Effectiveness of Sublaminar Mersilene tape Augmented Pedicle Screws Fixation for Osteoporotic Vertebral Compression Fracture: Low-cost Modality

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Research Article

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Abstract

Background: Gradually kyphosis and collapse are a natural history of osteoporotic vertebral compression fractures (OVCF). The principle of OVCF is fixing instability, providing anterior support, and decompression. The osteoporotic spine has weak and rarified trabeculae in the cancellous bone and pedicles, which offers little resistance against screw pull-out. The sublaminar implant relies on the lamina for holds that is the strongest part of vertebrae. The study purpose was to assess the safety and efficacy of sublaminar mersilene tape augmented pedicle screws fixation as a novel and low-cost modality for OVCFs instrumentation fixation.

Methods: A retrospective study of 40 consecutive patients of the OVCFs. All patients were operated with open decompression, pedicle screw fixation, and sublaminar mersilene tape augmentation. Preoperative and postoperative clinical (visual analog scale [VAS], modified Oswestry disability index [M-ODI], neurologic deficit, revision surgeries, and infection) and radiological (axial collapse, fracture union, implant failure/back out,) parameters were compared to describe the utility of sublaminar mersilene tape augmented pedicle screws for OVCFs treatment.

Results: Complete neurological improvement was noted in 38 patients and two patients had Frankel Garde D neurology. The mean VAS was significantly improved from preoperative 8.98±0.60 to 2.76±0.54, final follow-up and M-ODI from 80.10±6.90 to 15.30±6.90. The mean local kyphosis angle was improved from 23.20°±5.90° preoperatively to 5.30°±3.9°postoperatively and 3.30°±2.50°loss of correction at final follow-up. There was no pseudoarthrosis and implant failure noted. No iatrogenic dural or nerve injury.

Conclusion: Sublaminar mersilene tape augmentation relies on the lamina for its hold, which is the strongest part of an osteoporotic vertebra. Sublaminar mersilene tape augmented pedicle screws fixation is a novel and low-cost modality for OVCFs. It provides significant improvement in clinical and radiological outcomes. This technique is an easy learning curve, user-friendly and safe, which makes this a viable alternative option for OVCFs fixation.

Introduction

The incidence of osteoporotic vertebral compression fractures (OVCF) is gradually increasing with the increasing life expectancy of the population [1, 2]. The OVCFs can lead to delayed union or non-union (13%) and lead to progressive collapse (30%) that can result in kyphosis with the possibility of neurological deficit (3%) [3]. The principles of OVCF treatment are fixing instability, anterior support, and decompression. The pedicle screw is most popular for spinal fixation nowadays [4, 5]. In an osteoporotic spine, pedicle screws are at greater risk of pull out due to poor hold at the bone-screw interface. A weak trabeculae in the cancellous bone and pedicle offers little resistance against screw pull out in osteoporotic vertebra [6, 7, 8]. The natural history of OVCFs is gradual kyphosis, collapse, and non-union that leads to implant loosening and backout. The ideal procedure for OVCF should be the least invasive, smaller surgery duration, minimal blood loss, without implant-related complications, faster recovery, and
provide a good neurological and functional outcome. Mersilene tape is a nonabsorbable, braided, sterile surgical suture composed of polyethylene terephthalate fibers, the mechanical, tensile strength of this material with a 5 mm width is 1460 N, which is equivalent to that of clinically available stainless steel wire [9]. Mersilene fiber tape has been used in orthopaedic surgery for many years for many applications and is also used in paediatrics spine deformity correction surgeries [10, 11]. The width (5mm width and less than 0.5 mm thickness) and strength of these pliable tapes seem to provide a useful addition to the armamentarium of the experienced surgeon [12]. Supplementary augmentation by sublaminar mersilene tape relies on the lamina for its holds which is the strongest part of an osteoporotic vertebra. The newer techniques for pedicle screw augmentation in OVCFs are time-consuming, require an additional cost and longer learning curves. The study objectives were to assess the safety and efficacy of supplementary used sublaminar mersilene tape to augment pedicle screws as a novel and low-cost modality of spinal instrumentation for OVCFs treatment.

**Materials And Methods**

This is a retrospective study of 40 consecutive patients of OVCF who were operated from June 2015 to May 2018. Institutional ethics committee approval and informed written consent from all patients taken before conducting this study.

**Inclusion criteria**

1. Age 60-80 years
2. DEXA scan T score <2.5
3. Single level vertebral fracture
4. Loss of vertebral body height ≥50%
5. Neurological deficit (Frankel Grade C/D)
6. Minimum follow-up 24-months

**Exclusion criteria**

1. Other pathological fractures
2. Previously operated spine patients
3. Uncontrolled diabetes patients
4. Highly comorbid patients

**Clinical Assessment:**

a. Demographic data: Age, Sex, Mode of injury, Duration of injury to clinical presentation, duration of neurological deficit, Bone Density
b. Pain score - Visual Analog Score [VAS]
c. Modified Oswestry Disability Index [M-ODI]
d. Neurology - Frankel Grade

Radiological Assessment:

Standing spine radiographs, Magnetic Resonance Imaging, and computed tomograms (CT) scan, DEXA scan.

Radiological parameters: Local kyphosis angle measured from the superior endplate of immediate, intact cephalic vertebrae, and the inferior endplate of intact caudal vertebrae [9]. Fusion status was assessed by radiographs and dedicated CT scan of the surgical area after 9-months of the surgery.

The following parameters were considered to assess the safety and efficacy of the use of sublaminar mersilene tape augmentation in OVCFs fixation.

Safety parameters

- Neurologic deficit
- Implant failure/back out
- Revision surgeries
- Infection.

Efficacy parameters

- Back pain score
- Kyphosis angle correction
- Fracture union

Surgical procedure

A standard midline posterior approach was used. After midline exposure, paraspinal muscles were elevated and retracted bilaterally from spinous processes, laminae; pars interarticularis up to the tip of transverse processes. This not only helped in the wide exposure of the interlaminar area for SMT augmentation but also assisted in preparing a good fusion bed for bone grafting.

Stage-1: (Pedicle screw fixation, corpectomy, Decompression and fusion)

Pedicle screws were inserted in two vertebral levels above and two vertebral levels below fracture and one side connected with a connecting rod. After connecting rods and screw, bilateral hemilaminectomy at fracture level, with care to preserve medial one-third facetectomy was performed. A subtotal corpectomy of the fractured vertebral body was performed with an osteotome and curettes, leaving the lateral and anterior vertebral body wall in place. If a retropulsed bone fragment was recognized, it was pushed anteriorly with the use of a reverse-angled curette, with great care taken to avoid retraction of the dura. By gently distracting the spinal nerve on the more severely injured side. A 2 cm incision was placed over the
posterior superior iliac spine (PSIS) to harvest cancellous iliac crest autograft. A titanium mesh cage was inserted into the intervertebral space, which was of 80% to 100% length of fractured segmental height and filled with bone graft. The cage was then longitudinally aligned and set parallel to the axis of the spinal column using an impactor. The cage was placed in the center of the fractured body with the assistance of biplanar fluoroscopy. Compression was then applied across the fractured level to create a press fit for the cage. The nerve root was rechecked for any compression before placing the other rod and final tightening set caps. A crosslink was inserted in the standard fashion. Gelfoam was placed over the exposed dura.

**Stage-2: Sublaminar mersilene tape augmentation**

Supra/interspinous ligament and ligamentum flavum were excised, and a sublaminar space was created at each level for passing wires. After exposing the sublaminar spaces, a double loop of 20 gauge “cold cured stainless steel wires with ethibond suture at the end” was inserted around the laminae of to be instrumented cephalad and caudal vertebral levels by insertion, advancement, roll through, and pull-through technique. Needle for 35mm mersilene tape cut and removed. Mersilene tape passed through the lamina with help of an ethibond suture loop. On each side, each mersilene tape passed through the connecting rod with a cephalad end ending inside it, and a caudal end outside the connecting rod at all levels. These mersilene tapes were sequentially tightened clockwise. The extra length of mersilene tape was cut.

Posterolateral fusion with facet fusion with morselized cancellous autograft was performed. A surgical drain was inserted in all patients. Multilayer closure was performed. [Fig.1]

**Statistical analysis**

Patients preoperative and postoperative follow-up data collected. Statistical analysis was performed using SPSS software version 20.0 (SPSS Inc., Chicago, IL, USA) and paired Student's t-test. Data were presented as the means ± standard deviations A value of less than 0.05 was considered statistical significance.

**Results**

A total of 40 patients with OVCFs were included in this study. There were 16 males and 24 females and the average age was 72.22 years (61–80 years). The average follow-up period was 36.4 months (24–54 months). Level of fracture with the following frequency: T10 N=1, T11 N=6, T12 N=15, L1 N=17 and L2 N=1. The mean surgical time was 203.22 ± 21.5 min (range from 150 to 230 min). The mean blood loss was 430.5 ± 50.6 ml (ranging from 150 to 1200 ml). [Table 1]
Table 1
Patient demographic data (n = 40)

<table>
<thead>
<tr>
<th>Variables (mean)</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age</td>
<td>72.22 (61–80)</td>
</tr>
<tr>
<td>Male: Female Ratio</td>
<td>16:24</td>
</tr>
<tr>
<td>Delay in presentation (weeks)</td>
<td>14.31 (12–24)</td>
</tr>
<tr>
<td>Dexa scan T score</td>
<td>−3.89 (−2.6 to −5.4)</td>
</tr>
<tr>
<td>follow-up period (months)</td>
<td>36.4 (24–54)</td>
</tr>
</tbody>
</table>

Fracture level

| T10 | 01 |
| T11 | 06 |
| T12 | 15 |
| L1  | 17 |
| L2  | 01 |

Surgical Data

| Duration of Surgery (min)       | 203.22 ± 21.5 |
| Intraoperative blood loss(ml)   | 430.5 ± 50.6  |
| Hospital stay (Days)            | 6.2 ± 2.8     |

Efficacy Parameter Results

- Back pain score: The mean VAS for back pain was significantly improved from preoperative 8.98 ± 0.60 to 4.00 ± 0.54 at 1-month postoperative and 2.76 ± 0.54 at final follow-up (p < 0.05). Modified ODI for back pain was improved preoperatively from 80.10 ± 6.90% to 26.50 ± 6.90% at 1-month postoperative and 15.30 ± 6.90% at final follow-up (p < 0.05). [Table 2]
- Kyphosis angle: The mean local kyphosis angle was improved from 23.20°±5.90° preoperative to 5.30°±3.9°immediate postoperative and 8.60°±4.60°at final follow-up. There was 3.30°± 0.50°° loss of correction at final follow-up. [Table 3]
- There were no pseudoarthrosis and implant failure. No iatrogenic dural or nerve injury.
Table 2
Functional results of patients

<table>
<thead>
<tr>
<th></th>
<th>Mean ± SD</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>VAS for Back</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Preoperative</td>
<td>8.98 ± 0.60</td>
<td>&lt; 0.05</td>
</tr>
<tr>
<td>Postoperative 1 month</td>
<td>4.00 ± 0.54</td>
<td></td>
</tr>
<tr>
<td>Final follow-up</td>
<td>2.76 ± 0.54</td>
<td></td>
</tr>
<tr>
<td><strong>Modified ODI for Back (%)</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Preoperative</td>
<td>80.10 ± 6.90</td>
<td>&lt; 0.05</td>
</tr>
<tr>
<td>Postoperative 1 month</td>
<td>26.50 ± 6.90</td>
<td></td>
</tr>
<tr>
<td>Final follow-up</td>
<td>15.30 ± 6.90</td>
<td></td>
</tr>
</tbody>
</table>

VAS: Visual Analog Score; M-ODI: Modified Oswestry Disability Index; SD: Standard deviation

Table 3
Radiological parameters

<table>
<thead>
<tr>
<th>Variables</th>
<th>Value (Mean ± SD)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pre-Operative</td>
<td>23.20°±5.90°</td>
</tr>
<tr>
<td>Immediate postoperative</td>
<td>5.30°±3.9°</td>
</tr>
<tr>
<td>Final follow-up</td>
<td>8.60°±4.60°</td>
</tr>
<tr>
<td>Correction</td>
<td>18.20°±5.3°</td>
</tr>
<tr>
<td>Loss of correction</td>
<td>3.30°± 2.50°</td>
</tr>
</tbody>
</table>

Safety Parameter Result:

- Neurologic deficit: Preoperative 28-patients had Frankel-D that was completely improved postoperatively with Frankel Grade-E. 12-patients had Frankel-C neurology out of them 10 patients completely recovered with grade E and 2 had Frankel Grade-D. [Table 4].
Table 4

Pre- and post-operative neurological status using Frankel grading

<table>
<thead>
<tr>
<th>Pre-operative</th>
<th>No of patients</th>
<th>Post-operative</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>A</td>
</tr>
<tr>
<td>C</td>
<td>12</td>
<td>2</td>
</tr>
<tr>
<td>D</td>
<td>28</td>
<td>28</td>
</tr>
</tbody>
</table>

There was no implant-related complication found in follow-up. One patient had a proximal junctional failure during follow-up. That was managed surgically with an extension of spinal fixation. One patient had a superficial wound infection that was recovered with repeated dressing antibiotics. One patient had a deep surgical site wound infection which required wound debridement and finally, it was healed by secondary intention. [Table 5]

Table 5

Complications

<table>
<thead>
<tr>
<th>Complications</th>
<th>Number</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Superficial infection</td>
<td>1</td>
<td>2.5</td>
</tr>
<tr>
<td>Deep infection</td>
<td>1</td>
<td>2.5</td>
</tr>
<tr>
<td>Proximal junctional failure</td>
<td>1</td>
<td>2.5</td>
</tr>
<tr>
<td>Pedicle screw breakage</td>
<td>0</td>
<td>0.0</td>
</tr>
<tr>
<td>Screw Pull Out</td>
<td>0</td>
<td>0.0</td>
</tr>
</tbody>
</table>

Discussion

The vertebral compression fractures are common sequelae of osteoporosis and it comprises approximately 40% of osteoporotic fractures annually [13]. VCFs can lead to delayed union or non-union (13%) and lead to progressive collapse (30%) that can result in kyphosis with the possibility of neurological deficit (3%) [14]. The principles of OVCF treatment are fixing instability, anterior support, and decompression. The pedicle screws are most commonly used nowadays for the treatment of many spinal fixation surgeries and it is the strongest fixation in spine pathology like degenerative spine and deformity correction [15]. The ideal procedure for OVCFs in these fragile elderly patients should be the least invasive, smaller surgery duration, minimal blood loss, without implant-related complications, faster recovery, and provide a good neurological and functional outcome. The efficacy of various approaches is well documented in the literature. Anterior approach has high morbidity and mortality in elderly patients [16–21]. When anterior or posterior column fragments compress the spinal cord in OVCF, it is better to decompress all three columns of the spine. There are benefits of the posterior approach over the anterior transcavitary approach. Most surgeons are familiar with the posterior approach and it is less morbid in
elderly patients, it decompresses the spinal cord globally 360°. The posterior approach permits all three-column reconstruction and fusion [22]. It also allows up to 20–25° kyphosis correction segmentally [23]. The laminae are the strongest part of the osteoporotic vertebral body [24]. The sublaminar implant relies on the strongest extracortical part of the vertebra for hold. The mersilene tape augmentation technique is similar to sublaminar stainless steel wiring, but the wire has some disadvantages. Stainless steel and pedicle screw-rods have different materials, it may lead to galvanic corrosion between titanium alloy and stainless steel and may cause implant loosening. As an alternative to the metal wire, we have used mersilene fiber tape for the augmentation of pedicles in our study. The mersilene fiber tape is a high-strength material with soft, flexible, flat, and 5mm wide. These properties are important to avoid neural tissue damage and reduce laminar cut-out as a compress to stainless steel wire. A mersilene is radiolucent material so there is no artifact and it makes postoperative bony fusion monitoring better. Mersilene tape is also cost-effective, one-tenth of the cost compared to vertebroplasty cement and imported third-generation titanium implants. This is a novel method with the potential to reduce early-onset pedicle screws loosening and increase fixation strength. The sublaminar mersilene tape augmentation procedure is very easy to learn, user-friendly, safe, and effective, making it suitable for wider and global applications more in developing countries.

Lack of a comparative study group, short follow-up, and smaller data size was a limitation of our study. Longer surgical exposure is debatable. Future prospective comparative studies with a larger patient number and longer follow-up are required for confirmation of our results.

Conclusion

Sublaminar mersilene tape augmented pedicle screws fixation is a novel and low-cost modality for OVCFs. This supplementary augmentation relies on the lamina for its hold, which is the strongest part of an osteoporotic vertebra. It provides significant improvement in clinical and radiological outcomes. This technique is an easy learning curve, user-friendly, and safety makes this a viable alternative option for OVCFs fixation.

Declarations

Financial support and sponsorship: Nil

Conflicts of interest: There are no conflicts of interest.

References


**Figures**
Figure 1

Sublaminar mersilene tape augmentation technique. (A) After creating sublaminar space at each level for passing wires followed by ethibond suture loop with mersilene tape by insertion, advancement, roll through, and pull-through technique. (B, C) On each side, each mersilene tape passed through the connecting rod and both ends of each tape sequentially tightened. (D) Final clinical picture after
completion of sublaminar mersilene tape augmentation. (E) Mersilene tape augmentation on the bone model.

Figure 2

(A,B) 67-year-old female presented with Frankel Grade C neurology. Preoperative radiograph shows L1 osteoporotic fracture with local kyphosis; (C) CT Scan Horos Image shows osteoporosis given in HU
units. (D, E, F) T2 image of Lumbar spines- L1 wedge fracture with cord compression.

Figure 3

(A, B) Intraoperative images L1 wedge fracture instrumentation. (C, D) Immediate postoperative radiograph for the surgery.
Figure 4

(A, B) 3 months post-operative radiograph with posterior fixation and instrumentation of fracture body with correction of local kyphosis (C) Final follow-up lateral radiograph demonstrating healed fracture with minimal loss of correction.