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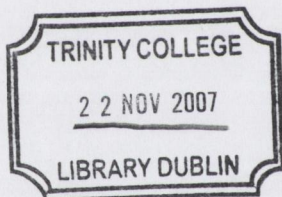
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Experimental reinforcement
of the vertebral endplate: A
biomechanical study on
prevention of intervertebral
cage subsidence

THESIS

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**Experimental reinforcement
of the vertebral endplate: A
biomechanical study on
prevention of intervertebral
cage subsidence**

**A thesis submitted to Trinity College
Dublin for the Degree of Master in
Surgery**

July 2007

by

Michael Leonard

DECLARATION

I declare that this thesis is entirely my own work and has not been previously submitted in any form for a degree or diploma at this or any other university.

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Michael Beaudry

Date

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SUMMARY

Study design - An in vitro biomechanical investigation to design an effective method of vertebral endplate reinforcement to decrease the risk of intervertebral implant subsidence.

Background - Anterior column interbody support plays an important role in spinal reconstruction. Subsidence of interbody structural support is a common problem and is brought about by the loss of interface strength between the implant and the vertebral endplate. This may lead to deformity, compromise of neural elements, and unfavourable biology leading to non-union. This can necessitate difficult revision surgery, often creating larger defects and more complex anterior column reconstruction. An effective method of endplate reinforcement which reduces the risk of subsidence with all its inherent complications would be of value to spinal surgeons.

Objectives - To design, biomechanically assess and compare four experimental methods of endplate reinforcement, with the overall purpose of designing the most effective reinforcing construct for clinical use.

Materials and Methods - Skeletally mature sheep lumbar vertebrae standardised for bone mineral density by dual energy radiograph absorptiometry were used for testing. The five subgroups comprised the following: 5 normal

vertebrae, 5 vertebrae with flat mesh plate, 5 with anchored mesh plate, 5 with screw fixation and 5 with bone cement reinforcement. Two batches of each subgroup were constructed with one batch undergoing uniaxial compressive loading via a hollow titanium mesh cage in test cycle 1, and the other batch via a solid indenter in test cycle 2. Both the mesh cage and the indenter were of the same geometry and diameter. The first test cycle examined the effect of the experimental constructs when compressed with a hollow implant, to simulate the early postoperative period before fusion has occurred across the segment. The load deformation data was recorded as Newton's applied versus vertebral penetration in millimetres. The second test cycle used a solid indenter to simulate the situation where fusion has occurred, and measured the maximal strength of the constructs by applying increasing load until construct failure had occurred, recorded as the maximum load to failure in Newton's.

Results- All four reinforcing constructs increased the vertebral resistance to increasing load, when compared with the normal subgroup. The anchored mesh plate provided the greatest overall reinforcement and had the highest maximum load to failure of all constructs.

Conclusion – Vertebral endplate reinforcement is a potential method of preventing implant subsidence and subsequent failure. The anchored mesh plate provides the most suitable option due to its high resistance to subsidence, its versatility, and ease of application in the operative setting. The impact of the mesh on bony fusion however needs to be further evaluated to ensure it does not impede the achievement of a solid arthodesis across the operative segment.

ABBREVIATIONS

BMP	Bone morphogenetic Protein
PEEK	Polyetheretherketone
BAK	Bagby-and-Kusich
PMMA	Polymethylmethacrylate
MLF	Maximum load to failure

1.0 - INTRODUCTION

1.1 Vertebral anatomy

The human vertebral column consists of 7 cervical, 12 thoracic, 5 lumbar, 5 sacral and 5 coccygeal vertebrae (Figure 1.1). Vertebrae in different regions of the vertebral column have specific characteristics and differ in size.

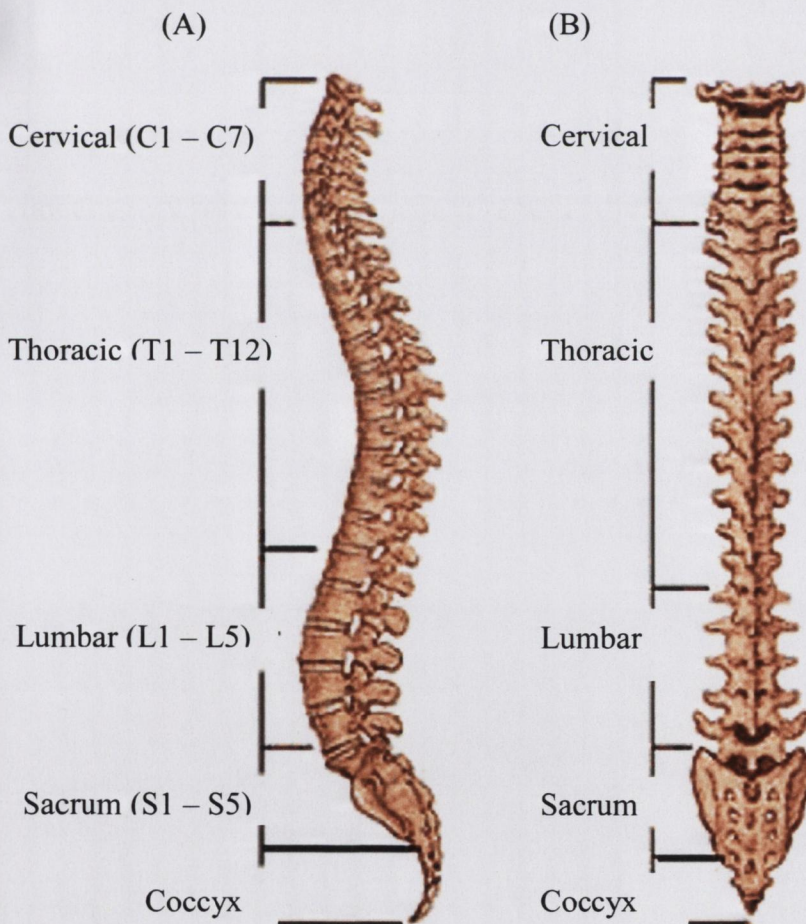


Figure 1.1. The vertebral column: A – lateral view, B – posterior view (Moore 1992)

A “typical” vertebra is composed of two parts (Figure 1.2): –

1. The body which comprises the large heavy anterior part in the form of a short cylinder. It is composed mainly of cancellous bone and is capped both superiorly and inferiorly by the endplates. Its function is to support weight. The bodies of the vertebrae become progressively larger in a caudal direction in order to bear progressively more weight.

2. The vertebral arch which is formed by two pedicles which project posteriorly from the body to meet two laminae which meet posteriorly to form a spinous process. Four articular processes and two transverse processes also arise from the vertebral arch. The space enclosed by the body and arch is the vertebral foramen. The succession of foramina in an articulated vertebral column forms the vertebral canal which contains the spinal cord, nerve roots and blood vessels (Figure 1.3).

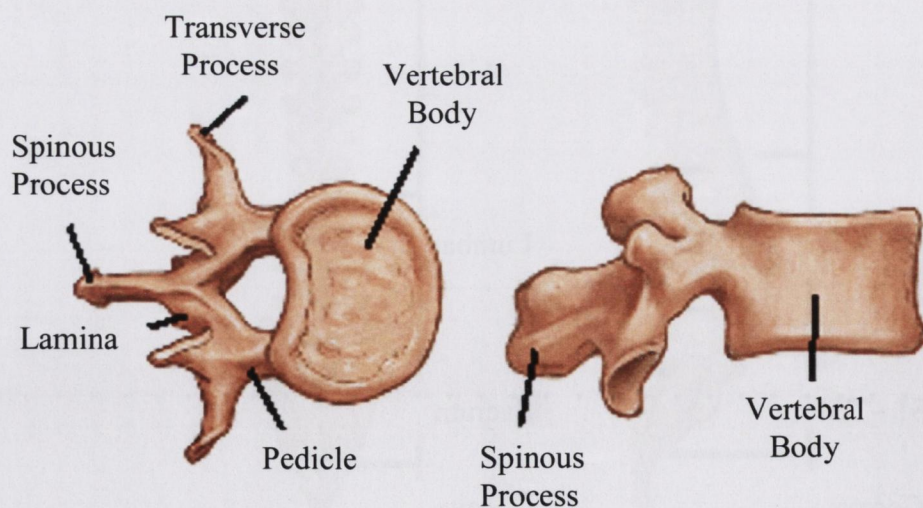


Figure 1.2. Anatomical features of a vertebra from both the axial and lateral views (Ellis 2002).

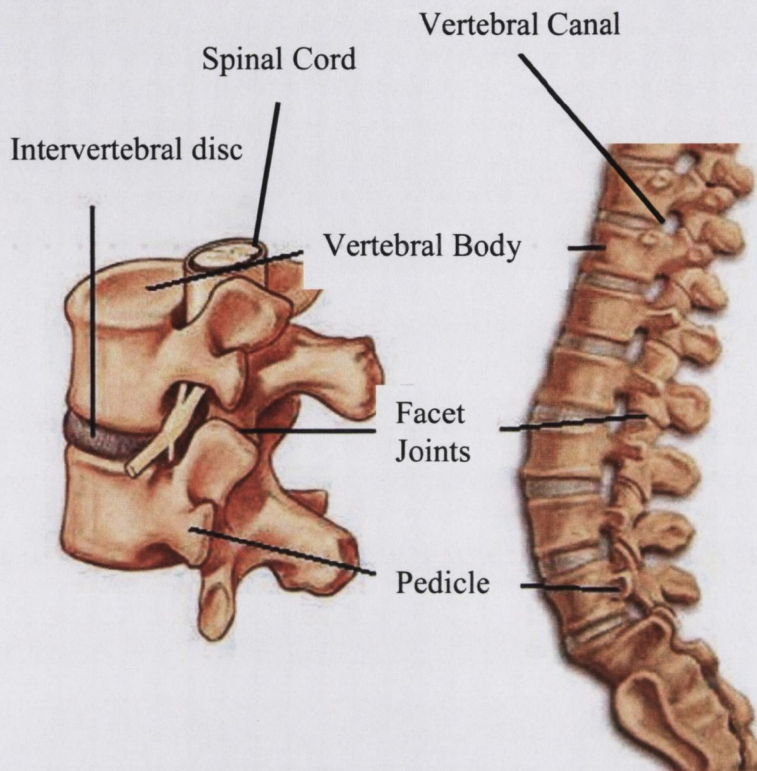


Figure 1.3. Vertebral articulation and spinal cord (Ellis 2002)

1.2 The endplate

The vertebral endplate consists of a thin layer of hyaline cartilage and cortical bone located on the cranial and caudal interface between the cancellous bone of the vertebral body and the cartilaginous intervertebral disc (Walmsley *et al* 1953) (Figure 1.4).

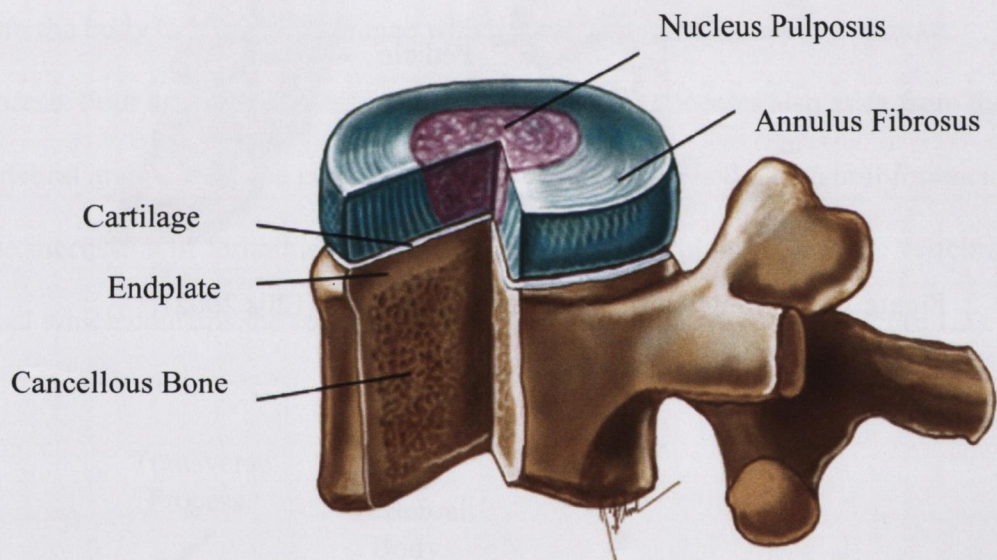


Figure 1.4. The vertebral endplate which lies between the cancellous bone of the vertebral body and the cartilaginous intervertebral disc (Netter 2003)

The endplates are recognisable from an early embryologic stage and retain their cartilaginous nature during normal maturation while the adjacent vertebrae undergo ossification (Taylor *et al* 1988). When the epiphysis fuse in the young adult spine, only the outer rim of the cartilage endplate is ossified leaving a broad central cartilaginous plate. The end plates are thin, particularly in the centre, measuring no more than 1mm at maturity (Edwards *et al* 2001).

The main chemical components of the endplates are similar to those found in hyaline cartilage and the disc itself, being proteoglycan, collagen, and water (Antoniou *et al* 1996). The general microscopic appearance of the endplate resembles that of articular cartilage, with chondrocytes interspersed in a cartilaginous matrix (Roberts *et al* 1999).

The endplate has two main functions, as well as providing the axis for the diffusion of nutrients eg. glucose to the avascular intervertebral disc, the end plates also are important for the mechanical function of the spine. In the course of normal physical activity, mechanical loading especially axial compression can alter the shape of the intervertebral disc to the extent that the end plates and the subchondral bone become deformed (Brinckman *et al* 1983). This deformation is reversible in young healthy endplates. Rockoff *et al* (1969) reported that the end plate contributes up to 75% of the peak strength of the vertebral body during compressive loading.

Morphologic changes to the endplates occur with advancing age but may also be seen in association with disc pathology eg. degenerative disc disease (Herkowitz *et*

al 2004). The earliest changes are microscopic and begin after maturity with the development of fissures and clefts along the length of the end plate in the horizontal plane. With time the cartilage becomes depleted with extension of ossification from the adjacent bony end plate. The most dramatic changes occur after the fifth decade, with macroscopic evidence of nuclear material protruding into the adjacent vertebral marrow (Schmorl node) and frequently the total loss of the cartilage endplate (Vernon-Roberts 1992)

1.3 The anterior spinal column

Structurally the spine can be regarded as consisting of three columns. This three-column concept of spinal stability was developed by Denis F (1984) and has been well described in the literature (Figure 1.5).

The anterior column (A). This is formed by the anterior two-thirds of the vertebral body and its ligaments

The middle column (M). This consists of the posterior one-third of the vertebral body and its associated ligaments

The posterior column (P). This comprises the neural arch, the pedicles, the spinous process and the posterior ligaments

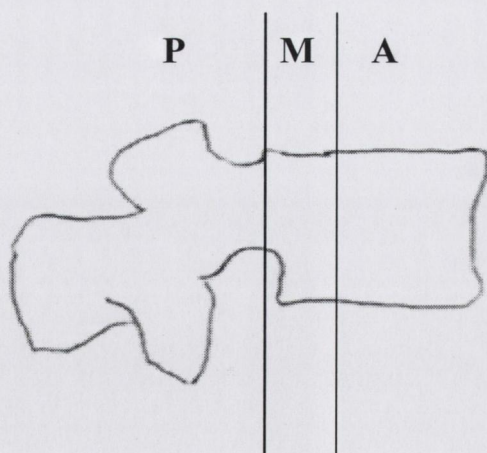


Figure 1.5. Diagram displaying the three spinal columns

Anterior column stability is essential for achieving normal spinal biomechanics. Surgical intervention is employed at this site in either degenerative conditions of the spine requiring fusion eg. degenerative disc disease, degenerative spondylolisthesis, or as a form of anterior column reconstruction after destruction by tumor, infection, or trauma (Herkowitz *et al* 2004).

1.4 Interbody fusion cages in reconstructive spinal surgery

Description: The aims of spinal reconstructive surgery include the potential for decompression, restoration of normal anatomic relations, immediate postoperative stability of the construct, and the resulting fusion. The area of decompression varies from the single disc level, e.g., in degenerative disc disease, to the long level lesion, e.g., in a spinal tumour. Fusion cages used to achieve these aims can be described as interbody spacers used to bridge or reconstruct the interval between two vertebral bodies.

The surgical technique used to insert fusion cages is dependent on a number of key factors, including the pathology in question and its location in the spine, the aim of operative intervention, patient co-morbidities, and the surgeons' preference and expertise. The two main approaches are anterior and/or posterior (Figure 1.6).

The advantages of an anterior approach include excellent access to the anterior spinal column, and avoidance of the significant muscle and nerve damage often associated with a posterior approach. The disadvantages include potential risk to major neurovascular structures' and the potential need for another surgical team in order to gain access, which can greatly increase financial cost.

The posterior approach avoids these potential pitfalls and allows for the placement of both the fusion cage and additional posterior instrumentation if required.

However in order to gain access posteriorly a certain amount of stripping of the paraspinal muscles from their bony attachments must be done. This may lead to

significant blood loss requiring transfusion, inadvertent nerve injury and chronic post surgical back pain (Herkowitz *et al* 2004).

Regardless of which approach is used a thorough knowledge of spinal anatomy, meticulous surgical technique, gentle tissue handling, and experience with the use of the relevant instruments and implants is essential.

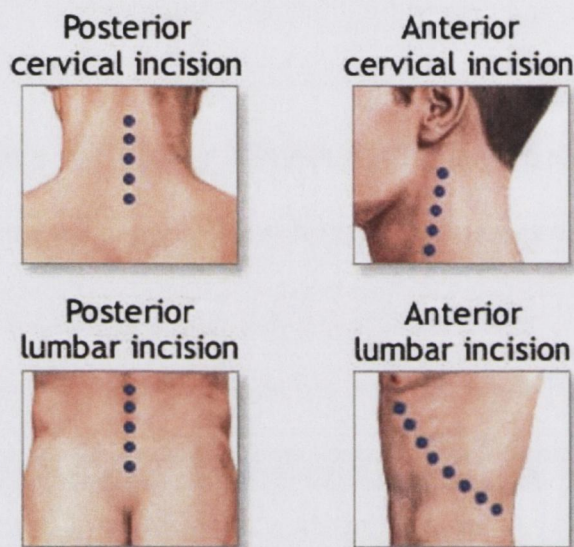


Figure 1.6. Diagram of approach options to both the cervical and lumbar spine

During the last five years, surgeons around the world have inserted more than 80,000 interbody fusion cages; in the United States alone, an estimated 5000 such devices are implanted each month (Mc Affee 1999). Cages as mentioned can be used on their own as 'stand alone cages' (Figures 1.7 and 1.8) or in combination with anterior and/or posterior instrumentation (Figures 1.9 and 1.10). There are many different designs, but they all aim to provide a mechanically strong scaffold inside of which osteoinductive or osteoconductive materials can be placed to achieve fusion across the segment. Such material maybe autogenous bone graft,

allograft, or more recently bone morphogenetic proteins (BMP) (Weiner *et al* 1998). An ideal graft for lumbar interbody fusion should provide an osteogenic, non-immunogenic matrix and immediate postoperative mechanical stability, while being technically easy to modify into an appropriate size and shape (Kozak *et al* 1994). Once the cage has been inserted the patient is usually allowed to mobilise a day or two postoperatively with fusion occurring across the segment in two to four weeks.



Figure 1.7. 'Stand alone' cage in the L4-L5 disc space.

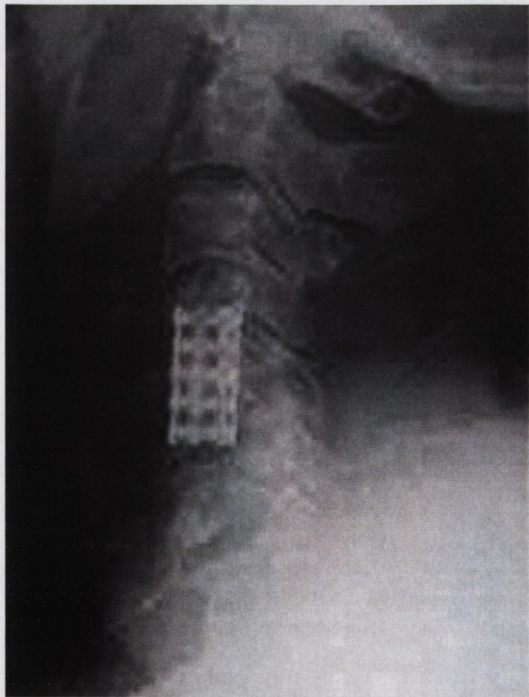


Figure 1.8. Anterior column reconstruction in cervical spine with an interbody fusion cage.



Figure 1.9. Interbody fusion cage combined with anterior plate in the cervical spine.



Figure 1.10. Interbody cages combined with posterior instrumentation in the thoracic spine

Harms titanium mesh cage: The cage design used in this study was the Harms titanium mesh cage, developed by Harms *et al* (1992, 1997), the cage has been in widespread clinical use since 1991 (Mc Affee 1999). Harms developed the concept of this device to provide anterior load-sharing support for corpectomy defects created after anterior decompression for the treatment of fractures and tumours. It is a vertical ring cage type which can be inserted from an anterior or posterior approach. The Harms titanium mesh cage fulfils all the requirements of an interbody fusion cage (Lowery *et al* 1996). It is composed of fenestrated titanium and is designed to allow the length to be cut as desired; therefore, they can be used to span either a single disc space or multiple segments in order to reconstruct the anterior column. (Figure 1.11). The cage is filled with bone graft or BMP (Figure 1.12), and can be combined with additional spinal instrumentation as required (Figure 1.13). The cage once *in-situ* will be subject to compression, although it may be required to resist some shear force that tries to slide the graft across the surface of the host bone. The immediate post surgical biomechanical aims are as follows: to carry reasonable loads that might correspond to moderate movement in the standing position and to be stiff and unmoving under these loading conditions (Evans 1985).

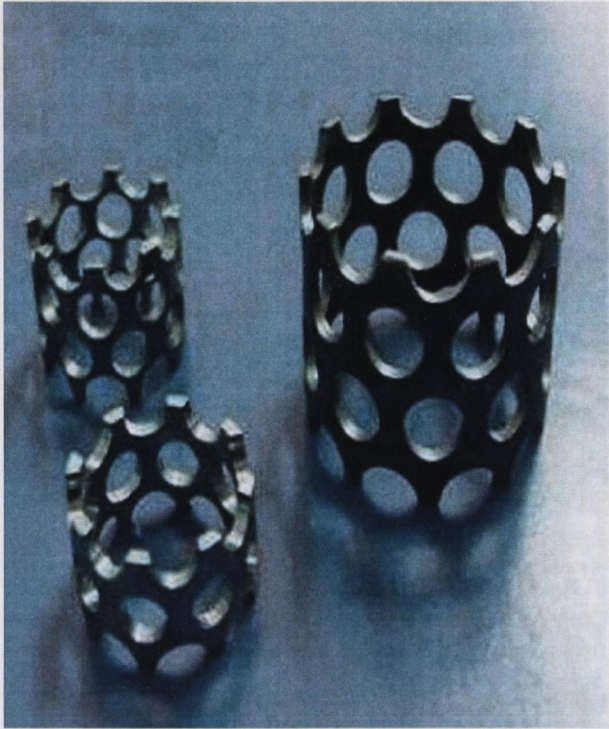


Figure 1.11. Different size titanium mesh cages which can be used throughout the spine

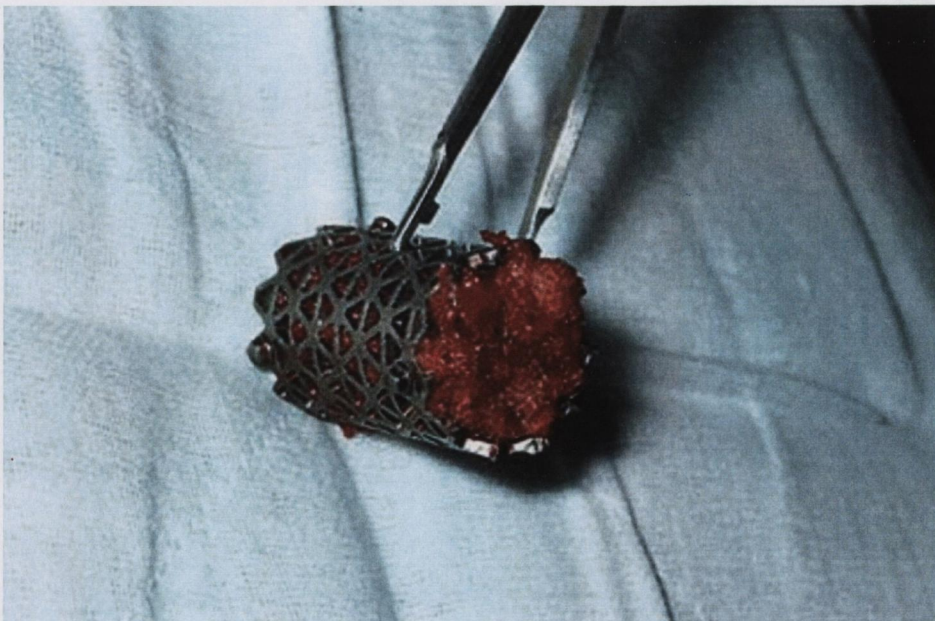


Figure 1.12. Titanium mesh cage packed with autogenous cancellous bone graft

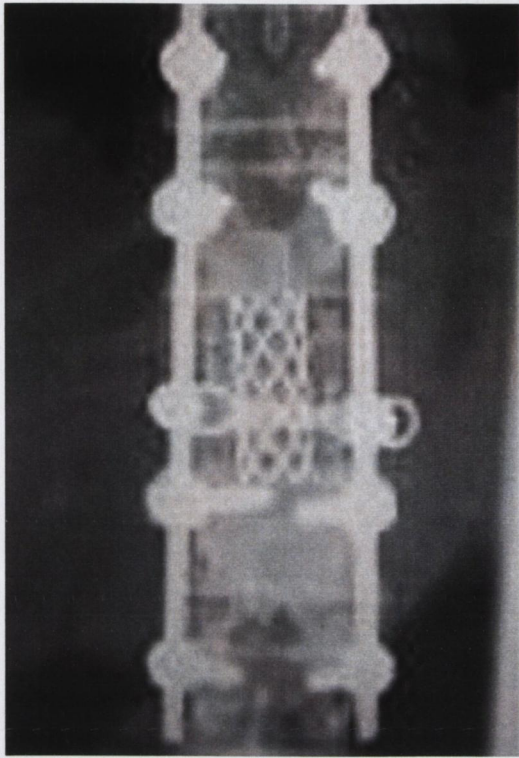


Figure 1.13. Titanium mesh cage in combination with posterior instrumentation

1.5 Implant subsidence

Along with the intrinsic benefits associated with the use of intervertebral fusion cages (enhanced mechanical stability, maintenance of intervertebral disc height and the avoidance of bone graft donor site morbidity), there are several possible complications that can be associated with their use. The most common of these problems is subsidence (or penetration) of the construct into the cancellous bone of the vertebral body (Lowe *et al* 2004) (Figure 1.14). Subsidence can lead to segmental kyphosis, loss of anterior column support, pseudoarthrosis, progressive deformity, and failure of anterior or posterior instrumentation (Brantigan *et al* 1991, Closkey *et al* 1993, Kozak *et al* 1994). These complications may lead to a return or even worsening of preoperative symptoms for the patient, and the need for difficult revision surgery, often creating larger defects and more complex anterior column reconstruction (Oxland *et al* 2003).

Once inserted into the spine fusion cages are subjected to compressive loading from body weight, compression on the lumbar spine is 1000 Newton's for standing and walking and is higher during lifting (Avinash *et al* 2001).

(A)



(B)

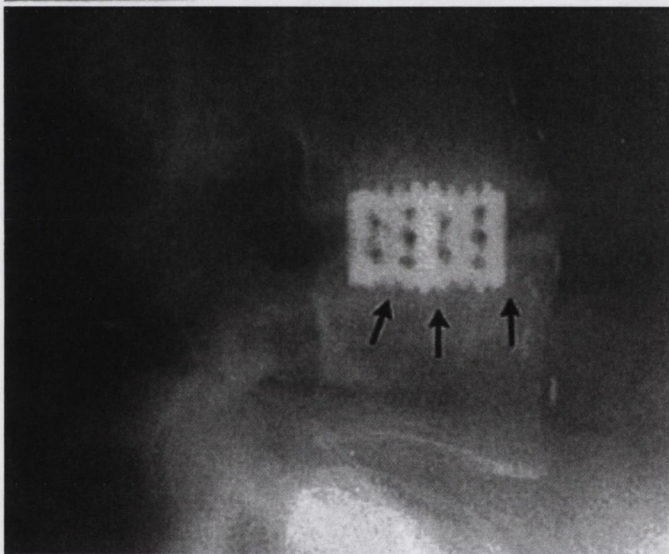


Figure 1.14. (A) Postoperative lateral X-ray revealing a fusion cage within the L4-L5 interspace. The cage is seated on top of the vertebral endplates. (B) lateral radiograph obtained 1 year postoperatively displaying significant subsidence of the implant into the L5 vertebral body. The *arrows* outline the extent of subsidence within the centre portion of the L5 vertebral body. A loss of segmental lordosis can be seen in comparison with the initial postoperative radiograph.

1.6 Experimental endplate reinforcing construct design

In this study four experimental models of endplate reinforcement were designed and tested:

Vertebroplasty - This is the percutaneous injection of polymethylmethacrylate (PMMA) into the vertebral body. This practice was initially presented as a treatment for vertebral angiomas and is now used clinically to provide strength and support to the vertebral body, in order to restore spinal alignment or decrease chronic pain in patients with spinal tumours or vertebral compression fractures respectively (Garfin *et al* 2001). Biomechanical studies of cement augmentation have shown that thoracolumbar and lumbar vertebral strength can be restored by the injection of 2mls of PMMA using the bipedicular approach (Belkoff *et al* 2001)

It was tested in this study as a potential way of increasing the endplates resistance to subsidence by reinforcing the cancellous bone of the vertebral body, which acts as a buttress, supporting the endplate from beneath.

Screw insertion – This involved the insertion of three screws anteriorly into the sub cortical bone of the vertebral body to act as a reinforcing mechanism for the endplate. Previous studies have examined the use of anterior screw placement in combination with intervertebral fusion constructs, Kuzhupilly *et al.*(2002) demonstrated increased stability in extension when integrated crossed anterior screws were applied through a femoral ring allograft into the adjacent vertebral bodies. Kozak *et al.* (1994) in a review of 45 patients reported a fusion rate of

97% when the intervertebral implants were combined with two anterior buttress screws. The primary function of the screws in these studies was to stabilise the implant, and to prevent implant extrusion respectively. In this study, screw insertion was designed to reinforce the endplate from beneath, thus strengthening its resistance to axial compression from above and decreasing subsidence.

Flat mesh plate - A flat steel mesh plate was used to cover the vertebral endplate. Steel mesh has been used extensively in hip arthroplasty, particularly in revision procedures where impaction grafting with morcellised cancellous bone grafting is necessary to replace extensive acetabular bone loss (Schreurs *et al* 1998, Welden *et al* 2000). In the case of an acetabular reconstruction, the wire mesh may be used to bridge a large cavitary bone defect at the bottom of the area with insufficient bone stock, the interfaces created being host bone-wire mesh-impacted graft-cement-cup, with fusion occurring across the mesh (Sloff *et al* 1996, Schreurs *et al* 2001).

The mesh plate was designed to provide a metal-on-metal interface with the cage and thus increase the resistance of the vertebra to compression, reducing the risk of subsidence. The mesh also allows for bone growth through it due to its fenestrations, thus allowing fusion to occur through the plate.

Anchored mesh plate – A flat mesh plate as used above with a vertical extension of 12mm. This extension then allowed for screw fixation through the vertical portion of the mesh into the vertebral body beneath the endplate. This design was based on increasing the interface strength between the endplate and the

implant and also the theory that anchoring the construct would increase its stability thus improving its overall function and safety in the operative setting.

1.7 Biomechanical testing

The experimental reinforcing constructs were applied to sheep lumbar vertebrae. . Sheep vertebrae have previously been successfully used in testing of interbody fusion cages (Cunningham *et al* 1998, Cunningham *et al* 1999). Uniaxial compression was applied to all experimental models and a control group of non-reinforced vertebrae (Figure 1.15).

Two testing cycles were run - compression was applied via both a hollow titanium mesh cage (Test Cycle 1) and a solid indenter (Test Cycle 2), both of the same geometry (vertical ring) and diameters (14mm). Lowe *et al* (2004) in their study on regional endplate strength and cage morphology used compressive loading to demonstrate that subsidence into the vertebral body was different for hollow and solid indenters (See Chapter 2.6).

The hollow titanium mesh cage alone was used to simulate the early postoperative period where the cage is in-situ but fusion has not yet occurred. Once a cage has been inserted it is designed to provide immediate mechanical stability, allowing for early patient mobilisation and weight bearing (Evans 1985). The solid indenter was used to simulate the later situation where fusion has occurred.

The overall aim of the study was to design and test the most effective, clinically applicable method of reinforcing the end plate, to prevent the common and potentially catastrophic complication of intervertebral implant subsidence.

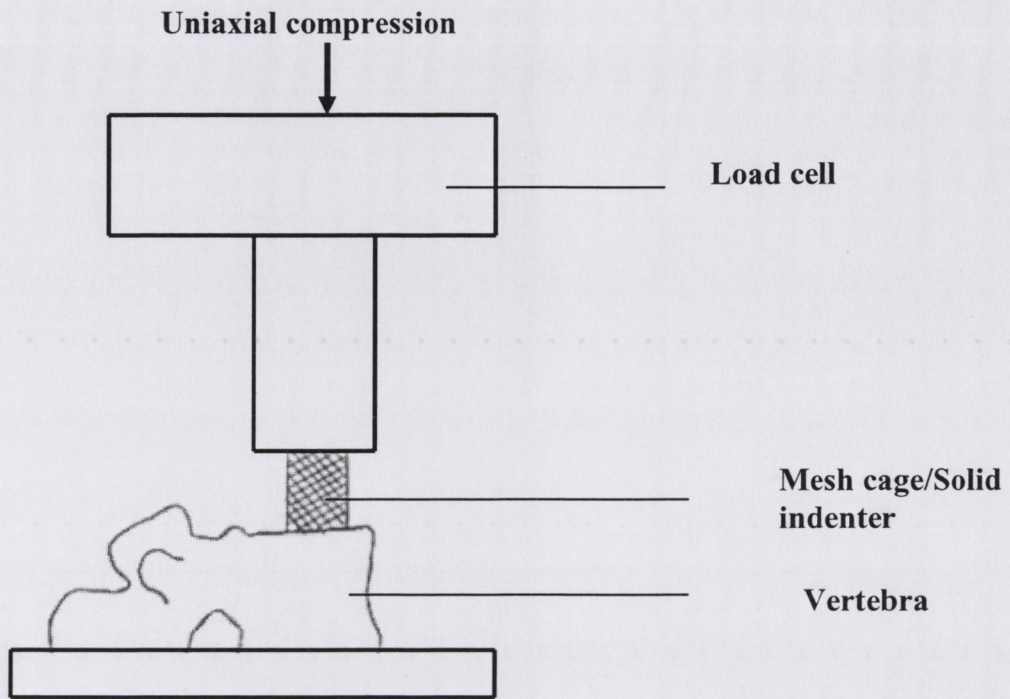


Figure 1.15. Experimental setup. Both normal and reinforced vertebrae will be tested with this apparatus.

2.0 Literature Review

2.1 Interbody Fusion cages: The recent interest in performing interbody arthrodesis with use of cages is attributable to three factors: the high rate of failure associated with use of bone graft alone (Crock 1976, Hutter 1983, Blume 1985); the high rate of failure associated with use of posterior pedicle-screw instrumentation (Steffe *et al* 1988, Grubb *et al* 1992, Weiner *et al* 1998); and the high rate of success associated with use of so-called stand-alone anterior fusion cages and autogenous bone graft, obviating the need to perform a 360-degree (combined anterior and posterior) lumbar arthrodesis with use of posterior instrumentation (Ray 1997).

2.2 Background: Early techniques of anterior column reconstruction and arthrodesis with use of allograft or autogenous graft and without instrumentation were associated with a high rate of failure. In a classic study, Stauffer *et al* (1972) reported on eighty-three patients who had had an anterior interbody arthrodesis using bone graft alone between 1959 and 1967. Of seventy-seven patients who were followed clinically for an average of 3.75 years after the procedure, twenty-eight (36 percent) had good (76 to 100 percent) relief of pain, fifteen (19 percent) had fair (26 to 75 percent) relief, and thirty-four (44 percent) had poor (0 to 25 percent) relief. Thirty (44 percent) of sixty-eight patients who were evaluated radiographically at a minimum of eighteen months postoperatively had a pseudarthrosis and failed fusion. These results, and the equally unfavourable results reported by other investigators (Lin *et al* 1983, Rish 1985, Fraser 1995)

prompted investigation into and development of various augmentation devices to improve the long-term outcome of spinal arthrodesis.

2.3 Evolution of interbody fusion cages: Bagby (1988) was responsible for the early development of the interbody fusion cage. Working with a series of thoroughbred horses that had wobbler syndrome (a form of spondylitic myelopathy that leads to ataxia), he found that the Cloward technique (1953), which requires obtaining bone from the iliac crest, resulted in unacceptable morbidity. Bagby then developed a novel device, the first interbody stainless-steel basket (the Bagby basket), which was a thirty-millimetre-long, twenty-five-millimetre-diameter cylinder that had two-millimetre fenestrations in its walls to allow bone ingrowth. During an anterior cervical decompression and fusion, cancellous-bone chips were removed from the posterior aspects of the cervical vertebrae. These chips then were packed inside the basket to promote anterior interbody cervical fusion. Subsequent studies revealed that horses treated with the Bagby technique had improved neurological function; some not only survived for many years but also won races (Grant *et al* 1985). Other investigators began making modifications of this technique, including threads in the basket (Yuan *et al* 1997), adaptation of the cage for use in posterior lumbar interbody arthrodesis, and increases in the pullout and compressive strength (Otero 1985); a two-cage technique also was developed, in 1988 (Crawley *et al* 1988).

2.4 Current types of fusion cages: There is as of yet no universally accepted classification for fusion cages. They can be broadly divided into different types by their design: horizontal cylinders, vertical rings and open boxes, and their material, either titanium or a carbon composite (polyetheretherketone [PEEK]) (Herkowitz *et al* 2004). A variety of cages are currently available including the Bagby-and-Kuslich device (BAK; Sulzer Spine-Tech, Minneapolis, Minnesota), the Ray cage (U.S. Surgical, Norwalk, Connecticut), the Brantigan rectangular and rounded cages (DePuy-AcroMed) and the Harms titanium-mesh cage (DePuy-AcroMed, Cleveland, Ohio). The long term effects of these implants are not yet known thus limitations have been placed on their use, the BAK device may be used only for posterior, anterior, or lateral laparoscopic procedures; the Ray cage, only as a posterior device; and the Brantigan cages, only as posterior devices and only in conjunction with posterior pedicle-screw instrumentation. Only the Harms cage has been approved for widespread, unrestricted use to date and was used as the cage model in this study (Mc Affee 1999).

2.5 Mechanical role of fusion cages: In an effort to establish a baseline for the comparison of investigations of the role of fusion cages, Dennis *et al.* (1989) studied thirty-one patients who had had an anterior interbody arthrodesis at a total of forty levels using both iliac allograft and autograft but not metal cages. The height of the disc space was measured in each patient preoperatively, early postoperatively, and at an average of twenty-nine months postoperatively. Although immediate postoperative radiographs showed an average increase in the disc-space height of 9.5 millimetres (89 percent), use of graft alone did not provide long-term distraction of the disc space or increased neuroforaminal height. At the time of the latest follow-up examination, the disc-space height had decreased in every patient (100 percent); at nineteen of the forty vertebral levels, the height at the most recent examination was less than the preoperative height. This study demonstrated that autogenous graft or allograft alone cannot maintain neuroforaminal distraction. Maintaining this distraction is important because it promotes anterior load-sharing, increases the amount of space for the nerve roots, and prevents flatback syndrome.

To gain perspective on the rates of fusion associated with lumbar interbody fusion cages, it is helpful to review the prospective study reported by Zdeblick (1993). One hundred and twenty-four patients were randomly assigned to one of three treatment groups: posterolateral arthrodesis with use of autogenous bone grafts (group I), posterolateral arthrodesis supplemented with semi rigid pedicle-screw instrumentation (group II), or posterolateral arthrodesis with autogenous grafts and rigid pedicle-screw-and-rod fixation (group III). The overall rate of fusion was 65 percent for group I, 77 percent for group II, and 95 percent for group III.

Kanayama *et al* (1998) used bench-top mechanical tests to assess different types of fusion cages in sixty functional calf-spine units, each consisting of one vertebral disc space and the adjacent vertebrae. There were six specimens in each treatment group. The methods of preparation of the cage, anterior discectomy, and annular distraction with use of sized distraction plugs before insertion of the cage were similar for all ten constructs. The devices that were tested included two BAK cages, two BAK proximity cages, two Ray cages, one Harms titanium-mesh cage, two Harms vertical titanium-mesh cages, two Brantigan rectangular carbon-fiber cages, and a larger rounded Brantigan anterior lumbar interbody fusion cage shaped to fit within the interbody disc space. The modes of testing included axial compression, torsion, flexion, and lateral bending. With the numbers available for study, no significant differences were detected among the ten cage constructs with regard to functional stability ($p > 0.05$, one-way analysis of variance). Other authors have determined that the surgical technique is as important to the overall stability of the construct as the individual characteristics of the fusion cage (Glazer *et al* 1996, Sandhu *et al* 1996, Brodke *et al* 1997).

2.6 Cage Subsidence: Subsidence of the cage is brought about by the loss of interface strength between the cage undergoing compressive loading, and the vertebral endplate on which the implant is pressing (Tan *et al* 2005). The vertebral end-plate functions as one of the key factors in preventing interbody structural support subsidence. A number of studies have highlighted the structural support provided by the end plates and the importance of maintaining their integrity to minimise the risk of graft subsidence. Lim *et al* (2001) used destructive compression tests to evaluate the effect of partial and complete removal of the end-plate on the biomechanical strength at the graft-endplate interface. In this study cervical vertebral specimens were assigned to one of three groups with different end-plate conditions (Group 1, intact; Group 2, partial removal; and Group 3, complete removal). All groups then underwent compressive loading until the maximum load to failure was determined. The findings clearly demonstrated that load to failure decreased with incremental removal of the end-plate ($p < 0.05$).

Lowe *et al* (2004) carried out a similar analysis on the vertebral end-plates resistance to compressive loads, in the thoracic and lumbar spine. Using destructive loading applied through both solid and hollow indenters they demonstrated a sequential decrease in the mean maximum load to failure that corresponded to the increased removal of the endplate ($p < 9.3 \times 10^{-5}$), with a decrease of approximately 39% in compressive strength with the complete removal of the end-plate. The effect of indenter geometry was also analysed in this study in order to simulate the early and late post-operative periods. The indenters with the highest maximum load to failure were the 19.10-mm diameter hollow and 12.70-mm diameter solid indenter, which produced similar peak loads.

They concluded that for a given diameter, solid spacers resulted in a higher maximum load than hollow spacers'; however, using a larger-diameter hollow spacer can produce a similar load to failure as a smaller solid spacer.

3.0 - MATERIALS AND METHODS

3.1 Outline

The purpose of this study was to design and biomechanically assess four experimental methods of end-plate reinforcement.

Four methods of vertebral endplate reinforcement which could potentially be applied in the clinical setting were designed and underwent uniaxial compressive loading.

Two test cycles were carried out –

- Test cycle 1 applied a compressive force through a hollow titanium mesh cage in order to record the effect of the reinforcing constructs on the pattern and depth of subsidence/penetration into the vertebral body. This test was carried out to simulate the early postoperative period before fusion has occurred across the cage, and to evaluate the constructs when compressed with a hollow implant.
- Test cycle 2 applied a compressive force through a solid steel indenter of the same geometry and diameter as the titanium cage used in the first cycle, this was to simulate the fused model. The maximum load failure which is the peak load at which the compression load decreases for the

first time was determined in order to ascertain the overall strength of the constructs in resisting axial load.

3.2 Specimen attainment, storage, preparation and disposal

Fifty disarticulated sheep lumbar vertebrae from L3 to L6 were obtained from 15 skeletally mature (>5years) female sheep. The fresh specimens were collected immediately after slaughter and routine processing at a local meat rendering facility (Irish Country Meats Ltd, Athboy, Navan, Co Meath, Ireland). ICM staff were instructed to select skeletally mature ewes, that is over 5 years of age at date of slaughter. All animals were checked prior to slaughter by ICM veterinary staff and only carcasses of healthy animals were allowed through the meat rendering process after slaughter, therefore only healthy animal bone was selected.

A fan beam dual energy x ray densitometer (QDR 4500 Elite, Hologic, Philadelphia, USA) was used to measure the bone density of the *ex vivo* sheep lumbar spine samples. There is a correlation between bone mineral content and ultimate compressive strength of vertebrae, the strength has been found to increase linearly as bone mineral content increases (Hansson *et al.* 1980). As compressive loading was used in this study, DEXA scanning of all vertebrae was undertaken to ensure a relatively homogeneous group with respect to bone mineral density. Previous studies have demonstrated the reproducibility and accuracy of measurement of bone mineral density in sheep models using DEXA scanning (Turner *et al.* 1995). A 60 cm long, 40 cm wide by 20 cm tall clear perspex tank (A.C. Taylor Ltd, Dublin, Ireland) was constructed to hold a water medium, simulating non bone soft tissue, and to allow standardised positioning of the bone samples for scanning. The tank was filled with water to a level of 10 cm prior to

sample positioning. All samples were scanned in isotonic saline made up prior to each scanning session by dilution of 216g of Sodium Chloride, in 24 L of water present in the scanning tank.

Following scanning the vertebrae were then stored in sealed plastic bags at -20C. Death and frozen storage have little effect on the mechanical properties of the spine (Adams 1995). Prior to testing, the vertebrae were thawed at +3C for twenty-four hours. Once thawed the vertebrae were disarticulated and the spinous and transverse processes were removed (Figures 3.1 A and B). Both the superior and inferior discs were removed from each vertebra, leaving the endplate and vertebral body intact.

Twenty five vertebrae were randomly assigned to each of the two testing cycles. Within each cycle five vertebrae were used as controls and the remaining twenty were divided into subgroups of five, each of which had a one of the four different reinforcing constructs applied.

For testing purposes each vertebra was placed in a specially designed metal pot and held in place with polymethylmethacrylate (PMMA) to prevent any movement of the samples during testing. All vertebrae were placed with the endplate parallel to the horizontal plane, to ensure that the endplates were perpendicular to the planned direction of loading.

Following completion of testing all biological specimens and implants were sealed in biohazard containers and incinerated as per institutional guidelines.

(A)



(B)



Figure 3.1 A and B. Disarticulated lumbar vertebrae after removal of all soft tissues, transverse and spinous processes

3.3 Application of reinforcing constructs

Vertebroplasty - The bipedicular injecting technique was used in this study. This involved placing two 2mm Kirschner (K) wires transpedicularly into the centre of the vertebral body (Figure 3.2 A and B). Insertion was defined by anatomical landmarks. Bone marrow biopsy needles (8 gauge) were then guided over the wires and the wires removed. Cement was delivered through a syringe filled with liquid PMMA attached to the cannulation needle. Two minutes after mixing the cement each vertebra was injected with 2mls of PMMA (CMW 1, bone cement, DePuy, Blackpool, England) via the needles (Figure 3.3). This procedure is equivalent to the *in vivo* intraoperative technique (Heini *et al* 2000).

(A)



(B)



Figure 3.2 A and B. K-wires inserted transpedicularly into the vertebral body, hollow bore needles were guided over the wires and used to inject PMMA.

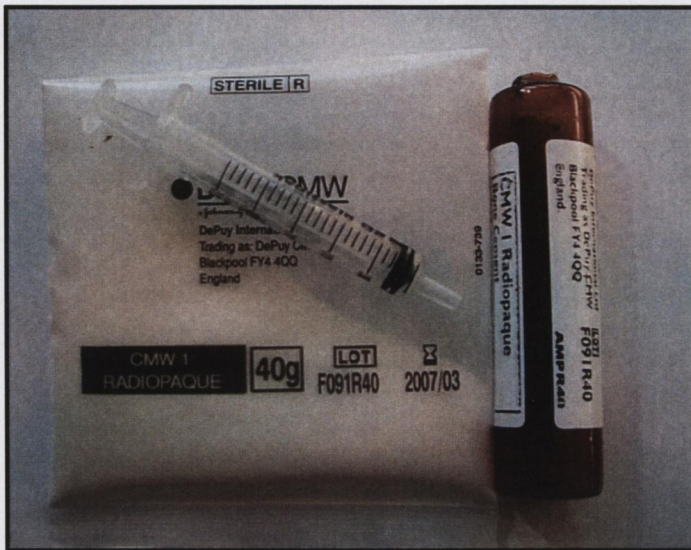


Figure 3.3. Polymethylmethacrylate and injecting syringe.

Screw insertion – Three 2.5 x 12mm crosshead countersunk screws were inserted to form a reinforcing tripod formation beneath the endplate within the subcortical bone (Figure 3.4). The screws were inserted 2mm below the upper border of the endplate, the first screw was inserted centrally and the two outer screws were inserted 15mm either side of the central screw (Figure 3.5). All screw insertion sites were predrilled with a 1mm drill bit (BOSCH PSR 1440). This method of insertion ensured the formation of a standard sized construct and prevented contact between the screws on insertion.

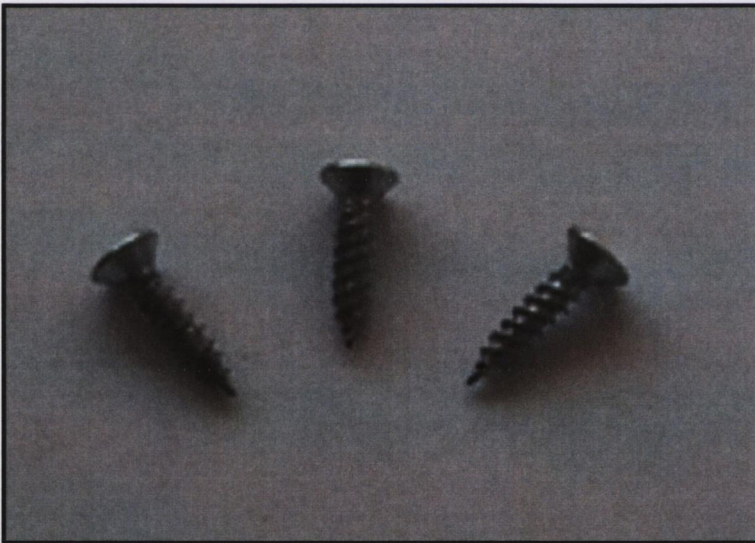


Figure 3.4. Three 2.5 X 12mm screws



Figure 3.5. Screws inserted to form a reinforcing tripod construct beneath the endplate.

Flat mesh plate – A flat steel mesh (CHARNLEY ACET MESH ORT90 PK5, De Puy Int. Leeds England) plate was used to cover the vertebral endplate (Figure 3.6). The plate, composed of steel fibres intertwined into a pliable mesh, was cut and shaped by hand with scissors and wire cutters to match the size of the vertebral endplate. Once prepared the mesh plate was placed directly over the endplate (Figure 3.7).

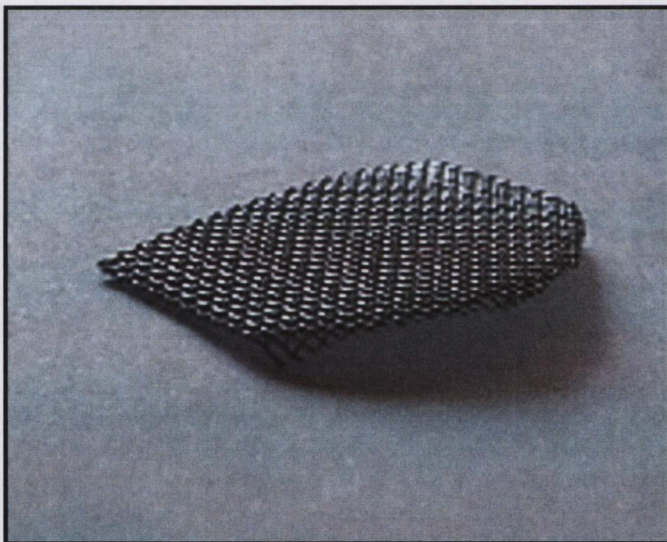


Figure 3.6. Mesh plate, composed of intertwined steel fibres

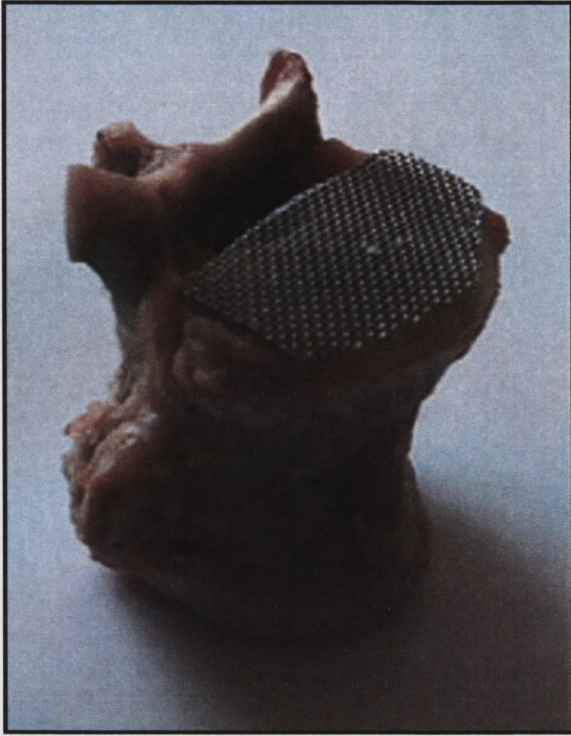


Figure 3.7. Mesh cut by hand to size and shape of vertebral endplate

Anchored mesh plate – A flat mesh plate with a vertical extension of 12mm (Figure 3.8). A longer piece of mesh was cut and a 90° angle formed by bending the mesh. This vertical extension then allowed for screw fixation using 2.5mm x 12mm crosshead countersunk screws (Figure 3.9). The screws were inserted parallel to one another through the mesh 6mm below the endplate into the vertebral body, thus anchoring the plate. The screw insertion sites were predrilled through the mesh and into the vertebral body using a 1mm drill bit.

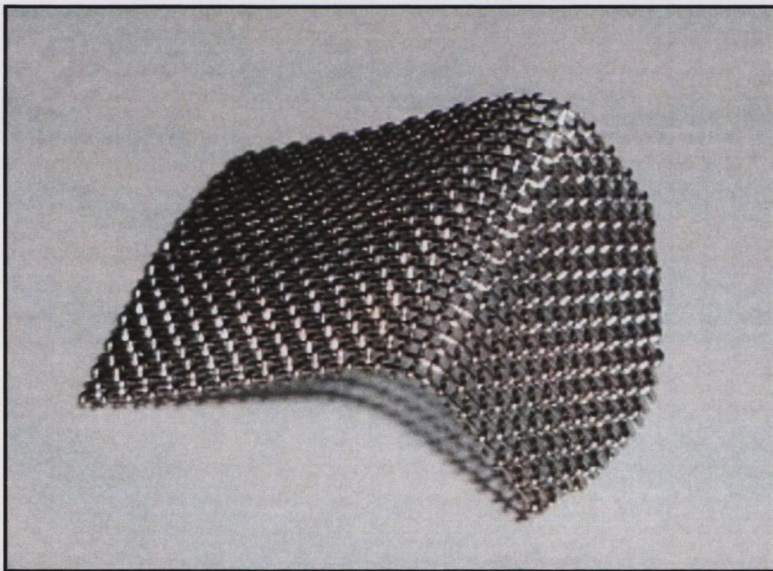


Figure 3.8. Anchored mesh plate, composed of horizontal and 12mm long vertical component.



Figure 3.9. Anchored mesh plate with two screws inserted through the plate into the vertebral body 6mm below the endplate.

3.4 Biomechanical testing

- Uniaxial compressive loading was applied to the superior endplates of the test specimens using an Instron testing machine, which recorded the depth and rate of subsidence/penetration in millimetres to progressively increasing load in Newton's.
- Instron test settings for both cycles were; Load range 0-8000N, displacement range 40mm, height 60mm, speed 10mm/minute.

Two testing cycles were carried out –

Test cycle 1 – Load applied to antero-central region of endplate via a 14mm hollow titanium mesh cage to a maximum load of 3000N (Figure 3.10).

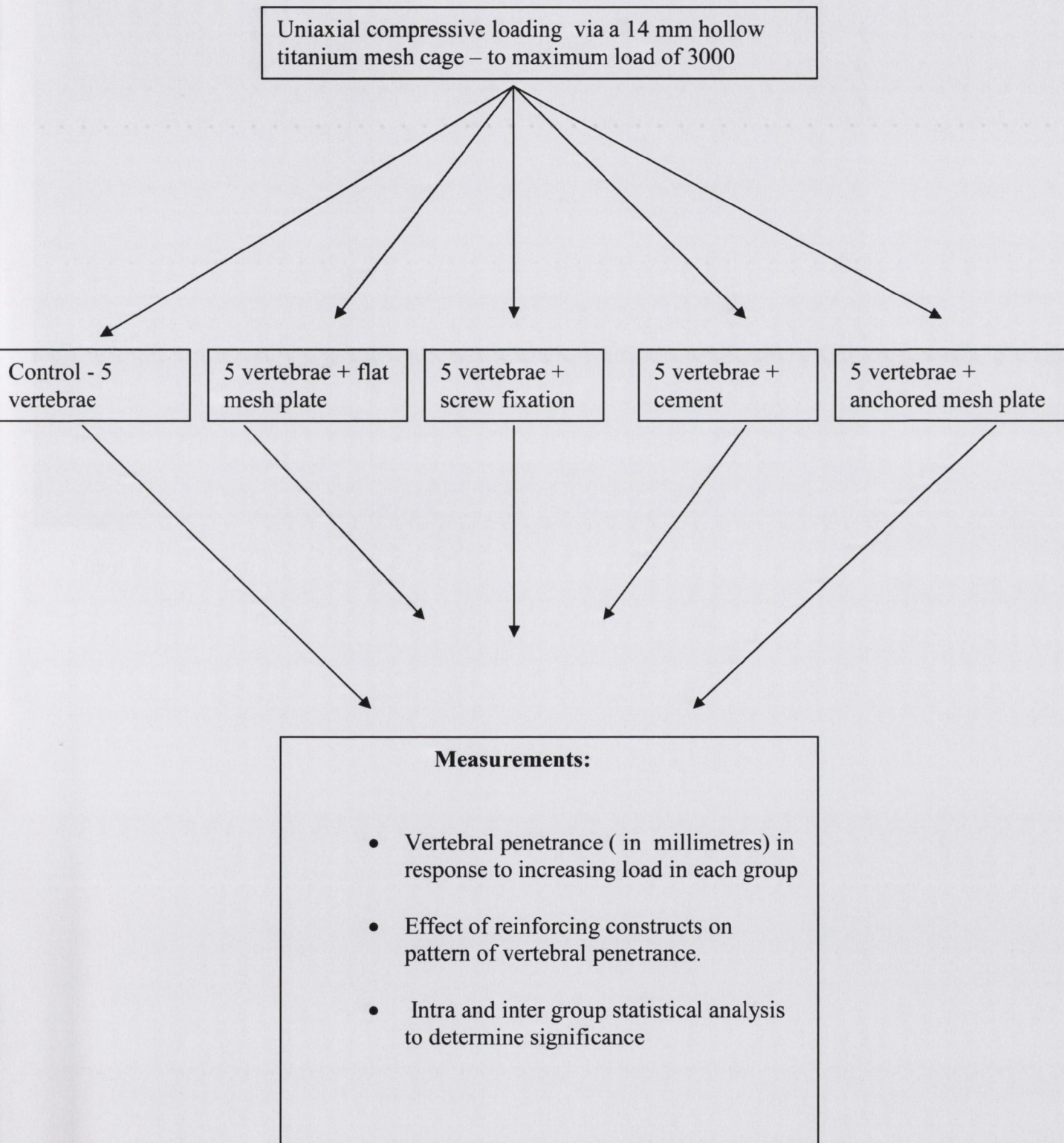
Increasing load was applied up to 3000N and the load-deformation data was recorded in order to analyse the differences in the depth of vertebral penetration in response to similar loads between the groups when compressed with a hollow implant. Loads beyond 3000N were not used in Test Cycle 1 as deformations in the cage itself began to appear beyond this. As previously discussed during normal physiological loading compression on the lumbar spine is 1000 N for standing and walking and is moderately increased during lifting, as a result testing up to 3000N was felt to be sufficient.

In the clinical setting the cage is packed with osteoinductive or osteoconductive materials to achieve bony fusion across the segment. Such material maybe

autogenous bone graft, allograft, or more recently bone morphogenetic proteins (BMP). Bony fusion may take several weeks to occur during which time the cage is axially loaded by the patients own body weight which may lead to subsidence. This test cycle assessed the response of the reinforcing constructs to the cage alone.

The cage size of 14mm was chosen as it is a commonly used implant and allowed for testing at a specific region of the endplate. As the strength of the endplate has been shown to vary depending on location it was essential that all tests be carried out at the same site to minimise variability (Lowe *et al* 2004).

Test cycle 1.



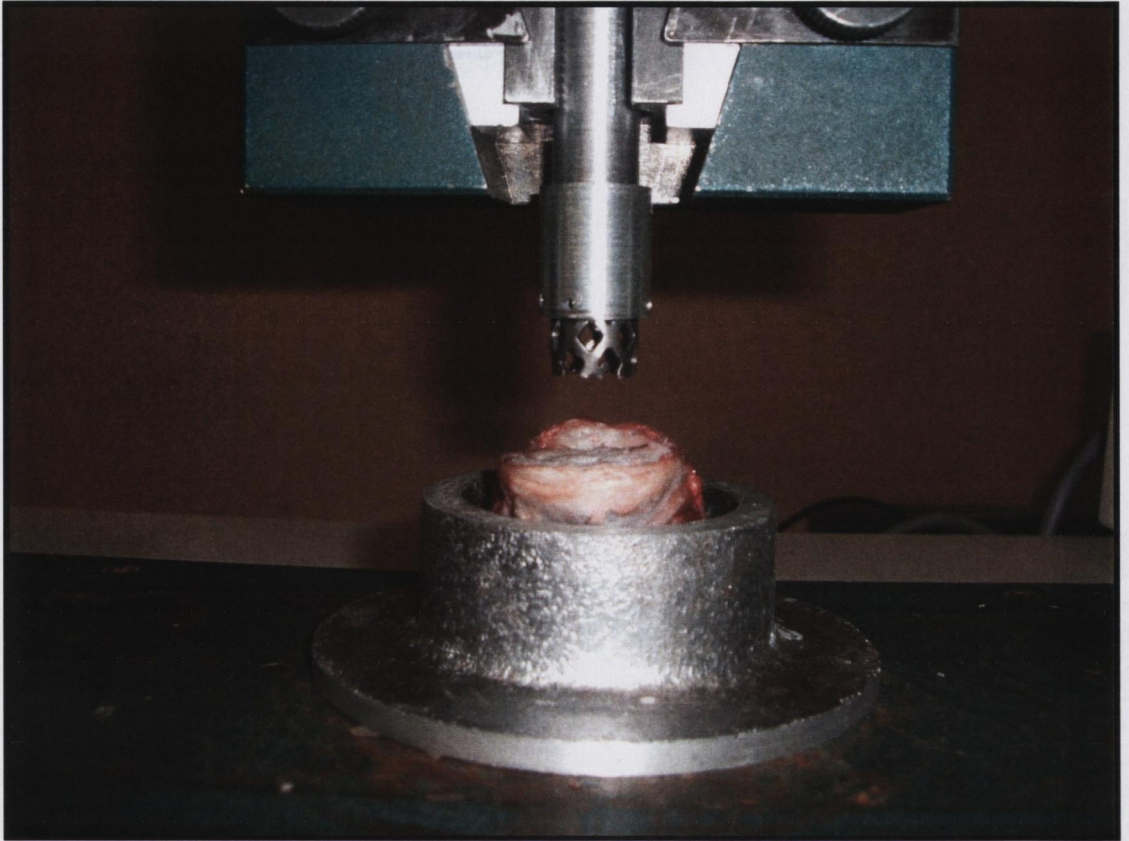


Figure 3.10. Test cycle 1 experimental set-up: Vertebra held in metal pot and load applied to the antero-central region of endplate via a 14mm hollow Harms titanium mesh cage.

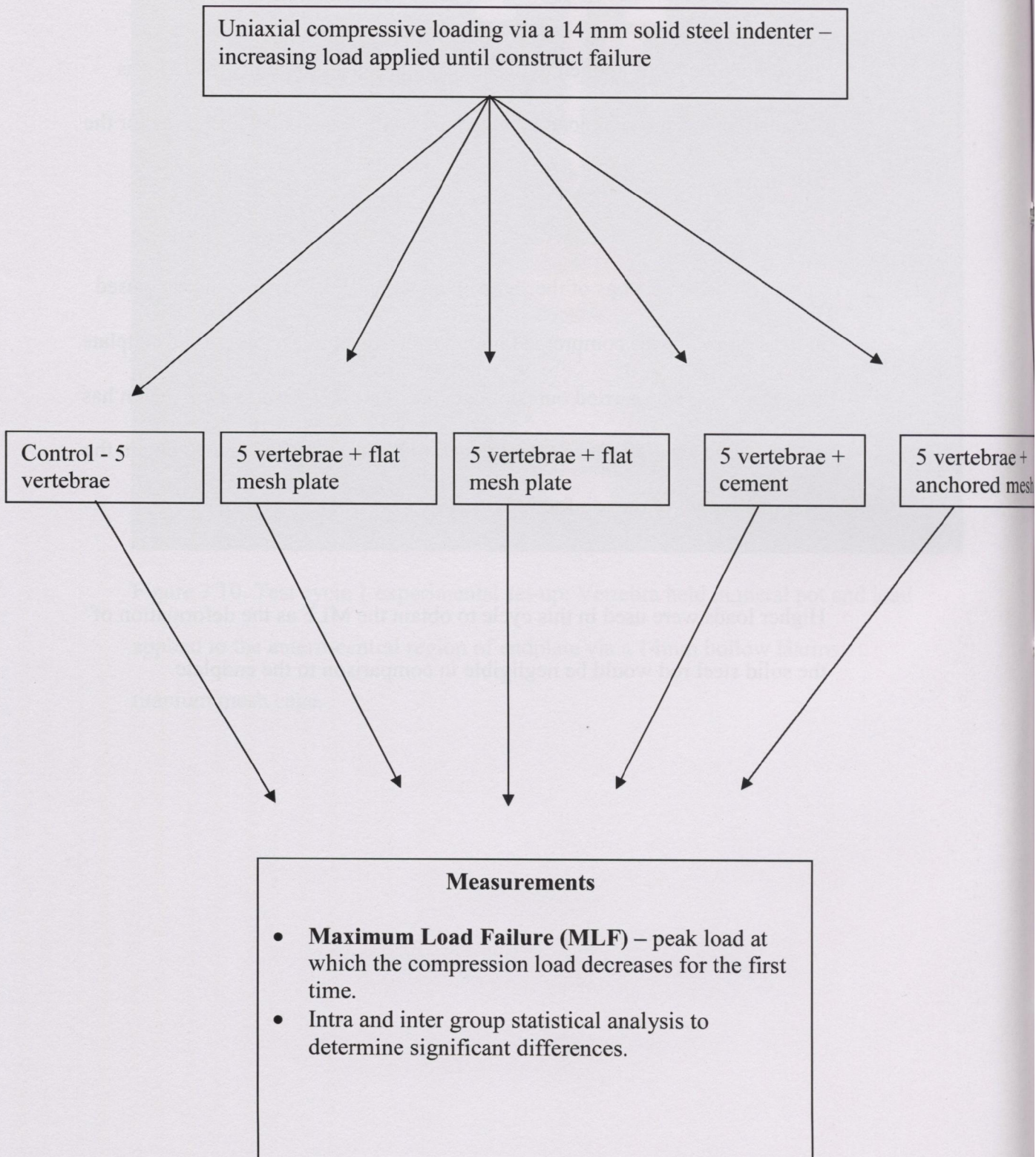
Test cycle 2 – Load applied to antero-central region of endplate via a 14mm solid steel rod (Figure 3.11).

Increasing load was applied until the maximum load to failure (MLF) was obtained, this is the peak load at which the compression load decreases for the first time.

The steel rod which was of the same diameter and geometry as the cage used in the first cycle was compressed into the antero-central region of the endplate. This test cycle was carried out simulate the clinical scenario where fusion has occurred and a solid intervertebral structure has formed, and also to obtain the overall strength of the reinforcing constructs.

Higher loads were used in this cycle to obtain the MLF as the deformation of the solid steel rod would be negligible in comparison to the endplate.

Test cycle 2.



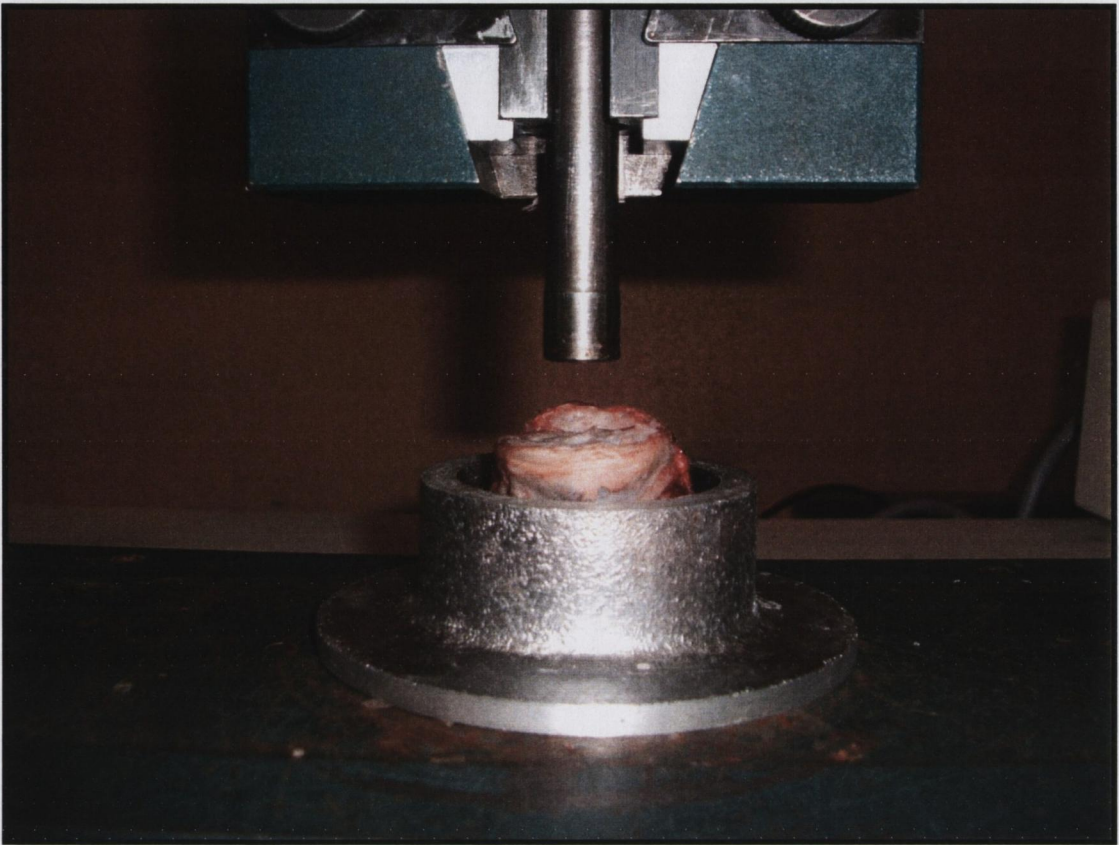


Figure 3.11. Test cycle 2 experimental set-up: Vertebra held in metal pot and load applied to antero-central region of endplate via a 14mm solid steel indenter.

3.5 Statistical analysis

Test cycle 1 - The degree of penetrance in millimetres into the vertebral body was recorded at 500, 1000, 1500, 2000, 2500, and 3000 Newton's. A two-way analysis of variance (ANOVA) to account for the two variables – group and load, was used to analyse the data. Post-hoc analysis was by Fisher's protected least significant difference (PLSD) test.

Test cycle 2 – The maximum load to failure in Newton's was determined for all constructs. A one-way ANOVA with post-hoc analysis by Fischer's PLSD was used to analyse the data.

4.0 - RESULTS

4.1 Bone mineral density

A mean bone mineral density of 0.828 (g.cm⁻²) (Range 0.780 – 0.894, S.D 0.047) was recorded for the fifteen lumbar spine segments (L3-L6) used. This was accepted as consisting of a relatively uniform sample group with respect to bone mineral density.

4.2 Test cycle 1

A two-way ANOVA statistical analysis was carried out in order to ascertain whether significance existed between the groups. The mean values, standard deviation (SD) and standard error (SE) were first determined for both of the independent variables – group and load. This demonstrated that a statistically significant interaction had occurred - Penetrance x Load: $F=37.75$ $df=20,100$ $p<0.0001$ (Appendix 1).

The amount of penetration in millimetres increased in all groups with increasing load. The load-penetrance curves of all five groups were linear up to the termination point of 3000N, however the four experimentally reinforced groups had a lower recorded degree of penetration in millimetres at all loads when compared to controls (Figure 4.1). The amount of vertebral penetration in response to loading was similar between the cemented group and the screw group, and between the flat and anchored mesh, this similarity however failed to persist

at the higher loads. The anchored mesh had the lowest level of penetration throughout the load range tested.

Post-hoc analysis was carried out by Fisher's PLSD (Table 4.1). All four of the reinforcing constructs were effective in reducing vertebral penetration in millimetres when compared with the normal/non-reinforced control group ($p < 0.0001$).

In comparative analysis the anchored mesh plate proved to be the most effective reinforcing construct in this test cycle, followed by the flat mesh, the screws, and the cemented group ($p < 0.0001$).

The greatest mean difference of 1.453mm ($P < 0.0001$) was between the normal/control group and the anchored mesh plate.

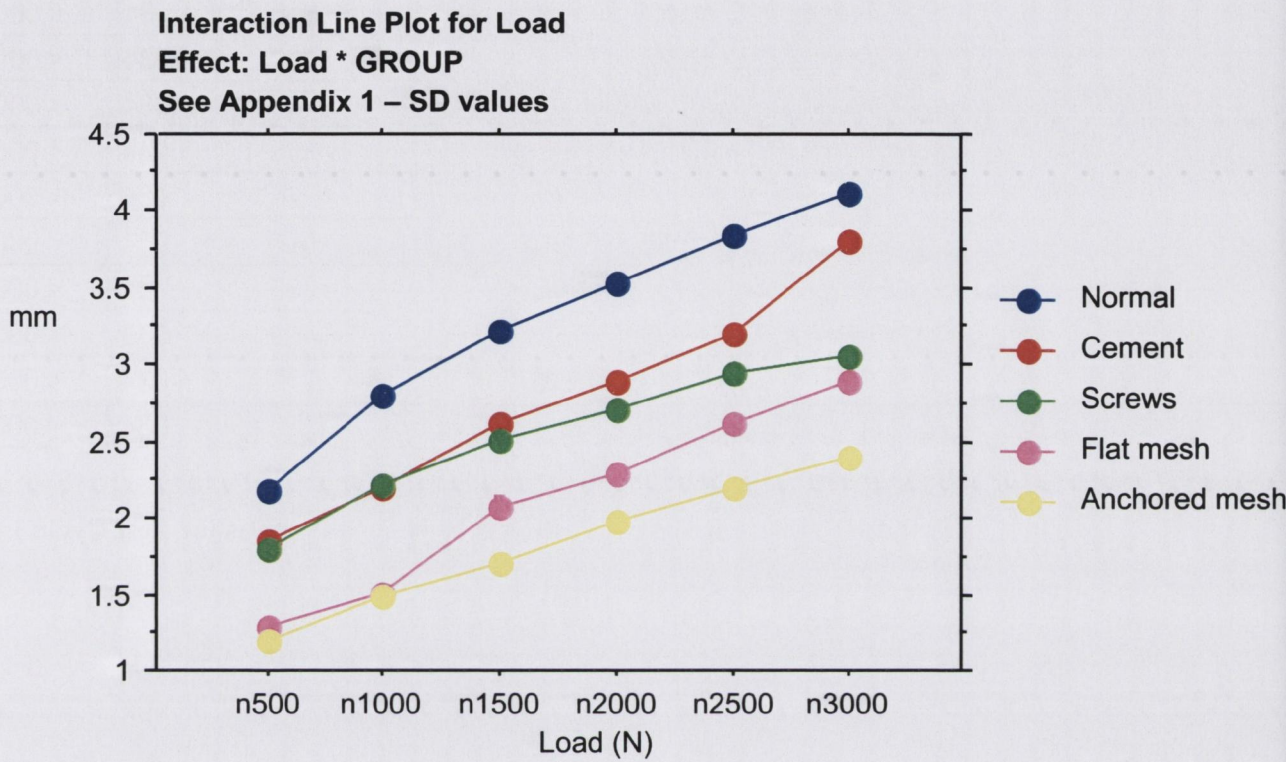


Figure 4.1 Load versus penetration for all 5 groups

Fisher's PLSD for Load
Effect: GROUP
Significance Level: 5 %

	Mean Diff.	Crit. Diff	P-Value	
1_NORMAL, 2_CEMENT	.518	.034	<.0001	S
1_NORMAL, 3_SCREW	.743	.034	<.0001	S
1_NORMAL, 4_FLAT_MESH	1.164	.034	<.0001	S
1_NORMAL, 5_ANCHORED_MESH	1.453	.034	<.0001	S
2_CEMENT, 3_SCREW	.225	.034	<.0001	S
2_CEMENT, 4_FLAT_MESH	.646	.034	<.0001	S
2_CEMENT, 5_ANCHORED_MESH	.935	.034	<.0001	S
3_SCREW, 4_FLAT_MESH	.422	.034	<.0001	S
3_SCREW, 5_ANCHORED_MESH	.711	.034	<.0001	S
4_FLAT_MESH, 5_ANCHORED_MESH	.289	.034	<.0001	S

Table 4.1 Post-hoc comparative analysis between all groups for Test Cycle 1 (max 3000N load)

4.3 Test cycle 2

The maximum load to failure was taken as the force in Newton's at which the compression load decreased for the first time. This point represents the stage at which the resistance of the vertebrae alone in the case of the normal/control group, or the vertebrae with their reinforcing construct in the four experimental groups has failed in response to axial loading. At this point no further increase in compressive force is needed to increase the depth of penetration (Figure 4.2).

A one-way ANOVA was carried out on the mean maximum load to failure values for each group and determined that a statistically significant difference existed between the groups, $F=712.43$ $df=4, 20$ $p<0.0001$ (Appendix 1).

The anchored mesh plate had the highest mean maximum load to failure (4598N, SD 37.18, SE 16.62) followed by the flat mesh (4220N, SD 44.72, SE 20.00), the screws (3972N, SD 48.68, SE 21.77) the cemented group (3786N, SD 42.48, SE 19.00), and the normal/control group (3263N, SD 33.65, SE 15.00), (Figure 4.3.).

Post-hoc analysis was carried out by Fisher's PLSD (Table 4.2).

A significant difference ($P<0.0001$) was found between all groups and the control specimens and between the experimental groups themselves ($p<0.0001$).

The greatest mean difference of 1335 Newton's was seen between the normal/control group and the anchored mesh plate group ($p<0.0001$). The smallest

mean difference was 185 Newton's between the cement and screw groups ($p < 0.0001$).

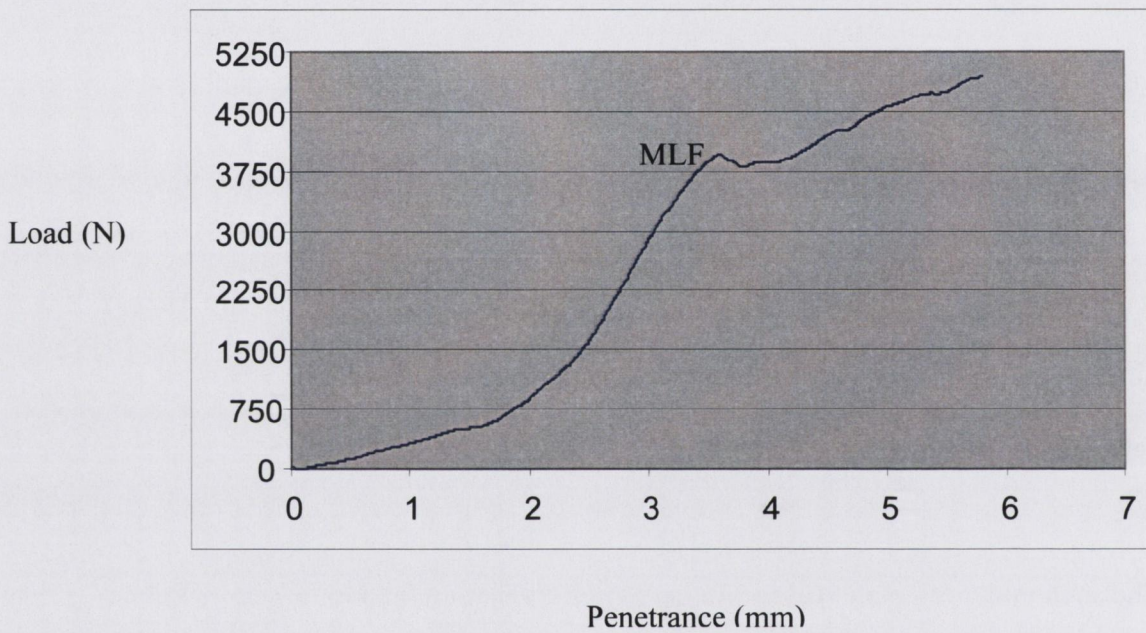


Figure 4.2 A representative destructive loading graph shown for a vertebra reinforced with screw insertion. The MLF represents the ultimate load causing failure and permanent deformation, no further increase in compressive force is necessary for ongoing penetration.

Interaction Bar Plot for Neutons
Effect: Group
Error Bars: ± 1 Standard Error(s)

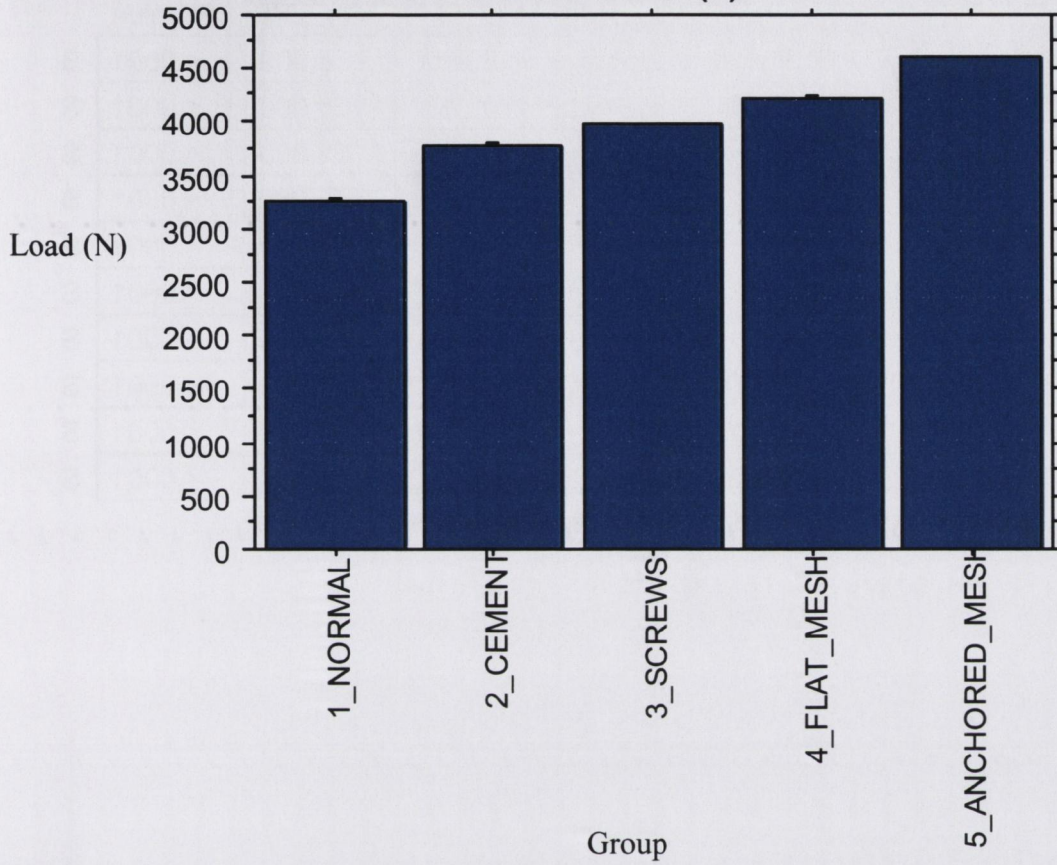


Figure 4.3 Maximum load to failure for each group

Fisher's PLSD for Neutons
Effect: Group
Significance Level: 5 %

	Mean Diff.	Crit. Diff	P-Value	
1_NORMAL, 2_CEMENT	-523.000	55.000	<.0001	S
1_NORMAL, 3_SCREWS	-709.000	55.000	<.0001	S
1_NORMAL, 4_FLAT_MESH	-957.000	55.000	<.0001	S
1_NORMAL, 5_ANCHORED_MESH	-1335.000	55.000	<.0001	S
2_CEMENT, 3_SCREWS	-186.000	55.000	<.0001	S
2_CEMENT, 4_FLAT_MESH	-434.000	55.000	<.0001	S
2_CEMENT, 5_ANCHORED_MESH	-812.000	55.000	<.0001	S
3_SCREWS, 4_FLAT_MESH	-248.000	55.000	<.0001	S
3_SCREWS, 5_ANCHORED_MESH	-626.000	55.000	<.0001	S
4_FLAT_MESH, 5_ANCHORED_MESH	-378.000	55.000	<.0001	S

Table 4.2 Post-hoc comparative analysis between all groups

5.0 - DISCUSSION

5.1 Discussion

Anterior column interbody support plays an important role in spinal reconstruction. It is often necessary to achieve decompression, restore appropriate sagittal alignment, facilitate coronal deformity correction, create a load-sharing construct with anterior or posterior instrumentation, and provide an optimal mechanical and biologic environment for fusion. The area of reconstruction varies in size from the single disc level, e.g., in degenerative disc disease, to the long level lesion, e.g., in a spinal tumour.

The spinal surgeon can draw from a number of alternatives to provide anterior column support to the spine. Depending on the level and magnitude of the deficiency, options include autogenous tricortical strut, allograft, prefabricated prosthetic replacement, or vascularized autograft, usually rib or fibula. A common feature of all these interbody implants is that they rely solely on the vertebral bodies for support, and as a result subsidence into the vertebral body is a common and significant complication. This may lead to deformity, compromise of neural elements, and unfavourable biology leading to non-union (Closkey *et al* 1993, Kozac *et al* 1994). This can necessitate difficult revision surgery, often creating larger defects and more complex anterior column reconstruction (Oxland *et al* 2003).

The use of interbody cages, such as the Harms titanium mesh cage, for spinal fusion procedures is well established (Weiner *et al* 1998, Zdeblick *et al* 2003). Fusion cages are now preferred clinically to other options as they have been shown to impart a number of advantages, namely enhanced mechanical stability and maintenance of intervertebral disc height (Mc Affee 1999). Hollowell *et al* (1996), reported on a comparative analysis of thoracolumbar interbody constructs in which thoracic vertebrae were loaded in compression by several constructs: titanium mesh cage, humerus, tricorticated iliac graft, and triple rib strut graft on intact vertebrae. The titanium mesh cage construct provided the greatest resistance to axial load and the lowest degree of subsidence into the vertebral body. Cages also facilitate the potential avoidance of bone graft donor site morbidity by using alternative osteoconductive and osteoinductive materials inside the cage. However, despite the proven advantages of fusion cages, subsidence into the bony anatomy of the vertebral body remains the most common complication of their use.

To address this issue, the authors embarked on a study to design and biomechanically assess four experimental methods of reinforcing the vertebral endplates resistance to implant subsidence, in an attempt to prevent this common and potentially grave complication.

In designing the experimental set-up, the anterocentral region of the endplate was chosen as the specific endplate site where all testing would be undertaken.

There is conflicting data based on *in vitro* studies in the literature pertaining to optimal endplate positioning of interbody supports and interbody support geometry with regards, to the best methods of avoiding implant subsidence (Grant

et al 2001, Hasegawa *et al* 2001). However, in the clinical setting issues regarding cage size and geometry as well as placement in the interbody space are usually based on segmental sagittal or coronal deformities being addressed. For instance, if there has been symmetric collapse of a disc and the segmental lordosis has been lost, a tapered, large-diameter cage filled with an osteoconductive material would be the best solution for treating the anterior column deficiency by allowing maximum restoration of lordosis and distraction of the interdisc space, which would facilitate foraminal nerve root decompression by an indirect means. If, however, scoliosis is the primary reconstructive goal, smaller, solid spacers placed in the posterolateral position in the concavity of the deformity may be the best strategy. This allows direct reduction of the deformity by compression of the convexity and provides the ability to gain additional correction by cantilever techniques. Thus the selection of implant design and position varies on an almost patient specific basis.

In the testing of the four experimental methods of endplate reinforcement designed in this study a single endplate position was used (antero-central) and a single implant design (cylindrical) although both the hollow and solid forms were tested in order to simulate early and late post-operative situations respectively. These selections were made in order to ensure that any differences recorded were as a result of the reinforcing construct alone and not due to any other factors.

Another important factor which had to be considered in the experimental design was endplate preparation. The practice of removing the vertebral endplate to improve fusion rates has been debated in the literature (Steffen *et al* 2000). It has been argued, that preservation of bony endplate is essential for prevention of

implant subsidence (Lin *et al* 1985, Kozak *et al* 1994). Conversely, partial removal of the endplate may facilitate the incorporation of the graft material, thereby increasing the likelihood of a solid interbody fusion (Prolo *et al* 1990, Boden *et al* 1995). Some authors have recommended complete removal of the bony endplate to allow the implant and/or graft material to rest on cancellous bone (Hollowell *et al* 1996), while others leave the endplate intact fearing structural anterior interbody subsidence (Steffen *et al* 2000).

On review of the literature several studies have highlighted the structural support provided by the endplates, the reported reduction in vertebral load to failure ranging from 39 to 75% following removal, and the importance of maintaining their integrity to minimize the risk of graft subsidence (Lowe *et al* 2004, Rockoff *et al* 1969).

No endplates were removed from the vertebrae in this study; however the reinforcing constructs were designed in such a way as to be applicable in the setting of endplate removal if desired. Indeed the removal of the end-plate with exposure of bleeding cancellous bone to provide an ideal fusion bed, combined with a porous reinforcing construct such as the mesh plate may provide an ideal, 'best of both worlds' situation. This hypothesis would require extensive investigation prior to trial in the clinical situation.

A number of experimental limitations are evident in this study. *In vivo* loads in the lumbosacral spine are complex, and external factors such as patient's weight, body habitus, occupation and level of activity etc., will typically result in more anteriorly, posteriorly, or laterally directed forces in a cyclical pattern. To be consistent in comparison, we chose to use an antero-centrally positioned axial

compressive force for all specimens, and progressively increasing load was applied, this does not accurately reflect *in vivo* loading conditions.

Another limitation was the removal of all surrounding soft tissues from the vertebrae, in particular the strong anterior and posterior spinous ligaments. *In vivo* these ligaments contribute significantly to maintaining normal spinal alignment, and their flexibility allows for the dissipation of applied forces to the spinal column (Herkowitz *et al* 2004). The disarticulation and soft tissue dissection of the vertebrae was necessary for this study, however this dissection may significantly weaken the overall resistance of individual vertebrae within the spinal column as a whole, to deforming forces.

The use of the solid indenter to simulate a fusion mass is another potential limitation. In the *in vivo* setting, once fusion has occurred a bony connection exists between the two vertebrae, above and below the area of fusion. This bony fusion mass although solid, will inevitably have a greater degree of flexibility when compared to a solid steel indenter, this combined with the complex cyclical distribution of load in the spine may result in a markedly different pattern of force distribution following fusion than was tested in this study.

The technique of vertebroplasty employed in this study involved the injection of 2mls of PMMA into the vertebral body. The vertebral body consists of cancellous trabecular bone which acts as a strut supporting the endplate. Vertebroplasty is used clinically to restore the strength of this trabecular bone where it has been fractured as a result of osteoporosis, trauma or malignancy. It is a minimally invasive procedure and has high levels of success reported in the literature (Cotten *et al* 1996, Cortet *et al* 1999, Barr *et al* 2000). In this study the injection of cement

reinforced the vertebral resistance to axial loading in both test cycles when compared to the control group, however it proved to be less resilient than the other reinforcing constructs. The similarity between the pattern of subsidence seen with the cemented group and the screw fixation group in test cycle 1, and the difference in their maximum load to failure recorded in Newton's (mean diff = 186N, $p < 0.0001$) was due to the fact that both of these reinforcing constructs were designed to increase the supporting strength of the bone beneath the endplate.

The main drawback of vertebroplasty as an endplate reinforcing strategy is that when the standard transpedicular technique is used to cement spreads throughout the vertebral body and is not concentrated beneath the endplate, so that subsidence may persist beyond a critical depth resulting in implant failure in spite of the reinforcement. It could be argued that the injection of a larger volume of PMMA may have improved the effectiveness of this method of reinforcement, however theoretical and *in vitro* biomechanical studies have shown that only small volumes of cement (eg. 2 ml), are necessary to increase vertebral strength (Belkoff *et al* 2001, Liebschner *et al* 2001). Overfilling of vertebrae (> 3mls) increases the risk of cement extrusion due to both the increased volume and the high pressure necessary to inject the cement (Moreland *et al* 2001). Cement extrusion is the most common complication of vertebroplasty, having been reported in 38% to 85% of vertebrae injected in clinical studies (Yeom *et al* 2003). The extrusion of cement may lead to pulmonary embolism, nerve root and cord compression, this has led to a limited application of this procedure in certain countries (Bhatia *et al* 2006).. There is also ongoing debate in the literature as to whether vertebroplasty increases the risk of adjacent vertebral fracture which would have to be considered

if multi-level anterior column reconstruction was being undertaken (Berlemann *et al* 2002).

The insertion of three screws into the subcortical bone of the vertebral body was designed as with the vertebroplasty technique to reinforce the endplate from beneath, thus increasing its resistance to subsidence in response to axial loading. The three screws having been inserted by a standard pre-measured technique resulted in the formation of a tripod like supporting structure directly beneath the endplate. In test cycle 1 the screw groups response to compression was similar to the cemented group initially. However as load increased the screw model proved more effective in resisting penetration at the higher loads. The reason for this difference was felt to be due to the fact that the screws were inserted beneath the endplate and provided a greater degree of reinforcement at that point. The maximum load to failure of the screw group was greater than controls and the cement group but less than both the mesh groups. The method of anterior screw site pre-measurement and insertion is not technically demanding however a potential limiting factor of this method in the operative setting is the increased exposure that would be necessary to insert the two outer screws. The anterior approach to the lumbar spine is gaining increasing popularity as it has many advantages over the posterior. These include the avoidance of muscle dissection, a common cause of persistent post-operative debility, excellent restoration of the disc space height, neuroforaminal decompression, and improved biomechanics (Herkowitz *et al* 2004). The main disadvantage of the anterior approach is the technical challenges of dissecting and manipulating major vessels; specifically, the iliolumbar vein, vena cava, common iliac vein, accompanying arteries and the hypogastric plexus. The insertion of the outer screws would necessitate increased

dissection and mobilisation of these structures which could increase the risk of intra and postoperative complications.

The flat mesh plate and the anchored mesh were both designed to increase the interface strength between the implant and the vertebral endplate. Tan *et al* (2005) have highlighted the importance of this interface, stating that interbody fusion device subsidence results from failure at the bone–implant interface rather than failure of the implant. Both designs produced a marked reduction in vertebral penetration in test cycle 1 when compared to non-reinforced controls and to the cement and screw groups, although to a lesser extent. Both designs also had greater maximum loads to failure value in comparison to controls in test cycle 2. The anchored mesh plate had a reduced degree of penetration (test cycle 1) and a higher load to failure (test cycle 2) when compared with the flat mesh plate and indeed to all other constructs. The increased reinforcement provided by the anchored mesh plate was felt to be due to the fixation of the mesh to the vertebral body which prevented any motion of the horizontal component when it came into contact with the cage (test cycle 1) and the solid indenter (test cycle 2). The anchoring screws which provided the fixation of the mesh plate to the vertebral body, may also have reinforced the end-plate from beneath, in much the same way as the three screws in the screw insertion group.

In the operative setting no extra dissection or exposure would be necessary for the insertion of the flat mesh with an interbody fusion construct, a small amount of further dissection would however be needed to fit and anchor the vertical component of the anchored mesh plate. The main concern with the use of a steel mesh in this situation however would be the potential negative effect it may have

on fusion across the operative level. Stainless steel wire mesh has been used extensively in acetabular reconstruction, with bony fusion occurring across the mesh between host bone and impacted bone graft (Slooff *et al* 1996, Schreurs *et al* 2001). There have been some reports in the literature highlighting the negative effects of the presence of a steel mesh on bony fusion, Roidis *et al* (2003) in their study on the role of stainless steel wire mesh in bone allograft incorporation state that in the rabbit tibia model graft incorporation seemed to be adversely affected by stainless steel wire mesh. This study however was limited in sample size with twenty tibias from 10 rabbits.

5.2 Conclusion

The recent interest in performing inter vertebral arthrodesis with the use of cages has been attributed in the literature to three main factors: the high rate of failure associated with the use of bone graft alone; the high rate of failure associated with the use of posterior pedicle-screw instrumentation; and the high rate of success associated with the use of anterior fusion cages filled with autogenous bone graft. However in spite of the success of intervertebral fusion cages subsidence of the cages into the vertebral body with all the potential deleterious effects remains one of the main concerns regarding their use.

In this study four experimental methods of preventing implant subsidence were designed and tested. The technique used for reinforcing the endplate from beneath, namely cementing and screw insertion proved to be less effective than applying a reinforcing mesh on top of the endplate. The anchored mesh plate resulted in the least amount of vertebral penetration in response to increasing load applied through a hollow implant in the first test cycle, and a significantly greater degree of load was required to result in construct failure in the second testing cycle.

Vertebral endplate reinforcement is a potential method of preventing implant subsidence and subsequent failure. The anchored mesh plate provides the most suitable option due to its high resistance to subsidence, its versatility, and ease of application in the operative setting. The impact of the mesh on bony fusion however needs to be further evaluated to ensure it does not impede the achievement of a solid arthrodesis across the operative segment.

Potential future study should involve examining the effect of the reinforcing constructs and in particular the anchored mesh plate on the fusion process. Hypothetically none of the experimental constructs should impede fusion; however this would need to be tested in a biological model.

Further study should focus on the effect of the reinforcing constructs following partial removal of the end-plate. The debate continues in the literature with regards to end-plate preparation, the advantages and disadvantages of both have already been described in this work. In the clinical setting spinal surgeons are regularly faced with the dilemma of creating an ideal fusion bed at the risk of sacrificing structural support. Thus a proven reinforcing construct which could be easily applied by the operating surgeon when required could prove invaluable.

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7 – APPENDIX 1

Test Cycle 1.

Means Table for Load
Effect: GROUP

	Count	Mean	Std. Dev.	Std. Err.
1_NORMAL	30	3.284	.655	.120
2_CEMENT	30	2.766	.654	.119
3_SCREW	30	2.541	.442	.081
4_FLAT_MESH	30	2.120	.581	.106
5_ANCHORED_MESH	30	1.831	.426	.078

Test Cycle 1.

Means Table for Load
Effect: Load

	Count	Mean	Std. Dev.	Std. Err.
n500	25	1.666	.381	.076
n1000	25	2.050	.507	.101
n1500	25	2.427	.528	.106
n2000	25	2.686	.539	.108
n2500	25	2.964	.567	.113
n3000	25	3.258	.635	.127

Test Cycle 1 -

ANOVA Table for Load

	DF	Sum of Squares	Mean Square	F-Value	P-Value	Lambda	Power
GROUP	4	38.383	9.596	2460.870	<.0001	9843.481	1.000
Subject(Group)	20	.078	.004				
Load	5	43.218	8.644	3258.099	<.0001	16290.494	1.000
Load * GROUP	20	2.003	.100	37.751	<.0001	755.011	1.000
Load * Subject(Group)	100	.265	.003				

Test Cycle 1 -

Means Table for Load
Effect: Load * GROUP

	Count	Mean	Std. Dev.	Std. Err.
1_NORMAL, n500	5	2.194	.021	.009
1_NORMAL, n1000	5	2.808	.044	.020
1_NORMAL, n1500	5	3.216	.019	.009
1_NORMAL, n2000	5	3.530	.043	.019
1_NORMAL, n2500	5	3.842	.047	.021
1_NORMAL, n3000	5	4.114	.069	.031
2_CEMENT, n500	5	1.852	.052	.023
2_CEMENT, n1000	5	2.210	.032	.014
2_CEMENT, n1500	5	2.616	.046	.021
2_CEMENT, n2000	5	2.896	.035	.016
2_CEMENT, n2500	5	3.212	.040	.018
2_CEMENT, n3000	5	3.810	.037	.016
3_SCREW, n500	5	1.794	.030	.014
3_SCREW, n1000	5	2.224	.038	.017
3_SCREW, n1500	5	2.516	.044	.020
3_SCREW, n2000	5	2.710	.032	.014
3_SCREW, n2500	5	2.948	.049	.022
3_SCREW, n3000	5	3.056	.088	.039
4_FLAT_MESH, n500	5	1.296	.036	.016
4_FLAT_MESH, n1000	5	1.518	.044	.020
4_FLAT_MESH, n1500	5	2.084	.157	.070
4_FLAT_MESH, n2000	5	2.302	.035	.016
4_FLAT_MESH, n2500	5	2.620	.049	.022
4_FLAT_MESH, n3000	5	2.898	.037	.017
5_ANCHORED_MESH, n500	5	1.192	.043	.019
5_ANCHORED_MESH, n1000	5	1.488	.042	.019
5_ANCHORED_MESH, n1500	5	1.702	.087	.039
5_ANCHORED_MESH, n2000	5	1.990	.041	.018
5_ANCHORED_MESH, n2500	5	2.200	.027	.012
5_ANCHORED_MESH, n3000	5	2.412	.048	.022

Test Cycle 2 -

ANOVA Table for Neutons

	DF	Sum of Squares	Mean Square	F-Value	P-Value	Lambda	Power
Group	4	4952844.000	1238211.000	712.434	<.0001	2849.738	1.000
Residual	20	34760.000	1738.000				

Test Cycle 2 -

Means Table for Neutons

Effect: Group

	Count	Mean	Std. Dev.	Std. Err.
1_NORMAL	5	3263.000	33.653	15.050
2_CEMENT	5	3786.000	42.485	19.000
3_SCREWS	5	3972.000	48.683	21.772
4_FLAT_MESH	5	4220.000	44.721	20.000
5_ANCHORED_MESH	5	4598.000	37.182	16.628