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Augmentation Improves Human Cadaveric Vertebral Body Compression Mechanics For Lumbar Total Disc Replacement

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Abstract

Study Design—Cadaveric biomechanical study.

Objectives—Quantify the effects of vertebral body augmentation on biomechanics under axial compression by a total disc replacement (TDR) implant.

Summary of Background Data—TDR is a surgical alternative to lumbar spinal fusion to treat degenerative disc disease. Osteoporosis in the adjacent vertebrae to the interposed TDR may lead to implant subsidence or vertebral body fracture. Vertebral augmentation is used to treat osteoporotic compression fracture. The study sought to evaluate whether vertebral augmentation improves biomechanics under TDR axial loading.

Methods—Forty-five L1-L5 lumbar vertebral body segments with intact posterior elements were used. Peripheral quantitative computed tomography scans were performed to determine bone density, block randomizing specimens by bone density into augmentation and control groups. A semi-constrained keeled lumbar disc replacement device was implanted providing 50% endplate coverage. Vertebral augmentation of $17.6 \pm 0.9\%$ vertebral volume fill with Cortoss was performed on augmentation group. All segments underwent axial compression at a rate of 0.2 mm/s to 6mm.

Results—The load-displacement response for all specimens was non-linear. Subfailure mechanical properties with augmentation were significantly different from control; in all cases the augmented group was 2× higher than control. At failure, the maximum load and stiffness with augmentation was not significantly different from control. The maximum apparent stress and modulus with augmentation were 2× and 1.3× greater than control, respectively. The subfailure stress and apparent modulus with augmentation was moderately correlated with bone density while the control subfailure properties were not. The augmented maximum stress was not correlated with bone density, while the control was weakly correlated. The maximum apparent modulus was moderately correlated with bone density for both the augmented and control groups.

Conclusion—Augmentation improved the mechanical properties of the lumbar vertebral body for compression by a TDR implant.

Introduction

Total disc replacement (TDR) is a viable surgical alternative to lumbar spinal fusion to treat painful degenerative disc disease (DDD). The procedure is FDA approved for use in the United States (2006) with long-term prospective studies¹ in addition to having a broad application worldwide with over ten years of follow-up reported²⁻⁴. A relevant concern among the current population of TDR patients is the future development of osteoporosis. Osteoporosis is an age-related progressive skeletal disease characterized by low bone mass, micro-architectural deterioration, a decrease in bone strength, and an increased susceptibility to fracture⁵. While osteoporosis is currently a contraindication for TDR^{1,6,7}, many of the aging population of current TDR patients will predictably become osteoporotic. Osteoporosis in the adjacent vertebrae to the interposed TDR presents a potential clinical problem of implant subsidence or vertebral body fracture^{7,8}. Subsidence, defined as a 2 mm deformation into the vertebral body, is dependent upon, among other factors, the stiffness and strength of the underlying trabecular bone and the endplate-implant interface.

Osteoporosis is responsible for 700,000 compressive vertebral body fractures annually in the US and osteoporotic vertebral fractures occur in approximately 20% of individuals over the age of 70^{9,10}. Vertebroplasty, percutaneous injection of cement into a collapsed vertebral body, was introduced in 1984 for treating vertebral haemangiomas and osteolytic neoplasms⁵. Clinical usage of bone cement in the spine via vertebroplasty and kyphoplasty procedures has since become an accepted medical practice for treating osteoporotic compression fracture^{11,12,13,14}. Injecting a material into the trabecular interior of the vertebral body provides strength and support. The mechanical stabilization by augmentation may reduce fracture-site motion and mitigate pain¹⁵. Several materials have been used for augmentation, including polymethylmethacrylate (PMMA) bone cement and a synthetic bone filler Cortoss (Orthovita, IncTM, Malvern, PA), a bioactive glass-ceramic composite material with a matrix of bis-phenol glycidyl dimethacrylate, bis-phenol ethoxy dimethacrylate, and triethyleneglycol dimethacrylate¹⁵⁻¹⁷. Cortoss is biocompatible, exhibits a lower setting exotherm than PMMA, is bone bonding, and has material properties more similar to bone¹⁵⁻¹⁷. Cortoss is both a non-biologic mechanical reinforcing agent and has properties of bonding to bone (like a biologic agent). There is no evidence in the literature or clinically that metabolic bone disease is associated with the use of Cortoss. Further to the reality of progressive osteoporosis, the use of a reinforcing agent (of either type) will minimize the risk of the natural disease progression creating a non-indicated (osteoporotic) condition for TDRs. Cortoss has completed IDE investigation in a multi-center prospective randomized study, and been approved by the FDA for use in vertebral augmentation in the US, and is marketed for use in Europe and Australia.

Laboratory studies using cadaveric human segments show that vertebral body augmentation increases strength under axial compression^{13,15,18}. Importantly, Higgins *et al.* augmented aged intact (non-fractured) osteoporotic segments with PMMA, increasing the failure strength over unfilled controls¹⁸. Tan *et al.* injected the pedicle screw tracts with PMMA for augmenting below an interbody fusion device¹³. Augmentation significantly increased failure load and strength under compression by the interbody device compared with un-augmented pedicle screws¹³. These results suggested that cement augmentation of pedicle screws may reduce interbody device subsidence in osteoporotic patients¹³. Cement augmentation into vertebral bodies and pedicle screw tracts have gained clinical application to reduce interbody fusion device subsidence^{13,14,19}.

Building on early clinical experience with two cases of subsidence, one of the current authors (Dr. Bertagnoli) routinely performs prophylactic vertebral body augmentation with bone cement in selected patients following TDR implant placement⁶. While early clinical

evidence suggests that subsidence or compressive fracture can be avoided by vertebral augmentation in TDR patients with osteopenia and osteoporosis⁶, the biomechanical basis to support TDR vertebral augmentation has not been established. The objective of this study was to quantify the effects of vertebral augmentation with Cortoss on vertebral body mechanics under axial compression by a TDR implant. We hypothesize that augmentation will increase the compressive stiffness and strength of the endplate-implant interface in a bone density-dependent manner.

Materials and Methods

Nine fresh-frozen lumbar spines were obtained (6 female and 3 male donors, average age 79, range 69 – 88 years), providing a total of 45 L1-L5 lumbar levels. Antero-posterior and lateral radiographs were performed on intact spines to exclude segments based on structural deformities such as fractures and endplate irregularities (n=3 excluded), leaving 42 specimens. Peripheral quantitative computed tomography (pQCT, XCT2000, Stratec Medisintech, Pforzheim, Germany) scans were performed on the intact lumbar spines to determine the vertebral body bone density. Three images were acquired below the bony endplate based and the trabecular bone density within a 10 mm diameter region of interest were averaged (Figure 1). Specimens were block randomized according to bone density and divided into two groups, augmented (n=22) and control (n=20).

Specimen Preparation

Single level vertebral body segments were prepared by excising the intervertebral disc tissue. The posterior elements were kept intact to maintain vertebral body integrity. The antero-posterior width and medial-lateral width of the superior endplate and the height of the vertebral body were measured three times with digital calipers and averaged. The endplate vertebral body was modeled as an elliptical cylinder to calculate the endplate area and vertebral body volume^{18,20}. A curette was used to remove the remaining cartilaginous endplate, taking care to keep the bony endplate intact. Endplate preparation has little effect on the yield or ultimate compressive strength of vertebral bodies²¹. The inferior endplate was prepared in the same fashion and the sample was potted superior surface up in a cylinder with PMMA to cover 2-3 mm of the vertebral body. A level was used to ensure a flat testing surface. Each specimen was then stored in vacuum sealed bag and refrozen at -20°C.

Prior to augmentation and testing each specimen was thawed at 3°C for 24 hours. Medial-lateral fluoroscopic views were taken pre-augmentation, post-augmentation, and post-testing. A semi-constrained keeled lumbar disc replacement device sized to provide approximately 50% endplate coverage was implanted using techniques similar to clinical procedures¹. The goal of TDR insertion, similar to that of interbody fusion cages, is to place the implant with maximal apophyseal rim coverage to prevent subsidence, 50% endplate coverage was chosen as a best estimate of what is feasible to place clinically. Tan et al. found that endplate coverage of 40% was biomechanically superior to 20%²². Anterior placement of an interbody implant has been shown to lead to early failure²³; while a posterior placement increased the implant-vertebral body unit strength up to 20%²⁴. Ensuring 50% endplate coverage along with posterior placement our study minimizes the variability that is introduced by different endplate coverage options, and allows us to isolate the effect of the augmentation.

Each augmented specimen was held at 37°C physiologic temperature in phosphate buffered saline (PBS) for 20 minutes prior to injection to ensure flow and dispersion. Fill volume was determined based upon dividing the amount of material injected by the anterior 2/3 vertebral body volume with a factorization for trabecular bone. Vertebral augmentation ($17.6 \pm 0.9\%$

vertebral volume fill) with Cortoss was performed via two posteromedially-directed 16G needles placed under the lateral borders of the implant (Figure 2A). The fill volume was selected based on experimental and modeling studies recommending 15-20% fill for vertebral augmentation to restore vertebral body stiffness and strength following compression fracture or in the case of osteoporosis^{18,25}. Fluoroscopic guidance was utilized to prevent material extravasation during augmentation, this is commonly utilized clinically during vertebroplasty to achieve optimal device placement. The TDR implant was inserted and the sample wrapped in 1% PBS soaked gauze then kept at 37°C for 24 hours allowing for the Cortoss to harden. The control group underwent the same procedures except for no needle insertion or augmentation.

Mechanical Testing and Data Analysis

Axial compression at a rate of 0.2 mm/s to 6 mm was performed in an Instron 8874 (Instron Corporation, Canton, MA) and load and displacement were recorded²². The 6 mm amount of total displacement corresponds to the clinical radiographic diagnosis of a compression fracture, which is a 25% collapse²⁶. Since load-displacement is nonlinear, mechanical properties were calculated in 2 regions: *subfailure* and *maximum*. The subfailure load was determined at 2 mm displacement, which corresponds to the clinical definition of implant subsidence^{27,28}. Subfailure stiffness was calculated by linear regression as the slope of the load-displacement response between 200 N and 400 N. Maximum load was taken as the peak in the load-displacement curve. In some cases the load-displacement response exhibited an early drop in load; as long as the load continued to rise over the subsequent 0.5 mm, these loads were not recorded as the maximum load. Similar definitions permitting a small drop in load that does not represent failure are established in the literature^{29,30}. Stiffness at max was calculated as the slope of the load-displacement response over a 200 N range 20% from the max load. Apparent material properties at subfailure and maximum were calculated by normalizing for geometry. Apparent stress was calculated as load divided by cross-sectional area. Apparent modulus was calculated as stiffness multiplied by initial specimen height divided by cross-sectional area.

Statistical Analysis

Statistical analysis included a t-test for an effect of augmentation (treatment) compared to intact control for each mechanical property. A Pearson's correlation was performed between bone density with apparent stress and modulus, separately for control and augmented groups. Significance was set at $p < 0.05$ and a trend was defined as $0.05 > p > 0.1$.

Results

Fluoroscopic images confirmed fill and repeatability of the augmentation technique. The only difference observed between pre-augmentation (Figure 2A) and post-augmentation (Figure 2B) is the removal of the remaining intervertebral disc. Extravasation of material occurred through the superior endplate and vertebral foramen during a few of the augmentation procedures, however based on previous studies, extravasation does not alter compression mechanics¹⁸. Cortoss maintained its structural integrity between post-augmentation (Figure 2B) and post-testing (Figure 2C).

The load-displacement response for all specimens was non-linear (Figure 3). Subfailure mechanical properties with augmentation were significantly different from control (Figure 4); in all cases the augmented group was significantly higher than control. The augmented subfailure load was 1795 N, 2X greater than the intact control (Figure 4A). The augmented stiffness was 698 N/m, 2X greater than control (Figure 4B). Upon normalization for

geometry, the augmented subfailure stress was 1 MPa, 2X control (Figure 4C) and modulus were 10 MPa, 2X control (Figure 4D).

At failure, with augmentation the maximum load (2311 N, Figure 4A) and stiffness (840 N/mm, Figure 4B) was not significantly different from control ($p=0.1$ and 0.2). With augmentation the maximum apparent stress (1.4 MPa, Figure 4C) and apparent modulus (13.6 MPa, Figure 4D) were 2X ($p=0.08$) and 1.3X ($p=0.07$), respectively, greater than control.

The subfailure stress with augmentation was moderately correlated with bone density ($R=0.61$, $p<0.05$, Figure 5A), as was the augmented subfailure apparent modulus ($R=0.44$, $p<0.05$, Figure 5B). The control subfailure properties were not significantly correlated with bone density. In contrast, the augmented maximum stress was not correlated with bone density, while the control was weakly correlated ($R=0.22$, $p<0.05$, Figure 5C). The maximum apparent modulus was moderately correlated with bone density for both the augmented and control groups ($R=0.71$ and 0.66 , respectively, $p<0.05$, Figure 5D).

Discussion

The interface between the TDR implant and the bony endplate needs to provide axial compressive strength sufficient to resist implant subsidence or vertebral fracture, as was previously established for spinal interbody fusion implants^{21,22}. Augmentation improved the mechanical properties of the lumbar vertebral body for compression by a TDR implant. This finding is consistent with prior studies that have shown vertebral augmentation to improve compressive mechanics and restore mechanical properties towards pre-fracture values³¹. Adjacent level risks are a factor³² however internal stresses of the intervertebral disc are unaffected after vertebroplasty. The use of CORTOSS provides better material dispersion within a vertebral body compared to PMMA, resulting in fewer intervertebral stress concentrations, mitigating the incidence of secondary fractures³³.

While the age of the subjects were outside the range of those who would typically receive a total disc replacement, this was intentional, as the lower bone density represented the aging TDR population. Values for maximum stiffness and load were consistent with previous studies (stiffness 400-800 N/mm, load 300-1500 N)^{13,18,22,29,34}. Osteoporosis is a looming clinical problem for an aging population with risk of subsidence or vertebral fracture. By improving the overall strength of the vertebral body and creating a larger surface area for the implant will allow for improved bone-implant strength at the time of initial implantation.

Subfailure properties were significantly increased with augmentation, a finding which has not been previously reported in vertebral body augmentation studies. Consistent with previous studies, augmenting the vertebral body improved the maximum (failure) load and stress but did not improve the maximum stiffness and modulus^{13,18}; while not significant the average stiffness and modulus increased in the present and previous studies. The mechanics of the vertebral body are highly variable, due to age and bone density variation in the sample population, which may explain some of the limited significance in cadaver studies.

Effect of augmentation on subfailure mechanics

The bony endplate is a concave and thin shelf less than ½ mm thick. While it inherently provides little strength, it serves to distribute axially-applied loads more evenly over the underlying trabecular bone³⁰. Due to its concavity, under the initial compression loading, only the periphery of the implant is in contact with the bony endplate. As loading continues, it compresses the endplate and subsides to some degree before it achieves more contact with

the underlying bone. Since in the sub-failure regime (at 2 mm displacement) the control stress and modulus did not correlate with trabecular bone density, these subfailure properties are likely dependent on the endplate and posterior rim, not the underlying trabecular bone. With augmentation, the Cortoss likely provided a buttressing support to the endplate. At this point, the implant itself acts as the endplate, distributing load over the trabeculae³⁰. This notion is supported by previous imaging studies during interbody device compression, where it was observed that the trabecular bone undergoes densification below the point of compression²². Augmentation below the endplate as performed in the present study would further enhance the mechanics in the early displacement regime.

Effect of augmentation on failure mechanics

It is well known that trabecular bone strength is correlated with bone density^{35,36,18,21,37,38}, as was observed in the present study. When augmented, the maximum stress was no longer correlated with density, as previously observed following augmentation of osteoporotic segments¹⁸. These findings confirm that augmentation increases the functional support provided by trabecular bone in the low density specimens. The performance of interbody fusion devices subsidence are also compromised by low bone mineral density^{13,38-40}, where in compression, trabecular bone failure occurs in a semi-elliptical zone underlying the interbody implant²². The observed failure below the implant suggests that local cement augmentation could increase the strength at the implant-vertebra interface¹³. Similarly, cement injection into pedicle screw tracts provides structural reinforcement to surrounding trabeculae. Together, the stiffer cement-bone composite located directly below the superior EP redistributes load onto large volumes of supporting trabecular bone and increases failure strength¹³.

Determination of failure load

Mechanical testing yielded three types of responses, a smooth rise to failure which was the typical response, a break in the data curve and an early drop in the data prior to the max load being achieved. This variability in shape is consistent with previous vertebral body compression studies^{41,29,30,22}. Similar variability has been seen during interbody device testing^{21,34}. The variability in load-displacement response (Figure 3) is likely due to implant settling and/or breaking through the posterior rim; this was observed during fluoroscopic video taken during mechanical testing. Determination of the failure load from the load – displacement curve can be difficult and several different definitions have been used. Some studies define failure from the first peak or plateau in the curve,^{21,22,34}. However, when considering the response in Figure 3, it isn't convincing that the early drop defines the specimen failure. Other studies use the overall peak load. However, with significant sub-catastrophic failure occurring over large displacements, this may overestimate the effective load carrying capacity. When the peak load was difficult to identify, the inflection point at the elastic limit has been used to identify the beginning of the failure mode¹⁸, however, this point is difficult to identify and its selection can be subjective. The definition of maximum failure load utilized in the present study, the value to which load fails to rise over the subsequent 0.5 mm, allows for equal comparisons to other vertebral body compression studies and is consistent with previous studies where failure was defined as the maximum load before a load decrease of greater than 5%³⁰.

The measurement of bone mineral density

The compressive strength of bone can be accurately predicted by bone mineral density measurements made using dual energy X-ray absorptiometry (DXA), quantitative computed tomography (QCT) or peripheral QCT (pQCT)⁴²⁻⁴⁵. The two-dimensional nature of DXA is influenced by surrounding non-vertebral tissue such as ribs, fat, aortic calcification, vertebral osteophytes, and posterior elements. The absence of body tissues such as fat limits

the correspondence between vertebral DXA bone density measured in vitro and clinical in vivo density by over 40%^{46,42,47}. Bone density was measured in the present study using pQCT, because with pQCT the region of interest can be placed in the three-dimensional space containing only trabecular bone and exclude irrelevant tissues^{42,47}.

In summary, augmentation improved the mechanical properties of the lumbar vertebral body for compression by a TDR implant. Subfailure properties correlated with bone density when augmented, maximum stress correlated with bone density in control only. These laboratory findings provide mechanical support for the early clinical evidence that prophylactic vertebral body augmentation with bone cement at the time of TDR implant placement may avoid future subsidence or compressive fracture in TDR patients⁶. Furthermore, biomaterials developed to augment trabecular bone strength may serve as treatment to prevent further implant subsidence, and potentially future device failure, when detected on radiographs in the course of routine follow-up examinations. While detailed discussion of revision lumbar TDR strategies is beyond the scope of the current study, others have discussed in detail the treatment options in this challenging clinical situation^{48,49}. Options include revision anterior spinal surgery with replacement of a new device, revision to an anterior spinal fusion using femoral ring allograft, coupled with posterior pedicle screw-based fixation, or posterior-only fixation/stabilization with pedicle screws. Longer-term follow-up from clinical studies will be required to determine the optimal treatment and to generate evidence-based guidelines. It remains to be determined whether this technique may be valuable to treat TDR patients that later develop osteoporosis or may be a technique to overcome current exclusion criteria for TDR in osteoporotic patients, which could extend disc replacement surgery to a more broad patient population in the future.

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Figure 1. Representative peripheral quantitative computed tomography (pQCT) scan of lumbar vertebral specimen. Trabecular bone density was evaluated in a 10 mm diameter region of interest (white circle).

Figure 2. Fluoroscopic images A) pre-augmentation (Arrow indicates point of Cortoss injection), B) post-augmentation, C) post-testing

Figure 3.

Representative load-displacement response from three specimens demonstrating variability in maximum load. Most samples exhibited the “typical” response of uniform load to failure. Some samples exhibited a small break in the curve (square) or an early drop followed by a continued increase to failure. The maximum load determined for each sample is indicated by #.

Figure 4. Average (standard deviation) sub-failure and maximum properties for control (white) and augmented (black) specimens. A) load, B) stiffness, C) apparent stress, and D) apparent modulus, *p 0.05.

Figure 5. Correlation with bone density for apparent material properties, normalized by geometry. A) sub-failure stress, (B) sub-failure modulus, (C) maximum stress, (D) maximum modulus, *p 0.05.