

Vertebroplasty with Calcium Composite Bone Graft Combined with Pedicle Screws Fixation in Thoracolumbar Fractures

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Abstract

Introduction: Posterior reduction probably reduces only the periphery of the endplate with its strong annular attachments while the central area remains depressed allowing for efficient realignment of the spine, direct and indirect decompression. With distraction force, restoration of vertebral body height and partial clearance of bone or discal fragments from within the spinal canal by ligamentotaxis can be achieved; the kyphosis gradually recurs in the rehabilitative phase.

Aim of the Work: To evaluate the therapeutic effect of vertebroplasty with calcium composite bone graft (GeneX) R* combined with pedicle screws fixation in thoracolumbar fractures.

Patients and Methods: The study was performed on 29 vertebrae in 24 patients with burst fractures for whom transpedicular calcium composite bone graft (GeneX) and posterior spinal fixation was performed.

Results: By using transpedicular calcium composite bone graft (GeneX) and posterior spinal fixation success was detected by immediate and follow-up of Cobb's angle.

Conclusion: Transpedicular restoration of endplate integrity and anterior column support by calcium composite bone graft (GeneX) and posterior spinal fixation is an effective and safe method to prevent later collapse.

Key Words: GeneX – Burst – Thoracolumbar fractures – Vertebroplasty.

Introduction

SURGICAL management of thoracolumbar injuries attempts to maximize function; facilitate nursing care; and prevent deformity, instability, or pain [1,2]. Optimal goals of the management include establishment of a painless, balanced and stable

spinal column with fusion of least number of vertebra. There exist different criteria for the choice of the management based on the severity of kyphotic deformity, canal compromise, vertebral height loss, and neurologic status [3].

Posterior spinal approaches allow for efficient realignment of the spine, direct and indirect decompression. With distraction force, restoration of vertebral body height and partial clearance of bone or discal fragments from within the spinal canal by ligamentotaxis can be achieved, the kyphosis gradually recurs in the rehabilitative phase [4]. An increase in deformity up to 12° has been reported following surgery by posterior methods. McNamara et al., reviewed 13 patients treated surgically and reported a post-operative kyphosis progression of 8.7° with only 69% return to pre-injury activity. In similar studies Stephens et al., and Kramer et al., reported a post-operative progression of 11.9° and 12.9°, respectively [5,6]. Farcy et al., [7] suggested that the main reason for correction loss is that trabecular bone structures inside the vertebrae cannot be adequately restored following posterior reduction. Hence, the fractured vertebrae, called "eggshell" vertebrae, still lack stable support [2].

When there is significant disruption of the load-sharing anterior column, the simple one level above and one level below short segment fixation does not ensure adequate stability, resulting in poor reduction in the kyphotic deformity and occurrence of instrument failure [8]. This necessitates more extensive approaches, such as anterior reconstruction via an anterior approach [9]. This approach may be more technically demanding, with increased potential for intraoperative complications compared with posterior approaches [10].

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Following a burst-type injury, both the central and peripheral parts of the endplate usually fracture, although the injury in the central portion is often more prominent because of the hydrostatic pressure in the nucleus that is built up during the traumatic impact [11]. Indirect reduction of a fractured endplate by traction on the annular fibers will easily restore the cortical periphery, giving the impression of a good restoration of the vertebral body on anteroposterior and lateral radiographs [12]. However, the central endplate portion cannot be reduced this way, leading to distorted disc space morphology. The nucleus can subsequently herniate through the fractured endplate and cause anterior column insufficiency [13].

Vertebral body augmentation through transpedicular introduction of biological cement recently has been investigated. Techniques using a single posterior approach for short-segment posterior stabilization, and transpedicular introduction of biological cement or bone have been reported. This seems to be a safe technique that allows circumferential stabilization through a single posterior approach. Improved results were seen when augmentation was performed in a bilateral fashion [14].

GeneX is bi-phasic calcium composite. It contains two different calcium salts; Porous β -tricalcium phosphate. Implant grade calcium sulphate, these components resorb over different time frames [15].

Patients and Methods

The study was performed on 24 patients, 10 females and 14 males. The mean age was 30 years old (ranged from 15-57 years). The study was conducted from July 2012 to October 2014.

Inclusion criteria:

- Adults.
- Any patient presenting with fresh unstable burst dorsolumbar fracture.

Exclusion criteria:

- Isolated spinous process and transverse process fractures.
- Fractures with associated neoplastic etiologies.
- Osteoporotic fractures of the spine without associated trauma.
- Old fracture-pediatric fractures.

The levels of dorso-lumbar fractures were as follow; one patient D9, one patient D11, 3 patients

D12, 14 patients L 1, 2 patients L2, 3 patients L3, 4 patients L4 fracture and one patient L5. There were 5 patients with double level vertebral fractures.

At presentation, history was obtained. Clinical examination of the traumatized patients was performed. Mechanism of injury was fall from height in 19 patients and motor car accident in 5 patients. Neurological assessment of all patients was done and 21 patients were neurologically free (Frankel E and ASIA impairment scale E), two patients Frankel D and one patient was Frankel C.

Plain X-rays (AP-lateral) with assessment of Cobb's angle and dorsolumbar CT were done in all patients. Cobb's angle ranged from 4 to 30 degrees pre operatively, the mean pre-operative Cobb's angle was 15.8 degrees.

According to Dennis classification all patients were burst type. According to AO classification Fig. (13), 12 vertebrae were classified as A3.1 (incomplete burst fracture), 5 vertebrae A3.2 (burst split fracture), 5 vertebrae A3.3 (complete burst fracture), 2 vertebrae B1.2 (posterior ligament disruption plus type A compression fracture), 2 vertebrae B2.3 (posterior osseous disruption plus type A compression fracture), and 3 vertebrae A1.1 (end plate impaction). Type A1.1 fractures were association with other vertebral fractures and treated conservatively.

According to Load Sharing classification; five patients had a load sharing classification point of, eleven patients had a load sharing classification point of 7, four patients had a Load sharing classification point of 8, four patients had a load sharing classification point of 9.

Operative data:

The posterior approach to dorsolumbar spine was done in all patients, the first surgical stage consisted of performing fixation of dorsolumbar fracture by transpedicular screws one level above and one level below the fractured vertebra with distraction performed in 22 patients.

Inclusion of fractured level by pedicular screws in 2 patients as follows; one patient with fracture L3 & L4 we did fixation L3 to L4. One patient with fracture D 12 & L 1 we did fixation D 11 & D12 to L2 with distraction of L1 vertebra and injection of GeneX material to L1.

Vertebroplasty by calcium composite bone graft (GeneX) was done through transpedicular canulae in all patients. Vertebroplasty performed in 24 vertebrae. Five vertebral fractures were not injected

by GeneX, two vertebrae were included in the fixation level and three were treated conservatively.

Postoperative management and follow-up:

During the follow-up period, all the patients underwent clinical assessments. The radiographic check-up systematically included postoperative X-rays views of the dorsolumbar spine including anteroposterior and lateral views immediate postoperative. The patients were followed-up as outpatients at the hospital ward: Residual pain was assessed and the results of radiography performed 3 months, 6 months and 1 years post-operatively were analysed.

Pain severity was measured by the Visual Analog Scale (VAS) at follow-up and sagittal plane deformity (kyphotic angle) was calculated in all radiographs using the Cobb's method, local kyphotic angle. Functional results were assessed in all patients by Oswestry Disability Index.

Results

The overall function and pain scores showed good clinical outcomes for all patients. Neural assessment of the patients revealed that no neurological deterioration of all patients and there is improvement of the neurological status of the three patients of incomplete neurological injury, two cases became neurologically free and one patient had residual urine incontinence.

The mean pre-operative pain intensity level was 6.8 on the VAS (range 4-8). The patients' pain levels improved significantly after the operation, since the mean VAS dropped to 1.1 (range 0-2) on the day of discharge and at final follow-up.

The mean health questionnaires Oswestry Disability Index (ODI) score was 8.3% (range from 2% to 24%). A total of 21 of 24 patients (87.5%) scored 0% to 20% representing "minimal disability". Three patients (12.5%) scored 21% to 40% representing "moderate disability". No patient scored higher than 40%.

No instrumentation failures occurred in any of the patients, and no patient required revision surgery for loss of correction or instrumentation failure.

The mean amount of GeneX injected was 4.3ml (range 3.8-5mL). Uniportal injection in 6 cases (25%) and biportal in 18 cases (75%). We have noticed that the evidence of GeneX disappears within the first 3 months in 18 cases (75%), 6 months in 4 cases (16.7%) and 1 year in 2 cases (8.3%).

Gexex leakage, defined as any amount of cement outside the confines of the vertebral body Fig. (1). Cement leakage occurred in 4 cases (16.6% of cases), no cement leakage had occurred into the spinal canal and two cases of lateral leakage and two cases of leakage inside the disc were diagnosed without clinical consequences.

Cobb's angle was measured pre-operative with mean 15.8 degree (range 1-30 degree) and improved post-operative to 1.3 degree (range 10 degree lordosis-13 degree kyphosis) with improvement of average 91.8% of kyphotic angle and at the final follow-up 2.7 (range 9 degree lordosis-14 degree kyphosis) with improvement of average 83% of kyphotic angle.

The mean loss of Cobb's angle correction was 1.4 (range 0-4 degree) with average loss of 8% of kyphotic angle correction and mainly during first 3 months post-operative.

Vertebral wedge angle was measured pre-operative with mean 19.3 degrees (range 8-32 degrees) and improved post-operative to 2.4 degrees (range 2 degree lordosis-8 degree kyphosis) with improvement of average 87.5% of vertebral wedge angle and at the final follow-up 3.2 (range 1 degree lordosis-10 degree kyphosis) with improvement of average 83.4% of vertebral wedge angle. The mean loss of vertebral wedge angle correction was 0.8 (range 0-2 degrees) with average loss of 4.1% of vertebral wedge angle correction.

Five patients had a load sharing classification point of 6 for those patients loss of correction averaged 1.23 degrees. Eleven patients had a load sharing classification point of 7 for those patients, the average loss of correction was 1.72 degrees. Four patients had a load sharing classification point of 8 for those patients loss of correction averaged 1.75 degrees. Four patients had a load sharing classification point of 9 for those patients loss of correction averaged 2 degrees.



Fig. (1): Leakage into the disc.

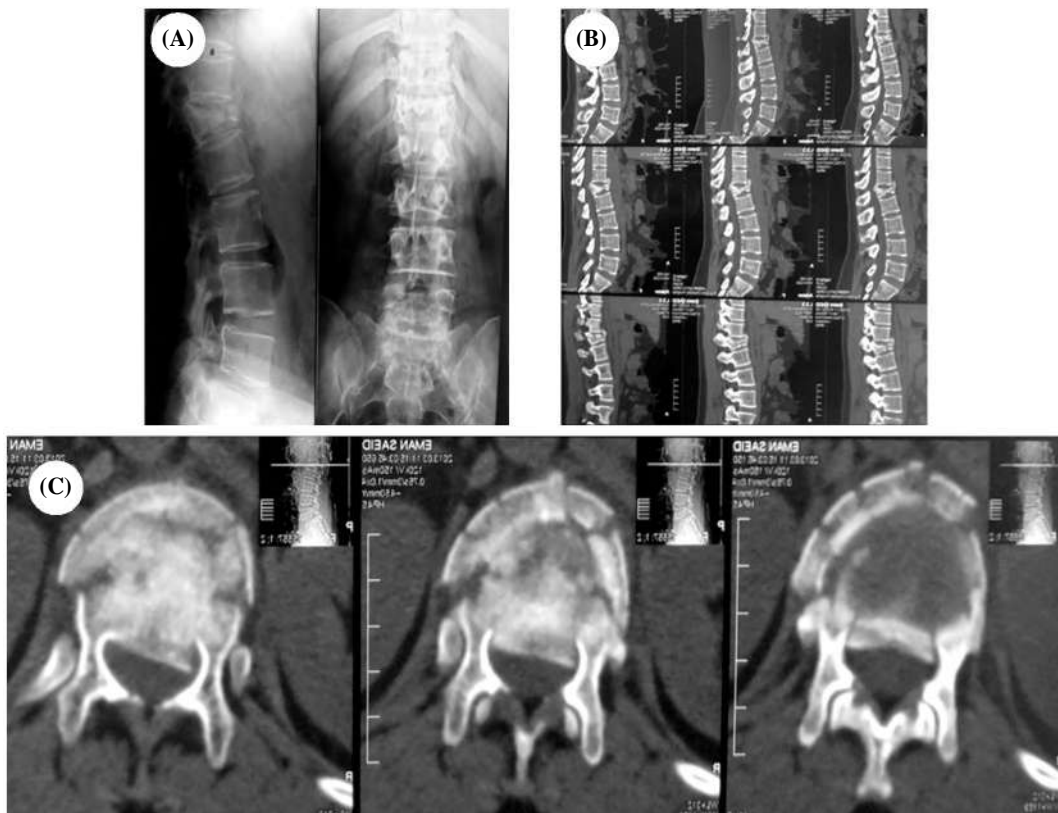


Fig. (2): (A) Pre-operative X-ray, (B) Pre-operative sagittal CT scan & (C) Pre-operative axial CT scan indicative of severe comminution of L1 and cobb's angle 30 degrees.

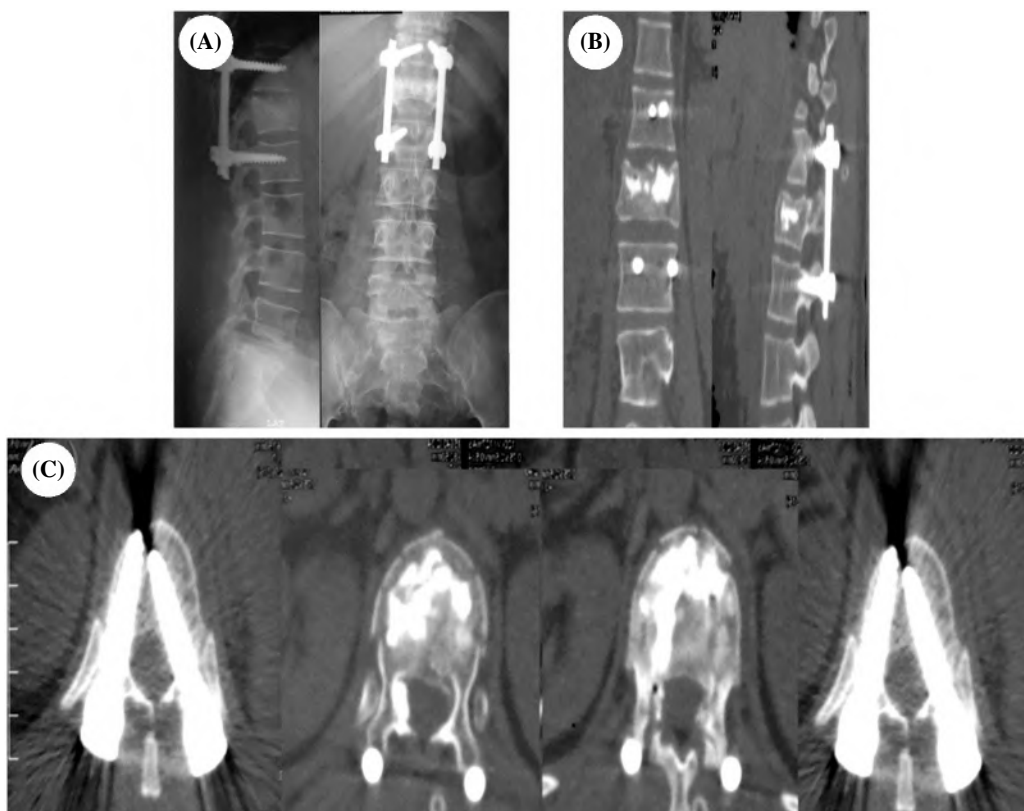


Fig. (3): (A) Post-operative X-ray, (B) Post-operative coronal, sagittal CT scan & (C) Post-operative axial CT scan showing reduction of kyphotic angle to 3 degrees and appearance of radio-opaque GeneX with clearance of spinal canal. The right pedicular screws penetrate the medial pedicular cortex without neurological problems.

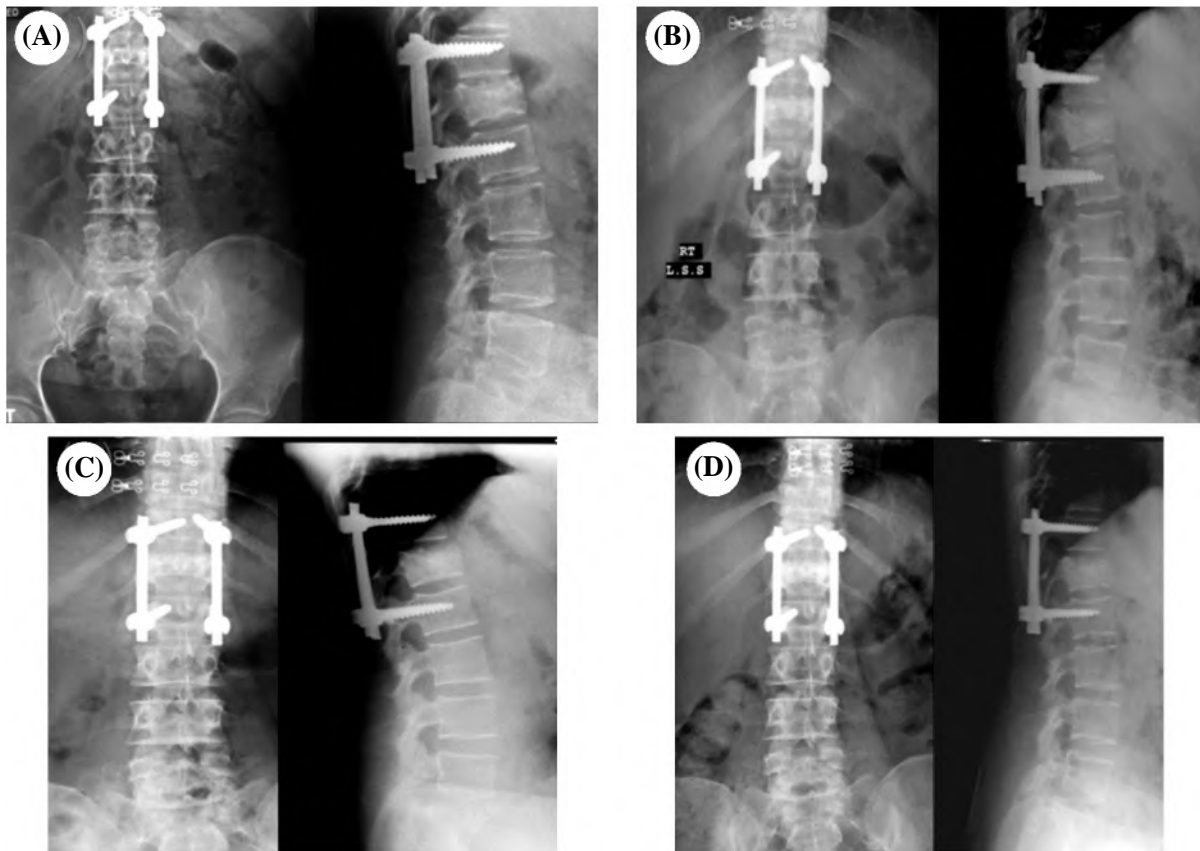


Fig. (4): (A) Post-operative follow-up X-rays 1 month, (B) 3 months, (C) 6 months & (D) 1 year revealing maintenance of the reduction of the kyphotic angle and complete resorption of Genex. There is loss of only one degree of Cobb's angle to be at the final follow-up 4 degrees.

Discussion

Several investigators have reported unacceptable high failure rates with posterior short-segment fixation, with a 20% to 50% incidence of pedicle screw failure and 50% to 90% loss of reduction of kyphosis with this technique [16]. Vertebroplasty could potentially provide the anterior column support and cement increases the strength, stiffness, and load-carrying capacity of the fractured vertebral body. This results in a shift of the loading forces to the newly strengthened anterior column [17].

In our series the mean loss of Cobb's angle correction was 1.4 (range 0-4°) with average loss of 8% of kyphotic angle correction and mainly during first 3 months post-operative and no implant failure was observed in any case of our cases.

We found in our series Cobb's angle was measured pre-operative with mean 15.8° (range 1-30°) and improved post-operative to 1.3° (range 10° lordosis-13° kyphosis) with improvement of average 91.8% of kyphotic angle and at the final follow-up 2.7 (range 9° lordosis-14° kyphosis) with improvement of average 83% of kyphotic angle. Jorrit-Jan Verlaan et al., (2014) in a series of

kyphoplasty and short segment fixation found that the average Cobb angle changed from 11.0° preoperatively to 4.5° and at follow-up it was 5.8°. The Cobb angle did not change significantly after removal of the pedicle screw instrumentation [18].

The goal of Genex is to "seal out" the intervertebral disc by aligning and lifting the fractured end plates to a (near) anatomical position, thereby preventing disc material to enter the vertebral body and resulting in physiological spinal alignment and when we augmented the vertebral body with Genex we achieved central end plate reduction in most of patients preventing anterior column insufficiency and decreasing disc space degeneration with subsequent minimizing disability resulted from the fracture.

Calcium phosphate cements are biocompatible materials without local heating or toxic effect on surrounding bone tissue. Additionally, calcium phosphate is a bioactive substance that is being degraded over time by creeping substitution and can stimulate formation of new bone substance at the bone-cement interface (osteoconductivity) with partial absorption of calcium phosphate by osteoclastic activity after 6 months [19].

The results indicate that no discrepancy between Cobb's angle and vertebral wedge angle at the final follow-up and this indicates good central body healing and support with minimal collapse of the fractured vertebrae at follow-up period.

However, when there is significant disruption of the load-sharing anterior column, the simple one level above and one level below short segment fixation does not ensure adequate stability, resulting in poor reduction in the kyphotic deformity and occurrence of instrument failure [20]. In our series 19 cases with severe disruption of the load-sharing anterior column (load shearing classification 7 or more) and we did short segment fixation plus vertebral augmentation without instrumentation failure at the final follow-up.

Eleven patients had a load sharing classification point of 7 for those patients, the average loss of correction was 1.72 degrees. Four patients had a load sharing classification point of 8 for those patients loss of correction averaged 1.75 degrees. Four patients had a load sharing classification point of 9 for those patients loss of correction averaged 2 degrees.

Although lacking a control group and based on a small number of patients, the results from the present short term follow-up study showed that GeneX, as a safe and low demanding adjunct to pedicle screw fixation for the treatment of traumatic thoracolumbar burst fractures, may lead to minimal residual deformity and reduce the number of secondary (anterior) procedures. Patient-reported outcomes were directly related to these positive findings as better correction of Cobb's angle leads to lesser discomfort and disability. Further researchs are needed with control group and long term follow-up to study disc degeneration after removal of instrumentation or not using pedicular screws from the start by minimally invasive reduction and augmentation.

Case example:

Female pt, 25 years old presented to our hospital after fall from height with burst fracture L 1 and intact neurological status, pre-operative cobb's angle was 30 degrees corrected to 3 degrees post-operative and 4 degrees at the final follow-up.

Conclusion:

- Vertebroplasty by calcium composite cement is a safe and low demanding adjunct to pedicle screw fixation for the treatment of traumatic thoracolumbar burst fractures.

- Vertebroplasty by calcium composite cement leads to minimal residual deformity and reduce the number of secondary (anterior) procedures.
- Patient-reported outcomes were directly related to these positive findings as better correction of Cobb's angle leads to lesser discomfort and disability.
- Further researchs are needed with control group and long term follow-up to study disc degeneration after removal of instrumentation or not using pedicular screws from the start by minimally invasive reduction and augmentation.

Conflict of Interest:

No conflict of interest and no benefits taken from the producing company.

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الملخص العربي

إن أهداف علاج كسور الفقرات الصدرية والقطنية تتلخص في وجود العمود الفقري بلا ألم، متوازن وثابت مع سمكرة أقل عدد ممكن من الفقرات. وتثبيت الفقرات من الخلف يسمح بإعادة إصلاح التحدب مع إزالة الضغط على الأعصاب بطريقة مباشرة وغير مباشرة، ومعظم زيادة التحدب يحدث في الشهور الأولى بعد الكسر.

رأب الفقرات يدعم الجزء الأمامي للفقرات كما أن أسمنت الفقرات يزيد من صلابة وقوة جسم الفقرة. وهدف مركب الكالسيوم جين إكس أن يرفع ويرفع قرص نهاية الفقرة للوضع التشريحي وعندما استخدمنا هذا المركب استطعنا رفع الجزء الأوسط لقرص نهاية الفقرة مما يقلل من إضعاف الجزء الأمامي من الفقرة ويقلل من الإعاقة الناتجة من كسور الفقرات.

وكما إتضح من النتائج أن زوايا التحدب في نهاية فترة المتابعة ما يؤثر إلى الإلتئام الصحيح للفقرات مع التقليل من عودة التحدب مرة أخرى. وحينما وجد تفتت شديد بجسم الفقرة فإن التثبيت الخلفي القصير للفقرات يؤدي إلى زيادة التحدب مع فشل التثبيت بالمسامير، ولكن حينما أضيف رأب الفقرات وجد أن زيادة التحدب قليلة جدا مع عدم وجود فشل في مسامير عنيق الفقرة.

والنتائج من هذه الدراسة ومن فترة المتابعة القصيرة تؤكد أن مركب الكالسيوم (جين إكس) آمن وفعال ولا يحتاج إلى تقنيات زائدة في الجراحة بالإضافة لمسامير عنيق الفقرة لعلاج كسور الفقرات الصدرية والقطنية، ويؤدي إلى التقليل من التشوهات والتدخلات الجراحية مرة أخرى.

وتأتي النتائج المقررة من المرضى متوافقة مع هذه النتائج الإيجابية للتقليل من زوايا التحدب التي أدت إلى التقليل من الألم مع الوصول لأفضل النتائج الوظيفية للمرضى.