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UNIVERSITY OF ALBERTA

The Design and Development of a Spinal Fracture Fixation System

BY

William Cottle

A thesis submitted to the Faculty of Graduate Studies and Research in partial fulfillment of the requirements for the degree of Master of Science.

DEPARTMENT OF MECHANICAL ENGINEERING

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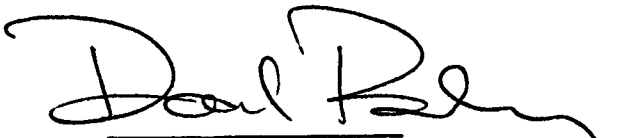

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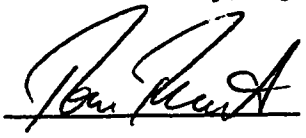

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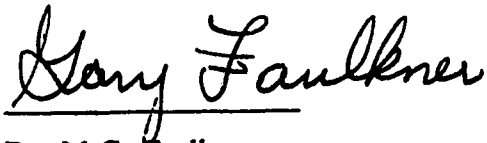

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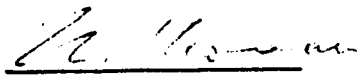

Dr. M. Moreau

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This work is dedicated to my parents

Abstract

Recent advances in fixation systems for the treatment of thoracolumbar fractures have improved neurological outcomes, decreased incidence of late deformity and pain and reduced hospital stays. However, problems remain with current systems including difficulty in implantation, poor accommodation of normal variation in vertebral morphology and a high incidence of mechanical complications. A study was undertaken to develop a new system to address these and other deficiencies.

The prototype pedicle screw fixation device has several advantages over existing instrumentation including a unique screw/rod junction that: accommodates differences in pedicle screw orientation within the normal range of vertebral morphology; permits custom production to provide the required level of stability; and is adaptable to different pathologic and traumatic conditions. This junction also enables installation without intentional or accidental plastic deformation of the device and application of undesirable forces on the vertebrae.

Though the prototype device addresses many of the deficiencies of existing systems, posterior fixation has difficulties that may be insolvable using only a posterior device. In cases with severely unstable fractures a large bending moment must be supported that can lead to failure of the device and/or the device/bone interface. To reduce the load on the posterior device, a device that provides support for the vertebral body and is implanted during the posterior fixation procedure was developed.

This anterior support consists of a collapsible mould that is filled with bone cement after implantation into the fractured vertebral body. Filling causes longitudinal expansion of the support so that contact is made with the intact endplates of the adjacent vertebrae. Radial expansion is limited preventing impingement on the spinal cord and allowing space for bone graft material.

Tests were performed to evaluate the expansion characteristics of the tubing and the compressive strength of the bone cement-filled supports. Significant longitudinal expansion was achieved with limited radial expansion and the mean compressive load capacity of the supports (6555 ± 1615 N) exceeds physiological loads.

In-vitro testing was performed to determine the efficacy of the support to reduce

Abstract

the loading on the posterior device. A mean reduction in the ratio of applied moment to moment carried by the fixation device of 43.7±15.6% was determined. In addition, the support significantly reduced the asymmetry of loading between the pair of devices.

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Chapter 1: Introduction

Treatment of unstable fractures of the thoracolumbar spine present a challenge to the orthopaedic surgeon. To prevent further neurological damage, late pain and deformity, invasive immobilization of the fracture is often required. Despite the availability of a variety of fixation devices and the attention of numerous researchers, technical problems remain with this procedure.

The preferred technique for stabilization of spinal fractures is posterior fixation and fusion. This entails implantation of a fixation device to provide immediate stability and an environment for obtaining fusion. Such a device must support the spine without complication during the critical post-operative period before and during fusion. Development of the fusion mass is critical to the stability of the fracture as without a successful fusion, fatigue failure of the instrumentation may occur.

Traditionally, conservative treatment of spinal fractures was performed that required long hospital stays and excessive demand on the nursing staff. The results obtained with this treatment were often not satisfactory. Use of early spinal fixation instrumentation such as Wilson plates, however, did not provide a better clinical outcome. Consequently, considerable debate occurred regarding the appropriate form of treatment. With the application of instrumentation developed for the correction of scoliosis to treatment of spinal fractures and, more recently, the development of pedicle screw instrumentation the results of invasive treatment have improved.

Despite excellent results with the use of pedicle screw instrumentation and the introduction of new devices many problems remain. These include difficulty in implantation, a high incidence of mechanical complications and a limited capability to accommodate normal variation in vertebral morphology. The intent of the present study was to develop a prototype device to address such deficiencies and represents part of an ongoing collaborative research program between the Department of Mechanical Engineering and the Division of Orthopaedic Surgery at the University of Alberta.

To accomplish the study's objective the performance of current instrumentation was reviewed and in consultation with orthopaedic surgeons the objectives for, and constraints on the design of, a posterior fixation device were determined. A prototype

device was then developed and finite element analysis performed to ensure its structural integrity.

Consideration of the objectives of surgical intervention and of the mechanics of the posterior fixation suggested further study. Minimizing the number of vertebra fused to retain flexibility entails the transfer of large loads by the screw/bone interface and the pedicle screw. This situation can result in failure of the screw and/or the interface. Reexamination of this problem led to the development of an innovative solution. A support for the vertebral body, the major load bearing structure of the spine, that is implanted transpediculary during implantation of the posterior device was conceived and developed.

Chapter 2: Anatomical and Surgical Considerations in Spinal Fracture Fixation

Knowledge of the anatomy of the human spinal column and vertebrae and applicable coordinate systems is essential to discussion of spinal fracture fixation. In addition, understanding of the various types of spinal fractures and the objectives of surgical intervention is necessary. Applicable medical terms are defined in the Glossary.

2.1 Coordinate Systems

Definition of the various anatomical structures and dimensions require the establishment of global and vertebral coordinate systems. The global coordinate system is shown in Figure 2.1 and the vertebral system in Figure 2.2. Referring to Figure 2.1 the median plane is described by the yz plane at x=0 and divides the body into equal halves. A sagittal or lateral plane is parallel to the median plane and divides the body into unequal parts. A transverse or axial plane is perpendicular to the median plane.

2.2 Anatomy of the Spinal Column

The spinal column is the major load bearing structure of the upper body. Its structure allows flexibility while providing protection for the spinal cord. It is composed

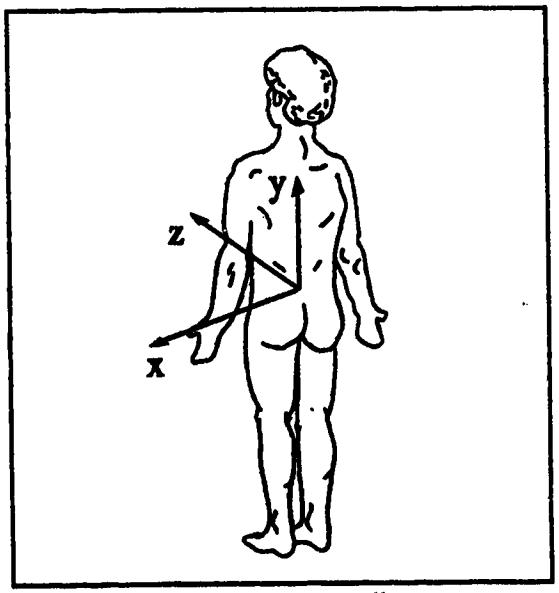

Figure 2.1: Global coordinate system. Modified from White and Panjabi (1978).

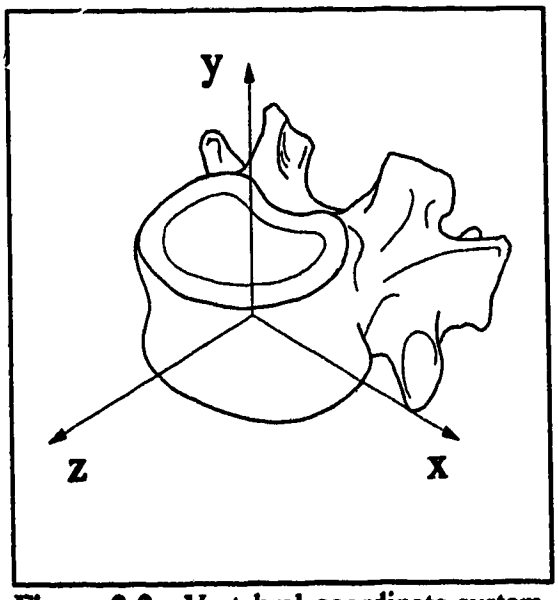

Figure 2.2: Vertebral coordinate system. Modified from White and Panjabi (1978).

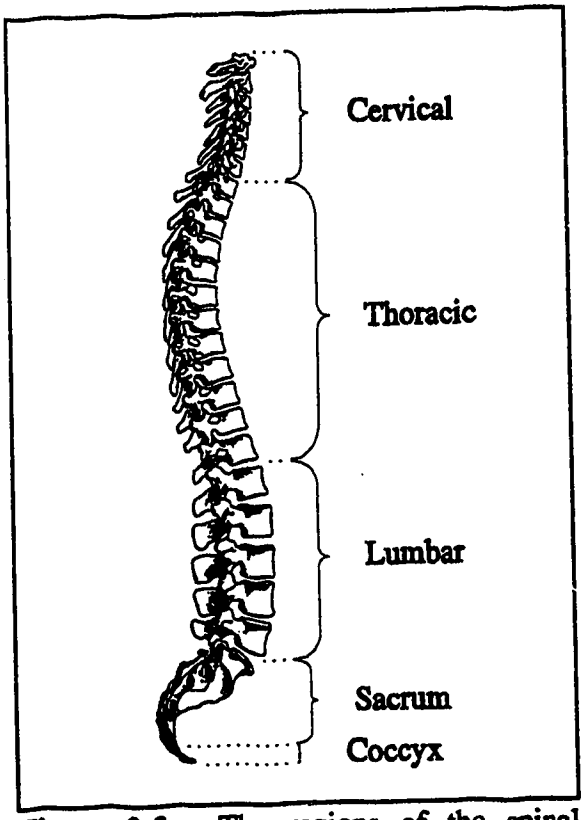

Figure 2.3: The regions of the spinal column. Modified from Grant (1972).

of 33 vertebrae which for descriptive purposes are divided into five regions (Figure 2.3). The upper seven cervical vertebrae form the neck. Although fractures of these vertebrae are common, due to their small size the procedures used to stabilize fractures in this region differ markedly from those used in the lower spine. The thoracic spine has a convex curve and the twelve vertebrae that form this region have joint surfaces for articulation of the ribs. The presence of the ribs gives rigidity to the thoracic region and fractures of the thoracic vertebrae are less common. The five lumbar vertebrae, forming a concave curve known as the lordotic curve, provide considerable flexibility to that part of the spine. The term thoracolumbar refers to the lower thoracic and lumbar vertebrae. The lower five vertebrae that form the sacrum are fused. The remaining four most caudal vertebrae form the coccyx.

For convenience the vertebrae are referred to by the first letter of the respective region and are numbered in a cephalo-caudal direction in the respective region, the upper (cephalic) vertebrae from the cervical, thoracic and lumbar regions are referred to as C1, T1, and L1, respectively.

The structure of the vertebrae is crucial to the design of spinal fixation. Figures 2.4 and 2.5 show the axial and lateral views, respectively, of a typical lumbar vertebra. The vertebrae are composed of spongy cancellous bone with an outer cortex of dense cortical bone. The vertebral body size varies with level, becoming shorter and wider caudally to L5 and thus accommodating the increased applied load. The structures posterior to the vertebral body are referred to as the posterior elements and include the

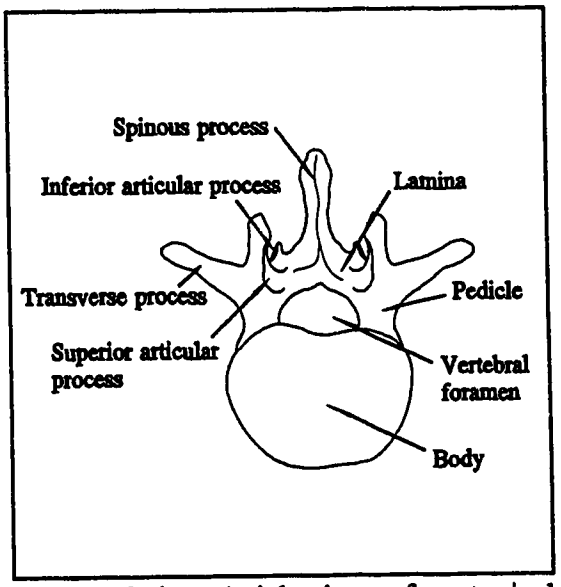

Figure 2.4: Axial view of a typical lumbar vertebra. Modified from Grant (1972).

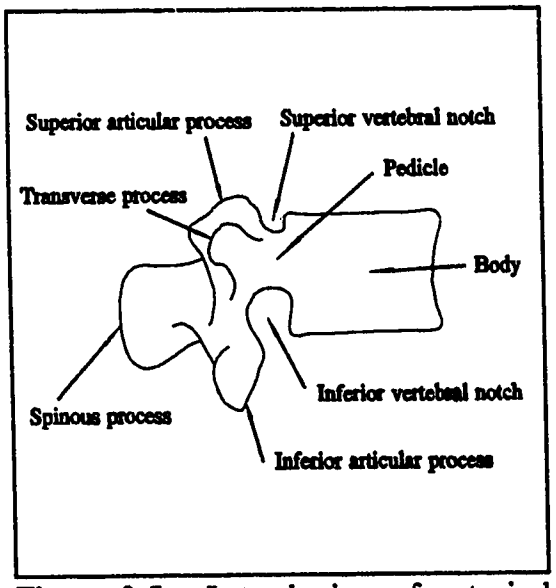

Figure 2.5: Lateral view of a typical lumbar vertebra. Modified from Grant (1972).

pedicles, laminae, spinous process, transverse processes and the articular processes (Figure 2.4). The laminae and pedicles form the vertebral arch. The various processes form attachment points for muscles and ligaments. The articular processes of adjacent vertebrae form synovial joints known as the facet joints. These provide for load transmission and flexibility. On the superior and inferior faces of the vertebral body are the endplates of hyaline cartilage.

The spinal cord passes through the vertebral foramen and is contained within the dura mater (dura), a tough outer coating. The dura provides protection for the spinal cord and its other covering membranes. Nerve roots, containing nerve fibres are located in the space between the inferior and superior vertebral notches of adjacent vertebrae.

Between each successive vertebral body is the intervertebral disc (Figure 2.6). Together the discs form approximately one quarter of the length of the spine and serve, in part, as shock absorbers. Two separate regions of the disc can be distinguished. An outer ring, the anulus fibrosus, composed of concentric layers of angled collagen fibres in a ground substance. The fibres of each layer of this ring are offset by 120° to the preceding layer. The second region, the central nucleus pulposus, is an ovoid gelatinous mass. The intervertebral discs are bound to the vertebral endplates and ligaments on the

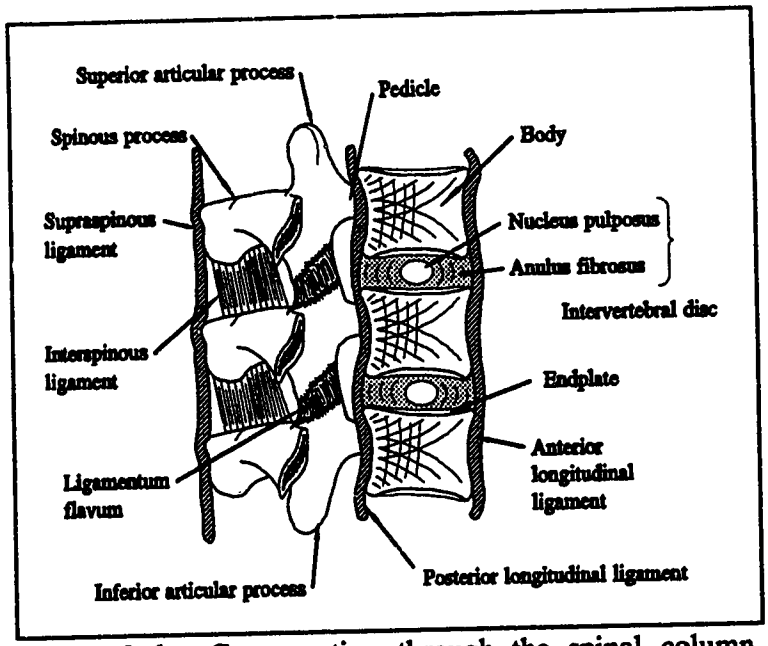

Figure 2.6: Cross-section through the spinal column. Modified from Kapandji (1974).

circumference of the vertebral body.

Several ligaments are of particular concern in the study of spinal fixation (Figure 2.6). Located vertically along the anterior circumference of the vertebral body is the anterior longitudinal ligament. The posterior longitudinal ligament lies vertically on the posterior surface of the vertebral body within the vertebral foramen. Connecting the posterior elements of adjacent vertebrae are a number of smaller ligaments.

The aorta and vena cava pass immediately anterior of the vertebral body and the proximity of these vessels is a concern in the design of spinal instrumentation.

2.3 Vertebra Morphology

Certain dimensions of the vertebra are critical to the design of a fixation device. These define the size of a number of components of the fixation device and are described with reference to both the axial (Figure 2.7) and lateral (Figure 2.8) view diagrams.

Referring to the axial view (Figure 2.7) these are:

(a) - The minimum pedicle diameter.

(b) - The transverse pedicle angle; the angle between the pedicle axis and the vertebral midline in the transverse plane.

(c) - The cortex-to-cortex distance measured along the axis of the pedicle.

(d) - The cortex-to-cortex distance measured parallel to the midline of the vertebra.

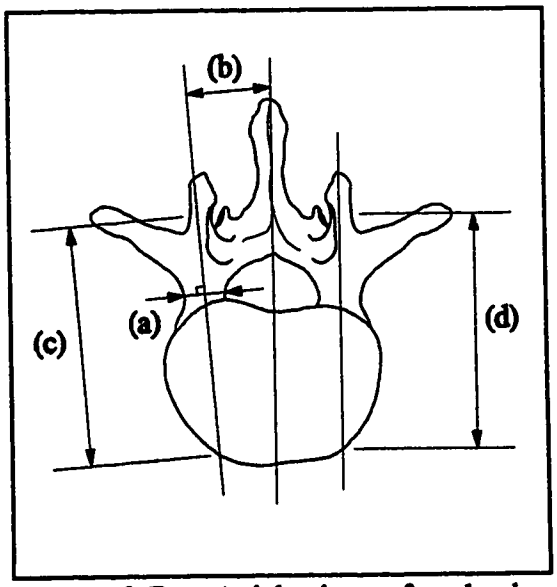

Figure 2.7: Axial view of a lumbar vertebra showing morphological dimensions.

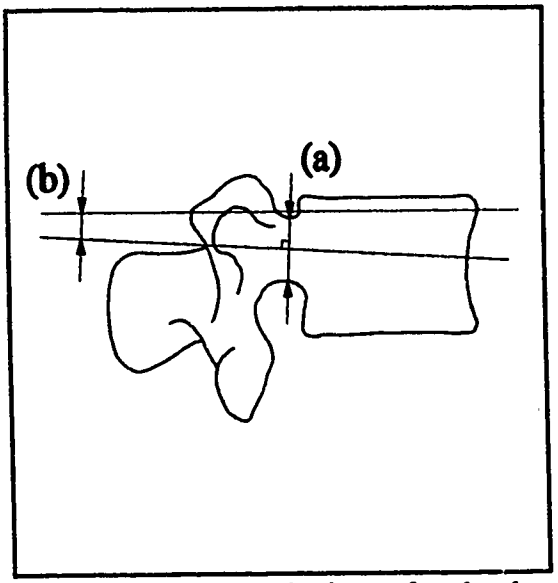

Figure 2.8: Lateral view of a lumbar vertebra showing morphological dimensions.

Referring to the lateral view (Figure 2.8) these are:

(a) - The maximum pedicle diameter.

(b) - The sagittal pedicle angle; the angle between the pedicle axis and the superior vertebral endplate in the sagittal plane.

A further dimension not included above but also of importance is the endosteal diameter of the pedicle (the diameter of the cancellous bone within the pedicle).

2.4 Thoracolumbar Vertebral Fracture Definition

Classification of vertebral fractures is based upon which structures are injured and on the configuration of the forces causing the injury. Denis (1983) developed a system of fracture classification considering the spine as three columns (anterior, middle and posterior). The anterior column includes the anterior longitudinal ligament and the anterior of the anulus fibrosus and vertebral body. The middle column is comprised of the posterior longitudinal ligament, the posterior of the anulus fibrosus and the posterior wall of the vertebral body while the posterior column includes the posterior elements and associated ligaments. Four major fracture types were defined based on which of the columns were injured and the mode of injury. In the compression fracture there is

compressive failure of the anterior column while the middle column remains intact. The burst fracture includes compressive failure of the anterior and middle columns. The compressive failure of the middle column results in fracture of the posterior wall of the vertebral body such that bone fragments are retropulsed into the spinal canal. A fracture dislocation entails failure of all columns in compression, tension, shear or rotation. The final category is the 'seat-belt type' fracture that results from failure of the middle and posterior columns in tension with compressive failure of the anterior column. Each of the four major categories of fractures includes a number of subgroups and the radiographic appearance of each type of fracture was described by Denis (1983).

2.5 Objectives of Surgical Intervention

Surgical intervention is performed to restore and stabilize the spine and to decompress the spinal canal. Stability must be provided for cases which can not support physiological loads without progressive deformity risking additional neurological damage and late pain. The degree of stability required varies with the type of fracture and dictates the method of treatment such that a device capable of supporting the applied loads is used. Numerous *in-vitro* studies have shown that the stability of the instrumented spine is device dependent (for example: Abumi et al., 1989; Ashman et al., 1989; Ferguson et al., 1988; Gaines et al., 1991; Gurr et al., 1988a,b; Puno et al., 1991). The ability of the fixation device to provide immediate stability also permits early mobilization of the patient and reduces the length of hospitalization. A further aim of surgical intervention is decompression of the spinal canal. This may improve neurological function and prevent late neurological damage from spinal stenosis in cases where compression is the cause of spinal cord dysfunction (Gertzbein, 1988).

As surgical intervention is undertaken, in part, to restore the anatomical alignment of the spine, subsequent loss of the operative correction is an important consideration in judging the success of the procedure. This late collapse of the fractured vertebra or the 'loss-of-correction' can be described as the change in the kyphosis angle or as the percent change in the posterior vertebral body height. The former is measured as either the local kyphosis angle, the angle between the adjacent endplates of the intact adjacent

vertebrae, or as the vertebral kyphosis angle, the angle between the endplates of the fractured vertebra. Loss of the surgical correction can lead to kyphotic deformity, loss of lordosis and/or neurological complications.

Fusion of the fixed vertebral levels is often performed. This consists of placement of bone fragments along the decortified posterior surfaces. The boney mass which develops serves to support the spine and reduce loading on the instrumentation. Once fusion has occurred the device can be removed.

It is advantageous to limit the number of vertebral levels that are fixed and/or fused to retain flexibility. This is especially important in treatment of fractures at the thoracolumbar junction and in the lumbar spine. Fusion of only adjacent vertebrae while temporarily fixing additional levels has been used to retain flexibility once the rods have been removed (Jacobs et al., 1980; Kinnard et al., 1986; Roy-Camille et al., 1986a,b). However, An et al., (1991) postulated that motion at temporarily fixed, unfused facet joints can lead to failure of the implant. Osteoarthritic changes to such joints have also been reported (Kahanovitz et al., 1984a,b), though the implications of this finding have been disputed (Gardner and Armstrong, 1990).

Chapter 3: Preliminary Design Considerations

Before design constraints were developed, consideration was given to the surgical approach required for implantation and the method used to obtain purchase on the vertebrae. These considerations greatly influence the device design and design constraints.

3.1 Invasive Fracture Fixation Techniques

Invasive fixation of vertebral fractures can be achieved either through an anterior or posterior approach. As the applied loads and the geometry of the structures (morphology) differ greatly between the two approaches, the design of a device for each application will be different.

3.1.1 Anterior Fracture Fixation

Fixation of the vertebral body via an anterior approach has several advantages over posterior fixation. Decompression of the spinal cord is best performed from the anterior. As the majority of the load is transmitted as a compressive load through the body of the vertebrae, an anterior fixation device is the most mechanically efficient form of support. A further advantage to an anterior device is that it can be used in cases of vertebral tumour excision; the anterior approach permits visual confirmation that adequate material has been removed. An anterior device can be installed within the space of the fractured vertebral body or attached to the lateral surfaces of the adjacent intact vertebrae.

Unfortunately, there are several inherent problems in the use of an anterior fixation device including the extensive surgery to obtain the required exposure. Proximity of the fixation device to major vessels is a concern as abrasion between the device and such vessels can lead to their rupture. (Brown et al., 1985; Jendrisak, 1986).

3.1.2 Posterior Fracture Fixation

Due to the inherent difficulties of anterior fracture fixation, the development of a posterior fixation system was investigated. The major advantage to use of posterior

instrumentation is the much simpler surgical approach. However, posterior fixation of a vertebral fracture requires that a large bending moment must be supported by the instrumentation. This can lead to failure of the device and/or device/bone interface and to loss-of-correction.

3.2 Posterior Fracture Fixation Techniques

Obtaining adequate purchase on the posterior surface of the vertebrae to support the applied loads is a major consideration in the design of a successful fracture fixation device and will greatly influence the device design. In current devices one of four techniques for achieving purchase on the vertebrae has been used: fixation to the spinous processes, sublaminar hooks, sublaminar wiring, and pedicle screws. These are described below with their beneficial and adverse features. The four techniques used for attachment are considered separately from the associated fixation devices as a review of the performance of all devices is beyond the scope of this study. From this evaluation a technique for use in a prototype device was chosen.

3.2.1 Fixation to the Spinous Processes

Vertebral fixation has been undertaken by wiring the spinous processes together (Kaufer and Hayes, 1966; Kinoshita et al., 1989) and by attaching devices to the processes. The former technique is relatively simple, quick and inexpensive and does not require the expertise necessary for use of pedicle screws or sublaminar hooks.

Several systems have been developed that attach to the processes to provide stability. These include metal plates (Wilson and Straub, 1952) and the use of bone cement (polymethylmethacrylate) with (Scoville et al., 1967) and without underlying stainless steel mesh (Spence, 1973). Attachment to the spinous processes limits the exposure required reducing the risk of infection and neurological complications.

Unfortunately, stabilization of the spine through attachment to the spinous processes has limited application due to their susceptibility to fracture. Holes made in the processes to facilitate attachment further weaken these structures. Fixation to the spinous processes also results in a long moment arm between the device and the applied

load resulting in high stresses on the device. Devices attached to the processes require fixation of multiple vertebrae above and below the injury to obtain stability.

Wiring of the processes, though successful in treatment of injuries of cervical vertebrae, does not provide sufficient stability for fixation of the thoracolumbar or lumbar vertebrae. *In-vitro* testing has shown that wires can easily cut through their insertion holes providing limited long term support (Nagel et al., 1981). Wiring also does not provide means for direct reduction of the fracture.

3.2.2 Sublaminar Hooks

Purchase to the vertebrae has been achieved by passing hooks either over or under the lamina depending on whether a tensile or compressive load is carried by the device. The hooks are attached to a rod and are held in position by distraction and compression forces. Insertion of hooks is less time consuming and results in less blood loss than insertion of either pedicle screws or sublaminar wires.

Limitations to the use of sublaminar hooks include the potential for neurological complications resulting from their intrusion into the spinal canal. However, a lower incidence of such complications occurs with the use of sublaminar hooks than with sublaminar wiring and pedicle screws (Edwards and Levine, 1989). As the hooks do not form a rigid connection to the vertebrae, fixation and fusion of multiple levels is required in order to obtain stability.

Further difficulties include hook migration and dislodgement. Edwards and Levine (1989) summarized the reported incidence of hook dislodgement in retrospective studies and reported an average dislodgement rate of 6%. Fracture of the lamina can also occur due, in part, to excessive distraction or compression forces. Devices employing sublaminar hooks tend to have limited resistance to torsion. This has been improved by the use of square-ended rods and locking hooks. The design of some sublaminar hooks has also been criticized (Hall et al., 1986). Edwards and Levine (1989) reported that poor hook design can lead to necrosis and resorption of the bone at the hook/lamina contact. A further difficulty with the use of sublaminar hooks is encountered if a laminectomy has been performed to decompress the spinal cord. This

procedure may remove potential sites for placement of the sublaminar hooks.

3.2.3 Sublaminar Wiring

Sublaminar wiring, an additional technique for attachment of a rod to the vertebrae, is more commonly used for correction of scoliosis than in the treatment of fractures. At each level wires are passed through the spinal canal adjacent to the lamina and over a rod lying against the lamina. Twisting together of the ends of the wires secures the rod to the posterior surfaces of the vertebrae.

Passage of the wire through, and its long term presence in, the spinal canal are two adverse features of this technique. Insertion of the wire can cause neurological complications, especially in cases of spinal injury where swelling of the spinal cord can reduce the space available for passage of the wire (Edwards and Levine, 1989). Edwards and Levine cited a study by Weber in which an incidence of neurological deficit of 17% followed the use of sublaminar wiring for treatment of spinal trauma. Haher et al. (1986) and Schrader et al. (1986) have reported the adverse effects of the long term presence of these wires within the spinal canal. In addition, as there is not a rigid connection between the vertebrae and the supporting rod, fixation and fusion of multiple vertebral levels is required. Lack of a rigid connection also results in the system having poor resistance to torsion. Systems employing sublaminar hooks have been augmented with sublaminar wiring to provide increased rotational support; however, Edwards and Levine reported that several researchers have found that tightening the wires can force the hook anteriorly into the canal. Direct reduction of the fracture can not be performed with the use of sublaminar wires.

3.2.4 Pedicle Screws

Pedicle screws are inserted from the posterior surface of the vertebra through the pedicle into the vertebral body. As the screw provides excellent purchase to the vertebra, devices employing pedicle screws achieve greater stability than those with other means of purchase to the vertebrae. As a rigid connection can exist between screw and rod, direct contact between the rod and the posterior elements is not required for stability

resulting in more space on the posterior surfaces for application of bone graft material than is available with techniques such as sublaminar wiring. The secure purchase of the pedicle screws enables direct reduction of the fracture and a reduction of the number of levels fused resulting in more flexibility being retained than with techniques requiring longer fixations. The increased stability also permits early mobilization of the patient. As components are not placed within the spinal canal this potential cause of neurological complications is reduced. Pedicle screws also facilitate the use of external fixation as they can be inserted transcutaneously.

There are several inherent difficulties in the use of pedicle screw instrumentation for the treatment of thoracolumbar fractures. Installation of the screws is technically difficult. Close proximity of the spinal cord and nerve roots to the pedicle implies that incorrect placement of the pedicle screw or use of an excessively large diameter screw can cause neurological complications. Edwards and Levine (1989) state that the Morbidity Committee of the Scoliosis Research Society determined the highest incidence of symptomatic impingement of the spinal cord or nerve roots occurred with pedicle screw instrumentation. However, *in-vivo* testing by Zdeblick et al. (1990) showed the incidence of neuropathologic changes in experiments using dogs treated with sublaminar wires was significantly higher than both those treated with pedicle screw instrumentation and with a sham operation and that there was no significant difference between the latter groups. Overpenetration can cause the pedicle screw to protrude through the anterior cortex of the vertebral body and risk damage to the adjacent major vessels. As the number of vertebral levels fused is limited, the load carried by each screw can be high. This can result in bending and/or fatigue failure of the screw. The high stress in the bone adjacent to the screw can lead to its necrosis and resorption resulting in breakdown of the screw/bone interface and migration of the screw within the vertebral body. Bending, fatigue failure or migration of the screw can all lead to loss-of-correction. A similar result occurs with loosening of the screw/rod junction. Further difficulties with the use of pedicle screws include the poor purchase provided by osteoporotic bone and that transcutaneous pedicle screws are subject to pin tract infections.

Reviewing techniques employed for obtaining purchase to the vertebrae shows that

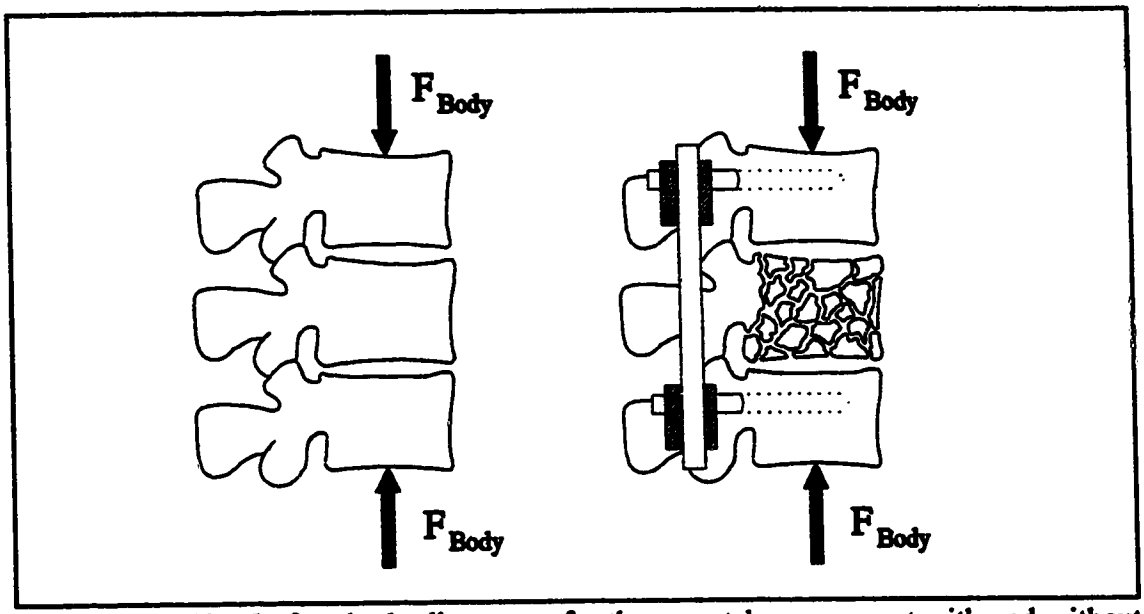

Figure 3.1: Simple free body diagrams of a three vertebrae segment with and without a fractured vertebra.

there are inherent problems with each technique. However, the beneficial features of the use of pedicle screws and the relative success achieved by surgeons in their application suggested that development of a device incorporating this means of attachment to the vertebrae would have the greatest potential for success. Development of such a device was, therefore, undertaken.

3.3 Mechanics of Posterior Fixation

The major portion of the load of the upper body is supported by the spinal column and, in particular, the vertebral body (White and Panjabi, 1978). A fractured vertebra can not support this load such that posterior instrumentation is required to provide this function. Simple free body diagrams of a three vertebrae segment with and without posterior fixation are shown in Figure 3.1. The loads applied to the vertebral column are more complex than as shown. For example, forces in ligaments and at facet joints also exist. However, these are known to be much less than the compressive force applied through the disk. Although the mechanics of load transfer between the vertebra and pedicle screw may be unknown, at the posterior cortex of the vertebra it is known from the free body diagram of the rod and screw/rod junction (Figure 3.2) that the

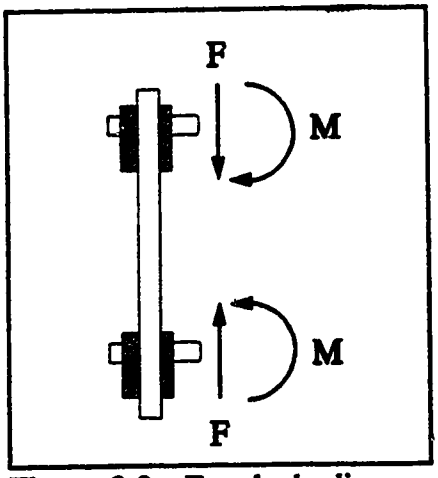

Figure 3.2: Free body diagram of the posterior instrumentation at the posterior bone surface.

instrumentation must support a bending moment and a shear force.

3.4 Physiological Load Levels

Estimates of the physiological load carried by the spine were determined from reviewing published reports. Table 3.1 presents values from intradiscal pressure measurements and biomechanical modelling for the predicted loads on the spine for various body positions and activities that may be encountered by the spinal fracture patient.

Estimation of the physiological load in the spine has been performed primarily by measuring of intradiscal pressure and by biomechanical modelling. Intradiscal pressure has been correlated with the applied compressive load on cadaveric intervertebral discs (Nachemson, 1959, 1963) and then used to estimate static (Nachemson and Morris, 1964) and dynamic (Nachemson and Elfström, 1970) *in-vivo* physiological loads. For activities performed by patients with spinal fractures a range of compressive loads from 295 N to

Activity	Physiological Load based on: (N)	
	Intradiscal Pressure †	Biomechanical Modelling ‡
Supine	295	-
Standing	685	440
Walking	835	-
Twisting	880	-
Bending sideways	930	-
Upright sitting, no support	980	380
Laughing	1175	-
Bending forward 20°	1175	-

† from Nachemson (1976). ‡ from Schultz et al. (1982b).

Table 3.1: Estimated loads on the lumbar spine at level L3 based on measurement of intradiscal pressure and biomechanical modelling.

1175 N have been predicted by this technique (Table 3.1). This technique assumes the compressive load on the spine is equal to the axial compressive load on the vertebral body and neglects load transferred through the facet joints, though these structures can transmit up to approximately 23% of the load at the L5 level (Pal and Routal, 1987). This method can not be used to determine other load components that occur due to the coupled motions in vertebral segments.

Biomechanical modelling of the applied loads and internal forces has alternately been used to determine the loads in the spine. While the results of numerous biomechanical studies estimating loads in the spine have been published, the work of Schultz et al. (1982a,b) and Andersson et al. (1980) has gained widespread acceptance. Many of the other studies have considered activities (such as weight lifting) that may not be applicable to the spinal fracture patient. In the studies of Schultz et al. (1982a,b) and Andersson et al. (1980) the internal forces and moments in the musculature and spinal loading were determined and validated by comparing the muscle forces with electromyography measurements (Andersson et al., 1980). Shear loads have also been predicted to reach a maximum of 200 N (Schultz et al., 1982a). As the shear components are small during tasks that are within the capacity of the spinal fracture patient these loads are neglected in this analysis. Schultz et al. (1982b) stated that the compressive spinal loads estimated by biomechanical modelling correlated well with intradiscal pressure measurements, though values for standing and upright sitting (Table 3.1) do not support this conclusion.

Two groups of researchers have measured *in-vivo* loads on spinal fixation instrumentation. However, neither have correlated their results to spinal load levels. Elfström and Nachemson (1973) measured the axial load in Harrington rods used in the treatment of scoliosis. High loads were recorded during and immediately after surgery. The axial load decreased rapidly to approximately 70% of the initial value during correction of the deformity. Schläpfer et al. (1989) applied load transducers to an external fixation device and monitored load levels in patients with spinal fractures and low-back pain. Relative changes in the loads with healing, external bracing, body position and activity were published.

Chapter 4: Performance of Pedicle Screw Fixation Systems

Knowing both beneficial and adverse features of current fixation devices will determine the need for, and aid in, the design of a new system. In addition, the performance of existing devices will assist in the determining design constraints. To obtain such information published retrospective studies on the performance of currently available pedicle screw systems for fracture fixation were reviewed.

4.1 Clinical Performance of Pedicle Screw Fixation Devices

The performance of a fixation device can be judged by its capacity to reduce the fracture, its ease of implantation and the quality of the clinical outcome achieved. It must enable the surgeon to obtain the required surgical correction with minimal difficulty and tissue damage and without damage to the fixation device. The ease with which the device is installed also influences both the operating time and blood loss as well as reducing possible complications due to incorrect installation. The clinical outcome depends on diverse factors, many of which are independent of the fixation device including placement of pedicle screws and the occurrence of infection. The outcome is also influenced by several factors which depend more on the device including maintenance of the surgical correction and achievement of a successful fusion. Mechanical complications likely to affect the clinical outcome may be minimized through improvements to the fixation system design.

Published retrospective studies on currently available pedicle screw fixation devices were reviewed to determine the loss-of-correction, incidence of pseudoarthrosis and type and incidence of mechanical complications encountered and their influence on clinical outcome (Appendix A). This review also includes a description of various devices currently available and a discussion of their operation. For this review the devices were subdivided into two major groups based on whether or not the screw is constrained at the screw/rod junction. If the screw is unconstrained, contact with the posterior surfaces of the vertebrae is required to achieve stability. Devices with constrained screws do not have this requirement. This difference has a major influence on the mechanics and design of the fixation device and on clinical outcome.

Differences in the population of patients selected, length of follow-up and operative technique make comparison of the published incidence of mechanical complications difficult. The population selected is critical as the number of cases reviewed tends to be small and, thus, studies may reflect inter-patient variability. This variability results from individual differences in the stability of the fracture, the level of physical activity of the patient, the quality of the fusion, the use of external bracing, the rigidity of the fixation device and the patient's weight and sex.

The reported rate of complications is influenced by the length of time cases are followed. Short follow-up periods or early device removal can result in low estimates of the rate of mechanical complications as these may occur as late as 26 months after surgery (Section B.2). Differences in operative technique include the amount of correction obtained and whether or not a transpedicular and/or anterior bone graft was introduced to supplement the posterior device.

Further difficulties in comparing retrospective reports include a lack of published reports on some fixation systems and differences in the completeness of the analysis. In many of the reports the results for all surgical indications and/or the results obtained using different instrumentation systems were combined (for example: LaGrone et al., 1989; Knight et al., 1989; McAfee et al., 1991a; West et al., 1991; Yashiro et al., 1991; Zucherman et al., 1988). In addition, in some studies data on the loss-of-correction, incidence of pseudoarthrosis and mechanical complications were not included or thoroughly analyzed (for example: Esses et al., 1991; Heinig et al., 1989; Herrmann (1979); Olerud et al., 1988; Whitecloud et al., 1989a; Zucherman et al., 1988). Consequently, there is limited information on the incidence and influence of mechanical complications following the use of some currently available devices for treatment of spinal fractures.

4.1.1 Implications of the Review of Current Devices

From the review of currently available pedicle screw fixation devices (Appendix A) several conclusions can be drawn which justify development of a new fixation device and contribute to its design. Some currently available devices (for example the Cotrel-

Dubousset and Variable Screw Placement systems) are difficult to install (Hirabayashi et al., 1991; Matsuzaki et al., 1990; Whitecloud et al., 1989a). This can extend the length of surgery and/or lead to mechanical complications. Many devices have limited or no ability to accommodate differences between the orientations of the pedicle screws. This is of concern as the angle at which the pedicle screw is inserted should be governed by the vertebral morphology rather than the limitations of the fixation device. In addition, if the device cannot accommodate the differences in screw orientations, installation and tightening of the components can impose undesirable loads on the vertebrae or cause plastic deformation of the screws that can lead to screw breakage (Appendix B; Zucherman et al., 1988).

Difficulty in accommodating differences in pedicle screw orientation can be further compounded if more than two screws are implanted. Installation of such screws is required for fusion of additional levels and/or insertion of screws into the fractured vertebra. Fusion of additional levels is required for devices that rely on direct contact with the posterior surfaces of the vertebrae for stability. Screws in the fractured vertebrae can be used to manipulate the vertebra to reduce translational displacements and to provide additional stability (Levine and Edwards, 1988). The Wiltse system is the only device presently available that can accommodate differences in screw orientation between more than two pedicle screws.

Devices that require direct contact with the posterior surfaces of the fused vertebrae are generally the simplest and least expensive. The most common form is the spinal plate. There are several further benefits to this type of system. They are relatively easy to install and are not conspicuous externally. In addition, as there is not a solid connection between the screw and the plate, the screws do not support a bending moment and experience only a tensile load. Thus, these screws would be expected to exhibit a lower incidence of fatigue failure compared to those in devices that do not require direct contact with the posterior vertebral surfaces. This conclusion is supported by the lower incidence of screw failure reported by some authors who used this type of device (see references in Appendices A and C).

Unfortunately, there are also a number of problems with devices requiring direct

contact with the posterior vertebral surfaces. Most have limited ability to accommodate differences in the orientations of the pedicle screws. In the transverse and sagittal planes accommodation is possible only by angling of the screw within the hole of the plate. In the sagittal plane, bending of the plate can aid in accommodating differences in screw orientation. In most plates the holes are a fixed distance apart such that the plate can accommodate only limited variation in inter-pedicle spacing. The lack of a solid connection between the screw and rod requires fixation of more than one level above and below the fracture site.

Further, these devices can not be used to provide reduction of the fracture as the screws in such devices are inserted over the plate. Reduction must be performed by external means before installation of the plates by hyperlordosis. Because the plate must be fastened tightly against the bone surface to achieve stability, resorption of bone under the plate may occur. Due to the viscoelastic nature of bone, it is difficult to retain the desired pressure of the screws against the device. Although the lower pressure would reduce the risk of resorption of the underlying bone, it can lead to loss-of-correction as reported by Luque (1987). In addition, placement of the device against the posterior surface of the fixated vertebrae reduces the area available for application of the bone graft.

Devices that do not require direct contact with the posterior surfaces of the vertebrae have a number of beneficial features. A shorter fusion can be used, retaining more flexibility. With these devices the pedicle screws can be used to reduce the fracture, fixation of fewer vertebrae is possible and more space is available on the posterior surface of the vertebrae for placement of bone graft material. This type of device can better accommodate differences in the pedicle screw orientations and provide more adaptability. For example, the Internal Fixator and Wiltse systems can accommodate an unlimited degree of misalignment between a pair of pedicle screws. In addition, several systems (Cotrel-Dubousset, Internal Fixator and Wiltse) can also accommodate unlimited variation in inter-pedicle spacing as screw/rod junction can be positioned at any location on the rod. Further, the Cotrel-Dubousset system can be used with either screws or sublaminar hooks for attachment to the vertebrae.

There are also a number of disadvantages with these devices due, in part, to the increased load on the pedicle screws. This results as the device is usually secured to one vertebra above and below the fracture site. The screw/rod junction can loosen resulting in loss-of-correction (Aebi et al., 1987; Esses et al., 1991; Olerud et al., 1988). These junctions if excessively large can also interfere with the adjacent unfused facet joints and be evident externally. Due to the requirement for a solid connection between the rod and screw and their greater ability to accommodate differences in pedicle screw orientation, devices that do not require contact with the posterior surfaces tend to be more complicated mechanically and more difficult to install.

The incidence of mechanical complications and pseudoarthrosis and the loss-of-correction associated with the treatment of spinal fractures with currently available fixation systems were determined. Mechanical complications have been shown to have a significant effect on the clinical outcome (Appendix B). For example, the reported incidence of screw breakage varies from zero to 58.3% (Section A.2.3). A discussion of this complication and its impact on the design of a pedicle screw is contained in Appendix C. Published reports of the occurrence of rod breakage are limited. The incidence of the pedicle screw losing purchase due to axial loading (screw pull-out) was very low and appears related to the presence and degree of osteoporosis.

Incidence of pseudoarthrosis that occurred with use of the various pedicle screw fixation systems for the treatment of spinal fractures was compared. Unfortunately, comparison of the incidence of pseudoarthrosis for different fixation systems is not conclusive as accurate assessment of fusion can be difficult and is frequently neglected. Often the surgical indication for the cases that developed pseudoarthroses was not described. As a result there are either no or limited reported rates for the various fixation systems. The incidence of pseudoarthrosis ranged from zero cases in 172 patients (Daniaux et al., 1991) to two cases in 14 patients (14.3%; Kraker et al., 1989). Georgis et al. (1989) and Zucherman et al. (1988) suggested that less rigid implants have higher rates of pseudoarthrosis; however, this was not supported by the findings of the current review as Variable Screw Placement (VSP) instrumentation, the most rigid of the non-contacting type devices, had the highest rates of pseudoarthrosis, ranging from 7.8%

(Akbarnia et al., 1988) to 14.3% (Kraker et al., 1989). Comparison of the incidence of pseudoarthrosis between devices with unconstrained and constrained pedicle screws can not be made as there has been only one report describing the success of fusion for treatment of spinal fractures with the former type of device.

A correlation between the occurrence of screw breakage and pseudoarthrosis in fracture cases could not be established. In studies that reported both the presence of broken screws and pseudoarthroses, several showed a correlation (Akbarnia et al., 1988; Sasso et al., 1991) while others did not (Ebelke et al., 1991; Esses et al., 1991; Kraker et al., 1989; Lindsey and Dick, 1991). Only more thorough analysis and reporting by authors of retrospective studies on the use of pedicle screw fixation devices in the treatment of fractures may provide insight into this question.

Loss of operative correction can have a major influence on the clinical outcome. This can be increased significantly by the development of a mechanical complication (Appendix B; Benazat et al., 1989; Ebelke et al., 1991; Kinnard et al., 1986). In addition, early removal of the device can lead to loss-of-correction (Edwards and Levine, 1989). Transpedicular bone grafting has been shown by a number of authors to reduce the loss-of-correction (Daniaux et al., 1991; Ebelke et al., 1991; Lindsey and Dick, 1991; Luque, 1990).

Comparing loss-of-correction between devices with unconstrained and constrained screws showed slightly better results for cases treated with the latter systems (see references in Appendix A). This conclusion is preliminary due to the lack of published studies which thoroughly analyze fracture cases treated with pedicle screw devices.

Chapter 5: Objectives for a Prototype Pedicle Screw Fixation System and Design Constraints

Objectives for a prototype fixation device were developed in consultation with orthopaedic surgeons and from the review of complications with existing systems (Section 4.1.1 and Appendix A). These served both as a guideline for design of the system and as criteria against which the performance of the prototype could be judged. The objectives included:

- The device must be sufficiently robust to limit motion at the fracture site and to support *in-vivo* cyclic loads.
- The device must be adaptable to different pathologic and traumatic conditions.
- The device must be adaptable to different spinal morphologies.
- Implant installation must be achieved without complication or difficulty.
- The device must provide a means of controlled and accurate reduction of the fracture.
- Installation of the implant must not risk damage to adjacent neurological and vascular structures.
- The device must be capable of maintaining the operative correction.
- The device must provide the optimal environment to obtain fusion.

Addressing the above objectives constraints on the design of a fixation device were compiled.

5.1 Design Constraints

Designs constraints were divided into three major categories: mechanical, surgical and anatomical. As the optimum solution for some constraints is unknown at present the device must be adaptable to accommodate possible modifications as data become available. Further, some constraints contradict others and, therefore, not all can be incorporated.

5.1.1 Mechanical Constraints

Among the constraints deemed mechanical in nature are the device's flexibility and fatigue resistance. . To limit motion at the fracture site resulting from elastic deformation and to prevent loss-of-correction due to plastic deformation of the implant the device must be rigid enough to support the spine under physiological loading (Section 3.4). The former characteristic would assist in achieving a successful fusion. Though the device must be capable of supporting cyclic loading it may not require an infinite fatigue life as the fusion mass is expected to support loading once fusion is successful. However, the device must withstand the cyclic loading before the fusion mass is capable of supporting the applied loads. There are no published reports on the number of cycles that a spinal fixation device should support without failure. To improve the device's fatigue resistance the influence of stress concentrations should be minimized.

The material must be biocompatible. This implies that the rate at which the material corrodes within the body is low and that the products formed by these reactions are not toxic. Mechanical damage to the implant due to corrosion is perhaps less important than the toxicity of the reaction products. Though the environment to which the device is exposed will accelerate the corrosion rates, surface treatments such as electropolishing and passivating can increase the material's resistance to corrosion. All components must be made from the same material to prevent galvanic corrosion.

The capacity to vary the degree and type of stability provided by the device may be required for it to be adaptable to different pathologic and traumatic conditions. As insertion of a pedicle screw into the fractured vertebra may be necessary to correct translational displacements and provide additional stability the device should be capable of accommodating this additional screw. The device must be capable of providing the required stability if additional procedures such as a laminectomy are performed. The device should also accommodate crosslinks if required.

As the orientation of the pedicles, and therefore, the pedicle screws, vary (Section 5.1.3.3 and Appendix D) the fixation device must be capable of accommodating the difference in alignment of the screws. Preferably this should be achieved without intentional and/or accidental plastic deformation of the device. Both compromise fatigue

resistance and the former may be difficult to perform accurately. The technique employed to accommodate the difference in screw orientation must not exert undesirable forces on the device or vertebrae and the corrected alignment must be maintained when the components are fastened.

An important constraint is that the device should not rely on intact ligaments to achieve stability and that it should not loosen *in-situ* such that loss-of-correction results. In addition, loading on the implant should be equally shared between the pair of implants as otherwise excessive loads may exist at the screw/bone interface.

5.1.2 Surgical Constraints

Installation of the implant and reduction of the fracture must be achieved without complication or difficulty. This will reduce risks due to incorrect installation, the degree of expertise required to perform the procedure and the time required for implantation. The last factor minimizes possible complications such as excessive blood loss.

The device must be capable of obtaining adequate reduction of the fracture, restoration of the vertebral height and decompression of the spinal cord. Lordosis and distraction must be controlled while reducing the fracture. This must be accomplished without danger of overcorrection which can lead to neurological complications. The device must also maintain the operative correction.

Installation of the implant must minimize damage to adjacent structures. In particular, the risk of neurological damage must be minimal. Components that are introduced into the spinal canal and may impinge on the spinal cord such as sublaminar hooks or sublaminar wires should be avoided if possible. Damage to the adjacent tissues should be minimized to reduce the recovery period. In addition, the implant must not risk damage to the major vessels anterior to the vertebral body. Minimizing the number of vertebral levels fused will maximize the flexibility retained by the patient after fusion and treatment of the fracture should entail the minimum number of surgical procedures. Damage to the adjacent facet joints resulting from temporary immobilization or from interference with either an excessively large screw/rod junction or an excessively long fixation plate, must be avoided.

The implant must allow adequate access to and surface area on the posterior vertebral surfaces for such procedures as application of the bone graft and transpedicular grafting. The implant must also be capable of providing asymmetric stabilization if either one implant is used or devices spanning different lengths are used in the same patient. In addition, it should be possible to remove the device in case of infection or when fusion is complete.

The device should provide the optimal environment for a successful fusion. Unfortunately, what this entails is uncertain, however, rigidity of the device is recognized to be important. The device must be rigid to limit motion at the fracture site. Mechanical testing of excised spines that have been fixated with implants of different degrees of rigidity has shown that increasing the rigidity of the implant results in stronger fusions (Johnston et al., 1990; McAfee et al., 1991b). However, rigid fixation has been shown to cause stress-shielding, evidenced by an increase in porosity, in the fused vertebrae (Goel et al., 1991; McAfee et al., 1989, 1991b; Smith et al., 1988, 1991), though, the clinical implications of this finding have not been discussed by these researchers. High stresses at the screw/bone interface resulting from a rigid implant may be a cause of bone resorption at the interface which in turn can lead to migration of the screw and loss-of-correction. Factors underlying this phenomena are unknown.

Additional constraints include that the device must be psychologically acceptable to the patient. An external fixation device or one that is excessively prominent can be unacceptable to some patients (Dick, 1989) and can irritate the overlying tissues (Georgis et al., 1989; Pinto, 1992). Sensitivity to the metal is a concern in a small percentage of cases (Edwards and Levine, 1989).

5.1.3 Anatomical Constraints

The design of a number of aspects of the device is constrained by the spinal and vertebral morphology. The device must adapt to a range of vertebral levels and accommodate normal variation among patients. Several constraints including restrictions on the overall length and height of the device can not be determined as data for such analysis are not available. The length of the device depends on the distance between the

pedicles of the vertebrae being instrumented. This distance varies with the vertebral level. Lateral radiographs of the spine can be used to determine this distance. The overall height of the device must be restricted so the device is not apparent externally. There are no published reports of the criteria used for determining this dimension in existing devices. The overall size of the screw/rod junction is constrained by both the distance between the screw entrance location and the spinous process as well as the space between the screw insertion point and the facet joints. If the device is wider than the first dimension, removal of the spinous process would be required. In addition, if its width exceeds the distance between the screw insertion point and the facet joint, interference with the joint can result that may lead to osteoarthritic changes (Georgis et al., 1989; Kahanovitz et al., 1984a,b).

The constraints on dimensions of other components can be analyzed from published data on spinal and vertebral morphology. In particular, restrictions on the pedicle screw diameter and length and on the range of angulation required to accommodate for differences in the screw orientations were determined by summarizing and analyzing information from the literature on vertebral morphology (Appendix D). The means and standard deviations calculated from these data are referred to as the combined means and combined standard deviations. The fraction of the population that could accommodate various screw sizes was estimated from these statistics (Appendix D). Data from Appendix D are applied below to determine constraints on several device dimensions.

5.1.3.1 Screw Diameter

The embedded diameter of the pedicle screw, i.e. diameter within the vertebra, is restricted by the size of the pedicle. Insertion must not cause injury to the spinal cord or nerve roots. Minimum pedicle and endosteal diameters, therefore, are essential to defining screw diameter.

Though a number of studies have provided data on the pedicle dimensions only two authors have proposed criteria to determine the maximum screw diameter from these results. Banta et al. (1989) suggested the maximal cancellous diameter (endosteal

diameter) of the pedicle determines the maximum diameter of pedicle screw that can be introduced without damage to the pedicle. Though they measured the endosteal diameter of sixteen spines by 'graduated sounding', they provided no experimental evidence to support their proposed criteria.

Misenhimer et al. (1989) also proposed criteria for determining the maximum pedicle screw diameter suggesting that the screw diameter should not exceed either the endosteal diameter or 80% of the pedicle's cortical diameter. They reported mean endosteal diameter measurements ranging from 50.9% to 76.5% of the minimum pedicle diameter for the thoracolumbar spine (Table E.2, Appendix E). These researchers based their criteria on tests in which screws of increasing diameter were inserted into the pedicle to determine the screw diameter that caused deformation of the pedicle. They found that plastic expansion of the pedicle occurred before either the pedicle fractured or the screw cut through the pedicle's cortex. However, whether or not fracture of the pedicle is an important complication has not been established. Krag et al. (1986) suggested that disruption of the pedicle cortex as a result of screw insertion may not cause neurological complications. Saillant (1976) reported that in 56 cases 10% of the 375 screws were not within the pedicle, yet in only two cases did radicular involvement result. Both of these cases recovered completely without removal of the screws. However, Misenhimer et al. (1989) found that 28% of the pedicle fractures and 42.8% of the cases of the screw cutting through the cortex occurred on the pedicle's medial side and suggested these conditions may present a danger of neurological complication. Gertzbein and Robbins (1990) reviewed 40 cases treated with the Internal Fixator and found that approximately 25% had up to 8 mm of encroachment into the epidural space. They postulated that up to 4 mm of canal encroachment could be tolerated without impinging on the spinal cord.

The criterion that the screw should not exceed the endosteal diameter was applied to published morphology data to estimate the minimum pedicle screw diameter. Banta et al. (1989) reported the mean endosteal diameter for each level in the thoracolumbar spine with the smallest occurring at T8 (4.89 ± 0.85 mm). This suggests a 4.0 mm diameter screw is acceptable in 84% of the population for use in the thoracolumbar

region, while a 3.0 mm screw is accommodated by 98% of the population. The data of Moran et al. (1989) suggests a larger diameter is possible. The data of Misenhimer et al. (1989) shows that a smaller maximum diameter (2.5 mm) would be necessary at T8. However, their data do not include the standard deviation, thus, it is not possible to estimate the populations for which various screw sizes would be appropriate.

The criteria can also be used to determine the maximum screw diameter. Data from Banta et al. (1989) show a maximum endosteal diameter of 5.85 ± 0.85 mm at L5. This suggests that a 5.0 mm screw would be acceptable in 84% of the population and a 4.0 mm screw in 98%. Misenhimer et al. (1989), however, reported mean maximum endosteal diameters up to 9.6 mm, implying that a 9.5 mm screw could be accommodated by 50% of the population. The findings of these two groups of researchers differ greatly for the low lumbar region. As VSP screws are available in diameters up to 7.0 mm this suggests that the estimates based on the results of Banta et al. (1989) are conservative. In keeping with this Olsewski et al. (1990) suggests larger screws than previously reported can be safely used in lumbar vertebrae.

Use of the criterion that the screw diameter must not exceed 80% of the pedicle's cortical diameter was also used to estimate screw sizes. This suggests that a 10.5 mm screw would be acceptable in 50% of L5 vertebrae, while an 8.5 mm screw would fit in 84% of the population and a 6.5 mm screw would fit in 98%.

This analysis suggests a larger range of screw diameters can be accommodated by the pedicle (4.0 mm to 8.0 mm) than are provided by currently available fixation systems. The pedicle screws in most systems are available in diameters from 5.0 mm to 7.0 mm. The Internal Fixator and the Puno/Winter/Byrd systems both use screws of only one diameter (5.0 mm and 6.5 mm, respectively) and the Roy-Camille system uses much smaller screws (4.0 mm and 4.5 mm).

To aid in choosing the screw diameter that will maximize purchase strength yet minimize risk of pedicle expansion and/or fracture, CT scans should be used to determine pedicle dimensions rather than lateral or A-P radiographs. CT scans have been shown to be accurate when compared with direct measurements (Krag et al., 1988b; Misenhimer et al., 1989).

5.1.3.2 Screw Length

As penetration of the anterior cortex of the vertebral body risks damage to major blood vessels, the length of screw within the vertebra (embedded length) must not exceed the cortex-to-cortex distance through the pedicle. The range of embedded screw lengths required was determined from the means and standard deviations of this measurement.

Influence of the depth of screw insertion on the screw's purchase has been studied by Krag et al. (1988a) and Zindrick et al. (1986). Strength of purchase was shown to increase with both increasing depth of insertion and contacting the anterior cortex (Krag et al., 1988a). However, shorter insertion depths have been recommended by other authors. Roy-Camille et al. (1986a) suggested that longer insertion depths did not increase the pull-out strength, while Whitecloud et al. (1989b) reported that only with insertion to 50% of the vertebral body could the surgeon be assured that penetration of the anterior cortex would not occur. Therefore, a range of screw lengths is required to accommodate both the inter-patient variability and the preference of the surgeon.

Insertion of screws along the pedicle axis results in a longer embedded length at most levels than if the screw is inserted parallel to the midline. This increases its resistance to pull-out. Angling the screw also increases the constructs' rigidity (Carson et al., 1990; Ruland et al., 1991).

The greatest mean cortex-to-cortex distance (measured along the pedicle axis, Figure 2.7) was 48.8±3.82 mm (L3) implying that embedded lengths of 52.5 mm and 56.5 mm would be the longest screw required by 84% and 98% of the population, respectively. The shortest mean cortex-to-cortex distance (measured parallel to the vertebral midline, Figure 2.7) in the thoracolumbar region was 34.4±5.76 mm (L5). If the shortest length screw available is 50% of this distance, screw lengths of 17.0 mm, 14.0 mm and 11.5 mm can be accommodated by 50%, 84% and 98% of the population, respectively.

Use of CT scans and lateral radiographs can be used to determine the required screw length; however, the latter has been shown to lead to erroneous estimates of the required screw length (Krag et al., 1989a; Whitecloud et al., 1989b). Currently available spinal fixation systems have screws with embedded lengths ranging from

approximately 25 mm to 50 mm, though the Schanz screw used in the Internal Fixator, is only available in one length (35 mm). The present study suggests a range of screw lengths from approximately 12 mm to 55 mm would be preferable. This broad range of screw lengths is presently only available in the VSP system (16 mm to 50 mm).

5.1.3.3 Required Range of Screw Angulation

To achieve maximum purchase, the pedicle screw must follow the axis of the pedicle (Krag et al., 1986) as this permits insertion of the largest diameter of screw without damage to the pedicle. Because the pedicle axis angle varies with vertebral level, a difference in the screw orientation is required between the superior and inferior instrumented vertebrae. This difference in screw angulation, which can be calculated from the transverse and sagittal pedicle angles, must be accommodated by the fixation device. Calculations were performed for fixation of three and four levels of the thoracolumbar spine (Appendix D).

The required angulation to accommodate differences between pedicle screw alignment was determined by combining the required angulation in the sagittal and transverse planes. Instrumentation of both three and four levels showed that the greatest angulation was required for fixation of the lower lumbar vertebrae. For fixation of three levels angulation of 35.1°, 53.2° and 71.6° will accommodate 50%, 84% and 98% of the population, respectively. Angulation of 40.2°, 59.1° and 78.1° will accommodate 50%, 84% and 98% of the population, respectively, for fixation of four levels.

Many currently available fixation systems have very limited ability to accommodate variation in pedicle screw alignment. For example, the VSP system can only accommodate variations in screw alignment by placing an angled washer between the screw and plate and/or by bending the plate. Unfortunately, the latter technique is only useful in the sagittal plane whereas the former is only available in one angle (15°) thus limiting its adaptability. Systems such as the Internal Fixator and Vermont Spinal Fixator permit unrestricted alignment between a pair of pedicle screws.

Chapter 6: Prototype Device Description

Based on the design constraints described in Chapter 5 a prototype posterior device was developed. A description and discussion of the device and its installation procedure are described below together with recommendations for further development.

6.1 Device Description

As shown in a cross-sectional view of the assembled device (Figure 6.1) the prototype spinal fixation device is composed of seven components: two pedicle screws, the rod, two conical sleeves and two locking nuts. The screw/rod junction has a spherical contact surface that allows the screw to pivot within the junction. The screw can be aligned at any angle within 20° from the vertical (Figure 6.2), the angle of the conical hole in the upper surface of the rod. The pedicle screw is locked into position by first sliding a conical sleeve over the screw, rotating it until it fits snugly in the conical hole and then tightening it into position with the locking nut. Conical sleeves with an offset central hole are used to accommodate angled screws (Figure 6.3). The design of various components of the device is described in detail below.

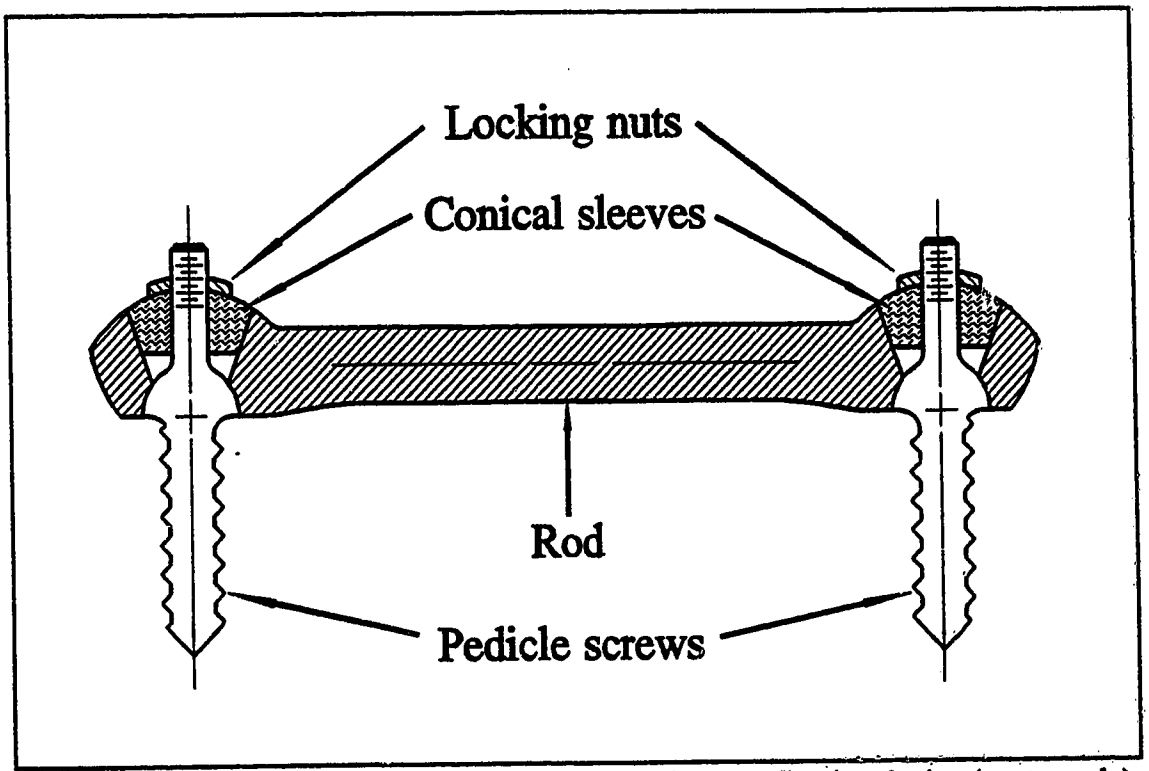

Figure 6.1: Cross-sectional view of the prototype fracture fixation device (not to scale).

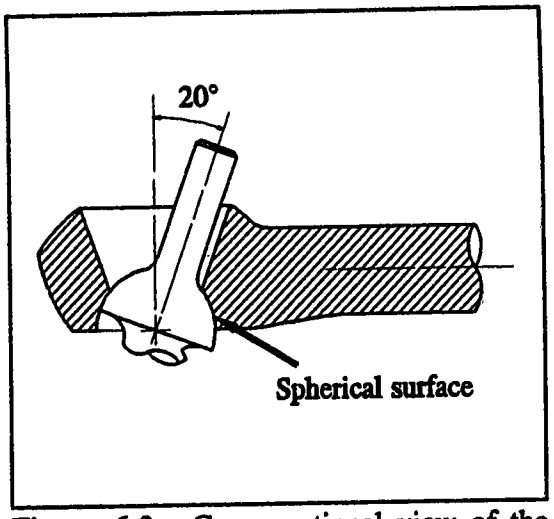

Figure 6.2: Cross-sectional view of the rod/screw junction showing angulation of the screw within the conical hole (not to scale).

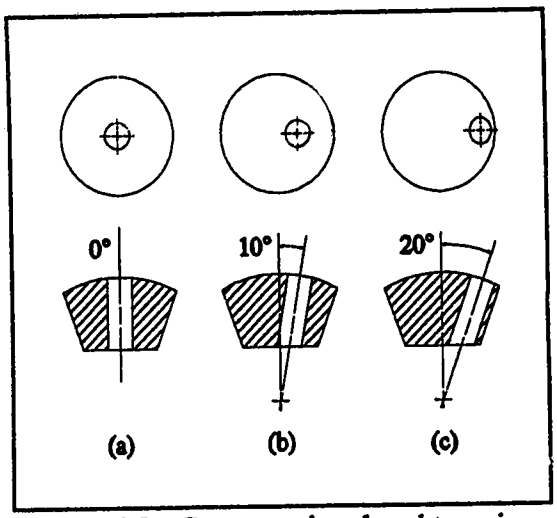

Figure 6.3: Cross-sectional and top views of conical sleeves with offset central holes at (a) 0°, (b) 10° and (c) 20° (not to scale).

6.1.1 Material Selection

Three basic types of metals; stainless steel, cobalt-base alloys and titanium-base alloys are commonly used for orthopaedic implant applications. Cobalt and titanium alloys are more biocompatible than stainless steel and have good mechanical properties, however, these materials are expensive. Cobalt alloys work-harden rapidly making machining difficult. Titanium alloys have good mechanical properties, but can be difficult to machine and have low shear strengths. Therefore, for development of the prototype device 316L stainless steel was chosen as it combines good mechanical properties, machinability, and relatively low cost. It is a low carbon ($<0.03\%$) and high chromium (16.00%-18.00%) stainless steel. The high chromium content results in an oxide layer that serves to restrict further corrosion. As the fixation device may be removed after fusion has occurred, superior corrosion resistance may not be justified. The applicable ASTM standard for this material is F138-86, 'Standard for Stainless Steel Bar and Wire for Surgical Implant Application'. This stainless steel is used in the manufacture of most spinal fixation systems presently available (for example, VSP, Cotrel-Dubosset).

Newer alloys such as MP-35-N, a cobalt-nickel-chromium-molybdenum alloy, or $Ti_5Al_2{\cdot}5Fe$, a titanium alloy, might well be considered for the device. The former

combines good corrosion resistance and excellent mechanical properties with better ductility than earlier cobalt alloys. Newer titanium alloys have very good corrosion resistance and mechanical properties and do not create artifacts on CT scans.

The final choice of material would be made when the design is complete and the mode of manufacture is determined. All components of the device must be made from the same material to prevent galvanic corrosion. Components should be electropolished and chemically passivated to help reduce corrosion. Nitrogen ion implantation, as described by Liu et al. (1990), may be considered to increase the fatigue life of the components.

6.1.2 Design of the Pedicle Screw

To assist in determination of the appropriate screw design a review of the performance of currently available pedicle screws was conducted (Appendix C). This includes a review of *in-vitro* tests on purchase and mechanical strength and on the clinical performance of the various screw designs.

The proposed pedicle screw has three functional regions (Figure 6.4) including the portion embedded within the vertebra, the spherical surface that contacts the rod and the cylindrical shaft that is threaded (10-24) over a portion of its length to accommodate the tightening nut. The prototype pedicle screw was designed to be made on a numerically controlled (CNC) lathe. Between the spherical contact surface and the embedded screw thread the radius is 2.95 mm. This provides a smooth transition from the embedded threads to the spherical contact surface without creating a stress concentration. The greater diameter also improves the resistance of this region to fatigue failure. The spherical surface has a 6.1 mm radius. The radius of the junction between the spherical surface and

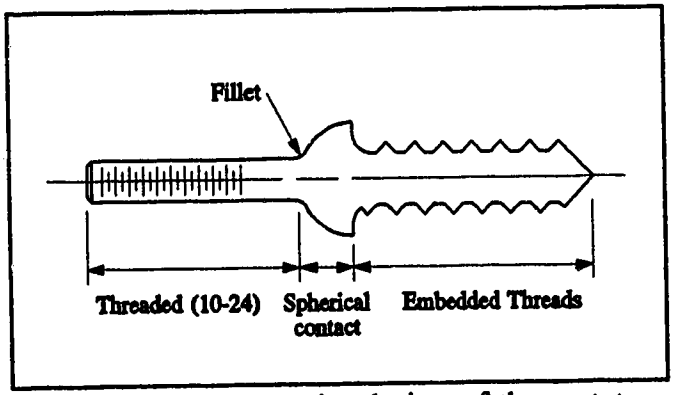

Figure 6.4: Cross sectional view of the prototype pedicle screw showing the three functional regions (not to scale).

the cylindrical shaft is 1.50 mm (Figure 6.4).

The thread design used for the prototype screws is a deep buttress profile thread similar to that used for the VSP screws. Krag et al. (1986) recommended the buttress profile suggesting it may be easier to install. As *in-vitro* tests have not shown statistical differences between threads of different pitch, that of the VSP screw was adopted. The final design of the screw thread should be based on further research including fatigue and purchase strength tests.

To accommodate inter-patient variability screws of a range of diameters and lengths will be required. Estimation of the anticipated range was described in Sections 5.1.3.1 and 5.1.3.2 based on the range in vertebral morphology. This has shown that the major diameter should range from 4.0 mm to 8.0 mm in increments of 1.0 mm. However, resistance to fatigue failure of the screws at the minimum of this range may be limited. The embedded lengths should range from 15 mm to 55 mm in increments of 10.0 mm.

6.1.3 Rod Design

The rod of the prototype device combines the rod and the screw/rod junction into a single unit. This increases the mechanical integrity of the device and reduces the number of components. The rod has been designed to be made on a CNC machine to reduce production costs and to ensure the precision of the product. Design of the central bar and of the screw/rod junction are discussed separately below.

6.1.3.1 Central Bar Design

The overall length of the device and of the bar is determined by the distance between the superior and inferior pedicle screws. As this distance varies, a range of lengths must be available. As indicated in Section 5.1.3 a study of the anticipated screw entrance points from lateral radiographs could be used to obtain an indication of the range of bar lengths required. The increment length of the bars has not been established and will determine the number of bars available within this range. However, a balance must be made between the number of rods required to adequately satisfy the

physiological variations and stock capabilities of hospitals.

In order for the device to accommodate a greater difference in pedicle screw orientation, rods with a central bend in the sagittal plane might also be made available. This would help to accommodate curvature of the spine, especially for fixation of the low lumbar vertebrae where the lordotic curve is greatest. If such rods were available the range of angulation required in the screw/rod junction would be reduced.

An alternative to supplying the range of devices required to accommodate the inter-patient variability, is for the device to be custom-made for the patient. This would result in a device with length and stiffness appropriate for the patient. Such a custom-made device is possible as the geometry of the bar is independent of the screw/rod junction. Thus, the bar length and diameter (9.5 mm in the prototype bar) can be varied without influencing other components of the prototype device. Modification of the central bar diameter would allow manufacture of a device with the appropriate stability for the patient to accommodate differences in fracture stability and patient build. If small diameter pedicle screws were required a smaller diameter bar could be used that would decrease the load on the screws and thus, their risk of fatigue failure. At present no spinal fracture fixation system is available in varying degrees of rigidity. Custom production of the device would require machining facilities either within the hospital or at a central facility.

The prototype device has been developed for fixation of fractures that would require fusion of either three or four levels. If this proves satisfactory, it may be applicable in short length fusions where only two levels are instrumented. This would require shorter rods and determination of the expected range of lengths for two-level fixations.

6.1.3.2 Screw/Rod Junction

In the prototype device the pedicle screw and the rod make contact on a spherical surface (Figure 6.2). This allows angulation of the screw within the range permitted by the conical hole, presently limited to 20°. As the same degree of angulation is available for both the inferior and superior pedicle screws, the total difference in screw orientation

available between the pedicle screws is 40°. As indicated above the angulation in the sagittal plane may be increased by the use of prebent rods.

6.1.4 Conical Sleeve Design

The conical sleeve has an external conical shape combined with a central cylindrical hole. This hole can be aligned with the central axis of the cone or offset at any of a range of angles up to the outer angle of the cone. This offset allows for differences in alignment between the fixed pedicle screws. At present the cones are available with offsets in increments of 10° though this dimension is not finalized. Maintaining a stock of sleeves with smaller increments of offset would not be expensive Due to the conical external shape a cone with an angular offset can accommodate this angular offset throughout 360°. The upper surface of the conical sleeve is spherical whose origin is the same as the spherical contact surface between the pedicle screw and the rod. This ensures that the tightening nut, with its spherical undersurface, will make solid contact with the upper surface of the conical sleeve independently of the angle of the screw. Due to friction between the conical surfaces, a single tightening nut is adequate to keep the components firmly together. Clearance between the cylindrical hole and the shaft of the pedicle screw must be minimal in order to limit bending of the screw.

6.2 Procedure for Surgical Implantation

Although details of the procedure used for surgical implantation of the device are dependent on the final design, consideration of the installation procedure must accompany design of the system. The surgical approach would be similar to that used with the posterior fixation devices presently available and was developed in consultation with orthopaedic surgeons. The screw entrance point, either that described by Roy-Camille et al. (1986a) or the more lateral location described by Weinstein et al. (1988), will depend on the surgeon's preference. Drilling and tapping of the pedicles of the adjacent vertebrae would then be performed possibly with the use of an image intensifier. The optimal screw diameter and length would be predicted from radiographs and CT scans.

The four pedicle screws would then be inserted. The screws would be inserted until the bottom of the spherical surface is flush with the surrounding bone. With the four pedicle screws installed a reduction frame would be attached to the screws and used to manipulate the screws and reduce the fracture through kyphosis correction and distraction. A suitable reduction frame has yet to be developed. With the vertebrae held in the reduced position by such a frame, the two pedicle screws on one side of the spinous processes would be released for attachment of the rod. As the other two pedicle screws are firmly held by the reduction frame, no loss of fracture reduction should occur. A rod of appropriate length is then selected and laid over the distal ends of the pedicle screws. If there is excessive angulation between the two pedicle screws (>40°) a prebent rod would be used to compensate for the angulation. With the rod in place over the pedicle screws, conical sleeves having the appropriate offsets are chosen to accommodate the angulation of the pedicle screws within the conical hole in the rod. The sleeves are placed over the protruding ends of the pedicle screws into the conical holes on the upper surface of the rod. The locking nuts are then applied and tightened. The other rod is then attached to the remaining two pedicle screws in the same manner. Once the second rod is in place and secured the closure can be completed as for other posterior fixation devices. Removal of the device should be easily achieved if necessary in cases of infection or when fusion is complete.

6.3 Discussion

The design constraints were reviewed to assess the capability of the device in fulfilling the objectives. This showed several advantages to the prototype device over existing systems. The screw/rod junction can accommodate differences in the pedicle screw alignment within a physiological range. This eliminates the need for plastic deformation of the rod during installation and simplifies the surgical procedure. This feature will also ensure that the device accommodates different pathologic and traumatic conditions and variability in spinal morphology. It will also reduce the possibility of accidental deformation and fatigue failure of the screws. The screw/rod junction enables the device to be secured without applying undesirable forces to the vertebrae and without

adversely altering the vertebral alignment. The design of the junction should minimize the possibility of loosening *in-situ*. This will assist in maintenance of the operative correction. The small size of the screw/rod junction reduces the possibility of interference with adjacent facet joints and ensures that the device is not excessively prominent.

An important feature of the prototype device is that the diameter of the central rod is independent of the screw/rod junction. This feature provides the capacity to custom make the device so as to supply the patient with the appropriate level of stability. Ensuring that there is adequate stability to limit motion at the fracture site should assist in minimizing loss-of-correction, incidence of pseudoarthrosis, fatigue failure of the device and number of vertebrae fused. The latter enables retention of spinal flexibility. The ability to vary the configuration of the central bar without changing the screw/rod junction makes the device adaptable to different pathologic and traumatic conditions. As well, it would serve to allow changes dictated by subsequent research on fracture fixation and vertebral morphology.

The prototype device incorporates several features that reduce the possibility of fatigue failure. These include providing the appropriate level of stability for the patient and limiting the number and severity of stress concentrations in the pedicle screw. In addition, the components of the device have all been designed for production by a numerically controlled machine to ensure consistently high quality.

As the fixation device has a limited number of components there should be little possibility of incorrect installation, unnecessary damage to adjacent tissue and time required for installation. Use of the proposed reduction frame will ensure that reduction, restoration of vertebral body height and decompression of the spinal cord can be safely achieved. As direct contact between the rod and posterior surfaces of the vertebrae is not required, the posterior surfaces are available for application of a bone graft. Asymmetric stabilization using the proposed device should be possible. The device should also be easily removed.

At present the prototype device has two possible limitations. Installation of an additional screw placed into the fractured vertebra can not be accommodated by the

prototype. Secondly, if there is an excessive difference between the orientation in the pair of pedicle screws to be fixed, it may be difficult to position the rod over the distal ends of the pedicle screws. After the final length of the distal shaft of the pedicle screw has been determined, the probability of this occurrence can be assessed. The length of the distal shaft is dependent, in part, on the design of the reduction frame (Section 6.4.2).

Further development of the prototype device is warranted. Recommendations regarding the design of additional components of the system and for mechanical and *in-vitro* testing are described in Sections 6.4 and 6.5.

6.4 Recommendations for Further Device Development

The dimensions of several components of the fixation device are not finalized. These include: the range and increment in length of the rods; the increment of offset of the central hole in the conical sleeves; the radius of the external spherical surface of the screw/rod junction; and the radius of the fillet in the pedicle screw between the shaft and spherical surface. With computer controlled manufacturing changes in the length and offset increments and ranges will not pose difficulties. Some components of the system, detailed below, have yet to be designed.

6.4.1 Crosslink Design

Crosslinking the vertical rods of the fixation devices has been shown to substantially increase the rigidity of the construct (Carson et al., 1990) and its resistance to screw pull-out (Kling et al., 1986; Ruland et al., 1991). A crosslink for the prototype has not been developed, though such an accessory would likely be advantageous for treatment of severely unstable fractures. Use of a crosslink may require removal of a portion of the spinous process, however, no adverse effects are expected with this procedure.

6.4.2 Reduction Frame

A system for reduction of the fracture is required. One possibility is a frame that

attaches to the implanted pedicle screws and applies distraction and rotation forces via the screws. The latter force reduces the kyphotic deformity. Once the fracture is reduced, the frame would be removed from one pair of pedicle screws and a fixation device applied over the screws. The conical sleeves would then be fitted and the device secured. The reduction frame would be then removed from the remaining pair of pedicle screws and a device attached to the screws. The outrigger system used with the Harrington Spinal Instrumentation (Zimmer, Inc.) is an example of a similar system presently in use.

6.4.3 Incorporation of Additional Screws

An additional screw inserted into the fractured vertebra can serve to provide additional stability and reduce translational displacements. A means to secure such a screw to the central bar is required.

6.4.4 Surgical Instruments

Design of specialized surgical instruments required for implantation of the device has been considered but not undertaken. Development of such instruments should be performed once experience has been gained with *in-vitro* implantation of the device.

6.5 Recommendations for Testing of the Prototype Device

Further development of the prototype posterior fixation device must include mechanical and *in-vitro* testing. Fatigue testing of the pedicle screw should be performed. Static and cyclic testing of the assembled device must be undertaken to determine the rigidity of the prototype and to ensure that loosening of the screw/rod junction will not occur *in-situ*. These tests should be performed with the device both independent of, and mounted on, a spinal segment. In addition, *in-vitro* testing of an asymmetrically mounted device(s) on a spinal segment should be performed to ensure that use of a single device or of two devices of different lengths is viable.

Chapter 7: Prototype Analysis

To assist in analyzing the performance of the prototype, finite element modelling was conducted on components of the device. This analysis was intended to ensure the structural integrity of the device and to determine the influence of various dimension changes on the stress distribution. Analysis was restricted to the pedicle screw and conical sleeves as the rod was considered more robust when compared with similar components of existing fixation devices which do not experience failure *in-vivo*. The finite element software ANSYS, version 4.4, (Swanson Analysis Systems, Inc.) was used for modelling components of the prototype fixation device.

7.1 Estimated Physiological Loads Used in the Analysis

Load levels to be used in the analysis were determined from estimates of physiological loads (Section 3.4) and from a review of published *in-vitro* and finite element studies. The maximum loads used for *in-vitro* testing of pedicle screw fixation systems in spinal segments differs greatly between published studies. Gurr et al. (1988a) used a maximum axial compressive load of 200 N whereas in their later study a maximum value of 500 N was used (Gurr et al., 1988b). Maximum applied flexion/extension bending moments range from 3.0 Nm (Goel et al., 1988b) to 31.2 Nm (Puno et al., 1991). The maximum applied lateral bending moments have ranged from 2.7 Nm (Gaines et al., 1991) to 31.2 Nm (Puno et al., 1991) whereas the maximum axial rotation used for in-vitro tests have ranged from 1.0 Nm (Gaines et al., 1991) to 12 Nm (Abumi et al., 1989). However, Edwards (1991) recommends the use of higher values, a static torsional load (20 Nm) and flexion/extension moment (40 Nm), for *in-vitro* testing.

Load levels previously used for finite element analysis of spinal instrumentation were also reviewed. Goel et al. (1988a, 1991) modelled two motion segments with and without pedicle screw instrumentation (VSP system). For analysis of the destabilized spine an axial compressive load of 405 N, a sagittal bending moment of 10 Nm or the combination of sagittal bending (10 Nm) with an axial preload (405 N) were used. These levels were based on the anticipated reduced activity of the injured patient. Mann and

Bartel (1990) investigated the influence of screw length and diameter and quality of the cancellous bone in the vertebral body on purchase strength of an implanted pedicle screw. A load of 500 N and a moment of 18.5 Nm were applied to the end of the screw. The former was based on half of the body weight divided equally between two pedicle screws and the moment was calculated for the 500 N load acting through the centrum of the vertebra.

For the purposes of finite element modelling of the prototype device a 900 N compressive load was assumed to act through the centre of the vertebral body. This load is based upon the reduced level of activity expected in injured patients (Table 3.1) and the facet joints not carrying a load. Assuming that the fractured vertebral body can not provide support the compressive load results in a 450 N shear load and a 8.0 Nm bending moment (at the screw entrance point on the posterior bone surface) in each screw. This assumes the compressive spinal load is shared equally by the two pedicle screws and acts at the centre of the vertebra such that there is a moment arm of approximately 17.7 mm to the posterior bone surface measured along the pedicle axis.

7.2 Analysis Of the Pedicle Screw

Finite element modelling of the pedicle screw analyzed the influence of fillet radius at the screw shaft/spherical surface junction (Figure 6.4) and angulation of the pedicle screw within the screw/rod junction (Figure 6.2) on the stress distribution. The influence on the stress distribution of the portion of the spherical surface of the screw in contact with the matching surface of the rod was also investigated. A further variable analyzed was the 'proximal screw/sleeve contact location' which is defined as the position of the innermost contact between the spherical surface of the pedicle screw and the bottom of the conical sleeve (Figure 7.1). Changing the location of the proximal screw/sleeve contact is equivalent to varying the length of the conical sleeve, affecting the stress due to bending.

7.2.1 Methods

Three configurations of the pedicle screw within the screw/rod junction were

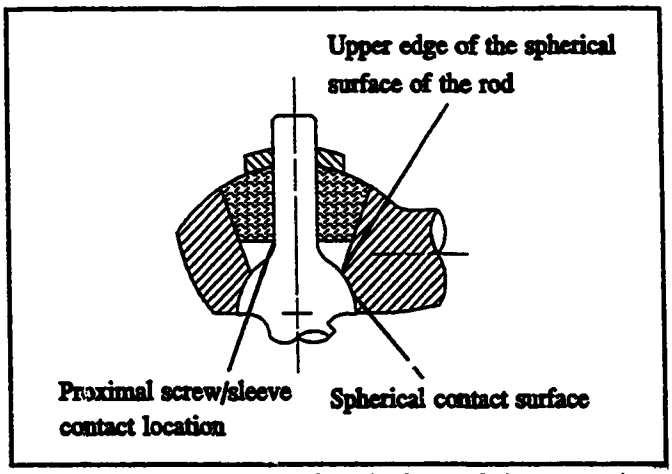

Figure 7.1: Cross-sectional view of the screw/rod junction.

considered in the analysis. Figure 7.2 shows these positions, straight, symmetrically offset and asymmetrically offset, in cross-sectional and top views. Changes to the fillet radius at the screw shaft/spherical surface junction, angulation of the pedicle screw within the screw/rod junction and the area of the spherical surface of the screw in contact with the matching surface of the rod were analyzed. The influences of these factors are interrelated as the region on the spherical surface constrained by contact with the rod is dependent on both the pedicle screw angulation accommodated by the screw/rod junction and on the fillet radius. Increasing the range of pedicle screw angulation accommodated by the junction reduces the contact area on the spherical surface (Figure 7.3). For example, if the pedicle screw can be offset up to 15° the constrained region is limited to 0° to 45° (Figure 7.3a), whereas to accommodate a 20°

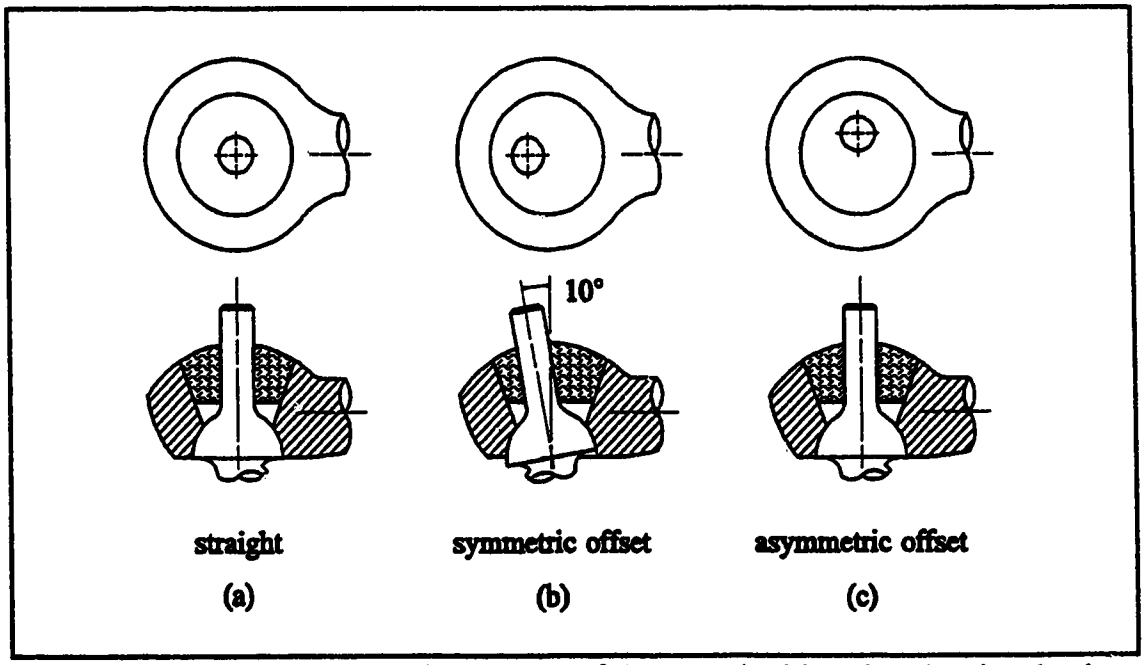

Figure 7.2: Top and cross sectional views of the screw/rod junction showing the three configurations analyzed. Locking nut is not shown for clarity.

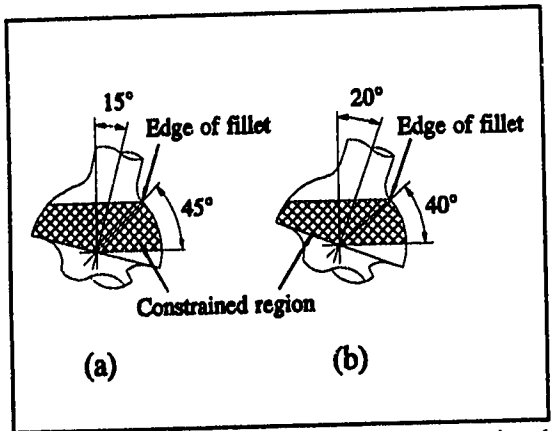

Figure 7.3: Variation of the constrained region of the spherical surface with accommodated pedicle screw angulation.

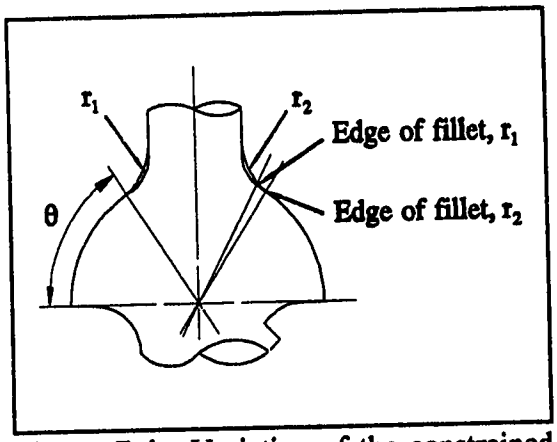

Figure 7.4: Variation of the constrained region of the spherical surface with the fillet radius.

offset, the region from 0° to 40° is constrained. Conversely, increasing the fillet radius reduces the angulation of the pedicle screw permitted by the screw/rod junction due to interference between the fillet and the shoulder of the spherical surface of the rod (Figure 7.4). As the angle between the shoulder of the spherical surface of the rod (θ, Figure 7.4) decreases the constrained region of the spherical surface decreases. Figure 7.5 shows the constrained regions for the three values of θ that were analyzed.

Isometric and cross-sectional views of the three dimensional, axially symmetric finite element mesh of the pedicle screw are shown in Figure 7.6 and 7.7, respectively. The model comprised approximately 3550 nodes and 3770 three-dimensional isoparametric solid elements. Though the model was axially symmetric, a three dimensional model was used to facilitate modelling of asymmetric screw angulation. The fillet between the shaft and spherical surface of the screw was modelled with a finer mesh (Figure 7.8). The origin of the system was along the centreline of the system at the centre of the spherical surface (Figures 7.7 and 7.9).

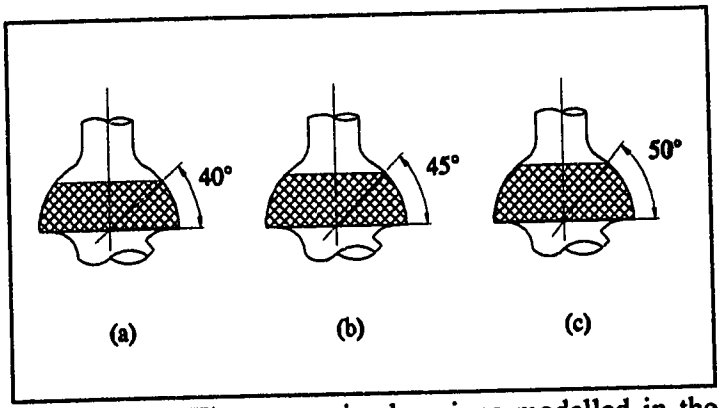

Figure 7.5: The constrained regions modelled in the finite element analysis (a) 0°-40° (b) 0°-45° and (c) 0°-50°.

Three loading

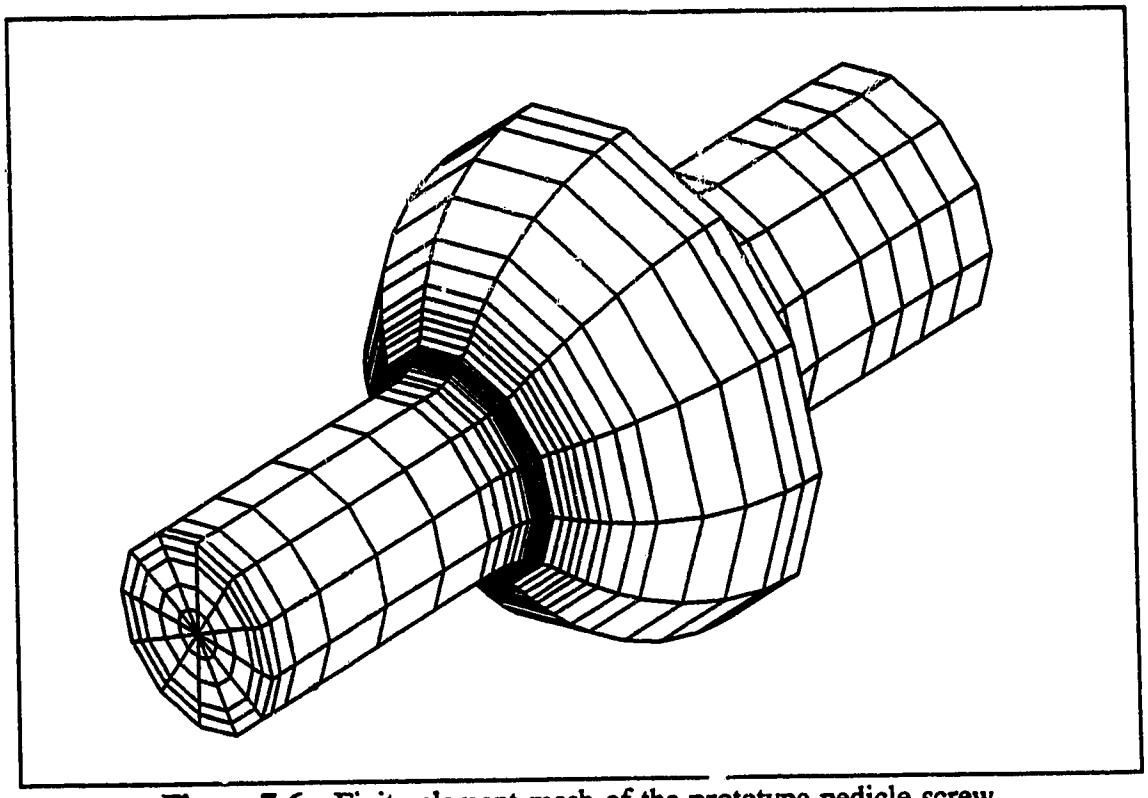

Figure 7.6: Finite element mesh of the prototype pedicle screw.

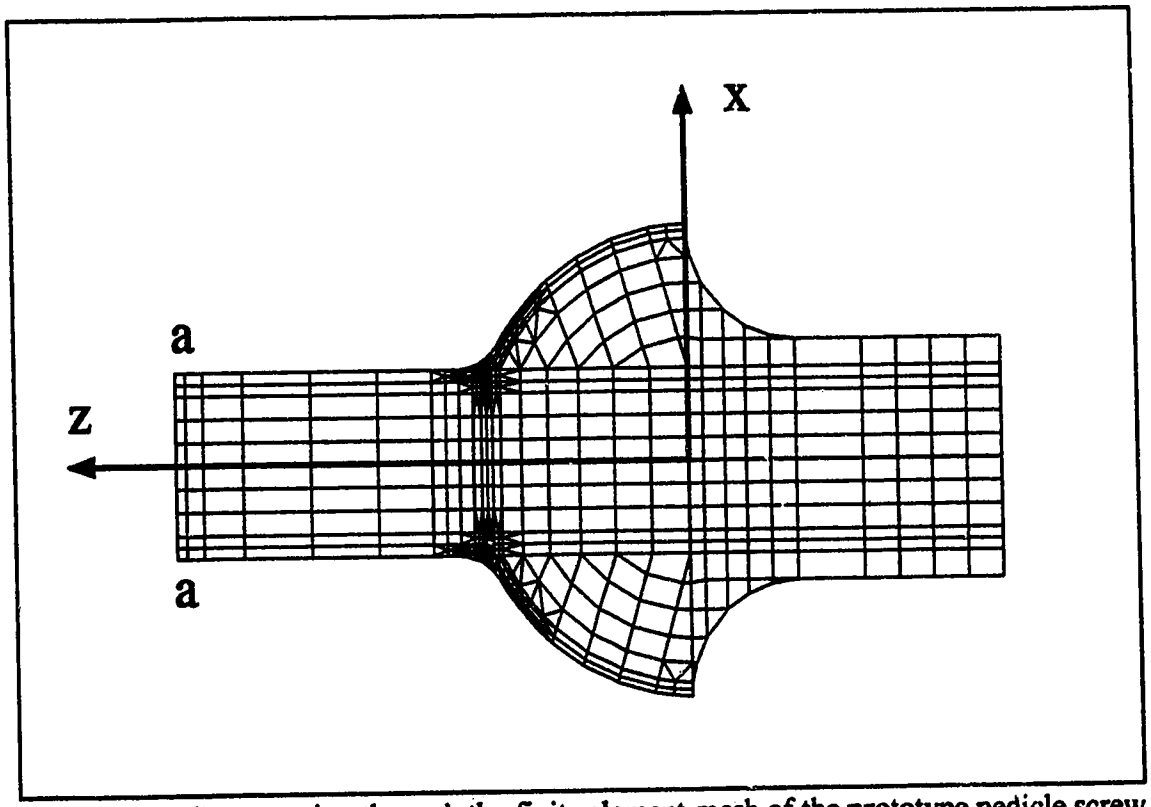

Figure 7.7: Cross section through the finite element mesh of the prototype pedicle screw along axis of symmetry.

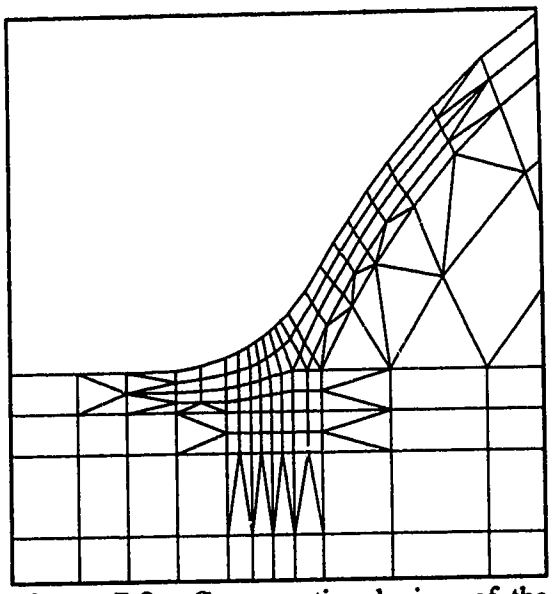

Figure 7.8: Cross-sectional view of the finite element mesh in the fillet region.

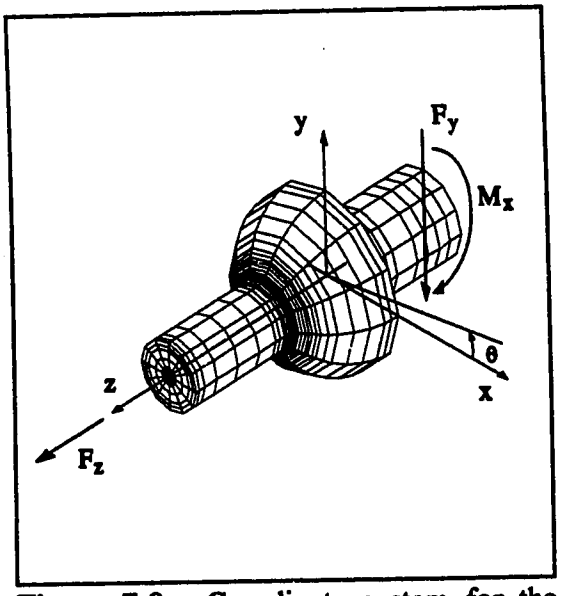

Figure 7.9: Coordinate system for the finite element mesh and applied loads.

configurations were analyzed. The initial configuration consisted of an axial tensile load on the screw shaft from tightening of the locking nut. This was modelled by a uniform displacement in the positive z direction at the distal end of the screw shaft (surface a-a, Figure 7.7). A nominal stress equivalent to the application of 3.0 Nm torque to the nut resulted. This is approximately equal to tightening the nut by hand and resulted in a nominal tensile stress of approximately 150 MPa ($+F_z$). The second configuration consisted of the tensile load combined with uniform bending moment of 8.0 Nm ($-M_x$). In the final configuration a shear force of 450 N ($-F_y$) and bending moment of 3.95 Nm ($-M_x$) were combined with the tensile load. A smaller bending moment was applied so that a similar bending moment (8.0 Nm) existed at z=0 mm. The shear force and bending moment were applied at z=-9.00 mm so that at z=0 mm edge effects would be negligible. Figure 7.9 shows the finite element mesh for the screw with the applied loads and coordinate system. The basis for the bending moment and shear loads was described in Section 7.1.

Nodes on the spherical surface of the pedicle screw in contact with the matching surface of the rod were constrained in the normal direction only. The region of the screw shaft in contact with the conical sleeve was constrained in the normal direction and at nodes along the plane of symmetry. For asymmetric cases the constraints on the plane

of symmetry were maintained to prevent rigid body motion. This represents a potential source of error as this is not a plane of symmetry and motion at these nodes may occur. Application of constraints only in the normal direction on contacting surfaces does not incorporate resistance in the tangential directions due to friction. However, this analysis should yield conservative results. In modelling cases under only axial tensile loads the normal constraints on the screw shaft were removed as tensile loading causes a reduction in the diameter of the screw shaft, such that contact between the shaft and conical sleeve does not occur. Pedicle screw angulation was modelled by application of constraints in the normal direction at contacting nodes on the spherical surface of the screw and on the portion of the screw shaft in contact with the conical sleeve. The 'constrained region' of the screw was defined by the angle on the spherical surface encompassed by the constraints for the straight screw case.

Constraint of nodes on contacting surfaces in the normal direction implies that separation of the surfaces is not possible. However, as this condition is not realistic an iteration process was performed whereby the constraints on nodes with tensile reaction forces, implying the surfaces should separate, were removed. This condition should be modelled with gap elements, however, preliminary study of these elements met with limited success. New gap elements in the updated version of the software may provide better results.

The stress distribution for three fillet radii (0.67 mm, 1.00 mm and 1.50 mm) were analyzed by changing the mesh within the fillet region. For analysis of the influence pedicle screw angulation on the stress distribution offset screws of 10° and 20° were modelled for cases under tensile loads (r=1.50 mm). For analyses in which bending loads were included only 10° of screw angulation was modelled (r=1.50 mm), though a limited number of cases were performed with a fillet radius of 0.67 mm and symmetric and asymmetric angulation of 13°.

Determination of the influence of screw/sleeve contact location on the stress distribution was conducted with models of a straight screw with a 1.50 mm fillet radius and a constrained region from 0° to 40° under combined tension and bending loads. Six proximal screw/sleeve contact locations were analyzed (6.6, 7.0, 7.4, 8.0, 8.4 and 8.95

mm). The six models were developed by removing the appropriate normal constraints on the screw shaft. The location of the distal surface of the sleeve was not changed.

7.2.2 Results

Results of finite element analysis of the pedicle screw for various screw positions, fillet radii and constrained regions of the spherical surface are presented in Tables 7.1, 7.2 and 7.3 for the loading configurations of axial tension, axial tension and bending and axial tension, bending and shear, respectively. A stress magnification factor, k, defined as the ratio of the maximum equivalent stress to the nominal equivalent stress for the straight screw of comparable geometry and loading, is also presented in these tables. Equivalent or von Mises stress is defined as:

$$\sigma_E = \frac{1}{\sqrt{2}}[(\sigma_1 - \sigma_2)^2 + (\sigma_2 - \sigma_3)^2 + (\sigma_3 - \sigma_1)^2]^{\frac{1}{2}} \qquad \text{(G.1)}$$

Results are grouped by the loading configuration except for the analysis of the influence of the unsupported length.

7.2.2.1 Axial Tension

The influence of fillet radius and range of constraint on the stress magnification factor for tensile loading is presented in Figure 7.10 and shows that with increasing radius there is a reduction in the stress magnification factor. Whereas, increasing the area of the spherical surface that is constrained caused an increase in the stress magnification factor.

Figure 7.10 also shows published stress concentration factors for a stepped round tension bar with a shoulder fillet (Figure 7.11) from Peterson (1974). Numerical and published results showed good agreement as values differed by less than six percent (Figure 7.10). As both fillet radius and constrained region increased the difference between the numerical and published results decreased.

The nominal equivalent stress, the equivalent stress in the distal end of the screw

Screw Position	Offset Angle (degrees)	Fillet Radius (mm)	Constrained Region of Spherical Surface	Nominal Stress † (MPa)	Maximum Stress (MPa)	k ‡	Location (z direction) (mm)
Straight	0	0.67	0° - 40°	140.8	247.5	1.757	6.1
			0° - 45°	148.7	262.5	1.766	6.1
			0° - 50°	154.6	274.5	1.776	6.1
		1.00	0° - 40°	141.5	223.8	1.582	6.2
			0° - 45°	149.5	237.7	1.590	6.2
			0° - 50°	155.4	248.8	1.601	6.2
		1.50	0° - 40°	142.7	205.1	1.437	6.4
			0° - 45°	150.8	218.0	1.446	6.4
			0° - 50°	156.8	228.4	1.456	6.4
Symmetric and Asymmetric	10	1.50	0° - 40°	142.7	214.7	1.504	6.4
			0° - 50°	156.8	241.1	1.537	6.4
	20		0° - 40°	142.7	230.2	1.614	6.4

‡ Stress magnification factor = Maximum equivalent stress / Nominal stress for straight screw of similar geometry under tensile loading.

† Nominal stress for straight screw of comparable geometry under axial tension loading.

Table 7.1: Results for straight and angled pedicle screw models under axial tension.

Screw Position	Offset Angle (degrees)	Fillet Radius (mm)	Constrained Region of Spherical Surface	Nominal Stress † (MPa)	Maximum Stress (MPa)	k ‡	Location (z direction) (mm)
Straight	0	0.67	0° - 40°	140.8	555.3	3.943	5.92
			0° - 45°	148.7	569.2	3.828	5.92
			0° - 50°	154.6	579.6	3.750	5.92
		1.50	0° - 40°	142.7	452.5	3.172	6.4
			0° - 45°	150.8	465.4	3.087	6.4
			0° - 50°	156.8	475.8	3.034	6.4
Symmetric	10	1.50	0° - 40°	142.7	457.7	3.208	6.1
			0° - 50°	156.8	492.0	3.137	6.1
	13	0.67	0° - 50°	154.6	673.2	4.355	5.92
Asymmetric	10	1.50	0° - 40°	142.7	463.8	3.251	6.4
			0° - 50°	156.8	478.9	3.054	6.4
	13	0.67	0° - 50°	154.6	568.7	3.679	5.92

‡ Stress magnification factor = Maximum equivalent stress / Nominal stress for straight screw of similar geometry under tensile loading.

† Nominal stress for straight screw of comparable geometry under axial tension loading.

Table 7.2: Results for straight and angled pedicle screw models under axial tension and bending.

Screw Position	Offset Angle (degrees)	Fillet Radius (mm)	Constrained Region of Spherical Surface	Nominal Stress † (MPa)	Maximum Stress (MPa)	k ‡	Location (z direction) (mm)
Straight	0	0.67	0° - 40°	140.8	556.7	3.953	5.92
			0° - 45°	148.7	570.5	3.836	5.92
			0° - 50°	154.6	580.9	3.758	5.92
		1.50	0° - 40°	142.7	453.1	3.176	6.4
			0° - 45°	150.8	465.9	3.090	6.4
			0° - 50°	156.8	476.3	3.031	6.4
Symmetric	10	1.50	0° - 40°	142.7	458.2	3.211	6.1
			0° - 50°	156.8	491.0	3.131	6.1
Asymmetric	10	1.50	0° - 40°	142.7	464.3	3.254	6.4
			0° - 50°	156.8	479.9	3.060	6.4

‡ Stress magnification factor = maximum equivalent stress / nominal stress for straight screw of similar geometry under tensile loading.

† Nominal stress for straight screw of comparable geometry under axial tension loading.

Table 7.3: Results for straight and angled pedicle screw models under axial tension, bending and shear.

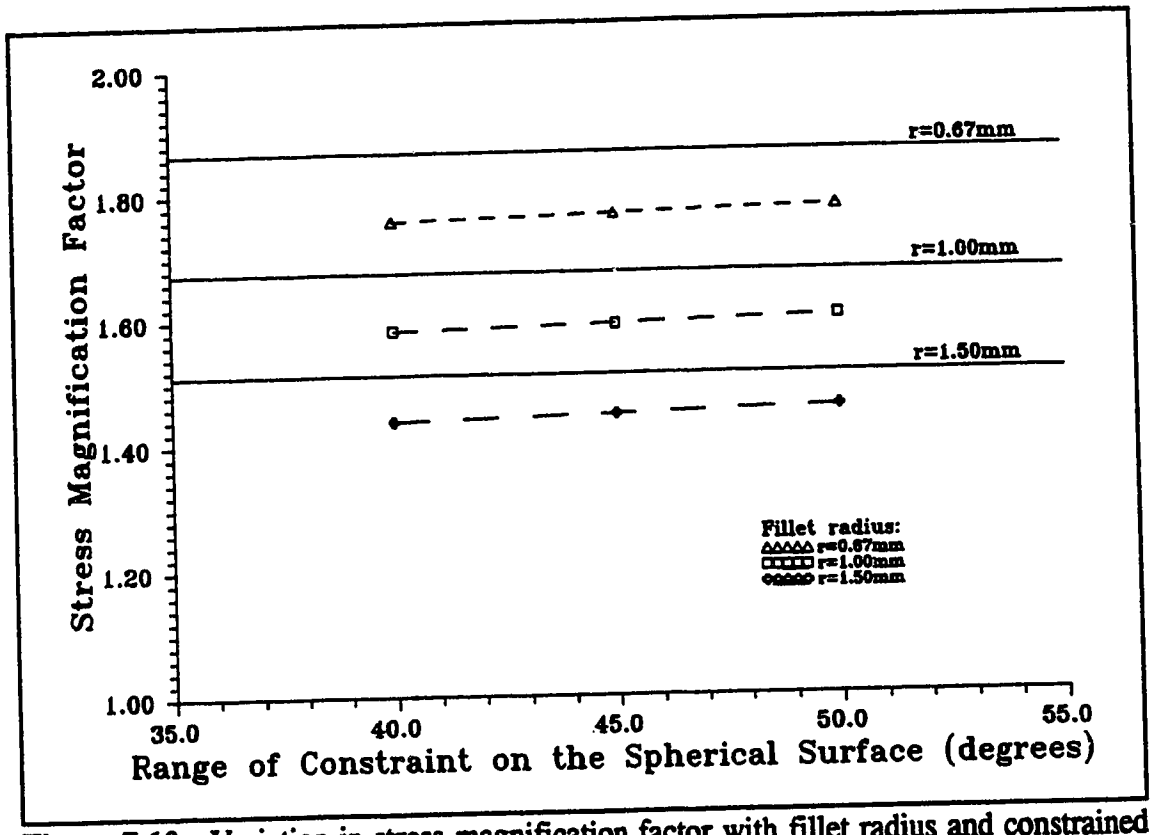

Figure 7.10: Variation in stress magnification factor with fillet radius and constrained area for the straight screw under tensile loading with published factors from Peterson (1974).

shaft, increased with an increase in the constrained region of the spherical surface (Figure 7.12). A small variation (<1.0%) also occurred between models of different fillet radius having the same constrained region. These variations resulted from application of the tensile load by a uniform displacement of the distal end of the shaft. This was required to prevent rigid body motion.

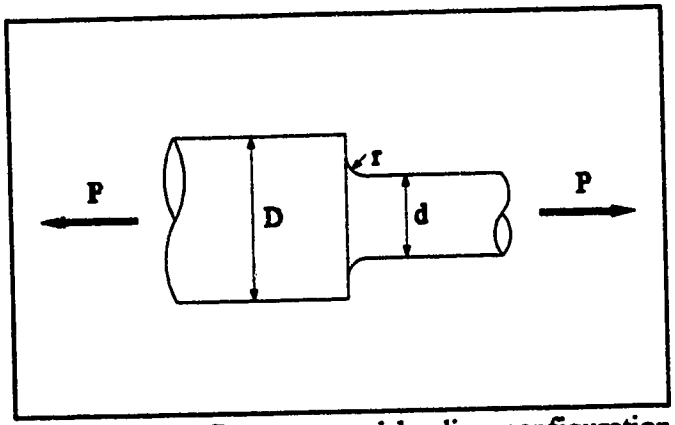

Figure 7.11: Geometry and loading configuration for published stress concentration factor data from Peterson (1974).

Under tensile loading angulation of the pedicle screw caused an increase in the stress magnification factor (Figure 7.13). This factor also increased with the portion of the spherical surface that is constrained.

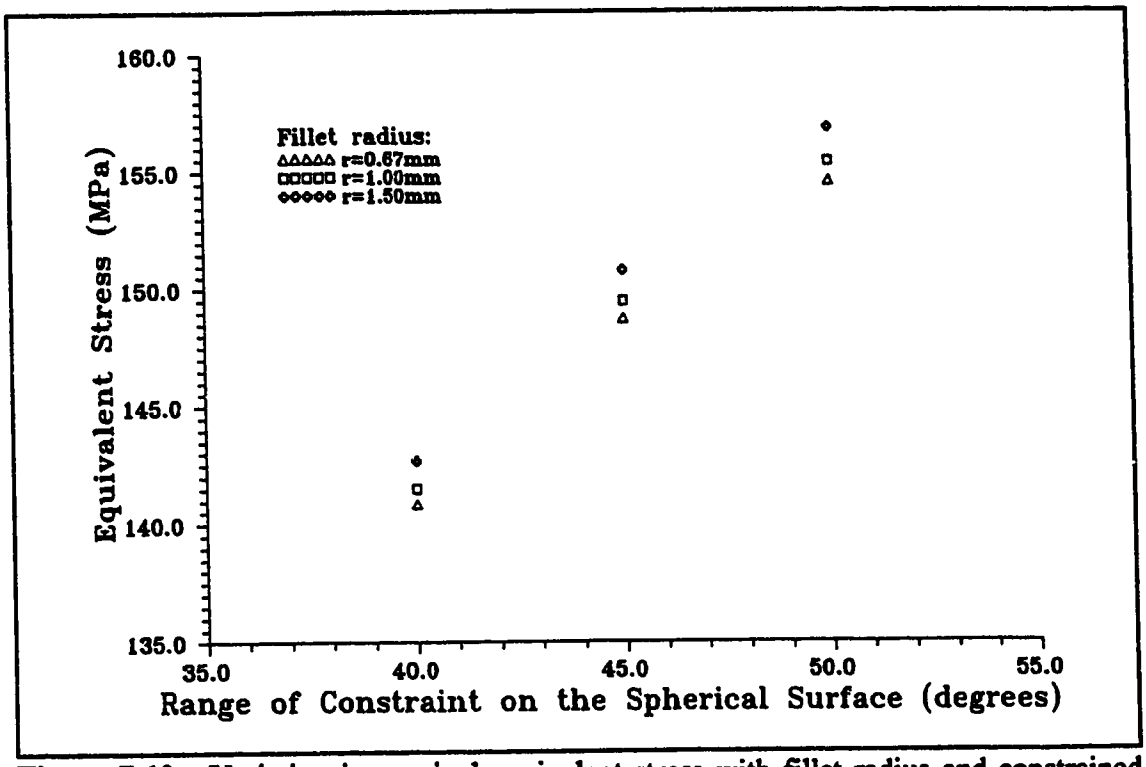

Figure 7.12: Variation in nominal equivalent stress with fillet radius and constrained area of the spherical surface for the straight screw under tensile loading.

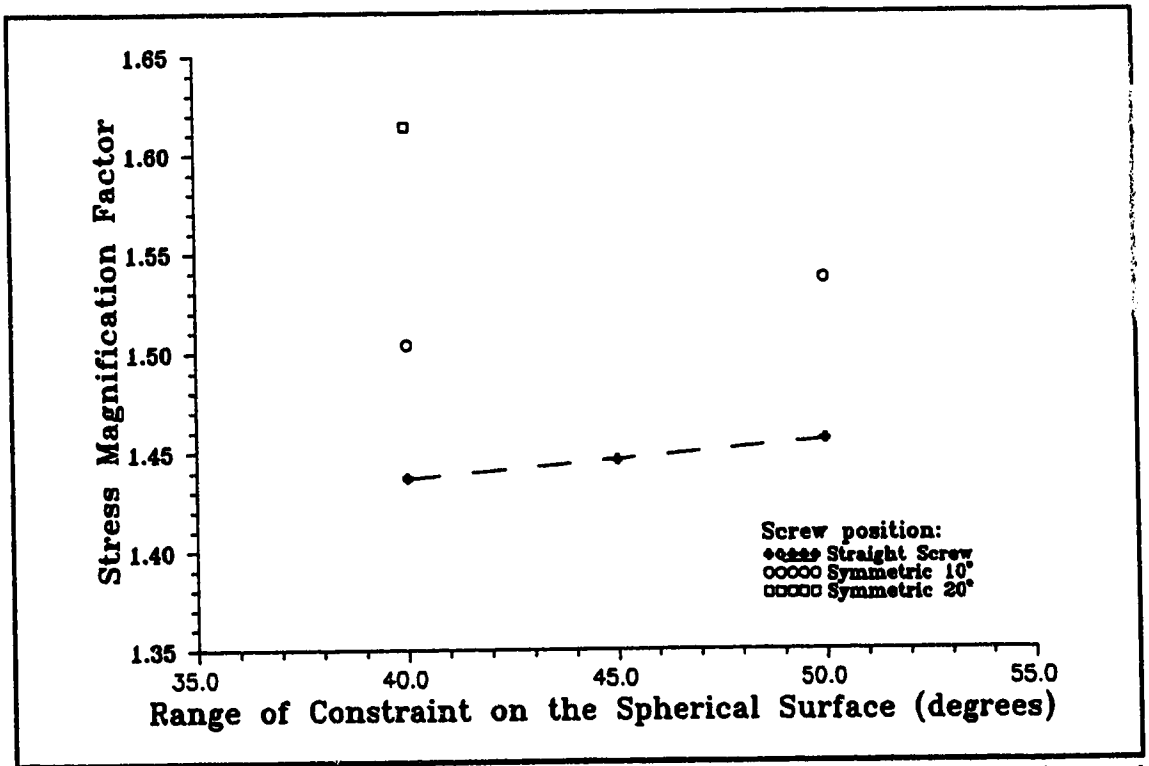

Figure 7.13: Variation in stress magnification factor with screw angulation and constrained area of the spherical surface under tensile loading (fillet radius: 1.50 mm).

7.2.2.2 Axial Tension and Bending

Analysis of the influence of fillet radius for the straight screw under combined axial tension and bending loads (Figure 7.14) also showed that increasing the fillet radius decreased the stress magnification factor. Contrary to the results from axial tension loading, the stress magnification factor decreased when the constrained area of the spherical surface was increased. However, the equivalent stress increased with increasing constrained area (Table 7.2). This suggests that increasing the region of the spherical surface that is constrained has a greater influence on the equivalent stress under tensile loading than for combined tension and bending loads. The maximum equivalent stress for nodes at each z location occurred along the axis of symmetry at θ=0°.

The influence of screw angulation on the stress magnification factor is presented graphically in Figure 7.15. Offset screws also showed a decrease in the stress magnification factor with increasing constrained regions. Of interest is the finding that for the asymmetric screw the stress magnification factor decreased more than the symmetric screw such that for constraint of the spherical surface to 50° the stress

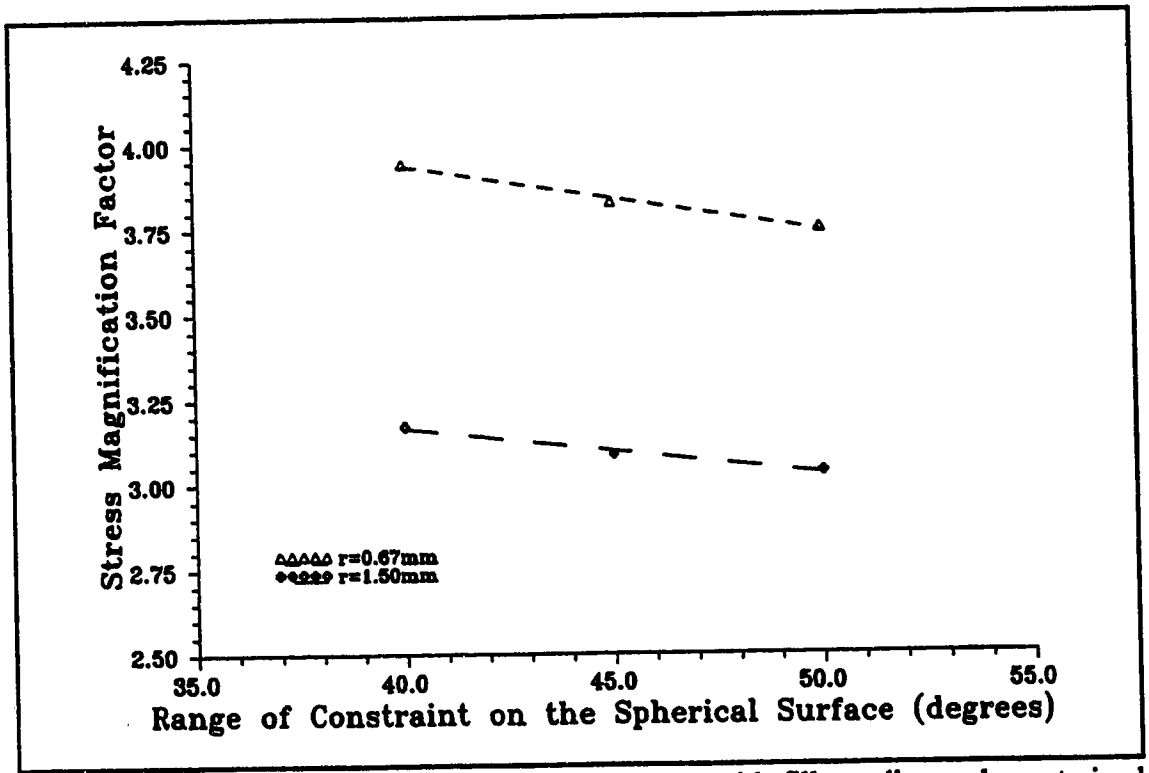

Figure 7.14: Variation in nominal equivalent stress with fillet radius and constrained area of the spherical surface for the straight screw under tensile and bending loads.

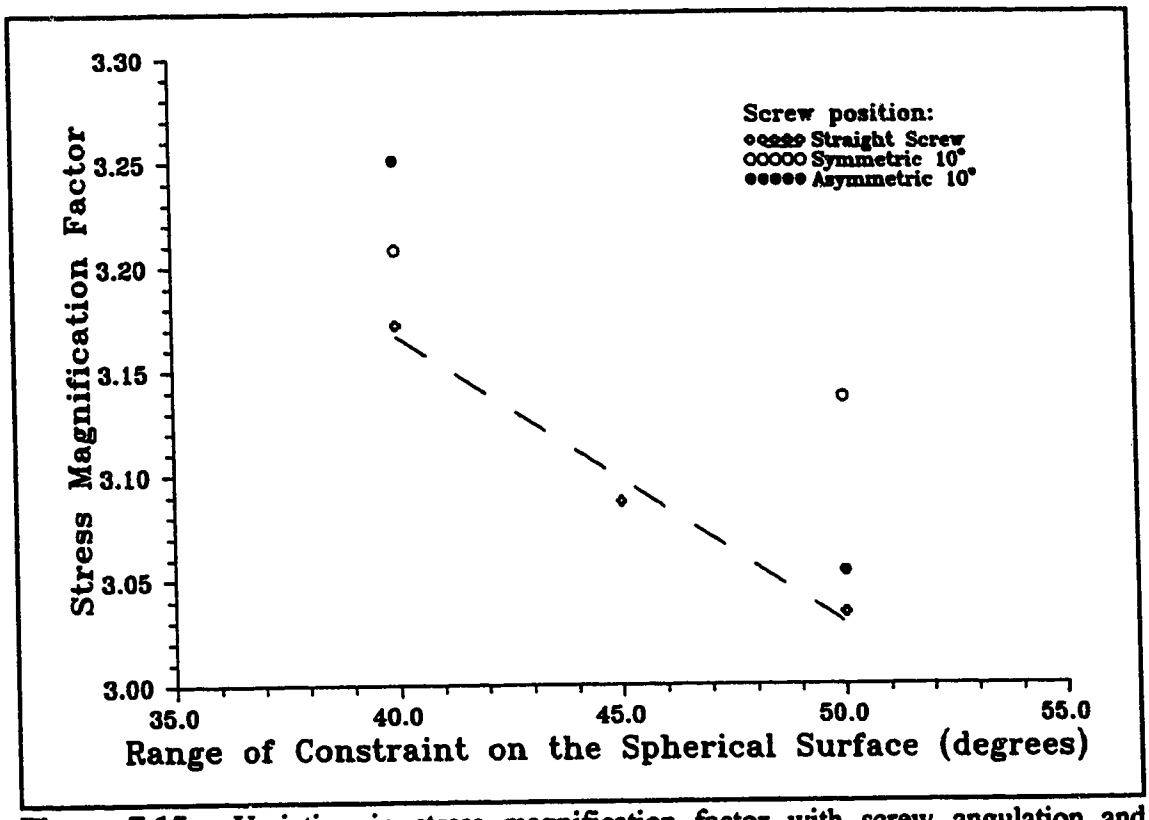

Figure 7.15: Variation in stress magnification factor with screw angulation and constrained area of the spherical surface under tension and bending loads (fillet radius: 1.50 mm).

magnification factor for the asymmetric screw was lower than for the symmetric screw. These results are contrary to the result for constraint of the spherical surface to 40°.

7.2.2.3 Axial Tension, Bending and Shear

As with the two previous loading conditions for combined axial tension, bending and shear the stress magnification factor decreased with increasing the fillet radius (Figure 7.16). Similar to the case of combined tension and bending increasing the constrained region of the spherical surface resulted in a decrease in the stress magnification (Figure 7.16), though an increase in the maximum equivalent stress occurred (Table 7.3). The influence of screw angulation (Figure 7.17) showed similar results as occurred for loading by tension and bending (Figure 7.15).

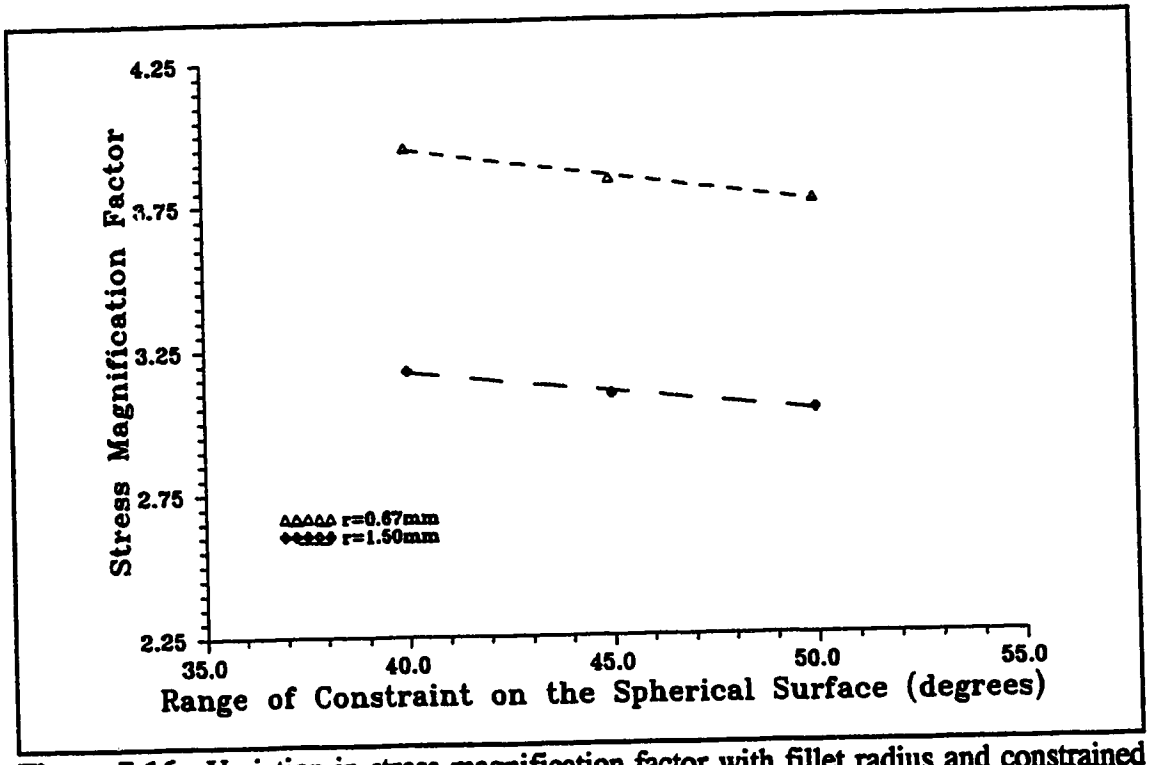

Figure 7.16: Variation in stress magnification factor with fillet radius and constrained region for the straight screw under axial tension, bending and shear loads.

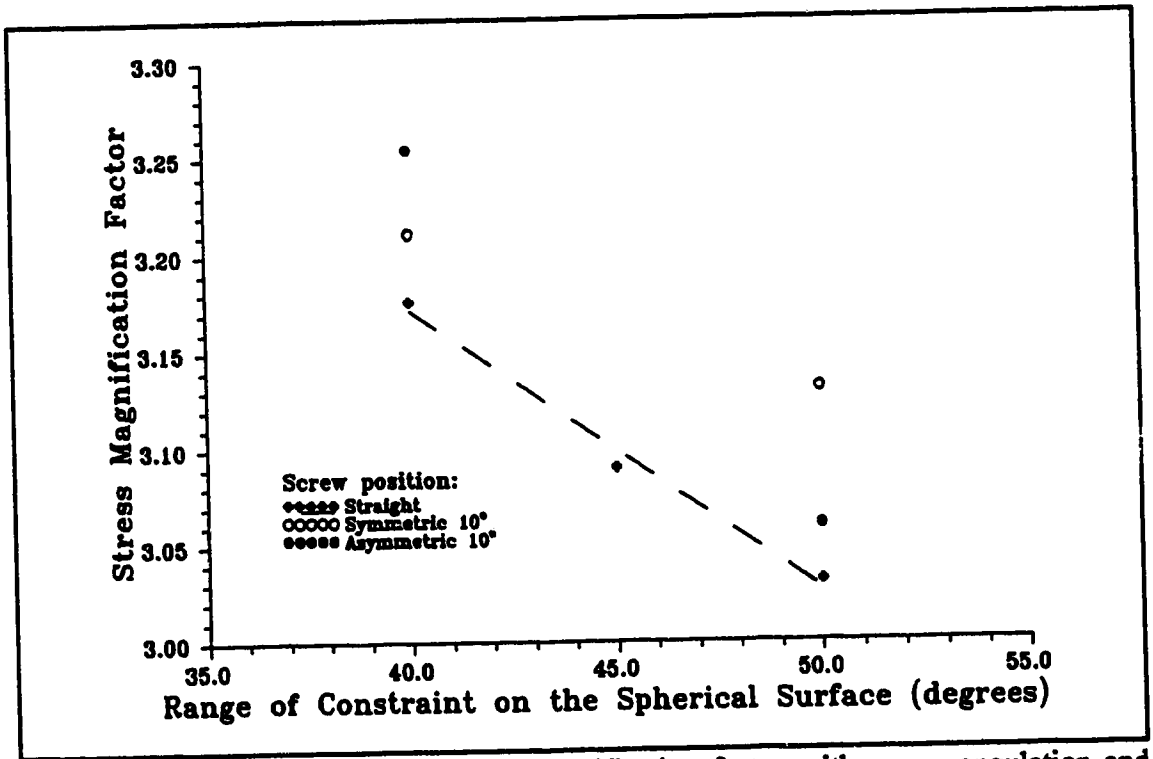

Figure 7.17: Variation in the stress magnification factor with screw angulation and change in the constrained area under tension, bending and shear loads (fillet radius: 1.50 mm).

7.2.2.4 Influence of Proximal Screw/Sleeve Contact Location on Maximum Equivalent Stress

Results for analysis of the influence of proximal screw/sleeve contact location on the maximum equivalent stress are presented in Table 7.4 and include the value and location of the maximum stress on the surface of the pedicle screw at each z distance over the fillet and proximal screw/sleeve contact region. The value of maximum equivalent stress at each z distance over the fillet region is also presented graphically in Figure 7.18. Over the unsupported length between the constrained spherical surface and the proximal screw/sleeve contact location several local maxima occur for each model and have been highlighted in the Table 7.4. From this table it can be seen that at proximal contact locations greater than or equal to 7.0 mm two maxima exist within the fillet region. For proximal contact locations greater than or equal to 7.4 mm a third maxima occurs at the contact point between the screw shaft and the lower surface of the

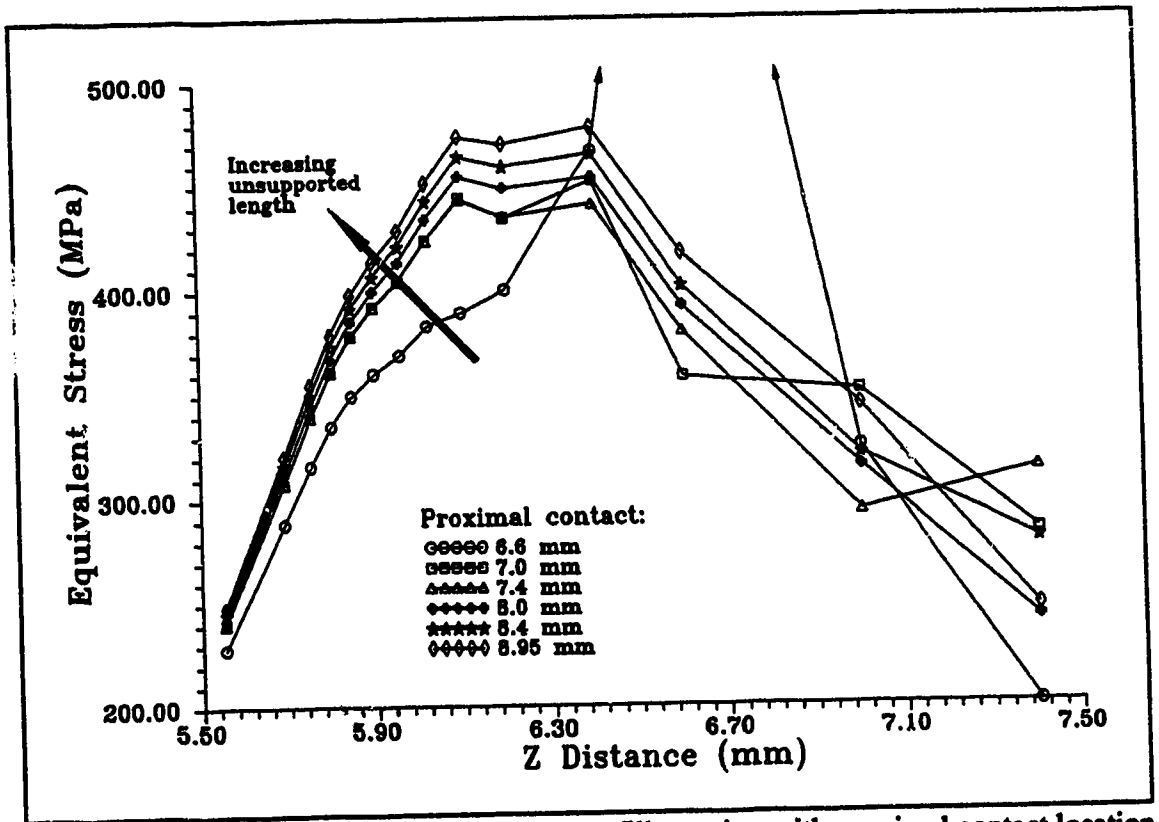

Figure 7.18: Variation in equivalent stress in fillet region with proximal contact location for the straight screw under tension and bending loads (radius: 1.50 mm, constrained: 0°-40°).

Z Position (mm)	Proximal Screw/Sleeve Contact Location											
	6.6 mm		7.0 mm		7.4 mm		8.0 mm		8.4 mm		8.95 mm	
	σ_e	θ	σ_e	θ	σ_e	θ	σ_e	θ	σ_e	θ	σ_e	θ
5.69	288.5	0°	307.8	0°	307.5	0°	312.1	0°	316.4	0°	320.4	0°
5.752	315.9	0°	339.2	0°	339.0	0°	344.6	0°	349.9	0°	354.7	0°
5.80	334.9	0°	361.2	0°	360.9	0°	367.3	0°	373.2	0°	378.7	0°
5.847	349.6	0°	378.7	0°	378.3	0°	385.3	0°	391.8	0°	397.9	0°
5.899	360.2	0°	392.3	0°	392.0	0°	399.9	0°	407.0	0°	413.7	0°
5.959	369.1	0°	404.9	0°	404.7	0°	413.5	0°	421.3	0°	428.7	0°
6.023	383.2	0°	424.1	0°	424.0	0°	434.2	0°	442.9	0°	451.5	0°
6.1	389.5	0°	444.1	0°	443.4	0°	454.7	0°	464.4	0°	474.1	0°
6.2	400.3	0°	434.4	0°	435.2	0°	449.0	0°	459.4	0°	470.5	0°
6.4	467.1	90°/270°	452.5	0°	441.1	0°	454.1	0°	465.5	0°	478.3	0°
6.6	736.9	90°/270°	358.1	0°	379.8	0°	392.1	0°	401.8	0°	417.4	0°
7.0	324.2	60°/90°	351.3	0°	293.5	0°	314.8	0°	320.7	0°	344.1	0°
7.4	200.3	0°	283.6	0°	313.5	0°	241.6	0°	279.7	0°	246.8	0°
8.0	-	-	-	-	-	-	322.0	0°	218.6	0°	-	-
8.4	-	-	-	-	-	-	189.0	0°	309.1	0°	-	-
8.95	164.1	0°	167.6	0°	161.6	0°	-	0°	-	0°	273.1	0°
9.30	-	-	-	-	-	-	169.2	0°	159.2	60°/300°	-	-
10.90	146.4	180°	156.9	180°	160.6	180°	166.9	180°	170.9	180°	172.7	180°
12.84	147.9	180°	159.7	180°	164.6	180°	171.7	180°	178.2	180°	186.3	180°

Table 7.4: Variation of the value and location of the peak equivalent stress with proximal screw/sleeve contact location for the straight screw under tension and bending loads (fillet radius: 1.50 mm, constrained: 0°-40°).

conical sleeve.

When only a single maximum exists (proximal contact at z=6.6 mm) the value is much higher than those in models with longer unsupported regions and occurs on the sides of the screw (90° and 270°) rather than at the centreline. This suggests that for short unsupported lengths of the distal screw shaft the influence of the fillet and screw/sleeve contact overlap to produce the very high stresses (736.9 MPa) evident in this model.

Analysis of the angular position (θ, Figure 7.9) where the maximum equivalent stress occurs for each z position (Table 7.4) shows that the peak stress on the distal end of the screw shaft was 180° from the location of the peak stress in the fillet. This implies that the distal shaft of the screw bends within the conical sleeve and that contact between the screw and sleeve shifts from θ=0° to θ=180°.

A representative contour plot of the equivalent stress through a cross-section of the unsupported region of the screw for proximal contact at z=7.4 mm is presented in Figure 7.19. This figure shows a region of high stress below the surface of the pedicle screw at the proximal screw/sleeve contact point as predicted by contact stress theory. The stress within this region (375-400 MPa) is lower than exists within the fillet (452.5 MPa).

Figure 7.20 presents the variation in the overall maximum equivalent stress with variation in the proximal screw/sleeve contact. The minimum equivalent stress occurs when the lower surface of the conical sleeve (the proximal screw/sleeve contact) is at z=7.4 mm (443.4 MPa).

7.3 Analysis of the Conical Sleeves

Finite element analysis of the conical sleeves investigated the influence of screw angulation on the stress distribution within the sleeve and determined the normal reaction forces on the conical surface contacting the rod.

7.3.1 Methods

Conical sleeves to accommodate the pedicle screw in one of three positions

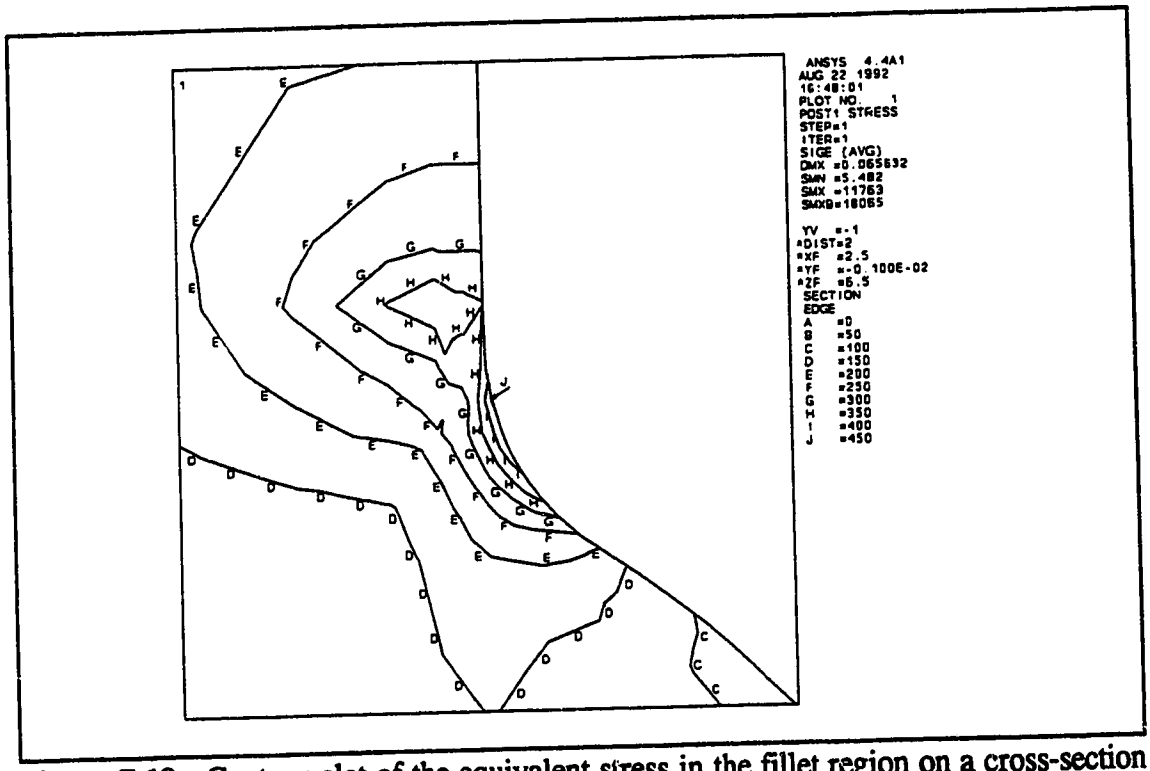

Figure 7.19: Contour plot of the equivalent stress in the fillet region on a cross-section along the plane of symmetry.

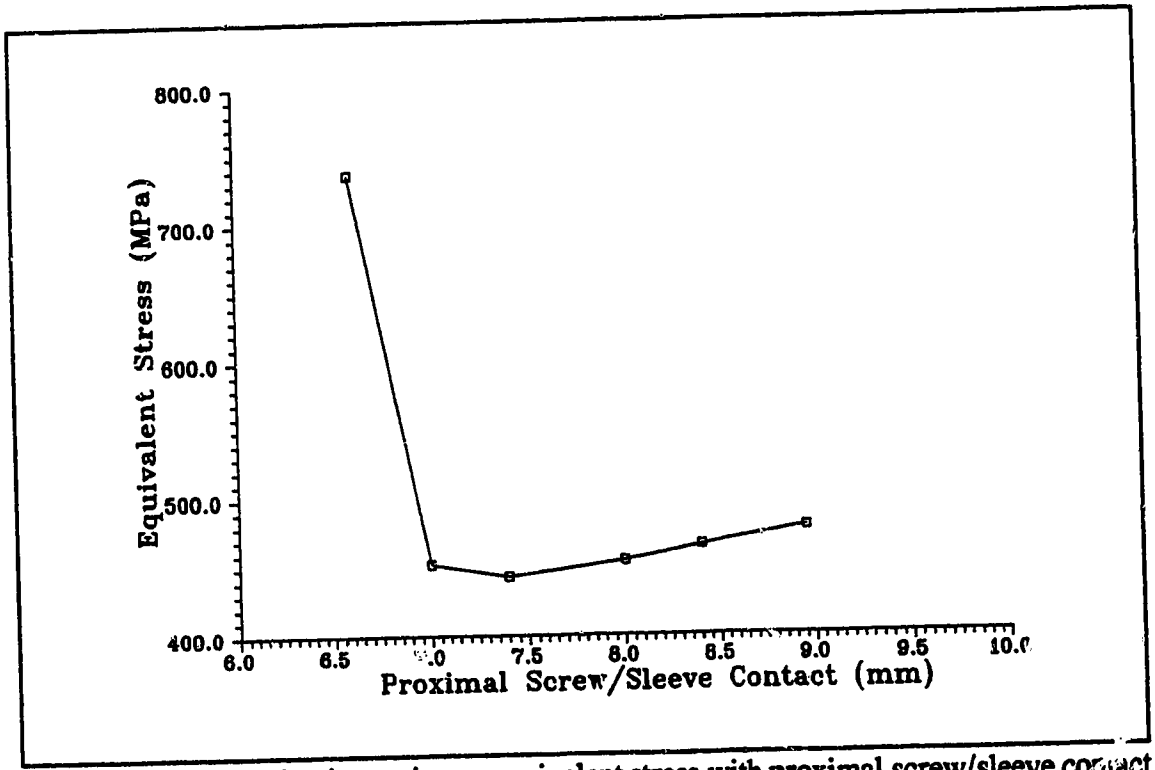

Figure 7.20: Variation in maximum equivalent stress with proximal screw/sleeve contact for the straight screw under tension and bending loads (radius: 1.50 mm, constrained: 0°-40°).

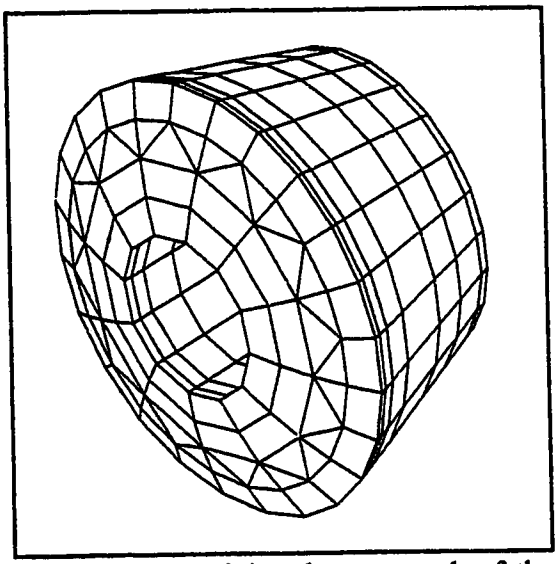

Figure 7.21: Finite element mesh of the conical sleeve to accommodate a straight screw.

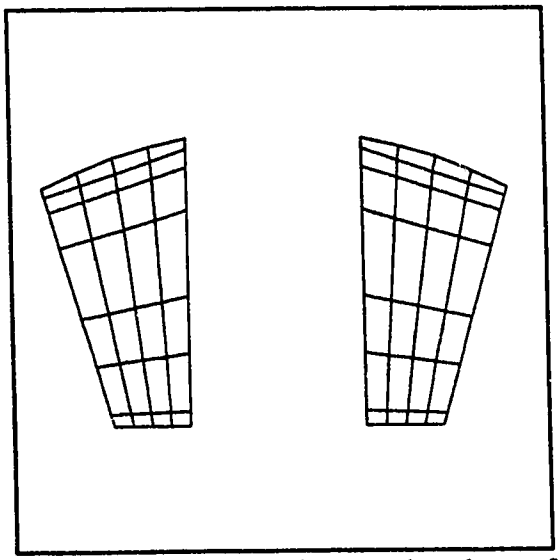

Figure 7.22: A section on the plane of symmetry through the conical sleeve to accommodate a straight screw.

including straight, symmetrically offset and asymmetrically offset (Figure 7.2) were analyzed. These configurations were modelled with one of two meshes. The first model, for a straight screw, had a central hole and was composed of 672 nodes and 588 elements. Isometric and cross-sectional views are shown in Figures 7.21 and 7.22, respectively. To analyze symmetrically and asymmetrically offset screws a second model was used (Figures 7.23 and 7.24). This model comprised 640 nodes and 490 elements

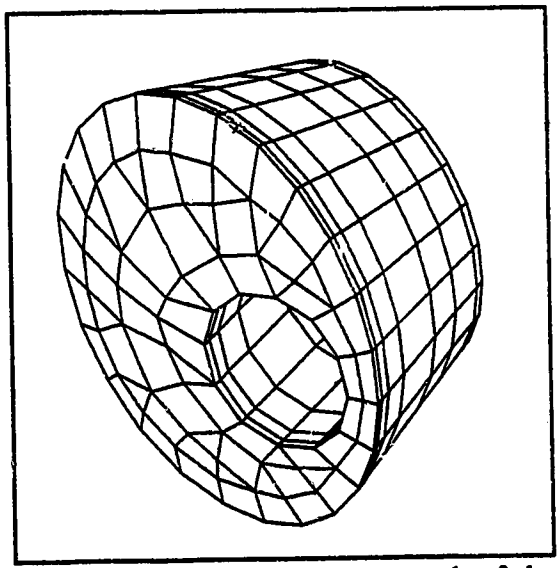

Figure 7.23: Finite element mesh of the conical sleeve to accommodate an offset screw.

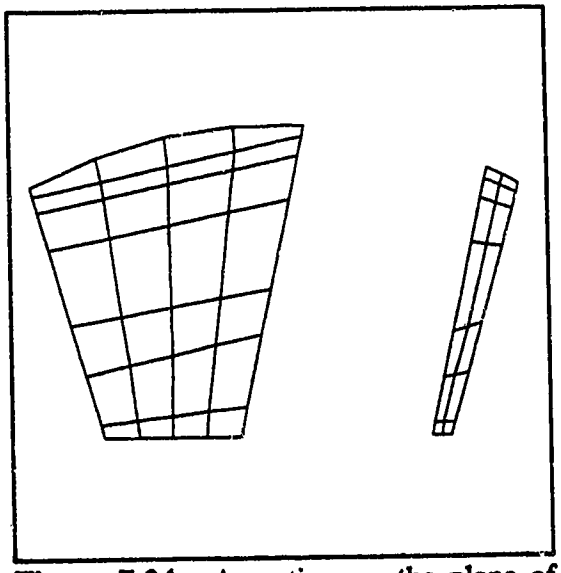

Figure 7.24: A section on the plane of symmetry through the conical sleeve to accommodate an offset screw.

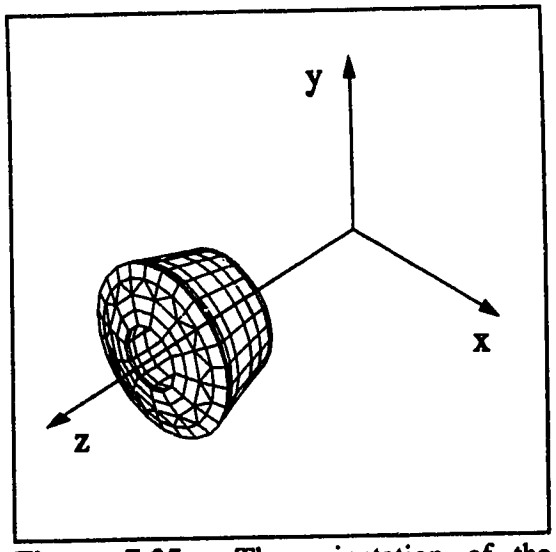

Figure 7.25: The orientation of the conical sleeve relative to the coordinate system.

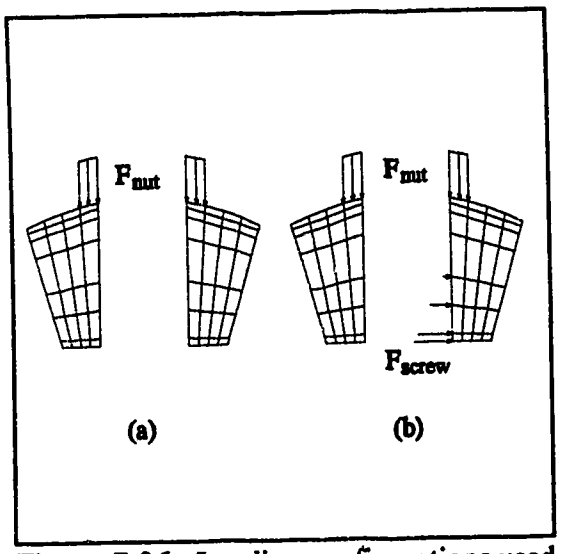

Figure 7.26: Loading configurations used in analysis of the conical sleeve.

and incorporated a 13° offset to the screw. Figure 7.25 shows the orientation of the conical sleeve relative to the coordinate system.

The conical sleeve models were tested in one of two loading configurations (Figure 7.26). Compression loading on the external spherical surface due to tightening of the nut (F_{nut}) was modelled by application of a pressure of 170 MPa to elements adjacent to the central hole. Compressive loading of the cylindrical surface from contact with the distal shaft of the pedicle screw (F_{screw}) was modelled by application of the reaction force from the applicable pedicle screw model at the corresponding nodes. Conical sleeves to accommodate the three screw positions were loaded with compression due to the locking nut only (Figure 7.26a) and with combined loads due to the locking nut and to contact with the distal shaft (Figure 7.26b).

Nodes on the conical surface in contact with the rod were constrained through 360° in the normal direction and on the plane of symmetry in the tangential direction. Friction between the conical surfaces of the sleeve and rod was not incorporated. To determine the contacting nodes on the conical surface, the iteration process used in the analysis of the pedicle screw was applied to the normal constraints.

Screw Position	Load Configuration	Maximum Equivalent Stress (MPa)	Sum of Normal Reactions on the Conical Surface (N)
Straight	F_{nut}	286.2	6627.8
	F_{nut} and F_{screw}	672.0	6549.7
Symmetric Offset	F_{nut}	367.4	5455.5
	F_{nut} and F_{screw}	1024.9	5813.6
Asymmetric Offset	F_{nut}	367.4 †	5455.5 †
	F_{nut} and F_{screw}	1718.6	5817.3

† Symmetric and asymmetric cases are identical for loading by the locking nut.

Table 7.5: Results from finite element analysis of the conical sleeves.

7.3.2 Results

High equivalent stresses were computed for cases where compressive loads due to contact with the screw shaft were considered (Table 7.5). The sum of the normal reaction forces on external conical surface (in contact with the rod) are also presented in Table 7.5. This sum is proportional to the friction force on the conical surface. Friction between the contacting surfaces is a factor in maintaining secure contact between the rod and conical sleeve. Angulation of the hole within the sleeve resulted in a decrease in this sum (Table 7.5). Representative contour plots of the conical sleeves for straight and symmetrically offset screws under compressive loads from the tightening nut and screw shaft are shown in Figures 7.27 and 7.28, respectively.

7.4 Discussion

Finite element analysis of the prototype was performed to determine its structural integrity and the influence of changing various dimensions on the stress distribution. Dimensions of interest were the constrained region of the spherical surface, the fillet radius and the location of the screw/sleeve contact location. Due to the number of dimensions that can be varied a thorough analysis of the inter-relationship of all variables was beyond the scope of this study.

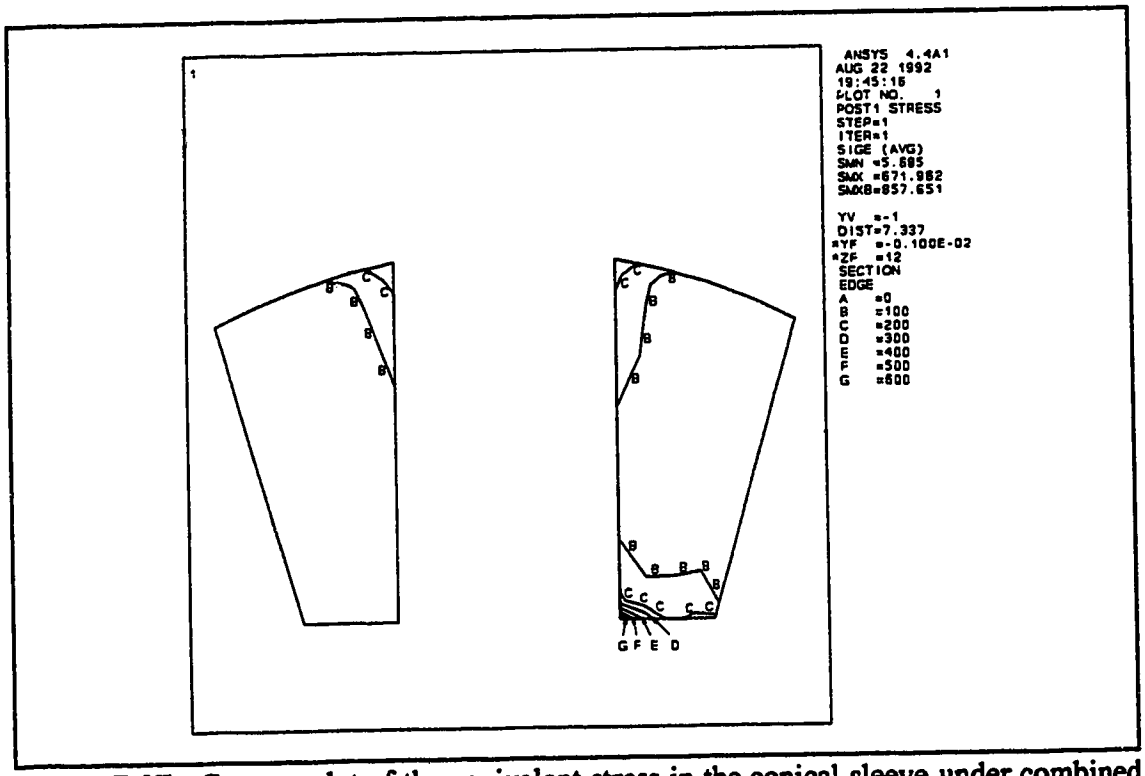

Figure 7.27: Contour plot of the equivalent stress in the conical sleeve under combined loading on a cross-section along the plane of symmetry.

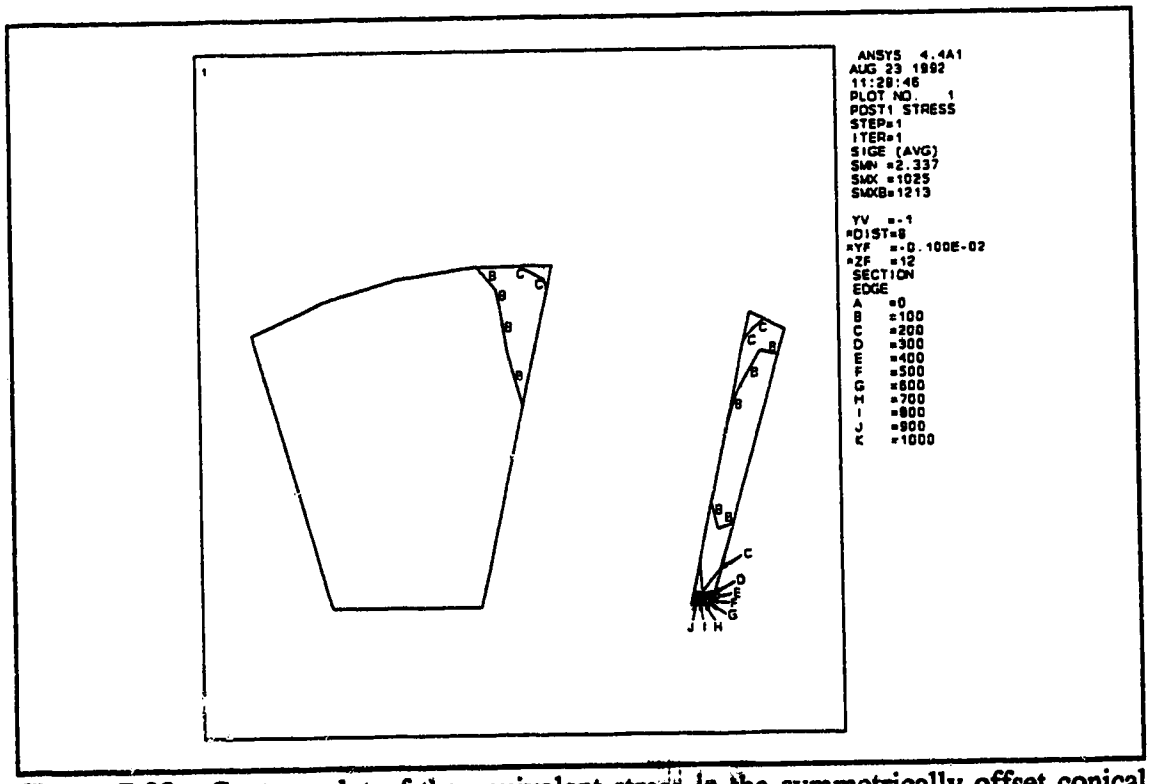

Figure 7.28: Contour plot of the equivalent stress in the symmetrically offset conical sleeve under combined loading on a cross-section along the plane of symmetry.

Increasing the fillet radius resulted in a decrease in the stress magnification factor suggesting the largest radius should be used while accommodating the required range of screw angulation. To maintain the desired range of angulation while increasing the fillet radius, the portion of the spherical surface of the pedicle screw in contact with the rod must be decreased. Therefore, the influence of changes to this constrained region on the stress in the pedicle screw and on the reaction forces at the boundaries are of interest. As the constrained region decreased the maximum equivalent stress decreased in all cases, though the stress magnification factor increased when a bending moment was applied. The sum of the reactions along the screw/sleeve contact increased with decreasing constrained region (Table 7.6).

Rounding the upper edge of the spherical surface of the rod (Figure 7.1) to prevent interference with the fillet would allow additional angulation of the pedicle screw. However, this results in contact of the spherical surface of the rod within the fillet. This constrains nodes within the fillet and increases the stress in this region.

Results of this analysis suggest that contact between the spherical surfaces of the screw and rod from 0° to 40°, as required to accommodate differences in screw orientation, is acceptable. Reducing the constrained area would enable the screw/rod junction to accommodate greater differences in screw orientation and may eliminate the possible need for production of rods with a central bend (Section 6.1.3.1). Additional analysis in which the boundary conditions are more accurately modelled is required to determine the influence of this modification on the integrity of the screw/rod junction. Increasing the fillet diameter and the diameter of the distal screw shaft should reduce the maximum stress in the pedicle screw. The largest fillet radius should be used while still maintaining the capability to accommodate the required range of differences in screw orientation.

Changing the location of the proximal screw/sleeve contact (equivalent to varying the length of the cone) was found to significantly effect the stress in the pedicle screw. For the prototype this location should be at z=7.5 mm; however, changes to the constrained region and fillet radius may influence this dimension.

Stresses in the conical sleeve were determined to be very high when the bending

Screw Position	Offset Angle (degrees)	Fillet Radius (mm)	Constrained Region of Spherical Surface	Tension and Bending (N)	Tension, Bending and Shear (N)
Straight	0	0.67	0° - 40°	1260.7	1257.5
			0° - 45°	1257.2	1254.2
			0° - 50°	1254.4	1251.1
		1.50	0° - 40°	1253.8	1250.3
			0° - 45°	1248.4	1247.0
			0° - 50°	1245.6	1244.1
Symmetric	10	1.50	0° - 40°	1186.5	1183.8
			0° - 50°	1164.3	1161.7
	13	0.67	0° - 50°	1161.0	-
Asymmetric	10	1.50	0° - 40°	1233.6	1230.5
			0° - 50°	1232.0	1229.0
	13	0.67	0° - 50°	1242.9	-

Table 7.6: Sum of the reactions at the contact between the screw shaft and conical sleeve for the three load configurations.

moment was applied. However, as these stresses were primarily compressive and as plastic deformation of the cone would assist in resisting loosening of the screw/rod junction, the stresses may be acceptable. The high stresses in the conical sleeve may reflect problems in the boundary conditions. Rigidly constraining the outside surface of the sleeve in the normal direction is conservative and modelling the interface with gap elements may provide more accurate results.

Stress levels predicted by finite element modelling were compared with published material properties for 316L stainless steel. Current devices using this material, such as the Cotrel-Dubousset system, conform to ASTM standard F138-86 Grade 2 (Standard specification for Stainless Steel Bar and Wire for Surgical Implants; Special Quality). This standard gives the minimum specification for the ultimate tensile and yield strength (0.2% offset) for various material sizes. For cold-worked material the minimum ultimate tensile strength ranges from 655 to 860 MPa and the minimum yield strength ranges from 310 to 650 MPa. Predicted values for the maximum equivalent stress in the prototype are high in comparison to these values. However, this analysis may be conservative as comparison of the maximum stress for the straight screw under tension and bending loads with the maximum equivalent stress in the Shanz screw of the Internal Fixator (Figure 7.29) showed the predicted stresses lower than those estimated for the Schanz screw whose incidence of fatigue failure is low (Section C.3).

Contact between the rod and screw along the spherical surface and between the rod and sleeve along the conical surface must be maintained to prevent loss-of-correction. For these surfaces to separate a force equal to the sum of the reactions at the distal end of the screw shaft must be applied in the negative z direction. This requires that the screw/bone interface must withstand a pullout load equal to this sum. Comparison of the sum of the reactions on the distal end of the screw shaft (Table 7.7) with published data for screw pullout strength (for example: Krag et al., 1986; Sell et al., 1988; Skinner et al., 1990; Zindrick et al., 1986) showed that breakdown of the screw/bone interface should occur before separation of the spherical surfaces. The sum of the reactions increased with decreasing constrained region of the spherical surface suggesting that reducing this region so as to accommodate greater screw angulation should not adversely

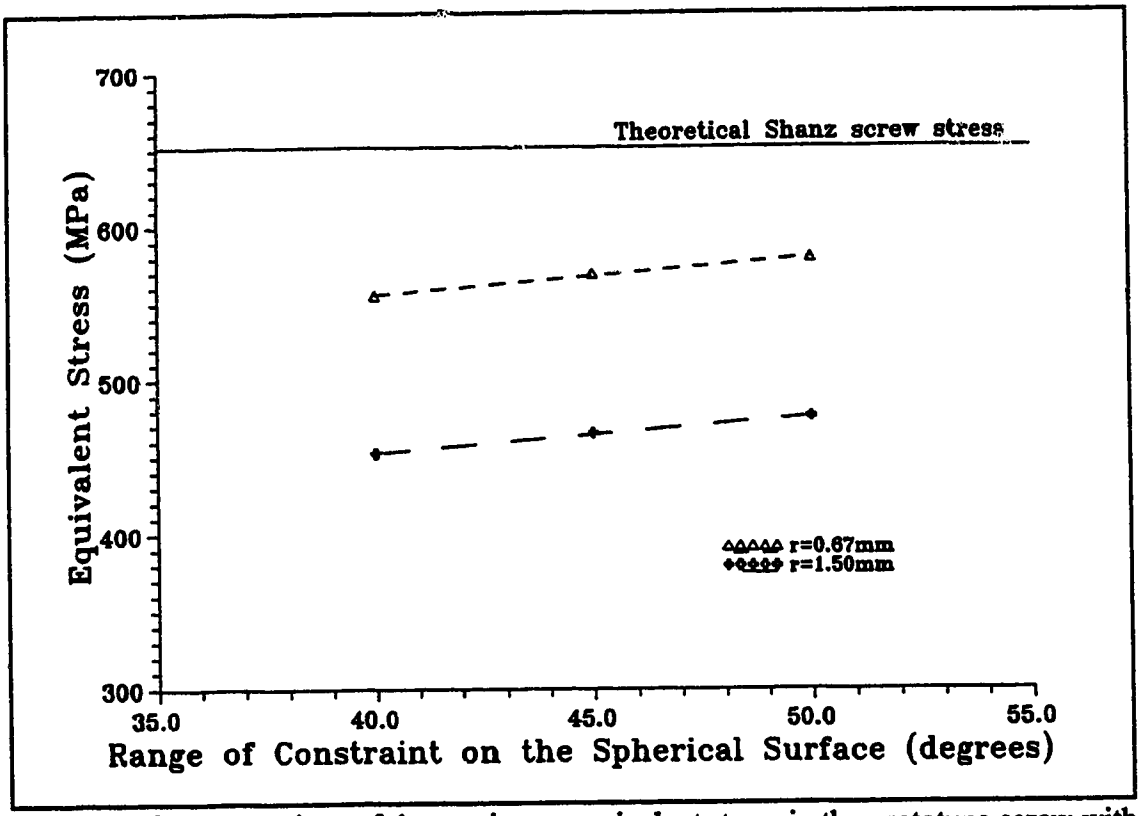

Figure 7.29: Comparison of the maximum equivalent stress in the prototype screw with theoretical stress in the Schanz screw under tension and bending (straight screw, fillet radius: 1.50 mm).

affect the resistance of the spherical surfaces to separation. However, the influence of friction must be considered to determine the efficacy of the screw/rod junction.

Though mesh refinement of the preliminary pedicle screw models showed convergence of the maximum equivalent stress, a thorough convergence study was not undertaken. However, the relatively smooth stress contours evident in the plot of maximum equivalent stress in the screw (Figure 7.19) suggests the mesh was adequate. Refinement of the mesh for the conical sleeve models, particularly those with an offset central hole, may be necessary due to the high stress gradients.

7.5 Recommendations for Further Analysis

A thorough convergence study should be performed on the mesh in the fillet region to ensure accuracy of the results. Use of elements with higher order polynomials should be undertaken to test the accuracy of the results. Verification of the results from

Screw Position	Offset Angle (degrees)	Fillet Radius (mm)	Constrained Region of Spherical Surface	Axial Tension (N)	Tension and Bending (N)	Tension, Bending and Shear (N)
Straight	0	0.67	0° - 40°	2641.3	2578.6	2581.0
			0° - 45°	2788.6	2723.4	2726.7
			0° - 50°	2898.9	2831.7	2836.5
		1.00	0° - 40°	2654.0	-	-
			0° - 45°	2802.9	-	-
			0° - 50°	2914.3	-	-
		1.50	0° - 40°	2675.8	2615.3	2617.6
			0° - 45°	2827.6	2764.6	2767.5
			0° - 50°	2942.6	2876.2	2881.0
Symmetric	10	1.50	0° - 40°	2748.5	2680.6	2680.7
			0° - 50°	2947.9	2886.2	2886.4
	20	1.50	0° - 40°	2684.7	-	-
Asymmetric	10	1.50	0° - 40°	-	2687.7	2690.1
			0° - 50°	-	2885.3	2890.3

Table 7.7: Sum of the reactions at the distal end of the screw shaft for the three loading configurations.

finite element modelling should be undertaken possibly using photoelastic analysis. Investigation of the iteration process used in this analysis could also be undertaken. This may be accomplished through the use of gap elements on the contact surfaces. The present analysis did not include friction on the constrained surfaces. The use of gap elements on these surfaces could incorporate this factor in the analysis.

Further analysis of the pedicle screw could determine the stress distribution under only bending loads. Several models of such cases were attempted, but a solution was not possible due to rigid body motion. Incorporating friction into the models may enable solution of these cases. Stress magnification factors from cases with only bending loads could be compared with published values from Peterson (1974).

The influences of additional geometry changes should be investigated. Analysis of changes to the constrained region and the fillet radius on the optimal location for the proximal screw/sleeve contact should be considered. Variation of the external diameter of the screw/rod junction and of the diameter of the spherical contact between the screw and rod should also be analyzed.

Use of gap elements on the spherical contact surfaces may enable application of pressure on the distal end of the screw model to model the tensile load due to the locking nut. This would allow better comparison between models as the nominal stress in the distal shaft should not vary.

Further analysis of the conical sleeves should include refinement[illegible] and modelling sleeves with a central hole at different angles. Friction[illegible] incorporated on the constrained surfaces.

Chapter 8: A Transpedicularly Implanted Spinal Support

Though the proposed device meets many of the design constraints and has several advantages over existing instrumentation, problems remain with posterior fixation instrumentation. In particular, use of this type of device without support for the anterior column may not be adequate for treatment of severely unstable fractures. In such cases the spine may be incapable of providing support such that the vast majority of the load must be carried by the fixation device. Transfer of such a large load to the fixation device may lead to fatigue failure of the pedicle screws or breakdown of the screw/bone interface. Loss of the operative correction is a potential consequence of both complications. Improving the fatigue resistance of the device may only exacerbate the problems of breakdown of the screw/bone interface and stress shielding within the fixed vertebrae. Unfortunately, redesign of the posterior device may not provide an adequate solution and novel approaches may be required. For example, to reduce loading on the posterior fixation device support for the anterior column of the spine that can be provided during implantation of the fixation device may be a possible solution. Design of such an anterior support was undertaken to complement the prototype posterior device.

8.1 Rationale for a Transpedicularly Implanted Support

Direct support for the vertebral body by anterior fixation provides the most effective mechanical form of stabilization for most physiological loading configurations (Sections 3.1.1 and 3.3). Anterior instrumentation for spinal fixation, however, has a number of dangers limiting its use (Section 3.1.1). Posterior instrumentation also has some inherent limitations. The large moment can lead to fatigue failure of the instrumentation or breakdown of the screw/bone interface (Section 3.2.4). To avoid such complications, anterior support (such as a strut graft) to augment posterior fixation has been recommended for cases of severe instability (Chapman, 1990). Unfortunately, the additional procedure increases the risk of further complications. Transpedicular bone grafting, though effective in reducing the loss-of-correction (Appendix A), and strut grafts only provide support once fusion has begun and will not reduce the loading on the posterior device during the early post-operative period. Strut grafts also are susceptible

to migration and resorption. Further, if anterior support can be achieved without using an anterior approach, the vertebral body's anterior cortex and the anterior longitudinal ligament can be left intact to protect the aorta and vena cava. A device that can be inserted during the posterior fixation procedure to provide support at the anterior of the vertebra would be invaluable as it would reduce loading on the posterior device during the critical period prior to fusion of the bone graft. It would be particularly applicable in cases with very unstable fractures that would otherwise be subject to late collapse.

8.2 Feasibility of the Transpedicular Approach

The transpedicular approach provides access to the vertebral body from the posterior through the pedicle. This approach has been used to obtain biopsy tissues for suspected vertebral tumours (Fidler and Niers, 1990) and to treat kyphosis and congenital scoliosis in children (King, 1988). McAfee et al. (1982) has also used the approach to reduce bone fragments impinging on the canal when distraction has not been successful. In addition, Daniaux et al. (1991) have used the transpedicular approach to make intra- and interbody bone grafts to augment posterior plating of burst fractures. They demonstrated a reduced incidence of screw breakage and reduced loss of correction for 62 fracture cases when transpedicular bone grafts were used to augment posterior instrumentation.

8.3 Device Concept

As the transpedicular approach appears to be a viable approach to the vertebral body, the possibility that a structure could be inserted through the pedicle to provide support for the anterior of the vertebra was considered. This anterior support would complement the posterior fixation device in cases of severe instability, tumour excision or in cases requiring transpedicular reduction of retropulsed bone fragments or bone grafting. The transpedicular approach permits a limited opening into the vertebral body, consequently, the device must contract to the 'insertion size' for implantation. Once in the vertebral body it must be manipulated into position and then into a configuration in which it can carry the applied load.

Development of a transpedicularly implanted spinal support (or anterior support) was undertaken in several stages. Initially, constraints on the design were developed, then a number of possible solutions were devised and analyzed. Finally, *in-vitro* testing of possible designs was undertaken.

8.3.1 Design Constraints

Constraints on the design of a transpedicularly implanted spinal support can be grouped into three categories: anatomical, mechanical and physiological.

8.3.1.1 Anatomical Constraints

The design of an anterior support is constrained in several ways by the local anatomy. Firstly, insertion of the support into the vertebral body must not damage the spinal cord or nerve roots. Secondly, the support must make firm contact with the intact endplates of the superior and inferior vertebrae. Thus, the overall support length is constrained by the distance between these structures. Finally, the overall diameter of the device cannot exceed the minimum internal diameter of the vertebral body's cortex in the transverse plane. This leaves the anterior cortex of the body and the anterior longitudinal ligament intact providing protection for the aorta and vena cava.

Determination of the maximum insertion size is difficult. If the cortex of the pedicle is kept intact so as to provide protection for the adjacent structures, the maximum insertion size is constrained by the pedicle's endosteal diameter, described in Section 2.3. However, two techniques could be used that would provide more space for the support's insertion. The first entails a basal osteotomy of the transverse process, an approach used by Arnold (described by Dick, 1989). The second technique requires removal of part, or all, of the pedicle, a procedure that can be performed without damage to the adjacent structures (Greenhill, 1988). Unfortunately, accurate data on the space available with either technique are not available. A minimum, but conservative, estimate of the second is the outer diameter of the pedicle. As described earlier (Section 2.3), the pedicle's cross-sectional profile varies with vertebral level and is defined by the minimum and maximum diameters. In the thoracolumbar and lumbar regions, where the

majority of vertebral fractures occur that may require such a support, the mean minimum pedicle diameter ranges from 7.5±2.0 mm (T10) to 13.5±2.7 mm (L5), whereas the mean maximum pedicle diameter ranges from 14.1±1.8 mm (L4) to 16.3±2.6 mm (T11) (Sections D.3.1 and D.3.3; Tables E.1 and E.3, Appendix E).

To determine the range in overall length of the support, data on vertebral body and the intervertebral disc heights were compiled from the literature (Tables E.20 and E.21, Appendix E). Differences in the data reported by various authors may be attributed, in part, to differences in measurement techniques (direct, radiograph), in site of measurement (anterior edge, posterior edge, centre) and in populations studied (Italian, Indian, Negro). As with the data on the pedicle morphology a combined mean was calculated for both the body and disc heights (Section D.2). However, unlike Section D.2, published data that included both the mean and the standard deviation were not available for all vertebral levels, therefore, a combined mean was calculated using all data for the mean heights (Table 8.1) and a combined standard deviation was not calculated. Table 8.2 presents the combined height of the vertebra and the two adjacent discs based upon the combined mean data. This indicates that the overall support length should range from 30.5 mm (T10) to 47.9 mm (L5) for the thoracolumbar and lumbar regions. Unfortunately, as the combined standard deviation was not calculated, it was not possible to estimate the range in overall support length required at each level. In addition, these calculations do not account for the curvature of the spine. Measurement of the combined height of the vertebral body and adjacent discs from lateral radiographs would provide an accurate estimate of the range of support lengths required.

Data on the internal or endosteal diameter of the vertebral body are not available. However, this constraint on the maximum diameter of the inserted device is very liberal as space must be available for bone graft to be placed around the support.

8.3.1.2 Mechanical Constraints

Mechanical constraints on the anterior support relate to load capacity and its structural and installation configurations. The device must be capable of carrying the total physiological load so failure of the support does not occur should the posterior

Level	Vertebral Body Height (mm)	Intervertebral Disc Height † (mm)
T1	15.4	4.1
T2	16.4	2.9
T3	17.1	2.6
T4	17.1	2.3
T5	18.0	2.6
T6	18.5	3.1
T7	18.6	3.7
T8	19.4	4.3
T9	20.1	4.6
T10	21.0	4.9
T11	22.3	6.5
T12	24.1	8.1
L1	25.5	8.0
L2	26.1	9.1
L3	26.5	10.0
L4	26.0	11.0
L5	25.9	11.0

† Height of disc below the vertebral level

Table 8.1: Combined mean vertebral body and intervertebral disc heights for levels T1 to L5.

instrumentation fail. Allowance for cyclic loading is a consideration, but as with the posterior instrumentation, an infinite fatigue life is unnecessary as fusion of the posterior and intra/interbody bone grafts should occur reducing the loading on the support. However, if the fusion is not successful the support may be subject to fatigue failure. The estimated physiological loads are discussed in Sections 3.4.

Load on the support differs with the type of fracture and the degree of instability.

Level	Overall Support Length (mm)
T10	30.5
T11	33.7
T12	38.7
L1	41.6
L2	43.2
L3	45.6
L4	47.0
L5	47.9

Table 8.2: Overall anterior support length required for implantation at levels T10 to L5.

Consideration must be given to how the design compensates for these differences. Implantation of one or more supports through or variation of the load-carrying capacity of the support are possible solutions.

Insertion, manipulation and extension must be undertaken through a narrow opening and must be carefully controlled. The device must also make solid contact with the adjacent endplates such that it can not be dislodged. In addition, it must be possible to remove the device should infection or other complication develop.

8.3.1.3 Physiological Constraints

Design of the anterior support has several physiological constraints. The device must be biocompatible. Its insertion and extension must not directly or indirectly, through displacement of bone fragments, damage either the spinal cord or nerve roots. As the device will support loading through contact with either intact endplates of the adjacent vertebrae or cancellous bone of the vertebral body, these structures must be capable of withstanding the applied load. Therefore, compressive strength of these structures is of interest. The compressive fatigue strength of the cancellous bone and endplates is also of concern due to the cyclic *in-vivo* loading.

Unfortunately, to date there are no published reports of *in-vitro* tests that replicate

the support's *in-vivo* loading on the vertebral endplate. Published studies on the *in-vitro* fracture strength of vertebrae have investigated a portion of the vertebral body, the complete vertebra, with or without the adjacent discs, and multi-vertebrae segments. Results for the compressive failure stress of the intact vertebral body range in mean failure strength from 1.578±0.466 MPa (Eriksson et al., 1989) to 4.63±2.69 MPa (Bell et al., 1967). Data reported by Bell et al. (1967) showed the greatest range (0.92 MPa to 15.14 MPa). The compressive strength of intact vertebrae are dependent on sex (Bartley et al., 1966), age (Mosekilde and Mosekilde, 1986; Rockoff et al., 1969), strain rate (Kazarian and Graves, 1977) and vertebral level (Hansson et al., 1980; Kazarian and Graves, 1977).

Testing of samples of vertebral body trabecular bone may more closely replicate the support's *in-vivo* loading than testing of the intact vertebral body. This is as the support loads a limited area of the endplate and failure of the endplate usually occurs after failure of the underlying trabecular bone (Brinckmann et al., 1988). Reported mean ultimate compressive stress values range from 1.55±1.11 MPa (Hansson et al., 1987a) to 4.25 MPa (Weaver and Chalmers, 1966). Data reported by Stein and Granik (1980) showed the greatest range (0.15 MPa to 16 MPa). A number of factors have been found to influence the compressive strength of cadaveric trabecular bone. These include: the orientation of the sample within the vertebral body (Galante et al., 1970); age (Mosekilde and Mosekilde, 1986; Weaver and Chalmers, 1966); sex (Lindahl, 1976; Weaver and Chalmers, 1966) and strain rate (Galante et al., 1970). No studies to date have reported results differentiated on the basis of vertebral level.

Few researchers have published compressive fatigue strength results for vertebrae. Studies on spinal motion segments have often been restricted to the behaviour of the intervertebral disc (Adams and Hutton, 1983; Liu et al., 1983) or have had limited sample sizes (Brown et al., 1957; Hardy et al., 1958; Liu et al., 1983). Hansson et al. (1987b) cyclically loaded lumbar motion segments to peak loads of 60% to 100% of the predicted ultimate strength based on the bone mineral content and suggested a relationship between the number of cycles to failure and the applied stress. Brinckmann et al. (1988) used peak compressive loads of 30% to 70% of the ultimate compressive

load and postulated that the former constituted an endurance limit. There are no published reports on the compressive fatigue strength of vertebral trabecular bone.

The application of load to the bone in contact with the support may stimulate bone growth in this region if the stress level is appropriate (Goldstein et al., 1991). However, if the stress is too great, necrosis of this tissue can occur. Therefore, the stress in this bone must be below the level of transition from growth to necrosis. Unfortunately, the stress level at which this transition occurs is uncertain as is this level relative to the estimated endurance limit. The design constraint should be that the stress in the bone is below these values.

8.4 Device Design

Mechanically operated devices were initially considered for the provision of anterior support for the vertebral body. Unfortunately, the mechanical concepts appeared extremely complicated to implant and/or unable to obtain adequate longitudinal extension while maintaining structural integrity. As an alternative, the concept of a support that used bone cement as the structural component was developed.

The design consists of a collapsible mould that is introduced transpedicularly into the fractured vertebral body, then filled with bone cement. The process of filling the mould causes a longitudinal expansion of the support within the body so that the support would contact the intact superior and inferior endplates of the adjacent intact vertebrae. Radial expansion is limited preventing impingement of the spinal cord and allowing space for bone graft material to be packed around the support.

8.4.1 Feasibility of the Use of Bone Cement

The physical properties of bone cement are fundamental to its success as the structural component of the anterior support. In particular, compression and fatigue strengths of cement are critical due to cyclical compressive nature of physiological loading. Adverse effects due to its implantation and its exothermic polymerization are also concerns. Therefore, a review of the properties of bone cement and their implications on the design is essential (Appendix F).

This review of physical properties of bone cement suggests its use as the structural component of an anterior support is feasible. For the purposes of the support design the compressive failure stress of the bone cement is assumed to be 56 MPa. This value was calculated from the ASTM (American Society for Testing and Materials) Standard of 70 MPa and the combined effect of relevant influences on the compressive strength of bone cement (-20%, Appendix F).

As the properties of bone cement are significantly affected by testing conditions its physical properties must be investigated under conditions resembling the *in-vivo* application. Of interest are the influences of cooling the monomer, centrifugation, pressurization and the addition of reinforcing material on the compressive strength of bone cement. Knowledge of maximum surface temperature, duration of elevated temperature, amount of irrigation required, and shrinkage rate in this application, will be necessary to ensure feasibility of the use of bone cement for vertebral support.

8.4.2 Diameter Required for Support of Physiological Loads

The device must be capable of carrying the total physiological load. On this basis the cross-sectional area that would be required to withstand this load was determined. Given the maximum compressive stress of 56 MPa and the estimated load at the thoracolumbar junction of 900 N (Section 7.1) a diameter of at least 4.5 mm is required to support physiological loads.

If the cyclic nature of physiological loading is taken into account, the endurance limit of bone cement must be used to estimate the required support size. Jaffe et al. (1974) suggested an endurance limit of 14-17 MPa (Appendix F). Using 14 MPa as the upper limit on the compressive stress, a minimum diameter of 9.0 mm would be required to ensure against fatigue failure of the bone cement.

The possibility of fracture of the bone in contact with the support is also a consideration in determining the required cross-sectional area of bone cement. If 2.5 MPa is used as the approximate mean compressive strength of the vertebral trabecular bone (Section 8.3.1.3) a minimum diameter of 21.4 mm is required to prevent compressive fracture of the bone. In addition, if the stress is kept below the suggested

endurance limit of 30% of the ultimate compressive stress suggested by Brinckmann et al. (1988) a minimum diameter of 39.1 mm would be necessary.

8.4.3 Collapsible Mould Designs

Several designs for a collapsible mould for the bone cement were investigated. A mixture of silicon diluted with toluene was used to make all mould prototypes. Early concepts such as a mechanical form and an inflatable bladder were unable to provide either adequate structural support or longitudinal expansion. However, tubing of uniform diameter with a double helix of inextensible fibres (dental floss) embedded within its wall (Figure 8.1) achieved significant longitudinal extension with limited radial expansion. The latter must be minimized to prevent retropulsing bone into the spinal canal. The double helix of inextensible fibres restricts radial expansion while allowing longitudinal expansion. The helical spacing of the reinforcement (Figure 8.1) defines how close successive wraps of the reinforcement are.

A cross-section of the design is shown in Figure 8.2. A number of components, endpieces, nozzle and nozzle-locking ring, are made from Delrin (Dupont Co.). The endpiece fits inside the tube and dental floss is tied around the tube's circumference to hold the endpiece in position. The v-groove at the circumferential edge of the endpieces

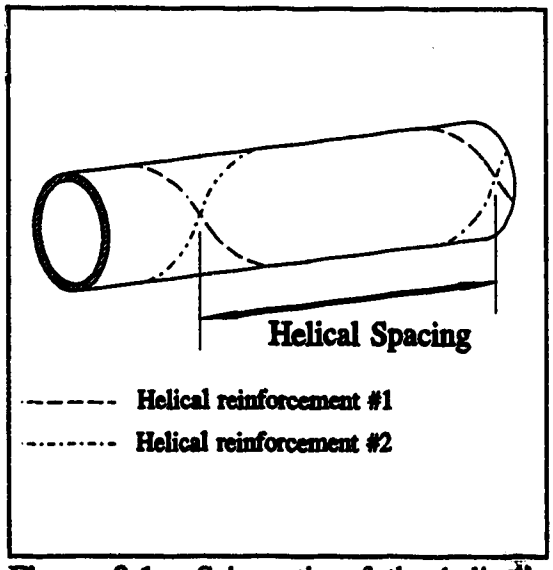

Figure 8.1: Schematic of the helically reinforced tubing showing the helical spacing.

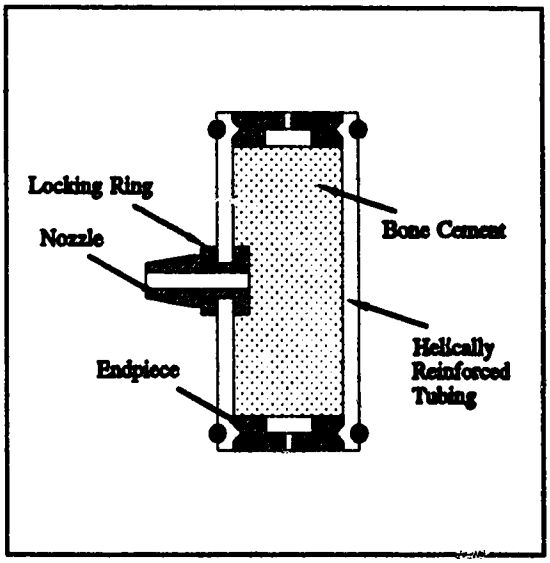

Figure 8.2: Cross-section through the filled anterior spinal support (not to scale).

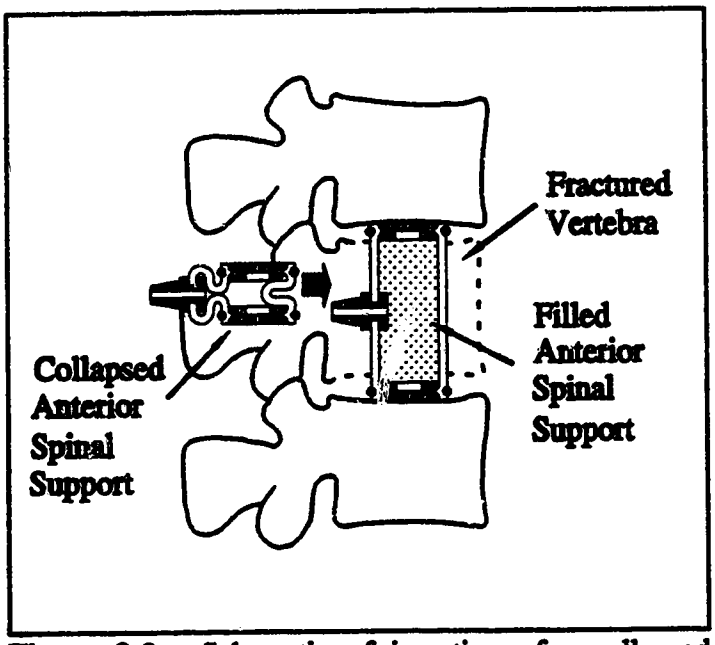

Figure 8.3: Schematic of insertion of a collapsed spinal support and location of filled support.

ensures seating of the dental floss. The nozzle was fitted through the support wall from the inside and was held in position by the locking ring as shown in Figure 8.2. The nozzle, which was required to ensure a good seal with the large-bore needle used to fill the support with bone cement, also served to prevent the tube wall from tearing at the insertion hole.

Prototype supports were made from tubing with an internal diameter of 12.7 mm and had a contracted size of 10 mm by 15 mm (Figure 8.3). Though this size of support did not meet the insertion space requirements it provided a prototype of realistic size for testing the feasibility of the design.

Helically reinforced tubing was produced on a wax mandrel with a steel core. The outer diameter of the wax equalled the desired internal diameter of the tubing. Then a series of layers of the mixture of silicon and toluene were applied until the wall thickness was half of the desired final thickness. With the mandrel mounted in a lathe, dental floss was wound onto it using the lead screw so that a uniform helix was obtained. Then, layers of silicon and toluene were applied until the desired outer diameter was achieved. The wax core was removed afterward by heating and residual wax removed by dissolving it in xylene.

8.4.4 Technique for Surgical Implantation

Details of the implantation procedure for the anterior support are dependent on the final support and insertion instrument design as well as experience gained from *in-vitro* implantation, however, the procedure must be considered in the design. The

proposed procedure was developed in consultation with orthopaedic surgeons. Initially, access to the vertebral body is obtained through the transpedicular approach. Selection of the appropriate surgical technique (Section 8.2) depends upon the vertebral level, size of the pedicle, nature of the injury and preference of the surgeon. Once the vertebral body is accessed, space must be made within it to enable insertion of the support. In the case of burst fractures with retropulsed fragments, this space will facilitate reduction of the fragments. The amount of space required within the body to install the support can only be accurately determined when trial installation procedures are attempted on porcine and cadaver spines. Bone removed from the vertebral body can be used later for either posterior or inter/intrabody bone grafts. Removal of a portion of the adjacent discs may be necessary to obtain solid contact with the intact endplates of adjacent vertebrae. Removal of this material may not be a concern as in fracture cases the adjacent discs may already be damaged and the posterior fusion of the injured vertebra to the adjacent vertebrae will make the disc nonfunctional. In addition, removal of a portion of the disc aids in obtaining an interbody bone graft as shown by Daniaux et al. (1991) to reduce the loss of correction.

The support can be inserted when space has been cleared within the vertebral body. A short length of stainless steel tubing is inserted into the nozzle of the anterior support and a stopcock is attached to the distal end of the tube. The support is held in the compressed position by locking forceps and then inserted into the vertebral body. The forceps are released and the support is manipulated into alignment with the stainless steel tube. Alignment of the support can be verified using fluoroscopy. The effect of misalignment or tipping of the support is difficult to assess before trial installation on cadaver spines is performed. However, the ability to expand and align the support before injection of the bone cement may be an asset.

Bone cement is first centrifuged to remove air bubbles. It is then injected into the support from a syringe or cement gun attached to the stopcock. After the support is filled the stopcock is closed so as to maintain pressure as the cement cures. Continuous irrigation of the support is necessary during curing to cool the cement. After curing the stainless steel tube can be removed or used as a rigid tether to the posterior fixation

device, if advantageous.

8.4.5 Removal of the Device

In the event of infection or other complication removal of the support must be possible. This could be carried out from an anterior approach.

8.5 *In-Vitro* Testing of the Transpedicularly Implanted Support

Tests were undertaken to verify the performance of the anterior spinal support. Tests were initially conducted to investigate the expansion characteristics of the helically reinforced tubing. Compression tests were performed on bone cement-filled supports to ensure that the support could carry physiological loads. Finally, supports were tested in a spinal fracture model to determine its efficacy at reducing the load on the posterior fixation device.

8.5.1 Expansion Tests

Expansion testing was undertaken to determine if helically reinforced tubing could obtain adequate longitudinal expansion with limited radial expansion.

8.5.1.1 Materials and Methods

The radial and longitudinal expansion of tubing of two internal diameters (12.7 mm and 18.1 mm) and two helical spacings (12.7 mm and 6.35 mm), pressurized with air, was determined.

8.5.1.2 Results

Tubing with closely-spaced reinforcement (helical spacing of 6.35 mm) had a maximum radial expansion of 1.4% and 3.1% for small and large diameter tubes, respectively. This compares with 8.6% and 5.8%, respectively, for widely-spaced reinforcement at the same pressure. Tests showed that the closely-spaced helix produced more longitudinal expansion than the widely-spaced helix regardless of tube diameter. At 2.4 psi the large diameter tubing with closely-spaced reinforcement achieved a

maximum longitudinal expansion of 33.3% compared to 23.5% for the widely-spaced reinforcement. The small diameter tubes were tested only at a lower maximum pressure (1.0 psi) and the difference between the percent longitudinal expansion for tubes with closely- and widely-spaced reinforcement was much smaller, 11.6% and 9.4%, respectively.

8.5.1.3 Discussion

Expansion tests of helically reinforced tubing showed that significant longitudinal expansion with limited radial expansion was possible. Comparing closely- versus widely-spaced helical reinforcement, shows that at the same pressure the former exhibited less radial and more longitudinal expansion. Although these tests confirmed the basic premise they did not provide information on the optimum geometry to achieve the maximum ratio of longitudinal to radial expansion. Variables that may influence the expansion ratio include wall thickness, internal diameter, helical spacing, as well as dimensions and properties of the reinforcing material. The latter may also affect the strength of the tube wall.

Tubing with closely-spaced helical reinforcement and the smaller internal diameter (12.7 mm) was used for design development and further *in-vitro* tests.

8.5.2 Compression Tests

The second phase of the *in-vitro* tests consisted of compression testing of the supports filled with bone cement. The compressive failure strength of the supports was compared with estimated physiological loads at the thoracolumbar junction. The failure strength was further compared with published results for the compressive failure stress of bone cement.

8.5.2.1 Materials and Methods

Helically reinforced silicon tubing with an internal diameter of 12.7 mm and helical spacing of 6.35 mm, with delryn endplates and nozzle, as described previously (Section 8.4.3), were assembled to form supports with overall length ranging from 20.0

to 40.5 mm. Initially, a number of supports were used to refine the filling and testing protocol. As the compression testing apparatus required parallel endplate surfaces, the filling protocol was adjusted such that the longitudinal expansion was restricted by two parallel surfaces. Fourteen tubes were filled with bone cement (Simplex P, RO; Howmedica International Ltd.) and cured from less than one day to seven days before testing. Compression testing of the tubes was carried out in a Universal Testing Machine (Instron Corp.) at a cross-head speed of 0.01 inches/minute until failure. This resulted in a mean strain rate of 1.46×10^{-4} sec^{-1}.

8.5.2.2 Results

The compressive strength of the spinal supports filled with bone cement ranged from 3560 to 8740 N with a mean of 6555 ± 1615 N. This is much greater than the estimated physiological load at the thoracolumbar junction.

A mean ultimate compressive stress, 54.1 ± 12.3 MPa, was determined with a range from 30.6 MPa to 67.5 MPa. No correlation was found between failure stress or failure load and filled- tube length, weight of cured bone cement used or curing time. Qualitatively, failure of the filled support appeared to be more related to the samples' porosity than the above factors.

8.5.2.3 Discussion

Compression testing of the cement-filled supports showed that they are capable of withstanding forces equivalent to or greater than predicted physiological loads. In addition, the mean failure stress (54.1 ± 12.3 MPa) was much greater than the estimated compressive failure strength of vertebral endplate and body (Section 8.3.1.3).

Comparing the mean ultimate compressive failure stress with reported values from the literature showed the experimental figure (54.1 ± 12.3 MPa) was approximately half that of published figures. Lee et al. (1978) and Robinson et al. (1981) reported ultimate compressive stresses of 89.2 ± 2.09 MPa and 113.149 ± 2.028 MPa, respectively, for similar experimental protocols. Differences are likely attributable to the mixing protocol, size of the specimen and strain rate, all factors that influence the compressive strength

of bone cement (Appendix F). In addition, estimation of the cross-sectional area of the cement within the support in the present study did not take into account voids, variation in outer diameter of the support and changes in the wall thickness due to expansion.

That the fracture load was qualitatively related to the porosity of the cement agrees with the results of compression testing by both Burke et al. (1984) and Carter et al. (1982). They found that failure of uncentrifuged cement samples occurred at voids within the cement. Though the presence of voids may be the major cause of failure, no control or quantification of the porosity of the cement was undertaken in the present study.

Factors that should be included in a more refined testing protocol are: control of the monomer temperature; centrifugation; pressurization; soaking the support in water at 37°C from filling to testing and testing at a set interval after mixing; the ASTM standard for bone cement (F451-86) suggests 24 ± 2 hours.

Several refinements to the support filling and testing protocols were developed during the initial phase of the testing program. In early tests a flat, delryn disc with a groove on the circumferential edge, was used as the support endpieces. During compression testing these supports failed prematurely due to slippage between the disc and bone cement. This was overcome by machining a recess on the interior surface of the endpieces. A further refinement to the endpiece was the addition of a small, 0.70 mm diameter, hole through its centre. This enabled air within the support to escape during filling so that large voids did not develop. However, some loss of cement occurred, but as the hole was small and the cement is viscous, this loss was minimal. Adequate longitudinal expansion was still achieved.

8.5.3 *In-Vitro* Testing of the Spinal Support

The ability of the anterior support to effect a reduction in the loading on posterior fixation devices is of prime concern. To determine its effectiveness, the loading on the posterior device was measured with and without the anterior support in a spinal segment with a fracture model. This required the development of transducers to monitor loading on the spinal fixation device (Appendix G).

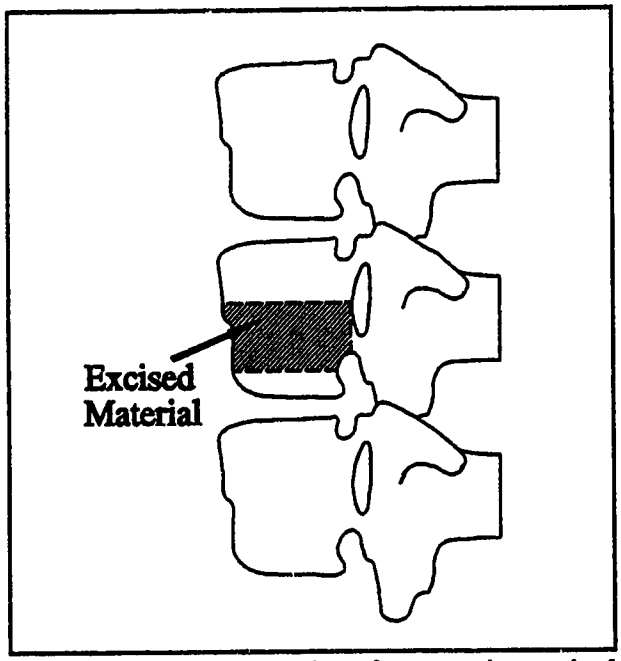

Figure 8.4: Schematic of a porcine spinal segment showing material removed to form a corpectomy fracture model.

8.5.3.1 Materials and Methods

To test the efficacy of the anterior spinal support four thoracic porcine spinal segments (T10 - T12) with a corpectomy fracture model were used. A lateral view of a typical porcine vertebra, Figure 8.4 shows the material removed to produce the fracture model. This reproducible model was chosen as it provides two parallel faces against which the support can obtain solid contact. Load transducers were mounted on 5.5 mm VSP Bone Screws (AcroMed Corp.) inserted into the pedicles of the intact superior and inferior vertebrae.

Four loading cycles of 5 Nm flexion were performed. The first three cycles were used to precondition the segment and the results of the fourth cycle used for analysis. This load level was based on the protocol of Russell (1988).

The instrumented spine was initially tested without the anterior support, the anterior support was then fitted and the spine retested at the same load (Figures 8.5 and 8.6, respectively). The support was filled with bone cement (Simplex P, RO) and allowed to set for a period of one to one and one-half hours before testing. This curing time was shorter than those used for published compression tests (Appendix F) and than that specified by the ASTM standard for acrylic bone cement (24$\pm$2 hours). This was necessary so the results with the spinal support could be compared to those before the device was installed. A longer delay could have introduced uncontrollable changes in the spinal segment such as drying of the specimen. In spite of this shorter curing time the cement had cooled and set before testing. Lee et al. (1978) reported that the ultimate compressive strength at 2 hours after mixing was approximately 85% of the maximum value for Simplex P (RO) indicating this as an acceptable curing period.

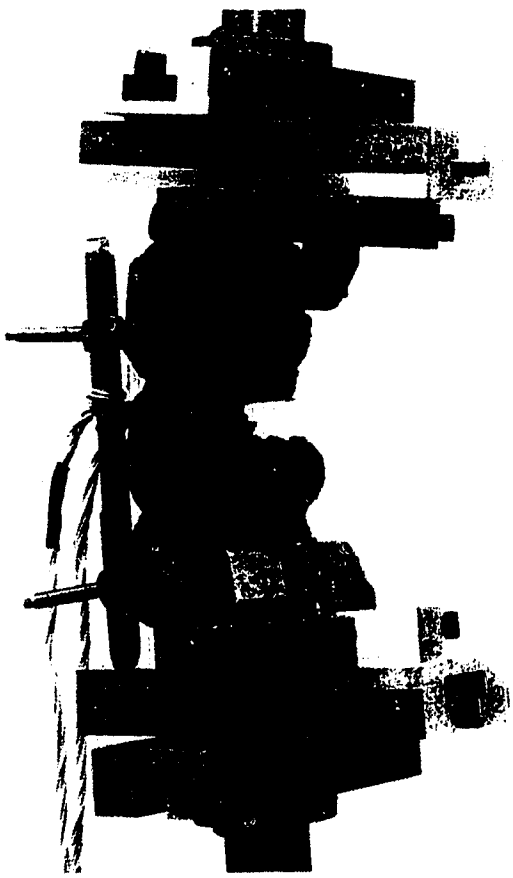

Figure 8.5: Instrumented spinal segment without the anterior support.

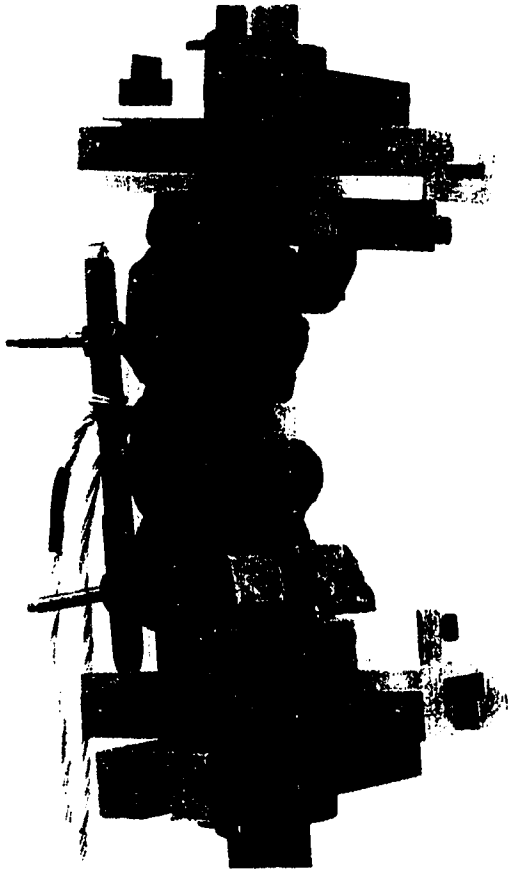

Figure 8.6: Instrumented spinal segment with the anterior support.

8.5.3.2 Results

The influence of the anterior spinal support on the loading of the fixation plates was studied at a flexion moment of five newton-metres. Figure 8.7 shows the mean moment ratio for the transducers with and without the anterior support. Table 8.3, which summarizes these data and gives the combined moment ratio, shows that the anterior spinal support reduces the combined moment ratio between 34.2% and 59.1% with a mean reduction of 45.7$\pm$12.3%. This reduction was significant ($p<0.001$) for each spine. When individual plates are compared the reduction in the moment ratio ranged from 18.4% to 67.4%. In addition, the difference in the moment ratio between the two plates decreased significantly with the addition of the anterior support (69.7% - 96.2%).

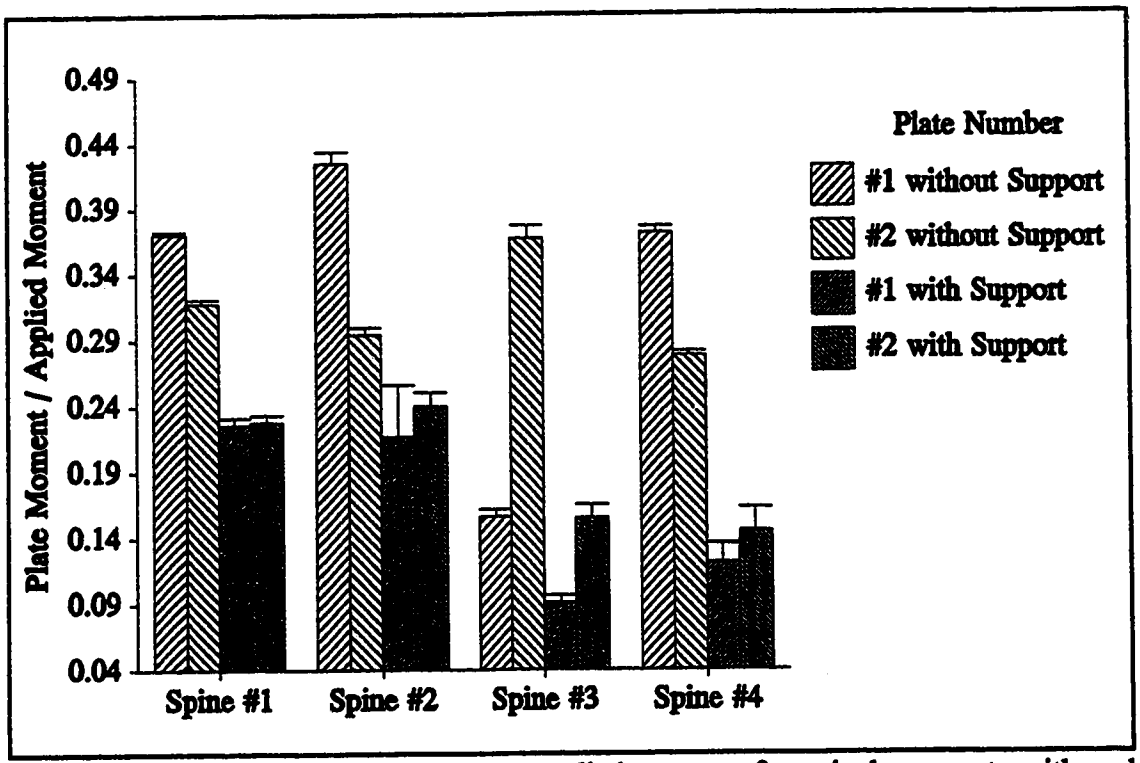

Figure 8.7: Ratio of plate moment to applied moment for spinal segments with and without the anterior spinal support over the fourth load cycle (mean±std.dev.).

8.5.3.3 Error Analysis

There are several possible sources of error in the *in-vitro* tests. Unfortunately, many of these are difficult to predict. Error due to bending of the plate was calculated to be approximately 0.5%. Theoretical analysis of the plate mechanics assumed that the angle between the plate and vertebral midline was constant. However, when mounted on a spinal segment this angle varies with level due to the variation in transverse pedicle angle with vertebral level (Section D.3.4) such that the plates are not aligned vertically. Also, the angle of each plate from the vertebral midline may differ at each instrumented level. These factors result in a more complex loading condition the effects of which are difficult to predict. In addition, there are errors in the estimated moment applied to the spinal segment. The moment arm was estimated to be the average of the inferior and superior distances from 10 mm anterior to the spinal canal to the centreline of the plates. As the applied moment was constant in all tests and the moment arm varied for each spine, the applied load varied. Thus, the stress in the transducer due to the axial load

Spine	without Anterior Spinal Support				with Anterior Spinal Support				Influence of the Anterior Spinal Support on Combined Moment Ratio (%)
	Applied Moment (Nm)	Plate #1 Moment Ratio	Plate #2 Moment Ratio	Combined Moment Ratio	Applied Moment (Nm)	Plate #1 Moment Ratio	Plate #2 Moment Ratio	Combined Moment Ratio	
1	4.95	0.371	0.318	0.345	5.01	0.226	0.228	0.227	-34.2
2	4.90	0.425	0.294	0.360	5.13	0.217	0.240	0.229	-36.4
3	4.93	0.156	0.367	0.262	4.92	0.091	0.155	0.123	-53.1
4	4.94	0.371	0.278	0.325	4.99	0.121	0.145	0.133	-59.1

Table 8.3: Influence of the Anterior Spinal Support on the plate moment ratio.

varied. Comparing the applied compressive load for the four tests showed a range in compressive stress of 0.7%. An additional source of error, fluctuation in the applied load, averaged approximately 6%.

8.5.3.4 Discussion

Implanting the anterior support resulted in a significant decrease in the combined moment ratio averaging 45.7±12.3%. This level of load reduction should effect a significant decrease in the possibility of failure of the posterior instrumentation and necrosis at the screw/bone interface.

The decrease in the difference in moment ratio between the two plates (80.6±11.6%) implies that addition of the anterior support results in a more equal distribution of the load between the plates. This may be significant clinically as failure of the fixation device may occur in cases where inequality in load distribution between the plates results in critically high stresses in one of the two posterior devices. This finding may underlie the advantage of using the posterior fixation combined with an anterior strut graft or instrumentation.

Upon completion of each test the support was found to be relatively loose within the fracture model. This may have been due to shortening of the support due to shrinkage or compression of the bone cement, slight closing of the fracture before fitting of the support or compression of the bone in contact with the support. Regardless of the cause, this finding implies that the percent reduction in moment ratio due to installation of the support was decreased. No damage to the bone from contact with the support was apparent.

As physiological loads are higher than those used in these tests, *in-vivo* effectiveness of the support would be expected to be greater than determined experimentally.

8.6 Further Considerations for Design Development

In-vitro testing of the helically reinforced tubing and the anterior supports show the design to be viable. However, further refinement of the anterior support is required.

The particular silicon elastomer used initially to make the design prototypes is not biocompatible. Therefore, a material is required that has the necessary properties and is biocompatible. Silastic MDC-4-421 Medical Grade Elastomer (Dow Corning Corp.) is a biocompatible silicon rubber that appears suitable for this application. Initial testing of this elastomer to make the tubing by the present production technique was attempted and gave promising results. However, even diluted to the maximum level, 10% by weight with 360 Medical Fluid (Dow Corning Corp.), it was still more viscous than the mixture used to make the prototypes and production of a tube with constant wall thickness was difficult. Further experience with this product, in particular to determine the effects of further dilution on its mechanical strength, is necessary. Ability of the elastomer to resist puncture and tearing must be evaluated. In addition, testing to determine if the elastomer and bone cement are compatible must also be undertaken. Further development of the elastomer tubing and its production technique could possibly be carried out in collaboration with suppliers of this product.

Biocompatibility of the material used for helical reinforcement must also be evaluated. Use of suture material may be a possibility as it is biocompatible and is readily available. Other possible materials that are biocompatible include carbon or Kevlar (aramid) fibres. These may be preferable due to their very high tensile strengths. Use of a material that is radiopaque would assist in visualizing the alignment of the support during and after insertion.

For purposes of design development and *in-vitro* testing Delrin, though not biocompatible, was used to make the endpieces and nozzle. Ultra-high molecular weight polyethylene as used in replacement hips may be suitable. Choice of a non-plastic material, such as stainless steel, may enable improvements to the nozzle and endpiece designs and facilitate making smaller-sized components. This could lead to a decrease in size of the contracted support and make it feasible to insert short length supports for cases where only a portion of the vertebra is to be removed.

The present endpiece has a flat contact surface. Better contact with vertebral endplates may be possible by surface serrations on the endplates or a porous-coated contact surface. The latter may be advantageous as it would allow bony ingrowth into

the endpieces to help prevent movement of the support. However, this may be simultaneously achieved by the bone graft surrounding the support making the porous coating unnecessary. A further modification to the present endpieces may be the method of attachment to the tubing. Use of a stiff, biocompatible o-ring or perhaps a stainless steel loop may be preferable for maintaining a tight seal.

The optimal tube diameter should be investigated further. The diameter is governed by the insertion size and by the expansion characteristics of the tubing. As insertion size limits the maximum possible size of the support, its accurate determination is imperative to selecting the optimal tube diameter. Knowing the expansion characteristics of the tubing would assist in determining how the support design will compensate for differences in applied loading resulting from differing degrees of spinal instability.

Depending on the degree of instability the load carried by the support may vary. This variation may be accommodated by having a range of diameters available with larger diameter supports implanted in cases of greater instability. If only one diameter of support is available, the variation could be accommodated by implanting several supports when necessary. The expansion characteristics of the tubing may be a factor in deciding which alternative is preferable. Further testing to determine the relationship between expansion ratio and both tube diameter and helical spacing will be necessary.

Another consideration is the form in which the supports will be available to the surgeon. One possibility is to have supports of preset lengths assembled in the factory. Another is to have the supports custom-made for each patient. Size of the former would be based upon the distance between the endplates of adjacent intact vertebrae (Section 8.3.1.1). Custom-made supports could entail the surgeon determining the length required from a lateral radiograph and choosing the appropriate tube length based on conversion tables that accommodate for the longitudinal expansion. Whether the support is custom-made or pre-assembled will impact on considerations such as how the endpieces and tubing are attached. It may be necessary to have the supports available in both forms to satisfy the preference of the surgeon.

A means by which the support could be expanded and aligned *in-situ* before the

bone cement is injected would be an asset. This would ensure that the support could not be irrevocably misaligned when filled with cement. Pressurization with saline or a spring within the support are possibilities. If the support was radiopacque it would permit visualization of its alignment before filling.

A further design consideration is whether or not the support should be connected to the posterior instrumentation and the form, either rigid or flexible, of such a connection. Lack of such a connection may result in migration of the support. However, a rigid tether that attaches to one of the bars of the posterior device may not be advisable. If a screw a broke the bar may lift away from the posterior bony surface and draw the support back into the spinal canal.

Finally, special surgical instruments for implantation of the support will be required. These may include special rongeurs for clearing space in the body and for excising the discs through the transpedicular approach. The latter is required to improve seating of the support. A sleeve through which the device is inserted would provide protection to the adjacent anatomy. Instruments to hold the collapsed support for insertion and then for its manipulation once in the vertebral body are also required. Instruments to facilitate injecting bone cement into the supports must also be available. These may incorporate a cement gun for pressurization of the cement. Development of such instruments should be in cooperation with a reputable instrument manufacturer.

8.7 Recommendations for Further Testing

Though results from these preliminary tests have been promising, further testing is required. As indicated above, testing of the expansion characteristics of helically reinforced tubing is necessary. The use of bone cement for the structural component of the support also requires further evaluation. The amount of shrinkage and heat generated in this application must be determined. Use of low viscosity cement should be considered as this will facilitate injection of the cement and prolong the setting time. Compression and fatigue testing of the cement-filled supports under *in-situ* conditions is necessary. The latter should be performed to ensure that the supports will not fail prior to fusion of the bone grafts.

Compression testing of the support against an intact vertebral body is also necessary in order to determine if damage to the endplate or trabecular bone will occur under physiological loads. Data gained from compressive fatigue testing of vertebral trabecular bone would be valuable for the above application. Static and cyclic testing to determine if the trabecular bone strength varies with vertebral level may also be of use. This basic data is not available at this time.

Further testing of the support in a spinal fracture model should be performed to determine variation in support effectiveness with load level, behaviour of the support at high strain rates, influence of cross-bracing between the posterior bars on the support's efficacy and the effectiveness of the support under other loading regimens. To accomplish the latter tests, the transducers must be recalibrated for the desired loading. However, the anterior support may have minimal effect in torsion and extension, though it should effect changes in the response of the fixation devices to lateral bending loads. Of interest is the relationship between the moment ratio and the applied load. Due to the viscoelastic nature of the specimen a nonlinear relation is expected. The performance of the support in other fracture models should also be investigated. *In-vitro* experimentation incorporating both the anterior and posterior devices and various configurations of the connection between them may provide information on the optimum form of such a connection.

When the final design of the support has been determined implantation in porcine spines or cadavers should be undertaken to elucidate the installation procedure and to ensure that implantation does not cause the detrimental displacement of bone fragments. *In-vivo* testing in an animal model should be performed to ensure that the procedure can be undertaken without complication and to compare loss-of-correction with and without the anterior support.

Chapter 9: Conclusions and Recommendations for Further Testing

From this study of posterior fixation instrumentation a number of conclusions can be drawn. Techniques for fracture fixation were reviewed and pedicle screw instrumentation has the most potential for achieving a successful outcome. However, evaluation of current pedicle screw instrumentation showed several deficiencies. Many are difficult to install and the incidence of mechanical complications is high. Many devices cannot accommodate normal variation in vertebral morphology without intentional or accidental plastic deformation of the device. Installation can also result in the application of undesirable forces that adversely affect the alignment of the vertebrae. A further difficulty with some devices is the inability to achieve direct reduction of the fracture.

A retrospective study on the Variable Screw Plate system was conducted to supplement published reports. A high incidence of mechanical complications occurred in the treatment of spinal fractures with this device. Such complications were found to significantly increase the loss-of-correction which, in turn, was related to the incidence of late pain.

Constraints on the design of a pedicle screw fixation device were developed based upon objectives that the device must fullfill. Published data on vertebral morphology were reviewed to compile constraints on several dimensions of the prototype device. The device should be capable of accommodating a relative difference in pedicle screw orientation of approximately 60°. A range of pedicle screws should be available in embedded lengths from 4.0 mm to 8.0 mm and in maximum diameters from 15 mm to 55 mm. Current devices do not supply this broad a range of screws. Constraints on several dimensions can not be determined due to lack of data.

The prototype device has several advantages over existing instrumentation. The design of the screw/rod junction ensures that differences in pedicle screw alignment can be accommodated without intentional or accidental plastic deformation of the device. This feature eases installation and ensures that the operative alignment is not adversely affected when tightening the components. As the screw/rod junction is independent of the configuration of the central bar the device can be custom-made to provide the

appropriate level of stability. This feature also makes the device adaptable to different traumatic and pathologic conditions. The screw/rod junction can accommodate a 40° difference in screw orientation. Additional angulation can be accommodated using prebent rods. The beneficial features of the prototype device suggest that further development is warranted.

Finite element modelling of the fixation device showed high stresses at the junction of the spherical contact surface and distal shaft of the pedicle screw. However, the stresses were less than those estimated for a current device. Increasing the fillet diameter and reducing the constrained area of the spherical surface of the pedicle screw should reduce the stress in this region. High stresses in the conical sleeves may not be critical to the performance of the component.

To address inherent problems of posterior fixation resulting from support of a large bending moment in severely unstable fractures, an anterior support was developed to supplement the posterior device. This support is implanted transpedicularly during the posterior procedure and serves to reduce both the device loading and the asymmetry in loading between the two fixation devices. This asymmetry in loading may otherwise result in critically high stresses in one of the pair of devices. The support, an inflatable mould that is implanted then filled with bone cement, can easily support physiological loads once filled. The mould is composed, in part, of helically-reinforced tubing that was developed for this application. *In-vitro* tests determined that the anterior support significantly reduced loading of the posterior device ($43.6 \pm 15.6\%$) and the asymmetry in loading between the devices. These results suggest that further development of the anterior support is warranted.

9.1 Recommendations for Further Testing

Numerous recommendations for further studies to address specific needs have been presented previously (Sections 6.5, 7.5, 8.7, B.5, C.4 and D.5). However, there are several additional studies that could provide important general information regarding spinal fracture fixation.

9.1.1 Time Dependent Behaviour

Important to the study of spinal fixation is information on the load imposed on the fixation device and the time dependence of this loading. An *in-vitro* study to determine the ratio of the load carried by the spinal segment to that carried by the fixation device would be informative. The latter can be obtained using the transducers described in Appendix G. Data on the creep compliance of the spinal segment is necessary to determine the time dependence of the ratio of the loads. Spinal segments, comprising three vertebrae, with and without a fracture model could be used. Evaluation of several fracture models would provide valuable information on how the model affects *in-vitro* tests. This testing could be extended to include cyclic creep.

9.1.2 Influence of Spinal Stability on Device Loading

The influence of fracture stability on the load carried by the fixation device is of interest. This may be determined by measuring the load on a fixation device mounted on a spinal segment during progressive removal of various vertebral structures. Load carried by the fixation device could be measured using load transducers described in Appendix G. Correlating the intact vertebral structures with the fracture classification of Denis (1983) would provide an estimate of the loading on the device and the level of support required to stabilize various fracture types. This could provide the surgeon with an indication of the level of stiffness required to stabilize a specific fracture type. Production of custom-made devices would facilitate provision of a device that matches the predicted stability requirements.

9.1.3 Theoretical Construct Stiffness

Calculation of the flexibility of current fixation devices would determine their capacity to support physiological loads without excessive motion at the fracture site. Several different geometries should be considered. One possible configuration would feature pedicle screws mounted parallel to the vertebral centreline. A second condition would evaluate superior and inferior pedicle screws offset from the centreline at equal angles. Both cases are simplifications as differences in the pedicle screw orientation will

exist due to variation in the transverse pedicle angle with vertebral level (Section D.3.4). A more realistic condition would consist of the superior screws mounted at one angle from the vertebral midline with the inferior screws inserted at a different angle. Placement of all screws at unequal angles and solution of the above conditions incorporating bent plates are further cases that should be considered, and may require numerical techniques. The flexibility of VSP instrumentation for the two preliminary cases have been reported by Carson et al. (1990). Fixation of three and four vertebral levels should also be considered.

9.1.4 *In-Vitro* Testing of Fixation Device Flexibility

In-vitro testing to confirm calculations of the theoretical flexibility of various devices should also be conducted. The results of such tests can be compared with previous reports of instrumentation flexibility (Carson et al., 1990; Dick et al., 1985b). The influence of cross-linking on the flexibility should be examined. Such testing should also evaluate the prototype device.

The load transducers described in Appendix G could be included in this testing program to determine how the load in the fixation device varies with the configuration of the construct. This information will assist in determining the origin of the asymmetry in device loading that was observed in the *in-vitro* tests on the anterior support (Sections 8.5.3.2 and 8.5.3.4).

9.1.5 Measurement of Kyphosis Angle on Post-Operative Flexion/Extension Radiographs

Comparison of early post-operative flexion and extension radiographs may be used to estimate the *in-vivo* loading on the fixation device. Change in the kyphosis angle between the two positions is due, in part, to elastic deformation of the fixation device. This deformation may be correlated to the applied load by *in-vitro* measurements of the flexibility of the fixation device.

Knowing the load carried by the fixation device from the change in kyphosis

angle, the percent of the total spinal load carried by the instrumentation may be estimated. The total spinal loading can be determined by biomechanical modelling or intradiscal pressure measurements (Section 3.4). The percent of the total spinal loading carried by the fixation device, therefore, will be the ratio of implant loading from measurement of the kyphosis angle to the estimated total spinal loading. If flexion and extension radiographs are not available use of radiographs of the patient lying, sitting and standing may be an alternative.

9.1.6 Comparison of Fracture Models

Several different techniques have been used to produce a fracture model in a spinal segment for *in-vitro* testing. The stability of the resulting segment can differ significantly between the models. The influence of such differences between the models on the stiffness of the instrumented spine have been compared (Ferguson et al., 1988; Jacobs et al., 1982; Mann et al., 1990; Nagel et al., 1981). However, these studies have not investigated differences in the load applied to the fixation device from the use of different models. This may provide a means by which the effect of fracture models can be compared. Spinal segments, comprising three vertebrae, with various fracture models could be used. Load on the fixation device could be determined using the transducers described in Appendix G. Fracture models that should be considered for the test program include the wedge defect model (Evenson, 1988), a corpectomy model (Section 8.5.3.1), an extensive corpectomy model (Ashman et al., 1989; Gurr et al., 1988b) as well as a total vertebrectomy.

9.1.7 *In-Vivo* Loading on a Fixation Device

The ability to monitor *in-vivo* loading on an internal fixation device would have numerous applications including studying the influence of implant rigidity on stress-shielding. It could also be valuable in determining how the device loading changes with time and for *in-vivo* studies on pedicle screws described in Section C.5. Monitoring of *in-vivo* loading of implants used for scoliosis correction has been conducted by several

researchers using dogs (Shapiro et al., 1978) and humans (Elfström and Nachemson, 1973; Waugh, 1966). Schläpfer et al. (1989) has measured *in-vivo* loads on a fixation device in thoracolumbar spinal fracture cases by using load transducers mounted on an External Spinal Skeletal Fixation system (Magerl, 1984). There have been no published reports of *in-vivo* measurement of the loads on a vertebral fracture fixation device in an animal model. Use of an external fixator to monitor *in-vivo* loading on a device as described by Schläpfer et al. (1989) may not be feasible in an animal model.

9.1.8 *In-Vivo* Study of Implant Induced Stress-Shielding

Further study of stress-shielding in the fixed vertebrae appears warranted. The effect of removal of the implant on bone porosity has not been considered in previous studies. With removal of the fixation device an increase in bone density may occur in response to the increased stress in the bone. The influence of device stiffness on the bone density should also be investigated. Use of the prototype fixation device may facilitate this study as a range of implant rigidities can easily be produced by using central rods of different diameters.

In this study the telemetric device described above (Section 9.1.7) could be used to estimate the loading on the fixation device. In addition to the fused segments, the bone density of the superior and inferior uninstrumented vertebrae should be analyzed. The adjacent facet joints should also be examined to determine if the stiffness of the implant has any affect on these structures.

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Glossary of Medical Terms

anterior	- the front of a structure or part facing the front
anteroposterior (A-P)	- from the front to the back of the body
caudal	- a position more toward the tail than some point of reference
cephalad	- a position more toward the head than some point of reference
collagen	- a main supportive protein of skin, tendon, bone and ligament
decompression	- relief of pressure on the spinal cord by means of surgery
distraction	- straightening the spinal column by application of axial tension on joint surfaces
extension	- the movement by which two ends of any joint are drawn away from each other
flexion	- the act of bending or condition of being bent
inferior	- in reference to the lower surface of a structure
in-vitro	- in an artificial environment
in-vivo	- within the living body
kyphosis	- abnormally increased convexity in the curvature of the thoracic spine from a lateral view
kyphotic	- affected with or pertaining to kyphosis
laminectomy	- excision of the posterior arch of a vertebra
lateral	- refering to a position farther from the median plane of the body or structure
lordosis	- the anterior concavity of the lumbar spine from a lateral view
lordotic	- pertaining to or characterized by lordosis
medial	- refering to a position closer to the median plane of the body or structure

osteoarthritis	- degenerative joint disease
osteoporosis	- abnormal rarefaction of the bone
necrosis	- death of tissue, usually in localized areas
posterior	- the back of a structure or part facing the back
process	- a projection or outgrowth of bone
pseudoarthrosis	- in the context of spinal fracture treatment a case in which fusion has not occurred and there is excessive motion at the fracture site
reduction	- to restore to the normal position
scoliosis	- a lateral deviation in the normally vertical line of the spine
superior	- situated above or higher, or directed upward
synovial joint	- a joint in which the bone surfaces are covered by cartilage and connected by ligaments lined with synovial membrane
transcutaneous	- through the skin
transpedicular	- through the pedicle

Appendix A: Review of the Clinical Performance of Existing Pedicle Screw Fixation Systems

The performance of currently available pedicle screw fixation devices for treatment of spinal fracture cases was assessed by reviewing published retrospective studies. The devices are separated into two groups on the basis of whether or not contact with the posterior surfaces of the vertebrae is required to achieve stability. Devices which have been the subject of several published reports are described separately.

A.1 Fixation Devices Requiring Bone Contact

The simplest spinal fixation devices are those that rely on direct bone contact for structural support. There are numerous types available, but most are plates that are screwed against the posterior surface of the vertebrae.

A.1.1 Interpeduncular Segmental Fixation (ISF)

The Interpeduncular Segmental Fixation (ISF) system was developed by Luque (1987). Originally, this system consisted of a stainless steel rod wired to pedicle screws (Luque, 1986), then a plate with a single slot to accommodate the screws was developed. To ensure that the slot does not widen, resulting in loss of contact between the screw and plate, metal bands are fitted around the plate. Cannulated pedicle screws (screws with a central bore) are used as the placement of the screw is determined by first inserting a short, stiff wire (K-wire) over which the thread tap and pedicle screw are inserted. Differences in the pedicle screw orientation are accommodated to a limited extent by bending the plate and by pivoting the screw in concave hollows on the upper surface of the plate.

Several problems are inherent in the use of the ISF system for treatment of spinal fractures. Insertion of the thread tap and pedicle screw over the K-wire poses a potential danger to adjacent vessels from accidental displacement of the K-wire. While this system can accommodate substantial screw orientation differences in the sagittal plane, its capacity to accommodate differences in the transverse plane is limited. In this plane the

pedicle screw can only be angled to a maximum of approximately 15°. The concave hollows in which the screws are set are 10 mm, centre-to-centre, and thus limit the plates ability to accommodate differences in inter-pedicular spacing. Fatigue strength of the pedicle screws which may be compromised by the central hole, has not been reported.

Retrospective studies on the use of the ISF system are available from two centres. In the most recent publication by the developer of the system (Luque, 1990), 47 fracture cases were reviewed. Cases that had supplemental anterior grafting or instrumentation (14 patients) had no loss of correction or implant failures. Those without the supplemental procedure (33 patients) had a mean loss-of-correction of 20% (range: 0% to 100%) and two implants failed, though the nature of the failure was not reported. In an earlier study in which all surgical indications were combined, a screw breakage rate of 1.2% (Luque and Rapp, 1988) was reported. Luque (1987) reported that all the screws loosened after two weeks, which resulted in some loss-of-correction. The cause of this loosening was not described. In a study of 52 cases treated with the ISF that included only two fracture cases, Trammel et al. (1990) reported three screws had backed out and one had broken during surgery. During the follow-up period there were no plate or screw breakages.

A.1.2 Roy-Camille Plates

Roy-Camille plates were the first pedicle screw fixation device and have been used since 1961 for treatment of spinal fracture cases . They are made of vitallium, a cobalt-chrome alloy, and at present time are the only spinal fixation device made of this alloy. The plates are contoured to fit the spinal curvature and are available in a range of lengths. The screws used in this system are the smallest diameter pedicle screws available.

There are a number of short comings to the Roy-Camille plates. Fixation of two vertebrae above and below the fractured level are required for adequate stabilization. To preserve mobility in these additional fixed levels, posterior fusion to supplement the plates was not recommended (Roy-Camille et al., 1986a,b). To improve stability, Roy-Camille et al. (1986a,b) recommended insertion of additional screws into the pedicles of

the fractured vertebrae and supplementary screws into the articular processes when possible. However, Kinnard et al. (1986) did not follow the latter recommendation suggesting that stability was adequate without them and that they were a potential source of pain after the plates were removed. Shorter length plates to span only the superior and inferior adjacent vertebrae, often combined with posterior fusion, have been used. Shorter length fixations may not provide adequate stability as Lesoin et al. (1986) reported that five of eleven cases with the shorter length fixations that did not have screws in the pedicles of the injured vertebra lost correction. A further difficulty with this system is that the centre-to-centre distance between holes in the plates is preset (13 mm) and thus can accommodate little variability in inter-pedicle spacing. This system also has limited ability to accommodate misalignment in the orientation of the pedicle screws. Misalignment can be accommodated only by pivoting of the pedicle screw within the hole of the plate and by the curvature of the plates.

Few retrospective studies have been published on the use of Roy-Camille plates for treatment of spinal fractures and those available do not present a thorough analysis of the data (Lesoin et al., 1986; Reynier et al., 1989; Roy-Camille et al., 1986a,b). A high incidence of failure of the distal pedicle screws has been reported. In a review of 21 trauma cases Kinnard et al. (1986) reported that five patients (23.8%) had broken screws. Twenty five of the 115 fracture cases (21.7%) reviewed by Roy-Camille et al. (1986b) had broken screws. Roy-Camille et al. (1986a,b) suggested that these screw failures were only an indication that spinal mobility had been recovered. However, Benazet et al. (1989) and Kinnard et al. (1986) reported that some loss-of-correction occurred with screw failure. Roy-Camille et al. (1986b) reported that there were no cases of plate breakage.

Limited loss-of-correction has been reported with the use of Roy-Camille instrumentation. Benazet et al. (1989) reported very limited mean loss of both vertebral and local kyphosis, though secondary kyphosis was reported in two cases with broken screws. Roy-Camille et al. (1986b) reported that in 115 patients with long-term follow-up the vertebral kyphosis was unchanged in 42 cases and the mean loss in the remainder was three degrees. The capacity of the plates to restrict the loss-of-correction reported

by the above authors was not confirmed by Kinnard et al. (1986) as five of their 21 patients lost ten to twelve degrees of correction. Reports of Roy-Camille et al. (1986a,b) and Benazet et al. (1989) indicating little loss-of-correction may be due to either inadequate correction during surgery or the lack of thorough analysis in the published studies. None of the published retrospective reports discuss the occurrence of pseudoarthrosis with this instrumentation.

A.1.3 Miscellaneous Direct Contact Devices

The Balgrist Transpedicular Fixation Device was described by Suezawa and Jacob (1986) and consists of a threaded rod that has opposing threads on the upper and lower halves of the rod that form a turnbuckle. Bosses to hold the pedicle screws are threaded over this rod. Unfortunately, this device has limited capacity to accommodate differences between the orientation of the pedicle screws. The bosses are available in three angles (0°, 15° and 30°) in the longitudinal plane of the rod, though additional small misalignments can be accommodated as the screws pivot slightly within the bosses.

A single published report on the Balgrist device (Suezawa and Jacob, 1986) described its use in 66 patients for treatment of spondylothesis, spinal stenosis and herniated discs. However, no fracture cases were included in the series and mechanical complications were not reported.

A number of bone plates have been applied for fixation of spinal fractures. Use of the Dynamic Compression (DC) plate, developed for fixation of tibial fractures, combined with 6.5 mm cancellous bone screws has been used for treatment of spinal fractures and is described by a number of researchers. This plate has ovoid holes that provide variability in the screw-to-screw distance. The plate is less rigid than that of the Variable Screw Placement (VSP) system and has also been used for anterior fixation of spinal fractures (Aebi et al., 1986). Sasso et al. (1991) reviewed 23 trauma cases treated with the DC plate. Breakage of both plates occurred in one patient who also developed a pseudoarthrosis. Only a single screw failure was reported (0.8%). There was a significant mean loss-of-correction postoperatively such that at three and six months the sagittal angle was not significantly different from the preoperative values.

A higher incidence of mechanical complications has been reported with use of the DC plate for fusion of the lumbar spine than for indications other than trauma. In non-trauma cases Thalgott et al. (1991) reported that in their series of 45 cases four patients had broken screws (8.9%) and one patient had a broken plate (2.2%). An earlier report by the same group (Thalgott et al., 1989) also reported five cases in which screws had loosened.

Daniaux et al. (1991) described the use of bone plates (either DC or 'notched' plates) for fixation of spinal fractures with either 'angle-stable' or regular screw systems. In the 'angle-stable' system the head of the pedicle screw is fastened to a threaded rod to provide more resistance to forces that cause loss-of-correction. In the regular system the screws were held in position by tightening against the plate. These two plate constructs were compared with and without transpedicular grafting performed either by intrabody or inter- and intrabody grafting. Without transpedicular bone grafting screw breakage rates of 11% and 41%, respectively, were determined for the regular and angle-stable system. With transpedicular grafting the rate for the latter system was reduced to 19%. No value was given for the regular system with the supplemental grafting. The authors indicated that design changes to the screws had been initiated to overcome the high failure rate. No plate breakage was reported.

With the addition of intrabody grafting the mean loss-of-correction within the vertebral body decreased by 6°. When inter- and intrabody grafting were used the above decrease was combined with a decrease in the loss-of-correction within the disk space of 3°. In this series eleven of the 172 patients with a minimum of one year follow-up were reported to have lost a large portion of the correction (20° - 29°), though the grafting technique used in the eleven patients was not detailed. No pseudoarthroses occurred in this series. Blauth et al. (1987) also reported on the use of the notched plate for spinal fixation, but combined the results for surgery with other fixation systems.

Several additional groups of researchers have reported on the use of other types of plates for spinal fixation. Bhojraj and Archik (1991) described the use of a custom-made plate in 20 cases including three fractures. No breakage of either the implant or screws occurred, though there was one case with a loosened screw. Herrmann (1979)

described the use of yet another type of bone plate in nine patients for stabilization of fractures; however, complications and results were not discussed.

A.2 Devices Not Requiring Bone/Plate Contact

There are a number of currently available pedicle screw fixation devices that do not rely on contact between the vertical member and the posterior surface of the vertebrae but rather require a solid junction between the rod and screw to maintain the operative correction.

A.2.1 Cotrel-Dubousset

The Cotrel-Dubousset (C-D) system was developed for correction of scoliosis by Cotrel and Dubousset (1984). The system is versatile using either sublaminar hooks or pedicle screws for attachment to the vertebrae. These are attached to the knurled rod by tightening small locking screws in the hooks and screws. As the connection between the hook or screw and rod must be at 90°, the knurled rod has to be contoured to accommodate misalignment between the pedicle screws. A number of accessories are available including crosslinks which have been shown to significantly increase the rigidity of the construct (Carson et al., 1990; Johnston et al., 1986). As the screws can be fastened to the knurled rod at any position along its length, this system can accommodate variations in the inter-pedicular distance. The system can be used in the cervical spine in addition to the thoracic and lumbar regions as the rods are available in two diameters. In addition, this system has been used for anterior fixation of spinal fractures (Hirabayashi et al., 1991).

There are a number of problems inherent in the C-D system. Contouring the rod and aligning the screws can make fixation of multiple levels difficult with a single rod. The consequent excessive manipulation can lead to screw loosening (Hirabayashi et al., 1991). Hall et al. (1986) reported a number of design problems including suboptimal shape of the hook holders, mediocre quality of the rod holders and flaws in the design of the hooks that lead to frequent shearing of the fixation nuts. In addition, there is some question as to the ability of the locking screws to maintain a solid connection between

the pedicle screw and knurled rod. Edwards and Levine (1989), referring to previous work by Kahn, stated that when the instrumentation was removed over 20% of the locking screws had loosened. Finally, the system is very expensive.

Several retrospective studies have been published on the use of the C-D instrumentation for treatment of spinal fractures. Often the results of other surgical interventions are included with those of spinal fractures and the results of cases in which screws and/or hooks were used are combined. In their study of C-D and VSP instrumentation in which the results of all surgical indications were combined McAfee et al. (1991a) reported bending of six C-D screws (3.4%). Unfortunately, they neglected to separate the reported screw breakage on the basis of the screw type (C-D or VSP) and combined the results for all surgical indications. Gurr and McAfee (1988a) reported that one of the seven fracture cases had a bent screw and further, that the pedicle screw had been redesigned and that larger screws had become available. Moreland et al. (1990) in a study of 15 fracture cases treated using the C-D system reported the breakage of two 5 mm screws in one patient. However, they neglected to specify how many of the cases had been treated with screws and the level of the injured vertebrae as fractures in the cervical and upper thoracic regions were also treated. For example, the screws that broke had been used in treatment of a fracture in the cervical spine. Moreland et al. (1990) indicated that larger screws (6 mm) were now being used and that up to the time of publication no failures had occurred. However, they neglected to specify the number used and the length of follow-up. Rousseau and Loisel (1990) used both 5 and 6 mm screws and reported breakage of one of the smaller screws in their study of ten cases. They suggested that the potential for reduction of the fracture was less and the loss-of-correction greater, for cases treated using the smaller screws. They were the only researchers to discuss loss-of-correction in trauma patients treated with pedicle screws stating that there had been some loss at six months. Use of the pedicle screws has resulted in fusion of fewer levels compared to when sublaminar hooks are used (Argenson et al., 1990).

Several authors have reported complications with the use of the C-D system with sublaminar hooks for the treatment of spinal fractures. These have included hook

dislodgement, pseudoarthroses and loss-of-correction. Akbarnia et al. (1990) and Ostermann et al. (1990) reported hook dislodgement in 5.9% and 2.7%, respectively, of the cases treated with this system. Pseudoarthroses were reported by Baynham et al. (1990) and Ostermann et al. (1990) with rates of 6.9% and 2.0%, respectively. In addition, Baynham et al. (1990) reported that in four patients there were five lamina fractures following surgery. Four of these fractures resulted in complete loss-of-correction and necessitated repeat implantation. However, Farcy and Weidenbaum (1988) and McBride (1989) reported no hardware failures occurred in their series of 27 and 23 patients, respectively. Argenson et al. (1990) stated that with hooks alone the stabilization was inadequate.

A.2.2 Internal Fixator

The Internal Fixator (Fixateur Interne) was developed by Dick et al. (1985a) based on the External Spinal Skeletal Fixation system of Magerl (1984). The pedicle screws used in this device (Schanz screws) have long shafts that are used as lever arms to achieve reduction of the fractured vertebra. Installation of the screws follows the standard procedure for insertion of pedicle screws, except the screws are self-tapping. The threaded bar and clamps are placed over the screws and then reduction of the fracture is undertaken. Kyphosis can be corrected by bringing the distal ends of the screws together by pivoting the screws against the fixation device. The lateral locking nuts are then tightened to hold the correction while distraction is obtained by screwing the clamps apart using the nuts on the threaded rod. Once adequate correction is achieved the nuts are locked in place by crimping them against the flattened sides of the threaded rod. The excess length of the screw shaft is then cut off using bolt cutters. As the screw/rod clamps can be positioned at any location along the length of the threaded rod, a wide variation in inter-pedicular distance can be accommodated by the device. If only two pedicle screws are used the device is able to accommodate almost unlimited misalignment between the screws in both the sagittal and transverse planes.

There are several problems inherent in the Internal Fixator in part due to its capacity to accommodate unlimited misalignment between a pair of pedicle screws. The

location of the lateral locking nuts in the original design made them difficult to tighten without consequent trauma to the adjacent tissues. The clamp has been redesigned to reduce this problem as the screw is now locked into the clamp by a nut on the upper surface. In some cases locking the nuts by crimping has been found inadequate to prevent loosening of the clamps (Esses et al., 1991).

Information on the mechanical complications that occur with use of the Internal Fixator in the treatment of spinal fractures is summarized in Table A.1. Gertzbein et al. (1989) reported the highest incidence with 13 screws breaking in 28 patients. Assuming four screws were used in each patient, this corresponds to approximately 12% of the screws. A breakage rate of 1% for both Esses et al. (1991) and Bednar (1992) was calculated on a similar basis as the estimate of Gertzbein et al. (1989). Only one author, Esses (1989), reported a bent screw, resulting in some loss-of-correction. Dick (1989) reported one case in which both threaded rods had broken. No instances of screw pull-out have been reported with this instrumentation. Loosening of the nuts due to inadequate crimping which lead to loss-of-correction was reported by Esses et al. (1991) and Aebi et al. (1987). Bednar (1992) reported loosening of the screw/rod clamp without loss-of-correction. Dick (1987) reported two cases of screw migration within the vertebra which led to loss-of-correction.

The effect of anterior grafting on the incidence of mechanical complications with the Internal Fixator can not be evaluated conclusively as most authors did not separate the incidence of complications according to the use of anterior grafting. Gertzbein et al. (1989) reported similar loss-of-correction both in cases with and without anterior decompression and suggested that the loss may have been due to either the fractures treated with the anterior procedure being initially more unstable or that the rib grafting was not an appropriate technique. On the other hand Lindsey and Dick (1991) concluded that transpedicular grafting was very effective as they found no loss in wedge index (the ratio of the anterior to posterior body height of the fractured vertebra). However, these researchers did not separate results for cases in which anterior grafting was and was not used.

Limited information is available on the loss-of-correction that occurs in fracture

Author	Number of Patients	Screw Breakage		Bent Screws		Loosened Nuts	
		Number of Patients	Number of Screws	Number of Patients	Number of Screws	Number of Patients	Number of Nuts
Aebi et al. (1987)	30	NA	NA	NA	NA	2 (6.7%)	NA
Bednar, (1992)	22	1 (4.5%)	1	NA	NA	1 (4.5%)	1
Esses et al. (1989)	24	‡	‡	1 (4.2%)	1	1 (4.2%)	1
Esses et al. (1991)	89	3 (3.4%)†	4	NA	NA	3 (3.4%)	NA
Gertzbein et al. (1989)	28	NA	13	NA	NA	1 (3.6%)	NA
Lindsey and Dick (1991)	80	5 (6.3%)	NA	NA	NA	NA	NA

‡ Two screw breakages were reported, but the indication for surgery was not reported.

† Calculated percentage where sufficient data was published.

Table A.1: Incidence of mechanical complications reported in retrospective studies of the Internal Fixator for treatment of spinal fractures.

cases treated using the Internal Fixator. Aebi et al. (1987) reported an average loss at one year follow-up of 3.6°. Louw (1989) reported a mean loss of 4° in 20 cases with thoracolumbar fractures and dislocations. Lindsey and Dick (1991) reported a similar loss (3.5°) at one year after surgery of which only 0.5° was within the vertebral body and the remainder in the upper disc. In the year following removal of the device (implant *in-situ* for one year) they found that an additional loss of 5.0° occurred most of which again was in the upper disc.

A low incidence of pseudoarthrosis has been reported with this instrumentation. Dick (1987) reported a single case of pseudoarthrosis in a total of 111 patients and Esses et al. (1991) found no cases in their series of 89 patients. None of the retrospective studies on this instrumentation have considered the incidence of bone resorption around the pedicle screw.

A.2.3 Variable Screw Placement (VSP) System

The Variable Screw Placement (VSP) or Steffee system (Acromed Corp.) was developed by Steffee et al. (1986). The screws are inserted and then fastened to the slotted plate with a nut that has a conically tapered undersurface. This surface fits into the bevelled upper surface of the slot. As there is an additional nut underneath the plate (replaced with an integral lower nut in the new screw design) the pedicle screw and plate are firmly fastened and do not rely on contact with the bone to facilitate load transfer. The fracture is reduced by manipulating the pedicle screws.

There are several difficulties associated with installation of the VSP system. Placement of the pedicle screws is critical with this system as variation in the screw alignment can only be accommodated by placing an angled washer between the screw and plate and/or by bending the plate. Unfortunately, this technique has limited application as the washers are only available in one angle (15°). Contouring the plate is useful only in the sagittal plane and it can be difficult to obtain the required 90° angle between the screw and plate (Matsuzaki et al., 1990). If this angle is not achieved, application of the plate can result in stripping of the machine threads of the pedicle screw, bending of the screw and/or undesirable changes to the inter-vertebral alignment (Zucherman et al.,

1988). The latter changes can result as tightening the locking nut forces the screw and plate into alignment. This can also further compromise the foramen resulting in impingement of the nerve roots (Pinto, 1992). Design changes to this system have been suggested by Matsuzaki et al. (1990) to accommodate misalignment between the plate and screw. This could also be achieved by the use of washers of the appropriate angles.

As the plates are only available in length increments of approximately 15 mm excess plate may protrude distal to the pedicle screw. This material may interfere with function of the unfused adjacent facet joints (Whitecloud et al. 1989a). McNamara et al. (1992) are critical of the VSP system suggesting that corrective forces can not be applied and maintained with this system and that anterior column height was not restored. Further, Whitecloud et al. (1989a) reported that in spinal fixation of slender patients the device can be evident externally.

Due to the limited information available on the influence of mechanical complications on both the loss-of-correction and the success of the fusion for spinal fracture cases a retrospective study was carried out based on spinal fracture cases treated with the VSP system by Dr. L. Davis at the University Hospital, Edmonton. This study, presented in Appendix B, was conducted with particular attention to the incidence and influence of mechanical complications. Since it was initiated several other retrospective studies on the use of this instrumentation in the treatment of fracture and non-trauma cases have been published. The results from studies of trauma cases together with those from Appendix B are presented in Table A.2. With the recent studies now available on the VSP instrumentation, a number of questions can be addressed where hitherto there was insufficient data.

Retrospective studies on use of the VSP instrumentation showed a low incidence of screw pull-out except for the report of McNamara et al. (1992). This condition may occur only in patients with osteoporosis. Schwaegler et al. (1991) reported the one case with this complication was osteoporotic. The only case of screw pull-out reported in Appendix B was in the oldest patient (63 years), but unfortunately there was no assessment of the degree of osteoporosis. Akbarnia et al. (1988) and McNamara et al. (1992) did not include data on the age of or degree of osteoporosis in cases in which

Author	Number of Patients	Screw Breakage		Bent Screws		Screw Pull-out	
		Number of Patients	Number of Screws	Number of Patients	Number of Screws	Number of Patients	Number of Screws
Akbarnia et al. (1988)	90	12 (13.3%)†	17 (3.5%)	NA	NA	2 (2.2%)	3 (0.6%)
Appendix B	12	7 (58.3%)	13 (27.1%)	6 (50.0%)	11 (22.9%)	1 (8.3%)	1 (2.1%)
Ebelke et al. (1991)	21	5 (23.8%)	NA	NA	NA	NA	NA
Kraker et al. (1989)	14	1 (7.1%)	2	NA	NA	NA	NA
McNamara et al. (1992)	13	3 (23.0%)	NA	NA	NA	3 (23.0%)	NA
Schwaegler et al. (1991)	20	2 (10.0%)	3	NA	NA	1 (5.0%)	2
Wenner et al. (1989)	13	0	0	NA	NA	NA	NA
Whitecloud et al. (1989a)	11	4 (36.4%)	NA	NA	NA	NA	NA

† Calculated percentage where sufficient data was published.

Table A.2: Incidence of mechanical complications reported in retrospective studies of the VSP system for treatment of spinal fractures.

screw pull-out occurred. That screw pull-out is likely to occur only in osteoporotic vertebrae is supported by the findings of the *in-vitro* testing of Zindrick et al. (1986). They concluded that the degree of osteoporosis of the specimens appeared to have the greatest effect on the fixation strength of the screw.

Other mechanical complications to which the VSP system is susceptible include screw bending and loosening of the locking nuts. A high incidence of screw bending was reported in Appendix B with 50% of the patients having at least one bent screw. A large percentage (83.3%) of the patients with a bent screw later developed additional complications including 45.5% of the bent screws breaking. The only reported case of a loosened nut in spinal fracture cases was that reported in Appendix B. Unfortunately, other retrospective studies on this instrumentation have not reported the incidence of bent screws or loosened nuts.

A wide range in the incidence of screw breakage has been reported, zero to 58.3% of cases (Wenner et al., 1989; Appendix B, respectively). The use of anterior grafting by some researchers and not by others may be responsible for the discrepancy between reports. Anterior grafting to supplement the posterior device, whether performed through an anterior or transpedicular approach, appears to reduce the incidence of mechanical complications with the VSP instrumentation. For example, Ebelke et al. (1991) reported that mechanical complications only occurred in patients who had not received anterior grafting. The much higher rate of screw breakage in Appendix B and Whitecloud et al. (1989a), Table A.2, may be attributed to the lack of anterior grafting in these studies. Analysis of the results presented by Ebelke et al. (1991) for patients without anterior grafting showed a screw breakage rate (38.5%) similar to that of Whitecloud et al. (1989a). The means by which anterior grafting reduces the incidence of mechanical complications is unclear, though it must reflect a reduced loading of the posterior device during the early post-operative period. However, during this period when loading on the fixation system is greatest the anterior graft would not be expected to provide support.

Of interest is the finding that the new design of pedicle screw introduced by the manufacturer to remove a stress concentration in the original design, produced a higher

failure rate, 50.0% versus 22.5% (Appendix B). This result confirms the finding of Zucherman et al. (1988).

Data on the loss-of-correction are often not provided (Heinig et al., 1988; Whitecloud et al., 1989a; Zucherman et al., 1988) or presented as 'maintained' or 'lost' without explanation of the criteria used for this determination. Akbarnia et al. (1988) reported that seven out of 90 patients had 'lost' correction while Kraker et al. (1989) stated that all patients had 'maintained' the correction. McNamara et al. (1992) reported a mean loss-of-correction of 8.7°. Ebelke et al. (1991) reported 'failures' in three patients (14.3%) due to excessive loss-of-correction. They also reported a statistically significant difference ($p=0.044$) in the loss-of-correction between cases with and without screw breakage (16° and 4°, respectively). This finding was confirmed here (Appendix B) though this study showed a greater loss for each category (22.1° and 7.5°, respectively).

Several authors reported occurrence of pseudoarthrosis when the VSP instrumentation was used in fracture cases. Akbarnia et al. (1988) reported four cases in 51 patients (7.8%). Ebelke et al. (1991) and Kraker et al. (1989) reported two cases of pseudoarthrosis in their studies (9.5% and 14.3%, respectively). McNamara et al. (1992) reported stable fusions in all thirteen cases that were reviewed.

A relationship between the presence of broken screws and pseudoarthrosis in spinal fracture cases has not been established. The four pseudoarthroses reported by Akbarnia et al. (1988) all occurred in patients with unspecified complications. Kraker et al. (1989) found the one patient with broken screws had a successful fusion. In a retrospective study that did not include fracture cases West et al. (1989) suggested that screw failure was not directly related to pseudoarthrosis. However, Zucherman et al. (1988), in a study in which the results of all surgical indications were combined, found pseudoarthrosis only in patients with broken screws. A relationship between mechanical complications and pseudoarthrosis may not be possible to establish as success of fusion with VSP instrumentation is difficult to determine radiographically due to the large size of the implant (Ebelke et al., 1991; Whitecloud et al., 1989a).

In reports of the clinical outcomes following treatment using the VSP system

several authors indicated an overall result. Whitecloud et al. (1989a) reported that four of 11 fracture cases (36.4%) were judged to have a poor result. Ebelke et al. (1991) stated that 38.1% of the fracture cases met one of their failure criteria. LaGrone (1989), however, reported that the five fracture cases in their retrospective study of 20 cases had a good or excellent result.

Comparison of results of cases of fractures versus those of other conditions requiring surgical intervention is of interest as the former provides the most unstable spine and the consequent loading on the fixation device is greatest. Most retrospective studies on VSP instrumentation have grouped the results of all cases regardless of surgical indication such that comparison of the incidence of mechanical complications for fracture and non-fracture cases is not possible. Only Whitecloud et al. (1989a) separated their results according to fracture and non-fracture cases. They showed a lower incidence of screw breakage in the non-fracture group (10.3% of patients) than that in the fracture group (36.4% of patients). Their result for the non-fracture group agrees with the results reported by other researchers from studies containing only non-fracture cases (Table A.3). A higher incidence of loosened nuts was reported in studies of non-fracture cases. The reason for this difference is uncertain. There were no reported cases of screw pull-out in non-fracture patients. The lower incidence of screw breakage and pull-out, complications that result from excessive loads on the fixation device, in the non-fracture group is in agreement with the hypothesis that in fractures cases there is a greater load on the fixation device. Only when vertebrae are removed for tumour excision would a comparable level of spinal instability be produced. Comparison of the loss-of-correction in fracture and non-fracture cases is not possible due to lack of data. This is also the case for comparison of the incidence of pseudoarthrosis.

A.2.4 Miscellaneous Non-Contacting Fixation Systems

There are a number of non-contacting spinal fixation devices for which there have been limited, if any, published reports. The Modular Spine Fixation System has been developed by Edwards (1986) for fixation of L4 and L5 spinal fractures. This system consists of a ratcheted rod which is used to apply distraction to hooks, similar to those

Author	Number of Patients	Screw Breakage		Other Complications	
		Number of Patients	Number of Screws	Number of Patients	Type of Complication
Davne et al. (1989)	200	7 (3.5%)†	12	23 (11.5%)	Loose nuts
Heinig et al. (1989)	116	12 (10.3%)	13 (1.9%)	7 (6.0%)	Loosened screws or nuts
Matsuzaki et al. (1990)	57	12 (21.0%)	17 (5.7%)	NA	NA
West et al. (1989)	62	9 (14.5%)	14	NA	NA
Whitecloud et al. (1989a)	29	3 (10.3%)	NA	NA	NA

† Calculated percentage where sufficient data was published

Table A.3: Incidence of mechanical complications reported in retrospective studies without fracture cases of the VSP system.

used in the Harrington system; however rather than attaching to the laminae the hooks are inserted into the head of the pedicle screws. The developers of this system suggest installation of a pedicle screw into the fractured vertebra to provide additional stability and to assist in reduction of the fracture (Edwards and Levine, 1989; Levine and Edwards, 1988).

Several reports on the use of this system to treat low lumbar fractures at the same institution have been published (Edwards and Levine, 1986; Levine and Edwards, 1988; Levine et al., 1989; Levine et al., 1990); however, there have been no published reports on fractures at other vertebral levels. These reports detail only a limited number of cases, the latest report reviewing the results of 20 patients. Mechanical complications encountered with this system have included 5% hook dislodgement and 5% pseudoarthrosis rate. At follow-up the average loss-of-correction was 5.9° and loss in vertebral body height was 12%. In addition, in two patients the device was so prominent externally it had to be removed. Reports on this instrumentation have not discussed either component breakage or the manner in which the system accommodates misalignment between the pedicle screws.

The Posterior Segmental Fixator was developed by Olerud et al. (1988) to overcome the problematic lateral locking nuts in the original Internal Fixator developed by Dick et al. (1985a). However, their modified design has not achieved widespread acceptance evidenced by the lack of published retrospective studies on its use. Olerud et al. (1988) in a review of 20 trauma cases treated using this device described one failure due to loosening of the screw/rod clamp resulting in loss of the operative correction. No other mechanical complications were described.

Development of the Vermont Spinal Fixator (VSF) was based on considerable background research (George et al., 1991; Krag et al., 1986, 1988a,b, 1989a,b). Installation of this device is relatively simple as there is only a single nut to tighten at each screw/rod junction. This nut has been designed to remain secure without the use of a locking nut. Reduction of the fracture is achieved with a reduction frame that is temporarily attached to the pedicle screws before the screw/rod junction and rod are applied.

A potential source of difficulty with use of the VSF system is loosening of the single screw used to fasten the screw/rod clamp. Another is that differences in the orientations of the pedicle screws is accommodated, in part, by rotation of the pedicle screw. This may result in the pedicle screws not being inserted to their optimum depth.

Though there have been several reports dealing with the design and development of the VSF system (Krag et al., 1986, 1988a,b, 1989a), there has been only one retrospective review on the use of this device to treat spinal fractures (Krag et al., 1989b). This report included 18 spinal fracture cases; however, the results were not separated according to surgical indication. Three broken screws (~4%) were reported. One screw was found to have loosened. No data on loss-of-correction were provided.

A single report on the Webb-Morley system, developed for use in the treatment of scoliosis, detailed its use in 19 cases, including 11 spinal fractures (Gibb et al., 1991). Loosening of the screw/rod connection occurred in two cases, but the surgical indication for these cases was not reported. No screw breakage was reported.

The Wiltse Pedicle Screw Fixation System, developed by Guyer et al. (1988) is a very adaptable, but complicated device. It is adaptable, in part, because the rods can be bent so that unlimited misalignment can be accommodated between any number of pedicle screws. In addition, each device can accommodate either one or two rods so that the stability provided by the device is variable. Further, as the rods can be bent in both the sagittal and transverse planes the installation of an additional screw into the fractured vertebra is possible. A potential difficulty with this system lies in the complicated and time consuming means used for bending the rods. The manner in which reduction is achieved was not discussed in the reports describing the system (Guyer et al., 1988).

Retrospective studies from three centres on the use of the Wiltse system have been published. In these reports the authors did not separate the results on the basis of surgical indication. The developers of the system (Horowitch et al., 1989) reported hardware failure in seven of the 99 cases. Of these cases several were reported to have multiple mechanical complications including: five cases with broken screws (5.1%); two cases with broken rods (2.0%); three cases with loosened screws (3.0%); and a single case with a loosened clamp (1.0%). Blumenthal et al. (1990) reported seven hardware

failures in 144 cases treated using the Wiltse system. They neglected to report the incidence and type of complication stating only that they ranged from loosening of the assembly to screw breakage. Guyer et al. (1991) reported on a series of 122 patients treated with the Wiltse system. However, only 31 of these were followed for at least one year. Among these were two broken rods, both in one patient with a pseudoarthrosis, and three broken screws. The indications for surgery in these cases were not detailed.

Several other pedicle screw devices currently in use for the treatment of spinal fractures have been briefly described. Blauth et al. (1987) reported the use of the Spinal Fixator, developed by Kluger, in twelve patients. Unfortunately, they combined the results obtained with this instrumentation with those using other fixation systems. The mechanism by which three other fixation devices function, whether by contact or non-contact with the posterior vertebral surfaces, has not been indicated. The H-frame system has been described in a single report (Slot and van Tiel, 1990). Though the number of cases in which it has been used was not reported no mechanical complications or pseudoarthroses have been attributed to its use. The Hartshill Rectangle, originally developed to use sublaminar wires for attachment to the spine has been adapted to use pedicle screws (Rahmatalla et al., 1991) and its use in the treatment of spinal fractures has been described in a single report (Valentine et al., 1990). In ten patients no mechanical complications or clinical failures were found to have occurred. Puno et al. (1991) described mechanical testing of prototypes of the Puno/Winter/Byrd (PWB) System (Cross Medical Products, Inc.), however, no clinical results on this instrumentation have been published. The FVM Vertebral Fixation System (Kirschner Medical Corp.) has only been described in advertising material from the manufacturer.

A summary of the conclusions and implications of this review is contained in Section 4.1.1.

Appendix B: Retrospective Study of Spinal Fractures Treated with the Variable Screw Placement (VSP) System

Although there have been many retrospective studies on the use of the Variable Screw Placement (VSP) system for treatment of thoracolumbar spinal fractures they do not provide adequate information for a detailed analysis. In some instances authors have included the results for other surgical indications without separating the results of each (for example: LaGrone et al., 1989; West et al., 1991; Yashiro et al., 1991; Zucherman et al., 1988). Other researchers have included other instrumentation systems in the results (for example: Knight et al., 1989; McAfee et al., 1991a) and/or did not include data on loss-of-correction (for example: Heinig et al., 1989; Whitecloud et al., 1989a; Zucherman et al., 1988). As definitive data on the use of the VSP system for treatment of spinal fracture cases was not available a retrospective study was undertaken of cases treated by Dr. L. Davis at the University Hospital, Edmonton. This study was conducted to determine the incidence and nature of mechanical complications reported with the use of the VSP instrumentation. Of particular interest was the influence of mechanical complications on the loss-of-correction and posterior vertebral body height. Comparisons of the occurrence of mechanical complication and loss-of-correction with clinical outcome and fracture type were also performed.

B.1 Methods and Materials

Twelve patients treated using the VSP system between October 1986 and June 1989 were included in the study. Table B.1 gives relevant data on patients and the nature of their injuries. The fracture type was based on the three-column classification system developed by Denis (1983). As the screw specifications changed during the study the table includes the type of screws used. The new design was introduced to strengthen the screw where it had been subject to plastic deformation and fatigue failure due to high stresses. No anterior grafting was performed. Loss-of-correction was determined by measuring the local kyphosis angle for each set of radiographs taken during the follow-up period. This angle is defined as the angle between the inferior face of the superior

Patient	Age	Sex	Cause	Injured Level	Fracture Type ‡	Fixed Levels	Screw Type
D.B.	33	F	MVA †	T11	Fracture Dislocation, Shear	T10/L1	old
E.B.	18	M	Fall	L4	Burst, Type B	L3/L5	old
B.D.	15	F	MVA	L1	Burst, Type B	T12/L2	new
C.F.	26	F	MVA	T12	Seat-Belt, Chance	T11/L2	new
C.I.	28	M	other	T12, L1	Burst, Type NA	T11/L2	old
J.J.	21	F	MVA	T12	Seat-Belt, Chance	T11/L1	old
W.L.	18	F	MVA	L4	Burst, Type A	L3/L5 (right) L4/L5 (left)	old
B.M.	17	M	MVA	L1, L2	Burst, Type B	T12/L3	old
T.O.	27	M	MVA	T12	Burst, Type B	T11/L1	old
B.R.	22	M	other	T10,T11	Fracture Dislocation, Shear	T9/T12	old
T.S.	31	M	MVA	L1	Burst, Type B	T12/L2	old
K.W.	63	M	MVA	L1	Burst, Type B	T1/L2	old

† Motor Vechicle Accident ‡ Fracture classification from Denis (1983)

Table B.1: Characteristics, injury description and treatment of subjects included in the VSP retrospective study.

instrumented vertebral body and the superior face of the inferior instrumented vertebral body. The posterior vertebral body height was calculated as a percentage of the average of that of the two adjacent vertebrae.

Clinical outcome was based on the Frankel grade, the pain score and an overall assessment. The pain score was based on the following criteria:

0 - 1: excellent, required no analgesic usage.
2 - 4: good, occasional analgesic usage.
5 - 7: poor, frequent narcotic analgesic usage.
8 - 10: failure, daily narcotic analgesic usage.

The overall clinical assessment was based on the following criteria:

Excellent: No symptoms except for occasional back pain, no medications required.
Good: Marked improvement in symptoms, occasional pain, occasional medication, no functional limitations and returned to work though perhaps not at the same job.
Fair: Some improvement, pain medications are routinely needed and there are functional restrictions.
Poor: No change in symptoms or the patient was worse.

B.2 Results

The mean follow-up was 12.6 ± 6.6 months with a range from 4.0 months to 26.0 months. An average of 5.6 sets of radiographs per patient were examined. The data for fracture type, Frankel grade, clinical assessment, pain score, posterior body, loss-of-correction and occurrence of mechanical complication are presented in Table B.2. There were two fracture dislocations, two seat belt-chance fractures and eight burst fractures of which one was Type A, six were Type B and one in which the type was not determined (type as defined by Denis, 1983).

There was a high incidence of mechanical complications, nine of the twelve patients having had broken and/or bent screws. One of these cases also had a screw pull-out within one month of surgery. In an additional case the nuts on one pedicle screw had loosened. Eleven bent screws occurred in six patients; five of these screws (45.5%) in three patients were later found to have broken. For patients in whom the screws bent

Patient	Fracture Type †	Mechanical Complication	Loss-of-Correction	Frankel Grade			Posterior Body Height			Pain Score	Clinical Assessment
				Pre-op	Final	Δ	Post-op	Final	Δ		
D.B.	Fracture Dislocation, Shear	-	5	A	D	+3	100%	100%	NC	0	Fair
E.B.	Burst, Type B	-	10	E	E	NC	96%	100%	+4	0	NA
B.D.	Burst, Type B	2 Broken	27.5	E	E	NC	100%	100%	NC	5	Good
C.F.	Seat-Belt, Chance	2 Broken	27	D	E	+1	97%	98%	+1	1	Excellent
C.I.	Burst, Type NA	1 Bent	8	C	D	+1	95%	88%	-7	0	Excellent
J.J.	Seat-Belt, Chance	2 Broken	27	C	D	+1	94%	100%	+6	NA	Excellent
W.L.	Burst, Type A	Loose Nuts	21.5	D	D	NC	88%	92%	+4	1	Good
B.M.	Burst, Type B	1 Broken, 1 Bent	17	E	E	NC	97%	91%	-6	3	Excellent
T.O.	Burst, Type B	4 Bent	6	D	E	+1	109%	105%	-4	1	Good
B.R.	Fracture Dislocation, Shear	2 Broken	8	A	A	NC	100%	NA	NA	0	Poor
T.S.	Burst, Type B	3 Broken	26	A	D	+3	100%	94%	-6	1	Good
K.W.	Burst, Type B	1 Pullout, 1 Broken	21.5	D	E	+1	95%	93%	-2	1	Good

† Fracture classification from Denis (1983)

Table B.2: Fracture type, mechanical complications and clinical outcome for cases included in the VSP retrospective study.

but did not break the mean length of follow-up after bending was 5.2 months (range: 0 to 12.0 months). Three screws in three patients were bent during surgery; further complications occurred in each case. In the three other patients with screws that bent post-operatively without such initial complication during surgery the mean time after surgery to the first radiograph showing a bent screw was 5.0 months (range: 4 days to 12.9 months).

A total of thirteen screws (27.1%) broke in seven patients. The new design of pedicle screw showed a greater failure rate (50.0%) than those of the older design (22.5%). Breakage did not appear related to position of the screw within the construct as 25.0% of the superior and 29.2% of the inferior screws broke. Failure of the screws always occurred in the unsupported region between the last cancellous thread and the proximal locking nut. The mean time to the first radiograph showing a broken screw was 9.6 months (range: 3.0 to 16.9 months).

In those subjects exhibiting an initial bent or broken screw additional complications were usually observed. Five patients with one bent, pulled-out or broken screw later developed at least one additional bent or broken screw. In an additional three patients, multiple complications were seen at the same time post-operatively. The only exception was one patient with a screw that bent soon after surgery but no further complications occurred during the follow-up period (12.0 months).

The mean operative correction in patients without mechanical complications tended to be less (mean: 12.0°, range: 0° - 24°) than for those with bent or broken screws (mean: 13.4°, range: 0° - 38°). This difference was not statistically significant.

There was a significant difference ($p < 0.05$) between the overall loss-of-correction in patients without complication (7.5°±3.5°) than for those with broken screws (22.1°±8.0°). Expressed as a percentage of the operative correction the total loss-of-correction was 62.5% for patients without complication and 164.9% for those with broken screws. In cases with screw fracture the mean loss-of-correction evident on the last radiograph before failure was only 5.3°±4.0° or 24.0% of the total loss.

The occurrence of mechanical complications was unrelated to both the overall clinical result or neurological status. However, there were more patients with high pain

scores among those with broken screws (range: 0 - 5) than among those with only bent screws (range: 0 - 1) and those without complications (all had pain scores of zero). Despite the high incidence of mechanical complications no case required reinstrumentation after the complication occurred.

Significant differences were seen in the loss-of-correction between cases with a pain score of zero ($7.8° \pm 2.1°$) and both those with a score of one ($20.5° \pm 8.5°$) and greater ($22.3° \pm 7.4°$). The difference between the last two was not significant.

Comparisons of the results for different types of fractures showed that fracture dislocations ($6.5° \pm 2.1°$) had significantly less loss-of-correction than both the burst ($17.2° \pm 8.3°$) and seat belt ($27.0° \pm 0.0°$) fractures. The difference in the loss-of-correction between the last two groups was also statistically significant. All fracture types showed a similar incidence of mechanical complications.

Change in the posterior body height could not be correlated with the incidence of mechanical complications, Frankel grade, pain score or clinical assessment. Comparing this measurement with fracture type showed that for the cases with seat belt type fractures the posterior body height increased, whereas in the majority of the burst fracture cases, this quantity decreased. There was an insufficient number of cases with fracture dislocations to establish a conclusion regarding this measurement.

Fracture type appeared to correlate with Frankel grade as all fracture dislocations had poor initial grades. Cases with seat belt type injuries had better initial grades and all showed improvement. Burst fractures were the only type in which there were cases with an initial grade of E. Of the five cases with an initial grade other than E only one remained unchanged and all others improved at least one grade.

Comparing the clinical assessment for the different types of fractures, cases with a fracture-dislocation all had either fair or poor results whereas those with a seat belt fracture all had excellent results. Cases with a burst fracture rated as either good or excellent. Of interest is that the fracture dislocation cases had a pain score of zero despite their low clinical assessment. Pain scores in burst fractures cases ranged from five to zero. There was no relationship between the pain score and clinical assessment as cases with good and excellent results had scores ranging from five to zero whereas the

pain score for cases with fair and poor assessments was zero.

When all fracture types were considered the clinical assessment showed no statistical difference in the loss-of-correction between cases with excellent (19.8°±9.1°) and those with good (20.5°±8.5°) results. However, among those with burst fractures only there was a statistical difference in the loss-of-correction between the excellent (12.5°±6.4°) and good (20.5°±8.5°) results.

B.3 Discussion

This study provides data on the incidence and influence of mechanical complications in the use of the VSP system for thoracolumbar and lumbar spine fractures. A high incidence of bent and broken screws was found to occur with numerous cases having multiple complications. Examination of the chronology of the complications showed that failure of one screw often leads to failure in other screws. The initial complication can occur soon after surgery possibly due to the greater load carrying requirements on the device at that time. In addition, a patient may unknowingly overstress the construct while under the influence of analgesics. External bracing during the early post-operative period would appear advisable in order to reduce the latter occurrence.

The high incidence of mechanical complications with the VSP instrumentation evident in this study is of concern. A review of published reports on the clinical use of this system (Appendix A) showed an incidence of screw breakage from zero to 36.4% as compared to 58.3% found here. The incidence of screw pull-out was similar to that given in previous reports. The reason for the high incidence of screw breakage found in the present study remains uncertain. It may be due to the lack of anterior grafting to augment the posterior support. On the other hand this study may present a more detailed analysis of mechanical complications than have previous studies. For example, other studies have not included the incidence of bent screws. However, the mean time to detection of screw breakage agrees well with a previous study (Ebelke et al., 1991) which reported a mean time of 9 months (range: 4 to 18 months). Whitecloud et al. (1989a) found such failure tended to occur somewhat earlier, at 4 to 6 months.

Failure of the device would depend also on the fatigue strength of the components. This can be compromised, for example, by plastic deformation of the screws during surgery. This was seen in the present study to have occurred in three patients and it led to further complications in each case. Zucherman et al. (1988) suggests that such deformation can occur when the screws are not correctly aligned. Unfortunately, other retrospective studies on this instrumentation have not discussed the occurrence of bent screws.

In several cases bent screws did not break. This may be due to a limited follow-up period after bending was first observed (range: 0 to 12.0 months). Some screws were also found to have broken without radiographic evidence of prior bending. This may be due to insufficient radiographs to make this assessment from the period between screw bending and breakage. Prediction of the time between screw bending and breakage was not possible due to the small number of screws that were observed to have been bent before they were later seen to have broken.

The new design of VSP pedicle screw had a high failure rate and all broke before radiographic evidence of bending. These screws appear to bend less easily, but are still susceptible to fracture. This supports the earlier finding of Zucherman et al. (1988) that breakage was still a problem with the new design of screw. A larger sample size would be necessary to validate this conclusion.

Resorption of bone around the pedicle screw, as evidenced by lucency on lateral radiographs, was found in six cases. Whereas those patients with resorption had either bent or broken screws, the reverse was not always the case. This may reflect the difficulty in assessing resorption radiographically. Unfortunately, it was not possible to establish if there was a correlation between the location of the resorption and screw failure. Bone resorption may be an indicator of excessive loading and its appearance may suggest that mechanical complications, if absent, may be anticipated.

Mechanical complications are related to the applied load and the strength of the device. The load is dependent on a number of factors including stability of the fracture, weight and physical activity of the patient, quality of the fusion and use of external bracing. Correlation of the incidence of mechanical complications with the level of

loading would be of interest, but it cannot be quantified accurately. For fracture-dislocations and seat belt fractures a relationship between fracture type and incidence of mechanical complication could not be established possibly due to the limited number of cases.

Loss-of-correction reflected mechanical complications. In patients with broken screws the majority of the loss-of-correction occurred after the screw broke. In addition, the total loss-of-correction was significantly greater in such patients than in those without complications. The reason for the loss-of-correction which occurred in the patients without mechanical complication is uncertain. It may have been due to migration of the screw within the bone and as such should be evident on lateral radiographs. Screw migration was observed in one case that otherwise did not exhibit other mechanical complications. In this patient the loss-of-correction was 10°. As all post-operative radiographs were examined a chronology of the loss-of-correction was established. This demonstrated that the loss-of-correction is initiated immediately after surgery.

Few published retrospective studies on the VSP instrumentation used in fracture cases have included data on loss-of-correction or indicate it only as 'maintained' or 'lost' without explanation of the criteria used in coming to this conclusion (Akbarnia et al., 1988; Kraker et al., 1989). Only Ebelke et al. (1991) compared loss-of-correction between cases with and without screw breakage. They also found a statistical difference between the two populations.

In the present study a relationship between the incidence of mechanical complications and successful fusion could not be established. Assessment of fusion was uncertain and in only approximately half of the cases could the state of the fusion be evaluated. Whitecloud et al. (1989a) and Ebelke et al. (1991) reported a similar difficulty.

Comparing the outcomes for treatment of the different fracture types, cases of fracture-dislocations showed poorer clinical assessments even though they had little pain and loss-of-correction. In these instances the lower loss-of-correction may have resulted from there being less damage to the vertebral body and, thus, less potential for late collapse than with other types of fractures.

That change in posterior body height could not be correlated with Frankel grade, pain or clinical assessment may result from a lack of a relationship between this measurement and the status of the posterior surface of the vertebral body. Though maintenance of posterior body height is important to preventing late impingement on the spinal cord, lateral radiographs may not present an accurate assessment of the condition of the posterior surface. Ballock et al. (1992) recently showed that fractures in which the posterior wall appeared intact on lateral radiographs showed evidence of retropulsed fragments in the spinal canal when examined on CT scans. This suggests that even if the posterior height is unchanged compression of the spinal cord may occur.

That the presence of mechanical complications did not appear related to the clinical assessment or neurological status may reflect the limited sample size and the high incidence of these complications. That mechanical complications were correlated to the pain score and loss-of-correction and that the latter was related to the clinical assessment in cases with burst fractures, suggests a relationship between mechanical complications and clinical result may exist. Though the relationship was not found significant in this study it does not imply that mechanical complications are inconsequential.

Due to the limitations of a retrospective study several questions can not be answered. The loss-of-correction before bending, between bending and breaking and after screw breakage could not be compared. Further, the loss-of-correction at the mean time of screw breakage in patients with and without complications also could not be compared. The small number of cases with fixation of four levels did not allow comparison with the results of three-level fixations. Correlation of fracture type with incidence and type of mechanical complication also may be possible with a larger sample.

B.4 Conclusions

Several conclusions can be drawn from this retrospective review of spinal fracture cases treated with the VSP instrumentation. The incidence of mechanical complications apparent in this review was higher than previously reported. Bending of the pedicle screw during or after surgery seriously compromises the fatigue life of the screw such that breakage of the screw may occur. The occurrence of a single complication often is

followed by further complications and loss-of-correction is significantly increased by screw breakage. Despite the high incidence of mechanical complications and the resulting increased loss-of-correction and pain, no cases required reinstrumentation or had a decrease in neurological function. Radiographic evidence of bone resorption around the pedicle screw may indicate that the construct is over stressed and that mechanical complications may occur. As the device is subjected to high loads during the early post operative period prior to bone fusion, external bracing to limit damage to the fixation device is indicated.

B.5 Recommendations

A larger sample size is necessary if correlations between mechanical complications and the clinical outcome are to be established. Increased numbers also may make it possible to investigate the influence of external bracing, level of activity, operative correction and fracture type on the incidence of mechanical complications. In addition, a comparison of the incidence of pseudoarthrosis with complications may also be possible. Further, a larger sample size would better establish the loss-of-correction due to screw bending.

Measurement of the change in the sagittal angle within the fractured vertebral body would provide data on the ratio of loss-of-correction in the intervertebral discs and vertebral body. Comparison of fracture and non-fracture cases treated using the VSP system by the same investigator would provide further information on the behaviour of the device. A prospective study in which the construct geometry is measured and then its rigidity determined theoretically and compared with the incidence of mechanical complications would assist in determining how the system should be applied *in-vivo* to prevent development of complications.

Appendix C: Performance of Pedicle Screws

Incorporation of the screw thread profile that will provide the maximum purchase and mechanical strength is an important aspect of the design. To assist in determination of the appropriate thread *in-vitro* tests of pedicle screws and the clinical performance of different screw types were reviewed. Recommendations for further testing of pedicle screws are discussed.

C.1 *In-Vitro* Screw Purchase Strength Studies

A number of loading configurations have been used to determine the *in-vitro* purchase strength of pedicle screws. The most commonly used has been an axial pull-out test. Frequent use of this test may be attributed to its previous use in determining the comparative strengths of cortical bone screws for anchoring fixation plates for long bones. However, the incidence of this mode of failure in spinal fracture cases treated with pedicle screw fixation systems is low and may only occur in osteoporotic bone (Section A.2.3). Thus, the use of this test to determine the optimum screw thread design may be inappropriate. Tests to determine the load required to cause fracture through the side of the pedicle were also performed. In these tests single or repeated loading in either the sagittal or transverse planes was used.

Using cadaveric vertebrae the strength of purchase of commercially available pedicle screws has been evaluated by several researchers (Ekström et al., 1990; Sell et al., 1988; Skinner et al., 1990; Zindrick et al., 1986). Unfortunately, as the screws tested had different major and minor diameters, pitches and thread profiles, the relative influence of each of these variables was not determined even though each may affect purchase strength.

However, some specific characteristics of thread design have been individually evaluated by a number of researchers. These have shown that pull-out strength increases with major diameter (Skinner et al., 1990; Soshi et al., 1991; Wittenburg et al., 1990a). Differences in thread profile have also been investigated and have shown that VSP (deep threads with a buttress profile) and Shanz (shallow threads with a V profile) screws of the same major diameter had no significant difference in pull-out strengths (Skinner et

al., 1990). Krag et al. (1986) compared pullout strength variation with minor diameter, pitch and thread profile. Decreasing the minor diameter (with constant major diameter) was found to increase the pull-out strength, whereas variations in pitch and thread profile were statistically insignificant.

Unfortunately, several other factors influence *in-vitro* purchase strength such that comparisons are difficult. Tests using cadaveric vertebrae have several limitations. Variation in bone density between vertebrae greatly affects the pull-out strength (Soshi et al., 1991; Yamagata et al., 1992; Zindrick et al., 1986). Compensation for variability in bone density has been made by testing two different screws within a single vertebra using each of the pedicles. However, Berry et al. (1987) showed that variations in size between left and right pedicles exist. This variation may influence the screw's purchase. Differences in pedicle size can result in screws of the same diameter having different purchase strengths as the screw whose diameter is closest to the maximal endosteal diameter should obtain better purchase. This, however, does not appear to have been a factor in paired comparison tests as Zindrick et al. (1986) and Sell et al. (1988) showed no statistical differences between pull-out values for similar screws inserted into the left and right pedicles. Bone mineral content, which has been correlated to pull-out load (Ekström et al., 1990; Soshi et al., 1991; Wittenburg et al., 1990a), may be used to compensate for density variations between the vertebrae.

A further variable is the location of the threads within the vertebra. For example, if the screw is not fully threaded, the threaded portion of the screw may be placed within the pedicle or in the vertebral body. As the quality of the cancellous bone of these regions differs, this could influence the purchase strength. Zindrick et al. (1986) reported that if the threads were only located within the pedicle a statistically higher pull-out strength resulted compared with that obtained if the threads were only located within the vertebral body. The technique by which the guide hole is made can also affect the quality of purchase. Probing rather than drilling the pedicle has been shown by Moran et al. (1989) to yield higher pull-out strengths, though George et al. (1991) were unable to show a statistical difference between the two techniques.

Other factors that may influence the quality of purchase that have not been

investigated include the size of the guide hole, strain rate, condition of the vertebrae and length of time the screw is within the vertebrae before testing. There have been no published comparisons of the purchase strength of tapping the pedicle and use of a self-tapping screw in vertebrae, though there are numerous reports on their differences in cortical bone. The alignment of the screw within the pedicle may affect the purchase strength and Moran et al. (1989) suggests the use of radiography to check the screw's alignment.

Statistical differences in purchase between different screw designs are difficult to establish as there can be considerable scatter in the results for pull-out tests with standard deviations as large as 57% of the mean load (Krag et al., 1986). Such scatter may reflect the condition *in-situ* so that subtle variations in the screw design may be inconsequential.

Testing of the quality of purchase of various screw designs has also been performed in alternate materials. Kling et al. (1986) reported data for axial pull-out tests in calf vertebrae were similar to those published for tests on human vertebrae suggesting the validity of the use of this model. Wittenburg et al. (1990a), however, reported higher bone density figures and pull-out strengths for calf vertebrae than those for human. Evenson (1988) reported that porcine pedicles are much more elongated and the transverse processes in a more anterior position than those in humans. As a result the pedicle is not as straight as that in humans so that it may be difficult to achieve the correct screw alignment within the pedicle. Whether or not the use of an animal model affects the relative performance of the different screw designs has not been established. However, use of animal vertebrae may be a source of more uniform vertebrae and should be investigated further. Comparison of morphology and internal structure of the pedicle in humans and various animals may determine the best animal model to use.

C.2 Mechanical Strength of Pedicle Screws

Mechanical strength of the screw is an important consideration in the thread design. Failure of the screw is dependent upon fatigue strength of the screw and on the mechanics of the fixation device. There is a significant difference in the mechanics, and

thus the loading on the pedicle screws, of devices requiring contact with the posterior surface of the vertebrae compared with those without this requirement. Devices not requiring contact must have a solid connection between the screw and the vertical member to achieve stability. Consequently, a bending moment is carried by the pedicle screw, whereas the pedicle screws of devices requiring bone contact are subjected only to tensile loads. Fracture stabilization using devices with unconstrained pedicle screws entails fixation of two or more levels above and below the fracture such that the load on each screw is reduced. These factors reduce the risk of fatigue failure in screws of these devices. For devices with constrained screws higher stresses in the bone adjacent to the screw resulting from fixation of only the adjacent levels increases the risk of necrosis and resorption of this bone. This can lead to higher loads in the unaffected screws.

Differences between the loading in devices with and without bone contact have been compared by several authors. Ashman et al. (1989) measured the strain on pedicle screws in instrumentation mounted on cadaver spines in the vertebrae adjacent to the fracture model. They reported that at low loads the stress in the screws of devices with a solid connection between the screw and rod all exceeded the endurance limit for the material. In comparison, the stress in screws of devices requiring direct contact with the bone surfaces did not exceed the endurance limit. In studies of cyclic testing of pedicle screw devices Ashman et al. (1989) and Wittenburg et al. (1990b) have reported implant failures in devices not requiring bone contact (Internal Fixator and VSP), whereas no failures occurred with devices requiring bone contact for stability (ISF).

There have been several published reports comparing the *in-vitro* strength of different pedicle screws. Geiger et al. (1989) performed cantilevered-bending fatigue tests on several different screw designs and sizes and reported that the 7.0 mm VSP screw with the integral nut (the new VSP screw design) had the highest fatigue strength. Fatigue life of the VSP screw without the integral nut (the old VSP screw design) was much lower. The 5.0 mm screws used in the Posterior Segmental Fixator (Olerud et al., 1988), similar to the Schanz screws of the Internal Fixator, were reported to have a fatigue life between that of the VSP screws with and without the integral nut. Moran et al. (1989) also conducted cantilevered-fatigue tests, but only tested an experimental screw

and two VSP screws of different diameters. Yamagata et al. (1992) reported that the 5.0 mm Schanz screw had highest failure strength of the five screw types tested in cyclic four point bending tests. However, the endurance limit for each type was below the calculated theoretical loading. Liu et al. (1990) has performed cyclic four point bending tests on VSP screws to investigate the influence of nitrogen ion implantation on the fatigue strength of the screws. A statistically significant increase in fatigue life of the screws occurred with ion implantation, though the percent increase appears dependent upon the applied moment. Though there have been a number of published reports of fatigue testing of pedicle screws none present a thorough study that includes all of the more common screw designs tested under a constant bending moment.

Two groups of researchers have reported the failure life of screws mounted in devices on spine segments. Ashman et al. (1989) reported that the number of cycles to failure for the 5.0 mm Shanz screws were an order of magnitude or more, depending on the screw position in the vertebrae, greater than 6.5 mm VSP screws without the integral nut. Wittenburg et al. (1990b) also reported more bent and broken 7.0 mm VSP screws than 5.0 mm Schanz screws and that the mean number of cycles to failure of the latter was approximately three times greater than for the former. However, Wittenburg et al. (1990b) did not state whether they used the old or new design of VSP screws.

Tests on the mechanical strength of pedicle screws suggest the screw with the largest major diameter that can be safely introduced into the pedicle minimizes the risk of fatigue failure while reduction of the minor diameter with constant major diameter, such as in cancellous bone screws, results in a decrease in the fatigue life of the screw. Differences in the types of screws tested and the experimental protocol make direct comparison of the fatigue test results impossible. The most vulnerable portion of any pedicle screw to fatigue failure is the unsupported region between the bone surface and the screw/rod junction where the bending moment is the greatest. This has been verified by the results of both *in-vitro* testing (Ashman et al., 1989; Beynnon et al., 1986; Liu et al., 1990; Moran et al., 1989; Wittenburg et al., 1990b) and clinical retrospective studies (Appendix B; Matsuzaki et al., 1990). By reducing this unsupported length or by increasing the strength of the screw in this region as achieved with the integral nut

on the new VSP screws, the incidence of such failure can be reduced. The prototype pedicle screws included both of these improvements.

C.3 Clinical Performance of Pedicle Screws

From the review of the clinical use of pedicle screw fixation devices (Appendix A) the *in-vivo* performance of different screws was compared, though several factors make such comparison difficult (Section 4.1). Comparison of the incidence of screw breakage is further hampered by lack of description of the type and size of screws used. However, comparison of failure rates of different screw types and the failure rates that occur in devices with constrained and unconstrained pedicle screws was undertaken. This is possible, in part, due to substantial differences between the screws used in the various devices.

Reviewing the clinical incidence of screw breakage in devices requiring bone contact (Table C.1) and those not requiring contact (Table C.2) suggests that the screw type may have more influence on the incidence of failure than the mechanics of the device. Of devices requiring bone contact, high failure rates were reported for the distal screws in the use of the Roy-Camille plates for the treatment of fracture cases (Roy-Camille et al., 1986a,b; Kinnard et al., 1986). However, this may be due to the smaller size of the pedicle screws used in this system and/or to motion at the distal joints that Roy-Camille et al. (1986a,b) recommended to temporarily fix without fusion. An et al. (1991) postulated that motion at such joints could lead to failure of the implant. Daniaux et al. (1991) also showed a high incidence of screw breakage in use of a device requiring bone contact, though possible reasons for this were not discussed.

Comparison of the incidence of screw breakage in devices not requiring bone contact shows a higher failure rate of the VSP screws than for the Schanz screws of the Internal Fixator. Differences between the systems include the use of crosslinks between the threaded bars of the Internal Fixator, the lower rigidity of the Internal Fixator and the pedicle screw design. Crosslinking the threaded bars, either with cerclage wire or with the rigid crosslink available with the Internal Fixator system, was used by a number of researchers whereas there were no reports of crosslinking with the VSP system.

Fixation Device	Author	Number of Patients	Fracture Cases		All Surgical Indications		Screw Type
			Number of Patients	Number of Screws	Number of Patients	Number of Screws	
ISF	Luque and Rapp (1988)	83	§	§	NA	6 (1.2%) †	5.5 & 6.5 mm Cancellous ‡
	Luque (1990)	14	0	0	-	-	
	Trammel et al. (1990)	52	§	§	0	0	
Roy-Camille	Benazet et al. (1989)	32	NA	2	-	-	3.5, 4.0 & 4.5 mm Cortical ‡
	Kinnard et al. (1986)	21	5 (23.8%)	12	-	-	
	Roy-Camille et al. (1986b)	115	25 (21.7%)	NA	-	-	
Miscellaneous	Bhojraj and Archik (1991)	20	§	§	0	0	4.5 mm Cortical
	Daniaux et al. (1991)	110	11%	NA	-	-	4 mm Cortical or 6.5 mm Cancellous ‡
		21	41%	NA	-	-	
		51	19%	NA	-	-	
	Sasso et al. (1991)	23	1 (4.3%)	1 (0.8%)	-	-	6.5 mm Cancellous
	Thalgott et al. (1991)	45	-	-	4 (8.9%)	NA	

† Calculated percentage where sufficient data was published. ‡ Did not specify the size of screws that fractured.
§ Fracture cases were included with other indications.

Table C.1: Incidence of broken screws reported in retrospective studies of fixation systems requiring contact with the posterior vertebral surface.

Fixation Device	Researchers	Number of Patients	Fracture Cases		All Surgical Indications		Screw Type
			Number of Patients	Number of Screws	Number of Patients	Number of Screws	
C-D	Moreland et al. (1990)	15	1 (6.7%) †	2	-	-	5 mm Cortical
	Rousseau and Loisel (1990)	10	1 (10.0%)	1	-	-	
Internal Fixator	Esses et al. (1991)	89	3 (3.4%)	4	-	-	5 mm Shanz (Cortical)
	Gertzbein et al. (1989)	28	NA	13	-	-	
	Lindsey and Dick (1991)	80	5 (6.3%)	NA	-	-	
VSP	Akbarnia et al. (1988)	90	12 (13.3%)	17 (3.5%)	-	-	5.5, 6.25 & 7.0 mm Cancellous ‡
	Appendix B	12	7 (58.3%)	13 (27.1%)	-	-	
	Ebelke et al. (1991)	21	5 (23.8%)	NA	-	-	
	Kraker et al. (1989)	14	1 (7.1%)	2	-	-	
	Schwaegler et al. (1991)	20	2 (10.0%)	3	-	-	
	Wenner et al. (1989)	13	0	0	-	-	
	Whitecloud et al. (1989a)	11	4 (36.4%)	NA	-	-	5.5 & 7.5 mm Cancellous ‡
Miscellaneous	Guyer et al. (1991)	31	§	§	NA	3	5.0, 5.8, 6.5 & 7.0 mm ‡
	Horowitch et al. (1989)	99	§	§	5	NA	
	Krag et al. (1989b)	46	§	§	NA	3	6.0 & 7.0 mm Cortical ‡

† Calculated percentage where sufficient data was published. ‡ Did not specify the size of screws that fractured.
§ Fracture cases were included with other indications.

Table C.2: Incidence of broken screws reported in retrospective studies of fixation systems with constrained screws.

Crosslinking has been shown to increase the stability of the construct (Carson et al., 1990; Johnston et al., 1986) and its resistance to pull-out (Kling et al., 1986; Ruland et al., 1991).

The lower rigidity of the Internal Fixator may result in more elastic deformation of the threaded rods when loaded. Though this may create more motion at the fracture site and increase the loss-of-correction, it would reduce the load carried by the pedicle screws. Increased motion at the fracture site may result in a higher incidence of pseudoarthrosis, however, preliminary comparison of the incidence of pseudoarthrosis reported in clinical reviews does not support this claim (Section 4.1.1).

There are a number of differences between the pedicle screws used in the VSP and Internal Fixator systems. The Schanz screw used in the Internal Fixator has a constant diameter shaft that is larger in diameter than the diameter of the junction between the two thread types in the VSP screw and the major diameter of the VSP screws' machine threads. The thread also has a larger minor diameter than the VSP screw and does not have the stress concentration that existed in the original VSP screws. These factors suggest the Schanz screw should have a greater fatigue life than the VSP screw.

C.4 Recommendations for Further Testing of Pedicle Screws

Further *in-vitro* tests should include individual evaluation of the design characteristics to determine if significant differences exist. Factors not studied previously and which should be investigated include influence of the guide hole size, strain rate, condition of the vertebra, screw alignment within the pedicle and installation torque. Use of other test configurations may be considered, for example, measurement of the withdrawal torque. This is suggested by the finding of Greenhill (1988) that some Shanz screws used in the Internal Fixator 'backed out' of the vertebrae. These evaluations may require use of an animal model or of an artificial material to provide a more uniform population of vertebrae. Before using an animal model, the morphology and internal structure of the pedicle of the particular species would have to be evaluated in comparison to human material. Use of either an artificial material or an animal model

would require tests to determine if the screws react differently in the model. This may be achieved by testing several distinctly different thread designs in human vertebrae, an animal model and in an artificial material to determine if only the relative difference in purchase strength is affected by the use of a model. A further recommendation for additional *in-vitro* testing would be a thorough study of the fatigue of various current pedicle screws and the prototype screw.

In-vivo testing of purchase strength of pedicle screws would provide useful information as the purchase is dependent on the quality of adjacent bone and its reaction to the insertion and presence of the screw. To date only *in-vitro* tests of pedicle screw purchase strength have been reported, however, these may not provide a good indication of the long term *in-vivo* condition. Schatzker et al. (1975) suggested that changes due to the trauma of screw insertion, the reaction of surrounding bone to the implant and remodelling and resorption processes have a profound effect on the purchase strength of the screw. This agrees with the report of Bechtol (1959) who found that if an implanted cortical bone screw stripped the threads in the bone within four weeks the load required to restrip the threads was greater than the initial force required to strip the threads. The influence of bone remodelling may be determined only by comparing results from screws implanted in an animal model and tested at a later date with those tested immediately after implantation.

A study of the performance of novel screw designs in which purchase strength may be greatly increased by bone remodelling process should be considered. One such design might entail cutting of notches into the threads of existing screw designs to allow space for bone growth into the screw as this might increase the withdrawal torque and pull-out strength. Further, the notched areas could also be porous-coated to facilitate bony ingrowth into the screw so as to enhance the purchase. Use of a porous-coated screw such as developed by Deporter et al. (1986) for fixation of dental implants may be advantageous. Porous-coated components may dictate the use of cobalt or titanium alloys rather than stainless steel as the latter is subject to crevice corrosion when porous-coated (Pilliar, 1987). A two-piece screw design (Figure C.1) that has an outer sleeve with deep cancellous threads and an inner screw that can expand the end of the outer

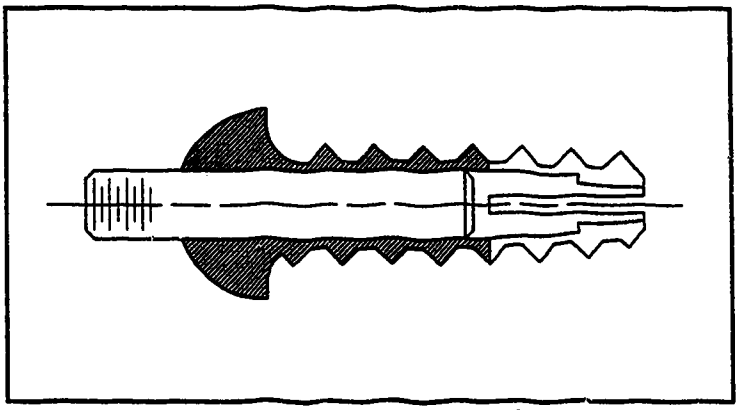

Figure C.1: Cross-section of pedicle screw with expanding proximal end (not to scale).

sleeve once the screw is implanted is a further possibility that might well be evaluated. Lesoin et al. (1983) reported on the use of such a screw in the cervical spine. Whether or not such a design would have the mechanical strength required by a fixation device for the thoracolumbar spine would have to be determined. A further novel design that should be tested *in-vivo* is the trilobal screw. This has a triangular cross-section and has been used extensively in plastic where the viscoelastic material relaxes into the area between the lobes. A cancellous bone screw with the trilobal cross-section is not currently available. In addition, a 'hi-lo' type screw with a dual-height thread design may be also effective. Future *in-vivo* and *in-vitro* testing must include measurement of the bone mineral content in order to account for differences in bone density in the test specimens.

Appendix D: Review of Vertebral Morphology

As a means to determine the anatomical constraints on the pedicle screw fracture fixation device a review of published vertebral morphology studies has been compiled. This contains summarized information from the literature and analysis of this data. A description of relevant vertebral dimensions is presented in Section 2.3 and Figures 2.7 and 2.8 illustrate the relevant dimensions.

D.1 Vertebral Morphology Literature Review

Early studies providing quantitative information on vertebral morphology were concerned primarily with total spinal column length, Todd and Pyle (1928), or vertebral body size, Lanier (1939). With the development of pedicle screw fixation systems a number of studies have focused on obtaining more specific anatomical measures relevant to such devices. However, in these studies the results have only been applied to the determination of appropriate pedicle screw diameter and length, whereas the implications of other morphological constraints were not considered. Saillant (1976) was the first to document vertebral morphology relevant to pedicle screw fixation by investigating 35 cadavers. However, only the mean values were published and the measurement technique was not described. Berry et al. (1987) studied 30 dry adult skeletons from the Hamann-Todd Osteological Collection in Cleveland, U.S.A. measuring all lumbar and selected thoracic vertebrae. Zindrick et al. (1987) measured all thoracic and lumbar vertebrae in his study of fresh disarticulated specimens and compared results obtained from radiographs and computerized axial tomograms. Krag et al. (1988b) studied 91 vertebrae from levels T9 through L5 with computerized axial tomography (CT) and an additional eight were scanned then measured directly to compare the accuracy of the CT scans for measurement. Selected thoracic and lumbar vertebrae from 50 specimens in the Hamann-Todd Collection were studied by Scoles et al. (1988) who separated his results based on sex. Banta et al. (1989) used sixteen embalmed cadaver spines to compare x-ray and direct measurements of the pedicle diameters in the transverse and sagittal planes. The maximal cancellous diameter of the pedicle was also determined by graduated sounding and compared with outer diameter measurements. Misenhimer et al.

(1989) also investigated the relationship between outer pedicle cortical diameter and cancellous (endosteal) diameter. They compared direct measurements with those of various CT imaging techniques and also measured outer cortical diameter changes as screws of increasing diameters were inserted through the pedicle. The work of Berry et al. (1987) was supplemented by Moran et al. (1989) who presented summarized data from the earlier study and results from an investigation of the internal architecture of the pedicle. The latter was accomplished by sectioning the pedicle and then radiographing the sections. However, in their study of the internal structure of the vertebra only two cadavers were used. Olsewski et al. (1990) studied the lumbar vertebrae from 49 embalmed cadavers comparing direct measures with radiographic results. In addition, measurements of vertebral morphology from radiographs and CT scans of 51 patients were compared. The measurement technique, state of the vertebra, dimensions studied, sample size and levels investigated in the above studies are summarized in Tables D.1 and D.2. In these studies different techniques were used by the various authors to obtain the measurements and the state of the vertebrae varied. The implications of these differences were investigated by several authors. Tabulated results from each researcher for the relevant dimensions (described in Section 2.3) are contained in Appendix E.

In the following review a mean and standard deviation were calculated for each dimension at each vertebral level from values reported in the literature. These calculated means and standard deviations have been termed 'combined means' and 'combined standard deviations' and are reported below.

D.2 Methods

Data from published reports were compiled and a mean and standard deviation calculated for each dimension at each level. The combined mean ($\bar{X}_c$) was calculated using the formula:

$$\bar{X}_c = \frac{\sum_{i=1}^{m} \bar{x}_i n_i}{\sum_{i=1}^{m} n_i} \qquad (D.1)$$

Author	Measurement Technique	Vertebrae State	Vertebral Dimension						
			Minimum Dia.	Endosteal Dia.	Maximum Dia.	Transverse Angle	Sagittal Angle	Cortex-to-Cortex	
								midline	parallel
Banta et al. (1989)	Direct, X-Ray	Cadaver	X	X	X	-	-	-	-
Berry et al. (1987)	Direct	Dry	X	-	X	X	-	-	-
Krag et al. (1988b)	Direct, CT	Cadaver, Living	X	-	-	X	-	X	-
Misenhimer et al (1989)	Direct, CT	Cadaver	X	X	-	-	-	-	-
Moran et al. (1989)	Direct	Cadaver, Dry	X	X	X	X	-	-	X
Olsewski et al. (1990)	Direct, X-ray, CT	Cadaver	X	-	X	X	X	-	X
Pal and Routal (1986)	Direct	Dry	-	-	-	-	X	-	-
Pal and Routal (1987)	Direct	Dry	-	-	-	-	X	-	-
Saillant (1976)	†	Cadaver	X	-	X	X	X	X	-
Scoles et al. (1988)	Direct	Dry	X	-	X	X	-	-	X
Zindrick et al. (1987)	Direct, X-Ray, CT	Cadaver	X	-	X	X	X	X	X

† Did not describe measurement technique.

Table D.1: Measurement technique, state of the vertebrae and dimensions measured by each author.

Author	n †	Vertebral Level															
		T1	T2	T3	T4	T5	T6	T7	T8	T9	T10	T11	T12	L1	L2	L3	L4	L5
Banta et al. (1989)	16 ‡	-	-	-	-	-	X	X	X	X	X	X	X	X	X	X	X	X
Berry et al. (1987)	30	-	X	-	-	-	-	X	-	-	-	-	X	X	X	X	X	X
Krag et al. (1988b)	41	-	-	-	-	-	-	-	-	X	X	X	X	X	X	X	X	X
Misenhimer et al. (1989)	6	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
Moran et al. 1989)	50	-	X	-	-	-	-	X	-	-	-	-	X	X	X	X	X	X
Olsewski et al. (1990)	49 ‡	-	-	-	-	-	-	-	-	-	-	-	-	X	X	X	X	X
Pal and Routal (1986)	44	X	X	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Pal and Routal (1987)	44	-	-	-	-	X	-	-	X	X	-	X	X	X	-	X	X	X
Saillant (1976)	35	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
Scoles et al. (1988)	50	X	-	X	-	-	X	-	-	X	-	-	X	X	-	X	-	X
Zindrick et al. (1987)	‡	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X

† number of vertebrae studied ‡ sample size, n, varied with level

Table D.2: Vertebral levels measured by each author.

where: $\bar{x}_i$ is the mean of the i^{th} author's data.

n_i is the sample size of the i^{th} author's data.

m is the total number of investigators.

The combined standard deviation (S_c) was calculated by:

$$S_c = \sqrt{\frac{\sum_{i=1}^{m} s_i^2 n_i}{\sum_{i=1}^{m} n_i}} \qquad (D.2)$$

where: s_i is the standard deviation of the i^{th} author's data.

As optimal purchase by the pedicle screw requires that it follow the central axis of the pedicle (Krag et al., 1986) there can be a difference in the orientation of the superior and inferior screws. This difference can be resolved into the transverse and sagittal planes and calculated from data for the pedicle angle in these planes. In the transverse plane (Figure D.1) the variation in screw angulation (α) is the difference between the transverse pedicle angle of the superior (γ_s) and inferior instrumented vertebrae (γ_i). In the sagittal plane (Figure D.2) the variation in screw angulation is the difference between the sagittal pedicle angle of the instrumented levels (β_s, β_i) plus the angle between the superior endplates of the instrumented vertebrae (δ).

The relative difference was calculated by two methods. First, by calculating the absolute value of the difference, in each plane, between the mean pedicle axis angles of the superior and inferior vertebrae. As only a small number of patients have both pedicles oriented at the mean angle, a second method was used to determine a larger estimate of the range of relative angle differences that would be encountered clinically. This entailed determination of the range of relative angle difference between the pedicle when the pedicle angles of the inferior and superior vertebra differ from the mean values. As the largest relative angle difference occurs when the pedicles' axes differ from the mean in opposite directions, calculations were performed for pedicles differing from the

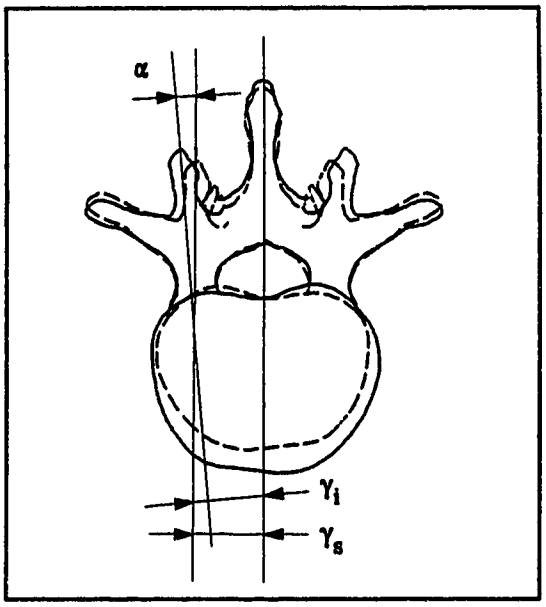

Figure D.1: Relative difference in the transverse pedicle angle.

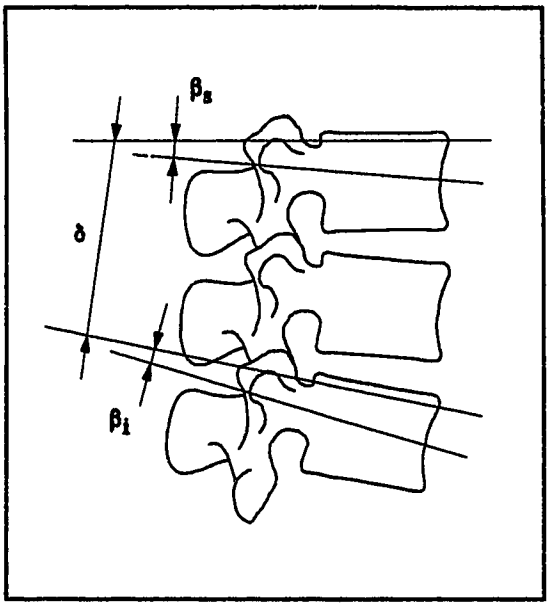

Figure D.2: Relative difference in the sagittal pedicle angle.

mean pedicle angle, in opposite directions, by both one and two standard deviations. For pedicles offset in opposite directions from the mean pedicle angle by one standard deviation, 70.8% of the population is included in the estimate. Incorporating an offset of two standard deviations includes 95.5% of the population.

In determining the largest relative difference, α, two cases arise depending upon the relative size of the mean pedicle angles of the superior vertebra, $\bar{x}_s$, and inferior vertebra, $\bar{x}_i$. For an offset of each screw of one standard deviation the two cases are:

1) if $\bar{x}_s > \bar{x}_i$ then:

$$\alpha = |(\bar{x}_s+s_s)-(\bar{x}_i-s_i)| \tag{D.3}$$

2) if $\bar{x}_s < \bar{x}_i$ then:

$$\alpha = |(\bar{x}_s-s_s)-(\bar{x}_i+s_i)| \tag{D.4}$$

where: s_s is the standard deviation of the superior pedicle angle.

s_i is the standard deviation of the inferior pedicle angle.

For the relative difference incorporating two standard deviations the cases are:

1) if $\bar{x}_s > \bar{x}_i$ then:

$$\alpha = |(\bar{x}_s+2s_s)-(\bar{x}_i-2s_i)| \quad (D.5)$$

2) if $\bar{x}_s < \bar{x}_i$ then:

$$\alpha = |(\bar{x}_s-2s_s)-(\bar{x}_i+2s_i)| \quad (D.6)$$

These calculations were performed on each author's results separately rather than using the combined means and standard deviations. This was done in order to reduce the error in the measurement due to possible differences in the authors' techniques to determine the pedicle angle. Calculations were performed for fixation of three and four levels of the thoracolumbar spine.

D.3 Results

The combined means and standard deviations for the thoracic and lumbar spine calculated from published data are shown in Table D.3. The summarized results of Berry et al. (1987), as reported by Moran et al. (1989), were used for calculation of the combined statistics as Berry et al. (1987) separated the data on the basis of left or right pedicle, while the latter combined the data. Results from papers in which only the mean values and/or ranges were given were not included in the calculations as the standard deviation is required to calculate the combined standard deviation. These combined statistics were not calculated for the endosteal diameter due to a lack of necessary data. Figures D.3 to D.16 show the variation of the respective critical dimension with vertebral level and the combined means and standard deviations; Tables in Appendix E summarize the published means and standard deviations from each researcher for each of the critical dimensions.

D.3.1 Minimum Pedicle Diameter

The combined mean minimum pedicle diameter (Figure D.3, Table E.1) is smallest at the T3 level, 4.1±0.9 mm, and increases caudally to L5, 13.5±2.7 mm. The average combined standard deviation is 1.7 mm, approximately 23% of the combined mean minimum diameter.

Level	Minimum Diameter (mm)	Maximum Diameter (mm)	Transverse Angle (degrees)	Sagittal Angle (degrees)	Cortex-to-Cortex Parallel (mm)	Cortex-to-Cortex Pedicle Axis (mm)
T1	7.1±1.17	9.0±1.21	27.8±4.34	19.4±6.15	26.7±5.80	31.7±3.06
T2	6.4±1.34	11.9±1.27	21.8±6.35	20.2±7.58	27.4±6.30	28.7±3.13
T3	4.1±0.91	11.5±1.11	15.2±3.32	17.3±6.00	31.1±3.10	32.3±3.21
T4	4.7±1.30	12.1±1.00	12.6±4.10	16.3±4.40	31.5±3.20	38.5±3.90
T5	4.5±0.90	11.9±1.40	9.4±4.40	19.6±5.74	35.9±4.10	41.9±4.70
T6	4.4±1.18	11.3±1.16	10.3±2.58	15.0±4.20	36.9±5.00	37.9±3.16
T7	5.7±1.52	11.9±1.25	7.6±4.90	15.7±4.20	39.5±3.70	38.6±3.77
T8	6.7±1.73	12.3±1.61	8.1±5.20	17.6±2.80	40.6±4.10	45.4±4.80
T9	5.2±1.44	12.6±1.46	9.0±2.11	18.2±3.51	42.4±4.87	41.7±3.25
T10	7.5±2.01	14.3±2.38	5.2±4.89	16.8±5.30	41.9±5.01	44.0±5.00
T11	8.5±2.18	16.3±2.64	0.8±4.17	18.2±4.02	41.4±4.36	41.8±6.50
T12	7.6±1.90	15.9±1.91	3.7±6.13	18.4±4.22	42.1±7.22	40.5±5.71
L1	7.5±1.88	15.4±1.66	9.6±4.37	4.9±3.99	43.9±4.64	46.5±3.50
L2	8.0±1.85	14.9±1.28	10.5±2.93	4.6±3.53	45.2±3.38	46.6±3.72
L3	9.3±1.93	14.4±1.59	13.7±3.13	3.3±4.69	43.5±4.87	48.8±3.82
L4	11.4±2.03	14.1±1.77	17.2±4.77	2.2±3.21	40.6±4.32	47.0±3.76
L5	13.5±2.71	15.7±3.05	26.7±5.27	3.6±4.89	34.4±5.76	47.1±4.17

Table D.3: Combined means and standard deviations for the morphological dimensions (mean±std.dev.).

There is good agreement between values reported by the various authors at most levels as their results are within one combined standard deviation of the combined mean. The major exception is at the L5 level where the largest discrepancy between authors is found.

D.3.2 Endosteal Diameter

Three authors measured the endosteal diameter of the pedicle but, as the number of samples was small and the standard deviations were not given combined means and standard deviations were not calculated (Figure D.4 expressed as a percent of the minimum pedicle diameter). As a percent of the minimum diameter the endosteal diameter ranged from 46% to 85%. Table E.2 presents the endosteal diameter data both in millimetres and as a percent of the minimum pedicle diameter. Of these studies only Misenhimer et al. (1989) showed a relationship between endosteal diameter and vertebral level with the diameter increasing caudally. The results of Moran et al. (1989) are of

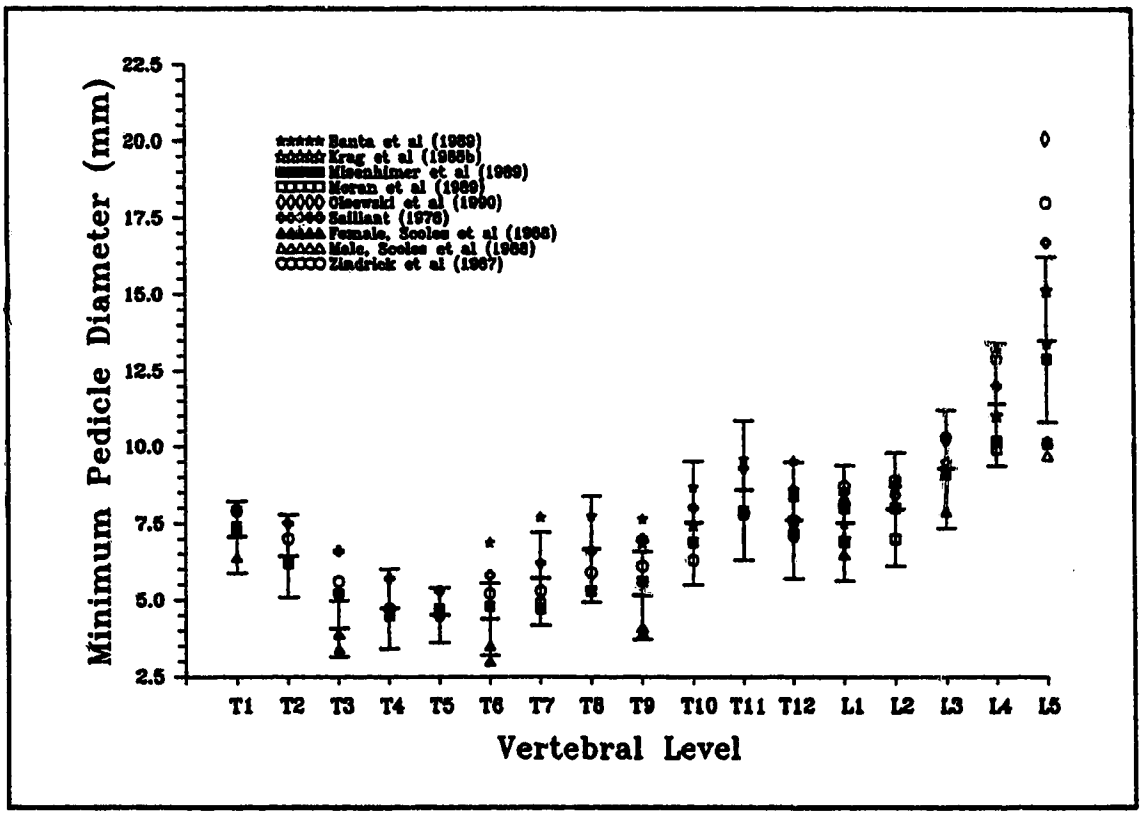

Figure D.3: Published data for the minimum pedicle diameter at levels T1 to L5 with the calculated combined means and standard deviations.

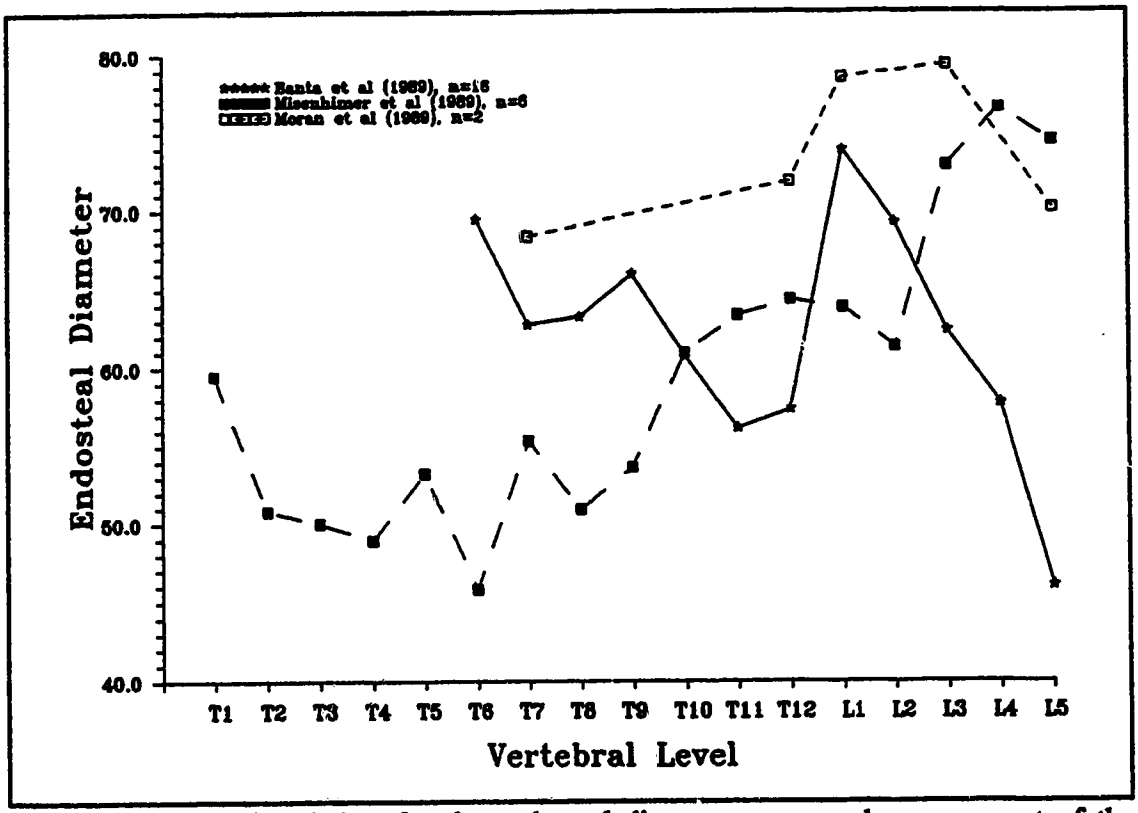

Figure D.4: Published data for the endosteal diameter expressed as a percent of the minimum pedicle diameter for levels T1 to L5.

limited value as their sample was small (two at each level). Banta et al. (1989) reported that several of the pedicles in the upper and mid-thoracic spine did not have a medullary cavity suggesting that these may be unable to accommodate pedicle screws.

D.3.3 Maximum Pedicle Diameter

The combined mean maximum pedicle diameter (Figure D.5, Table E.2) is smallest at T1 (9.0±1.21 mm) and increases through to T12 (15.9±1.91 mm). Throughout the lumbar region the maximum diameter is relatively constant: at level L1, 15.4 mm and at L5, 15.7±3.05 mm. Though the combined standard deviations calculated for a number of levels are large, when expressed as a percentage of the combined mean they are smaller than those calculated for the minimum pedicle diameter. Results of the various authors were within one combined standard deviation of the combined mean at all levels except for the values from Banta et al. (1989) at levels T8 and T9 and Saillant (1976) at levels T6 and T9.

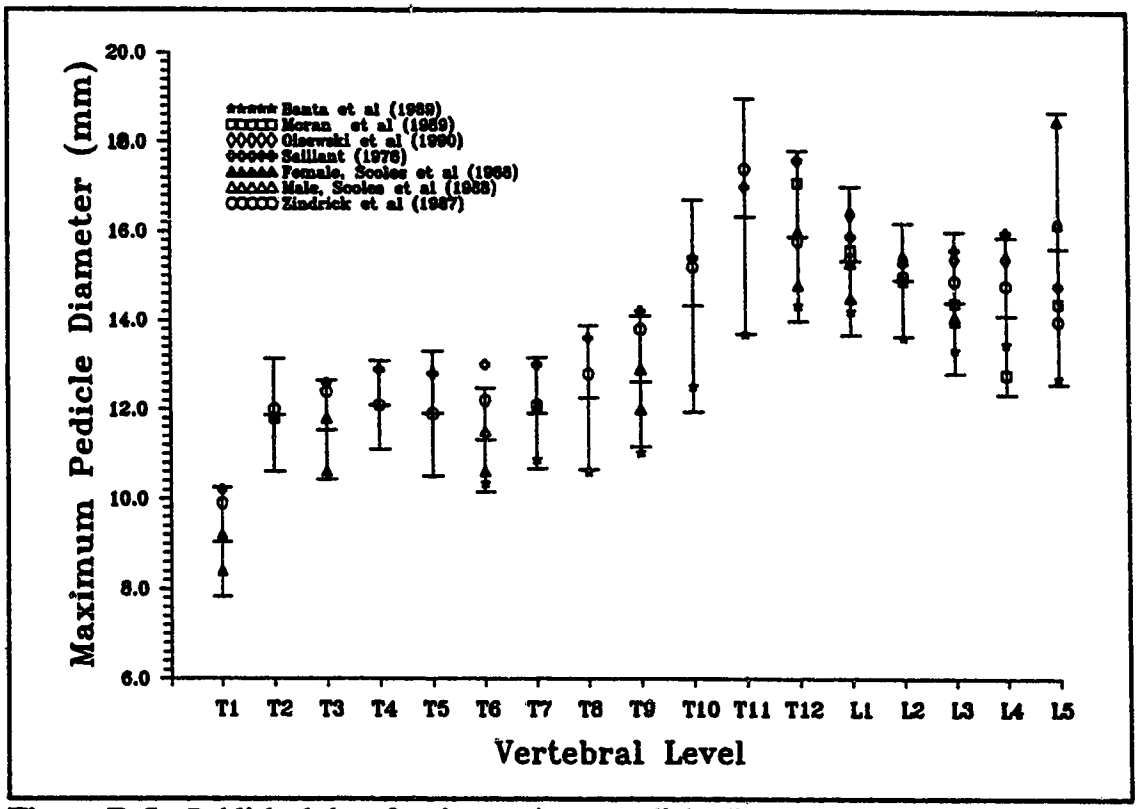

Figure D.5: Published data for the maximum pedicle diameter at levels T1 to L5 with calculated combined means and standard deviations.

The ratio of the combined mean maximum pedicle diameter to the combined mean minimum pedicle diameter provides an indication of the cross-sectional shape of the pedicle (Figure D.6). In the upper thoracic region the pedicle is most ovoid. From a maximum value of 2.80 at T3 the ratio decreased caudally. In the thoracic region the maximum diameter is approximately twice the minimum diameter. In the lumbar region the pedicles are more cylindrical.

D.3.4 Transverse Pedicle Angle

At T1 the combined mean angle is largest (27.8±4.34°) and decreases through the thoracic region to 0.8±4.17° at T11 (Figure D.7, Table E.3). From that level the transverse angle increases caudally to 26.7±5.27° at L5. The average combined standard deviation for this dimension is 4.3°.

Results from most authors showed close agreement except for those reported for the T12 level. The results of Saillant (1976) for the mid-thoracic and upper lumbar

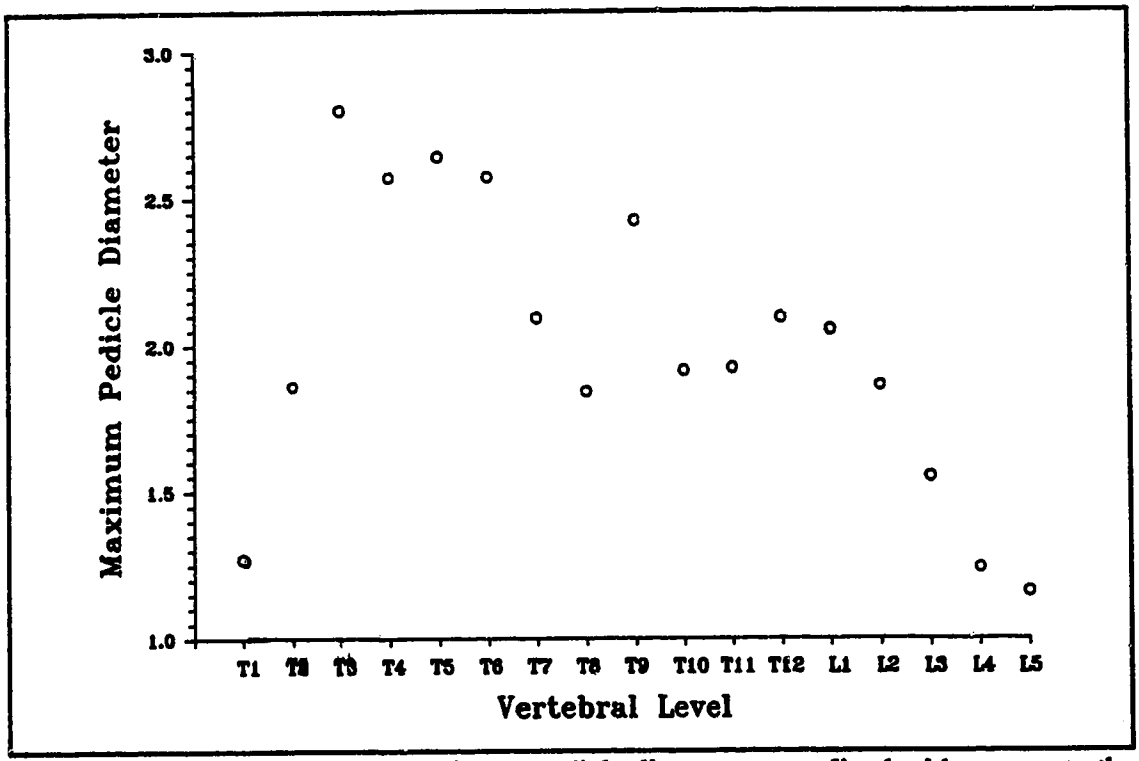

Figure D.6: Combined mean maximum pedicle diameter normalized with respect to the combined mean minimum pedicle diameter.

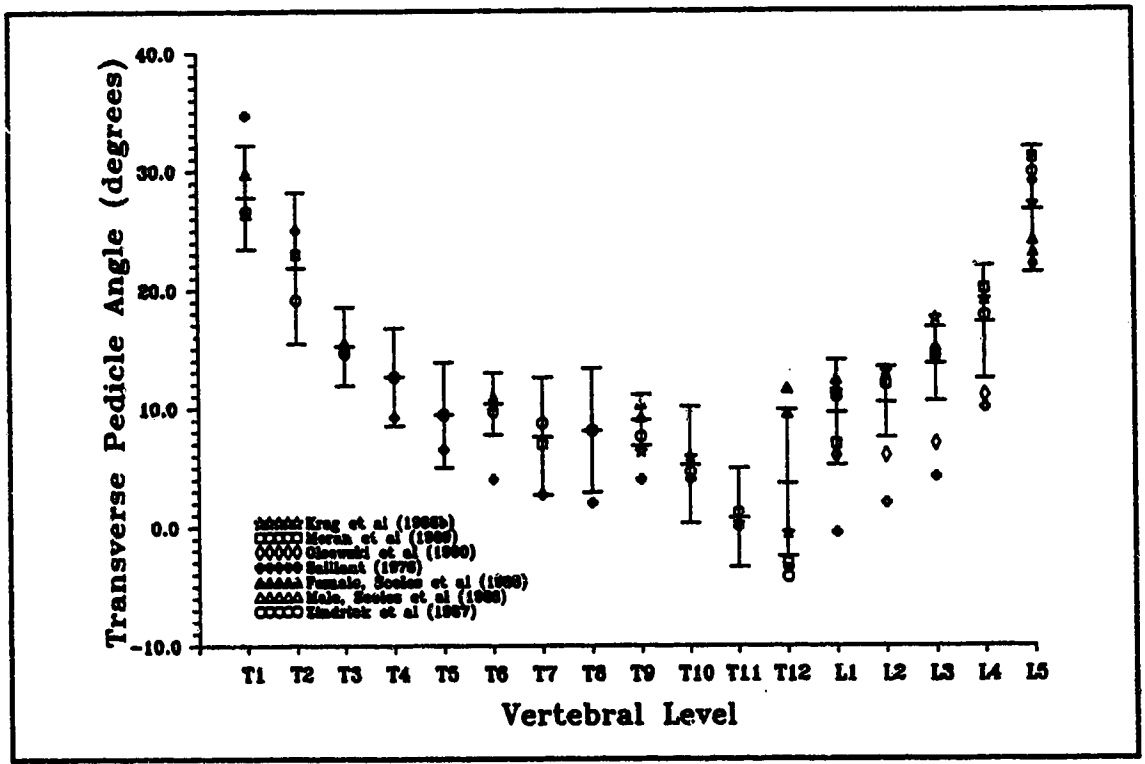

Figure D.7: Published data for the transverse pedicle angle at levels T1 to L5 with calculated combined means and standard deviations.

regions are an exception. These were often more than one combined standard deviation from the combined mean.

D.3.5 Sagittal Pedicle Angle

In the thoracic region the sagittal pedicle angle is approximately constant at 15° (Figure D.8, Table E.4). This angle is also relatively constant in the lumbar region, but at a lower value (~4°). Olsewski et al. (1990) divided the data at the L5 level into two groups, depending upon the pedicles' orientation caudally or cephaladly. They determined a statistical difference between the two groups and suggested that if the two groups were combined an erroneous indication of the pedicle angle would be obtained. However, if their results are combined they agree well with those of Saillant (1976) and Zindrick et al. (1987).

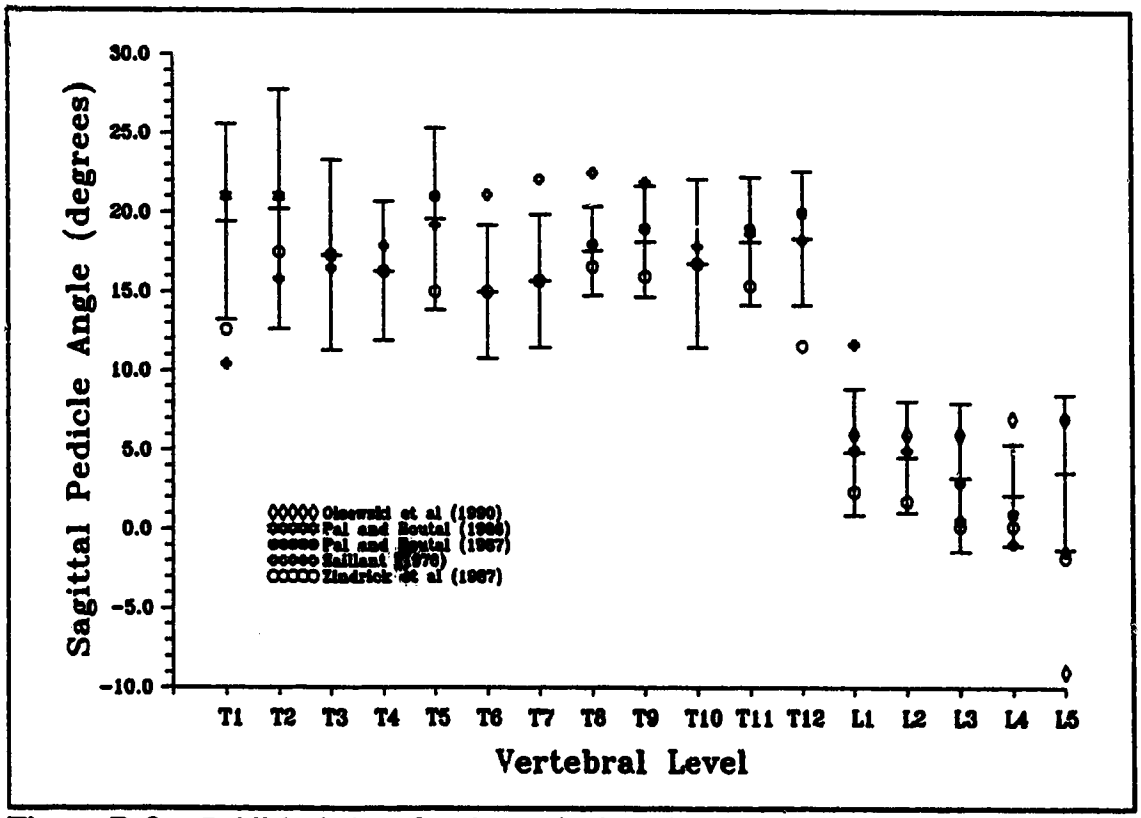

Figure D.8: Published data for the sagittal pedicle angle at levels T1 to L5 with calculated combined means and standard deviations.

D.3.6 Cortex-to-Cortex Distance

The cortex-to-cortex distance through the pedicle can be defined either parallel to the vertebral midline or along the pedicle axis.

D.3.6.1 Measured Parallel to Vertebral Midline

The maximum mean cortex-to-cortex distance measured parallel to the vertebral midline is 45.2±3.38 mm and occurs at L2 (Figure D.9, Table E.5). A gradual increase in this dimension is apparent from the T1 to T9 levels. Over the thoracolumbar junction this distance is relatively constant at approximately 42 mm then decreases in the lower lumbar region to 34.4±5.76 mm at L5. The average combined standard deviation for the cortex-to-cortex distance measured parallel to the vertebral midline is 4.7 mm or expressed as a percentage of the combined mean, approximately 13%.

For the upper and mid-thoracic regions only two authors published data. Of these

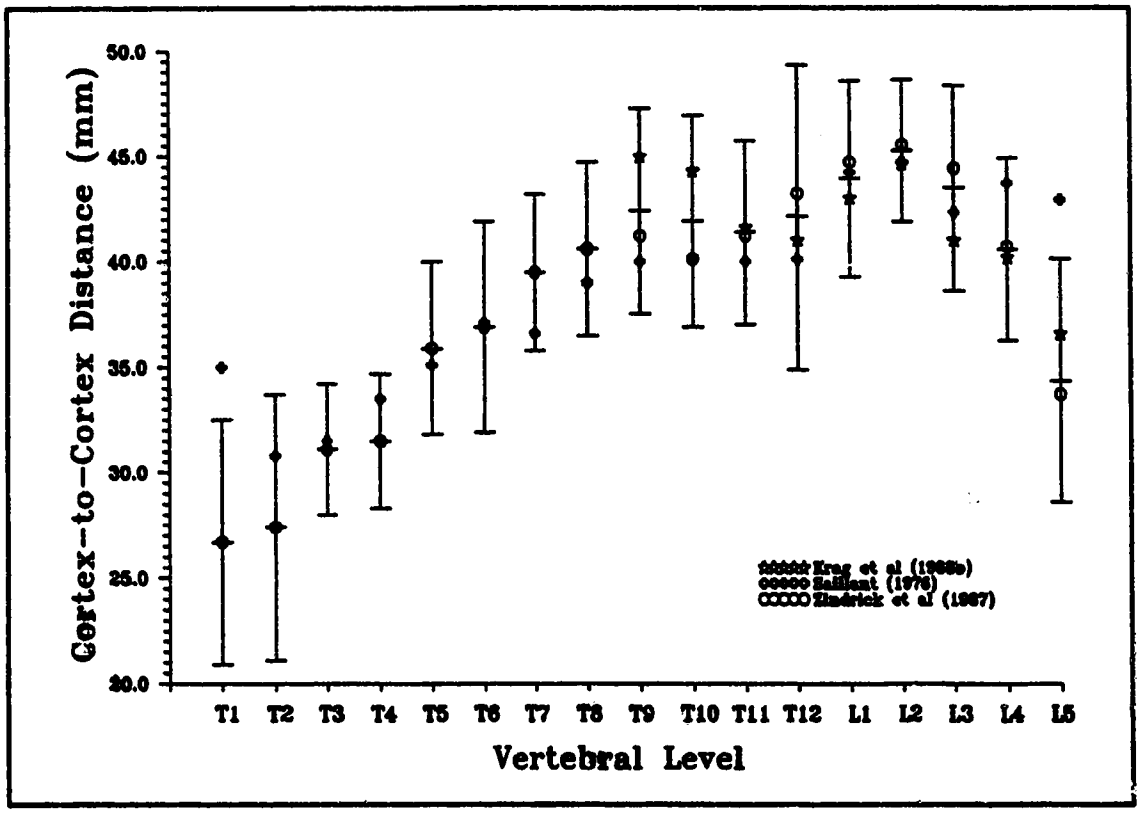

Figure D.9: Published data for the cortex-to-cortex distance measured parallel to the vertebral midline for levels T1 to L5 with the calculated combined means and standard deviations.

Saillant (1976) presented only mean values, such that the combined means and standard deviations presented here are the results of Zindrick et al. (1987).

D.3.6.2 Measured along the Pedicle Axis

The combined mean cortex-to-cortex distance measured along the axis of the pedicle (Figure D.10, Table E.6) increases from T2 (28.7±3.13 mm) through T8 (45.4±4.80 mm) and then decreases to 40.5±5.71 mm at T12. Throughout the lumbar region the distance is approximately constant at 47 mm. The maximum mean distance is 48.8±3.82 mm and occurs at L3.

Comparing the combined means of measurements along the axis with those from measurements parallel to the midline shows the former results in larger values at all but three levels (T7, T9 and T12) where the latter averages 1.1 mm longer. At the other levels the combined mean measurements along the axis averages 4.1 mm longer. These results are comparable with those of Zindrick et al. (1987) whose measurements along

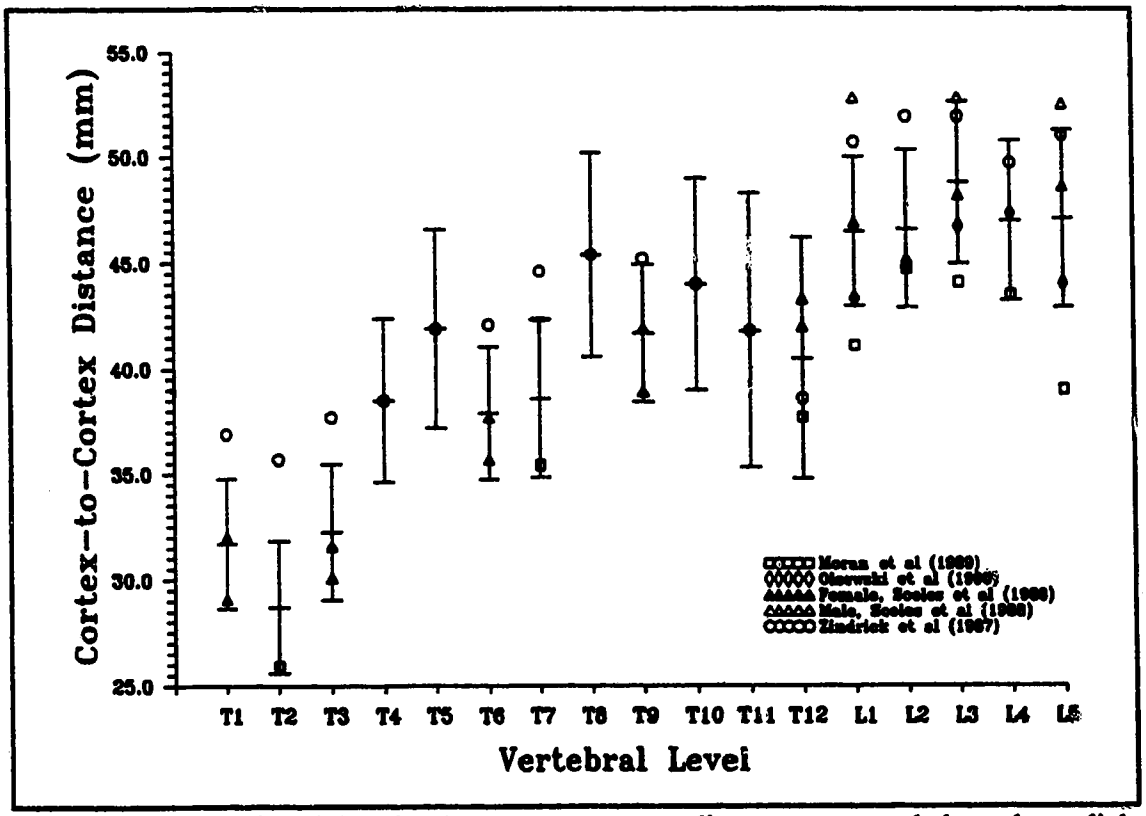

Figure D.10: Published data for the cortex-to-cortex distance measured along the pedicle axis for levels T1 to L5 with the calculated combined means and standard deviations.

the axis were significantly larger ($p=0.05$) than those parallel to the midline at all levels except T11 and T12. Comparison of the published results shows better agreement between researchers for measurements parallel to the midline than for those along the pedicle axis.

D.3.7 Relative Pedicle Angle Difference in the Transverse Plane

The relative difference in the transverse pedicle angle was calculated for fixation of three and four levels. For fixation of three levels based on the difference in the mean transverse angle the mean relative angle difference ranges from 4.0° (L1/L3) to 14.2° (L3/L5) (Figure D.11, Table E.7). With an offset of one standard deviation to each pedicle the mean relative difference ranges from 10.1° (L1/L3) to 25.8° (T12/L2) (Figure D.11, Table E.8). A range in the mean relative difference from 16.3° (L1/L3) to 36.7° (T12/L2) (Figure D.11, Table E.9) is evident with an offset of two standard deviations to each pedicle.

For fixation of four levels the mean relative difference in the transverse plane based on the difference in the mean pedicle angle ranges from 4.5° (T8/T11) to 18.8° (L2/L5) (Figure D.12, Table E.10). Calculations with one standard deviation offset to each pedicle present a range in the mean difference from 11.8° (T9/T12) to 26.0° (L2/L5) (Figure D.12, Table E.11). The relative difference between the superior and inferior pedicles with an offset of two standard deviations shows a range from 18.5° (T9/T12) to 35.3° (L2/L5) (Figure D.12, Table E.12).

D.3.8 Relative Pedicle Angle Difference in the Sagittal Plane

The relative difference in the sagittal plane must include both the difference in pedicle angulation between the superior and inferior vertebrae and the difference in angulation of the vertebrae due to the normal curvature of the spine. Though a number of studies have determined the overall lordosis and kyphosis angles in the normal population (Fon et al., 1980; Propst-Proctor and Bleck, 1983) there is only one published report of the inter-vertebrae angulation (Stagnara et al., 1982). Data from this source was used here to determine the relative difference in pedicle angulation in the sagittal plane.

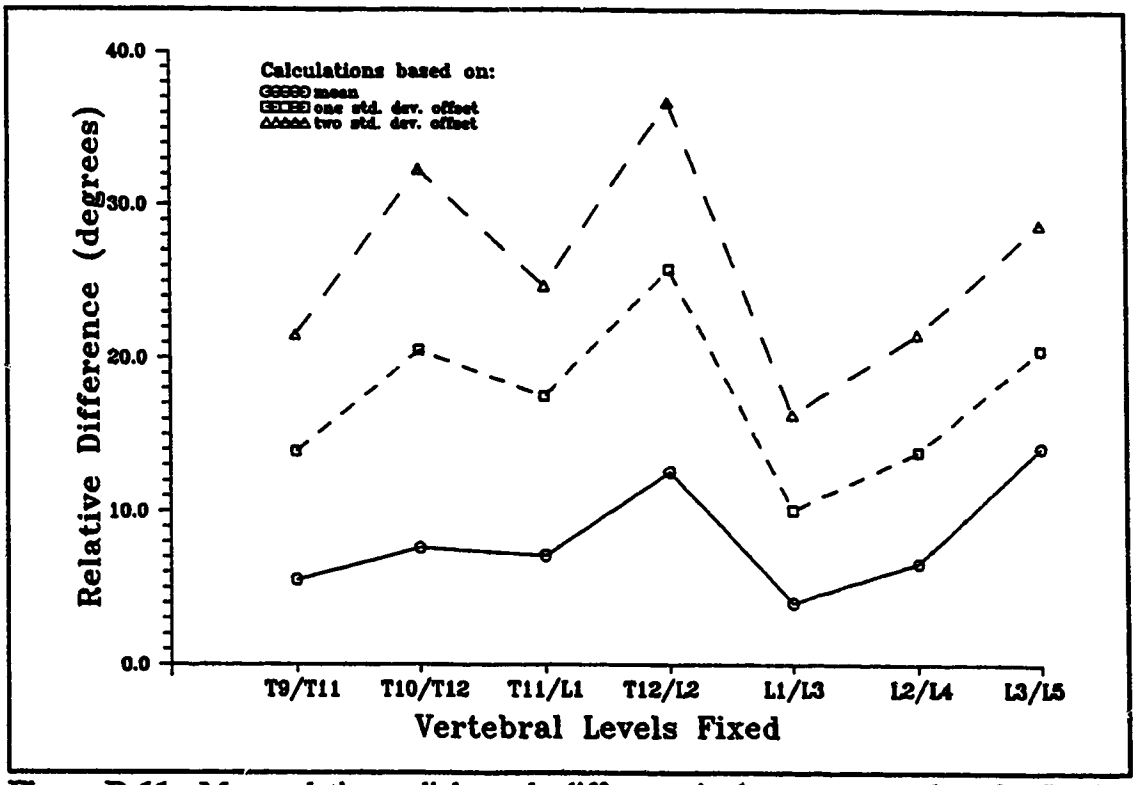

Figure D.11: Mean relative pedicle angle difference in the transverse plane for fixation of three levels.

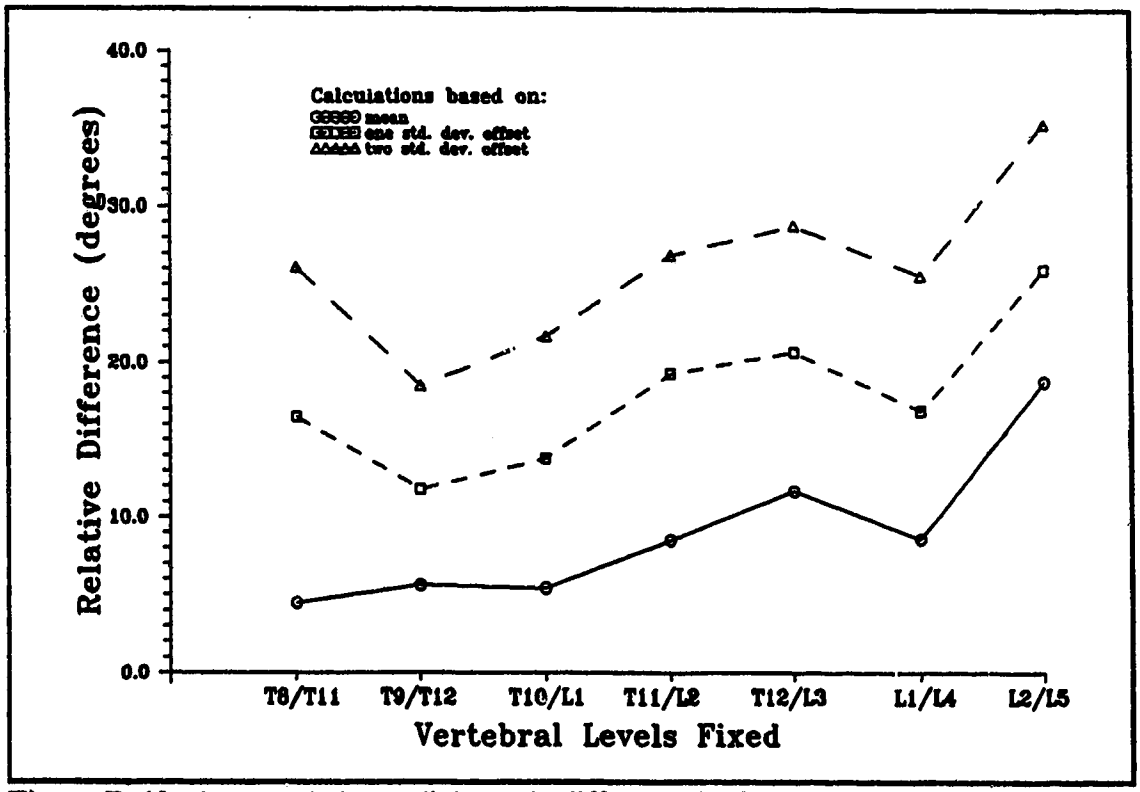

Figure D.12: Mean relative pedicle angle difference in the transverse plane for fixation of four levels.

For fixation of three levels the mean relative pedicle angle based on the mean pedicle and spinal curvature angles ranges from 5.7° (L1/L3) to 32.1° (L3/L5) (Figure D.13, Table E.14). Incorporating a one standard deviation offset to each angle results in a range of the mean relative pedicle angle from 21.8° (L1/L3) to 49.0° (L3/L5) (Figure D.13, Table E.15). If an offset of two standard deviations is used a range from 36.9° (L1/L3) to 65.6° (L3/L5) is found (Figure D.13, Table E.16).

For instrumentation of four levels the mean relative pedicle angle ranges from 8.4° (T12/L3) to 35.5° (L2/L5) for calculations based on the mean angles (Figure D.14, Table E.17). A one standard deviation offset to each angle shows a range of mean relative pedicle angles from 23.9° (T12/L3) to 53.1° (L2/L5) (Figure D.14, Table E.18). A two standard deviation offset results in a range from 40.6° (T12/L3) to 69.7° (L2/L5) (Figure D.14, Table E.19).

The relative pedicle angle is strongly dependent on the inter-vertebrae angle due to the spinal curvature. In the lower lumbar region this angle for a three level fixation is approximately $33°\pm8°$ and for fixation of four levels approximately $40°\pm9°$. However, for fixation of some levels the difference between the angulation of the superior and inferior pedicles cancelled the influence of the spinal curvature.

The relative angle difference in the two planes (transverse and sagittal) were combined to determine the range of angulation that must be accommodated by the fixation device. For fixation of three levels the variation in combined relative angles is shown in Figure D.15 for calculation based on the mean angles, one and two standard deviation offsets. The respective maximum angulation is 35.1°, 53.2° and 71.6°. Fixation of four levels, Figure D.16, shows respective maximums of 40.2°, 59.1° and 78.1°. All maximum values occur for fixation of the lowest lumbar vertebrae.

D.4 Discussion

Discrepancies in the data reported by various authors can be attributed to differences in the measurement technique, population studied (sex, age and race) and the condition of the vertebrae. In addition, the definition of the particular dimension differs between authors. For example, Berry et al. (1987) present the minimum pedicle

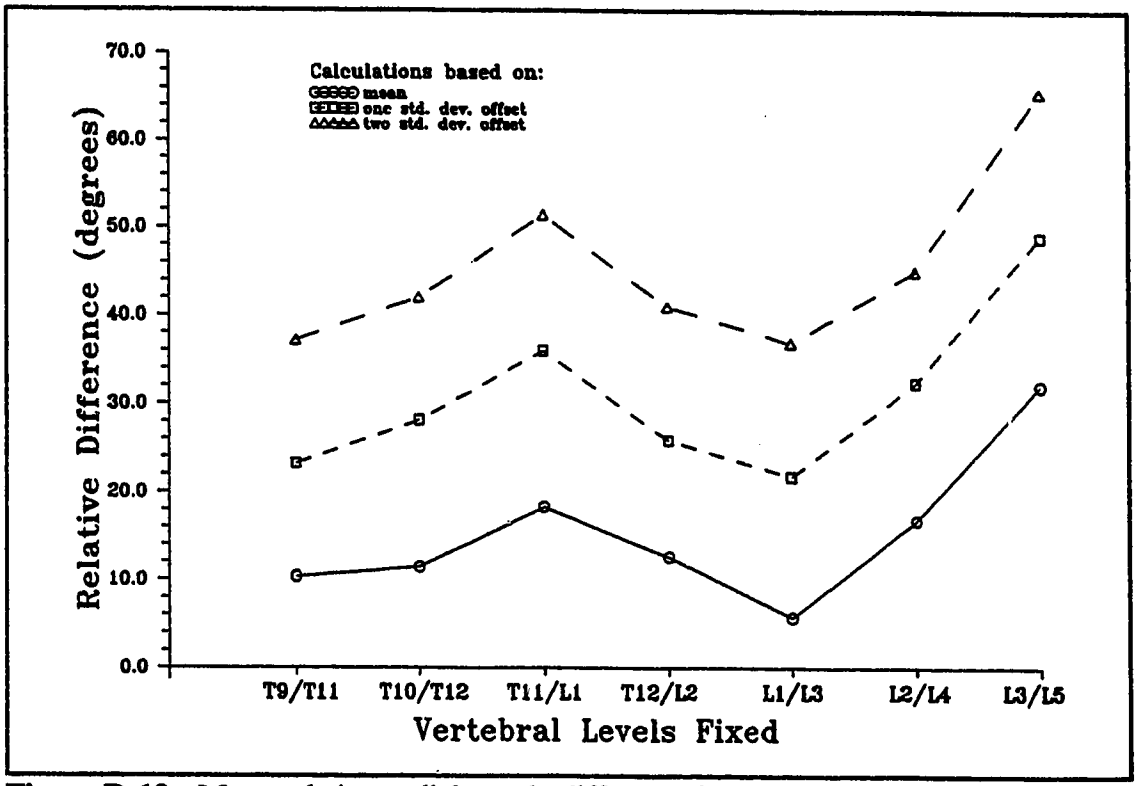

Figure D.13: Mean relative pedicle angle difference in the sagittal plane for fixation of three levels.

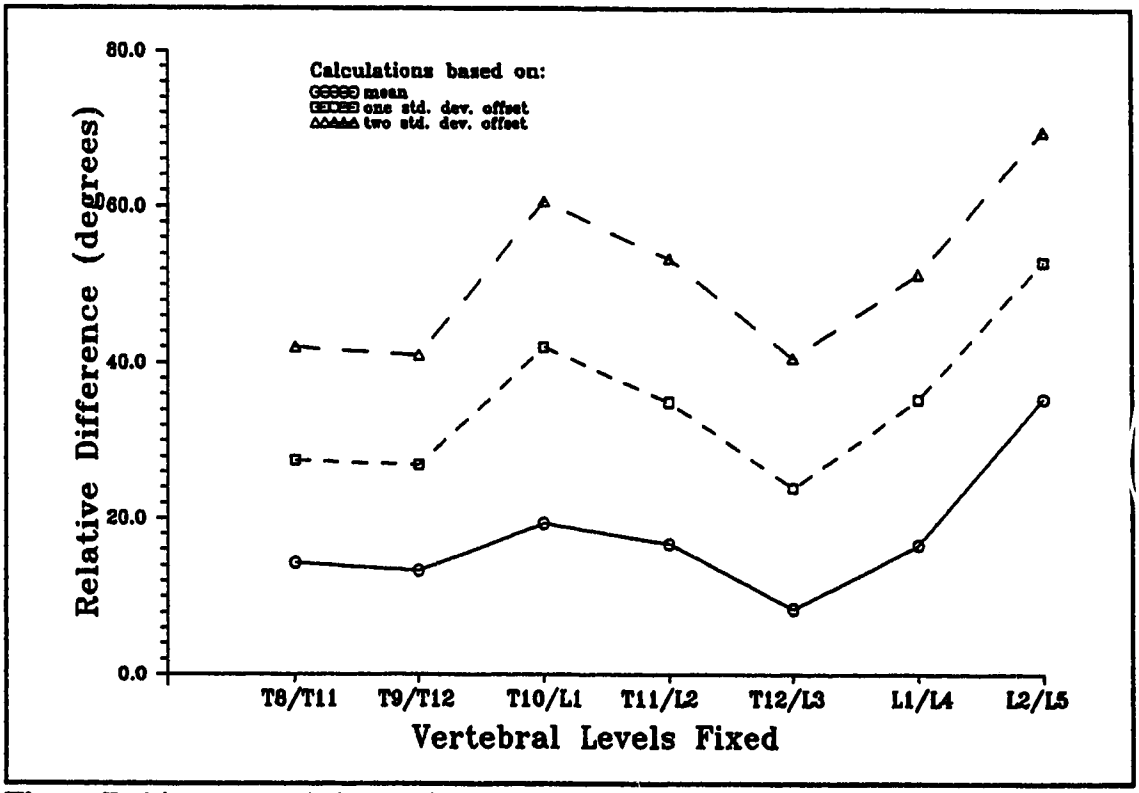

Figure D.14: Mean relative pedicle angle difference in the sagittal plane for fixation of four levels.

diameter regardless of the plane, while Zindrick et al. (1987) measured this dimension in the transverse plane. However, determination of the relative importance of these factors is beyond the scope of the present study.

D.5 Recommendations for Further Study

The estimates of the angulation that may be required *in-vivo* should be verified. Measuring the differences in screw angulation during surgery or the differences in expected sagittal plane screw angulation from lateral radiographs would assist in verifying these estimates.

Anatomical constraints on a number of dimensions of the fixation device have not been determined due to a lack of morphological data. The range of inter-screw distances could be determined from measuring the distance between anticipated screw entrance points on lateral radiographs. This would provide an indication of the range of rod lengths necessary. Measurement of the distances between the screw entrance point and both the spinous process and the facet joints would establish limits to the size of the

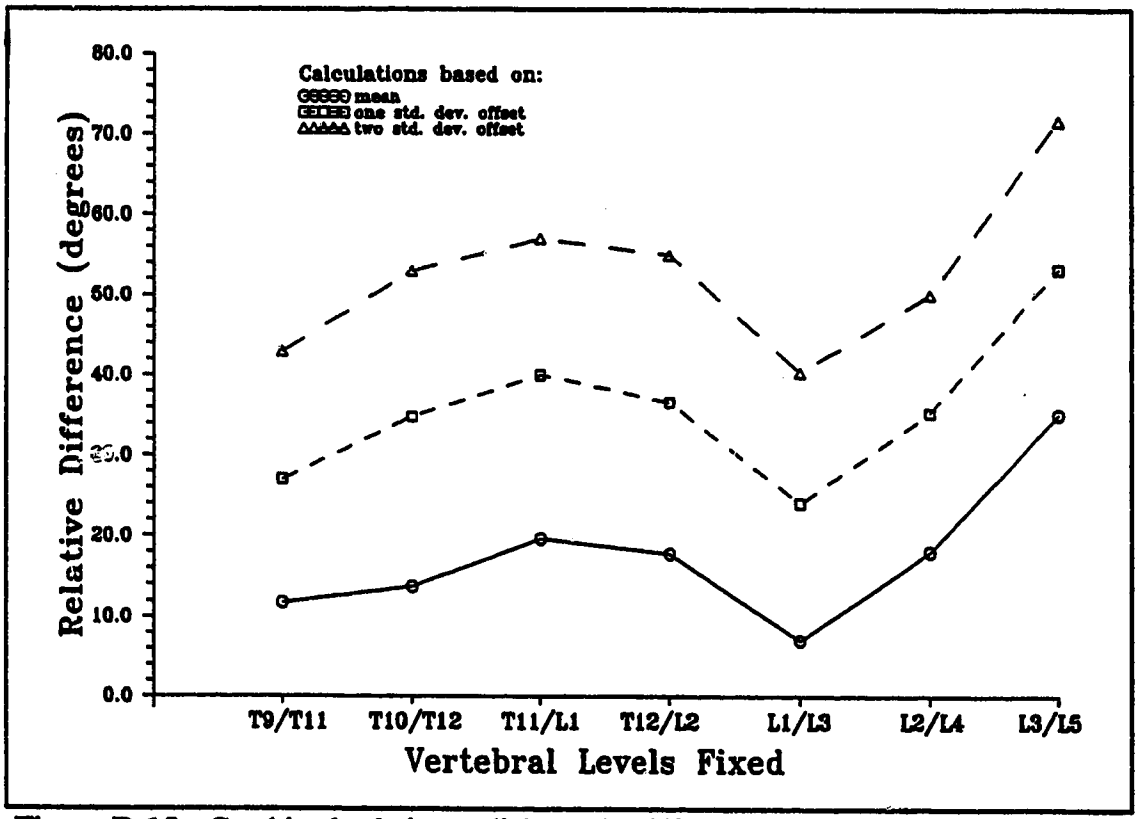

Figure D.15: Combined relative pedicle angle difference for fixation of three levels.

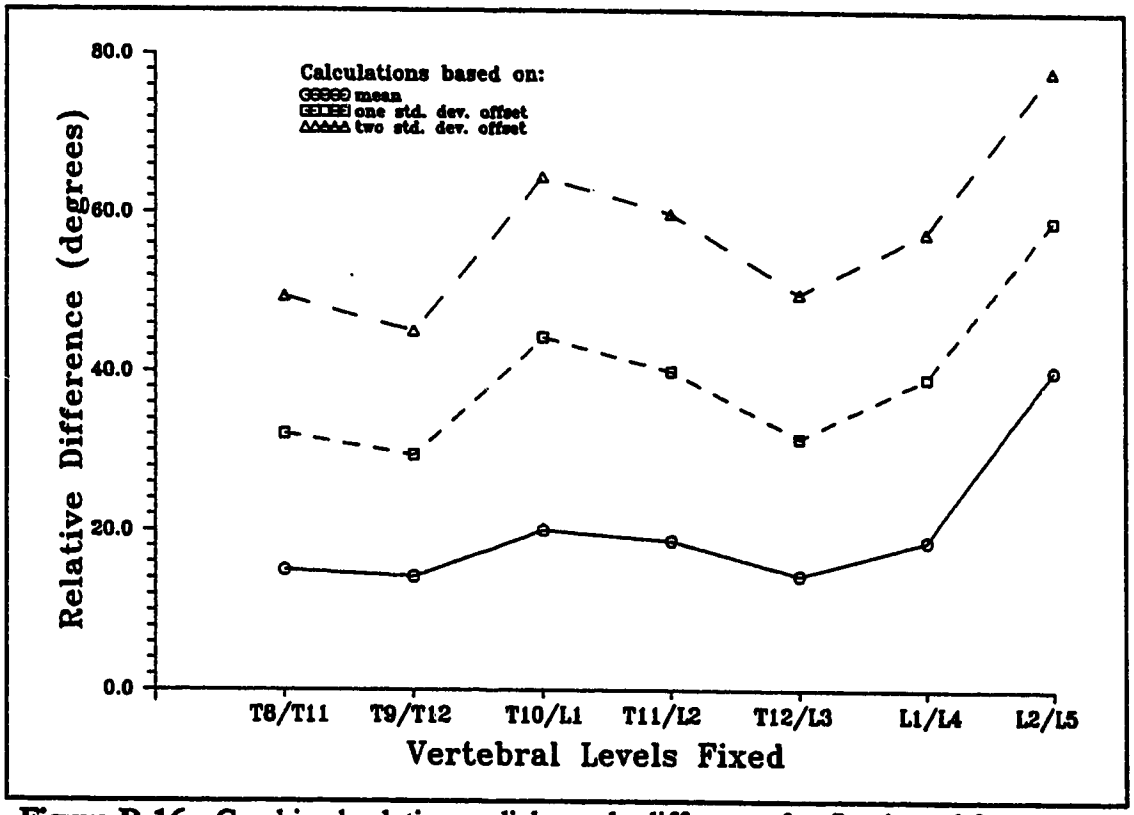

Figure D.16: Combined relative pedicle angle difference for fixation of four levels.

screw/rod junction. Use of the Grant Collection at the University of Toronto for this purpose is possible (Stuart-MacAdam, 1989).

Further study of the internal architecture of the pedicle is necessary as in previous studies sample size has been limited. Information on the ratio of cancellous to cortical diameter within the pedicle and on the relationship between pedicle size and maximal screw size would be useful.

Appendix E:
Morphology Tables

Level	Banta et al. (1989) (mm)	Krag et al. (1988b) (mm)	Misenhimer et al. (1989) (mm)	Moran et al. (1989) (mm)	Olsewski et al. (1990) (mm)	Saillant (1976) (mm)	Scoles et al. (1988)		Zindrick et al. (1987) (mm)
							Female (mm)	Male (mm)	
T1			7.4			8.0	6.4±1.2	7.3±1.0	7.9±1.4
T2			6.3	6.2±1.1		7.5			7.0±1.8
T3			5.2			6.5	3.4±0.9	3.9±0.5	5.6±1.4
T4			4.5			5.5			4.7±1.3
T5			4.7			5.3			4.5±0.9
T6	6.86±1.73		4.8			5.8	3.0±0.9	3.5±1.1	5.2±1.0
T7	7.69±2.10		4.7	4.9±1.4		6.2			5.3±1.0
T8	7.74±1.91		5.3			6.6			5.9±1.6
T9	7.63±1.85	6.88±2.23	5.6			7.0	4.1±1.3	3.9±0.9	6.1±1.5
T10	8.66±2.10	7.47±2.24	6.9			8.0			6.3±1.7
T11	9.58±2.66	7.83±1.56	7.9			9.4			7.8±2.0
T12	9.53±2.16	7.63±1.79	8.4	7.6±1.8		8.7	7.2±1.8	7.4±1.7	7.1±2.3
L1	7.47±2.08	7.01±1.84	8.0	6.9±1.7	8.2±2.3	8.5	6.5±1.8	8.3±1.4	8.7±2.3
L2	8.02±2.25	8.67±0.64	8.0	7.0±1.4	8.4±2.1	8.8			8.9±2.2
L3	9.12±2.03	9.30±1.51	9.2	9.1±1.5	10.2±2.5	9.5	7.9±1.5	9.1±1.5	10.3±2.6
L4	10.1±2.58	11.0±1.36	10.2	9.9±1.5	13.2±2.5	12.0			12.9±2.1
L5	13.4±3.26	15.2±1.97	12.9	10.1±1.3	20.1±3.7	16.7	10.2±1.4	9.7±2.0	18.0±4.1

Table E.1: Published data for the minimum pedicle diameter data for levels T1 to L5 (mean±std.dev.).

Level	Banta et al. (1989) n=16			Misenhimer et al. (1989) n=6			Moran et al. (1989) n=2		
	Min. Dia.	Endosteal Dia. †	%	Min. Dia.	Endosteal Dia.	%	Min. Dia.	Endosteal Dia. ‡	%
T1				7.4	4.4	59.5			
T2				6.3	3.2	50.8	6.3	5.3 (0.99)	84.8
T3				5.2	2.6	50.0			
T4				4.5	2.2	48.9			
T5				4.7	2.5	53.2			
T6	6.86	4.76 (0.803)	69.4	4.8	2.2	45.8			
T7	7.69	4.82 (0.936)	62.7	4.7	2.6	55.3	5.1	3.5 (0.49)	68.3
T8	7.74	4.89 (0.851)	63.2	5.3	2.7	50.9			
T9	7.63	5.03 (0.830)	65.9	5.6	3.0	53.6			
T10	8.66	5.26 (0.831)	60.7	6.9	4.2	60.9			
T11	9.58	5.37 (0.825)	56.1	7.9	5.0	63.3			
T12	9.53	5.46 (0.820)	57.3	8.4	5.4	64.3	5.9	4.2 (0.42)	71.8
L1	7.47	5.51 (0.890)	73.8	8.0	5.1	63.8	8.2	6.4 (3.39)	78.5
L2	8.02	5.56 (1.064)	69.2	8.0	4.9	61.3			
L3	9.12	5.68 (1.074)	62.3	9.2	6.7	72.8	7.5	6.0 (0.07)	79.3
L4	10.13	5.85 (1.109)	57.7	10.2	7.8	76.5			
L5	12.72	5.85 (0.854)	46.0	12.9	9.6	74.4	7.7	5.4 (2.83)	70.1

† published mean and standard deviation ‡ calculated mean and standard deviation from published data

Table E.2: Published results for the endosteal diameter and calculated result as a percentage of the minimum diameter.

Level	Banta et al. (1989) (mm)	Moran et al. (1989) (mm)	Olsewski et al. (1990) (mm)	Saillant (1976) (mm)	Scoles et al. (1988)		Zindrick et al. (1987) (mm)
					Female (mm)	Male (mm)	
T1				10.2	8.4±1.0	9.2±0.7	9.9±2.0
T2		11.8±1.3		11.7			12.0±1.2
T3				12.5	10.6±1.2	11.8±0.8	12.4±1.3
T4				13.0			12.1±1.0
T5				12.8			11.9±1.4
T6	10.34±1.82			13.0	10.6±1.0	11.5±1.2	12.2±1.0
T7	10.86±2.50	12.0±1.0		13.0			12.1±1.0
T8	10.60±2.46			13.6			12.8±1.2
T9	11.03±2.37			14.2	12.0±1.2	12.9±1.5	13.8±1.3
T10	12.52±3.01			15.4			15.2±2.0
T11	13.69±2.97			17.0			17.4±2.5
T12	14.34±3.16	17.1±1.5		17.6	14.8±1.4	16.0±2.1	15.8±2.4
L1	14.21±2.23	15.6±1.4	16.4±1.7	15.8	14.5±1.4	15.3±1.3	15.4±2.8
L2	13.63±1.73	14.9±0.8	15.4±1.5	15.4			15.0±1.5
L3	13.35±2.59	14.4±1.1	15.4±1.6	15.5	14.0±1.5	14.1±1.2	14.9±2.4
L4	13.49±1.81	12.8±1.2	15.4±2.0	16.0			14.8±2.1
L5	12.72±2.00	14.4±3.3	16.2±2.1	14.9	18.5±2.4	16.2±4.5	14.0±2.3

Table E.3: Published data for the maximum pedicle diameter for levels T1 to L5 (mean±std.dev.).

Level	Krag et al. (1988b) (mm)	Moran et al. (1989) (mm)	Olsewski et al. (1990) (mm)	Saillant (1976) (mm)	Scoles et al. (1988)		Zindrick et al. (1987) (mm)
					Female (mm)	Male (mm)	
T1				34.7	26.4±3.1	29.8±4.7	26.6±5.6
T2		23±6		25.0			19.1±7.1
T3				14.5	15.5±3.1	15.3±2.8	14.6±4.4
T4				9.2			12.6±4.1
T5				6.5			9.4±4.4
T6				4.0	10.9±1.8	10.2±1.4	9.6±4.5
T7		7±5		2.7			8.7±4.7
T8				2.0			8.1±5.2
T9	6.4±4.1			4.0	10.3±1.6	9.2±0.9	7.6±2.8
T10	5.9±5.9			4.0			4.6±4.6
T11	0.3±3.9			0.0			1.2±4.4
T12	-0.5±4.4	-3±9		-3.5	11.6±2.2	9.5±1.3	-4.2±9.5
L1	11.3±3.8	7±8	6±2	-0.5	12.3±2.0	11.6±1.6	10.9±2.2
L2	13.0±3.3	12±3	6±2	2.0			12.0±3.5
L3	17.5±2.7	14±4	7±3	4.2	15.1±2.0	14.7±1.9	14.4±3.8
L4	19.1±4.7	20±4	11±5	10.0			17.7±5.2
L5	27.1±9.0	31±5	22±5	29.0	24.1±3.7	23.1±2.8	29.8±6.3

Table E.4: Published data for the transverse pedicle angle for levels T1 to L5 (mean±std.dev.).

Level	Olsewski et al. (1990) † (degrees)		Pal & Routal (1986) (degrees)	Pal & Routal (1987) (degrees)	Saillant (1976) (degrees)	Zindrick et al. (1987) (degrees)
T1			21±6.23		10.4	12.6±5.8
T2			21±7.54		15.8	17.5±7.7
T3					16.5	17.3±6.0
T4					17.9	16.3±4.4
T5				21±6.30	19.2	15.0±3.4
T6					21.1	15.0±4.2
T7					22.1	15.7±4.2
T8				18±2.12	22.5	16.6±4.1
T9				19±3.40	21.9	16.0±3.8
T10					17.9	16.8±5.3
T11				19±3.71	18.7	15.4±4.9
T12				20±4.51	18.3	11.6±2.6
L1	6±2			5±3.95	11.7	2.4±6.3
L2	6±2				5.0	1.8±5.5
L3	6±2			3±5.53	0.6	0.2±4.7
L4	7±2			1±3.22	-0.9	0.2±3.9
L5	7±4	-9±5		7±5.71	-1.4	-1.8±3.5

† Data for L5 occurred in either cephalad or caudal direction with results reported separately

Table E.5: Published data for the sagittal pedicle angle for levels T1 to L5 (mean±std.dev.).

Level	Krag et al. (1988b) (mm)	Saillant (1976) (mm)	Zindrick et al. (1987) (mm)
T1		35.0	26.7±5.8
T2		30.8	27.4±6.3
T3		31.5	31.1±3.1
T4		33.5	31.5±3.2
T5		35.1	35.9±4.1
T6		37.1	36.9±5.0
T7		36.6	39.5±3.7
T8		39.0	40.6±4.1
T9	45.0±3.8	40.0	41.2±5.3
T10	44.3±5.5	40.1	40.1±4.6
T11	41.6±5.0	40.0	41.2±3.8
T12	41.0±8.9	40.1	43.2±5.0
L1	43.0±4.8	44.2	44.7±4.5
L2	44.6±2.4	44.7	45.5±3.7
L3	41.0±4.2	42.3	44.4±5.1
L4	40.2±4.4	43.7	40.7±4.3
L5	36.6±6.3	42.9	33.7±5.6

Table E.6: Published data for the cortex-to-cortex distance measured parallel to the vertebral midline for levels T1 to L5 (mean±std.dev.).

Level	Moran et al. (1989) (mm)	Olsewski et al. (1990) (mm)	Scoles et al. (1988)		Zindrick et al. (1987) (mm)
			Female (mm)	Male (mm)	
T1			29.1±2.0	32.0±2.0	36.9±5.8
T2	25.9±2.2				35.7±4.7
T3			30.1±2.5	31.6±2.5	37.7±5.1
T4					38.5±3.9
T5					41.9±4.7
T6			35.7±2.3	37.7±2.8	42.1±4.7
T7	35.4±3.8				44.6±3.7
T8					45.4±4.8
T9			38.9±2.6	41.9±2.5	45.2±4.9
T10					44.0±5.0
T11					41.8±6.5
T12	37.7±3.8		42.0±4.3	43.3±5.1	38.6±11.0
L1	41.1±3.5	43.3±2.6	46.9±3.1	52.8±4.0	50.7±4.3
L2	44.7±4.0	45.0±3.3			51.9±3.7
L3	44.1±3.5	46.7±3.5	48.2±3.1	52.8±4.0	51.9±4.6
L4	43.5±3.0	47.3±3.5			49.7±4.4
L5	39.0±3.1	44.0±3.9	48.6±4.6	52.5±4.3	51.0±4.7

Table E.7: Published data for the cortex-to-cortex distance measured along the pedicle axis for the levels T1 to L5 (mean±std.dev.).

Calculated from:	T9/T11	T10/T12	T11/L1	T12/L2	L1/L3	L2/L4	L3/L5
Krag et al. (1988b)	6.1	6.4	11.0	13.5	6.2	6.1	9.6
Moran et al. (1989)				15.0	7.0	8.0	17.0
Olsewski et al. (1990)					1.0	5.0	15.0
Saillant (1976)	4.0	7.5	0.5	5.5	4.7	8.0	24.8
Scoles et al. (1988), Female					2.8		9.0
Scoles et al. (1988), Male					3.1		8.4
Zindrick et al. (1987)	6.4	8.8	9.7	16.2	3.5	5.7	15.4

Table E.8: Relative difference in the mean transverse pedicle angle, calculated from published data, for fixation of three levels.

Calculated from:	T9/T11	T10/T12	T11/L1	T12/L2	L1/L3	L2/L4	L3/L5
Krag et al. (1988b)	14.1	16.0	18.7	21.2	12.7	14.1	21.3
Moran et al. (1989)				27.0	19.0	15.0	26.0
Olsewski et al. (1990)					6.0	12.0	23.0
Scoles et al. (1988), Female					6.8		14.7
Scoles et al. (1988), Male					6.8		13.1
Zindrick et al. (1987)	13.6	24.9	16.3	29.2	9.5	14.4	25.5

Table E.9: Relative difference in the transverse pedicle angle, calculated from published data, for fixation of three levels with one standard deviation offset from the mean to each pedicle.

Calculated from:	T9/T11	T10/T12	T11/L1	T12/L2	L1/L3	L2/L4	L3/L5
Krag et al. (1988b)	22.1	25.6	26.4	28.9	19.2	22.1	33.0
Moran et al. (1989)				39.0	31.0	22.0	35.0
Olsewski et al. (1990)					11.0	19.0	31.0
Scoles et al. (1988), Female					10.8		20.4
Scoles et al. (1988), Male					10.3		17.8
Zindrick et al. (1987)	20.8	39.0	22.9	42.2	15.5	23.1	35.6

Table E.10: Relative difference in the transverse pedicle angle, calculated from published data, for fixation of three levels with two standard deviations offset from the mean to each pedicle.

Calculated from:	T8/T11	T9/T12	T10/L1	T11/L2	T12/L3	L1/L4	L2/L5
Krag et al. (1988b)		6.9	5.4	12.7	18.0	7.8	14.1
Moran et al. (1989)					17.0	13.0	19.0
Olsewski et al. (1990)						5.0	16.0
Saillant (1976)	2.0	7.5	4.5	2.0	7.7	10.5	27.0
Scoles et al. (1988), Female		1.3			3.5		
Scoles et al. (1988), Male		0.3			5.2		
Zindrick et al. (1987)	6.9	11.8	6.3	10.8	18.6	6.8	17.8

Table E.11: Relative difference in the mean transverse pedicle angle, calculated from published data, for fixation of four levels.

Calculated from:	T8/T11	T9/T12	T10/L1	T11/L2	T12/L3	L1/L4	L2/L5
Krag et al. (1988b)		15.4	14.4	19.9	25.1	16.3	26.4
Moran et al. (1989)					30.0	25.0	27.0
Olsewski et al. (1990)						12.0	23.0
Scoles et al. (1988), Female		5.1			7.7		
Scoles et al. (1988), Male		2.5			8.6		
Zindrick et al. (1987)	16.5	24.1	13.1	18.7	31.9	14.2	27.6

Table E.12: Relative difference in the transverse pedicle angle, calculated from published data, for fixation of four levels with one standard deviation offset from the mean to each pedicle.

Calculated from:	T8/T11	T9/T12	T10/L1	T11/L2	T12/L3	L1/L4	L2/L5
Krag et al. (1988b)		23.9	23.4	27.1	32.2	24.8	38.7
Moran et al. (1989)					43.0	37.0	35.0
Olsewski et al. (1990)						19.0	30.0
Scoles et al. (1988), Female		8.9			11.9		
Scoles et al. (1988), Male		4.7			11.8		
Zindrick et al. (1987)	26.1	36.4	19.9	26.6	45.2	21.6	37.4

Table E.13: Relative difference in the transverse pedicle angle, calculated from published data, for fixation of four levels with two standard deviations offset from the mean to each pedicle.

Author	T9/T11	T10/T12	T11/L1	T12/L2	L1/L3	L2/L4	L3/L5	
Olsewski et al. (1990) †					8.0	20.0	34.0	18.0
Pal and Routal (1987)	9.0		21.0		6.0		37.0	
Saillant (1976)	12.2	8.6	14.0	14.3	3.1	13.1	31.0	
Zindrick et al. (1987)	9.6	14.2	20.0	10.8	5.8	17.4	31.0	

† Data for L5 occurred in either cephalad or caudal direction with results reported separately.

Table E.14: Relative difference in the sagittal pedicle angle, calculated from published data, for fixation of three levels.

Author	T9/T11	T10/T12	T11/L1	T12/L2	L1/L3	L2/L4	L3/L5	
Olsewski et al. (1990) †					19.0	31.0	48.0	33.0
Pal and Routal (1987)	22.1		34.7		22.5		56.2	
Zindrick et al. (1987)	24.3	28.1	37.2	25.9	23.8	33.8	47.2	

† Data for L5 occurred in either cephalad or caudal direction with results reported separately.

Table E.15: Relative difference in the sagittal pedicle angle, calculated from published data, for fixation of three levels with one standard deviation offset from the mean to each pedicle.

Author	T9/T11	T10/T12	T11/L1	T12/L2	L1/L3	L2/L4	L3/L5	
Olsewski et al. (1990) †					30.0	40.0	62.0	48.0
Pal and Routal (1987)	35.2		48.3		39.0		75.5	
Zindrick et al. (1987)	34.0	42.0	54.4	41.0	41.8	50.2	63.4	

† Data for L5 occurred in either cephalad or caudal direction with results reported separately.

Table E.16: Relative difference in the sagittal pedicle angle, calculated from published data, for fixation of three levels with two standard deviations offset from the mean to each pedicle.

Author	T8/T11	T9/T12	T10/L1	T11/L2	T12/L3	L1/L4	L2/L5	
Olsewski et al. (1990) †						22.0	41.0	25.0
Pal and Routal (1987)	12.0	10.0			10.0	17.0		
Saillant (1976)	16.8	14.6	15.2	16.7	10.7	8.4	33.6	
Zindrick et al. (1987)	14.2	15.4	23.4	16.6	4.4	18.8	36.4	

† Data for L5 occurred in either cephalad or caudal direction with results reported separately.

Table E.17: Relative difference in the sagittal pedicle angle, calculated from published data, for fixation of four levels.

Author	T8/T11	T9/T12	T10/L1	T11/L2	T12/L3	L1/L4	L2/L5	
Olsewski et al. (1990) †						35.0	56.0	41.0
Pal and Routal (1976)	24.8	24.9			28.0	33.2		
Zindrick et al. (1987)	30.2	28.8	42.0	35.0	19.7	38.0	54.4	

† Data for L5 occurred in either cephalad or caudal direction with results reported separately.

Table E.18: Relative difference in the sagittal pedicle angle, calculated from published data, for fixation of four levels with one standard deviation offset from the mean to each pedicle.

Author	T8/T11	T9/T12	T10/L1	T11/L2	T12/L3	L1/L4	L2/L5	
Olsewski et al. (1990) †						48.0	71.0	57.0
Pal and Routal (1987)	37.7	39.8			46.1	49.3		
Zindrick et al. (1987)	46.2	42.2	60.6	53.4	35.0	57.2	72.4	

† Data for L5 occurred in either cephalad or caudal direction with results reported separately.

Table E.19: Relative difference in the sagittal pedicle angle, calculated from published data, for fixation of four levels with two standard deviations offset from the mean to each pedicle.

Level	Berry et al. (1987)		Lanier (1939)		Nissan & Gilad (1986)		Postacchini et al. (1983)		Scoles et al. (1988)		Taylor & Twomey (1984)		Todd & Pyle (1928)	
	Ant. n=30	Post. n=30	White n=96	Negro n=88	Ant. n~157 †	Post. n~157 †	Italian n=63	Indian n=58	Male n=25	Female n=25	Male n=23	Female n=17	Ant. n=43	Post. n=43
T1			14.72	14.25					16.8±1.0	15.7±1.0			15.9	17.1
T2	17.6±1.2	16.5±1.2	15.49	15.51									17.7	17.9
T3			15.98	15.82					18.6±1.0	17.6±0.9			18.3	18.4
T4			16.67	15.98									18.3	19.1
T5			17.34	16.43							21	19	18.7	19.8
T6			17.89	17.02					19.8±1.3	18.8±1.1			18.7	20.6
T7	18.7±2.8	19.1±1.8	18.40	17.60									19.0	21.0
T8			18.76	18.06							23	21	19.3	21.4
T9			19.54	18.75					21.8±1.8	20.5±0.9			20.1	22.0
T10			20.92	19.93									21.5	23.1
T11			22.23	20.94									22.5	25.0
T12	23.4±2.0	24.8±1.8	23.76	22.35					25.9±1.3	24.6±1.2			24.0	26.3
L1	25.0±2.9	25.8±2.1	24.63	23.73	25.4±2.2	27.1±2.1	26±2	21±2	27.4±1.1	26.4±1.1	25	25	25.7	27.3
L2	27.9±1.9	25.2±2.2	24.26	23.66	27.2±2.0	28.0±2.1	27±5	22±2					27.2	27.5
L3	27.4±1.7	26.0±1.6	23.88	23.23	27.9±2.1	27.9±2.1	28±3	23±1	27.4±1.3	27.8±1.3	26	26	28.1	27.2
L4	26.7±1.5	26.4±1.7	23.63	22.92	27.4±2.2	27.1±2.3	28±3	23±2					28.2	26.1
L5	28.7±1.9	23.1±1.5	23.09	22.34	28.3±2.1	25.7±2.5	30±4	24±1	27.6±1.9	28.1±1.8	24	24	28.1	23.7

† sample size varies with vertebral level

Table E.20: Published data for vertebral body height for levels T1 to L5 (mean±std.dev.).

Level	Nissan & Gilad (1986)		Todd & Pyle (1928)		Twomey & Taylor (1985)	
	Anterior n~157 †	Posterior n~157 †	White n=33	Negro n=15	Male, 20-35 yrs. n=48	Female, 20-35 yrs. n=48
T1/T2			4.4	3.4		
T2/T3			3.1	2.5		
T3/T4			2.7	2.3		
T4/T5			2.1	2.7		
T5/T6			2.5	2.9		
T6/T7			3.0	3.4		
T7/T8			3.8	3.5		
T8/T9			4.3	4.2		
T9/T10			4.5	4.7		
T10/T11			4.9	5.0		
T11/T12			6.4	6.7		
T12/L1			8.0	8.2		
L1/L2	8.9±1.6	6.7±1.6	9.7	10.2	9.2±1.0	6.1±2.5
L2/L3	10.3±1.8	7.2±1.8	11.3	11.6	9.8±1.2	8.0±1.3
L3/L4	12.0±1.8	7.7±1.5	12.4	12.1	10.3±1.0	8.2±1.2
L4/L5	14.1±2.2	7.5±1.6	14.8	14.7	11.3±1.3	8.5±1.3
L5/S1	15.1±3.1	6.1±1.5	17.1	17.5	10.6±1.6	8.1±1.2

† sample size varies with level

Table E.21: Published data for intervertebral disc height for levels T1 to L5 (mean±std.dev.).

Appendix F: Review of the Physical Properties of Bone Cement (Polymethylmethacrylate) Applicable to a Transpedicularly Implanted Spinal Support

Bone cement (polymethylmethacrylate) is set by mixing the liquid monomer component with polymer powder. The mixture is initially a viscous liquid, but as the exothermic polymerization reaction occurs it becomes increasingly viscous. Setting time and maximum temperature of the curing cement are highly variable as are mechanical properties, the latter partly due to the porous nature of cured cement. ASTM standard F451-86 provides specifications for analysis and testing of acrylic bone cement.

A summary of published results of compressive tests (Table F.1), shows a range of compressive failure stress from 49.79 MPa (Saha and Pal, 1983) to 129.0 MPa (Lee et al., 1978). This wide range is probably due to differences between cement types and mixing and testing protocols. Of interest are values reported by Saha and Pal (1983) that are below the ASTM requirement of 70 MPa for the compressive strength of bone cement.

Fatigue, fracture toughness, bending, tension and compression testing have shown that properties of cement are influenced by a wide range of variables including:

1. cement from different manufacturers (Lee et al., 1978; Rimnac et al., 1986; Robinson et al., 1981)
2. variation between batches (Haas et al., 1975)
3. quantity mixed (Davies and Harris, 1990)
4. initial monomer temperature (Stubbs et al., 1975)
5. presence of reinforcing materials (Robinson et al., 1981; Saha and Pal, 1986)
6. presence of foreign materials such as blood and water (Gruen et al., 1976)
7. temperature of equipment used for mixing (Haas et al., 1975)
8. mixing technique (hand, vacuum, mechanical) (Lindén, 1988; Wixson et al., 1987)
9. mixing speed and duration (Haas et al., 1975; Lee et al., 1978)
10. centrifugation (length of time and angular velocity) (Burke et al., 1984; Davies et al., 1987a,b, 1988; Rimnac et al., 1986)
11. time between mixing the cement and its insertion into the mould (Lee et al., 1978)
12. specimen size (Brown and Barger, 1984)
13. application of pressure during curing (length of time and level) (Bayne et al., 1975; Lee et al., 1978)

Author	Sample Size	Specimen Size † (mm)	Pressure (MPa)	Monomer Temp. (°C)	Strain Rate (sec^{-1})	Cement Type	Storage		Failure Stress (MPa)
							Time	Condition	
Bayne et al. (1975)	5	D = 4 H = 8	Ambient	20±1	$1.0x10^{-3}$	Simplex P[1]	-	-	76.5±2.5 ‡
			27.6						83.9±1.7 ‡
Lautenschlager et al. (1976a) Lautenschlager et al. (1976b)	5	D = 6 H = 12	-	23	$34.7x10^{-3}$	Simplex P (RO)	24 hrs	-	80.66±5.10
Lee et al. (1978)	7-10	D = 9 H = 27	0.2 MPa for 15 sec	20±1	$3x10^{-3}$	Simplex P (RO)	2 hrs	37°C Saline	80.2±1.6
					$90x10^{-3}$		2 days		122.6±2.7
					$3x10^{-3}$	Simplex P	2 hrs		80.7±2.0
					$90x10^{-3}$		7 days		129.0±2.0
					$3x10^{-3}$	CMW[2]	2 hrs		79.5±2.5
					$90x10^{-3}$		7 days		124.9±3.5
					$3x10^{-3}$	Palacos R[3]	2 hrs		78.4±2.5
					$90x10^{-3}$		7 days		117.6±3.0
Robinson et al. (1981)	9-10	D = 6 H =12	-	23	$33.3x10^{-3}$	Simplex P	24 hrs	-	89.2±2.09
						Zimmer[4]			84.4±2.08
						Zimmer LVC			84.7±7.81
Saha and Pal (1983)	10	D = 17 H = 30	Ambient	~25	$0.62x10^{-3}$	Simple P (RO)	-	~25°C	49.79±4.39
	9				$12.3x10^{-3}$		48 hrs	~25°C	61.37±5.42
Stubbs et al. (1975)	≤12	D = 9.5 H = 19	-	"room"	$2.2x10^{-3}$	Simplex P	2 weeks	37°C water	81.9±7.6
				3					77.3±2.4

† D = Diameter, H = Height ‡ compressive yield stress 1 Howmedica International Ltd. 2 CMW Laboratories 3 Kulzer Bros. 4 Zimmer Inc.

Table F.1: Published data for the compressive failure stress of bone cement.

14. curing conditions (equilibrium temperature and if immersed in liquid) (Haas et al., 1975; Lee et al., 1978)
15. time between mixing and testing (Lee et al., 1978)
16. strain rate (Lee et al., 1978; Saha and Pal, 1983)

In the proposed support design many of the above variables that affect the strength are pertinent (Table F.2). Moisture content and equilibrium temperature invariably influence the strength of the *in-vivo* support, however, variables such as cement type and mixing technique must be selected to produce the optimum strength. Depending on the support design other variables must also be considered. These include pressurization of cement during implantation and initial monomer temperature. Application of pressure to cement while setting increases the mechanical strength and should be included in the implantation protocol. Unfortunately, the pressure that is developed *in-situ* is difficult to predict, thus, its impact on the mechanical properties for this application can not be determined. Cooling the monomer results in a longer period of low viscosity and prolonged setting time (Burke et al., 1984). Stubbs et al. (1975) documented a significant 5% decrease in the compressive failure stress with chilling of the monomer. Under the worst conditions these variables may result in a decrease of approximately 20% in the ultimate compressive strength (estimated summation of individual influences) and must be considered in the support design. The inter-relationship of these many variables has not been fully investigated.

The influence of several other factors that may affect compressive strength of bone cement and be applicable to the design have not been investigated. Mixing in a vacuum chamber and centrifugation after mixing are two methods that have been used to reduce the porosity of the cement, as the presence of voids has been correlated with premature failure of test specimens (Burke et al., 1984).

Addition of a number of materials (carbon, aramid and ultra-high molecular weight polyethylene fibres) to bone cement have been shown to improve the mechanical properties of the cement. An improvement in the compressive failure stress of 10.7% was reported by Saha and Pal (1986) with carbon fibre reinforcement. Creep resistance has been shown to improve with addition of carbon or aramid fibres (Pal and Saha,

Experimental Variable	Author	Influence
Cement Type	Lee et al. (1978)	up to 20% difference between manufacturers
	Robinson et al. (1981)	up to 5% difference between manufacturers
Initial Monomer Temperature	Stubbs et al. (1975)	-5% with chilled monomer
Mixing Technique	Lee et al. (1978)	up to 21% difference between vigorous and minimal
Delay in Moulding	Lee et al. (1978)	up to 40% decrease with delay in insertion
Equilibrium Temperature	Lee et al. (1978)	-10% at 37°C compared with 20°C
Pressurization	Bayne et al. (1975)	+9% with 27.6 MPa for 0.5 hr.
	Lee et al. (1978)	+12% with 0.2 MPa for 15 sec.
Strain Rate	Lee et al. (1978)	+67% for impact rates over lower rates
	Saha and Pal (1983)	+23% from 0.6×10^{-3} to 12.3×10^{-3} sec^{-1}
Ageing	Jaffe et al. (1974)	negligible
	Lee et al. (1978)	-10% over 10 years though, increase in first week
Moisture Content	Lee et al. (1978)	-3% when saturated compared with dry

Table F.2: Influence of experimental variables on the compressive failure stress of bone cement.

1982). Also the maximum exothermic reaction temperature was lowered significantly by such additions (Knoell and Maxwell, 1975; Saha and Pal, 1986). Improvements in physical properties of the cement by fibre reinforcement or by mixing protocol may enhance the design and should be investigated further.

The only published results of the compressive fatigue behaviour of bone cement are those of Jaffe et al. (1974). Their specimens had been stored in bovine serum (blood plasma without fibrin) for up to two years. Though the influence of stress level was investigated, the small sample size (1) used for each level and the high loading frequency that resulted in a considerable rise in temperature within the specimen, make the results questionable. However, an estimate of the endurance limit (14.0 - 17.0 MPa) was suggested. Although further testing of compressive fatigue of bone cement would appear necessary, Gates et al. (1983) have suggested that the effect of compression in fully-reversed uniaxial tension fatigue is small or negligible, and that fatigue failure is strongly influenced by the tensile strain.

Bone cement exhibits a time-dependent response that may have implications on the design. Pal and Saha (1982) studied its stress relaxation and creep behaviour and reported that for a constant strain of 1% the percent relaxation at one hour was approximately 14% and at eight hours was approximately 23%. This time-dependent response of bone cement may be minimal compared to the response of neighbouring soft tissues. *In-vitro* tests of an anterior support in a spinal fracture model would possibly provide information on this question.

Shrinkage of bone cement during polymerization may also affect the efficacy of a cement-based design. Haas et al. (1975) reported a shrinkage rate from $2.3 \pm 0.3\%$ to $3.2 \pm 0.6\%$. This was dependent on a number of variables including mixing technique and the presence of barium (used to make the cement radiopaque). Shrinkage, should it occur, might decrease the effectiveness of the support as it may cause poor contact with the intact adjacent endplates. However, this may be inconsequential as the support is implanted when the patient is supine and the spine is subjected to a minimal load. When the patient is mobile the additional compressive load on the spine results in displacement of the vertebral body that should compensate for any shrinkage.

A major concern in the use of bone cement to provide anterior stability is the exothermic nature of the polymerization reaction. Damage to adjacent tissues could occur if the temperature remains high over an extended period of time. Estimation of peak temperature at the surface of the support is difficult given the number of variables that influence the reaction. *In-vitro* experimentation to determine surface temperature and amount of heat produced by a support of actual dimensions and design is essential. These tests would also indicate if irrigation of the support would be adequate to cool the curing cement.

Another concern is that implantation of bone cement has undesirable physiological effects. Curing bone cement may release monomer into adjacent tissues and the circulatory system. This can affect pulmonary function (Phillips et al., 1971; McLaughlin et al., 1973) and/or cause local toxic effects (Linder, 1976). As the quantity of cement required in this application would be small compared to that used in joint arthroplasty and in spinal surgery (Scoville et al., 1967; Spence, 1973) and as the cement would be encased within the mould material, except for possible leakage, minimal adverse physiological effects of the cement would be expected.

Appendix G: Development of Spinal Fixation Load Transducers

Accurate knowledge of the loading of a spinal fixation device was necessary to evaluate the effectiveness of the anterior support. Several researchers have applied strain gauges to existing spinal fixation devices to measure *in-vitro* loading on the device (Ashman et al., 1989; Carson et al., 1990; Russell, 1988). Attaching strain gauges to VSP plates (Ashman et al., 1989; Carson et al., 1990) also poses some difficulties. Gauges must be placed on a non-symmetrical, non-uniform cross-section and near the edges of the cross-section. Therefore, their outputs may include axial loading effects as well as response to torsional loads.

To overcome the problems encountered in instrumenting existing spinal fixation devices, load transducers, based on the VSP plate, were developed. The transducers, Figure G.1, are similar in geometry to a three-slot VSP plate except that the central slot is replaced by a solid section upon which four strain gauges are mounted. These transducers are mounted like VSP plates and, after calibration, accurately measure the applied moment.

G.1 Calibration of the Load Transducers

The load transducers were calibrated to obtain bending loads for use in spinal segments loaded in flexion, though this mode of loading subjects the transducers to combined axial compression and bending.

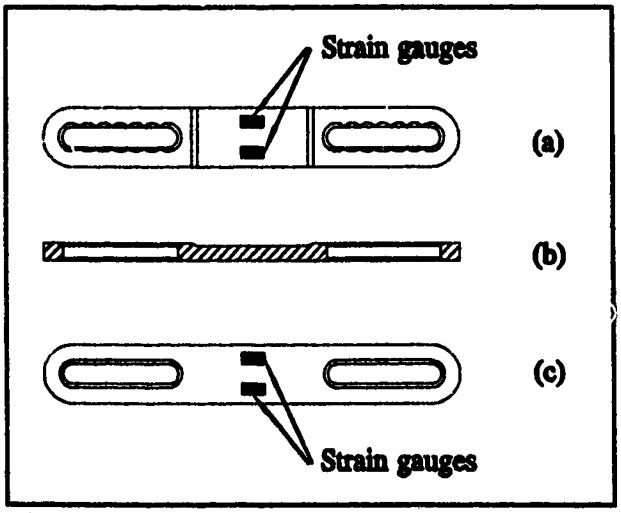

Figure G.1: Top, cross-sectional and bottom views (a,b and c, respectively) of the load transducers.

G.1.1 Materials and Methods

The transducers were calibrated to a maximum applied load of 10.7 Nm by application of a compressive load on two 3/8 inch square bars mounted at the distal ends of the plates (Figure G.2). The compressive load was applied by a

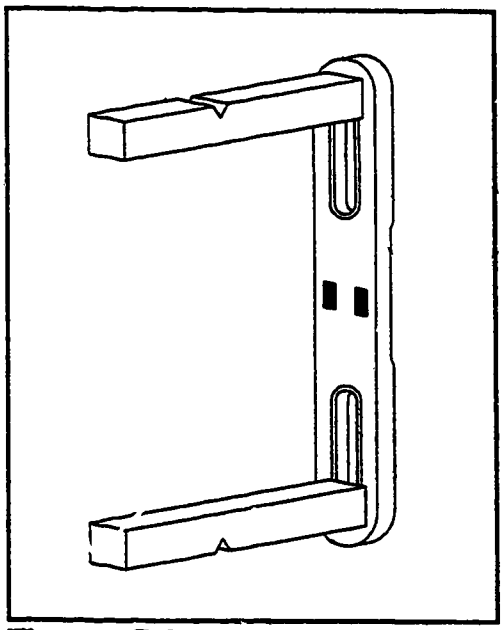

Figure G.2: Configuration for calibration of the load transducers.

Universal Testing Machine (Instron Corp.) at a fixed distance from the centreline of the plate. The transducers' voltage output was conditioned by a Strain Gage Conditioner (Vishay Measurements Group) with its gain set to provide a peak output of ten volts at the maximum load. Output from the strain gauge conditioner was recorded on an XY Plotter (Watanabe Instruments Corp.).

G.1.2 Results

The mean calibration factors for the two plates were 1.133 ± 0.021 Nm/V and 1.143 ± 0.016 Nm^{-1}, respectively, these correspond to 2.904×10^{-3} mV/V and 2.872×10^{-3} mV/V, respectively, at 10.0 Nm flexion.

G.1.3 Error Analysis

Bending of the load transducer due to the applied moment is a potential source of error as the design assumes a constant distance between the point of load application and the neutral axis of the plate. The error due to this assumption can be estimated by comparing the peak stress, σ_{max}, calculated with and without bending. The peak stress for the case without bending is calculated from:

$$\sigma_{max} = \frac{Mc}{I} + \frac{P}{A} \qquad \text{(G.1)}$$

where: M is the applied moment

P is the compressive load

c is the distance from the neutral axis to the outside edge

I is the moment of inertia

A is the cross-sectional area of the plate

When bending of the plate is incorporated the peak stress becomes:

$$\sigma_{max} = \frac{P}{A}\left(1 + \frac{ec}{r^2}\sec\frac{L}{r}\sqrt{\frac{P}{4EA}}\right) \qquad (G.2)$$

where: e is the moment arm

r is the radius of gyration

L is the distance between the square bars at the distal ends of the plates

E is the modulus of elasticity

Comparing the results obtained using the above equations at the maximum applied moment, 10.7 Nm, shows a 2.3% difference between the peak stress without bending (Equation G.1) and with bending (Equation G.2). This small difference indicates the validity of the assumption that bending of the plate does not occur. This is further confirmed by the finding that output from the transducer is linear over the calibrated range.

G.2 Verification of Load Transducer Performance

During *in-vitro* testing of the anterior support in a spinal fracture model the transducers were mounted in a configuration such that they were subjected to a complex loading regimen. This configuration differs from that in which they were calibrated. Evaluation of this difference was achieved by initially studying the mechanics of the loaded fixation plate and then by *in-vitro* testing of the transducers in the configuration when installed on a spinal segment.

G.2.1 Mechanics of Fixation Device Loading

Figure G.3 shows a free body diagram of the implanted transducers mounted at an angle (θ) to the vertebral midline. The applied moment (M_A) is the product of the applied compressive load (F) and the distance between the point of load application and the axis of rotation of the transducers (d). Each plate experiences a moment of $0.5M_A$. Resolving the moment on each plate into components in the plane of the transducer and

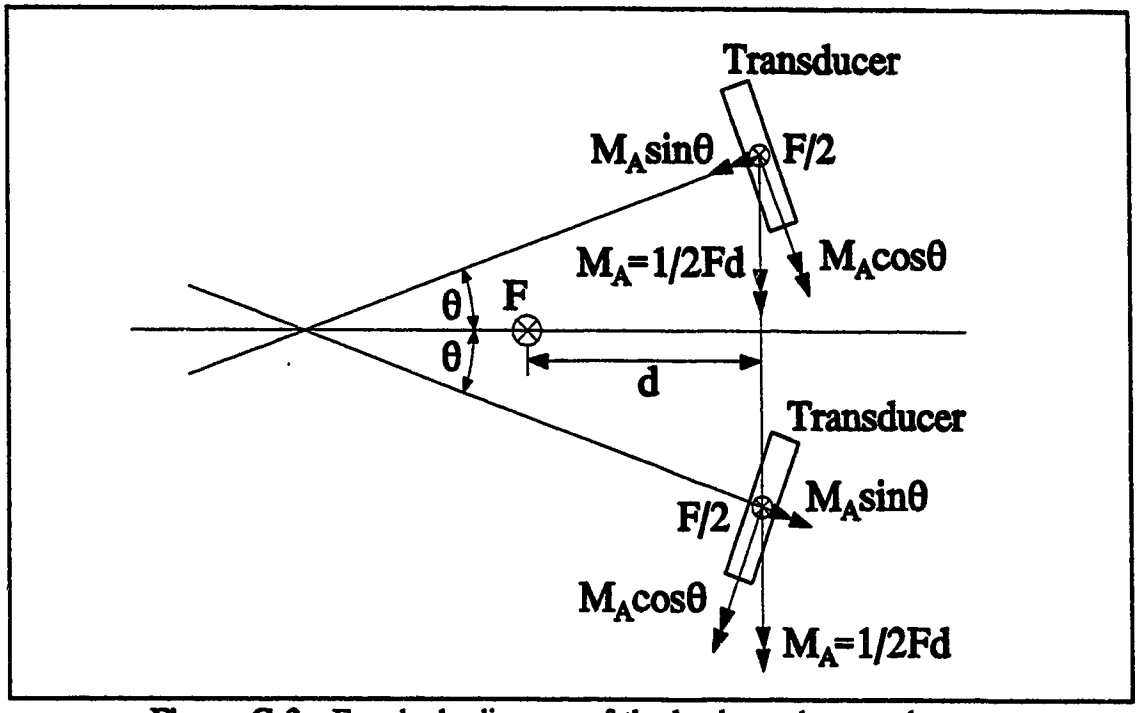

Figure G.3: Free body diagram of the loads on the transducers.

perpendicular to the plane of the transducer shows that the component $0.5M_A\cos\theta$ causes loading for which the transducers are calibrated. The transducers are designed to be insensitive to the component perpendicular to the plane of the component ($0.5M_A\sin\theta$). Therefore, the theoretical moment ratio (ratio of the recorded moment, M, to the applied moment, M_A) for each plate is $0.5\cos\theta$.

G.2.2 Testing of the Load Transducer Performance

To verify their use in the complex loading regimen that occurs during *in-vitro* testing in a spinal fracture model, the transducers were mounted so as to represent an idealized configuration of implantation on a spinal segment. In the idealized configuration the superior and inferior pedicle screws on each side of the vertebral midline are oriented at the same angle and screws at each level are oriented in equal, but opposite angles from the midline.

G.2.2.1 Materials and Methods

The transducers were mounted as shown in Figure G.4 and loaded to a maximum

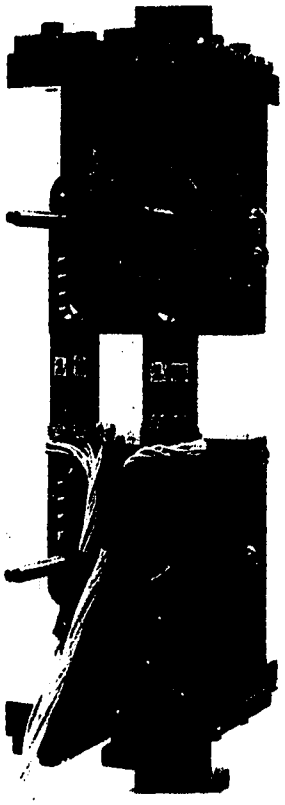

Figure G.4: Load transducers mounted in the test apparatus.

flexion moment of approximately 10 Nm in a Universal Testing Machine (MTS Systems Corp.). Seven tests were performed with a maximum of five loading cycles per test and a maximum of ten data points collected per cycle. The data collected in each cycle was averaged.

G.2.2.2 Results

The ratio of applied moment to indicated moment from the transducer (moment ratio) was determined for each transducer (0.504 ± 0.006 and 0.529 ± 0.012, respectively). Combining these results gives the mean combined moment ratio (0.516 ± 0.010) that was 4.8% greater than the theoretical value ($M_A \cos\theta$, $\theta = 10°$).

G.2.2.3 Discussion

The small difference between the experimental and theoretical values (4.8%) shows that the use of transducers to estimate the loading on the fixation plates is accurate. The error may be due, in part, to fluctuations in applied load. At low levels the average standard deviation in the applied load was approximately 11%. In addition, errors due to bending of the transducers (maximum of 2.8% at 10.7 Nm), measurement of the moment arm and the alignment of the transducers may affect the experimental result.