A novel percutaneous system for bone graft delivery and containment for elevation and stabilization of vertebral compression fractures

Technical note

SANDI LAM, M.D., AND LARRY T. KHOO, M.D.

Division of Neurosurgery and Comprehensive Spine Center, University of California at Los Angeles, California

Object. Vertebroplasty and kyphoplasty are minimally invasive procedures used to treat persistently symptomatic vertebral compression fractures (VCFs). Both interventions usually involve injection of polymethyl methacrylate (PMMA). The purpose of this technical note was to review the theory and surgical technique for a novel percutaneous system for fracture reduction and stabilization of VCFs by using bone graft.

Methods. This technical note highlights the Optimesh system as an alternative method of minimally invasive VCF reduction and stabilization with the delivery of a bone graft containment device. Instead of using PMMA as in vertebroplasty or kyphoplasty, this system allows the delivery of allograft and/or autograft bone, with its osteoinductive, osteoconductive, and osteogenic properties.

Conclusions. This system allows for restoration of sagittal alignment of the spine with direct control of bone graft delivery by using a mesh graft containment device that allows for ingrowth of new bone and vascular tissue.

KEY WORDS • vertebral compression fracture • vertebroplasty • kyphoplasty • fracture reduction • percutaneous vertebral augmentation • osteoporosis

As the population ages, an increasing number of people are sustaining VCFs secondary to osteoporosis. Traditionally these fractures have been treated nonsurgically, but clinical implementation of operative innovations such as vertebroplasty and kyphoplasty have contributed to a growing body of literature about percutaneous vertebral augmentation. Despite heightened interest in VCFs, there remains a void in scientific knowledge about the natural history of these injuries, and there are no prospective randomized studies establishing the benefits of percutaneous vertebral augmentation procedures over nonsurgical treatment.

A number of case series are available that document the vertebroplasty and kyphoplasty experience. Both procedures generally use PMMA, which polymerizes, conferring load-bearing capacity and stiffness to the fractured vertebral segment. Vertebroplasty involves direct injection of PMMA into the compressed VB, whereas kyphoplasty involves the use of an inflatable balloon tamp to create a void in the compressed VB while restoring its height, with the void subsequently filled with PMMA. Neither procedure delivers osteoconductive or osteoinductive materials for vertebral augmentation, and thus there is no potential for remodeling or incorporation for the injected PMMA. Although the exact mechanism by which these procedures provide symptomatic relief is not clear, restoration of vertebral stiffness and load-bearing capacity is thought to eliminate painful micromotion and also to restore normal sagittal alignment of the spine, counteracting the increased forward bending moment caused by the kyphotic deformity from VCFs.

An alternative to vertebroplasty and kyphoplasty is a novel system for treatment of VCFs, which provides minimally invasive delivery of allograft or autograft bone into an expandable mesh graft containment device within the involved VB. Although PMMA provides biomechanical stiffness and load-bearing capability, it is limited in its lack of potential for biological activity, incorporation, or remodeling once it is deposited in bone. Also, the use of bone cement has been associated with reported cases of morbidity and death.

The Optimesh system (Spineology, Inc., Stillwater, MN) combines the advantages of minimally invasive surgical access with the ability to deliver bioactive and biomechanically load-bearing injectable bone graft material into the fractured VB, restoring vertebral height and sagittal alignment, providing structural stability by withstanding physiological loading, and allowing for incorporation of the graft material into native vertebral bone (Fig. 1). An allograft bone graft is prepared in granular flowable form.

Abbreviations used in this paper: CT = computerized tomography; PMMA = polymethyl methacrylate; VB = vertebral body; VCF = vertebral compression fracture.
and is thus deliverable much like PMMA, with the advantages of osteoconductivity with corticocancellous bone chips and osteoinductivity with demineralized bone matrix (Fig. 2). This mixture can also be supplemented with morselized autograft bone or bone marrow aspirate to provide further osteogenic potential. We describe the use of the Optimesh system for percutaneous augmentation of vertebral fractures by delivery of an expandable bone graft containment device, and we outline this attractive alternative to vertebroplasty and kyphoplasty, which traditionally use PMMA as the load-bearing vertebral augmentation material (Figs. 3 and 4).

Description of Technique

As with most vertebroplasty and kyphoplasty procedures, the patient is positioned prone on a radiolucent table with adequate padding. Intraoperative image guidance is essential in this procedure to localize and delineate the extent of the fracture, and to guide instrument placement, minimize the risk of neural and soft-tissue injury, avoid pedicle disruption, assess fracture reduction, and assess volume and placement of bone graft (Fig. 5). Biplanar fluoroscopy is typically adequate for visualization during this procedure. If available, CT guidance may also be used intraoperatively in place of fluoroscopy or to supplement this modality in patients with difficult anatomy.2,9,28 Choice of anesthesia must be made jointly by the anesthesia team and the surgical team, taking into account the patient’s overall medical condition and the surgeon’s technical considerations for the case.43 Because routine vertebroplasty and kyphoplasty are often performed with the patient receiving sedation and local anesthesia and remaining awake to give feedback, this is similarly feasible for the Optimesh procedure performed by an experienced surgeon.

Sterile technique is crucial as in all surgical cases. The patient is thus prepared and draped in a sterile fashion. The procedure begins by gaining access to the central–anterior portion of the VB with the aid of intraoperative image guidance. This can be achieved using a transpedicular or posterolateral/parapedicular approach. Currently the standard working channel for the Optimesh system has an outer diameter of 8 mm and an inner diameter of 7.75 mm; thus the parapedicular approach is advocated to avoid pedicle disruption and spinal canal intrusion.

The guide pin is directed to the entry point at the superior and lateral margin of the pedicle on the anteroposterior or fluoroscopy projection, and at the posterior part of the

Fig. 1. Photograph showing the Optimesh graft containment device in its unfilled state (left), and in its filled state (right).

Fig. 2. Photograph showing allograft bone material prepared for the bone filling tube.

Fig. 3. Preoperative and postoperative lateral x-ray films showing a VCF, with some restoration of VB height after implantation of the Optimesh device filled with allograft bone.

Fig. 4. Preoperative and postoperative CT scans of three-level Optimesh implantations for treatment of three vertebral fractures.
VB at the junction of the pedicle on the lateral projection (Fig. 6). A stab incision is made laterally based on fluoroscopic localization of the target level, usually 5 to 10 cm laterally from the midline depending on the level, and the guide pin is advanced into the VB with the aid of biplanar fluoroscopic guidance. When the tip of the guide pin is in the central-middle part of the VB, a cannulated drill is used to prepare this entrance channel, into which the fixed-diameter working portal is placed. The position of the working portal is confirmed by fluoroscopic visualization to direct the proper placement of working tools and of the Optimesh device. Once the working portal is placed, it can be connected to the fixed bar system that attaches to the operating table. The portal is thus conveniently held in a fixed position for the remainder of the procedure.

Next, a small-diameter expandable reamer is passed through the working channel to the appropriate depth. This tool is available in various diameter models (5, 8, and 10 mm); these cutting blades can be serially expanded, controlled by a knob at the proximal end of the instrument, and produce cavities as large as 14, 22, and 25 mm, respectively. The cutting blades are retracted when the reamer is to be passed in or out through the fixed working cannula (Fig. 7). The Optimesh graft containment device is then passed through the tube (Fig. 8) into the cavity created by the reamer, and its position is confirmed with the aid of fluoroscopy. At this point, the Optimesh expandable mesh balloon may be filled with the graft material of choice, including PMMA, autograft bone, or allograft bone. The Musculoskeletal Transplant Foundation (Edison, NJ) has produced an allograft mixture specifically for use with the Optimesh system, and it is available in prefilled tubes. The graft material is loaded into long metal cylinders and delivered sequentially into and filling the Optimesh container that expands in situ within the VB. While packing the graft into the cavity with a tamp and mallet, the graft delivery tube should be rotated 90° at regular intervals to ensure even distribution of the graft material toward all directions in the cavity (Fig. 9). Increasing resistance from the cavity is transmitted through the column of graft material as the graft becomes packed more and more tightly. This correlates with fluoroscopy images as the cavity becomes more radiopaque and the VB fracture is reduced (Fig. 10). Once a sufficient amount of graft material has been delivered based on tactile cues from the filling system and visual assessment of the VB with image guidance, the Optimesh bag is detached from the distal tip of the cannula, and all instruments are withdrawn. The surgical wound is small, and can be closed by the surgeon’s chosen method.

**Graft Characteristics**

The Optimesh container is a hollow, expandable mesh balloon for retention and containment of bone graft or bone graft substitutes. The mesh material is a woven polyester (Dacron) that is also used in other applications such as vascular grafts. The finely woven mesh restricts leakage of graft material outside of the cavity but at the same time theoretically allows passage of liquids, cells, proteins, and other macromolecules, as well as vascular, osteoconductive, and osteoinductive ingrowth. The structural component of the Optimesh graft comes from its...
granular mechanical properties. The Optimesh system takes advantage of the unique characteristics of granular materials like bone graft in its finely ground and mor-selized form, creating the tools and conditions for delivery of the morselized bone graft through a small access portal. After the cavity is filled, further application of pressure can cause a granular material to change phase from a flowable liquid to a rigid solid. In its solid phase, the bone graft material is thus able to withstand physiological compression loads and not flow back through the access portal.\textsuperscript{18,19}

The surgeon may choose between a variety of graft materials, including combinations of autograft, allograft alone, allograft with bone marrow aspirate, allograft with bone morphogenic proteins, autograft extended with allograft, autograft with other bone graft extenders, or PMMA. There are preprocessed allograft mixtures that meet the specific flow characteristics of the Optimesh system graft delivery tubes and that are commercially available through a collaboration with the Musculoskeletal Transplant Foundation. The dry mix is a demineralized bone matrix and freeze-dried corticocancellous chip mixture that is hydrated with the patient’s blood or bone marrow aspirate immediately before application. Ground autograft may also be added to this mixture. Prefilled tubes have recently been developed that are ready for implantation into the Optimesh balloon without mixing.
DISCUSSION

Although Optimesh is in its infancy in terms of clinical implementation, this unique system combines minimally invasive surgical access with the ability to restore sagittal alignment of the spine and deliver an osteoinductive and osteoconductive intravertebral load-bearing bone graft that is expandable in situ for controlled delivery of a contained biological bone-filling material. The modulus of the solid Optimesh graft is close to that of bone, unlike the stiffer characteristics of solid PMMA. This may theoretically have an impact on reducing the relative risk of subsequent fracture in adjacent vertebral segments after treatment with Optimesh and allograft compared with vertebroplasty or kyphoplasty and bone cement, but this would need to be further investigated with biomechanical studies and prospective clinical studies.

With the increasing clinical implementation of vertebroplasty and kyphoplasty, there have been a number of serious complications, and others that are related to misplacement of instruments. Cement leakage has been well described, occurring both through cortical defects and through the venous system. Complications associated with percutaneous vertebral augmentation procedures include hypotension, pulmonary embolism, pulmonary cement embolism, cerebral cement embolism, adult respiratory distress syndrome, paraplegia due to spinal cord compression from cement leakage into the spinal canal, intravascular leakage and extension of cement, cement toxicity, epidural hematoma, and infection. There is also the hypothetical risk of thermal injury from the exothermic reaction during PMMA polymerization, a process that has resulted in a measurable increase in temperature in animal studies, although no clinical cases of thermal injury have been reported. These cement-related complications may be eliminated with the Optimesh system, which gives the option for use of allograft or autograft preparations in place of PMMA or other bone cements. There remain risks related to anesthesia and surgical instrumentation, as with any procedure. In theory, the reaming and manipulation of the VB during the approach, cavity creation, and fracture reduction may expose the patient to the same risks of embolism from the bone marrow, fat, and air as in kyphoplasty (especially during balloon inflation) and other orthopedic reaming, but this complication has not been encountered in clinical implementation of Optimesh procedures to date. There may be a risk of extrusion of the bone graft material as well, but with a discrete cavity created to receive it, the presence of the graft containment mesh, and the design adapted to take advantage of the granular mechanics of the filling material, the risk of extrusion appears to be minimized. As the VB cavity and graft containment mesh are filled and exposed to the exertion of pressure, the flowable state of the graft material in the tube changes to a solid state, thus preventing the backflow of graft material through the bone defect created for the working cannula, and also making the graft immediately ready to handle physiological loading stresses of the spine.

Kyphoplasty has been reported to allow for injection of PMMA under lower pressures than are required during vertebroplasty, with the packing of the cancellous bone at the periphery toward the endplates being thought to aid in protecting against transcortical cement extravasation, and with the void created by the inflatable balloon tamp representing a lower-pressure cavity than direct injection into the fracture site as is done in vertebroplasty. This also enables the cement to be inserted in a more cured form. Thus, proponents of kyphoplasty state that it allows superior control of PMMA delivery. The Optimesh graft containment system allows for even more control of the graft material, because the mesh bag with its finely woven configuration prevents frank extravasation.

The ability of the Optimesh system to restore VB height mechanically can be observed in animal studies and in clinical cases (unpublished data). Although both bone graft and PMMA can technically fill a void created in bone, the biological advantage of bone graft is obvious with the osteoconductive and osteoinductive potential in the Optimesh graft. Especially in younger patients, in whom there is higher demand and longer expected use of the intravertebral stabilization construct, this new minimally invasive approach to delivering both solutions for fracture reduction and stabilization with potential for graft incorporation provides a viable option for achieving a good long-term result. Minimally invasive techniques such as kyphoplasty have been called useful in certain traumatic VB fracture patterns. Similarly, Optimesh is also well suited for traumatic VB fractures, and in Europe it has been used successfully for such cases with and without posterior instrumented fusion.
CONCLUSIONS

The Optimesh system is a novel implantable and expandable device that can be delivered with a minimally invasive surgical approach to reduce and stabilize VCFs by using biologically active allograft or autograft bone instead of PMMA. This procedure is approved by the Food and Drug Administration for intravertebral use in VCFs and offers an exciting and promising alternative to minimally invasive stabilization procedures in which bone cement is used. This system allows for the restoration of sagittal alignment of the spine with direct control of bone graft delivery by using a mesh graft containment device that allows for ingrowth of new bone and vascular tissue. Small retrospective case reviews are being conducted, currently only with anecdotally favorable results, but this powerful modality, which has the ability to restore VB height and achieve solid stabilization with minimally invasive delivery of osteoconductive and osteoinductive bone graft warrants larger-scale prospective studies.

References

33. Takahashi S, Kitagawa H, Ishii T: Intraoperative pulmonary...


44. Wilcox RK: The biomechanics of vertebroplasty: a review. *Proc Inst Mech Eng [H]* **218**:1–10, 2004


Manuscript received January 18, 2005.
Accepted in final form February 28, 2005.

**Address reprint requests to:** Sandi Lam, M.D., Comprehensive Spine Center, Division of Neurosurgery, University of California at Los Angeles, 1245 16th Street, Suite 220, Santa Monica, CA 90404. email: salam@mednet.ucla.edu.