THE UNIVERSITY OF ALBERTA

BIOMECHANICAL EVALUATION OF PEDICLE SCREW FIXATION DEVICES.

BY

GEORGE GORDON QUINE RUSSELL

A THESIS

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301-10520 80 Street,
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Department of Graduate Studies and Research,
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Dear Sirs,

Permission is granted to Dr. G. Gordon Q. Russell to reproduce a drawing of "The Triple Transducer System" in figure 9, page 150 of his thesis. This drawing was previously published in my thesis entitled "A System for Evaluating Spinal Fixation Devices" which was submitted to the department of graduate studies and research at the University of Alberta as partial fulfilment of the requirements for the degree of Master of Science in Mechanical Engineering, spring, 1988.

Yours Sincerely,

Robert Evenson

Robert Evenson.

THE UNIVERSITY OF ALBERTA

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The undersigned certify that they have read, and recommended to the Faculty of Graduate Studies and Research for acceptance, a thesis entitled Biomechanical Evaluation of Pedicle Screw Fixation Devices. Submitted by George Gordon Quine Russell in partial fulfilment of the requirements for the degree of Master of Science in Experimental Surgery.

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DEDICATION

TO MARGARET, AND THREE GENERATIONS OF RUSSELL'S.

FOR YOUR PATIENCE, UNDERSTANDING AND SUPPORT.

ABSTRACT

Instrumentation systems developed for spinal surgery have run into problems when used clinically. To help avoid these problems, methods of in-vitro evaluation are necessary.

Methods of evaluating spinal fixation devices have been criticized because of their inability to exclude many variables. Consequently doubt exists as to the usefulness of such tests. As a result, some modern instrumentation systems have not been subjected to wide spread evaluation prior to their in-vivo use. These problems are addressed in this thesis.

In an effort to improve present methods of biomechanical testing, a new system was designed which excludes many of the variables which have been so problematic in the past. This system includes a vertebral fracture model, an end cap which holds the vertebra and allows accurate application of loads, and a transducer system which allows local motion at the fracture site to be accurately determined in all six degrees of freedom.

Using this system, a comparison of four pedicle screw fixation devices was performed. The basis of comparison was the amount of motion permitted at the fracture site by each device with the application of similar loads. The four systems tested were: Steffee, A.O. fixateur

interne, Roy-Camille, and Cotrel Dubousset. Each of the four devices was tested using a forward flexion mode, a torsional test, a combination of torsion and flexion, and a fourth test using a higher forward flexion load. All loads were within the estimated human physiological range. Four repetitive tests were performed on each spine before the final readings were taken to minimize the effects of time dependent behaviour.

Results showed that the Steffee system best prevented motion at the fracture site during both torsion and flexion loading, but the screw design presented a problem with screw bending at a stress riser. The AO fixateur interne was also excellent at preventing motion during torsion tests, but was less effective during flexion. The other two systems did not fare as well.

The improved testing procedure described allows valid evaluation of spinal fixation devices.

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LIST OF NOMENCLATURE, AND ABBREVIATIONS

A.O.	Arbeitsgemeinschaft fur Osterosynthesefragen. (Association for the Study of Internal Fixation).
C.D.	Cotrel Dubousset.
C.T.	Computed Tomography
Creep	Change in dimension with time at a given load.
Cyclic Testing	Repetative loading at a rate of several thousand cycles per minute in which each cycle consists of compression and tension.
End-Cap	Device used to secure the spinal model to the testing machine allowing accurate load application.
Instantaneous Centre of Rotation.	The axis of the spinal fracture about which sagittal plane motion occurs.
Instron	Testing machine made by Instron Corporation, Canton, Mass.
Kyphosis	Spinal curvature in the antero-posterior plane with the concavity foreward.
M.T.S.	MTS Systems Corporation. Makers of the MTS Materials Testing Machines.
mm	Millimeter.
Moment	Application of a force at a distance.
Nm	Newton meter. A Standard International unit of moment equivelent to one Newton acting through one meter.

Newton	A Standard International unit of force. One pound is equal to 4.47 Newtons.
Pseudarthrosis	Failure of fracture union resulting in a false joint.
R.C.	Roy-Camille.
Relaxation	Loss of strees with time at a constant deformation.
Repetative Testing	Repetitions of the same type of load with an allowance for time dependent behaviour.
Scoliosis	Lateral spinal curvature.
Static Testing	The analysis of forces and stresses on an object at rest.
T.D.B.	Time Dependent Behaviour.

CHAPTER I

INTRODUCTION

The first report of spinal surgery dates back to the 1700's; the first use of spinal rods was reported by Professor Fritz Lange in 1902 (135). With the advances in asepsis and the development of radiological techniques controversies have arisen in relation to the indications for conservative or operative treatment of certain spinal conditions including fractures. Surgery can be performed posteriorly, anteriorly, or in combination, and there are numerous possible instrumentation devices available for internal stabilization.

The function of any spinal instrumentation system is to hold the spine immobilized for a long enough period to allow either fusion to occur or for the fracture to heal. If the fracture does not heal, or a fusion fails, added stress on the instrumentation system increases the chances of failure (19).

Since the late 1960's newer methods of spinal instrumentation have become available. These include pedicle screws combined with plates or rods. Initial clinical reports on these systems appears encouraging with excellent fusion rates and minimal complications. Due to the recent introduction of many of these methods, in-vitro testing in comparing the methods is sadly lacking.

To produce an accurate in-vitro comparison of spinal fixation devices, it was necessary to develop a vertebral fracture which could be produced in a homogenous population of spines. This fracture had to be reproducible, and clinically relevant. The pattern of time dependent behaviour for this model was calculated and from these results a suitable test regime was established. Specially designed end caps were used to allow accurate application of suitable loads, and a transducer system was used to measure fracture site motion.

To establish the background to this investigation review of the literature dealing with treatment of fractures, methods of immobilization, and the clinical results of the posterior instrumentation systems presently in use is presented. Methods available and results of spinal implant testing are reviewed.

OBJECTIVES

The primary objective of this investigation was to compare four methods of pedicle screw fixation on a spinal fracture model. The fundamental basis of this evaluation was the ability of the devices to prevent fracture site motion during and after the application of physiological loads.

The secondary objective of this investigation was to fully implement a newly developed testing program which included the use of a vertebral fracture model, a method of load application, and a device to accurately measure fracture site motion.

CHAPTER II

LITERATURE REVIEW

INTRODUCTION

Reports of the diagnosis and treatment of fractures of the thoracolumbar spine have appeared in the literature for hundreds of years, and even in the twentieth century there is debate as to whether certain fractures should be treated by conservative or operative means. For those who believe that operative treatment is the mainstay for these fractures there is again discussion as to whether the treatment should be directed anteriorly or posteriorly and what is the best method of fixation is. Methods available for posterior fixation include Harrington distraction rods, Harrington compression rods, Luque instrumentation, the Cotrel Dubousset instrumentation system, and pedicle fixation devices.

To understand the treatment of thoracolumbar fractures it is important to appreciate the attempts made at classification of these fractures over the years including the mechanisms of injury and the stability of the particular fracture or fracture dislocation.

CLASSIFICATION OF THORACOLUMBAR FRACTURES

Arthur Davis first attempted classification of thoracolumbar fractures in 1929 (33) followed by Robert Jones in 1931 which was later published in his book "Fractures and Other Bone and Joint Injuries" in 1940 (225). Their classification was based on the mechanism of injury (flexion or extension) and on the integrity of the posterior elements. Nicoll in 1949 (165) reclassified the fractures into anterior wedge fracture, lateral wedge fracture, fracture dislocation and isolated fractures of the neural arch. Holdsworth (108) added the burst fracture and classified the types of spinal cord injuries including sacral sparing, complete, and partial cord lesions. Frankel (69) in 1969 published his classification of grades of neurological damage. He defined them as complete, sensory only, motor useless, motor useful, and intact. This classification is still in use.

In 1963 Holdsworth and Hardy divided spinal injuries into those involving the anterior or posterior portions of the vertebra (108). They reviewed the fractures and dislocations of the spine and pointed out that the spine may be subjected to four types of violence: flexion, flexion and rotation, extension, and compression. They claimed that the type of fracture or fracture dislocation which resulted from these types of violence would depend upon whether or not the posterior ligament complex was intact or not and modified their classification system accordingly. They described the burst fracture which corresponded to the comminuted wedge fracture previously described by Nicoll and Watson Jones. Based on this classification they put forward a plan for treatment. They classified stable injuries as the wedge compression fracture and compression burst fracture. They felt that these could be treated conservatively. The unstable injuries were the dislocations, extension fracture dislocations, and rotation fracture dislocations. For all these unstable injuries operative treatment was recommended.

Until the 1980's the classification of Holdsworth was accepted which divided the spine into two columns, anterior, and posterior (108). In 1983 Denis (35, 37, 38) published his work on the classification of thoracolumbar spinal injuries in which the spine was divided into three columns. The anterior column consists of the anterior portion of the annulus fibrosis, the anterior portion of the body and the anterior longitudinal ligament, the middle column is composed of the posterior portion of the body, the posterior part of the annulus fibrosis and the posterior longitudinal ligament, and the posterior column includes the facet joints, the posterior bony structures and the posterior ligament complex. Denis separated Holdsworth's anterior column into the anterior and the middle column. From this classification fracture types were reclassified into one, two or three column injuries. If only one or two columns are involved the spine is theoretically stable. If all three columns are involved it is unstable. A recent study by Haher et al (94) confirmed the increasing instability which occurs as one, two, and three columns are disrupted.

With regard to the description of various fracture types, a compression fracture consists of anterior column compression with possible distraction of the posterior column. A burst fracture consists of compression of both the anterior and middle column with an intact posterior column. An unstable burst fracture involves all three columns. A seatbelt type injury consists of distraction of the middle and posterior columns and possibly slight compression of the anterior column. A fracture dislocation involves compression of the anterior column and distraction or rotation of the middle and posterior columns therefore involving all three columns.

Until the 1950's, little was understood about the true anatomy and mechanism of injury (186) or the cause of the neurological damage which can accompany these fractures. In 1953 Holdsworth and Hardy (109) wrote a classic paper on the early treatment of paraplegia from fractures of the thoracolumbar spine. They presented a study of the relationship of the vertical column to the spinal cord and nerve roots and explained the various types of cord lesions possible including sacral sparing. They explained the effects of spinal shock and classified spinal injuries based on their observations, clinical experience, post-mortum dissection, and surgical exploration in patients.

TREATMENT OF THORACOLUMBAR SPINE FRACTURES PRE - 1900

This part of the literature review is based on a paper which was reproduced in " Paraplegia" and presented by Sir Ludwig Guttmann at the 1968 scientific meeting, outlining the history of vertebral fracture treatment (91).

Hypocrates recognized the gibbus deformity secondary to tuberculosis or injury and described methods available to treat it. He used an extension bench for re-alignment of the spine which was achieved by forceful and brisk procedures.

In the sixteenth century Vidus Vidius produced a manuscript illustrating the methods of reducing gibbus deformities, portraying a poor victim lying on a bench in a prone position pulled cranially from the shoulders and caudally from the hips, while the medical attendant either stood or sat on the gibbus, or pressed it with a crossbar until it disappeared. This violent procedure was still used with some modification up to the nineteenth century by Jean Francis Calot who manipulated spinal deformities with his fists. Sir Ludwig Guttmann himself witnessed this method of reduction in 1917 at the Axton Hospital for coal miners in Upper Silesia. The reduction was executed by the surgeon (Dr. Hartman) in the case of a fracture-dislocation of the thoracolumbar junction with paraplegia. In Calot's technique the patient was suspended in a supine position by four assistants, while the surgeon reduced the dislocation by forceful manipulation from below.

TREATMENT OF THORACOLUMBAR SPINAL FRACTURES FROM 1900'S TO DATE

Forceful manipulation was carried out into the beginning of the 20th century. This technique was modified in the 1920's and 1930's when methods of postural reduction by hyperextension were introduced. Arthur Davis (32, 33) in 1929 described a method for hyperextending the back to reduce crushed fractures of the thoracolumbar region. He believed that hyperextension would reduce the fractures based on the assumption that the anterior longitudinal ligament is strong, the posterior spinal joints act as a fulcrum, the intervertebral discs are firmly attached, and the density and resistance of the lateral muscles prevent further displacement. He used a hyperextension apparatus in which the patient was placed on a table and his legs were elevated via a sling, forcing the back into hyperextension. In this position a cast was applied. Prior to this time many fractures had been treated with the old Bradford frames which often resulted in pressure areas and inability to mobilize a patient resulting in often fatal outcome due to recurrent infections and massive bed sores.

Watson-Jones (224) a famous Liverpool surgeon presented a paper at the Annual General Meeting of the British Orthopaedic Association in November 1930 indicating that he had also been treating fractures of the thoracolumbar junction by hyperextension bracing. He used a simple procedure of lying the patient face down with head supported on one table, which was about 18 inches higher than another table supporting the legs. The trunk sagged between these two points causing hyperextension of the spine and the trunk was then left free for application of a body cast. He claimed that using this method patients could be mobilized within a few days. No anaesthetic was necessary as the procedure was relatively pain free. He reported this method in more detail in the Journal of Bone and Joint Surgery in 1934 (226). Rogers from Boston also published an article in "Surgery Gynaecology and Obstetrics" in 1930 with regards to the use of an extension frame for reduction of thoracolumbar fractures (187). His apparatus was slightly more complex. It could be fitted on to a bed and then cranked to produce hyperextension of the spine. All of the above personnel were in agreement that to leave the kyphos deformity caused by a fracture could result in long-term problems of back pain unrelated to the fracture but related to the residual deformity. They all therefore felt it important to reduce the fracture. Reports later appeared indicating loss of this reduction with time causing late deformity (165, 207).

During the ~~Second World War,~~ Guttmann (91) introduced a method of postural reduction in hyperextension by placing the patient in a supine position on pillows, with additional pillow support underneath the fracture, and regular two hourly turning day and night from the supine on to the lateral position by three or four members of the staff. By this gentle method of postural reduction the normal curvature of the spine could be restored. By regular turning, pressure sores were avoided. When the fracture had consolidated, the patient was allowed to get up wearing only a light plastic support. The disadvantage of this technique however was the strain on the nursing staff, and therefore in 1965 he introduced an electrically controlled turning and tilting bed which greatly eased this burden.

Nicoll (165) quoted Watson-Jones' words "Perfect recovery is possible only if perfect reduction is insisted upon; even slight degrees of wedging of the vertebra may cause a persistent aching pain". Nicoll described in his paper a review of 166 fractured dislocations of the thoracolumbar spine occurring in 152 miners and showed that Watson Jones' remarks are not necessarily true in that good results can be obtained in the presence of residual deformity and poor results can be obtained with no deformity present.

During the 1940's and 1950's the practise of active reduction with or without anaesthetic was condemned by various workers (109, 207) and open reduction of internal fixation with either plates or wiring became more popular. Guttmann (91), still believed that postural reduction as described above prevented a lot of the complications due to the surgery and also believed that surgical fixation using the Meurig-Williams plate could result in loss of reduction and residual stiffness and deformity. Guttmann did, however, in 1949 (90) publish an article which listed indications for operative treatment of thoracolumbar injuries and divided his indications into early and late.

Holdsworth claimed restoration of alignment could be achieved by either manipulation or by open operation. He felt manipulation was only safe if the true nature of the injury was appreciated and in their series this was not always possible. He stated that any patient who had severe displacement which encroached on the neural canal should be treated operatively. He commented that "the operation is safe and simple and affords an opportunity of judging the stability of the spine by examination of the posterior elements". He added that "internal fixation is also simple, safe and effective". They used plates for internal fixation attached to the spinous process (Plate 1). In 1954 Holdsworth publicly withdrew his statement that this method of treatment was simple. Despite this warning however a great number of orthopaedic surgeons continued to treat fracture dislocations of the thoracic spine with Meurig-Williams plates.

As recently as the 1960's Holdsworth and Guttmann still held opposing views regarding treatment of fractures. Guttmann tended to be conservative and Holdsworth tended to be more aggressive, using surgical stabilization (91, 108).

Advocates of surgical treatment have reported poor results in patients treated conservatively (112), whereas those who prefer non-operative treatment have reported good results in patients treated conservatively (34).

Hardy in 1965 (98) compared the results at the Sheffield Spinal Injury Unit of patients treated conservatively versus those treated operatively and found no real difference between the two groups. He also mentioned that whether or not surgery is performed, the post-operative treatment was almost identical in that ambulation following internal fixation was not allowed.

More recently, Ahn et al (2) reviewed 1385 patients treated for traumatic paraplegia, and found that those patients treated operatively did better than those managed conservatively.

Lewis (139) believed that surgical intervention prevents kyphotic deformity and late pain. Dewald (39) believed that conservative treatment can result in increased deformity at a later date and this is definitely related to increased pain. Nicholl (165) showed that late deformity can occur even after a good reduction and also that good results occur even with residual deformity. More recent work by

Hu (110) has shown that there does not appear to be a definite correlation between residual deformity and chronic back pain in a conservatively treated group.

In general, there is a considerable number of people who consider that surgery is the best method of treatment for certain thoracolumbar spine fractures. Each has his own indication for surgery but no one set of indications is universally accepted (15, 35, 39, 40, 67, 68, 74, 111, 112, 119, 121, 130, 139, 140, 151, 154, 209, 212, 234). Those who believe that conservative treatment is adequate for unstable thoracolumbar spine fractures in general seem to be diminishing in number (11, 34, 69, 157).

With thoracolumbar spine injuries, each case has to be independently assessed. However there are some generally accepted rules and some individual indications for treatment. Bohlman (15) believes that any fracture in which there is a 40% collapse in the anterior portion such as a wedge compression fracture or a burst fracture should be stabilized posteriorly. Whiteside on the other hand (234) believes that the compression needs to be greater than 60% before surgery is recommended unless there is neurological injury. Bohlman believes that any unstable fracture which includes the unstable burst fracture and any fracture dislocations should be stabilized and fused posteriorly. Whiteside is in general agreement with this but believes that stable burst fractures can be treated conservatively unless neurological injury is evident in which case they should be treated surgically. He also believes that unstable burst fractures and fracture dislocations should all be treated operatively. Gaines (74) states that the only absolute indication for surgery is in grossly translated fractures that are generally associated with complete neurological deficit in which there is extremely poor or absent opposition of the fracture fragments. He then mentions relative indications which include patients in whom recumbent management would be detrimental such as the multiply injured patient. He also feels that there are certain indications for conservative management particularly in younger patients who will return to manual labour in the future. He believes that, in general, any patient with a neurological deficit would be better stabilized to allow early ambulation and to allow the possibility of further recovery in the partial or complete neurological injury. He believes there are arguments for treating them both conservatively and operatively. Gaines is somewhat conservative compared to other contemporary North American surgeons. He feels that surgery which is planned to prevent a problem from developing in the future may be unnecessary and thinks it is reasonable to wait from two to four months from the time of the injury to see if problems are going to occur as it has been shown that decompression or correction of deformity at a later date can still result in good neurological recovery.

The majority of references quoted believe that a posterior approach to the spine is adequate for stabilization and reduction of thoracolumbar fractures. However there are advocates who recommend anterior fixation, decompression and fusion (14, 119, 120, 121, 130), despite the high complication rate (20). Another controversy exists with respect to timing of the surgery. Should it be done immediately or at the earliest convenient time once spinal shock has subsided and the patient's general condition is stable, or should a person wait for one to two weeks to assess the neurological state, or as Gaines mentioned, should surgery be deferred for two to four months in the hope of preventing unnecessary intervention ?. Steiner (212) found in his study that the best results were obtained in patients whose surgery was delayed an average of 11 days compared to those who had surgery sooner and also noted better results were obtained when the operation was performed by a specialist in a teaching center. Whiteside (234) believes that surgery should be performed in the first 24 to 36 hours to ensure a better chance of neurological recovery in the neurologically compromised patient.

Assuming that surgery is indicated, what type of surgical procedure should be performed. Two possibilities exist: to approach the fractured vertebra posteriorly or anteriorly. Those who recommend anterior decompression state that a thorough decompression of the spinal cord can only be adequately performed by the anterior approach using anterior fixation methods (14, 119, 120, 121, 130, 131). Those who recommend posterior surgery believe that if the fracture can be adequately reduced from the posterior approach the reduction itself results in decompression, and maintaining the reduction with rigid internal fixation allows adequate recovery. This hypothesis is based on the assumption that the posterior longitudinal ligament remains intact and helps to reduce the retropulsed fragments when distraction is applied. Golimbu et al (84) used pre, and post-operative C.T. scans to see how much reduction occurs after distraction instrumentation. They found that reduction occurs in less than 50% of cases and concluded that the posterior longitudinal ligament is probably disrupted in many cases.

Recently Friedman (97) described a method for decompressing the spinal canal using a posterior transpeduncular approach thus avoiding anterior surgery.

This thesis is concerned with posterior instrumentation and further details of these methods will be described in the following chapters. Two points should be mentioned here. Firstly, posterior instrumentation has never been proven to improve the neurological status of a partial or complete cord lesion (31) but it is generally accepted that the posterior instrumentation can decrease residual deformity which may result in a decrease in chronic low back pain at a later date and prevent progressive kyphosis. It allows early ambulation, preventing complications of prolonged recumbency. It decreases the total hospital stay and rehabilitation time, and the reduction may decompress the cord allowing some recovery of the neurological lesion although this has not been proven. Disadvantages of this type of surgery include the general risks of anaesthesia and surgery, together with the fact that part of the spine is being immobilized and in the case of the Harrington, and Luque Rods, as many as three segments above and below the fracture have to be immobilized to increase the chance of a fusion at the fracture level. This necessitates removal of the rods at a later date to allow return of back mobility and therefore a second operation is necessary. This temporary immobilization can result in premature osteo-arthritic changes (118).

The second and final point is that many of the advocates of operative treatment of potentially unstable thoracolumbar fractures even in the neurologically intact patient believe that it prevents late kyphotic deformity; however, the literature is divided as to whether this residual deformity is in fact related to chronic back pain.

In summary, since the days of Hypocrates methods have been available to treat fractures of the thoracolumbar spine and with the advent of radiography and asepsis a better understanding of the thoracolumbar fractures has become apparent. Now a good classification system is available and good prediction of stability of the fracture is possible. In spite of this, controversy exists as to whether comparable fractures should be treated conservatively or operatively and if treated operatively whether an anterior or posterior approach should be used. If a posterior approach is used what method of instrumentation should be employed?.

THE HISTORY AND DEVELOPMENT OF POSTERIOR SPINAL INSTRUMENTATION

The earliest known method of posterior spinal instrumentation was presented by Professor Fritz Lange (135), who described the use of buried steel bars attached to the spinous process of vertebrae for the treatment of spondylitic spines, as early as 1910. His original presentation was made at the American Orthopaedic Association meeting in Washington, D.C. in 1910 and was based on the development of a spinal instrumentation system in which two metal rods were attached to the spinous processes using braided silk. His initial result was poor due to the use of steel with relatively sharp edges which resulted in skin breakdown and other associated problems. Later, use of a tin-coated steel eliminated some of the problems due to the metal itself. Modifying the length and thickness of the steel bars as well as the method of attachment further improved his results. Following this report in 1910, very little appeared in the literature until the 1940's.

In 1944 and again in 1948 King (125, 126) described the use of screws to aid fusion and found the pseudoarthrosis rate was reduced. The screws he used went through the lateral articulations and were associated with the Hibb's fusion (105).

In 1947 Boucher from Vancouver (18) started using screws through the inferior portion of the lamina, through the pedicle and into body of the vertebrae below. He combined this with a Hibb's fusion and claimed it gave better results, and a more stable fixation. He reported his findings in 1959.

Thompson (217) followed 1,096 spinal fusions and found a pseudoarthrosis rate of 16.6% using Hibb's technique and when he combined this with stainless steel screws passed across the facet joints similar to the method described by King he found the pseudoarthrosis rate had risen to 55.1%. This was partly due to the inadequate fixation and secondly due to the fact that these patients were allowed up immediately with minimal external support. Following this article Thompson started to place his post-operative patients on bedrest and used casts with apparently better results.

Around 1947 William Spence started to use methyl-methacrylate as an adjunct to spinal surgery. He treated fractures by placing a plastic peg through a drill hole in the spinous process above and below the fracture and then incorporated methyl-methacrylate after reduction of the fracture. This held the fracture so stable that he used no external support and claimed excellent results. If the spinous process had by any chance been damaged in the trauma he then used sublaminar wires to incorporate into the cement (206).

In the late 1940's and early 1950's many workers throughout the world experimented with different types of posterior spinal instrumentation. The most well known of these was Harrington who developed his rod in the years between 1947 and 1949, and then used it in clinical practice from 1949 to 1954 in 19 patients. More modifications were then made and by 1960 he had come up with a method which seemed reliable in scoliosis. He described the distraction rod and a compression rod which are still in use today with certain modifications (Plates 1, 2, and 3). These were made of stainless steel and included hooks at the superior and inferior end to attach to the inferior articular process and the lamina of the vertebrae respectively. Since this time the Harrington Rod has been almost universally accepted although more modifications have been made.

Also in the 1950's, Pennal (175) described a further method for spinal fusion which was similar to the method used by Boucher which combined with the Hibb's fusion gave good results. Again these were probably the first reports (18, 175) of the use of screws through the pedicles of the vertebrae for rigid internal fixation. Straube (214), in the 1950's also used a method of internal fixation to aid spinal fusion.

He used plates attached to the spinous process (Plate 1). The plates had been described by Wilson in an instructional course lecture for the American Academy in 1952 (238).

On the other side of the Atlantic, at around about the same time, Holdsworth and Hardy described the use of plates bolted to the spinous process for the treatment of fractures. In 1953, they published their results of 19 patients treated with this method of internal fixation with good results (109). They commented that this method was simple and easy but later withdrew this comment due to complications which had arisen.

The plate that Holdsworth and Hardy had used was similar to the Williams plates described finally by Williams in 1963 although used for many years before this (237). Lewis (139) in Cardiff, Wales in the late 1950's looked at a series of patients treated conservatively versus those treated operatively using spinal plates and found that the operative group tended to do better. The plates used in this study were mainly William's plates but in the latter part of his study a Wilson plate was used. Both plates were bolted to the spinous processes and depended on the integrity of the spinous process above and below the fracture site for their fixation. These plates are no longer in clinical use.

Kaufer (123) from Michigan described the use of spinous process wiring which he had been using since 1956 to aid in the fusion and maintenance of reduction of fractures. He found this method to be simple and effective. Similar methods are still in use for certain types of fractures.

In 1965 Weiss (228) described the use of springs which were attached to the vertebrae above and below the fracture and allowed gradual reduction of the fracture. The advantage of this method of fixation over other methods used at the same time such as the Harrington or the plates was that the segment was not immobilized and therefore the more dynamic stabilization achieved was believed to be more physiological and would afford improved results. Initial reports were promising however this technique has since fallen by the wayside.

In 1965, Knodt introduced his rod. Good (200, 232), and bad (137) reports emerged, and the Knodt rods are now rarely used.

From the late 1960's onwards the almost universal acceptance of the Harrington rod resulted in many reported modifications of this technique. Some of the more important modifications are mentioned for interest sake. Harrington initially described his rod in the early 1960's although he had been using it himself since 1949 (100). In the 1960's Harrington described the use of his rod for the treatment of spondylolisthesis which was a new concept because prior to this his rod was recommended only for treatment of scoliosis (99). In 1973 Jesse Dickson (42) a colleague of Paul Harrington described the use of the Harrington Rod for treatment of fractures and fracture dislocations of the spine. Their first operation on such a patient was performed on 01 January 1960 and they recommended instrumentation from two levels above to two levels below the fracture site. In the first twenty-nine patients operated on they had had no complications and excellent results. A few years later they again reported on the use of the Harrington Rod for thoracolumbar fractures (41) and in this paper they quoted the treatment of 95 patients between 1962 and 1976 with twenty-six complications which included six fractured rods, four of which were associated with pseudoarthrosis. There were six hook displacements, seven incorrect placement of rods at surgery and seven other complications including post-operative pain and infection. This seemed to be the first article which described the fairly high complication rate with this procedure. The fact that the rods break at a specific point suggested a stress riser.

Out of forty patients, Flesch (68) described four who developed pseudoarthrosis and thirty in whom an incomplete reduction of the fracture was obtained. Two patients developed fractures of their rods and two had problems with dislodgement of the rods. Irwin (57) in association with Dickson and Harrington reviewed 2,016 patients treated with Harrington instrumentation. Of these 1,128 were treated in the days before autogenous bone was used as an augment to the fusion and in this group of patients 12.5% developed broken rods. In the next group of 888 patients in which autogenous bone graft had been utilized the broken rod rate dropped to 2.1%. This would suggest that the Harrington device is in fact reliable as long as the surgical procedure is adequate. In other words the Harrington rod cannot be expected to support the spine indefinitely and is only meant to support the spine until the fusion is complete.

Various other reports in the literature (9, 23, 25, 36, 80, 111, 140, 155, 236) have shown similar problems with the Harrington rod; namely, hook dislodgement or displacement and fractures of the rods. Associated with the rod failures are the underlying pseudoarthroses.

In one study by Barrack (9), twenty-eight Harrington Rods were retrieved from patients due to failures of the rods or hooks. Analysis of the twenty-eight Harrington Rods showed that twenty-six of these rods had no underlying abnormality and the failures were therefore due to the poor placement or a problem with the basic design of the rods. Two of the twenty-eight rods however were shown to have abnormal areas within the metal or some corrosion present.

In an effort to reduce the complication rate associated with the Harrington device, reports began to appear in the literature of modifications to the instrumentation system.

Gaines (72) added sublaminar wires to the Harrington Distraction Rods and reported seventeen cases of unstable fractures treated with this method with good results between 1979 and 1983. Jacobs (114) patented his modification of the Harrington rod in 1981. He used a locking hook system in an attempt to prevent hook pull out, and changed the rods slightly to allow easier contouring of the rods In 1980 Jacobs (111) presented his hypothesis that "rod long fuse short" with instrumentation from three levels above to three levels below the fracture with only a three level fusion was the best method. He claimed his results were better but this is still a controversial point. Edwards (53, 54) since 1979 has been using sleeves on the Harrington rods, claiming that the plastic sleeves act as a fulcrum allowing corrective forces to be applied in any direction. Purnell (181) modified the Harrington compression rods, but found problems with hex nut loosening.

The introduction of sublaminar wiring in association with the Harrington System seemed at first to be an improvement on the basic Harrington System. Akabarnia (242) compared two groups of patients; one treated for spinal fractures with the Harrington Rods and wires and one treated with the Harrington Rods alone and the complication rate in both series appeared to be the same although better stabilization was obtained using the wires. Other reports however (3, 22, 72, 215, 216, 233) suggested that the rod failure and hook failure rates when the Harrington is associated with sublaminar wiring was much reduced. The largest of these series was by Sullivan (216). He reported on thirty-two patients treated for fractures with the Harrington Rod and sublaminar wires with no rod failures and no pseudoarthrosis. More recently however it has become apparent that there are problems associated with the use of sublaminar wires (221). Firstly, removal of the wires is not without risk and when the Harrington's are used over a "rod along fuse short" distance it is inadvisable to use sublaminar wires because of the problems with removal. Rossier (189) reported on two cases of Harrington compression rods causing direct cord injury due to the hooks protruding dangerously into the spinal canal when associated with the use of sublaminar wires. At the Scoliosis Research Society meeting in 1986 Schrader (196) and Haher (93) both described canine experiments in which cord damage was observed due the use of sublaminar wires. Schrader's experiment showed macroscopic and microscopic damage to the neuro-structures in dogs and suggested that the technique of segmental sublaminar spinal instrumentation is not innocuous to the dural-sac and its contents. The reactive tissue response was not adequate in providing protection during wire removal in specimens with the implant present for up to 155 days. In his study, Haher concluded that animals which were neurologically intact following sublaminar wiring were shown to have signs of long tract degeneration which were chronic in nature and progressive over time. Slabaugh (205) recently showed that sublaminar wire removal is safe if the wires have been in situ for a few months, and if 18 Gauge wire is used. He demonstrated the presence of a tough pseudomembrane. Obviously a longer clinical follow-up will be needed to assess whether neurological damage due to sublaminar wiring occurs in humans.

Another specific complication of the rod long technique as used in the Harrington System is the so-called flat back syndrome (101, 112, 240). Loss of lumbar lordosis is secondary to the use of the Harrington instrumentation without contouring of the rods. This has resulted in gait abnormalities and chronic problems. The ability to contour rods has alleviated this problem to some extent.

A problem with the large number of segments immobilized using the Harrington technique is facet joint degenerative changes. It has been shown (77, 118) that in the segments immobilized by the Harrington rod, but not fused, there are changes which occur within the facet joints as early as 6 months after insertion of the rods. Histological changes present within the facet joints are comparable to early degeneration. Whether these changes will be symptomatic in the future has yet to be proven.

Dodd (43) showed that even after removal of Harrington rods, the segments which were immobilized but not fused do not regain their pre-operative mobility for at least 6 months, and possibly never. He also showed that even after an arthrodesis motion can still be identified at the level of the fusion. One other report by McAffe (155) included a case of progressive ascending liquefactive necrosis and infarction of the cord secondary to over-distraction by the Harrington rods. He reported the complication rate in forty patients; the majority of whom were treated elsewhere and referred to his center for further treatment. In this group of forty patients there were thirty-six complications. A total of four cases in which the neurological symptoms had worsened, eleven cases of incomplete reduction of the initial fracture, eighteen cases of rod disengagement or dislodgement and seven cases of deep infection. He therefore recommended that treatment of fractures by Harrington instrumentation should be performed by expert surgeons in a spinal injury center.

In vitro testing has also shown that failure of Harrington Rods occurs due to hook pull out or rod displacement. Dove (45) had the opportunity of testing a fresh cadaver in whom a double Harrington distraction rod with sublaminar wires had been inserted prior to his unexpected death. In testing the fresh spine biomechanically they found that failure occurred at the same place as it did in "in vitro" testing but that the force required to result in failure of the rod was significantly higher than in most in vitro tests in animal models. This would suggest that in vitro testing even on an animal model is useful in predicting the outcome in vivo.

In view of complications associated with the Harrington Rod, Luque (148) in Mexico City had been working on a system to improve on the Harrington. In 1972 combined with the work of Dr. Verdura a Neurosurgeon from the same centre, they began working on segmental fixation. In 1973, they worked on the use of sublaminar wires attached to the Harrington but still had problems with the stress riser due to the configuration of the Harrington Rod. In 1975 they developed their own smooth rod but had problems with migration. They modified their technique between 1977 and 1980 and came up with the Luque Rod which is in use today (Plate 2, and 3). The rod is smooth and therefore has no stress risers. The fact that there are no hooks means that the growth of the immature skeleton can continue without the need to replace the Harrington Rods. This reduces the amount of surgery necessary in certain conditions. His method of instrumentation has been accepted in many parts of the world.

Developments of the Luque Segmental Spinal Instrumentation System occurred in the early 1970's and by 1979 Eduardo Luque (148) had performed 316 cases using the various modifications of his segmental spinal instrumentation system. In the first six years of its use he had only one neurological complication and three pseudoarthrosis. Of his first 316 cases thirteen were acute fractures. In 1982 he published a report on the treatment of fourteen patients with either acute or chronic effects of spinal trauma (144). Using his segmental spinal method of instrumentation, and an outrigger which he described for the reduction of the fracture by applying distraction, he reported no complications in fourteen patients. No external support was necessary post-operatively allowing quicker return to normal. Luque further modified his technique for the treatment of fractures (147, 149) by including pedicle screws with his specially designed fixation bars. With this newer technique he was able to immobilize less segments, allowing fusion without the complication associated with immobilization of a larger number of segments. His initial report of twenty and then fifty patients showed some technical difficulties but no complications. Following these, (145) he reported 722 cases of various types of back pathology treated by segmental spinal instrumentation in which there were only seven pseudoarthrosis.

Other workers, however, have been less fortunate regarding complications using Luque's method. Ferguson (64) treated fifty-four fractures between 1976 and 1981 using the Luque technique. He found that this gave secure internal fixation allowing early mobilization with no external support and was able to get good secure fixation to the pelvis when necessary. However he found that this technique required a longer operative time than the traditional Harrington's and was a more demanding procedure. The technique did not allow longitudinal distraction in the reduction of fractures in order to reduce the posterior body fragments, and there were also problems maintaining longitudinal distraction for reduction. Herndon (102) reported on sixty-two patients treated between 1978 and 1984 mainly for neuromuscular spinal deformity. However eight of these patients developed fracture of the rods and fourteen of them developed some loss of correction of curvature. He recommended that external support and improved fusion techniques could reduce the number of complications due to rod failure using this method. Kling (128) reported twenty-four unstable fractures treated by the Luque instrumentation system. He immobilized three segments above and two below the fracture and did not use any post-operative immobilization. He reported four broken wires which were not a problem and one rod prominence which required removal. In comparison of rehabilitation time he found that the Luque gave better fixation than Harrington and allowed much faster rehabilitation.

The main problem with the Luque technique is the increased risk of neurological damage due to the sublaminar wire placement. Wilber (235) reported a retrospective study of 137 patients treated for spinal conditions. Forty-nine of these were treated with Harrington Rods plus sublaminar wires and twenty by Luque Rods with sublaminar wires. In this group there was a 17% incidence of neurological complications of which 13% were transient sensory changes, and 4% major cord injuries. In contrast, there was only one neurological complication (1.5%) in sixty-eight patients treated by Harrington instrumentation alone.

O'Brien (166) developed nylon sublaminar straps in an effort to decrease the number of neurological complications due to the passage of sublaminar wires, while maintaining Luque's principal for immobilization of the spine. Although this is still in the early stages of research and development it is showing great promise in that the first twenty-five patients treated for various back problems show no neurological problems and the actual operative technique is much faster. (Approximately one hour shorter than when using sublaminar wires.) Luque instrumentation is generally accepted for use in neuromuscular scoliosis but because of the problems with neurological complications its use in the treatment of fractures has not been universally accepted. It may be that the use of nylon sublaminar straps increases the safety margin of the procedure, but for the present time segmental spinal instrumentation using the Luque system is not the method of choice for the treatment of thoracolumbar fractures.

Other workers have described their own devices for posterior stabilization of short segments. Kaneda (122) from Japan, claims good results in fifty-four patients treated with his instrumentation system.

Although the Harrington and Luque systems have obtained almost world wide recognition there were certain centers in Europe where research into the methods of internal fixation of the spine took a different direction. Roy-Camille (190, 191) in Paris, working under the guidance of Judet, designed a method of pedicle screw and plate fixation. He used a screw which went through the posterior elements of the vertebrae into the pedicle and along the pedicle into the body of the vertebrae. The only previous report of the use of pedicle screws was that by Boucher (18) which was a modification of the method used by King (125, 126). The advantage of pedicle screw fixation was that the screw allowed rigid fixation of all three columns of the vertebrae as it passed from the posterior column through the middle column and into the anterior column. One screw was used in each pedicle of the vertebrae above and below the fractured vertebrae and thus only three segments were immobilized compared to five or seven segments using other techniques available such as the Harrington Rod. Better fixation was obtained, reduction was possible and no post-operative external support or bracing was necessary. Roy-Camille plates were recently introduced in the United States and Canada. Rene Louis (143) also from France modified Roy-Camille's original technique but used the same basic method of pedicle screws and plates.

The next report of pedicle screws came from Germany where Herrmann (104) published a report in 1979 of the use of the AO plates and screws for spinal stabilization. Dick (40) published an article in 1985 in which he described the fixateur interne. This was a newly designed spinal fixation device which included the use of pedicle screws in the form of schanz screws and a new type of bar which fixes the screws together. The bar had a threaded area on it which allowed distraction and compression of the fracture fragments and the long schanz screws permitted manipulation of the fracture into a reduced position.

Zielke from West Germany used pedicle screws in the design of his system. Encouraging reports of its use are beginning to appear in the literature (44, 182, 204).

Eventually the European influence of pedicle screws reached North America and Steffee in Cleveland devised his own method of pedicle screw fixation (210, 211). His screw and plate designs were different but the basic principle was the same. His method can be used as can the others for either trauma, or elective spinal fusions and again the advantage is the small number of segments which require immobilization.

Much has been written about the anatomy of the pedicle (13, 106, 124, 133, 138, 142, 243, 245) and its role in internal fixation (133, 204). Krag (133, 146) designed an internal fixator similar to the one described by Dick but with modification. As previously mentioned Luque (147) used pedicle screws in conjunction with wiring, and Magerl (58, 150, 239) devised a method for introducing a type of schanz screw into the pedicles from the outside without the use of major surgery. This external skeletal fixation method has been used successfully in the spine for immobilization of segments, butthere have been problems with pin-site infections.

Olerud (168) in Sweden used external transpedicular fixation as a test. He placed percutaneous pedicle screws into the segment which they felt was pathological and immobilized it using an external fixateur. If this cured the patient's symptoms he felt that it was reasonable to go on to do a fusion in an effort to help the patient's pain. However in the eighteen patients in which this method was tried there was one reported leakage of cerebral spinal fluid and one report of sciatica due to penetration of the fixation screw. One patient developed minor changes in the L5 root probably due to penetration of the screw. There was minor wound irritations in several patients. It is unlikely that this method of diagnosis of a painful segment will be universally accepted.

Three types of pedicle screw fixation devices have been in clinical use for a number of years. They are the Roy-Camille Plate, the fixateur interne and the Steffee Plate. The newer Cotrel-Dubousset system also includes pedicle screws. These four systems are described in more detail below and are shown in plate 4.

Roy-Camille (190, 191) has been using his own design of plates since 1961. In his initial treatment of 84 spinal fractures and in a follow-up series of 123 acute spinal fractures he found that he was able to reduce and maintain a good reduction of the fracture in 75% of the cases with a loss of reduction of between 3^o and 10^o in approximately 25% of cases. There were two specific problems related to the fixation device. The first is that due to the drilling of the pedicles in close proximity to the neurological structures he encountered a number of radicular symptoms in his early series, and post-operative radiographs showed that 10% of the initial screws inserted were outside of the pedicles. However with increasing experience the incidence of this particular complication in his series is now nil. The second specific complication is that one of the outer screws, usually the inferior one, broke in 25% of his cases. This occurred between five and twenty-four months after fixation and he suggested that this is a sign that the spine mobility has increased and the plates should be removed. Kinnard (127) reviewed twenty-one fractures treated in Quebec using the Roy-Camille system between 1979 and 1982. Interestingly he found the same complication rate. There was a 25% loss of correction of the spinal deformity in acute fractures and a 25% instance of screw breakage. They had two neurological problems out of the twenty-one patients post-operatively which were not present pre-operatively and may possibly represent radiculopathy due to the operative technique. However this has not been confirmed in their report.

It would seem that the Roy-Camille plate which has now been in use for approximately 15 years is a relatively safe system when used correctly for the treatment of acute fractures.

In 1984 Dick, from Switzerland, introduced a fixation device which he referred to as the fixateur interne (40) which was developed for the treatment of spinal fractures. Four schanz screws were inserted into the pedicles of the vertebrae above and below the fracture and the application of two threaded bars with universal joints to the schanz screws allowed immobilization of the fracture as well as manipulative reduction of the fracture. Compression or distraction could also be applied with this particular fixation device. In 1985 he described his initial results with forty-five patients treated for highly unstable and dislocated lumbar spine fractures. He had one death from unrelated causes. He had one patient who developed a secondary kyphosis of 10^{0} due to a malposition of one of the schanz screws and one patient with a wound infection requiring removal of the implant at seven months but with no problems after that. He did not have any neurological problems as a direct result of the placement of the implant and due to the initial encouraging report of the first forty-five cases they have abandoned the use of other posterior implants for the treatment of fractures and rely solely on the fixateur interne.

Steffee in Cleveland, Ohio designed his own posterior spinal plate and pedicle screws and presented his initial results in 1986 (210). Of the first 120 patients operated on for various spinal conditions including fractures he had two nerve root impingements secondary to the bone graft and eight problems associated with the spinal plate system. Most of these problems occurred with the early versions of the device and have since been addressed. These problems included loosening, screw migration and screw breakage (Plate 9). The addition of a second anterior tapered nut to lock the spinal plates in position has reduced the incidence of these complications. He is presently working on a newly developed pedicle screw which he hopes will address the problem of screw breakage. In his initial series he has also had five cases of pseudoarthrosis; two of these were associated with infection.

Reed (184) has been using the Steffee plate and screws since 1984 and presented his initial results on fifty-two patients. His complications included a transient motor weakness in four patients one of whom was re-explored with no abnormality found. There was leg pain attributed to the fixation device in two patients, both of whom eventually had the hardware removed. Minor wound problems in three patients and pseudoarthrosis in one patient.

The most recent type of posterior instrumentation developed, and in clinical use, was again designed in France by Cotrel and Dubousset (27, 79). Research was performed by Yves Cotrel from 1978 to 1982 and the first clinical application was performed on 23 January 1983 at St. Vincent De Paul Hospital in Paris, France by Jean Dubousset. This instrumentation device is similar in some ways to a Harrington but also utilizes the optional use of pedicle screws and allows for three dimensional correction of scoliotic curves as well as small segment stabilization for fractures.

Cotrel and Dubousset presented the initial clinical results of their new posterior spinal instrumentation system at the Scoliosis Research Society meeting in 1984. The design of the system enables it to be used for instrumentation of long segments in treatment of scoliosis either neuromuscular or idiopathic, or for immobilization of short segments either using the lamina hooks or pedicle screws. In this respect it is a true universal spinal instrumentation system which is theoretically useful for any spinal condition requiring fusion. It has the definite advantage of being able to correct deformities three dimensionally. As well as correction of spinal curvature in the antero-posterior and lateral planes, it is also capable of correcting vertebral rotation. The advantage of being able to immobilize small segments only for the treatment of fractures can prevent many of the complications alluded to above due to unnecessary immobilization of long segments. The system requires no post-operative external immobilization.

The system was first described in 1984 and had only been in clinical use since January 1983. Cotrel & Dubousset described their initial findings in fifty patients who had been treated for scoliosis. They reported that no post-operative bracing was necessary. They had no neurological complications. They had six cases of late loosening but this was due to the poor initial operative technique at the beginning of their series and no further recurrence of this problem has occurred. The follow-up in this series was only one year (27). Further reports by Dubousset (50) confirmed the good results and lack of complications. One further report however (51) by Dubousset in which spinal deformities associated with pelvic obliquity were treated showed that there were two slippages between the rod and the sacral fixation staples in the thirty-two patients treated, and one broken screw with associated pseudoarthrosis. However this complication rate is low considering the type of patient he was dealing with. Other reports are appearing in the literature (115, 201) in which patients treated in North America with the Cotrel-Dubousset instrumentation system have been reported as having good results with minimal instrumentation problems and no neurological complications. In one report from Shufflebarger (201) there was only one hook dislodgement out of seventy patients and this required no further treatment. Hall (95) showed slight pessimism after treating thirty-five patients with scoliosis and achieving a 60% correction of the Cobb angle. He noted two early instrument failures. He also felt that there was some problems with the operative technique due to the rod holders and the hook holders. He felt that more modifications may be necessary and that he would not accept it as a universal spinal instrumentation system.

All the initial reports on the Cotrel-Dubousset instrumentation system dealt with the treatment of scoliosis, (idiopathic and neuromuscular). However, recent in-vitro testing has shown that the instrumentation system is good for short segment immobilization as in the treatment of burst fractures (79). The system allows both compression and distraction to be applied and lordosis can be preserved in the case of lumbar fractures by pre-bending the rods. Either hooks or pedicle screws can be used in association with the system and four hooks can be used in each lamina (79, 202). More in-vitro testing needs to be performed on the Cotrel-Dubousset system, however, initial reports are very encouraging.

Various other modifications of existing techniques are still being developed an example of which is the Hartshill Rectangle which is a modification of Luque Rods (46, 47). However it seems that the most universally accepted system so far has been the Harrington Rod and the Luque Rod each of which have their own indications for use. The more recent introduction of the pedicle screw seems promising especially for small segment fixation with definite advantages for the treatment of fractures over the old Harrington and Luque Rods which required five and seven segment immobilization, and it may be that the Cotrel-Dubousset instrumentation system which can be used for either long or short segment immobilization may be the system of the future.

SUMMARY

The above chapter details some of the clinical results associated with the more commonly used instrumentation systems. The systems described are those which have either been universally accepted or which are new with considerable potential for the future. The main advantage of the newer pedicle screw fixation methods and the Cotrel-Dubousset are that for the specific treatment of fractures, only small segments of the spine need to be immobilized, and immediate post-operative immobilization is possible. More clinical studies need to be performed, and further in-vitro testing is necessary in order to accurately compare the methods of pedicle screw fixation.

CHAPTER III

RELEVANT BIOMECHANICS OF THE SPINE

INTRODUCTION.

A knowledge of the relative spinal biomechanics is necessary for three reasons. Firstly, understanding the function of the spine as both a structure and a mechanism allows better assessment of the same spine when instrumented. Secondly, such an understanding allows criticism of the methods and models reported in the literature for testing spinal implants. Thirdly, this understanding enables a more physiological testing regime to be developed.

To plan a testing regime the following questions need to be answered.

(1) What are the physiological loads transmitted through the various vertebral levels of an un-instrumented human spine, and how are these loads affected by various movements such as forward bending, sitting, standing, and lying ?

(2) What are the estimated in vivo upper limits of motion at each level in a normal, un-instrumented human spine; and what is instability ?

(3) How should time dependent behavior (creep or relaxation) be accounted for in in-vitro biomechanical testing ?

(4) Should in vitro biomechanical testing be performed under static or repetative conditions ?

(5) What consideration of these factors should be made to allow testing of a spine with a fracture that has been instrumented ?

1. IN-VIVO LOADS ACROSS VERTEBRAL SEGMENTS

Calculation of in-vivo loads at various vertebral levels can be accomplished by in-vivo, and in-vitro studies, or by the use of mathematical models.

Nachemson (161) used in-vivo pressure measurements of human lumbar intravertebral disks and also EMG studies of the vertebral portion of the psoas muscle in order to try and establish the force transmitted through various vertebral levels. Before embarking on the in-vivo test he studied cadaver vertebral units and concluded that the pressure increase inside a vertebral disk is directly related to the external force applied. From the pressure measurements obtained from the discs, he was able to calculate in-vivo, the amount of force acting across the disc.

Their results showed that in the upright sitting position with no support the load taken through the L1 disk is approximately three times the body weight above the L1 level. In a 70 kg man this is approximately 1400 Newtons. In the standing posture the force taken through the disc is actually less by about 30% and was measured at approximately 1000 Newtons. The reason for this drop in load is twofold. Firstly, the psoas muscle and other muscles acting on the lumbar vertebra are more active in the sitting posture than in the standing posture, and secondly, the supported weight is centered nearer the discs when standing. When lying in the lateral decubitus position 50% less load is taken through the discs than in the sitting position (approximately 700 Newtons). When anaesthetized this load drops down to 200 Newtons.

When sitting forward flexed approximately 20°, the load increases from 1400, to 1900 Newtons, and if 20 kg total weight is carried in the hands while sitting and bending forward this force increases to 2700 Newtons. The figures for standing with and without weights are 1450 and 2150 Newtons respectively. Posner (177) tested eighteen functional spinal units of human lumbar vertebra in-vitro. The idea of his experiment was to assess the effects of dividing various ligaments. Based on Nachemson's work, Posner used appropriate pre-loads and added loads to the pre-load to imitate the loads taken during bending. Starting at the baseline pre-load level he increased the load slowly to reach the maximum load which represented maximum flex and then waited four minutes at this level before making any measurements. He then reduced the load down to the pre-load level and again waited four minutes to allow for the creep before making measurements.

Nachemson (162) in a different study used forty-two fresh human cadaver lumbar spine motion segments to compare age, disk degeneration, sex, and the spinal level of different motion segments. For his testing he used a pre-load of 400 Newtons and added an additional 20.5 Newton meter moments in increments to imitate bending and torsion. In this experiment he only allowed 15 seconds for creep to occur after each load increment but agreed that a longer period of time is necessary. Lin (141) investigated the rate of loading and concluded that a rate of loading of up to 0.5 inches per minute on universal testing machines gives similar load deformation curves. However loading at a rate greater than 0.5 inches per minute results in different load deformation curves. He used what he described as physiological loads for his testing. This included 445 Newtons, 899 Newtons and 1,334 Newtons of actual loading and 45 Newton increments up to a total of 135 Newtons of sheer force. He concluded again that if loading occurs slowly, the creep that occurs is less than 10%. He also tested the spinal segments to failure which occurred at between 1500 and 5500 Newtons with plastic deformation occurring just prior to failure. Panjabi (172) used what he described as physiological loads which were a pre-load of 250 Newtons with the addition of 15 Newton meter moments with time allowed for creep to occur. In a separate article (170), he again commented on the usefulness of pre-loads. He states that in a 70 kg man the pre-load would vary from 250 Newtons in a supine position to up to 1500 Newtons in a sitting position, again, similar to Nachemson's work. Panjabi used pre-load of 400 Newtons and 1,000 Newtons to represent the lying and sitting posture and then added additional loads on top allowing three minutes for creep before each reading. In yet another one of his articles (169) he again describes the creep that occurs and allows four minutes for this to occur before making the final reading.

Jacobs (113) claims that as much as 80 Newton meter moments may be taken by the T 11, 12 region during forward bending to 90°. Krag (133), on the other hand gives five reasons why it is unlikely to be greater than 12 Newton meters.

Included for interest sake is the work of Granhed et al (85) who calculated the loads taken through the lumbar spine in power weight lifters. In there most extreme example they calculated that the total load on the L3 vertebra occurring when a 90kg man lifts 335kg is 36,400 Newtons.

Schultz and co-workers (12, 197, 198, 199) have devised a mathematical model for studying the lumbar spine. Their model is based on cadaver geometry and stiffness. Using this model, they have calculated the loads on the human lumbar spine, and their results are comparable to in-vivo values.

From this brief review it seems that most workers are in agreement that a pre-load is essential for any type of in-vitro testing which is designed to mimic in-vivo loads. The pre-load at the L1 level has been defined and confirmed by more than one worker, and the additional load necessary to represent various activities have also been estimated using in vivo and in vitro tests, and from mathematical models.

2. NORMAL MOTION AT VERTEBRAL LEVELS

In-vivo and in vitro measurements of vertebral motion at various levels have been performed and reported in the literature over the last two decades (1, 12, 43, 89, 113, 163, 173, 174, 188, 230). The most reliable method appears to be biplanar radiology and using this technique the normal motion at the lumbar vertebral levels, specifically between L1 and L2, is as follows. The maximum flexion extension appears to be a 14^{o} arc with flexion being slightly more than extension. The maximum axial rotation occurring at the L1,2 level is 2^{o} and the maximum anterior posterior translation is 2 mm. Lateral bending to a maximum of 10^{o} can occur. The method of biplanar radiology used to make these estimations is accurate to within less than two millimeters for translations, and two degrees for rotations.

This technique also demonstrated the coupling which occurs during spinal motion. It was shown that lateral bending is always associated with extension and axial rotation; flexion and extension are associated with minimal axial rotation and lateral bending only; and axial rotation to the right is accompanied by lateral bending to the left and vice versa.

Any motion at the vertebral level L1,2 of greater than these parameters in-vivo is due to instability. This leads to the definitions available for instability (63, 70, 71, 176, 177). Pope (176) described instability as loss of stiffness. Stiffness being the ratio of load applied and motion that occurs. Frymoyer (71) referred to segmental instability as loss of motion segment stiffness such that force application to the motion segment will produce greater displacements than would occur in a normal structure. Friberg (70) defines instability as "a condition in which, in the absence of a new injury, a physiological load induces abnormally large deformations at the intervertebral disc".

Clinical instability as described in the article by Posner (177), was previously defined by White and Panjabi as "the loss of the ability of the spine under physiological loads to maintain relationships between vertebra in such a way that there is neither initial damage nor subsequent irritation of the spinal cord or nerve roots, and in addition there is no development of incapacitating deformity or pain due to structural changes".

It seems logical that, at a specific level, any motion in excess of the maximum described is due to instability. The ability to prevent or correct this instability would be useful when comparing fixation devices biomechanically.

Diurnal variations in the stresses on the lumbar spine due to posture can cause changes in the maximum range of movement at various levels. Adams et al (1) showed that the maximum range of motion at various vertebral levels is increased in relation to the time spent in the upright posture. The mobility is least on rising in the morning after a night's sleep. These changes can be accounted for by time-dependent behavior.

3. TIME DEPENDENT BEHAVIOUR

Although time independence is a satisfactory approximation to the behavior of structural materials in the majority of engineering applications, there are an appreciable number of exceptions. Creep, the change in dimension with time at a given load, and relaxation, the loss of stress with time at a given deformation, are two of the manifestations of time effects.(48)

Creep varies depending on the properties of the substance tested, but there are three phases to it. The first phase is characterized by a relatively fast rate of change of strain, and occurs soon after the load is applied. The second phase, the "steady-state creep" follows and can continue for long periods. If the level of stress is high enough, the creep rate eventually increases again and failure may occur.

In a biomechanical model, creep can be significant, and can be demonstrated by applying a constant load to a spine, and measuring the deformation which occurs with time. It can be shown that for a period of time after application of the force the displacement will change slightly. Panjabi (169) has shown that 4 minutes after the application of a load the displacement is at 97% of its final value. Other worker's (161, 162) also believe that creep is a significant problem and therefore that any loading should be done slowly and time should be allowed before measurements are made to allow for the creep to occur.

The rate of creep varies for all materials and it is necessary to determine how much occurs, and when it is completed to enable accurate assessment of data. For any spinal model creep should be defined before biomechanical testing is performed. With this in mind it will be seen that repeated testing should allow sufficient time between load applications to allow for creep to occur, and the time between load applications cannot be determined until creep has been calculated. It has also been demonstrated that creep can be influenced by the rate at which a load is applied. (141) It is recommended that loads be applied slowly to minimize these effects.

The clinical significance of creep has been described by Adams et al (1) and is mentioned above.

4. STATIC VERSUS CYCLICAL TESTING

Panjabi (171) described three methods for biomechanically testing implants in a spinal model. Loading to failure tests the strength of an implant and is a static test. Cyclical loading to failure is a fatigue test, and stability is tested by applying physiological loads and measuring motion which occurs. He believes that the latter method is best.

Static testing to failure determines the strength of the implant system but is not related to its effectiveness under physiological loads. Cyclic testing implies repeated testing at high rates and may prove to be useful in testing implants particularly to assess loosening and fatigue failure, but it is not physiological. Static testing using physiological loads assesses the rigidity of the system, and if done repeatedly the effects of time dependent behaviour can be greatly reduced.

The initial published work on spinal testing involved static testing to failure. Spinal models were instrumented, placed in a testing machine, loads were applied and the point of failure of either the spine or the instrumentation system was the end point of the test. Methods of fixation were compared using this technique and it appeared that the in-vitro results were comparable to in-vivo findings of instrument failure (45).

The next logical stage after testing to failure was to test to sub-failure and measure displacement at the fracture side in an effort to compare various fixation devices, and following on from this repetitive testing with physiological loads has been advocated.

Insufficient data is available on cyclic testing of spinal implants, but it appears that the term "cyclic testing" is sometimes used in error to describe static repetitive testing.

In summary, each kind of test may have some validity, but each test has a different objective. Loading to failure is an un-physiological test which uses an overload situation to determine time mode of failure of an implant. Cyclic testing determines loosening, and fatigue failure but is also un-physiological due to the rapid rate of cycling and the number of cycles used. Static loading using physiological loads allows the flexibility and rigidity of a system to be evaluated, and by measuring local motion at a fracture site the effectiveness of a fixation device can be assessed.

5. WHAT CONSIDERATION OF THESE FACTORS SHOULD BE MADE TO ALLOW TESTING OF A SPINE WITH A FRACTURE THAT HAS BEEN INSTRUMENTED ?

This chapter has described the estimated loads at various vertebral levels during certain activities, the normal amount of motion present at these levels, and the effects of time dependent behaviour as assessed in vitro. The load sharing nature of various instrumentation systems, or their ability to affect motion at normal vertebral levels have not been detailed in the published literature.

Assessment of time dependent behaviour can be calculated for an instrumented spine in vitro, but this will be different from that which occurs in vivo.

It is known that creep and relaxation occur in vivo; this is easily demonstrated by the diurnal variation in height of an average human. Creep, loss in height, occurs during the time that a person is upright due mostly to the intervertebral discs loosing height. The effect of this creep will be to subject instrumentation systems to slightly increasing loads during the time the person is upright.

Dove demonstrated that to produce a certain deformation in a spine that had been instrumented in vivo required a higher load than to produce the same effect when instrumented in vitro. This suggests that the physiological loads described above may be too large if used for in vitro testing.

In summary there is a lack of data relating to the biomechanical effects of instrumentation systems in vivo.

CHAPTER IV

REVIEW OF SPINAL FRACTURE MODELS USED FOR IN VITRO TESTING

THE SPINAL FRACTURE MODEL

When selecting a spinal fracture model for biomechanical testing, as many variables as possible must be excluded to enable reliable interpretation of results. To exclude variables there are two main topics which need to be addressed. These are the choice of spine, and the creation of a fracture in the spine.

(1) TYPE OF SPINE

Three basic spinal models can be employed for in-vitro testing: a human spine, an animal spine, or an artificial spine. Each one of these has its advocates in the literature. To perform comparison biomechanical tests it is necessary to have more than one spine and ideally an endless supply should be available. Each of these spines should come from a homogenous group of individuals, either humans or animals. They should be the same age, sex, height, and weight, and should be disease free. The spines should be removed in a similar manner with the same amount of soft tissue on each specimen, and they should be stored in the same way. Conditions of testing should be identical in regard to temperature and humidity.

In practical terms it is impossible to get such a group of human spines and for this reason sheep, pig and cow spines have been used. The third alternative, is artificial spines.

A review of the literature shows that many workers have used human cadaver spines in their work (16, 27, 52, 65, 78, 79, 113, 134, 152, 153, 163, 180, 202). The problem with this is the unavoidable difference in age, sex, height, and weight (160). The possibility of underlying diseases such as osteoporosis (96), and malignancy, and the presence or absence of embalming which has been shown by, Evans (59) to affects the results of biomechanical testing.

To obtain a more homogeneous population of spines some workers have used bovine spines usually from calves six to eight weeks old (28, 49, 103, 107, 116, 156, 185, 222, 229), while others use sow spines (24, 158, 164, 223).

There is evidence that immature spines may shear at the growth plates affecting the results of the biomechanical tests (159). It is known that the growth plate of the calf is bony whereas that of the human is cartilaginous (87), and there are also soft tissue differences between animal and human spines. For example, the anterior longitudinal ligament of the calf spine is significantly weaker than the human (73). There are few direct comparisons in the literature between animal and human spines (29, 45, 73, 87, 159), but biomechanical tests using animal models have been shown to produce results very similar to those in humans (45).

Other researchers have instrumented live dogs and then slaughtered them and tested the spines (117).

Plastic spine models have been described in the literature (66, 179). These were developed because of the reasons given above, namely that a homogenous population of human spines is almost impossible to obtain. Interestingly one worker (179) performed tests on a plastic spinal model initially and then repeated them on a human cadaver and found the results to be similar suggesting that plastic models may be useful.

Ideally a homogenous population of human spines should be used for testing. Due to the inability to obtain these, it is reasonable to use animal models. When choosing an animal model, consideration should be given to problems associated with the use of immature vertebrae. The use of plastic spinal models is relatively expensive and unphysiological.

ANATOMICAL COMPARISON OF HUMAN, PORCINE, AND BOVINE SPINES FOR BIOMECHANICAL TESTING

"The many similarities in physiology and gross and microscopic anatomy between swine and humans have resulted in the widespread use of swine in medical and biomedical training and research. The current indications are that the pig is best suited of any of the domesticated animals for such purposes (81)".

The above statement was published by the late Robert Getty who was the distinguished professor and head of the Department of Veterinary Anatomy, Iowa State University. Another similarity between the pig and the human is in the taste. This dates back to the time of cannibalism when humans where referred to as "big pigs" due to the similarity in taste (193).

The pig is a quadriped and therefore the curvature of the spine is different from that of the human. In the pig spine there is a fairly straight cervical component with a gentle kyphosis throughout the thoracic and lumbar area. The bovine spine is a similar shape. The upright posture of the human has resulted in the development of a lordotic cervical spine, a kyphotic thoracic spine, and a lordotic lumbar spine.

The gently kyphotic spine of the quadriped has received much attention in the literature (7, 8, 88). It is concluded that the bow and string theory is the most likely explanation of the curvature. This theory states that the body axis consist of a series of rigid elements (vertebrae) which, together with the intervertebral discs form a bow with variable curvature. The curvature is momentarily stabilized by the intrinsic ligaments of the vertebral column. This can be varied by the action of three series of muscular "strings" with adjustable tension. There are three layers of strings. The first are the posterior paraspinal muscles which by contracting tend to straighten the bow. The second are the interrupted portion of the ventral string, including the longis capitis, longis colli, and the psoas. The final string is the uninterrupted string comprising the anterior abdominal wall and including the oblique transverse and straight abdominal muscles. With the interaction of these muscles the spine has kept its kyphotic curvature even when the animal is standing.

Although the ligaments play some part in the maintenance of the gentle kyphotic spine of quadripeds, they do not play as great a part as the surrounding musculature. It has also been stated that the sow spine can be straightened if the anterior abdominal wall muscles are cut (8).

Cotterill et al (29) published a paper on the comparison of human and bovine thoracolumbar spines. This was based on the anatomical dissection and radiography of ten human and bovine spines. They concluded that it is necessary to use six to eight week old bovine spines to obtain vertebrae similar in size to corresponding human vertebrae. The use of immature vertebrae can be associated with shearing of the growth plate, and it would seem that a mature animal is preferable as long as the vertebral dimensions are similar to those of the human.

(2) TYPE OF FRACTURE

Production of a reproducible, unstable fracture for use in biomechanical testing has not received sufficient attention in the literature. There are many reports which deal with testing of spinal implants in fracture models (16, 28, 49, 66, 73, 78, 79, 113, 134, 136, 152, 153, 159, 180, 192, 208, 227), but only a few of these give details of the exact mechanism of creation of the fracture, and none of these papers specify a parameter which confirms reproducibility. In some instances the "fracture" is nothing more than a gap between two segments of an articulated spine (16, 49, 66, 159). One worker described a fracture created by disrupting the posterior ligaments and testing the spine to failure in flexion with axial loading, but failure occurred through the disk not bone (180).

A closer look at some of the ingenious methods described for producing experimental "fractures" reveals a lack of reproducibility. Stauffer

(208) incised the posterior ligaments and the ligamentum flavum and the superior facet joints of L1 vertebrae and applied a flexion rotation force until an oblique fracture occurred through the body of the L1 vertebrae. At this point the testing was stopped quickly before the anterior longitudinal ligament also ruptured. This was performed on twenty preserved cadaver spines with production of a similar fracture in each case. Unfortunately there was no mention of the loads (including range) necessary to produce the fracture and no x-rays to show the homogeneity of the fracture. Jacobs (113) was able to produce three different types of fractures in vertebrae. He described an injury in which the posterior ligaments were divided and an osteotomy was then performed through the vertebral body with preservation of the anterior longitudinal ligament. This fracture was created purely by the use of a knife and osteotome and without any loads being applied. For his anterior injury he used an osteotome to produce a comminuted fracture of the body again preserving the anterior longitudinal ligament and for combined injury he combined his posterior and his anterior injury producing an unstable spine. Once again there was no actual force applied to the vertebrae to produce the fracture. The fracture was created purely using surgical instruments.

Gaines (73) produced an experimental slice fracture although details were not given. McAfee (153) dropped a 140 Newton weight a distance of 1.6 meters on to the top of a spine having previously created a stress riser by making multiple osteotomy cuts at the level to be fractured. He claims to be able to reproduce a fracture, but his spines came from twenty-five cadavers varying in age from eighteen to ninety-one. Three of the spines were embalmed and the other twenty-two were fresh frozen.

Gepstein (78) created an L1 burst fracture by drilling holes into the body of the vertebra to be fractured, disrupted the supra-spinous ligaments and ligamentum flavum, and loaded them to failure. Insufficient data was given in his paper to fully establish that the fracture was reproducible.

Cotterill et al (28) in Toronto are able to create a reproducible burst fracture but the method is rather laborious and messy. Immature calf spines were used on which stress risers were created at the appropriate level. The spines were mounted in end caps of cerrubend metal which in turn were placed in metal cups, wrapped in saran wrap, plaster of paris, a sewer pipe and more plaster of paris and when this is finished a 32 kg weight is dropped 1.55 meters onto the spine causing it to fail.

In total contrast, Lavoie et al in Edmonton devised a method in which an anterior defect is precisely made in a single lumbar vertebra which is then loaded to failure in a universal testing machine using suitable end caps and a compressive force. This rather simple method produced an identical fracture in every case. The load necessary to produce the fracture was similar, and the displacements of the vertebrae anteriorly which occurred at the time of failure were also compatible (136). The fracture produced involved three columns and was therefore unstable. During creation of the fracture compression forces occur anteriorly with distraction forces posteriorly with the fulcrum in the middle column. This is in keeping with the mechanism of injury described in the literature (92). Modification of this technique for application in segmented vertebrae is described later in this thesis.

CHAPTER V

RESULTS OF IN-VITRO TESTING

In order to biomechanically test spinal implants, a reliable and accurate testing system must be used. This should include a suitable spinal model as previously described, a method of applying loads to the spine, and a valid basis for comparing the implants.

To enable a better understanding of the critique a review of the methods used to apply loads to the spine, and the measurements which have been used to compare the implants is presented.

APPLICATION OF LOADS

Application of loads for biomechanical testing requires the use of an "End Cap" which firmly attaches to the end vertebrae of a spinal test segment, and allows the transmission of force from a loading device to the spine in a reliable, repeatable, and precise manner.

Although the literature is full of biomechanical spinal testing procedures, there is a sad lack of published data on end-cap design. Most workers have used either an encapsulation method with either polymer which sets giving firm attachment (78, 161, 162, 164, [illegible], 219) or low melting point metal (28), or metal devices such as pins rods (113, 169), These methods have disadvantages which outweigh their advantages.

Polymers commonly used are plaster-of-paris, and polymethyl methacrylate. Both of these are exothermic, and potentially harmful to tissues. Damage caused by the heat may well alter the properties of the soft tissues and affect results. A low melting point metal has been successfully used but it necessitates the application of heat either directly or indirectly. Metal rods or screws rely on penetration into the end vertebrae for their fixation. The damage caused will weaken the spine and affect results. Systems with metal rods and screws are excessively flexible.

BASIS FOR COMPARING IMPLANTS

The evaluation of devices used for stabilization of spinal fractures can be accomplished in-vitro by testing to failure using static, or repetitive loads, or by applying physiological loads and assessing motion at the fracture site.

If static testing to failure is performed, the measurement used for comparison of implants is the load, or displacement at failure. If cyclic testing is performed the number of cycles resulting in failure or loosening is used for comparison. If static testing using physiological loads is employed, the implants can be assessed by their ability to prevent movement at the fracture site.

Based on the assumption that the best measure of effectiveness of implants is the ability to prevent motion at the fracture site during healing, methods of measuring this motion have been developed by various workers. Photographic methods have been successfully employed, but their accuracy is doubtful (132, 158, 183). A transducer capable of measuring local motion was tried by one worker, but was criticized because it joined the two parts of the fractured vertebra together and increased the stability of the fracture (73, 75, 159).

A transducer has now been developed which accurately measures fracture site motion without affecting the stability of the fracture or fixation device (61).

CRITIQUE OF IN-VITRO TESTING OF SPINAL IMPLANTS

Numerous articles have appeared in the recent literature on the subject of in-vitro testing of spinal implants (4, 6, 16, 26, 30, 40, 45, 49, 52, 55, 56, 65, 66, 75, 76, 78, 79, 103, 107, 113, 114, 116, 129, 133, 134, 150, 152, 153, 156, 159, 163, 164, 167, 171, 179, 180, 185, 194, 202, 203, 208, 219, 220, 222, 223, 227, 228, 229, 244, 245). Some of these papers lack detailed descriptions of in-vitro testing methods and can therefore not be criticized. The following is a review of the methods used.

In 1975 Stauffer (208) used cadaver spines with an experimentally produced fracture to test the Weiss dynamic compression springs, Harrington distraction rods, and Harrington compression rods. He tested each device to failure and concluded that the distraction rods failed by hook pull-out which is in agreement with in vivo findings, and failure of the Harrington compression rods occurred due to a fracture or dislocation below the device. The Weiss springs were statistically worse at controlling rotation compared to the other systems tested. Some of the problems with his experimentation were that cadaver spines were used which were not matched for age, sex, disease and osteoporosis. The artificial fracture used was created by cutting the posterior ligamentous structures and applying a flexion rotation force to the vertebrae which resulted in a fracture through the body obliquely. This was probably not a reproducible fracture and there was no information given as to the loads necessary to create this fracture. He used plaster of paris end caps to hold the vertebrae in place and tested to failure using non-physiological loads. The central axis of the spine was used to calculate the moment arm, but this is not necessarily the instantaneous centre of rotation of the fractures vertebra, and may result in inaccuracies. Despite this criticism his results are comparable to others.

Laborde (134) used both fresh and embalmed cadavers for his experiments. A three point loading system was used, and loads were applied quite quickly resulting in failure of the spines within five to fifteen seconds. Once failure had occurred in the spine, the spines were instrumented using Harrington distraction and compression rods and titanium mesh. Each spine was instrumented using each system and the systems were always applied in the same order namely the Harrington distraction rod first, the Harrington compression rod second and the titanium mesh last. Testing [illegible]re was then performed in flexion, extension and lateral bending. Results showed that Harrington compression rods were the stiffest, the mesh was the strongest and the distraction rod had strengths and stiffness in the mid-range. No statistical analysis was presented, but results suggested that the distraction rod was stronger than the compression rod contrary to other results (208). This discrepancy may be partly due to the fact that the Harrington distraction rod was always tested before the Harrington compression rod and there may have been some weakening within the specimen resulting in this reversal of the normal finding. Another criticism with this method is the use of fresh and embalmed cadavers which have been shown to produce different results in-vitro. Also load application during fracturing was applied faster than recommended in the literature (141).

Purcell in 1981 (180) produced an interesting study in which Harrington rods were compared in-vitro for the treatment of fractured vertebrae. A statistical comparison was made between the immobilization of two segments ~~above and~~ below the fracture with immobilization of three segments above and two below. He found that immobilizing the extra segment resulted in a 65% stronger fixation when tested to failure. This would fit with the clinical finding of Jacobs (111) who found that the pseudoarthrosis rate decreased when the rod long fuse short method of immobilization was used. The criticism with his experimental technique is that he again used thirteen cadaver spines whose age varied from fifty to eighty-one years. In order to create an unstable segment a defect was made posteriorly at the T12 L1 junction and the spines then tested to failure which occurred through the disc. There was therefore no actual bony injury. During loading of the instrumented spine, time was not allowed for creep to occur and once failure had occurred the rods were re-positioned on the same spine at the level above the failed segment allowing the same spine to be retested. Comparison of the implants was based on the force necessary to produce failure, and was measured in Newton meters. From the description of the loading system it would appear that the moment arm increases in length as the applied load causes deformation of the spine. This may drastically affect the interpretation of results.

Nagel (163) performed an unique experiment with five human bodies. Incisions were made posteriorly allowing access to the thoracolumbar junction. Steinmann pins were inserted through the pedicles of the L1 and L2 vertebrae. A transducer was applied between these two levels, allowing motion to be accurately measured. The intact human cadavers when then put through a range of movement, and motion at the L1, 2 level was measured. Normal range of motion was measured and then progressive disruption at this level was performed by soft tissue incisions in to the posterior elements spreading slowly anteriorly. Once an unstable situation had been produced three different types of external braces were compared, and the Harrington rod was compared to spinous process wiring. Motion at the L1, 2 vertebral level measured using this technique were very similar to those measured in-vivo using biplanar radiography (43, 89, 173, 174, 188, 230). Criticism of this method is again related to the fact that the human cadavers used were of various ages and sizes, and the range of movement that the cadavers were put through was performed by a laboratory assistant physically holding the cadavers with no measurement of the amount of force used to produce the movements.

Gepstein and Shufflebarger (78, 79, 202) have used a fracture model produced in human vertebrae to test various posterior fixation devices. Initially they tested to failure comparing the Harrington distraction rod to the Cotrel-Dubousset instrumentation system and found that the latter system was statistically twice as strong. Their initial testing was performed on human vertebrae taken from cadavers of various ages. A burst fracture was created by drilling holes in the body and applying an axial load at 3 mm per second, which is faster than the recommended loading rate, and no details were given as to the reproducibility of the spinal fracture. A further criticism is that in the initial investigations, testing was only performed in axial compression and flexion. Also the same spine was used for each system tested. More recently the same authors (202) have been testing the Cotrel-Dubousset instrumentation system in what they describe as a pseudostatic cyclic loading. Again in this experiment the human vertebrae used were not from a homogenous population, the loads used were not physiological, they were applied too rapidly and time was not allowed for creep to occur. The term cyclic is technically wrong and should be replaced by repeatative. Although the general results were the same as those found in other centers the small number of spines used, and the large number of variables leave this research open to criticism.

McAfee (152, 153) compared the Harrington distraction rod, Harrington with sublaminar wires, and the Luque system. Twenty-two fresh and three embalmed cadaver spinal segments were used with an age range of eighteen to ninety-one years. The systems were fractured in three different ways. First, an axial pre-load was applied followed by rotation to failure, secondly, a "burst fracture" was created and tested, and thirdly a "slice fracture" was used. In comparing these instrumentation systems they found that in the unstable burst fracture, the segmentally wired Harrington system resisted the axial compression the best, and for the slice fracture without commuqution the Luque system was the best. Criticism of this method is the non-homogenous population of spines with a seventy-three year age difference, and the additional variable of embalmed and unembalmed spines. The second criticism is that the fractures created were not reproducible, and finally the only testing performed on each specimen were those felt to be relevant to the fracture types. One good point about this experiment was that they did allow three minutes for creep to occur after each loading.

D'Angelo et al (30) described their experiments on twenty-four spines instrumented with various fixation devices and tested repeatetively. Their unpublished data does not mention the fracture creation or whether or not his spines came from a homogenous population. No reason is given for the use of repeatetive loading, and the test described was a static repetitive test not a dynamic cyclic one. They commented that the Luque system when applied to the spine and tested was weaker than the un-instrumented spine had been. This is likely due to the fact that the posterior spinal elements had to be removed from the calf spine in order that the Luque system could be applied. There are too many unanswered questions and variables in their work.

Munson, and Gaines (73, 75, 159) used a homogenous population of calf spines and their fracture although not mechanically produced is certainly reproducible, as they merely remove a two centimeter portion from one segment of the vertebral column. They described the use of end caps, and they tested the spine in all six degrees of freedom. Initial work used a transducer for measuring motion at the fracture site but the type of transducer used led to criticism as it joined together the two portions of the fractured vertebrae. They now use a travelling microscope to measure accurately the position of three pins on each level of the spine. The pins represent the X, Y and Z axis of movement. Using this system they are able to measure the global motion present at the level above and the level below the fracture as well as at the fractured level itself. In the experiment they allowed three minutes for creep to occur before making measurements. The loads applied during testing were within the physiological range. They compared the Steffee plate, the Harrington with and without sleeves and wires, and the Luque rectangle and found that the Steffee system was the best in all 5 modes of loading and testing, namely axial compression, flexion, extension, lateral flexion and torsion. They commented that the immature calf spines used in the experiment had a problem with the end plate (159). In one case the immature vertebral end plate was the cause of the failure.

Other have compared the various types of pedicle screws presently in use in the hope of finding the ultimate design (6, 55, 133, 220, 244, 246). Pull-out strengths, effects of cyclic loading, depth of screw penetration into the pedicle, screw major and minor diameters, tooth profiles, and pitch were analysed.

Controversy exists as to whether pedicle screws should penetrate 50%, 80% or 100% of the vertebral body. It is generally accepted that penetration of the anterior cortex of the body is not a good idea due to the close proximity of the aorta and vena cava. It appears that 80% penetration is better than 50% but that the loads necessary to pull out or loosen these screws are so great that it is unlikely to be encountered in in-vivo conditions. It is therefore recommended that the screw penetrates a minimum of 50% and a maximum of 80% of the body of the vertebrae Edwards (55) found that 6.5 mm cancellous self-tapping screws with a tapered proximal shank were the ideal screw design. Zendrick (244, 246) found that 6.5 mm cancellous screws were superior to 4.5 mm screws and the full threaded screws were better than partially threaded ones. Krag (133) published an excellent paper on the development of his own fixation system and in it he looked very closely at the various types of screw designs available in order to try and find an optimum one. His findings were that a 6 mm major diameter screw with a 2 mm pitch and a Buttress tooth pattern was the ideal design. Transfeldt et al (220) concluded that an increased major diameter ~~increased~~ the pull out strength of the screw, and increased pitch increased the amount of displacement necessary to cause failure. Ashman et al (6) used plastic spines to compare pedicle screws and found the Steffee to be the best.

Despite the criticism of the various methods used for testing of the posterior spinal implants, the results published from such testing are similar. In particular the Harrington distraction rod affords less stability when torsional loads are applied compared to the Luque which is less stable when axial loads are applied (26, 52, 78, 79, 113, 134, 156, 164, 185, 208, 223, 229). The same articles have shown that the failure of the Harrington distraction rod usually occurs due to hook pull out.

None of the articles have dealt specifically with pedicle screw fixation devices although many of the articles have compared one or more of these devices to the more conventional systems such as the Harrington and the Luque. In each case the pedicle screw fixation device has been shown to be superior (103, 113, 179). The introduction of the Cotrel-Dubousset has resulted in testing of this instrumentation system also, but reports have dealt with this system alone or this system compared to the Harrington rods only (79, 116, 202).

CHAPTER VI

MATERIALS

CHOICE OF SPINE FOR IN-VITRO TESTING

The ideal spinal model for use in biomechanical testing of any fixation device is a homogenous population of human spines. Such a population is impossible to obtain and this has led to the use of animal spines for in-vitro testing.

In this investigation mature sow spines were used. The reasons for this choice are threefold. Firs[illegible] animal is better than an immature one as the unfused e[illegible]ature animal spines tend to shear which may affect [illegible] Secondly, in comparing the anatomy o[illegible] human spine they are as similar if not more so t[illegible] Thirdly, eighty sow spines from one source we[illegible] added to the homogeneity of the population.

HOMOGENEITY OF THE SAMPLE OF PIG SPINES

The sow spines used come from a reasonably homogenous population. They were all two year old sows weighing approximately 300 pounds when sacrificed, and they all came from one producer. The spines were

3 of/de 3

1.0 2.8 2.5 3.2 2.2 3.6 2.0 4.0 1.1 1.8 1.25 1.4 1.6

MicroD

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APPENDIX

TECHNICAL DATA OF THE PEDICLE SCREW FIXATION DEVICES

The pedicle screw fixation devices evaluated were of two types; pedicle screw plates, and pedicle screw rods. Each of the four systems is discussed below in detail.

STEFFEE PLATES AND SCREWS

The Steffee system uses 316 LVM stainless steel in the manufacture of its implants (AcroMed Corp. Cleveland, Ohio). The plates come in various sizes, and each has a number of slots in it. The plates used in this study are 120mm in length, and contain three slots. Each slot is contoured to allow for variations in screw placement yet providing firm attachment of the screws to the plate. The contouring of the slots allows screw placement at four mm intervals.

The screws used in the system have a major diameter of 6.5mm, and a minor diameter of 4.0 mm. The screw pitch is 2.65mm. The screws come in various lengths but for this study 73mm screws were used which have 32mm of thread available. A buttress thread type is used. The remainder of the screw length consists of a finer thread on which three nuts are placed to allow firm attachment of the screw to the plate.

ROY-CAMILLE SYSTEM

This system is made of vitallium (Benoist Girard et cie, Division of Pfizer Hospital Products, affiliate of Howmedica International Inc, Bagneux, France). The plates are contoured to the shape of the spine, and come in various lengths. Each Lumbar plate used in this study contains 10 holes and was cut from an 11 hole plate so that the plate length was similar to the Steffe. The 10 hole plate used was 127 mm in length.

The screws used were 60 mm long, and the threaded portion was 56 mm in length. The major diameter was 3.6mm, and the minor was 2.7mm. The screw pitch was 1.3mm in a "V" configuration.

A.O. FIXATEUR INTERNE

The fixateur interne is made in Switzerland, and constructed of stainless steel. (A.O./Association for the Study of Internal Fixation. Synthes Canada Ltd.). It consists of a rod with a maximum diameter of 6mm which is threaded on two edges. The rods come in various lengths, and for this study they were cut into 130 mm lengths. A device allows the screws to be attached to the rods at any angle, and also allows compression or distraction forces to be applied to the spine.

The schanz screws used have a major diameter of 5mm, a minor diameter of 4mm, and a pitch of 1.75mm. A buttress thread is used. The threaded portion of the screw is 35mm long, and after insertion the shaft is cut to the desired length.

COTREL DUBOUSSET SYSTEM

This system is made of ASTM.F:138 grade 2 stainless steel. (Sofamor Company, Cedex, France). The rods are 6mm in diamater, and tubular in shape with a criss-cross outer layer.

The screws have a major diameter of 5mm, a minor diameter of 3.7mm, and a modified "V" thread with a pitch of 3mm. The screws used were 56mm long with a thread length of 37mm. The top of the screw is expanded into a cube shape which has a 6mm hole in it to allow the rod to be threaded through. The screw is held onto the rod by two small bolts which grip the criss-cross outer layer of the rod.