Percutaneous Vertebral Augmentation and Reconstruction with an Intravertebral Mesh and Morcelized Bone Graft

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Citation

Abstract
This presentation is to discuss the percutaneous outpatient vertebral augmentation (VA) and reconstruction with a polyethylene intravertebral mesh (OptiMesh® Spineology, Inc., Stillwater, MN, USA) and biologic morcelized bone graft, the surgical indications, operating technique, case illustrations and clinical outcome. In the past vertebroplasty and kyphoplasty have provided excellent pain relief for vertebral compression fracture (VCF), but with a high incidence of complication; i.e., leakage of Polymethylmethacrylate (PMMA) into spinal canal or vasculature, cardiopulmonary complication, and adjacent vertebral fracture.

This percutaneous VA system, is designed, developed, and used for VCF treatment without above complications, and is a true biologic vertebral reconstruction. An OptiMesh® consists of, multi-strand polyester mesh or sac to be packed with specially ground bone chips or morcelized bone chips inside the mesh device to create a hyperdensed graft pack for restoring height resulting in pain relief.

This minimally invasive outpatient percutaneous OptiMesh® VA provides an efficacious and controlled delivery mechanism to stabilize and treat painful osteoporotic, traumatic and neoplastic VCF. In addition it can easily be used as an excellent intravertebral spacer and for intravertebral spinal fusion/fixation.

INTRODUCTION
Approximately 700,000 patients per year, in the United States, are afflicted with vertebral compression fracture (VCF) secondary to osteoporosis. The lifetime risks of symptomatic vertebral compression fracture (VCF) secondary to osteoporosis is 16% for females, and 5% for males. Osteoporotic VCF survival rate, five years after diagnosis made, is 61%. VCF affects 25% of females over the age of 50 and 40% of females over the age of 80. VCF is defined as the reduction of vertebral body (VB) height by 15% or greater and can be classified by the degree and type of deformity, which includes wedge, biconcavity, and compression fractures. The most commonly compressed VB levels are lower thoracic vertebrae, L1 and L4. Of course, there is also post-traumatic type of VCF and other types of pathology causing VCF. Traditional conservative treatment of vertebral body compression fracture includes analgesics, immobilization, muscle relaxant, physiotherapy, and external bracing, if indicated. The resulting painful collapse and kyphosis leads to the development of chronic pain syndrome in one-third of these patients. In greater than 50% of osteoporotic patients with more than one VCF, activities of daily living cannot be performed without assistance. The resulting spinal deformity from VCF is the increased risk factor for hip fracture, cardio pulmonary complication, and physical debilitation from inactivity.

Many other potential consequences are obvious with chronic severe pain, decreased lung function, inactivity, severe anxiety, and depression with 23% increase in mortality rate. The goals of vertebral augmentation are; correction of VB deformity, significant reduction of pain, improvement of quality of life, to improve ability to perform daily living activities and to lower complication rate, e.g., hip fracture, cardio pulmonary complication and physical debilitation from inactivity, subsequent adjacent VCF and reduced mortality rate.

Historically, vertebroplasty and kyphoplasty have provided excellent pain relief for VCF, but with very high incidence
of complication, i.e., leakage of Polymethylmethacrylate (PMMA) into spinal canal or vasculature, cardiopulmonary complication, and adjacent vertebral fracture. Therefore, vertebral augmentation (VA) is indicated for painful VCF.

A percutaneous vertebral augmentation system with a polyethylene mesh sac (OptiMesh® Spineology, Inc., Stillwater, MN) and morcelized bone graft, is designed, developed and used for VCF treatment without above complications, and is a true biologic vertebral reconstruction. This provides excellent pain relief and fewer technological risks and is osteoconductive and osteoinductive.

With accumulated surgical experience in percutaneous endoscopic minimally invasive spinal surgery, this vertebral augmentation procedure can be easily performed percutaneously with minimal or no blood loss, for vertebral body reconstruction, for excellent pain relief, and to improve quality of life.

**INDICATIONS**

Treatment criteria for this polyethylene mesh sac and morcelized bone graft (OptiMesh®) percutaneous vertebral augmentation system are:

1. Treatment of painful osteoporotic or post-traumatic vertebral compression fracture and secondary kyphosis
2. Intractable pain in a focal band like radiation that is worse with weight bearing and is relieved with rest or in a recumbent position
3. Intractable pain unrelieved by analgesics and narcotics
4. Painful compression fracture of vertebra due to osteoporosis, aggressive hemangioma, 15 metastatic disease, osteogenic imperfecta, trauma or vertebral osteonecrosis
5. Chronic trauma fracture with non-union of fracture fragments
6. Internal stabilization of unstable post-traumatic vertebral compression fracture
7. Patient with multiple compression fractures with risk of pulmonary compromise

**ABSOLUTE CONTRA-INDICATION IN THE FOLLOWING SITUATIONS**

1. Patient with painless asymptomatic stable VCF
2. Massive “burst” osteoporotic or non osteoporotic fractures
3. Patient with fracture that is clearly responding to medical therapy
4. Osteomyelitis of target vertebra
5. Prophylactic treatment with no evidence of fracture
6. Uncorrected coagulation disorder or bleeding disorder

**RELATIVE CONTRA-INDICATION IN THE FOLLOWING SITUATIONS**

1. Medically high risk patient or unstable patient
2. Patient with retropulsed fragment causing spinal canal compromise of greater than 20%
3. Restless patient, unable to lie prone for the entire procedure under IV conscious sedations
4. Patient with pain due to herniated spinal disc, facet arthropathy, spinal stenosis or degenerative change and not due to VCF
5. Pathological fracture with tumor significantly extending into the spinal canal

**OPERATING ROOM SET UP**

Both local anesthesia (under IV conscious sedation) and general anesthesia can be used. It is Author's preference to use local anesthesia with IV conscious sedation for a single level, and general anesthesia for multiple levels.

**PATIENT POSITIONING (FIG. 1A, B, C):**

In prone as for thoracic or lumbar surgery on a radiolucent Jackson table or a Kambin frame. Digital C-arm fluoroscopy with image intensifier is to be utilized for monitoring of the procedure for radiographic visualization of the position and surgical instrumentation. The patient is prepped and draped in the usual sterile fashion.
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SURGICAL TECHNIQUE

IMPLANT DEVICE (FIG. 2):

A polyethylene mesh sac (OptiMesh®) consists of three dimension multi-strand polyester mesh or sac to be packed with bony allograft inside the polyethylene mesh with specially ground bone chips or morcelized bone chips inside the mesh sac device creating a hyperdensed graft pack for restoring height resulting in pain relief.

Figure 2
Figure 2: Polyethylene mesh sac (OptiMesh™) and 2 sac packed with bone chips

GRANULAR MECHANICS

Granules flow like liquid when uncontained but act like solid when contained. The granular packs are known to be porous even in their most rigid state.

SURGICAL PROCEDURES

INSTRUMENTS AND PREPARATION:
SURGICAL INSTRUMENTS ARE DEMONSTRATED IN THE ILLUSTRATIONS.

The procedure is performed under fluoroscopic guidance with a guide pin to the desired target position as “50/50 image” on AP and lateral view of the spinal vertebra. Usually, the stylette or the guide pin starts approximately 5-10cm from mid-line (thoracic 5-7cm and lumbar 8-10cm) para-pedicularly (Fig. 3a), approximately 45° angle to contact the superior lateral quadrant of the pedicle and vertebral body junction. The portal of entry is extrapedicular approach (Fig. 3 b, c), with stylette inserted just lateral and superior to the pedicle on the lateral view, centered within the pedicle although anatomically it would be lateral to it. On the PA view the needle should appear to enter the bone at the superior lateral aspect of the vertebral body with a trajectory aiming inferomedially, approximately 20 degrees towards the spine process, and toward the desired target position as “50/50 image” on AP view (Fig. 4a). On the lateral view, the trajectory is directed toward the anterior inferior aspect of the vertebral body and toward the desired target position as “50/50 image” on lateral view (Fig. 4b). The spinal cord is less at risk with a more lateral starting position than the transpedicle approach, especially at the thoracic spine region. Lateral deviation risks pneumothorax. Also lateral vertebral body violation can injure the segmental artery, great vessels or lungs.

Figure 3
Figure 3: Portal of entry and trajectory for the guide pin for desired position “50/50 image”

Figure 4
Figure 4: Guide pin trajectory toward and beyond desired target position of “50/50 image” (red dot) under fluoroscopy

A dilator is inserted over the guide pin and impacted into the vertebra (Fig. 5 a, b). Then a working channel or cannula (access portal) is placed over the dilator and secured to the
metal frame connected to the operating table (Fig. 6a,b,c).

**Figure 5**
Figure 5: Dilator of the guide pin impacted onto the vertebra

![Figure 5: Dilator of the guide pin impacted onto the vertebra](image)

**Figure 6**
Figure 6: Working cannula placed over the dilator

![Figure 6: Working cannula placed over the dilator](image)

After removal of the guide pin and dilator, a drill was utilized to create a cavity in the vertebra (Fig. 7a,b,c).

**Figure 7**
Figure 7: Drilling the vertebra

![Figure 7: Drilling the vertebra](image)

The polyethylene mesh sac (OptiMesh®) size is based on the anticipated height, drill depth, and the cavity created by the shaper (Fig. 8a), after drilling to insure good fit for the cavity created and mesh pore distension (Fig. 8b).

**Figure 8**
Figure 8: Shaper

![Figure 8: Shaper](image)

The polyethylene mesh sac is inserted through the working channel (access portal) into the vertebral cavity (Fig. 9a, b). Then the mesh is filled with morcelized bone graft from diverted fill tubes (Fig. 10a, b, c, d, e).

**Figure 9**
Figure 9: Mesh sac is inserted through the working channel (access portal) into the vertebral cavity

![Figure 9: Mesh sac is inserted through the working channel (access portal) into the vertebral cavity](image)
After compacting the mesh with the bone chips, the neck of the mesh sac is crimped (Fig. 11 a,b). The instruments are removed and the wound is closed.

Figure 11
Figure 11: The mesh sac is crimped at the neck and is detached, before the instruments are removed.

ILLUSTRATIONS STEP-BY-STEP (FIG. 12A-F)

Step 1 (Fig. 12a) Insert the guide pin
Dilator placed over the guide pin

Step 2 (Fig. 12b) Access portal over dilator
Dilator and guide pin are removed
Drill initiates cavity creation

Step 3 (Fig. 12c) Cavity is enlarged with shaper

Step 4 (Fig. 12d) Insert OptiMesh® implant or mesh sac

Step 5 (Fig. 12e) OptiMesh® filled with morcelized bone graft

Step 6 (Fig. 12f) OptiMesh® is detached
Instruments removed

CASE ILLUSTRATIONS
Case 1 (Fig. 13a-e) is a 70 year old male with severe thoracolumbar pain on activity from T10 post-traumatic osteoporotic vertebral compression fracture. Under conscious sedation and local anesthesia, OptiMesh® vertebral augmentation was performed as an outpatient. The patient had immediate excellent postoperative pain relief (VAS scores) and was discharged from the surgical unit in two hours.
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Figure 13
Figure 13: 70 year old male with severe thoracolumbar pain on activity from T10 osteoporotic post-traumatic vertebral compression fracture (VCF).

Case 2 (Fig. 14a-d) is a 72 year old female with severe thoracolumbar pain from T12 post-traumatic osteoporotic vertebral compression fracture. IV conscious sedation and local anesthesia were utilized for OptiMesh® vertebral augmentation with immediate significant postoperative pain relief right after the outpatient surgery and was discharged from the surgical unit in one hour.

Figure 14
Figure 14: 72 year old female with severe thoracolumbar pain from T12 post traumatic osteoporotic vertebral compression fracture (VCF).

Case 3 (Fig. 15a-e) is a 71 year old female manager with painful post-traumatic osteoporotic compressive T7 fracture. As an outpatient under IV conscious sedation and local anesthesia, OptiMesh® vertebral augmentation was performed. She had immediate postoperative almost complete pain relief (VAS) and returned to work in three days. Seven weeks after surgery her CT scan demonstrated the evidence of osteointegration of the bone graft at T7 vertebra.

Figure 15
Figure 15: 70 year old female manager with painful post-traumatic osteoporotic wedge T7 vertebral compression fracture (VCF).

DISCUSSION
Painful osteoporotic fractures significantly reduce quality of life and are a significant risk factor for hip fracture, for secondary pulmonary insufficiency, physical disability from inactivity and increased mortality among the VCF patients. The economic burden related to management of the osteoporotic VCF has been estimated to be $700 million per year. While success in producing pain relief has been reported by many authors using PMMA techniques, numerous problems have developed. There is a risk of leakage into the disc or paraspinal region, into spinal neural foramen and spinal canal causing secondary significant neurological complications necessitating immediate surgery. Some have resulted in permanent neurological deficit in spite of immediate evacuation of PMMA. Interestingly, the incidence of compressive complication from cement leakage is higher with kyphoplasty than vertebroplasty, perhaps related to higher incidence of surgical pedicle fracture. Also, hypotension may be produced by absorption of PMMA.
Occasionally from its cardiotoxic and arrhythmogenic properties. Deaths have been documented from these procedures, pulmonary embolism and fat embolism have also been reported. Of course, incidence of adjacent level fracture from VCF is as high as 52% after vertebroplasty, 29% for kyphoplasty are significant.

Minimally invasive percutaneous vertebral augmentation with intravertebral polyethylene mesh sac (OptiMesh®) is a new fill material containment technology for use in the minimally invasive vertebral biologic reconstruction procedure. It consists of a polyethylene mesh sac that is introduced into the vertebral body and filled with morcelized bone allograft. Compaction of the allograft bone inside the OptiMesh® device creates a hyperdense graft pack capable of reducing the fracture and restoring height by realigning fracture fragments resulting in pain relief and functional improvement.

Obvious advantages of percutaneous vertebral augmentation with an intravertebral polyethylene mesh sac (OptiMesh®) filled with morcelized bone graft, over vertebroplasty and kyphoplasty are numerous. It includes no risk of leakage of PMMA into the spinal canal causing neurological complication or into the vasculature system, with cardio-pulmonary complications including cardio-toxicity, arrhythmia, and pulmonary embolism, and even lower risk of fatty embolism, indication for broader spectrum of pathology and the prospect of bone fusion and integration of the prosthesis over time by using bone rather than PMMA. The physical properties of the bone graft more closely approximate those to the adjacent vertebral segment in density tend to avoid subsequent adjacent vertebral fracture. The bony construct is also osteo-conductive and osteo-inductive to accomplish biologic vertebral reconstruction. It can be used to treat painful spinal hemangioma, other osteolytic vertebral lesions and other types of VCFs.

CONCLUSION

1. Minimally invasive percutaneous vertebral augmentation with intravertebral mesh (OptiMesh®) and bone graft provides an efficacious and controlled delivery mechanism to stabilize and treat painful osteoporotic, traumatic and neoplastic VCF, and also avoids serious complications from PMMA.

2. Due to the osteoconductive and osteoinductive properties, it can be used to create biologic vertebral reconstruction. This mesh containment eliminates complications of intra-vascular embolism, spinal canal encroachment, from PMMA application in Vertebroplasty and Kyphoplasty, and subsequent VCF. The adjacent vertebra integrity should be more protected by the construct with a similar elasticity and physical characteristics of the morcelized bone, more matched to that of adjacent bone than PMMA.

3. Patient satisfaction and excellent clinical outcome are achieved with this minimally invasive vertebral augmentation technique.

References

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