Local Bone Graft Harvest in Anterior Lumbar Spine Surgery

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November, 1998

A Thesis Submitted to the Faculty of Graduate Studies and Research in Partial Fulfillment of the Requirements of the Degree of Masters of Experimental Surgery

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PREFACE

The experimental work for this Masters thesis was carried out during the year 1997/1998 at the Orthopaedic Research Laboratory, Division of Orthopaedic Surgery, McGill University, Montreal. The institution was founded in May 1993 by Dr. M. Aebi.

The Orthopaedic Research Laboratory combines the fields of applied and basic orthopaedic research, with a special interest in spine. The facility is active in the fields of biomechanics, biochemistry, and electrophysiology, providing a rich environment for basic scientists as well as clinicians to work. The multidisciplinary laboratory has provided an excellent collaborative atmosphere for the completion of this work.
ACKNOWLEDGEMENTS

The Orthopaedic Research Laboratory was founded by Dr. M. Aebi, my co-supervisor. It is under his leadership as Chairman of the Division of Orthopaedics, McGill University, that I chose to complete this work. He has provided the environment for me, and the other residents of Orthopaedic Surgery at McGill University to pursue numerous interests in research and clinical work, and I am very grateful to him for that.

Dr T. Steffen, co-supervisor as well, is the director of the Orthopaedic Research Laboratory in which this study was completed. Throughout this project, he has been a continuous source of inspiration and guidance. His tireless efforts have led to the completion of this and other research endeavors, and I thank him for his patients and supervision.

This project could not have been completed without the help of others. Mr. L. Beckmen was instrumental in providing the testing apparatus and technical support. For the help in specimen DEXA and computer software assistance, I thank Mr. A. Tsantrizos. For general assistance throughout this work, I thank Dr. H. Baramki. Thanks also to the Anatomy Department, McGill University, and the Nuclear Medicine Department, Royal Victoria Hospital.
I would like to thank the companies for providing testing materials. The bone harvesting tools were provided by Stratec Medical. The filler materials were provided by Norian Corp., Mathys AG, and Implex Corp. The author did not receive any financial support for the completion of this work.
ABSTRACT (English)

The harvesting of a local bone graft from the lumbar vertebral body adjacent to an anterior interbody fusion was suggested, to avoid secondary morbidity associated with iliac bone harvest. Instrumentation using a cannulated core drill was developed and assessed in an anatomic safety study. The biomechanical implications of plug removal were assessed in single vertebra and multisegment models. Plug removal using the tools developed was considered safe. The removal of a cylinder bone plug from the vertebral body affected flexion/compression load significantly. The yield strength of the vertebra could be restored effectively using the filler materials studied.
ABSTRACT (French)

L’obtention d’un greffon osseux à partir d’un corps vertébral adjacent à une fusion intercorporéale antérieure a été proposée afin d’éviter les complications associées au prélèvement du greffon osseux de la crête iliaque. Une foreuse canulée a été développée et testée par une étude anatomique. Les conséquences biomécaniques du prélèvement du greffon ont été évaluées en utilisant des modèles vertébraux unisegmentaires et plurisegmentaires. Le prélèvement du greffon a été jugé sécuritaire. Le prélèvement du cylindre osseux à partir de corps vertébral a diminué la force résistante du corps vertébral en flexion/compression. La force résistante de la vertèbre a été restituée après remplissage par les matériels étudiés.
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1 INTRODUCTION

1.1 Clinical Problem

Segmental spine fusion is widely used today in the management of spinal disorders. Anterior interbody fusion is gaining widespread acceptance as the procedure of choice in a number of spinal maladies. Various biomaterials have been used in the past for bone graft substitutes to stimulate a stable interbody fusion. At this point, though, autologous bone graft remains the gold standard, and is usually placed in an interbody fusion implant. Little attention has been given thus far to alternative sites from which autologous bone graft can be harvested.

Presently, autologous graft is harvested primarily from the pelvic iliac wing. In anterior spine surgery, because of the position of the patient, bone is harvested through a separate incision over the anterior iliac wing. Studies have illustrated the morbidity associated with this procedure, placing the incidence for chronic pain at 20%, and minor complications at 30-40%.

The merits of harvesting bone adjacent to the area of the primary procedure have been illustrated in other areas of orthopaedics, including trauma and arthroplasty surgery. To our knowledge, harvesting bone locally from the vertebral body above or below the interbody fusion has not been suggested by others. Obviously, with such a procedure, a cancellous defect is created in the vertebral body. Filling
of bone defects has been investigated in other regions of the body using various filler materials such as the ceramic and porous metal implants.

1.2 Anterior Spine Arthrodesis Overview

The treatment of spinal disorders has evolved considerably in recent years. Since the early descriptions of spinal arthrodesis by Hibbs for the treatment of Potts disease, the indications and techniques of spinal arthrodesis have changed dramatically [1]. The basic objectives of spinal fusion, though, have not changed. Sonntag outlined the indications for spinal fusion: correction or control of deformity, pain relief, and functional improvement [2]. Key developments in diagnostic techniques and the ability to support the patient during more invasive surgical procedures has allowed the more recent development of anterior and circumferential spinal fusion techniques.

In a review by Katz, some interesting aspects of lumbar surgery were highlighted [3]. The rates of lumbar fusion procedures are increasing rapidly, particularly for lumbar spinal stenosis in older patients [3]. Fusion rates appear to vary markedly among individual surgeons, among small and large geographic regions in the nation, and between the United States and England [3]. Fusion for spinal stenosis with spondylolisthesis is associated with higher costs and complication rates than is decompressive surgery without fusion [3]. Fusion rates are increasing rapidly
and show dramatic geographic variations, suggesting differences in opinion within the surgical community regarding the appropriate indications for lumbar fusion. This illustrates clearly the need to standardize investigation and treatment algorithms based on outcomes research.

### 1.3 Anterior Fusion Indications

The indications for spinal fusion, particularly anterior fusion of the lumbar spine, are becoming more specific as the diagnostic and outcome assessment tools become more refined. Fraser recently outlined the current status of interbody, posterior, and combined lumbar fusion [4]. The concept of fusion in the treatment of lumbar spinal deformity is to maintain a position that has been reduced or corrected by internal fixation with or without traction or bracing. The choice of anterior or posterior fusion techniques is usually dictated by the form of fixation as well as the release of soft tissue or osteotomy which best corrects the deformity [4]. The Mayo Clinic indications for anterior arthrodesis of the lumbar spine are the following: debridement of infection, tuberculosis, excision of tumor, correction of kyphosis, scoliosis, neural decompression after fracture, and to achieve stability when posterior arthrodesis is not feasible; less frequently in the treatment of spondylolisthesis or intervertebral disc derangements [5]. As the indications for anterior lumbar fusion continue to expand, surgical outcomes become more important in guiding the use of this invasive procedure.
1.4 Outcome of Anterior Fusion

The drive to perform a new procedure is tempered by the experience gained with time. The success rates for lumbar surgery vary considerably, attributing to the differences in opinion as to what constitutes success. In a comparison of 14 outcome measures, it was revealed that the proportion of success varied according to the outcome measure used, ranging from 60% to 97% [6].

Early results of interbody lumbar fusion were less than encouraging. In a review by Flynn, fifty patients who underwent anterior lumbar spine fusion with autogenous fibular and iliac bone grafts were followed for two to fifteen years [7]. The clinical results were successful in twenty-six patients (52%) and unsuccessful in twenty-four patients (48%) [7]. Paradoxically, about one-half of the patients with clinical success had a non-union and one-half of the failures had bony union [7].

The poor results following anterior lumbar fusion have recently been linked to poor prognostic indicators. Christensen reported a success rate of approximately 66% following anterior lumbar spinal fusion after a mean follow-up of 8 years [8]. There was a clear trend towards poorer results for patients who had undergone previous spinal surgery, those aged above 45 years, those operated at the L4/L5 level and those who had responded poorly to the preoperative test brace [8]. In a literature review by Hanley, factors which were related to a better result for lumbar fusion were assessed [9]. Success rates were higher in isthmic
spondylolisthesis, unstable spinal stenosis syndromes (degenerative spondylolisthesis, degenerative scoliosis), and in patients with objective segmental instability [9]. Variable success rates were reported for disc-related low back pain conditions and in patients with failed previous surgery [9]. Instrumentation appeared to be beneficial in situations where complex deformities or obvious instability was present [9].

When applied to other diagnoses (e.g., internal disc disruption), fusion results appeared to be no better than with traditional surgical techniques [9]. Other studies have reported significantly higher success rates. In a report of 85 patients who underwent anterior lumbar interbody fusion (ALIF) for treatment of painful disc disruption or symptomatic pseudarthrosis, there was a fusion rate of 80% by disc [10].

In an effort to better characterize patient’s surgical outcome based on subjective indicators rather than purely objective findings, Butterman assessed pain and functional outcome after primary lumbar fusion surgery by a self-assessment questionnaire [11]. In this study, 165 patients underwent a primary lumbar fusion procedure during the 3-year period from 1988 to 1990 [11]. They had a chart and radiograph review and were categorized into five major diagnostic groups: 1) pediatric, 2) grade I-II spondylolisthesis (low-slip), 3) grade III-IV spondylolisthesis (high-slip), 4) degenerative disc disease, and 5) post-discectomy [11]. At a mean follow-up period of 5 years after the fusion, patients were mailed
a questionnaire in which they described their pain and functional status before and after their lumbar fusion surgery [11]. For all diagnostic groups, lumbar fusion resulted in a significant decrease in back pain and leg pain (visual analog scale), which was maintained throughout the follow-up period [11]. For back pain, the pediatric and high-slip groups showed significantly greater improvement than the degenerative disc disease or post-discectomy groups [11]. In a study evaluating the subjective results following anterior lumbar surgery, a total of 113 patients (excluding those with tumor, spondylitis, and idiopathic scoliosis) were analyzed [12]. All patients underwent (ALIF) with autologous iliac crest graft between 1984 and 1991 [12]. The overall results yielded an improvement in the Oswestry score of 35.7 percentage points [12]. Younger patients with additional dorsal distraction prior to ALIF for reduction of severe spondylolisthesis fared better than patients with ALIF alone [12].

More recent studies have highlighted the fact that a considerable number of anterior spine fusion procedures are carried out on patients for whom posterior surgery has not been successful. In a review by Tiusanen of 83 cases of ALIF, 72% of patients previously had undergone 1 or more spine operations [13]. In 54% of patients, the main indication for anterior fusion was failed back surgery [13]. Solid fusion was achieved in 104 (81%) of 129 levels or 59 (71%) of 83 patients [13]. Patient rated efficacy of the procedure was the following: 74% very much improved, 12% little improved, 10% no improvement, and 4% worse [13].
More recent work directly compared the results of anterior and posterior fusion procedures in lumbar surgery. Greenough reported a retrospective review, with a minimum follow-up period of 2 years, comparing ALIF and posterolateral fusion with pedicle screw and plate fixation performed by one surgeon [14, 15]. Although the fusion rate for ALIF was less than that for posterolateral fusion with internal fixation, there was no difference in the subjective opinion of fusion between the two groups. There was a difference in assessment of outcome by the more objective Low Back Outcome Score [16], with patients treated by anterior interbody fusion demonstrating significantly better results for both compensation and noncompensation cases. It would appear that part of the benefit of anterior fusion is removal of the pain source itself [4, 15].

The success of lumbar arthrodesis is reliant not only on proper patient selection, but also on the appropriate selection of various surgical fusion techniques. Once a decision has been made to fuse the spinal motion segment anteriorly, a decision must then be made as to the fusion technique to employ. The decisions include: whether or not to use an implant, which implant to use, graft material and source, and surgical approach.
1.5 Anterior spinal fusion implants

The past decade has seen a dramatic increase in the number of anterior fusion devices available to the surgeon. These devices have been developed to address the problems associated with placing bone graft alone in the interbody space, including graft extrusion, loss of disc space height, and pseudarthrosis [17, 18]. The aims of these devices are[19]:

1. to correct existing mechanical deformation
2. to provide stability to the segment until arthrodesis is obtained
3. to provide the best environment for successful arthrodesis, and
4. to achieve this with limited morbidity

The introduction to interbody fusion was made by Cloward in the early 50's for the treatment of degenerative conditions [20]. A procedure was described in which a posterior interbody fusion was used to treat degenerative conditions [20]. Since the description of this procedure by Cloward, there has been considerable advances made in anterior fusion techniques. One particular area of evolution is with the interbody fusion devices. This evolution has led to the development of 2 major classes of cages: horizontal and vertical cylinder types.

The early description of the horizontal cylinder style cage was made by Wagner for the treatment of wobbler syndrome in the cervical spine of horses [21]. Wagner's co-author and designer of the original cage began working with Kuslich
on the development of a similar implant to be used in humans, and reported their findings in 1988 [22]. Similar cages to the type first described by Bagby have been developed [17]. Testing of these implants has revealed favorable initial stability in terms of ultimate compressive strength [23], as well as fatigue strength [24]. Another advantage of these cages is the fact that they can be placed through a smaller annular window, thus decreasing the risk of iatrogenic instability. The main criticism of these cages has been the limited available space for fusion material within the implant as well as limited interface between the surface of the implants and the native bone (as little as 10%) [25].

The clinical evaluation of the horizontal cylinder type implants has highlighted their stabilizing and fusion characteristics. In a study by Tencer, a threaded insert was found to increase vertebral motion segment stiffness and decrease laxity by distracting intervertebral structures [23]. These implants were not found to be sensitive to placement, except if vertebral structures were injured during insertion [23]. These inserts produced constructs with more consistent mechanical properties than bone grafts alone [23]. In a study evaluating another type of threaded interbody fusion device, the safety, fusion success rate, and clinical outcome of a lumbar interbody hollow, threaded titanium fusion cage was assessed in a multicenter, prospective 236-case study [17]. Forty-five percent of cases had previous spinal surgeries, and none were posterior lumbar interbody fusions [17]. Fusion success was judged by absence of motion on flexion-extension radiographs, absence of bone halo around the implants, and
maintenance of visible bone inside the cages on Ferguson view radiographs [17]. Segments fused rapidly; the pilot study cases fused at 10 of 11 levels (91%), with a reported 80% average clinical improvement [17]. Ninety-six percent of the 208 2-year follow-up cases had fusion, and the Prolo socioeconomic/functional improvement scale showed: 40% excellent, 25% good, 21% fair, and 14% poor results [17]. Less than 1% of cases had complications that persisted beyond the average 5 days of hospitalization, and none were serious [17]. This threaded implant method was found to be an effective, rapid, safe procedure for lumbar spine fusions, demonstrating a high fusion rate and clinical success with rare serious, or permanent complications [17].

The use of the vertical type cage implant was first described in 1975 by Ono for the treatment of metastatic cervical spine disease [26]. Similar designs have been described including an allograft implant filled with autologous bone [27]. These devices preserve the vertebral interbody height as well as lordosis and sagittal alignment [18, 28]. The most important factors for preserving height and alignment when using these cages is limited endplate subchondral bone removal and adequately sized cages contacting the endplate periphery [28]. This type of implant presents a large surface area of fusion material to the endplates and has a large inner volume for graft placement [28]. The major disadvantage of these cages is the amount of annulus excisions which must be performed to insert the cage [28]. This decreases the distraction-compression mechanism, and therefore increases the risk of destabilization [28].
The early evaluation of these vertical cages has been favorable. In a ten year follow-up study, disc height was maintained, with an average loss of only 1mm over an average of 1 year [29]. In the same study, it was found that lordosis was preserved, with an average loss of only 1 degree at 1 year [29]. Penta stated that the thicker-walled devices were less likely to lead to subsidence, combined with the limited endplate bone removal [29].

### 1.6 Graft Materials

There have been a multitude of graft materials investigated since the first recorded bone graft attempt by the Dutch surgeon Job Van Meekiren in 1668. The major types of bone graft or bone graft substitute which have been investigated include: autograft, bone marrow cells, allograft, xenograft, ceramics, osteoinductive growth factors (ex. BMP), and porous metal spacers. The distinction between these various materials is their varying degrees of osteoconductive, osteoinductive, and osteogenic properties. Osteoconduction refers to the physical property of a graft material to allow the ingrowth of neovasculature and infiltration of osteogenic precursor cell during the phase referred to as creeping substitution [30]. Osteoinduction is the process in which a factor or substance stimulates an undetermined osteoprogenitor stem cell to differentiate into an osteogenic cell type [31, 32, 33]. Osteogenic graft materials contain viable cells
that can form bone (osteogenic precursor cells), or differentiate into bone-forming cells (inducible osteogenic precursor cells) [33].

1.6.1 Autograft

The superiority of fresh autogeneic grafts has repeatedly been confirmed in experimental studies and clinical experience [34, 35, 36, 37, 38]. Autologous bone graft remains the gold standard for use in anterior and posterior spinal fusions [34, 39, 35]. Heiple stated that despite 30 years of experimental bone grafting research, the fresh cancellous bone graft remains the most osteogenic and reliable bone grafting material [39]. It is the only graft material presently available which alone possesses qualities of osteoconduction, osteoinduction, and osteogenesis. The presence of these 3 properties makes it ideal as a stimulus for arthrodesis.

In a controlled animal study, Shaffer studied the biologic and mechanical characteristics of vascularized versus nonvascularized autologous bone [40]. Both the strength and stiffness of the vascularized grafts were found to be significantly greater at 6 weeks to 6 months postoperation. The mechanical testing demonstrated superior strength and stiffness of the vascularized grafts throughout the repair process. In another study the efficacy of free vascularized bone grafts, conventional segmental autografts, matchstick autografts, and fresh
segmental allografts in terms of their ability to reconstruct a 7-cm segmental diaphyseal defect created in the canine femur was studied [41]. Arteriography, microangiography, fluorochrome, and histologic studies all supported the concept that microsurgically revascularized grafts, when successful, maintained their viability [41]. Revascularization of the nonvascularized autografts was complete at 3 months, while, in the avascular allografts, the process was not complete at 6 months [41].

Despite the continued evidence that autologous bone is superior as a stimulus for bony fusion, significant research has been directed at finding an alternative as of the morbidity associated with bone graft harvest from the pelvis.

1.6.2 Allograft

To avoid the problems of quantity and morbidity associated with autograft, allograft bone has been studied extensively. Allograft bone possesses variable degrees of osteoconductive and osteoinductive [42, 43, 32, 31] as well as mechanical properties [44, 45]. The risk of disease transmission is the major drawback for its use and the reason for the development of various sterilization techniques [44].
The biomechanical properties of allograft bone can be altered by the methods chosen for its preservation and storage [44], as well as host immune response [46]. In terms of preservation and storage, the effects are minimal with deep-freezing or low-level radiation [46]. Freeze-drying, however, markedly diminishes the torsional and bending strength of bone allografts but does not deleteriously affect the compressive or tensile strength [44]. Irradiation of bone with more than 3.0 megarad or irradiation combined with freeze-drying appears to cause a significant reduction in breaking strength [44].

The overall outcome for anterior lumbar fusion using allograft bone has been mixed. In a retrospective study performed by Wetzel, 32 patients underwent multiple-level anterior cervical disectomy and fusion utilizing fibular strut allograft, and 24 underwent anterior lumbar disectomy and fusion using fibular strut allograft [47]. In the cervical group, the rate of clinical success (87.5%) exceeded the arthrodesis rate [47]. By inspection, 65% fused, at a mean time of 23.5 months postoperatively [47]. In the lumbar group, the overall clinical success rate was 68% [47]. This correlated quite strongly with a fusion rate of 58% [47]. Based on these data, Wetzel stated that primary anterior vertebral body fusion with allograft in the lumbar spine could not be recommended as a viable alternative to conventional autograft [47].
Another alternative to the autograft and allograft material are the synthetic ceramics and naturally occurring corals. These materials, to varying degrees, model the mineral phase of human bone and therefore create a scaffolding for native bone ingrowth (osteocoduction).

One of the earlier studied ceramics was a material manufactured from marine corals [48]. This possessed a highly interconnected, three-dimensional porosity that was uniform and consistent [48]. The hydroxyapatite manufactured from marine corals is biocompatible and nontoxic [48]. The material is essentially pure hydroxyapatite, with the balance consisting of tricalcium phosphate and is approximately 55 to 65 per cent porous [48]. Once implanted in a bony defect, from 50 to 88 per cent of the porosity within the implant is filled with woven and lamellar bone within 3 months [48]. The biomechanical properties of blocks of this material are similar to those of a cancellous bone graft [48]. Hydroxyapatite with interconnected porosity reacts differently than materials with limited or no porosity [48]. In animals, porous hydroxyapatite exhibits 0 to 5 per cent biodegradation per year. Moreover, this minimal biodegradation is compensated by regeneration of bone and therefore, responds in accordance to Wolff's law [48].

To better assess the ingrowth and biomechanical properties of coralline hydroxyapatite as a bone-graft substitute in cortical and cancellous bone defects,
Martin performed a controlled canine study [49]. The model consisted of a 10 x 30mm window defect in the shaft of the canine radius (a cortical site), and a 10mm diameter cylindrical defect in the head of the humerus (a cancellous site) [49]. In the cortical site, bone ingrowth increased from 52% at 16 wk to 74% at 1 yr. In the cancellous site, bone ingrowth was 38% after 4 wk, then fell monotonically, reaching 17% at 1 yr. [49]. Bending and compressive strength and stiffness of the radius implants increased throughout the post-implantation year, but compressive strength and stiffness of the humerus implants did not change after the first 2-4 months [49]. Mechanical properties were strongly correlated to bone ingrowth in the cortical, but not the cancellous site [49]. The volume fraction of the coralline hydroxyapatite material diminished significantly with time in the cortical, but not the cancellous site [49].

To assess the properties of coral derived material in an anterior spinal fusion model (cervical), Pintar assessed the difference of this coralline material versus autologous bone in a goat model [50]. The fusion rate and biomechanical stiffness were evaluated for 56 goat spinal units from 14 animals that had anterior discectomy and grafting procedures completed using hydroxyapatite and autogenous bone and survived for 6, 12, and 24 week healing times [50]. A 55% fusion rate for bone preparations and a 50% fusion rate for the hydroxyapatite (HA) units was found for the 12 and 24 week preparations [50]. The HA preparations were better at maintaining disc space height [50]. These results must be questioned, though, based on such a low fusion rate in control.
As previously stated, porous ceramic implants act as matrix for native bone ingrowth. In a canine study by Johnson with regard to their ability to heal a 2.5 cm defect created surgically in bilateral canine radii, it was concluded that the addition of bone marrow aspirate was essential for tricalcium phosphate and hydroxyapatite to achieve results comparable with those of cancellous bone [51]. In this study, the biomechanical and radiographic parameters of tricalcium phosphate with bone marrow were roughly comparable with those of cancellous bone at 12 and 24 weeks [51].

1.7 Complications of Fusion Procedure

The surgical procedure to fuse the anterior portion of the lumbar spine is one of the most invasive procedures carried out in Orthopaedic surgery. The operating surgeon must be well aware of the principals of spinal anatomy and biomechanics as well as have a firm understanding of the abdominal anatomy and physiology.

A direct consequence of the invasiveness of the procedure is the significant complication rate. In a review by Watkins, it was found that complications of anterior lumbar fusion could be divided into several categories[52]. The first of these were complications related to patient selection, the second were visceral complications, and the third were vascular complications [52]. Complications of
interbody fusion techniques occur at both the graft site (fusion site) and graft donor site [52].

The adult population has been assessed for the specific complications related to anterior lumbar surgery. In a retrospective review of 1223 thoracic and lumbar anterior spinal fusions performed from 1969 through 1992, the complication rate directly attributed to the anterior spinal surgery was 11.5% [53]. The risk of complication was increased for patients over age 60 years, for women, and for patients with multiple preexisting health problems. Serious complications, such as death (0.3%), paraplegia (0.2%), and deep wound infection (0.6%) were rare [53].

The pattern of complications within the pediatric age group is somewhat different than the adult population undergoing anterior lumbar surgery. A retrospective chart review was conducted by Grossfeld, in which 599 anterior procedures performed between 1967 and 1991 were analyzed (24 anterior only, 300 staged anterior/posterior, 175 combined anterior/posterior procedures) [54]. Major complications occurred in 7.5% of procedures and minor complications in 33%. Risk factors for major complications were age > 14 years, male gender, kyphotic curve type, curve sizes > 100 degrees, vital capacity < 40% of predicted, and use of thoracotomy [54].
One of the most dreaded and, therefore, extensively researched is the complication of retrograde ejaculation in the male population leading to sterility following anterior lumbar fusion. On average, the incidence of retrograde ejaculation as a complication of anterior interbody lumbar fusion has been very low, averaging 5.9% of cases in male patients [55]. In a retrospective study of 40 male patients with severe low back pain treated with anterior interbody fusion, retrograde ejaculation occurred in nine patients [55]. Permanent retrograde ejaculation developed in seven of these patients (17.5%) [55]. There is literature which supports the fact that this complication is over estimated [56]. In a retrospective review by Loguidice, retrograde ejaculation occurred in 1 of 85 male patients [10]. In a worldwide survey of 20 surgeons with 15-20 years of experience (4,500 cases) by Flynn, the frequency of retrograde ejaculation was 19 cases (0.42%) and impotence 20 cases (0.44%) [57]. One-quarter of the retrograde ejaculation cases resolved and became normal [57]. Impotence was of non-organic origin [57].

1.8 Complications of Pelvic Bone Graft Harvest

The driving force for the development of the myriad of autologous bone graft substitutes is the morbidity associated with graft harvest. Although the rate of
complications varies somewhat between published series, there remains a significant concern regarding complications related to bone graft harvest.

The complications associated with iliac wing graft harvest are numerous. Documented donor site complications include pain, nerve and arterial injury, peritoneal perforation, sacroiliac joint instability, and herniation of abdominal contents through defects in the ileum [58]. Major complications in a retrospective review of 414 consecutive cases of iliac crest bone graft procedures by Arrington included herniation of abdominal contents through massive bone graft donor sites, vascular injuries, deep infections at the donor site, neurologic injuries, deep hematoma formation requiring surgical intervention, and iliac wing fractures [59].

The rate of occurrence of these complications varies. In a retrospective review of 239 patients with 243 autogenous bone graft harvests, the overall major complication rate was 8.6% [60]. Major complications included infection (2.5%), prolonged wound drainage (0.8%), large hematoma (3.3%), reoperation (3.8%), pain greater than 6 months (2.5%), sensory loss (1.2%), and unsightly scars [60]. Minor complications (20.6%) included superficial infection, minor wound problems, temporary sensory loss, and mild or resolving pain [60]. There was a much higher complication rate (17.9% major) if the incision used for the surgery was also the same incision used to harvest the bone graft [60]. A retrospective chart review as well as Sickness Impact Profile and a detailed questionnaire on pain was completed on 192 patients by Goulet [61]. Major complications were
recorded in four (2.4%) patients in whom infections developed requiring
readmission [61]. Thirty-seven (21.8%) patients had minor complications [61].
Thirty-three of 87 (37.9%) patients reported pain 6 months postoperatively [61].
The incidence of pain decreased with time, with 16 of 87 (18.7%) patients
continuing to report pain more than 2 years postoperatively [61]. The morbidity
of iliac crest grafting remains substantial.
2 OBJECTIVES

This study was carried out to evaluate an alternative source of autologous bone graft in anterior spine surgery. The concept of regional bone graft harvest is not new, but to our knowledge, has not been applied to anterior spine surgery.

First, the inner volume of the more commonly used interbody fusion cages was to be evaluated. These measurements would help to determine the volume of graft bone required to fill the interbody fusion implant. Vertebral morphology data was to be gathered to determine the maximal size and quantity of bone that potentially can be harvested from a vertebral body.

A safe procedure for harvesting an appropriately sized bone plug, compatible with the surgical approach (e.g. retroperitoneal, transperitoneal), and remaining within safe anatomical boundaries, was then be to be standardized and validated. In order to carry out this novel procedure, bone harvesting tools would be designed. These tools would be in keeping with the standard anterior lumbar spinal approaches as well as within the concept of Minimally Invasive Spine Surgery (MISS) techniques now being developed at the Orthopaedic Research Laboratory, McGill University.
The essential features of these bone harvesting tools would be:

1. sized according to the vertebral body measurement attained
2. appropriate for the approach in anterior lumbar surgery
3. cannulated for fluoroscopic guidance
4. simple and reliable

The mechanical consequences of a bone defect created by such a procedure were to be assessed. No experimental data, to our knowledge, exists on the mechanical strength of a vertebra with a geometric defect in the body region. Likewise, the possibility of restoring the mechanical strength of the vertebra with such a defect, plugged using various filler materials, was to be studied.

These various filler materials can be classified into distinct groups with different material properties and application techniques. The groups of particular interest are the porous metal implants, porous ceramic implants, and self setting ceramic cements. The porous metal and ceramic implants were to be prefabricated to fit the defect created after graft removal. The self setting cement fillers were to fill the defect created.

The biomechanical implications of removing a cylinder bone plug and then filling this defect were to be assessed first in a single vertebra model with specimens
subjected to three different load conditions: flexion/compression, side bending/compression, and axial rotation. The questions to be answered with this model were:

1. What is the percent change in yield strength with a cylindrical defect in the vertebral body under any of the three load conditions?
2. What is the effect on yield strength of plugging this defect with a filler under the three load conditions?
3. Is there a difference in the fracture pattern (endplate, lateral vertebral body, posterior wall) between load conditions?

Secondly, a multisegmental model was to be used for biomechanical testing with specimens consisting of 2 adjacent spine motion segments (3 vertebrae, 2 intervertebral spaces). The questions addressed by this model were:

1. What is the effect of an interbody fusion cage and the intervertebral disc, both adjacent to the vertebral body with a cylindrical defect, on the yield strength and failure pattern of that vertebra?
2. Is there an effect of various filler materials on the yield strength and mechanical failure pattern?
3 MATERIALS AND METHODS

3.1 Graft Volume:

The volume of bone graft required to fill different cages used for interbody fusion was estimated. The cages studied were: Titanium Interbody Spacer (T.I.S., Mathys AG, Bettlach, Switzerland), Syncage (Mathys AG, Bettlach, Switzerland), Brantigan ALIF (Acromed CORP., Cleveland, Ohio), Moss Cage (DePuy-Motech, Warsaw, Indiana), and BAK cage (Sultzer-Spinetech Inc., Minneapolis, Minnesota). The outer volume of the cage was determined by directly measuring its dimensions using a caliper. The cage was then immersed in a graduated cylinder. The volume of water displaced by the cage was subtracted from the estimated outer volume to determine the inner volume (filled with bone graft).

3.2 Vertebral Body Dimensions:

To determine the maximum size and orientation of a cylindrical plug which could be safely harvested from a lumbar vertebral body, measurements were made of the minimum vertebral body endplate separation (min VB height), and minimum anterior to posterior vertebral body diameter (min VB AP diameter), both on patient MRI (16 patients, 80 lumbar vertebrae), and cadaver specimens retrieved from autopsy cases (43 lumbar vertebrae).
Sixteen consecutive MRI studies of the adult lumbar spine (10 female, 6 male, age 36 - 53 years) were chosen. Sagittal T2 images were assessed for min VB AP diameter and min VB height. The measurements were made utilizing the ruler available with MRI software. The lumbar vertebra from 15 human autopsy cases (adult spines, age 20 to 85 years) were measured using a caliper device for min VB AP diameter and min VB height.

3.3 Tool Design:

Tools were designed to remove a bone plug from the vertebral body. The cutting and extracting tools were a modification of tools presently being used for bone graft harvest in other body sites (Stratec Medical, Oberdorf, Switzerland). The cutting drill is a cylinder drill with a diamond cutting edge, has an outer diameter of 17.50mm, inner diameter of 16.45mm and a 15cm cannulated extension connected to a standard cannulated AO drill (Synthes Spine, Paoli, USA). The cutting drill cuts the core from the anterior vertebral body wall to the posterior vertebral body.

The extracting tool is a cylinder with longitudinal fins, and a 15 cm. cannulated T-handle extension. The tool is inserted straight in the slot prepared by the cutting drill. Once in the depth of the cut, the tool is rotated a quarter turn to release the
plug from its posterior attachment and then withdrawn with the bone plug inside (Figure 3.1).

**Bone Harvest Tools:**

![Figure 3.1: Bone Harvesting Tools.](image)

3.4 **Safety Study:**

The surgical procedure of removing the bone plug was validated in a cadaveric study. Fifteen embalmed cadavers underwent the bone plug removal procedure. The lumbar spine, from L1 to L5, was accessed transperitoneally for plug removal, displacing the great vessels lateral to the midline. The orientation of the
disc in the sagital plane was determined by inserting a 18 gauge needle parallel to the vertebra endplate. A 2.5mm Kirschner wire was placed centrally in the vertebral body (L1-L5) from anterior to posterior. The bone plug was cut through the entire vertebral body from anterior vertebral body wall through the posterior vertebral body wall using the cannulated core drill (clinical procedure would limit cutting depth, so as not to breech the posterior vertebral body wall).

All lumbar spines were removed en bloc from the cadavers and split along the midsagital plane for visual inspection. This inspection assessed if any violation of the vertebral endplates had occurred. The length of the retrieved core was measured.

3.5 Biomaterials

Different materials filling the vertebral body defect were mechanically tested (Table 3.1). These materials included: Beta-tricalcium phosphate (Ceros, Mathys AG, Bettlach, Switzerland), porous tantalum (Hedrocel, Implex Corp., Allendale, NJ.), and bone cement (Norian SRS, Norian Corp., Cupertino, CA.).
**Filler Materials**

<table>
<thead>
<tr>
<th></th>
<th>type</th>
<th>E modulus</th>
<th>porosity</th>
<th>compression strength</th>
<th>bio-resorbed</th>
<th>size</th>
</tr>
</thead>
<tbody>
<tr>
<td>human cancellous bone</td>
<td></td>
<td>22.5MPa - 55.6MPa</td>
<td></td>
<td>1.55MPa - 4.6MPa</td>
<td></td>
<td></td>
</tr>
<tr>
<td>TCP</td>
<td>Pre-made plug</td>
<td>1.9GPa +/- 0.4GPa</td>
<td>70%</td>
<td>7.6MPa +/- 0.6MPa</td>
<td>variable</td>
<td>17.65mm X 25.0mm</td>
</tr>
<tr>
<td>porous tantalum</td>
<td>Pre-made plug</td>
<td>4GPa</td>
<td>78%</td>
<td>54MPa</td>
<td>no</td>
<td>17.55mm X 25.0mm</td>
</tr>
<tr>
<td>Norian SRS</td>
<td>setting cement</td>
<td>3GPa</td>
<td>0%</td>
<td>55MPa</td>
<td>variable</td>
<td>conforms</td>
</tr>
</tbody>
</table>

Table 3.1: Filler material characteristics, information from company specifications, acquired data, and ref. [62]

The three biomaterials are quite different in nature. The tantalum implant is a porous material formed by chemical vaporization of 98% tantalum onto a carbon skeleton [63]. This produces a material with 70-80% porosity with interconnected pores of dodecahedron shape. The material is biologically inert and can be
manufactured into a number of shapes and sizes. The compressive strength of the porous implant is 54 MPa. Native bone ingrows into the implant with time through the interconnected pores.

The Norian SRS is a self setting cement composed of monocalcium phosphate monohydrate, alpha-tricalcium phosphate, and calcium carbonate mixed with sodium phosphate solution. The paste is injectible for approximately 5 min. and hardens in a non-exothermic reaction in 10 min. The ultimate compressive strength is reached at 12 hours and is approximately 55MPa. The material remolds in a manner similar to that of human bone, with remodeling most pronounced in cortical regions of implantation [64].

The TCP implant is a prefabricated implant made of beta-tricalcium phosphate. The implant is bioresorbed in a manner similar to human cancellous bone turnover [65]. The mechanical properties in the area of implantation more closely match that of the native bone as the implant is resorbed.
3.6 Biomechanical Testing

The biomechanical implications of removing a bone plug from the vertebral body were examined. Fresh frozen cadaveric lumbar spines were used for biomechanical tests. The spine donors ranged in age from 36 to 85 years and were 49 male and 63 female.

Dual Energy X-ray Absorptiometry (DEXA, Lunar DPX-L, Lunar Radiation Corporation, Madison Wisconsin) was performed for each specimen. Whole lumbar spines were imbedded in a plastic container filled with rice to a depth of approximately 10cm, simulating soft tissue coverage in vivo [66], and scanned in lateral projection. Bone mineral density (BMD) and bone mineral content (BMC) were quantified for each vertebra.

3.6.1 Single Vertebra Model

3.6.1.1 Study Groups

Single vertebra testing was performed on three groups, with three subgroups in each. The three groups were flexion/compression (FC), side bending/compression (SC), and axial rotation (AR). The subgroups were intact vertebra 'intact', plug removed 'defect', and defect filled 'plugged' with 8
specimens per subgroup. Specimens were stratified such that there was no significant difference in BMD or vertebral level between subgroups.

3.6.1.2 Specimen Potting

Single vertebrae (L1-L5) were isolated and excessive soft tissue removed, leaving intact all bony elements. For the intact subgroup, the unaltered vertebra were potted. The defect subgroup had the bone plug removed under direct vision using the removal tools, drilling to a depth of 25mm and removing the plug with the extracting device. The plugged subgroup had the plug removed and the porous tantalum implant inserted into the defect.

The potting molds consisted of aluminium cylinders of 15 cm inner diameter, and 1cm depth. These molds were filled with PMMA cement to a depth of approximately 5mm. The vertebrae were lowered into these pots allowing the cement to conform to the endplate and articular processes, minimizing contact with the vertebra side wall. Potting the vertebrae in a shallow manner was important so as not to artificially strengthen the construct for compressive loading. The mechanical center of the vertebra was aligned with the center of the potting cylinder. The mechanical center of the vertebra was a point one third the distance from the posterior to the anterior vertebral body wall, measured in the midsagittal plan [67, 68, 69].
3.6.1.3 Mechanical Testing Protocol

The prepared specimens were secured to the testing apparatus (858 Mini Bionix, MTS Systems Corp., Eden Prairie, MN, USA) [Figure 3.2]. For both FC and SC loads, the inferior pot was secured to the baseplate of the MTS without the possibility for translation in the horizontal plane. For AR, the inferior pot was secured to a XY-sliding table to allow translation in the horizontal plane.

MTS Testing Apparatus

![MTS testing apparatus](image)

Figure 3.2: MTS testing apparatus.
For FC and SC, an off center axial load was applied. This offset for flexion/compression was 1 cm. anterior to the mechanical center; and for side bending compression, 1 cm. lateral to the mechanical center. A ramped load was applied for both FC and SC at a rate of 100N/s until mechanical failure. For AR, a ramped moment around the axis vertical to the specimen was applied at a rate of 1Nm/s until failure. Yield strength was determined as the first point at which there was a sudden increase in angular displacement (Figure 3.3).
3.6.1.4 Data Analysis

For each of the 3 groups (FC, SC, and AR), the percent change in average yield strength compared to the intact group was calculated. The mode of failure (i.e. endplate, side wall, or facet fracture), was documented. For each group (FC, SC, and AR) the yield strength was compared between subgroups (intact, defect, and
filled) using ANOVA. Analysis of covariance was used to assess the impact of bone mineral density, segmental level (L1-L3 or L4-S1), and vertebral dimensions (measured prior to testing) on yield strength.

3.6.2 Multisegment Model

3.6.2.1 Study Groups

The biomechanical implications of plug removal and defect filling using various biomaterials were further assessed by means of a multisegment model. Five groups were tested, each containing 8 specimens. Specimens were stratified such that there was no significant difference in BMD or vertebral level between groups. Each test specimen consisted of 2 adjacent spinal motion segments (i.e., 3 adjacent vertebrae, either L1-L3, or L4-S1). Specimens of the first group were left intact 'intact'. For the second group 'defect', a bone plug was removed from the middle vertebrae (L2 or L5). For the remaining three groups, a bone plug was removed from the middle vertebra and this bony defect was filled using one of 3 different filler materials. Biomaterials for the 3 filled groups were: TCP (Ceros. Mathys AG. Bettlach, Switzerland), porous tantalum (Hedrocel. Impex Corp., Allendale, NJ.), and Norian SRS (Norian SRS, Norion Corp., Cupertino, CA.).
3.6.2.2 Specimen Preparation

Each specimen consisted of 2 adjacent spinal motion segments (i.e. three adjacent vertebrae, L1-L3 or L4-S1). All ligamentous structures were preserved. An interbody fusion cage (Syncage, Synthes Spine, Paola, USA), was inserted in the interbody space of either L2-3 or L4-5, while the L1-2 or L5-S1 intervertebral discs were preserved. Preparation for cage insertion (medium sized Syncage implant) involved excising a portion of the anterior annulus fibrosis and removal of the entire nucleus pulposus. The superior and inferior endplates had the cartilagenous layer removed using a ring curette, in an area approximately equal to the cage superior and inferior surfaces. The interbody fusion implant was then inserted such that the anterior cage wall was 3-4mm deep to the anterior vertebral body wall. The distance from the upper vertebra’s superior endplate to the lower vertebra’s inferior endplate (initial specimen height) was measured with a caliper.

The middle vertebra (donor vertebra, L2 or L5) was prepared once the cage was in place. For the intact group the middle vertebra remained intact. For the defect group, a bone plug was removed. The bone plug was removed to a depth of 25mm using the core drill and released with the extraction tool. The TCP and porous tantalum group had the defect filled using pre-shaped implants. The Norian SRS group had the defect filled using the injectable, calcium-phosphate bone cement. The bone cement was mixed following manufacturer instructions and injected with a syringe such that the deepest portion of the defect was filled first, followed gradually by more superficial layers. All specimens were wrapped in a sealed
plastic bag and placed in an incubator at 37 degrees Celsius for 12 hours. Incubation was required for the Norian SRS cement to reach its ultimate strength, but for consistency, the same protocol was applied to all groups.

The vertebral bodies of the most superior and inferior vertebrae were then potted. The potting molds were aluminum cylinders with a 1.5 cm inner diameter and 1 cm height. They were filled with PMMA cement to a depth of 0.5 cm and first the superior and then the inferior vertebrae were lowered into their respective pots. The superior endplate of the middle vertebrae was aligned horizontally. The mechanical center of the middle vertebra (point one third the distance of the vertebra's AP diameter, measured from posterior in the midsagittal plane) was aligned with the center of the superior mold (Figure 3.4).
Multisegment Specimen

Figure 3.4: Potted multisegment specimen with interbody fusion cage and TCP filler in place.

3.6.2.3 Mechanical Testing

The inferior pot was fastened to the loading apparatus (858 Mini Bionix, MTS Systems Corp., Eden Prairie, MN, USA) and load was applied to the superior pot. A flexion/compression load was applied using an axial force at a point 1cm.
anterior to the center of the superior mold (center lined up with the donor vertebra's mechanical center) at a rate of 100N/s until failure. Yield strength was defined as the load at which there was a sudden increase in vertical displacement or a 10% loss of the total specimen height, whichever came first. The yield point was determined for each specimen in the 5 groups. The failure pattern (e.g., endplate or vertebral body sidewall) was documented for each specimen.

3.6.2.4 Data Analysis

Analysis of variance (ANOVA) including post hoc tests were used to assess for a difference in yield strength (dependent variable) between test groups (independent variable). Analysis of covariance was used to assess the impact of bone mineral density and segmental level (L1-L3 or L4-S1) on yield strength.
4 RESULTS

4.1 Cage inner volume:

The inner volume of interbody fusion cages was measured (Table 4.1) to estimate the volume of graft material required. The cages assessed were: Titanium Interbody Spacer (T.I.S., Mathys Ltd., Bettlach, Switzerland), Syncage (Mathys Ltd., Bettlach, Switzerland), Brantigan ALIF (Acromed CORP., Cleveland, Ohio), Moss Cage (DePuy-Motech, Warsaw, Indiana), and BAK cage (Spine-Tech Inc., Minneapolis, Minnesota).

Cage Inner Volume

<table>
<thead>
<tr>
<th>Cage</th>
<th>Inner Volume</th>
</tr>
</thead>
<tbody>
<tr>
<td>T.I.S.</td>
<td>3.5 - 5.5 cc</td>
</tr>
<tr>
<td>Syncage</td>
<td>2.5 - 5.0 cc</td>
</tr>
<tr>
<td>Moss Cage</td>
<td>1.8 - 7.0 cc</td>
</tr>
<tr>
<td>Brantigan ALIF</td>
<td>4.0 - 7.5 cc</td>
</tr>
<tr>
<td>BAK (single)</td>
<td>1.1 - 3.4 cc</td>
</tr>
</tbody>
</table>

Table 4.1: Volumes needed to fill the different interbody fusion cages with bone. The range of volumes refers to different sizes available for any given implant model.
4.2 Vertebral Dimensions:

Morphology measurements (Figures 4.1 and 4.2) were made on both MRI of adult lumbar spines (MRI group) and lumbar vertebra specimens (cadaveric group). The age range for the MRI group was 55 to 75 years, for the cadaveric group, 20 to 82 years. The morphology measurements from MRI (n=80) and cadaveric specimens (n=43) indicate the safe dimensions of a bone plug which may be harvested from the vertebral body.

### Minimum Vertebral Body AP Diameter

![Graph showing minimum vertebral body AP diameter](image)

**Figure 4.1:** Minimum vertebral body AP diameter (mean +/- 3SD) measured from MRI (MRI, n=80) and cadaveric specimens (Cadaveric, n=43).
The minimum vertebral body AP diameter (min VB AP diameter) was not significantly different comparing MRI and cadaveric vertebrae from L1 to L5 (p<0.05). Likewise, the minimum vertebral body height (min VB height) was not significantly different comparing MRI and cadaveric vertebra from L1 to L5 (p<0.05).
4.3 Safety Study

The safety study showed that 71 of 75 procedures had not violated the anatomical boundaries of the vertebral body. Four vertebrae had the inferior endplate breached by approximately 2mm. All endplate violations occurred during the first 4 cadavers, two in the L4 and two in the L5 vertebrae. The measured bone plug length for all specimens retrieved was in access of 25mm.

4.4 Single vertebra biomechanics

The direction significantly affected by plug removal was flexion/compression (FC). Removal of the bone plug reduced yield strength to 53% of intact values, which was significantly decreased compared to intact (p=0.01). There was no significant difference between intact and plugged groups in FC (p<0.05). Bone plug removal in SC reduced yield strength to 71% of intact, and in AR, yield strength was reduced to 74% of intact, both of these values did not reach the significance level of p<0.05. Filling the defect using the porous tantalum implant restored yield strength to within 76%, 77%, and 78% of intact values for FC, SC, and AR respectively (Table 4.2, Figure 4.3, 4.4, and 4.5).
Yield Strengths (Single Vertebra Model)

<table>
<thead>
<tr>
<th></th>
<th>intact</th>
<th>defect</th>
<th>plugged</th>
</tr>
</thead>
<tbody>
<tr>
<td>FC</td>
<td>5503.4N +/- 2339.1N</td>
<td>2900.3N +/- 1060.4N</td>
<td>4174.3 +/- 2172.6N</td>
</tr>
<tr>
<td>SC</td>
<td>6206.8N +/- 2382.1N</td>
<td>4428.6 +/- 2096.6N</td>
<td>4798.0 +/- 2053.3N</td>
</tr>
<tr>
<td>AR</td>
<td>65.76Nm +/- 27.09Nm</td>
<td>48.70Nm +/- 22.77Nm</td>
<td>50.60Nm +/- 22.62Nm</td>
</tr>
</tbody>
</table>

Table 4.2: Yield strengths for groups (mean +/- 1SD) FC, SC, and AR: subgroups intact, defect, and plugged.

Flexion/Compression Strength (single vertebra model)

Figure 4.3: Yield strength (mean +/- 1SD) for group FC, subgroups intact, defect, and plugged.
Side Bending/Compression Strength (single vertebra model)

Figure 4.4: Yield strength (mean +/- 1SD) for group SC, subgroups intact, defect, and plugged.
Axial Rotation Strength (single vertebral model)

![Graph showing Axial Rotation Strength for intact, defect, and plugged groups.](image)

Figure 4.5: Axial rotation strength (mean +/- 1D) for groups intact, defect, and plugged.

Analysis of covariance was performed for each of the groups to assess for the significance of various independent variables on yield strength. The independent variables were: bone mineral density, and vertebral dimensions (height, coronal.
and sagittal diameter). The only covariable to have a significant effect on yield strength was bone mineral density in the FC group (p=0.03).

4.5 Multisegment Biomechanics

The yield strength in multisegment testing was significantly reduced comparing defect to intact group (p=0.003) in ANCOVA. There was a significant increase in yield strength comparing all three filler materials to defect group (p=0.002, <.0001, and <.0001 for porous tantalum, TCP, and Norian SRS respectively). When comparing intact group to the 3 filler material groups, there was a significant increase in yield strength for TCP (p=0.03), and Norian SRS (p=0.03). (Table 4.3. Figure 4.6).
**Yield Strength (Multisegment Model)**

<table>
<thead>
<tr>
<th>Material</th>
<th>Yield Strength (N)</th>
</tr>
</thead>
<tbody>
<tr>
<td>intact</td>
<td>4443.7N +/- 1919.5N (100%)</td>
</tr>
<tr>
<td>defect</td>
<td>2604.0N +/- 1020.2N (59%)</td>
</tr>
<tr>
<td>porous tantalum</td>
<td>4729.5N +/- 2009.8N (106%)</td>
</tr>
<tr>
<td>TCP</td>
<td>6173.0N +/- 1852.7N (139%)</td>
</tr>
<tr>
<td>Norian SRS</td>
<td>6131.0N +/- 3077.4N (131%)</td>
</tr>
</tbody>
</table>

Table 4.3: Yield Strength (mean +/- 1SD) for 5 groups in Multisegment Model.
Analysis of covariance for the multisegment model assessed the significance of various independent variables on yield strength. The independent variables were bone mineral density and vertebral level. Bone mineral density was found to be a significant covariable ($p=.0002$).
The failure patterns for each group were slightly different. The intact group failed with the interbody fusion cage pushing through the endplate. The defect group failed with the cage first pushing through the endplate, and then the vertebral body split in the sagittal plane. The porous tantalum and Norian SRS groups failed with the cage pushing through the endplate until it came into contact with the plug which then slowed the progression of the cage through the vertebral body. There was no failure of the plug for either porous tantalum or Norian SRS. The TCP group failed with the cage pushing through the endplate, and then the cage crushing the TCP plug.
5 DISCUSSION

This study was carried out to determine the feasibility of a novel procedure for harvesting autologous bone graft from the vertebral body adjacent to an interbody spinal fusion. To accomplish this, relevant vertebral morphology data, interbody fusion cage inner volume, bone plug harvesting tool design and related safety, as well as biomechanical testing was carried out.

5.1 Vertebral Morphology and Tool Design

Morphology measurements were made to conceptualize the maximum sized bone plug which could be removed from the vertebral body without violating its anatomic boundaries. The minimum endplate to endplate distance (min VB height) as well as minimum anterior to posterior vertebral body diameter in the sagital plane (min AP VB diameter) were measured.

Panjabi documented vertebral morphology measurements for the entire spine [70, 71, 72]. Although Panjabi's work lists important anatomic dimensions, the min VB height, and min. AP VB diameter, taking into consideration the convexity of the vertebral side wall and endplate, were not assessed. The min VB height and min AP VB diameter in our study were considerably smaller than the values...
measured by Panjabi [70]. There is a trend for *min VB height* to decrease from L1 to L5, while the *min AP VB diameter* tends to increase from L1 to L5.

The first objective of the morphometric study was to assess the differences between MRI and direct specimen measurements. Direct measurements were considered the gold standard. Patient's preoperative assessment frequently includes MRI diagnostic. If MRI measurements would be a reliable estimates of the vertebral body dimensions, they could be used to evaluate the maximum safe plug size preoperatively. As shown with our data, there is no significance difference between direct measurements from cadaveric specimens and MRI. Pre-operative MRI measurements are, therefore, a valid tool in confirming the safe size of a plug which could be safely harvested from the vertebral body.

The second objective of the morphometric study was to conceptualize the size, shape, and orientation of a bone plug to be safely removed in anterior lumbar spine surgery. A cylinder shaped plug would be the simplest to design extracting tools for and therefore the simplest to remove from a vertebral body. A cylindrical defect is most easily filled by potential filler materials, especially if these materials are pre-fabricated.

Based on the morphology data, a cylinder cutting drill as well as extracting tool was designed to remove the plug from the vertebral body. The dimensions of the core drill and extracting tool were 17.50mm outer diameter and 16.45mm inner
diameter. The cannulated core drill system had positive stop at 20mm or 25mm cutting depth. The unmorcelized volume of bone removed by the core drill was 4.3cc and 5.5 cc (20mm and 25mm length, respectively).

The inner dimensions of interbody fusion implants were measured to determine if the volume of bone harvested from the vertebral body would be sufficient to fill the cage. The values for these measurements ranged from smallest (small Moss Cage, volume 1.8cc) to largest (large Brantigan ALIF cage, volume 7.5cc). When comparing the inner volume of the cages with the harvested bone volume, our data suggest that an interbody fusion implant can be adequately filled with bone harvested from the vertebral body, as morcelization likely increases the volume of available cancellous bone.

5.2 Safety Study

The safety and practicality of the harvesting tools was determined in the safety study. Only 4 of 75 procedures violated anatomic boundaries. The four failures occurred within the first four procedures, illustrating the learning curve. In the early procedures, the degree of lumbar lordosis was underestimated and therefore the inferior endplate was the point of breech in all four failed procedures. The length of all bone cores was in access of 25mm., and therefore would not have encroached on the spinal canal if stopped at 25mm.
The tools worked well throughout the procedure. The guiding K-wires were placed without fluoroscopy, but could be more accurately placed using radiographic guidance. The drill cut a precise core in all procedures. There was a tendency for the cutting instrument to run hot if it was not continuously irrigated with cooling solution. Insertion of the extracting tool into the cut prepared by the cutting tool was sometimes difficult. Once the extracting tool was inserted past the anterior cortex, and was properly aligned, it progressed to the depth of the cut without difficulty and twisted the bone core out without mishap.

The harvesting tools were designed to remove the largest possible sized plug from the vertebral body. This may not be required for every patient. For a smaller cage to be inserted, a smaller plug likely could be harvested. Such a smaller plug would be safer to harvest and would likely affect the vertebra strength less compared to the presently suggested plug size.

The retroperitoneal approach for this local graft harvest will require the ligation and control of the segmental vessels overlying the vertebral body from which the bone plug is to be taken. Unlike a simple one level interbody fusion, it will be necessary to control these vessels in order to gain sufficient access to the anterior vertebral body.
The cadaveric safety study had a number of limitations. The use of a direct anterior approach was artificial because to access the L1 to L4 vertebrae, a retroperitoneal approach is usually chosen. The anterior approach was performed because mobilizing the soft tissues in an embalmed cadaver was otherwise too difficult. However, in our opinion, it would not be more difficult to harvest a bone plug form the vertebrae from an orientation other than straight anteriorly. The vertebral body has its narrowest diameter in the mid-sagittal plane [71], and therefore, a non-sagital oriented plug would not breech the vertebra side wall if it passed through the center of the vertebral body.

5.3 Biomechanics

Implications of removing a bone plug was determined in various spine load conditions in the single vertebra model. Flexion/compression, side bending/compression, and axial rotation loads were applied to the specimens. For the FC and SC groups, specimens were subjected to a combined bending moment/compression load. The AR groups experienced a pure torque load with the XY table allowing for unconstrained translation in the horizontal plane. This unconstrained translation in the horizontal plane is necessary because the center of rotation is not constant for the entire range of motion [67].
The creation of a cylindrical vertebral body defect affects flexion/compression loads significantly. This is not surprising in that the defect created removes a significant portion of cancellous bone in the anterior vertebral body. Side bending/compression was expected to place maximum load on the ipsilateral vertebral body and facet joints, while axial rotation loaded mainly the facet joints. Since the lateral and posterior vertebral side wall, as well as facet joints, were left intact during plug removal, the vertebra strength did not decrease significantly in these load applications.

It was important to show that the reduction in yield strength in flexion/compression could be effectively restored using the porous tantalum implant as it is this type of movement which in vivo places maximum load on the spine [73, 74]. The porous tantalum filler effectively restored yield strength. There was no significant difference between intact and plugged subgroups in the flexion/compression group. There was no damage to the implant observed throughout testing.

The failure patterns observed in the single vertebra model emphasize the differences in load distribution for the three test groups. Failure occurs through the anterior vertebral body in flexion/compression and through the lateral vertebral body in side bending/compression. In axial rotation, the vertebra fails bilaterally through the facet joints. In all three load applications, mechanical failure occurs as a gradual increase in vertical or angular displacement, followed
by a sudden increase in displacement velocity. This observation is in keeping with the findings of Fyrie, who showed that the primary mechanism of failure in compression tests of human vertebra cancellous bone is microscopic cracking rather than overt failure of the trabecular elements [75].

The ANCOVA was carried out to assess the effect of bone mineral density, vertebral body height, and vertebral body sagital, and coronal dimensions on yield strength. The bone mineral density was the only significant covariable for the group flexion/compression. This is in keeping with the findings of previous work demonstrating a positive corelationship between bone mineral density and yield strength [76].

A limitation of the single vertebra model was the unphysiologic load distribution across the vertebra. Due to the PMMA embedding, the load in the single vertebral model was equally distributed across the entire endplate and facet joints. Load in vivo, however, is distributed variably across the centrum and shell of the vertebral body [77, 78, 79]. For healthy discs, the highest effective stresses are found in the center of the endplate, while for degenerated discs, stresses are found in the lateral aspects of the end-plates, and in the cortical sidewall [77, 78, 79, 76, 80].

Load distribution is likely also affected by the placement of an interbody fusion implant. The load distribution across the endplate and mechanical failure patterns
likely differ for various interbody fusion implants. The Syncage implant, featuring a convex implant face in contact with the endplate, was chosen for this study as it was the implant which appeared to distribute load most evenly across the endplate.

Based on the results of the single vertebral model, flexion/compression loading was assessed in the multisegment model. The yield strength for each group was compared using ANCOVA, with bone mineral density and vertebral level entered as a covariable. The bone mineral density was shown to be a significant independent variable in multisegment model, again in keeping with previous work [76]. The significant reduction in yield strength between intact and defect groups emphasizes the loss of supporting cancellous bone from the vertebral body that underwent plug removal.

Although the difference between intact and defect groups for both single vertebral model (flexion/compression subgoup) and multisegment model were significant, the reduction in strength after plug removal appears to by greater in the multisegment model. This greater effect of plug removal can be attributed to the load modifications of the intact disc and interbody fusion implant.

When compared using ANCOVA, all three filler materials restored yield strength to values equal to or greater than the intact group. The TCP and Norian SRS implants restored yield strength to values greater than intact.. This may be
attributed to the fact that they better filled the defect left by plug removal. The tantalum implant was 0.1mm smaller in diameter than the TCP implant. The Norian SRS cement can be assumed to optimally conform to the defect created. However, there was no significant difference observed for the Norian SRS group when compared to the TCP group. Another possible reason for the improved performance of TCP and Norian SRS may be their closer E-modulus match compared to native cancellous bone. The tantalum implant has the highest E-modulus, therefore less able to correct the stress riser created by plug removal.

Differences exist in failure patterns between test groups. The intact group fails with the cage subsiding into the endplate. The defect group fails with sagittal splitting of the vertebral body. This is likely due to horizontal shear forces acting across the vertebral body, through the area of the defect [75]. For all three filled groups, the degree of sagittal splitting is less pronounced and occurs at higher loads than in the defect group, emphasizing the ability of the implant to transfer load across the vertebral body.

There are obvious limitations to performing the biomechanical tests on in vitro specimens. The removal of a core of bone adjacent to the vertebral endplates likely has an effect on the vascular supply to these areas. The implications of this vascular insult on the endplate and intervertebral disc were not addressed in this study.
5.4 Filler Materials

The ability to reconstruct the mechanical strength of the vertebral body was assessed using three different filler materials. The materials were chosen as they each represent different qualities relevant to defect filling. These qualities include, ease of insertion, resorbability, and stress transfer across cancellous bone.

There exist a practical difference in the ease of implant insertion between the three implants. The TCP and porous tantalum implants were similar for their insertion technique. Once the implant was properly aligned for insertion, it could be placed in the defect with no difficulty. The most difficult part, however, was the initiation of insertion through the cortical shell of the vertebral body. The Norian SRS filler was the easiest to use. The consistency of the cement allows it to be injected into, and remain within the defect. It hardens non-exothermically, and is therefore safe when implanted in heat sensitive body regions.

The advantage of TCP and Norian SRS is their biological resorbability. The rates of resorption and bone ingrowth differ somewhat depending on anatomic site of insertion. Native bone replacement of both beta-tricalcium phosphate and Norian SRS occurs in a manner similar to normal bone turnover [64, 81, 82, 49, 51]. Initially bone is spongy, but becomes lamellar after approximately 6 months [81, 82]. It would seem beneficial that the material is eventually resorbed to some degree. The degree of resorption for the TCP and Norian SRS fillers may not be the same as in other applications because of the different location of implantation.
as well as the large implant volume. The porous tantalum filler remains a foreign body along with the interbody fusion implant. An advantage of the tantalum implant is that its mechanical strength does not decrease with time, as it is not resorbed.
6 CONCLUSIONS

Based on the results of this study, the following conclusions can be made.

1) The volume of autologous bone required to fill the presently available interbody fusion implants is available within the vertebral body of a single vertebra.

2) A cylinder bone plug can be safely harvested from the vertebral body using the techniques described.

3) Removal of this bone plug diminishes the yield strength of the vertebral body most significantly with a flexion/compression type load application.

4) The strength of the spinal motion segment can be reconstructed using any one of the three filler materials described. The reconstructed vertebra is at least as strong as the intact vertebra.

5) The mode of failure in a quasi static flexion/compression type load application is one in which the interbody fusion cage is forced through the endplate followed by sagital splitting of the vertebral body.

6) Clinical studies are still required to validate this bone harvesting procedure.
7 BIBLIOGRAPHY


