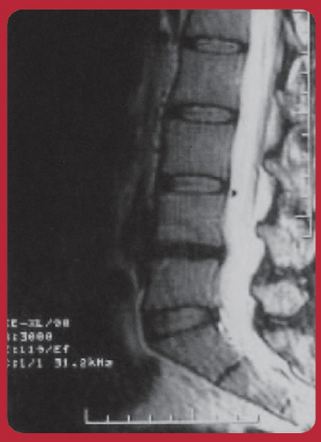
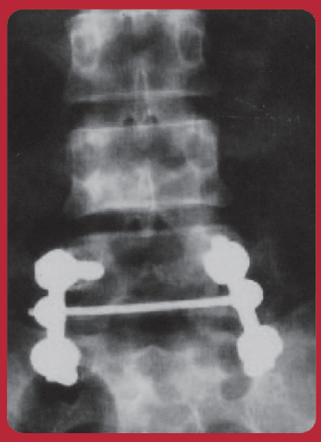
Advances in Spinal Fusion

Molecular Science, Biomechanics, and Clinical Management





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Preface

Spinal fusion presents a challenge to all clinicians; the rate of failure can be high. Current approaches to the problem involve the mechanics and biology of spinal fusion. Extensive work is currently underway to improve healing and decrease the morbidity associated with conventional bone grafting using autologous material from the iliac crest. Less rigid implant systems, more bioactive and mechanically sound bone graft substitutes, and growth factor applications comprise some of the new approaches. Their clinical application has facilitated development of less invasive procedures, such as vertebroplasty. Experimental stimulation of spinal fusion has progressed to the DNA level, with the potential seen for gene therapy applications to overcome the problems with delivery vehicles for bone morphogenic protein (BMP)-based bone graft substitutes. Hence, alternative osteoinductive proteins and new delivery methods are currently under investigation and add to current concepts of local gene therapy for spine fusion. Cloned and sequenced complementary deoxyribonucleic acid (cDNA) of novel osteoinductive proteins are being developed that may foster expression of the genes needed to initiate the cascade of osteoinduction. In fact, transient local gene therapy may prove applicable to the induction of bone formation, thereby offering new clinical treatments for patients with a variety of spine disorders.

The illustrative description of the development of a new generation of materials and devices capable of specific biological interactions to enhance spinal fusion is the heart of this new reference. Improvement of these materials and devices is in a constant state of activity, with the challenge of replacing older technologies with those that allow better exploitation of advances in a number of technologies—e.g., biodegradable implants, drug delivery, recombinant DNA techniques, bioreactors, stem cell isolation and transfection, cell encapsulation and immobilization, and 2D and 3D scaffolds for cells. The book deals with issues in the selection of proper biomaterials that address biocompatibility, biostability, and structure–function relationships. Several chapters focus on the use of specific biomaterials, based on their physiochemical and mechanical characterizations. Integral to these chapters are discussions of standards in analytical methodology and quality control.

Readers will find this book to be derived from a broad base of backgrounds ranging from the basic sciences (e.g., polymer chemistry and biochemistry) to more applied disciplines (e.g., mechanical/chemical engineering, orthopedics, and pharmaceutics). To meet varied needs each chapter provides clear and fully detailed discussions. This in-depth, but practical, coverage should also assist recent inductees to the biomaterials circle. We trust that this reference book conveys the intensity of this fast-moving field in an enthusiastic presentation.

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Contents

Advances in Spinal Fusion

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Reduction and Fixation of Sacroiliac Joint Dislocation by the Combined Use of S1 Pedicle Screws and an Iliac Rod

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I. INTRODUCTION

Sacroiliac dislocation, which usually accompanies disruption of the symphysis pubis or fractures of the pelvic rami, is the most unstable type of pelvic ring injury. In sacroiliac dislocation, both the anterior and the posterior columns of the pelvic ring are disrupted, and the affected hemipelvis rotates internally or externally with vertical displacement (Fig. 1). Deformities of the pelvic ring remain with high frequency after nonoperative treatment of the sacroiliac dislocation [1]. According to published reports, the long-term functional prognosis of sacroiliac dislocation might be poor if reduction was not exact [1–3]. Tile described in a review article that patients with vertically unstable disruption of the pelvis had many problems, 60% of which were persistently painful. According to the investigator, the pain was usually present in the posterior sacroiliac area or the lower lumbar spine and was most frequently associated with unreduced sacroiliac dislocations [2]. Dujardin et al. showed in their report on sacroiliac dislocation that pure sacroiliac lesions were associated with poor functional results, especially if reduction was not exact [1].

External skeletal fixation has been popularly used for unstable pelvic injuries. This procedure provides enough stability for the pelvic injury without severe sacroiliac disruption in a way similar to that for Type B injury classified by Tile [4] (Table 1). However, anterior stabilization using an external fixator alone does not provide sufficient stability for Type C injury with severe disruption of the pelvic ring. Some reports have shown that optimum reduction of sacroiliac dislocation with large pelvic deformities comprises vertical displacement and that rotational deformity is sometimes difficult to treat with an external fixator alone [1,5–8]. Furthermore, long-term maintenance of nonanatomical position with an external fixator has been associated with difficulties in later posterior reduction [5]. An external fixator, which decreases blood loss

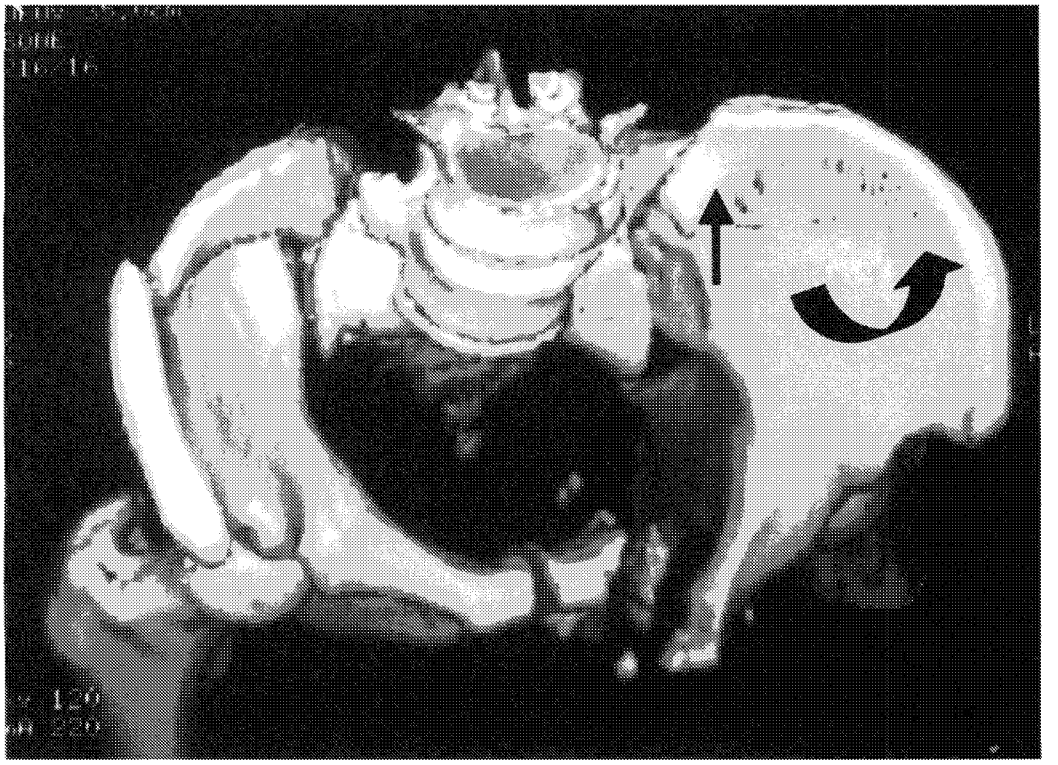


Figure 1 Pelvic deformity in sacroiliac dislocation. In sacroiliac dislocation, both the anterior and the posterior columns of the pelvic ring are disrupted, and the affected hemipelvis rotates internally or externally (curved arrow) with vertical displacement (arrow).

Table 1 Classification of Pelvic Ring Disruption by Tile

Type A	Stable injury
A1	Avulsion of the innominate bone
A2	Stable iliac wing fracture or stable minimally displaced ring fractures
A3	Transverse fractures of the sacrum
Type B	Partially stable injury: rotationally unstable, vertically stable
B1	Open-book injury
B2	Lateral compression injury
B3	Bilateral Type B injuries
Type C	Unstable injury: rotationally and vertically unstable
C1	Unilateral
C2	Bilateral, one side Type C, one side Type B
C3	Bilateral Type C lesions

Source: Ref. 4.

and allows patients to move, can be used for provisional fixation in the acute stage of the injury. On the other hand, open reduction and internal fixation procedures have been advocated by many investigators in terms of the management of sacroiliac dislocation and have been generally accepted [2,4,9,10]. However, the optimum reduction of sacroiliac dislocation with large vertical displacement sometimes becomes difficult even with a conventional internal fixator such as a screw, plate, or rod [18].

Some surgeons have reported the results of the management of sacroiliac dislocation using iliosacral screw fixation [6,11–14]. This simple internal fixation is useful for stabilization of sacroiliac dislocation, whereas the complicated anatomy of the sacral foramina causes a risk of nerve injury due to a screw [15–17] and the acquired stability may be not sufficient in the absence of support with an external fixator [5,14,18]. Sacral bars have been preferred by other surgeons [7,8,19]. Besides these procedures, Albert et al. utilized a reconstruction plate [20].

Among the anchors for lumbosacral fixation, a rod inserted between the inner and outer cortices of the ilium has been used for the most caudad anchor in reconstruction of the lumbosacral spine (Galveston technique) [21]. Van Savage utilized the Galveston technique for fixation of fracture-dislocation of the lumbosacral junction [22]. On the other hand, pedicle screw fixation has been developed as the procedure for posterior internal fixation of the thoracic, lumbar, and lumbosacral spines. Several reports have shown reduction and fixation of traumatic lumbosacral dislocation by lumbosacral pedicle screw fixation [23–25]. One article described results with seven patients with sacroiliac dislocation treated by combined use of pedicle screws of the sacrum and the Galveston technique [26]. Korovessis et al. published a similar work concerning the surgical treatment of sacral fractures in 12 patients and sacroiliac dislocation in 2 patients using iliac screws and S1 pedicle screws [27]. One major difference between the two techniques is the reduction capability of vertical translation with rotational deformity of the pelvic ring [28,29]. An iliac rod and two S1 pedicle screws converged medially in a triangular fashion, penetrating the anterior cortex of the sacrum in our series, provided sufficient reduction and immediate stability for the sacroiliac dislocation. However, as Korovessis et al. mentioned in their article, the displacement at the sacroiliac joint did not change significantly.

In this chapter we explain the surgical technique of reduction and fixation of sacroiliac dislocation by the combined use of pedicle screws of the sacrum and the Galveston technique, and present briefly the result in 15 patients.

II. SURGERY

A. Preoperative Management

If the general condition is unstable for injuries of the intra-abdominal or intrapelvic organs, including the major vessels, life-saving management should take precedence over internal fixation of sacroiliac dislocation. Internal stabilization should be performed after confirmation of the stability of the patient's general condition. In such cases external fixation can be used for provisional fixation in the acute stage of the injury, followed by rigid internal fixation after recovery of patient's general condition and adequate assessment of the stability of the pelvic ring. In addition, external fixation decreases blood loss and allows patients to move. Anteroposterior and inlet plain radiographs of the pelvis and computed tomographic (CT) scans are useful to evaluate the stability and deformities of the pelvic ring. Reconstructive CT is helpful to image the deformity three dimensionally (Fig. 1).

B. Surgical Techniques

The patient is placed in the prone position on longitudinal bolsters. Taking into consideration reduction of pelvic ring deformities, the use of a Relton-Hall frame, which applies lateral

compression force on the iliac wings, should be avoided. A straight transverse skin incision is made across the pedicle level of S1 (Fig. 2). Both sides of the paravertebral muscles are divided transversally at the same level as for the skin incision and are retracted craniad and caudad to expose the posterior cranial portion of the sacrum and the affected posterior iliac crest and to observe directly the disrupted sacroiliac joint during reduction. The superior portion of the origin of the musculus gluteus maximus is detached subperiosteally from the iliac crest, and the posterior portion of the iliac wing is exposed to control the direction of an iliac probe and the rod. The cartilaginous surface of the sacroiliac joint disrupted by fracture-dislocation is treated by debridement and extraction of the bony fragment, which may disturb the reduction.

Pedicle screws are inserted into the S1 pedicles bilaterally according to the ordinary pedicle screw insertion technique with the help of lateral x-ray image intensifier. The S1 pedicle screws are converged medially in a triangular fashion and penetrate the anterior cortex of the sacral vertebral body for the purpose of increasing the stability of screws. A block bone measuring approximately 2 $\times$ 2 cm is excised from the rod insertion point of the iliac crest to avoid skin irritation due to the rod (Fig. 3). Prior to the rod insertion, an iliac probe should be inserted between the inner and outer cortex of the ilium about 30° caudally to the coronal plane of the pelvis. A straight iliac rod is inserted tentatively to confirm the direction and the length under control of anteroposterior x-ray image intensifier. The position of the femoral head is the good landmark to determine the direction and the depth of the rod. The straight rod of the Isola spinal system is inserted once into the probing hole and then pulled out. The pulled-out rod is bent gently to be medially adapted to the prominence of the sacral lamina (open arrow) and bent sharply at the screw insertion point of the ilium (arrow head) at an anatomical angle of 45° between the iliac wing and the frontal plane of the sacrum. The rod is inserted into the probing hole between the inner and outer tables of the iliac wing. Two rod-screw connectors are attached to the inserted rod caudally placed in the rod connection portion to avoid irritation of the L5-S1 facet joint due to the connector (Fig. 4A). For reduction of vertical displacement and angular deformity of sacroiliac dislocation, compression force is applied between the inserted rod and each S1 pedicle screw using a rod holder and a compressor (Figure 4B). If the space of the sacroiliac joint is still widened, further compression force is applied between each S1 pedicle

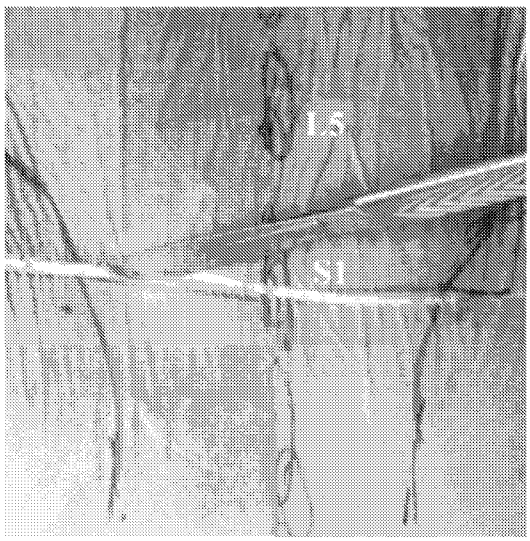


Figure 2 Skin incision. A straight transverse skin incision is made across the pedicle level of S1.

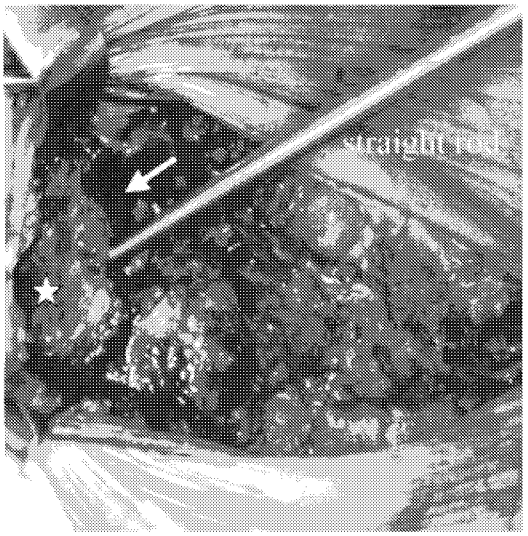


Figure 3 Iliac rod insertion. A block bone measuring approximately 2 × 2 cm is excised from the rod insertion point of the iliac crest to avoid skin irritation due to the rod. Prior to the rod insertion, an iliac probe should be inserted between inner and outer cortex of the ilium (asterisk) about 30 degrees caudally to the coronal plane of the pelvis. Straight iliac rod is inserted tentatively to confirm the direction and the length under control of anteroposterior x-ray image intensifier.

screw and the rod to close the opening (Fig. 5). After completion of internal fixation, divided paravertebral muscles are resutured, and ordinary skin closure is performed. No patients require bone grafting on the disrupted sacroiliac joint.

For patients with major disruption of the symphysis pubis with wide separation, additional fixation of the disrupted symphysis pubis in the supine position using a dynamic compression plate after the reconstruction of the posterior column of the pelvis is recommended (Fig. 6).

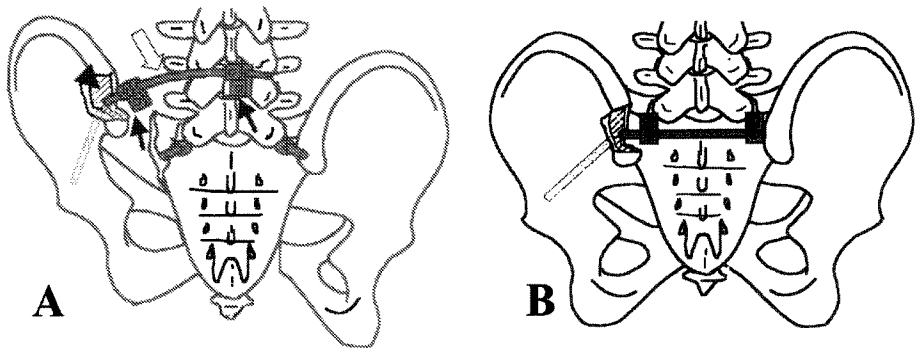


Figure 4 Reduction. (A) Two rod-screw connectors (arrow) are attached to the inserted rod caudally placed in the rod connection portion to avoid irritation of the L5-S1 facet joint due to the connector. (B) After introduction of the rod-screw connectors to the pedicle screws, nuts attached to the two screws are alternately tightened for further reduction.

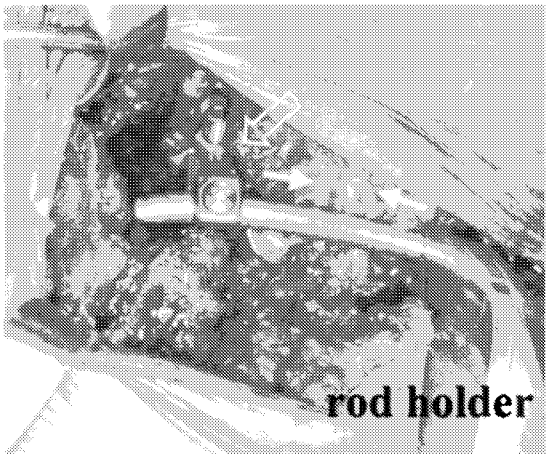


Figure 5 Closing the opening gap. If the space of the sacroiliac joint was still widened, compression force would be applied between each S1 pedicle screw and the rod to close the opening using a rod holder and a compressor.

Patients with anterior injury as the form of fractured anterior rami and with minor disruption of the symphysis pubis can be treated by the posterior procedure alone (Fig. 7).

C. Postoperative Care

Postoperatively, all patients are encouraged to take a sitting position and to use wheelchairs for transfer within one week after surgery. Timing of the start of the gait with weight bearing varies mainly with the course of the treatment for associated injuries of the lower extremities. The weight-bearing gait is initiated 3 weeks postoperatively in the most of the patients without associated injury of their lower extremities.

D. Results

Between August 1993 and April 2001, 15 patients with dislocation of the sacroiliac joint underwent reduction and fixation by the combined use of pedicle screws for the sacrum and the Galveston technique at the authors' institutions. According to the classification system for pelvic ring disruption by Tile (Table 1) [4], all 15 patients had Type C pelvic injury associated with unilateral complete disruption of the sacroiliac joint. Nine of the 15 patients had Subtype C1 injury with unilateral sacroiliac dislocation, and 5 patients had Subtype C2 injuries associated with Type C on one side and Type B external rotational instability on the other side. The remaining patient had Subtype C3 injury associated with Type C on both sides. With regard to injury patterns of the anterior column, 5 of the 15 patients had disruption of the symphysis pubis, and the remaining 10 patients had fractures of the anterior rami. Four of 5 patients with major disruption of the symphysis pubis subsequently underwent additional plate fixation of the disrupted symphysis pubis.

1. Radiographical Evaluation

Postoperative alignment of the pelvic ring was evaluated using the published method [26]. Reduction of the vertical displacement was completed in 9 patients, and correction of the rota-

tional deformity was completed in 8 patients. In 2 patients, both reduction of vertical displacement and rotational deformity were incomplete. At the final follow-up, postoperative reduction was maintained in all patients except one, who underwent metal removal for skin irritation by screwhead prominence. A radiolucent zone around the rod inside the ilium in anteroposterior x-ray film, probably caused by physiological motion of the sacroiliac joint, was observed in all patients except one, who underwent removal of the implants for deep infection. However, no patients complained of problems associated with the lucency, and the implants were not removed.

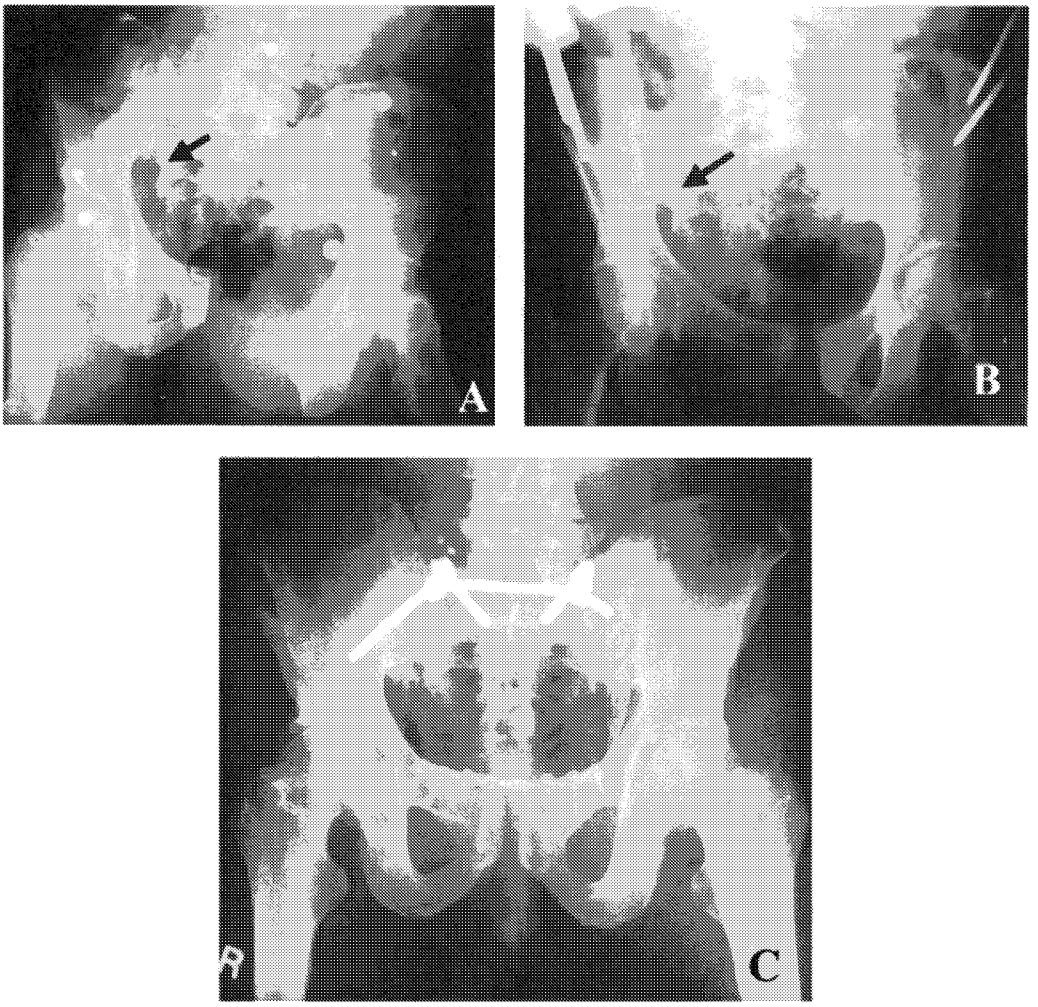
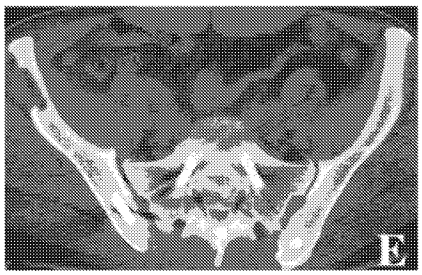


Figure 6 Type C patient with major disruption of the symphysis pubis. (A) The patient sustained Subtype C2 injury, Type C on right and Type B on left, with major disruption of the symphysis pubis. (B) External fixation was utilized for provisional fixation in the acute stage of the injury until the sufficient recovery of patient's general condition. Correction of both of the rotational deformity and vertical displacement was not sufficient. (C) Reduction and stabilization was performed using the iliac rod and S1 pedicle screws. For this patient with major disruption of the symphysis pubis with wide separation, additional fixation of the disrupted symphysis pubis using a was conducted after the reconstruction of the posterior column of the pelvis. (D,E) Pre- and postoperative CTs demonstrate reduction of the rotational deformity.



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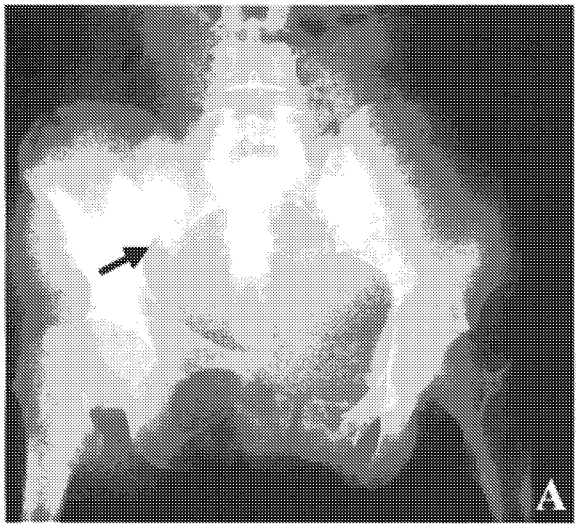
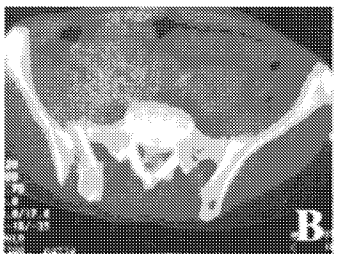




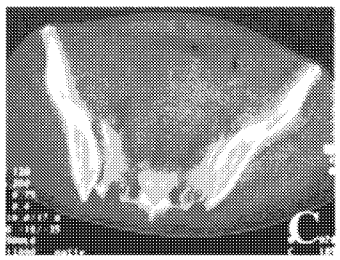
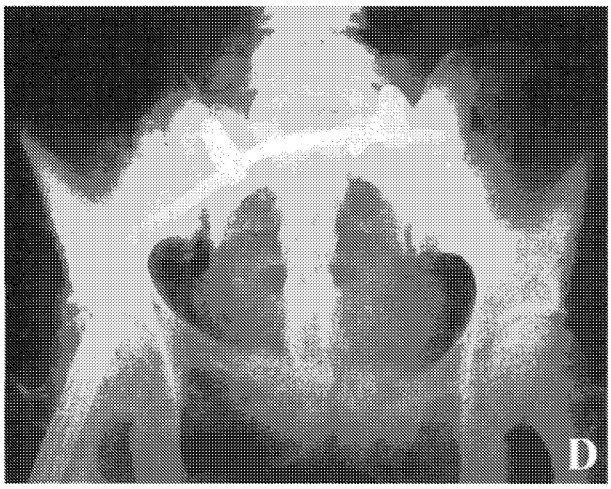


Figure 7 Type C patients with fractured anterior rami. (A) The patient sustained Subtype C1 injury with anterior injury as the form of fractured anterior rami. Plain anteroposterior x-ray film demonstrates rotational deformity and vertical translation of the right pelvis. (B,C). Preoperative CTs show internal rotation of the right pelvis. (D) Reduction and stabilization was performed using the iliac rod and S1 pedicle screws. Postoperative x-ray film demonstrates sufficient reduction of rotational and translational deformity. (E) Postoperative CT shows sufficient correction of rotational deformity.



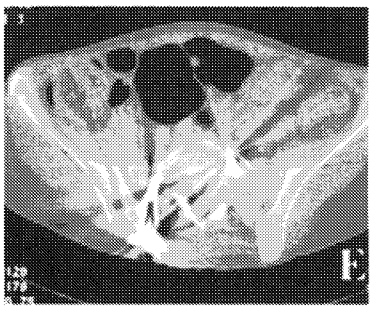


Figure 7 Continued.

2. Daily Activity

All patients showed normal walking capability at the final follow-up except one patient with associated femoral and sciatic nerve injury. Recovery of the nerve function was incomplete, and the patient required a cane and an orthosis to stabilize his frail lower extremity for ambulation. Three patients complained of mild pain on gait: one at the inguinal and gluteal region and two at the low back region, but they did not need pain medication. Regarding the working status at the final follow-up, a patient with femoral and sciatic nerve palsy was unemployed. A middle-aged female patient who postoperatively sustained deep infection was unemployed despite complete recovery of physical function. The remaining 13 patients had returned to their original jobs.

3. Complications

No patients experienced problems caused by transverse division of the paravertebral muscles, but one patient required secondary suture of the wound 2 weeks postoperatively. No patients sustained neurovascular complications of the inserted S1 pedicle screw. One patient had late deep infection around the iliac rod and the S1 screws 2 months postoperatively. The infection healed as a result of complete removal of the internal fixation devices and 2-week continuous irrigation, and progression of the pelvic ring deformity was not observed after removal of the

devices. Loss of correction was observed in one patient who required metal removal for skin irritation by screwhead prominence.

III. DISCUSSION

In sacroiliac dislocation, besides the posterior column disruption of the pelvis in the sacroiliac joint, the anterior column of the pelvis is usually disrupted as the forms of disruption of the symphysis pubis or the fractured anterior rami. Accordingly, sacroiliac dislocation is considered most unstable among the various types of traumatic pelvic ring disruption. In this type of injury, the vertically and rotationally unstable pelvis is associated with the loss of bilaterally symmetrical ring structure [2,4]. Several biomechanical studies have demonstrated that the use of an external fixator alone does not provide sufficient stability for a vertical shear injury of the sacroiliac joint and showed that the additional use of sacral bars substantially increases the strength and rigidity of fixation provided by external fixation alone [19,30,31]. Stocks et al. [31] also demonstrated that the combined use of sacral bars and symphysis plate for fixation provided the same stabilizing effect as that of external fixation with the additional use of sacral bars.

Pedicle screw fixation has been developed as a procedure for posterior internal fixation of the thoracic, lumbar, and lumbosacral spines. In our study the S1 pedicle screws were converged medially in a triangular fashion as the anchor of the sacrum. The triangulation has been presented in a biomechanical study to significantly enhance loads on pullouts of the pedicle screws [32]. In addition, the sacral pedicle screws penetrated the anterior cortex of the sacrum to increase the pullout resistance [33]. With regard to another fixation anchor for iliosacral fixation, we utilized a rod inserted between the inner and outer cortices of the ilium (Galveston technique). This fixation anchor has been demonstrated in biomechanical studies to be the most stable for lumbosacral fixation among the various fixation procedures [34,35]. The combined use of S1 pedicle screws and the Galveston technique, utilized in our series, provided sufficient reduction and good stabilization in the treatment of sacroiliac dislocation. With other posterior sacroiliac fixation techniques using sacral bars and iliosacral screws, reduction must be performed prior to internal fixation. On the other hand, the hybrid anchoring technique, which uses S1 pedicle screws and an iliac rod, provides sufficient reduction prior to fixation. From this point of view, the combined use of the S1 pedicle screw and the Galveston technique may be superior to other posterior internal fixation procedures for reduction and fixation of sacroiliac dislocation. However, further biomechanical studies are required for comparison of the stabilizing capability with those of other fixation procedures.

The iliac rod in the frontal plane was bent to 90° and inserted into the iliac wing in a horizontal direction, as reported by Allen and Ferguson [21]. Since then the Galveston technique has been performed by most surgeons with a more angled downward bent. The upward or horizontal direction, which allows one to introduce the rod into the thinner portion of the iliac wing, may enhance the stability of the rod. However, rod insertion into the thinner portion introduces the difficulty of rod setting and the risk of rod perforation from the iliac wing. The downward direction employed in most cases in our series provided immediate stability and sufficient reduction of the deformities, and the reduction was maintained without loss at the time of the final follow-up. Therefore we recommend the downward direction of the iliac rod considering the insertion facility.

Sacroiliac dislocation can be divided into two types according to the patterns of anterior injury: one for fractured anterior rami and the other for disruption of the symphysis pubis. With regard to internal stabilization of sacroiliac dislocation, posterior fixation using a sacral bar with additional anterior fixation using a symphysis plate has been revealed to be the most rigid

fixation procedure in biomechanical studies [19,36,37]. Kellam et al. advocated the combined use of external fixation of the pelvis and internal sacroiliac fixation for sacroiliac dislocation with this type of anterior pelvic fracture [7]. In our series we employed additional anterior stabilization in 4 patients with major disruption of the symphysis pubis. As a result, however, sufficient reduction and internal stabilization were achieved by posterior fixation alone in the remaining 10 patients with fractured anterior rami and one patient with disruption of the symphysis pubis. The 4 patients with sacroiliac dislocation with disruption of the symphysis pubis in our series, who were treated by the combined use of anterior and posterior internal fixation procedures, might have been managed by the posterior procedure alone without additional anterior fixation.

IV. CONCLUSION

The hybrid internal fixation procedure, combining the use of S1 pedicle screws and an iliac rod (Galveston technique), is useful for the reduction and fixation of sacroiliac dislocation associated with vertical and rotational instability of the pelvic ring.

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2

Percutaneous Vertebroplasty in the Treatment of Osteoporotic Fractures

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I. INTRODUCTION

Vertebroplasty is a percutaneous technique used to treat vertebral body injuries that produce pain and/or risk of vertebral compression fractures due to weakening of bone structure. It consists of the injection of polymethylmethacrylate (PMMA) cement into the weak vertebral body in order to harden the vertebra to give it greater strength and stability, thus avoiding progression of collapse and pain. This technique was first used in 1987 by Galibert et al. [1] for the treatment of painful vertebral hemangiomas, myelomas, and metastatic lesions, with which they obtained magnificent results in pain management. Other small series subsequently stressed its efficacy in the treatment of these diseases [2,3].

The first results obtained with the use of this technique in the treatment of osteoporotic vertebral fractures were published in 1989 [4]. This study included a series of 5 patients with pain resistant to medical treatment who obtained immediate relief of their pain after a percutaneous vertebroplasty was carried out. Since then, different publications have demonstrated the good results obtained with this technique, with pain improvement in more than 80% of the cases [5–9].

II. INDICATIONS

The principal indication to perform a vertebroplasty is pain associated with a vertebral compression fracture in cases of osteolytic metastatic lesions, vertebral plasmocytomas, vertebral hemangiomas, and osteoporosis. The decision to use this technique is made by a multidisciplinary team that should assess the need for treatment, other than medical, either with radiotherapy, surgery, or a combination of several procedures. The final decision will depend on factors such as symptoms and signs, degree of dissemination of the disease, general health status, and foreseen survival.

III. OSTEOPOROSIS COMPRESSION FRACTURES

Osteoporosis is the most frequent bone metabolic disease. It affects more than 30% of the female population above 65 years of age, and it is expected that its incidence will quadruple in the world population during the next 50 years [10]. The spine is the most frequently affected region, with compression fractures of the vertebral bodies being produced.

Although most vertebral fractures are related to loss of bone density due to age, certain diseases, surgical procedures, and medications associated with the appearance of osteoporosis, such as steroid therapy, chronic pulmonary obstructive disease, and chronic alcoholism, are equally a cause of vertebral fracture due to microtraumatism.

Bone mineral density below 2 standard deviations and the existence of a previous vertebral fracture increase the risk of suffering a new vertebral fracture 7–20 times.

Fracture of the vertebral body by osteoporosis can be defined as reduction of more than 15% in height. The most frequent form is collapse at the expense of the superior plateau with or without anterior wedge deformity.

Vertebral compression fractures may occur spontaneously or after minimum trauma and are associated with some degree of pain in 84% of cases. They frequently cause acute and incapacitating pain, posing an important limitation of the person's daily activities [11]. In general, treatment with rest, analgesics, and use of external supports for a period of 2–12 weeks is effective in 85% of the cases [12]. However, in some cases the pain is persistent and very incapacitating, requiring the use of narcotics for its treatment.

In such cases, vertebroplasty has shown great efficacy, with decrease of pain in up to 90% of cases [7,8]. These effects are long-lasting; it has been demonstrated that there is no progression of the collapse in the cemented vertebrae and that a greater risk of fracture in the vertebrae adjacent to the cemented ones does not exist [13].

Although the candidate selection criteria for this procedure have not been clearly described in the literature, after a review of the first 250 cases of vertebral fractures due to osteoporosis treated in our center, we can recommend this technique in those patients who suffer vertebral compression fractures with severe and incapacitating vertebral pain, who do not respond to medical treatment, and in whom a spinal MRI confirms the presence of a loss of vertebral body volume, usually at the expense of the superior plateau, and with an alteration of the signal consisting in hyposignal in T1 and hypersignal in T2 and with a fat suppression technique (STIR). The presence of an intravertebral cyst of necrosis (Kümmel disease) is frequently observed, which supports the osteoporotic etiology of the lesion and does not contraindicate the procedure. When several vertebrae are affected, it is the location of the pain by clinical examination and the MRI image that indicates the pain-causing vertebra. Pain evolution time has little effect on the results, although it seems that better results are obtained in those cases of acute lesion having 6 weeks and worse ones in those that have more than one year of evolution.

Although the technique was initially developed to treat patients who did not respond to medical treatment [7,14,15], its use is indicated increasingly earlier because of the results obtained and the scarce number of complications observed [16–18]. However, we should continue to consider that this is a disease that is cured with medical treatment in more than 85% of cases and that there can be overtreatment of these lesions.

We have obtained worse results in those patients who have lost more than 70% in vertebral body height. In addition, the technique is not indicated in cases of vertebra plane with loss of 90% of its height. Furthermore, at present it is not considered to be indicated as a prophylactic treatment in patients with an important loss of bone mineral density in which there is no evidence of vertebral fracture.

IV. TECHNIQUE

A. Preprocedure Assessment

A presurgical study is performed with a chest x-ray, ECG, and blood biochemistry examination with hemorrhage and coagulation times. In our service, we perform a plain x-ray and MRI of

the spine in the days prior to the intervention to verify the present status of the process and the condition of the vertebra or vertebrae to be treated.

The patient and family are informed of the risks and benefits and treatment alternatives, and consent is obtained. If the patient is ambulatory, he or she is admitted to the hospital the afternoon before, and no premedication is administered normally.

B. Procedure

During recent years, different techniques to perform the percutaneous vertebroplasty have been developed in both Europe as well as the United States [7,16,17,19]. All have a similar base to that initially devised, there being, above all, differences in the cement injection method. This is a minimally invasive technique that basically consists of accessing the diseased vertebra body by posterior percutaneous route with a needle having sufficient caliber to make it possible to inject the cement into its interior.

Access is performed transpedicaularly in the dorsal and fifth lumbar vertebrae via a posterolateral approach in the rest of the lumbar vertebrae. In the cervical spine, the access is anterolateral with computed tomography and fluoroscopy arc control for the injection of the cement.

In the authors' experience, the procedure is performed with mild sedation and local anesthesia for the dorsal site and spinal, intradural anesthesia for the lumbar region. The patient is monitored cardiologically with oxymetric control, given that the patients are normally elderly and in prone decubitus situation, at least in the dorsal site.

Once the pedicles are located radiologically in posteroanterior projection, the skin and the pathway to the cortical wall are anesthetized and a small incision is made in the skin. Then the 14 gauge needle is introduced with diamond-tipped trocar until the upper third of the pedicular image is reached. A small blow with the hammer makes it possible to perforate the body cortical wall and, with lateral fluoroscopic guidance, to introduce the needle to the anterior third of the body, either with successive small blows or with mild pressure and rotation of the needle, depending on the consistency of the vertebra. Returning to the posteroanterior projection, the needle site is verified and puncture of another pedicle is performed.

In our experience, it is practically impossible or very dangerous to access the contralateral half of the body by transpedicular route, since we would need to perform a more external and oblique puncture with the risk of pedicular rupture. Therefore, we always perform a bilateral transpedicular puncture.

In the posterolateral route, the patient is placed in the left lateral decubitus position. The cutaneous puncture is performed 4 cm above the spinous line, and the vertebral body is accessed outside the transversal apophysis in the dihedral angle formed by the lateral and posterior sides of the body. Once the body cortical wall is perforated, the needle is advanced until it reaches the anterior third of the vertebral body, after the mean line of the anteroposterior projection.

In all cases, vertebrography with nonionic isoosmolar iodine contrast media was performed, with acquisition in digital subtraction and lateral projection. When there is lateral vein filling, it is also useful to perform a vertebrography in anteroposterior projection. The vertebrography results are very useful to orient the performance of the vertebroplasty. In most cases, the trabecula spongy bone is filled and, more or less rapidly, the basivertebral vein and posterior peridural venous plexus or a lateral segmental vertebral vein are filled with drainage towards the vena cava or azygous complex. Due to fracture of the superior or inferior plateau, contrast escape to the intervertebral disc is sometimes observed.

The immediate filling of one of these veins or the disc without trabecular filling makes it necessary to reposition the needle point, a maneuver that is sometimes not successful. In these cases, very slow injection of a drop of cement should be done with exhaustive fluoroscopic

control, visualizing the cement progress in the vein and stopping when the cement reaches the plexus.

The cement used is mixed with a small amount of tantalum or tungsten power to provide radio-opacity. The result is a semiliquid compound that should be very homogeneous, without lumps. When mixing in cold, we lengthen the hardening time of the cement, permitting a slower and more prolonged injection. Some cements with barium sulfate and appropriate viscosity have been manufactured especially for this procedure.

The mean amount of cement to be injected in a vertebra varied from 3 to 7 cc both in the transpedicular as well as posterolateral route. Injection of the cement should always be performed under direct and continuous fluoroscopic control. There are several mechanisms to perform the cement injection: direct manual injection with 1 and 2 cc syringes, injection by a pistol system, or injection by screw system. The authors prefer to use the screw systems because they allow slower and more controlled cement injection. With the manual or pistol systems it is difficult to prevent massive leakage of cement into the venous system if a sudden communication with the basivertebral plexus occurs during the procedure and with this an abrupt decrease of resistance to the injection. In addition, with the screw systems, higher injection pressure is obtained than with the other systems, which makes it possible to use lower caliber needles (14G vs. 10 and 11G).

It is very important to have radiology equipment with high-quality features such as those used in vascular radiology, with very good radioscopy and the possibility of enlarging the image and performing digital subtraction and even road mapping, and to have a previously made reference image of the vertebrography in order to have possible leakage points controlled at all times (Fig. 1).

Once the vertebroplasty is completed, the patient is maintained at rest for several hours, allowing mobilization according to tolerance. A control study should be done by CT scan of the vertebra treated to verify the filling and the presence of extravasations. In general, the patients can be discharged the next day, with ambulation and with analgesics according to the degree of pain. Afterwards they can gradually take up their usual daily activities (Fig. 2).

V. CONTRAINDICATIONS

The only absolute contraindication to performing a vertebroplasty is the existence of a serious coagulation alteration. Patients who are under dicumarinic treatment should discontinue the treatment 2 days before and use preventive doses of low molecular weight heparin. The technique should be avoided in patients with known infection. Existence of a practically flat vertebra makes it impossible to inject the cement. Furthermore, presence of a longitudinal fracture that produces a complete division of the anterior wall contraindicates the technique.

VI. COMPLICATIONS

The number of complications described in the literature using this technique is very low. On some occasions an increase in pain has been described during the procedure, probably due to the increase in pressure in a painful vertebra and during the first hours after the cement injections [2,20]. However, the most serious complications are related to cement leakage outside the vertebral body margins, both directly as well as through the venous plexus.

Cotten et al. [2] demonstrated the presence of both cortical wall as well as venous cement leakage in 29 of 40 patients treated for metastasis or myeloma in whom a CT scan was performed after the procedure. Most of these leakages were asymptomatic, but two that were in the intraver-

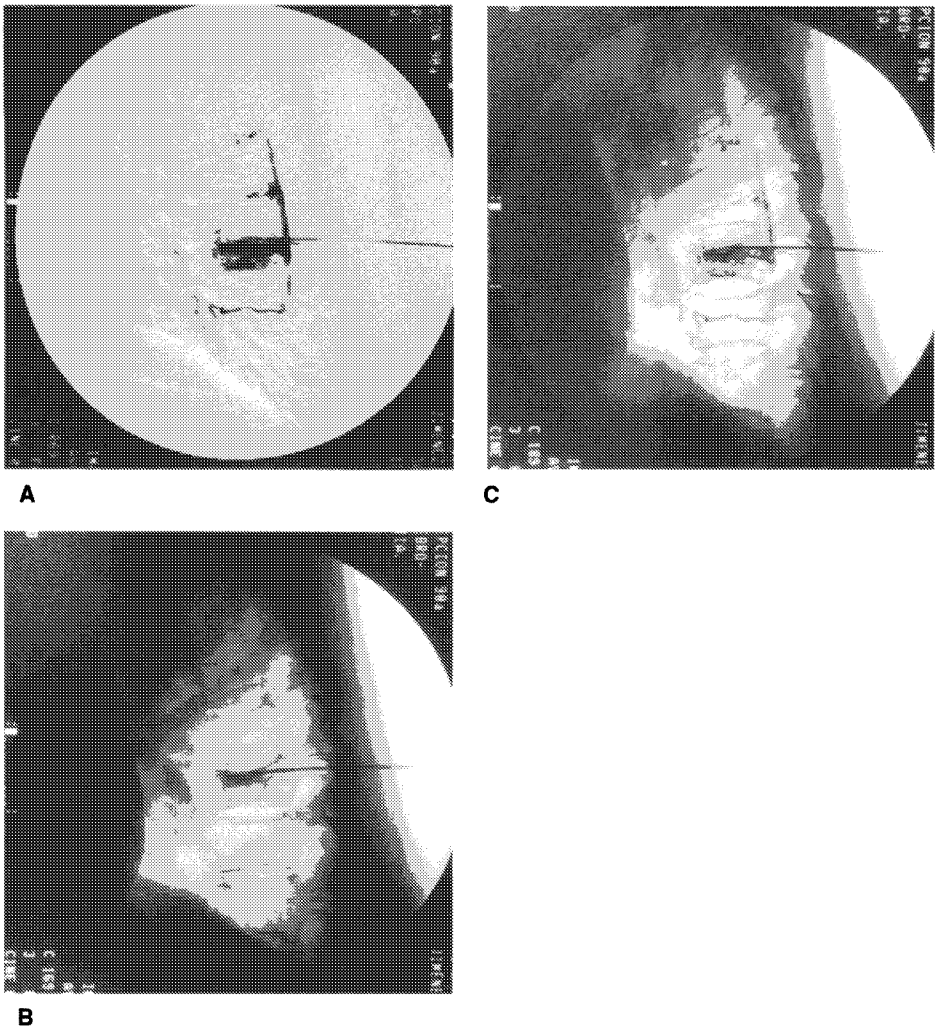

Figure 1 (A) Vertebrograph with a digital substraction showing complete trabecula filling and drainage to the posterior epidural venous plexus and an anterior azygous vein. (B) The image is retained and the cement is injected very slowly, stopping when it reaches the drainage points. (C) The result is the filling of the vertebral body.

tebral foramen needed surgical decompression. In a review, a larger series of patients [21] described one case of radicular compression out of 258 patients treated and 13 cases of radicular pain, 3 of whom needed surgical decompression of the root; the remaining cases abated with anti-inflammatory treatment. Most of the authors describe a low incidence of transitory neuritis (0–6%) [2,14,16,21–23], although there are cases of massive cement leakages that require emergency decompressive surgery [24]. In every case, the cause of the appearance of the complication was due to a defect in the technique, either in the preparation of the cement, its scarce visualization, or its uncontrolled injection.

The presence of leakage of the cement into the vertebral venous plexus does not interfere in the technique success. The heat released by the cement in its polymerization process could injure the nearby nervous structures, but as Wang et al. [25] demonstrated in an experimental

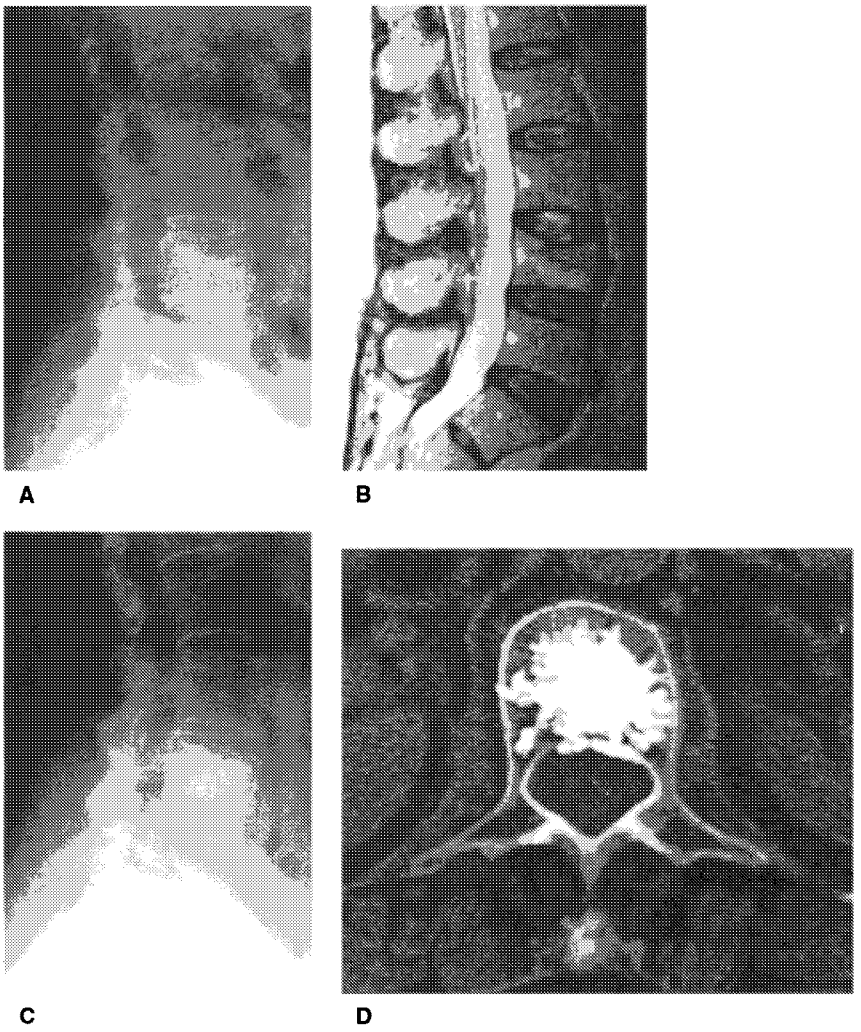

Figure 2 (A) Osteoporotic vertebral compression fracture of L4 in a patient with pain refractory to medication. (B) MRI shows a hyperintense T_2-weighted signal. (C) Vertebroplasty is performed with good filling of the vertebral body and an excellent result. (D) A postprocedural CT scan shows a small leakage of cement into the epidural venous plexus.

study in dogs, it seems that both the presence of the posterior vertebral common ligament, which would act as a barrier, as well as the continuous flow of cerebrospinal fluid that acts as a refrigerant prevent the locally reached temperature from being sufficient to cause this injury [26].

The presence of cement outside the vertebral frame was observed in 47% of 250 patients in whom postprocedure CT was performed. The functional results were similar in both the cases showing cement leakage as well as in the absolutely normal ones [9].

Other complications described in the literature include costal fractures, paravertebral hematomas, epidural abscesses, esophageal compression, and pulmonary embolism. The latter is due to massive leakage of cement into the central circulation [27].

VII. FUTURE DEVELOPMENTS

Percutaneous vertebroplasty has evolved very rapidly in recent years, and we have had the opportunity of seeing articles that retrospectively gather short series appear in the literature and prospective studies and longer series begin to arise [18]. It is expected that we will soon have better knowledge of the long-term results and that we will improve our inclusion criteria.

Two research fields are presently being developed: biocements and kyphoplasty.

Biocements are compounds of calcium phosphate that can be injected in liquid form and that harden at body temperature. They were initially developed for filling of the bone cavities and are totally reabsorbable products. In vitro experiments have demonstrated that the product, once hardened, is capable of strengthening the bone structure in the same way as PMMA cements [28–31]. However, its application in persons and its clinical indications must still be defined. We have found many difficulties in its use in experimental animals. When the mixture obtained has the viscosity characteristics recommended by the manufacturers, the pressure exerted for the injection of the product causes the separation of the solid and liquid phases within the puncture needle, producing its taponade. However, when the mixture obtained is more liquid and the injection is performed, the product is "washed" from the vertebral body by the blood flow so that the desired effect of strengthening the bone structure is not obtained. In addition, considering the magnificent results obtained with the use of the present PMMA cements, the advantages of absorbable cements, which may not prevent progression of the collapse of the treated vertebra, must still be defined [29]. However, it is possible that the development of these products will have great utility in the future as a prophylactic treatment more than as a treatment of symptoms.

Kyphoplasty is a technique by which an attempt is made to treat the pain caused by an osteoporotic vertebral fracture but that also aims to recover the vertebral body height and restore the sagittal plane lost by the wedging suffered. The technique consists in the placement of a balloon inside the affected vertebral body which, on being inflated at high pressure, restores the vertebral body height, posteriorly performing a filling of the rest of the remaining space with cement. The results obtained initially seem to be similar to those of the vertebroplasty regarding the improvement of the functional situation, with a 48% restoration of vertebral height, especially in patients treated within 6 weeks after fracture [32,33].

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3
Biomechanics of Vertebroplasty

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I. INTRODUCTION

For almost four decades, vertebroplasty has been used to augment the purchase of pedicle screws for spinal instrumentation [1] and to fill voids resulting from tumor resection as a means of reducing the risk of fracture subsequent to the weakening caused by resection [2–5]. Vertebroplasty, initially an open procedure, introduced bone graft or some biomaterial, typically polymethylmethacrylate (PMMA) cement, into vertebral bodies (VBs) [2–4,6–12]. Percutaneous vertebroplasty (PV), a relatively new variant, is performed by injecting acrylic cement into VBs via cannulae. This procedure was reportedly first performed in 1984 to stabilize a C2 vertebra invaded by an aggressive hemangioma [13]. The successful mechanical stabilization of the VB and the resulting pain relief experienced by the patient led investigators to adapt the procedure for patients with painful osteoporotic vertebral compression fractures [14]. In recent years, the procedure has gained acceptance by many clinicians [15] and is being performed with increasing frequency, partly because of the often dramatic pain relief that reportedly occurs after the procedure [16–18] and partly because of the need for an alternative procedure to nonoperative therapy (bed rest and pain medication) for the growing numbers of elderly patients with osteoporotic compression fractures. Osteoporosis is a daunting public health concern and is the most common cause of vertebral compression fractures (VCFs) in the United States [19]. The incidence of VCF exceeds that of hip fractures [20]. Furthermore, as treatments for primary tumors become more effective, resulting in longer periods of patient survival, the incidence of metastatic lesions increases. The spine is the most common site for metastases, and osteolytic metastases and myeloma are the most frequent malignant lesions occurring in the spine [3]. PV is being used more frequently to augment mechanically VBs compromised by lytic lesions.

Accompanying the increase in the practice of PV are increases in the number of clinical investigations into the efficacy of the procedure and of basic science investigations into evaluating materials, instruments, and techniques. This chapter focuses on those biomechanical investigations.

II. MECHANISMS OF PAIN RELIEF

According to the literature, pain relief after PV treatment is experienced by approximately 90% of patients with osteoporotic VCFs [18,21] and approximately 60–70% of patients with various tumors [22,23]. Although the definitive mechanism of pain relief remains unidentified, proposed

mechanisms include mechanical stabilization [24,25] and thermal or chemical interaction with vertebral periosteal [26,27] or intraosseous pain receptors [28].

A. Thermal Effects

When PMMA polymerizes, it does so exothermically. Some hypothesize that the heat generated in the exothermic reaction of PMMA is sufficient to cause thermal necrosis of neural tissue and is therefore the mechanism responsible for pain relief [24]. Most investigations regarding thermal injury and PMMA polymerization stem from the use of PMMA cement in arthroplasty procedures, for which the volumes of cement used are substantially greater than those used in PV [29–31]. In those investigations, temperatures as high as 122°C have been measured [29]. However, at least one ex vivo study suggests that temperature is not a mechanism of pain relief [32]. In that study, temperature was measured at three locations (inside the anterior cortex, in the center of the VB, and in the spinal canal) after concurrent bipedicular injection of 10 mL of PMMA cement. Although temperatures exceeded 50°C for more than 1 minute at the center of the VB, the authors concluded that temperature was an unlikely mechanism of pain relief for several reasons. First, because the experiments were conducted on ex vivo VBs, the effect of active heat transfer due to blood profusion, as would be the case in vivo, was not included. Profusion would be expected to remove much of the heat generated during cement polymerization. Second, the volume of cement injected was greater than that typically used for PV [33]. And third, the cement was injected concurrently via both pedicles to maximize the thermal effect for experimental measurement. Clinically, PV would be performed in a staged procedure in which half of the cement would be injected through one cannula placed in a pedicle [25], and then the second half would be injected through the other cannula in the contralateral pedicle. Thus, the heat of polymerization from the initial injection would likely have dissipated to negligible levels before the second injection began polymerizing. However, in that same study, the experimental protocol departed from clinical practice in that the cannulae remained in the VBs during cement polymerization and may have served as cooling fins, reducing the intravertebral body temperature. That study was recently repeated except that the cannula were removed immediately after the cement injection [33a]. Temperatures were substantially higher in VBs from which the cannulae were removed than in those in the previous study, which retained the cannulae during polymerization. Thus, the issue of thermal injury during cement polymerization remains unresolved. To the author's knowledge there are no reported animal model histological investigations into any thermal effect on neural tissue of cement polymerization during PV, and in vivo measurements of intravertebral temperatures during VP are not currently available.

The threshold above which thermal necrosis of osteoblasts occurs is typically 50°C if that temperature is sustained for more than 1 minute [34,35]. Neural tissue may be more sensitive to temperature than osteoblasts [36]. Thermal necrosis follows an Arrhenius relationship in which temperature and exposure time are factors. Thus, tissue exposed to lower temperatures, but for longer periods of time, may also become necrotic. Conversely, tissue exposed to higher temperatures would require less exposure time to become injured. For example, a recent study reports that apoptosis occurred in osteoblasts exposed to 48°C for 10 minutes [37].

It should be noted that in both those ex vivo studies, temperatures recorded in the spinal canal did not reach 50°C [32,33a]. The spinal cord appears to be at little risk of thermal injury as long as the cement is properly injected and contained within the VB. If cement were to leak into the spinal canal and come into direct contact with the cord, it is not unrealistic to expect that thermal injury might occur.

B. Cytotoxicity

The methylmethacrylate (MMA) monomer component of PMMA cement is cytotoxic and therefore has been implicated as a mechanism of pain relief [24]. Cell cultures show that MMA monomer is toxic to leukocytes and endothelial cells when concentrations exceed 10 mg/mL [38], but its effect on neural tissue remains unknown. During knee arthroplasty, blood serum levels immediately after cementation and tourniquet release have been measured as high as 120 μg/mL but are typically much lower (<2 μg/mL) and drop precipitously minutes after implantation [39]. MMA monomer is highly volatile and, as such, is mostly expelled through the lungs during respiration. Thus, after the blood has circulated once through the body, the MMA concentration in the blood drops to negligible levels. Other investigators have reported blood serum concentration between 0.02 and 59 μg/mL during total hip replacement [40]. Considering that the volumes of cement used for total hip replacements and knee arthroplasty are two to three times greater than those typically used with PV, and that monomer concentrations measured for those procedures are 10–100 times less than MMA concentrations reported to be cytotoxic to tissue cultures [38], it seems unlikely that MMA toxicity is responsible for pain relief experienced with PV. Even so, local serum monomer concentrations measured immediately after PV are needed to determine definitively if MMA monomer cytotoxicity plays a role in pain relief.

MMA monomer toxicity has also been implicated in the necrosis of tumor cells. In histological sections taken postmortem from a patient who had previously undergone PV, a zone of necrosis was noted in the tumor cells nearest the injected cement [41]. In one study, necrosis of breast cancer cells occurred at concentrations greater than 5 μg/mL for a 1-hour exposure time, whereas apoptosis occurred at concentrations greater than 1 μg/ml for a 1-hour exposure [42]. The exposure times and concentrations are much greater than what would be expected to occur in vivo; therefore, it seems unlikely that cytotoxicity plays a role in creating the zone of necrosis noted histologically.

C. Mechanical Stabilization

Despite the possible roles played by cytotoxicity and thermal injury, mechanical stabilization appears to be the most likely mechanism of pain relief [32,43]. Pain associated with osteoporotic VCF is thought to be caused by motion at the fracture, which stimulates nociceptors concentrated in the periosteal region [25]. PV stabilizes the fractured VB [43–47], minimizes micromotion, and likely prevents painful nerve aggravation. PV appears to satisfy the requirements of fracture stabilization consistent with those of other sites in the body; namely, to prevent painful micromotion and provide a mechanically stable and biologically conducive environment for fracture healing. Several factors contribute to the mechanical stabilization achieved by PV, including the density of the VB, the volume and location of the cement injected, and the material properties of the cement. The optimal cement volume and material properties have not yet been determined.

III. MECHANICAL CONSIDERATIONS

How much cement is needed to stabilize VCFs has been a clinical concern since the onset of PV practice. A recent ex vivo study reported that only 2 mL of PMMA were needed to restore strength in osteoporotic VBs, but that larger volumes (4–6 mL) were needed to restore stiffness [43]. These volumes are lower than what was typically used and previously thought necessary, both clinically and in biomechanical investigations [32,44,46]. The correlation between cement volume and restoration of strength and stiffness was very weak [43]. It is likely that other factors, such as bone density and the geometry of the injected cement, affects restoration values. Those

authors hypothesized that strength and stiffness restoration would more closely correlate to the percentage of the VB volume filled than just the cement volume injected, but the correlation was not stronger [47a]. Finite element modeling of PV has suggested that a fill of 14%, or about 3.5 mL for an L1 VB, would be sufficient to restore stiffness [48]. Although that study showed that fill volume may restore stiffness for the single specimen evaluated, the results of an experimental study did not support that conclusion for all L1 VBs [47a].

Restoring initial strength would be expected to prevent refracture of the treated vertebra. If the spine were subjected to a load of the magnitude required to cause the original fracture, other vertebral levels would be expected to fracture before the repaired level refractured. Stiffness, not strength, is the mechanical parameter likely most closely linked with pain relief. Although fixation stiffness plays a large role in fracture healing [49], restoring or increasing VB stiffness relative to prefracture levels may not be necessary or even preferable [49]. As with other fractures, avoiding the extremes of mechanical stability is desirable. Repairs that are too stiff may result in stress shielding, remove mechanical feed back to osteoblasts, and impede fracture healing. Conversely, repairs that are not stiff enough allow too much motion and may result in nonunion.

Concerns have been raised that PV hypothetically creates a stress concentration, alters spine kinematics, and places adjacent levels at risk of fracture. This concern seems unfounded for several reasons. First, PV appears to restore, or nearly restores, stiffness and does not increase stiffness relative to prefracture levels [43–47]. Thus, adjacent levels should be at no greater risk than they were in the prefracture state. Even if the VB stiffness were increased relative the prefracture state, the stiffness of an individual level is unlikely to affect spinal kinematics. Most spinal motion occurs at the level of the disc, which is much more compliant than the VB. Therefore, only if cement were injected into the disc space would one expect disc mechanics to be altered and subsequently alter spine kinematics. Clinically, a preliminary report has suggested that the incidence of fractures in adjacent levels is no higher than that in remote levels [50].

In one study, pain relief was experienced in 90% of patients ($n = 29$) whose VBs were injected with an average volume of 7.1 mL (2.2–11.0 mL) of PMMA [18]. A recent clinical report showed that injection of 2–3 mL into the thoracic and 3–5 mL into the lumbar regions resulted in 97% moderate to complete pain relief [51]. These results suggest that pain relief may be achieved with volumes consistent with those needed to restore mechanical integrity ex vivo [43]; however, no correlation of level treated, volume injected, and clinical outcome has been explicitly reported. The volume of cement needed to produce a desired outcome still needs to be determined by carefully controlled, prospective, randomized clinical studies.

A. Unipedicular versus Bipedicular Injection

The ability to stabilize VBs through unipedicular injections may result in reduced procedure time and risk associated with bilateral cannulae. Tohmeh et al. [44] found that VB strength may be restored via a unipedicular cement injection without risk of VB collapse on the uninjected side. The amount of cement injected unipedicularly in that study, however, was 6 mL. It is unknown if the restoration was related to the volume of cement or to how and where it was injected. On the other hand, in a study using a finite element model, Liebschner et al. [48] suggested that unipedicular injections may place the VB at risk for collapse on the uninjected side. Clinically, the unipedicular procedure has been performed on a limited number of patients, and the clinical outcomes have been encouraging [51]. Even so, a prospective clinical trial needs to be conducted to determine the long-term benefits of unipedicular PV relative to bipedicular PV.

B. Height Restoration

Restoring height to collapsed VBs is of interest clinically because it has the potential benefit of reducing postfracture kyphosis and its associated sequelae [26,52–55]. A new device, the inflatable bone tamp, has been developed as a means of restoring height [56,57]. This tamp is placed inside the VB under fluoroscopic guidance via a percutaneously introduced cannula and inflated to create a void into which bone cement may be injected to stabilize the VB. In the process of inflating the tamp, the endplates are separated from each other, thereby reducing the fracture. The procedure has been termed kyphoplasty. Ex vivo tests have suggested that the tamp treatment restores significantly more height than does standard PV treatment and achieves similar mechanical restoration [56–59]. Ex vivo studies of osteoporotic VBs that were compressed to create simulated fractures and repaired with PV suggested that half of the compressed height recovers elastically [56,58]. A similar phenomenon has been reported in vivo [60]. When the ex vivo specimens were repaired using PV, about 30% of the permanent height loss was recovered [56]. There are no reports of height restoration subsequent to PV in vivo. The first results from a clinical trial indicated that height was restored in 70% of the patients treated using the tamp [61]; in 30% of those patients, however, no height restoration was achieved. The indications for the procedure need to be investigated more fully to determine which patients would benefit from the tamp. Additionally, there is an anecdotal report of height restoration being achieved by use of mild extension and traction [51]. The efficacy of such manual techniques remains unknown and needs evaluation. Furthermore, the clinical value of height restoration needs to be evaluated, not as an end in itself, but in terms of what effect it has on kyphosis reduction and, ultimately, on length and quality of life for the patient. An additional hypothetical benefit of the kyphoplasty procedure is that cement may be injected into the void under lower pressure than that needed for PV. This would allow more viscous cements such as hydroxyapatite cements to be injected. Such cements have been injected in ex vivo evaluations [58], but the issue of reducing injection pressure has yet to be verified.

IV. CEMENT CONSIDERATIONS

There is currently no commercially available cement specifically designed for PV in the United States, but some have received approval for use and are now available in Europe. When cements specifically manufactured for PV are not commercially available, the composition of the cements that are available are routinely altered by clinicians to make them amenable to PV [18,62,63]. This is typically accomplished by increasing the monomer-to-copolymer ratio to increase working time and decrease viscosity [18,63,64] and by adding radiopacifiers to increase cement visualization under fluoroscopy [18,63,64].

A. Cement Modifications

1. Monomer-to-Powder Ratio

Increasing the monomer-to-copolymer ratio decreases the compressive material properties of the cement [65,66]. Most PMMA cements are prepackaged for mixing 0.5 mL of monomer with 1 g of powder, or with a monomer-to-powder ratio of 0.5 mL/g. This mixture typically results in a cement with maximum compressive properties. The ratio of monomer to copolymer is about 0.56 mL/g, because $BaSO_4$ used to opacify the cement accounts for some of the weight (usually 10% w/w) of the powder. When agents are added to increase opacity of the cement for use in PV, typically the opacifying agent needs to constitute 30% of the mass of the powdered contents.

Such a concentration provides for proper fluoroscopic visualization, but it also increases the nonreactive component of the powder and increases the monomer-to-copolymer ratio to approximately 0.72 mL/g [62,66]. This increased monomer volume is needed to wet the powder, but because not all of the extra monomer is involved in the polymerization process, there is an increased amount of unbound monomer available to enter the circulatory system. Although the monomer-to-polymer ratio is larger, the quantity of cement injected (<10 mL) is smaller than that for hip arthrodesis (>40 mL) [39,40,67]. For this reason, the actual blood serum concentration of monomer during PV may be lower than that measured during total hip arthrodesis.

2. Radiopacification

Altering the concentration of radiopacifiers affects the cement's material properties, as does the combined alteration of monomer-to-powder ratio and opacification [62,66,68]. Although these modifications significantly alter the material properties of the cement [62,66,68], there have been no reported clinical problems associated with the cement's material properties. The composition that has been used clinically during the past decade in the United States with no complications associated with mechanical failure of the cement [18] is the weakest and least stiff of the cements used for vertebroplasty [62,66,68].

Although there are no reports of complications associated with the material properties of the cement, extravasation of the cement is a not infrequent occurrence of the procedure and may result in clinical complications [18,69–71]. Proper flouroscopic visualization during cement injection is essential for the safe practice of PV. As a general guide, approximately 30% of the dry cement component weight should be an opacifying agent so that the cement can be visualized under fluoroscopy and extravasation can be prevented [62]. Therefore, using a cement that can be injected easily and with proper opacification appears to take precedence over maintaining the ultimate material properties of the cement.

B. Alternative Cements

Recent attention has focused on using cements that are bioactive or bioresorbable [72–74], are naturally radiopaque [62,74], and have a lower or nonexistent exothermic reaction [32,72,74] than PMMA cements. Some of the calcium phosphate and hydroxyapatite cements have been difficult to inject, putting their application to PV in question [72], but recent advances suggest a more promising future for these cements [47,58,74]. One study reported the successful injection of calcium carbonate (coral) into osteoporotic VBs. Details of the injection process were not given and the mechanical effects of that augmentation were not measured [75]. Such more "biocompatible" cements may eliminate concerns about thermal necrosis and cytotoxicity and appear to result in mechanical stabilization of fractured VBs similar to that of PMMA [47,58,74]. Yet, if thermal and toxicity mechanisms are determined to play a role in pain relief, then the non-PMMA cements may not be as effective. The bioresorbable cements are appealing for use in prophylactic augmentation and in younger patients [76] because injected VBs would be mechanically augmented immediately and theoretically provide an osteoconductive material for subsequent bone repair and remodeling [75]. In the presence of osteoporosis, it is unknown whether the VB would once again be at risk of fracture after the cement is remodeled or resorbed.

V. CONCLUSIONS

PV appears to provide pain relief for 90% of patients with osteoporotic VCFs and approximately 60% of patients with metastatic lesions. Although pain relief may result from thermal or chemical

mechanisms, it is most likely the result of mechanical fracture stabilization. Restoration of VB stiffness is weakly correlated with the volume of cement injected, yet there seems little reason to completely fill the VB with cement. The PV procedure is accompanied by a risk of extravasation of the cement. To reduce this risk, smaller volumes of cement are now being injected than were injected previously. The risk of extravasation can also be reduced by using a properly opacified cement and monitoring the injection fluoroscopically. The role of non-PMMA cements for use in PV needs to be investigated clinically, as do the hypothetical benefits of height restoration and kyphosis reduction.

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4

Kyphoplasty and Vertebroplasty for the Treatment of Painful Osteoporotic Vertebral Compression Fractures

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I. INTRODUCTION

Spine care is trending towards procedures that are less invasive and motion sparing. Among the most innovative are kyphoplasty and vertebroplasty for the treatment of osteoporotic vertebral compression fractures (VCFs). They are performed percutaneously and focus on restoring the mechanical properties of the injured vertebra without fusing motion segments. These techniques have filled a void between prolonged nonoperative care and open surgical procedures by offering a highly effective treatment for pain relief with minimal risks to patients who otherwise would have few, if any, alternatives.

Vertebroplasty involves high-pressure injection of a bone filler material (e.g., bone cement) into a compressed vertebral body. While an effective method of pain relief, it is associated with a high rate of cement extrusion and does not enable fracture reduction. Kyphoplasty was developed in response to these pitfalls. The technique consists of inserting an inflatable bone tamp into the vertebral body that can restore height to the compressed bone and create a void into which bone cement can be introduced under low pressure. The rate of pain relief is comparable to vertebroplasty, while 50–90% height restoration can be achieved if treatment is performed within three months of injury [1–4].

The effectiveness of kyphoplasty and vertebroplasty relies on proper patient selection, meticulous technical application, and the quality of the injected materials. While methacrylate bone cement is currently the most frequent augmentation material used, the development of injectable bioabsorbable substances could have profound effects on exanding the indications of this procedure.

II. OSTEOPOROSIS: A PERVASIVE PROBLEM

Advances in modern medicine have increased the average life expectancy. An increasing proportion of the population is elderly. With this increased longevity comes a corresponding emphasis

on quality of life. These issues have made geriatric care an increasingly important focus of medical practice.

Osteoporosis is a significant problem in aging and postmenopausal people and is an increasingly recognized cause of painful fractures in the spine [5–10]. Women are more commonly affected, as they are subject to both postmenopausal and senile osteoporosis [11]. However, aged men are also sensitive to the sequelae of progressive bone loss [12,13].

The histological appearance of osteoporotic bone is normal. It is a disorder of quantity, not quality, with a decreased amount of bone per volumetric unit. Osteoporosis is caused by an imbalance of bone production and resorption, in contrast to osteomalacia, in which mineralization is altered [14]. While advances in pharmacological management promise better treatment and prevention of osteoporosis, they will have minimal impact on the large number of individuals with already advanced disease [15]. Other disorders, including vitamin deficiencies, improper diet, systemic diseases, and corticosteroid use, can also cause progressive bone loss, but through different pathomechanisms. These disorders should be recognized when evaluating patients with osteoporosis, addressing the underlying problem, rather than just the "symptom" of bone loss.

The relationship between loss of bone mineral density and skeletal weakening has been well established. While the entire skeleton is affected, particular regions are at proportionately higher risk for fracture. The vertebral column is the most frequently injured, followed by the distal radius (wrist) and upper femur (hip) [11]. Within the spine, there is a predilection for osteoporotic vertebral compression fractures (VCFs) in the upper lumbar and lower thoracic spine [13,16].

VCFs present different clinical challenges than wrist or hip fractures. Some osteoporotic VCFs can be asymptomatic, while pain associated with many symptomatic fractures resolves with time. This makes them difficult to diagnose and localize, in contrast to fractures of the wrist and hip, which are almost always painful, easy to localize, and do not resolve if left untreated.

In many cases, however, VCFs can be a troubling source of back pain, potentiating medical morbidity and mortality. Multiple, consecutive VCFs, common in untreated individuals, can lead to progressive anterior column shortening that results in painful thoracic, lumbar or thoracolumbar kyphosis. Such deformities can limit ambulatory function and pulmonary capacity and lead to eating disorders, such as early satiety, in an elderly population that is likely to have many concomitant comorbidities [5,7–9].

III. MECHANICS OF VERTEBRAL OSTEOPOROSIS

Osteoporosis affects a bone's mechanical structural properties. While bone quality is unaffected, strength is diminished by an overall decrease in the amount of bone present. The histological appearance of the bone is unchanged. Microstructurally, there is increased porosity. This can be assessed by measuring bone mineral density (BMD) with the use of dual-energy x-ray absorptiometry (DEXA) or quantitative computerized tomography (QCT). Critically low BMD values are associated with a predisposition to VCF.

In the cancellous portion of a normal vertebral body (VB), there are horizontal and vertical trabeculations. Osteoporosis causes a loss primarily of the horizontal trabeculations, leaving the vertical components unsupported. This causes significant weakness in resisting axial loads. Vertebral bodies bear the majority of the axial compressive forces sustained by the spine. Flexion moments increase these forces and, if they exceed the bone's capacity to resist them, can result in fracture.

Fractures first involve the anterior aspect of the VB (i.e., anterior column), which can result in wedge-type fractures. With further load the fracture can propagate to the posterior

VB wall (i.e., middle column), creating a burst-type patterns. Some osteoporotic fractures lie somewhere between a wedge and burst type, resulting from pure axial loading. These more uniform compression deformities of the VB appear as a crush type, which involves a portion of the posterior aspect of the VB. However, because the plane of the fracture is basically transverse, there is typically no fragment retropulsion. These lesions should be considered VCFs and are amenable to vertebral augmentation with kyphoplasty or vertebroplasty.

Treatment can be directed at one or both of two essential features, which are the vertebra being weakened and compressed. Metabolic therapy can address weakness by influencing the balance of bone deposition and resorption. Alendronate, estrogen, and calcitonin have demonstrated clinical efficacy in slowing, arresting, or reversing this process [15]. While they should be initiated in osteoporotic patients, they have limited effects on fracture risk in advanced cases. Vertebroplasty and kyphoplasty address bone fragility in a much more direct way. In vitro studies have demonstrated that both stiffness and strength are increased with PMMA in osteoporotic bone [17–19].

Because the fractured osteoporotic bone is so weak, the vertebra's mechanical properties after augmentation are virtually that of the bone filler. Not all bone cements are equal. Different substances create different changes in strength and stiffness. In a cadaveric study, Orthocomp (Orthovita, Malvern, PA) resulted in significantly stronger and stiffer vertebrae than Simplex P (Howmedica, Rutherford, NJ) [19]. The former restored initial prefracture stiffness values. Cranioplastic cement (CMW, Blackpool, England) and Simplex P did not completely restore stiffness to intact values [18]. The long-term clinical implications of these variables on augmentation durability remains to be seen [20]. Additionally, it is not known how much strength is needed to support the osteoporotic bone and spinal column. The senior author has routinely used Simplex P in over 100 kyphoplasty procedures with excellent long-term reuslts [1]. This is also true for most physicians who perform kyphoplasty. The cement powder/monomer ratio and addition of radiopaque media (e.g., barium) may alter material properties and should be considered when testing new formulations of filler.

Cement volume influences the mechanical properties after vertebral augmentation. In general, a greater amount of cement can be inserted using a bilateral, as compared to a unilateral, approach. In most cases a bilateral approach is recommended with kyphoplasty, though in some only unilateral injection might be possible. With vertebroplasty, unilateral injection is considered accetable if more than 50% of the VB is filled [3]. In cadaveric spines, bipedicular injection of 10 mL (5 mL on each side) resulted in significantly greater strength versus unipedicular injection of 6 mL of cement [17]. Both methods, however, resulted in restoration of initial stiffness. From these data, delivery of at least 6 mL of cement affords adequate stabilization to a vertebra.

IV. KYPHOSIS REDUCTION AND SAGITTAL BALANCE

The normal thoracic spine's sagittal kyphosis is approximately 20–40 degrees, with an apex around T6 or T7. It is primarily produced by physiological anterior vertebral body wedging. This is in contrast to the lumbar spine, which is in approximately 50 degrees of lordosis, produced primarily by the discs, which are larger anteriorly than posteriorly. These curves must be considered in concert. Overall sagittal balance can be assessed using a long-plate lateral radiograph, taking into account both thoracic and lumbar curvatures. A vertical plumb line (weightbearing line) is drawn from the base of the occiput. Sagittal balance is realized if that line intersects the seventh cervical VB cranially and lies within 1 cm of the sacral promontory caudally, centered over the hips. Increased kyphosis in the thoracic spine moves the weight-bearing line anteriorly.

However, this can be compensated by exaggerated lordosis in the lumbar spine. This moves the weight-bearing line back to its balanced position over the sacral promontory.

Because it is generally less mobile and is subject to fractures in both regions, there is little compensatory capacity in the osteoporotic spine. Sagittal deformity is usually characterized by uncompensated thoracic and lumbar kyphosis. Eventually, these can progress to a point at which the weight-bearing line can no longer return to a balanced point, resulting in a self-propagating imbalance. This can be compared to the leaning tower of Pisa. The tower presently remains erect because the weight-bearing line, or center of mass, falls within its base. This functions to maintain its current position. If, however, it continues to lean over so much that the center of mass lies outside its base, the tower will no longer be balanced. Therefore, the weight of the tower will be contributing to its own fall.

Corrective measures attempt to restore the weight-bearing line, or center of mass of the body, to the anatomical base, which is the sacral promontory. By increasing VB height at one or more levels, kyphoplasty can achieve this goal. An average of 96% VB height restoration has been documented in in vitro investigations [21]. This is corroborated by clinical evidence, demonstrating 99% and 92% of predicted anterior and middle VB dimensions, respectively, when kyphoplasty is performed less than 3 months after fracture [1]. Some surgeons claim that vertebroplasty can restore some VB height, although this has not been demonstrated in a clinical trial [21].

V. INDICATIONS

A. Kyphoplasty

1. As a Pain-Relieving Procedure

A major complaint of patients with osteoporotic VCFs is pain. This pain can become progressive and intractable, affecting the patient's ability to perform his or her daily activities. As a vertebral augmentation procedure, kyphoplasty is indicated for progressive or intractable pain associated with an osteoporotic VCF. In recent clinical series, greater than 90% of patients reported long-standing pain relief after surgery [1,2,22]. The most likely mechanism of pain relief is fracture stabilization, provided by the injected polymethylmethacrylate bone cement. However, some believe that the exothermic reaction during cement curing can have a denervation effect within the VB, although this remains hypothetical and unlikely based on the long-term maintained clinical success.

2. For Deformity Correction

In the proper setting, kyphoplasty has the ability to correct kyphotic deformtiy associated with osteoporotic VCFs. The benefits of kyphosis reduction are multifold. By placing the spine in a more balanced position, realignment may help reduce the incidence of further fractures. In addition, pulmonary dysfunction has been correlated to the severity of kyphotic deformities in osteoporotic patients [5,23]. While it is not known if the converse relationship is true, i.e., if kyphosis correction reverses or minimizes these sequelae, it is reasonable to think that kyphoplasty of correctable osteoporotic kyphosis may have beneficial effects on pulmonary function. Additional study of the effects of kyphoplasty on postcorrection pulmonary function is warranted.

Better height restoration can be expected in acute fractures (<3 months old) than chronic ones [1,22]. While the authors have observed some correction in VCFs one year or more after fracture, it is difficult to predict. Severe, rigid deformities from multiple healed fractures that compromise function, or quality of life, are probably better treated by other surgical methods,

if indicated. Moderately painful progressive VB collapse, if detected radiographically, is a developing indication for kyphoplasty. Though current reports of the safety of kyphoplasty are encouraging, subsequent study is needed to more clearly demonstrate a positive balance between the potential benefits of kyphosis correction versus procedural complications.

B. Vertebroplasty

Vertebroplasty is indicated for the treatment of painful osteoporotic VCFs. The rates of pain relief are comparable to those with kyphoplasty [24–27]. While some physicians claim that vertebral height restoration can be obtained by prone positioning followed by vertebroplasty, this has not been substantiated in a clinical series. Fracture reduction or kyphosis reduction cannot not be considered an indication for this procedure. Though restoration of ambulation and mobility from significant pain relief may have positive effects on overall health, it can be presumed that vertebroplasty would have minimal, if any, effect on compromised pulmonary function related to osteoporotic kyphosis.

VI. CONTRAINDICATIONS

Kyphoplasty and vertebroplasty are contraindicated in stable, healed, nonpainful fractures and in the presence of infection. Concomitant medical problems can make surgery and anesthesia dangerous. In patients with clotting disorders, epidural hematoma may result from VB cannulation, particularly if the pedicle borders, or posterior VB, have been violated. Though some surgeons have performed kyphoplasty in patients with osteoporotic burst fractures, it is the authors' opinion that this is a relative contraindication to either procedure. Fractures with severe VB height loss, as occurs with severe vertebra plana, may not be amenable to vertebral augmentation because of the inability to cannulate the VB.

VII. PREOPERATIVE PLANNING

For successful vertebral augmentation, the practitioner must first be confident that the osteoporotic VCF(s) is the source of the pain. Other causes of back pain, such as sacral insufficiency fractures, must be ruled out by a complete history and physical examination. Once this has been established, the next challenge is determining the symptomatic level. By percussing the midline of the spine, the most tender level is determined. This can then be marked by a radiopaque marker, such as paper clip, prior to obtaining radiographs. Also, the examiner can attempt to identify the number of the spinous process. Plain radiographs are useful in assessing overall spinal balance. Cobb angles can be measured to better quantitate the degree of deformity. Vertebral compression can be measured by comparing respective anterior and posterior VB heights to the closest adjacent normal levels. While the presence and morphology of a VCF can be well appreciated on plain films, the acuity of the fracture cannot be determined. If the symptomatic level is unclear by physical examination, advanced imaging modalities should be pursued. The authors routinely obtain an MRI prior to performing kyphoplasty (Figure 1). Acute fractures demonstrate increased signal intensity on T2 images [28,29]. STIR images are particularly helpful in differentiating fracture from malignancy. For patients in whom MRI cannot be performed, a computerized tomogram (CT) is another option. These images give better bony detail and are

superior to MRI for characterizing the fracture, but they should be used in conjunction with a bone scan to determine fracture acuity [28].

VIII. SURGICAL TECHNIQUE: KYPHOPLASTY

A. Setup

Either general or local anesthesia with sedation can been used. General anesthesia may be more suitable for multilevel procedures, while local anesthesia may be sufficient for one- or two-segment augmentation. The patient is positioned supine on a radiolucent table. Transverse rolls across the chest and thighs/iliac crests maintain epidural decompression and help extend the spine. If available, two image intensifiers (C-arms) should be used so that simultaneous antero-posterior (AP) and lateral views can be obtained. Prior to prepping and draping, it should be ensured that the spine can be adequately imaged. The pedicle and VB should be seen clearly on all views. The pedicle can be viewed en face by angling the beam about 10 degrees towards the midline, giving it an end-on appearance. This is useful for judging containment of the cannulation instruments within the pedicle borders.

B. Approaches

1. Transpedicular Approach

This is the preferred approach for any level with a pedicle diameter of at least 4–5 mm. It may not be suitable for upper thoracic levels with small pediclular dimensions. Also, lumbar pedicles in small individuals may not be amenable to the transpedicular approach, which may necessitate

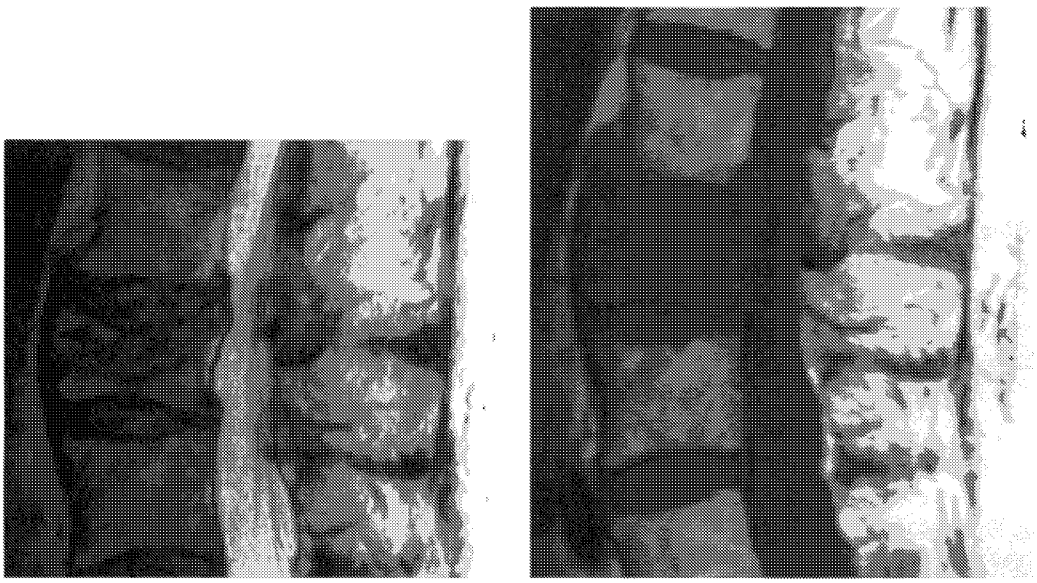

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Figure 1 MR images (A, T_2-weighted; B, T_1-weighted) can demonstrate increased bone edema as well rule out fracture retropulsion into the canal.

a posterolateral technique (see below). This determination can be made using axial MRI or CT images. Bilateral VB cannulation can be performed using this approach. The endangered structures are the spinal cord medially and the nerve root superiorly and inferiorly if the pedicle is missed or its cortex violated. The pulmonary cavity is lateral, and large vessels are anterior to the vertebral body.

After the correct level of surgery is determined by orthogonal C-arm views, the midline is palpated and marked. Next, using the AP view, the skin is marked just lateral to the lateral border of the pedicle. Slight medial angulation of the instruments during pedicle cannulation is necessary. A 1 cm stab wound incision is created over this mark. The spinal, or Jamshidi, needle is then inserted. It should be angled approximately 10 degrees toward the midline in the thoracic and lumbar spine. In the lower lumbar spine, particularly at L5, more medial orientation may be needed. The needle should be advanced into the bone about 2–3 mm. The location is then checked on both radiographic views to confirm proper orientation. The Jamshidi needle is slowly advanced with a gentle twisting motion. Tactile feedback should help guide the instrument within bone. However, this may be difficult to discern because of decreased bone density. Sudden "giving way" can indicate that the pedicle borders have been violated. Radiographic appearance of optimal needle placement is the tip within the confines of the pedicle at all times. Gentle tapping of the needle into the bone with a light mallet can also be used.

The needle is advanced to the junction of the posterior cortex of the VB and the pedicle. As a general rule, the tip should not cross the midline on the AP view at any point during insertion, although the tip of a well-placed needle may appear slightly medial to the pedicle border once within the VB. If acceptable positioning is questionable, the en face view should be obtained. In this view, the needle should be entirely contained within the pedicle. If proper orientation cannot be confirmed, the needle should be repositioned.

In order to maximize the amount of cancellous bone between the bone tamp and the fractured endplate, the instruments can be directed towards the uninjured endplate. For example, if the superior endplate is depressed, the tools are directed towards the anterior lip of the inferior endplate. Importantly, the instruments should not be advanced through the intact endplate, as this can lead to cement extravasation into the disc space. Cranial/caudal orientation in the pedicle is best judged on the lateral view. If the vertebra is uniformly compressed, the tool is advanced towards the mid-body.

2. *Lateral Extrapedicular Approach*

This approach is appropriate for thoracic levels at which the pedicles are too small to cannulate, usually above T8. Bilateral cannulation can be performed using this approach. It is not appropriate for lumbar vertebrae, which are better instrumented through a posterolateral method, if the transpedicular approach is not achievable. The lateral extrapedicular approach relies on considering the rib head and the thoracic pedicle together as a larger "effective pedicle." Through a similarly located incision as for the transpedicular method, the needle is inserted just lateral and superior to the pedicle. As it is advanced, the needle enters the lateral aspect of the pedicle near its junction with the rib lateral to it. In general, it is directed to the anteroinferior aspect of the vertebral body on the lateral view. More medial angulation of the needle, approximately 20 degrees, is usually necessary, as the starting position is more lateral. With a more lateral position, the spinal cord is at less risk than with the transpedicular method. However, lateral deviation endangers the lungs and risks pneumothorax. Penetration of the lateral vertebral body cortex can injure the segmental artery. The goal is to use the rib to protect the lungs, and the pedicle protects the cord.

3. Posterolateral Approach

For lumbar levels, in particular L2 to L4, at which the pedicles are too small to accept the kyphoplaty instruments, a posterolateral approach is recommended. The approach is similar to that for a discogram, except that it is directed at the VB. The needle is inserted about 8–10 cm lateral to the midline and directed at a 45 degree angle towards the midline. The needle path is anterior to the transverse processes, as the pedicle is not cannulated at any time. The lateral view is critical; the needle should lie anterior to the transverse process and neural foramen at all times. This avoids injury to the exiting nerve root. The en face view is not useful with this approach. The posterolateral approach enables unilateral cannulation only. Therefore, the needle must cross the midline to ensure adequate augmentation of the contralateral aspect of the VB.

C. Bone Tamp Insertion

The center sylet is removed from the Jamshidi needle and a flexible guidewire is inserted until it is just past the needle tip. The Jamshidi needle is removed with a slow, controlled twisting motion while holding the guidewire in place. The needle tract is dilated and a channel in the pedicle created by inserting a centering stylet over the guidewire. This dilator should be inserted just past the border of the pedicle and the VB. The guidewire is then removed and a larger diameter cannula is inserted over the centering stylet. The centering stylet can then be removed, leaving the working cannula in place. A hand-driven twist drill bit is inserted and advanced to, but not through, the anterior cortex of the VB (Figure 2). This must be performed carefully under radiographic guidance to avoid penetration of the cortex, as the osteoporotic bone is soft.

After the drill bit is removed, the inflatable balloon tamp is inserted (Figure 3). Tamps are available in large and small sizes. Most lumbar vertebra accept a large (20–25 mm) balloon, while smaller thoracic or lumbar vertebrae might accept only the small (15 mm) tamp. It should be inserted until the entire balloon tamp is contained within the VB. This can be judged by

Figure 2 The drill bit is inserted into, but not through, the anterior vertebral body cortex. In this anterior wedge compression fracture, the instruments must be carefully directed so as not to penetrate the superior or inferior endplates.

Figure 3 The balloon tamp is inserted into the vertebral body. The two radiopaque markers along the tamp should be within the bone, ensuring proper positioning of the device.

ensuring that the two radiographic markers, positioned at either end of the otherwise radiolucent balloon, are anterior to the posterior VB cortex. To provide more uniform compression within the cylindrically shaped bone, the balloon is "cinched" at its waist. This effectively creates anterior and posterior tamps instead of one large sphere that would have a tendency to expand maximally in the center. This facilitates en masse reduction of the fractured endplate.

The tamp is then inflated with radiopaque dye under manometrically controlled pressure using a screw-operated piston-like device (Figure 4). Inflation pressures are initially low as the balloon expands within the soft cancellous bone until it meets the resistance of the harder cortical endplates. Pressures can intermittently drop and rise again, representing "giving" of the endplates and, hopefully, reduction of the fracture. *Warning:* If pressure suddenly drops and remains low, the balloon should be removed and inspected. This is an indication that the balloon has ruptured. A replacement balloon should be inserted and the inflation process should be started again. During inflation, both volume and pressures should be noted. Volume measurements can be used to approximate the amount of cement needed to fill the bone void.

Fracture reduction is judged on the lateral fluoroscopic view. Importantly, there is a limit to the amount of reduction possible before the balloon ruptures or the cortical borders of the VB are violated. The most common area for this to occur are the endplates, which can appear as a small, well-defined protuberance of the balloon into the disc space noted best on the lateral view. If this occurs, inflation should not continue further. Care must be taken while injecting cement to avoid extravasation into the disc space. This complication is more common in older fractures.

D. Cement Composition

Currently, the major component of the bone filler material is polymethylmethacrylate (PMMA) cement. This material has been used for vertebral body replacement and augmentation with

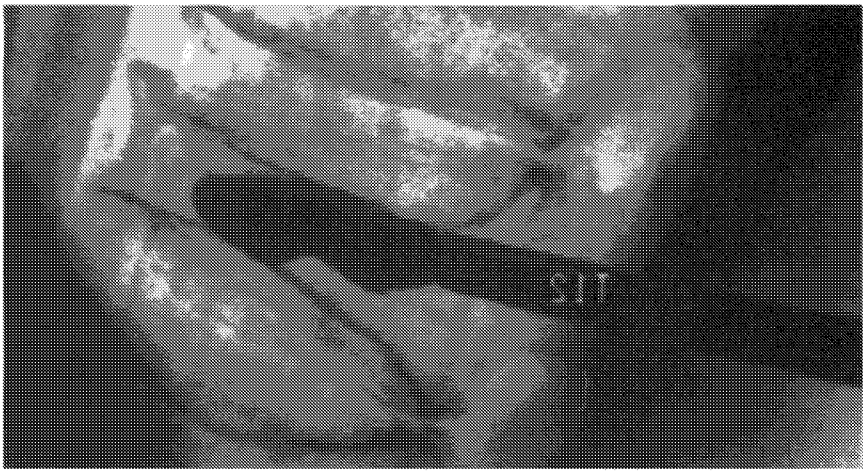

Figure 4 The tamp is inflated using a radiopaque dye to achieve and visualize fracture reduction.

open surgery for other pathological diagnoses and has demonstrated biocompatability. Though standard formulation of PMMA are somewhat radiopaque, the radiographic density is not enough for safe visualization of the small amounts injected into the VB during kyphoplasty. Therefore, a small amount of barium sulfate is added to the mixture to increase the cement radiopacity. To minimize the infection risk, antibiotic powder is also added. The following formula has been used successfully in the authors' clinical practice: PMMA powder 40 cc, liquid monomer 10 cc, barium sulfate 6 g, and one vial of antibiotic powder. Heat-stabile antibiotics, such as cefazolin (1 g), vancomycin (1 g), or tobramycin (1.2 g), are preferred.

E. Cement Delivery

The balloon tamps are kept inflated until the cement is ready for insertion. While it is still quite fluid, cement is injected into several 3 cc bone filler devices (BFD). The remaining cement is used to judge its readiness for injection. When a freshly expressed cement bead no longer has a glossy appearance and appears to be relatively viscous, the balloon tamps are deflated and removed. In particularly unstable fractures, a contralateral tamp can remain inflated to maintain reduction while cement is injected ipsilaterally. The BFDs are placed into the working cannula and advanced to within a few millimeters of the anterior cortex (Figure 5). A pusher stylet is used to inject the cement into the bone void. The tip of the next 3 cc BFD is located more towards the center of the VB, and the subsequent device closer to the posterior cortex. This enables uniform fill of the VB defect. *Warning*: The BFD tip should always be positioned within the confines of the VB. Injection should never proceed with the BFD tip within the pedicle.

Low-pressure cement injection proceeds until one of the following occurs: (1) cement has filled the anterior two thirds of the VB, (2) cement begins leaking through the cortical boundaries of the VB (including endplates), or (3) cement starts to fill the posterior aspect of the body or pedicle. Cement extravasation outside of the VB can occur if the mixture is too fluid. In this case, injection is temporarily stopped, allowing the peripheral cement to begin to cure. Optionally, the tamp can be reinserted and gently reinflated to distribute the cement peripherally. As the cement hardens, this acts to "plug the holes," after which injection can be resumed. Injection is performed bilaterally. Between 2 and 6 mL of cement can usually be injected on each side.

Figure 5 The cement is injected under low pressure into the vertebral body to fill the cavity/void created by the balloon tamp. Once cement has reached the posterior aspect of the vertebral body, injection is stopped.

The cement should be allowed to harden. This can taken from 5 to 10 minutes depending on the room temperature. The working cannulae are removed using a twisting action to dissociate it from the surrounding PMMA. Final intraoperative fluoroscopic views confirm fracture reduction and cement placement. The patient should remain prone for an additional 10 minutes to ensure final PMMA curing within the reduced fracture. In multilevel procedures, final cement curing should be allowed before proceeding to subsequent levels (Figure 6).

IX. SURGICAL TECHNIQUE: VERTEBROPLASTY

Set-up and approach are similar to those for kyphoplasty, with either general or local anesthesia suitable. Cannulation techniques are also similar. Mathis et al. [30] described three approaches: transpedicular, parapedicular (akin to extrapedicular), and posterolateral. Leakage appears to be more frequent with vertebroplasty than kyphoplasty. Vertebroplasty requires a lower cement viscosity to enable a higher pressure injection because there is no true bone void. The cement simply fills the interstices of the fractured vertebral body. The posterolateral approach has a higher propensity for extravasation than the other vertebroplasty approaches. In the current authors' experience, this has not been observed with kyphoplasty. Because of this higher risk, vertebrograms are routinely performed prior to vertebroplasty. This entails injection of radiopaque dye through the cannulation needle and estimates the most likely path of the cement. If a nearby vessel enhances, the needle is repositioned and retested.

Two to 3 mm of cement is injected though the cannulation needle with a syringe. Bone fill is monitored using the C-arm. As with kyphoplasty, injection is stopped when cement has reached the posterior aspect of the VB. The syringe is then removed, and the stylet is replaced into the needle to avoid leaving a "tail" of cement. Vertebroplasty can be performed unilaterally or bilaterally. While some routinely perform bilateral vertebroplasty when possible, Deramond

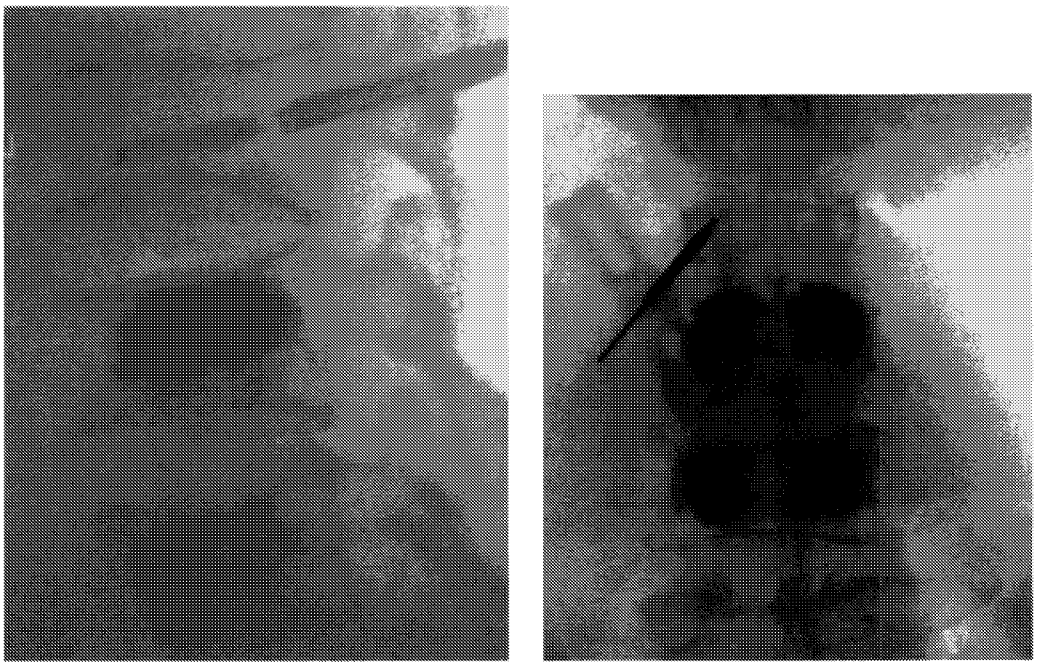

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Figure 6 Multiple kyphoplasties may be performed. In the authors' practice, two to three levels can be augmented during a single procedure. If more levels are planned, staged procedures, with a 3- to 4-week interval delay, might be more prudent.

et al. [3] recommend a unilateral vertebroplasty first. More than 50% fill of the VB is considered adequate. If less than 50% fill is achieved, contralateral injection is recommended. Unilateral and bilateral cement injections have comparable restoration of strength and stiffness after vertebroplasty, with the cement volume being a more probable determinant of mechanical properties [17].

A. Postoperative Care

Both kyphoplasty or vertebroplasty can be performed on an outpatient basis. If general anesthesia was used, it is the authors' feeling that an overnight stay is more prudent particularly in an elderly, frail population. Minimal blood loss and reliable pain relief, usually within 24 hours, aid in a quick recovery. Narcotic pain medication is usually not necessary for more than 2 days after surgery. After this, pain can be typically managed with extra-strength acetaminophen or nonsteroidal anti-inflammatory drugs, if not contraindicated. Bracing is usually not of benefit unless the patient has multiple additional fractured levels which are planned to be addressed in a subsequent procedure(s). The patient is advised to avoid heavy lifting for a few weeks to minimize further fracture risk. Follow-up radiographs should be obtained one month postprocedure and repeated as indicated by clinical findings. Radiographic follow-up may be considered for one year because of the propensity for subsequent fractures.

B. Complications

While radiographic evidence of cement leakage occurs in up to 8.6% of cases, clinically significant complications have occurred in only 1.2% of patients and 0.7% of fractures [1,2,22]. Cement extravasation is usually clinically benign. However, neurological deficit secondary to cement in the spinal canal or neural foramina has been reported in both vertebroplasty and kyphoplasty [1,31].

Transient pyrexia is the most commonly reported clinical complication and is most likely from a mild systemic reaction to the cement [3]. This appears to be more frequent after vertebroplasty than kyphoplasty [1,3]. This may be related to the pressure of injection. Epidural hematomata can occur, particularly if the pedicle or VB borders have been violated. Anticoagulation, if used by the patient, should be delayed for at least 4 days to avoid this complication.

X. CLINICAL OUTCOMES

A. Kyphoplasty

The senior author (S.R.G.) has participated in an ongoing prospective evaluation of a collection of kyphoplasty cases performed for osteoporotic VCFs. Information from over 375 procedures has been analyzed, and the results are extremely encouraging. More than 90% of patients reported symptomatic relief and functional improvement at up to 18 months follow-up. Anterior and midline vertebral height was restored to within 99% and 92% of predicted dimensions, respectively. Pain relief and fracture reduction were highly consistent between centers and technicians.

Four important clinical complications were noted. Transient pyrexia, associated with a brief period of intraoperative hypoxia after cement injection, was documented in one patient. This was attributed to the cement being in too fluid a state. The patient's blood pressure quickly recovered with no apparent sequelae. An epidural hematoma developed in another patient after heparin anticoagulation had been initiated just 8 hours after the procedure. As with any other spinal or brain procedure, anticoagulant therapy should be delayed for 4 days. Two other patients had neurological complications. Anterior cord syndrome developed after a thoracic kyphoplasty performed through an extrapedicular approach. Reexamination of the preoperative MRI revealed an unrecognized fracture at the pediculo-body junction. The other neurological complication was a case of paraparesis from extrusion of cement into the spinal canal secondary to improper needle placement. The medial pedicle wall had been inadvertently violated by the Jamshidi needle. This complication was not related to use of the inflatable bone tamp itself. The paraparesis somewhat improved following emergent laminectomy and decompression. Neurological damage from cement most likely occured from mechanical compression; experimental data have demonstrated little chance of thermal damage during exothermic cement hardening. The major complications occurred within the first 100 fractures treated and have not occurred since then.

In a smaller prospective series, Lieberman and associates [22] reported similarly excellent results in 70 consecutive procedures in 30 patients. Outcomes were prospectively assessed with SF-36 scores for bodily pain, physical function, vitality, and mental health; statistically significant improvement was reported for these measurements. In contrast to the series by Garfin et al. [1], an average of only 35% of lost VB height was restored. It must be considered, however, that the average fracture age was almost 6 months, with a range of 0.5–24 months, so that the majority of fractures would not be considered acute. Similar rates of cement extravasation were reported. Other complications (pulmonary edema in one case and rib fractures in two cases) were not related to the kyphoplasty procedure itself.

B. Vertebroplasty

Numerous retrospective clinical reports of vertebroplasty for osteoporotic VCFs have been published since its conception, though few prospective series have been performed [4]. Barr et al. [25] retrospectively reviewed their results in 38 patients. Ninety-five percent of patients reported marked or moderate pain relief. One case of T3 radiculitis was documented, which resolved with oral steroids. Grados and associates [27] reported pain relief in 24 of 25 patients one month after the procedure in a similar retrospective series. Interestingly, the authors did not report immediate postprocedural pain values, limiting distinction between the treatment effect and eventual fracture healing. Two cases of transitory radiculitis were treated with nonsteroidals. Cement leakage into the disc space occurred in seven cases (28%), and asymptomatic pulmonary cement embolism occurred in one case. A substantially higher fracture risk adjacent to the augmented vertebrae was noted. Heini et al. [26] performed percutaneous vertebroplasty under local anaesthesia and sedation in 17 patients with 45 fractures. All patients reported significant pain relief at 1 day, 12 weeks, and 1 year after the procedure. Despite a high rate of cement extrusion (17%), with five cases of leakage into the paravertebral muscles, two cases into the spinal canal, and one case into a segmental spinal vein, no clinical sequelae were reported. Other reported complications from vertebroplasty are transitory fever, temporary worsening of fracture pain, infection, and rib fracture (probably from positioning) [4,32–35]. Spinal cord compression has been documented as well [31].

XI. FUTURE APPLICATIONS AND ADVANCEMENTS

Currently, kyphoplasty and vertebroplasty are primarily used for the treatment of painful osteoporotic compression fractures. The indications have been expanded by some for augmentation of neoplastic spinal lesions [32,36–38]. In selected cases these techniques have been employed with good results for metastatic and multiple myeloma lytic vertebral body lesions [32,37]. The principles of application are the same. Preoperative imaging should affirm that the tumor does not involve the pedicle or posterior vertebral body as to prevent inadvertent cement extrusion into the spinal canal. Of note, these techniques are best used for isolated, symptomatic lesions that are not associated with any neurological deficit. Specific guidelines are lacking as to its role among other modalities such as local beam radiation, bracing, and open surgical techniques [39].

A major concern with the current techniques is the implantation of PMMA into the VB. Because this is a nonresorbable (though biocompatible) material, it persists as a foreign substance. While this may be less of an issue in elderly patients, it may be more important if augmentation is considered in younger individuals. The development of bioactive, bioresorbable filler materials would help to expand the indications of these procedures for the treatment of acute, traumatic, nonosteoporotic VB fractures. Kyphoplasty, in particular, could be used to percutaneously reduce and stabilize an acute compression fracture with the potential of eventual native osseous replacement of the filler material. The optimal characteristics of such a material would be (1) sufficient immediate strength/stiffness, (2) adequate fatigue strength to endure repeated loads on the spine with activity, and (3) osteoconductivity/osteoinductivity. It is likely that the development of injectable bone morphogenic proteins in a bioresorbable carrier will have a place in future applications of kyphoplasty.

Cement extrusion is an inevitable sequela of PMMA/filler injection into the VB. This complication, however, would be obviated if the cement could be contained within an artificial, but resorbable device. At the present time, the inflatable balloon tamp is constructed of a nonresorbable, synthetic, silastic material. While it sustains the imparted mechanical stresses placed

on it by inflation within the bone, development of a tamp constructed of a resorbable material strong enough to endure these demands would be ideal. Injection of the bone filler directly into the tamp would eliminate material extravasation, while still providing the potential for complete osseointegration of the injected substance.

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5

Carbon Fiber–Reinforced Polymer Implants for Spinal Fusion: Biomechanical and Clinical Advantages of a New Material

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I. INTRODUCTION

Treatment of painful degenerative disc disease has been dominated by several facts that have been well understood for more than half a century: excision of a herniated lumbar disc does not treat back pain, and the loads supported by a lumbar disc are very large. In a classic series of articles, Nachemson studied loading in vitro and in human volunteers [1–3] and determined that a normal individual leaning forward while holding a 10 kg weight carries of load between 2400 and 3300 N. Schultz measured intradiscal pressures at L3–4 in four human volunteers and reported loads as high as 2400 N with a subject in the upright position, flexed, and with arms out holding 8 kg [4].

Dr. Ralph Cloward defined the problem as the treatment of a broken intervertebral joint damaged by a disc rupture. Cloward felt that this broken joint was the most common cause of mechanical back pain, a problem that was not solved by removing more of the joint. In an effort to repair this broken joint, Cloward developed the posterior lumbar interbody fusion (PLIF) operation. Cloward noted that standard surgical procedures were successful in relieving sciatica, but many patients continued to have incapacitating low back pain. Standard posterior fusion procedures required long recovery times and usually did not allow patients to achieve a high functional capacity. In replacing the damaged disc with as many as five blocks of rectangular-shaped tricortical iliac crest allograft, Cloward's objective was to achieve immediate stability and prompt healing [5,6]. Although Cloward reported high rates of fusion and clinical success, he described the operation as "a difficult operation requiring a high degree of technical skill" [7].

Cloward's success was followed by other surgeons who made significant contributions, including Gabriel Ma, who developed mortising chisels that allowed more exact fit of the bone graft [8], and Paul Lin [9,10], who preferred tricortical iliac crest autograft. All of the surgeons who reported success with PLIF favored weight-bearing bone grafts that were rectangular in shape. As Ma stated frequently, square on round is unstable; square on square is stable.

Unfortunately, many other surgeons failed to duplicate the favorable results reported by Cloward, Lin, and Ma. In describing this operation, Wiltse [11] wrote "when used alone, failure of fusion is the rule." Wetzel and LaRocca reviewed a series of patients with failed interbody

fusion and concluded "we are unable to recommend any successful salvage for the failed PLIF" [12]. Cloward's PLIF operation fell into disrepute for many years.

Anterior lumbar interbody fusion (ALIF) was pioneered in Hong Kong by Hodgson [13] in 1956 and further developed by Crock [14] in Melbourne and O'Brien [15] in London. ALIF achieved worldwide popularity, but was slow to be accepted in the United States after a cautionary study was reported by Stauffer [16] at the Mayo Clinic. Although the procedure appeared to work well in smaller Asian individuals, it did not appear to work satisfactorily in individuals of higher body mass. Denis et al. [17] reported that 100% of patients lost disc space height during the postoperative healing of traditional ALIF grafts. O'Brien et al. noted that combined posterior fixation was necessary to achieve reliable results in ALIF [15].

In the early 1980s Art Steffee [18] observed that in treatment of complex degenerative conditions of the lumbar spine, previous types of spinal instrumentation were not possible. Hooks, wires, and other attachments to the vertebral lamina could not be used if the lamina had already been surgically excised. Furthermore, distraction rods decreased lumbar lordosis and resulted in a painful flat-back condition. Steffee popularized the use of screw fixation in the vertebral pedicles and began a revolution in treatment of degenerative lumbar conditions. However, when other surgeons used the pedicle screw implants improperly, complications and poor results were followed by a frenzy of litigation.

Failures of these efforts to repair the broken intervertebral joint damaged by a disc rupture, whether PLIF or ALIF, have been largely due to the limitations of the allograft bone commonly used. The graft must bear substantially all of the patient's body weight while it achieves healing by the erosive process of "creeping substitution." In a mechanical study of commercially available allograft for interbody fusion, it was determined that up to 35% of the allograft implants were of inadequate strength to support the required loads [19]. Clearly a new type of implant made of a new type of material was required to meet the mechanical and biological requirements that were already clearly defined.

Our group has worked since the mid-1980s with the support of the DePuy AcroMed Corporation in the development of a family of implants made of a carbon fiber–reinforced polymer (CFRP) material to separate the mechanical functions of interbody fusion from the biological requirements and replace them with improved elements. The CFRP implants provide a device designed to meet the mechanical requirements of interbody fusion, and they are filled with autologous cancellous bone graft, undoubtedly the best material for bony fusion success. These implants were described by Steffee as "cages" in the late 1980s, the first use of a title that has come to describe a generic class of implants. The Brantigan cage for PLIF shown in Figure 1 maintains Cloward's essential principles. The rectangular implants are seated precisely on flattened vertebral endplates. The entire disc is removed. And the disc space is filled with the greatest possible amount of autologous bone graft.

During the past 15 years we have described a number of cases in which we successfully reconstructed failed pedicle screw constructs with carbon fiber fusion cages and new screws of the exact same type that had previously failed when used alone [20]. We carried out laboratory validation of these principles with mechanical testing in cadaver spines [21] and with a 2-year animal study in the Spanish goat [22]. We have completed a 2-year investigational device study [23], which has resulted in FDA approval of these devices. Other surgeons have reported favorable clinical series [24,25]. This is the first approved and widely used application of carbon fiber–reinforced polymer as an implant material. Additional CFRP "cage" implants have been designed to meet the anatomical requirements of various spinal areas, including a large oval ALIF cage, a cervical cage, and stackable corpectomy cages for thoracolumbar tumors and fractures. The polymer material — currently PEEK-Optima (Invibio Inc., Greenville, SC) — is from the family of plastics known as polyaryletherketones. The purpose of this chapter is to

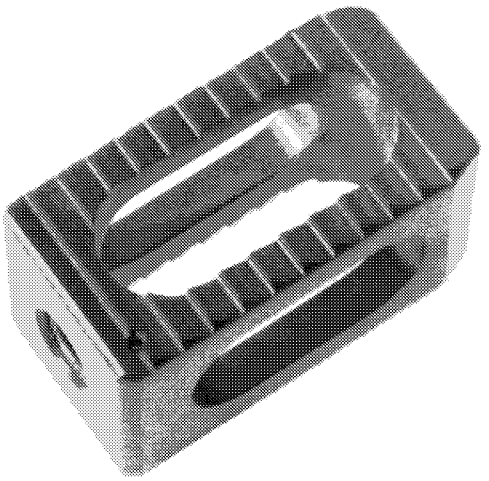


Figure 1 Photograph of the Brantigan CFRP cage for PLIF. (From Ref. 33.)

describe the mechanical, biological, radiographic, and clinical properties of the CFRP material that make it superior to titanium and other metals as an orthopedic implant material.

II. MECHANICAL REQUIREMENTS

The mechanical requirements of interbody fusion are summarized in Table 1. The static compressive strength of the CFRP cages is summarized in Figure 2, along with the static compressive strength of competing cages and tricortical allograft bone. The average vertebral body strength, about 8000 N, is shown by a horizontal line. The average compressive strength of tricortical allograft bone was determined by our group by compression tests of allograft bone that we purchased from commercial sources that sold this material for medical implant use [19]. It is immediately apparent that the average tricortical allograft is of insufficient strength to support the physiological loads of interbody fusion. The average CFRP cage, which is twice as strong as the average vertebral bone, has a significant strength margin over the physiological requirements. The competing cages, however, are excessively strong because the extra strength compromises the biological function of the implants. Once an adequate strength level is achieved, it is important to open the architecture of the cage to increase the bone graft surface area to facilitate bony union.

An important conclusion of our test of allograft bone strength is that even radiographically dense bone has inconsistent strength. Figure 3 shows a comparison between radiographic density of allograft bone specimens vs. static compressive strength. Although the specimens of greater density have a trend toward greater load to failure, there is no specific density that would assure adequate strength. It is well known that processing of bone by freeze-drying, ethylene oxide sterilization, or irradiation significantly decreases the mechanical strength of cortical allografts. Freeze-drying particularly creates microcracks in the bone that render mechanical properties unpredictable [26,27]. The unreliable compressive strength of cortical allograft should be kept in mind when considering use of allograft blocks machined into cage-like shapes for interbody fusion.

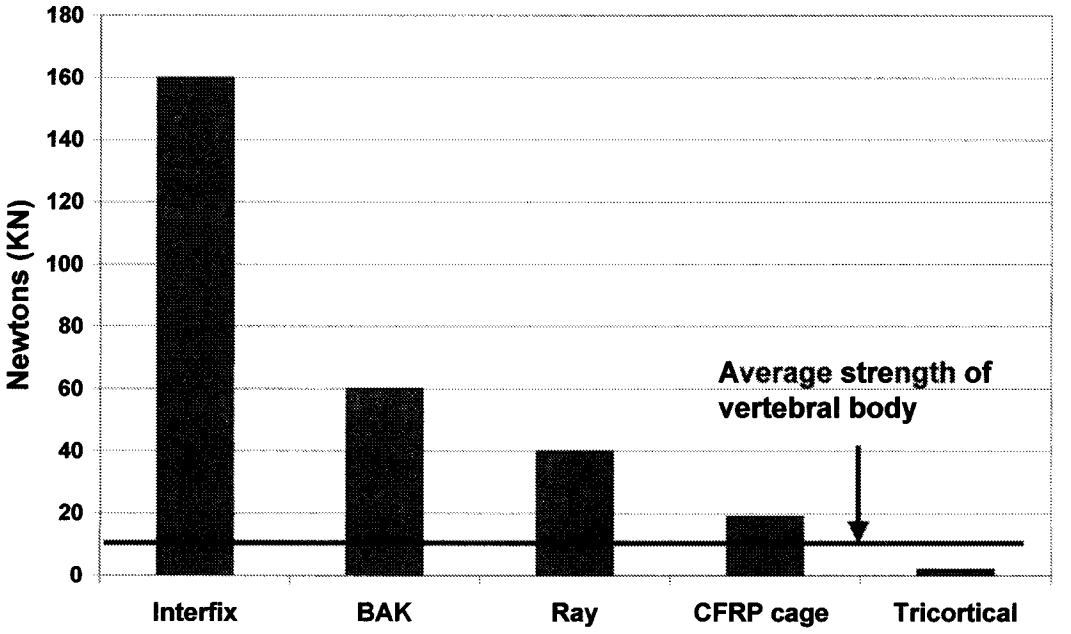


Figure 2 Static compressive strength of cages versus allograft. (Courtesy of H. Serhan, DePuy AcroMed Corp.)

Table 1 Required Properties of Interbody Fusion Devices

Adequate compressive strength
Adequate fatigue strength
Correct stiffness to match vertebral bodies
Correct stiffness to avoid stress shielding
Ability to resist retropulsion
Provide immediate stability during fusion
Provide adequate surface area to resist subsidence

Source: Courtesy of H. Serhan, DePuy AcroMed Corp.

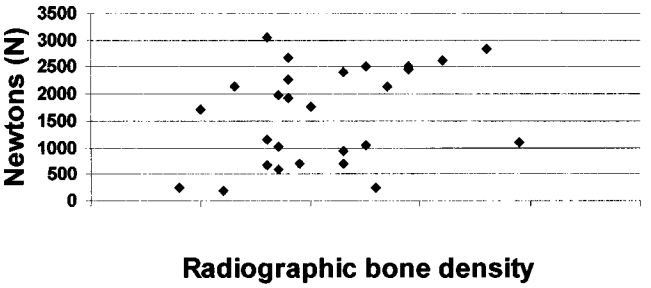


Figure 3 Allograft bone load to failure. (From Ref. 19.)

An implant should be evaluated to explore any known failure modes. For a posterior lumbar interbody fusion application, retropulsion of the graft historically has created neural impingement and foot drop in a percentage of cases, and subsidence of the graft with loss of disc space height has been a factor. For the traditional PLIF, Cloward used three to five blocks of tricortical allograft in order to increase the load-bearing capacity of the graft. Having more than two implants made it very difficult from a carpentry standpoint to equally compress all grafts. Consequently there were frequently one or more grafts relatively loose and subject to retropulsion. Supporting physiological loads with two side-by-side devices improves the probability of secure placement.

The CFRP cage has been tested mechanically in a series of fresh frozen cadaver spines [21] to assess these properties. When pulling against the broad posterior surface of the cage, an average force of 672 N was required to remove the CFRP cages from cadaver specimens, almost six times the 126 N measured for allograft. Motion segments were then prepared with bilateral CFRP cages and compressed to the point of mechanical failure (Figure 4). Unmodified motion segments failed at an average load of 6043 N compared with CFRP cage specimens that failed at an average load of 5288 N. The average compressive force, displacement, stiffness, and energy to failure for the CFRP cage specimen were statistically no different than the unmodified motion segments, indicating that subsidence is not a problem.

Mechanical properties of the bone/implant interface make important contributions to stability, load transfers, and bony healing. Figure 5 lists the Young's modulus of elasticity for various materials. The CFRP cage material is very close to the modulus of elasticity of human bone, whereas metal materials commonly used for implants are up to 10 times as stiff. Kanayama et al. [28] studied 11 different cage types in calf spines to determine construct stiffness and stress shielding. They found that no statistically significant differences existed in construct stiffness

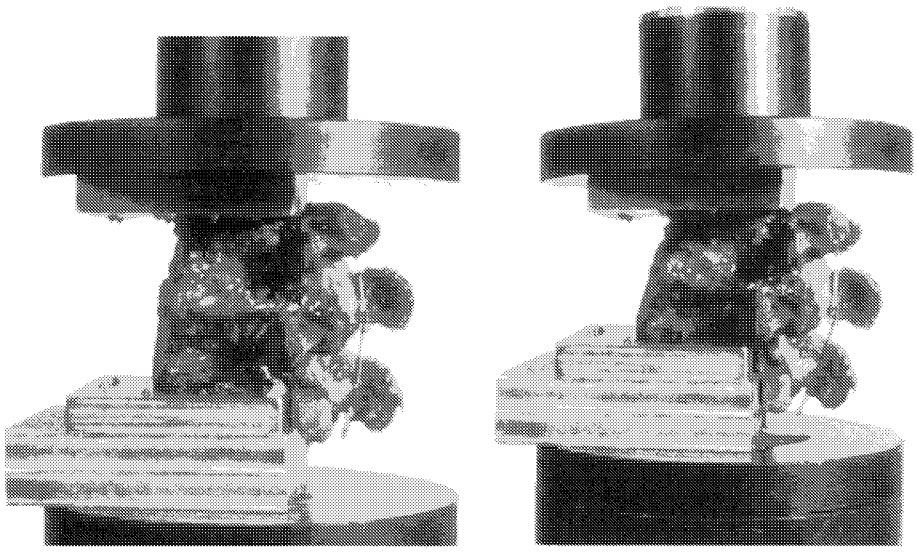


Figure 4 CFRP cage construct subject to compression testing: (A) before compression; (B) after compression failure. (From Ref. 21.)

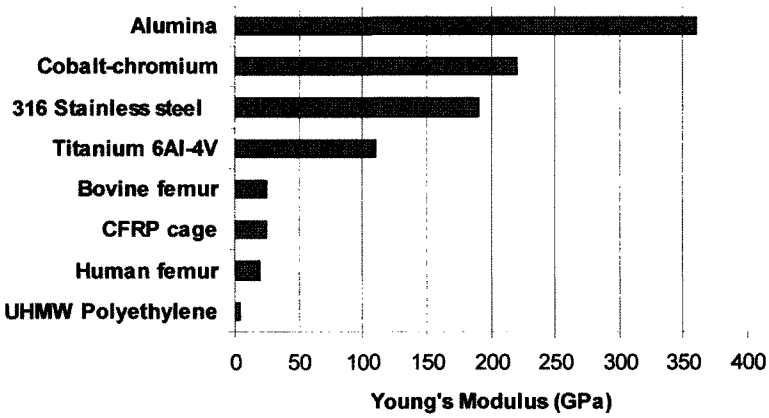


Figure 5 Modulus of elasticity of implant materials. (Courtesy of H. Serhan, DePuy AcroMed Corp.)

among the metal threaded cages and nonthreaded devices, concluding that the threaded devices did not achieve a greater stand-alone stability. However, the CFRP cage transmitted a significantly greater pressure to the elastomer inside the cage, higher by a factor of three, compared with the metal threaded cages. The reduced stress-shielding of the bone inside the CFRP cages would be expected to result in improved rate of bony healing.

Table 2 summarizes the mechanical properties of CFRP material compared with metal implants and allograft.

III. BIOLOGICAL REQUIREMENTS

Biocompatibility requirements for implant materials are defined by ASTM ISO-10-993 standards. These include chemical tests of sensitivity, toxicity, and carcinogenicity, summarized in Table 3. All of these tests were successfully completed for the CFRP cage material.

The most significant biological test was a 2-year implantation study in the Spanish goat [22] in which CFRP cages were compared with interbody fusion using allograft prepared from vertebral bodies of other goats and processed by a human bone bank in accordance with clinical standards. Because of the anatomical properties of goats, a lateral interbody fusion was done

Table 2 Comparison of CFRP, Metal, and Allograft

CFRP carbon	Metal	Allograft
Modulus of elasticity similar to bone	Modulus of elasticity 10× as stiff as bone	Modulus of elasticity same as surrounding bone
Mechanically compatible bone/implant interface	Greater stress shielding	Made brittle by processing; mechanically unreliable
Chemically inert	Subject to corrosion	Subject to "creeping substitution"
Radiolucent—allows visualization of bony healing	Radioopaque—blocks visualization of bony healing	Radiographically dense (cortical portion)—blocks visualization of changes in cancellous bone graft

Table 3 ISO-10-993 Tests for Material Biocompatability

Cytotoxicity—L929 mouse fibroblast
Pyrogenicity—rabbit
Acute systemic toxicity—mouse
Acute intracutaneous reactivity—rabbit
Genotoxicity—*Salmonella typhimurium*
Genotoxicity—DMSO extract
Muscle implantation—rabbit
Sensitization—guinea pig
Lymphoma mutagenesis—mouse
Carcinogenicity—2-year rat study

Source: Courtesy W. Christianson, DePuy AcroMed Corp.

using a single cage or allograft implant. No additional internal fixation was used. The specimens were studied with three-dimensionally reformatted CT scans and with histology. Figure 6 shows coronal, mid-coronal, and axial views of a 24-month cage specimen. Living bone clearly bridges the interspace with ossification of the anulus fibrosis. In comparison, Figure 7 shows the coronal and mid-coronal view of an allograft specimen at 24 months. The allograft has been apparently resorbed, there is loss of disc space height, and incomplete fusion has occurred by partial ossification of the anulus. Figure 8 shows histology of a 12-month specimen in which living bony trabeculae inside the cage are in continuity with the trabeculae above and below. There are no areas of pseudarthrosis. Ossification of the anulus is apparent outside the cage.

In this study, an independent radiologist and pathologist reported the result as 100% fusion success. There was minimal microscopic debris typical of that experienced around other implants. There was no inflammatory response, no osteolysis, no migration of carbon particles, and the cage levels healed quicker and more reliably than allograft.

In comparison, no animal study was done in support of the Ray cage. A study in the baboon was done for the BAK cage. The presentation of this study to the Food and Drug Administration indicated that the BAK cage did almost as well as allograft, and this study was never published. Weiner and Fraser [29] reported a study of metal cylindrical cages in sheep and reported that "solid fusion through the cages did not occur — bony 'locking' with some growth through the holes but with intervening cartilaginous tissues remaining centrally, was the rule." It is likely that the higher stress shielding of the metal material is a primary cause of the lower fusion rate.

Obtaining a fusion using a cage implant requires understanding of more than just the mechanical and biological properties of materials. The cage must have a sufficiently open architecture and broad surface area of bone graft to allow a blood supply to grow from the adjacent bony surfaces. The orthopedic aphorism "no blood, no bone" applies equally to fracture healing and to interbody fusion. The Brantigan CFRP cage was designed to maintain this open design consistent with a broad enough surface area of support.

Obtaining a fusion biologically requires more than the simple implantation of a device, no matter how well designed. Cloward, Lin, Ma, and all the pioneers of PLIF have stated that a complete discectomy must be carried out with removal of all of the nucleus and all of the cartilaginous vertebral endplate. After the implants are placed, all crevices should be filled with as much cancellous bone graft as can be inserted. If additional bone graft is not placed, the segment has the possibility of obtaining bony healing beyond the cage because this area will

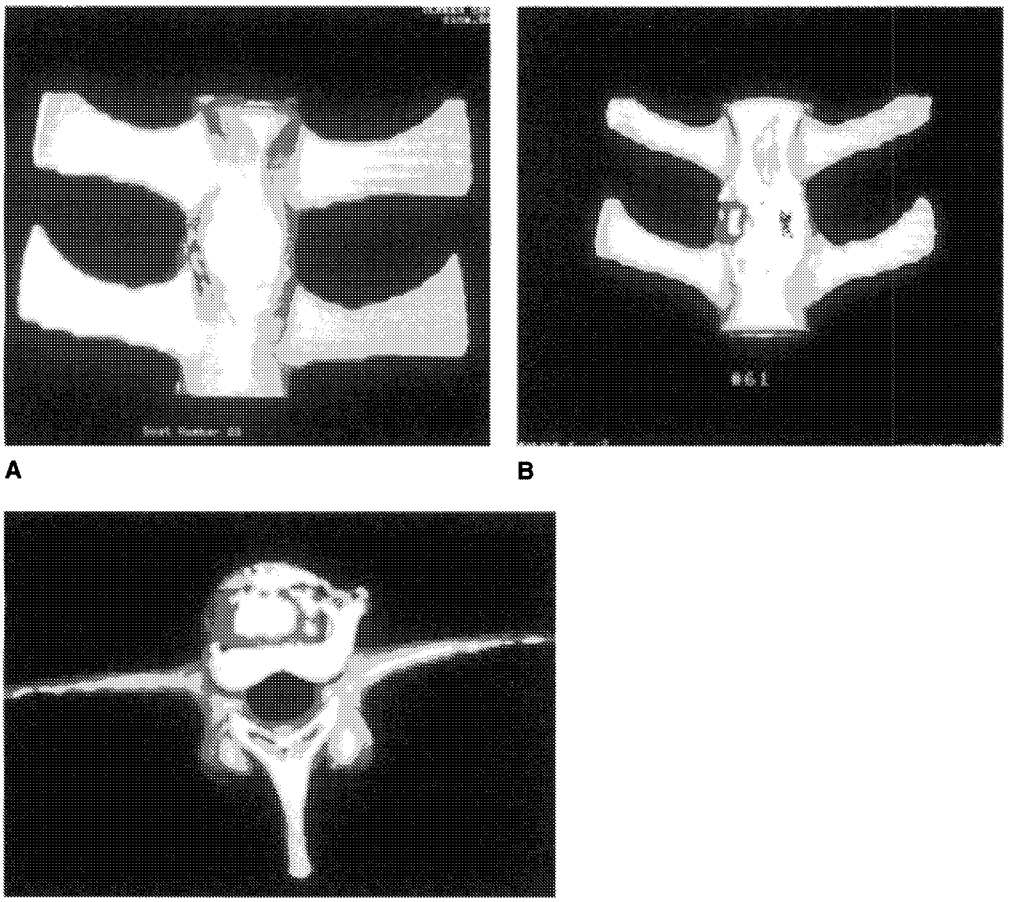


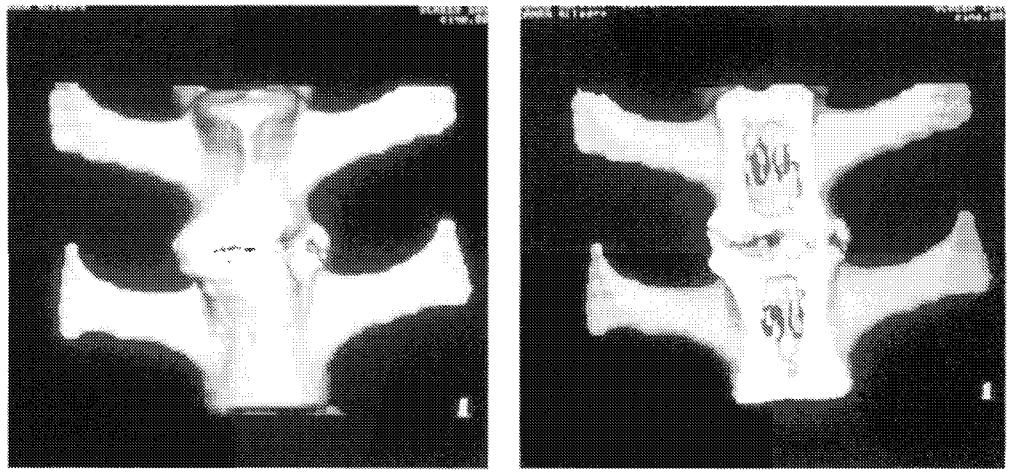
Figure 6 Reconstructed CT scans of CFRP cage after 2-year goat implantation: (A) coronal view; (B) mid-coronal sectional view; (C) axial view. (From Ref. 22.)

be filled with blood after surgery and become the equivalent of a fracture hematoma, but only if the vertebral endplate is curetted down to bleeding bone.

IV. CLINICAL TESTING OF THE CFRP CAGE

The Brantigan CFRP cage for PLIF was tested clinically in a investigational device exemption study under the supervision of the U.S. Food and Drug Administration. Inclusion criteria included degenerative disc disease in patients with prior failed discectomy surgery. The average patient had two prior failed decompression surgeries at two levels. Clinical success as evidenced by improvement in pain and function scores was achieved in 86%, and radiographic fusion success was achieved in 100% as evidenced by bone bridging the fusion area with no lucencies [23]. The Brantigan Cage for PLIF was approved by the FDA in February 1999.

Since then, successful clinical series have been reported by others [24,25]. Molinari reported a study of active-duty United States servicemen, in which 80% of CFRP cage patients



A B

Figure 7 Reconstructed CT scans of allograft interbody fusion after 2-year goat implantation: (A) coronal view; (B) mid-coronal view. (From Ref. 22.)

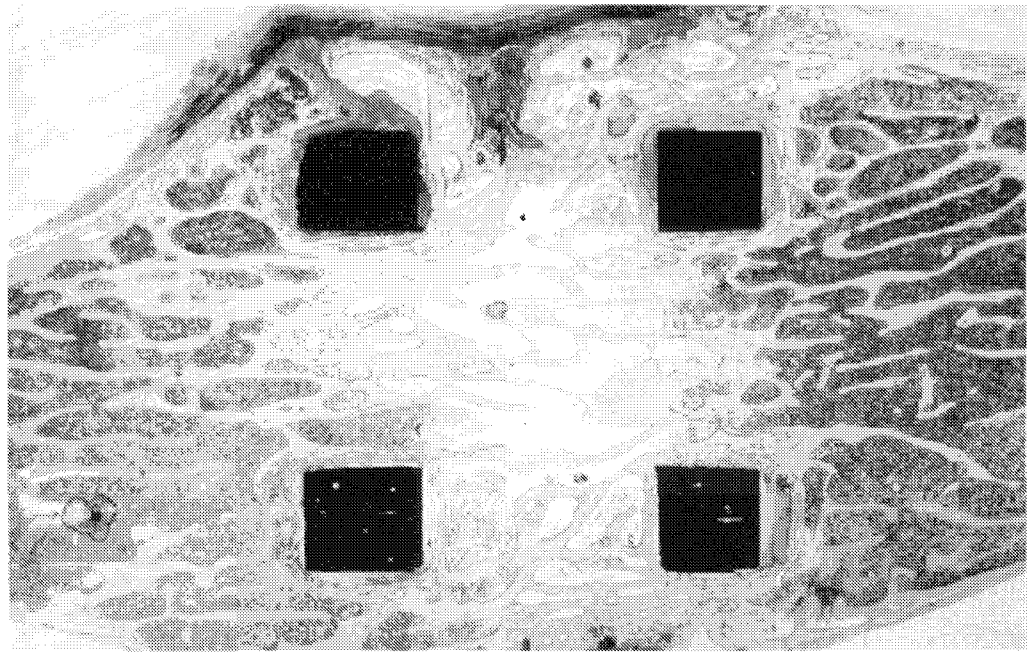


Figure 8 Histological appearance of cage fusion after 12-month goat implantation. (From Ref. 22.)

passed the rigorous army physical fitness test and retuned to full military duty, and 20% returned to military duty with some physical limitations. Additionally, Togawa et al. [30] studied a series of biopsy results in patients with radiographically successful CFRP cage fusions and reported histologically normal bone inside the cages.

Our group has shown that a wedged version of the CFRP cage achieves normal sagittal plane alignment in spondylolisthesis [31]. A 10-year study of the original IDE patients has revealed that although some patients develop adjacent segment degeneration, the rates of fusion and clinical success remain satisfactory at this time period [32].

V. RADIOGRAPHIC PROPERTIES OF CFRP MATERIAL

One of the greatest advantages of the CFRP material is radiolucency, allowing the biological changes of bony consolidation to be followed by normal plane radiographs. Because cages have the same density as cancellous bone, cage struts provide a constant density against which metabolic increases in bony density and maturation of the fusion can be compared. The carbon fiber–reinforced polymer material is compatible with all imaging methods, and MRI scans demonstrate normal bone after cage fusion. The radiolucency is best illustrated with a case report from the IDE study [33].

A 46-year-old male patient was evaluated in 1992 for the complaint of disabling back pain. He had injured his back in 1987 carrying a heavy load while working in a meatpacking plant. He had prior lumbar surgery, including discectomy at L5-S1 in 1988, but received no benefit from this surgery. His pain was described as unbearable. His walking was limited to two blocks. He was unable to participate in activities outside the home and he required assistance with dressing. He was receiving Medicaid and Medicare disability benefits. A lateral x-ray showed mild decrease in disc space height at L4-5 and L5-S1 (Figure 9). An MRI scan showed extensive degenerative change (Figure 10).

Figure 9 Preoperative lateral x-ray in case study. (From Ref. 33.)

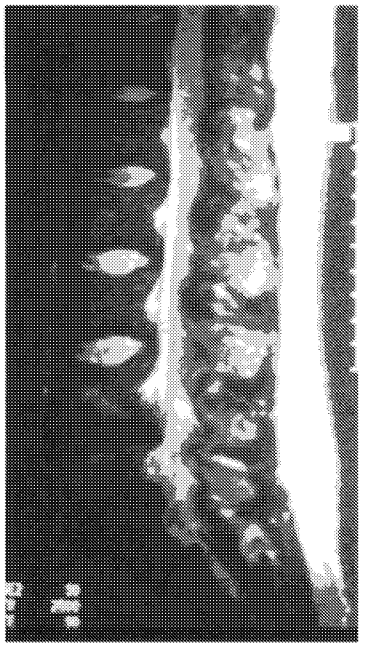


Figure 10 Preoperative MRI view in case study. (From Ref. 33.)

The patient had surgery on July 22, 1992, including CFRP cage PLIF at L4-5 and L5-S1 with VSP spinal fixation as part of the IDE study of these devices. Three months after surgery, routine x-rays documented bone inside the cages at both levels (Figures 11 and 12). Because the carbon cages are radiolucent, the bone density is clearly visible inside the cages. At this point, bone density is about the same as that of the carbon cages.

By 6 months after surgery, the patient reported that his pain was mild. He routinely walked 2–3 miles a day and had restriction of only strenuous activities. X-rays documented increased bone density in the fusion area (Figures 13 and 14). The cage struts are clearly visible on the up-angled AP x-ray, indicating that the bone density inside the cages has increased.

At one year postop, pain and function continued to improve slowly, and the patient returned to work in a light-duty capacity in a food processing plant. X-rays showed consolidation of bone inside the left-sided cage but some resorption of the bone inside the right-sided cage (Figures 15 and 16).

At 2 years postop the patient reported that he had no pain and no restriction of activities. He was working full-time in a heavy manual capacity in the food-processing company. X-rays showed increased bone density in all fusion areas.

At 4 years postop the patient continued to have no pain and no restriction of activity. He was taking no medication and continued to work full-time in a heavy capacity. X-rays showed solid bony fusion in all areas, including the bone inside the cage on the right (Figures 17 and 18).

The increased density and maturation of the bone graft and fusion is apparent in the sequence of films. The integrity of the fusion and any areas of fusion failure are fully visible on good-quality films.

Figure 11 Three-month postoperative AP x-ray. The densities of cage and cancellous bone graft are approximately the same. (From Ref. 33.)

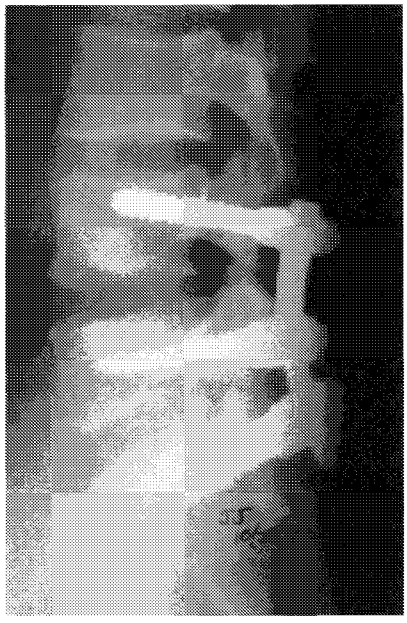


Figure 12 Three-month postoperative lateral x-ray. (From Ref. 33.)

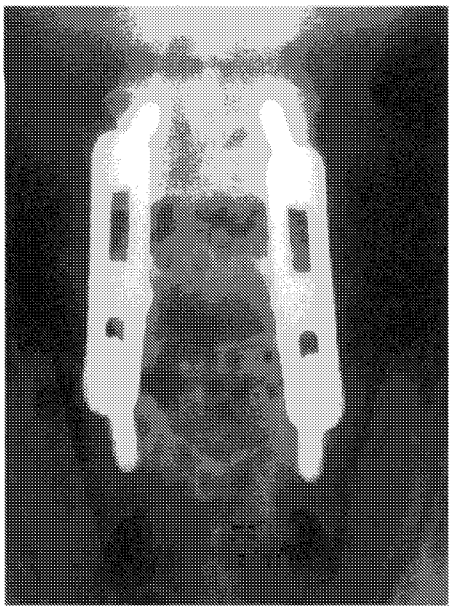


Figure 13 Six-month postoperative AP x-ray. The square cage struts are clearly visible, indicating that the bone density inside the cages has increased. (From Ref. 33.)

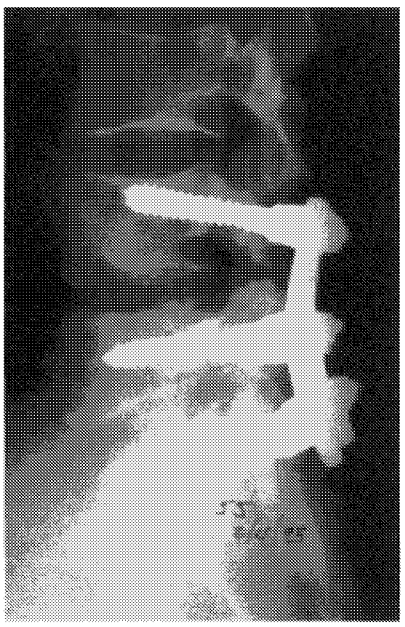


Figure 14 Six-month postoperative lateral x-ray. (From Ref. 33.)

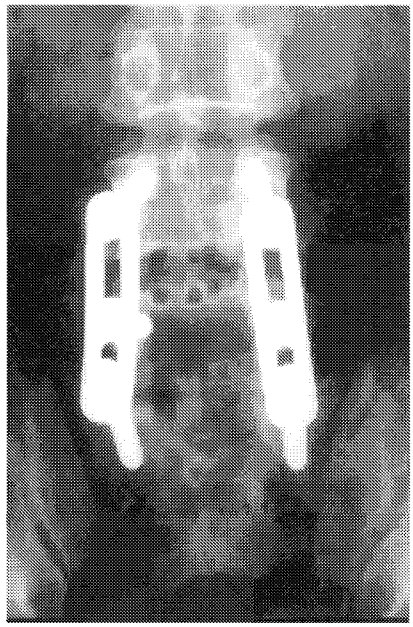


Figure 15 One-year postoperative AP x-ray. Bone inside the left-sided cage has consolidated; however, there is some resorption of bone inside the right-sided cage at L4–5. (From Ref. 33.)

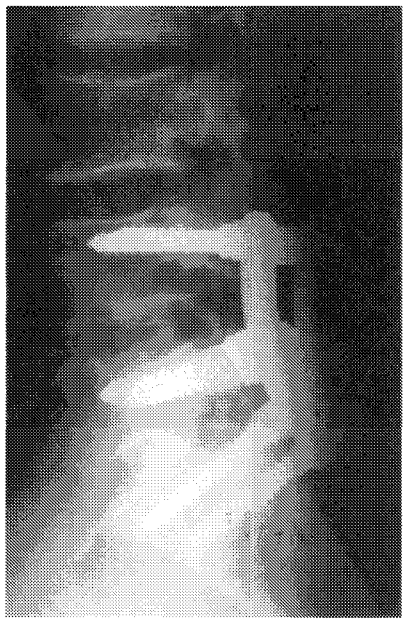


Figure 16 One-year postoperative lateral x-ray. (From Ref. 33.)

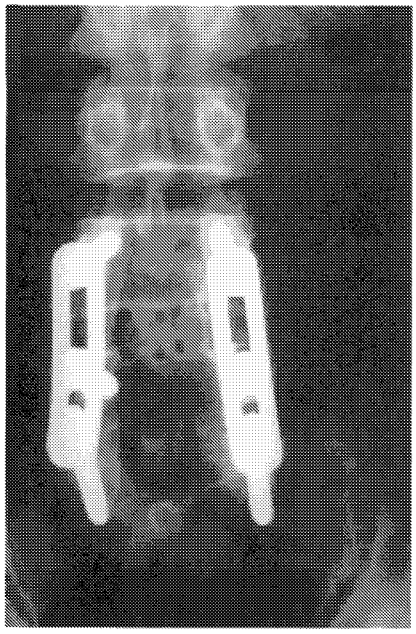


Figure 17 Four-year postoperative AP x-ray shows solid bony fusion in all areas, including the bone inside the cage on the right at L4–5. (From Ref. 33.)

Figure 18 Four-year postoperative lateral x-ray. (From Ref. 33.)

VI. CONCLUSION

The CFRP cage for PLIF has achieved the design objectives of meeting all mechanical requirements of the lumbar spine, meeting all requirements for long-term biocompatibility and allowing documented reliable fusion success when implanted according to established physiological principles. This is the first FDA-approved use of this type of implant material and the first in a family of implant devices designed to restore anterior column support and achieve fusion success in a variety of pathologies throughout the spine.

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