



# Efficacy of using titanium expandable mesh cages with DBM bone graft in management of vertebral compression fractures

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## ABSTRACT :

- Study design:

Quasi-experimental study

- Objective:

This study was conducted to evaluate the efficacy of using expandable mesh with DBM bone graft in short and long term treatment clinically, back to normal activities and complications.

- Methods:

Forty patients with thoracolumbar vertebral compression fractures underwent this operation from August 2013 to August 2015 at one center under one surgeon at Soliman Fakeeh Hospital. We evaluated pain relief and improvement of daily activity function using visual analogue scale (VAS) score and Oswestry disability index (ODI) system pre-, post and one year after the operation. At the same times, we also assessed kyphotic angles (KA) and Cobb angle (CA) using plain x-rays and computed tomography (CT).

- Results:

We found significant improvement of daily activity functions and pain relief as we found a statistically significant decrease in VAS score when compared pre-operatively ( $8.80 \pm 1.13$ ) to immediately and one year post-operatively respectively ( $4.2 \pm 1.27$ ,  $1.18 \pm 1.36$ ,  $P = 0.018$ ). There was also a statistically significant decrease in ODI system scores when pre-operative scores ( $91.35\% \pm 2.24\%$ ) were compared to immediate and one year post-operative scores ( $40.3\% \pm 16.43\%$ ,  $29.40\% \pm 16.63\%$ ,  $P = 0.012$ ). Both KA and CA showed significant improvements postoperatively (KA  $20.33^\circ \pm 6.16^\circ$  to  $10.55^\circ \pm 4.11^\circ$ ,  $P = 0.002$ / CA  $10.5^\circ \pm 4.273^\circ$  to  $7.12^\circ \pm 2.99^\circ$ ,  $P = 0.001$ ). There was no statistically significant difference in terms of KA and CA during the follow-up period ( $P > 0.05$ ).

- Conclusions:

This approach is effective in treatment of such cases providing better quality of life by immediate and sustained relief of pain and less hospital stay. It also improves both KA and CA immediately after the operation with maintenance of stable radiological progression through the period of follow-up. Also, it is also a safe procedure.

**KEYWORDS:** Spine, fracture , vertebral compression fractures , vertebroplasty , kyphoplasty

## I. INTRODUCTION

About 20% of people over the age of 70 are found to suffer from vertebral compression fractures (VCF) with an increasing incidence In Saudi Arabia; it was found that two out of ten women aging over 50 years suffer from a vertebral fracture. These fractures have direct social, economic, physical and psychological hazards on the patients and their families.

In patients with no neurological deficits, pain management is the cornerstone of treating spinal fractures through vertebral body stabilization. However this Back pain is usually incapacitating for few weeks then diminishes in severity, but it remains intense for 2 to 3 months.

VCF treatment strategies include some noninvasive options such as using pain killers or using braces, which would yield adequate control of pain in less than 20%\_25% of patients. Treatment modalities include also minimally invasive procedures including Vertebroplasty and Kyphoplasty that can be considered long- and well-established techniques .As these treatment strategies are cement-based, so it carry risk of extra-vertebral cement leakage and refractures, 65% and 63% respectively.



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Another disadvantage with cement based treatment modalities is the nonabsorbability of the required Polymethyl methacrylate (PMMA) cement this can cause a life-long rigid implant that can support adjacent vertebral fractures. Till now, it is not well established whether the extensive filling of cement in a vertebral body has a worse effect on vertebral healing.

Both vertebroplasty and kyphoplasty have reported several procedural problems such as loss of the restored height or suffering new fractures 4% - 26%.

In order to overcome these disadvantages we used expandable titanium mesh cages with DBM bone graft to manage vertebral compression fractures cases. Demineralized bone matrix is allograft bone that has been decalcified to produce a product of collagen and noncollagenous proteins with fusion rates were 54% and 74% for the allograft/DBM and autograft groups, respectively, at a minimum of 1-year follow-up.

This technology is used nowadays by some orthopedic surgeons in repairing bones broken by injuries, tumors, and other defects. The study, therefore, will determine the effectiveness of bone graft technology fitted with implants as compared with other clinical methods for treating fractured vertebrae.

The surgery accurately and efficiently heals the fractured vertebrae, which can be used to improve the condition of the injured patient and increase the discharge rates in the clinics as the patient's bone heal faster as compared to other clinical methods or therapies.

This study was conducted to evaluate the efficacy of using of mesh with bone graft in short and long term treatment of fractured vertebrae clinically.

## II. SUBJECTS AND METHODS

Retrospective study for forty patients presented with one or two levels of A1.1, A1.2, or A1.3 (AO Spine Fracture classification) at the thoracic and lumbar spine attended to minimally invasive insertion of expandable vertebral device with injection of demineralized bone graft, at Soliman Faqeeh Hospital in Jeddah, Saudi Arabia, from August 2013 to August 2015.

The mean age of patients (29 males, 11 female) was  $43.58 \pm 13.8$  years. The average duration of symptoms was 7.6 weeks (range: 2 to 16 weeks). Twenty four patients presented post significant trauma and sixteen patients presented with osteoporotic fractures.

**Inclusion criteria** : were persistent, painful, Dorsal or lumbar vertebral fractures (proven by X-ray and MRI) and intractable pain after 2 weeks of conservative treatment.

**Exclusion criteria** were neurological deficits, spinal canal involvement due to posterior vertebral wall fracture and known sensitivity to DBM.

We conducted radiological follow-up using standing anteriorposterior and lateral radiographs at six different time points: preoperatively, postoperatively, one month, three months, six months and after one year of follow up postoperatively. Additional CT scan was used to evaluate the condition and progress of healing in both the pre-operative and post-operative (for a year) settings. We analyzed all radiographs for changes in sagittal alignment referring to the posterior (Hp), middle (Hm), and anterior vertebral body height (Ha) according to six defined points on the fractured vertebra (A-F, Figure 1). The sagittal index (SI) as measurement of segmental kyphosis at the level of one spine segment was calculated from the posterior and anterior height. We measured the kyphotic angle (KA) of the vertebral body using means of the intersections connecting points AE and BF. We also calculated the Cobb angle as measure for the sagittal alignment at the fracture level from the intersections of the tangents to the endplates of the corresponding vertebral bodies superior and inferior from injury level. We assessed kyphotic angles (KA) and Cobb angle (CA) pre-operatively, immediately post-operatively, and after one year of follow-up.

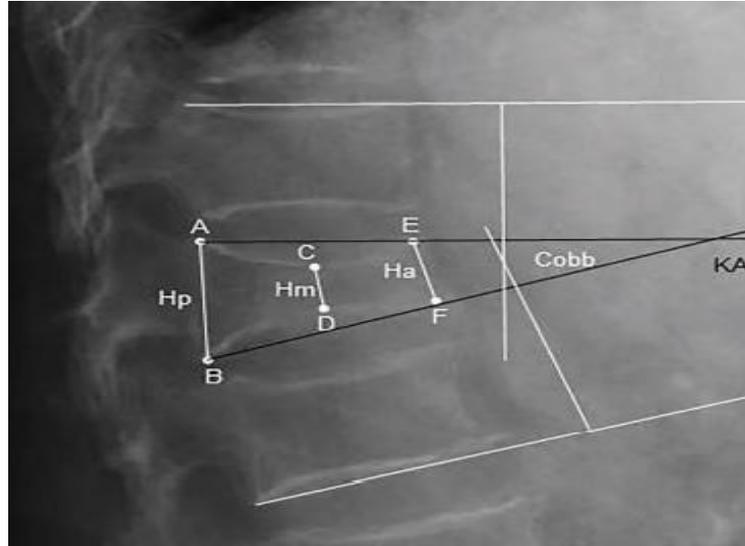


Figure (1)

Figure (1): Radiological measurement by means of a fractured vertebra body of the thoracolumbar spine. Height in sagittal alignment is defined using 6 points: A and B are on the most dorsal-superior and dorsal-inferior endplate margins, E and F correspond to the most anterior-superior and anterior-inferior margins, and C and D are on the midpoint of a perpendicular line drawn from A to E and B to F on the superior and inferior vertebral endplates. Resulting Cobb and vertebra body kyphotic angle.

Our clinical follow-up included the evaluation pain rate using visual analogue scale (VAS) pre-, post and one year after the operation. We also used Oswestry Disability Index as standardized subjective and functional assessment of the spine (29) pre-, post and one year after the operation.

According to data analysis, IBM SPSS Statistics 20 program was used for data analysis. CI at 95%, p value of 0.05 was used as the limit of statistical significance. T-test and chi-square test were conducted.

Institutional Review Board approval: Our study was approved by the local institutional review board of Soliman Fakeeh hospital and is in accordance with the declaration of Helsinki. We obtained written consent from all patients enrolled in this study

**Surgical Technique:** In order to reduce and stabilize the collapsed vertebral body, the patient was brought into a prone position on a Jackson's table keeping the thoracolumbar area on neutral or slight extension to help in expansion the body of vertebra, with the standard preparations and drappings, the size of the incision was made vertically between 8mm - 1.4 cm dorsolaterally just 0.5 mm lateral from the lateral boarder of the pedical shadow after fluoroscopic identification of the injured vertebra using orthogonal views . Using a targeting needle, two K-Wires were placed transpedicularly into the vertebral body under fluoroscopic control in two planes trying to put the tip of the wire away from the upper end plate if possible, two diameters of dilators passed through the Kwire followed by cannulated drilling of the pathway into the anterior third of the vertebral body. A titanium implant delivery system helped to insert the two titanium mesh cages which had been selected regarding their proper size according to preoperative planning from preoperative CT scans, there are three sizes available 4.5, 5.5 and 6.5 mm . A mechanical actuation system was used to deploy the expandable cages in a controlled manner, using the same probes to pass the cement in vertebroplasty we use it to pass the bone grafting average 3mm for each portals. Postoperatively, full weight bearing was allowed immediately according to the patient's pain threshold, avoiding bending forward for the next three months in addition we used calcium and vitamin D to initiate the healing process.

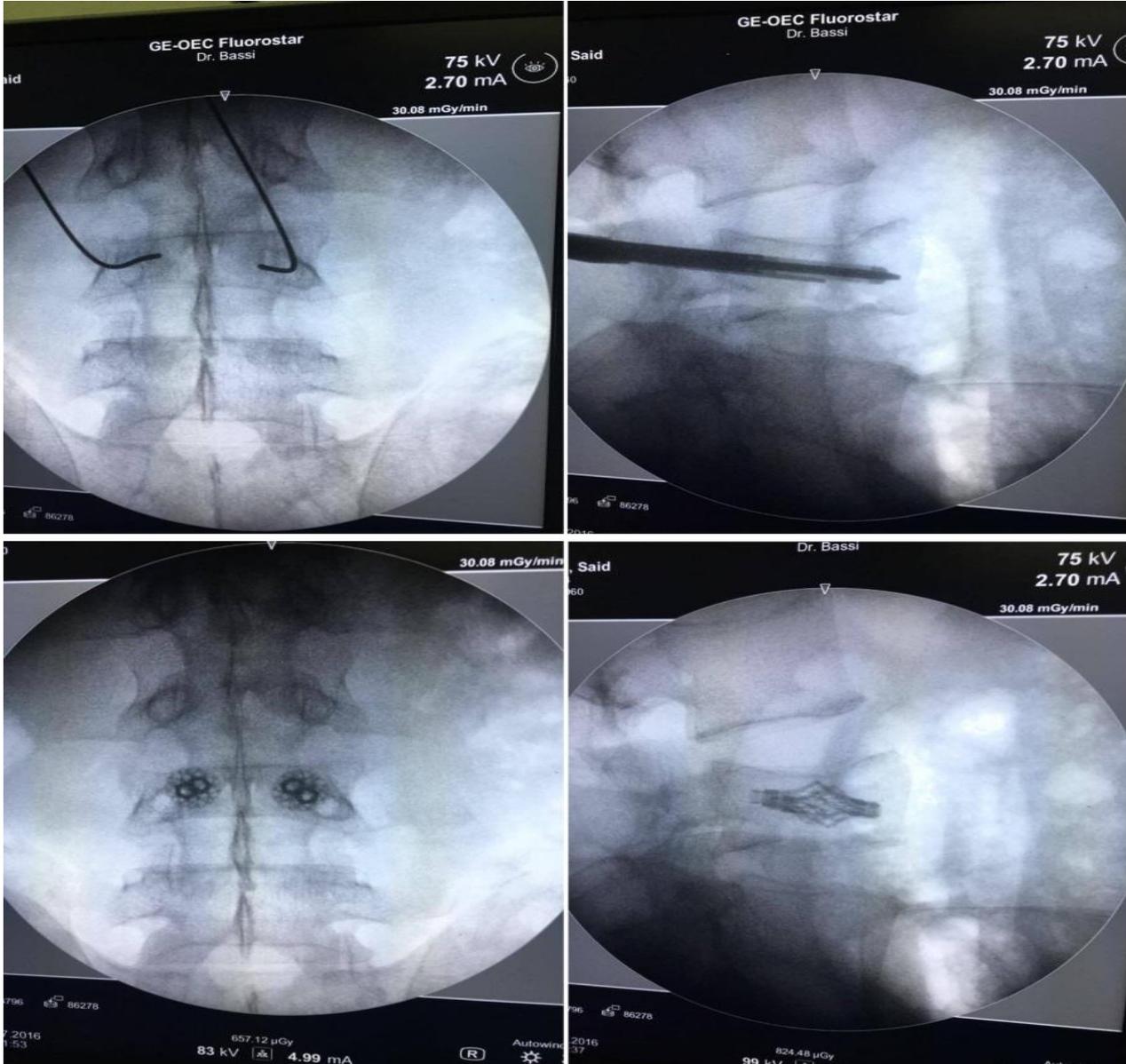


Figure (2)

Figure (2): Steps of the surgical technique: A: Insertion of the guide wire after position with insertion of the guide needle under image. B: Cage insertion cage after good size drilling. C: Cage expansion.

### III. RESULTS

This study was conducted on forty patients ( $43.58 \pm 13.8$  years) with vertebral compression fractures to evaluate the efficacy of minimally invasive expandable device and injection of DBM using some variables such as return back to normal activities after the surgery, mean hospital stay and some radiological and functional measures. The mean duration of hospital stay after the operation was  $51 \pm 8.2$  hours. The mean duration to return to mild work was  $2.3 \pm 1.1$  weeks,  $6.3 \pm 2.4$  to soft work and about  $12.3 \pm 2.7$  to full work.

- Radiological Results:

We achieved intraoperative vertebral body restoration of the height partially or full with respect to body angle and decrease of kyphotic angulation of the adjacent vertebra segments.

Successful vertebral body restoration was proved by KA measurement revealing significant improvement from  $20.33^\circ \pm 6.16^\circ$  ( $10^\circ-27^\circ$ ) to  $10.55^\circ \pm 4.11^\circ$  ( $2^\circ-26^\circ$ ),  $P = 0.002$ . During the duration of follow-up, a slight insignificant loss of restoration was observed ( $10.81^\circ \pm 4.61^\circ$  ( $5^\circ-26^\circ$ ),  $P > 0.05$  (Figure 1).

The Cobb angle as parameter for the sagittal alignment of the fracture level improved from  $10.5^\circ \pm 4.27^\circ$  ( $1^\circ-20^\circ$ ) to  $7.12^\circ \pm 2.99^\circ$  ( $4^\circ-14^\circ$ ) showing less kyphosis ( $P = 0.012$ ). During the duration of follow-up, a slight insignificant return of kyphosis was observed ( $7.13^\circ \pm 2.81^\circ$  ( $4^\circ-14^\circ$ ),  $P > 0.05$  (Figure 3).

Follow-up X-rays and CT scan after one year revealed good bony healing in all patients with no observed implant dislocations. Throughout the duration of the study, we did not notice any adjacent vertebral fractures.

	KA Preoperatively	KA Postoperatively	KA one year after the operation	CA Preoperatively	CA Postoperatively	CA one year after the operation
Mean	20.33°	10.55°	10.81°	10.50°	7.12°	7.13°
Standard Deviation	6.16°	4.11°	4.61°	4.27°	2.99°	2.81°
Range	10-27°	2-26°	5-26°	1-20°	4-14°	5-14°

Table (1)

Showing the radiological findings pre-, post and one year after the operation.

- Functional Results:

Pain progress as evaluation by VAS accounted for  $8.80 \pm 1.13$  (7–10) preoperatively and improved significantly to  $4.2 \pm 1.27$  (3–6) postoperatively. A further significant improvement was noticed during the follow up period one year after the surgery ( $1.18 \pm 1.36$  (0-5),  $P = 0.018$ ) (Figure 1). In terms of subjective and functional assessment of the spine, there was a statistically significant decrease Oswestry disability index (ODI) system scores when pre-operative scores ( $91.35\% \pm 2.24\%$ ) were compared to immediate and one year post-operative scores ( $40.3\% \pm 16.43\%$ ,  $29.40\% \pm 16.63\%$ ,  $P = 0.012$ ).

	ODI Preoperatively	ODI Postoperatively	ODI one year after the operation	VAS Preoperatively	VAS Postoperatively	VAS one year after the operation
Mean	91.35%	40.3%	29.4%	8.8	4.2	1.18
Standard Deviation	2.24%	16.43%	16.63%	1.13	1.27	1.36
Range	86%-94%	26%-80%	20%-72%	7-10	3-6	0-5

Table (2)  
Showing the functional evaluation results pre-, post and one year after the operation

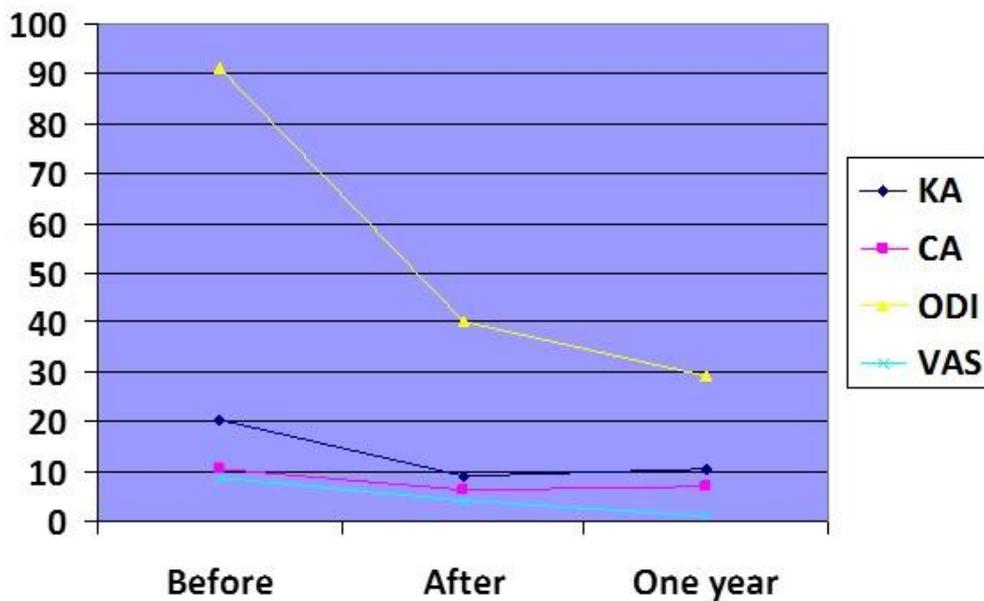


Figure (3)  
Radiological and functional evaluation results progress through the duration of the study

#### IV. DISCUSSION

The cementless stabilization method by vertebral expandable titanium device with DBM bone graft allowed adequate primary reduction and stable fixation through a less invasive percutaneous instrumentation. Pain relief and quality of life are better in comparison to traditional cement based methods that have many complications that may occur after years such as cement loss or leakage in the disc or epidural spaces in the some severe fracture types.

Our study showed that the height of the vertebral body restoration was successful which is proved by KA measurement revealing significant improvement ( $P = 0.002$ ) from  $20.33 \pm 6.16$  o ( $10$  o  $-27$  o) preoperative comparing with  $10.55 \pm 4.11$  o ( $2$  o  $-26$  o) after surgery which was similar to Eschler et al study which reported that all cases in the study showed decrease of KA of the adjacent vertebral segments with improvement from  $14.5 \pm 2.2$  o ( $6$  o  $-19$  o) preoperative comparing to  $10.7 \pm 3.0$  o ( $7$  o  $-21$  o) postoperative . Slight insignificant ( $P > 0.05$ ) loss of reduction was observed  $10.81 \pm 4.61$  o ( $5$  o  $-26$  o) shown in our study after one year of follow up in comparison to  $12.1 \pm 2.9$  o ( $3$  o  $-21$  o) which reported in another study . Another study by Eschler et al showed that KA improved significantly ( $p < 0.001$ ) from  $13.7 \pm 1.2^\circ$  ( $2-21^\circ$ ) preoperative to  $7.4 \pm 0.8^\circ$  ( $2-17^\circ$ ) postoperative with a slight loss of reduction to  $8.3 \pm 1.1^\circ$  ( $2-18^\circ$ ), in the follow up period.

The Cobb angle as parameter for the sagittal alignment of the fracture level showed significant improvement ( $P = 0.012$ ) from  $10.5^\circ \pm 4.27^\circ$  ( $1^\circ-20^\circ$ ) preoperatively to  $7.12^\circ \pm 2.99^\circ$  ( $4^\circ-14^\circ$ ) postoperatively. Eschler et al reported that improvement from  $10.1 \pm 1.8^\circ$  ( $6^\circ-14^\circ$ ) preoperative to  $8.3 \pm 1.2^\circ$  ( $5^\circ-13^\circ$ ) postoperative (28). Another study showed that The Cobb angle improved significantly ( $p < 0.002$ ) from  $9.6 \pm 1.1^\circ$  ( $2-28^\circ$ ) preoperative to  $6.0 \pm 0.9^\circ$  ( $1-22^\circ$ ) postoperative with final follow-up  $8.7 \pm 1.7^\circ$  ( $1-22^\circ$ ) angulation of Cobb angle was measured (30). While in our study during the duration of follow-up a slight insignificant ( $P > 0.05$ ) rekyphosis was observed  $7.13^\circ \pm 2.81^\circ$  ( $4^\circ-14^\circ$ ). Another study reported that six months after surgery  $8.9 \pm 1.1^\circ$  ( $5-12^\circ$ ) angulation was measured and 28 months after surgery was  $10.7 \pm 1.3^\circ$  ( $5-13^\circ$ ).



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Functional assessment of the surgery in our study showed that VAS improved significantly from  $8.80 \pm 1.13$  (7–10) preoperatively to  $4.2 \pm 1.27$  (3–6) postoperatively in comparison to  $8.8 \pm 3.5$  (8–10) preoperatively which improved to  $4.8 \pm 6.4$  (3–7) on the first day after surgery in a study conducted by Eschler et al. A further significant improvement ( $P = 0.018$ ) was noticed in our study during the follow up period one year after the surgery  $1.18 \pm 1.36$  (0–5) which agrees with the findings reported by Eschler et al as the final observed improvement was  $2.8 \pm 7.5$  (1–5) (28). Another study conducted also by Eschler et al showed that VAS scale accounted for  $7.6 \pm 0.5$  (2–10) preoperatively and improved significantly ( $p < 0.001$ ) to  $5.7 \pm 0.6$  (0–9) directly after surgery and further decrease to  $2.6 \pm 0.4$  (0–6) for final follow-up which agrees with our study findings.

Another functional assessment of the surgery in our study showed that statistically significant ( $P = 0.012$ ) decrease of ODI from ( $91.35\% \pm 2.24\%$ ) pre-operative to ( $40.3\% \pm 16.43\%$ ) immediately after the surgery and ( $29.40\% \pm 16.63\%$ ) one year post-operative. These results are similar to Eschler et al findings as they reported that the ODI confirmed moderate disability with  $26.3 \pm 8.1\%$  (10–53%) for six months follow-up with further declining tendency to  $20.5 \pm 3.6\%$  (6–30%) for final follow-up (28).

When our method was compared to other methods of management in terms of cost effectiveness, we found that the cost of our study was about 6600\$ while the cost of kyphon and truss were 5300\$ and 1300\$ respectively. (31) However, this difference in cost can be compensated with the facts of early recovery and back to work in patients of our study when compared to other methods of management. In other hand we need further studies to perform further cost effectiveness analysis comparison using an appropriate model.

## V. CONCLUSION

Minimally invasive vertebral expandable device with injection of DBM result in significant pain relive and better quality of life with less complication risks, make it a good alternative to established traditional cement based techniques. -

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