 and MP2 was not significantly different (P = 0.354). CONCLUSIONS: Implant stability within each implant group was influenced by BMD and load bearing cross-sectional area. The angulation of the two screws did not have a significant influence on cut-out. As conclusion from this study, promising approaches for further implant development are: 1) increase of load-bearing cross-sectional area (e.g., larger outer diameter of the anchorage device), 2) screw positioning in areas of higher BMD (e.g., opposite cortex, proximity to pedicles or the endplates).

Roderer, G., et al. (2013). "Mechanical assessment of local bone quality to predict failure of locked plating in a proximal humerus fracture model." Orthopedics **36**(9): e1134-1140.

The importance of osteoporosis in proximal humerus fractures is well recognized. However, the local distribution of bone quality in the humeral head may also have a significant effect because it remains unclear in what quality of bone screws of standard implants purchase. The goal of this study was to investigate whether the failure of proximal humerus locked plating can be predicted by the DensiProbe (ARI, Davos, Switzerland). A 2-part fracture with metaphyseal impaction was simulated in 12 fresh-frozen human cadaveric humeri. Using the DensiProbe, local bone quality was determined in the humeral head in the course of 6 proximal screws of a standard locking plate (Philos; Synthes GmbH, Solothurn, Switzerland). Cyclic mechanical testing with increasing axial loading until failure was performed. Bone mineral density (BMD) significantly correlated with cycles until failure. Head migration significantly increased between 1000 and 2000 loading cycles and significantly correlated with BMD after 3000 cycles. DensiProbe peak torque in all screw positions and their respective mean torque correlated significantly with the BMD values. In 3 positions, the peak torque significantly correlated with cycles to failure; here BMD significantly influenced mechanical stability. The validity of the DensiProbe was proven by the correlation between its peak torque measurements and BMD. The correlation between the peak torque and cycles to failure revealed the potential of the DensiProbe to predict the failure of locked plating in vitro. This method provides information about local bone quality, potentially making

it suitable for intraoperative use by allowing the surgeon to take measures to improve stability.

Sadowski, C., et al. (2003). "Fixation of fractures of the proximal humerus with the PlantTan Humerus Fixator Plate: early experience with a new implant." J Shoulder Elbow Surg **12**(2): 148-151.

The majority of fractures of the proximal humerus can be managed nonoperatively. However, displaced fractures generally require operative repair, and in the young patient with good bone quality, the results are usually satisfactory. In contrast, the osteoporosis found in the elderly patient makes internal fixation problematic and frequently contributes to failure of fixation and poor results. We report our early experience with a new plate that locks two humeral head cancellous screws to the plate. In 3 of 7 patients, all under 65 years of age, the results were good. However, in the remaining 4 patients, all over the age of 75 years, there was a 100% failure rate, with screw penetration of the head in 3 patients and secondary displacement of the fracture at 7 days postoperatively in another. We conclude that this implant is unsatisfactory for patients with osteopenic bone in the humeral head.

Sarzier, J. S., et al. (2002). "Increased pedicle screw pullout strength with vertebroplasty augmentation in osteoporotic spines." J Neurosurg **96**(3 Suppl): 309-312.

OBJECT: The authors conducted a biomechanical study to evaluate pedicle screw pullout strength in osteoporotic cadaveric spines. Nonaugmented hemivertebrae were compared with pressurized polymethylmethacrylate (PMMA)-augmented hemivertebrae. METHODS: Six formalin-fixed cadaveric thoracolumbar spines at least two standard deviations below the mean bone mineral density (BMD) for age were obtained. Radiographic and BMD studies were correlated to grades I, II, and III osteoporosis according to the Jekei scale. Each of the 21 vertebrae underwent fluoroscopic placement of 6-mm transpedicular screws with each hemivertebra serving as the control for the contralateral PMMA-augmented hemivertebra. Pedicle screws were then evaluated for biomechanical axial pullout resistance. Augmented hemivertebrae axial pullout forces were increased ($p = 0.0005$). The mean increase in pullout force was 181% for Grade I, 206% for Grade II, and 213% for Grade III osteoporotic spines. Augmented Grade I osteoporotic spines demonstrated axial pullout forces near those levels reported in the literature for nonosteoporotic specimens. Augmented Grade II osteoporotic specimens demonstrated increases to levels found in nonaugmented vertebrae with low-normal BMD. Augmented Grade III osteoporotic specimens had increases to levels equal to those found in nonaugmented Grade I vertebrae. CONCLUSIONS: Augmentation of osteoporotic vertebrae in PMMA-assisted vertebroplasty can significantly increase pedicle screw pullout forces to levels exceeding the strength of cortical bone. The maximum attainable force appears to be twice the pullout force of the nonaugmented pedicle screw for each osteoporotic grade.

Sawakami, K., et al. (2012). "Polymethylmethacrylate augmentation of pedicle screws increases the initial fixation in osteoporotic spine patients." J Spinal Disord Tech **25**(2): E28-35.

STUDY DESIGN: A retrospective comparative study. OBJECTIVES: To investigate the clinical efficacy of polymethylmethacrylate (PMMA) augmentation in vertebral pseudarthrosis after osteoporotic vertebral fractures. SUMMARY OF BACKGROUND DATA: Despite being the most rigid form of posterior instrumentation, pedicle screws sometimes achieve poor initial fixation primarily in patients with osteoporosis. One method for improving pedicle screw fixation in osteoporotic spines is pedicle augmentation using bone cement such as PMMA. Although various biomechanical studies of osteoporotic spines have shown improved pullout strength of pedicle screws augmented with bone cement, there have been few studies that have examined the clinical significance of PMMA augmentation. METHODS: Thirty-eight patients with posterior fusion using pedicle screws for vertebral pseudarthrosis after osteoporotic vertebral fracture were included in the study. The level of fracture ranged from T7 to L5. The mean follow-up period was 31 months. Patients were divided into 2

groups: those with posterior instrumentation using pedicle screws augmented with PMMA (group C, N=17) and those without PMMA augmentation (group NC, N=21). Clinical and radiographic results for the 2 groups were compared. RESULTS: With the exception of osteoporotic status, there were no significant differences in the baseline data of the 2 groups. The incidence of clear zones around the pedicle screws was significantly suppressed in group C compared with group NC (29.4% vs. 71.4%). Correction loss was significantly decreased (3 degrees vs. 7.2 degrees) and fusion rate was significantly higher in group C (94.1% vs. 76.1%). Back pain improved in 64.7% of the group C patients. There were no perioperative complications related to the PMMA cement in group C. CONCLUSIONS: Reinforcement of pedicle screws using PMMA augmentation may be a feasible surgical technique for osteoporotic spines.

Schneider, E., et al. (2005). "The challenge: fracture treatment in osteoporotic bone." Osteoporos Int **16 Suppl 2**: S1-2.

Seebeck, J., et al. (2005). "Mechanical behavior of screws in normal and osteoporotic bone." Osteoporos Int **16 Suppl 2**: S107-111.

Fracture fixation in severe osteoporotic bone by means of implants that rely on screw anchorage is still a clinical problem. So far, a sufficiently accurate prediction of the holding capacity of screws as a function of local bone morphology has not been obtained. In this study the ultimate pullout loads of screws in the epi-, meta-, and diaphyseal regions of human tibiae were correlated to the cortical thicknesses and cancellous bone mineral densities at the screw axes determined from QCT densitometric data. Stepwise multiple linear regression showed that in regions with cortical thicknesses below 1.5 mm, cancellous density determined the ultimate pullout load ($R2 = 0.85$, $p < 0.001$), while in regions with cortices above 1.5 mm, cortical thickness alone significantly influenced the holding capacity of a screw ($R2 = 0.90$, $p < 0.001$). The findings of this study provide a basis for a bone morphology-related pre-operative estimation of the holding capacity of screws, which could help to improve their proper application in osteoporotic bone.

Seebeck, J., et al. (2004). "Effect of cortical thickness and cancellous bone density on the holding strength of internal fixator screws." J Orthop Res **22**(6): 1237-1242.

Internal fixators are a new class of implants designed to preserve the periosteal blood supply of the bone. In contrast to conventional plate fixation in which the screws have spherical heads and are loaded mainly by axial pullout forces, screws in internal fixators are "locked" within the plate and therefore subjected to axial as well as bending loads. In this study the ultimate loads of screws of a commercially available internal fixator system were tested in a pullout ($n = 72$) and cantilever bending mode ($n = 72$) in metaphyseal and diaphyseal regions of four pairs of human tibiae with different bone qualities. Cortical thickness and cancellous bone density were determined at the screw insertion sites. Stepwise multiple linear regression revealed that cortical thickness and cancellous density can explain 93% and 98% of the variance of the ultimate load of the screws in an axial pullout and cantilever bending mode. Screws in internal fixators are better suited to transmit shear forces and thereby make better use of the strength potential of bone than screws used in conventional plate fixation: this is especially advantageous when bone strength is reduced, e.g. due to osteoporosis.

Sokol, S. C., et al. (2011). "Biomechanical properties of volar hybrid and locked plate fixation in distal radius fractures." J Hand Surg Am **36**(4): 591-597.

PURPOSE: We compare the biomechanical properties of a volar hybrid construct to an all-locking construct in an osteoporotic and normal comminuted distal radius fracture model. METHODS: Groups of 28 normal, 28 osteoporotic, and 28 over-drilled osteoporotic left distal radius synthetic bones were used. The normal group consisted of synthetic bone with a standard foam core. The osteoporotic group consisted of synthetic bone with decreased

foam core density. The over-drilled osteoporotic group consisted of synthetic bone with decreased foam core density and holes drilled with a 2.3 mm drill, instead of the standard 2.0 mm drill, to simulate the lack of purchase in osteoporotic bone. Within each group, 14 synthetic bones were plated with a volar locking plate using an all-locking screw construct, and 14 synthetic bones were plated with a volar locking plate using a hybrid screw construct (ie, both locking and nonlocking screws). A 1-cm dorsal wedge osteotomy was created with the apex 2 cm from the volar surface of the lunate facet. Each specimen was mounted to a materials testing machine, using a custom-built, standardized axial compression jig. Axial compression was delivered at 1 N/s over 3 cycles from 20 N to 100 N to establish stiffness. Each sample was stressed to failure at 1 mm/s until 5 mm of permanent deformation occurred. RESULTS: Our results show no difference in construct stiffness and load at failure between the all-locking and hybrid constructs in the normal, osteoporotic, or over-drilled osteoporotic synthetic bone models. All specimens failed by plate bending at the osteotomy site with loss of height. CLINICAL RELEVANCE: Although volar locking plates are commonly used for the treatment of distal radius fractures, the ideal screw configuration has not been determined. Hybrid fixation has comparable biomechanical properties to all locking constructs in the fixation of metaphyseal fractures about the knee and shoulder and might also have a role in the fixation of distal radius fractures.

Spangler, L., et al. (2001). "Biomechanical factors and failure of transcervical hip fracture repair." Injury **32**(3): 223-228.

OBJECTIVE: To assess the association between biomechanical measurements (bone quality of the femoral neck, comminution, fracture angle, and fracture level) and the likelihood of fixation failure among patients who have a multiple screw stabilisation of an intracapsular hip fracture. METHODS: A cohort study of 139 Washington State residents greater than 60 years of age who sustained a fall-related transcervical hip fracture treated from 1990 to 1996 inclusive. Measurements of bone quality, fracture angle, fracture level, and comminution were taken from perioperative X-rays. The outcome measure was clinical failure of the internal fixation procedure within 12 months of hospital discharge, as measured by readmission for further surgery to that hip. RESULTS: Of the four biomechanical aspects examined, only bone quality, as measured by presence of an ICD code for osteoporosis, was significantly associated with risk of subsequent hospitalisation for revision surgery (adjusted hazard ratio 7.7, 95% CI 1.8-32.8). CONCLUSION: A diagnosis code for osteoporosis was related to the outcome of intracapsular fractures repaired with multiple pins. Other biomechanical measurements from diagnostic X-rays were not related to the need for further surgery.

Stoffel, K., et al. (2008). "Comparative stability of perpendicular versus parallel double-locking plating systems in osteoporotic comminuted distal humerus fractures." J Orthop Res **26**(6): 778-784.

In distal humerus fractures, the restoration of stability is important to allow early mobilization and hence more favorable functional outcomes. In this article, we compare the biomechanical stability of perpendicular and parallel locking plating systems for the internal fixation of AO Type C2 distal humerus fractures in osteoporotic bone. Fractures were simulated in paired cadaveric bones and fixed using either the perpendicular 3.5 mm LCP distal humerus plating system (Synthes; Sydney, Australia) or the parallel Mayo Clinic Congruent elbow plate system (Acumed; Hillsboro, OR), using locking screws in both systems. Both systems were then tested for their stiffness (in compression and internal/external rotation), plastic deformation, and failure in torsion. Comparatively, the parallel locking plate system provided a significantly higher stability in compression ($p = 0.005$) and external rotation ($p = 0.006$), and a greater ability ($p = 0.005$) to resist axial plastic deformation. Stability for both constructs appeared to be dependent on bone quality, however the stability of the perpendicular system was generally more sensitive to bone mineral density, indicating a possible need for additional independent interfragmentary screws. A disadvantage of the parallel locking plate system was wear debris produced by its

tapping system. In summary, the biomechanical findings of this study suggest that both locking plate systems allow early mobilization of the elbow in patients with osteoporotic bone following fixation of a comminuted distal humerus fracture. However, the parallel locking system showed improved stability compared with the perpendicular locking system, and therefore may be more indicated.

Suzuki, T., et al. (2001). "Improving the pullout strength of pedicle screws by screw coupling." J Spinal Disord **14**(5): 399-403.

The objective of this study was to determine the effect of pedicle screw coupling on the pullout strength of pedicle screws in the osteoporotic spine. The vertebral bone mineral density (BMD) of 33 cadaveric lumbar vertebrae were measured by quantitative computed tomography. Pedicle screws were inserted into each pedicle. The pullout strength and displacement of the screws, without coupling and with single or double couplers, were studied, and the relationship between pullout strength and BMD was analyzed. The average pullout strength of the pedicle screws without screw coupling was 909.3 +/- 188.6 N (n = 9), that coupled with a single coupler was 1,409.0 +/- 469.1 N (n = 9), and that with double couplers was 1,494.0 +/- 691.6 N (n = 9). The pullout strength of the screws coupled with single or double couplers was significantly greater than that of screws without couplers ($p < 0.01$); however, there was no significant difference between the groups of single and double couplers. The improvement of pullout strength by screw coupling was significant in a test group with BMD of more than 90 mg/ml ($p < 0.01$), but was not in the group with BMD less than 90 mg/ml ($p = 0.55$). These results suggest that the coupling of pedicle screws improves pullout strength; however, the effect tends to be less significant in severely osteoporotic spines.

Tankard, S. E., et al. (2013). "Does maximum torque mean optimal pullout strength of screws?" J Orthop Trauma **27**(4): 232-235.

OBJECTIVES: To determine the relationship between insertion torque and pullout strength of 3.5-mm-diameter cortical screws in cadaveric humeri with different bone mineral densities (BMDs). METHODS: Five pairs of human humeri from each of 3 BMD groups (normal, osteopenic, and osteoporotic) were used. Holes were drilled in each humerus, and maximum insertion torque (T(max)) was measured by tightening a screw until stripping occurred. In the remaining holes, screws were tightened to 50%, 70%, or 90% of the T(max). A servohydraulic testing machine pulled each screw out at 1 mm/s while resulting force and axial displacement were recorded at 10 Hz. The authors checked for an effect of insertion torque (percent T(max)) on pullout strength using a general linearized and latent mixed model (Stata10), controlling for cortical thickness and BMD (T-score). RESULTS: Pullout strength for normal and osteoporotic bone was greatest for screws inserted to 50% T(max) and was significantly greater than that at T(max) but not significantly different from that at 70% or 90% T(max). For osteopenic bone, pullout strength was greatest at 70% peak torque, but it was not significantly different from the pullout strength at the 50% or 90% T(max) levels. CONCLUSIONS: Tightening screws beyond 50% T(max) does not increase pullout strength of the screw and may place bone at risk for damage that might result in loss of fixation. Even after adjusting for bone thickness and density, there is no clear relationship between pullout strength and screw torque.

Thiele, O. C., et al. (2007). "Factors affecting the stability of screws in human cortical osteoporotic bone: a cadaver study." J Bone Joint Surg Br **89**(5): 701-705.

We investigated several factors which affect the stability of cortical screws in osteoporotic bone using 18 femora from cadavers of women aged between 45 and 96 years (mean 76). We performed bone densitometry to measure the bone mineral density of the cortical and cancellous bone of the shaft and head of the femur, respectively. The thickness and overall bone mass of the cortical layer of the shaft of the femur were measured using a microCT scanner. The force required to pull-out a 3.5 mm titanium cortical bone screw was

determined after standardised insertion into specimens of the cortex of the femoral shaft. A significant correlation was found between the pull-out strength and the overall bone mass of the cortical layer ($r(2) = 0.867$, $p < 0.01$) and also between its thickness ($r(2) = 0.826$, $p < 0.01$) and bone mineral density ($r(2) = 0.861$, $p < 0.01$). There was no statistically significant correlation between the age of the donor and the pull-out force ($p = 0.246$), the cortical thickness ($p = 0.199$), the bone mineral density ($p = 0.697$) or the level of osteoporosis ($p = 0.378$). We conclude that the overall bone mass, the thickness and the bone mineral density of the cortical layer, are the main factors which affect the stability of a screw in human female osteoporotic cortical bone.

Tingart, M. J., et al. (2006). "Proximal humeral fractures: regional differences in bone mineral density of the humeral head affect the fixation strength of cancellous screws." J Shoulder Elbow Surg **15**(5): 620-624.

The purpose of this study was to investigate the 3-dimensional trabecular bone mineral density (BMD) in the humeral head and determine the effects of trabecular BMD on the pullout strength of cancellous screws. Five regions of interest (ROIs) were defined in the humeral head (superior- anterior, superior-posterior, central, inferior-anterior, and inferior-posterior). The trabecular BMD of each ROI was determined by use of peripheral quantitative computed tomography. Cancellous screws were inserted in each ROI and cyclically loaded. The superior-anterior ROI had a lower trabecular BMD than all other ROIs ($P < .001$). The central ROI had a higher trabecular BMD than the inferior-anterior ROI ($P < .01$), whereas no differences were found between the inferior-posterior, superior-posterior, and central ROIs. Pullout strength was lower in the superior-anterior ROI compared with all other ROIs ($P < .01$). The trabecular BMD and pullout strength were significantly correlated ($P < .01$). Placement of screws in regions with a higher trabecular BMD may help to prevent implant loosening and may improve patient outcome.

Unger, S., et al. (2012). "The effect of in situ augmentation on implant anchorage in proximal humeral head fractures." Injury **43**(10): 1759-1763.

INTRODUCTION: Fracture fixation in patients suffering from osteoporosis is difficult as sufficient implant anchorage is not always possible. One method to enhance implant anchorage is implant/screw augmentation with PMMA-cement. The present study investigated the feasibility of implant augmentation with PMMA-cement to enhance implant anchorage in the proximal humerus. MATERIALS AND METHODS: A simulated three part humeral head fracture was stabilised with an angular stable plating system in 12 pairs of humeri using six head screws. In the augmentation group the proximal four screws were treated with four cannulated screws, each augmented with 0.5ml of PMMA-cement, whereas the contra lateral side served as a non-augmented control. Specimens were loaded in varus-bending or axial-rotation using a cyclic loading protocol with increasing load magnitude until failure of the osteosynthesis occurred. RESULTS: Augmented specimens showed a significant higher number of load cycles until failure than non-augment specimens (varus-bending: 8516 (SD 951.6) vs. 5583 (SD 2273.6), P=0.014; axial-rotation: 3316 (SD 348.8) vs. 2050 (SD 656.5), P=0.003). Non-augmented specimens showed a positive correlation of load cycles until failure and measured bone mineral density (varus-bending: r=0.893, P=0.016; axial-rotation: r=0.753, P=0.084), whereas no correlation was present in augmented specimens (varus-bending: r=0,258, P=0.621; axial-rotation r=0.127, P=0.810). CONCLUSION: These findings suggest that augmentation of cannulated screws is a feasible method to enhance implant/screw anchorage in the humeral head. The improvement of screw purchase is increasing with decreasing bone mineral density.

Vishnubhotla, S., et al. (2011). "A titanium expandable pedicle screw improves initial pullout strength as compared with standard pedicle screws." Spine J **11**(8): 777-781.

BACKGROUND CONTEXT: Pedicle screws are now standard for spinal arthrodesis as they provide three-column spinal stabilization. Decreased vertebral body bone density because of

aging reduces the stability of the bone-screw interface, potentially increasing screw pullout or pseudarthrosis. Modifications to standard pedicle screw designs to improve screw stabilization may help to compensate for the detrimental effects of decreased vertebral bone density. PURPOSE: To evaluate differences in initial pullout strength of an expandable titanium pedicle screw as compared with a standard titanium pedicle screw. STUDY DESIGN: In vitro human cadaveric biomechanical investigation. METHODS: Fresh thoracolumbar spines from four human cadavers were imaged using quantitative computed tomography to obtain standard lumbar osteoporosis (Dual-energy X-ray absorptiometry [DXA]) T scores. Six bodies were sectioned per spine, and standard titanium 6.5-mm diameter pedicle screws and expandable 6.5-mm diameter titanium screws (maximum expanded diameter=10 mm) were randomized to right and left sides. Screw testing, in axial pullout at 25 mm/min, was randomized to reduce the effects of testing order. Data for stiffness (N/mm), yield load (N), ultimate load (N), and energy (N mm) (area under the load-displacement curve) were analyzed using a one-way analysis of variance ($p<.05$). RESULTS: Lumbar DXA scores averaged -3.6. There were no statistical differences between screw types for stiffness. Yield load was not statistically different between groups, although the expandable screw yield load was nearly 25% greater than that of the standard screw. Ultimate load was found to be statistically greater (approximately 30%) for the expandable screw compared with the standard screw ($p<.05$). The energy required to cause bone-implant failure was also statistically greater for the expandable screw compared with the standard screw ($p<.0001$). CONCLUSIONS: Expandable titanium pedicle screws demonstrated improved screw pullout stability compared with standard titanium screws in osteopenic or osteoporotic bone. Further studies are warranted examining other loading methods to evaluate the stability provided by an expandable pedicle screw.

von der Linden, P., et al. (2006). "Biomechanical evaluation of a new augmentation method for enhanced screw fixation in osteoporotic proximal femoral fractures." J Orthop Res **24**(12): 2230-2237.

A biomechanical investigation on eight pairs of human cadaver proximal femurs was performed to evaluate the impact of a new augmentation method on the internal fixation of osteoporotic proximal femur fractures. The study focused on enhancing implant purchase to reduce the incidence of implant cut-out in osteoporotic bone. In a left-right comparison, a conventional hip screw fixation (control) was compared to the new cement augmentation method. After bone bed preparation through high pressure irrigation to remove fat, blood, and bone debris, the bones were augmented with low viscosity polymethylmethacrylate (PMMA) cement. Step-wise fatigue testing was performed by cyclically loading the femoral heads in a physiological manner, beginning at 1,500 N and increasing 500 N every 5,000 cycles to 4,000 N, and continuously monitoring head displacement. Failure was defined as >5.0 mm head displacement. The head displacement at 2,000 N was significantly smaller ($p=0.018$) for the augmented group as compared to the conventionally treated bones (0.09+/-0.01 mm vs. 0.90+/-0.32 mm; mean+/-SEM). The displacement rate at the second load step was significantly higher ($p=0.018$) for the conventionally treated bones as compared to the augmented ones. All of the nonaugmented specimens failed during testing, where 50% of the augmented specimens did not fail. The promising results of these experiments suggest that this new standardized irrigation/augmentation method enhances the implant anchorage and offers a potential solution to the problem of implant cut-out in osteoporotic metaphyseal bone.

Wahnert, D., et al. (2013). "The potential of implant augmentation in the treatment of osteoporotic distal femur fractures: a biomechanical study." Injury **44**(6): 808-812.

PURPOSE: Osteoporotic fractures of the distal femur are an underestimated and increasing problem in trauma and orthopaedic surgery. Therefore, this study investigates the biomechanical potential of implant augmentation in the treatment of these fractures. METHODS: Twelve osteoporotic surrogate distal femora were randomly assigned to the

augmented or non-augmented group. All specimens were fixed using the LCP DF. In the augmented group additionally 1ml Vertecem V+ was injected in each screw hole before screw positioning. The construct represents an AO 33 A3 fracture. Biomechanical testing was performed as sinusoidal axial loading between 50 and 500N with 2Hz for 45,000 cycles, followed by loading between 50 and 750N until failure. RESULTS: The augmented group showed significant higher axial stiffness (36%). Additionally the displacement after 45,000 cycles was 3.4 times lower for the augmented group (0.68+/-0.2mm vs. 2.28+/-0.2mm). Failure occurred after 45,130 cycles (SD 99) in all of the non-augmented specimens and in two specimens of the augmented group after 69,675 cycles (SD 1729). Four of the augmented specimens showed no failure. The failure mode of all specimens in both groups was a medial cut-out. CONCLUSIONS: This study shows a promising potential of implant augmentation in the treatment of osteoporotic distal femur fractures.

Wall, S. J., et al. (2010). "Mechanical evaluation of a 4-mm cancellous "rescue" screw in osteoporotic cortical bone: a cadaveric study." J Orthop Trauma **24**(6): 379-382.

OBJECTIVES: Obtaining sufficient fracture fixation in osteoporotic bone is challenging. The purposes of the current study were (1) to compare the pullout strength of a 4-mm cancellous screw (cancellous screw group) with that of a 3.5-mm cortical screw (cortical screw group), and (2) to measure the pullout strength of a 4-mm cancellous screw placed as a rescue screw (rescue screw group) in a stripped 3.5-mm cortical screw (stripped screw group) hole while controlling for bone density and cortical thickness. METHODS: We inserted 4 screws, one from each experimental group, into 11 osteoporotic cadaveric radii, while recording the insertion torque. Radii were mounted on a servohydraulic testing machine, and each screw was pulled out at a rate of 5 mm/min. Pullout strength was recorded. The effects of cortical thickness (near, far, and total), bone density, insertion torque, and the experimental screw group (cortical, cancellous, stripped, and rescue screw groups) on pullout strength were analyzed using multiple linear regression with random effects. Statistical significance was set at $P < 0.05$. RESULTS: There was no significant difference in pullout strength between the cortical and cancellous screw groups. The rescue screw group had significantly less pullout strength than did the cortical and cancellous screws, and only partly increased pullout strength compared with stripped screws. Bone density significantly affected pullout strength, but insertion torque and cortical thickness were not significant covariates. CONCLUSIONS: There seems to be no advantage in using a cancellous screw over a cortical screw in bicortical fixation in osteoporotic bone. Although the rescue screw provided greater pullout strength than the stripped screw, it is unknown if the purchase it provides is clinically sufficient.

Wittenberg, R. H., et al. (1991). "Importance of bone mineral density in instrumented spine fusions." Spine (Phila Pa 1976) **16**(6): 647-652.

The effect of equivalent mineral density on pedicular screw fixation strength was investigated. The equivalent mineral density of human vertebral bodies was correlated highly with the pullout force of Kluger screws (r2 = 0.61, P less than 0.02). A moderate to high correlation existed between density and vertical force (r2 = 0.42 for Kluger screws, r2 = 0.55 for Steffee screws, P less than 0.02). In calf vertebral bodies of higher density (146 +/- 14 mg/cc), the forces were significantly higher than in the human vertebral bodies (P less than 0.05). Human lumbosacral spines were instrumented with three different fixators: Steffee plates, AO fixateur interne, and Kluger fixateur interne. Of five specimens with a mean density of 88 +/- 11 mg/cc, one screw loosened. More than one screw loosened in six specimens with a mean density of 63 +/- 12 mg/cc, and no screw loosened in four specimens with a mean density of 114 +/- 38 mg/cc. Measurement of equivalent mineral density correlates with the fixation strength of the intrapedicular screws in vitro and should be considered in patients with signs of osteopenia before using pedicular screws for spinal fusions. It is also concluded that calf spines are a good model for testing implants because they tend to focus failure processes in the implant rather than in the implant-bone interface.

Wu, Z. X., et al. (2012). "Surgical treatment of osteoporotic thoracolumbar compressive fractures with open vertebral cement augmentation of expandable pedicle screw fixation: a biomechanical study and a 2-year follow-up of 20 patients." J Surg Res **173**(1): 91-98.

BACKGROUND: The incidence of screw loosening increases significantly in elderly patients with severe osteoporosis. Open vertebral cement augmentation of expandable pedicle screw fixation may improve fixation strength in the osteoporotic vertebrae. MATERIALS AND METHODS: Twenty cadaveric vertebrae (L1-L5) were harvested from six osteoporotic lumbar spines. Axial pullout tests were performed to compare the maximum pullout strength (Fmax) of four methods: 1. Conventional pedicle screws (CPS), 2. Expandable pedicle screws (EPS), 3. Cement augmentation of CPS (cemented-CPS), 4. Cement augmentation of EPS (cemented-EPS). Thirty-six consecutive patients with single-vertebral osteoporotic compressive fractures received posterior decompression and spinal fusion with cemented-CPS (16 cases) or cemented-EPS (20 cases). Plain film and/or CT scan were conducted to evaluate the spinal fusion and fixation effectiveness. RESULTS: The Fmax and energy absorption of cemented-EPS were significantly greater than three control groups. The mean BMD in the severe osteoporosis group was significantly lower than that in the osteoporosis group (t = 2.04, P = 0.036). In the osteoporosis group, cemented-EPS improved the Fmax by 43% and 21% over CPS and cemented-CPS group. In the severe osteoporosis group, cemented-EPS increased the Fmax by 59%, 22%, and 26% over CPS, EPS, and cemented-CPS, respectively. The clinical results showed that all patients suffered from severe osteoporosis. Six months after operation, the JOA and VAS scores in cemented-EPS group improved from 11.4 +/- 2.6 and 7.0 +/- 1.4 mm to 24.9 +/- 1.6 and 2.1 +/- 1.3 mm, respectively. No screw loosening occurred in the cemented-EPS group and spinal fusion was achieved. In the cemented-CPS group, four screws loosened (4.2%) according to the radiolucency. Six months after operation, the JOA and VAS scores improved from 13.1 +/- 1.9 and 7.6 +/- 1.5 mm to 22.8 +/- 2.2 and 2.5 +/- 1.6 mm, respectively. No cement leaked into the spinal canal in both groups. CONCLUSIONS: Cemented-EPS could increase fixation strength biomechanically. It could reduce the risks of screw loosening in patients with severe osteoporosis, requiring instrumented arthrodesis.

Wu, Z. X., et al. (2012). "A comparative study on screw loosening in osteoporotic lumbar spine fusion between expandable and conventional pedicle screws." Arch Orthop Trauma Surg **132**(4): 471-476.

INTRODUCTION: The aim of this study is to compare the rate of screw loosening and clinical outcomes of expandable pedicle screws (EPS) with those of conventional pedicle screws (CPS) in patients treated for spinal stenosis (SS) combined with osteoporosis. METHODS: One hundred and fifty-seven consecutive patients with SS received either EPS fixation (n = 80) or CPS fixation (n = 77) to obtain lumbosacral stabilization. Patients were observed for a minimum of 24 months. Outcome measures included screw loosening, fusion rate, Japanese Orthopaedic Association (JOA) scores and Oswestry disability index (ODI) scoring system, and complications. RESULTS: **In the EPS group, 20 screws became loose (4.1%) in 6 patients (7.5%), and two screws (0.4%) had broken. In the CPS group, 48 screws became loose (12.9%) in 15 patients (19.5%), but no screws were broken.** The fusion rate in the EPS group (92.5%) was significantly higher than that of the CPS group (80.5%). The rate of screw loosening in the EPS group (4.1%) was significantly lower than that of the CPS group (12.9%). Six EPS (1.8%) screws were removed. In the EPS group, two screws had broken but without neural complications. Twelve months after surgeries, JOA and ODI scores in the EPS group were significantly improved. There were four cases of dural tears, which healed after corresponding treatment. CONCLUSIONS: EPS can decrease the risk of screw loosening and achieve better fixation strength and clinical results in osteoporotic lumbar spine fusion.

Wuisman, P. I., et al. (2000). "Augmentation of (pedicle) screws with calcium apatite cement in patients with severe progressive osteoporotic spinal deformities: an innovative technique." Eur Spine J **9**(6): 528-533.

Screw augmentation with calcium apatite cement (CAC) was used in seven patients with a progressive osteoporotic spinal deformity. Thirty-nine spinal segments (64 screws) were augmented: 15 anteriorly (three patients) and 24 posteriorly (five patients). Dorsally, hemilaminectomy was performed at the level of all augmented screws to rule out CAC leakage. Autogenous bone graft was applied in all patients to induce fusion. Screw augmentation failure occurred in only one patient: 1 of the 16 ventral augmented screws (5.5%) was still loose after the augmentation procedure. In three other patients, 4 out of 48 augmented dorsal screws (5.5%) showed CAC leakage at the pedicle corpus vertebra level. Pedicle wall damage was present at two levels, while at two other levels no wall damage was found during visualization. No CAC-related complications were observed perioperatively. No implant migration was observed, and fusion was observed in all cases at follow-up examination performed at a mean of 32 months after surgery.

Zahn, R. K., et al. (2012). "A contoured locking plate for distal fibular fractures in osteoporotic bone: a biomechanical cadaver study." Injury **43**(6): 718-725.

OBJECTIVE: Fixation of ankle fractures in elderly patients is associated with reduced stability conditioned by osteoporotic bone. Therefore, fixation with implants providing improved biomechanical features could allow a more functional treatment, diminish implant failure and avoid consequences of immobilisation. MATERIALS AND METHODS: In the actual study, we evaluated a lateral conventional contoured plate with a locking contoured plate stabilising experimentally induced distal fibular fractures in human cadavers from elderly. Ankle fractures were induced by the supination-external rotation mechanism according to Lauge-Hansen. Stage II fractures (AO 44-B1) were fixed with the 2 contoured plates and a torque to failure test was performed. Bone mineral density (BMD) was measured by quantitative computed tomography to correlate the parameters of the biomechanical experiments with bone quality. RESULTS: The locking plate showed a higher torque to failure, angle at failure, and maximal torque compared to the conventional plate. In contrast to the nonlocking system, fixation with the locking plate was independent of BMD. CONCLUSION: Fixation of distal fibular fractures in osteoporotic bone with the contoured locking plate may be advantageous as compared to the nonlocking contoured plate. The locking plate with improved biomechanical attributes may allow a more functional treatment, reduce complications and consequences of immobilisation.

Zhang, C., et al. (2009). "[Complications of surgical treatment for femoral intertrochanteric fractures using dynamic hip screw]." Zhongguo Gu Shang **22**(8): 624-626.

OBJECTIVE: To investigate the complications of surgical treatments for femoral intertrochateric fractures using dynamic hip screw (DHS). METHODS: From Jan. 2002 to Dec. 2007, sixty-nine patients with intertrochanteric fractures were treated by dynamic hip screw fixation included 27 males and 42 females,with an average age of 72.9 years ranging from 53 to 96 years. According to Evans classification there were 10 cases in type I ,21 in type II, 22 in type III, and 16 in type IV, of which 51 patients (73.9%) suffered from systematic diseases preoperatively. RESULTS: Fifty-seven patients were followed up for 8 to 70 months (41 months on average). Four patients died, 17 cases occurrenced systematic complications postoperatively. Internal fixation related complications occurred in 12 patients. There were 8 cases with mechanical failure of DHS including 4 of screw loosen,3 of cutting-out of device through femoral head and neck and 1 of plate breakage. Five patients had a coxa vara, and delayed union occurred in 4 patients. CONCLUSION: Unstable fracture pattern produced high percentage of mechanical failure. In such cases DHS should not be the first choice for treatment. The appropriate treatment should be in relation to pre-operative fracture stability and osteoporosis.

Sanchez-Sotelo, J., et al. (2007). "Complex distal humeral fractures: internal fixation with a principle-based parallel-plate technique." J Bone Joint Surg Am **89**(5): 961-969.

BACKGROUND: Severe comminution, bone loss, and osteopenia at the site of a distal humeral fracture increase the risk of an unsatisfactory result, often secondary to inadequate fixation. The purpose of this study was to determine the outcome of treating these fractures with a principle-based technique that maximizes fixation in the articular fragments and stability at the supracondylar level. METHODS: Thirty-four consecutive complex distal humeral fractures were fixed with two parallel plates applied (medially and laterally) in approximately the sagittal plane. The technique was specifically designed to satisfy two principles: (1) fixation in the distal fragments should be maximized and (2) screw fixation in the distal segment should contribute to stability at the supracondylar level. Twenty-six fractures were AO type C3, and fourteen were open. Thirty-two fractures were followed for a mean of two years. The patients were assessed clinically with use of the Mayo Elbow Performance Score (MEPS) and radiographically. RESULTS: Neither hardware failure nor fracture displacement occurred in any patient. Union of thirty-one of the thirty-two fractures was achieved primarily. Five patients underwent additional surgery to treat elbow stiffness. There was one deep infection that resolved without hardware removal and did not impede union. At the time of the most recent follow-up, twenty-eight elbows were either not painful or only mildly painful, and the mean flexion-extension arc was 99 degrees . The mean MEPS was 85 points. The result was graded as excellent for eleven elbows, good for sixteen, fair for two, and poor for three. CONCLUSIONS: Stable fixation and a high rate of union of complex distal humeral fractures can be achieved when a principle-based surgical technique that maximizes fixation in the distal segments and stability at the supracondylar level is employed. The early stability achieved with this technique permits intensive rehabilitation to restore elbow motion.

Sanchez-Sotelo, J., et al. (2008). "Complex distal humeral fractures: internal fixation with a principle-based parallel-plate technique. Surgical technique." J Bone Joint Surg Am **90 Suppl 2 Pt 1**: 31-46.

BACKGROUND: Severe comminution, bone loss, and osteopenia at the site of a distal humeral fracture increase the risk of an unsatisfactory result, often secondary to inadequate fixation. The purpose of this study was to determine the outcome of treating these fractures with a principle-based technique that maximizes fixation in the articular fragments and stability at the supracondylar level. METHODS: Thirty-four consecutive complex distal humeral fractures were fixed with two parallel plates applied (medially and laterally) in approximately the sagittal plane. The technique was specifically designed to satisfy two principles: (1) fixation in the distal fragments should be maximized and (2) screw fixation in the distal segment should contribute to stability at the supracondylar level. Twenty-six fractures were AO type C3, and fourteen were open. Thirty-two fractures were followed for a mean of two years. The patients were assessed clinically with use of the Mayo Elbow Performance Score (MEPS) and radiographically. RESULTS: Neither hardware failure nor fracture displacement occurred in any patient. Union of thirty-one of the thirty-two fractures was achieved primarily. Five patients underwent additional surgery to treat elbow stiffness. There was one deep infection that resolved without hardware removal and did not impede union. At the time of the most recent follow-up, twenty-eight elbows were either not painful or only mildly painful, and the mean flexion-extension arc was 99 degrees . The mean MEPS was 85 points. The result was graded as excellent for eleven elbows, good for sixteen, fair for two, and poor for three. CONCLUSIONS: Stable fixation and a high rate of union of complex distal humeral fractures can be achieved when a principle-based surgical technique that maximizes fixation in the distal segments and stability at the supracondylar level is employed. The early stability achieved with this technique permits intensive rehabilitation to restore elbow motion.

Santoni, B. G., et al. (2009). "Cortical bone trajectory for lumbar pedicle screws." Spine J **9**(5): 366-373.

BACKGROUND CONTEXT: Achieving solid implant fixation to osteoporotic bone presents a clinical challenge. New techniques and devices are being designed to increase screw-bone purchase of pedicle screws in the lumbar spine via a novel cortical bone trajectory that may improve holding screw strength and minimize loosening. Preliminary clinical evidence suggests that this new trajectory provides screw interference that is equivalent to the more traditionally directed trajectory for lumbar pedicle screws. However, a biomechanical study has not been performed to substantiate the early clinical results. PURPOSE: Evaluate the mechanical competence of lumbar pedicle screws using a more medial-to-lateral path (ie, "cortical bone trajectory") than the traditionally used path. STUDY DESIGN: Human cadaveric biomechanical study. METHODS: Each vertebral level (L1-L5) was dual-energy X-ray absorptiometry (DXA) scanned and had two pedicle screws inserted. On one side, the traditional medially directed trajectory was drilled and tapped. On the contralateral side, the newly proposed cortical bone trajectory was drilled and tapped. After qCT scanning, screws were inserted into their respective trajectories and pullout and toggle testing ensued. In uniaxial pullout, the pedicle screw was withdrawn vertically from the constrained bone until failure occurred. The contralateral side was tested in the same manner. In screw toggle testing, the vertebral body was rigidly constrained and a longitudinal rod was attached to each screw head. The rod was grasped using a hydraulic grip and a quasi-static, upward displacement was implemented until construct failure. The contralateral pedicle screw was tested in the same manner. Yield pullout (N) and stiffness (N/mm) as well as failure moment (N-m) were compared and bone mineral content and bone density data were correlated with the yield pullout force. RESULTS: New cortical trajectory screws demonstrated a 30% increase in uniaxial yield pullout load relative to the traditional pedicle screws (p=0.080), although mixed loading demonstrated equivalency between the two trajectories. No significant difference in construct stiffness was noted between the two screw trajectories in either biomechanical test or were differences in failure moments (p=0.354). Pedicle screw fixation did not appear to depend on bone quality (DXA) yet positive correlations were demonstrated between trajectory and bone density scans (qCT) and pullout force for both pedicle screws. CONCLUSIONS: The current study demonstrated that the new cortical trajectory and screw design have equivalent pullout and toggle characteristics compared with the traditional trajectory pedicle screw, thus confirming preliminary clinical evidence. The 30% increase in failure load of the cortical trajectory screw in uniaxial pullout and its juxtaposition to higher quality bone justify its use in patients with poor trabecular bone quality.

Sarzier, J. S., et al. (2002). "Increased pedicle screw pullout strength with vertebroplasty augmentation in osteoporotic spines." J Neurosurg **96**(3 Suppl): 309-312.

OBJECT: The authors conducted a biomechanical study to evaluate pedicle screw pullout strength in osteoporotic cadaveric spines. Nonaugmented hemivertebrae were compared with pressurized polymethylmethacrylate (PMMA)-augmented hemivertebrae. METHODS: Six formalin-fixed cadaveric thoracolumbar spines at least two standard deviations below the mean bone mineral density (BMD) for age were obtained. Radiographic and BMD studies were correlated to grades I, II, and III osteoporosis according to the Jekei scale. Each of the 21 vertebrae underwent fluoroscopic placement of 6-mm transpedicular screws with each hemivertebra serving as the control for the contralateral PMMA-augmented hemivertebra. Pedicle screws were then evaluated for biomechanical axial pullout resistance. Augmented hemivertebrae axial pullout forces were increased (p = 0.0005). The mean increase in pullout force was 181% for Grade I, 206% for Grade II, and 213% for Grade III osteoporotic spines. Augmented Grade I osteoporotic spines demonstrated axial pullout forces near those levels reported in the literature for nonosteoporotic specimens. Augmented Grade II osteoporotic specimens demonstrated increases to levels found in nonaugmented vertebrae with low-normal BMD. Augmented Grade III osteoporotic specimens had increases to levels

equal to those found in nonaugmented Grade I vertebrae. CONCLUSIONS: Augmentation of osteoporotic vertebrae in PMMA-assisted vertebroplasty can significantly increase pedicle screw pullout forces to levels exceeding the strength of cortical bone. The maximum attainable force appears to be twice the pullout force of the nonaugmented pedicle screw for each osteoporotic grade.

Sawakami, K., et al. (2012). "Polymethylmethacrylate augmentation of pedicle screws increases the initial fixation in osteoporotic spine patients." J Spinal Disord Tech **25**(2): E28-35.

STUDY DESIGN: A retrospective comparative study. OBJECTIVES: To investigate the clinical efficacy of polymethylmethacrylate (PMMA) augmentation in vertebral pseudarthrosis after osteoporotic vertebral fractures. SUMMARY OF BACKGROUND DATA: Despite being the most rigid form of posterior instrumentation, pedicle screws sometimes achieve poor initial fixation primarily in patients with osteoporosis. One method for improving pedicle screw fixation in osteoporotic spines is pedicle augmentation using bone cement such as PMMA. Although various biomechanical studies of osteoporotic spines have shown improved pullout strength of pedicle screws augmented with bone cement, there have been few studies that have examined the clinical significance of PMMA augmentation. METHODS: Thirty-eight patients with posterior fusion using pedicle screws for vertebral pseudarthrosis after osteoporotic vertebral fracture were included in the study. The level of fracture ranged from T7 to L5. The mean follow-up period was 31 months. Patients were divided into 2 groups: those with posterior instrumentation using pedicle screws augmented with PMMA (group C, N=17) and those without PMMA augmentation (group NC, N=21). Clinical and radiographic results for the 2 groups were compared. RESULTS: With the exception of osteoporotic status, there were no significant differences in the baseline data of the 2 groups. The incidence of clear zones around the pedicle screws was significantly suppressed in group C compared with group NC (29.4% vs. 71.4%). Correction loss was significantly decreased (3 degrees vs. 7.2 degrees) and fusion rate was significantly higher in group C (94.1% vs. 76.1%). Back pain improved in 64.7% of the group C patients. There were no perioperative complications related to the PMMA cement in group C. CONCLUSIONS: Reinforcement of pedicle screws using PMMA augmentation may be a feasible surgical technique for osteoporotic spines.

Schandelmaier, P., et al. (2001). "Distal femoral fractures and LISS stabilization." Injury **32 Suppl 3**: Sc55-63.

In recent years, the technique of surgical stabilization in the distal femur has changed. This change decreased the number of non unions and the need for bone grafting. Minimally invasive surgical techniques with a submuscular plate placement have replaced the emphasis on anatomical reduction in the shaft area. Reconstruction of complex articular injuries has been simplified by more direct visualization of the articular surface with the lateral peripatellar approach. Problems remaining are surgical technique and implant considerations. The Less Invasive Stabilization System (LISS) simplifies the surgical technique for percutaneous plate osteosynthesis. An insertion guide is used to insert monocortical, self-tapping screws through a stab incision. A thread in the plate provides the angular stability for the anchoring of these screws. In extra-articular fractures and simple intra-articular fractures, the distal femoral nail permits intramedullary stabilization. A spiral blade improves fixation of the distal femoral condylar block. Despite the enhanced surgical technique and implant possibilities, a great number of patients show a functional deficiency. These are particularly patients with complex intra-articular fractures. The 'fatigue failure' of the osteoporotic implant-bone construct is a problem in elderly patients. The LISS represents a good option to avoid the addition of bone cement to an osteosynthesis.

Schneider, E., et al. (2005). "The challenge: fracture treatment in osteoporotic bone." Osteoporos Int **16 Suppl 2**: S1-2.

Schoenfeld, A. J., et al. (2008). "Pullout strength and load to failure properties of self-tapping cortical screws in synthetic and cadaveric environments representative of healthy and osteoporotic bone." J Trauma **64**(5): 1302-1307.

BACKGROUND: The parameters of self-tapping screw (STS) performance in normal and osteoporotic bone have been defined in representative environments, but the question remains as to the clinical application of such findings. The goal of this study was to analyze the biomechanical performance of STSs in cadaveric and synthetic environments representative of healthy and osteoporotic bone. METHODS: Ninety-six Synthes STSs were inserted into cadaveric and synthetic models representative of osteoporotic and healthy bone. Screws were inserted to depths of 1 mm short of the far cortex, flush and 1 mm and 2 mm beyond the far cortex. Screws were tested with an Instron 8511 material testing system utilizing axial pullout forces. A SAS procedure was used to conduct analysis of variance for unbalanced datasets. RESULTS: Substantial differences were appreciated with respect to screw performance between osteoporotic and healthy bone specimens. Although a similar pattern of increased pullout strength and loading energy with increasing depth of insertion was demonstrated, absolute values were lower in osteoporotic specimens. Although performance trends were similar in cadaveric and synthetic testing models for both osteoporotic and healthy bone, values obtained during testing were different. Incomplete insertion of STSs resulted in a 21.5% and 37% reduction of biomechanical properties in osteoporotic and normal bone, respectively. CONCLUSIONS: These results indicate that previously published findings on the performance of STSs in synthetic models cannot reasonably be applied to the clinical realm. Although trends may be similar, screw performance in synthetic, as compared with cadaveric, models is markedly different.

Schultheiss, M., et al. (2003). "Enhanced primary stability through additional cementable cannulated rescue screw for anterior thoracolumbar plate application." J Neurosurg **98**(1 Suppl): 50-55.

OBJECT: The authors conducted a study to investigate the biomechanical in vitro influence of a new anchorage system for fixation of anterior stabilization devices and the possibility of using additional cement after screw insertion to compensate for poor bone quality. The incidence of osteoporosis-related fractures has increased nearly twofold in the last decade. Because of problems associated with anterior screw fixation such as loosening, mechanical failure, and the weakness of osteoporotic bone, current surgical treatments of vertebral body (VB) fractures are problematic. This is due to poor fixation strength of anterior screws in the adjacent segments. The aim of this study was to determine whether a new cemented and uncemented VB screw provides improved primary stability following placement of anterior instrumentation in cases of fracture. METHODS: The primary stability-related parameters of a new uncemented/cemented screw were compared with those of conventional monocortical screw fixation in a burst fracture model in which strut graft and anterior overbridging instrumentation were used. The use of the new uncemented screw improved the range of motion (ROM) of the stabilized spine in flexion-extension by approximately 22%, in rotation by 20%, and in lateral bending by 15%. Additional cementation improved the ROM by approximately 41% in flexion-extension, 32% in rotation, and 30% in lateral bending compared with conventional monocortical screw fixation. CONCLUSIONS: The new cannulated screw improves fixation strength and primary stability parameters. It is useful in the initial treatment of fractures in cases of poor bone quality and as a rescue device if previously inserted screws do not remain securely in place.

Schwarzenbach, O., et al. (2005). "Posterior dynamic stabilization systems: DYNESYS." Orthop Clin North Am **36**(3): 363-372.

Posterior dynamic stabilization systems have to neutralize injurious forces and restore painless function of the spine segments and protect the adjacent segments. Because degenerative disc disease has many clinical manifestations, pedicular screw systems and interspinous implants have their indications. A dynamic stabilization device has to provide stability throughout its lifetime, unless it activates or allows reparative processes with a

reversal of the degenerative changes. Anchorage to the bone is crucial, at least for pedicular systems. This is a great demand on spinal implants and assumes rest and motion going together. Our experience with DYNESYS has shown that this method has limitations in elderly patients with osteoporotic bone or in patients with a severe segmental macro-instability combined with degenerative olisthesis and advanced disc degeneration. Such cases have an increased risk of failure. Only future randomized evaluations will be able to address the potential reduction of accelerated adjacent segment degeneration. The few posterior dynamic stabilization systems that have had clinical applications so far have produced clinical outcomes comparable with fusion. No severe adverse events caused by these implants have been reported. Long-term follow-up data and controlled prospective randomized studies are not available for most of the cited implants but are essential to prove the safety, efficacy, appropriateness, and economic viability of these methods.

Seebeck, J., et al. (2005). "Mechanical behavior of screws in normal and osteoporotic bone." Osteoporos Int **16 Suppl 2**: S107-111.

Fracture fixation in severe osteoporotic bone by means of implants that rely on screw anchorage is still a clinical problem. So far, a sufficiently accurate prediction of the holding capacity of screws as a function of local bone morphology has not been obtained. In this study the ultimate pullout loads of screws in the epi-, meta-, and diaphyseal regions of human tibiae were correlated to the cortical thicknesses and cancellous bone mineral densities at the screw axes determined from QCT densitometric data. Stepwise multiple linear regression showed that in regions with cortical thicknesses below 1.5 mm, cancellous density determined the ultimate pullout load ($R2 = 0.85$, $p < 0.001$), while in regions with cortices above 1.5 mm, cortical thickness alone significantly influenced the holding capacity of a screw ($R2 = 0.90$, $p < 0.001$). The findings of this study provide a basis for a bone morphology-related pre-operative estimation of the holding capacity of screws, which could help to improve their proper application in osteoporotic bone.

Seebeck, J., et al. (2004). "Effect of cortical thickness and cancellous bone density on the holding strength of internal fixator screws." J Orthop Res **22**(6): 1237-1242.

Internal fixators are a new class of implants designed to preserve the periosteal blood supply of the bone. In contrast to conventional plate fixation in which the screws have spherical heads and are loaded mainly by axial pullout forces, screws in internal fixators are "locked" within the plate and therefore subjected to axial as well as bending loads. In this study the ultimate loads of screws of a commercially available internal fixator system were tested in a pullout ($n = 72$) and cantilever bending mode ($n = 72$) in metaphyseal and diaphyseal regions of four pairs of human tibiae with different bone qualities. Cortical thickness and cancellous bone density were determined at the screw insertion sites. Stepwise multiple linear regression revealed that cortical thickness and cancellous density can explain 93% and 98% of the variance of the ultimate load of the screws in an axial pullout and cantilever bending mode. Screws in internal fixators are better suited to transmit shear forces and thereby make better use of the strength potential of bone than screws used in conventional plate fixation: this is especially advantageous when bone strength is reduced, e.g. due to osteoporosis.

Sessa, G., et al. (2011). "Osteosynthesis systems in fragility fracture." Aging Clin Exp Res **23**(2 Suppl): 69-70.

Atraumatic fractures, more commonly known as "fragility fractures", have as their basis the decreased bone strength due to osteoporosis. The major technical problem is the difficulty in obtaining secure fixation in osteoporotic bone, because the pull-out strength of implant is significantly reduced. The high rate of complications has encouraged extensive research into the development of implant which can improve the bone-implant interface by preventing high stress and distributing the forces transmitted to bone in a load-sharing, rather than load-bearing way.

Shea, T. M., et al. (2014). "Designs and techniques that improve the pullout strength of pedicle screws in osteoporotic vertebrae: current status." **2014**: 748393.

Osteoporosis is a medical condition affecting men and women of different age groups and populations. The compromised bone quality caused by this disease represents an important challenge when a surgical procedure (e.g., spinal fusion) is needed after failure of conservative treatments. Different pedicle screw designs and instrumentation techniques have been explored to enhance spinal device fixation in bone of compromised quality. These include alterations of screw thread design, optimization of pilot hole size for non-self-tapping screws, modification of the implant's trajectory, and bone cement augmentation. While the true benefits and limitations of any procedure may not be realized until they are observed in a clinical setting, axial pullout tests, due in large part to their reproducibility and ease of execution, are commonly used to estimate the device's effectiveness by quantifying the change in force required to remove the screw from the body. The objective of this investigation is to provide an overview of the different pedicle screw designs and the associated surgical techniques either currently utilized or proposed to improve pullout strength in osteoporotic patients. Mechanical comparisons as well as potential advantages and disadvantages of each consideration are provided herein.

Smith, T. O., et al. (2009). "The clinical and radiological outcomes of the LISS plate for distal femoral fractures: a systematic review." Injury **40**(10): 1049-1063.

PURPOSE: The purpose of this systematic review was to assess the literature evaluating the clinical and radiological outcomes following less invasive surgical stabilisation system (LISS) fixation of distal femoral fractures (AO 32/33). METHODS: A review of EMBASE, Medline, CINAHL and AMED from their inception to November 2008, sources of grey literature and a pertinent hand search of specialist orthopaedic journals was undertaken. RESULTS: Twenty-one studies assessing 663 patients with 694 fractures were reviewed. The findings suggest that the LISS system may be an appropriate fixation method for the management of distal femoral fractures. However, there remains a high incidence of loss of reduction (n=134; 19%), delayed or non-union (n=40; 6%) and implant failure (n=38; 5%). On analysis, such complications were largely confined to articles published before 2005, therefore during the infancy of the widespread clinical application of this trauma system. On critical appraisal, the evidence-base remains limited by recruiting small, under-powered sample sizes and poorly accounting for confounding variables such as osteoporosis, diabetes, multi-trauma and fracture classification. CONCLUSION: Further study is required to assess the outcomes of LISS fixation in specific patient populations, and to compare the outcome of this fixation method to condylar plates and intramedullary devices, to determine the optimal management strategy for this complex patient group.

Snow, M., et al. (2008). "A mechanical comparison of the locking compression plate (LCP) and the low contact-dynamic compression plate (DCP) in an osteoporotic bone model." J Orthop Trauma **22**(2): 121-125.

OBJECTIVE: To determine if locking compression plates (LCP) are mechanically advantageous compared to low-contact dynamic compression plates (DCP) when used as a bridging plate in a synthetic model of osteoporotic bone. METHODS: Five synthetic bars (Synbone Osteoporotic bone) were initially tested in compression and the Young's modulus determined. It was found to be comparable to that of tibial cancellous bone in an 80-year-old woman; thus, the synthetic bars were deemed usable to simulate some properties of osteoporotic bone. Six bars were then instrumented with an 8-hole narrow large fragment DCP with six 4.5-mm cortical screws (placed in holes 1-3 and holes 6-8). Six bars were instrumented with a narrow 8-hole LCP using four 5-mm locking screws (placed in the 1st, 3rd, 6th, and 8th holes). In a third group, 6 synbone bars were instrumented with a narrow 8-hole large fragment DCP. Cortical screws were placed in holes 2-3 and holes 6-7. In holes 1 and 8, two 6.5 fully threaded cancellous screws were inserted. A 1-cm osteotomy was

created in the Synbone at the center of each plate to represent a comminuted fracture. Initially, quasi-static testing was carried out on all specimens in compression to a maximum load of 450 N. Then 4-point bend tests were carried out in two planes (0 degrees and 90 degrees) with the maximum bending moment at 3.5 Nm. Finally, torsional testing was done to a maximum load of 3.5 Nm. The specimens were then cycled in axial compression 350 N at 5 Hz for 30,000 cycles. The static nondestructive tests were repeated. The slope of the load deformation curve indicated the relative stiffness of the construct. The slopes were determined pre- and postcycling and the loss of stiffness in each group compared. Statistical analysis was carried out using the paired t-test. The specimens were then loaded to failure in compression. RESULTS: There was no statistical difference in the stiffness of the LCP or in the osteotomy gap postcycling. All specimens in the DCP groups failed initial static testing in axial compression. No fatigue testing could be undertaken in this group. CONCLUSIONS: In a synthetic model, the LCP was mechanically superior to the DCP when used as a bridging plate and tested in axial compression.

Sokol, S. C., et al. (2011). "Biomechanical properties of volar hybrid and locked plate fixation in distal radius fractures." J Hand Surg Am **36**(4): 591-597.

PURPOSE: We compare the biomechanical properties of a volar hybrid construct to an all-locking construct in an osteoporotic and normal comminuted distal radius fracture model. METHODS: Groups of 28 normal, 28 osteoporotic, and 28 over-drilled osteoporotic left distal radius synthetic bones were used. The normal group consisted of synthetic bone with a standard foam core. The osteoporotic group consisted of synthetic bone with decreased foam core density. The over-drilled osteoporotic group consisted of synthetic bone with decreased foam core density and holes drilled with a 2.3 mm drill, instead of the standard 2.0 mm drill, to simulate the lack of purchase in osteoporotic bone. Within each group, 14 synthetic bones were plated with a volar locking plate using an all-locking screw construct, and 14 synthetic bones were plated with a volar locking plate using a hybrid screw construct (ie, both locking and nonlocking screws). A 1-cm dorsal wedge osteotomy was created with the apex 2 cm from the volar surface of the lunate facet. Each specimen was mounted to a materials testing machine, using a custom-built, standardized axial compression jig. Axial compression was delivered at 1 N/s over 3 cycles from 20 N to 100 N to establish stiffness. Each sample was stressed to failure at 1 mm/s until 5 mm of permanent deformation occurred. RESULTS: Our results show no difference in construct stiffness and load at failure between the all-locking and hybrid constructs in the normal, osteoporotic, or over-drilled osteoporotic synthetic bone models. All specimens failed by plate bending at the osteotomy site with loss of height. CLINICAL RELEVANCE: Although volar locking plates are commonly used for the treatment of distal radius fractures, the ideal screw configuration has not been determined. Hybrid fixation has comparable biomechanical properties to all locking constructs in the fixation of metaphyseal fractures about the knee and shoulder and might also have a role in the fixation of distal radius fractures.

Sommer, C., et al. (2004). "Locking compression plate loosening and plate breakage: a report of four cases." J Orthop Trauma **18**(8): 571-577.

The Locking Compression Plate (LCP) system offers a number of advantages in fracture fixation combining angular stability through the use of locking screws with traditional fixation techniques. This makes the implant particularly suitable for use in poor bone stock and complex joint fractures, especially in the epimetaphyseal area. However, the system is complex, requiring careful attention to biomechanical principles, and a number of potential pitfalls need to be considered. These pitfalls are illustrated in the 4 cases described herein, in which treatment was unsuccessful due to implant breakage or loosening. In each case, treatment failure could be attributed to the choice of an inappropriate plate and/or fixation technique, rather than to the features of the Locking Compression Plate system itself. Such experiences highlight the importance of detailed understanding of the biomechanical

principles of plate fixation as well as careful preoperative planning for the successful use of the Locking Compression Plate system.

Soshi, S., et al. (1991). "An experimental study on transpedicular screw fixation in relation to osteoporosis of the lumbar spine." Spine (Phila Pa 1976) **16**(11): 1335-1341.

In order to elucidate the relationship between the severity of osteoporosis and the fixation strength of a pedicle screw, screw pull-out tests were performed using cadaveric lumbar vertebrae. The severity of osteoporosis was evaluated by the Jikei osteoporosis grading scale (Jikei method), bone mineral density, and microdensitometry. When a 7.0-mm screw was used, the pull-out force of the screw was 1,056.4 N in the normal group (as determined by the Jikei method), while it was 495.6 N in the Grade I osteoporosis and 269.5 N in the Grade II osteoporosis groups, respectively. There were also positive correlations between the pull-out force and bone mineral density and each parameter of the microdensitometry method. When bone cement was used in an osteoporotic vertebra, twofold stronger pull-out force was obtained in comparison to that obtained without bone cement.

Spangler, L., et al. (2001). "Biomechanical factors and failure of transcervical hip fracture repair." Injury **32**(3): 223-228.

OBJECTIVE: To assess the association between biomechanical measurements (bone quality of the femoral neck, comminution, fracture angle, and fracture level) and the likelihood of fixation failure among patients who have a multiple screw stabilisation of an intracapsular hip fracture. METHODS: A cohort study of 139 Washington State residents greater than 60 years of age who sustained a fall-related transcervical hip fracture treated from 1990 to 1996 inclusive. Measurements of bone quality, fracture angle, fracture level, and comminution were taken from perioperative X-rays. The outcome measure was clinical failure of the internal fixation procedure within 12 months of hospital discharge, as measured by readmission for further surgery to that hip. RESULTS: Of the four biomechanical aspects examined, only bone quality, as measured by presence of an ICD code for osteoporosis, was significantly associated with risk of subsequent hospitalisation for revision surgery (adjusted hazard ratio 7.7, 95% CI 1.8-32.8). CONCLUSION: A diagnosis code for osteoporosis was related to the outcome of intracapsular fractures repaired with multiple pins. Other biomechanical measurements from diagnostic X-rays were not related to the need for further surgery.

Stadelmann, V. A., et al. (2010). "Calcium phosphate cement augmentation of cancellous bone screws can compensate for the absence of cortical fixation." J Biomech **43**(15): 2869-2874.

An obvious means to improve the fixation of a cancellous bone screw is to augment the surrounding bone with cement. Previous studies have shown that bone augmentation with Calcium Phosphate (CaP) cement significantly improves screw fixation. Nevertheless, quantitative data about the optimal distribution of CaP cement is not available. The present study aims to show the effect of cement distribution on the screw fixation strength for various cortical thicknesses and to determine the conditions at which cement augmentation can compensate for the absence of cortical fixation in osteoporotic bone. In this study, artificial bone materials were used to mimic osteoporotic cancellous bone and cortical bone of varying thickness. These bone constructs were used to test the fixation strength of cancellous bone screws in different cortical thicknesses and different cement augmentation depths. The cement distribution was measured with microCT. The maximum pullout force was measured experimentally. The microCT analysis revealed a pseudo-conic shape distribution of the cement around the screws. While the maximum pullout strength of the screws in the artificial bone only was 30+/-7N, it could increase up to approximately 1000N under optimal conditions. Cement augmentation significantly increased pullout force in all cases. The effect of cortical thickness on pullout force was reduced with increased cement augmentation depth. Indeed, cement augmentation without cortical fixation increased pullout forces over that of screws without cement augmentation but with cortical fixation. Since

cement augmentation significantly increased pullout force in all cases, we conclude that the loss of cortical fixation can be compensated by cement augmentation.

Stein, P. S., et al. (2005). "Composite resin in medicine and dentistry." J Long Term Eff Med Implants **15**(6): 641-654.

Composite resin has been used for nearly 50 years as a restorative material in dentistry. Use of this material has recently increased as a result of consumer demands for esthetic restorations, coupled with the public's concern with mercury-containing dental amalgam. Composite is now used in over 95% of all anterior teeth direct restorations and in 50% of all posterior teeth direct restorations. Carbon fiber reinforced composites have been developed for use as dental implants. In medicine, fiber-reinforced composites have been used in orthopedics as implants, osseous screws, and bearing surfaces. In addition, hydroxyapatite composite resin has become a promising alternative to acrylic cement in stabilizing fractures and cancellous screw fixation in elderly and osteoporotic patients. The use of composite resin in dentistry and medicine will be the focus of this review, with particular attention paid to its physical properties, chemical composition, clinical applications, and biocompatibility.

Stern, R., et al. (2011). "Prospective randomised study comparing screw versus helical blade in the treatment of low-energy trochanteric fractures." Int Orthop **35**(12): 1855-1861.

PURPOSE: The purpose of this study was to compare femoral head placement, rates of reoperation and cephalic implant cut-out of a screw versus a blade for patients over age 60 with low energy trochanteric fractures (AO/OTA 31-A1, A2, and A3) treated either with sliding hip screw or cephalomedullary nail. METHODS: After surgeon selection of either hip screw or nail, hip screw patients were randomised to either a DHS (dynamic hip system screw) or DHS blade (dynamic hip system blade), while nail patients were randomised to either a Gamma3 Trochanteric Nail or a PFNA (proximal femoral nail antirotation). This resulted in a screw group (DHS and Gamma nail), and a blade group (DHS blade and PFNA). Outcome measures included tip-apex distance and zone location of the cephalic implant, as well as reoperation and implant cut-out within the first postoperative year. RESULTS: A total of 335 patients were randomised, 172 to a screw and 163 to a blade. There was no significant difference concerning mean tip-apex distance, percentage of patients with a tip-apex distance >25 mm, and patients with a centre-centre position of the cephalic implant. There were 137 patients in the screw group and 132 in the blade group available for follow-up. They did not differ regarding rates of reoperation or cut-out (screw group = 2.9%; blade group = 1.5%). CONCLUSIONS: Both a screw and a blade performed equally well in terms of implant placement in the femoral head and outcome.

Stoffel, K., et al. (2007). "A comparison of conventional versus locking plates in intraarticular calcaneus fractures: a biomechanical study in human cadavers." Clin Biomech (Bristol, Avon) **22**(1): 100-105.

BACKGROUND: Internal fixation of displaced intraarticular calcaneal fractures in patients older than 50 years remains controversial. This is, in many cases, due to fear of loss of fixation and the risk of implant failure in osteoporotic bone. It is the objective of this study to compare the fixation strength obtained using calcaneal plates with and without locking screws, in the fixation of osteoporotic cadaveric intraarticular calcaneal fractures. METHODS: In seven pairs of fresh frozen lower limbs cadavers, intraarticular calcaneal fractures were created with a dynamic single impact loading device and stabilized using either the low profile locking plate, or the conventional calcaneus plate. Radiographs were obtained to assess reduction. The specimens were then subjected to cyclic loading followed by loading to failure, using matched pairs of cadaveric lower limbs. The Wilcoxon signed rank test was used to test for differences in the results. FINDINGS: The locking plate showed a significant lower irreversible deformation during cyclic loading and a significant higher load to failure. The difference between the ultimate displacement, and work to failure was not significant. A low bone mineral content in the area of the posterior facet correlated

only in the conventional plate group with increased irreversible deformation.
INTERPRETATION: This study supports the mechanical viability of using locking calcaneal plates for the fixation of intraarticular calcaneal fractures in elderly patients.

Stoffel, K., et al. (2008). "Comparative stability of perpendicular versus parallel double-locking plating systems in osteoporotic comminuted distal humerus fractures." J Orthop Res **26**(6): 778-784.
In distal humerus fractures, the restoration of stability is important to allow early mobilization and hence more favorable functional outcomes. In this article, we compare the biomechanical stability of perpendicular and parallel locking plating systems for the internal fixation of AO Type C2 distal humerus fractures in osteoporotic bone. Fractures were simulated in paired cadaveric bones and fixed using either the perpendicular 3.5 mm LCP distal humerus plating system (Synthes; Sydney, Australia) or the parallel Mayo Clinic Congruent elbow plate system (Acumed; Hillsboro, OR), using locking screws in both systems. Both systems were then tested for their stiffness (in compression and internal/external rotation), plastic deformation, and failure in torsion. Comparatively, the parallel locking plate system provided a significantly higher stability in compression ($p = 0.005$) and external rotation ($p = 0.006$), and a greater ability ($p = 0.005$) to resist axial plastic deformation. Stability for both constructs appeared to be dependent on bone quality, however the stability of the perpendicular system was generally more sensitive to bone mineral density, indicating a possible need for additional independent interfragmentary screws. A disadvantage of the parallel locking plate system was wear debris produced by its tapping system. In summary, the biomechanical findings of this study suggest that both locking plate systems allow early mobilization of the elbow in patients with osteoporotic bone following fixation of a comminuted distal humerus fracture. However, the parallel locking system showed improved stability compared with the perpendicular locking system, and therefore may be more indicated.

Stoffel, K. K., et al. (2008). "A new technique for cement augmentation of the sliding hip screw in proximal femur fractures." Clin Biomech (Bristol, Avon) **23**(1): 45-51.
BACKGROUND: Fractures of the osteoporotic proximal femur are a significant source of mortality and morbidity in today's ageing population. Even with modern fixation techniques such as the sliding hip screw, a certain percentage of fixations will fail due to cut-out of the screw. This study presents a new method for augmenting hip screws with cement to reinforce the fixation. METHODS: Unstable pertrochanteric fractures were created in paired osteoporotic cadaver femora (n=10). The fractures were fixed using either standard fixation techniques (dynamic hip screw), or using a dynamic hip screw augmented with cement. Cement was introduced using a customised jig to guide cement into a region superior to the screw in the femoral head. Cut-out resistance was assessed using a biaxial material testing machine, with loading applied in compression until failure. FINDINGS: The new cement augmentation technique significantly improved the cut-out strength of the fixation (mean 42%; P=0.032). The failure mechanism for both groups was the same, with failure occurring through compression of the cancellous bone superior to the screw. The mean increase in temperature at the femoral neck was 3.7 degrees C in augmented bones, which is much lower than values previously reported for polymethylmethacrylate cements.
INTERPRETATION: Several benefits with this technique have emerged. The method is technically straightforward. The risk of cement penetration into the joint is reduced, and cement is targetted to the areas of the femoral head where it is most needed. The exothermic reaction is minimised by reducing the volume of cement used. The first clinical results are promising.

Strauss, E. J., et al. (2007). "Calcium phosphate cement augmentation of the femoral neck defect created after dynamic hip screw removal." J Orthop Trauma **21**(5): 295-300.
OBJECTIVE: To determine the effect of reinforced calcium phosphate cement augmentation of the femoral neck defect created after dynamic hip screw removal in a cadaveric model.

METHODS: The lag screws of dynamic hip screw implants were inserted and subsequently removed in 8 matched pairs of cadaveric, osteoporotic femurs to create a femoral neck defect. One of each pair had the defect augmented with osteoconductive calcium phosphate cement reinforced with poly(lactide-coglycolide) fibers (Norian Reinforced, Synthes, West Chester, PA), and the other defect was not augmented. Each specimen was first cyclically loaded with 750 N vertical loads applied for 1000 cycles to simulate early weightbearing, and then loaded to failure. RESULTS: Calcium phosphate cement augmentation of the lag screw defect significantly increased the mean femoral neck failure strength (4819 N) compared to specimens in which the defect was left untreated (3995 N) ($P < 0.004$). The mechanism of failure for each specimen was a fracture through the femoral neck. Regression analysis demonstrated that load to failure was directly related to the bone mineral density at Ward's triangle, and the impact of cement augmentation on failure strength was greatest for specimens with the lowest bone mineral density (correlation coefficient: -0.82, $P < 0.0001$). CONCLUSION: This study demonstrates that augmentation of the bony defect created by dynamic hip screw removal with reinforced calcium phosphate cement significantly improved the failure strength of the bone. Cement augmentation after hardware removal may decrease the risk of refracture and allow early weightbearing, especially in elderly patients with osteoporotic bone.

Struhl, S., et al. (1990). "Cemented internal fixation for supracondylar femur fractures in osteoporotic patients." J Orthop Trauma **4**(2): 151-157.

Seventeen, supracondylar femur fractures in 15 severely osteoporotic patients (average age, 81.9 years) were treated with a 95 degree supracondylar plate and dynamic compression screw supplemented with intramedullary methyl methacrylate and massive cancellous bone graft harvested from the distal femoral metaphysis. Interfragmentary compression and rigid fracture fixation was obtained in all cases with the use of the A-O compression device. Patients were allowed early protected weight bearing without external immobilization. At follow-up observation (average, 2.1 years), bony union was noted in all cases, and knee flexion averaged 100.4 degrees. There were no malunions or cases of implant failure. Complications included two early postoperative deaths and three femur fractures above the plate. This technique was effective in rapidly restoring patient mobility while avoiding the complications of implant failure.

Stubinger, S., et al. (2014). "Evaluation of local cancellous bone amelioration by poly-l-dl-lactide copolymers to improve primary stability of dental implants: a biomechanical study in sheep." Clin Oral Implants Res.

OBJECTIVES: The aim of this study was to evaluate the clinical performance of local cancellous bone amelioration by a 70:30 poly-(l-lactide-co-d,l-Lacide) copolymer with two different implant designs on primary stability and after 4 and 12 weeks of healing time. MATERIAL AND METHODS: In six sheep, n = 36 implants (TH) with a conditioned, sandblasted, thermal acid-etched micro-rough surface and n = 36 implants (NB) with a highly crystalline and phosphate-enriched anodized titanium oxide surface were placed in the pelvic bone. Using an ultrasound-based process named Constant Amelioration Process (CAP), half of peri-implant trabecular bone structures were locally tested with 70:30 poly-(l-lactide-co-d,l-Lacide) copolymer in both implant groups, TH and NB. The CAP technology employs ultrasonic energy to liquefy 70:30 poly-(l-lactide-co-d,l-Lacide) which enters the inter-trabecular space, leading to local reinforcement of the cancellous bone structure after solidification of the copolymer. The CAP test group was compared with reference implants placed with the conventional site preparation according to the manufacturers' description. Primary stability was assessed by the measurement of torque-in values and implant stability quotient (ISQ; n = 18 per group). Secondary stability was analyzed by biomechanical removal torque testing after 4 and 12 weeks (n = 9 per group). RESULTS: **Insertion torque value (23.3 N cm +/- 13.6) of reference TH implants demonstrated a statistically significant (P = 0.00) difference in comparison with test TH implants (41.9 N cm +/-**

19.5). Reference NB implants revealed a statistically significant (P = 0.03) lower insertion torque value (23.7 N cm +/- 13.5) than test NB implants (39.7 N cm +/- 18.6). ISQ values increased for all implants from initial implant placement until sacrifice at 12 weeks. Reference TH implants tended to result in an increase in torque values from 4 weeks (181.9 N cm +/- 22.8) to 12 weeks (225.7 N cm +/- 47.4). This trend could be also proven for implants of test sites (4 week: 176.8 N cm +/- 24.1; 12 week: 201.5 N cm +/- 53.4). For reference, NB implants a non-significant increase in removal torque values from 4 weeks (146. 7 N cm +/- 18.0) to 12 weeks (170.2 N cm +/- 40.4) was observed. Removal torque values of test NB implants did not increase from 4 weeks (153.3 N cm +/- 21.5) to 12 weeks (146.1 N cm +/- 37.5). CONCLUSION: Biomechanical data proved significantly enhanced primary stability of dental implants after local amelioration without long-term sequelae and irrespective of implant design. **After 4- and 12-week healing time, removal torque of locally test implants was as high as for control implants, and osseointegration was therefore not influenced by the CAP process**. No correlation between ISQ values and torque values was found.

Sudo, H., et al. (2010). "One-stage posterior instrumentation surgery for the treatment of osteoporotic vertebral collapse with neurological deficits." Eur Spine J **19**(6): 907-915.

The number of reports describing osteoporotic vertebral fracture has increased as the number of elderly people has grown. Anterior decompression and fusion alone for the treatment of vertebral collapse is not easy for patients with comorbid medical problems and severe bone fragility. The purpose of the present study was to evaluate the efficacy of one-stage posterior instrumentation surgery for the treatment of osteoporotic vertebral collapse with neurological deficits. A consecutive series of 21 patients who sustained osteoporotic vertebral collapse with neurological deficits were managed with posterior decompression and short-segmental pedicle screw instrumentation augmented with ultra-high molecular weight polyethylene (UHMWP) cables with or without vertebroplasty using calcium phosphate cement. The mean follow-up was 42 months. All patients showed neurologic recovery. Segmental kyphotic angle at the instrumented level was significantly improved from an average preoperative kyphosis of 22.8-14.7 at a final follow-up. Spinal canal occupation was significantly reduced from an average before surgery of 40.4-19.1% at the final follow-up. Two patients experienced loosening of pedicle screws and three patients developed subsequent vertebral compression fractures within adjacent segments. However, these patients were effectively treated in a conservative fashion without any additional surgery. Our results indicated that one-stage posterior instrumentation surgery augmented with UHMWP cables could provide significant neurological improvement in the treatment of osteoporotic vertebral collapse.

Sugimoto, Y., et al. (2009). "Posterior spinal fusion using a pedicle nail system with polymethylmethacrylate in a paraplegic patient after vertebral collapse caused by osteoporosis." Spine J **9**(1): e5-8.

BACKGROUND CONTEXT: Because posterior decompression and fusion for vertebral collapse in an osteoporotic spine sometimes results in a pullout of the pedicle screw. Several authors reported that fixation of pedicle screws in severely osteoporotic bone could be improved by inserting polymethylmethacrylate (PMMA) into the hole before inserting the screw. However, pedicle screws were not designed to be used with PMMA. PURPOSE: To report a patient with vertebral collapse who were treated using a novel-concept, pedicle nail using with PMMA. STUDY DESIGN: Case report. METHODS: The patient was a 74-year-old female who experienced back pain after some heavy lifting 3 months before. She was laid up for 2 months because of the back pain and weakness of her lower legs. Radiographs and magnetic resonance imaging showed vertebral collapse and neural severe compression from the posterior wall of vertebra T12. The pedicle nail consists of an outer sheath with evenly spaced holes and an internal, removable, threaded component. The outer sheath and the internal component were connected before insertion. The pedicle nail attaches to and is

bound by the PMMA through the holes of the outer sheath. We performed a T11-L1 posterior fusion and laminectomy using the pedicle nail, and we used a hydroxyapatite block to perform a transpedicular vertebroplasty of T12. RESULTS: Bone union was observed on a lateral radiograph without pedicle nail loosening. CONCLUSIONS: The authors speculate that posterior spinal fusion and vertebroplasty using the pedicle nail will be a reasonable choice for delayed paraplegia after osteoporotic vertebral fracture.

Sun, S. G., et al. (2011). "Application of locking plate in long-bone atrophic nonunion following external fixation." Orthopedics **34**(5): 358.

The treatment of atrophic fracture nonunion continues to represent a therapeutic challenge. Large segmental osteopenia is often seen in patients who received uniplanar or hybrid external fixators as the definitive method of fixation for high-energy fractures, and this adds more difficulties to the treatment of fracture nonunion. This retrospective study was designed to assess the outcome of locking compression plating with autologous bone grafting in patients with long-bone atrophic nonunion following external fixation.From January 2004 to December 2009, a series of consecutive patients with atrophic nonunion of the long bone following external fixation were treated with this method in our institution. The clinical outcomes and complications of these patients were retrospectively analyzed. Twenty-seven patients with 28 fracture nonunions were involved in this study. Mean follow-up was 14.2+/-3.4 months. Bony union was achieved in all 27 patients within a mean 18.6+/-4.8 weeks after revision surgery. Two patients developed superficial wound infections. No deep infections were found, and no implant failure was seen. Three patients reported minor pain in the donor site of the bone graft, and no other donor site complications were found.Revision osteosynthesis of long-bone atrophic nonunion following external fixation by locking compression plating with autologous iliac crest bone grafting represents a safe and efficacious modality for the treatment of these challenging conditions.

Suzuki, T., et al. (2013). "Posterior-approach vertebral replacement with rectangular parallelepiped cages (PAVREC) for the treatment of osteoporotic vertebral collapse with neurological deficits." J Spinal Disord Tech **26**(5): E170-176.

STUDY DESIGN: A retrospective clinical study. OBJECTIVE: To assess the efficacy of a new spinal reconstruction technique (posterior-approach vertebral replacement with rectangular parallelepiped cages: PAVREC) for the treatment of osteoporotic late vertebral collapse with neurological deficits. SUMMARY OF BACKGROUND DATA: Poor bone quality and medically complicated situations obfuscate precise treatment for paraplegia caused by osteoporotic vertebral collapse. Recently, posterior-approach corpectomy and replacement with a cylindrical cage have been proposed. However, postoperative cage subsidence and kyphosis progression frequently occurs. METHODS: Surgical invasiveness, perioperative complications, and clinical and radiographic outcomes in a total of 19 consecutive patients with osteoporosis (7 men and 12 women; mean age, 75 y) who underwent PAVREC with a mean follow-up period of 45.6 months (range, 16-79 mo) were reviewed. The affected vertebral levels ranged from T12-L4. The mean bone mineral density of the femoral neck was 0.611+/-0.077 g/cm(2) (mean+/-SD). RESULTS: Mean operative time was 261 minutes (range, 155-326 min). Mean blood loss was 664 mL (range, 197-1595 mL). There were no reported surgical complications. Neurological deficits evaluated with the Frankel grading score improved >1 grade after surgery in all patients. Mean preoperative visual analog scale scores for back or leg pain (7.2; range, 6-9) significantly improved after surgery (1.4; range, 0-2) ($P<0.05$). Local kyphosis improved from a mean of 24.6 degrees before surgery to a mean of 1.5 degrees after surgery ($P< 0.05$), and it was maintained at a mean of 2.5 degrees at the final follow-up. Although screw loosening, cage subsidence, and subsequent vertebral fracture were seen in several cases, no additional surgeries were needed. Solid bony fusion was confirmed in all cases. CONCLUSIONS: PAVREC provided a satisfactory clinical and radiologic outcome without severe complications. This procedure can be a

treatment option for osteoporotic vertebral collapse and an alternative to an anterior-approach or single posterior-approach reconstruction with a cylindrical cage.

Suzuki, T., et al. (2001). "Improving the pullout strength of pedicle screws by screw coupling." J Spinal Disord **14**(5): 399-403.

The objective of this study was to determine the effect of pedicle screw coupling on the pullout strength of pedicle screws in the osteoporotic spine. The vertebral bone mineral density (BMD) of 33 cadaveric lumbar vertebrae were measured by quantitative computed tomography. Pedicle screws were inserted into each pedicle. The pullout strength and displacement of the screws, without coupling and with single or double couplers, were studied, and the relationship between pullout strength and BMD was analyzed. The average pullout strength of the pedicle screws without screw coupling was 909.3 +/- 188.6 N (n = 9), that coupled with a single coupler was 1,409.0 +/- 469.1 N (n = 9), and that with double couplers was 1,494.0 +/- 691.6 N (n = 9). The pullout strength of the screws coupled with single or double couplers was significantly greater than that of screws without couplers ($p < 0.01$); however, there was no significant difference between the groups of single and double couplers. The improvement of pullout strength by screw coupling was significant in a test group with BMD of more than 90 mg/ml ($p < 0.01$), but was not in the group with BMD less than 90 mg/ml ($p = 0.55$). These results suggest that the coupling of pedicle screws improves pullout strength; however, the effect tends to be less significant in severely osteoporotic spines.

Szpalski, M., et al. (2004). "Prevention of hip lag screw cut-out by cement augmentation: description of a new technique and preliminary clinical results." J Orthop Trauma **18**(1): 34-40.

Cement augmentation of hip lag screws to avoid cut-out displacement is classically described, along with a number of technical drawbacks. In a series of six elderly patients with hip fractures in osteoporotic bone, we illustrate catheter-assisted delivery of limited amounts of a new bisphenol-a-glycidyl dimethacrylate (bis-GMA)-based composite into hip compression screw threads, enabling significant increase in insertional torque compared with unaugmented screws. In two patients, unaugmented screws that did not initially purchase were tightened with a minimum torque of 1 N-m after augmenting with bis-GMA-based composite. No screw or femoral head displacement relative to baseline (2 days postoperative) was seen in any patient on serial x-rays taken up to 6 months after surgery. This technique adds approximately 10 minutes to surgery time. Advantages of bis-GMA-based composite over traditional PMMA augmentation include mixing on-demand, the ability to make repeated injections over extended periods in the event of femoral head perforations (in one patient in this series), precise placement of adequately small volumes of material, and a lower exotherm. Potentially, this bis-GMA-based composite may reduce the frequency of cut-out complications by enhancing bone-implant interface.

Szpalski, M. and R. Gunzburg (2001). "Prevention of hip lag screw cut-out in osteoporotic patients: rationale and review of the literature." Bull Hosp Jt Dis **60**(2): 84-88.

Tan, J. S., et al. (2007). "Cement augmentation of vertebral screws enhances the interface strength between interbody device and vertebral body." Spine (Phila Pa 1976) **32**(3): 334-341.

STUDY DESIGN: An in vitro cadaveric study comparing cage-vertebra interface strengths for 3 different screw-cement configurations. OBJECTIVES: To determine the effects of cement augmentation of pedicle screws on cage-vertebra interface failure properties for 2 interbody device shapes (elliptical or cloverleaf); and to compare between pedicle and anterior vertebral body screws with cement augmentation. SUMMARY OF BACKGROUND DATA: Pedicle or anterior screw fixation is commonly used with interbody device fixation. Cement has recently been shown to augment screw fixation in the osteoporotic spine by improving the screw-bone interface strength. The effect of cement augmentation of pedicle or anterior screws on cage-vertebra interface properties has not been previously studied or

compared. METHODS: An elliptical or a cloverleaf-shaped indentor covering 40% of the endplate was axially compressed against the superior endplate of 48 thoracolumbar vertebrae. Each vertebra had polymethylmethacrylate cement augmentation of 1) anterior screws, 2) pedicle screws, or 3) pedicle screws without cement. Compressive load was applied through a mechanism that allowed unconstrained rotation of the indentors. RESULTS: Cement augmentation of pedicle screws resulted in significantly higher failure loads (54%) and failure strength (69%) for both shaped indentors when compared with uncemented pedicle screws. There was no significant difference in failure load and failure strength between pedicle and anterior screws with cement augmentation. Indentor shape was not a significant factor on failure load or failure strength. CONCLUSIONS: Cage-vertebra interface properties were improved when cement was used to augment vertebral and pedicle screws. Cement augmentation of pedicle or anterior screws may reduce interbody device subsidence.

Tan, S. L. and Z. J. Balogh (2009). "Indications and limitations of locked plating." Injury **40**(7): 683-691.

The goal of fracture fixation is to achieve bone healing and restore the function of the injured limb in the shortest possible time without compromising safety. Newer technologies such as the locking compression plate (LCP) and its derivatives are valuable additions to the orthopaedic traumatologist's armamentarium. As with any emerging technology, the indications will be extended until a threshold is reached and the limitations of the technology are seen. It is vital that surgeons involved in fracture care are aware of when locked plating is superior to other methods and also when they should use another treatment modality. This paper reviews the use of locked plating as a fixation method. Five topics covered in this review are: a historical perspective on locked plating, general indications, specific modes and techniques, patterns of failure, and an anatomical overview of current indications for locked plating.

Tang, X., et al. (2010). "Preliminary effect of proximal femoral nail antirotation on emergency treatment of senile patients with intertrochanteric fracture." Chin J Traumatol **13**(4): 212-216.

OBJECTIVE: To retrospectively analyse the clinical outcome of emergency treatment of senile intertrochanteric fractures with proximal femoral nail antirotation (PFNA). METHODS: From September 2008 to March 2009, 35 senile patients with intertrochanteric fracture, aged from 65 to 92 years with an average age of 76.5 years, were treated with PFNA within 24 hours after injury. There were 10 type I fractures, 19 type II and 6 type III according to upgraded Evans-Jensen classification system. All patients were complicated with osteoporosis, and 19 patients had preexisting internal medical diseases. According to the rating scale of disease severity by the American Society of Anesthesiologists (ASA), there were 9 grade I, 14 grade II, 8 grade III, and 4 grade IV. RESULTS: The duration for operation ranged from 45 to 73 minutes with an average of 57.6 minutes. The volume of blood loss during operation ranged from 50 to 120 ml with an average of 77.5 ml. Patients could ambulate 2-4 days after operation (mean 3.5 days). Hospital stay was 4-7 days (mean 5.3 days). Full weight bearing time was 10-14 weeks (mean 12.8 weeks). During hospitalization period, there was no regional or deep infection, hypostatic pneumonia, urinary tract infection and bedsore except for 2 cases of urine retention. All cases were followed up with an average period of 12.3 months, and bone healing achieved within 15-18 weeks (mean 16.6 weeks). No complications such as delayed union, coxa vara or coxa valga, screw breakage or backout occurred and only 2 cases had trochanter bursitis because of thin body and overlong end of the antirotated nail. According to the Harris grading scale, the results were defined as excellent in 21 cases, good in 9 cases and fair in 5 cases, with the excellent and good rates of 85.7%. CONCLUSION: The emergency treatment of senile intertrochanteric fracture with proximal femoral nail antirotation has the advantages of minimal invasion, easy manipulation, less blood loss, shorter length of stay, less complications, and the preliminary clinical effect is satisfactory.

Taniwaki, Y., et al. (2003). "Enhancement of pedicle screw stability using calcium phosphate cement in osteoporotic vertebrae: in vivo biomechanical study." J Orthop Sci **8**(3): 408-414.

We conducted an experimental study using female beagles with and without ovariectomy-induced osteoporosis to determine the effect of calcium phosphate cement (CPC) on the mechanical stability of inserted pedicle screws. A drill hole was created from the base of the transverse process to the vertebral body; CPC was injected into the hole, and then a screw was inserted into the same hole. In the presence of osteoporosis evidenced by dual X-ray absorptiometry, the stability of the inserted screw augmented by CPC against pull-out and cephalocaudal forces were significantly greater by 28% and 54% at 1 week after operation, 48% and 71% at 2 weeks, and 56% and 68% at 4 weeks compared with those without CPC. The pull-out strength increased progressively with time after surgery, probably reflecting new-bone growth from the surrounding cancellous bone, which was in direct contact with the CPC, as shown in the histologic study. At each time point the cephalocaudal rigidity was similar and the pull-out strength greater than that for the screws inserted without CPC in nonporotic dogs. These findings suggest that CPC augments the stability of the inserted pedicle screws and increases the stiffness of fixed osteoporotic motion segments using instrumentation.

Tankard, S. E., et al. (2013). "Does maximum torque mean optimal pullout strength of screws?" J Orthop Trauma **27**(4): 232-235.

OBJECTIVES: To determine the relationship between insertion torque and pullout strength of 3.5-mm-diameter cortical screws in cadaveric humeri with different bone mineral densities (BMDs). METHODS: Five pairs of human humeri from each of 3 BMD groups (normal, osteopenic, and osteoporotic) were used. Holes were drilled in each humerus, and maximum insertion torque (T(max)) was measured by tightening a screw until stripping occurred. In the remaining holes, screws were tightened to 50%, 70%, or 90% of the T(max). A servohydraulic testing machine pulled each screw out at 1 mm/s while resulting force and axial displacement were recorded at 10 Hz. The authors checked for an effect of insertion torque (percent T(max)) on pullout strength using a general linearized and latent mixed model (Stata10), controlling for cortical thickness and BMD (T-score). RESULTS: Pullout strength for normal and osteoporotic bone was greatest for screws inserted to 50% T(max) and was significantly greater than that at T(max) but not significantly different from that at 70% or 90% T(max). For osteopenic bone, pullout strength was greatest at 70% peak torque, but it was not significantly different from the pullout strength at the 50% or 90% T(max) levels. CONCLUSIONS: Tightening screws beyond 50% T(max) does not increase pullout strength of the screw and may place bone at risk for damage that might result in loss of fixation. Even after adjusting for bone thickness and density, there is no clear relationship between pullout strength and screw torque.

Tarantino, U., et al. (2007). "Surgical approach to fragility fractures: problems and perspectives." Aging Clin Exp Res **19**(4 Suppl): 12-21.

The frequency of osteoporosis is constantly increasing all over the world. This pathology generates several problems, mostly due to fragility fractures, the worst consequence of impaired bone quality. Osteoporotic fractures often cause disability and loss of independence, partly because fracture fixation is not always easy and durable. So orthopedic surgeons need to learn and use new techniques to improve bone healing and surgical outcome, in order to grant fragility fracture patients a good quality of life. There are nails, screws and plates designed to maximize the bone-implant interface, substances which can be used locally to stimulate bone formation, and systemic therapies which can be used as adjuvants to decrease bone loss and/or enhance bone formation. Here, we report our personal experience, describing our surgical patients and their response to a bone-forming agent, such as teriparatide.

Tejwani, N. C. and E. Guerado (2011). "Improving fixation of the osteoporotic fracture: the role of locked plating." J Orthop Trauma **25 Suppl 2**: S56-60.

The use of locking technology has expanded significantly over the last decade. This technology has led to improvements in implant design for fixation in osteoporotic bone and allowed more secure and stable constructs. Locking plates and screws have been helpful in surgical repair of metaphyseal fractures and those with significant comminution and in the elderly. Biomechanically, creating a fixed-angle design leads to stronger constructs and potentially decreases failure rates. The use of this technology must be tempered by awareness of the complications associated with both the technique and implants.

Tejwani, N. C., et al. (2005). "The effect of locked distal screws in retrograde nailing of osteoporotic distal femur fractures: a laboratory study using cadaver femurs." J Orthop Trauma **19**(6): 380-383.

OBJECTIVES: To examine the effects of locked distal screws in retrograde nails used in unstable osteopenic distal femur fractures. DESIGN: Biomechanical testing of paired human cadaveric femurs. INTERVENTION: Seven matched pairs of embalmed, moderately osteopenic cadaver femurs were instrumented with 12-mm intramedullary nails in a statically locked, retrograde fashion. One femur of each pair had locked distal screws and the other femur had unlocked distal screws. A 2.5-cm gap of bone was cut nine centimeters from the distal condyles to simulate an unstable fracture. The locked distal screw nails were compared to unlocked distal screw nails for collapse of the fracture gap, medial-lateral and anterior-posterior translation of the nail within the fracture site, and fracture angulation. The femurs were axially loaded, cycled, and then loaded to failure. MAIN OUTCOME MEASURES: Motion at the fracture site with axial cyclic loading and site of failure when loaded to failure. RESULTS: After cycling, both locked distal screw and unlocked distal screw nails demonstrated several millimeters medial and anterior translation within the fracture site and approximately 1 mm collapse of the fracture gap. Although no statistically significant differences were found, the locked distal screw nails had less anterior and medial translation, angulation, and collapse of the fracture gap after cycling. Loads to failure were similar for both locked distal screw and unlocked distal screw nails. It was noted that proximal femur failure occurred at the level of the proximal screw hole in the nail at the subtrochanteric level in 7 (4 locked distal screws and 3 unlocked distal screw groups) of the 14 samples. Four other samples failed through the intertrochanteric region (2 locked distal screw and 2 unlocked distal screw groups) and the remainder within the distal fragment by fracture of the femur along the medial cortex. CONCLUSIONS: Although most differences in fixation stability were not significant, the locked distal screw nails exhibited less fracture collapse and anterior and medial translation of the nail at the fracture site than the unlocked distal screw nails. The degree of varus angulation after cyclic loading was also less for the locked distal screw nails. The length of the nail chosen should avoid having proximal locking screws distal to the lesser trochanter, thus averting proximal femur stress risers and fractures.

Thiele, O. C., et al. (2007). "Factors affecting the stability of screws in human cortical osteoporotic bone: a cadaver study." J Bone Joint Surg Br **89**(5): 701-705.

We investigated several factors which affect the stability of cortical screws in osteoporotic bone using 18 femora from cadavers of women aged between 45 and 96 years (mean 76). We performed bone densitometry to measure the bone mineral density of the cortical and cancellous bone of the shaft and head of the femur, respectively. The thickness and overall bone mass of the cortical layer of the shaft of the femur were measured using a microCT scanner. The force required to pull-out a 3.5 mm titanium cortical bone screw was determined after standardised insertion into specimens of the cortex of the femoral shaft. A significant correlation was found between the pull-out strength and the overall bone mass of the cortical layer ($r(2) = 0.867$, $p < 0.01$) and also between its thickness ($r(2) = 0.826$, $p < 0.01$) and bone mineral density ($r(2) = 0.861$, $p < 0.01$). There was no statistically significant correlation between the age of the donor and the pull-out force ($p = 0.246$), the cortical

thickness (p = 0.199), the bone mineral density (p = 0.697) or the level of osteoporosis (p = 0.378). We conclude that the overall bone mass, the thickness and the bone mineral density of the cortical layer, are the main factors which affect the stability of a screw in human female osteoporotic cortical bone.

Tingart, M. J., et al. (2003). "Pullout strength of suture anchors used in rotator cuff repair." J Bone Joint Surg Am **85-a**(11): 2190-2198.

BACKGROUND: Surgical treatment of rotator cuff tears may be complicated by osteoporosis of the proximal part of the humerus. The purpose of this study was to determine whether pullout strength of suture anchors is affected by the location of the anchor placement and by bone mineral density. We hypothesized that higher bone mineral density is associated with higher pullout strength of suture anchors. METHODS: Peripheral quantitative computed tomography was used to measure total, trabecular, and cortical bone mineral density in different regions of the lesser and greater tuberosities in seventeen cadaveric humeri. Suture anchors were inserted into individual regions and subjected to cyclic loading. Repeated-measures analysis of variance was used to assess differences in bone mineral density and load to failure between regions of interest. Pearson correlation was used to determine the association between bone mineral density and pullout strength of suture anchors. RESULTS: Total, trabecular, and cortical bone mineral densities were an average of 50%, 50%, and 10% higher, respectively, in the proximal part of the tuberosities compared with the distal part ($p < 0.01$). Within the proximal part of the greater tuberosity, trabecular bone mineral density of the posterior region and cortical bone mineral density of the middle region were, on the average, 25% and 16% higher, respectively, than the densities in the other regions ($p < 0.01$). Load to failure in the proximal part of the tuberosities was an average of 53% higher than that in the distal part ($p < 0.01$). The lesser tuberosity showed, on the average, a 32% higher load to failure than did the greater tuberosity ($p < 0.01$). Within the proximal part of the greater tuberosity, loads to failure in the anterior and middle regions were, on the average, 62% higher than the load to failure in the posterior region ($p < 0.01$). Overall positive correlations were found between bone mineral density and load to failure ($0.65 </= r </= 0.74$, $p < 0.01$). CONCLUSIONS: We found that pullout strength of suture anchors correlates well with bone mineral density of the tuberosities. Higher loads to failure were found in regions in the proximal part of the tuberosities. Placement of anchors in these regions may prevent anchor loosening, formation of a tendon-bone gap, and failure of the rotator cuff repair.

Tingart, M. J., et al. (2006). "Proximal humeral fractures: regional differences in bone mineral density of the humeral head affect the fixation strength of cancellous screws." J Shoulder Elbow Surg **15**(5): 620-624.

The purpose of this study was to investigate the 3-dimensional trabecular bone mineral density (BMD) in the humeral head and determine the effects of trabecular BMD on the pullout strength of cancellous screws. Five regions of interest (ROIs) were defined in the humeral head (superior- anterior, superior-posterior, central, inferior-anterior, and inferior-posterior). The trabecular BMD of each ROI was determined by use of peripheral quantitative computed tomography. Cancellous screws were inserted in each ROI and cyclically loaded. The superior-anterior ROI had a lower trabecular BMD than all other ROIs ($P < .001$). The central ROI had a higher trabecular BMD than the inferior-anterior ROI ($P < .01$), whereas no differences were found between the inferior-posterior, superior-posterior, and central ROIs. Pullout strength was lower in the superior-anterior ROI compared with all other ROIs ($P < .01$). The trabecular BMD and pullout strength were significantly correlated ($P < .01$). Placement of screws in regions with a higher trabecular BMD may help to prevent implant loosening and may improve patient outcome.

Torres, J., et al. (2008). "Management of atrophic maxilla in severe osteoporosis treated with bisphosphonates: a case report." Oral Surg Oral Med Oral Pathol Oral Radiol Endod **106**(5): 668-672.

Studies investigating whether osteoporosis is a risk factor for using implants have revealed no correlation between possible implant failure and the severity of osteoporosis. However, osteoporotic patients frequently require bone regeneration techniques, because they do not fulfil optimum conditions for implant placement owing to the diminished bone structure and rapid resorption of the alveolar bone. We present a successful case of advanced implant therapy using platelet-rich plasma in a patient with severe osteoporosis who had been previously treated with bisphosphonates. We are not aware that this technique has been previously described in literature.

Tsai, K. J., et al. (2009). "Pedicle screw fixation strength: a biomechanical comparison between 4.5-mm and 5.5-mm diameter screws in osteoporotic upper thoracic vertebrae." J Surg Orthop Adv **18**(1): 23-27.

The purpose of this study was to evaluate the difference between 4.5-mm and 5.5-mm diameter pedicle screws inserted into the pedicles of upper thoracic vertebrae (T2 to T5). Seven fresh human spines were obtained. The bone mineral density was measured by dual-energy radiograph absorptiometry. The 4.5-mm and 5.5-mm diameter screws were inserted alternately in the right or left pedicle of each vertebra. The insertion torque and force (applied in the cephalic direction) to produce loosening of the screw were measured. The average bone mineral density for the seven thoracic spines was 0.710 g/cm(2). All of the vertebrae were classified as osteoporotic. The torque of insertion for the 5.5-mm diameter screws was significantly greater (59% greater on average) than that for the 4.5-mm diameter screws (p =. 001). Although the average force to loosening for the 5.5-mm diameter screws was higher than the average force to loosening for the 4.5-mm diameter screws (14%), the difference was not significant (p =. 33).

Unger, S., et al. (2012). "The effect of in situ augmentation on implant anchorage in proximal humeral head fractures." Injury **43**(10): 1759-1763.

INTRODUCTION: Fracture fixation in patients suffering from osteoporosis is difficult as sufficient implant anchorage is not always possible. One method to enhance implant anchorage is implant/screw augmentation with PMMA-cement. The present study investigated the feasibility of implant augmentation with PMMA-cement to enhance implant anchorage in the proximal humerus. MATERIALS AND METHODS: A simulated three part humeral head fracture was stabilised with an angular stable plating system in 12 pairs of humeri using six head screws. In the augmentation group the proximal four screws were treated with four cannulated screws, each augmented with 0.5ml of PMMA-cement, whereas the contra lateral side served as a non-augmented control. Specimens were loaded in varus-bending or axial-rotation using a cyclic loading protocol with increasing load magnitude until failure of the osteosynthesis occurred. RESULTS: Augmented specimens showed a significant higher number of load cycles until failure than non-augment specimens (varus-bending: 8516 (SD 951.6) vs. 5583 (SD 2273.6), P=0.014; axial-rotation: 3316 (SD 348.8) vs. 2050 (SD 656.5), P=0.003). Non-augmented specimens showed a positive correlation of load cycles until failure and measured bone mineral density (varus-bending: r=0.893, P=0.016; axial-rotation: r=0.753, P=0.084), whereas no correlation was present in augmented specimens (varus-bending: r=0,258, P=0.621; axial-rotation r=0.127, P=0.810). CONCLUSION: These findings suggest that augmentation of cannulated screws is a feasible method to enhance implant/screw anchorage in the humeral head. The improvement of screw purchase is increasing with decreasing bone mineral density.

Uruc, V., et al. (2014). "A new anchor augmentation technique with a cancellous screw in osteoporotic rotator cuff repair: an in vitro biomechanical study on sheep humerus specimens." Arthroscopy **30**(1): 16-21.

PURPOSE: The aim of this study was to test a simple technique to augment the pullout resistance of an anchor in an over-drilled sheep humerus model. METHODS: Sixty-four paired sheep humeri were harvested from 32 male sheep aged 18 months. Specimens were divided into an augmented group and non-augmented group. FASTIN RC 5-mm titanium screw anchors (DePuy Mitek, Raynham, MA) double loaded with suture material (braided polyester, nonabsorbable USP No. 2) were used in both groups. Osteoporosis was simulated by over-drilling with a 4.5-mm drill. Augmentation was performed by fixing 1 of the sutures 1.5 cm inferior to the anchor insertion site with a washer screw. This was followed by a pull-to-failure test at 50 mm/min. The ultimate load (the highest value of strength before anchor pullout) was recorded. A paired t test was used to compare the biomechanical properties of the augmented and non-augmented groups. RESULTS: In all specimens the failure mode was pullout of the anchor. The ultimate failure loads were statistically significantly higher in the augmented group (P < .0001). The mean pullout strength was 121.1 +/- 10.17 N in the non-augmented group and 176.1 +/- 10.34 N in the augmented group. CONCLUSIONS: The described augmentation technique, which is achieved by inferior-lateral fixation of 1 of the sutures of the double-loaded anchor to a fully threaded 6.5-mm cancellous screw with a washer, significantly increases the ultimate failure loads in the over-drilled sheep humerus model. CLINICAL RELEVANCE: Our technique is simple, safe, and inexpensive. It can be easily used in all osteoporotic patients and will contribute to the reduction of anchor failure. This technique might be difficult to apply arthroscopically. Cannulated smaller screws would probably be more practical for arthroscopic use. Further clinical studies are needed.

Van Brussel, K., et al. (1996). "Internal fixation of the spine in traumatic and scoliotic cases. The potential of pedicle screws." Technol Health Care **4**(4): 365-384.

Internal fixation techniques are in common used to stabilize vertebral fractures and correct severe scoliosis. Consolidation of injured vertebrae with neighbouring intact vertebra is the goal in the former case whilst fusion of the vertebrae in a corrected position is aimed at in the latter case. Degenerative spine diseases are not considered in this paper. Classical instrumentation consists of rods (e.g., Cotrel-Dubousset, Harrington, Luque-Galveston) attached to the bone by means of hooks or wires. More recently, transpedicular screws are introduced as an alternative bone/implant interface. Comparing the results of several studies, the posterior pedicle screw based devices demonstrate the ability to produce the most rigid constructs. However, the insertion of pedicle screws implicates a relatively high complication risk and its success strongly depends on the experience of the surgeon. Incorrect drilled holes or malplacement of the screws can result in nerve root injuries and fracture of the pedicle. Studies reported complication ratios up to 30% with substantial neurological implications. A certain degree of automation of the critical actions may be necessary to enhance the safety of pedicle screw insertion. Two techniques of computer assisted spine surgery are compared. Both techniques permit a computer assisted surgical planning based on CT images. During operation the first system permanently observes the position of the drill relative to the spine and informs the surgeon on the deviation of the actual drill path to the planned drill path. The second system uses a pre-operative surgical planning to design and construct a mechanical drill guide, fitting perfectly on the patient's spine.

Van Houwelingen, A. P. and M. D. McKee (2005). "Treatment of osteopenic humeral shaft nonunion with compression plating, humeral cortical allograft struts, and bone grafting." J Orthop Trauma **19**(1): 36-42.

Surgical stabilization of humeral shaft nonunions can be difficult to achieve if severe osteopenia or loss of bone stock is present. We present a technique whereby a 4.5-mm standard dynamic compression plate is used in conjunction with a humeral cortical allograft strut and bone grafting to stabilize humeral shaft nonunions complicated by severe bone loss. Six patients with established nonunion of the humeral shaft underwent this technique.

Union was achieved at an average of 3.4 months (range 2-6 months). Our method using onlay allograft struts can provide an effective alternative in the management of humeral shaft nonunion complicated by severe osteopenia of various etiologies.

van Steenberghe, D., et al. (2002). "The relative impact of local and endogenous patient-related factors on implant failure up to the abutment stage." Clin Oral Implants Res **13**(6): 617-622.
The aim of the present study was to assess the influence of endogenous and local factors on the occurrence of implant failure up to the abutment stage. The study comprised a group of 399 consecutive patients, which represented the total of patients who had been treated from 1995 to 1997 (with a total of 1263 Branemark Bran-system implants) at the Department of Periodontology of the University Hospital, Catholic University Leuven. For each patient, the medical history was carefully examined. Data collection and analysis were mainly focused on endogenous factors such as hypertension, osteoporosis, hypo- or hyperthyroid function, chemotherapy, diabetes type I or II, Crohn's disease, some local factors (e.g. bone quality, reason for tooth loss) and breach of sterility during surgery. The reason for tooth loss, smoking habits, radiotherapy and other local bone factors (bone quality and quantity) were also recorded. Implant failures were recorded up to the abutment connection. The present study indicated a success rate until this stage of 97.8%. General factors such as heavy smoking, chemotherapy plus poor bone quality increased implant failure rate. Radiotherapy, limited bone volume and claustrophobia, which led to breaching the strict preoperative rules of asepsis, appeared to be the most relevant local factors for early implant failures.

Vishnubhotla, S., et al. (2011). "A titanium expandable pedicle screw improves initial pullout strength as compared with standard pedicle screws." Spine J **11**(8): 777-781.
BACKGROUND CONTEXT: Pedicle screws are now standard for spinal arthrodesis as they provide three-column spinal stabilization. Decreased vertebral body bone density because of aging reduces the stability of the bone-screw interface, potentially increasing screw pullout or pseudarthrosis. Modifications to standard pedicle screw designs to improve screw stabilization may help to compensate for the detrimental effects of decreased vertebral bone density. PURPOSE: To evaluate differences in initial pullout strength of an expandable titanium pedicle screw as compared with a standard titanium pedicle screw. STUDY DESIGN: In vitro human cadaveric biomechanical investigation. METHODS: Fresh thoracolumbar spines from four human cadavers were imaged using quantitative computed tomography to obtain standard lumbar osteoporosis (Dual-energy X-ray absorptiometry [DXA]) T scores. Six bodies were sectioned per spine, and standard titanium 6.5-mm diameter pedicle screws and expandable 6.5-mm diameter titanium screws (maximum expanded diameter=10 mm) were randomized to right and left sides. Screw testing, in axial pullout at 25 mm/min, was randomized to reduce the effects of testing order. Data for stiffness (N/mm), yield load (N), ultimate load (N), and energy (N mm) (area under the load-displacement curve) were analyzed using a one-way analysis of variance ($p<.05$). RESULTS: Lumbar DXA scores averaged -3.6. There were no statistical differences between screw types for stiffness. Yield load was not statistically different between groups, although the expandable screw yield load was nearly 25% greater than that of the standard screw. Ultimate load was found to be statistically greater (approximately 30%) for the expandable screw compared with the standard screw ($p<.05$). The energy required to cause bone-implant failure was also statistically greater for the expandable screw compared with the standard screw ($p<.0001$). CONCLUSIONS: Expandable titanium pedicle screws demonstrated improved screw pullout stability compared with standard titanium screws in osteopenic or osteoporotic bone. Further studies are warranted examining other loading methods to evaluate the stability provided by an expandable pedicle screw.

von der Linden, P., et al. (2006). "Biomechanical evaluation of a new augmentation method for enhanced screw fixation in osteoporotic proximal femoral fractures." J Orthop Res **24**(12): 2230-2237.

A biomechanical investigation on eight pairs of human cadaver proximal femurs was performed to evaluate the impact of a new augmentation method on the internal fixation of osteoporotic proximal femur fractures. The study focused on enhancing implant purchase to reduce the incidence of implant cut-out in osteoporotic bone. In a left-right comparison, a conventional hip screw fixation (control) was compared to the new cement augmentation method. After bone bed preparation through high pressure irrigation to remove fat, blood, and bone debris, the bones were augmented with low viscosity polymethylmethacrylate (PMMA) cement. Step-wise fatigue testing was performed by cyclically loading the femoral heads in a physiological manner, beginning at 1,500 N and increasing 500 N every 5,000 cycles to 4,000 N, and continuously monitoring head displacement. Failure was defined as >5.0 mm head displacement. The head displacement at 2,000 N was significantly smaller (p=0.018) for the augmented group as compared to the conventionally treated bones (0.09+/-0.01 mm vs. 0.90+/-0.32 mm; mean+/-SEM). The displacement rate at the second load step was significantly higher (p=0.018) for the conventionally treated bones as compared to the augmented ones. All of the nonaugmented specimens failed during testing, where 50% of the augmented specimens did not fail. The promising results of these experiments suggest that this new standardized irrigation/augmentation method enhances the implant anchorage and offers a potential solution to the problem of implant cut-out in osteoporotic metaphyseal bone.

Wahnert, D., et al. (2010). "Does cancellous bone compaction due to insertion of a blade implant influence the cut-out resistance? A biomechanical study." Clin Biomech (Bristol, Avon) **25**(10): 1053-1057.

BACKGROUND: For the treatment of hip fractures helically shaped implants, like the Dynamic Hip Screw (DHS) Blade, are often used. One consequence of blade implantation, the compaction of cancellous bone, is still believed to increase cut-out resistance. This in vitro study investigates implant anchorage of Dynamic Hip Screw Blades in femoral heads due to insertion with or without predrilling under cyclic physiological loading conditions. METHODS: Six pairs of fresh frozen (-20 degrees C) human cadaveric proximal femora were instrumented with DHS Blades. Bone pairs were randomly assigned to two study groups: 1) predrilled; 2) non-predrilled. Prior instrumentation, bone mineral density was determined in the center of the femoral head by Xtreme-CT measurement. After instrumentation biomechanical testing was performed under cyclic loading. The bone-implant interface was monitored by means of fluoroscopic imaging throughout the experiment. Paired t-tests were performed to identify differences regarding bone mineral density, stiffness and cycles to failure. FINDINGS: No significant differences were found between study groups with regard to axial stiffness (P=0.626) and number of cycles to failure (P=0.961). INTERPRETATION: This in vitro study did not show differences in biomechanical stability of proximal femora instrumented with a helical blade implant with or without predrilling. Clinically, the findings suggest that predrilling may be performed to ease the surgical procedure without compromising the implant anchorage.

Wahnert, D., et al. (2011). "Distal femur fractures of the elderly--different treatment options in a biomechanical comparison." Injury **42**(7): 655-659.

BACKGROUND: Fractures of the distal femur, especially in the elderly patient, are an unsolved problem in orthopaedic and trauma surgery. Poor bone stock quality caused by osteoporosis often results in bad implant anchorage in the distal part with a high risk of secondary failures such as cutout. This study investigates the biomechanical characteristics of four implants with different distal locking options under quasi-static torsional and cyclic axial loading. Therefore, an osteoporotic bone model simulating severe osteoporotic conditions was used. METHODS: Four different implants (T2 intramedullary nail, supracondylar nail (SCN), distal femoral nail (DFN) and the AxSOS angular stable plate) with different distal locking options were instrumented using an osteoporotic bone model. Five specimens per implant and per loading type (torsional and axial) were used. Mechanical

testing was performed under physiologic loading conditions. First, a torsional test was performed in internal and external rotation (10 Nm), with a new specimen; a stepwise cyclic axial loading was conducted until failure of the construct. FINDINGS: For torsional loading, the lowest range of motion (ROM) and neutral zone (NZ) was found for the AxSOS plate construct. The SCN and T2 constructs showed similar results, and the highest ROM and NZ were found for the constructs treated with the DFN. Axial stiffness was highest for SCN constructs and in the same range for DFN and T2. The lowest stiffness showed in the AxSOS plate constructs with 47% of SCN stiffness. Under cyclic axial loading, the SCN constructs showed the highest number of cycles to failure, followed by AxSOS (70%), DFN (69%) and T2 (48%). INTERPRETATION: In conclusion of this biomechanical study, we can clinically suggest that, if, in general, torsional stability is required (e.g., for bedridden patients) the AxSOS plate will be sufficient. By contrast, the findings of this study support the fact that the SCN should be considered for mobile patients where early postoperative mobilisation for rehabilitation is desired.

Wahnert, D., et al. (2010). "Internal fixation of type-C distal femoral fractures in osteoporotic bone." J Bone Joint Surg Am **92**(6): 1442-1452.

BACKGROUND: Fixation of distal femoral fractures remains a challenge, especially in osteoporotic bone. This study was performed to investigate the biomechanical stability of four different fixation devices for the treatment of comminuted distal femoral fractures in osteoporotic bone. METHODS: Four fixation devices were investigated biomechanically under torsional and axial loading. Three intramedullary nails, differing in the mechanism of distal locking (with two lateral-to-medial screws in one construct, one screw and one spiral blade in another construct, and four screws [two oblique and two lateral-to-medial with medial nuts] in the third), and one angular stable plate were used. All constructs were tested in an osteoporotic synthetic bone model of an AO/ASIF type 33-C2 fracture. Two nail constructs (the one-screw and spiral blade construct and the four-screw construct) were also compared under axial loading in eight pairs of fresh-frozen human cadaveric femora. RESULTS: The angular stable plate constructs had significantly higher torsional stiffness than the other constructs; the intramedullary nail with four-screw distal locking achieved nearly comparable results. Furthermore, the four-screw distal locking construct had the greatest torsional strength. Axial stiffness was also the highest for the four-screw distal locking device; the lowest values were achieved with the angular stable plate. The ranking of the constructs for axial cycles to failure was the four-screw locking construct, with the highest number of cycles, followed by the angular stable plate, the spiral blade construct, and two-screw fixation. The findings in the human cadaveric bone were comparable with those in the synthetic bone model. Failure modes under cyclic axial load were comparable for the synthetic and human bone models. CONCLUSIONS: The findings of this study support the concept that, for intramedullary nails, the kind of distal interlocking pattern affects the stabilization of distal femoral fractures. Four-screw distal locking provides the highest axial stability and nearly comparable torsional stability to that of the angular stable plate; the four-screw distal interlocking construct was found to have the best combined (torsional and axial) biomechanical stability.

Wahnert, D., et al. (2013). "Feasibility study on the potential of a spiral blade in osteoporotic distal femur fracture fixation." Arch Orthop Trauma Surg **133**(12): 1675-1679.

INTRODUCTION: Osteoporotic fractures of the distal femur (primary as well as periprosthetic) are a growing problem in today's trauma and orthopaedic surgery. Therefore, this feasibility study should identify the biomechanical potential of a (commercially available) spiral blade in the distal femur as compared to a single screw without any additional plate fixation. Additionally, the influence of cement augmentation was investigated. MATERIALS AND METHODS: An artificial low density bone model was either instrumented with a perforated spiral blade or a 5 mm locking screw only. Additionally, the influence of 1 ml cement augmentation was investigated. All specimens were tested with static pull-out and

cyclic loading (50 to 250 N with an increment of 0.1 N/cycle). RESULTS: In the non-augmented groups, the mean pull-out force was significantly higher for the blade fixation ($p < 0.001$). In the augmented groups, the difference was statistically not significant ($p = 0.217$). Augmentation could increase pull-out force significantly by 72 % for the blade and 156 % for the screw, respectively ($p = 0.001$). The mean number of cycles to failure in the non-augmented groups was 12,433 (SD 465) for the blade and 2,949 (SD 215) for the screw, respectively ($p < 0.001$). In the augmented group, the blade reached 13,967 (SD 1,407) cycles until failure and the screw reached 4,413 (SD 1,598), respectively ($p < 0.001$). CONCLUSION: The investigated spiral blade was mechanically superior, significantly, as compared to a screw in the distal femur. These results back up the further development of a distal femoral blade with spiral blade fixation for the treatment of osteoporotic distal femur fractures.

Wahnert, D., et al. (2013). "Cement augmentation of lag screws: an investigation on biomechanical advantages." Arch Orthop Trauma Surg **133**(3): 373-379.

BACKGROUND: In trauma surgery, lag screws are commonly used. However, in osteoporotic bone, anchorage can be considerably compromised. This study investigates the biomechanical potential of cement augmentation in terms of improved fixation. METHODS: 36 Surrogate osteoporotic bone specimens were utilised in three biomechanical experiments, each comparing 6 augmented with 6 non-augmented samples. Standard partially-threaded lag screws (Synthes) were placed following surgical standard. For the augmented groups, 0.4 ml of polymethylmethacrylate was injected into the pre-drilled hole prior to screw placement. Interfragmentary compression was determined using a cannulated ring compression sensor. Maximum torque was recorded with a torque wrench. Compressive relaxation after 24 h, relaxation after loosening and re-tightening the screw as well as maximum compression and torque at failure were measured. FINDINGS: Mean relaxation was significantly lower for the augmented group ($p < 0.01$). After 24 h, a remaining fragmental compression of 62 % for the augmented and 52 % for the non-augmented specimens was found. Loosening and re-tightening of the screw did not affect the compressive relaxation when augmentation was applied ($p = 0.529$), compared to an increased relaxation after re-tightening in the non-augmented group ($p = 0.04$). The mean maximum compression and torque until failure were significantly higher for the augmented group ($p < 0.001$). INTERPRETATION: Cement augmentation of lag screws can improve fixation stability in terms of installing and maintaining interfragmentary compression. Effects of relaxation can be reduced and re-tightening of screws is possible without compromising the fixation. Particularly in reduced bone mass, augmentation of lag screws can markedly increase the security of the technique.

Wahnert, D., et al. (2013). "A laboratory investigation to assess the influence of cement augmentation of screw and plate fixation in a simulation of distal femoral fracture of osteoporotic and non-osteoporotic bone." Bone Joint J **95-b**(10): 1406-1409.

The augmentation of fixation with bone cement is increasingly being used in the treatment of severe osteoporotic fractures. We investigated the influence of bone quality on the mechanics of augmentation of plate fixation in a distal femoral fracture model (AO 33 A3 type). Eight osteoporotic and eight non-osteoporotic femoral models were randomly assigned to either an augmented or a non-augmented group. Fixation was performed using a locking compression plate. In the augmented group additionally 1 ml of bone cement was injected into the screw hole before insertion of the screw. Biomechanical testing was performed in axial sinusoidal loading. Augmentation significantly reduced the cut-out distance in the osteoporotic models by about 67% (non-augmented mean 0.30 mm (sd 0.08) vs augmented 0.13 mm (sd 0.06); $p = 0.017$). There was no statistical reduction in this distance following augmentation in the non-osteoporotic models (non-augmented mean 0.15 mm (sd 0.02) vs augmented 0.15 mm (sd 0.07); $p = 0.915$). In the osteoporotic models, augmentation significantly increased stability ($p = 0.017$).

Wahnert, D., et al. (2013). "The potential of implant augmentation in the treatment of osteoporotic distal femur fractures: a biomechanical study." Injury **44**(6): 808-812.

PURPOSE: Osteoporotic fractures of the distal femur are an underestimated and increasing problem in trauma and orthopaedic surgery. Therefore, this study investigates the biomechanical potential of implant augmentation in the treatment of these fractures. METHODS: Twelve osteoporotic surrogate distal femora were randomly assigned to the augmented or non-augmented group. All specimens were fixed using the LCP DF. In the augmented group additionally 1ml Vertecem V+ was injected in each screw hole before screw positioning. The construct represents an AO 33 A3 fracture. Biomechanical testing was performed as sinusoidal axial loading between 50 and 500N with 2Hz for 45,000 cycles, followed by loading between 50 and 750N until failure. RESULTS: The augmented group showed significant higher axial stiffness (36%). Additionally the displacement after 45,000 cycles was 3.4 times lower for the augmented group (0.68+/-0.2mm vs. 2.28+/-0.2mm). Failure occurred after 45,130 cycles (SD 99) in all of the non-augmented specimens and in two specimens of the augmented group after 69,675 cycles (SD 1729). Four of the augmented specimens showed no failure. The failure mode of all specimens in both groups was a medial cut-out. CONCLUSIONS: This study shows a promising potential of implant augmentation in the treatment of osteoporotic distal femur fractures.

Wall, L. B., et al. (2012). "The effects of screw length on stability of simulated osteoporotic distal radius fractures fixed with volar locking plates." J Hand Surg Am **37**(3): 446-453.

PURPOSE: Volar plating for distal radius fractures has caused extensor tendon ruptures resulting from dorsal screw prominence. This study was designed to determine the biomechanical impact of placing unicortical distal locking screws and pegs in an extra-articular fracture model. METHODS: We applied volar-locking distal radius plates to 30 osteoporotic distal radius models. We divided radiuses into 5 groups based on distal locking fixation: bicortical locked screws, 3 lengths of unicortical locked screws (abutting the dorsal cortex [full length], 75% length, and 50% length to dorsal cortex), and unicortical locked pegs. Distal radius osteotomy simulated a dorsally comminuted, extra-articular fracture. We determined each construct's stiffness under physiologic loads (axial compression, dorsal bending, and volar bending) before and after 1,000 cycles of axial conditioning and before axial loading to failure (2 mm of displacement) and subsequent catastrophic failure. RESULTS: Cyclic conditioning did not alter the constructs' stiffness. Stiffness to volar bending and dorsal bending forces were similar between groups. Final stiffness under axial load was statistically equivalent for all groups: bicortical screws (230 N/mm), full-length unicortical screws (227 N/mm), 75% length unicortical screws (226 N/mm), 50% length unicortical screws (187 N/mm), and unicortical pegs (226 N/mm). Force at 2-mm displacement was significantly less for 50% length unicortical screws (311 N) compared with bicortical screws (460 N), full-length unicortical screws (464 N), 75% length unicortical screws (400 N), and unicortical pegs (356 N). Force to catastrophic fracture was statistically equivalent between groups, but mean values for pegs (749 N) and 50% length unicortical (702 N) screws were 16% to 21% less than means for bicortical (892 N), full-length unicortical (860 N), and 75% length (894 N) unicortical constructs. CONCLUSIONS: Locked unicortical distal screws of at least 75% length produce construct stiffness similar to bicortical fixation. Unicortical distal fixation for extra-articular distal radius fractures should be entertained to avoid extensor tendon injury because this technique does not appear to compromise initial fixation. CLINICAL RELEVANCE: Using unicortical fixation during volar distal radius plating may protect extensor tendons without compromising fixation.

Wall, S. J., et al. (2010). "Mechanical evaluation of a 4-mm cancellous "rescue" screw in osteoporotic cortical bone: a cadaveric study." J Orthop Trauma **24**(6): 379-382.

OBJECTIVES: Obtaining sufficient fracture fixation in osteoporotic bone is challenging. The purposes of the current study were (1) to compare the pullout strength of a 4-mm cancellous

screw (cancellous screw group) with that of a 3.5-mm cortical screw (cortical screw group), and (2) to measure the pullout strength of a 4-mm cancellous screw placed as a rescue screw (rescue screw group) in a stripped 3.5-mm cortical screw (stripped screw group) hole while controlling for bone density and cortical thickness. METHODS: We inserted 4 screws, one from each experimental group, into 11 osteoporotic cadaveric radii, while recording the insertion torque. Radii were mounted on a servohydraulic testing machine, and each screw was pulled out at a rate of 5 mm/min. Pullout strength was recorded. The effects of cortical thickness (near, far, and total), bone density, insertion torque, and the experimental screw group (cortical, cancellous, stripped, and rescue screw groups) on pullout strength were analyzed using multiple linear regression with random effects. Statistical significance was set at $P < 0.05$. RESULTS: There was no significant difference in pullout strength between the cortical and cancellous screw groups. The rescue screw group had significantly less pullout strength than did the cortical and cancellous screws, and only partly increased pullout strength compared with stripped screws. Bone density significantly affected pullout strength, but insertion torque and cortical thickness were not significant covariates. CONCLUSIONS: There seems to be no advantage in using a cancellous screw over a cortical screw in bicortical fixation in osteoporotic bone. Although the rescue screw provided greater pullout strength than the stripped screw, it is unknown if the purchase it provides is clinically sufficient.

Wan, S., et al. (2010). "Biomechanical and histological evaluation of an expandable pedicle screw in osteoporotic spine in sheep." Eur Spine J **19**(12): 2122-2129.

Transpedicular fixation can be challenging in the osteoporotic spine as reduced bone mineral density compromises the mechanical stability of the pedicle screw. Here, we sought to investigate the biomechanical and histological properties of stabilization of expandable pedicle screw (EPS) in the osteoporotic spine in sheep. EPSs and standard pedicle screws, SINO screws, were inserted on the vertebral bodies in four female ovariectomized sheep. Pull-out and cyclic bending resistance test were performed to compare the holding strength of these pedicle screws. High-resolution micro-computed tomography (CT) was performed for three-dimensional image reconstruction. We found that the EPSs provided a 59.6% increase in the pull-out strength over the SINO screws. Moreover, the EPSs withstood a greater number of cycles or load with less displacement before loosening. Micro-CT image reconstruction showed that the tissue mineral density, bone volume fraction, bone surface/bone volume ratio, trabecular thickness, and trabecular separation were significantly better in the expandable portion of the EPSs than those in the anterior portion of the SINO screws ($P < 0.05$). Furthermore, the trabecular architecture in the screw-bone interface was denser in the expandable portion of the EPS than that in the anterior portion of the SINO screw. Histologically, newly formed bone tissues grew into the center of EPS and were in close contact with the EPS. Our results show that the EPS demonstrates improved biomechanical and histological properties over the standard screw in the osteoporotic spine. The EPS may be of value in treating patients with osteoporosis and warrants further clinical studies.

Wang, J. P., et al. (2010). "Minimally invasive technique versus conventional technique of dynamic hip screws for intertrochanteric femoral fractures." Arch Orthop Trauma Surg **130**(5): 613-620.

INTRODUCTION: Intertrochanteric fractures of femur are common in elderly patients. The compression hip screw has become the predominant method for osteosynthesis of intertrochanteric fractures. However, the conventional dynamic hip screws (CDHS) technique has some disadvantages. Recently, we have used a minimally invasive dynamic hip screws (MIDHS) technique to reduce these disadvantages. This prospective study is to compare curative effect of MIDHS with that of CDHS with open reduction on Evans type 1 intertrochanteric fractures. MATERIALS AND METHODS: All 97 fractures were classified according to the Evans systems. The MIDHS group included 47 patients with an average age of 68.7 years, and the CDHS group included 50 patients with an average age of 68.7

years. The Singh index was used as a measure of osteoporosis. RESULTS: Both groups were similar in injury mechanism, fracture types, mean Singh index and medical diseases (all P > 0.50). All fractures were healed within 4 months in both groups except three cases who were implant failure and nonunion in the CDHS group. The MIDHS group had significantly smaller wound size, shorter surgery time, less blood loss, lower blood transfusion rate, earlier active mobilization of fractured hip joint, shorter hospital stay, lower serious complication rate and higher Harris hip score than the CDHS group (all P < 0.05). The satisfactory reduction, adequate screw position, healing time and union rate was not significantly difference between two groups (all P > 0.05). CONCLUSION: When the fractures are treated adequately, either the MIDHS or the CDHS with open reduction is an effective and safe method, but the MIDHS is superior to the CDHS with open reduction for the treatment of Evans type 1 intertrochanteric fractures of femur.

Wang, M. Y. and P. V. Mummaneni (2010). "Minimally invasive surgery for thoracolumbar spinal deformity: initial clinical experience with clinical and radiographic outcomes." Neurosurg Focus **28**(3): E9.

OBJECT: Adult degenerative scoliosis can be a cause of intractable pain, decreased mobility, and reduced quality of life. Surgical correction of this problem frequently leads to substantial clinical improvement, but advanced age, medical comorbidities, osteoporosis, and the rigidity of the spine result in high surgical complication rates. Minimally invasive surgery is being applied to this patient population in an effort to reduce the high complication rates associated with adult deformity surgery. METHODS: A retrospective study of 23 patients was undertaken to assess the clinical and radiographic results with minimally invasive surgery for adult thoracolumbar deformity surgery. All patients underwent a lateral interbody fusion followed by posterior percutaneous screw fixation and possible minimally invasive surgical transforaminal lumbar interbody fusion if fusion near the lumbosacral junction was necessary. A mean of 3.7 intersegmental levels were treated (range 2-7 levels). The mean follow-up was 13.4 months. RESULTS: The mean preoperative Cobb angle was 31.4 degrees , and it was corrected to 11.5 degrees at follow-up. The mean blood loss was 477 ml, and the operative time was 401 minutes. The mean visual analog scale score improvement for axial pain was 3.96. Clear evidence of fusion was seen on radiographs at 84 of 86 treated levels, with no interbody pseudarthroses. Complications included 2 returns to the operating room, one for CSF leakage and the other for hardware pullout. There were no wound infections, pneumonia, deep venous thrombosis, or new neurological deficits. However, of all patients, 30.4% experienced new thigh numbness, dysesthesias, pain, or weakness, and in one patient these new symptoms were persistent. CONCLUSIONS: The minimally invasive surgical treatment of adult deformities is a promising method for reducing surgical morbidity. Numerous challenges exist, as the surgical technique does not yet allow for all correction maneuvers used in open surgery. However, as the techniques are advanced, the applicability of minimally invasive surgery for this population will likely be expanded and will afford the opportunity for reduced complications.

Waschke, A., et al. (2013). "Anterior cervical intercorporal fusion in patients with osteoporotic or tumorous fractures using a cement augmented cervical plate system: first results of a prospective single-center study." J Spinal Disord Tech **26**(3): E112-117.

STUDY DESIGN: Prospective observational clinical study. OBJECTIVE: The aim of this study is to evaluate the technical feasibility and the safety of additional cement augmentation of anterior cervical implants in patients with poor bone quality because of osteoporosis or tumor infiltration. SUMMARY OF BACKGROUND DATA: With an increasing number of elderly patients in spinal surgery the problem of implant dislocation after cervical instrumentation will become a more and more important problem. Whereas in the thoracolumbar area cement augmented screws have become widely accepted to ensure a rigid fixation in patients with reduced bone quality there are no data concerning an additional intravertebral cement augmentation after cervical plating. METHODS: Nine patients (4

males, 5 females, mean age 62.8 y) with newly diagnosed fractures of 1 or 2 cervical vertebrae because of tumor infiltration (6 cases) or osteoporosis (3 cases) were included in our study. A standard 1-level or 2-level cervical corpectomy with vertebral body replacement by an in situ expandable titanium cage and additional anterior plating was carried out. After this, additional cement augmentation was performed as a vertebroplasty of the anterior two thirds of the cranial and caudal adjacent vertebra by a new anterior hole. The cement should enclose the screws and stabilize the endplates of the adjacent vertebrae. Follow-up comprised clinical examinations, SF-36 questionnaire and visual analog scale 3, 6, and 12 months after surgery. Cervical spine radiographs were obtained 3 and 6 months after surgery and computed tomography scans 6 and 12 months after surgery. RESULTS: The median follow-up was 10 months with a range of 4-18 months. There was no intraoperative cement leakage into the spinal canal. The visual analog scale decreased from 8.2 to 4.2 at 6 months, physical and mental component summaries of SF-36 increased significantly from 27.7 to 36.1 and 31.5 to 48.6 at 6 months, respectively. Loosening of screws or plates was not detected throughout the whole observation period. There was 1 subsidence of a titanium cage into an adjacent vertebra without any clinical consequences. There was no adjacent fracture during the follow-up period and other surgical interventions or revisions were not necessary in any patient. CONCLUSIONS: In patients with severe osteoporosis or in patients with advanced tumor disease, excellent surgical, clinical, and radiologic results are possible following our method. In our opinion, a second-step posterior approach can be avoided by this technique.

Watanabe, K., et al. (2010). "Proximal junctional vertebral fracture in adults after spinal deformity surgery using pedicle screw constructs: analysis of morphological features." Spine (Phila Pa 1976) **35**(2): 138-145.

STUDY DESIGN: A retrospective comparative study. OBJECTIVE: To investigate the morphologic features of proximal vertebral fractures in adults following spinal deformity surgery using segmental pedicle screw instrumentation. SUMMARY OF BACKGROUND DATA: Fractures above pedicle screw constructs are a clinical problem that warrants further investigation for prevention and treatment. METHODS: Ten adult patients (6 lumbar scoliosis, 4 degenerative sagittal imbalance) who underwent segmental spinal instrumented fusion were analyzed. Patients were divided into 2 groups according to the features of vertebral fracture: upper instrumented vertebral collapse + adjacent vertebral subluxation (SUB group: n = 5), and adjacent vertebral fracture (Fracture group: n = 5). RESULTS: Both groups demonstrated a high frequency of osteopenia and all patients in the SUB group had comorbidities before surgery. The SUB group demonstrated a shorter interval between initial surgery and the fracture (subluxation: 3 +/- 1.9 months; fracture: 33 +/- 25.3 months, P < 0.05), and hypokyphosis (T5-T12) in the thoracic region before surgery (SUB: 13 degrees +/- 6.4 degrees; fracture: 33 degrees +/- 15.6 degrees). Both groups demonstrated severe global sagittal imbalance (SUB: 151 +/- 62.8 mm; fracture: 94 +/- 102.2 mm), and hypolordosis (T12-S1) in the lumbar spine (SUB: -19 degrees +/- 24.4 degrees ; fracture: -33 degrees +/- 22.7 degrees) before surgery. Global sagittal imbalance in the SUB group was corrected to 8 +/- 17.4 mm immediately postoperative (P < 0.05), but increased to 64 +/- 19.9 mm after the junctional fractures (P < 0.05). The SUB group demonstrated a significantly higher wedging rate (SUB: 65% +/- 12.4%; fracture: 36% +/- 16.0%, P < 0.05) and greater local kyphosis (SUB: 42 degrees +/- 11.1 degrees; fracture: 17 degrees +/- 4.1 degrees, P < 0.05) after the fracture. Two of 5 patients in the SUB group demonstrated severe neurologic deficit from E to B after the fractures by a modified Frankel classification. CONCLUSION: Old age, osteopenia, preoperative comorbidities, and severe global sagittal imbalance were found to be frequent in patients with proximal junctional fracture. In addition, marked correction of sagittal malalignment might be considered as a risk factor of upper instrumented vertebra collapse followed by adjacent vertebral subluxation, which occurred in the first 6 months after corrective surgery with the potential for causing severe neurologic deficit because of the severe local kyphotic deformity.

Weller, S. J., et al. (1997). "Cervical spine fractures in the elderly." Surg Neurol **47**(3): 274-280; discussion 280-271.

BACKGROUND: Cervical spine fractures in the elderly are relatively common. The management of such injuries may be complicated by underlying medical debility and osteopenia as well as reduced tolerance to halo immobilization. METHODS: Over a 1-year period, 43 cervical spine fractures were treated at our institution. Ten (23%) were in persons 70 years of age or older. This retrospective analysis describe the clinical features, treatment, and outcome of these 10 elderly patients. All fractures in this patient population involved the atlantoaxial complex, including five combination C1-C2 fractures. Six patients were treated with early halo immobilization and three were initially managed with a rigid cervical collar. Three patients required posterior cervical fusion. RESULTS: Of the six patients undergoing halo immobilization, five progressed to osseous union. Three patients were immobilized in a Philadelphia collar resulting in one osseous union, one nonunion, and one death. Three patients underwent posterior cervical fusion with subsequent osseous union in all three. CONCLUSIONS: Although external immobilization with a halo device is our treatment of choice for most C1 and C2 fractures in elderly patients, a Philadelphia collar is useful in select cases when halo immobilization or early surgical fusion is contraindicated. Posterior cervical fusion can be safely and effectively performed in elderly patients and should be strongly considered for initial therapy in the elderly with fracture types unlikely to progress to osseous union with external immobilization alone.

Widjaja, W. and C. Hartung (2001). "Biomechanical comparison of different fixations of femur-interlocking-nails." Clin Biomech (Bristol, Avon) **16**(8): 702-705.

OBJECTIVE: A new design of intra-medullary nailing fixation is investigated in this study. The strength properties of the new design are compared to the standard fixation method. DESIGN: The bone-implant-compound is examined by using experimental methods. BACKGROUND: Failure of bone substance in the region of the interlocking screws is a complication in particular in treating fractures of osteoporotic bone. A new additional implant is investigated, which should improve the fracture fixation of the bone-implant-compound. METHODS: The experiments were performed by using an universal testing machine. The bone-implant-compound was loaded by different compressive forces and the stiffness of the bone-implant-compound was measured. The maximum force to failure was also determined by a destructive test. RESULTS: The experimental results indicate that the additional implant increases the stiffness of the bone-implant-compound. The highest stress concentrations occur at the drill holes of the interlocking screws. Failure of the bone-implant-compound occurs at higher maximum forces by using the additional implant. CONCLUSIONS: The additional implant improves the strength of the bone-implant-compound. In the case of osteoporotic bone, the use of the additional implant is recommended. RELEVANCE: In surgical treatment of fractured femurs, the fracture is bridged by a medullary nail fixed with interlocking screws. Failure of bone substance in the region of the interlocking screws is the most common complication in the treatment of osteporotic bone. With the aim of preventing this complication, a new additional implant is developed and investigated.

Widjaja, W. and C. Hartung (2001). "[Biomechanical studies and finite element analysis of a bone-implant interface]." Biomed Tech (Berl) **46**(12): 351-354.

In the present study, the fixation system of a femoral medullary nail connection was investigated. In surgical treatment of fractured femurs, the fracture is bridged by a medullary nail that is fixed by interlocking screws in the bone. Bone failure around these screws is the most common complication associated with the treatment of fractures of osteoporotic bone. The present study analyses the stresses present in the region of the implant/bone system. Three-dimensional finite element models were generated, a nonlinear structure analysis performed, and the stresses at material interfaces investigated. The highest concentration of

stresses is to be found in the middle of the interlocking screws and the holes drilled in the bone. This is in agreement with the results of experimental investigations.

Winkler, S. (2010). "Extraordinary implant failure." J Oral Implantol **36**(5): 391-400.
Every attempt must be made to keep implant failures to a minimum. Dental implant failure can roughly be divided into 3 broad categories: bacterial factors, occlusal (mechanical factors), and systemic and psychologic factors. All failures should be carefully analyzed and evaluated to identify their causes in order to prevent future reoccurrence. Failures should be documented and used to advantage when treatment planning future implant cases. A panoramic radiograph, mounted diagnostic casts, medical and dental histories, and surgical guides are accepted standards of care prior to beginning oral implant procedures. The identification and management of nutritional deficiencies is a useful adjunct to successful implant treatment.

Wirtz, C., et al. (2013). "High failure rate of trochanteric fracture osteosynthesis with proximal femoral locking compression plate." Injury **44**(6): 751-756.
INTRODUCTION: Stable reconstruction of proximal femoral (PF) fractures is especially challenging due to the peculiarity of the injury patterns and the high load-bearing requirement. Since its introduction in 2007, the PF-locking compression plate (LCP) 4.5/5.0 has improved osteosynthesis for intertrochanteric and subtrochanteric fractures of the femur. This study reports our early results with this implant. METHODS: Between January 2008 and June 2010, 19 of 52 patients (12 males, 7 females; mean age 59 years, range 19-96 years) presenting with fractures of the trochanteric region were treated at the authors' level 1 trauma centre with open reduction and internal fixation using PF-LCP. Postoperatively, partial weight bearing was allowed for all 19 patients. Follow-up included a thorough clinical and radiological evaluation at 1.5, 3, 6, 12, 24, 36 and 48 months. Failure analysis was based on conventional radiological and clinical assessment regarding the type of fracture, postoperative repositioning, secondary fracture dislocation in relation to the fracture constellation and postoperative clinical function (Merle d'Aubigne score). RESULTS: In 18 patients surgery achieved adequate reduction and stable fixation without intra-operative complications. In one patient an ad latus displacement was observed on postoperative X-rays. At the third month follow-up four patients presented with secondary varus collapse and at the sixth month follow-up two patients had 'cut-outs' of the proximal fragment, with one patient having implant failure due to a broken proximal screw. Revision surgeries were performed in eight patients, one patient receiving a change of one screw, three patients undergoing reosteosynthesis with implantation of a condylar plate and one patient undergoing hardware removal with secondary implantation of a total hip prosthesis. Eight patients suffered from persistent trochanteric pain and three patients underwent hardware removal. CONCLUSIONS: Early results for PF-LCP osteosynthesis show major complications in 7 of 19 patients requiring reosteosynthesis or prosthesis implantation due to secondary loss of reduction or hardware removal. Further studies are required to evaluate the limitations of this device.

Wittenberg, R. H., et al. (1991). "Importance of bone mineral density in instrumented spine fusions." Spine (Phila Pa 1976) **16**(6): 647-652.
The effect of equivalent mineral density on pedicular screw fixation strength was investigated. The equivalent mineral density of human vertebral bodies was correlated highly with the pullout force of Kluger screws (r2 = 0.61, P less than 0.02). A moderate to high correlation existed between density and vertical force (r2 = 0.42 for Kluger screws, r2 = 0.55 for Steffee screws, P less than 0.02). In calf vertebral bodies of higher density (146 +/- 14 mg/cc), the forces were significantly higher than in the human vertebral bodies (P less than 0.05). Human lumbosacral spines were instrumented with three different fixators: Steffee plates, AO fixateur interne, and Kluger fixateur interne. Of five specimens with a mean density of 88 +/- 11 mg/cc, one screw loosened. More than one screw loosened in six

specimens with a mean density of 63 +/- 12 mg/cc, and no screw loosened in four specimens with a mean density of 114 +/- 38 mg/cc. Measurement of equivalent mineral density correlates with the fixation strength of the intrapedicular screws in vitro and should be considered in patients with signs of osteopenia before using pedicular screws for spinal fusions. It is also concluded that calf spines are a good model for testing implants because they tend to focus failure processes in the implant rather than in the implant-bone interface.

Wronka, K. S., et al. (2011). "Management of displaced ankle fractures in elderly patients--is it worth performing osteosynthesis of osteoporotic bone?" Ortop Traumatol Rehabil **13**(3): 293-298.

BACKGROUND: Ankle fractures in the elderly with osteoporotic bones are often difficult to manage. It is debatable whether we should treat such fractures conservatively, surgically, or even plan primary arthrodesis. Furthermore, there is a risk of difficult or failed fixation. MATERIAL AND METHODS: The study was a retrospective evaluation of the management and follow up of 126 patients presenting with displaced ankle fracture between 2001 and 2007. All patients were over 60 years old at the time of injury. RESULTS: About 75% of our patients underwent open reduction and internal fixation (ORIF). The remaining had closed manipulation under anaesthesia (MUA) performed. Some patients had multiple co-morbidities including diabetes (14% of patients). The results of fixation were satisfactory. Early complications included superficial wound infection (13% of patients) and one chest infection. There was no difference in diabetic patients. Metalwork failure occurred in one case only. Satisfactory union of fracture was achieved in all patients. Amongst patients who underwent MUA, more than 22% had chronic ankle pain. Significant ankle deformity was reported in 9% of patients. CONCLUSION: Our results show that accurate reduction and internal fixation of ankle fractures in elderly patients is beneficial and associated with lower complication rates compared to MUA alone. The osteosynthesis failure rate was very low and patients spent less time in plaster and started physiotherapy earlier.

Wu, Z. X., et al. (2010). "Application of an expandable pedicle screw in the severe osteoporotic spine: a preliminary study." Clin Invest Med **33**(6): E368-374.

PURPOSE: To investigate the clinical abstract and radiographic outcome of multi-axial expandable pedicle screws (MEPS) in patients with osteoporosis. METHODS: One hundred and twenty-five consecutive patients received MEPS from the UPASS spinal fixation system to obtain thoracolumbar or lumbosacral stabilization. All patients underwent bone mineral density (BMD) scans. The indications for use of the MEPS were spinal diseases with severe osteoporosis (degenerative diseases 46 cases, compression fractures 28 cases, lumbar tuberculosis 27 cases and revision spine surgery 24 cases). The pre-operative and three months post-operative functional evaluations were graded with JOA and VAS scoring system. One week, six months and 12 months after surgery, plain film and three-dimensional CT scans were obtained to evaluate the spinal fusion and fixation effectiveness of MEPS. RESULTS: The mean follow-up period was 18 months (ranged from 6 to 33 months). All patients suffered from severely osteoporosis with a decrease of 25.3% in BMD. The pre-operative JOA and VAS scores were 11.3+/-3.0 and 6.7+/-1.8 mm, respectively. Three months after operation, the JOA and VAS scores were 25.2+/-2.0 and 2.3+/-1.7 mm. The recovery rate was 78.1+/-11.5 and the clinical results were satisfying. There were no instances of screw loosening or pullout of the MEPS and the screw-bone interface was excellent. The radiographic results showed that bone healing, both around the screws and inter-vertebral, was achieved. CONCLUSION: In osteoporosis spine surgery, excellent bone-screw interface and fixation strength can be achieved by using MEPS. MEPS are a novel approach to increase the pedicle screw fixation in osteoporotic and revision spine surgeries.

Wu, Z. X., et al. (2012). "Surgical treatment of osteoporotic thoracolumbar compressive fractures with open vertebral cement augmentation of expandable pedicle screw fixation: a biomechanical study and a 2-year follow-up of 20 patients." J Surg Res **173**(1): 91-98.

BACKGROUND: The incidence of screw loosening increases significantly in elderly patients with severe osteoporosis. Open vertebral cement augmentation of expandable pedicle screw fixation may improve fixation strength in the osteoporotic vertebrae. MATERIALS AND METHODS: Twenty cadaveric vertebrae (L1-L5) were harvested from six osteoporotic lumbar spines. Axial pullout tests were performed to compare the maximum pullout strength (Fmax) of four methods: 1. Conventional pedicle screws (CPS), 2. Expandable pedicle screws (EPS), 3. Cement augmentation of CPS (cemented-CPS), 4. Cement augmentation of EPS (cemented-EPS). Thirty-six consecutive patients with single-vertebral osteoporotic compressive fractures received posterior decompression and spinal fusion with cemented-CPS (16 cases) or cemented-EPS (20 cases). Plain film and/or CT scan were conducted to evaluate the spinal fusion and fixation effectiveness. RESULTS: The Fmax and energy absorption of cemented-EPS were significantly greater than three control groups. The mean BMD in the severe osteoporosis group was significantly lower than that in the osteoporosis group (t = 2.04, P = 0.036). In the osteoporosis group, cemented-EPS improved the Fmax by 43% and 21% over CPS and cemented-CPS group. In the severe osteoporosis group, cemented-EPS increased the Fmax by 59%, 22%, and 26% over CPS, EPS, and cemented-CPS, respectively. The clinical results showed that all patients suffered from severe osteoporosis. Six months after operation, the JOA and VAS scores in cemented-EPS group improved from 11.4 +/- 2.6 and 7.0 +/- 1.4 mm to 24.9 +/- 1.6 and 2.1 +/- 1.3 mm, respectively. No screw loosening occurred in the cemented-EPS group and spinal fusion was achieved. In the cemented-CPS group, four screws loosened (4.2%) according to the radiolucency. Six months after operation, the JOA and VAS scores improved from 13.1 +/- 1.9 and 7.6 +/- 1.5 mm to 22.8 +/- 2.2 and 2.5 +/- 1.6 mm, respectively. No cement leaked into the spinal canal in both groups. CONCLUSIONS: Cemented-EPS could increase fixation strength biomechanically. It could reduce the risks of screw loosening in patients with severe osteoporosis, requiring instrumented arthrodesis.

Wu, Z. X., et al. (2012). "A comparative study on screw loosening in osteoporotic lumbar spine fusion between expandable and conventional pedicle screws." Arch Orthop Trauma Surg **132**(4): 471-476.

INTRODUCTION: The aim of this study is to compare the rate of screw loosening and clinical outcomes of expandable pedicle screws (EPS) with those of conventional pedicle screws (CPS) in patients treated for spinal stenosis (SS) combined with osteoporosis. METHODS: One hundred and fifty-seven consecutive patients with SS received either EPS fixation (n = 80) or CPS fixation (n = 77) to obtain lumbosacral stabilization. Patients were observed for a minimum of 24 months. Outcome measures included screw loosening, fusion rate, Japanese Orthopaedic Association (JOA) scores and Oswestry disability index (ODI) scoring system, and complications. RESULTS: **In the EPS group, 20 screws became loose (4.1%) in 6 patients (7.5%), and two screws (0.4%) had broken. In the CPS group, 48 screws became loose (12.9%) in 15 patients (19.5%), but no screws were broken.** The fusion rate in the EPS group (92.5%) was significantly higher than that of the CPS group (80.5%). The rate of screw loosening in the EPS group (4.1%) was significantly lower than that of the CPS group (12.9%). Six EPS (1.8%) screws were removed. In the EPS group, two screws had broken but without neural complications. Twelve months after surgeries, JOA and ODI scores in the EPS group were significantly improved. There were four cases of dural tears, which healed after corresponding treatment. CONCLUSIONS: EPS can decrease the risk of screw loosening and achieve better fixation strength and clinical results in osteoporotic lumbar spine fusion.

Wuisman, P. I., et al. (2000). "Augmentation of (pedicle) screws with calcium apatite cement in patients with severe progressive osteoporotic spinal deformities: an innovative technique." Eur Spine J **9**(6): 528-533.

Screw augmentation with calcium apatite cement (CAC) was used in seven patients with a progressive osteoporotic spinal deformity. Thirty-nine spinal segments (64 screws) were

augmented: 15 anteriorly (three patients) and 24 posteriorly (five patients). Dorsally, hemilaminectomy was performed at the level of all augmented screws to rule out CAC leakage. Autogenous bone graft was applied in all patients to induce fusion. Screw augmentation failure occurred in only one patient: 1 of the 16 ventral augmented screws (5.5%) was still loose after the augmentation procedure. In three other patients, 4 out of 48 augmented dorsal screws (5.5%) showed CAC leakage at the pedicle corpus vertebra level. Pedicle wall damage was present at two levels, while at two other levels no wall damage was found during visualization. No CAC-related complications were observed perioperatively. No implant migration was observed, and fusion was observed in all cases at follow-up examination performed at a mean of 32 months after surgery.

Xiao, J. R., et al. (2013). "Evaluation of fixation of expandable implants in the mandibles of ovariectomized sheep." J Oral Maxillofac Surg **71**(4): 682-688.

PURPOSE: This study aimed to investigate the effects of an expandable implant (EI) in ovariectomized sheep. METHODS: The EI and taper implant (control group) were produced and placed in mandibles of ovariectomized sheep. Twelve weeks after implantation, resonance frequency analysis, biomechanical tests, histomorphometry, and micro-computed tomography were applied to detect the osseointegration in the 2 groups. RESULTS: The implant stability quotient values, maximal pullout forces, and bone-implant contact (BIC) were 60.3 +/- 7.9, 511.0 +/- 18.7 N, and 53.14% +/- 4.56%, respectively, in the EI group and 58.3 +/- 8.9, 394.5 +/- 54.5 N, and 46.85% +/- 5.04%, respectively, in the control group. There was no significant difference between the 2 groups in implant stability quotient values ($P > .05$); however, in the EI group the maximal pullout force and BIC were increased significantly ($P < .05$ and $P < .01$, respectively). Micro-computed tomography analysis showed that the bone volume/total volume ratio and trabecular number increased significantly ($P < .01$) and trabecular separation decreased significantly ($P < .05$) in the EI group. CONCLUSIONS: EI could improve osseointegration in osteoporosis after 12 weeks of implantation by increasing BIC around the implant and by supplying an extra osseointegration surface.

Yamana, K., et al. (2010). "Clinical application of a pedicle nail system with polymethylmethacrylate for osteoporotic vertebral fracture." Eur Spine J **19**(10): 1643-1650.

The instrumentation of the osteoporotic spine may sometimes result in failure due to the loosening or pullout of the conventional pedicle screw. Moreover, augmentation of screws with polymethylmethacrylate (PMMA) has risks of complications. We developed a new and original pedicle nail system with PMMA for osteoporotic vertebral fractures. A clinical evaluation of this novel pedicle nail system utilized in patients with an osteoporotic vertebral collapse was performed to determine the effectiveness and safety of this technique. Thirty-four elderly patients who suffered from osteoporotic compression fractures were treated by posterolateral fusion using the pedicle nail system. The mean follow-up period was 37 months. Of the 25 patients with neurological symptoms, two patients improved two stages at the Frankel level. Fifteen patients improved one stage at the Frankel level, and eight other patients improved, however, their improvement did not exceed a Frankel level. Nine cases with neuralgia symptoms improved from 4.4 to 2.2 points on average on the Denis pain scale ($p < 0.01$). The fusion rate was 94% as determined by X-rays of flexion and extension, and the correction of the compression fracture site was maintained well. A pedicle nail system stabilizes the spinal column with osteoporosis and reduces the instrumentation failure. The technique for the insertion of the pedicle nail reduces complication from cement augmentation. The authors speculate that the strategy using the pedicle nail system for osteoporotic spine may be effective and safe when the surgery is performed through a posterior approach.

Yanez, A., et al. (2010). "Biomechanical evaluation of a new system to improve screw fixation in osteoporotic bones." Med Eng Phys **32**(5): 532-541.

In this paper an experimental analysis is undertaken of the affect a new screw-to-bone fixation system has on the stiffness of fixation systems of osteoporotic fractures based on osteosynthesis plates. The proposed system, which we have named the screw locking element (SLE), is made with elements manufactured from a biocompatible polymer material known as polyetheretherketon (PEEK) which act like a lock nut, holding the end of the threaded screw shank after this has passed through both bone corticals. Seventy-two osteoporotic synbone simulated fracture models were instrumented with one of four constructs: locking compression plate with 6 locking screws (LCP), dynamic compression plate with 6 cortical screws (DCP), DCP with 2 SLEs or DCP with 6 SLEs (DCP+6SLEs). Each group of 18 simulated fracture models were further split into 3 subgroups of 6. One subgroup was tested under cyclic cantilever bending, another under cyclic compression and the third under cyclic torsion. Loss of stiffness was determined in each test every 1,000 load cycles, between 0 and 30,000 cycles. Regardless of the load type, it was seen that the DCP system had the highest stiffness loss percentages of all the tested systems. The inclusion of SLEs significantly decreased the stiffness loss of the DCP system. Unlike the cyclic compression loads, where the LCP performed slightly better, on terminating the cantilever bending and torsion load cycles no statistically significant difference was noted (Tukey test, $p>0.05$) between the percentage stiffness loss of the DCP+6SLEs system and the LCP system. It is concluded that the proposed SLEs enable DCPs to lower the high failure rate that these exhibit in osteoporotic fracture repairs, at significantly lower costs than those resulting from the use of LCPs.

Yang, H., et al. (2011). "[Analysis of the failure reason of internal fixation in peritrochanteric fractures]." Beijing Da Xue Xue Bao **43**(5): 699-702.

OBJECTIVE: To analyze the reasons and precautions for the failure of internal fixation in peritrochanteric fractures. METHODS: A retrospective study of 256 patients treated in surgical way during the period of May 2005 to June 2009 in our hospital was utilized by Logistic regression via analyzing age, sex, type of fracture, bone quality, type of internal fixation device, neck-shaft angle, Garden index and the initial load time. RESULTS: The ages of 256 patients ranged from 14 to 103 years. All the patients were treated by internal fixation, of whom 194 were followed up after surgery. The follow-up rate was 75.8% and follow-up time 12-53 months, with an average of 17.8 months. Ten cases failed after surgery because of penetration, cut and break-up of screw and bone non-union. The failure rate was 5.15%. The failure cases were 31-A2.2 (4 cases, 1.56%), 31-A2.3 (5 cases, 1.95%), and 31-A3.1 (1 cases, 0.39%). The type of failure devices: Dynamic hip screw (DHS) 3 cases, proximal femoral nail (PFN) 2 cases, proximal femoral nail anti-rotation (PFNA) 1 case, less invasive stabilization system (LISS) 4 cases. According to statistic results, initial load time after operation was a risk factor of internal fixation failure. Generally, the older, the more osteoporosis and the less effect of internal fixation. According to our experience, the more complex fracture, the more time before operation, the more difficult the reduction and the higher the rate of device failure. CONCLUSION: The initial load time after operation is crucial to the destiny of internal fixation. We should keep patients from early loading after operation and make a time table for the individual according to the patient's own condition.

Yazu, M., et al. (2005). "Efficacy of novel-concept pedicle screw fixation augmented with calcium phosphate cement in the osteoporotic spine." J Orthop Sci **10**(1): 56-61.

Pedicle screw instrumentation has become increasingly popular for rigid internal stabilization of the thoracolumbar spine. However, when pedicle screws are used in elderly osteoporotic patients, the screw-bone interface is stripped easily. Therefore, the risk of screw loosening and backing-out after surgery has increased. The purpose of this study was to evaluate the efficacy of the novel-concept pedicle screw fixation augmented with calcium phosphate cement (CPC) in the osteoporotic spine. The novel-concept screw has the same shape as the ordinary screw, but it is hollow and fabricated with 20 small holes (1.3 mm in diameter) leading to the hollow part on the bottom of the thread. Fifteen embalmed cadaveric lumbar

vertebrae were instrumented with two types of pedicle screw (the ordinary screw and the novel-concept screw) in each pedicle. Only the novel-concept screws were augmented with CPC after insertion. Seven days later, axial pull-out testing was performed at a crosshead speed of 10 mm/min. The mean maximal pull-out strength of the ordinary screws was 258 N, and that of the novel concept screws was 637 N. These results suggest that the novel-concept screw augmented with CPC can be useful for pedicle screw fixation of the osteoporotic spine.

Yin, Q. S., et al. (2010). "Transoral atlantoaxial reduction plate internal fixation for the treatment of irreducible atlantoaxial dislocation: a 2- to 4-year follow-up." Orthop Surg **2**(2): 149-155.

OBJECTIVE: To evaluate the mid-term outcomes of transoral atlantoaxial reduction plate (TARP) internal fixation for the treatment of irreducible atlantoaxial dislocation. METHODS: From April 2003 to April 2005, 31 patients with irreducible atlantoaxial dislocation were treated with TARP internal fixation. The average age was 37.9 years (range, 15-69 years). The subjective symptoms, objective signs, and neurological function of the patients were assessed. Radiography and magnetic resonance imaging (MRI) were performed and the results analyzed according to the Symon and Lavender clinical standard, Japanese Orthopaedic Association (JOA) score for spinal cord function and imaging standard for spinal cord decompression. RESULTS: Complete or almost complete anatomical reduction was obtained in all 31 patients. No screw-loosening or atlantoaxial redislocation was found in 29 cases. According to the Symon and Lavender clinical standard, 14 cases had recovered completely, 7 to mild, 6 to moderate, and 4 to severe type by final follow-up, compared to the preoperative classifications of 4 as moderate, 15 as severe, and 12 as extra severe type. The outcome for 26 patients was evaluated as excellent and in 5 as adequate. The average postoperative improvement in spinal cord function was 73.3% and of decompression of the cervical cord 92.6%. The only complication was loosening of screws in two cases with senile osteoporosis. One case underwent TARP revision surgery and the other posterior occipitocervical internal fixation. Both of them were eventually cured. CONCLUSION: The TARP operation is a good choice for patients with irreducible atlantoaxial dislocation and has valuable clinical application.

Ying, S. H., et al. (2012). "Fixation strength of PMMA-augmented pedicle screws after depth adjustment in a synthetic bone model of osteoporosis." Orthopedics **35**(10): e1511-1516.

The purpose of this study was to determine the change of fixation strength after adjusting the height of polymethylmethacrylate (PMMA)-augmented pedicle screws.Cement-augmented cannulated pedicle screws with or without PMMA augmentation with a radial hole in the distal third of the screw thread were inserted into synthetic bone blocks used to model osteoporosis. Screws were left unchanged (in situ), screwed in 3 threads, or screwed out 3 threads. The change in screw height was made 24 hours after cement placement. Radiographs of the samples were taken before and after screw adjustment, and pullout strength testing was performed. In the cement group, a radiolucent cavity was present after screwing in due to the screw-cement complex migrating downward, whereas no obvious change in the boneicement complex existed after screwing out. Mean pullout strength was significantly higher in the groups with cement as compared to those without cement. However, in the cement groups, the screw-in group had the lowest mean pullout strength among 3 groups, and the mean pullout strength in the screw-out group was also significantly lower than that in the in situ group (P<.05).Adjustment of pedicle screw height after cement augmentation in a severely osteoporotic spine can significantly reduce the pullout strength of the screw.

Yu, B., et al. (2010). "[Choice of bone cement augmentation techniques when sacral pedicle screw loosening]." Zhongguo Xiu Fu Chong Jian Wai Ke Za Zhi **24**(2): 211-214.

OBJECTIVE: To biomechanically compare the maximum pull-out strengths among two pedicle screws and three salvage techniques using poly methylmethacrylate (PMMA)

augmentation in osteoporotic sacrum, and to determine which PMMA augmentation technique could serve as the salvage fixation for loosening sacral pedicle screws. METHODS: Eleven sacral were harvested from fresh adult donated cadavers, aged from 66 to 83 years (average 74.4 years) and included 5 men and 6 women. Radiography was used to exclude sacral that showed tumor or inflammatory or any other anatomic abnormalities. Following the measurement of bone mineral density, five sacral screw fixations were sequentially established on the same sacrum as follows: unicortical pedicle screw (group A), bicortical pedicle screw (group B), unicortical pedicle screw with the traditional PMMA augmentation (group C), ala screw with the traditional PMMA augmentation (group D), and ala screw with a kyphoplasty-assisted PMMA augmentation technique (group E). According to the sequence above, the axial pull-out test of each screw was conducted on a MTS-858 material testing machine. The maximum pull-out forces were measured and compared. The morphologies of PMMA augmented screws after being pulled-out were also inspected. RESULTS: The average bone mineral density of 11 osteoporotic specimens was (0.71 +/- 0.08) g/cm2. By observation of the pull-out screws, groups C, D, E showed perfect bonding with PMMA, and group E bonded more PMMA than groups C and D. The maximum pull-out forces of groups A, B, C, D, and E were (508 +/- 128), (685 +/- 126), (846 +/- 230), (543 +/- 121), and (702 +/- 144) N, respectively. The maximum pullout strength was significantly higher in groups B, C, and E than in groups A and D ($P < 0.05$), and in group C than in groups B and E ($P < 0.05$). There was no significant difference in pull-out strength between groups A and D, and between groups B and E ($P > 0.05$). CONCLUSION: For sacral screw fixation of osteoporotic patients with bone mineral density more than 0.7 g/cm2, bicortical pedicle screw could acquire significantly higher fixation strength than the unicortical. Once the loosening of pedicle screw occurs, the traditional PMMA augmentation or ala screw with kyphoplasty-assisted PMMA augmentation may serve as a suitable salvage technique.

Yu, B. S., et al. (2010). "Biomechanical comparison of 4 fixation techniques of sacral pedicle screw in osteoporotic condition." J Spinal Disord Tech **23**(6): 404-409.

STUDY DESIGN: An in vitro biomechanical cadaver study. OBJECTIVES: To compare the subsidence displacement after cyclic loading among 4 sacral pedicle screw fixations of bicortical, tricortical, standard polymethylmethacrylate (PMMA) augmentation, and sub-endplate PMMA augmentation in osteoporotic condition. SUMMARY OF BACKGROUND DATA: Implant failure caused by screw loosening is a clinical problem for lumbosacral fusions, especially in osteoporotic patients. To improve sacral screw anchoring strength, the main fixation techniques need to be evaluated biomechanically. METHODS: For this study, 11 fresh osteoporotic cadaver sacra were harvested and bone mineral density was measured with dual-energy radiograph absorptiometry. A 7 mm diameter monoaxial pedicle screw (S1) was randomly assigned by side (left vs. right) and placed bicortically or tricortically. The 2 screws, followed 2000 cyclic compression loading of 30 to 250 N, were removed. The screw tracts were filled up with PMMA, then, screws 5 mm shorter than the bicortical or tricortical fixation were reinserted (defined as standard and sub-endplate PMMA augmented sacral screw fixations, respectively). The PMMA augmented screws were then retested as before. Screw subsidence displacement after 2000 cyclic loading was measured and compared. RESULTS: The average bone mineral density of 11 specimens was 0.71 g/cm, ranged from 0.65 to 0.78 g/cm. No significant difference of subsidence displacement was detected between tricortical and standard PMMA augmented screws ($P>0.05$), however, the 2 fixations exhibited markedly less subsidence than bicortical screw ($P<0.05$). Sub-endplate PMMA augmented screw showed the least subsidence among all the screws ($P<0.05$). CONCLUSIONS: PMMA augmentation can increase the bonding strength of sacral screw-bone interface and the sub-endplate PMMA augmented sacral screw could obtain the highest stability among the 4 fixation techniques in osteoporotic condition.

Yu, X. W., et al. (2009). "Augmentation of screw fixation with injectable calcium sulfate bone cement in ovariectomized rats." J Biomed Mater Res B Appl Biomater **89**(1): 36-44.

The objective of this study was to determine the effect of augmenting screw fixation with an injectable calcium sulfate cement (CSC) in the osteoporotic bone of ovariectomized rats. The influence of the calcium sulfate (CS) on bone remodeling and screw anchorage in osteoporotic cancellous bone was systematically investigated using histomorphometric and biomechanical analyses. The femoral condyles of 55 Sprague-Dawley ovariectomized rats were implanted with screw augmented with CS, while the contralateral limb received a nonaugmented screw. At time intervals of 2, 4, 8, 12, and 16 weeks, 11 rats were euthanized. Six pair-matched samples were used for histological analysis, while five pair-matched samples were preserved for biomechanical testing. Histomorphometric data showed that CS augmented screws activated cancellous bone formation, evidenced by a statistically higher ($p < 0.05$) percentage of osteoid surface at 2, 4, and 8 weeks and a higher rate of bone mineral apposition at 12 weeks compared with nonaugmented screws. The amount of the bone-screw contact at 2, 8, and 12 weeks and of bone ingrowth on the threads at 4 and 8 weeks was greater in the CS group than in the nonaugmented group ($p < 0.05$), although these parameters increased concomitantly with time for both groups. The CS was resorbed completely at 8 weeks without stimulating fibrous encapsulation on the screw surface. Also, the cement significantly increased the screw pull-out force and the energy to failure at 2, 4, 8, and 12 weeks after implantation, when compared with the control group ($p < 0.05$). These results imply that augmentation of screw fixation with CS may have the potential to decrease the risk of implant failure in osteoporotic bone.

Yuan, G. X., et al. (2012). "Biomechanical comparison of internal fixations in osteoporotic intertrochanteric fracture. A finite element analysis." Saudi Med J **33**(7): 732-739.

OBJECTIVE: To compare the biomechanical characteristics of dynamic hip screw (DHS) and proximal femoral nail anti-rotation (PFNA) for the treatment of 3 types of osteoporotic femoral intertrochanteric fracture (OFIF) by modeling, and virtual reduction with finite element analysis, and to provide some theoretical basis and reference to select the best internal fixation for clinical treatment of OFIF. METHODS: The experiment was conducted at the Laboratory of Biomechanics, Shanghai Institute of Orthopedics and Traumatology, Shanghai Jiaotong University School of Medicine, Shanghai, People's Republic of China from February to December 2011. The CT scan was performed in 3 cases with different types of OFIF (Evans-Jensen II, III, and IV). Upon validation, fracture models with different internal fixations were developed to simulate and analyze. Under the conditions of 7 different apparent bone densities and 3 different loads, the Von Mises stresses, and the failure rates were calculated, and the stress distribution patterns were compared. RESULTS: The PFNA internal fixation system has better stress distribution than DHS. The former has smaller maximum Von Mises stress of femur and internal fixation, and the femoral element failure rate, as well. The safety range of osteoporosis in PFNA is wider than the DHS. CONCLUSION: The experiment verifies, from the view of biomechanics, that PFNA should be taken into consideration firstly for OFIF (Evans-Jensen II, III, and IV).

Zahn, R. K., et al. (2012). "A contoured locking plate for distal fibular fractures in osteoporotic bone: a biomechanical cadaver study." Injury **43**(6): 718-725.

OBJECTIVE: Fixation of ankle fractures in elderly patients is associated with reduced stability conditioned by osteoporotic bone. Therefore, fixation with implants providing improved biomechanical features could allow a more functional treatment, diminish implant failure and avoid consequences of immobilisation. MATERIALS AND METHODS: In the actual study, we evaluated a lateral conventional contoured plate with a locking contoured plate stabilising experimentally induced distal fibular fractures in human cadavers from elderly. Ankle fractures were induced by the supination-external rotation mechanism according to Lauge-Hansen. Stage II fractures (AO 44-B1) were fixed with the 2 contoured plates and a torque to failure test was performed. Bone mineral density (BMD) was measured by quantitative computed tomography to correlate the parameters of the biomechanical experiments with bone quality. RESULTS: The locking plate showed a higher

torque to failure, angle at failure, and maximal torque compared to the conventional plate. In contrast to the nonlocking system, fixation with the locking plate was independent of BMD. CONCLUSION: Fixation of distal fibular fractures in osteoporotic bone with the contoured locking plate may be advantageous as compared to the nonlocking contoured plate. The locking plate with improved biomechanical attributes may allow a more functional treatment, reduce complications and consequences of immobilisation.

Zdeblick, T. A., et al. (1993). "Pedicle screw pullout strength. Correlation with insertional torque." Spine (Phila Pa 1976) **18**(12): 1673-1676.

This study was designed to correlate several parameters regarding pedicle screw bone/metal interface strength. The insertional torque measured during tapping and placement of pedicle screws was correlated with the bone mineral density of the vertebral body, the dimensions of the pedicle, the method of preparation of the pedicle, and the amount of load and number of cycles to failure of the bone/metal interface. Thirty human cadaveric lumbar vertebrae were instrumented with 6.5-mm pedicle screws. The maximum torque achieved during insertion was digitally recorded. A cyclic pedicle screw pullout test was performed. A linear correlation existed between both the insertional torque when tapping or when inserting a screw and the number of cycles to ultimate pedicle screw pullout. An inverse linear relationship was found between the pedicle width and cycles to failure. There was no linear correlation found when comparing the number of cycles to failure to bone mineral density. These findings suggest that insertional torque is a good predictor of bone-metal interface failure. Bone mineral density of the vertebral body was less effective as a predictor of failure. Smaller pedicle width correlated with increased insertional torque and cycles to failure. This may explain why patients with osteoporosis on radiography may still obtain stable fixation with pedicle screws. Other factors, such as pedicle dimensions and shape, affect screw purchase as much as vertebral body bone density. Insertional torque less than 4.0 inch-pounds led to early pedicle screw pullout. This study forms the basis for the authors' clinical use of an instrumented torque screwdriver to measure insertional torque in the operating room.

Zdero, R., et al. (2009). "Cortical screw purchase in synthetic and human femurs." J Biomech Eng **131**(9): 094503.

Biomechanical investigations of orthopedic fracture fixation constructs increasingly use analogs like the third and fourth generation composite femurs. However, no study has directly compared cortical screw purchase between these surrogates and human femurs, which was the present aim. Synthetic and human femurs had bicortical orthopedic screws (diameter=3.5 mm and length=50 mm) inserted in three locations along the anterior length. The screws were extracted to obtain pullout force, shear stress, and energy-to-pullout. The four study groups (n=6 femurs each) assessed were the fourth generation composite femur with both 16 mm and 20 mm diameter canals, the third generation composite femur with a 16 mm canal, and the human femur. For a given femur type, there was no statistical difference between the proximal, center, or distal screw sites for virtually all comparisons. The fourth generation composite femur with a 20 mm canal was closest to the human femur for the outcome measures considered. Synthetic femurs showed a range of average measures (2948.54-5286.30 N, 27.30-35.60 MPa, and 3.63-9.95 J) above that for human femurs (1645.92-3084.95 N, 17.86-24.64 MPa, and 1.82-3.27 J). Shear stress and energy-to-pullout were useful supplemental evaluators of screw purchase, since they account for material properties and screw motion. Although synthetic femurs approximated human femurs with respect to screw extraction behavior, ongoing research is required to definitively determine which type of synthetic femur most closely resembles normal, osteopenic, or osteoporotic human bone at the screw-bone interface.

Zehnder, S., et al. (2009). "The effects of screw orientation in severely osteoporotic bone: a comparison with locked plating." Clin Biomech (Bristol, Avon) **24**(7): 589-594.

BACKGROUND: Techniques such as varying screw insertion angles and the use of locked plating have been shown to improve the strength of fixation in bone. The effects of these methods is less clearly understood in bone of exceedingly poor quality. METHODS: Forty plate-bone constructs were assembled and divided into four groups of ten. Perpendicularly placed screws were placed in one group, convergently placed crossing screws were placed in a second group, an oblique end screw was placed in a third group, and a fourth group utilized perpendicularly placed locking screws in a locking plate. All test subjects were mounted and loaded in cantilever bending to the point of failure. Stiffness, initial load to failure, and maximal load tolerated were all analyzed. FINDINGS: All four groups demonstrated evidence of failure at similar loads (21.8-26.1N). The locked group was able to tolerate significantly higher loads overall (37.3N, P=.044). All three non-locked groups demonstrated similar failure patterns and load to failure. Locking constructs demonstrated a distinctly different failure pattern. No significant differences were detected with regard to screw orientation and load to failure. The group with an oblique end screw was significantly less stiff than the other three constructs (P=.017). INTERPRETATION: In a severely osteoporotic model, failure in cantilever bending at low forces will take place regardless of fixation methods used. The mechanism of failure is different in locked constructs compared to traditional constructs. The added benefit of oblique screw placement observed in healthy bone is not observed in osteoporotic bone.

Zeller, R., et al. (2009). "Technique for drilling instrument monitoring electrical conductivity in pediatric cervical spine screw insertion: a preliminary report." J Pediatr Orthop **29**(7): 760-764.

BACKGROUND: To detail a technique of assisted screw placement in pediatric patients with cervical spine disorders. The use of a recently produced wireless electronic freehand drilling instrument is documented. METHODS: We performed fixation of the cervical spine using different screws in 5 consecutive patients with various cervical spine disorders (posttraumatic, neoplastic or metabolic). Clinical and radiologic features of all cases are reported. The surgical technique is described. RESULTS: Twenty-six cervical screws (lateral mass, pars, and/or laminar) were placed with the use of the same pedicle screw pilot hole preparation device, and by the same surgical team. The average age of this patient group was 13.4 years (range: 6 to 16 y). Average follow-up was 10 months (range: 5 to 14 mo). All screws were inserted after the correct trajectory was identified. No breaches were detected. No screw failure was encountered. However, 8 of 26 (30.8%) screws were, on average, 1.3 mm longer that expected (range: 0.5 to 2.4 mm). None of the patients developed neurologic or vascular complications as a result of screw placement. CONCLUSIONS: Cervical screws placement, although safe, is not free of complications: neurovascular injuries, dural tears, and paraplegia have been described. The use of a wireless electronic handheld pedicle screw pilot hole preparation instrument is a useful tool in the armamentarium of the spinal surgeon dealing with patients with complex spinal deformities or difficult anatomy. Our experience outlines the applicability of this technique at different cervical levels. However, this device is not satisfactory in predicting the length of the screws. The device should be modified or a preoperative computed tomography scan should be used to estimate safe the length of the screws. LEVEL OF EVIDENCE: Level IV (case series).

Zha, G. C., et al. (2011). "Treatment of pertrochanteric fractures with a proximal femur locking compression plate." Injury **42**(11): 1294-1299.

BACKGROUND: Pertrochanteric femoral fractures are one of the most common fractures in old patients. However, fixing pertrochanteric fractures properly is clinically challenging. There are also no routine treatments for this fracture. Here, we report the clinical trial of pertrochanteric fracture treatment with a proximal femur locking compression plate (PFLCP). By recording and analysing the radiographic and clinical results from patients treated with PFLCP, we found that PFLCP could provide three-dimensional fixation mechanical advantages compared with conventional treatments, even in the case of unstable fractures in the osteoporotic bone. METHODS: The report included a total of 110 patients (72 females

and 38 males) with pertrochanteric femoral fractures who were subjected to PFLCP treatment. The mean age of the patients was 75 (48-93) years. Pertrochanteric fracture includes both intertrochanteric and subtrochanteric femoral fractures: intertrochanteric fractures were classified according to Jensen (1980), whereas subtrochanteric fractures were classified according to Zickel (1980). Detailed clinical conditions of all patients, including blood loss, drainage and length of incision, were recorded individually. The duration of image intensification was also monitored. Patients were revisited at 6 weeks, 3 months, 6 months and 1 year after the operation. The progress of healing, as well as the occurrence of complications, was recorded. RESULTS: Amongst the 110 patients, 108 (98%) were available for follow-up check-up at 6 weeks, 104 (95%) at 3 months, 100 (91%) at 6 months and 94 (85%) at 1 year. The other patients were lost to follow-up because of death. The union rate was 95% (99/104), 98% (98/100) and 100% (94/94) at the 3-month, 6-month and 1-year period during the follow-up check-up, respectively. The patients healed satisfactorily and had no complications, such as cut-out in most cases. However, there was one case of breakage of the implant and one case of non-union at the 3-month period during the follow-up check-up. Amongst all patients, 77 cases were successfully reduced with traction on a fracture table under fluoroscopy; the others were opened to correct the displacement. The average operation time was 35.5 min, and the mean bleeding amount was 150 ml (including operative blood loss and wound drainage). The mean image intensifier time was 5 min and the mean length of incision was 9 cm. CONCLUSION: The PFLCP can be a feasible alternative to the treatment of pertrochanteric fractures. Treatment with a PFLCP can provide good-to-excellent healing for pertrochanteric fractures, with a limited occurrence of complications.

Zhang, C., et al. (2009). "[Complications of surgical treatment for femoral intertrochanteric fractures using dynamic hip screw]." Zhongguo Gu Shang **22**(8): 624-626.

OBJECTIVE: To investigate the complications of surgical treatments for femoral intertrochateric fractures using dynamic hip screw (DHS). METHODS: From Jan. 2002 to Dec. 2007, sixty-nine patients with intertrochanteric fractures were treated by dynamic hip screw fixation included 27 males and 42 females,with an average age of 72.9 years ranging from 53 to 96 years. According to Evans classification there were 10 cases in type I ,21 in type II, 22 in type III, and 16 in type IV, of which 51 patients (73.9%) suffered from systematic diseases preoperatively. RESULTS: Fifty-seven patients were followed up for 8 to 70 months (41 months on average). Four patients died, 17 cases occurrenced systematic complications postoperatively. Internal fixation related complications occurred in 12 patients. There were 8 cases with mechanical failure of DHS including 4 of screw loosen,3 of cutting-out of device through femoral head and neck and 1 of plate breakage. Five patients had a coxa vara, and delayed union occurred in 4 patients. CONCLUSION: Unstable fracture pattern produced high percentage of mechanical failure. In such cases DHS should not be the first choice for treatment. The appropriate treatment should be in relation to pre-operative fracture stability and osteoporosis.

Zhang, J. D., et al. (2011). "Comparison of vertebroplasty and kyphoplasty for complications." Orthop Surg **3**(3): 158-160.

Vertebroplasty (VP) and kyphoplasty (KP) have been proven equally effective in providing pain relief in patients with vertebral compression fractures (VCF). Both have been reported to have multiple complications which, though rare, are potentially devastating. This literature review focuses on comparing the incidence of various types of complication of VP and KP. Local cement leakage and pulmonary cement embolism have been reported more commonly after VP than KP. It is questionable whether the relative risk of developing an adjacent level new fracture after VP is greater than after KP The relationship between a new VCF and each of these procedures has also not been clearly established. Although the majority of complications are clinically silent, their potential risks, which include a fatal outcome, should always be kept in mind by the practitioner.

Zhu, Q., et al. (2012). "Enhancing pedicle screw fixation in the aging spine with a novel bioactive bone cement: an in vitro biomechanical study." Spine (Phila Pa 1976) **37**(17): E1030-1037.

STUDY DESIGN: A paired biomechanical study of pedicle screws augmented with bone cement in a human cadaveric and osteoporotic lumbar spine model. OBJECTIVES.: To evaluate immediate strength and stiffness of pedicle screw fixation augmented with a novel bioactive bone cement in an osteoporotic spine model and compare it with polymethylmethacrylate (PMMA) cement. **SUMMARY OF BACKGROUND DATA: A novel bioactive bone cement, containing nanoscale particles of strontium and hydroxyapatite (Sr-HA), can promote new bone formation and osteointegration and provides a promising reinforcement to the osteoporotic spine. Its immediate mechanical performance in augmenting pedicle** screw fixation has not been evaluated. METHODS: Two pedicle screws augmented with Sr-HA and PMMA cement were applied to each of 10 isolated cadaveric L3 vertebrae. Each screw was subjected to a toggling test and screw kinematics were calculated. The pedicle screw was subjected to a pullout test until failure. Finally, the screw coverage with cement was measured on computed tomographic images. RESULTS: Screw translations in the toggling test were consistently larger in the Sr-HA group than in the PMMA group (1.4 +/- 1.2 mm vs. 1.0 +/- 1.1 mm at 1000 cycles). The rotation center was located closer to the screw tip in the Sr-HA group (19% of screw length) than in the PMMA group (37%). The only kinematic difference between Sr-HA and PMMA cements was the screw rotation at 1000 cycles (1.5 degrees +/- 0.9 degrees vs. 1.3 degrees +/- 0.6 degrees ; P = 0.0026). All motion parameters increased significantly with more loading cycles. The pullout force was higher in the PMMA group than the Sr-HA group (1.40 +/- 0.63 kN vs. 0.93 +/- 0.70 kN), and this difference was marginally significant (P = 0.051). Sr-HA cement covered more of the screw length than PMMA cement (79 +/- 19% vs. 43 +/- 19%) (P = 0.036). CONCLUSION: This paired-design study identified some subtle but mostly nonsignificant differences in immediate biomechanical fixation of pedicle screws augmented with the Sr-HA cement compared with the PMMA cement.

Zhuang, X. M., et al. (2010). "Effect of the degree of osteoporosis on the biomechanical anchoring strength of the sacral pedicle screws: an in vitro comparison between unaugmented bicortical screws and polymethylmethacrylate augmented unicortical screws." Spine (Phila Pa 1976) **35**(19): E925-931.

STUDY DESIGN: An in vitro laboratory study. OBJECTIVE: (i) To evaluate the effect of osteoporotic degree in determining the strength of sacral screw fixation and (ii) to compare the strength of unaugmented bicortical pedicle screw and polymethylmethacrylate (PMMA) augmented unicortical pedicle screw in sacral fixation. SUMMARY OF BACKGROUND DATA: Screw loosening is a clinical problem in lumbosacral fusions, especially in osteoporotic patients. To improve the screw anchoring strength of sacrum, bicortical and PMMA augmented sacral pedicle screw fixation techniques are widely used in clinical practice. However, the biomechanical strength of the bicortical and PMMA augmented sacral screw fixations remains undetermined in different degrees of osteoporosis. METHODS: Twenty-five fresh osteoporotic cadavers were used in this study. According to the value of lumbar bone mineral density (BMD) assessed by DEXA, specimens were divided into 3 groups: group A (N=9): BMD=0.7 to 0.8 g/cm, group B (N=8): BMD=0.6 to 0.7 g/cm, and group C (N=8): BMD<0.6 g/cm. In each specimen, S1 pedicle screw was inserted bicortically on the left side, and S1 pedicle screw with PMMA augmentation was inserted unicortically on the right side of the sacrum. Following a dynamic cyclic loading from 30 to 250 N on the screw head for 2000 cycles, the subsidence displacement and axial pull-out strength of each screw were measured. RESULTS: No anchoring failure (defined as the subsidence displacement exceeding 2 mm within 2000 loading cycles) occurred in group A and B. However, in group C, 6 cases (75%) in bicortical fixation and 5 cases (63%) in PMMA augmented fixation failed during cyclic loading. In group A, no significant difference between the bicortical and PMMA augmented fixations was detected in terms of the subsidence and

maximal pull-out strength. In group B, significantly less subsidence and higher maximal pull-out strength were demonstrated in the PMMA augmented technique than that in the bicortical fixation. Both techniques exhibited lower subsidence of the screw in group A than in group B. The bicortical technique exhibited higher maximum pull-out strength in group A than that in group B. However, statistical difference in terms of PMMA augmentation was not detected between group A and B. CONCLUSION: **For BMD value more than 0.70 g/cm, bicortical sacral pedicle screw fixation could obtain sufficient anchoring strength comparable with the PMMA augmented technique. When BMD value is within 0.6 to 0.7 g/cm, the PMMA augmented technique would be more beneficial in improving the fixation strength than the bicortical fixation. For BMD values less than 0.6 g/cm, early screw loosening may occur in both bicortical and PMMA augmented fixations.**