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Minimally invasive bone harvesting tools

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Abstract The most readily available source for autologous bone graft used in spinal fusion (the gold standard) is the iliac crest. However, the open surgical approach for harvesting corticocancellous iliac bone is associated with a marked increase in morbidity. This study suggests two alternatives to the traditional open harvesting procedure. For anterior interbody fusion procedures using a cage, the autologous bone is harvested regionally from a neighboring vertebral body. Alternatively, using minimally invasive techniques, a custom bone graft harvester with a flexible tube and cutting tip allows harvesting of autologous bone from a single entry point at the iliac crest. The effect on the mechanical strength of a lumbar vertebra of removing a cylindrical regional bone graft was studied in a cadaveric model. The bone defect was filled using three different filler materials: a porous tricalcium phosphate plug, a porous tantalum plug, and a self-setting calcium phosphate cement. After plug removal, the vertebral body's

strength in flexion/compression loading was reduced significantly, but could be restored to at least intact values with any of the three filler materials. The minimally invasive bone graft harvester was tested in three cadaveric pelves. With the cutting tip being guided within the cortical boundaries of the pelvis, cancellous bone volumes of 10–20 cc could be harvested from each iliac bone. Regional bone graft harvest in anterior spine surgery is suggested to be anatomically safe and biomechanically acceptable. Any of the three filler materials can restore the vertebral body's mechanical strength, but the filler's long-term resorption/remodeling or osteointegration behavior is unknown. The minimally invasive bone graft harvester is a novel tool, which performed satisfactorily under laboratory conditions, but clinical results are still missing.

Key words Pelvic bone harvest · Regional bone harvest · Minimally invasive surgery · Surgical instrument

Introduction

Traditionally, posterior and anterior lumbar spinal fusions need autologous bone graft to promote spinal arthrodesis. Autologous bone remains the gold standard of all graft materials in clinical use. The most readily available source is the iliac crest, but the open surgical approach for

harvesting corticocancellous iliac bone, usually by using a curved chisel, is associated with a marked increase in morbidity. A major complication rate associated with the donor site of as high as 10% has been reported [1]. Major complications include iliac wing fracture and pelvic ring instability [6], vascular aneurysm [3], hematoma requiring surgical revision [16], severe pain [16], and lumbar herniation [4, 7]. A minor complication

rate as high as 39% has also been reported [1]. Minor complications include chronic pain at the donor site [14], dysesthesia [16], and diminished sensitivity in the lateral femoral cutaneous nerve territory [1, 7]. Other disadvantages of the secondary harvesting procedure are the longer operating time and the limited supply of autologous material.

Allograft bone has been used as an alternative to autologous bone to avoid donor site-related complications. Unfortunately, the possible risk of infection [12], an inferior rate of union and healing [9], and a reduced mechanical strength [15] have limited its use. Conservation and sterilization techniques applied to the allograft bone appear to considerably compromise its healing potential and result in significantly lower fusion rates [11]. In the future, bone graft substitutes may become an acceptable replacement for autologous bone, but most studies have been done only in animals, and clinical experience to date is somewhat limited.

This study suggests two alternatives to traditional open bone graft harvest from the iliac bone, yet using autologous bone. The first uses a local source for autologous bone, avoiding a second incision for its retrieval from the iliac bone [8]. The concept of regional bone graft harvest is not new, but to our knowledge has not been applied to anterior spine surgery. Stand-alone instrumented anterior interbody fusion requires approximately 4–6 cc compacted corticocancellous bone to fill an interbody spacer's empty cavity. This relatively small bone volume can be harvested easily as a plug from the adjacent vertebral body, mercerized, and used instead of iliac crest bone. The cylindrical defect in the vertebral body can then be filled with a biomaterial that, over time, will either be osteointegrated or resorbed and replaced with bone. The results of a cadaveric study analyzing the anatomical safety and the biomechanical implications of the plug removal are presented.

Posterolateral fusions demand larger bone volumes (approximately 15 cc compacted bone per fused level), which can not be entirely harvested locally. Therefore, the second alternative uses autologous graft from the pelvic bone, but a custom bone graft harvester allows minimally invasive surgical techniques to be applied. This technique is expected to result in reduced complication rates compared to traditional open procedures. Preliminary results of a cadaveric study demonstrating the method's feasibility are presented.

Materials and methods

Regional bone graft harvesting technique

The minimal endplate separation distance and the minimal anteroposterior vertebral body diameter, both measured in the midsagittal plane, were measured from dried anatomical specimens on magnetic resonance images of lumbar spines. A three standard devia-

Fig. 1 Cannulated core drilling system for retrieval of a regional bone graft plug from the vertebral body

tion safety margin was assumed when estimating the maximum length and diameter of a plug that can be safely harvested from any lumbar vertebral body. A cannulated drilling system using a diamond-coated core drill, cooled with a continuously rinsing saline solution, was devised (Fig. 1). The system allowed removal of a cylindrical plug from the anterior center aspect of any lumbar vertebra.

Three filler materials were chosen, based on their unique defect filling qualities: Tantalum (Hedrocel, 78% porous tantalum, Implex Corp., Allendale, N.J., USA); TCP (Ceros, 70% porous betatricalcium phosphate, Mathys Medical Ltd., Bettlach, Switzerland); and CP-cement (Norian SRS, self-setting calcium phosphate bone cement, Norian Corp., Cupertino, Calif., USA). Tantalum and TCP implants were ready-made material cylinders. CP-cement was an injectable material with micro-porosity, which once cured in-situ gained mechanical compressive strength comparable to cortical bone [5].

In an initial study using a single-vertebra test model, three loading modalities (flexion/compression, side bending/compression, and axial rotation) were assessed to determine which was affected most by the harvesting procedure. The only loading modality significantly weakened by the plug removal was flexion/compression. Therefore, flexion/compression was identified as the worst-case loading scenario.

A multisegmental test model was used to compare the three filler materials in flexion/compression loading. Specimens consisted of two adjacent spinal motion segments (L1–L3, or L4–S1). Five experimental groups of eight specimens each were used. Specimens of the 'intact' group had no plug removal. For the 'defect' group, a bone plug was removed from the middle vertebra (L2 or L5). For the remaining three groups, again a bone plug was removed, but this bony defect was filled using one of the three filler materials. All specimens had the lower of the two disc spaces (L2/L3, or L5/S1) prepared and instrumented with a titanium disc spacer (SynCage, Mathys Medical Ltd., Bettlach, Switzerland). They were tested applying axial compressive load (Fig. 2). A point 1 cm anterior to the center of the body of the middle vertebra was chosen as the load application center. Failure was defined as the first sudden increase in vertical displacement. Statistical analysis was performed using analysis of covariance (ANCOVA, bone mineral density used as covariable).

Minimally invasive graft harvest from iliac bone

A power-driven bone graft harvesting tool was developed (Fig. 3) that can be connected to an AO compact drill (Synthes-Stratec,

Fig. 2 Multisegmental biomechanical test setup, showing a TCP plug (arrows) filling the cylindrical defect in the middle vertebra and a box-shaped cage inserted into the disc space below

Fig. 3 Minimally invasive bone graft harvesting tool for retrieval of cancellous bone graft from the iliac bone

Oberdorf, Switzerland). A rotating shaft of 7.2 mm outer diameter and 120 mm working length was mounted to a transparent plastic container. Two different shaft versions were available: a flexible and a rigid type. Airtight seals for all connections and vacuum applied to the container allowed continuous transport of bone debris from the tip of the flexible shaft into the container. A removable metal basket with fine mesh resting within the container collected the bone debris, while excess blood passed through.

Different cutting tips (Fig. 4) were tested for their effectiveness at removing a sufficient volume of cancellous bone debris from the iliac bone within a reasonable time. The flexible and rigid shaft versions were tested for their ability to be guided within the iliac

Fig. 4 Four different cutting tips investigated for cancellous bone graft harvest

bone for harvesting cancellous bone through a minimal opening in the iliac crest. The risk of perforating the tabula interna or externa of the iliac bone with any of the cutting tips was estimated. Three fresh-frozen human pelves were used to measure the volume of cancellous bone that could be safely removed from an anterior or posterior access to the iliac bone.

Results

Regional bone graft harvesting technique

The mean value for the minimal endplate separation for each of the five lumbar levels ranged from 22.7 to 24.3 mm. The smallest value was found for L5 (22.7 ± 1.8 mm). Similarly, the mean value for the minimal anteroposterior vertebral body diameter ranged from 27.6 to 30.5 mm, with the smallest value found for L1 (27.6 ± 2.5 mm). Assuming a three standard deviation margin, the maximum plug size safely removed from any lumbar vertebra was estimated at 17.4 mm diameter and 20 mm length. The cutting tools adapted from an existing drill set featured a 17.55 mm outer diameter core drill and used a positive stop at 20 mm cutting depth.

The results of the biomechanical tests using the multi-segmental model are presented in Fig. 5. The compressive strength of the 'defect' group was significantly reduced compared to 'intact' ($P = 0.003$). There was a significant increase in strength comparing any of the three filler materials to 'defect' ($P = 0.002$, $P < 0.0001$, and $P < 0.0001$ for tantalum, TCP, and CP-cement, respectively). When comparing any of the three filler materials to 'intact', a significant increase in strength for TCP ($P = 0.03$), and CP-cement ($P = 0.03$) was evident.

The failure pattern for each group was slightly different. The 'intact' group failed with the interbody fusion cage pushing through the endplate. The 'defect' group failed with the cage first pushing through the endplate, and then the vertebral body splitting in the sagittal plane. The tantalum and CP-cement groups failed with the cage initially pushing through the endplate, but once in proximity with the plug, the cage's subsidence was partially resisted. There was no mechanical failure observed for

Fig. 5 Compressive strength in flexion/compression loading. Significant differences (ANCOVA and Fisher's posthoc, $P < 0.05$) compared to 'intact' are marked with an asterisk (*)

Fig. 6 Removal of harvested bone graft material from the opened plastic container

either tantalum or CP-cement plugs. The TCP group also failed with the cage first pushing through the endplate, but the cage then crushed the TCP plug.

Minimally invasive graft harvest from iliac bone

Of the four different cutting tips tested, the one with a roof-shaped cutting profile (Fig. 4, *left-most tip*) was most efficient. This tip was also the only one that could be used directly to perforate the iliac crest cortical bone for gaining an entry point. The suction mechanism was effective for removing cancellous bone debris and, once through the cortical bone, had no tendency to clog. The flexible shaft could be directed to reach more distant regions from the entry point, but had somewhat of a tendency to fall back into existing cutting paths. The rigid shaft, on the other hand, was less effective at reaching more distant regions, but could be guided more easily when fanning throughout the iliac bone from a single entry point in the iliac crest.

Both shaft versions provided good tactile feedback when the tip encountered cortical bone. Perforation of the

tabulae was possible with any of the tips, but after an initial learning curve this could be easily avoided. The bone volume that could be harvested through a single entry point varied between 10 and 20 cc of mercerized cancellous bone. The plastic container could be opened at any time, and the harvested bone within the perforated metal basket could be retrieved using a spatula (Fig. 6).

Discussion

Two alternatives to traditional open bone graft harvest from the iliac bone were introduced. The proposed technique for regional bone graft harvest from the vertebral body adjacent to the fused level is a novel concept. The anatomical safety of the plug removal procedure has been validated (unpublished data, P. Downer et al. 1999) in 15 embalmed cadavers (75 lumbar vertebrae). All spines were visually inspected for possible violations of vertebral body anatomical boundaries. Four out of 75 harvesting procedures breached the inferior endplate by approximately 2 mm. All violations occurred during the first three cadavers, two in the L4 and two in the L5 vertebrae. None of the procedures breached the posterior vertebral body wall, and therefore none entered the spinal canal. We attributed the violations to the learning curve of the surgeon and the lack of fluoroscopic guidance to verify the Kirschner wire's position before drilling the core.

The biomechanical study demonstrated that the defect created by plug removal significantly reduced the vertebral body's strength under a flexion/compression load, but this strength could be restored with any of the three filler materials to values equal to or greater than the intact specimen. The vertebral bodies for any of the filler material groups always experienced a compression-type fracture. Burst fractures, which would put the spinal cord at risk of being compressed by a posteriorly dislocated fragment of the posterior vertebral body wall, were not observed.

Potential advantages of the TCP and CP-cement materials are their biological resorbability [10, 13]. Even though specific resorption rates for these materials in the vertebral body are unknown, eventually they will be completely resorbed and replaced with bone. The tantalum material, on the other hand, remains a foreign body that will likely osteointegrate [2]. A possible advantage of tantalum is that it will maintain its original mechanical strength over time, whereas the TCP and CP-cement materials may collapse later on. Lastly, the CP-cement is a self-setting material, which easily conforms to any defect geometry, but the cement application and curing time may result in a slightly longer surgery time. Animal experimentation must be conducted to determine osteointegration and/or resorption characteristics of various filler materials. Studies should also assess whether endplate vascularity is compromised by plug removal – a concern so far not addressed.

The minimally invasive bone graft harvesting tool was tested on cadaveric iliac bone, and its usefulness was demonstrated under laboratory conditions. Clinical experience so far has been collected in only two operations. A long-term benefit to the patient for minimally invasive iliac bone graft harvest using this technique has not yet been established.

Conclusions

We propose that regional bone graft harvest from the vertebral body adjacent to the interbody fusion level is a

valid surgical procedure that is anatomically safe and biomechanically acceptable. All three filler materials tested were biomechanically effective in restoring a vertebral body's compressive strength. To favor a particular filler material over others, biological data from animal models on the osteointegration and/or resorption characteristics will first be needed. The minimally invasive bone graft harvesting tool constitutes a novel approach to cancellous bone graft retrieval from the iliac bone, but its clinical usefulness still needs to be proven.

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