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Compressive strength of interbody cages in the lumbar spine: the effect of cage shape, posterior instrumentation and bone density

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Abstract One goal of interbody fusion is to increase the height of the degenerated disc space. Interbody cages in particular have been promoted with the claim that they can maintain the disc space better than other methods. There are many factors that can affect the disc height maintenance, including graft or cage design, the quality of the surrounding bone and the presence of supplementary posterior fixation. The present study is an in vitro biomechanical investigation of the compressive behaviour of three different interbody cage designs in a human cadaveric model. The effect of bone density and posterior instrumentation were assessed. Thirty-six lumbar functional spinal units were instrumented with one of three interbody cages: (1) a porous titanium implant with endplate fit (Stratec), (2) a porous, rectangular carbon-fibre implant (Brantigan) and (3) a porous, cylindrical threaded implant (Ray). Posterior instrumentation (USS) was

applied to half of the specimens. All specimens were subjected to axial compression displacement until failure. Correlations between both the failure load and the load at 3 mm displacement with the bone density measurements were observed. Neither the cage design nor the presence of posterior instrumentation had a significant effect on the failure load. The loads at 3 mm were slightly less for the Stratec cage, implying lower axial stiffness, but were not different with posterior instrumentation. The large range of observed failure loads overlaps the potential in vivo compressive loads, implying that failure of the bone-implant interface may occur clinically. Preoperative measurements of bone density may be an effective tool to predict settling around interbody cages.

Key words Spine · Interbody · Fusion · Compression · Biomechanics · Implant · Posterior lumbar intervertebral fusion

Introduction

Posterior lumbar intervertebral fusion (PLIF) was introduced to clinical practice in the mid-1940s independently by Jaslow [33] and by Cloward [14–16]. The theoretical bases of this procedure were outlined: mechanical stability is provided by the intervertebral fusion, the original disc height is restored and the intervertebral foramina are

distracted. Lin et al. [38] postulated four biomechanical principles to get a high rate of fusion: preservation of the integrity of the posterior portion of the motion segment; partial preservation of the integrity of the cortical endplates; attempted maximal removal of disc material, especially the nucleus pulposus, as a potential source of chronic low back pain; and the use of several "unicortical peg grafts" as opposed to smaller "chips" or "strips" of bone [36]. These variables and others impact the clinical results

of PLIF. This may explain the reported large range of fusion rates: between 65% and 96%, using auto/allogenous bone grafts with or without posterior instrumentation [21, 22, 37, 38, 50]. Despite the theoretical advantages of PLIF, the technical difficulty of the operation and the possible complications have reduced widespread acceptance of this procedure [37, 57].

Various clinical studies have reported that in PLIF with interbody bone graft, the postoperative disc height returns to or even falls below the preoperative level. These changes occur with and without additional posterior fixation and are not dependent upon the type of bone graft used [19, 32, 47, 53]. It is not known whether the disc height decrease is due to graft subsidence into the adjacent vertebral body or graft collapse. Failure of the bone graft is a distinct possibility: allograft bone loses one-half of its strength during the first 6 months and persists in the weakened state for another 6 months before regaining strength [7, 10].

To avoid these disadvantages, interbody implants of many different designs and manufactured from engineering materials have been developed in the past few years. They can be implanted using an anterior or posterior approach [2, 6, 35, 48]. The goal of these implants is to provide mechanical support to the segment or segments being fused, simultaneously taking into account the biology of arthrodesis by allowing the use of autogenous bone to promote fusion. The first clinical report on interbody implants came from Brantigan and Steffee in 1993 [5]. They reported a successful fusion in all of their 28 patients using a carbon-fibre reinforced polymer implant with pedicle screw fixation. In a more recent study by Tullberg et al. [56], a fusion rate of 86% was achieved using the same implant. All patients except one in this series maintained the immediate postoperative disc height during the follow-up period of 1 year. Clinical results for interbody implants without posterior fixation have been reported, with fusion rates between 83% and 100% [34, 48, 59]. Many early investigations do not report disc height changes and/or do not acknowledge the limited accuracy of X-ray analysis [5, 38, 49], for evaluation of fusion, as established by a number of investigators [1, 46]. Other clinical and basic biomechanical approaches for the investigation of interbody implant performance have recently started to be applied.

Despite the growing clinical interest and use of intervertebral cages, only relatively few studies have been conducted evaluating their biomechanical behaviour. Two important biomechanical considerations are the compression strength of the cage-vertebra interface and the immediate three-dimensional flexibility changes due to cage insertion. The latter topic has been addressed at our laboratory [39] and by other investigators [9, 11, 54, 58], while compression strength is the focus of the current study. The compression strength of the construct provides a simple indication of the factors that are relevant in maintaining a distracted disc height. Disc height loss has been observed,

shortly after operation, with cages in in vivo animal models [27, 51]. Tencer et al. [54] measured the maximum compressive load that could be supported by a threaded cylindrical implant in an in vitro calf model. There could be significant differences between these animal models and the human case in the assessment of interbody implants. This is due in particular to the immature endplates of many animal models [17] and the fact that interbody implants rely on the endplate for fixation.

It is remarkable that only a few studies [6, 13, 54] utilised a human cadaveric model for biomechanical evaluation. Closkey et al. [13], using an in vitro thoracic spine model, found that endplate coverage by a bone graft of at least 30% of the endplate area was necessary to prevent subsidence. Brantigan et al. [6] compared a carbon-fibre implant with bone graft in compression tests of lumbar specimens and reported similar failure loads. Tencer et al. [54] compared bone graft and threaded metal inserts using a flexibility protocol.

Although the relationship between bone mineral density (BMD) and PLIF bone graft compression strength has been examined and found to be important [13], no previous studies have investigated the effect of BMD on interbody implant compression performance.

The goal of the present study was to compare the biomechanical behaviour of three different posterior lumbar interbody cage designs under axial compression loading. Each cage used a significantly different mechanical means to distract and maintain the disc space. The effect of bone density and the effect of additional posterior instrumentation was also investigated.

Materials and methods

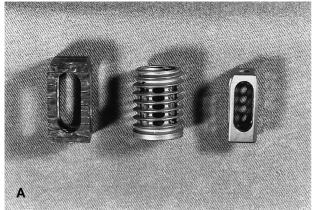
Specimen preparation

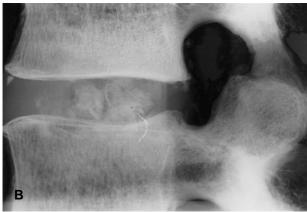
Thirty-six human cadaveric lumbar functional spinal units (FSUs) were used in the current investigation (1 \times L1-2, 14 \times L2-3, 4 \times L3-4, 15 \times L4-5, 2 \times L5-S1). The specimens were carefully dissected of all non-ligamentous soft tissue and stored at $-20^{\circ}C$ until tested. Care was taken to keep the specimens moist, with saline solution, throughout the preparation and testing phases.

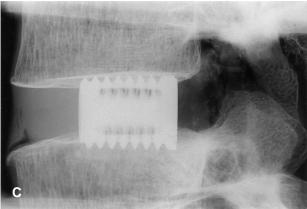
Prior to testing, the bone mineral density (BMD) of the upper and lower vertebra of every specimen was determined using dual-energy X-ray absorptiometry (DEXA; QDR 2000, Hologic, Waltham, Mass.) from both a lateral and a postero-anterior (PA) direction. For all measurements, the specimens were placed in a plastic container and surrounded by granular semolina to simulate the soft tissues surrounding the spine. This resulted in four measures of bone quality, two for each vertebra. The BMD is expressed in grams of hydroxyapitite per unit area (g/cm²). After density measurement, the vertebrae were mounted in rectangular blocks of polymethylmethacrylate (PMMA) such that the mid-disc plane was oriented horizontally.

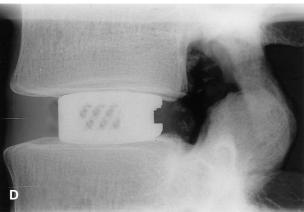
Experimental protocol

The 36 specimens of the present study were tested after insertion of one of three different interbody implant designs from a posterior









direction. Twelve specimens were used for each implant type, six with and six without posterior instrumentation. The implants were (1) a porous titanium cage designed to fit the endplate contours (Stratec Medical, Oberdorf, Switzerland), (2) a rectangular carbon-fibre cage (Brantigan, Acromed, Cleveland, Ohio) and (3) a cylindrical threaded titanium cage (Ray TFC, Surgical Dynamics, Concord, Calif.). Photographs of the different cages and lateral plain radiographs after insertion of each cage type are shown in Fig. 1. The cages were inserted into specimens randomly to avoid any bias due to anatomic level of cage implantation. In 14 cases the implants were tested in L2-3 specimens, in 15 cases they were tested in L4-5 specimens, in four cases in L3-4 and in one case each in L1-2 and L5-S1.

The posterior insertion typically required removal of the medial portion of the articular facets. Prior to insertion, the cages were filled with autogenous bone; bone chips from the decompression required for the procedure were sufficient to fill the cages. All specimens had two parallel intervertebral implants inserted following the manufacturer's guidelines for surgical technique. For the Stratec implant, after removal of the nucleus pulposus and the posterior annulus, the bony endplate was carefully exposed by removing cartilaginous material with a curette. The cage was inserted so that it rested directly on the bony endplate. In contrast, for both the Ray and the Brantigan implants the disc space was prepared with pilot drills and finishing broaches. For the Ray cage, slight bony endplate penetration was necessitated by the surgical technique. In the case of the Brantigan implant, the rectangular shape of the instruments and of the cage normally did not prevent slight penetration of the anatomical endplate contours in some locations.

All disc spaces were distracted to achieve a tight annulus as per the manufacturer's instructions. The posterior instrumentation was a standard pedicular fixation system (Universal Spine System, Stratec Medical).

Axial compression measurement

The compression tests were performed in a computer-controlled, servo-hydraulic material testing machine (Instron 1270, High Wycombe, UK). The upper and lower vertebrae were constrained from rotation during the test (see Fig. 2. An axial compression displacement was applied to the specimen at a rate of 0.4 mm/s (i.e. 1.0 in./min). The compression was allowed to continue until obvious failure of the bone-implant interface, usually indicated by a significant drop in the real-time compressive load-displacement curve (Fig. 3). Often, loud cracking could be heard, indicating bony damage to the specimen. Marker carriers with light-emitting diodes (LEDs) were placed on the vertebral PMMA mouldings such that the rigid body motion of the upper vertebra with respect to the lower vertebra could be measured using an optoelectronic camera system (Optotrak 3020, Northern Digital, Waterloo, Ontario, Canada). Marker carriers were also attached to the interbody implants (Fig. 2). Custom software was used to calculate the translations of the upper vertebra and implants with respect to the lower vertebra.

From each load-displacement curve (Fig. 3) the failure load and compressive load at an axial displacement of 3 mm were calculated. The force-displacement plots were all analysed by a single blinded observer (T.R.O.). The wide variability in the shape of the load-displacement plots made it difficult to use a strict failure cri-

Fig. 1A–D Photographs of the different cage designs and lateral plain radiographs from a typical specimen after insertion of two parallel interbody cages. **A** *Left* and **B**: Brantigan cage – a rectangular, porous carbon-fibre implant. **A** Centre and **C**: Ray cage – a cylindrical, threaded, porous titanium implant. **A** *Right* and **D**: Stratec cage – a porous titanium implant designed to fit on the end-plate contours

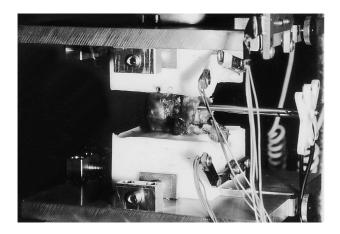
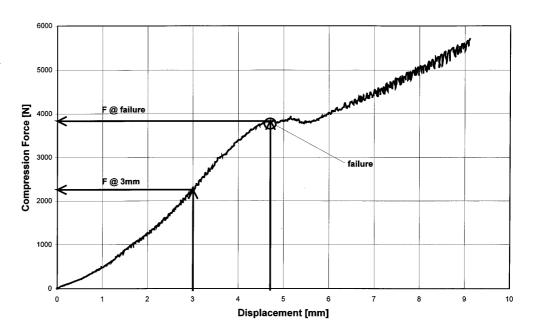


Fig. 2 The testing apparatus for axial compression testing. The upper and lower vertebrae were constrained from rotation during the test. Marker carriers with LEDs are attached to the vertebral mounts such that the rigid body motion of the upper vertebra with respect to the lower vertebra could be measured by an optoelectronic camera. The two white marker carriers (right) were attached to each interbody cage, using the stainless steel rods visible passing from posterior into the specimen. The interbody cages are hidden within the anatomic specimen

terion. Instead, the observer drew a straight line on the linear loading portion of the curve which was beyond any initial low stiffness region. The failure point was located where the curve deviated from the straight line. The force at 3 mm provided a measure of stiffness since the curves were generally not linear. The 3 mm displacement was deemed clinically significant as the maximum elastic deformation of the endplate is in the range of 0.5–1.0 mm [8].

The relative motion of the cages during the compression test were calculated with respect to the fixed lower vertebra. The motions consisted of three Euler angles and three translations of the central point of the implant.

Fig. 3 Typical compressive load-displacement curve. Failure load was defined as a significant deviation from the initial loading slope. The force at 3 mm of overall displacement was defined as shown



Statistical methods

Pearson product moment correlation coefficients were calculated between measured load and BMD values. If the BMD values were significantly correlated to the load value the most strongly correlated one was selected as a covariate. A two-factor analysis of covariance (ANCOVA) was used to determine the effect of cage design and posterior instrumentation on the failure load and the load at 3 mm displacement. Where the ANCOVA indicated significant differences between groups a Student-Newman-Keuls (SNK) test was used to isolate differences. Statistical significance was assumed for P < 0.05.

Results

The range of failure loads observed was from 1700 N to 9900 N. There was a statistically significant relationship between the failure load and each of the four bone densities (P < 0.02). The lateral DEXA scan values (upper vertebra $R^2 = 0.61$; lower vertebra $R^2 = 0.60$) revealed a higher correlation than the PA values (upper vertebra $R^2 = 0.38$; lower vertebra $R^2 = 0.15$). Therefore, the upper lateral DEXA was used as the covariate in the statistical analysis. A scatterplot of the failure load versus the upper lateral bone density, for all tests, is shown in Fig. 4. This plot clearly shows that there are higher compressive failure loads at greater bone densities. There was no significant difference in the bone densities of the specimens when grouped by cage design (P = 0.84) or posterior instrumentation (P = 0.23).

Neither the implant design nor the posterior instrumentation had a significant effect on the compressive strength (cage P = 0.58, posterior instrumentation P = 0.32). A plot of the failure loads for the different cage designs with and without posterior instrumentation is shown in Fig. 5. The median failure loads for all three cages were approx-

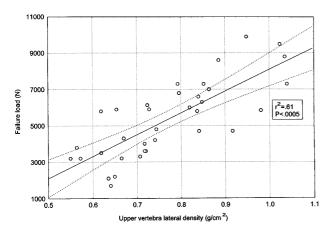


Fig. 4 Scatterplot of compressive failure load versus upper vertebra lateral DEXA density for all tests. The least-squares fit and associated 95% confidence interval are illustrated. The correlation between the failure load and the bone density was significant (P < 0.0005)

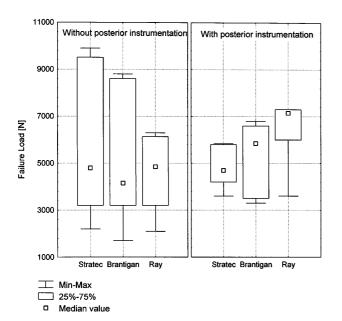


Fig. 5 Box and whisker plots of the failure loads for the three cage designs with and without posterior instrumentation. No significant effect of cage design or posterior instrumentation was found

imately 5000 N. The mode of failure in all specimens was penetration into one or both vertebral bodies. Two of the rectangular carbon implants (Brantigan) fractured during testing in specimens with failure loads of 5800 N and 8800 N, an example is shown in Fig. 6. Cracks appeared in the longitudinal and vertical structural members of the cage. No instances of cracks propagating completely through the members (i.e. complete failure) were observed. No other implant failures were observed.

The range of loads observed at 3 mm displacement was from 800 N to 3700 N. The average load for all three

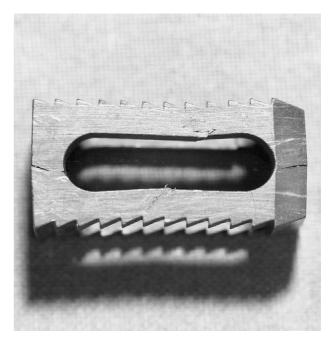


Fig. 6 One of the two carbon-fibre Brantigan cages fractured during compression testing. Cracks are visible running part-way through each of the four visible structural members of the cage

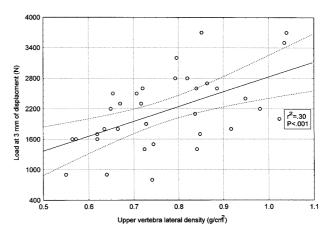
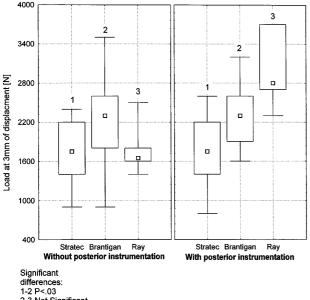


Fig. 7 Scatterplot of the load at 3 mm displacement versus upper vertebra lateral DEXA scan. The least-squares fit and associated 95% confidence interval are illustrated. The correlation between the load and bone density was significant (P < 0.001)

cages was about 2000 N. A scatterplot of load at 3 mm versus upper vertebra lateral bone density is shown in Fig. 7. Only the lower vertebra AP bone density did not significantly correlate to load at 3 mm displacement (P = 0.48). At 3 mm displacement, there was a significant effect, on the load of cage type (P = 0.009) but not of posterior instrumentation (P = 0.16). A plot of the load at 3 mm for the different cage designs with and without posterior instrumentation is shown in Fig. 8. The highest loads at 3 mm were observed for the Brantigan and the Ray designs (about 2300 N), which were both significantly larger



1-2 P<.03 2-3 Not Significant 1-3 P<.03 Min-Max 25%-75%

Median value

Fig. 8 Box and whisker plots of the loads at 3 mm displacement for the three cage designs with and without posterior instrumentation. There was a significant effect of cage design but not posterior instrumentation. Paired Student-Newman-Keuls comparisons of cages, after combining specimens with and without posterior instrumentation, indicated significant differences between the Stratec and Brantigan and Stratec and Ray cages. The difference between the Brantigan and Ray cages was not significant

than those observed for the Stratec cage (about 1700 N, P < 0.029).

The implant motions during compression were quite variable. Rotations in the sagittal plane (i.e. cage flexion or extension) and frontal plane (i.e. cage lateral bending) were observed frequently. Transverse plane rotation was always of very low magnitude (i.e. 0.5°). Cage translations were virtually always in the superior-inferior direction. The cage usually penetrated into only one vertebral body, but sometimes penetrated into both vertebrae. The motions of one cage pair in a typical specimen are shown in Fig. 9.

Discussion

Relevance of measured loads

A large range of failure loads was observed in this study (min = 1700 N, max = 9900 N, average = 5000 N). Brantigan et al. [6] measured similar failure loads in a comparable in vitro setup with the same carbon-fibre cage investigated in this study. These observed failure loads

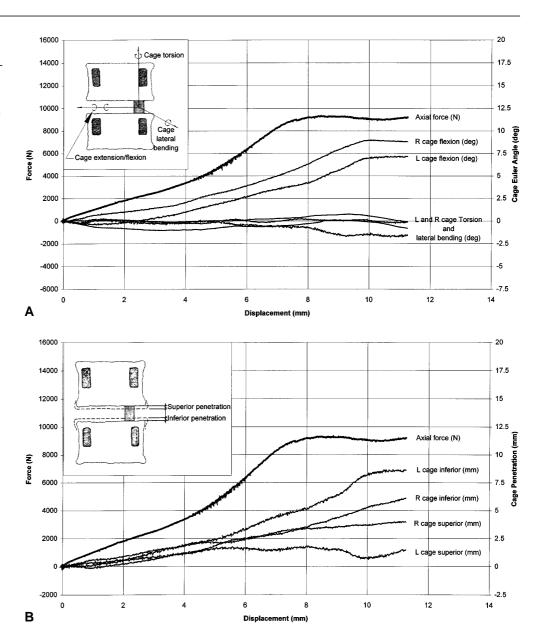
overlap the potential in vivo compressive loads known from in vivo intradiscal measurements [29, 40–43, 52] and biomechanical models [12, 29, 52]. In vivo disc pressure measurements have usually been performed using healthy young volunteers. Even considering the difference between this population and average candidates for PLIF surgery it is likely that loads in the human lumbar spine are between 1000 N and more than 3000 N during most everyday activities, and increase in different body positions with possible values in excess of 3000 N during significant lifting. Based upon these data, Brantigan et al. [4] suggested that a PLIF construct must bear an immediate postoperative load at the bone-implant interface of at least 2400 N during activities of daily living. In another study [45] the authors specified a fatigue strength of 9600 N for a cylindrical threaded titanium cage. Potential in vivo loads compared to the measured failure loads imply that failure of the bone-implant interface may occur clinically.

Effect of cage shape and posterior instrumentation

There was no significant difference in the failure loads due to cage type or posterior instrumentation. This suggests that the combination of cage shape and technique of endplate preparation does not have a significant effect on the strength of the bone-implant interface. From an engineering perspective, the area of endplate coverage and the local bone quality would be expected to be the determining factors for the interface strength. Gill suggested that, for successful interbody spinal fusion, between 50% and 80% of the vertebral body cross-sectional area should be covered by graft [25]. Closkey et al. [13] showed that for thoracic vertebral bodies the minimum necessary graft area to prevent subsidence under moderate physiologic loads was between 30% and 40%. The situation is probably too complex to simply state a required cross-sectional area. In our study the vertebral bone density was the covariate in the ANCOVA and therefore an important factor in determining the compression behaviour. The fact that no significant difference between failure loads for the three cages was detected implies that there was no difference in the combination of contact area and local bone quality. The Stratec and Brantigan cages both have a relatively large central opening but do not, or only slightly, penetrate the endplate, while the Ray cage has small fenestrations at the base of the threads and always penetrates the endplate. There appears, therefore, to be a trade-off between the area of endplate coverage and whether there is penetration of the endplate.

The posterior instrumentation did not significantly affect the failure load, which may be due to the posterior eccentricity of the instrumentation. It has been shown in other studies [18, 20, 26] that with pedicle screw constructs significant loads continue to be transmitted through the anterior column. It is, however, important to recognise the

Fig. 9A, B Typical implant motions of a cage pair during compression testing. The relative motion of the cage was calculated with respect to the fixed lower vertebra. Motion consists of three rotations (A) and penetrations of the implants into the superior and inferior vertebrae (B)



relatively limited scope of this study and interpret the results accordingly. For example, Lund et al. [39] demonstrated that posterior instrumentation significantly increases the stabilisation of lumbar spine segments after PLIF with intersegmental cages. It would not be appropriate, therefore, to conclude that posterior instrumentation offers nothing to the clinical success of a PLIF.

The mode of compression failure was always fracture of one or both of the endplates. Brantigan et al. [6] observed the same failure mechanism with fracture of the cancellous bone of the vertebral bodies directly superior and inferior to the cages. Fyhrie and Schaffler [24] found as a primary step of this failure mechanism a microscopic cracking rather than overt failure of the trabecular elements and a possibility of recovering, but with reduced

stiffness. Whether these microfractures are responsible for the observed postoperative settlement after PLIF [19, 47, 48] is still in question.

Two implant failures were observed in the carbon-fibre cage. This has been observed clinically [55]. Failures of the type observed may lead to an overall decrease in implant height – interpreted clinically as a loss of disc height – and ultimately to implant collapse.

In contrast to the failure load, the load at 3 mm was greater for the Brantigan and Ray cages than for the Stratec cage. These differences are believed to be related to implant surface area and initial quality of the bone-implant interface. With respect to the first point, the Stratec implant had the narrowest width (in the frontal plane) in the study and therefore would be expected to have less re-

sistance to deformation. Secondly, the Stratec implant was designed to fit to the anatomic contours of the vertebral endplate, while the Brantigan and Ray cages had planar and cylindrical interface surfaces respectively. The Stratec implants, in contrast to the other implants, which penetrated the bony endplate, were frequently observed to have a relatively poor fit against the endplate. The variation inherent in anatomic endplates may make it difficult to fit all specimens with a single implant contour. For this reason as well, the interface may not have been as stiff as with the Brantigan or the Ray cages.

Effect of bone density

Universally, there were higher failure loads and greater loads at 3 mm displacement for higher bone densities. These results agree with those of numerous other investigators who have reported a relation of the fracture type of the vertebral body to bone density [30], a strong relation of delayed fusion to osteoporosis [38] and a direct relationship of the compressive strength to bone density [3, 13, 28, 30–32].

There are almost certainly factors, in addition to the BMD, that affect the measured strength and stiffness values. For example, in a previous study in which the specimens used in this study were part of a larger data set [44], it was postulated that the DEXA-based BMD values were inflated by peripheral osteophytes in very degenerated discs. The BMD values for the vertebral centrum may actually have been lower. Further, in that study the amount of disc degeneration was related to failure loads and to the BMD values.

The observed loads in this study, particularly those for 3 mm displacement, are in the range of probable in vivo compressive loads. Preoperative BMD measurements may thus be an effective clinical tool for predicting settling around interbody cages. Our results suggest that patients with relatively low BMD may be predisposed to early postoperative disc height loss.

Limitations

This experiment addresses only the immediate, primary compressive behaviour of the various implant configurations. The effect of bony ingrowth was not modelled and therefore information regarding time-related changes in the measured parameters was not obtained. Another limitation was that each of the groups studied consisted of either five or six specimens. Under these conditions the power of the statistical procedures used is relatively low and it could be that undetected differences between tested groups existed. This is a common disadvantage when human cadaveric material, of limited availability, is used.

Clinical relevance

The focus of this study was the immediate postoperative compression strength of the PLIF construct. The effects of cage shape, the insertion technique and the endplate preparation as well as the presence of posterior instrumentation were not as important for the immediate in vitro postoperative compressive strength of the PLIF construct as expected. The extent to which these factors prevent the settlement of the construct in vivo is not yet clear.

The correlation of failure load and load at 3 mm displacement with BMD suggests vertebral bone must be relied on for disc height maintenance. Augmentation with posterior instrumentation may not improve the cage subsidence behaviour. Clinically, it is possible that bone density measurements could be used to predict postoperative cage settling. Further corroboration in biomechanical and especially clinical studies is necessary, however.

Conclusions

- Neither the cage design nor the posterior instrumentation had a significant effect on the measured failure loads. This suggests vertebral bone must be relied on for disc height maintenance and augmentation with posterior plates and screws may not improve the cage subsidence behaviour.
- 2. Direct relationships were observed between both the failure load and the load at 3 mm displacement and the DEXA bone density measurements. Preoperative measurements of BMD may be an effective tool in predicting settling around interbody cages.

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