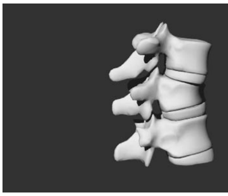
Less Invasive Surgical Treatment of Traumatic Thoracolumbar Fractures

J.J. Verlaan



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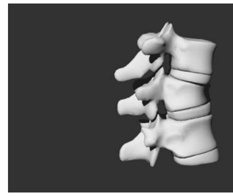
Less Invasive Surgical Treatment of Traumatic Thoracolumbar Fractures

Minder Invasieve Chirurgische Behandeling van Traumatische Thoracolumbale Wervelfracturen

(met een samenvatting in het Nederlands)



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Joannes Jacobus Verlaan

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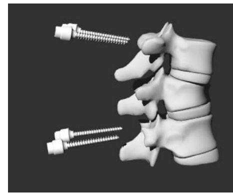
1.
Verlaan JJ, Diekerhof CH, Buskens E, van der Tweel I, Verbout AJ, Dhert WJA, Oner FC. Surgical treatment of traumatic fractures of the thoracic and lumbar spine. A systematic review of the literature on techniques, complications and outcome. *Spine* 2004;29(7):803-14.

2.
Verlaan JJ, Van Helden H, Oner FC, Verbout AJ, Dhert WJA. Balloon vertebroplasty with calcium phosphate cement augmentation for direct restoration of traumatic thoracolumbar vertebral fractures. *Spine* 2002;27(5):543-548.

3.
Verlaan JJ, Oner FC, Verbout AJ, Dhert WJA. Vertebroplasty with inflatable bone tamps and calcium phosphate cement for traumatic spinal conditions. In: Internal Fixation in Osteoporotic Bone (Chapter 34); Springer Verlag, H.An, editor. 2002. ISBN 1588900878 / 3131284714.

4.
Verlaan JJ, van de Kraats EB, van Walsum Th, Dhert WJA, Oner FC, Niessen WJ. 3D Rotational X-Ray imaging for less invasive spine surgery. A quantitative validation study comparing reconstructed images with corresponding anatomical sections. In press *Spine* 2004.



5.
Verlaan JJ, van de Kraats EB, Oner FC, van Walsum Th, Niessen WJ, Dhert WJA. The reduction of fractured endplates during balloon vertebroplasty. A detailed radiological analysis of the treatment of burst fractures using pedicle screws, balloon vertebroplasty and calcium phosphate cement. Submitted to *Spine* 2004.

6.
Verlaan JJ, van de Kraats EB, Oner FC, van Walsum Th, Niessen WJ, Dhert WJA. Bone displacement and the role of longitudinal ligaments during balloon vertebroplasty in traumatic fractures. Submitted to *Spine* 2004.

7.
Verlaan JJ, Oner FC, Slootweg PJ, Verbout AJ, Dhert WJA. Histologic changes after vertebroplasty. In press *Journal of Bone and Joint Surgery (Am)* 2004.

8.
Verlaan JJ, Oner FC, Verbout AJ, Dhert WJA. Temperature elevation after vertebroplasty with polymethyl methacrylate in the goat spine. *J Biomed Mater Res.* 2003;67B:581-585.

9.
Verlaan JJ, Dhert WJA, Verbout AJ and Oner FC. Balloon vertebroplasty in combination with pedicle screw instrumentation: A novel technique to treat thoracic and lumbar burst fractures. Submitted to *Spine* 2004.

10.
Verlaan JJ, van der Veen AJ, Smit TH, Oner FC, Dhert WJA. Minimally invasive burst fracture treatment with an external fixator and balloon vertebroplasty. Submitted to *Spine* 2004.

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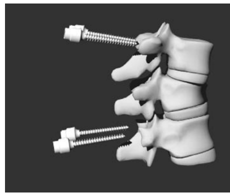
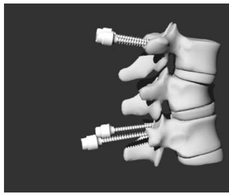


Chapter 1

Introduction to the surgical treatment of traumatic thoracolumbar fractures.

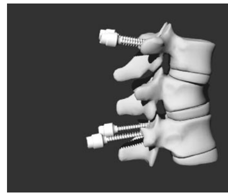


A traumatic fracture of the spine is a serious medical condition that can have a profound impact on the quality of life of a patient. Pain, spinal deformity, paraplegia, and even death are associated with the instability of the spinal column that can result from a fracture.[1-3] Although the true incidence of traumatic fractures is unknown, the number of traumatic burst fractures sustained annually in the United States is estimated to be approximately 25,000.[4] From a long history of general fracture management it has been learned that realignment and stabilization of fractured bone parts normally leads to healing of the fractured bone and functional recovery. In the appendicular skeleton, the path from traumatic fracture diagnosis to treatment is usually straightforward and therefore often successful. The management of traumatic spine fractures has, however, until the invention of X-rays in 1895 by Röntgen, been hampered by the impossibility of diagnosing a fracture with refinement or detail. Furthermore, contrary to the relatively simple geometry of long bones in the appendicular skeleton, the spine is an anatomically and biomechanically complex structure that cannot easily be aligned or immobilized if its mechanical integrity is violated. The difficulty of immobilizing the spine has led to a long-standing tradition of recumbency (bed rest), braces and casts for the treatment of traumatic conditions that still has many proponents today.[5,6] Notwithstanding the good results obtained with these methods for some types of spine fractures, gross instability has often confined patients to bed or other forms of immobilization for several months before fusion occurred. Furthermore, an imminent or progressive neurological deficit, as a consequence of spinal cord compression after, for example, dislocation, could not be treated adequately with a conservative approach. The obvious shortcomings of the regular treatment options in those days were recognized by surgeons who have used, on a regular basis since the midst of last century, various types of instrumentation that were originally developed for the treatment of scoliosis or appendicular skeleton fractures, to internally realign and stabilize the traumatized spine. Especially the Harrington rods and Roy-Camille plates both had obtained adequate results in reduction and long term stabilization of fractures and were used from the early '60s until well into the '80s.[7-12] However, the surgical treatment from this period was often accompanied by complications, and because the implants that were used had not been designed specifically for fracture stabilization, technical (hardware) failure was fairly common.[8,13] Retrospectively, the best indications for surgical intervention were probably the gross mechanical instabilities of the spine with rotational or translational displacement and/or neurological deficits; the benefits of treating less severe fractures were probably outbalanced by the complication rate and might better have been managed conservatively.

Contemporary techniques In the last two decades, two techniques have emerged that have become the standard in operative spine fracture management today. The first technique (and foremost, if number of published scientific papers and patients treated is taken into account) is the posterior pedicle-screw instrumentation introduced by Walter Dick in 1984.[14] This technique has proven to be efficient, reliable and safe for the reduction and stabilization of traumatic fractures and only fixated the directly adjacent levels compared to the multiple levels that were fused with the Harrington rods or any other previously used internal instrumentation. The relatively simple procedure, coupled to the shortest surgical duration and lowest blood loss has made the pedicle-screw instrumentation the most popular choice today among spine trauma professionals.[15] As with any surgical intervention though, its use has not been free of complications and it might, as an increasing amount of studies show, frequently have been used for indications where a more conservative treatment could have been just as, or even more, appropriate.[6,16,17]

The second technique is the anterior approach that was developed in the early '80s after computed tomography images of burst fractures showed that bone fragments were often present in the spinal canal of patients with neurological deficits.[18,19] It was reasoned that the bone fragments were, by occupying valuable space in the spinal canal, directly responsible for the neurological deficits. These fragments could typically not be completely reduced by indirect reduction via ligamentotaxis with the pedicle-screw instrumentation.[20] Using the anterior approach, the surgeon was able to directly visualize the fracture and could also completely remove any retropulsed bone that was located in the vicinity of the spinal cord. After a (partial) vertebrectomy was performed, the vertical defect could be bridged with a solid bone graft or metal cage to restore the support of the anterior column. The leading assumption was (and still *is* according to some authors) that the longer surgical duration, higher loss of blood and increased morbidity was justified by the clearance of the spinal canal, giving the spinal cord a better opportunity to recover.[3,21,22] Since the introduction of the anterior technique, however, several studies both of clinical and experimental nature, have not been able to prove the direct relation between the percentage of spinal canal area occupied by bone and neurological deficit, or a relation between surgical canal clearance and improved chances for neurological recovery.[23-25] It is suggested that the radiological findings obtained at admission probably do not adequately reflect the mechanical damage the spinal cord could have sustained during the traumatic impact itself, due to recoiling of bone fragments after impact.

Proponents of both surgical approaches have used many arguments to credit 'their' technique (and to discredit the other) but it is beyond doubt that both have become widespread with mainly retrospective case series (± 90 % of all reports in the literature are retrospective) as 'proof' of their effectiveness.[15] Unfortunately, a large-scale multi-center randomized controlled trial has never been conducted. The accumulation of over twenty years of indirect evidence has resulted in a lively debate between the respective advocates of the various treatment options, but not in a consensus about how to treat spine fractures. Although a large scale randomized controlled trial could (still) lead to conclusive data with respect to optimal treatment regime, the relatively low incidence of traumatic spine fractures and highly specialized care needed would necessitate an international academic effort that has until now, unfortunately, proved too difficult to realize.[26] As a first step towards making the (lower level of evidence) studies comparable, the introduction of fracture classification schemes using advanced imaging modalities, such as computed tomography and magnetic resonance imaging, has helped to improve the

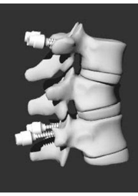


level of detail and reproducibility of the diagnosis.[27-29] Without a generally accepted fracture classification, any attempt to compare treatment effect would be doomed to fail.
Although not as convincing or powerful as a well-conducted randomized controlled trial, an important conclusion can be drawn from a systematic review of the current literature: stabilization of the fracture will, regardless of how it is achieved, eventually lead to good clinical results in the majority of cases. The exact duration of stabilization needed for good results has not been studied, but it has been hypothesized by many that it will take as long as necessary for the fracture to fuse and form a stable segment.[21,30-32] If indeed adequate stabilization is the key- (or at least most important) requirement for good outcome, the way to stabilize the fracture should be chosen as to minimize complications, morbidity and patient discomfort. It is in this respect that the spectrum of treatments, ranging from early ambulation with or without a brace, to circumferential (360º) osteosynthesis, can be investigated, since the perioperative complications, morbidity and patient discomfort are highly treatment specific and do not necessary correlate directly with fracture type or severity. Conservative therapy with a cast or brace, although appearing an ideal treatment in this light, might not be as innocent as it seems due to various complications associated with a long period of immobilization. On the other hand, the most thorough of operative fixations, the circumferential or combined anterior/posterior approach, is not free of some serious postoperative morbidity and could prove to be technical overtreatment to achieve adequate stabilization in many fractures.[2,33] Somewhere in-between these extremes lie the anterior and posterior short-segment procedures that received the greatest following.
Unfortunately, most surgeons are, due to practical, institutional and personal preferences, unlikely to get proficient with more than one approach, thereby effectively reinforcing the belief of superiority of their technique that prevents the initiation of a randomized controlled trial that could *prove* them right.

Performance assessment of past and contemporary techniques To gain an insight into the performance and complications of mainstream surgical techniques, a systematic review of the literature encompassing approximately the period from the first reports on the Roy-Camille and Harrington devices until present day practice, can be considered. This type of research can never replace a well-conducted randomized controlled trial, but is an established alternative to increase estimates of treatment effect, by pooling previously published data.[34-36] Since the '70s a large number of papers have been published on the outcome of spine fracture management, whence it seems feasible to collect enough data to learn the strong points and weaknesses of each technique. One of the objectives would be to learn under which circumstances, with respect to the various surgical techniques, further improvements in clinical outcome could most likely be gained.

Shortcomings of pedicle-screw instrumentation Notwithstanding the good results obtained normally, a relatively limited success of short-segment posterior (pedicle-screw) instrumentation was demonstrated by several authors, including from our own department, in the presence of extensive fracture comminution of the vertebral body.[16,28,37] In the 'Load Sharing Classification' paper, written by the group of Gaines in 1994, factors were investigated that could predict recurrent kyphosis and hardware failure.[28]
In this work the detailed morphology of the fracture, as demonstrated with radiographs and computed tomography, was used to assess the load transfer capabilities of the anterior spinal column after traumatic fractures. In a sequel study by the same group six years later, they demonstrated that the successful outcome of pedicle-screw fixation for burst fracture treatment depended on the proper selection of the fractures with the classification.[38]
In our own institution, Speth *et al.* demonstrated that a loss of fracture reduction leading to recurrent kyphosis, mainly took place in the disc space and was not the result of a collapsed vertebral body.[16] Oner demonstrated in his thesis, the corresponding relevant changes in disc space morphology in sixty-three trauma patients, on sagittal magnetic resonance images.[39]
Redistribution –creeping– of disc tissue, through the fractured central part of the endplate into the vertebral body, was the cause of recurrent kyphosis, not disc degeneration. This condition could lead to spinal deformity, pain and sometimes neurological deficit. Since it was demonstrated that pedicle-screw instrumentation was able to restore the periphery of the endplate adequately, but left the central depression largely untouched, it was suggested that a new technique for restoration of the endplate (and thus disc morphology) had to be developed.
In several studies, the anterior approach has been shown to lead to good alignment of the spine, although at a price.[21] Often a corpectomy had to be performed, requiring a massive autograft or cage implant, and the postoperative morbidity would often outweigh the advantage of immediate stability of the anterior spine.[40] In these instances it is debatable whether patients would actually benefit from such a treatment. Therefore, we required that a new technique be comparable to the pedicle-screw instrumentation in terms of burden to the patient. Two considerations were thought to be essential:
1 the optimal restoration of the anatomy of the fractured vertebral body, endplates and adjacent disc space;
2 the ability to maintain the restoration during the healing phase.

Vertebroplasty and balloon vertebroplasty for the reduction of endplates
For these two considerations, we adopted a new concept that has been used for the pain treatment of osteoporotic vertebral compression fractures. In 1987, Galibert and Deramond described a technique in which poly(methyl methacrylate) bone cement was injected through the pedicles into the vertebral body of patients with painful hemangiomas in that location.[41] The rationale behind the technique was that the cement would stabilize the vertebral body and decrease painful intravertebral micromotion. The results were encouraging with over 80 percent of the patients, treated in this manner, experiencing an immediate and long lasting pain relief.
The indication for this new treatment, called vertebroplasty, was subsequently expanded to osteoporotic compression fractures and osteolytic processes of the spine. A vast number of clinical trials has been conducted in the last decade to assess the feasibility and safety of vertebroplasty.[42-49] The results have been largely similar; good results obtained in a majority of



patients with low complication rates. However, cement leakage often occurred and has incidentally resulted in major complications such as spinal cord compression, pulmonary embolism and even death.[50-54]
In 1997, the US based company Kyphon patented inflatable bone tamps to be used in a vertebroplasty procedure prior to the injection of cement. With these bone tamps, voids could be created in osteoporotic vertebral bodies to facilitate the low-pressure injection of poly(methyl methacrylate) cement, thereby lowering the risk for cement extravasation.[55] This technique to treat osteoporotic compression fractures with balloons and subsequent cement injection has become known as 'balloon vertebroplasty', 'balloon kyphoplasty' or just 'kyphoplasty'. Several studies have shown that by using this technique, the complication rate could be decreased even more while inflation of the balloons might also achieve some restoration of vertebral body height in some patients, although convincing evidence is limited.[49,56-58] In a cadaveric study, Belkoff *et al.* demonstrated that balloon vertebroplasty was able to significantly restore compressed vertebral bodies that were under load, simulating in vivo conditions.[59] However, no data were provided on the amount of vertebral body height loss after deflation of the balloons. It is currently under discussion whether a significant amount of fracture reduction can be achieved with this technique in patients and what clinical relevance this might represent. Disadvantages of the technique are the more difficult procedure and the very expensive (disposable) instrumentation that is needed.
During the reduction of burst fractures with posterior instrumentation, distraction is performed to achieve anatomical alignment, restore the vertebral body height and reduce bone fragments by ligamentotaxis.[60-62] In the work by Oner *et al.* it was shown that distraction of burst fractures resulted in the height restoration at the periphery of the vertebral body but the impression of the endplate persisted.[29,63] A possible explanation for this phenomenon can be found in the physiologic and anatomical properties of the intervertebral disc. The annulus fibrosis of the intervertebral disc is firmly attached to the outer rim of the vertebral body. Hence, it is reasonable to suggest that distraction of the levels adjacent to the fractured vertebral body leads, via the annulus fibrosis, to a distracting force exerted on the outer rim of the fractured vertebral body. The nucleus pulposus, on the other hand, is not rigidly attached to the vertebral body but is encapsulated between the lower and upper endplate of the two adjacent vertebral bodies and the annulus fibrosis.[64-66] The elasticity of the intervertebral disc is caused by the water molecule attracting chemical properties of the nucleus pulposus and it has been demonstrated by Sato *et al.* that the intradiscal pressure in healthy volunteers is approximately 91 kPa in prone position.[67] The expansion of the nucleus pulposus is limited by the boundaries described above, therefore the endplate of a fractured vertebral body will probably be under constant pressure by the intervertebral disc, even after distraction. This persistence of pressure on the fractured endplate might be the key to the problem of reducing the endplate of burst fractures indirectly (i.e. with pedicle-screw constructs) and could be responsible for the observed failures.
It was hypothesized that the balloons could be used to directly restore the endplate of the burst vertebral body, after the pedicle-screw instrumentation reduced and stabilized the fracture first.

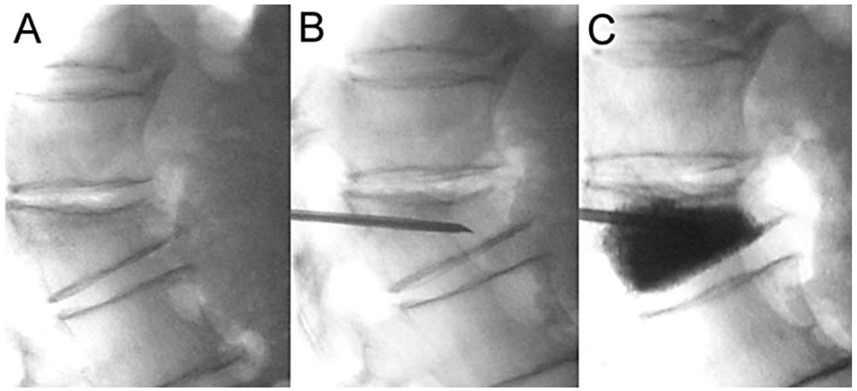


Figure 1 **Vertebroplasty: Lateral fluoroscopic image series demonstrating**

A
An osteoporotic vertebral compression fracture.

B
The same fracture with a biopsy needle inserted through a pedicle.

C
The same fracture after stabilization with PMMA cement.

Poly(methyl methacrylate) cement and calcium phosphate cement as bone void fillers Since most patients with burst fractures are otherwise healthy and relatively young (in most clinical studies the mean age is approximately 35 years) it is to be expected that the elasticity and intradiscal pressure are largely comparable to the results from the study by Sato *et al.*[15,67] This finding might imply that deflation and removal of the balloons will be followed by loss of the achieved reduction of the endplate as a direct result of the counter-pressure from the intravertebral disc. Therefore, a bone void filler should be used to immediately fill the defects in the vertebral body after balloon removal. This bone void filler, ideally, would have the following characteristics:

- injectable through the, relatively small, diameter of a pedicle;
- short setting time;
- isothermic curing;
- adequate stiffness and failure strength;
- bioresorbable.

In (balloon) vertebroplasty for osteoporotic compression fractures, poly(methyl methacrylate) has been the mostly used cement. This cement has already been used for decades in total joint arthroplasty and its properties are well-studied.[68-72] It is strong and provides almost immediate support due to the short setting time. Two main disadvantages of poly(methyl methacrylate) have been recognized. The cement sets during an exothermic polymerization process and is not bioresorbable.[73-80] These properties might not pose a problem during, for example total hip arthroplasty, but for spinal applications this might prove unfavorable. Although the incidence is low, leakage of cement into the spinal canal after (balloon) vertebroplasty has been described. In the proximity of the vulnerable spinal cord an exothermally curing cement can cause irreversible damage.[74,78] The inert nature of poly(methyl methacrylate) cement is mainly a concern for young patients. Several studies have demonstrated osteolytic processes to occur when poly(methyl methacrylate) particles have formed.[81,82] In the spine of osteoporotic patients, a group that in general consists of elderly humans, chances for these events to become a problem are probably not large due to their relatively short life expectancy. However, for young and active patients with burst fractures, the long term consequences of injecting poly(methyl methacrylate) cement in the vertebral body are an important consideration and some reluctance is justified.[83]

Approximately twenty years ago a new bone void filler, hydraulic calcium phosphate cement, was discovered by Brown and Chow that might provide an interesting alternative to poly(methyl methacrylate) cement.[84] Their cement consists of dicalcium phosphate and tetracalcium phosphate that, if mixed in equimolar amounts in an aqueous solution at room temperature, forms a porous cement consisting of hydroxyapatite. The chemical reaction proceeds isothermally and is completed after approximately 24 hours, although a considerable compressive strength is already achieved after four hours.[84,85] Calcium phosphate cements have extensively been studied in both in vivo and in vitro conditions and their properties are well documented.[86-88] This type of cement is comparable in compressive stiffness to poly(methyl methacrylate) cement, but it is much more fragile due to the very low intrinsic tensile strength.[89,90] The biocompatibility is superior to poly(methyl methacrylate) cement, since it can be resorbed in ‘creeping substitution’ by combined osteoclast/osteoblast activity.[91] The speed at which the cement is replaced by bone is dependent on various factors, including chemical structure and porosity but probably also on host-specific factors such as general rate of bone turn-over, mechanical stimulation and/or stress shielding.[91-93] Several other calcium phosphate cements have now been developed that differ (slightly) in chemical composition, porosity and biodegradability.[94-96] Considering the properties of poly(methyl methacrylate) cement and calcium phosphate cement, the choice for the latter as bone void filler in young burst fracture patients seems defendable. In fractures where shear forces are to be expected (such as B-type and especially C-type fractures), however, calcium phosphate cement will probably fail to maintain its integrity and should therefore be protected by a rigid (posterior) instrumentation to neutralize these forces.

Imaging during spinal interventions Minimally invasive procedures have successfully replaced a large number of open procedures in various disciplines of medicine and often resulted in less complications, shorter hospital stay and lower costs.[97-101] One of the main drawbacks of performing minimally- or less invasive procedures is the inherent decreased direct view of the operating area. Various endoscopical and radiological techniques have been invented to allow sufficient visualization of the field of interest. Imaging during spinal procedures relies heavily on two imaging modalities; computed tomography (CT) and fluoroscopy. While CT is able to provide high-resolution images and can perform multi-planar reformatting (slicing through a 3D volume at the user’s preference), it is a cumbersome device during surgical interventions because of size, the relatively long delay in the display of images, and operating area accessibility/sterility concerns during interventions. Its strengths lie mainly in diagnostics. Fluoroscopy, sometimes also in combination with computer navigation equipment, is frequently used in the operating theatre due to its mobility, ease of use, and near instant display of images of the region of interest. However, the images from this modality are of poor quality compared to CT and are always restricted to the projected two-dimensional plane. Newer (computer-based) techniques such as image guided surgery systems have, until now, hardly resulted in benefits to the patient due to longer surgical durations, additional tissue dissection for registration (matching the ‘virtual’ and the ‘real’ patient) purposes and the lack of image updating possibilities during the intervention.[102,103] The potential advantages of these computer-assisted techniques are offset by the drawbacks and will remain so until the registration process can be realized quickly and, more important, non-invasively.

Exploring a new imaging modality (3DRX) for use in less invasive procedures A new technique, called three-dimensional rotational X-ray imaging (3DRX), has the potential to merge the positive properties of both CT and fluoroscopy.[104-106] The 3DRX device obtains multiple images (similar to a fluoroscopic device) during a 180-degree rotation around the object of interest (more or less in analogy with the concept of a CT scanner) and can, by processing the images in a workstation, provide true 3D visualizations and perform multi-planar and volumetric reformatting, but also display ‘simple’ 2D projection images quickly. The novelty of the technique is mainly the processing of images into a 3D volume; the imaging hardware is largely conventional and already installed in radiology suites of many hospitals. Although the 3DRX technique is considered an attractive imaging modality for (the development and practice of) less and minimally invasive interventions, its use until now has always been for gaining global insight in three-dimensional structures (for example: the location and shape of cranial aneurysms), instead of using the quantitative information in the image. To use this technique, for example, to place instruments through the pedicles into a vertebral body however, the displayed anatomic features have to be very accurate

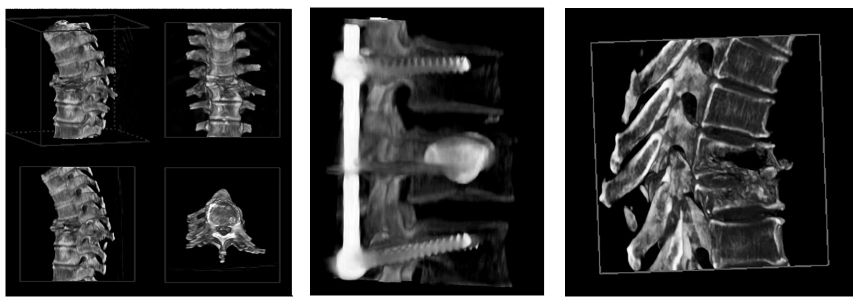
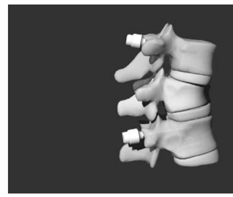


Figure 2

3DRX 1-3: Various reconstructed 3DRX images obtained from the dataset of experimental thoracolumbar spine specimens. These images show the high level of detail and volumetric reformatting options of this imaging technique.

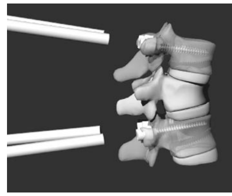


since vulnerable structures, such as the spinal cord, are close by. A validation study establishing the accuracy of the reconstructed images could render this imaging modality useful for diagnostic, interventional and research purposes.

Towards a less invasive approach As mentioned before, the most widely used instrumentation for traumatic (burst-) fractures of the thoracic and lumbar spine is the pedicle-screw fixation first described by Walter Dick in 1984. Its principle is based on the external spine fixator invented by Friedrich Magerl that was the first minimally invasive device for treatment of traumatic fractures.[107] The external spine fixator consisted of two metal plates to which transpedicular Schanz screws, seated in the vertebral bodies of the levels adjacent to the fracture, could be attached. The plates were connected with three threaded rods that, after rotation of one or more of the rods, allowed the plates to be translated and angled relative to each other. With this device, fracture reduction and fixation was possible with only the four 6.0 millimeter diameter screws entering the patient's body percutaneously. After healing of the fracture, the screws could be removed without the need for another operation. Unfortunately, the aftercare for the patient was less elegant. The patient had to wear the bulky device permanently for four to sometimes six months before fusion occurred. All this time, the four stab wounds had to be cleaned daily otherwise abscesses would form subcutaneously. In this respect its successor, the internal fixator, was a big improvement since it could be 'placed and forgotten'.[14]
However, for some types of fracture, such as A types according to the Comprehensive Classification (representing the majority of spine fractures, by the way), it is still not clear whether this type of surgical intervention is really superior to a more conservative approach.[6,17,108] For these patients it can be argued that placement of the internal fixator is overtreatment.
In these instances patients could also be treated functionally, in combination with analgesics or with (a short period of) bed rest. It is clear from the literature that most of these patients will eventually end up with the same clinical (functional) outcome as patients who were treated with pedicle-screw fixation.[6,25] However, it is also clear from the literature that these conservatively treated patients often have a worse radiological outcome, meaning pronounced wedge and kyphosis angles of the affected part of the spine.[109-111]
This finding is very likely based on the same mechanism of endplate impression and disc redistribution as described and discussed earlier. Although the clinical outcome of patients from these studies (with mean follow-up periods of between two and five years typically) may be the same as surgically treated patients, little is known about the chance of degeneration or discomfort of this more deformed spine later in life. It might be interesting to learn whether the (now virtually defunct) external spine fixator in combination with newer techniques such as vertebroplasty and/or balloon vertebroplasty with calcium phosphate or poly(methyl methacrylate) cement, can be of value in the treatment of these patients. This less invasive treatment could consist of the percutaneous placement of Schanz screws and subsequent fracture reduction and fixation, followed by endplate reduction and anterior column augmentation using inflatable bone tamps and a bone void filler. The anterior column might be sufficiently augmented (in these A type fractures, the anterior column has only been subjected to axial forces) after the (balloon-) vertebroplasty procedure to warrant removal of the screws after setting of the cement, which would normally be within 24 hours.
Another interesting less invasive treatment option would be the development of an expandable implant that can be inserted percutaneously and act as a strut within the fractured vertebral body. If provided with a means to deliver a bone void filler intravertebrally, it might be used as a stand-alone implant to reduce and fixate burst fractures combining the advantages of the external spine fixator (just stab-incisions needed for insertion) and the internal spine fixator ('place and forget').
In this thesis the investigation and discussion of the ideas and considerations mentioned above are described.

Questions to be addressed in this thesis

- what can be learned from previously published papers with respect to the performance and outcome of surgical treatment of traumatic thoracolumbar fractures?
- can a new imaging modality, 3D rotational X-ray imaging, be used for an accurate intraoperative 2D/3D visualization of the human spine?
- can balloon vertebroplasty with calcium phosphate cement in combination with posterior instrumentation safely be used for the direct restoration of thoracolumbar burst fractures?
- what is the biological response of surrounding tissue after injection of poly(methyl methacrylate) cement or calcium phosphate cement in the vertebral body?
- can minimally invasive techniques be used for the treatment of traumatic fractures of the thoracolumbar spine?



Contents of this thesis From the abundance of international publications pertaining to the performance of surgical spine fracture management, our aim was to learn where improvements in patient outcome were most likely to be found. In **Chapter 2**, a systematic review of the literature is presented that evaluates the technique, outcome and complications of the treatment of traumatic fractures of the thoracolumbar spine from the period 1970-2001.
In **Chapter 3**, the text from an interview held with Friedrich Magerl, inventor of the AO external spine fixator, AO internal fixator, and the AO comprehensive spine fracture classification, is presented. In this chapter, his views on the history and current status of traumatic spine fracture management are represented.
In order to evaluate a new technique to restore the anatomy of traumatic burst fractures of the spine, an *in vitro* study was designed. **Chapter 4** reports on the feasibility and safety of balloon vertebroplasty with calcium phosphate cement after posterior instrumentation for the treatment of burst fractures in human cadaveric thoracolumbar spines.
The thorough assessment of the accuracy of a promising new imaging modality, that could be used intraoperatively, was called for in a controlled experimental setting. **Chapter 5** addresses the validation of the 3D Rotational X-ray imaging technique by quantitatively comparing reconstructed images with corresponding anatomical sections. In **Chapter 6**, a human cadaveric

study is presented in which the 3DRX technique is used to quantitatively assess the reduction of the endplates during balloon vertebroplasty for burst fractures after posterior fixation.

The study from **Chapter 7** is a sequel of the aforementioned study and addresses the feasibility and safety of treating B-type and C-type fractures using the same experimental techniques. The importance of intact longitudinal ligaments for the reduction of retropulsed bone fragments and chance of cement leakage is assessed. In **Chapter 8**, differences in histology after vertebroplasty with calcium phosphate cement and poly(methyl methacrylate) cement are investigated in an animal (goat) model with intact and fractured endplates. In **Chapter 9**, the temperature elevation of surrounding tissues after vertebroplasty with poly(methyl methacrylate) cement in the goat spine is studied. **Chapter 10** describes the preliminary results of balloon vertebroplasty with calcium phosphate cement as an additional procedure to pedicle-screw fixation in twenty patients with traumatic burst fractures. In **Chapter 11**, the restoration of vertebral body height and axial stiffness is evaluated in a cadaveric burst fracture model in which the external spine fixator is used in combination with balloon vertebroplasty with calcium phosphate cement. In **Chapter 12**, the design of a device is proposed, that could be used as a stand-alone implant for the treatment of osteoporotic and traumatic spine fractures.

The last chapter, **Chapter 13**, is reserved for a discussion of the previous chapters, conclusions, and proposes some future perspectives.

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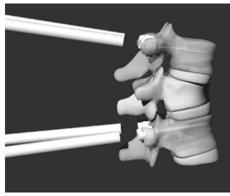

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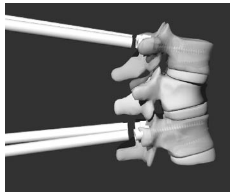

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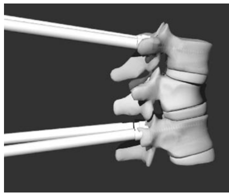
Chapter 2

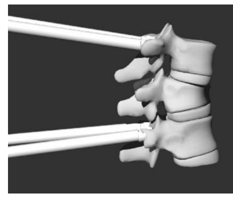
Surgical treatment of traumatic fractures of the thoracic and lumbar spine. A systematic review of the literature on techniques, complications and outcome.

Verlaan JJ, Diekerhof CH, Buskens E, van der Tweel I, Verbout AJ, Dhert WJA, Oner FC. ***Spine*** **2004;29(7):803-14.**



Introduction

The management of traumatic fractures of the thoracic and lumbar spine remains controversial. A large number of publications, describing various surgical techniques for the reduction and fixation of spinal fractures, followed by discussions among the authors has not led to a general consensus on the optimal treatment.[1,2] There is insufficient evidence in the literature to choose between the various options. Different ‘schools’ may all claim to be providing the optimal care yet evidence-based guidelines are not available. Irrefutable proof of treatment superiority would, in theory, most easily be obtained by performing a prospective randomized multi-center trial directly comparing the different treatment options. Until now the difficulties in executing a study comparing the performance of operative treatments for traumatic spinal fractures in a reasonable timeframe, have appeared insuperable. In general, surgical treatment of fractures of the thoracic and lumbar spine is deemed necessary if the biomechanical stability of the spine is severely compromised and/or if a neurological deficit is imminent or already present.[3-11] Several operative methods exist to achieve fracture reduction and fixation, but none has a proven advantage in terms of patient outcome in comparison with others. The first widely used effective technique was by distraction and fixation using Harrington rods, originally developed for scoliosis correction in the late ’50s. This became the standard operative procedure for the stabilization of vertebral fractures of the thoracic and lumbar spine during the ’70s and ’80s.[12] Drawbacks included the need for multiple segment fixation, the inability to correct the deformity in all three dimensions, the frequent hook-dislodgement and the biomechanically disadvantageous posterior fixation points often leading to a recurrent kyphosis. The practice of ‘rod long, fuse short’ to prevent fusion of multiple healthy segments, technical evolution of the implants and modifications to the surgical technique did little to overcome the limitations of this type of surgery. Roy-Camille *et al.* reported the first use of posterior plates with screws placed in the pedicles.[13-15] The major benefit of this technique was its ability to obtain and maintain a satisfactory reduction of the fracture with fewer instrumented levels compared to the Harrington system. After computer tomography imaging of spinal fractures became possible in the ’70s, the so-visualized bony fragments that compressed the neural structures in the spinal canal led some surgeons to develop anterior decompression and fixation techniques. The rationale behind this surgical technique was to improve the neurological status of the patient by direct decompression of the spinal cord under visual inspection compared to the indirect, and incomplete, decompression that resulted from ligamentotaxis by the posterior techniques that are mainly performed without direct access to the spinal canal. Dunn and Kaneda were among the first authors to describe the indications, techniques and results of the anterior approach.[16-18] Subsequently, the combined anterior and posterior technique was developed as an augmentation of the single approach, either anterior or posterior, to provide fracture stability in all the three planes and prevent recurrent kyphosis. Unfortunately, all described techniques have appeared in clinical practice without proper randomized controlled trials to prove their efficacy and any comparison has only yielded lively debate by their respective advocates. Since then, a few small randomized controlled trials comparing the different anterior and posterior techniques have been published in the literature, therefore the present authors presume that most institutions have specialized largely in one approach.[19,20] This training-/surgeon-/institution dependent preference for a technique could be one of the main reasons a randomized trial within a center has proven difficult to perform, the relatively small numbers of traumatic vertebral fractures per center as well as their diversity being potential co-factors. In absence of conclusive studies, a systematic review or meta-analysis can be an alternative to obtain more convincing information. Combining existing data from previously published articles can lead to better estimates of effect. Overall validity, however, still depends on the design of the original studies.[21,22] Numerous papers, the majority based on retrospective studies, describing the various surgical spinal techniques and their respective outcomes in detail, have been published. To the authors’ best knowledge, the only meta-analysis on the outcome of operative spinal fracture management was performed by Dickman in 1994.[23] The main conclusion of this study, which covered the period from 1975 to 1993, was a significantly better performance with pedicle-screw based implants compared to anterior instrumentation and hook-rod devices. Insufficient data, however, prevented comparison of the radiological deformity and neurological recovery from admission to follow-up for the different techniques. Many publications about the results of various operative techniques have appeared in the literature since this review. In the present study, we performed a systematic review of the different techniques, their respective outcome in terms of radiological deformity, neurological recovery, pain, employment and complications reported in the literature from 1970 to 2001.



Materials and Methods

In order to identify the relevant publications on surgical treatment of traumatic thoracic and lumbar spinal fractures, a Medline thesaurus search (database 1970-2001) was performed. From the results of the search parameter ‘spinal fractures’ references containing ‘osteoporosis’, ‘cervical’, ‘odontoid’, ‘axis’ and ‘atlas’ in the medical subject headings were excluded. The remaining references were combined with the search parameter ‘surgery’. From the results of this step, articles in languages other than English, German and French and articles without an abstract or published before 1970 were excluded. Next, the abstracts of the resulting references were read and the articles were included in the database (Reference Manager Professional Edition 9.0) if all of the following criteria were met:

- the patients were adults;
- the number of patients treated surgically was 10 or greater;
- the follow-up of the patients was twelve months or longer;
- the fractures were clearly caused by adequate trauma;
- the time from trauma to surgery was less than or equal to three weeks;
- the surgical procedure or procedures was/were sufficiently described;
- outcome criteria (clinical, neurological, radiological) were presented in generally accepted and comparable scores.

After collection of all relevant full-text papers, the whole contents were read and the articles meeting all inclusion criteria were included in the final database. A cross-reference search was performed to obtain the remaining relevant articles. Two of the authors (JJV and CHD) did all the actual close-reading and data extraction of papers independently to minimize selection bias and errors. A scoring chart was designed for clearly defined data extraction and recording (Table 1). The data obtained from both readers were compared and where parameters differed, the pertaining paper was re-read until a value for the parameter could be agreed on. Multiple publications from one author, group of authors or institution were checked for overlap and, if present, the least informative paper was excluded. Following deletion of all values that could not be fitted in the pre-defined categories, the data were imported in an electronic spreadsheet (Excel, Microsoft Office) for further processing. Based on the reading of all articles, we recognized five basic operative approaches reported:

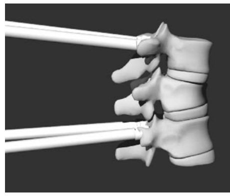
- The first subgroup comprised of papers reporting exclusively on posterior fracture reduction and fixation with the instrumentation bridging one or two disc-spaces, the so-called posterior short-segment instrumentation (PS);
- The second subgroup consisted of the papers reporting exclusively on posterior fracture reduction and fixation bridging more than two disc spaces, the so-called posterior long-segment instrumentation (PL);

Table 1. Parameters extracted from the papers

Parameter	Definition
name and affiliation of the authors	
year of publication and name of the journal	
study design	prospective, retrospective
follow-up	months
gender ratio	number of males divided by the total number of patients
mean patient age	years
radiological deformity	mean Cobb angle in degrees
neurological status	classical Frankel score (Frankel A-E)
fracture level	thoracic, lumbar or thoracolumbar (Th11-L2)
fracture type	compression-, burst-, flexion/extension- or rotation type
polytrauma	percentage polytrauma patients of the total number
implant type	as described by the authors
peri-operative bloodloss	milliliters
duration of surgery	minutes
graft type	autograft, allograft or xenograft
transpedicular spongiosaplasty	number of patients
hospital stay from admission to discharge	days
method of post-operative immobilization	brace, plaster jacket or none
duration of post-operative immobilization	weeks
post-operative complications	temporary neurological deterioration, deep venous thrombosis, pulmonary embolism, superficial infection, deep infection, implant malposition, early implant failure (< 3 months) and miscellaneous complications (scored if reported at least two times in the total study population)
late (> 3 months) implant failures	broken, loosened, dislodged or severely bended implants or parts of implants
non-elective re-operations	number of patients re-operated on a (semi-)urgent basis with an indication related directly to the primary surgery
pain	Denis pain scale[90]
employment	Denis work scale for previously employed patients[90]

- The third subgroup consisted of papers in which short-segment and long-segment techniques were reported together or compared directly, i.e. the posterior short- or long-segment instrumentation (PSL). This group represented the transition period in which the long-segment technique became gradually replaced by the short-segment technique;
- The fourth group comprised the papers reporting exclusively on the anterior decompression and reduction/fixation technique, the anterior instrumentation (A);
- The fifth subgroup consisted of the papers reporting exclusively on the combined anterior and posterior technique (although not necessarily performed in that order surgically), the so-called anterior and posterior combined instrumentation (AP).

Articles that did not fit in the strict separation regime were excluded from the database leaving clearly defined surgical groups in the end. The groups were subsequently analyzed quantitatively for pre-operative comparability using the most readily available parameters: Cobb angle (angle between the superior endplate one level above the fracture and the inferior endplate one level below), fracture type (i.e. burst fracture, flexion/extension fracture or rotation/dislocation fracture corresponding to the A-type, B-type and C-type respectively in the AO-classification[24]) and percentage of polytrauma patients. The AP group was left out of this pre-operative comparison due to the limited number of patients. The statistical techniques used were one-way analysis of variance for the Cobb angle with Dunnet's correction for multiple comparisons with the same reference group, multinomial logistic regression analysis to assess the relation of the surgical group with the fracture type and a meta-analysis of variance for polytrauma percentage comparison resulting in weighted, pooled estimates for the percentages.[25] For all analyses, PS was taken as the reference group as this represented the largest number of patients reported. The level at which the fracture occurred was not compared as abundant evidence from the literature shows the vast majority of all traumatic fractures to occur at the thoracolumbar junction defined here from the eleventh thoracic vertebra to, and including, the second lumbar vertebra.[26-28] The subsequent surgical and post-operative data were assessed within the surgical groups as well as the clinical and radiological performance at final follow-up.



Results

The literature search and cross-referencing, resulted in a total of 376 references of which 186 were rejected due to the off-topic content of their abstracts or the failure to meet the inclusion criteria. From the remaining 190 papers the full-texts were read and the data extracted. A further 58 papers were excluded on the basis of inadequate distinction between surgical groups (n=25), insufficient or vague data (n=20), overlap with another paper from the same author or institution (n=9) and delayed time from trauma to surgery (n=4). The remaining 132 papers, consisting of 117 (=88.6%) retrospective case-series, 13 (=9.8%) prospective case-series and 2 (=1.6%) randomized controlled trials, described the treatment of 5748 patients with the following distribution;

PS **2075 patients**[2,3,19,20,29-74]
PL **1870 patients**[75-123]
PSL **879 patients**[124-141]
A **607 patients**[2,18-20,28,46,61,75,99,110,112,126,128,139,142-151]
AP **317 patients**[2,33,34,41,61,66,75,78,85,96,125,128,135,139,145,147,152,153]

General information on the study population The mean duration of follow-up for the five subgroups was between 28 and 35 months. The mean age of the patients was 33 to 34 years while 69 to 74 percent were of male gender. Most reports (67%) were on patients treated, on average, between 1988 and 1990 although the patients from the PL group were treated around 1983. Table 2 and Figure 1 present further details on the study population.

Pre-operative status of the study population The mean pre-operative Cobb-angle varied between 13.8° for the PS group and 22° for the A group. The difference between the reference (PS) group and all other groups was significant ($p < 0.001$). Burst fractures were the most frequently diagnosed injuries with a mean incidence between 60% for the PL group and 82% for the A group. The PL group and the A group contained significantly less ($p < 0.05$) and more ($p < 0.01$) burst fractures respectively than the reference group. Flexion/extension fractures accounted for 1-10% of all fractures with a statistically significant ($p \leq 0.05$) higher number of these fractures in the PSL group compared to the reference group PS. Rotation-dislocation fractures accounted for 11-28% of all fractures with a statistically significant ($p < 0.05$) lower percentage of these fractures in the A group and a significant ($p < 0.01$) higher percentage in the PSL and PL group compared to the reference group. Polytrauma patients accounted for 25% of the PS group (CI: 16%-38%), 52% of the PL group (CI: 34%-70%), 31% of the PSL group (CI: 12%-60%), and 56% of the A group (CI: 27%-81%). The difference relative to the reference group (PS) with respect to the polytrauma percentage was statistically significant for the PL group ($0.001 < p < 0.01$) and for the A group ($0.02 < p < 0.05$) but not for the PSL group. Table 3 lists the details of the above-mentioned pre-operative parameters for the five groups. The pre-operative neurological data (Table 4) show a difference between the surgical groups with respect to neurologically intact (Frankel E) and mildly impaired (Frankel D) patients. In all groups except A, the percentage of patients without neurological deficits was above 30% (14% for group A) while the percentage of mildly impaired patients (Frankel D) was below 20% for the posterior groups and 63% for the A group. For the remaining Frankel scales (A-C) no obvious differences were apparent between the groups.

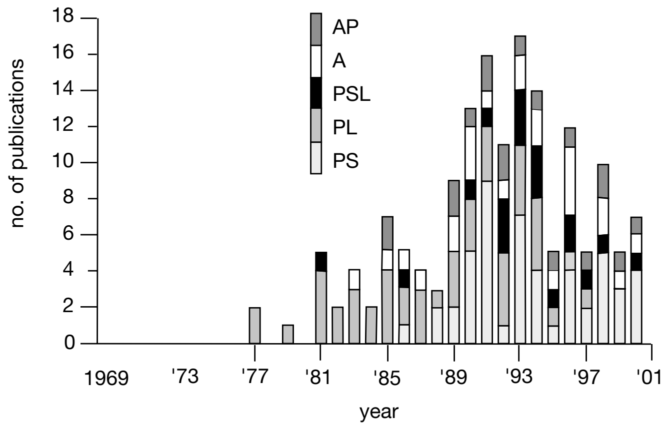


Figure 1.

The number of publications per year for the subgroups. Note that, because more than one subgroup could be reported in a single paper, n > 132.

Table 2. General information on the study population

Patients/studies	PS 2075/50	PL 1870/49	PSL 879/18	A 607/24	AP 317/18
follow-up (months)	30	33	28	32	35
range	12-77	12-85	12-79	12-96	15-79
mean age (years)	34	33	33	33	33
range	27-43	25-46	27-38	27-41	29-40
gender-ratio	0.69	0.74	0.73	0.71	0.71
range	0.47-0.90	0.55-1.00	0.54-0.85	0.53-1.00	0.53-0.90

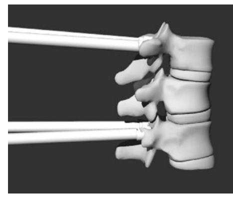


Table 3. Pre-operative status of the study population

Fracture characteristics	PS	PL	PSL	A	AP
Type (%), patients reported→	1328	1227	473	179	65
compression type	11	10	7	1	5
burst type	68	60	67	82	66
flexion-extension type	10	9	4	6	1
rotation-dislocation type	11	21	22	12	28
Level, patients reported→	1179	677	374	293	35
thoracic level	2	8	7	1	6
thoracolumbar level	82	85	76	84	60
lumbar level	16	7	17	15	34
Cobb angle, patients reported→	1206	1309	366	255	75
mean Cobb-angle	13.8°	18.9°	15.4°	22.0°	17.5°
std deviation	5.2	5.3	4.8	5.3	6.5

Table 4. Pre-operative neurological status of the study population

Neurological status (%)	PS	PL	PSL	A	AP
patients reported→	1013	1136	569	286	74
Frankel A	12	23	20	4	20
Frankel B	6	10	9	7	14
Frankel C	14	17	22	12	4
Frankel D	17	19	17	63	23
Frankel E	52	32	33	14	39

Table 5. Surgical information on the study population

Number of reports	PS	PL	PSL	A	AP
pedicle screw/rod	54	1	14	0	13
pedicle screw/hook/rod	1	6	0	0	1
hook/rod	2	43	9	0	9
plates	2	5	6	17	4
wires	1	0	0	0	0
rods	0	0	0	14	4
solid bone grafts	0	0	0	3	15
Transpedicular spongiosaplasty					
patients reported→	750	0	59	0	0
Blood loss, duration					
patients reported→	523	522	270	226	186
median blood loss (ml)	828	1250	1277	1362	1453
range	330-1602	200-3175	380-1856	829-2338	820-2541
patients reported→	488	474	270	112	186
median duration (min)	153	202	221	275	412
range	110-330	80-280	169-354	210-438	252-635

In summary, these combined pre-operative data (Cobb angle, polytrauma percentage and neurological status) suggest that the A group contained the most severely injured patients, the PS group contained the least injured patients and the injury severity of the other groups was in-between.

Surgical information on the study population The most frequently used posterior implant was the pedicle screw and rod system followed by the hook-rod system. Other, sparsely used, implants were pedicle screws in combination with hooks and rods ('hybrids'), plates and wires. Transpedicular spongiosaplasty additional to posterior instrumentation, was performed in 809 patients. In the anterior surgery groups (A and AP) plates, rods and solid bone grafts (mostly in combination with metal implants although sometimes as a stand-alone implant) were used as anterior implants. In the AP group additional pedicle screw and rod systems, rod-hook systems and rod-hook pedicle screw hybrid systems were used as posterior implants. Transpedicular spongiosaplasty was not performed in these two groups.
The median intra-operative blood loss varied from 828 milliliter for the PS group to 1453 milliliter for the AP group. The median operation time ranged from 153 for the PS group to 412 minutes for the AP group. See also Table 5 for a detailed overview of implants used, blood loss and surgical duration of each group.

Table 6. Post-operative results

Hospital stay	PS	PL	PSL	A	AP
patients reported→	634	765	364	241	15
median duration (days)	16	35	19	18	22
range	10-43	14-144	9-207	12-42	15-28

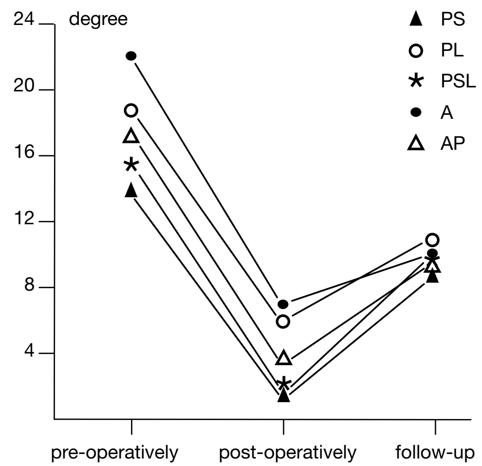


Figure 2.

Graphical representation of the Cobb-angle, in degrees, for the subgroups at three time-points: pre-operatively, post-operatively and at follow-up.

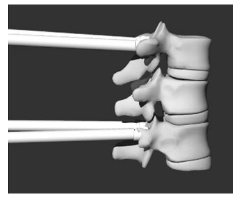
Table 7. General complications

Complications (%)	PS	PL	PSL	A	AP
patients reported→	1508	1514	674	457	151
temp. neurologic deterioration	0.6	0.9	0.7	0.2	0.7
deep venous thrombosis	0.1	2.4	0.6	0.4	0.7
pulmonary embolism	0.1	0.9	0.3	0.4	2.0
superficial infection	0.9	2.0	0.7	0.7	0.0
deep infection	1.6	1.4	3.1	0.7	2.0
implant malposition	3.4	1.7	8.3	1.4	2.0
early implant failure	2.1	3.7	2.8	2.8	0.0
miscellaneous	2.9	9.4	4.8	12.2	4.6

Table 8. Miscellaneous complications

Misc. complications (n)	PS	PL	PSL	A	AP
patients reported→	1508	1514	674	457	151
aseptic bone necrosis[1]	11	nr	nr	nr	nr
atelectasis	nr	nr	nr	11	nr
death	3	5	2	nr	4
decubitus	4	28	7	nr	nr
dural tear	5	3	6	1	1
gastric ulcer	nr	2	1	nr	nr
ileus	2	nr	nr	nr	nr
lamina fractures	nr	4	nr	nr	nr
meningitis	nr	2	1	nr	1
pain at donorsite (crista)	1	nr	6	8	nr
peri-articular ossification	nr	3	nr	nr	nr
pneumonia	3	5	1	nr	nr
pneumo/haemato-thorax	nr	nr	nr	3	1
pseudoarthrosis	nr	nr	nr	4	nr
seroma/haematoma	5	nr	1	4	nr
sympathectomy effects	nr	nr	nr	15	nr
transfusion hepatitis	nr	nr	2	nr	nr
transient dysaesthesia	nr	nr	nr	5	nr
urinary tract infection	10	91	6	5	nr
total	44	143	33	56	7
(% of total)	(2.9%)	(9.4%)	(4.8%)	(12.2%)	(4.6%)

nr = not reported, [1]= of graft after transpedicular spongiosaplasty



Post-operative results The median length of hospital stay ranged from 16 days for the PS group to 35 days for the PL group. See also Table 6. The mean Cobb-angle post-operatively was 1.1° for the PS group representing an average correction of 12.8°. For the PL group the mean post-operative angle was 5.9° with a correction of 13.0°. In the PSL group the mean angle post-operatively was 1.3° with a correction of 14.1°. For the A group it was 6.9° with a correction of 15.1° and for the AP group it was 3.4° with a correction of 14.1°. See also Figure 2 for a visual representation of the Cobb angle in the different groups over time. General complications of the surgery were relatively rare and differences between the surgical groups were small (Table 7). Table 8 presents a detailed overview of the miscellaneous complications per surgical group.

Results at follow-up At follow-up the mean Cobb-angle from the PS group was 8.7° representing a correction loss of 7.6° since surgery. For the PL group the mean Cobb-angle at follow-up was 10.8° representing a loss of 4.9°. For the PSL group it was 9.9° with 8.6° loss of correction, for the A group it was 10.0° with 3.1° loss of correction and for the AP group it was 9.3° with 5.9° loss of correction. See also Table 9 and Figure 2 for more details. The neurological recovery of individual patients depended on the Frankel scale at admission as is demonstrated in Table 10. Patients with a Frankel A score had a poor chance for total recovery while Frankel E scores could, by definition, not improve. Two patients, both from the PL group, deteriorated one scale from Frankel E to D. Patients with a mild neurological deficit at admission had a greater chance for total recovery, regardless of the surgical technique, than patients admitted with more severe neurological deficits.
In 84% of the patients from the PS group the result in terms of pain was considered satisfactory at follow-up (P1 and P2 scores combined meaning no or minimal pain). This result was 80% for the PL group, 64% of the PSL group, 83% of the A group and 91% of the AP group. See also Table 11 for more details. Considering the employment status, a satisfactory result (W1 and W2 scores combined meaning the same or a lighter job) was obtained in 83% of the previously employed patients from the PS group. This result was 67% for

Table 9. Radiological deformity

Mean Cobb-angle	PS	PL	PSL	A	AP
patients reported→	1206	1309	366	255	75
pre-operatively	13.9°	18.9°	15.4°	22.0°	17.5°
std deviation	5.2	5.3	4.8	5.3	6.5
range	4.2-23.0	10.0-31.0	8.4-21.5	18.0-32.0	10.5-22.2
patients reported→	1766	1360	546	397	247
postoperatively	1.1°	5.9°	1.3°	6.9°	3.4°
std deviation	8.6	3.7	5.7	3.7	5.3
range	-10.0-9.4	-1.0-14.6	-11.0-10	2.0-12.0	-5.0-12.0
correction gained	12.8°	13.0°	14.1°	15.1°	14.1°
patients reported→	1630	1376	458	392	238
follow-up	8.7°	10.8°	9.9°	10.0°	9.3°
std deviation	6.2	5.3	5.9	7.8	4.7
range	-14.8-19.9	0.5-23.0	-2.0-17.5	-7.9-15.0	3.3-18.5
correction lost	7.6°	4.9°	8.6°	3.1°	5.9°
overall correction	5.2°	8.1°	5.5°	12.0°	8.2°

Table 10. Individual neurological recovery from admission to follow-up

Neurological recovery (%)	PS	PL	PSL	A	AP
number of complete records→	576	1149	422	364	61
Frankel A-A	8.7	17.7	12.3	4.7	3.3
Frankel A-B	1.2	1.1	1.9	0.0	0.0
Frankel A-C	0.9	1.9	1.9	0.5	0.0
Frankel A-D	0.5	0.7	1.7	0.5	1.6
Frankel A-E	0.0	0.1	0.2	0.0	0.0
Frankel B-A	0.0	0.0	0.0	0.0	0.0
Frankel B-B	0.5	1.2	1.7	0.5	0.0
Frankel B-C	2.1	3.0	2.4	1.4	3.3
Frankel B-D	3.8	5.2	2.8	6.0	8.2
Frankel B-E	1.7	0.8	0.5	2.5	1.6
Frankel C-A	0.0	0.0	0.0	0.0	0.0
Frankel C-B	0.0	0.0	0.0	0.0	0.0
Frankel C-C	2.1	2.2	3.1	1.9	1.6
Frankel C-D	6.8	9.7	8.8	9.1	16.4
Frankel C-E	9.5	4.1	16.4	3.6	0.0
Frankel D-A	0.0	0.0	0.0	0.0	0.0
Frankel D-B	0.0	0.0	0.0	0.0	0.0
Frankel D-C	0.0	0.0	0.0	0.0	0.0
Frankel D-D	6.3	7.9	0.9	8.5	3.3
Frankel D-E	15.5	13.0	10.2	46.2	21.3
Frankel E-A	0.0	0.0	0.0	0.0	0.0
Frankel E-B	0.0	0.0	0.0	0.0	0.0
Frankel E-C	0.0	0.0	0.0	0.0	0.0
Frankel E-D	0.0	0.2	0.0	0.0	0.0
Frankel E-E	40.5	31.2	35.3	14.6	39.3

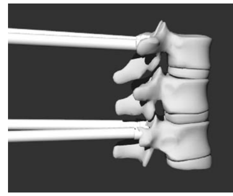


Table 11. Denis pain and work scale at follow-up

Denis pain scale (%)	PS	PL	PSL	A	AP
patients reported→	355	332	324	209	32
P1 (no pain)	47	23	28	73	72
P2 (minimal pain)	37	57	38	16	19
P3 (moderate pain)	11	15	6	7	3
P4 (severe pain)	2	3	23	2	0
P5 (constant pain)	3	2	5	2	6
Denis work scale (%)					
patients reported→	121	180	109	38	5
W1 (return to job)	79	47	41	50	
W2 (lighter job)	4	20	13	34	
W3 (change of job)	6	14	22	0	
W4 (part-time job)	0	1	0	3	
W5 (no work)	11	18	24	13	

Table 12. Late implant failure and non-elective re-operation

	PS	PL	PSL	A	AP
patients reported→	1427	1600	846	496	161
% late implant failure	11	10	19	5	5
patients reported→	1492	1627	793	482	120
% re-operation	4	9	6	5	7

the PL group, 54% for the PSL group and 84% of the A group. The number of patients in the AP group, for whom employment status was reported, was too small (n=5) to draw any conclusions. See Table 11 for more details. At the time of follow-up material failure, excluding early implant failure, was detected in 11% of the PS group, 10% of the PL group, 19% of the PSL group, 5% of the A group and 5% of the AP group. Non-elective re-operations were performed in 4% of the PS group, 9% of the PL group, 6% of the PSL group, 5% of the A group and in 7% of the AP group (Table 12).

Transpedicular spongiosaplasty The results from papers in the PS group that described transpedicular spongiosaplasty (TS+) as an additional procedure were compared to the results from authors from the PS group that did not perform this technique (TS-). The TS+ group consisted of the reports of 1151 posterior short-segment patients of whom 750 patients (65%) had

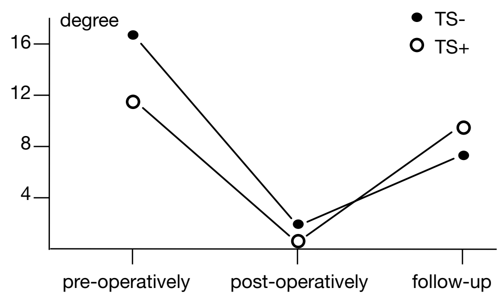


Figure 3.

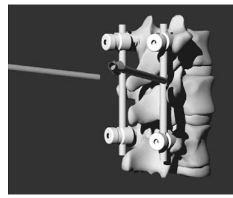
Graphical representation of the Cobb-angle, in degrees, for the PS group with (65% of 1151 patients) and without (0% of 924 patients) transpedicular spongiosaplasty at three time-points: pre-operatively, post-operatively and at follow-up.

Table 13. PS *versus* PS with transpedicular spongiosaplasty (TS)

	TS- 0/924	TS+ 750/1151[1]		TS-	TS+
follow-up (months)	30	31	% P1 (no pain)	52	36
gender ratio	0.71	0.65	% P2 (minimal pain)	33	44
age (years)	34	34	% P3 (moderate pain)	10	13
% burst fractures	68	68	% P4 (severe pain)	3	0
% thoracolumbar level	84	81	% P5 (constant pain)	2	7
bloodloss (ml)	860	1009	% W1 (return to job)	81	74
duration surgery (min)	183	186	% W2 (lighter job)	6	0
Cobb pre-operatively (º)	16.5	11.6	% W3 (changed job)	2	16
Cobb post-operatively (º)	1.7	0.7	% W4 (part-time job)	0	0
correction gained (º)	14.8	10.9	% W5 (no work)	11	10
Cobb follow-up (º)	7.4	9.6	% implant failure	12	10
correction lost (º)	5.7	8.9	% re-operation	6	2
overall correction (º)	9.1	2.0			

[1] The TS+ group consisted of 1151 patients of whom 750 (65%) had undergone transpedicular spongiosaplasty

undergone additional transpedicular spongiosaplasty. The TS- group consisted of 924 patients none of them having undergone transpedicular spongiosaplasty. Both groups were comparable in terms of follow-up, gender-ratio, age, type of fracture and fracture level. See also Table 13 for more details of these groups. Blood loss and the duration of surgery were both marginally smaller in the TS- group (860 versus 1009 milliliter and 183 versus 186 minutes respectively). The Cobb-angle pre-operatively was 11.6º for the TS+ group and 16.5º for the TS- group. Post-operatively this was reduced to 0.7º and 1.7º respectively. At follow-up the angles were 9.6º and 7.4º for the TS+ and TS- groups respectively indicating a greater loss of correction in the TS+ group. See also Figure 3. The outcome in terms of pain was satisfactory (P1 and P2 combined) in 80% of the TS+ group and 85% of the TS- group. The re-employment was considered good (W1 and W2 combined) in 74% of the TS+ group and 87% of the TS- group. Late failure of the implant was present in 10% of the TS+ group and 12% of the TS- group (the difference not being significant with $p > 0.05$), while non-elective re-operations were performed in 2.1% of the TS+ group compared to 5.8% of the TS- group (not significant with $p > 0.05$). The number of patients with additional transpedicular spongiosaplasty in the PSL group, 59 in total, was considered too small for evaluation.



Discussion

Numerous papers have described the results of a variety of treatment options but large-scale prospective randomized multi-center trials that could provide insight in an optimal treatment regime have not been conducted. Therefore, the choice of treatment for traumatic spine fractures lacks a solid scientific foundation. Even basic questions whether to treat acute vertebral fractures surgically at all have not yet been answered for the total spectrum of traumatic lesions.[3,65,154-156] In the present study an absence of selection bias, meaning pre-operative comparability of the surgical groups, was a pre-requisite if one was to draw solid conclusions from the statistical analyses of the data. As can be concluded from the pre-operative status of the study population in the results section, this presumed comparability was not the case. This renders, in the authors' opinion, direct quantitative comparison of surgical techniques, post-operative complications and subsequent outcome impossible. The posterior long-segment Harrington system has for many years been the only available, generally accepted, surgical option and the pre-operative parameter values of the PL group can therefore be assumed to be representative (at least in that time-era) for the average population of patients with spinal fractures treated surgically. Our data suggest that the A group contained patients that were more severely injured (having the largest Cobb angle, the highest percentage of polytrauma patients, and the highest neurological deficits percentage) than the PL group at the moment of hospital admission while patients from the PS group were the least injured according to the same parameters. We hypothesize that with the advent of the new techniques the trauma population has, subtly but significantly, shifted to more severely injured patients being treated by anterior decompression and

fixation and less severely injured patients being treated with pedicle screw based implants. The AP group was too small to draw any conclusions from in this respect. In a systematic review it is impossible to elucidate the mechanism by which centers with a specialization in anterior decompression and fixation could have admitted the most severely injured patients but referral from nearby hospitals not familiar with these techniques could be an explanation. The surgical observations reflect the generally held opinion that the posterior short-segment technique is the shortest surgical procedure with the least blood loss while the anterior and posterior combined group is the most demanding for the patient in these respects. It is interesting to note however that the surgical duration in the PSL group was prolonged approximately one hour compared to both the PS and PL group, probably accounting for the time initially needed for safe pedicle screw insertion. The median number of days spent in the hospital was the highest in the PL group. Surgical factors such as an extensive operating area, a long skin incision and the existing tradition of recumbency treatment for spinal fractures could explain the long hospital stay of patients from this group. The Cobb angles post-operatively and at follow-up show a remarkably similar trend in all groups. Although it must be stressed again that the groups were probably not similar at the pre-operative entry point, the mean Cobb angle of all patients converged to almost 10 degrees independent of the surgical treatment. Since the anterior and posterior combined technique was designed with maintenance of the surgically corrected wedge and Cobb angles in mind, it was surprising to find a similar performance from the other groups. In any case the results show that, regardless of injury severity, no technique was able to correct and maintain the fractured segment to the physiological level. The same conclusion applied for the practice of transpedicular spongiosaplasty. Although some authors have claimed good results in maintaining the wedge and Cobb angles by means of intra- or intercorporal grafting after pedicle screw fixation, various recent publications were unable to find a beneficial effect of the additional technique.[31,51,55,157-160] Our data support the latter findings and serious doubts about the usefulness of the procedure could not be relieved. Unfortunately, standard deviations of the Cobb-angle were seldom reported thus highly accurate estimates for this parameter were not available.
The neurological recovery as listed in Table 10 may need explanation. Following the literature, a complete paraplegia did not resolve and the few patients that did improve more than one scale (including two patients with complete paraplegia that recovered completely) might have been diagnosed too pessimistically at admission or might have suffered from other than pure disruptive mechanical causes of paraplegia.[161-167] From a partial cord lesion, however, a substantial part of the patients recovered completely. Patients with the least deficits at admission clearly had the best prospects of complete recovery regardless of the surgical group they were into. At least two mechanisms could be involved in this finding. Firstly, it is reasonable to suggest that mild deficits corresponded to lightly damaged spinal cords and these patients would have a good chance for healing without sequels. Secondly, as several authors have pointed out in the literature, neurological deficits can improve even two to three years after the initial damage although then the gain is usually small.[168,169] In this respect it is interesting to note that the relatively short *mean* follow-up of the study group, between 28 and 35 months, leaves open the possibility that in some studies patients with deficits were not at their neurological end-points yet. The complete recovery percentages of the patients initially diagnosed with Frankel B to D scores were not only different within a surgical group but also different between surgical groups although it remained unclear whether the surgical technique, the indistinctness of the Frankel classification (with a special reference to the rather 'vague' Frankel D scale) or other, unknown, factors were responsible. The data do not clearly point to a superior or inferior treatment strategy. Two patients from the total reported group, consisting of 2572 patients, deteriorated (one scale, Frankel E to D, no recovery at follow-up) in neurological function.
The Denis pain and work scales yielded similar results for the patients from all groups although it should be noted that the patients from the PS and A group had the highest percentage good to excellent results in both scales. The number of patients in the AP group was too small to draw conclusions from the work scale.
When comparing our findings with two large studies from the literature (the Multicenter Spine Fracture Study (MSFS) by Gertzbein *et al.* and the study from the German Society of Trauma Surgery (GSTS) by Knop *et al.* some similarities as well as marked differences can be pointed out.[2,26] The pre-operative patient characteristics of the total populations from these studies are, on average, quite similar to that from the present study enabling us to make some comparative remarks (Table 14). In the MSFS it is apparent that, because of lack of randomization before the treatment, the average injury severity of the patients is not likely to be equal for all the treatment groups making direct comparison of the groups unjustified. The same holds for the GSTS study although here the pre-operative patient characteristics for the different treatment groups have been described in detail providing at least a certainty about the *inequality* of the groups. All claims in both studies pertaining treatment effect must be regarded with the inequality of these pre-operative patient characteristics in mind. In the present study it was decided that if, after statistical analysis of the data, a difference between the groups was found with respect to the injury severity of the patients, only the data

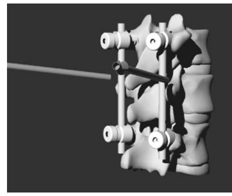


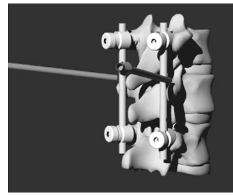
Table 14. Comparison of pre-operative data from the current study with two large prospective studies (Scoliosis Research Society Multicenter Spine Fracture Study and German Society of Trauma Surgery Spine Fracture Study)

pre-operative data	MSFS (n=1019)	GSTS (n=682)	current study (n=5748)
follow-up (months)	24	27	31
mean age (years)	32	39	33
gender-ratio	0.67	0.64	0.71
% T11-L2	>52	99	82
% burst fracture	64	57	66
% Frankel A	19	5	15
% Frankel B	2	2	8
% Frankel C	7	4	15
% Frankel D	17	9	21
% Frankel E	55	79	41
Cobb-angle	18.4	15.8	16.4

within a surgical group should be described leaving the, admittedly more interesting, questions of performance between the groups unanswered. The surgical parameters, blood loss and duration of surgery, from the GSTS study show largely comparable results to our findings. The MSFS does not provide details about these parameters. Complications were not discussed in detail for the different surgical groups in the MSFS or the GSTS study other than that 24.9% of all operatively treated patients had a significant complication (MSFS), 14.1% in the posterior short-segment group (GSTS), 29.7% in the anterior group (GSTS) and 13.7% in the combined group (GSTS). In the present study general surgical complications (deep venous thrombosis, pulmonary embolism, superficial infection) were rare with percentages not exceeding 2.5 %. Complications more specifically associated with spinal surgery (a temporary neurological deficit, implant malposition and early implant failure) were more frequently reported but, with the exception of the implant malposition in the PSL group (a likely learning curve effect), the percentages stayed below 4% and the complications were almost never associated with a permanent deterioration of the neurological status. The miscellaneous complications were reported most frequently and are suggested to be attributable mainly to a long recumbency period (resulting in the frequently reported decubitus and urinary tract infection in the PL group) and anterior surgical approach (resulting in the frequently reported atelectasis and sympathectomy effects in the A group). At time of follow-up only 40% of the patients from the MSFS and 55% of the GSTS group were available for assessment of their functional, radiological and neurological outcome, therefore the present authors feel that a descriptive comparison does not add much to the discussion. In the present study only complete sets of outcome parameters (lost-to-follow-up 0%) were included. The high lost-to-follow-up percentages reflect the difficulty of performing a large-scale study on this subject. Although the authors from both studies presented arguments claiming that valid conclusions could still be drawn from the resulting population, one has to exactly question why so many young (mean age < 40 years) and otherwise relatively healthy patients left the studies prematurely. The importance of randomized controlled trials, uniformity in reporting results and the prevention of lost-to-follow-up of study subjects is stressed once more by the findings and must be encouraged strongly.

Finally, we draw the following conclusions from this literature study:

1 Evidence-based guidelines for the treatment of traumatic fractures of the thoracic and lumbar spine are lacking.
2 The scientific evidence is largely based on retrospective case-series.
3 The surgical approach is possibly determined by injury severity and institutional preference.
4 No surgical method is able to maintain the corrected kyphosis angle.
5 Partial neurological deficits have potential for recovery, the amount depending more on the initial deficit and the time elapsed since the initial deficit, than the treatment strategy.
6 Although complications after surgery for traumatic spine fractures have been reported frequently, serious complications are rare.
7 The added value of transpedicular spongiosaplasty is questionable.
8 The outcome in terms of pain and employment seems to be better than generally believed.
9 Valid designs, e.g. randomized controlled trials are needed for comparison of different surgical techniques.



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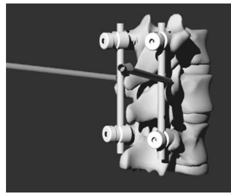

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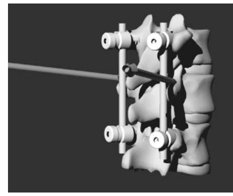

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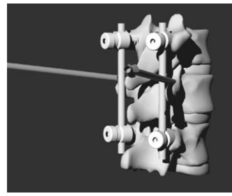
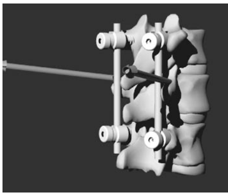


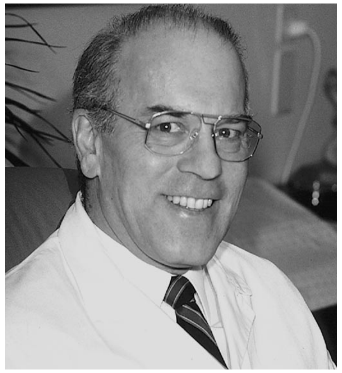
Chapter 3

Interview with Prof. Dr. Friedrich Magerl

03-12-2003



Friedrich Paul Magerl (1931) became an orthopaedic surgeon in 1970 after his general surgical and orthopadic training in Graz and St.Gallen, Switzerland. He received his PhD degree in 1986 from the University of Bern and became professor in orthopaedic surgery in 1992 at the same university. His main interests in orthopaedics are spinal surgery and surgery of the foot. He was inventor of the AO external and internal spine fixator that were to radically change the management of the fractured spine. In 1994 he published a paper on a new classification scheme for thoracic and lumbar fractures that became the AO-classification. Although he retired from orthopaedic practice in 1999, he continues to be active as a member of editorial and advisory boards of various international scientific journals.



How did you get involved in the operative management of traumatic spine fractures while conservative treatment was the more common practice and spine surgery was something exotic during your training period?

During my work as a resident in Graz, we treated most thoracic and lumbar pathology conservatively. This changed when we had a Japanese colleague over for some time in Graz who had experience in the anterior reduction and fusion of cervical dislocations. From him we learned how to become more comfortable with the operative treatment of the upper spine. This was, by the way, all back in the early sixties.

How did you proceed from then?

Slowly, we worked our way down from the cervical to the thoracic and lumbar levels as we gained more experience. The indications were mostly deformity and degenerative pathology. At that time we usually did not operate on spinal fractures. In the mid-to-late '60s, we (Weber, Zimmermann, Magerl) performed a large series of anterior interbody fusions according to the technique described by Mercer. Our results were surprisingly good compared to other series. The secret of our success was mainly due to the fact that only the three of us performed this surgery, so we got experienced fast. A later series, in which much more surgeons were involved, had a complication rate of up to 40%. As it turned out, too many surgeons had too little experience in this particular procedure. The complications from these degenerative spine series were mostly the result from pseudarthrosis. It prompted them (and us well in some instances) to augment the anterior fusion by additional posterior screw fixation through the facet joints. More importantly, it did stress that some procedures should be carried out by dedicated surgeons that were familiar with these structures.

And traumatic fractures were still treated conservatively or did that change with the increased knowledge you gained from the degenerative series?

Well, in the early sixties we sometimes *did* operate on traumatic spine fractures; but mostly on paraplegics. The paraplegia was not considered treatable, but the gross spinal instability that often accompanied it, was. To facilitate better nursing and earlier mobilization, in a wheelchair for example, we aimed to stabilize the spine as quickly as possible without all those cumbersome treatments like bedrest, skull traction or plaster jackets that had to be applied for several months. In 1963, in St. Gallen, my later colleague Weber begun to stabilize the spine by wiring the spinous processes and 'cementing' them together with polymethyl methacrylate cement. Some years later, AO plates with transpedicular fixation were used in St. Gallen for treatment of severe spine fractures at thoracic as well as at lumbar levels (Figure 2a-b).

But, who taught you how to safely insert these pedicular screws?

Hmm, no one. In these days you learned and taught yourself and others in the OR. Mind you, we started fixating these spines in paraplegics only in order to facilitate their treatment. In the end, the credit for transpedicular fixation goes to Harrington who performed the very first clinical pedicle screw insertion to get a better 'three-point fixation' for his rod instrumentation. And before that, in 1949, the anatomists Michele and Krueger had already thought of the transpedicular route to access the vertebral body for biopsies, for example.

You did not go to the anatomy lab to see if it could be done in a safe way?

No, as I said we learned as we got along with the operations. That was the usual practice and also the way to advance techniques and treatments. However, in this context I would like to mention, that I worked for nine years at the Department of Anatomy in Graz, prior to starting with clinical practice. For our treatment of paraplegics, we got massive critique from the followers of Guttmann. Guttmann was the most prominent proponent of the

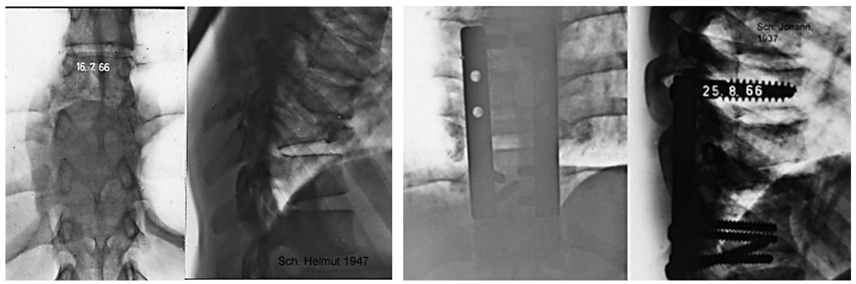
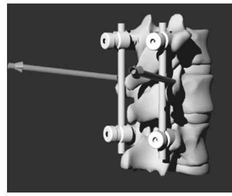


Figure 2.

A
A patient with thoracic fracture dislocation and paraplegia (1966).

B
Same patient with the spine stabilized with AO plates and transpedicular screws.



conservative treatment of paraplegia in his days and long after that. We operated because we wanted to get the patient's spine stable enough to get him/her out of bed as soon as possible instead of the, then usual, treatment of bed rest, logrolling and other bedridden activities. I still do not see anything wrong with our policy. Anyhow, surgical intervention in those days was strongly advocated against. This is something, which, considering the, then, widespread practice of laminectomies as a form of neurologic decompression that made things only worse (especially decreasing the stability of the spine), might have turned out not too bad after all. Guttman's authority on the conservative treatment however, made *any* surgical practice suspicious, which I think has seriously delayed advancements in this field.

Who or what influenced you during these early days of traumatic fracture management?

Weber's work that I mentioned, was among the first that I encountered because we worked together a lot. But Harrington's system, originally developed for scoliosis correction surgery, was becoming the regular treatment of burst fractures of the spine. Although it was possible to fixate a fracture with the Harrington rods, restoration of lordosis was not possible and one had to fuse five to seven levels to get adequate stability. I wasn't a big fan of this multilevel fusion practice. I wanted a short fixation system that could provide immediate stability and good alignment without the need of postoperative treatment with plaster jackets or braces. It just had to be stable from the beginning to the end. So, one day a young patient presented with an L3 burst fracture. Stabilization with Harrington rods or AO plates would mean a fusion from at least L1 to L5, meaning no motion left in the lumbar area. That was unacceptable to me. In this case we needed a device that could guarantee adequate stability and a correction of the sagittal angle without the multisegmental immobilization. Since we had quite some experience

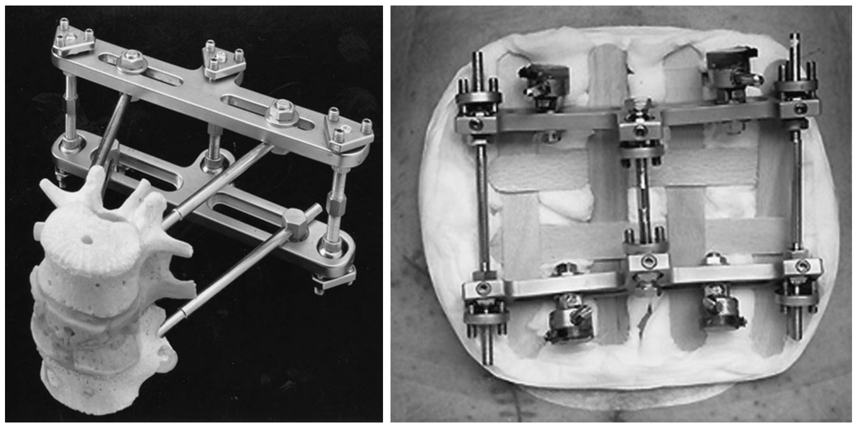


Figure 3.

A
The external spine fixator attached with Schanz screws to a sawbone model.

B
The external spine fixator used in clinical practice, note the custom wound dressing made from gauzes and wooden spatulas.

with external fixation of fractures of the extremities, I decided to treat this spine fracture with such an external fixation device. It worked! It worked well. The external spine fixator was developed shortly afterwards (Figure 3). The compliance of the Schanz screws in combination with the external spine fixator was key in the technical success of this new spine fracture treatment. We did not encounter failures because the combination of external fixator and Schanz screws was flexible enough to withstand peak pressures. It just did not fail.

The external spine fixator was the first true minimal invasive device for the treatment of traumatic conditions of the spine. However, to my knowledge just one international paper, written by you, has been published in the literature. [1] Why did this new treatment not succeed?

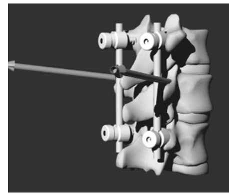
That is not completely true. There have been quite some fracture series with very acceptable results after external fixation but they did not get a lot of attention.

Why is that?

Probably because there is more than just patient outcome and the number of complications, it is about the acceptance of a new technique.

It sounded like you had a very promising technique up your sleeves. Why would colleagues or journals not accept it?

First of all, the aftertreatment of these external fracture fixations was difficult, also for the patient. It was much easier with the internal fixator, which was developed only some years later. But I am not sure whether a commercial aspect might have played a role also. You can use one external fixator over and over so, commercially, it was not very interesting. That significantly decreases the support you get from some parties. Mathys, the company that manufactured it, has maybe sold twenty or thirty, probably not much more than that. I think (pointing to an assortment of external fixators on his desk) I have twenty percent of all the external fixators that were ever made here in my office. You and I together have around thirty percent.



Then the internal fixator followed and became a big success. Were you involved in the development of the AO internal fixator?

Yes, in another patient I was confronted with the problem of a serious instability at the levels L4 to S1 following discectomy. In this case we needed a prolonged period of stabilization in a lordotic position for an interbody fusion to occur. This would have been possible with the external fixator (and impossible with the Harrington rods) but it would be quite patient unfriendly due to the extended period that it had to be attached to the patient's back.
I asked Mathys to redesign the fixator to a more compact layout so that it could be implanted under the paraspinal muscle. We used it in combination with anterior lumbar interbody fusions at both levels and with good result (Figure 4). Walter Dick, who was a junior staff member at Basel, asked me if he could use this principle to treat traumatic fractures with it and to redesign

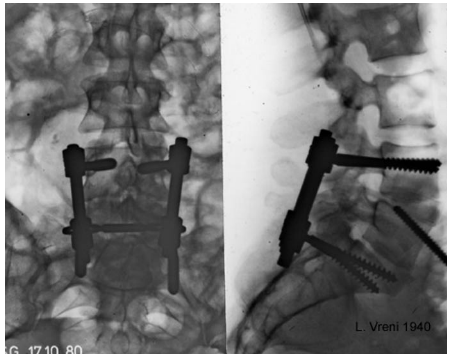


Figure 4.

Postoperative radiographs of the first patient with the internal fixator in situ. The screw on the right of the radiograph was used to fixate the allograft in the defect of the iliac crest that resulted from the autograft procedure for the interbody fusion.

the instrumentation together with Mathys. I agreed and that is, more or less, how the AO internal fixator got born.[2]

Do you think it was necessary to perform posterolateral bone grafting after fixation with the internal fixator in fracture treatment?

Walter Dick did not perform posterolateral fusions, I almost always did. Our clinical results were virtually identical but I wanted to have a 'second line of defense' in case something happened during the healing period with the fixator *in situ*. I realized, though, that restoration of the anterior column support was the most important job. Without an adequate anterior column, kyphosis would invariably develop, even with a posteriorly fused spine, due to bone remodeling under the forces that acted upon the spine.

How did you classify spine fractures in the '70s and '80s before the classifications invented by Denis and yourself? [3,4]

In the early days we used the Holdsworth classification but it didn't really capture the whole spectrum of lesions that we encountered. We used the Denis classification and after that McAfee's for a while but the same problem arose. Since we saw a quite a number of spine fractures that could not be classified by these classifications, the amount of 'miscellaneous' grew bigger and bigger.

Why did you feel the need for a new classification and how did you proceed?

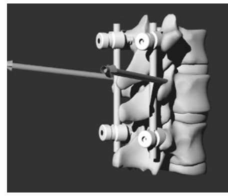
If I think of a 'fracture dislocation' and you think of a 'fracture dislocation', the chances are very small that we think of an identical fracture type. The main reason for the development of the classification was thus quite an academic one; I wanted the spectrum of possible lesions to be described in detail, making discussion between physicians about fractures more meaningful, and in the process, simultaneously, decrease the size of the 'miscellaneous' group. I had very long conversations with Jurgen Harms and the other co-authors of the paper, about how to set up a classification. We agreed that the AO concept, using the familiar 3-3-3 structure might be a good basis for the spinal fracture classification as well. It took us ten years to develop the classification.

Do you think a relation exist between the level of detail of the AO-classification and a more reliable prediction of prognosis?

For a lot of fractures, I think there is. In case of A-2 type fractures, for example, I think that you need an anterior procedure instead of a posterior or conservative treatment. In classifications with less detail, they probably would be called stable burst fractures for instance, and treated accordingly. Possibly with failure as a result. So, yes I think this level of detail is useful, sometimes even needed, for deciding how to treat certain fractures and that has a direct influence on outcome, obviously. The most important thing is the discrimination between A-type, B-type and C-type fractures because this is most decisive for the treatment. The majority of the first, which are A1 fractures, will heal with little or no intervention while the other two, in my opinion, almost always require stabilization otherwise will develop into severe malalignment or even neurologic deficit.

In a recent paper in Spine about spine fracture management, I was a little surprised to see that the Denis classification is not dead at all. There still seems to be a lot of support for that classification, especially in the United States. Why has the AO-classification not become the golden standard?

(meaningful smile) Probably because the AO-classification was "not invented here"? Whatever the reasons, if you feel comfortable with a particular classification you should use it. It also has a lot to do with training; who you were taught by and what you will teach the next generation etcetera.



How would you comment on relatively new techniques such as anterior and circumferential approaches; do they offer advantages in traumatic spine fracture management over posterior techniques?

For selected cases I think the anterior technique is valuable. Take for instance severely impacted wedge fractures, coronal split burst fractures or fractures with severe comminution of the vertebral body. You will find it hard to restore the anterior column support in these types of fractures from posterior. In these cases I would seriously consider the anterior approach as the treatment of choice.

Ok, but what about the circumferential technique; what would be the indication?

Jurgen Harms was the first to advocate this technique. He was forced to go anteriorly because the posterior instrumentation he used was too weak to function as stand-alone implant for severe burst fractures. I would say that nowadays, the circumferential technique might be useful for some specific indications and maybe also if you want to come up with nice X-rays showing excellent alignment of the spine. But as you will recall, the correlation between radiographics and final clinical outcome is weak. The circumferential approach is very invasive so it should be reserved for those special occasions in which a single approach cannot stabilize the spine sufficiently.

Why did transpedicular spongiosaplasty, used to augment the anterior column from posteriorly and described first by Daniaux, perform worse than expected? [5]

It depended on the type of spongiosaplasty that was performed. In my opinion it is impossible to achieve an interbody fusion using the transpedicular intervertebral spongiosaplasty technique. You just do not have enough working space when going through the pedicles to remove the disc completely, even partly. In the end it probably made things worse by adding instability to that segment. *Intra*vertebral spongiosaplasty has been more successful because it was only meant to fill the defect in the vertebral body that resulted from the traumatic impact. We performed it in a lot of patients and were quite pleased with the results we obtained, meaning lower instrument failure rates.

Still, various recent papers have failed to find a beneficial effect from the intravertebral spongiosaplasty.

It is not unreasonable to suggest that the pedicle screw instrumentation itself has improved in the last two decades. That could be the reason that instrument failure has decreased enough to make the spongiosaplasty procedure become superfluous. In the early days of the internal fixator we were confronted with a substantial number of failures due to instrument fatigue.
I think it was a useful additional procedure then.

Do you think (patient-) factors exist that are overlooked or ignored, that might influence the outcome of spinal surgery in general profoundly?

Beside all the obvious factors, I would suggest that collaboration between physicians, or more specifically, the willingness to collaborate is an important factor for patient outcome. Furthermore, I think psychological and social factors of the patient influence outcome more than the type of treatment that is performed. Maybe, now that I think of it, bone mineral density might also play a role in deciding how to treat patients. Maybe young healthy patients with high BMD's could be treated more conservatively. On the other hand the same holds for elderly patients with low BMD's. It would actually be interesting to see if BMD could be a parameter in deciding how to treat patients.

Do you think that conservative fracture treatment is gaining popularity again and if yes, can you explain?

No, it is not gaining popularity. It should however, because more cases could and should be treated conservatively. I have the impression that there are some hospitals where you are at risk of undergoing a circumferential fusion operation if you are diagnosed with a fracture that, in my opinion, could be treated conservatively. They sometimes seem to treat spines, not patients.

What do you think of the development of spinal surgery in the last three/four decades in general. Which ideas in particular do you consider to be good?

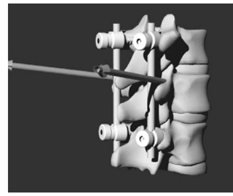
What I consider to be good practice is wanting to know everything about the nature of the pathology of the patient's spine. It is a prerequisite if you want to be of help to your patients. Furthermore, it is good practice if you know how to vary your treatment scheme according to the type of pathology. And of course, that is only possible if you know about its nature. Furthermore, and especially in degenerative disorders, we must consider, that psychic factors may significantly influence the clinical symptomatology and thus the treatment modalities.

What would you consider bad practice today in traumatic spine fracture management?

Over-treatment. As I just mentioned, when confronted with a spinal fracture you should choose your treatment according to the fracture type. In a lot of cases that would mean: 'Stay off!'. But that is one of the hardest problems for a surgeon, to not operate on something that is broken.

What technique or type of treatment would you like to develop today if you were to start over now?

Hmm, another difficult question. I would focus my attention on inventing minimal or at least less invasive techniques to be used intravertebrally or for interbody fusions. Implants that I would use in these techniques would be bio-resorbable, elastic enough to transmit physiological forces, but sturdy enough not to break during the initial healing period. Also, they would be radiolucent or at least not cause these awful artifacts on computed tomography or magnetic resonance images. It is a big nuisance when diagnosing problems in that area and you cannot see anything due to all these streak artifacts.



Do you see a place and/or function for robots and computer assistance in the OR?

Yes, if you mean navigation; it is a useful addition. For very experienced surgeons it is really easy to insert screws through the pedicles. But even for them it becomes a lot harder when confronted with severely degenerated or scoliotic spines. The navigation techniques today are a little cumbersome to handle and it takes extra operation time but, in general, it would be beneficial to the patient. Every technique that holds the potential to decrease iatrogenic damage should be considered and tested even if it is not perfect yet and not very cheap. Just think what costs are involved, if we for arguments sake ignore the much more important social drama, if you cause a paraplegia in one patient; you could buy an OR full of navigation devices for that.
The matching process of the navigation is still the weak point however, one should improve on that. The use of skin markers and modern imaging techniques, like the rotational X-ray imaging modality that you are involved in, might provide a solution. Robots I am not familiar with. I cannot think of a purpose for a robot in spine surgery right away. We will see what will happen.

Currently, spine surgery is performed by orthopaedic surgeons, neurosurgeons and sometimes traumatologists. Do you foresee the advent of a separate specialty: spine surgery?

Absolutely. And it would be a big step forwards. Just like urologists and thoracic surgeons, for example, are mainly concerned with one organ or system, some of the surgeons you mentioned above, should be trained thoroughly in spine surgery. The results from the past show that it takes experience and practice to become good in this work. Neurosurgeons do not understand or handle bone as well as orthopaedic surgeons, who, in turn, do not understand so much of the central nervous system, which is important for decompressions for example. Combining their knowledge for the treatment of spinal pathology would be advantageous. So I would strongly advocate for an 'official' spine specialism, definitely.

In our center we are currently considering treating some traumatic fractures (A-3.1 and some A-3.3s) by reduction and stabilization with the external spine fixator and subsequent balloon vertebroplasty with calcium phosphate cement. The Schanz screws are to be removed after the cement is cured. What do you think of such a treatment?

Sounds interesting, you probably already asked yourself at what time you can safely remove the external fixator considering the various types of fractures and whether the reduction will be maintained after fixator removal?

Yes, we did and do not know the answer, do you?

Well, no but you just have to try, I think. I know that in the '70s and '80s it was probably easier than today with all these institutional review boards watching over your shoulder, but in the end you just have to learn from the experience you gain by treating patients. Not everything can be revealed by cadaveric or animal experiments. You just go ahead and tell us in five years if it was a good idea or not.

(All photographs were kindly provided by Professor dr. F.M. Magerl)

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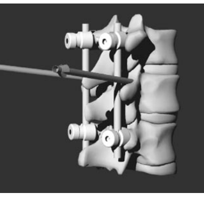
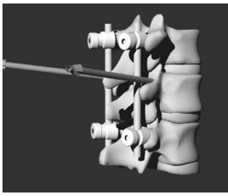


Chapter 4

Balloon vertebroplasty with calcium phosphate cement augmentation for direct restoration of traumatic thoracolumbar vertebral fractures.

Verlaan JJ, Van Helden H, Oner FC, Verbout AJ, Dhert WJA.
***Spine* 2002;27(5):543-548.**



Introduction

The first choice of treatment for traumatic thoracolumbar vertebral fractures that are unstable or cause neurological deficits is surgical reduction by distraction and posterior stabilization using short segment pedicle screw instrumentation.[1] Notwithstanding the overall good clinical results following this procedure, failure defined as instrumentation breakage and/or loss of kyphosis correction after removal of the instrumentation have been reported to be 0-45%.[2,3,4] A lack of anterior column stability due to the large defect in the vertebral body after height restoration is held responsible for these failures. A magnetic resonance imaging study by us demonstrated a redistribution of intervertebral disc material in the fractured vertebral body and a subsequent collapse of the anterior disc space causing instrumentation fatigue and recurrent kyphosis after removal of the instrumentation (Figure 1).[5] In order to prevent these conditions, several techniques have been developed to augment the anterior column. Additional anterior instrumentation and strut grafting have proven to be effective but require an invasive approach associated with prolonged operation time, blood-loss and morbidity.[6,7] Transpedicular bone grafting has not demonstrated to be advantageous while being potentially dangerous if not placed carefully.[8,9,10,11] In this study it was hypothesized that reconstruction of the intervertebral disc space by direct restoration of the vertebral endplates, after routine fracture posterior reduction and stabilization, could restore the anterior column and prevent failure of the posterior construct. The vertebral body defect that would result from reduction of the endplates could be augmented by injecting a bone cement, effectively creating support for the cranial endplate and disc, thereby reducing the risk of recurrent kyphosis after removal of the instrumentation.. The technique to achieve reduction and augmentation resembles the 'kyphoplasty' procedure, in which inflatable balloons and injection of PMMA cement are used to correct the spinal deformity following osteoporotic vertebral compression fractures.[12,13] The use of PMMA cement for augmentation of the void was rejected in favor of calcium phosphate cement (CPC) because the latter combines good biocompatibility, biodegradability, osteoconductive properties and an isothermic setting-phase, which we consider as favorable for use in relatively young spine trauma patients.[14,15] The mechanical properties of CPC have been demonstrated not to differ significantly from PMMA, with regard to resistance to compressive forces, after *in vitro* vertebroplasty.[16] The purpose of this investigation was to assess the feasibility and safety of balloon vertebroplasty for the direct restoration and augmentation of the anterior column in experimental high energy thoracolumbar vertebral fractures in a human cadaver model.

Figure 1.

Detail of a sagittal MR-image of a thoracic spine demonstrating the kyphotic deformity as a consequence of disc space collapse after intrusion of disc material through the fractured endplate in the vertebral body.

Material and Methods

Eleven cadaveric non-osteoporotic spines from level T8-S1 were obtained (donor age: 55-80 years, mean age: 69 years, male/female ratio: 10/1). All soft tissue, except for the ligaments, was removed and the spines were bisected at a high lumbar level to create 22 specimens. Both the cranial and caudal segments of each specimen were fixated in polyurethane cups with plastic foam, leaving the middle segment free. A specially designed and validated weight dropping device was used for the creation of burst fractures of these segments. [17] All specimens were subjected to an axial impact (10-20 kg weight from 1.50 m height) until manual crepitation, signifying fracture, was evident (figure 2a). Afterwards all fractures were reduced and stabilized posteriorly by an experienced spinal surgeon (FCO), using titanium pedicle screws and rods (BWM-system, Stryker Howmedica). The entrance of the pedicles of the fractured vertebra were identified and pierced with an orthopaedic awl. After probing the pedicles with a 4 mm pedicle probe, inflatable bone tamps (KyphX, Kyphon Inc.) were inserted into both pedicles of the fractured vertebra and advanced until final paramedian localization in the anterior third of the vertebral body. This was confirmed fluoroscopically. The bone tamps were inflated simultaneously by gradually forcing a radiopaque fluid from a pressuregauge-equipped syringe into the balloons.

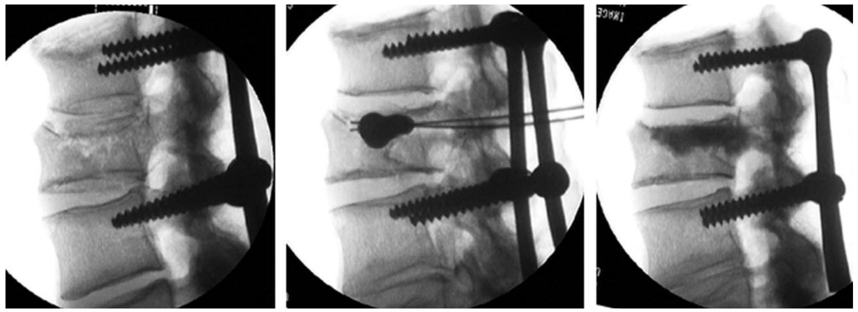


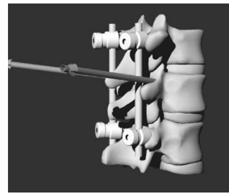
Figure 2A-C.

Sequence of fluoroscopic images demonstrating the balloon vertebroplasty procedure.

A
Lateral fluoroscopy image of an instrumented vertebral burst fracture.

B
Lateral fluoroscopy image of the same vertebral fracture with inflated balloons in situ after optimal reduction of the endplates.

C
Complete filling of the defect, without evidence of extracorporal leakage, after bilateral injection of CPC in the void.



Both the volume and the pressure of the balloons were recorded carefully during the procedure. A fluoroscopic check was performed after each milliliter of added volume. Inflation was continued until satisfactory fluoroscopic reduction of the endplates was achieved as judged by the surgeon (Figure 2b). Indications to stop inflation were displacement of bone fragments into the spinal canal, exceeding the maximum inflation rate of the bone tamps or a build-up of pressure without an accompanying increase in balloon volume, displacement of the balloons, and insufficient visualization of the vertebral anatomy with the fluoroscopic device. Both balloons were actively deflated and retracted after optimal reduction had been accomplished. The cement (BoneSource®, Stryker Howmedica Osteonics) was prepared by mixing 20 g of calcium phospate, consisting of dicalcium phosphate and tetracalcium phosphate in equimolar amounts, with 6 ml of saline to form a smooth and injectable paste. The cement was subsequently transferred to two 10 ml syringes with a 3 mm needle and injected transpedicularly, bilaterally, in the vertebral body. Injection continued until, fluoroscopically, a complete filling of the defect was achieved (Figure 2c). The total amount of injected cement was recorded for each specimen. Indications to stop injection were leakage of cement outside the vertebral body, a build-up of pressure necessary to inject the cement and poor visualization of the vertebral anatomy fluoroscopically. After injection, the cement was allowed to harden at room temperature and the specimens were subsequently frozen to –20 degree Celsius. Macroscopic examination of sagittal slices (sawed at 4 mm thickness using an electric bandsaw) of the frozen specimens was performed to assess the filling of the defect and to detect any leakage of cement.
During the experimental procedure plain radiographs (AP and lateral) and magnetic resonance images (T1 and T2 weighted with a 0.5 Tesla Philips NT5scanner) were obtained of all fractures at three time points: -t1- after creation of the fracture, -t2- after reduction and posterior stabilization and -t3- after balloon vertebroplasty. Using both the plain radiographs and the MR images of -t1-, the fractures were classified according to the system described by Magerl et al.[18] The MR images of all time-points were used for quantitative assessment of changes in vertebral body and disc space morphology. The two central sagittal slices (distance 3 mm) of each scan were digitized and randomized. Dedicated software (NIH Image for Windows, Beta 4.0.2 Scion Corporation) was used to analyze the data by measuring the following parameters: (AB) - Anterior bulging of the vertebral body, defined as the maximum length of the line perpendicular to the line drawn from the anterior, inferior margin of the adjacent cranial vertebral body to the anterior, superior margin of the adjacent caudal vertebral body; (PB) - Posterior bulging of the vertebral body, defined as the maximum length of the line perpendicular to the line drawn from the posterior, inferior margin of the adjacent cranial vertebral body to the posterior, superior margin of the caudal vertebral body; (PI) - Proximal endplate impression, defined as the largest depression measured perpendicular to a line drawn from the anterior, superior margin to the posterior, superior margin of the vertebral body; (DI) - Distal endplate impression, defined as the largest depression measured perpendicular to a line drawn from the anterior, inferior margin to the posterior, inferior margin of the vertebral body (see Figure 3 for graphical explanation). Multi-level analysis, designed to detect relative rather than absolute differences and taking into account spine number, fracture type, level of the fracture (thoracic or lumbar), was used to assess the differences for all four parameters between the baseline fractures (t1), the distraction / fixation (t2) and the balloon vertebroplasty (t3).

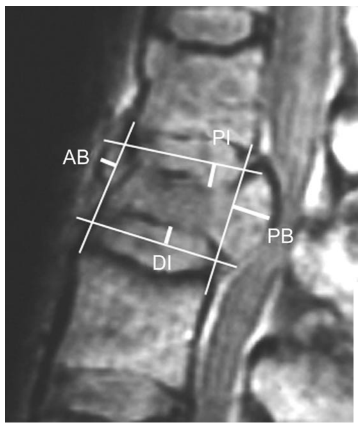
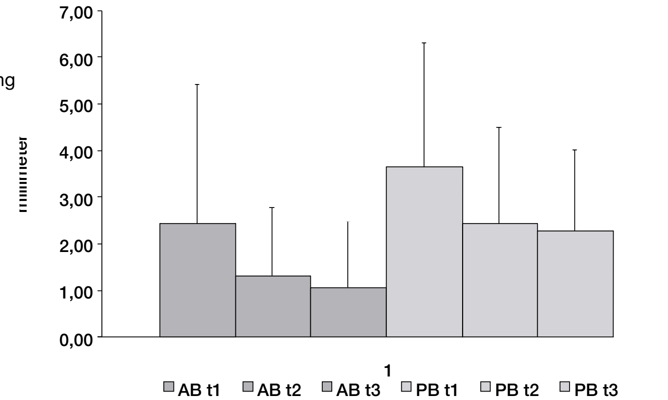


Figure 3.

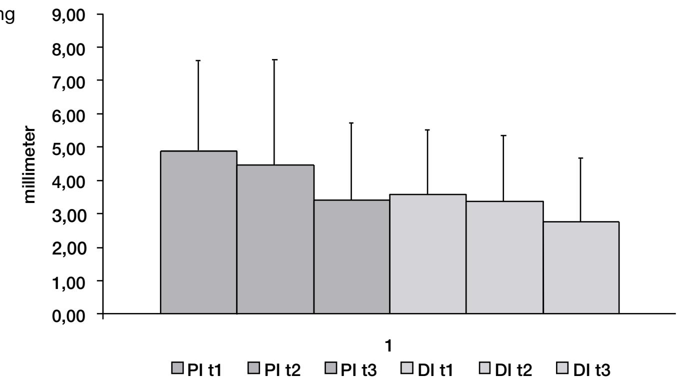
Graphical representation of the method used for assessing anterior bulging (AB), posterior bulging (PB), proximal impression (PI) and distal impression (DI) projected on a MR image of a vertebral fracture.

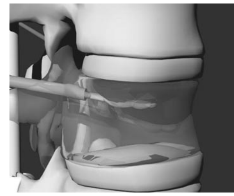
Figure 4a-b.

A
Chart demonstrating the mean anterior and posterior bulging at t1-t2-t3.



B
Chart demonstrating the mean proximal and distal impression at t1-t2-t3.





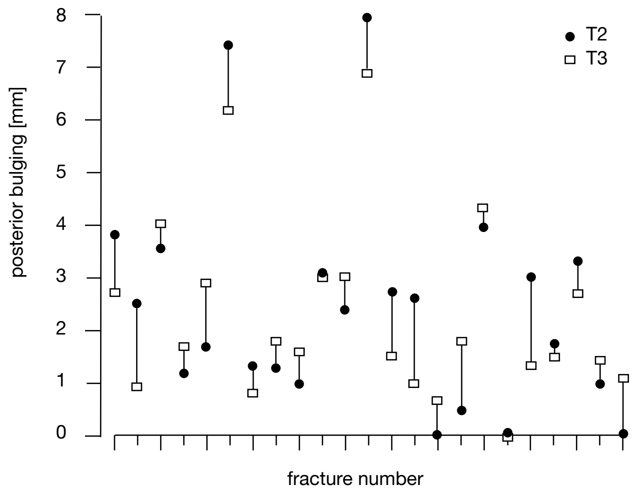


Figure 5.

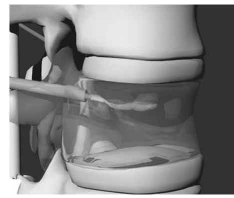
Chart demonstrating the individual data for posterior bulging at t2 and t3.

Results

In the 22 spine segments a total of 23 fractures was created, of which 17 classified as pure burst fractures (A 3), four split fractures (A 2), one impaction fracture (A 1) and one rotation-impaction fracture (C 1) according to the AO classification by Magerl et al.[18]. In all specimens the posterior longitudinal ligament (PLL) was intact. The balloon vertebroplasty procedure was performed without technical difficulties in all specimens. The maximum intravertebral pressure of the balloons varied between 50 and 200 psi (mean 105 psi). The amount of injected CPC needed for, fluoroscopically, complete filling of the defect ranged from 6.0 to 22.1 g (mean 14.3 g). No indications to prematurely stop inflation of the balloons or end cement injection were encountered. In Figure 4a-b, the results of the effect of the experimental procedure on each of the four parameters are presented. No difference in distal impression was measured at any of the three time points. Distraction of the specimens resulted in a negative displacement (inward bulging) of both the anterior and posterior wall (p=0.0056 and p=0.0013 respectively) but no difference was detected for both parameters following the balloon vertebroplasty. As a result of the balloon vertebroplasty, a significant (p=0,0014) decrease in impression of the proximal endplate was measured. After individual judgement of the data ten (43 %) specimens showed a positive (> 0 mm) posterior bulging at -t3- of which three exceeded 1 mm (Figure 5). The maximum posterior bulging measured was 1.3 mm. No cement leakage outside the vertebral body could be detected by the investigators during the procedure and after macroscopical examination (Figure 6).

Discussion

In this study we demonstrated balloon vertebroplasty with calcium phosphate cement to be a feasible procedure for direct restoration of traumatic vertebral body fractures in human cadaveric spines. Relying on the results from the study, the primary goals - to reconstruct the anatomical disc space and to demonstrate the safety and feasibility of the procedure - have been achieved. Reduction of the impression of the endplate is, based upon our previous studies, a prerequisite to decrease the risk of intrusion of the disc in the vertebral body.[5] After individual judgment of the MRI data it was concluded that no neurological damage could have resulted from posterior displacement of bone fragments as a result of the balloon vertebroplasty. Severe complications due to cement leakage, including pulmonary embolism and spinal cord compression, have been reported after classic vertebroplasty with PMMA cement for the treatment of osteoporotic vertebral compression fractures.[19,20,21,22] The use of inflatable bone tamps facilitated endplate reduction and, by simultaneously creating a bone void, cement could be injected under low pressure thereby decreasing the risk of leakage and unwanted displacement of bone fragments. The intact PLL in all specimens may also have contributed to the absence of cement in the spinal canal. Studies to evaluate the risks and indications of balloon vertebroplasty for burst fractures which have a high risk for PLL tears, due to an additional flexion/extension or rotational component (B- and C-type fractures), are currently under investigation. In the event of CPC leakage, the damage to surrounding tissue will be minor compared to PMMA, by virtue of its isothermic properties during the setting-phase.[23,24] Although the use of PMMA cement in vertebroplasty is widespread, no data on the longterm behavior of the material for spinal applications have been published. Since the majority of patients with traumatic vertebral fractures is aged between 20 – 50 years, the use of a more biocompatible bone cement is preferred.[25,26] Calcium phosphate cement has been demonstrated to be osteoconductive and is slowly resorbed allowing for the deposition of newly formed bone.[14,15,16]
It can be concluded from the current investigation that balloon vertebroplasty is a safe and feasible procedure for the restoration and augmentation of the anterior column in traumatic thoracolumbar vertebral fractures.



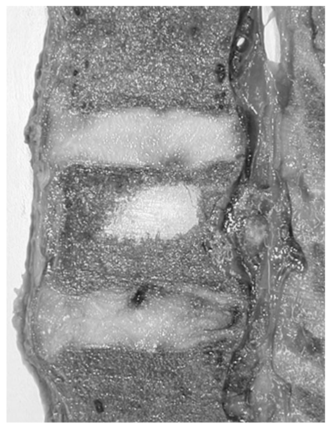


Figure 6.

Photograph of a sagittal slice of a frozen specimen after balloon vertebroplasty demonstrating a complete filling of the defect without evidence of cement leakage.

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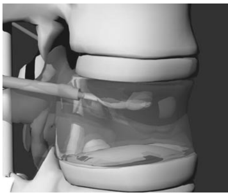
Chapter 5

3D rotational X-ray imaging for less invasive spine surgery. A quantitative validation study comparing reconstructed images with corresponding anatomical sections.

Verlaan JJ, van de Kraats EB, van Walsum Th, Dhert WJA, Oner FC, Niessen WJ. In press *Spine* 2004.

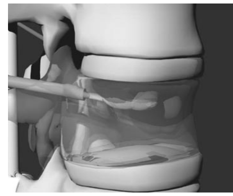


Introduction

In search of better clinical results, less complications and a shorter hospital stay, a considerable amount of medical research has been directed at minimizing the collateral damage that occurs during surgical interventions. Minimally invasive procedures have been developed in various surgical fields and have proven quite successful as alternatives for a multitude of open treatments.[1-6] An unfavorable property inherent with this type of procedure is a lack of direct vision of the operating area. This drawback has, at least partly, been solved with visualization by endoscopy, computed tomography, fluoroscopy and ultrasound among others, all with their specific pros and cons. Although computed tomography is sometimes utilized during spinal surgery, the most frequently used imaging modality is fluoroscopy because of its flexibility in the operating room and almost realtime projection of the area of interest.[7-10] In favor of computed tomography are high resolution imaging and the ability to perform multiplanar reformatting, allowing the surgeon to determine the viewing plane to his/her own specification instead of being limited to the projection plane. Additionally, the data obtained by computed tomography can be reconstructed to three-dimensional datasets giving the viewer a better appreciation of the spatial orientation and relation of the anatomical structures. The differences between the two imaging techniques; ease of use, short acquisition and processing time on one side, image quality and resolution on the other, have resulted in a mainly diagnostic role for computed tomography and a mainly interventional purpose for fluoroscopy devices. Three-dimensional rotational X-ray imaging (3DRX) is a new imaging technique where, by use of a motorized and calibrated C-arm connected to an otherwise conventional fluoroscopy device, multiple projection images can be acquired and reconstructed on a workstation into a 3D volume. The reconstruction technique of 3DRX is largely similar to reconstruction techniques in computed tomography. In 3DRX, however, 2D projection images are used to reconstruct a 3D volume instead of the data from one or more detector rings in computed tomography. This generally leads to a higher resolution in the z-direction and more isotropic datasets in 3DRX compared to computed tomography. 3DRX may be able to merge the advantages of computed tomography and fluoroscopy; realtime 2D projections for fast visual feedback and 3D reconstructions for detailed volumetric imaging of complex anatomy and/or position of instruments or implants. To date, the clinical use of 3DRX includes preoperative evaluation of cranial arteriovenous malformations (in which field it is known as 3D Rotational Angiography or 3DRA), cranial aneurysms, renal artery stenosis and cholangiography.[11-15] Spinal interventions could benefit from 3D imaging, since the display of realistic anatomical relations could increase the safety in procedures such as C1-C2 screw fixation, difficult pedicle screw placement or vertebroplasty. Several studies have demonstrated the usefulness of 3DRX in establishing diagnoses and assisting in treatment planning, but validation studies to assess the accuracy of 3DRX in an interventional setting have, to the authors' knowledge, not been carried out.[12,16,17] In validation studies using phantoms, all variables capable of disturbing the measurements are deliberately eliminated in order to get optimal (and thus rather theoretical) data. The resulting accuracy from such studies could therefore be in stark contrast to the daily practice where image quality can be negatively affected by, for example, surrounding inhomogenous structures. In the current study, the usefulness of a clinical 3DRX system in imaging the spinal anatomy was assessed by direct quantitative comparison of reconstructed midsagittal images, from fractured human cadaveric spine specimens that were treated with pedicle screw instrumentation and balloon vertebroplasty, with their corresponding anatomical sections.

Material and methods

Ten fresh cadaveric spines (T8-S1) without radiological signs of osteoporosis or other gross pathology were obtained (donor age: mean 64.6 years, range 56-76 years, male/female ratio: 8/2). Most of the soft tissue, except for the ligaments, was removed and the spines were bisected at T11-T12 resulting in 20 specimens. A weight-dropping device was used for the creation of burst fractures in these specimens (20 kg weight from 1.50 m height). All fractures were reduced and stabilized posteriorly with titanium pedicle screws and rods (BWM-system, Stryker Howmedica Osteonics). Subsequently, balloon vertebroplasty with calcium phosphate cement (BoneSource®, Stryker Howmedica Osteonics) was carried out as described in a recent study.[18] Immediately after this procedure, the fracture with the two adjacent levels were visualized. To accomplish this, a motorized fluoroscopy device (INTEGRIS BV5000, Philips Medical Systems) was used to acquire 100 cone-beam projection images, each 512^2 pixels large, from which a 3D image of 256^3 isotropic voxels (each 0.43*0.43*0.43 mm large) could be reconstructed (Figure 1). The 3D data set was subsequently transferred to a Clinical Workstation EasyVision system (Philips Medical Systems) for further processing. Using coronal and transverse views of the specimens, the anterior midlines of the upper and lower vertebral body of the specimen were aligned with the y-axis resulting in an upright position of the specimen. On the transverse plane, the midline of the 3D volume was subsequently determined by locating the tip of the spinous process and the midline of the anterior part of the fractured vertebral body. The sagittal cutting plane was defined by the



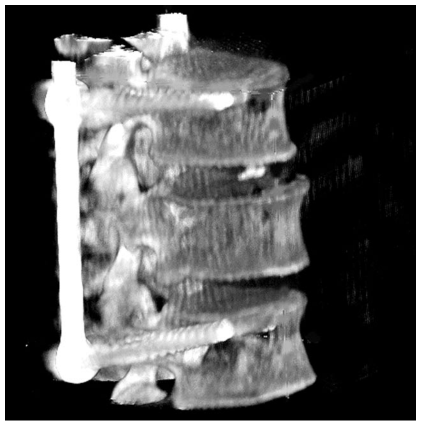


Figure 1.

Image showing the complete 3D reconstruction of an instrumented lumbar spine segment.

plane through this transverse midline parallel to the y-axis. A screenshot was captured from the reconstructed midline image (after 0.4 millimeter offset to the left to compensate for the loss of substance caused by the 0.8 millimeter wide cutting sawband, see later in text), showing the fractured and adjacent levels together with a virtual 50 millimeter ruler, and stored in JPEG (352*240 pixels, pixelsize 0.35 mm) format for further processing. In order to minimize mechanical disturbance, the anatomical specimen was frozen to minus 20 degrees Celsius and the pedicle screws and connecting rods were carefully removed. Using an electric bandsaw (Exakt Systems E310, 0.8 mm wide cutting sawband) the frozen specimen was sliced at the same mid-sagittal plane as described above and a digital photograph (JPEG 1600*1200 pixels, pixelsize 0.35 mm, Nikon Coolpix 950) was obtained from the left hand slice together with a measuring tape. Both anatomical and 3DRX images were subsequently imported in a personal computer and analyzed using 2D/3D modeling software (Rhinoceros version 3.0, Seattle USA). Twelve points (nodes) were put on the outer corners of the three vertebral bodies and a connecting line was drawn to provide an outline. Subsequently, on the bisection of the top and bottom horizontal lines, nodes were added and a line was drawn between them (the central line). Then, nodes were put on this line at the transitions between vertebral body and intervertebral disc. Lastly, lines were drawn from these nodes to the outline to provide an

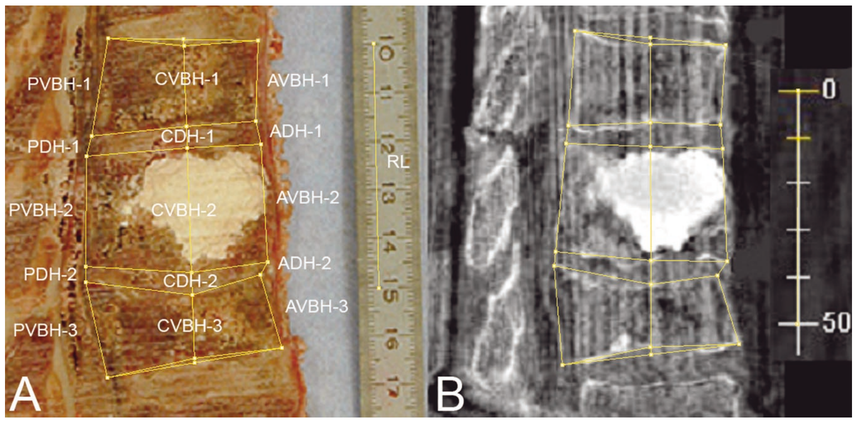


Figure 2.

A
Photograph of a spinal specimen, after burst fracture treatment with pedicle screw instrumentation and balloon vertebroplasty with calcium phosphate cement, cut in the midsagittal plane. On the photograph, points and connecting lines are drawn on anatomical landmarks that were used for the length and angle measurements (see text also);

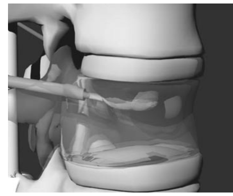
- PVBH = posterior vertebral body height;
- PDH = posterior disc height;
- CVBH = central vertebral body height;
- CDH = central disc height;
- AVBH = anterior vertebral body height;
- ADH = anterior disc height;
- RL = ruler.

B
Reconstructed image corresponding to the anatomical specimen from Figure 2a. Points and lines are drawn according to the same principle as in Figure 2a.

approximation of the contour of the intervertebral disc. See also Figure 2 for a graphical explanation. This method proved to be easily reproducible on both the anatomical and the 3DRX sections. For all acquired images (anatomical and 3DRX) the following parameters were measured and recorded two times by two independent observers (JJV and EBK):

- the length of the 50 millimeter ruler (for real world dimension conversion);
- the anterior vertebral body height of the three vertebrae;
- the posterior vertebral body height of the three vertebrae;
- the central vertebral body height of the three vertebrae;
- the anterior intervertebral disc height of the two adjacent discs;
- the posterior intervertebral disc height of the two adjacent discs;
- the central intervertebral disc height of the two adjacent discs;
- the anterior displacement of bone at the fractured level;
- the posterior displacement of bone at the fractured level;
- the wedge angle of the fractured vertebral body;
- the 'Cobb'-angle between the uppermost endplate and lowest endplate of the two outer vertebral bodies.

The first and second measurements were separated by approximately one month to minimize the risk of redrawing lines and nodes from memory. No blinding or randomization was used since the used imaging modality (photograph or reconstructed X-ray) was easily recognizable and the images were consecutively processed before proceeding to the other modality, but the observers were not allowed to compare corresponding sections. All measurements were then imported in a spreadsheet (Excel, Microsoft Office 2002). From the difference of the anatomical and 3DRX measurements and the difference between the two timepoints the mean and standard deviation were calculated for each parameter to assess the variability.



Results

The fracture reduction and vertebroplasty procedures were uneventful for all twenty specimens. In the thoracic specimens, 12 grams of calcium phosphate cement was injected on average, while in the lumbar specimens this was 23 grams on average. In one specimen, a minor leakage was detected macroscopically outside the vertebral body anteriorly. This could not be confirmed with 3DRX probably due to manipulation that accidently removed the cement before the acquisition run was performed. After mid-sagittal sawing, no cement leakage was detected in the spinal canal although in one specimen it was observed in the cranial disc space. This could be confirmed with 3DRX and was due to a large fracture of the endplate (Figure 3).
The mean difference between the corresponding values (anatomy minus 3DRX) was small, ranging between -1.1 and 2.1 millimeter for all parameters. The standard deviation for the differences per parameter ranged between 1.2 and 3.2 millimeter. For the wedge angle the difference ranged between -2.7 and 0.9 degrees (standard deviation between 3.5 and 4.7 degrees) and for the Cobb angle between -3.6 and 2.8 degrees (standard deviation between 2.3 and 3.6 degrees). See also Table 1 for details of the

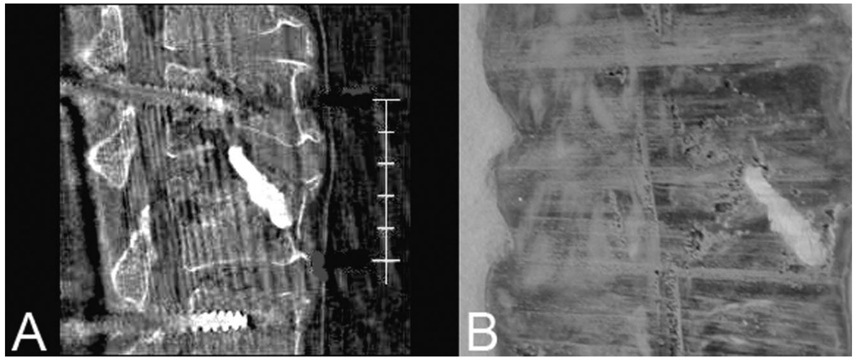


Figure 3.

A
Reconstructed image showing the midsagittal plane of an instrumented burst fracture in which some cement was observed in the cranial disc space. The vertical stripes in this image are reconstruction artifacts.

B
Photograph of the same specimen cut in the midsagittal plane demonstrating the leakage of cement in the cranial disc space, confirming the findings on the 3DRX image from Figure 3a. The horizontal stripes are artifacts that resulted from cutting the specimen.

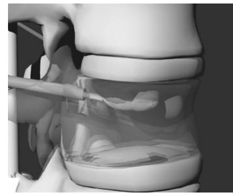
Table 1. Mean differences of anatomical sections and 3DRX images and the standard deviations of the differences.

Difference anatomy-3DRX (mm)	Observer 1		Observer 2	
	mean/stdev	mean/stdev	mean/stdev	mean/stdev
anterior vertebral body height 1	0.2/1.9	0.0/2.6	0.0/1.8	-0.3/1.6
anterior vertebral body height 2	-0.1/1.8	-0.6/2.2	1.9/2.5	0.6/2.7
anterior vertebral body height 3	0.0/2.4	-0.5/2.8	2.1/3.2	0.4/2.8
posterior vertebral body height 1	1.0/2.3	-0.2/2.7	0.3/2.0	-0.2/1.8
posterior vertebral body height 2	0.6/1.7	-0.3/1.8	0.4/1.8	0.2/2.0
posterior vertebral body height 3	0.5/2.0	0.4/1.9	-0.1/2.4	-0.4/2.6
central vertebral body height 1	0.6/1.7	-0.2/2.2	0.3/1.6	0.6/2.2
central vertebral body height 2	-0.6/1.9	-1.0/2.1	1.0/2.4	1.1/2.3
central vertebral body height 3	-0.7/1.8	-0.5/1.7	1.1/2.5	1.0/2.4
anterior disc height 1	-0.5/1.9	0.1/2.2	-0.2/2.4	0.6/3.2
anterior disc height 2	-0.9/2.2	-0.8/1.9	-0.9/2.7	0.3/2.4
posterior disc height 1	-0.7/1.5	-0.1/1.4	-0.6/1.7	0.2/1.6
posterior disc height 2	-1.0/1.7	-0.1/1.8	0.4/1.6	0.8/2.0
central disc height 1	-0.2/1.6	0.2/1.8	-0.4/1.4	-0.4/1.6
central disc height 2	-0.5/3.1	0.2/1.6	-0.4/1.3	-0.3/1.7
anterior bone displacement	-1.1/1.2	-0.5/1.2	0.3/1.2	0.5/1.3
posterior bone displacement	0.5/1.3	0.5/1.5	-0.3/1.5	-0.3/1.4
wedge angle fracture (degree)	0.9/3.9	0.5/3.5	-2.7/4.2	-0.1/4.7
Cobb angle fracture (degree)	2.3/3.6	2.8/3.6	-3.6/3.0	-1.8/2.3

differences. The intra-observer differences (anatomy t1-t2 and 3DRX t1-t2 for both observers) ranged from -0.8 to 1.4 millimeter and the standard deviation varied between 0.4 and 2.4 millimeter. For the wedge angle the intra-observer difference ranged between -1.7 and 1.0 degrees (standard deviation between 1.2 and 2.9 degrees) and for the Cobb angle between -1.7 and 0.2 degrees (standard deviation between 1.6 and 3.6 degrees). Table 2 lists the intra-observer details.

Table 2. Mean differences of anatomical sections at t1-t2 and 3DRX images at t1-t2, and the standard deviations of these differences.

Intra-observer difference (mm)	Observer 1		Observer 2	
	anatomical mean/stdev	3DRX mean/stdev	anatomical mean/stdev	3DRX mean/stdev
anterior vertebral body height 1	0.1/2.0	0.4/1.2	0.5/1.4	0.2/0.6
anterior vertebral body height 2	-0.6/1.8	0.0/0.6	1.1/1.5	-0.3/1.1
anterior vertebral body height 3	-0.5/1.5	0.1/0.7	1.4/1.8	-0.3/0.6
posterior vertebral body height 1	-0.8/1.7	0.4/0.8	0.7/1.1	0.3/0.6
posterior vertebral body height 2	-0.8/1.8	0.2/0.6	0.4/1.4	0.2/0.6
posterior vertebral body height 3	-0.4/1.5	-0.3/0.8	0.3/1.4	0.1/1.1
central vertebral body height 1	-0.7/1.1	0.1/1.1	-0.2/2.0	0.1/0.6
central vertebral body height 2	-0.3/0.9	0.2/0.7	0.3/0.8	0.3/1.1
central vertebral body height 3	-0.3/1.0	-0.5/1.1	0.2/1.1	0.1/1.0
anterior disc height 1	0.6/1.9	0.0/0.6	-0.8/1.7	0.0/0.8
anterior disc height 2	0.1/1.4	0.0/0.6	-0.8/1.7	0.4/0.9
posterior disc height 1	0.5/1.7	-0.1/0.5	-0.8/1.5	0.0/0.5
posterior disc height 2	1.0/1.5	0.0/0.8	-0.5/1.4	-0.1/0.6
central disc height 1	0.6/0.7	0.2/0.6	-0.2/0.8	-0.2/0.8
central disc height 2	0.2/1.0	-0.5/2.4	-0.3/0.7	-0.2/1.0
anterior bone displacement	0.4/1.4	-0.3/0.7	-0.5/0.8	-0.2/0.4
posterior bone displacement	0.2/0.9	0.2/0.9	-0.6/1.2	-0.5/1.1
wedge angle fracture (degree)	-0.2/2.6	0.2/1.2	-1.7/2.9	1.0/2.4
Cobb angle fracture (degree)	-0.3/3.6	-0.7/2.1	-1.7/1.9	0.2/1.6



Discussion

In this study we demonstrated the accurate correspondence of 3DRX images with anatomical sections, for each individual observer, by direct comparison of reconstructed midline images and photographs. The results showed that a high accuracy, already demonstrated in phantoms, is also valid for more clinically oriented models.[19]
The graphical method that was used to measure the various parameters, was highly reproducible as was clearly shown by the intra-observer scores at two time points. The intra-observer differences, however, were not equal to zero thereby imposing a limit on the accuracy of the 3DRX anatomy comparison measurements. Considering that the mean differences and standard deviations between the 3DRX and anatomy parameters were barely larger than the intra-observer differences and standard deviations, the 3DRX data did correspond very well with the 'golden standard' of anatomy. We hypothesize that a (small) variability in the graphical method of measuring was probably responsible for most of the observed differences. For the graphical method to work, it was assumed that both observers would point to identical landmarks on both image modalities. This may have been hampered somewhat by differences in interpretation of the anatomy due to degeneration and less than perfect alignment of the 3DRX images with the anatomical images, possibly leading to a decrease in correspondence. In the current study, only mid-sagittal images were extracted from the datasets therefore no information was obtained on the accuracy for the (infinite number of) other planes that could be visualized. Since the 3D volume was built from isotropic (cubic) voxels, it is to be expected that assessment of other planes would yield the same values. The presence of a large amount of very radiodense material (the 3DRX

acquisition runs were obtained with four titanium pedicle screws, two titanium rods and more than 10 grams of calcium phosphate cement in situ) was expected to seriously affect the quality of the reconstruction since it would be projected over a large part of the anatomical specimen in all images.[13,17] The large streak artifacts that can appear are well-known in computed tomography. These result from the difficulty of reconstructing and visualizing relatively radiolucent structures without much contrast (for example human tissue) in the presence of structures that represent the maximum attenuation value. However, we did not find any obvious detrimental effect of these radiodense materials on the reconstruction quality and the visualized (cortical) bone provided sufficient contrast for the study purposes. One has to keep in mind, though, that the signal to noise ratio was undoubtedly positively affected by the absence of practically any soft tissue. For example in severely osteoporotic patients, the visualization of bone surrounded by a large volume of soft tissue could be considerably worse than we experienced during the current investigation. Although we did not perform a bone mineral density scan, the bone quality of our specimens was, considering the age of the donors, probably somewhere between young, healthy bone and severely osteoporotic bone.

We focused on the accuracy of 3DRX images in an experimental setting, not on utility or ease of use of the device. In the experimental situation, the actual reconstruction required a considerable amount of computational time (> 10 min) and specialized personnel to operate the 3DRX workstation. These are practical considerations, however, that do not appear insuperable in the near future. Already, the computational time has been reduced to 1-2 minutes due to improved hardware and reconstruction algorithms although these improvements were not yet available during the experiments.

The results from our study suggest that a single 3DRX system can be used in the same way that both fluoroscopy and CT are utilized nowadays, thus fulfilling the expectations that were stated in the introduction section: providing intraoperative 2D projection images and accurate 3D volumetric reconstructions. Further development and refinement of the 3DRX technique is warranted and assessment of its utility in patients is currently under investigation by the authors.

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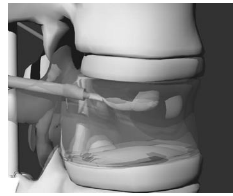
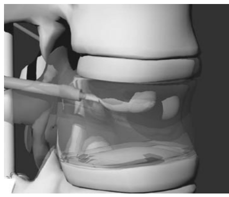


Chapter 6

The reduction of fractured endplates during balloon vertebroplasty. A detailed radiological analysis of the treatment of burst fractures using pedicle screws, balloon vertebroplasty and calcium phosphate cement.

Verlaan JJ, van de Kraats EB, Oner FC, van Walsum Th, Niessen WJ, Dhert WJA. Submitted to *Spine* 2004.



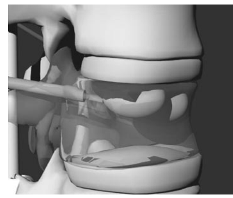
Introduction

Balloon vertebroplasty, also known as kyphoplasty or balloon kyphoplasty, seems to be an effective and relatively safe procedure to treat pain resulting from osteoporotic vertebral compression fractures. Several studies have shown that by using this technique, instead of conventional vertebroplasty, the risk of cement leakage is diminished and a kyphotic deformity can sometimes be corrected.[1-3] In other experimental studies, the role of (balloon) vertebroplasty was also investigated for the treatment of traumatic fractures. Mermelstein *et al.* found in their cadaveric burst fracture study that vertebroplasty with calcium phosphate cement (CPC) reinforced the anterior column and reduced stress on the pedicle screw construct.[4] In another cadaveric study, balloon vertebroplasty was performed on traumatic burst fractures after posterior short-segment pedicle screw fixation.[5] It was found that endplate impression could be reduced significantly following the experimental procedure. However, limited quantitative data exist on the amount of fracture reduction that can be achieved with the inflatable bone tamps and, especially, how much of the reduction will be lost after deflation and removal of the bone tamps before the cement is injected. Belkoff *et al.* showed that inflation of the bone tamps resulted in some height restoration of osteoporotic vertebral bodies held under simulated physiological loads.[6] It can be speculated that a partial loss may occur after deflation and removal of the bone tamps. This can be due to the hydrostatic disc pressure, muscle tonus and possibly also from a diminished support caused by the void under the endplates that is created by the bone tamps. To our current knowledge, no studies have been performed that have quantitatively investigated the amount of endplate reduction that is achieved (and subsequently lost) during balloon vertebroplasty.

In the current study, a relatively new imaging modality, 3D Rotational X-ray (3DRX) imaging, was used to assess, in traumatically fractured human cadaveric spines, the central height and sagittal area of the affected vertebral bodies and adjacent discs in five parallel sagittal planes at various phases during balloon vertebroplasty after posterior fixation. We were specifically interested in the reduction of the fractured endplate and potential loss of reduction after deflation of the balloons, and after injection of the cement.

Material and Methods

Ten fresh frozen cadaveric spines (T8-S1) without gross signs of osteoporosis, compression fractures or other pathology as demonstrated by anteroposterior and lateral radiographs, were obtained (donor age: mean 65 years, range 56-76 years, male/female ratio: 8/2). Most of the paraspinal and psoas muscle were removed, while preserving the ligaments, and the spines were subsequently bisected at T11-T12 to create a total of twenty specimens. The cranial and caudal extremities of the specimens were rigidly embedded in cups with plastic foam leaving the middle vertebra free. During the entire experiment, the exposed parts of the specimens were kept from drying out by frequent appliance of gauzes saturated with physiologic saline. A weight-dropping device was used (20-25 kg from 1.50 m height) to create burst type fractures (ten thoracic, ten lumbar).[7] Each specimen was given a basic AO classification after inspection, palpation and careful manipulation: A (load mainly axial); B (axial in combination with flexion/extension); or C (axial in combination with rotation). All fractures were reduced with careful distraction and stabilized with titanium pedicle screws and rods (BWM system, Stryker Howmedica). The goal of the posterior instrumentation was to get an anatomical alignment of the specimen and provide distraction, as is regular practice in traumatic spine fracture management. After achieving an optimal reposition, two cannulas were inserted transpedicularly in the posterior part of the fractured vertebral body under fluoroscopic guidance. A hand drill was used to create space under the most depressed part of the endplate to allow introduction of the inflatable bone tamps (KyphX, Kyphon Inc.). These bone tamps had been used before once, in a clinical setting, but were otherwise regular. After positioning the balloons in the space under the endplate, they were inflated simultaneously with 1.0 ml increments, each increment followed by a fluoroscopic image to monitor the expansion. After an optimal endplate reduction was achieved, the amount of bone cement needed for a complete filling was estimated from the total balloon volume. The cement (BoneSource, Stryker Howmedica) was prepared by adding 0.33 milliliter to each gram of powder and mixing it by hand until an injectable paste resulted. The cement was subsequently transferred to a 10 ml syringe with a large bore needle that was flushed with physiologic saline first to allow unimpeded flow of the cement. After deflation and removal of the balloons the needle was inserted through one of the pedicles into the anterior part of the vertebral body and, using continuous fluoroscopy to assess the distribution, the cement was injected until a complete filling was achieved. Pressurization of the cement was not performed to avoid extracorporeal cement leakage. See Figure 1a-c for a chronologic image series obtained during the procedure. A 3DRX dataset was obtained (INTEGRIS BV5000, Philips Medical Systems) for the following phases:



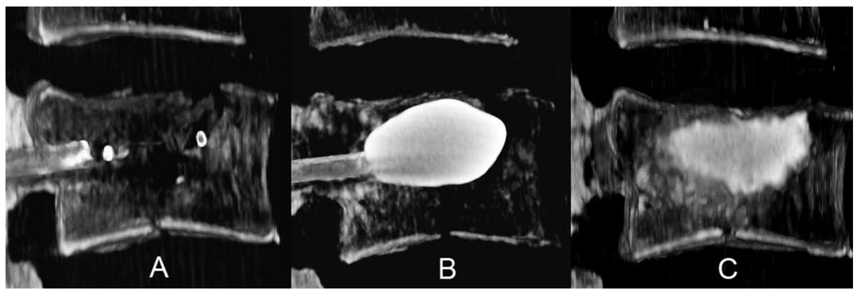


Figure 1. **A reconstructed 3DRX sagittal image of a lumbar (split-) burst fracture after posterior instrumentation and distraction demonstrating.**

A
The inflatable bone tamps in situ before inflation; note the radiodense spheres that indicate the proximal and distal end of the balloon.

B
The inflated balloon and the achieved reduction of the endplate.

C
The situation after injection of the cement; note the intimate interdigitation of the cement with the surrounding cancellous bone.

- intact (T_{intact});
- fractured ($T_{fractured}$);
- after insertion of the inflatable bone tamps but before inflation ($T_{reduction}$);
- after optimal reduction of the endplate with the balloons inflated ($T_{inflation}$);
- after deflation of the balloons but before cement injection ($T_{deflation}$);
- 10 minutes after injection of the cement (T_{cement}).

Mid-sagittal and parallel images (two to the left and two to right at 5.0 mm distance each) were reconstructed on a workstation (EasyVision system Philips Medical Systems) together with a virtual 50-millimeter ruler and exported to a personal computer. Dedicated 2D/3D modeling software (Rhinoceros version 3.0, Seattle USA) was used for the analysis of the following parameters (see Figure 2 for a graphical explanation of the measurements used):

- the length of the 50 millimeter ruler (for real world dimension conversion);
- the Minimum Central Vertebral Body Height (MCVBH) of the fracture, defined as the length of the vertical line from the most impressed part of the cranial endplate to the most impressed part of the caudal endplate;
- the Maximum Central Intervertebral Disc Height (MCIDH) of the two adjacent discs, defined as the length of the vertical line from the most impressed part of the adjacent vertebral body to the most impressed part of the fractured vertebral body;
- the Sagittal Area of the fractured Vertebral Body (SAVB): the area within the hexagon defined by the four points on the outer corners of the fractured vertebral body and the two endpoints from the line describing the minimum central vertebral body height;

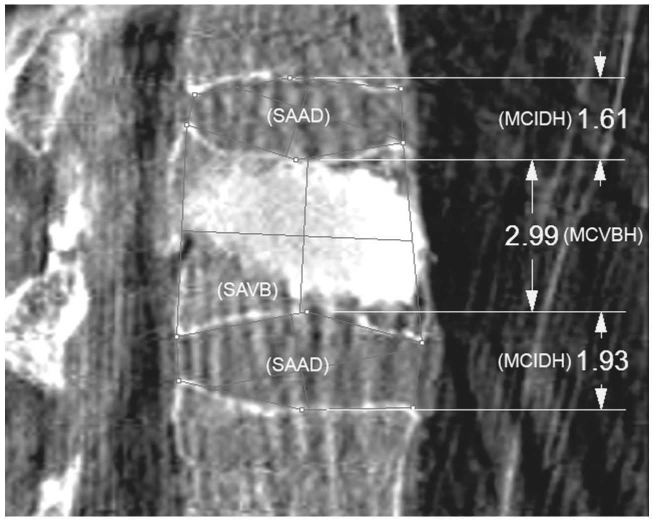


Figure 2.

A reconstructed 3DRX sagittal image after injection of the cement demonstrating the graphical measuring method used. The middle points from the three (connected) hexagons, outlining the cranial disc/vertebral body/caudal disc respectively, are used for the height measurements (MCVBH/MCIDH). The numbers on the right are computer output before conversion to real world dimensions.

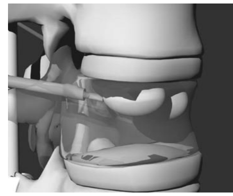
- the Sagittal Area of the Adjacent Discs (SAAD): the area within the hexagon defined by the outer corners of the fractured vertebral body and cranial / caudal vertebral body respectively and the two endpoints from the line describing the maximum central intervertebral disc height.

The parameters from all five slices were averaged and means and standard deviations calculated to provide information about the average amount of reduction of the endplate at the six phases. Furthermore, to assess whether the endplate could be reduced evenly, the measurements from the outer two parallel images, each at 10.0 millimeter from the center, were averaged and compared with the measurements from the mid-sagittal image for all six phases.

Finally, the anatomical specimens were sliced in the midsagittal plane to detect unwarranted leakage of cement in the spinal canal.

Statistical analysis The parameters were analyzed for differences between the phases with an ANOVA test. In case of significance, subsequent differences between phases were analyzed with the T-test (paired, single-tailed). The statistics were performed using SPSS v.11.0 ($p \leq 0.05$).

Results



After inspection, four fractures could be classified as A-type, four as B-type and twelve as C-type fractures. Furthermore they were all burst fractures as far as the involvement of the vertebral body was concerned, *i.e.* including a fracture of the posterior wall. The pedicle-screw instrumentation and subsequent alignment, distraction and stabilization were uneventful. It was observed that the inflatable bone tamps were often difficult to place in the desired intravertebral location under the most depressed part of the endplate. This was due to the orientation of the pedicles relative to the vertebral body and the flexibility of the tips of the balloons. Additionally, the direction of the expansion of the balloons could not be controlled; it was dictated mainly by the 'route of least resistance'. This is very likely to be dependent on the density of the cancellous bone; its resistance to the expansion of the balloons would probably be higher in spines of younger patients. In the elderly population (forming the largest part of the vertebroplasty patient group), however, this 'route of least resistance' effect might be even more pronounced than we experienced in our specimens although the incidence of burst fractures, on the other hand, is much lower in this group.

The total mean balloon volume was 7.2 ml (range 6-9 ml) at the thoracic levels and 13.6 ml (range 5-20 ml) at the lumbar levels. The mean amount of cement injected in order to achieve a complete filling was 12 gram (range 10-15 grams) at the thoracic levels and 23 grams (range 10-30 grams) at the lumbar levels. No obvious associations between balloon volume and amount of cement injected were found in relation to the AO fracture type. A small amount of cement extravasation was seen in one (A-type fracture) lumbar specimen where it leaked through the anterolateral wall of the vertebral body into the psoas compartment.

Table 1. **The mean height and surface area, and their respective standard deviations, of the thoracic and lumbar specimens for all six phases.**

height (mm) /sd		T_{intact}	$T_{fractured}$	$T_{reduction}$	$T_{inflation}$	$T_{deflation}$	T_{cement}
cranial disc	thoracic	5.6/1.2	6.9/1.0	7.0/1.0	7.0/0.9	7.0/1.0	7.0/0.9
	lumbar	12.6/3.0	14.8/3.0	17.0/2.9	14.0/2.5	16.0/3.5	15.0/2.9
vertebral body	thoracic	19.5/2.2	14.6/3.8	17.3/2.2	20.1/2.0	18.0/2.0	17.8/1.8
	lumbar	23.2/3.8	14.7/3.0	18.4/2.5	23.2/3.5	19.3/2.3	20.2/2.8
caudal disc	thoracic	6.2/1.4	7.4/1.6	8.0/1.3	8.0/1.2	8.0/1.3	8.0/1.3
	lumbar	14.4/2.9	15.3/3.2	16.0/3.7	15.0/2.8	16.0/3.7	15.0/3.4

area (cm^2) /sd		T_{intact}	$T_{fractured}$	$T_{reduction}$	$T_{inflation}$	$T_{deflation}$	T_{cement}
cranial disc	thoracic	1.3/0.2	1.5/0.3	1.6/0.3	1.6/0.3	1.6/0.3	1.7/0.3
	lumbar	3.6/0.9	4.2/1.2	4.6/1.2	4.1/1.0	4.5/1.2	4.4/1.1
vertebral body	thoracic	6.3/1.0	5.3/1.0	5.9/1.0	6.6/1.1	6.0/1.0	6.0/1.0
	lumbar	9.2/1.4	7.3/1.2	8.2/1.2	9.7/1.7	8.5/1.2	8.7/1.2
caudal disc	thoracic	1.4/0.3	1.6/0.3	1.8/0.3	1.8/0.2	1.8/0.3	1.8/0.3
	lumbar	4.0/1.0	4.2/1.1	4.5/1.2	4.3/1.0	4.4/1.2	4.3/1.1

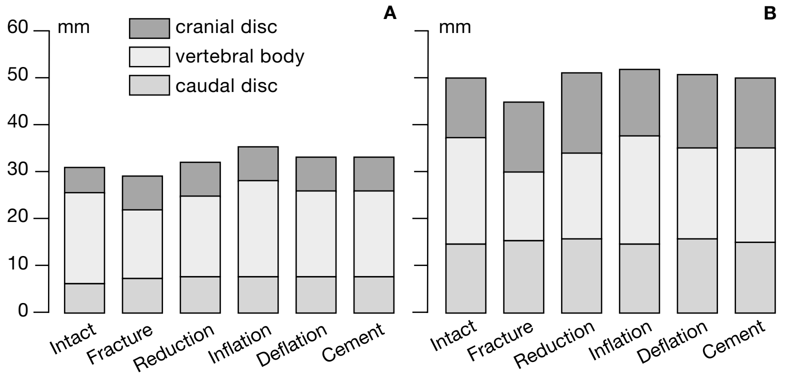


Figure 3.

Graphs showing:

A
The maximum height of the thoracic cranial disc, minimum height of the vertebral body and maximum height of the caudal disc at the six phases.

B
Idem for lumbar specimens.

The MCVBH (mean ± standard deviation) at the thoracic level during the various phases was: T_{intact}= 19.5 ± 2.2 mm; $T_{fractured}$= 14.6 ± 3.8 mm; $T_{reduction}$= 17.3 ± 2.2 mm; $T_{inflation}$= 20.1 ± 2.0 mm; $T_{deflation}$= 18.0 ± 2.0 mm; T_{cement}= 17.8 ± 1.8 mm. The overall change in MCVBH between these phases was significant ($p<0.001$). At the lumbar level MCVBH (mean ± standard deviation) was T_{intact}= 23.2 ± 3.8 mm; $T_{fractured}$= 14.7 ± 3.0 mm; $T_{reduction}$= 18.4 ± 2.5 mm; $T_{inflation}$= 23.2 ± 3.5 mm; $T_{deflation}$= 19.3 ± 2.3 mm; T_{cement}= 20.2 ± 2.8 mm. The overall change in MCVBH between these phases was also significant ($p<0.001$). In Table 1 the numerical data of the abovementioned measurements and those for the cranial and caudal MCIDH

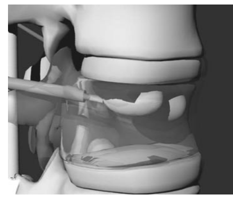
Table 2. **P-values demonstrating the difference in minimum central vertebral body height and mean sagittal area between the various phases.**

MCVBH thoracic	$T_{fractured}$	$T_{reduction}$	$T_{inflation}$	$T_{deflation}$	T_{cement}
T_{intact}	0.0038	0.0035	0.2358	0.0139	0.0032
$T_{fractured}$		0.0141	0.0003	0.0084	0.0099
$T_{reduction}$			0.0002	0.0115	0.0404
$T_{inflation}$				0.0002	0.0002
$T_{deflation}$					0.0965

MCVBH lumbar	$T_{fractured}$	$T_{reduction}$	$T_{inflation}$	$T_{deflation}$	T_{cement}
T_{intact}	0.0000	0.0020	0.4826	0.0033	0.0131
$T_{fractured}$		0.0001	0.0000	0.0000	0.0000
$T_{reduction}$			0.0000	0.0260	0.0001
$T_{inflation}$				0.0004	0.0007
$T_{deflation}$					0.0214

SAVB thoracic	$T_{fractured}$	$T_{reduction}$	$T_{inflation}$	$T_{deflation}$	T_{cement}
T_{intact}	0.0100	0.0383	0.0819	0.1477	0.0889
$T_{fractured}$		0.0361	0.0025	0.0296	0.0248
$T_{reduction}$			0.0003	0.0419	0.0378
$T_{inflation}$				0.0013	0.0003
$T_{deflation}$					0.2040

SAVB lumbar	$T_{fractured}$	$T_{reduction}$	$T_{inflation}$	$T_{deflation}$	T_{cement}
T_{intact}	0.0000	0.0012	0.0380	0.0048	0.0186
$T_{fractured}$		0.0060	0.0001	0.0002	0.0005
$T_{reduction}$			0.0000	0.0076	0.0027
$T_{inflation}$				0.0001	0.0003
$T_{deflation}$					0.1261



are presented in detail. In Figure 3a-b a graphical representation of these data in combination with the mean cranial and caudal MCIDH is shown. It was also found that changes in MCVBH from consecutive phases were all significantly different with the exception of the change in MCVBH after cement injection in thoracic vertebrae (Table 2).
The sagittal SAVB (mean ± standard deviation) at the thoracic level was T_{intact}= 6.3 ± 1.0 cm^2; $T_{fractured}$= 5.3 ± 1.0 cm^2; $T_{reduction}$= 5.9 ± 1.0 cm^2; $T_{inflation}$= 6.6 ± 1.1 cm^2; $T_{deflation}$= 6.0 ± 1.0 cm^2; and at T_{cement}= 6.0 ± 1.0 cm^2. The change in sagittal SAVB at these phases was significant ($p<0.001$). At the lumbar level the SAVB (mean ± standard deviation) was T_{intact}= 9.2 ± 1.4 cm^2; $T_{fractured}$= 7.3 ± 1.2 cm^2; $T_{reduction}$= 8.2 ± 1.2 cm^2; $T_{inflation}$= 9.7 ± 1.7 cm^2; $T_{deflation}$= 8.5 ± 1.2 cm^2; and at T_{cement}= 8.7 ± 1.2 cm^2. The change in sagittal SAVB at these phases was also significant ($p<0.001$). The data pertaining to the changes in sagittal area are also presented in Figure 4a-b and Table 1, in combination with the mean cranial and caudal sagittal SAAD.
The difference (mean ± standard deviation) between the MCVBH of the mid-sagittal and (averaged) peripheral images at the thoracic level was T_{intact}= 0.1 ± 0.8 mm; $T_{fractured}$= -0.4 ± 1.9 mm; $T_{reduction}$= 0.1 ± 1.3 mm; $T_{inflation}$= 0.2 ± 1.5 mm; $T_{deflation}$= 0.1 ± 1.2 mm; T_{cement}= -1.1 ± 2.0 mm.
At the lumbar level the difference was T_{intact}= 0.7 ± 1.1 mm; $T_{fractured}$= 0.8 ± 2.5 mm; $T_{reduction}$= 1.2 ± 1.7 mm; $T_{inflation}$= 0.4 ± 1.4 mm; $T_{deflation}$= 0.7 ±

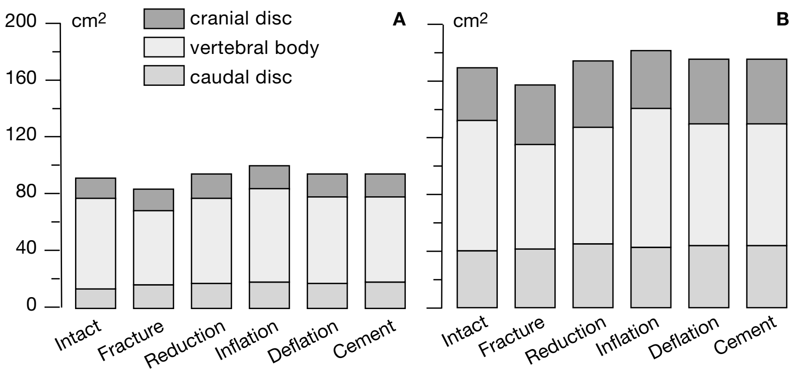


Figure 4.

Graphs showing:

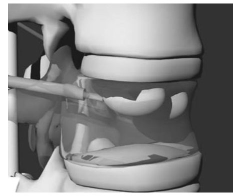
A
The surface area of the thoracic cranial disc, vertebral body and caudal disc at the six phases.

B
Idem for lumbar specimens.

1.2 mm; T_{cement}= 0.3 ± 1.5 mm. The differences were not significant at any of the phases.
After inspection of the sliced specimens, no cement was observed in the spinal canal.

Discussion

In the current study, the effect of balloon vertebroplasty on the reduction of the endplate was demonstrated in a traumatic cadaveric fracture model after posterior instrumentation. The 3DRX technique we used was validated in earlier work and showed to be accurate.[8] Both distraction with the pedicle-screw construct and inflation of the bone tamps resulted in a significant reduction of the impressed endplates. This effect was more prominent in the lumbar than the thoracic levels, because the lumbar endplates were more severely deformed after the traumatic impact as can be concluded from the results. This difference could have resulted from the stronger compression and subsequent greater release of energy from the lumbar disc to the endplate directly after the initial impact causing a 'wedging effect', as proposed by Ochia *et al.*[9] The height and surface area (and therefore volume) of thoracic discs are considerably smaller compared to the lumbar levels and contact of the vertebral body rims will occur earlier thereby also transferring energy through the cortex of the vertebral body.
Endplate reduction as a result of the balloon vertebroplasty procedure was achieved mainly by indirect compression of disc tissue by the balloons as was clearly shown by a decrease of both the maximum central intervertebral disc height and disc surface area from time point $T_{reduction}$ to $T_{inflation}$. Our findings correlate well with the results from the study by Belkoff *et al.*[6] In their study, the use of inflatable bone tamps in osteoporotic compression fractures that were under physiological loads, resulted in a significant restoration of vertebral body height in all, and a complete restoration in 22% of the specimens. Our use of pedicle screw distraction and fixation after the creation of a fracture, but before the balloon vertebroplasty procedure, is not identical to the design of the Belkoff study but it can be regarded as a realistic condition for the treatment of burst fractures with additional balloon vertebroplasty. The presence of the (rigid) posterior instrumentation will, in the end, limit the amount of reduction that is possible in the fractured vertebral body and adjacent discs. However, since we applied distraction first, which is regular practice, we probably facilitated the reduction of the endplates more than we limited it.[10,11]
One of the drawbacks from the Belkoff study is that they did not study the events after deflation of the balloons. In the present study, we demonstrated that almost all of the achieved reduction was lost after deflation and removal of the bone tamps. Several factors could play a role in this loss of endplate reduction. The most obvious would be the expansive capacity of the intervertebral disc. Although it is not unreasonable to suggest that most discs from our cadaveric specimens would have had some signs of degeneration, because the high incidence of spinal degeneration in elderly patients is well known, it was easy to deform the disc tissue elastically with the inflatable bone tamps.[12,13] During the experiment, the specimens were held moist with physiologic saline to keep the nucleus pulposus as hydrated as possible, therefore some of the elastic properties of the disc might have been preserved and this could, in turn, have been responsible for the observed loss of reduction. The reduction loss, as a consequence of the counter-pressure of the disc, might also have been facilitated by the large defects under the endplate that often resulted after maximum inflation and subsequent deflation (Figure 5). The empty space that was present after balloon removal would normally have been occupied by cancellous bone and contribute to the axial stiffness of the vertebral body. During clinical balloon vertebroplasty, irrespective whether it is used for osteoporotic or traumatic fracture treatment, several other factors could attribute to the loss of height restoration, such as paraspinal or abdominal muscle tonus, manipulation of the patient on the operating table and the effect of potentially more hydrated and more elastic intervertebral discs.



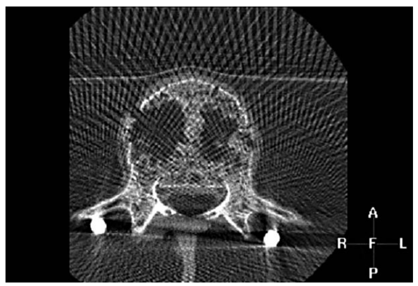


Figure 5.

A reconstructed 3DRX transverse image of a lumbar burst fracture obtained after removal of the balloons demonstrating the cavities that are created by the balloons.

The endplate was partly re-restored after injection of the calcium phosphate cement. This was significant in the lumbar specimens but not in thoracic specimens. The results show that the minimum vertebral body height increased, while the disc height decreased at the same time, instead of an absolute increase in the combined disc-body-disc specimen. Since we did not pressurize the cement, this partial restoration was probably the result of expanding the space that was only loosely occupied by disc tissue. This might imply that the forces exerted on the endplate by the disc after deflation of the balloons are not very large, therefore it can be argued that part of the reduction loss can be ascribed to the aforementioned loss of support under the endplates.
The balloon vertebroplasty procedure was effective in reducing the center of the endplate as well as the periphery. Before the experiment it was suggested that the placement of the inflated balloons, side by side in the vertebral body, leaving the middle (central) part of the endplate unsupported by them, would result in a less than optimal reduction of the mid-sagittal part of the endplate compared to the more peripherally located parts that were directly lifted by the bone tamps. Our results demonstrated that the central part could be lifted to a similar degree as the peripheral part.
From the present cadaveric study we conclude the following:

- reduction of fractured endplates, both in the center and at the periphery, seems feasible and safe with balloon vertebroplasty;
- after deflation of the bone tamps, the endplate reduction that was gained by the inflation, is lost again significantly;
- the injection of cement will partially restore the reduction that is lost after deflation of the bone tamps in lumbar vertebrae without having to pressurize the cement;
- overall, a significant reduction of the fractured endplates and a complete filling of the intravertebral void can be achieved by balloon vertebroplasty with calcium phosphate cement in both the thoracic and lumbar vertebrae.

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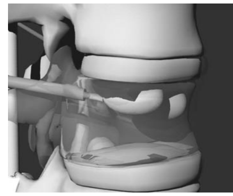
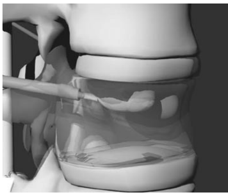


Chapter 7

Bone displacement and the role of longitudinal ligaments during balloon vertebroplasty in traumatic thoracolumbar fractures.

Verlaan JJ, van de Kraats EB, Oner FC, van Walsum Th, Niessen WJ, Dhert WJA. Submitted to *Spine* 2004



Introduction

Balloon vertebroplasty with poly(methyl methacrylate) cement is a relatively new and successful intervention for the pain treatment of osteoporotic compression fractures.[1-4] Compared to conventional vertebroplasty, the incidence of cement leakage during balloon vertebroplasty was reported to be lower.[5-8] The importance of preventing cement leakage was demonstrated in several cases, in which severe complications could be attributed to cement extravasation both anteriorly and posteriorly.[9-12] Several authors also claim height restoration of the treated vertebra with balloon vertebroplasty that cannot be gained with conventional vertebroplasty.[13,14] The lower risk for cement leakage probably result from 'autografting' cancellous bone to the periphery during expansion of the balloons, effectively lining the cavity with cancellous bone of higher density.

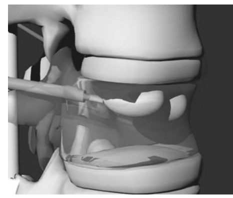
In traumatic spine fracture management, (balloon-) vertebroplasty has also received attention as supplement to pedicle-screw instrumentation to reinforce the anterior column after burst fractures.[15-17] The rationale of adding balloon vertebroplasty to the posterior instrumentation is that recurrent kyphosis and/or secondary procedures may be prevented if the fractured vertebral body and adjacent disc spaces are restored to their physiological shapes and intravertebral defects are filled with bone cement.[17-19]

However, the fracture morphology is considerably different between osteoporotic compression fractures and traumatic burst fractures.[20] The most important distinction is, without doubt, the integrity of the posterior vertebral body wall. This structure is, per definition, damaged in burst fractures and is one of the main criteria to call a thoracolumbar spine fracture 'unstable'.[20,21] Furthermore, it is this structure that can cause direct damage to the spinal cord during a traumatic impact, and is also responsible for spinal cord compression due to secondary retropulsion. The expansion of inflatable bone tamps in a burst vertebral body is a reason for concern, since it could enhance this retropulsion of bone fragments. Although recent *in vitro* work demonstrated balloon vertebroplasty, after posterior instrumentation, to be feasible and safe in traumatic burst fractures, minimal data are available on the risk of unwarranted bone displacement during inflation of the balloons or the risk of cement extravasation after injection.[16] It has been suggested that retropulsion of bone and leakage of cement in the spinal canal is prevented by the presence of an intact posterior longitudinal ligament. Similarly, anterior bone displacement and anterior cement leakage would be prevented by the presence of an intact anterior longitudinal ligament. In the current *in vitro* study, traumatic burst fractures with flexional and rotational components, known to have a high incidence of longitudinal ligament lesions, were created in cadaveric spine specimens and subsequently treated with balloon vertebroplasty after pedicle-screw instrumentation. A relatively new imaging modality, 3D rotational X-ray (3DRX) imaging, was used to quantitatively evaluate bone displacement and cement leakage in these fractures during the various phases of balloon vertebroplasty.[22]

The aims of the study were to assess the amount of anterior and posterior bone displacement during balloon vertebroplasty after pedicle-screw instrumentation in a traumatic fracture model. Furthermore, the relation of longitudinal ligament continuity with bone displacement and the chance of cement leakage was evaluated.

Material and Methods

Ten fresh frozen cadaveric spines (T8-S1) without gross signs of osteoporosis, compression fractures or other pathology as demonstrated by anteroposterior and lateral radiographs, were obtained (donor age: mean 65 years, range 56-76 years, male/female ratio: 8/2). The paraspinal and psoas muscle were removed, while the longitudinal and interspinal ligaments were preserved, and the spines were subsequently bisected at T11-T12 to create a total of twenty specimens. The most cranial and caudal vertebrae of the specimens were rigidly embedded in cups with plastic foam, leaving the middle vertebrae free. During the entire experiment, the exposed parts of the specimens were kept from drying out by frequent appliance of gauzes saturated with physiologic saline. Through the bottom of both cups a hole was drilled and a 40 cm long metal rod (10 mm diameter) was inserted horizontally for fixation to a groundplate (lower cup) and manipulation purposes (upper cup) respectively. On the groundplate a weight-dropping device was constructed. During the fall of the weight (20-25 kg from 1.50 m height) the upper cup could be manipulated by an investigator in all directions. For the first ten specimens, axial torque was applied manually to the upper cup, causing it to rotate 45 degrees (clockwise or counter clockwise at random) relative to the groundplate cup, one second before impact. For the other ten specimens, 45 degrees of flexion was applied to the upper cup one second before impact. The thoracic and lumbar spine segments were distributed evenly over the two groups. After the creation of a fracture, each specimen was given a basic AO classification after inspection and careful manipulation: A-type (fracture mainly due to axial load); B-type (fracture mainly due to axial load in combination with flexional injury); or C-type (fracture mainly due to axial load in combination with rotational injury).[20] All fractures were reduced with careful distraction, under fluoroscopic monitoring, and stabilized with pedicle-screws and rods (BWM system, Stryker Howmedica). The goal of the posterior instrumentation was to get an anatomical alignment of the spine and provide some distraction, as is regular practice in traumatic spine fracture management. After the reposition was considered optimal, two cannulas were inserted transpedicularly in the posterior part of the fractured vertebral body under fluoroscopic guidance. A hand drill was used to create space under the most depressed part of the endplate to allow introduction of the inflatable bone tamps (size 20/3, KyphX, Kyphon Inc.). After positioning the balloons in the space under the endplate, they were inflated simultaneously with 1.0 ml increments, each increment followed by a fluoroscopic image to monitor the expansion. After the endplate reduction was considered to be optimal, the amount of bone cement needed for a complete filling was estimated from the total balloon volume. An injectable calcium phosphate cement (BoneSource, Stryker Howmedica) was prepared by adding 0.33 milliliter of physiologic saline to each gram of powder and mixing it by hand until an injectable paste resulted. The cement was transferred to a 10 ml



syringe with a large bore needle that was flushed with physiologic saline first to allow unimpeded flow of the cement. After deflation and removal of the balloons, the needle was inserted through one of the pedicles into the anterior part of the vertebral body and, using continuous fluoroscopy to assess the distribution, the cement was injected until a complete filling was achieved. Pressurization of the cement was not performed. A 3DRX dataset was obtained (INTEGRIS BV5000, Philips Medical Systems) for the following phases:

- intact (T_{intact});
- fractured ($T_{fractured}$);
- after insertion of the inflatable bone tamps but before inflation ($T_{reduction}$);
- after optimal reduction of the endplate with the balloons inflated ($T_{inflation}$);
- after deflation of the balloons but before cement injection ($T_{deflation}$);
- 10 minutes after injection of the cement (T_{cement}).

Mid-sagittal and two parallel images (one to the left and one to right at 5.0 mm distance each) were reconstructed on a workstation (EasyVision system Philips Medical Systems, Best, The Netherlands), together with a virtual 50-millimeter ruler, and exported to a personal computer. Dedicated 2D/3D modeling software (Rhinoceros version 3.0, Seattle USA) was used for the analysis of (see Figure 1 for a graphical explanation of the measurements):

- the Posterior Bone Displacement (PBD), defined as the maximum posterior distance (mm) between bone fragments and the line that was drawn from the upper and lower corner of the posterior vertebral body;
- the Anterior Bone Displacement (ABD), defined as the maximum anterior distance (mm) between bone fragments and the line that was drawn from the upper and lower corner of the anterior vertebral body;

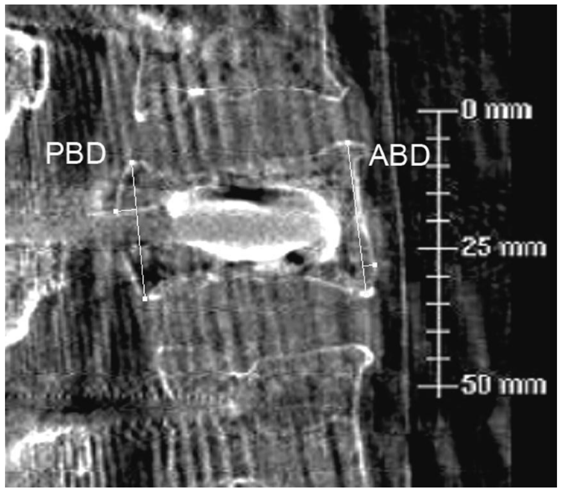


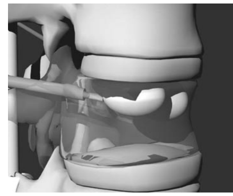
Figure 1.

A reconstructed 3DRX midsagittal image showing a lumbar burst fracture with the balloons inflated. The small (horizontal) lines demonstrate the graphical assessment of the posterior bone displacement (on the left) and the anterior bone displacement (on the right). The virtual ruler on the right was used for real world conversion of the parameters.

The parameters from the three slices were averaged and means and standard deviations were calculated to provide information about the average amount of bone displacement, both posteriorly and anteriorly, during reduction of the fracture and the balloon vertebroplasty procedure.
The specimens were frozen to -20 degrees Celsius and the pedicle-screw instrumentation was removed. Finally, the specimens were cut in mid-sagittal and parallel planes (at 5.0 mm distance each) and, after thawing, the continuity of the anterior and posterior longitudinal ligaments was assessed by inspection and dissection. The inspected ligaments were classified as: longitudinal ligaments with continuity (no damage or partial rupture) and without continuity (complete rupture).

Statistical analysis The PBD and ABD were analyzed for differences between the phases with a Repeated Measures ANOVA test. The continuity of the longitudinal ligaments was used as between-subjects factor. In case of significance, subsequent differences between phases were analyzed with the T-test (paired, two-tailed). The statistics were performed using SPSS v.11.0 ($p \leq 0.05$).

Results



The fractures created were classified as four A-type, four B-type and twelve C-type fractures. Damage (partial or complete rupture) to at least one of the longitudinal ligaments was sustained in all but two fractures. In Table 1, the fracture type and continuity of the longitudinal ligaments is presented in detail. The pedicle-screw instrumentation and balloon vertebroplasty proce-

Table 1. Fracture characteristics and associated damage to the longitudinal ligaments.

specimen	applied force	level	AO classification	ALL	PLL
1	rotation	thoracic	C	continuous	continuous
		lumbar	A	continuous*	continuous*
2	rotation	thoracic	C	ruptured	ruptured
		lumbar**	A	continuous*	continuous*
3	rotation	thoracic	C	ruptured	ruptured
		lumbar	C	continuous*	ruptured
4	rotation	thoracic	C	ruptured	continuous
		lumbar	C	continuous*	continuous
5	rotation	thoracic	A	continuous*	continuous
		lumbar	A	continuous*	ruptured
6	flexion	thoracic	C	continuous	continuous
		lumbar	C	ruptured	ruptured
7	flexion	thoracic	B	continuous*	ruptured
		lumbar	C	continuous	continuous
8	flexion	thoracic	B	ruptured	ruptured
		lumbar	C	continuous	continuous
9	flexion	thoracic	B	continuous	ruptured
		lumbar	C	ruptured	ruptured
10	flexion	thoracic	B	continuous*	continuous
		lumbar	C	continuous	continuous

* no obvious damage
** this specimen had cement leakage

dure was performed without technical difficulties. The mean pressure in the balloons, after an optimal reduction of the fractured endplates was achieved, was 50.0 ± 17.6 psi. No significant differences in pressure were observed between the left or right balloon, between fractures created with rotational or flexional force, or between the thoracic or lumbar level. The total mean balloon volume was 7.2 ± 1.3 ml (range 6-9 ml) at the thoracic levels and 13.6 ± 2.6 ml (range 5-20 ml) at the lumbar levels. The mean amount of cement injected in order to achieve a complete filling was 12 gram (range 10-15 grams) at the thoracic level and 23 grams (range 10-30 grams) at the lumbar level. No obvious associations between balloon volume or amount of cement injected were found in relation to the AO fracture type. A small amount of cement extravasation was seen in one lumbar A-type fracture where it leaked through the anterolateral wall of the vertebral body into the psoas compartment. This specimen had intact longitudinal ligaments both anteriorly and posteriorly.
The overall changes of PBD and ABD were significant ($p<0.05$) at both levels for all consecutive phases. The mean PBD at the lumbar levels was T_{intact}: 0.0 mm; $T_{fractured}$: 3.4 mm; $T_{reduction}$: 2.1 mm; $T_{inflation}$: 2.4 mm; $T_{deflation}$: 2.1 mm; and T_{cement}: 2.0 mm. The PBD at the thoracic levels was T_{intact}: 0.0 mm; $T_{fractured}$: 3.5 mm; $T_{reduction}$: 1.8 mm; $T_{inflation}$: 2.7 mm; $T_{deflation}$: 1.8 mm; and T_{cement}: 1.8 mm. In Table 2, the numerical data of the PBD (and ABD), with their respective standard deviations, are presented in detail. In Figure 2, a graphical representation of the mean PBD with standard deviations is presented for the lumbar and thoracic specimens. The individual changes in PBD in the lumbar specimens were significant from T_{intact} to $T_{fractured}$ ($p<0.0001$) and also from $T_{fractured}$ to $T_{reduction}$ ($p<0.01$) but not for the other phases. In the thoracic specimens the changes in PBD were significant for all phases except for $T_{deflation}$ to T_{cement}.
The ABD at the lumbar levels was T_{intact}: 0.0 mm; $T_{fractured}$: 1.9 mm; $T_{reduction}$: 1.4 mm; $T_{inflation}$: 2.7 mm; $T_{deflation}$: 1.7 mm; and T_{cement}: 1.9 mm. The ABD at the thoracic levels was T_{intact}: 0.0 mm; $T_{fractured}$: 2.3 mm; $T_{reduction}$: 1.1 mm; $T_{inflation}$: 1.8 mm; $T_{deflation}$: 1.3 mm; and T_{cement}: 1.6 mm. In Figure 3, a graphical representation of the mean ABD with standard deviations is presented for the lumbar and thoracic specimens. The changes in ABD in the lumbar speci-

Table 2.

	T_{intact}	$T_{fractured}$	$T_{reduction}$	$T_{inflation}$	$T_{deflation}$	T_{cement}
PBD lumbar	0.0 ± 0.0	3.4 ± 1.4	2.1 ± 1.4	2.4 ± 1.1	2.1 ± 1.2	2.0 ± 0.9
significance		0.0000	0.0012	0.3661	0.1149	0.2949
PBD thoracic	0.0 ± 0.0	3.5 ± 1.3	1.8 ± 1.2	2.7 ± 0.9	1.8 ± 0.9	1.8 ± 0.9
significance		0.0000	0.0002	0.0175	0.0308	0.8531
ABD lumbar	0.0 ± 0.0	1.9 ± 1.8	1.4 ± 1.2	2.7 ± 1.5	1.7 ± 1.3	1.9 ± 1.1
significance		0.0087	0.1836	0.0066	0.0115	0.1806
ABD thoracic	0.0 ± 0.0	2.3 ± 2.2	1.1 ± 1.1	1.8 ± 1.0	1.3 ± 1.2	1.6 ± 1.2
significance		0.0146	0.1262	0.0173	0.0201	0.2847

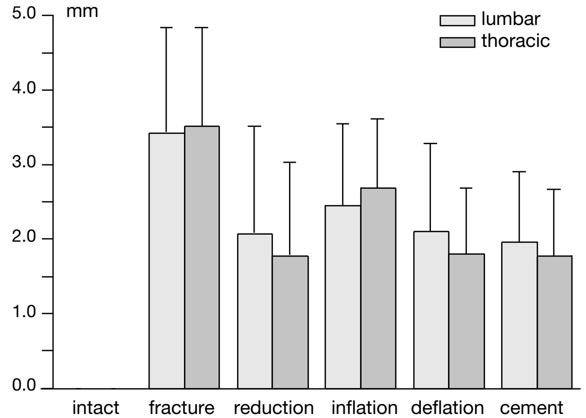
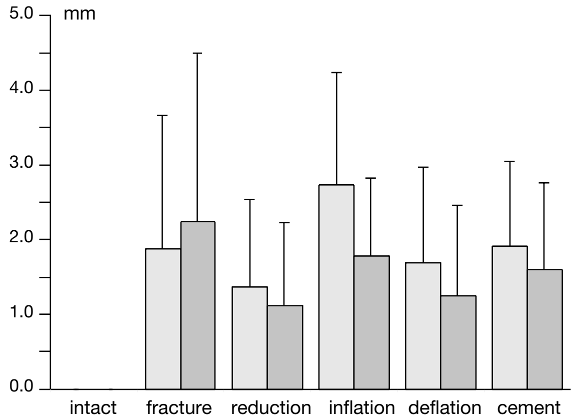


Figure 2.

Graph demonstrating the posterior bone displacement, during the various phases of the experiment, at the thoracic and lumbar level.



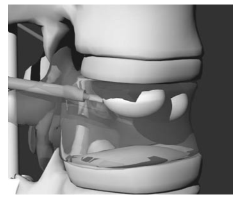


Figure 3.

Graph demonstrating the anterior bone displacement, during the various phases of the experiment, at the thoracic and lumbar level.

mens were significant for T_{intact} to $T_{fractured}$ ($p<0.01$), for $T_{reduction}$ to $T_{inflation}$ ($p<0.01$) and also for $T_{inflation}$ to $T_{deflation}$ ($p<0.05$). In the thoracic specimens the changes in ABD were significant for T_{intact} to $T_{fractured}$ ($p<0.05$), for $T_{reduction}$ to $T_{inflation}$ ($p<0.05$) and also for $T_{inflation}$ to $T_{deflation}$ ($p<0.05$).
No differences in PBD or ABD were detected for specimens with or without continuity of the corresponding longitudinal ligament, irrespective of the level, at any of the phases during the experiment ($p>0.5$ in all cases). In

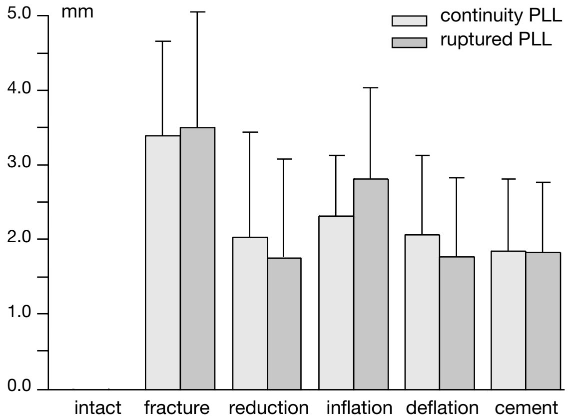


Figure 4.

Graph demonstrating the posterior bone displacement in specimens with and without continuity of the posterior longitudinal ligament during the various phases of the experiment.

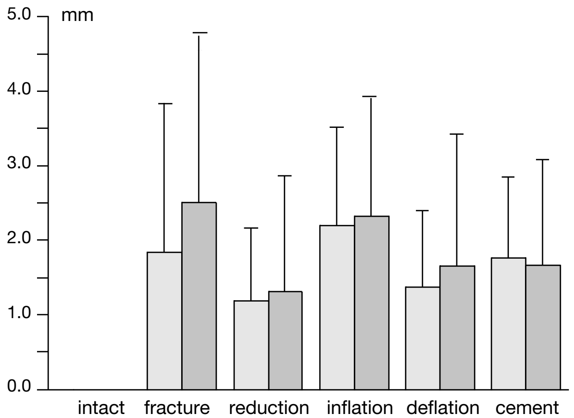


Figure 5.

Graph demonstrating the anterior bone displacement in specimens with and without continuity of the anterior longitudinal ligament during the various phases of the experiment.

Figure 4, the PBD is shown for specimens with (n=11) and without (n=9) continuity of the posterior ligament. In Figure 5, the ABD is shown for specimens with (n=14) and without (n=6) continuity of the anterior ligament.

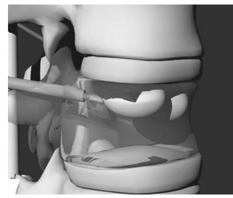
Discussion

In the present study, we demonstrated the limited amount of bone displacement as a direct consequence of balloon vertebroplasty after pedicle-screw instrumentation, in cadaveric traumatic burst fractures with damaged longitudinal ligaments. Furthermore, the discontinuity of longitudinal ligaments was shown not to be an additional risk factor for extracorporal leakage of cement.

The importance of an intact posterior longitudinal ligament for the successful indirect reduction of traumatically retropulsed bone fragments has been questioned by some authors.[23-25] It was suggested that an intact outer annulus fibrosis, with special regard to the integrity of Sharpey's fibers, played a crucial role in the reduction of bone fragments after distraction. The anteriorly directed force, generated by stretching the posterior longitudinal ligament during distraction, would not be sufficient for an adequate reduction of the retropulsed fragments. The necessity of an intact posterior longitudinal ligament for the reduction of retropulsed bone fragments could also not be confirmed by our work, since the reduction in PBD was not different between the group with a continuous or discontinuous posterior longitudinal ligament after pedicle-screw distraction. The same conclusions could be applied to the ABD as no difference was found as well.

Recent *in vitro* work by Wilcox *et al* demonstrated, in a bovine fracture model, the posterior longitudinal ligament to function (together with the outer annular fibers) mainly as a first barrier against the retropulsion of bone fragments during the actual impact.[26,27] Furthermore, the authors showed that maximum canal occlusion occurred during the impact itself and was decreased immediately afterwards, probably as a result of a recoiling effect facilitated by the stretched annulus fibers and posterior longitudinal ligament, and also by the elastically compressed dura and spinal cord. It is currently not known whether the impact causes the posterior longitudinal ligament to deform elastically, or to become permanently stretched. In the latter case, its possible attribution to (secondary) indirect reduction of bone fragments is likely to be inadequate since no anteriorly directed force can then be generated at all during distraction within safe limits.

After inflation of the balloons, a significant increase in the lumbar and thoracic ABD and in the thoracic PBD was found. The PBD did not increase significantly at the lumbar level during inflation. This discrepancy in PBD may be explained by the relatively large balloons (identical in size for lumbar and thoracic specimens) that were used in the thoracic vertebrae. Compared to the smaller size, these balloons are longer and a larger volume of contrast fluid is subsequently needed in the larger balloons before they start to expand in a vertical direction. The amount of extra volume may have resulted in an increase in intravertebral pressure, but without attributing much to the reduction of the endplate, leading to an increase of the PBD. The absolute increase in PBD (< 1.0 millimeter), however, is unlikely to be of high clinical relevance since the resulting total PBD was smaller than the PBD directly after the traumatic impact as can be concluded from the results presented in Figure 2.



The increase in ABD for both levels can be explained by the presence of the cannulas in the posterior part of the vertebral body, effectively restricting the balloons to expand in the posterior direction thus forcing them anteriorly. Furthermore, the most severe damage was often present in the anterior two/thirds of the vertebral body and since the balloons were positioned under the most deformed part of the fractured endplate, it is likely that expansion would affect anterior bone displacement more prominently.
Although a significant increase in ABD was temporarily present during the inflation of the balloons, the absolute values are not considered to be of high clinical relevance since no structures as vulnerable as the spinal cord are located anteriorly. Deflation of the balloons resulted in a return of the ABD and PBD to the same level as before inflation, while the injection of cement did not alter the ABD and PBD significantly after that.
One of the shortcomings of our model could be that, during the balloon vertebroplasty procedure, the longitudinal ligaments were damaged as a consequence of inflation of the balloons. Since the continuity of the ligaments could only be evaluated reliably after the experiment, partially ruptured longitudinal ligaments may have become completely ruptured due to the restoration of the vertebral body height. However, we did not observe any phenomenon, such as snapping or a sudden decrease in balloon pressure during the experiment, that could indicate to this mode of failure and therefore we do not think that this was an issue. Secondary longitudinal ligament rupture as a consequence of the pedicle-screw distraction, could not be ruled out either (although it seems equally unlikely since it would probably be detected during the distraction), but it would not have changed any of the conclusions from this investigation.
Cement leakage was observed once during the experiment, in one of the two specimens that had no obvious damage to the longitudinal ligaments. A small amount of calcium phosphate cement leaked into the psoas compartment and would probably not be of any concern in a clinical situation.
It was concluded from the current *in vitro* work that balloon vertebroplasty after pedicle-screw instrumentation may safely be used, even in fracture types where damage to longitudinal ligaments is to be expected.

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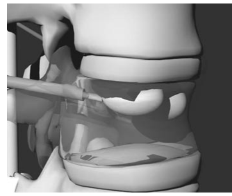
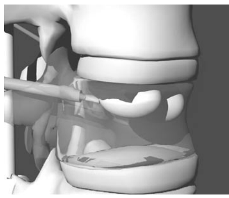


Chapter 8

Histologic changes after vertebroplasty.

Verlaan JJ, Oner FC, Slootweg PJ, Verbout AJ, Dhert WJA.
In press *Journal of Bone and Joint Surgery (Am)* 2004.



Introduction

Vertebroplasty using poly(methyl methacrylate) is rapidly gaining popularity in the treatment of some specific painful lesions of the spine, such as osteoporotic compression fractures, spinal myeloma, haemangioma and metastatic lesions.[1-12] It remains unclear by which pathway the procedure achieves pain reduction and what possible side effects the cement might have after a prolonged period of time in the vertebral body. The widespread assumption that stabilization of the vertebral body is the key to pain reduction has led many physicians to try and achieve a cement pillar from endplate to endplate during the procedure.[11] Following the publication of several *in vitro* studies pertaining to vertebroplasty with calcium phosphate cement, Nakano *et al.* were the first to describe the results of calcium phosphate based vertebroplasty in osteoporotic patients.[13-15] Interestingly, their twelve patients responded to treatment in terms of pain reduction, similarly to patients treated with poly(methyl methacrylate) cement. Their data provide further support that stabilization of the vertebral body is an important factor for the reduction of pain as opposed to thermal or chemical destruction of nociceptors.[16]
Although the histologic effects of poly(methyl methacrylate) cement have been studied extensively in arthroplasties, limited data are available on spine applications.[17-20] Surprisingly, considering the large number of patients already treated with poly(methyl methacrylate) vertebroplasty, no studies have been conducted to assess the effects of the injection of poly(methyl methacrylate) in the proximity of the endplate. Since the endplate is the main nutritional pathway to the disc, a disturbance of this structure could lead to an impairment in the transport of nutrients and waste products.[21,22 23]
Some fractures, both the traumatic burst type and the osteoporotic compression type, are accompanied by fractures of the endplate, therefore direct contact of cement with disc tissue can be expected at least in some patients. However, the interaction of these materials with disc or endplate tissue has not been studied *in vivo*. For instance, it can be questioned whether poly(methyl methacrylate) cement should be used for vertebroplasties in younger patients, as it is a permanent cement and does not have the potential of calcium phosphate cement to be replaced by host tissue.[24-27]
In the present study a histologic and radiographic analysis of the endplate and intervertebral disc was performed to determine if there was a difference between vertebroplasty with poly(methyl methacrylate) cement and vertebroplasty with calcium phosphate cement in the surrounding tissue of the goat spine. Furthermore, we assessed whether the presence of a defect in the endplate, simulating an endplate fracture and allowing for direct contact between cement and disc tissue, had an effect on endplate or disc degeneration.

Material and Methods

Study design After approval from the local institutional review board for animal experiments, twenty-four mature dairy goats (approximately 2.5 years of age) were obtained from a professional stockbreeder. The animals were divided between a follow-up period of six weeks or six months. All animals underwent a bilateral transpedicular vertebroplasty at two levels of the lumbar spine (L3 and L5), where one of the following treatments was applied according to a randomized, balanced implantation schedule: vertebroplasty with calcium phosphate cement with (CPC+) or without endplate fracture (CPC-), and vertebroplasty with poly(methyl methacrylate) cement with (PMMA+) or without (PMMA-) endplate fracture. This resulted in a sample size of six for each of the treatments per follow-up period. At the end of the implantation period, the animals were killed and the effect of the various treatments on the integrity of the adjacent intervertebral disc, endplate and surrounding tissue was examined by semiquantitative histology and radiography. To assess the natural history of disc degeneration in the goat, we obtained six lumbar spines from goats from a different study (not spine related) but of the same breed and same age. The vertebral bodies and cranial discs of L3 and L5 from these six spines served as controls for the study.

Surgical procedure The animals received an intravenous line for the administration of an anesthetic (thiopental 10 mg/kg) and antibiotics (amoxicillin 500 mg) and were intubated endotracheally for inhalation anesthesia (isoflurane 2%). The goats were prepared for surgery in a prone position. After shaving, draping and desinfecting the lumbar area, a midline incision at the L2-L6 level was performed, followed by dissection and hemostasis of the dorsal musculature to access the entrance of the pedicles of L3 and L5. Through a transpedicular approach from both sides, a 2.5 mm. diameter high-speed drill was used to gain access to the cranial part of the vertebral body (Figure 1). The orientation and length of the drill trajectory was practiced beforehand on cadaveric material, to minimize the risk of pedicle wall penetration. Two mills of increasing diameter (3.0 and 4.0 mm.) were used to ream a central cavity in the cranial part of the vertebral body, under continuous cooling with physiologic saline. In half of the goats (groups CPC+ and PMMA+), a defect (diameter 2.5 mm.) was reamed in the cranial end-

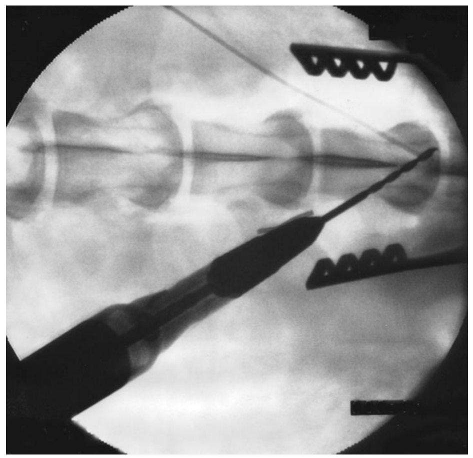
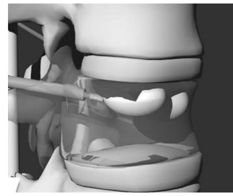


Figure 1.

Anteroposterior fluoroscopic image, with the caudal part on the lefthand side, demonstrating the access route to the vertebral body.



plate, to allow for direct contact of nucleus pulposus material with the cavity, thereby simulating an endplate fracture, as frequently encountered in vertebral fractures.
After rinsing of the defect with physiologic saline and drying by suction with a small diameter cannula through the pedicles, the cement was injected. For the poly(methyl methacrylate) cemented group, twenty grams of Simplex® P radiopaque bone cement (Stryker Howmedica Osteonics), a poly(methyl methacrylate) co-polymer cement with barium sulphate (13%) frequently used for vertebroplasty, was prepared. The liquid and powder components (stored at room temperature) were thoroughly hand mixed in an aluminum bowl with a wooden spatula for one minute and then transferred to a 10 ml. syringe. For the calcium phosphate cemented group, ten grams of BoneSource® (Stryker Howmedica Osteonics) and 3.4 ml. of physiologic saline were hand mixed for one minute using the same type of instruments. Depending on the implantation schedule, the appropriate cement was slowly injected through the right pedicle, until clean cement flowed out the left pedicle (indicating complete filling of the cavity). The cement was not pressurized since the preceding cadaveric practice showed that complete and intimate bone contact was easily achieved without pressure. All excess cement was subsequently removed from the operative field while keeping the pedicle entrances dry. Approximately five minutes after injection of the cement into the second vertebral body, the muscles and skin were closed in layers (Vicryl 2.0, Ethicon Inc.) and the inhalation anesthesia was stopped. An anteroposterior fluoroscopic image was obtained of the lumbar spine to determine the disc height. After recovery, the animals were housed separately for three days and received intramuscular analgesics (buprenorphine, twice a day) and antibiotics (neomycin and penicillin) during this period. Thereafter, the animals were housed in groups until they were killed at six weeks or six months after surgery.

Post mortem sample acquisition All animals were killed using an overdose of barbiturates and anteroposterior fluoroscopic images were obtained while the animal was on the operating table in the same position as during surgery. After removal and inspection of the lumbar spine (L2-L6), the vertebral bodies of L3 and L5 were cut out and fixed in glutaraldehyde (Karnovsky's) fixative. After stepwise ethanol dehydration, the bodies were embedded in poly(methyl methacrylate) and cut in four sagittal slices of 4.0 mm., using an electric band saw (Exact 300, Exact Vertriebs GMBH Norderstedt, Germany). Following staining with methylene blue and basic fuchsin, 10 micron sections were cut from the four slices with a Leica microtome (Leica SP1600, Leica Microsystems Rijswijk, The Netherlands). The fourth slice was cut on both sides resulting in a total of five tissue sections that were subsequently prepared for histological evaluation (Figure 2). The same histological preparation was used for the twelve vertebral bodies from the control group.

Histological and radiological scoring system Two authors (PJS, JJV) assessed the following parameters using low magnification light microscopy:

- inner annulus failure according to Osti (absent, present);[28]
- nuclear degeneration according to Osti (absent, moderate, marked);

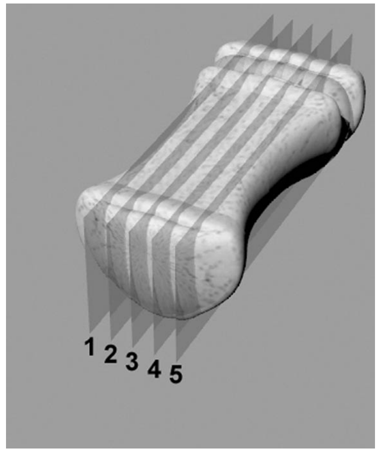
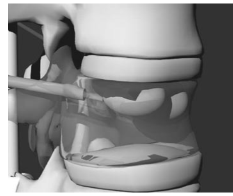


Figure 2.

Artist impression of the vertebral body, including the disc and the adjacent cranial level, demonstrating the five sections that were processed from the four 4mm slices for histological analysis.

- narrowing of the disc space according to Osti (absent, moderate, marked);
- degeneration of the disc according to Moore (absent, mild, moderate, marked);[29]
- secondary changes to the endplate (absent, moderate, marked);
- former growth plate (absent, partly present, present);
- herniation of nucleus pulposus into the vertebral body (absent, present);
- inflammatory reaction surrounding the cement (absent, mild: solitary lymphocytes and/or macrophages, moderate: focal aggregations of lymphocytes and/or macrophages, marked: general presence of lymphocytes and/or macrophages);
- fibrous layer surrounding the cement (absent, incomplete, complete);
- bone formation following cement resorption (absent, moderate, marked);
- zone (≈ 2 mm) surrounding cement (woven (immature) bone; lamellar (mature) bone; tissue other than bone). For each vertebral body the histological scores were reduced to four main parameters:
- signs of disc degeneration (inner annulus failure, nuclear degeneration, narrowing of the disc space);
- signs of endplate degeneration (secondary changes, endplate erosion);
- inflammatory reaction surrounding the cement;
- type of tissue in the zone surrounding the cement.

Any sign of disc degeneration in any of the five slices would render the disc degeneration outcome as 'present'; otherwise it was 'absent'. Any sign of endplate degeneration in any of the five slices would render the endplate degeneration outcome as 'present'; otherwise it was absent. The inflammatory reaction surrounding the cement was determined for the vertebral body by the histologically most unfavorable score ('absent' being the most favorable and 'marked' the least favorable score) in any of the five slices. Similarly, the zone surrounding the cement was determined for each vertebral body by the histologically most unfavorable score ('lamellar' being the most favorable and 'other tissue than bone' the least favorable score) in any of the five slices.
The anteroposterior fluoroscopy images were digitized and, because it was technically difficult to get exact 1:1 (life size) fluoroscopic images that could be compared postoperatively and after termination, the ratio of the maxi-



mum disc height and the width of the lower endplate from the adjacent cranial vertebra was determined. Since we were mainly interested in a change of disc height instead of the absolute values, this approach ensured a dimension-free and repeatable measurement of the disc height without calibration.

Statistical Methods The radiographic postoperative values were compared with the values at termination using a two-tailed paired t-test for dependent samples to assess the changes in disc height ($p \leq 0.05$).

Results

All surgical procedures and the subsequent recovery of all animals were uneventful. The estimated amount of cement that could be injected into the vertebral body was 0.5-0.8 ml, corresponding to a vertebral body filling percentage of 14% to 22% (based on measurements on the cadaveric material), which is comparable to the human vertebroplasty situation. In two goats, leakage of cement was observed after the animal was killed. In one case, some calcium phosphate cement entered the spinal canal, in the other case

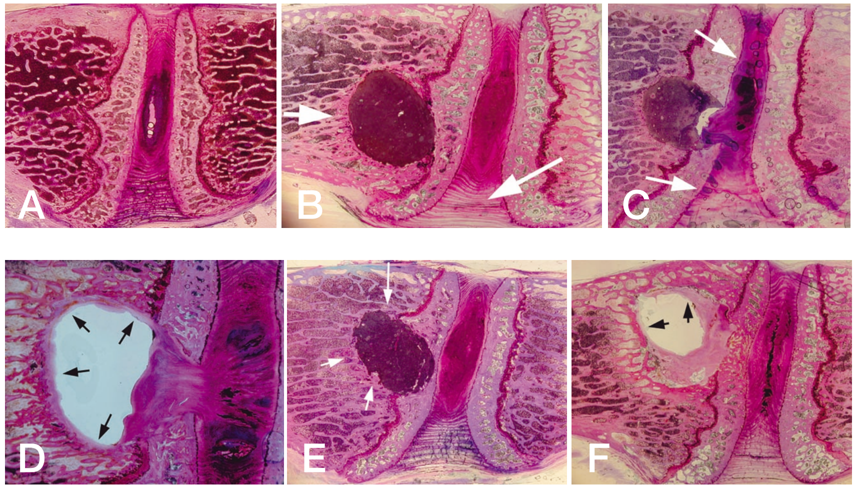


Figure 3. **Low magnification (approx. 10x) sagittal sections from a selection of vertebral bodies demonstrating intervertebral discs and endplates without signs of degeneration.**

A Control section.
B Calcium phosphate cement without endplate defect at six weeks. Notice the regular annular pattern (long arrow) and the new, immature, bone formation surrounding the cement (short arrow).
C Calcium phosphate cement with endplate defect at six weeks. Although this section contains more preparation artefacts the annular pattern is regular and the endplate, except for the obvious defect, is intact (arrows).
D Poly(methyl methacrylate) cement with endplate defect at six weeks. The cement has been largely dissolved during embedding but the fibrous layer outlining its former place is clearly visible (arrows).
E Calcium phosphate cement without endplate defect at six months. The bone surrounding the cement is partly mature (long arrow) and partly immature (short arrows).
F Poly(methyl methacrylate) cement with endplate defect at six months. The defect in the endplate is not visible in this section and some fixation artefacts exist in the nucleus pulposus but the intact morphology of the disc is clear. Also notice the fibrotic layer in the cavity (arrows).

Table 1. **Results of the main parameters.**

Follow-up 6 weeks→		PMMA+	PMMA-	CPC+	CPC-
Disc degeneration	absent/present	6/0	6/0	6/0	6/0
Endplate degeneration	absent/present	6/0	6/0	6/0	6/0
Inflammatory reaction	absent/present	4/2	6/0	6/0	6/0
Zone (2 mm)	bone/other tissue	6/0	6/0	6/0	6/0
Follow-up 6 months→		**PMMA+**	**PMMA-**	**CPC+**	**CPC-**
Disc degeneration	absent/present	6/0	6/0	6/0	6/0
Endplate degeneration	absent/present	6/0	6/0	6/0	6/0
Inflammatory reaction	absent/present	3/1[a]	3/1[a]	6/0	6/0
Surrounding zone	bone/other tissue	6/0	6/0	6/0	6/0

[a] =in two specimens it could not be determined (see text)

some poly(methyl methacrylate) cement entered the psoas compartment. Both animals recovered from surgery without apparent disability. In two goats, a superficial wound infection was noticed that resolved within a week without additional treatment.
Overall, no signs of disc degeneration or endplate degeneration were seen in any of the 300 analyzed sections, which included the controls (Figure 3). An inflammatory reaction was found in four vertebral bodies. In all four cases it was a mild reaction and occurred only in poly(methyl methacrylate) cement treated animals. The zone surrounding the cement consisted of bone in all vertebral bodies (Table 1). In the controls all bone was mature (lamellar) and the former growth plate was always visible. A summary of the findings in the eight groups follows.

PMMA + , at 6 weeks The cement was completely covered by a fibrous layer in all vertebral bodies (Figure 4). A mild inflammatory reaction surrounded the cement in two vertebral bodies. In one vertebral body the former growth plate was absent and in one the zone around the cement, at the

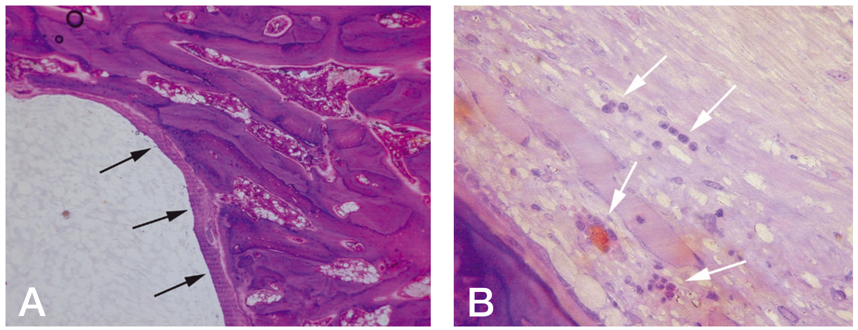
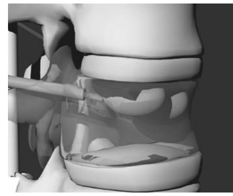


Figure 4.

In these higher magnification photographs (100x and 400x respectively) from a six weeks PMMA+ section, the fibrous layer (A) and a few inflammatory cells are demonstrated (B).



outer side of the fibrous layer, consisted of mature bone as opposed to the other five in which the zone consisted of immature bone.

PMMA - , at 6 weeks No inflammatory reactions were seen in any of the vertebral bodies. A complete fibrous layer around the cement was seen in five specimens. In one section, some nucleus pulposus material had herniated into the corpus (Figure 5). In the same vertebral body, the zone at the outer side of the fibrous layer around the cement was comprised of partly mature and partly immature bone. In the other vertebral bodies this zone consisted of immature bone.

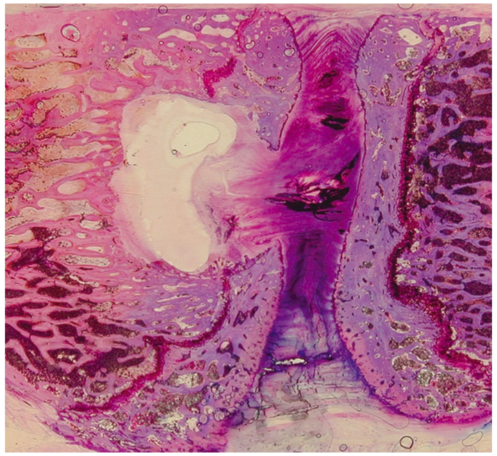


Figure 5.

A section through a PMMA+ specimen (six weeks) in which some nucleus pulposus material herniated in the cavity.

CPC + , at 6 weeks No inflammatory reactions were seen in any of the specimens. An incomplete fibrous layer was present around the cement in three specimens. Immature bone was deposited against the cement in one specimen. Some cement resorption was found in one specimen. The former growth plate was partly present in one and the zone surrounding the cement consisted of immature bone in all specimens.

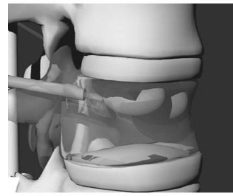
CPC - , at 6 weeks No inflammatory reactions and no fibrous layers were found in any of the vertebral bodies. In two, immature bone was formed as a result of replacement of cement by bone. The former growth plate was found to be absent in one specimen and partly present in two. The zone around the cement consisted of immature bone in all vertebrae.

PMMA + , at 6 months In this group a mild inflammatory reaction was found in one vertebral body; in two other specimens the presence of an inflammatory reaction could not be determined because the cement was located too lateral in the corpus to be present in the sections (this was probably due to our efforts not to damage the anterior cortex, thereby staying lateral of the midline). A complete fibrous layer around the cement was present in four specimens; in two specimens it could not be determined for the same reasons stated above. The former growth plate was partly present in four specimens and absent in one. In three vertebral bodies the zone around the cement, at the outer side of the fibrous layer, consisted of mature bone, in the other three there was immature bone.

PMMA - , at 6 months A mild inflammatory reaction was found in one vertebral body and could not be determined in two (same reason as above). A complete fibrous layer was found in three and could also not be determined in two. Absence of the former growth plate was found in one body as was a slight herniation of nucleus pulposus material in one. All surrounding bone was mature.

CPC+ , at 6 months No inflammatory reactions or fibrous layers were seen. The former growth plate was partly present in three specimens. The zone of surrounding bone was mature in four specimens and immature in two.

CPC - , at 6 months No inflammatory reactions or fibrous layers were seen in any of the specimens. Some bone formation after cement resorption was found in two vertebral bodies. The former growth plate was partly present in four vertebral bodies and a slight herniation of nucleus pulposus material was found in one. The surrounding bone was mature in four vertebral bodies and immature in two.



Summary of results Regarding the degeneration of the disc and the endplate, no differences were found between any of the treatment groups and controls since no degeneration was detected at all. Regarding the inflammatory reaction surrounding the cement, a difference between the poly(methyl methacrylate) cement group and the calcium phosphate cement group was found. A mild inflammatory reaction was present in four poly(methyl methacrylate) cemented vertebral bodies (2 out of 12 in the six weeks group and 2 out of 8 in the six months group; it could not be determined in four) but absent in all calcium phosphate cemented specimens. A thin fibrous layer surrounding the cement, indicating incomplete osteointegration, was found in almost all poly(methyl methacrylate) cemented vertebral bodies (11 out of 12 in the six weeks group and 7 out of 8 in the six months group; it could not be determined in four). In three calcium phosphate cemented bodies, an

Table 2. **Disc height ratios postoperatively and at termination (n=6 per group).**

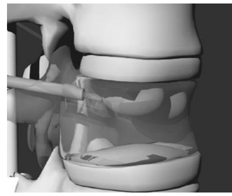
6 weeks	mean postoperatively	sd	mean at termination	sd	significance
PMMA+	0.14	0.02	0.13	0.01	ns
PMMA-	0.14	0.01	0.15	0.02	ns
CPC+	0.15	0.02	0.14	0.04	ns
CPC-	0.13	0.02	0.14	0.03	ns
6 months					
PMMA+	0.16	0.02	0.16	0.02	ns
PMMA-	0.13	0.03	0.16	0.01	p= 0.05
CPC+	0.14	0.02	0.16	0.03	ns
CPC-	0.14	0.02	0.15	0.02	ns

incomplete, thin layer of fibrous tissue was found (3 out of 12 in the six weeks group and none in the six months group) indicating that in the majority of cases the osteointegration was complete. An endplate defect did not seem to induce disc degeneration, endplate degeneration or influence the integration of the cement in the vertebral body. Bone formation following cement resorption was present in five specimens from the calcium phosphate cemented group (3 out of 12 in the six weeks group and 2 out of 12 in the six months group) while, not surprisingly, it was not present in the poly(methyl methacrylate) cemented group. The mean disc height did not decrease from the postoperative period to follow-up in any group thereby supporting the histologic findings of a healthy intervertebral disc (Table 2).

Discussion

We have demonstrated in this goat model that, regardless of which of the two types of cement is used or the presence of an endplate defect, vertebroplasty does not lead to degeneration of the disc or endplate. The current literature does not provide us with any clues as to what the long-term fate of these structures might be after vertebroplasty in humans, since the follow-up periods have typically not been more than a few years and histologic evaluations of human retrievals have rarely been reported.[30] Several human anatomical studies have pointed out that degeneration as part of the natural history of the disc can start as early as the second or third decade of life, while the quality of the disc can be reduced dramatically in the seventh decade and onwards.[31-35]
Many studies have clearly demonstrated the progressive degeneration and poor regenerative capacity of the disc once part of the annulus is damaged.[35-42]
Some of the abovementioned (and our current) studies have used quadruped models and therefore questions can arise about the relevance for the clinical situation. However, the predominant trabecular bone orientation in sheep and goats as well as human beings is in the cranial to caudal direction suggesting that loading of the spine is mainly in the axial plane in all three.[43-45]
Furthermore, the high bone density in the animals (much higher than humans even when corrected for age) suggests that the compressive forces that quadruped spines sustain are substantial.[43] Creating a control group with reamed defects in the cranial vertebral body (and endplates) combined with high axial loading could very well lead to a mechanical failure of the disc or endplate. However, since we were mainly interested in the biocompatibility of the cements (and not the biomechanical properties of the cements *versus* untreated defects), spines from unrelated research were used as controls to reflect the natural history of goat disc aging.
Minimal histological data exist on the short or long term effects of poly(methyl methacrylate) cement on the integrity of the endplate and intervertebral disc. Although several, mostly *in vitro*, studies have reported the temperature elevation caused by the polymerization of poly(methyl methacrylate) to be high enough to cause tissue necrosis, a recent *in vivo* study in goats did not support these findings.[16,46,47] Consistent with these studies, the data in the current study support the absence of thermal necrosis around poly(methyl methacrylate) cement. Calcium phosphate cements cure isothermically thus do not pose this potential problem.

Although both cements had good outcomes in the present study, the calcium phosphate cement group demonstrated superior osteointegration, compared to the poly(methyl methacrylate) cement group. No long term (> 5 years) clinical follow-up studies have been published yet on the application of calcium phosphate cements, but several studies have shown the biological properties of calcium phosphate cement to be superior to poly(methyl methacrylate) cement.[48,49,50] In a recent biomechanical and histomorphological study in goats, calcium phosphate cement was gradually replaced by bone while maintaining its mechanical integrity in subchondral defects of the femur.[51] Thus, we postulate that calcium phosphate cements may be preferred over poly(methyl methacrylate) cement particularly when vertebroplasty is to be performed in younger patients and long-term biocompatibility becomes an issue.[27]
In the present study, the histological effects of two types of cement were studied in a vertebral body with either an intact disc or a, deliberately created, defect in the endplate to simulate the local environment after an endplate fracture. In contrast to previous studies pertaining to annular lesions and subsequent disc degeneration a considerable defect in the endplate did not lead to disc degeneration in any of our specimens.[36,52] The nucleus pulposus has been shown to be inflammatogenic after disc herniation, but direct contact of vertebral bone and / or cement with nucleus pulposus material was not followed by histological evidence of inflammation in our model. [53,54]
Therefore, it is hypothesized that the endplate defect led to a condition similar to a Schmorl's node.[55] Further support for the hypothesis that endplate defects / fractures do not lead to disc degeneration but probably have a benign course comes from the MR-study by Oner *et al.*[56] It was found that a fracture of the endplate resulted in a redistribution of disc material through the endplate in the vertebral body but did not lead to disc degeneration.
One of the limitations of the goat model is that the high bone density and probably higher bone turnover of these animals does not reflect the typical human vertebroplasty population, where the incidence of osteoporosis is high. Also, in contrast to vertebral compression fractures in humans, the cortex in the treated vertebral bodies was intact and thus could continue to transmit loads without (macroscopic) deformation. The resulting stability might have influenced some of the study parameters, such as new bone formation, immune cell response or fibrous tissue formation.
Although our longest follow-up was only six months, we think this time to be sufficient for detection of the first signs of degeneration by histologic analysis.
In conclusion, we have demonstrated in an in vivo vertebroplasty model with and without endplate defects, that calcium phosphate cement and poly(methyl methacrylate) cement both seem to be adequate bone void fillers in terms of biological behavior in the vertebral body. Histologic or radiographic evidence of degeneration of the disc or endplate was not found in any of the specimens. Calcium phosphate cements might be a better choice than poly(methyl methacrylate) cement if long-term biocompatibility becomes an issue, although its mechanical properties have yet to be determined in the clinical setting.



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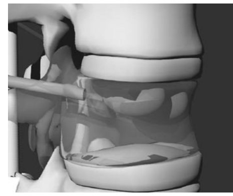
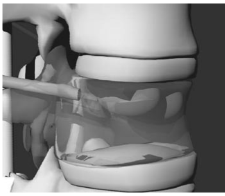


Chapter 9

Temperature elevation after vertebroplasty with polymethyl methacrylate in the goat spine.

Verlaan JJ, Oner FC, Verbout AJ, Dhert WJA.
***J Biomed Mater Res.* 2003;67B:581-585.**



Introduction

Vertebroplasty with polymethyl-methacrylate (PMMA) cement for the treatment of painful osteoporotic fractures is gaining in popularity due to the immediate and long-lasting relief of pain, the relative simplicity of the procedure and the low complication rate.[1-8] Although reports have described serious adverse events, such as nerve-root compression, paralysis and even death after vertebroplasty, their incidence is low.[3,6,9,10,11,12,13,14,15] The majority of authors however, assume that a substantial part of the complications can be ascribed to two properties of the cement: firstly, the viscosity of the cement strongly influences the risk of extracorporal cement leakage and its potentially harmful sequelae, of which pulmonary embolus and nerve-root compression are feared most.[9,16] Secondly, the exothermal polymerization of methyl-methacrylate can cause a temperature elevation high enough to lead to (soft-) tissue necrosis. This has been recognized and studied since the practice of cemented total joint arthroplasty but has, to our knowledge, not been studied *in vivo* after cement injection in the proximity of the intervertebral disc and spinal cord.[17-24] In the present study, the thermal effects of transpedicular vertebroplasty with PMMA cement are quantified in an animal model to provide data concerning the risks of thermal tissue-damage.

Materials and Methods

After approval from the local institutional review board for animal experiments, four Dutch milk-goats (approximately three years of age) were obtained from a professional stock-breeder. The animals received an intravenous line for the administration of an anaesthetic (thiopental 10mg/kg) and were intubated endotracheally for inhalation anaesthesia (isoflurane 2%). The goats were prepared for surgery in a prone position while body temperature was maintained using a electrically heated blanket. After shaving the lumbar area, a midline incision at the level L2-L6 was performed, followed by dissection and haemostasis of the dorsal musculature to get access to the entrance of the pedicles of L3, L4 and L5. Through a transpedicular approach from both sides, a 2.5 mm. diameter high-speed drill was used to drill until the contralateral cortex of the vertebral body was reached. Two mills of increasing diameter (3.0 and 4.0 mm.) were used to ream a central cavity in the cranial part of the vertebral body, under continuous cooling with physiologic saline. A thermocouple probe (K-type calibration) was inserted through the left pedicle into the vertebral body with the tip placed in the cranial and ventral part of the cavity, touching bone. A second thermocouple was placed in the center of the cranial intervertebral disc space through an 11G biopsy needle using a left dorsolateral approach, under fluoroscopic guidance. The third probe was inserted in the epidural space close to the cavity through an 11-G biopsy needle, put through the right foramen (Figure 1a-b). The correct position of the probes was verified again with AP and lateral fluoroscopy images, and subsequently the probes were connected to a digital multi-channel thermometer (Fluke 2176 series). The mean systemic body temperature was measured by an intranasal probe. To compensate for the direct loss of body heat to the air and the saline coolant, the

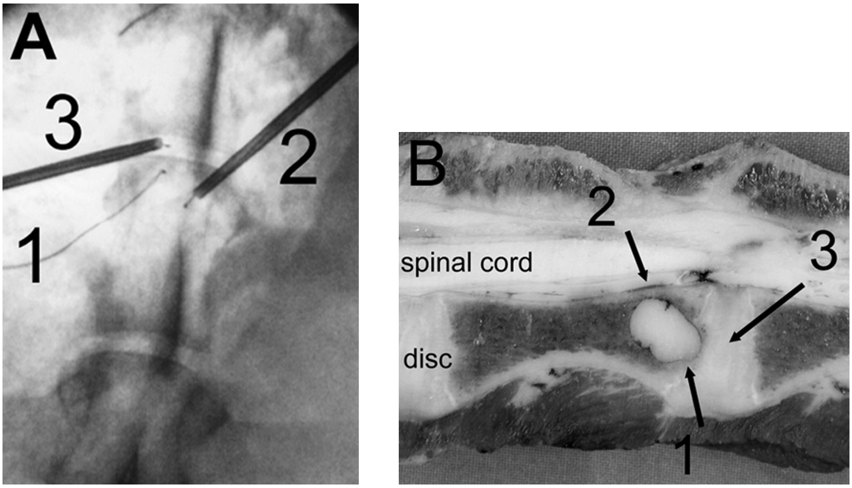
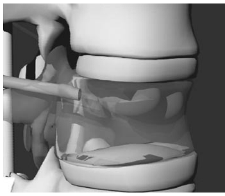


Figure 1.

A
Intraoperative antero-posterior fluoroscopic image for verification of the probes before cement injection. Probe 1 is positioned in the cranial part of the cavity, probe 2 is located in the epidural space above the cavity and probe 3 is placed in the center of the disc space.

B
Detailed photograph of the mid-sagitally divided spine (in horizontal position with the caudal part of the spinal cord on the left-hand side) demonstrating the cavity after cement injection and the postion where the probes 1-3 were located during the experiment.



exposed part of the spine was rinsed with 500 ml. of physiologic saline (37º C.), each time before cement injection and dried afterwards with gauzes. Twenty grams of Simplex P radiopaque bone cement (Stryker Howmedica Osteonics), a polymethyl-methacrylate cement with barium sulphate (13%) frequently used for vertebroplasty, was prepared for injection. The liquid and powder components (stored at room-temperature) were thoroughly hand-mixed in an aluminium bowl with a wooden spatula for one minute and then transferred to a 10 ml. syringe. The cement was slowly injected through the right pedicle, until clean cement flowed out the left pedicle (indicating a complete filling of the cavity). All excess cement was manually removed from the operating area. Five minutes after the start of the cement mixing (defined as t=0), the temperature of the three probes was recorded at distinct intervals (0, 10, 20, 30, 40, 50, 60, 70, 80, 90, 120, 150, 180, 210, 240, 300 and 360 seconds). All measurements were obtained and recorded for a single level before proceeding to the next. The order in which the temperature in the three vertebrae was measured was different for each animal as to minimize a possible relation between the first cemented level and the remaining spinal circulation that could influence measurements at the subsequent two levels. Upon completion of the experiment, the animal was killed with an overdose of barbiturates and the lumbar spine was removed and frozen at -20º C. After sawing in the mid-sagittal plane and macroscopical inspection, the cement in the vertebral bodies was removed and the volume of the cavities was determined by titration with water until complete filling, using a 2 ml syringe. Subsequent reaming of all the cancellous bone out of the verte-

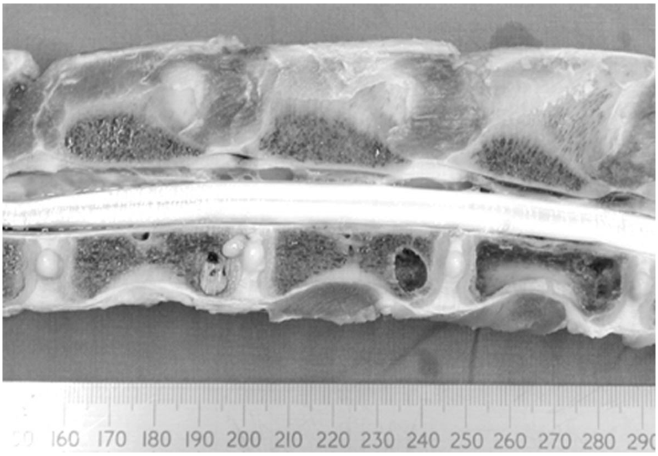


Figure 2.

Photograph of the split spine (in horizontal position with the caudal part of the spinal cord on the left-hand side) demonstrating from left to right: L5 with cement in situ, L4 with the cement removed and L3 with the cancelleous bone reamed out the corpus for volume measurement purposes.

bral body enabled us to measure the total intracorporal volume with the same technique (Figure 2). The cavity volume divided by the intracorporal volume yielded the filling-percentage. Detailed photographs of the hemispines together with a ruler were used to determine the shortest distance from the bone-cement interface to the location of the tip of the second and third probe respectively. The Wilcoxon Signed Ranks Test, in which $p \leq 0.05$ denoted significance, was used for statistical analysis of the data.

Results

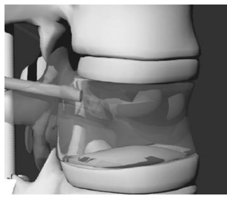
In all animals, the preparation of the cavities and insertion of the probes was without major difficulties, but in two cases we observed a small penetration of the anterior cortex after drilling. The duration of surgery, up to this point, was 135 minutes (range 120-150 min.) with a mean bloodloss of 140 ml. (range 100-150ml.). The filling of the cavities and subsequent temperature probing of the three levels took approximately fifty minutes and was uneventful. However, in one case the tip of a probe moved through the small anterior cortical defect of the vertebral body after injection of the cement. As a consequence, reliable measurements at the bone-cement interface could not be obtained and the results from this location were discarded from the study. The mean systemic body temperature was 36.8° C. (range 35.5-38.2° C.) at the time of cement injection. At t=0, the mean temperatures of the bone-cement interface, epidural space and disc space were 36.1, 35.8 and 36.2° C. respectively. The mean peak temperature at the interface was 44.6° C. (range 38.7-58.7° C.). In the epidural space, the mean maximum temperature was 37.0° C. (range 35.3-38.5° C.) and in the center of the disc space a mean temperature maximum of 37.5° was reached (range 35.5-40.3° C.).

Table 1.

Individual peak temperatures for the three locations.

case number	bone-cement	epidural space	disc space
1	42.1	38.1	35.5
2	46.9	35.3	37.3
3	41.2	36.3	38.1
4	38.7	36.3	36.3
5	probe malposition	36.1	36.5
6	40.7	35.9	36.8
7	44.2	38.1	38.1
8	44.3	37.9	37.8
9	39.7	36.4	36.6
10	47.7	38.5	40.3
11	46.1	37.2	37.3
12	58.7	37.4	39.8

See also Table 1 for the individual measurements. In all three locations the difference between the temperature measured at t=0 and the peak temperature was significant ($p<0.005$). In nine vertebral bodies, the maximum temperature measured at the bone-cement interface exceeded 40° C. (mean peak 45.8° C.), which lasted for an average of 124 seconds (range 50-350 sec.). In one case (case number 10), the temperature in the disc exceeded 40° C and this lasted for 30 seconds. In the other eleven discal and twelve epidural locations the temperature was always below 40° C. In Figure 3, the curves representing the mean temperature for each time interval are shown. Within six minutes after the onset of the temperature registration at the individual probes (eleven minutes after start of the cement mixing), the temperatures measured at the bone-cement interface had returned to within 2.0° C. of their baseline, and returned to within 1.5° C. of their baseline for the disc/epidural probes. Macroscopical inspection of the mid-sagittally divided



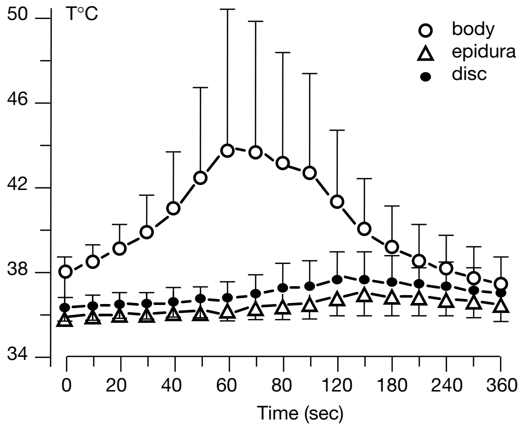


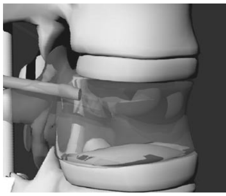
Figure 3.

Graph showing three curves representing the average measurements of all specimens for each time interval at the bone-cement interface, epidural space and disc space.

spines did not reveal any extracorporal manifestation of the cement anteriorly, in the disc or in the spinal canal. The mean volume of the cavities that were created measured 0.8 ml. (range 0.6-1.1 ml.). The volume was dictated by the size and morphology of the goat vertebrae. Since the average intracorporal volume measured 3.6 ml., the resultant mean filling percentage was 22% (range 18-26%). In the nine vertebral bodies of three goats the shortest distance from the probes to the cement was measured and in one goat the values could not be obtained. In these vertebral bodies, the distance from cement to the epidural probe ranged from 1.9 to 5.8 mm. (average 4.6 mm.) while for the probe in the disc space the distance to the cement ranged from 3.2 to 6.3 mm. (average 4.4 mm.).

Discussion

The clinical outcome of the treatment of painful osteoporotic vertebral fractures has improved considerably by the introduction of vertebroplasty, although severe complications were reported and evidence of the underlying beneficial mechanism remains unclear.[1,3,7,8,25-38] In this study, an animal model was used to assess the risk of thermal damage of adjacent tissue by measuring local temperature changes during the setting-period of PMMA cement after intravertebral injection. The extent of thermal tissue damage is determined by the absolute (maximum) temperature, the duration of the supra-physiological temperature, and by the tissue-specific vulnerability to heat exposure. The absolute temperature, as measured at the transition zone between cement and bone, is determined mainly by the immediate release of energy which depends on the polymerization rate of the cement. The duration of the temperature elevation depends mainly on the total thermal energy that is released and the capacity of adjacent tissue to conduct (by thermal diffusion at the cement-tissue interface) and convect (by the circulation of blood and cerebrospinal fluid) this energy to surrounding structures. The vulnerability of tissue to heat exposure has been studied in various animal models. Eriksson *et al.* demonstrated a significant decrease of bone regeneration in rabbits after heating tibiae to 50° C. for one minute, compared to the group that was heated to 44° C. for the same period.[39,40] In a recent study, pertaining to human histology after transpedicular vertebroplasty with polymethyl-methacrylate cement, Togawa *et al.* noted some foci of necrotic bone at the bone-cement interface, possibly as a result of thermal damage, from five vertebral body retrievals. The histology was also suggestive of remodeling of bone around the cement, but conclusions were not drawn due to the limited material.[41] We injected approximately 2.5 grams of polymethylmethacrylate cement in the cavities of the vertebral bodies. This amount accounts for about half of what has been demonstrated to have a beneficial effect in patients.[34,42,43] The cement volume fraction in our model, however, closely resembled that in clinical vertebroplasty. Liebschner *et al.* demonstrated, in an experimentally calibrated and anatomically accurate human model, a 14% cement-filling to be sufficient to restore the stiffness of the vertebral body to the pre-fracture value.[44] In present-day practice, an average of 2-6 ml. cement, depending on the level, is recommended for a single vertebral body.[34,43] This corresponds to a filling-percentage of 8-25%, which is comparable to the filling-percentage calculated from our model (18-26%). The steep increase of the bone-cement temperature curve before peaking indicates the vertebral body to be incapable of immediately soaking up all the energy that is generated by the methyl-methacrylate polymerization. However, the temperature/time graph in Figure 3, representing the mean temperature for each time interval at the three locations, and the individual maximum temperatures of the epidural- and disc space (located, on average, within 5 millimeters of the bone-cement interface) as shown in Table 1, demonstrated the efficacy of the goat spine to disperse thermal energy even if this was present for a prolonged period of time (≥ 45° C. for as long as two minutes in case 12). Our results can be related to the *in vitro* findings by Deramond *et al.*, who measured temperatures in human cadaveric vertebrae (placed in a 37° C. water-tank) after transpedicular injection of 10 ml. of Simplex P bone cement.[19] In their study, the average peak temperature measured in the center of the cement was higher than we observed at the bone-cement interface (61.8 *versus* 44.6° C.). A possible explanation for this difference could be the location of the probe (center versus periphery of the cement lump, where the effect of conduction is smallest), the difference in the absolute amount of cement used (10 *versus* 0.8 ml generating a much larger amount of energy to be dissipated), and the absence of an active 'heat-sink' mechanism (water-bath *versus* active circulation of blood and cerebrospinal fluid as convection method). Their mean temperature in the epidural space was 38.5° C. which compares well to our finding of 37.0° C. No comparison could be made with their third probe (situated at the anterior part of the vertebral body) as we decided to measure the intradiscal temperature. Taking into account the low amount of cement (< 10 ml.) that is recommended in contemporary vertebroplasty and the presence of a possibly protective convection mechanism, our results as well as their data give reason to speculate that, in clinical vertebroplasty practice, the use of poly-



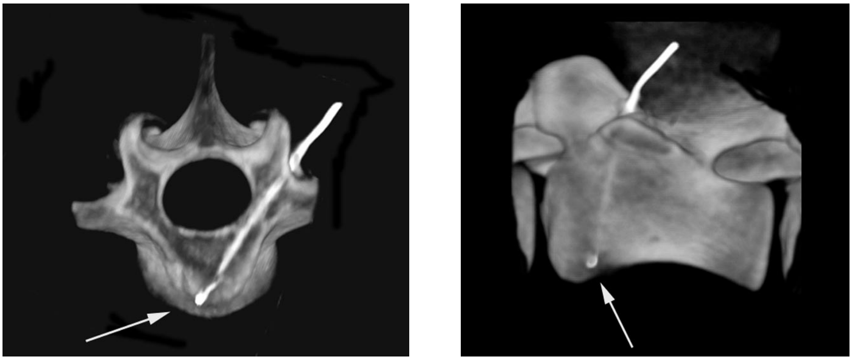


Figure 4.

A
Reconstructed transverse 3DRX image from case number 5, in which the probe migrated through the anterior cortical defect outside the vertebral body (arrow).

B
Reconstructed 3D image from the same case, demonstrating the extravertebral location of the probe's tip (arrow).

methyl-methacrylate cement, as long as it remains in the vertebral body, will not cause clinically significant local thermal damage. Furthermore, the suggestion that the beneficial effect of vertebroplasty (i.e. relief of pain) results from a thermal destruction of pain receptors seems less likely in this respect.[4] Nevertheless, it should be noted that the protective contribution of a heat-convection mechanism could deteriorate rapidly as vertebral blood flow decreases significantly with age.[45] Therefore, since local thermal necrosis after vertebroplasty is potentially very harmful, it still deserves serious consideration and further scientific attention, regardless of the fact that until now no study, clinical or experimental, has demonstrated a negative result that could be directly attributed to this phenomenon.

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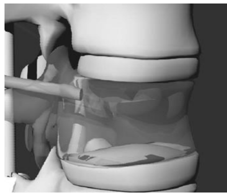

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Chapter 10

Balloon vertebroplasty in combination with pedicle screw instrumentation: A novel technique to treat thoracic and lumbar burst fractures.

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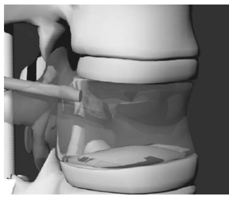
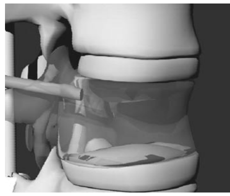


Introduction

A traumatic fracture of the spine is a serious medical condition that can have a major impact on the quality of life of the patient.[1,2] Although no consensus has been reached by treating physicians, surgical fixation of a traumatic fracture of the thoracic or lumbar spine is considered necessary if axial and rotational stability is severely impaired or if a neurological deficit is present or imminent. Short-segment pedicle screw instrumentation is a well-described technique to reduce and stabilize thoracic and lumbar spine fractures.[3,4] It is a relatively easy procedure but can only indirectly reduce a fractured vertebral body and the means of augmenting the anterior column are limited. Hardware failure and a loss of reduction are recognized complications caused by insufficient anterior column support.[5-7] Anterior procedures using iliac grafts or cages have been proposed to address the problem of this anterior column insufficiency, sometimes also in combination with posterior instrumentation. The anterior approach offers good visualization of the fracture and allows a direct restoration of the defect. Disadvantages, compared to pedicle screw instrumentation, are a longer duration of the procedure, higher blood loss and an increase in postoperative morbidity.[8-13] Combined anterior/posterior approaches are major surgical undertakings for the patient and do not seem to provide any real advantages over the anterior procedure alone.[9,14-16] Transpedicular spongiosaplasty, in which procedure autologous bone grafts are impacted in the vertebral body through the pedicles after reduction to increase the stiffness of the anterior column, was developed and promoted by Daniaux in 1986 as an interesting addition to posterior surgery.[17] Recent studies have shown that this technique does not prevent the recurrence of kyphosis reliably and reproducibly.[5,18] It has been noted by several authors that the loss of reduction after treatment of a fracture mainly takes place in the disc space. Previous studies suggest that the intrusion of the disc through the fractured endplate into the weakened vertebral body, instead of degenerative disc changes, is the likely cause of this collapse.[19,20] [5,21,22] Preventing the disc intrusion, by restoring the endplate anatomy after fracture reduction/fixation and filling of the resulting bone defect, was the subject of a recent cadaveric study.[23] It was concluded that anterior column augmentation by transpedicular balloon vertebroplasty with calcium phosphate cement (CPC) injection was safe and feasible. The purpose of the current study was, in a small scale investigation in twenty patients with traumatic burst fractures, to look for preliminary evidence of efficacy and side-effects of balloon vertebroplasty with CPC, additionally to posterior short-segment reduction and fixation (Phase II clinical study).

Patients and Methods

The clinical study proposal was approved by the medical ethical committee of our institution. Patients, eighteen years of age or older with a recent (< 5 days) burst fracture (AO classification A-3) of the thoracic or lumbar spine, without neurological deficits were included.[24] Exclusion criteria were a complete rupture of the posterior longitudinal ligament on MRI, a Glasgow coma scale less than 15 at admission and preexistent pathology that could compromise the surgical procedure. Preoperative antero-posterior and lateral radiographs of the fractured spine were obtained as well as MRI scans (sagittal and transverse; T1 and T2 weighted with a Philips Gyroscan NT5 (0.5 T) scanner) for assessment of damage to the endplate, vertebral body and discoligamentous structures. All patients signed an informed consent agreement after being informed about the procedure by the senior author (FCO) who performed all the procedures and has experience with the pedicle screw approach. The patients were operated on a priority rather than an emergency basis within a week after trauma. Short-segment pedicle screw and rod reduction and fixation (Diapason, Stryker Spine Bordeaux, Cestas, France) under general anesthesia and antibiotic prophylaxis (2 grams of Cefazoline during surgery and four times 1 gram in the following 24 hours) was performed in all cases. The goal of the posterior instrumentation was to re-align the adjacent vertebral bodies anatomically. The pedicles of the fractured vertebral body were subsequently identified and probed. Two cannulas were inserted into each pedicle under fluoroscopic guidance and placed with the tips just ventral to the posterior wall in the vertebral body to prevent the balloons from accidentally being inflated inside the pedicles and from expanding in a posterior direction. A hand drill was introduced in the vertebral body under the impressed endplate to create space for the inflatable bone tamps (KyphX Introducer Tool Kit, Kyphon Inc., Sunnyvale, California). Subsequently, both inflatable bone tamps (KyphX Inflatable Bone Tamp) were introduced through the cannulas into the fractured vertebral body. After positioning the balloons with fluoroscopic guidance under the most impressed part of the endplate, the bone tamps were inflated simultaneously with 1 milliliter increments of contrast fluid while the pressure on the digital pressure readout on the syringe (KyphX Inflation Syringe) was observed and recorded. After each increment, a fluoroscopic image was obtained to assess the amount of reduction achieved and to monitor unwarranted (posterior) displacement of bone fragments. Subsequent individual inflation of the bone tamps allowed some fine-tuning of the endplate reduction and correction of asymmetrical (scoliotic) deformities. The amount of calcium phosphate cement (BoneSource®, Stryker) needed to fill the resulting defect in the vertebral body was estimated from the total balloon volume and prepared. For each gram of CPC powder, 0.34 ml of physiologic saline was used to produce an injectable paste. The syringe (regular, 10 ml) and needle (KyphX Bone Filler) that were used to inject the cement, were flushed first with physiologic saline in order to reduce friction and allow for a controlled injection. The balloons were actively deflated and removed, while the reduced state of the endplates was monitored carefully. The cement was slowly injected under fluoroscopy to monitor the distribution. Injection continued until the defect was filled completely fluoroscopically without any attempt to pressurize the cement. See Figure 1a-c for graphical details of the experimental procedure. Following posterolateral autografting with iliac crest cancellous bone, the cannulas were removed and the wound closed. Immediately after waking up, a neurological examination was performed. The first 24 hours after surgery the patients were confined to bed in a supine position. The patients were mobilized wearing removable plastic jackets from the third day after surgery and radiographs (AP and lateral, first supine then standing a few days later)



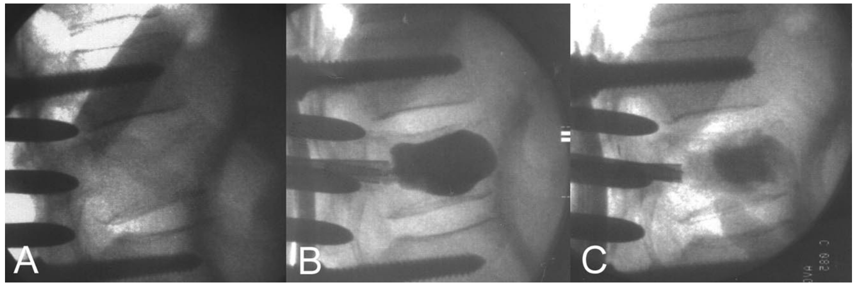


Figure 1a-c (case 17).

A
Lateral fluoroscopic image demonstrating a T12 burst fracture after reduction with pedicle screw instrumentation; note the impression of the cranial endplate.

B
Image of the same fracture showing the reduction of the endplate with the balloons.

C
Image after injection of the cement; note a small loss of reduction of the endplate.

were obtained to evaluate the reduction of the fracture, the distribution of the cement and/or any possible complications. At discharge the patients were encouraged to pick up daily routine but were advised to wear the jacket for eight weeks. One month after surgery the patients were seen at the outpatient clinic and screened for neurological complications and again underwent an MRI examination. Pre- and postoperative Cobb angles were measured on the lateral radiographs. The central and anterior vertebral body height was measured on the mid-sagittal MR slices. The fractured and restored heights were calculated as a percentage of the estimated, intact vertebral body height by averaging the respective central and anterior heights from the adjacent levels. The MR images were also used to evaluate a possible bone displacement towards the spinal canal. Differences between the preoperative and postoperative Cobb angles and vertebral body heights were analyzed with a single-sided paired t-test.

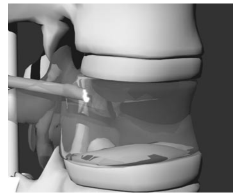
Results

Eight males and twelve females (age 18-75 years) with a burst fracture (AO classification A-3) that resulted from a motor vehicle accident or a fall from height, were included in the study. The affected levels were T12 (n=5), L1 (n=10), L2 (n=2), L3 (n=2) and L4 (n=2). One patient (case 19) had burst fractures at T12 and L4 that were both treated as isolated fractures using the same technique. Accompanying traumatic injuries are shown in Table 1. No complications of instrumentation were seen and following reduction, substantial though incomplete canal clearance was observed in every patient. In one patient (case 6) a lesion of the posterior ligamentous complex that was not recognized on MRI, was found peroperatively. This lesion was not considered severe enough to exclude the patient. The peak pressure in the balloons varied from 40 to 170 psi with a mean maximum pressure of 109 psi

Table 1. Patient characteristics.

Case	age	gender	level	classification	cause	accompanying traumatic injuries
1	28	m	Th12	A3.1	fall from height	none
2	32	m	Th12	A3.3	fall from height	calcanei and distal radius #
3	67	m	L1	A3.3	motorcycle accident	teardrop # C6, acromion #
4	18	m	L2	A3.2	motorcycle accident	medial malleolar #
5	40	m	L3	A3.1	motorcycle accident	pelvic #s, sternum #
6	59	m	L1	B2.3	car accident	none
7	33	f	L2	A3.1	car accident	none
8	36	f	L1	A3.1	fall from height	none
9	44	f	L1	A3.3	fall from height	none
10	48	f	L1	A3.1	fall from height	none
11	35	f	L4	A3.3	fall from height	none
12	19	f	T12	A3.1	car accident	none
13	75	m	L1	A3.3	fall from height	none
14	62	f	L3	A3.1	fall from height	none
15	20	f	L1	A3.1	fall from height	none
16	30	f	L1	A3.1	car accident	none
17	60	f	T12	A3.1	fall from height	none
18	38	f	L1	A3.3	fall from height	none
19	35	m	T12/L4	A3.1/A3.1	fall from height	none
20	57	f	L1	A3.1	fall from height	L3 # type A1.1

after 'setting', in which phase the balloon actually expanded and reduced the endplate. In all cases, substantial reduction of the fractured endplates was achieved with the bone tamps. In one incident a balloon ruptured while being inflated in the vertebra to approx. 3 ml with a pressure of approx 75 psi. We did not have an explanation for this event, but the procedure could be finished without problems aside from a temporary presence of contrast fluid in the operation area that could be flushed with saline. The total amount of injected CPC varied from 12 to 36 grams (Table 2). The median duration of the total procedure was 120 minutes (range 75-180 min.) and



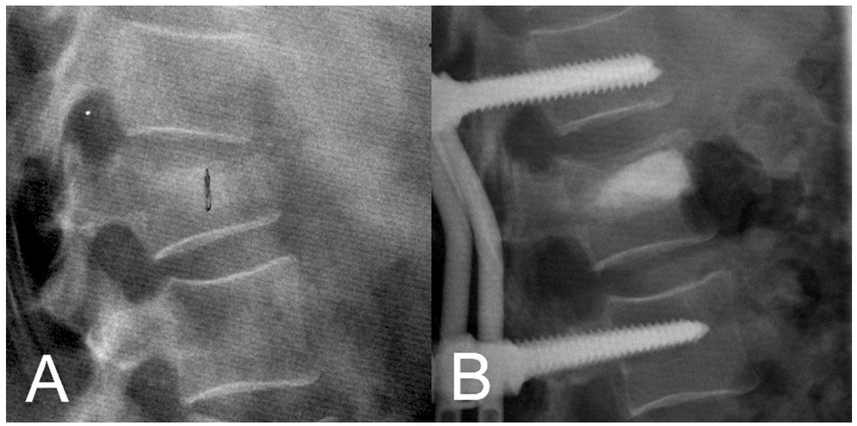


Figure 2a-b (case 20).

A
Lateral radiograph demonstrating a L1 burst fracture.

B
The radiograph of the same fracture three days after pedicle screw fixation and balloon vertebroplasty with CPC.

Table 2. Surgical details

Case	duration (min)	bloodloss (ml)	mean pressure (psi)	total balloon volume (ml)	injected CPC (gr)
1	180	1200	120	6	16
2	150	2000	90	12	36
3	110	700	100	10	27 *
4	120	500	90	7	24
5	120	500	110	6	20
6	105	1000	100	8	24 *
7	135	400	130	7	13
8	120	300	170	10	14
9	90	400	100	12	20 *
10	120	300	130	7	16
11	135	400	40	7	13
12	140	700	100	8	16
13[1]	120	500	75	10	18
14	120	850	60	8	20
15	120	200	140	8	20
16	100	200	140	7	15
17	75	400	110	7	20 *
18	90	250	140	10	16
19[2]	180	1000	120/100	8/6	16*/15 *
20	100	400	120	8	16

[1] postoperative wound hematoma
[2] this patient had two burst fractures (T12 and L4) and transient loss of sensibility
* extracorporal cement leakage

the median blood loss was 450 ml (range 200-2000 ml). In all patients, the postoperative radiographs and MR images demonstrated a good position of the pedicle screw construct and the CPC in the fractured vertebral body (see examples in figure 2a-b). Cement leakage, defined as any cement out of the confines of the vertebral body, was observed on the postoperative radiographs and MR images in five patients; twice in the spinal canal, twice in the psoas muscle, twice in the cranial disc space and once anterior of the fractured vertebral body (Figure 3a-e). The presence of cement in the spinal canal was observed during surgery in one case (and was the reason to stop further injection) and on a transverse postoperative MRI image in the other (where it was not noticed earlier due to the very small volume). All patients recovered uneventfully and the neurological examination revealed no deficits. In one patient (case 19), a transient loss of sensibility of the ventral skin of the upper legs (nervus cutaneous femoris lateralis area) was reported that was probably due to the longer time on the OR table in a prone position needed to treat his two fractures. This complication resolved completely during the patient's hospital stay. In one case, a wound leakage was observed that resolved in one week without signs of an active infectious process. The average Cobb angle preoperatively was 11.0 degrees (range: -11.4 – 15.2; standard deviation: 9.2) and -1.6 degrees postoperatively (range: -20.9 – 12.9; standard deviation: 9.5). The average central vertebral body height increased from 66 % preoperatively (range: 44-92 %; standard deviation: 10.7) to 81 % of the estimated intact central height postoperatively (range: 62-100 %; standard deviation: 10.4). The average anterior vertebral body height increased from 71 % preoperatively (range 49-104 %; standard devia-

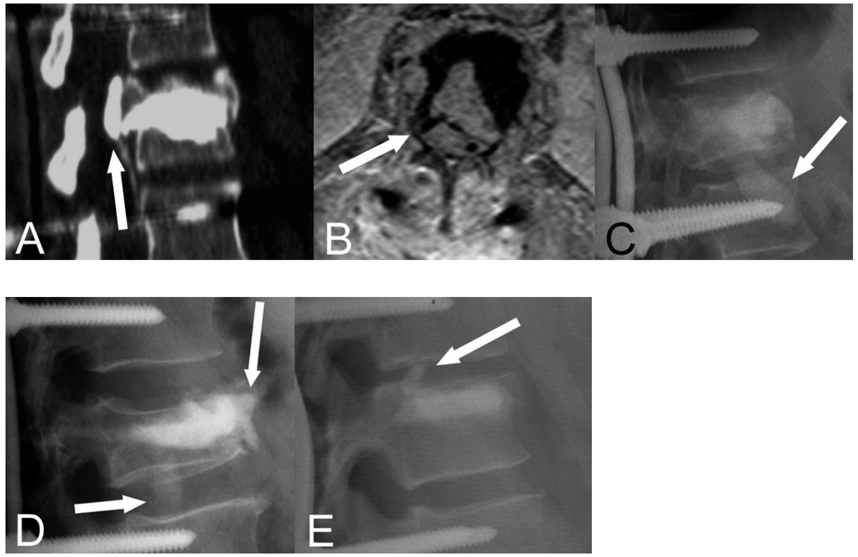


Figure 3a-e (case 9; 3; 17; 6 and 19 respectively).

A Reconstructed CT image demonstrating a leakage of CPC in the spinal canal, the patient recovered without neurological deficit.
B A transverse MR image showing a small amount of cement in the spinal canal that was not noticed during surgery.
C Lateral radiograph showing leakage of cement into the psoas compartment.
D Lateral radiograph showing leakage of cement anteriorly of the vertebral body and in psoas compartment.
E Lateral radiograph showing a small amount of cement that entered the cranial disc space through the fractured endplate.

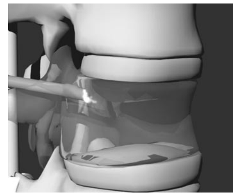


Table 3. Percentage of central and anterior height.

Case	% central height preoperative	% central height 1 month	% anterior height preoperative	% anterior height 1 month
1	66	83	71	97
2	61	81	62	97
3	58	78	87	96
4	70	89	63	87
5	61	74	83	95
6	51	77	50	79
7	59	75	65	76
8	73	79	71	80
9	73	91	64	104
10	57	71	70	88
11	67	67	64	74
12	60	62	58	86
13	65	67	104	106
14	77	81	95	96
15	52	83	48	84
16	71	77	70	87
17	44	78	49	87
18	71	98	84	103
19 [1]	92/75	98/100	82/83	99/111
20	74	88	64	100

[1] this patient had two burst fractures (T12 and L4)

tion: 14.9) to 92 % of the estimated intact anterior height postoperatively (range: 74-111 %; standard deviation: 10.3). Table 3 lists the details of the MR data. Both the Cobb angle correction and the central and anterior vertebral body height gains were highly significant ($p < 0.0001$). No increase in posterior bone displacement was seen in any patient following the instrumentation and balloon vertebroplasty. The cohort has been followed for an average of 14 months (range 3-25 months) of which the first ten patients have a follow-up longer than one year. In these ten patients the average Cobb angle was 10.2 degrees preoperatively, -1.5 degrees postoperatively and 3.5 degrees at one year follow-up. Table 4 lists the radiographic results for these ten patients.

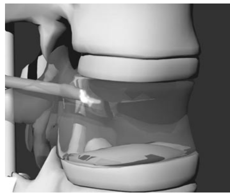
Table 4. Cobb angles of the first ten patients.

Case	Preoperative (supine)	Postoperative (standing)	One year follow-up (standing)
1	15.2	0.1	1.1
2	24.1	8	16.1
3	9.6	-9.9	7.9
4	4.6	-4.2	4.3
5	-7.0	-10.3	-3.5
6	14.1	9.2	15.9
7	13.6	0.0	-3.3
8	9.6	-0.7	-2.6
9	12.1	3.2	7.4
10	6.3	-10.3	-8.1
mean	10.2	-1.5	3.5

Surgical observations The additional balloon procedure did not cause any surgical difficulties. The procedure required approximately 20 minutes of extra operation time. In the first two cases, probing of the pedicles of the fractured vertebra at the same time as the adjacent pedicles caused substantial blood loss from the fractured vertebral body during the instrumentation and reduction. Postponing the pedicle probing of the fractured vertebra until after the instrumentation and reduction decreased the blood loss substantially. Bleeding from the vertebra stopped as soon as the balloons were inflated and did not interfere with cement injection. Although this could not be quantified, in several cases we observed a partial loss of reduction of the (fractured) endplates after removal of the balloons, prior to injection of the cement. The five cases of cement leakage were associated with a slight build-up of pressure needed to inject the cement. It was found that if an open pathway existed from one pedicle through the defect in the vertebral body to the other pedicle (confirmed by injecting saline from one cannula and observing unimpeded flow from the other) the injection pressure could be kept low. Furthermore, it was noted that immediate removal of the cannulas could result in backward leakage of cement out of the pedicles, possibly caused by the exerted pressure of the intervertebral disc. In one patient with a fractured pedicle, this phenomenon probably resulted in the small amount of cement entering the spinal canal that was detected on the postoperative MRI. In the cases we performed after this particular patient, we removed the cannulas just before closing the wound allowing a bit more time for the cement to set from a paste into a more solid state. The experimental procedure required one minute of extra fluoroscopy time per patient on average.

Discussion

In the current study we demonstrated the feasibility and relative safety of a new technique to directly reduce the fractured vertebral body and reinforce the anterior column after posterior indirect reduction and stabilization.
During the trial, several challenges, both safety concerns and practical issues, were encountered that could be addressed as described in the *surgical observations* section.
Several studies have been conducted to assess the strength and stiffness of vertebral compression fractures after vertebroplasty with poly(methyl methacrylate) cement and CPC.[25-29] It was found that both types of cement were able to restore the strength and stiffness to intact values, even increase them, in osteoporotic specimens. In the cadaveric biomechanical study by Mermelstein *et al.* it was found that the injection of CPC in a burst fracture reduced the load on the pedicle screw construct that was inserted for fracture stabilization.[30] They concluded from their *in vitro* work that vertebroplasty with CPC after posterior instrumentation might reduce hardware failure and anterior column collapse and decrease the need for a secondary anterior approach.



It has been proposed by some authors that the fractured and impressed endplate increases the chance of intrusion of the intervertebral disc in the corpus and may cause subsequent spinal deformity.[19,21] However, the possibilities of vertebroplasty to reduce the endplate impression are limited and can only be achieved by building pressure on the cement, which is strongly associated with an increase in cement leakage that can result in spinal cord compression and pulmonary embolism.[31-33] The use of inflatable bone tamps in the treatment of osteoporotic compression fractures has received a lot of attention the last few years.[34-36] Although primarily invented to correct the deformity by lifting the compressed part of the vertebra to a more physiologic position before poly(methyl methacrylate) cement injection, a positive side-effect resulting from the use of the balloons was noticed. During inflation, the balloons push aside intravertebral cancellous bone, effectively autografting it around them. This results in a layer of higher density bone, lining the cavity in which the cement is to be injected. In addition to decreasing the chance of cement leakage due to the presence of a cavity that allows for a lower injection pressure, this bone lining might act as a shield. Whatever factor predominates, in practice the number of cases with cement leakage is considerably lower for balloon vertebroplasty than for conventional vertebroplasty.[37]
Reducing a (traumatic) fracture by ligamentotaxis before performing (balloon) vertebroplasty might also decrease the risk of cement leakage due to the resulting alignment of cortical bone fragments. In the current study the inflatable bone tamps were used for yet another purpose, besides creating a lined cavity. Since the study by Oner *et al.* demonstrated the recurrent kyphosis to be the result of a change in the disc space morphology, we aimed to reduce the endplate fracture directly with the balloons thereby restoring

the morphology of the disc space.[38] In a recent cadaveric study it was demonstrated to be feasible and safe to reduce the endplate in burst fractures after pedicle screw stabilization.[23] Although we could confirm these findings in the current patient trial, some limitations were apparent. It was noticed that an anatomical reduction was hard to accomplish since the balloons could not always be positioned under the most depressed, often central, part of the endplate. This was due to the anatomical orientation of the pedicles, the posterior construction that was already *in situ* (frequently blocking the optimal entrance to the pedicles) and the inability to steer the flexible balloon tips. Furthermore, a secondary (partial) loss of achieved endplate reduction was seen in a majority of cases after deflation of the balloons probably due to the hydrostatic counterpressure of the adjacent intervertebral disc. This problem was probably enhanced by the relatively slow setting time of the CPC, during which a further loss of reduction could develop. Lastly, contrary to the aforementioned cadaveric study, we encountered leakage of cement in 6 out of the 21 fractures that in one case (cement in the spinal canal) could have had clinical consequences. Since clinical problems did not occur, we presume that the slow setting (and therefore long lasting plasticity) and isothermic properties of the CPC, compared to poly(methyl methacrylate) cement, probably greatly reduce the chance of mechanical and/or thermal damage to neurovascular structures. The need for optimal visualization of the operation area is underlined by these findings.

The choice for calcium phosphate cement, instead of poly(methyl methacrylate) cement, stems from long-term biocompatibility concerns with the latter. Various studies have demonstrated the superior biocompatibility of CPCs, in terms of biocompatibility and osteoconductivity, over poly(methyl methacrylate) cement, although most of these studies were in the appendicular skeleton of animals.[39,40] Since the mean age of the human population with traumatic spine fractures is considerably lower (in the current study it was 42 years) compared to the population were vertebroplasty with poly(methyl methacrylate) cement is usually performed, we preferred to use a cement that performs favorably in these biocompatibility areas.

Our patients have been followed long enough to detect any immediate complication from the surgical procedure. Potential hazards included retropulsion of bone fragments following balloon expansion, extracorporal cement leakage resulting in pulmonary embolism or spinal cord compression and infection. None of these serious complications were observed in the current study, however the finding that 5 out of 20 patients (6 out of 21 fractures) displayed cement leakage, emphasizes the delicacy of the procedure. The logical next step will be to start a full scale Phase III study with adequate controls in order to weigh our preliminary evidence against statistical proof. Furthermore, prolonged and stringent follow-up examinations in the current study will demonstrate whether this technique will be sufficient to prevent the recurrence of kyphosis and limit the number of secondary anterior procedures or has some unforeseen long term complications.

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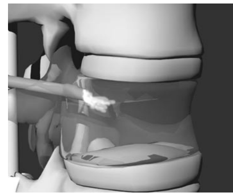

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Chapter 11

Minimally invasive burst fracture treatment with an external fixator and balloon vertebroplasty.

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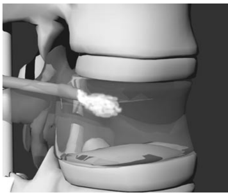


Introduction

The treatment of traumatic fractures of the thoracic and lumbar spine is controversial and scientific guidelines for treatment are lacking.[1-5] Surgery is generally proposed if the biomechanical stability of the spine is severely compromised or if a neurological deficit is present or imminent. Otherwise, a conservative approach is preferred.[6,7] The local kyphosis angle tends to decline more in patients treated conservatively, but no clear relation exists with discomfort or pain.[7,8] Most authors however, have not followed their conservatively treated population for longer than a few years and the effects of the altered biomechanics, resulting from the greater kyphosis angle, on eventual discomfort, pain or degeneration later in life, are not known.

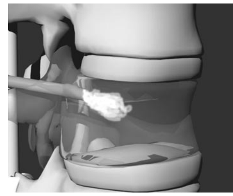
An important advantage of operative treatment is the quick and nearly unrestricted mobilization that can be tolerated by the patient after internal stabilization. Due to the relatively easy technique, low complication rate (approximately 10 % of the patients have minor complications, serious complications are rare) and good outcome, pedicle-screw instrumentation is the most popular intervention to reduce and stabilize traumatic fractures of the thoracic and lumbar spine.[9,10] However, a substantial part of the postoperative morbidity (approximately 25% of the observed complications) is associated with tissue damage due to the open surgical procedure of pedicle-screw and rod instrumentation.[9,11,12] Minimizing this ‘collateral damage’ could further improve the short-term results by decreasing blood loss, incidence of wound pathology and length of hospital stay.

Recent experimental *in vitro* studies have investigated the use of (balloon-) vertebroplasty, sometimes in combination with pedicle-screw instrumentation, for the treatment of traumatic thoracolumbar fractures.[13,14] It was suggested that reinforcement of the anterior spinal column after injection of cement could prevent late kyphosis and decrease the chance for secondary procedures.[14,15] Some authors have published about the successful use of percutaneous (balloon-) vertebroplasty as, additional or stand-alone, treatment of burst fractures, although the distinction between severe osteoporotic compression fractures and true traumatic burst fractures has not always been clear.[16,17]

In the ’70s, an alternative to the Harrington rods was developed for fixating traumatic fractures of the thoracic and lumbar spine: the ‘AO external spine fixator’.[18] Using the external fixator, burst fractures could be reduced and stabilized by means of four percutaneous Schanz screws placed in the vertebrae adjacent to the fracture. By comparison, internal fixation with Harrington rods required fusion of multiple (five to seven) levels. Furthermore, the reduced fracture could be adjusted during treatment since the external fixator could, once the screws were *in situ*, be manipulated without additional invasive procedures. However, the advantages of the minimally invasive approach with the external fixator were sometimes offset by the need for an additional incision and subsequent paraspinal muscle dissection if posterolateral autografting was to be performed. The solid external fixator had to be worn permanently by the patient for four to five months, and because the aftercare was often problematic due to superficial wound infections, it did not become widely accepted. The device was superseded by the AO internal fixator, derived from the external fixator, which became the most successful method for the treatment of traumatic thoracolumbar fractures.[19-22] Although the external spine fixator was an interesting concept and certainly one of the first attempts to decrease the invasiveness of spinal procedures, its use has been limited.

In search of a minimally invasive surgical technique for repositioning and stabilizing the fractured spine, we investigated a new application for the external fixator in combination with balloon vertebroplasty. With the external fixator, a fracture can be reduced anatomically and stabilized temporarily. Balloon vertebroplasty can subsequently be used for the reduction of the impressed endplates and augmentation of the anterior column with a bone void filler.[13] After setting of the bone cement, the anterior column might be reinforced enough to warrant removal of the external fixator and screws without needing posterolateral fusion for stability. The current *in vitro* cadaveric study investigates the restoration of vertebral body height and axial stiffness after treatment with the AO external fixator in combination with balloon vertebroplasty using calcium phosphate cement.

Materials and Methods



Four fresh frozen human spines (three male, one female, mean age 63 years), without signs of osteoporosis or significant pathology, were divided in thoracic (Th8-Th10), thoracolumbar (Th11-L1) and lumbar (L2-L4) segments. After thawing at room temperature and subsequent removal of the skin and subcutaneous tissue, but retaining the paraspinal musculature, all segments were embedded in cups with plastic foam, leaving the middle vertebra and adjacent discs free (phase 1). A weight-dropping device (20 kg from 1.0 m height) was used to create burst fractures in the middle vertebrae.[23] The occurrence of a fracture was confirmed by palpation and radiographs (phase 2). Four Schanz screws (6.0 mm diameter) were inserted, under fluoroscopic guidance, through the paraspinal musculature and pedicles into the vertebral bodies of the levels cranial and caudal to the fractured vertebra. Subsequently, an AO external spine fixator was attached to the screws. The external fixator was distracted and extended under fluoroscopic guidance, to create anatomical alignment and height restoration. Then, a hand drill was advanced through the paraspinal muscle and pedicles into the fractured vertebral body. A cannula was placed over the drill on both sides and positioned with the tip in the posterior part of the vertebral body, approximately 2-3 mm from the posterior cortical wall. After removal of the drill, two inflatable bone tamps (KyphX, Kyphon Inc.) were positioned under the most deformed part of the endplates. The balloons were inflated with contrast fluid under frequent fluoroscopic monitoring until an optimal (complete, if possible) reduction of the fractured endplates was achieved prior to the injection of calcium phosphate bone cement (BoneSource, Stryker Howmedica Osteonics). The amount of cement needed for a complete filling of the defect was estimated from the total volume of the balloons. Each gram of calcium phosphate cement powder was mixed with 0.33 ml of physiologic saline to produce an injectable paste. This paste was subsequently transferred to a 10 ml syringe with a large bore needle that was flushed first with physiological saline for unimpeded cement flow. After deflation and removal of the balloons, the cement was injected under continuous fluoroscopic monitoring until the defect was filled completely. The specimens were stored for 24 hours at room temperature to allow the cement to cure. See Figure 1a-d for a radiological overview of the procedure. Then, the external fixator and screws were removed (phase 3). During the entire experiment the cadaveric material was kept moist by wrapping with gauzes saturated with physiologic saline. Furthermore, care was taken throughout the experiment to protect the integrity of the foam in which the outer vertebrae were embedded to ensure the correct seating in the cups during biomechanical testing. At all three phases, lateral radiographs were obtained for inspection of the specimens, classification of the fractures and in order to detect leakage of cement or bone displacement after balloon vertebroplasty.

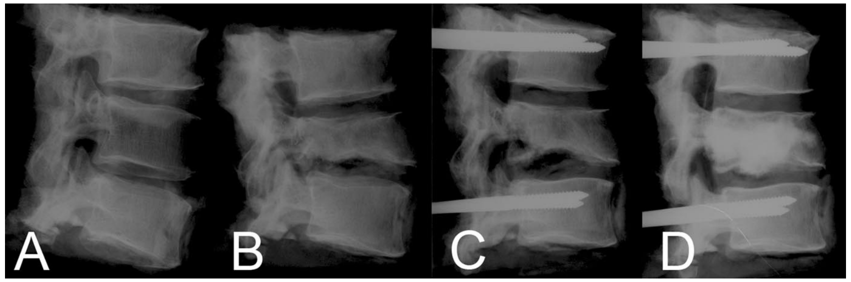


Figure 1. **Lateral radiographs of a lumbar specimen**

A In intact state.
B In fractured state.
C After reduction with the external fixator.
D After balloon vertebroplasty with calcium phosphate cement; note that in this specimen some cement leaked in the caudal disc space.

Biomechanical analysis All specimens were subjected to axial compression tests (Instron 8872, High Wycombe, UK) at the following time points:

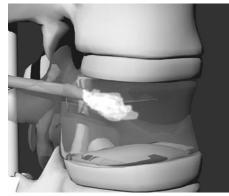
- phase 1: intact (thawed) specimen;
- phase 2: directly after the creation of a fracture;
- phase 3: 24 hours after reduction with the external fixator and balloon vertebroplasty with calcium phosphate cement, but after removal of the external fixator and Schanz screws.

The height of the specimens was measured from the lower to the upper cup. For all measurements, the lower cup was placed on a horizontal groundplate in such way that the upper cup, and center of the most cranial vertebral body, was placed directly under the hydraulic mechanical testing device.
All compression tests started with a preload of 20N (duration 1.0s) to eliminate any ‘slack’ in the cups, foam or specimens. In the next test phase the specimens were subjected to a ramp (136N/s) until the maximum load of 700N was reached (duration 5.0s). This load was sustained for another 5.0 seconds. Finally, the load was completely removed in 1.0 second. The height of the specimen was recorded at a sample frequency of 10Hz. The stiffness of the segments was calculated from the average slope of the load/displacement curve in the interval from 20-700N. The mean loss of height of the specimen due to the fracture was defined as the difference between the mean height of the intact and the fractured segment. The mean restored vertebral body height was defined as the difference between the mean height of the fractured and the repaired segment. The mean final loss of height was calculated as the difference between the mean height of the intact and the repaired segment.
After the last test-cycle, the specimens were cut through the midsagittal plane with an electric bandsaw for visual inspection of possible cement leakage/intrusion in the spinal canal.

Statistical analysis The difference in mean stiffness and height between the individual phases were analyzed using a paired two-tailed T-test ($p<0.05$).

Results

All fractures were classified as axial type burst fractures (A-3 according to the AO classification).[24] The reduction and fixation with the external spine fixator was uneventful, as was the direct endplate reduction with the inflatable bone tamps. The average total volume of the balloons, when the endplates were optimally reduced, was 8.3 ml (range 4-13 ml). The average amount of CPC injected was 19 grams (range 10-30 grams). In one case, a small amount of CPC leaked through a fractured endplate into the adjacent disc space during injection. In the other eleven specimens, no leakage was observed in the disc space or any other extracorporal location. The mean stiffness of the intact specimens was 224 ± 75 N/mm, of the fractured speci-



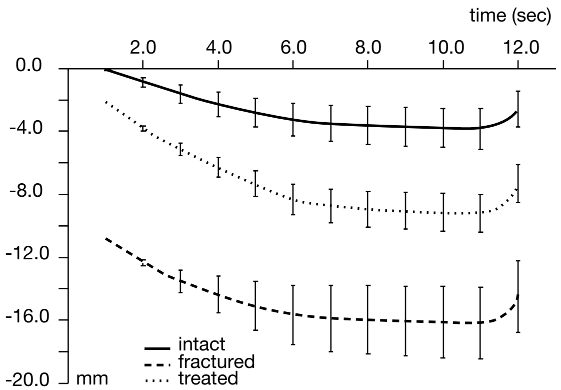


Figure 2.

Graph demonstrating the mean displacement versus time with standard deviations for all specimens at the three phases.

mens it was 139 ± 35 N/mm, and of the treated specimens it was 120 ± 32 N/mm. The difference in stiffness between the intact and fractured specimens was significant (p<0.003), between the fractured and treated specimens it was not (p<0.08) and between the intact and treated specimens it was also significant (p<0.004). In Figure 2, a graphical representation of the average displacement *versus* time from the twelve specimens is shown with the standard deviations. All specimens showed non-recurring displacements because the height at the end of the test-cycle was consistently and significantly lower than at the start of the test-cycle.

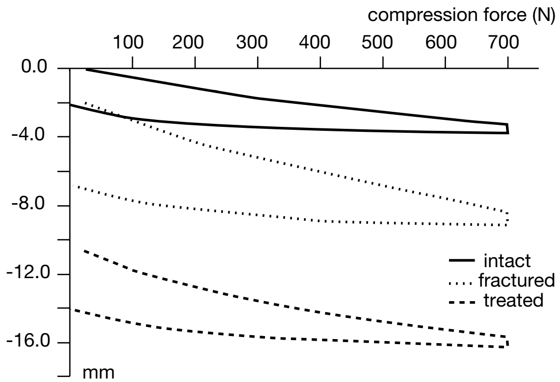


Figure 3.

Graph demonstrating the load versus displacement for the specimens at the three phases. Note that the test-cycles led to non-recurring displacement.

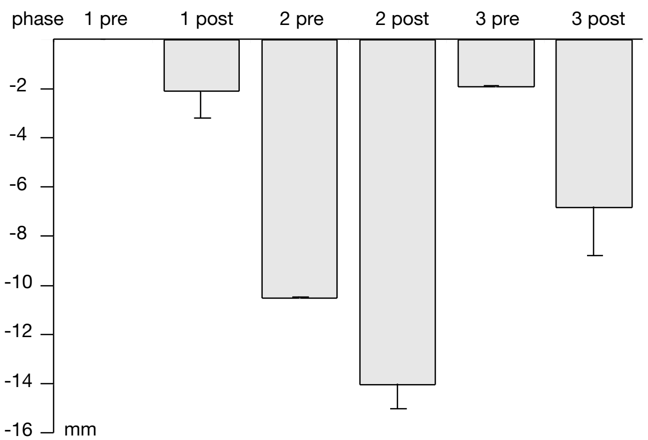
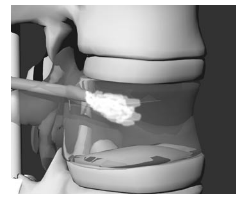


Figure 4.

Bar graph showing the changes in height relative to the intact state (phase 1 pre), before and after loading during the three phases of the test. The changes were all significant (p<0.001).

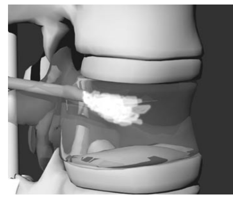
The mean loss of height of the intact specimen due to the compression was 2.6 ± 1.1 mm. The mean loss of height due to the burst fracture was 10.5 ± 3.9 mm. The additional loss of height due to the compression test was 4.0 ± 1.0 mm leading to a mean total loss of 14.5 mm. This difference between phase 1 and phase 2 was significant (p<0.001). The mean gain in height after balloon vertebroplasty was 12.6 mm (87%) leading to a mean restored height of -1.9 ± 1.8 mm compared to the intact state. The loss of height due to the subsequent compression test was 5.4 ± 2.1 mm (43%). This difference between phase 2 and phase 3 was significant (p<0.001). Also, the difference between phase 1 and phase 3, the final vertebral body height loss, was significant (p<0.001).
In Figure 3 the load *versus* displacement is shown. The graph shows that the non-recurring effects of treated segments display a mechanical behavior during loading that is similar to the intact segments, but is more prominent. In Figure 4 the changes before and after loading during the three phases of the test are presented. At inspection of the radiographs and sliced specimens, no leakage or intrusion of cement was observed in the spinal canal.

Discussion



The restoration of burst fractures with the external spine fixator and balloon vertebroplasty with calcium phosphate cement was investigated. It was demonstrated that the loss of height of the spine specimens, after the traumatic impact, could be restored almost completely, to almost 90% of the intact height, by the experimental procedure of external reduction and fixation followed by balloon vertebroplasty with calcium phosphate cement. After loading the treated specimens, almost 60% of the restored height remained.
The relatively low stiffness in the treated specimens (after treatment it was 53 % of the intact value) can be explained by several factors. Although the vertebral body height and gross morphology were restored considerably, the load transfer capability of the specimens was probably impaired by the loss of cortical integrity; the fractured endplate; the crushed intravertebral cancellous bone and possibly also damage to the intervertebral disc. Injection of calcium phosphate cement has been demonstrated to restore the vertebral body stiffness to initial levels in several osteoporotic compression fracture studies.[15,25,26] Most of these studies have used isolated vertebral bodies (without adjacent discs and/or posterior elements) to test stiffness and strength after cement injection, which is defendable since osteoporotic collapse of the vertebral body usually leaves the disc and endplate intact. In the current traumatic fracture model, the anatomy of interest consisted of the cranial disc, vertebral body and caudal disc. Damage to these load-bearing structures of the spine, resulting from the traumatic impact, may have resulted in a less homogenous load transfer during the test-cycles, than the more linear behavior that can be expected from compressed, isolated vertebral bodies.
During the balloon vertebroplasty procedure, the inflatable bone tamps reduced the fractured endplates by pushing cancellous bone from the center towards the periphery, and it is therefore likely that after injection of the

cement, a layer of cancellous bone was present between the fractured endplates and cement. Since this cancellous bone probably lost a substantial part of its (vertical) organization after the traumatic impact, it is reasonable to suggest that it could not transmit loads as well as when intact, resulting in a further loss of stiffness. The cement itself could also be the subject of mechanical deformation although the visual inspection afterwards did not show obvious signs of failure (i.e. fragmenting, crumbling, etc.). Since calcium phosphate cement is a brittle biomaterial, repeated load-cycles will almost certainly cause it to fragmentize over time. The effect of cement fragmentation on the load transfer capabilities within the vertebral body and possible changes in resorbability are not known and require further attention.
Another suggestion for the lower stiffness in the treated specimens could be that during the 24-hour period of distraction with the external fixator attached, the intervertebral discs were given the opportunity to rehydrate more than in the intact or fractured state.[27,28] This might have resulted in easier compression (and thus more displacement) during the following load cycle.
It is clear from the results that, regardless of the amount of individual attribution of the factors mentioned above, a considerable amount of height loss due to ‘settling’ must be taken into account during the initial loading of treated spine segments. With the current procedure, some 57% height restoration could be maintained under the test circumstances. Few studies exist that provide data on the intravertebral loads that are sustained *in vivo*. Nachemson investigated this subject in the early ’80s and found that, whilst in a supine position, the load on the L3 disc was 250N; standing it was 500N and sitting without support yielded 700N.[29] A more recent study by Sato *et al.* found slightly higher loads in L4 discs of 8 healthy subjects in these positions.[30] Extension and flexion both increased the load considerably. The loads in the thoracolumbar junction, where the majority of the traumatic burst fractures occur, are unknown but theoretically one can expect somewhat lower values than in the lower lumbar spine. In the current study it was decided to use load values (identical for all levels) that represent the *in vivo* conditions of unsupported sitting in the lower lumbar spine, which is the highest value a patient will likely be subjected to immediately after treatment. The results from our work and the aforementioned studies suggest that if burst fractures are to be treated with temporary external fixation in combination with balloon vertebroplasty, the height after treatment should probably be overcorrected in order to compensate for the ‘settling’ effect. Furthermore peak loading, extreme extension and, especially, flexion should probably be avoided during the healing period. This suggestion is in contrast to one of the advantages of internal fixation in which almost unrestricted mobilization can usually be permitted because acting forces are transferred through the rigid pedicle-screw instrumentation instead of the fractured vertebral body. In this respect, however, it is interesting to note that a slow, but definite, ‘settling’ probably also occurs in regular internal pedicle-screw fixation for the treatment of traumatic fractures, since much of the achieved correction is lost at follow-up.[9]
The comminution of the fractured vertebral body could play an important role in the loss of height. Unfortunately, the fractures could not be differentiated in greater detail during the investigation to assess which fractures were more susceptible to loss of height under loading. It is to be expected that the cortical shell of complete burst fractures will provide the least support leading to the greatest loss of height in the vertebral body and adjacent disc space.[31]
In a retrospective case series with a follow-up of four years, Shen *et al.* demonstrated a good clinical outcome without neurological deterioration after functional treatment (i.e. no or minimal bracing and immediate ambulation as tolerated by the patient) of traumatic thoracolumbar burst fractures.[6] The mean local kyphosis angle at follow-up was 24 degrees, with a range of 12 to 38 degrees, indicating to a substantial structural loss of anterior column support. Limited data are available in the current literature to predict the effects of these large kyphosis angles on discomfort, pain or degeneration later in life. From their work it can be concluded that functional treatment of burst fractures is feasible, although at a considerable price regarding spinal deformity.
It is suggested that after performing the technique described in the present work, the postoperative management of patients may be functional as well, but with the possible advantage of a (partially) restored anterior column.
We conclude from the current cadaveric exploration of the possibilities for minimally invasive treatment of thoracic and lumbar burst fractures, with the temporary use of the external fixator in combination with balloon vertebroplasty, that the height of the vertebral body and adjacent disc spaces can largely be restored but will probably not be fully maintained after loading with values similar to *in vivo* conditions. Almost 60% of the height loss can be expected to be restored and maintained under conditions of maximum load. Reduction of the maximum load by restriction of some types of motion may limit this height loss considerably and the authors are encouraged by the prospect of at least 60% anterior column height restoration with a minimally invasive procedure for burst type fractures.



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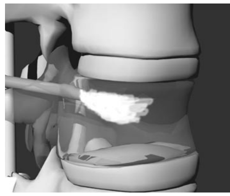
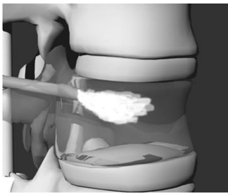


Chapter 12

Description of a device to be used as stand-alone implant for the treatment of traumatic fractures of the thoracolumbar spine.



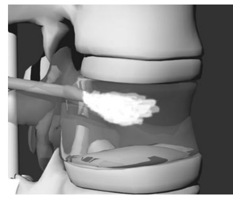
Description of a device to be used as stand-alone implant for the treatment of traumatic fractures of the thoracolumbar spine.

As we gained clinical experience in the balloon vertebroplasty procedure, some improvements were considered that could decrease the physical demand for the patient while retaining a good clinical outcome. Several important observations were made (**Chapter 10**). Typically, the surgical stabilization of the thoracolumbar fracture took almost two hours, of which approximately one third was used for surgical exposure, haemostasis and closure of the wound. The blood loss, as a direct result of surgery, was normally between 300 and 800 ml. The length of hospital stay, from admission to discharge, was around a week. This duration was determined mainly by the care for the surgical wound (the length of skin incision was approx. 10-15 cm) that was created.

During surgery it was noted that the experimental setup had some significant drawbacks that could be traced back to the instruments and implants used. The rods that connect the pedicle-screws after reduction and fixation, run in the long axis of the patient thereby partially blocking the pedicle entrance of the fractured vertebra. This often leads to a less than optimal insertion and orientation of the cannulas and drill that is necessary to create the space for the balloons. Since the purpose of the balloons is, predominantly, to lift the endplate, it is recommended to place them under the most depressed part of the endplate. Until now, optimal positioning of the balloons has not always been feasible due to the offset and angulation of the drilled trajectory and also due to the flexibility of the balloons, making reliable guidance awkward. Once in place in the vertebral body, a potentially dangerous complication can arise from inflation of the balloons. Due to the morphology of the vertebral body fracture ('burst' fracture) large pieces of bone can be displaced in unwarranted directions because of the *radial expansion* of the balloons. Bone displacement towards the spinal cord, although not encountered in the previous studies (**Chapter 4, 7 and 10**), must especially be feared in this respect. A further drawback is that the balloons are filled with (and expanded by) a radiopaque fluid for fluoroscopic visualization. In order to reduce the fracture directly, contrast fluid is forced in the balloons thereby increasingly obscuring parts of the field of interest in the vertebral body. This problem is worsened when the balloons are not evenly aligned, which is often the case because of the initial placement inaccuracy, in the lateral fluoroscopic line of view. Sometimes, deflation of the balloons must be performed to secure the visibility of the operation area, which can be accompanied by a spontaneous repositioning of the balloons followed by loss of reduction. The loss of reduction is also of concern in the interval between deflation and removal of the balloons and the setting of the subsequently injected calcium phosphate cement (**see Chapter 6 and 10**). If the reduced fracture collapses while the cement did not have enough time to set (depending on multiple variables, this time interval is between 30 and 240 minutes), cement could be forced in unwarranted directions (*e.g.* the spinal canal). Notwithstanding the good results from our clinical series, we would not recommend the procedure in its present form to be performed without rigorous training.

In summary, the experimental treatment is feasible but leaves a lot to be desired for convenient clinical practice. In order for the patient with a traumatic thoracolumbar fracture to fully benefit from our treatment 'philosophy', the instruments would need a major redesign. An ideal replacement for the pedicle screw instrumentation with additional balloon vertebroplasty should have the following properties:

1. It can be implanted by a percutaneous and transpedicular approach to minimize damage to healthy tissue;
2. it fixates only the injured level(s) leaving the uninjured segments untouched to allow for maximum spinal flexibility after the healing period;
3. it is simple and intuitive to handle, resulting in a short learning curve for the treating physician and, eventually, a shorter surgical duration;
4. it is able to restore the vertebral body shape to (near) physiological proportions;
5. it provides immediate stability in three dimensions for several types of fractures the thoracolumbar spine;
6. it will not cause any unwarranted bone displacement that could lead to a deterioration of the present neurological status;
7. it is clearly visible with fluoroscopical or conventional radiological imaging modalities under all circumstances;
8. it is biocompatible;
9. it is able to provide an access route for the injection of a (calcium phosphate) cement to further augment the vertebral body;
10. preferably, it is MRI compatible;
11. it has to be removable if necessary.



After critical appraisal of the current technique for the treatment of vertebral fractures, it becomes apparent that the ideal properties listed above cannot be incorporated in the contemporary implants and instruments.

Ad 1: Until now, the insertion and construction of pedicle screw based implants requires a direct access to, and view of, the dorsally located spinal elements. This access is not possible without damaging the overlying healthy tissues, i.e. skin and muscle, that have to be surgically dissected. The resulting damage to the soft-tissues is associated with a substantial part of the postoperative complications and also with the duration of hospital admission. Percutaneous techniques hold the promise of minimizing tissue damage.

Ad 2: The current technique of fracture reduction and fixation requires the involvement of two adjacent, uninjured vertebral bodies in the construction. Since pedicle screw insertion is associated with a low, but significant, incidence of complications, reducing the number of transpedicular implants may decrease adverse events. Furthermore, fusion of multiple levels impairs spinal flexibility significantly, especially in the lower lumbar spine.

Ad 3: The safe and effective manipulation of all instruments involved in pedicle screw reduction with additional balloon vertebroplasty, requires thorough training and skill. An implant that could easily be inserted and left *in situ*, not requiring additional instruments or skills, would greatly reduce the surgical duration and expertise needed.

Ad 4: The experimental balloon vertebroplasty was invented to prevent late-occurring deformation. Although long-term follow-up is needed for justification of the extra effort and cost, the first (preliminary) clinical and radiological results look promising. A new device would, at least, have to provide the same performance in reducing the fracture deformity. The proposed device would have to have properties that forego the current drawback of suboptimal positioning under the impressed endplate.
Ad 5: Nowadays, different techniques (anterior, posterior or combined) and implants (pedicle screw constructs, anterior plates and rods, solid bone grafts etc.) are used for different fracture types. Pedicle screw based implants are mainly used for burst fractures in which a decrease of axial support is the principal (biomechanical) consideration for surgical intervention. By providing three-dimensional stability after reduction and cement augmentation, a wide variety of fractures could potentially be treated with a single device.
Ad 6: The balloons used in balloon vertebroplasty do not only provide fracture reduction (vertical reduction) but expand in all directions. This is a potential safety problem and serious shortcoming of the device. The new device should expand unidirectional (i.e. vertically only).
Ad 7: For maximum control and safety during the fracture reduction, an excellent visualization of the implant and vertebral body is a prerequisite. The use of, increasing amounts of, radiopaque fluid would preferably not be necessary in the new device.
Ad 8: Since the proposed device is to be used as an implant, excellent biocompatibility is mandatory.
Ad 9: The augmentation of the reduced fracture with calcium phosphate cement is an important step in the restoration of the anterior column support. The device should provide an access route for the cement *while retaining* the optimal reduction during the setting of the cement. With the current technique, a considerable amount of achieved reduction is lost since the intradiscal pressure and muscle tonus force the fracture towards the initial unreduced position directly after balloon removal (**Chapter 6 and 10**).
Ad 10: A new spinal implant should preferably be MR-compatible to allow for detailed undistorted imaging of the fracture post-operatively and at follow-up.
Ad 11: In the unfortunate situation an implant becomes infected or dislocates to a dangerous position, a safe and easy removal has to be performed. The new device should therefore be readily dismantled if necessary, using either an posterior or anterior approach.

The Proposed Device

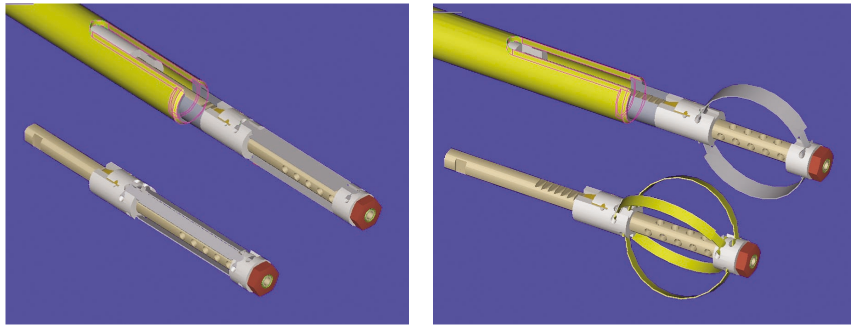
In conjunction with the technical department (Medical Technology and Multimedia, MTM) of our hospital, a device was designed to achieve the following primary goals:

1 to replace the inflatable bone tamps in balloon vertebroplasty for traumatic vertebral fracture treatment;
2 to replace the inflatable bone tamps for kyphoplasty of osteoporotic vertebral fractures.

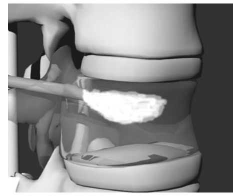
With future applications in mind that could be achieved with no or minimal adaptations to the basic design, secondary goals were to:

3 create a new instrument/implant for posterior lumbar interbody fusion procedures;
4 create a new instrument/implant for tibia plateau fracture treatment;
5 create a new instrument/implant for distal radius fracture treatment;
6 create a new instrument/implant for femoral head collapse treatment.

For all applications the device will be used to displace bone (in case it is used as an instrument) or to permanently fixate bone (in case it is used as an implant).



The proposed device

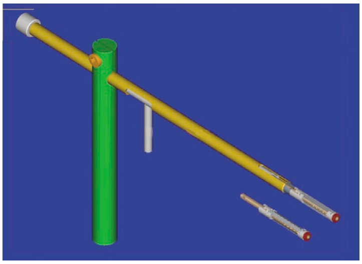


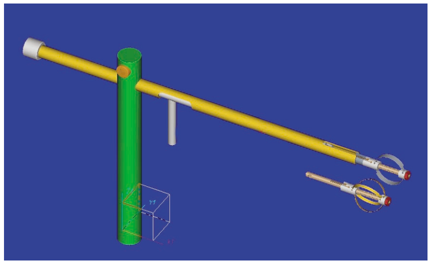
The device consists of a rod with a rack incorporated at one side. Connected at the far side of the rod are two spring leaves in such manner that the rod can rotate around its long axis independent of the spring leaves. On the near side the spring leaves are connected to a small cylinder that can move from the near to the far side over the rod. The mechanism by which the cylinder can be moved is similar to that found in a rivet gun. In the cylinder is a latch that interlocks with the rack. This allows the cylinder to move to the far end but not to return. Only after rotating the rod 90 degrees, the latch will become unlocked and the cylinder can move fore and aft freely. By derotating the rod the locking mechanism is enabled again. The movement of the cylinder towards the far end compresses the spring leaves and forces them in the curved position that is shown in the lower part of the picture. This change of configuration allows the spring leaves to displace bone vertically. The rack and latch mechanism holds the spring leaves in place after final positioning. A central bore in the rod connected to outlets at the far end allows cement to be injected from the near end, thereby creating a reinforcement of the bone structure without any loss of reduction. See also below for more drawings of the device and the applicator. Notice that a ‘four spring leaves’ and ‘six wire’ configuration was also designed to provide better purchase and stability in seriously unstable environments.

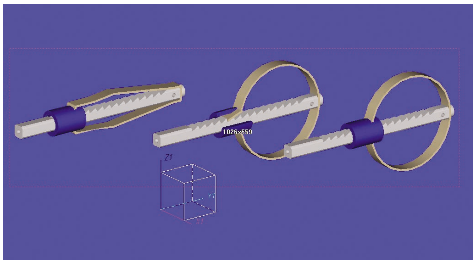
In an experimental human cadaveric burst fracture model, a prototype was tested to assess the utility of the device. This test proved the feasibility of the design in an *in vitro* setting.

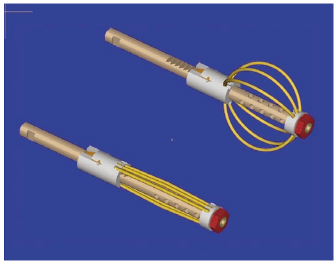
New cadaveric and animal studies are currently considered to assess the biocompatibility and biomechanical characteristics of the device. Furthermore, several technical aspects of the device are being re-engineered to reduce internal complexity and increase stability.

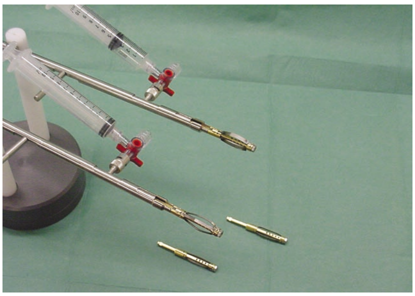
The prospect of reducing and stabilizing traumatic thoracolumbar burst fractures by a bilateral percutaneous approach is encouraging and would, without a doubt, decrease the demand on the patient.

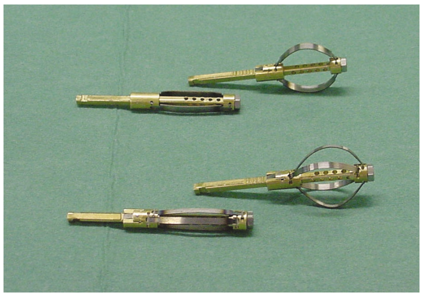


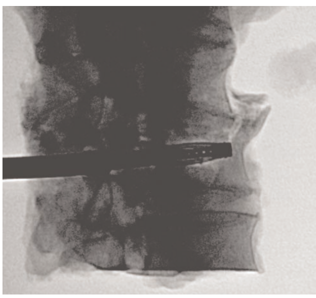


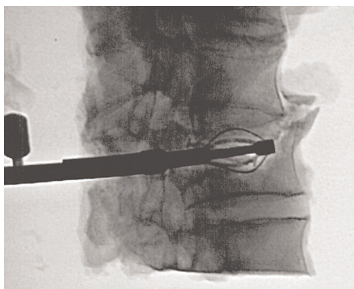






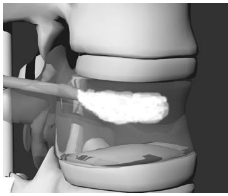






Chapter 13

Summary and conclusions.



Summary and conclusions

In this chapter, the results of the studies that were performed for this thesis are summarized by addressing the five questions that were formulated in Chapter 1 (Introduction and aims).

Question 1: What can be learned from previously published papers with respect to the performance and outcome of surgical treatment of traumatic thoracolumbar fractures?

After reviewing the available literature on the performance and outcome of surgical techniques for the treatment of thoracolumbar fractures in **Chapter 2**, some interesting conclusions could be drawn. The most important finding was that the injury severity of patients was not comparable between the various groups that were treated surgically, making direct comparisons between the groups impossible. Furthermore, it was found that in almost all papers a retrospective study design was followed. The lack of more solid study designs in spine fracture management (only two small-scale randomized controlled trials were available) may reflect the relative immaturity of this orthopedic subspecialty.

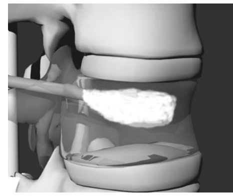
The kyphosis angles at follow-up were highly similar for all treatment groups, and none of the surgical techniques was able to maintain the corrected kyphosis angle reliably. Although it must be emphasized again that the treatment groups were not identical in injury severity, this radiological feature was likely the result of insufficient anterior column support in the majority of cases, as was described in detail in the thesis by Oner.

Another interesting finding was the good functional outcome and low complication rate after surgical treatment of traumatic thoracolumbar fractures, irrespective of the surgical method used. An explanation could be that stabilization of the spine, regardless of how it is achieved, will result in good functional outcome. The encouraging results from studies describing the nonoperative management of thoracolumbar fractures with plaster jackets or recumbency, add further proof that adequate support, not rigid fixation, is important for fracture healing and final outcome. In this light, general advancements in the surgical treatment of the majority of traumatic (A-type) fractures are most likely to be gained by improving the least demanding operative technique; *i.e.* the pedicle-screw technique. This technique allows a rapid and relatively painless mobilization of the patient (in contrast to the conservative approach) but, as the literature review demonstrated, the pedicle-screw technique is not free of perioperative complications such as clinically relevant blood loss, and postoperative complications such as delayed wound healing and infection.

This systematic review resulted in the following goals for the consecutive studies in this thesis: (1) minimizing tissue damage associated with inserting a pedicle-screw construct and (2) preventing recurrent kyphosis by reinforcing the anterior spinal column.

Question 2: Can a new imaging modality, 3D rotational X-ray imaging, be used for an accurate intraoperative 2D/3D visualization of the human spine?

Several minimally invasive techniques have been developed in the last few decades as alternatives for many open surgical procedures. The advantages of minimally invasive procedures are shorter hospital stay, less wound pathology and less blood loss. However, all these procedures require an excellent imaging technique to visualize the operating area, since a direct view is usually not available. The most commonly used imaging modalities for spinal interventions are fluoroscopy and computed tomography. The former is more suited to intraoperative visualization by virtue of the (near-) instant display of the region of interest, while the latter is better suited to detailed multiplanar imaging in a diagnostic situation. Three-dimension Rotational X-Ray (3DRX) imaging could combine the advantages of both techniques. In **Chapter 5**, an experiment is described that was used to assess the accuracy of this new imaging modality. From a quantitative *in vitro* validation study, in which reconstructed 3DRX images from human cadaveric spine specimens were compared to photographs of the corresponding anatomical specimens, it was found that the 3DRX technique was accurate in displaying the spinal anatomy. Although the scanned region of interest was full of (potentially) artifact producing materials, such as titanium pedicle-screws and rods and calcium phosphate cement, the reconstructed images were very similar to the photographs and anatomical landmarks could easily be identified and measured with both modalities. The time needed to reconstruct and display the 3DRX images during the experiment, was unacceptably long for a clinical setting (± 10 minutes). This practical drawback has already been solved partially; the time needed to display images is reduced to one minute and more reduction in time is expected in the near future, due to faster hardware and improved reconstruction algorithms. It is concluded from this study that the 3DRX technique can be used for real-time 2D visualization (similar to fluoroscopy) and for 3D volumetric imaging (in analogy with computed tomography) and may become a useful imaging tool for a variety of (spinal) interventions.



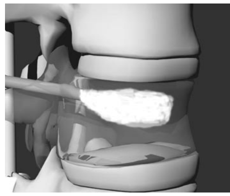
Question 3: Can balloon vertebroplasty with calcium phosphate cement in combination with posterior instrumentation safely be used for the direct restoration of thoracolumbar burst fractures?

From earlier work by Oner *et al.* it was demonstrated that late-onset spinal deformity after a traumatic fracture can be caused by a redistribution of intervertebral disc tissue through the fractured endplate into the vertebral body. Fractured endplates can usually not be restored to their anatomical position by indirect reduction, via distraction, with pedicle-screw instrumentation. This is due to the intrinsic expansive properties of the intervertebral discs that keep the fractured endplates under pressure, despite distraction at the outer edges of the endplate. From the experiments described in **Chapters 4, 6, 7 and 10**, we wanted to learn whether balloon vertebroplasty (*i.e.* injecting cement in a cavity in the vertebral body that was created with an inflatable bone tamp, originally developed for the pain treatment of osteo-

porotic and metastatic lesions of the spine) can be used safely and effectively as additional procedure to the pedicle-screw instrumentation for the *direct* reduction of burst vertebral bodies.
In the study described in **Chapter 4**, initial experience with balloon vertebroplasty was gained in a human cadaveric traumatic spine fracture model. It was found that the reduction of traumatic burst fractures after inflation of bone tamps in the vertebral body, and subsequent filling of the created void with a calcium phosphate bone cement, was superior to reduction with pedicle-screws alone. Furthermore, the expansion of the balloons in the vertebral body did not cause anatomically significant retropulsion of bone fragments anteriorly or, more important, posteriorly towards the spinal cord.
However, questions remained whether the same promising results could also be obtained in fracture types with severely compromised stability due to rupture of longitudinal ligaments or damage to the posterior elements that are frequently found in B-type (flexion/extension) and C-type (rotation) spine fractures.
In **Chapters 6 and 7**, the reduction of endplates, unwarranted bone displacement and chance of cement leakage were investigated in detail (by using 3D rotational X-ray imaging), in experimental human cadaveric traumatic B-type and C-type fractures.
In **Chapter 6**, the impression of the endplates was measured at six phases during the experiment: in intact state; in fractured state; after pedicle-screw reduction; after inflation of the balloons; after deflation of the balloons and after injection of the calcium phosphate cement. It was found that the endplate reduction, obtained after inflation of the bone tamps, was improved significantly compared to reduction with pedicle-screws alone. However, almost all of the reduction was lost after deflation and removal of the bone tamps. A partial re-restoration of endplate reduction was achieved after injection of the cement.
In Chapter 7, radiological data regarding bone displacement and cement leakage were obtained from the experiment as described in **Chapter 6**. Additionally, the integrity of the longitudinal ligaments was examined in the anatomical specimens. It was concluded that bone displacement, both anteriorly and posteriorly, did occur during inflation of the bone tamps, although the absolute value was not likely to be of relevance in a clinical setting. Furthermore, the posterior bone displacement after injection of the cement returned to values comparable to the situtation after distraction with the pedicle-screw instrumentation. The small, but significant, anterior displacement was unlikely to be of high clinical importance since structures as vulnerable as the spinal cord are not in the direct proximity. Another important finding was that the integrity of the longitudinal ligaments, whether intact or ruptured, did not influence these bone displacement parameters. A small amount of cement extravasation, through the anterior cortex into the psoas loge, was observed in one specimen during the experimental procedure.
In **Chapter 10**, a clinical trial is presented in which the initial results of balloon vertebroplasty with calcium phosphate cement, as additional procedure for the direct reduction of thoracolumbar burst fractures using pedicle-screw instrumentation, are described. Twenty patients with A-3 traumatic fractures were enrolled in the study after obtaining informed consent. All patients were carefully followed up after surgery with radiographs and magnetic resonance images. It was found that the experimental surgical procedure did not pose a big demand for the patient and, although cement extravasation was observed intraoperatively in some patients, the postoperative period was uneventful for all. To date, the first ten patients have been followed for over one year and the clinical and radiological results have been very promising so far, although the widespread use of balloon vertebroplasty for traumatic fractures cannot yet be recommended by the authors, due to the steep learning curve and lack of long term clinical results.
From the studies described above, it was concluded that balloon vertebroplasty with calcium phosphate cement, in combination with pedicle-screw fixation, may be a safe and feasible additional procedure for the treatment of traumatic thoracolumbar fractures.

Question 4: What is the biological response of the surrounding tissue after injection of poly(methyl methacrylate) cement or calcium phosphate cement in the vertebral body?

To treat pain resulting from metastatic or osteoporotic lesions of the spine that does not respond to analgesics sufficiently, conventional vertebroplasty and balloon vertebroplasty have been used on a large scale for almost a decade now. The bone void filler that is regularly used in (balloon-) vertebroplasty is poly(methyl methacrylate) cement. This cement has also been used in total joint arthroplasties for many years and its properties are well documented for these applications. The effects of poly(methyl methacrylate) cement in the vertebral body are, however, unknown. Calcium phosphate cement is a relatively new bone void filler that can (potentially) be resorbed and replaced by host tissue. Its mechanical properties, however, are less favorable for vertebroplasty as compared to poly(methyl methacrylate) cement, due to the lower resistance to impact and shear stress. The short-term and long-term fate of calcium phosphate cement in the vertebral body is also unknown.



In **Chapter 8**, the histological effect of poly(methyl methacrylate) cement and calcium phosphate cement on surrounding tissues was investigated in an *in vivo* vertebroplasty model. In twenty-four goats, forty-eight vertebroplasty procedures were performed with both cements. To simulate an endplate fracture, an endplate perforation (allowing direct communication between cement and disc tissue) was performed in half of the vertebral bodies, before injection of the cement. The animals were killed at six weeks or six months and (early) signs of disc degeneration and osteointegration of the cement were studied histologically. Histological signs of disc degeneration were detected in none of the treatment groups. The osteointegration of calcium phosphate cement was superior to poly(methyl methacrylate) cement since a fibrous tissue layer was formed around the latter in nearly all specimens.
In **Chapter 9**, the effect of the exothermal polymerization reaction of poly(methyl methacrylate) cement on the surrounding tissues was investigated, again using our *in vivo* model of vertebroplasty in the goat. In four goats, twelve vertebroplasty procedures were performed with poly(methyl methacrylate) cement, and the temperature elevation was measured at the

bone-cement interface, in the adjacent disc space and in the epidural space. Although a significant temperature elevation was measured at all three locations during the polymerization of the cement, this temperature elevation was limited, both in height and in duration. Therefore, we conclude that the chances of thermal tissue necrosis of the intervertebral disc or spinal cord to occur are negligible, provided that the cement remains in the vertebral body. It was concluded from the animal studies that both cements are suitable bone void fillers for use in (balloon-) vertebroplasty, but calcium phosphate might be preferred in young patients in which long-term biocompatibility can become an issue.

Question 5: Can minimally invasive techniques be used for the treatment of traumatic fractures of the thoracolumbar spine?

From the previous chapters it was learned that balloon vertebroplasty with calcium phosphate cement, can be used as an additional procedure to pedicle-screw instrumentation for the treatment of traumatic thoracolumbar fractures. The clinical trial provided us with information that compared favorably, especially regarding the (little) loss of the corrected kyphosis angle, to a historical burst fracture cohort from our department treated with pedicle-screw instrumentation alone. The results from the clinical trial suggest that the anterior column was reinforced substantially after direct restoration with inflatable bone tamps and calcium phosphate cement. Mermelstein *et al.*, hypothesized that mechanical stress on the (internal) posterior instrumentation can be relieved considerably if the anterior spinal column is reinforced by (balloon-) vertebroplasty. During the design of a sequel study, we suggested that for some type of fractures, pedicle-screws become superfluous after curing of the cement. In these instances a percutaneous approach to fracture reduction and stabilization could become an interesting alternative.

In **Chapter 11**, the height restoration and axial stiffness (which is directly related to the 'anterior column reinforcement') of burst fractures treated with the AO *external* spine fixator and balloon vertebroplasty with calcium phosphate cement was evaluated. Twelve human cadaveric spine specimens were obtained and tested biomechanically at three phases of the experiment: in intact state; after creation of a burst fracture; and after initial alignment with the external spine fixator and subsequent balloon vertebroplasty with calcium phosphate cement, but with the external fixator and pedicle screws already removed. It was found that a significant height restoration was achieved after treatment with the external spine fixator and balloon vertebroplasty. It was also found, however, that the stiffness of the treated specimens was significantly lower compared to intact specimens. It was concluded from this study that, for selected burst fractures, this minimally invasive procedure can be used in cases where a considerable deformity is present but a (more) conservative approach is preferred.

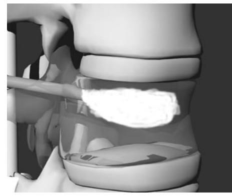
Although balloon vertebroplasty seems to be a promising and useful addition to the regular use of pedicle-screws in traumatic spine fracture management, the procedure is not without its flaws.

In **Chapter 12**, some practical concerns and disadvantages of the current balloon vertebroplasty procedure are discussed. From a critical review of the pros and cons of balloon vertebroplasty, it was concluded that some structural problems could not be solved with the current instruments. In collaboration with engineers from the Technical Department of the University Medical Center Utrecht, a device was developed for the minimally invasive stabilization of thoracolumbar fractures. The device and its potential use is described in detail in this chapter.

Conlusions

From the studies described in this thesis, investigating the possibilities to treat traumatic thoracolumbar fractures in a less invasive manner, the following conclusions can be drawn.

The choice for anterior, posterior or circumferential reduction and stabilization of traumatic thoracolumbar fractures is, predominantly, based on the surgeon's personal preference, since scientific evidence in favor of one of these techniques is non-existent in the literature. The clinical results, obtained after surgical spine fracture treatment in general, are good as long as adequate stabilization of the fracture can be achieved. The perioperative and postoperative complication rate is low for all current techniques although a substantial part of the observed complications can be ascribed to the open nature of the surgical procedure. In order to reduce the invasiveness of surgical fracture reduction and stabilization, the posterior transpedicular approach is probably best suited, provided that the anterior column can be reinforced using the same route.



Anterior column support is often insufficient in burst fractures of the vertebral body, and should be restored because a recurrent kyphosis, even neurological deficit, could otherwise develop. With balloon vertebroplasty, fractured endplates can be reduced directly and the intravertebral defect can be filled with bone cement. In combination with pedicle-screw instrumentation, used for anatomical alignment and indirect reduction, fracture stabilization and anterior column augmentation can be achieved with a posterior approach only. From an *in vivo* study in goats it was concluded that both poly(methyl methacrylate) and calcium phosphate cement can safely be used as bone void fillers, but the latter is preferred in young patients due to its superior biocompatibility.

An excellent and accurate visualization of the operating area is mandatory for minimally invasive procedures since a direct view is normally not available. Three-dimensional rotational X-ray imaging can provide 2D projection images for quick visualization of the operating area and accurate 3D volumes for detailed spatial information of complex anatomical structures. With this imaging modality, less invasive procedures are feasible since extensive tissue dissection, necessary to obtain a direct view of the operating area, can largely be prevented.

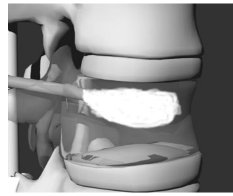
In a clinical trial with 20 patients suffering from traumatic thoracolumbar burst fractures, the balloon vertebroplasty procedure (additional to a pedicle-screw construct) proved to be feasible and safe although the learning curve was steep. The postoperative and follow-up periods were uneventful for all patients and, to this date, no adverse events were observed. Compared to a historical cohort from our department, the mean local kyphosis angle is significantly less although the current follow-up period is too short (18 months) to draw solid conclusions yet.

In a biomechanical study, cadaveric burst fractures were treated with the external fixator and Schanz screws in combination with balloon vertebroplasty. The external fixator and Schanz screws were removed after curing of the cement. It was concluded that a significant height restoration can be achieved under simulated *in vivo* loads. This completely percutaneous procedure may, in selected cases, become an interesting alternative for internal pedicle-screw fixation; a small-scale clinical trial is currently considered.

Finally, a device is presented that could be used as transpedicular stand-alone implant for the reduction and stabilization of traumatic fractures of the thoracic and lumbar spine. A prototype has already been developed and initial tests have been encouraging, although much more research will have to be performed before it can be introduced in clinical practice.

Minimizing the invasiveness of surgical procedures to treat traumatic thoracolumbar fractures was the subject of this thesis. Traumatic spine fractures are serious medical conditions that can have a deep impact on patients and society. The final conclusion of this thesis is that every effort that could improve patient outcome, both immediately and in the long run, is worth investigating and should be considered.

Samenvatting en conclusies.



In dit hoofdstuk worden de resultaten van de eerder beschreven hoofdstukken samengevat door de vragen welke werden gesteld in ‘Introductie en Doel’ van dit proefschrift in **Hoofdstuk 1**, te beantwoorden.

Vraag 1: Wat leert het grote aantal reeds gepubliceerde studies ons over de klinische uitkomst van de operatieve behandeling van traumatische wervelfracturen?

Na bestudering van de literatuur, hetgeen beschreven is in **Hoofdstuk 2**, aangaande de resultaten van operatieve behandeling van traumatische wervelfracturen, kunnen de volgende conclusies getrokken worden. De verschillende chirurgische technieken om traumatische wervelfracturen te reduceren en fixeren, zijn niet met elkaar vergelijkbaar omdat de ernst van het letsel niet gelijk is tussen de groepen. De studie-opzet van het merendeel van de studies is retrospectief; gerandomizeerd prospectief onderzoek is zelden uitgevoerd. Harde conclusies kunnen daarom niet getrokken worden betreffende de effectiviteit van de behandelopties.

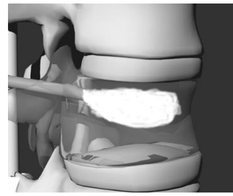
De lokale kyfosehoek ten tijde van het laatste poliklinische onderzoek was vrijwel gelijk bij alle chirurgische vormen van behandeling en geen van de technieken was in staat om de gecorrigeerde kyfose hoek te handhaven. Dit correctieverlies lijkt het resultaat van inadequate steun van het anterieure deel van de wervelkolom, zoals eerder beschreven in het proefschrift van Oner. Progressie van de lokale kyfosehoek kan leiden tot instabiliteit, pijn en neurologische uitval.

Een andere conclusie uit de literatuurstudie is dat bij de meeste patiënten een goed eindresultaat wordt bereikt wat betreft pijn, arbeidsgeschiktheid, en aantal complicaties, ongeacht de toegepaste chirurgische techniek. Waarschijnlijk leidt adequate stabilisatie, hoe dit ook wordt bereikt, uiteindelijk tot goede klinische resultaten. De goede resultaten welke zijn behaald bij patiënten met traumatische fracturen die conservatief, d.w.z. met een corset of bedrust, zijn behandeld, wijzen ook op het belang van stabilisatie in plaats van rigide immobilisatie, voor de genezing van de fractuur. Als adequate stabilisatie bereikt kan worden met alle huidige chirurgische technieken, dan is de patiënt het meest gebaat bij behandeling met de minst belastende operatie met het laagste aantal complicaties. De ‘pedikel-schroef’ techniek is op dit moment de meest gebruikte techniek vanwege voornoemde voordelen. Deze techniek stelt, in tegenstelling tot de conservatieve behandeling, patiënten in staat om direct te mobiliseren en kent een laag percentage complicaties. Deze complicaties zijn echter niet verwaarloosbaar en bestaan onder meer uit klinisch relevant peroperatief bloedverlies, stoornissen in de wondgenezing en diepe infecties. Een deel van de complicaties vloeit voort uit de open benadering welke nodig is om de ‘pedikel-schroef constructie’ te plaatsen.

Het literatuuronderzoek resulteerde in twee doelen die in het volgende onderzoek werden nagestreefd: (1) het minimaliseren van de iatrogene schade bij het inbrengen van posterieure instrumentatie en (2) het verstevigen van het anterieure deel van de wervelkolom om lokale kyfose tegen te gaan.

Vraag 2: Kan een nieuwe beeldvormende techniek, 3D rotational X-ray imaging, worden gebruikt om de humane wervelkolom accuraat weer te geven in 2D en 3D?

Minimaal invasieve technieken, ontwikkeld voor verschillende ingrepen die voorheen ‘open’ werden verricht, zijn in opmars vanwege de kortere opnameduur voor de patiënt, verminderd bloedverlies en lager aantal wondgenezingsstoornissen. Een nadeel van bijna alle minimaal invasieve ingrepen is het ontbreken van een direct zicht op het operatieterrein. Voor het intraoperatief in beeld brengen van de wervelkolom wordt meestal doorlichting en soms ook computer tomografie gebruikt. Doorlichting is zeer geschikt tijdens operatieve ingrepen vanwege de snelle weergave van botstructuren, terwijl computer tomografie geschikter is voor diagnostiek van de wervelkolom vanwege de hoge afbeeldingsresolutie en de mogelijkheid tot het weergeven van anatomische structuren in ieder gewenst afbeeldingsvlak. ‘3D rotational X-ray imaging’ is een nieuwe beeldvormende techniek die de voordelen van beide eerder genoemde technieken zou kunnen combineren. In **Hoofdstuk 5** is een experiment beschreven waarbij de precisie van deze beeldvormende techniek is onderzocht. Anatomische preparaten werden gescand met de 3D rotational X-ray imaging techniek, en gereconstrueerde sagittale beelden werden kwantitatief vergeleken met de foto’s van corresponderende plakken van het anatomisch preparaat. De resultaten van deze studie laten een hoge mate van overeenkomst zien tussen de werkelijke (anatomische) en virtuele (radiologische) sagittale beelden, zelf wanneer verstorende ‘radiodichte’ elementen zoals botcement en metaal in het preparaat aanwezig zijn. De tijd benodigd voor de reconstructie van de beelden was ongeveer 10 minuten hetgeen (te) lang is voor chirurgische interventies. Dit probleem is intussen opgelost door toepassing van snellere hardware en betere reconstructie algoritmen. De conclusie, dat 3D rotational X-ray imaging gebruikt kan worden voor de intraoperatieve 2D (snelle projectiebeelden) en 3D (complexe anatomie) visualisatie van, onder meer, de wervelkolom lijkt met deze studie gerechtvaardigd.

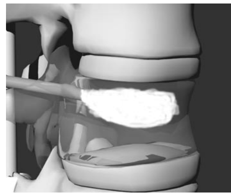


Vraag 3: Kan ballon vertebroplastiek met calciumfosfaat cement, in combinatie met posterieure instrumentatie, veilig worden gebruikt om traumatische wervelfracturen te behandelen?

Oner toonde in zijn proefschrift aan dat, na behandeling van een wervelfractuur, op langere termijn een deformiteit van de wervelkolom kan ontstaan door redistributie van discus materiaal door de gefractureerde dekplaat in het wervellichaam. De gebroken dekplaten kunnen normaliter niet worden hersteld met pedikel-schroef distractie. Dit komt waarschijnlijk omdat de elastische en expansieve discus druk blijft uitoefenen op het centrale deel van de dekplaat terwijl slechts het perifere deel, via tractie aan de annulus fibrosus, indirect kan worden gereduceerd. In de **Hoofdstukken 4, 6, 7** en **10** worden de experimenten beschreven waarin het nut en de veiligheid van ballon vertebroplastiek met calciumfosfaat cement voor de behandeling van traumatische fracturen wordt onderzocht.

Ballon vertebroplastiek is een techniek welke in toenemende mate wordt gebruikt om bij osteoporotische wervelinzakkingen een caviteit in het wervellichaam te vormen waarin stabiliserend botcement kan worden gespoten. De resulterende stabiliteit zorgt voor een onmiddellijke reductie van de pijnklachten welke het gevolg waren van de inzakking.
In **Hoofdstuk 4**, wordt de eerste ervaring met ballon vertebroplastiek voor de *directe* reductie van traumatische fracturen, in humane kadaver wervelkolommen na pedikel-schroef instrumentatie, beschreven. De experimentele techniek leidde tot een significant betere reductie van de gefractureerde dekplaat in vergelijking met alleen pedikel-schroef instrumentatie. Het defect in het wervellichaam, dat resulteerde na de directe reductie met de ballonnen, kon geheel worden opgevuld met calciumfosfaat cement. Tijdens het opblazen van de ballonnen werd geen (klinisch relevante) posterieure verplaatsing van botfragmenten gevonden. Cement lekkage buiten het wervellichaam werd niet gezien. In het fractuurmodel waren de longitudinale ligamenten intact hetgeen de laatste twee bevindingen zou kunnen verklaren. Bij sommige traumatische fracturen, met name de B-type (flexie) en C-type (rotatie) fracturen is de kans op letsel van de longitudinale ligamenten groot.
In **Hoofdstuk 6 en 7** werden, opnieuw in humane kadaver wervelkolommen maar nu bij B-type en C-type fracturen, de dekplaatreductie, botverplaatsing en cementlekkage gedurende de ballon vertebroplastiek procedure in detail onderzocht met behulp van de 3D rotational X-ray imaging techniek. In de studie van **Hoofdstuk 6** werd de impressie van de dekplaat gemeten op zes verschillende tijdstippen gedurende het experiment: intact, gebroken, na pedikel-schroef instrumentatie, na expansie van de ballonnen, na verwijderen van de ballonnen, en na injectie van het cement.
De impressie van de dekplaat na expansie van de ballonnen was significant verminderd ten opzichte van alleen distractie met pedikel-schroef instrumentatie, maar de bereikte reductie van de dekplaat ging bijna geheel verloren na het verwijderen van de ballonnen. Na injectie van het cement werd een hernieuwde reductie van de dekplaat bereikt. In de studie van **Hoofdstuk 7** werd de verplaatsing van botfragmenten als gevolg van de experimentele procedure gekwantificeerd en gerelateerd aan de continuiteit van de longitudinale ligamenten. De resultaten van dit onderzoek tonen aan dat verplaatsing van bot na expansie van de ballonnen voorkomt (zowel naar anterieur alsook naar posterieur), maar dat de absolute verplaatsing waarschijnlijk klinisch weinig relevant is. Na injectie van het cement keerden de naar posterieur verplaatste botfragmenten terug naar de positie welke was bereikt met pedikel-schroef distractie. De naar anterieur verplaatste botfragmenten keerden niet terug naar de uitgangspositie, maar de geringe absolute verplaatsing is waarschijnlijk van weinig klinische betekenis. De staat van de longitudinale ligamenten, continue of discontinue, had statistisch geen invloed op de verplaatsing van botfragmenten tijdens de experimentele procedure. Een kleine hoeveelheid cementlekkage werd gezien in de psoasloge in een preparaat met intacte ligamenten.
In **Hoofdstuk 10** worden de eerste resultaten van een klinische trial naar de behandeling van traumatische thoracolumbale fracturen, met ballon vertebroplastiek en calciumfosfaat cement in combinatie met posterieure instrumentatie, beschreven. Twintig patiënten met A-3 ‘burst’ fracturen werden na ‘informed consent’ geïncludeerd en binnen één week na trauma geopereerd. Alle patiënten werden vervolgens poliklinisch en radiologisch (met röntgenfoto’s en MR onderzoek) vervolgd. De experimentele procedure lijkt geen extra belasting voor de patiënt te zijn en hoewel cement lekkage bij sommige patiënten als intraoperatieve complicatie voorkwam, was het postoperatieve beloop bij allen zonder noemenswaardige problemen.
Tien patiënten zijn nu langer dan een jaar gevolgd en de eerste (voorzichtige) conclusie is dat het verlies van kyfosecorrectie minder is dan beschreven in de literatuur. Langere follow-up en gerandomizeerd onderzoek zijn nodig om deze voorlopige resultaten te onderbouwen, en uiteraard zijn de metingen na uitname van de pedikel-schroef instrumentatie daarbij van groot belang.
De algemene conclusie van de bovenstaande studies is dat ballon vertebroplastiek met calciumfosfaat een veilige en nuttige additionele procedure kan zijn bij pedikel-schroef instrumentatie voor de behandeling van traumatische wervelfracturen.

Vraag 4: Wat is de biologische reactie van omliggend weefsel op de injectie van poly(methyl methacrylaat) cement of calciumfosfaat cement in het wervellichaam?



Vertebroplastiek en ballon vertebroplatiek worden sinds tien jaar in toenemende mate gebruikt voor de behandeling van pijn na (en soms ook ter voorkoming van) een osteoporotische inzakking van het wervellichaam. Voor het opvullen van het wervellichaam wordt meestal poly(methyl methacrylaat) cement gebruikt. Dit cement wordt al langer en op zeer grote schaal gebruikt bij gewrichtsvervangende ingrepen en de chemische en mechanische eigenschappen van het cement zijn goed onderzocht. Het effect van injectie van dit cement op het omliggende weefsel in een wervellichaam is echter onbekend. Calciumfosfaat cement is een relatief nieuw type botcement dat door de chemische gelijkenis met de minerale component van botmatrix zeer biocompatibel is (‘botvriendelijk’). Daarnaast kan, afhankelijk van de exacte chemische samenstelling, porositeit en kristalstructuur, het cement worden geresorbeerd en worden omgebouwd tot lichaamseigen bot. De mechanische eigenschappen van calciumfosfaat zijn echter minder gunstig in vergelijking met poly(methyl methacrylaat) cement, met name door de relatieve broosheid en minder goede weerstand tegen schuif- en buigbelasting. Ook voor calciumfosfaat cement is het biologisch gedrag na injectie in een wervellichaam onbekend. In **Hoofdstuk 8** wordt een studie beschreven waarbij de interactie van poly(methyl methacrylaat) cement en calciumfosfaat cement met omliggend weefsel na een vertebroplastiek werd onderzocht. In 24 geiten werden 48 vertebroplastieken uitgevoerd met beide typen cement. Bij de helft van deze vertebroplastieken werd tevens een defect in de craniële dekplaat gemaakt, om een direct contact tussen cement en discus, zoals dat ook in sommige fracturen kan ontstaan, te bewerkstelligen. Na een periode van zes weken of zes maanden werden de wervellichamen uitgenomen en histologisch onderzocht op tekenen van degeneratie van de discus of dekplaat, en op de integratie van het botcement. In geen van de onderzochte wervellichamen werd degeneratie van discus of dekplaat waargenomen.

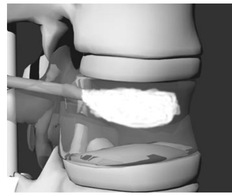
Calciumfosfaat cement was beter geïntegreerd in het omliggende botweefsel dan poly(methyl methacrylaat) cement, daar bij de laatste, bij vrijwel alle onderzochte wervellichamen, een fibreuze laag aanwezig was rond het cement.
In **Hoofdstuk 9** is de studie beschreven waarin de lokale temperatuurstijging door de polymerisatie van poly(methyl methacrylaat) cement na vertebroplastiek werd bestudeerd in de geit. Bij vier geiten werden 12 vertebroplastieken uitgevoerd nadat drie thermoprobes waren ingebracht in het wervellichaam, in de aangrenzende craniële discusruimte en in de aangrenzende epidurale ruimte. Een significante temperatuurstijging werd gemeten in alle drie lokaties, maar zowel de absolute stijging alsook de duur van deze stijging gaf in geen van de drie lokaties een vergrote kans op thermische weefselschade.
Er werd geconcludeerd dat, zolang poly(methyl methacrylaat) cement in het wervellichaam blijft, de kans op weefselnecrose zeer gering is.
De twee studies laten zien dat beide typen cement geschikt zijn als vulmiddel voor defecten in het wervellichaam, maar dat in jongere patiënten calciumfosfaat cement, wegens een betere biocompatibiliteit, de voorkeur verdient.

Vraag 5: Kunnen minimaal invasieve technieken worden gebruikt voor de behandeling van traumatische thoracolumbale wervelfracturen?

In de voorgaande hoofdstukken werd het nut en de toepasbaarheid van ballon vertebroplastiek met calciumfosfaat cement als additionele procedure bij pedikel-schroef instrumentatie voor de behandeling van traumatische wervelfracturen onderzocht. Uit de voorlopige resultaten van de klinische studie kan worden geconcludeerd dat het verlies aan kyfosecorrectie waarschijnlijk minder is dan na een operatie met alleen pedikel-schroef instrumentatie.
Dit effect is waarschijnlijk gerelateerd aan de versteviging van het anterieure deel van de wervelkolom na de ballon vertebroplastiek procedure.
Mermelstein suggereerde in een *in vitro* studie dat de mechanische stress op de posterieure instrumentatie afneemt als de anterieure wervelkolom wordt verstevigd na een (ballon-) vertebroplastiek procedure. In ons vervolg onderzoek suggereerden wij dat bij sommige fracturen de instrumentatie zelfs overbodig wordt na het uitharden van het cement.
Voldoende anterieure stabilisatie bij een intacte posterieure kolom zou de percutane behandeling van wervelfracturen mogelijk kunnen maken. In **Hoofdstuk 11** wordt een studie beschreven waarbij de hoogtecorrectie van het gefractureerde wervellichaam en de axiale stijfheid werd onderzocht na reductie met een fixateur *externe* in combinatie met ballon vertebroplastiek. Twaalf humane kadaver wervelsegmenten, zonder tekenen van osteoporose, werden biomechanisch getest op de volgende drie tijdstippen: intact, gefractureerd, en na behandeling met externe reductie en ballon vertebroplastiek, maar met de fixateur externe reeds verwijderd. De resultaten toonden aan dat een significante restoratie van de hoogte van het wervellichaam kon worden bereikt met deze, in essentie, percutane techniek. Bij belasting met waarden, welke zijn gevonden bij *in vivo* onderzoek, treedt echter ook een aanzienlijk verlies van de gecorrigeerde hoogte op.

Tevens bleek de stijfheid van de behandelde segmenten significant lager dan bij de intacte segmenten. Er werd geconcludeerd dat deze minimaal invasieve procedure ter correctie van deformiteit bij geselecteerde traumatische wervelfracturen kan worden toegepast waar anders een conservatief beleid zou worden gevoerd.
Ballon vertebroplastiek lijkt een nuttige toevoeging bij pedikel-schroef instrumentatie voor de behandeling van traumatische wervelfracturen. Er zijn echter gedurende de experimenten meerdere tekortkomingen van deze techniek aan het licht gekomen welke voor verbetering vatbaar zijn.
In **Hoofdstuk 12** worden onze verschillende klinische en technische observaties tijdens de ballon verteboplastiek procedures besproken. Voor enkele structurele problemen welke zich voordeden tijdens de experimenten lijkt een grondige aanpassing van de instrumenten noodzakelijk. In samenwerking met de afdeling Medische Technologie en Multimedia is een nieuw instrument/implantaat ontwikkeld voor de minimaal invasieve behandeling van wervelfracturen. Dit instrument en de mogelijkheden voor toekomstig gebruik worden tevens besproken in dit hoofdstuk.

Conclusies



Uit de resultaten van de studies zoals beschreven in dit proefschrift kan het volgende worden geconcludeerd:
De chirurgische keuze om traumatische wervelfracturen anterieur, posterieur of circumferentieel te reduceren en fixeren is gebaseerd op persoonlijke voorkeur, daar een wetenschappelijke onderbouwing voor de keuze van deze technieken ontbreekt in de literatuur. De klinische eindresultaten zijn over het algemeen goed indien een adequate stabilisatie van de fractuur kan worden bereikt, en de postoperatieve morbiditeit is gering. Een aanzienlijk deel van de complicaties kan worden gerelateerd aan de weke delen schade welke optreedt bij het inbrengen van het instrumentarium. Het verminderen van deze weefselschade kan waarschijnlijk het best geschieden door middel van een posterieure benadering, vooropgesteld dat het anterieure deel van de wervelkolom via dezelfde benadering ook kan worden verstevigd. De steun van het anterieure deel van de wervelkolom is vaak insufficiënt bij een burst fractuur van het wervellichaam en moet worden hersteld, daar anders kyfose en neurologische uitval kan ontstaan. Door middel van ballon vertebroplastiek met calciumfosfaat cement is het mogelijk het gefractureerde wervellichaam en de dekplaat te reduceren en het ontstane defect te verstevigen.
Pedikel-schroef instrumentatie in combinatie met ballon vertebroplastiek kan fractuur stabilisatie en versteviging van de anterieure wervelkolom bereiken via een posterieure benadering. Zowel poly(methyl methacrylaat) cement alsook calciumfosfaat cement kunnen worden gebruikt als vulmiddel in het wervellichaam, hetgeen werd aangetoond in de twee dierexperimentele studies, maar calciumfosfaat cement verdient, door de superieure biocompabiliteit, de voorkeur in jongere patiënten.
Tijdens minimaal invasieve ingrepen behoort de beeldvorming van het operatie-terrein van goede kwaliteit te zijn daar direct zicht meestal niet mogelijk is. Met 3D rotational X-ray imaging is het mogelijk zowel snelle projec-

tiebeelden in 2D, alsook gedetailleerde complexe anatomische structuren in 3D accuraat weer te geven. Deze nieuwe beeldvormende techniek zou waardevol kunnen blijken voor verschillende, minimaal invasieve, interventies wegens het ontbreken van de noodzaak tot uitvoerige weefseldissectie voor het verkrijgen van een goed zicht op het operatie-terrein.
In de klinische trial werden 20 patiënten, met traumatische thoracolumbale wervelfracturen, behandeld met pedikel-schroef instrumentatie gevolgd door ballon vertebroplastiek met calciumfosfaat cement. Hoewel de chirurgische ‘learning curve’ steil was en cement lekkage werd gezien, lijkt de additionele procedure toepasbaar, veilig en niet belastend voor de patiënt. Vergeleken met een historisch cohort van onze afdeling - deze patiënten werden geopereerd met alleen pedikel-schroef instrumentatie - zijn de eerste resultaten hoopgevend daar het verlies van kyfosecorrectie aanzienlijk minder is. De kortere gemiddelde follow-up (18 *versus* 35 maanden) maakt het echter nog niet mogelijk hier conclusies aan te verbinden.
Uit de biomechanische studie, waarbij burst fracturen kortdurend werden gestabiliseerd met de fixateur externe in combinatie met ballon vertebroplastiek, werd geconcludeerd dat, ook na fysiologische belasting, een significante hoogte-winst van het gefractureerde wervellichaam kan worden bereikt. Deze volledig percutane techniek kan in geselecteerde fracturen een interessant alternatief vormen voor de interne pedikel-schroef fixatie.
Als laatste wordt een ‘stand-alone’ implantaat voorgesteld, welke percutaan zou kunnen worden ingebracht, voor de interne stabilisatie van een wervelfractuur. Dit implantaat kan de fractuur tegelijkertijd reduceren en fixeren en staat daarna ook nog de injectie van botcement, ter versteviging van de anterieure kolom, toe. Het verlies van reductie, zoals werd gezien na het verwijderen van de ballonnen in de klinische trial, zou met dit implantaat voorkomen kunnen worden. Hoewel de eerste prototypen tijdens kadaverexperimenten naar behoren functioneerden, zal nog veel onderzoek nodig zijn voordat de eerste patiënten hiermee behandeld kunnen worden.
Het minimaliseren van de invasiviteit van de chirurgische behandeling voor traumatische thoracolumbale wervelfracturen is het onderwerp van dit proefschrift. Traumatische wervelfracturen zijn ernstige aandoeningen en hebben een grote impact op de patiënt en zijn/haar omgeving. De laatste conclusie van dit proefschrift is dat iedere inspanning die kan resulteren in een verbetering van het eindresultaat voor de patiënt, de moeite van het onderzoeken waard is.

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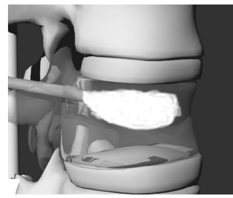

Curriculum Vitae.

The author of this thesis was born on December 21, 1971 in Voorhout, The Netherlands. In 1991 he graduated from high school (VWO, Rijnlands Lyceum Oegstgeest) and started to study medicine the same year at the University of Leiden. In 1996 he followed several courses in physical anthropology at the department of Anatomy (head: prof. dr. G.J.R. Maat) and was assistant physical anthropologist during the International Nova Zembla Expedition in 1998. After receiving his degree in medicine in 1999, he left Leiden to work as a non-training orthopaedic resident at the University Medical Center Utrecht (head: prof. dr. A.J. Verbout). In July 2000 he started working as fulltime research-resident on the traumatic thoracolumbar spine project that was based on the thesis by dr. F.C. Oner (1999). The present work has resulted in several publications, a number of presentations at international conferences and this thesis. Since January 2004 he is a surgical resident at the Meander Medical Center in Amersfoort (head: dr. G.H. Verberne) which is part of his training to become an orthopaedic surgeon.