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Evaluation of Posterior Stabilization Reinforced with Intravertebral Titanium Mesh Cages in Treating Acute Thoracolumbar Burst Fractures

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ABSTRACT

Background Data: Burst fractures are commonly provoked by axial compression which disrupts the anterior column. In this setting, posterior stabilization using pedicle screws alone may lead to delayed kyphosis and instrumentation failure due to inadequate support of the anterior column.

Purpose: To evaluate the efficacy of pedicle screw instrumentation combined with transpedicular titanium mesh cage augmentation for treatment of burst fractures.

Study Design: Prospective descriptive cohort clinical case study.

Patients and Methods: Fourteen neurologically intact patients with acute incomplete thoracolumbar burst fracture (AO type A 3.1), and operated upon through period from January 2016 to June 2017 were included. Patients were treated using a three vertebrae pedicle screw fixation construct combined with bilateral transpedicular titanium mesh cage augmentation of the fracture. Patients were followed for at least one year. Data about pain (VAS), function (ODI) and vertebral body deformity (Beck index and local kyphotic angle) were recorded prospectively.

Results: Patients were operated within 5 days after trauma. The mean VAS score improved after surgeryfrom 8.2±1.3 to 3.7±1.1 postoperatively and to 1.8±0.7 at final follow up ($P<0.05$). The mean ODI score improved from 69.4±5.2 preoperatively to 17.2±2.4 at final follow up. The mean Beck index improved from 0.63 preoperatively to 0.81 postoperatively and to 0.79 at final follow up. The mean local kyphotic angle improved from 20.4° preoperatively to 11.5° postoperatively and declined to 13.7° at final visit. No patient had neurological deterioration or hardware failure during the follow up.The mean follow up was 13.4±1.8 months.

Conclusion: Posterior stabilization using pedicle screw fixation in combination with titanium mesh cage augmentation can maintain vertebral restoration, prevent hardware failure and lead to better clinical outcome. (2018ESJ162)

Keywords: burst fractures; thoracolumbar; kyphosis; titanium mesh cage

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INTRODUCTION

Thoracolumbar fractures are common in clinical practice, with an estimated prevalence of 1% among young adults.[2] Approximately 10-15% of these fractures are burst fractures, which are commonly provoked by compression forces following high-energy injuries like falls and traffic accidents.[15] If axial compression is the main force implied, about 80-85% of this force is transmitted via the anterior vertebral column.[17] The consequence is isolated failure of the anterior column, loss of integrity of the vertebral endplates and vertebral body compression leaving the posterior column intact.[13] According to the energy of the trauma, the axial load can also produce an incomplete or complete burst fractures, and significant disruption of posterior elements may also develop.[52]

Surgical treatment of thoracolumbar fractures aims at preservation of the physiologic balanced form of the vertebral column through maintenance of the integrity of the spinal functional units, preservation of free motion segments as possible, and restoration of the vertebral alignment. This can provide initial stability, allows early mobilization and prevents future painful deformity or worsening of the neurologic functions.[19] Traditional pedicle screw instrumentation remains the most utilized surgical treatment for thoracolumbar burst fractures. Although this method is safe and simple, many concerns exist over its efficacy if there is anterior column insufficiency.[39] In this setting, the stress concentrated at the pedicle screws leads to a high incidence of instrumentation failure (loosening, breakage), nonunion of the fracture, and progressive loss of the achieved kyphosis reduction.[9,26] Therefore, additional load-sharing through anterior column reconstruction should be added.[20]

Many authors have advocated anterior approach using strut grafts or cages and plates to establish anterior vertebral support.[44,38] Anterior instrumentation is biomechanically stronger in every loading condition compared with pedicle screw instrumentation, and can be considered the most reliable method of obtaining short segment stabilization especially in case of severe segmental kyphosis.[52,27] However, the invasiveness of the anterior approach is associated with significant operative morbidity and longer recovery period.[50] To diminish the risks of anterior surgery, many techniques have been developed to establish a sufficient and safe anterior column reconstruction via a posterior transpedicular approach utilizing transpedicular inflatable balloons, implantable stents or other reinforcement devices.[51]

The Osseofix® fracture reduction system (AlphaTec Spine, USA) is a stent-like, deformable titanium device that has been typically developed for reduction of osteoporotic vertebral compression fractures.[10] This device belongs to the third generation vertebral augmenters that were designed to overcome the disadvantages of vertebroplasty and kyphoplasty.[16] As an extension of its typical indication, Osseofix has been used in treatment of fresh traumatic non-osteoporotic thoracolumbar fractures.[49]

The purpose of the present study was the clinical and radiological evaluation of acute incomplete thoracolumbar burst fractures (AO type A 3.1) after stabilization utilizing three vertebrae pedicle screw construct reinforced with transpedicular titanium mesh cages.

PATIENTS AND METHODS

This prospective follow-up study was conducted in the period from October 2015 to January 2017, and comprised 14 patients (11 males and 3 females), with an average age of 34 years (range 23-51years). Patients with traumatic incomplete thoracolumbar burst fractures (Type A3.1according to AO/ Magerl classification),[37] and medically fit for surgery were included. We excluded patients with neurological deficits, associated serious injuries, pre-existing thoracolumbar deformity, or osteoporosis. The study proposal was approved by the medical committee of the authors' hospital, and a written informed consent form was signed

by eligible patients before surgery. The mechanism of injury was traffic accidents in 9 patients and falls in the remaining 5 patients (Table1). Fractures were surgically stabilized in prone position using 6 pedicle-screws construct (two pairs above, and one pair below the fracture) via the standard posterior approach, reinforced with bilateral intravertebral expandable titanium mesh cages (OsseoFix®, Alphatec Spine, USA) into the fractured vertebral body via the transpedicular approach. (Figure1) From the second postoperative day, all patients were allowed for ambulation while wearing a thoracolumbar brace for 6 weeks with avoidance of strenuous physical activity. Assessments of back pain intensity on the ten pointsVisual Analogue Scale (VAS) were collected preoperatively, postoperatively before discharge from hospital, and at final follow-up. Evaluation of the functional outcome of the spine according to the activity level on the Oswestry Disability Index (ODI)[12] was carried out as a percentage score preoperatively, early at time of discharge from hospital and was repeated at final follow-up.

Radiological assessment included plain radiographs on admission, 2-3 days postoperatively, and at final follow-up. The actual segmental deformity at the fractured vertebra was evaluated on lateral radiographs through measurement of the Beck Index[36] (ratio between anterior and posterior heights of the fractured vertebra), and the local kyphotic angle (angle between the base plate and the cover plate of the fractured vertebral body). Computed tomography scans, including reconstruction images, were performed during the follow up to evaluate fracture healing and position of the implants. Differences in clinical and radiographic data preoperatively, post-operatively, and at final follow-up visit were tested using t test for differences between means. The difference was considered to be significant if $P<0.05$.

Surgical Technique:

The patients were operated under general anesthesia in prone position over a spinal frame and a radiolucent operating table. Fluoroscopic views were taken in AP and lateral projections to define the pedicles and vertebral bodies clearly. The standard posterior midline approach was used and an intermediate segment fixation without the fracture segment was performed (pedicle screws were inserted into the pedicles of the two adjacent vertebrae above and one vertebra below the fracture level). With the aid of cannulated targeting needle, two k-wires were inserted into the pedicles of the fractured vertebra under fluoroscopic guidance, followed by cannulated drilling of the pathway through the pedicle towards the anterior third of the fractured body. According to the width of the involved pedicles on the preoperative CT scan, two proper-size titanium mesh cages (available in three measures) were selected and handled by an implant delivery system to be inserted into the fractured vertebral body. Another working mechanical system was used to deploy the expandable cages inside the vertebral body in a controlled manner till obtaining the desired endplate reduction. Finally, two longitudinal rods were contoured and connected to the pedicle screws without applying any compression or distraction forces.

RESULTS

Fourteen patients with single-level acute incomplete thoracolumbar burst fractures (AO type A3.1) were evaluated preoperatively, postoperatively, and at final follow up. All patients were operated within 5 days from injury. A total of 9 lumbar (N=6 L1, N=3 L2) and 5 thoracic (N=1 T11, N=4 T12) vertebrae were stabilized using pedicle-screw fixation above and below the fracture level combined with bipedicular titanium mesh cages as mentioned above. All surgical procedures were performed without technical difficulties or intraoperative complications. The mean operative time was 145±17.6 minutes (Range, 135-180 min), and the mean intraoperative blood loss was 325±74 ml (Range, 300-650 ml) and no blood transfusions were required. The overall hospital stay averaged six days (Range, 5-8 days), then patients were followed up for 13.4±1.8 months (Range, 12-18 months) with a minimum of 12 months on outpatient basis. Clinical evaluation

showed remarkable pain relief and functional improvement in all patients postoperatively. The mean preoperative back pain score on the Visual Analogue Scale (VAS) was 8.2±1.3 and improved significantly to a score of 3.7±1.1 postoperatively (P<0.05), and to a score of 1.8±0.7 at final follow up. The mean Oswestry Disability Index (ODI) also improved from 36.7±5.2 (Range, 29-47) at time of discharge from hospital to become 17.2±2.4 (Range, 12-31) at final follow up, which represents a statistically significant increase in activity level (P<0.05) and corresponds to minor disability.

Radiological evaluation revealed achievement of reasonable vertebral body reduction in all patients. The mean postoperative Beck Index was 0.81±0.04 (Range, 0.68-0.87), representing a statistically significant improvement (P<0.05) over the preoperative Beck Index 0.63±0.11 (Range, 0.45-0.72). At final follow up, slight loss of the reduction occurred as the Beck Index declined to 0.79±0.03 (Range, 0.65-0.84). Correspondingly, the mean local kyphotic angle improved significantly from 20.4±3.7° (Range, 17°-33°) preoperatively to 11.5±1.3 (Range, 8-16°) postoperatively (P<0.05), therefore the mean initial correction achieved was 8.9°. The mean local kyphotic angle increased slightly at final follow up to 13.7±1.6° (Range, 10-17°). There were no statistically significant differences between the postoperative and the final assessments of the Beck Index or the local kyphotic angle (Table 2).

Postoperative plain radiographs and CT scans showed radiologically healed fractures in all patients, and demonstrated modest positioning of the titanium mesh cages inside the vertebral bodies without changes in the position of the posterior vertebral wall. Position of pedicle screws was accurate in all procedures except in 3 patients who demonstrated minimal cortical breaches (<2mm) of the lateral pedicle wall in their CT scans, but without any remarkable sequelae (Figure2,3). None of our patients developed postoperative complications in terms of neurological deterioration, wound infection, instrumentation failure or need for additional surgery.

Table 1. Preoperative Demographic Data

Parameters		No. (%)
Gender	Male	11 (79%)
	Female	3 (21%)
Age	20-	5 (36%)
	30-	7 (50%)
	40-	2 (14%)
Level of fracture	D11	1 (7%)
	D12	4 (29%)
	L1	6 (43%)
	L2	3 (21%)
Mechanism of injury	Road traffic	9 (64%)
	Fall	5 (36%)

Table 2. Clinical and Radiological Outcome Parameters Data of Study Patients

Parameters	Preoperative	Postoperative (2-7 days post op)	Final Follow Up (12-18 months post op)	P Value
VAS	8.2±1.3(6-9)	3.7±1.1(4-6)	1.8±0.7 (3-4)	P< 0.05*
ODI	69.4±5.2 (72-65)	36.7±5.2(29-47)	17.2±2.4(12-31)	P< 0.01#
Beck Index	0.63±0.11(0.45-0.72)	0.81±0.04(0.68-0.87)	0.79±0.03(0.65-0.84)	P< 0.05*
Kyphotic Angle	20.4±3.7(17-33)	11.5±1.3(8-15)	13.7±1.6(11-16)	P< 0.05*

P*; preoperative compared with postoperative value, **P#**; postoperative compared with final value.

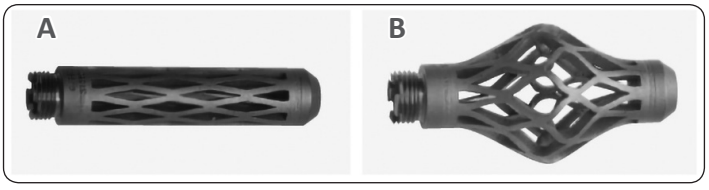

Figure 1. The titanium mesh cage (Osseofix Fracture Reduction System)®, un-expanded implant (A), and expanded implant (B).[47]

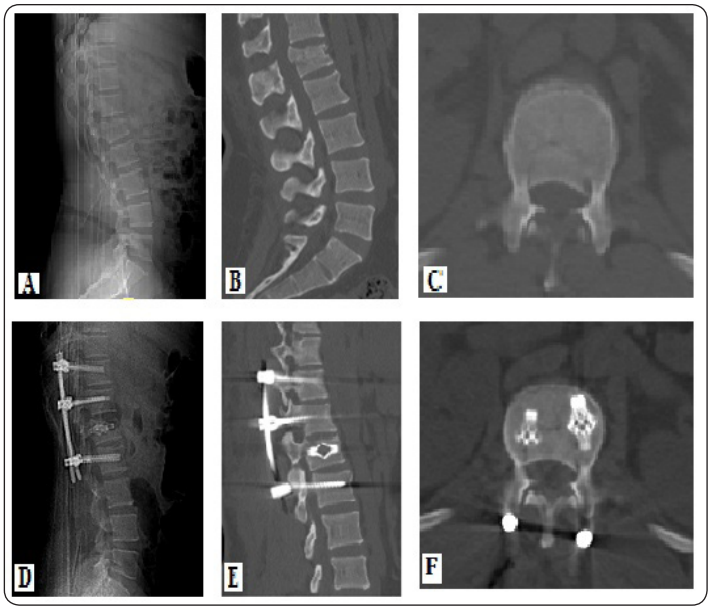

Figure 2. Twenty-eight year-old builder had fallen at work, he presented to the emergency unit with back pain. Preoperative plain radiograph (A), and CT scan (B, C) of the thoracolumbar junction showed a burst fracture at L1. Postoperative erect plain radiograph (D), and CT scan (E, F) 5 days after surgery showed fair endplate reduction and good position of the titanium mesh cage within the fractured body.

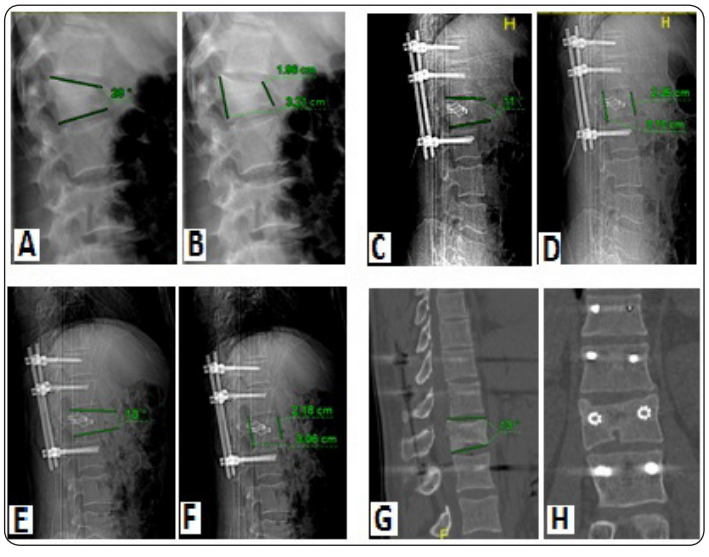

Figure 3. Plain radiographs preoperative (A, B), early postoperative (C, D), and final (14 months) follow-up (E, F) lateral radiographs of L1 burst fracture treated with pedicle screw fixation and titanium mesh cage augmentation. The Beck index and local kyphotic angel improved from 0.61 and 28° preoperatively to 0.72 and 11° three days after surgery, and declined to 0.71 and 13° at final (14 months) follow up respectively. CT scan with sagittal (G) and coronal (H) reconstructions of the same patient 14 months after surgery.

DISCUSSION

Short segment posterior fixation is frequently regarded as the procedure of choice for treatment of thoracolumbar burst fractures, with the advantages of incorporating fewer motion segments and a relatively lesser morbidity.[3,42] Biomechanical studies however, have shown that the thoracolumbar segment represents a point of great transition between the stiff thoracic cage and the more mobile lumbar spine where pedicle screw fixation alone without vertebral body reconstruction may not provide adequate

support.[6] Moreover, application of ligamentotaxis and distraction force over the posterior construct during surgery may create a defect in the fractured body after reduction of the depressed cortices, which may potentiate early loss of the vertebral body reduction because of more likely space for re-collapse.[46]This explains why implant failure and re-kyphosis after short segment fixation alone has been numerously reported, with an incidence of 9-54% in the long term follow up.[23,35,39]

To avoid this shortcoming, several methods, such as transpedicular bone grafting, bone cement injection, and placement of body augmenter have been developed to maintain kyphosis correction, and prevent implant failure.[33] Transpedicular bone grafting was introduced to achieve intrabody fusion and to increase the stiffness of the fractured body.[48] Nevertheless, many authors reported that transpedicular bone grafting have not prevented early implant failure and correction loss, and was associated with lower intrabody fusion rates (33%) in the long term.[25,30]

In recent years, cement augmentation (vertebroplasty/kyphoplasty) using polymethylmethacrylate (PMMA) in conjunction with short segment fixation has been used in traumatic burst fractures with promising short term results,[5,14] and was reported to offer immediate spinal stability, reduce the incidence of implant failure, and provides better postoperative pain control.[8] However, involvement of the posterior vertebral wall with potential cement leakage was a limiting factor for this procedure in acute trauma setting,[53] and the long term effect of PMMA cement especially in young patients is still inconclusive.[4]

Biodegradable bone fillers, such as calcium phosphate and hydroxyapatite, have been then introduced to substitute PMMA in augmentation procedures owing to their favorable biocompatibility and the ability to stimulate new bone formation at the bone-cement interface without local heating or toxic effect on surrounding bone tissues.[31,40] Although this method have achieved excellent immediate reduction of the segmental kyphosis,[45] many studies have revealed that the average loss of correction after posterior instrumentation reinforced with biodegradable bone cement is not significantly different from that following posterior fixation alone over the long term,[18] which could be related to the liability of such materials todisintegrate over time.[36]

On 2005, the results of vertebral augmentation utilizing the transpedicle body augmenter (TpBA) through the pedicle of the collapsed vertebral body were published.Theauthors reported that reconstruction with a TpBA can maintain correction of kyphosis, prevent hardware failure and lead to better clinical results over the long term.[33] The procedure depends on manual reduction and reconstruction of the fractured body via the posterior approach, with prevention of all cement-related complications in vertebroplasty or kyphoplasty.

In the present study, we performed vertebral body augmentation utilizing the Osseofix fracture reduction system via a transpedicular approach in conjunction with posterior pedicle screw construct as an alternative option in the treatment of incomplete thoracolumbar burst fractures. The Osseofix device have been originally developed in 2009 for intravertebral stabilization of vertebral osteoporotic fractures from T6 to L5 (AO types A1.1, A1.3, or A3.1). Afterwards, it was utilized in the treatment of acute stable traumatic vertebral fractures of the same types in young patients.[47] This device is made of titanium mesh cage which expands into the vertebral body with the aim of indirect reduction of the body fracture via compaction of the surrounding trabecular bone which in turn restores the vertebral body height.[10] This mechanism is termed "structural osteoplasty" which permits controlled directional reduction without applying direct lift mechanism,[16] which is the working mode of Spine Jack® and Vertebral Body Stenting®. In addition, the interdigitation of trabecular bone occurring through the mesh stabilizes the device in place without the need to add bone cement which may disable the natural bony healing.[11]

Our clinical outcome revealed an average reduction in pain intensity based on VAS from 8.2

before surgery to 1.8 for final follow-up which is better than pain scores following short segment fixation alone (7.3 Pre-op Vs 3.4 Post-op),[21] and following short segment fixation reinforced with transpedicular bone grafting (8.5 Pre-op Vs 3.5 Post-op),[42] or reinforced with calcium phosphate kyphoplasty (9 Pre-op Vs 3.4 Post-op),[28] and represent comparable results to short segment fixation reinforced with PMMA cement (9.2 Pre op Vs 1.4 Post-op),[46] or reinforced with the transpedicle body augmenter (90% with no or minimal or occasional pain, N=81).[32]

Radiological evaluation demonstrated that an average initial reduction of 8.9° have been achieved postoperatively. At final follow up, slight loss of kyphosis correction averaged 2.2° was observed at final visit which could be related to endplate subsidence after mobilization with full weight bearing. Previous studies have reported average correction loss ranging from 5 to 12° following short segment fixation alone,[40] from 4° to 10° following short segment fixation reinforced with transpedicular bone grafting,[1,24] and from 4.2° to 5.7° following short segment fixation reinforced with biodegradable bone cements.[45,46] The average loss of correction in our series is preferable to those following short segment fixation reinforced with the transpedicle body augmenter (4.3°),[32] and did not differ significantly from the mean correction loss following posterior fixation reinforced with PMMA Kphoplasty (3.3°),[43] with the advantage of preventing possible cement related complications.

The number of segments to be involved in spinal fixation to achieve stability with minimal loss of the normal mobility is still controversial. Because of the high incidence of implant failure following short segment fixation, alternative methods of variable length for stabilization of thoracolumbar fractures have been developed. Many authors[22,29] have reported that two level fixation above and one level below fractures of the thoracolumbar junction (intermediate segment fixation) provides stability and forms a rigid construct with minimal correction loss or implant failure. Carl et al,[7] suggested two level fixation above fractures of the thoracolumbar junction where the compressive forces act more anteriorly, and one level fixation below the fracture where the compressive forces act more posteriorly in the more lordotic lumbar spine. In the present study, we preferred the intermediate segment fixation technique, and this was advantageous in preserving one distal mobile lumbar segment especially in the relatively young patients of the present study.

No instrumentation failure was observed in the present study, which can be explained by the adequate anterior column support provided by the intravertebral titanium mesh cages. Furthermore, the immediate spinal stability, provided by the augmented posterior construct, allowed for early and safe ambulation, and prevented any immobilization related complications.

There are some limitations of the present study. Firstly, the sample size was small, and there was no control group for comparison which renders the statistical power inadequate. Secondly, the clinical and radiologic outcomes were evaluated by the authors, which could bias interpretation of the findings.

CONCLUSION

Posterior stabilization using pedicle screw fixation in combination with titanium mesh cage augmentation in treatment of acute incomplete thoracolumbar burst fractures can maintain vertebral restoration, prevent hardware failure and lead to better clinical outcome.

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الملخص العربى

تقييم التثبيت الخلفى باستخدام المسامير العنيقية المدعوم بأقفاص التيتانيوم داخل جسم الفقرة لعلاج كسور الفقرات الصدرية القطنية الإنفجارية

البيانات الخلفية: يعتبر الضغط المحورى أهم الأسباب المؤدية لكسور الفقراتالصدريةالقطنية الإنفجارية. هذا الضغط يكون ملازم لإصابات العمود الفقرى الناجمة عن حوادث السيارات أو السقوط من مرتفعات. ينتقل هذا الضغط بنسبة كبيرة عبر العمود الفقارى الأمامى و هو ما قد يسبب تلف للفقرات يتراوح بين إنضغاط فى جسم الفقرة او كسر إنفجارى للفقرة و ذلك حسب شدة الإصابة. يعتمد العلاج الجراحى للكسور الإنفجارية على إستخدام المساميرالعنيقية. على الرغم من سهولة و أمان هذه الطريقة إلا انها أحيانا تكون مصحوبة بنسب انتكاس عالية و قد تؤدى لحداب بالعمود الفقرى إن لم تكن مصحوبة بتدعيم للعمود الفقارى الأمامى أثناء الجراحة.

الغرض: تقييم التثبيت الخلفى للفقرات باستخدام مسامير عنيق الفقرة المدعوم بأقفاص التيتانيوم داخل جسم الفقرة لعلاج كسور الفقرات الصدرية القطنيةالإنفجارية.

تصميم الدراسه: دراسة سريرية وصفية.

المرضى و الطرق: فى هذة الدراسة تم جمع و مقارنة البيانات الإكلينيكية والجراحية بأثر مستقبلى لعدد 14مريض يعانون من كسور بالفقرات الصدرية القطنية غير مصحوبة بأى اضرار عصبية. خضع هؤلاء المرضى لجراحة تثبيت للفقرات باستخدام مسامير عنيق الفقرة المدعوم بأقفاص تيتانيوم داخل جسم الفقرة, وتم متابعتهم سريريا وإشعاعيا بعد الجراحة لمدة عام على الأقل.

النتائج: أظهرت النتائج أن طريقة تثبيت الفقرات من الخلف والمدعوم بأقفاص تيتانيوم داخل جسم الفقرة أدى الى تحسن ملحوظ لكلا من درجة ألم الظهر والقدرة على الحركة والحالة الوظيفية بعد الجراحة. كذلك أظهرت نتائج الأشعات تحسن فى متوسط زاوية حداب العمود الفقرى من 20,4 درجة قبل الجراحة الى 11,5 درجة عند التقييم النهائى. لم تحدث أى مضاعفات عصبية أو مضاعفات لها علاقة بالمسامير أو الاقفاص التيتانيوم فى أى من المرضى.

الإستنتاج: مما سبق يستنتج أن جراحة تثبيت الفقرات الصدرية القطنية من الخلف و المدعوم بأقفاص تيتانيوم داخل جسم الفقرة تعتبرطريقة فعالة وآمنة لعلاج حالات معينة من كسور هذ الفقرات. وهو ما ينعكس على المريض فى صورة تحسن اكلينيكى أفضل مع عودة أسرع لأنشطة الحياة اليومية.