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AXIALLY COMPRESSIBLE FRACTURE FIXATION PLATES

by

ALAN YEADON, B.A.Sc.

A thesis submitted to

the Faculty of Graduate Studies and Research

in partial fulfilment of

the requirements for the degree of

Master of Engineering

Department of Mechanical and Aerospace Engineering

Ottawa-Carleton Institute

for Mechanical and Aerospace Engineering

Carleton University

Ottawa, Ontario

January 1996

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ISBN 0-612-13853-4

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submitted by
Alan Yeadon, B.A.Sc.
in partial fulfilment of the requirements for
the degree of Master of Engineering

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Abstract

The hypothesis that bone fracture healing is improved with internal fixation plates having reduced axial stiffness was tested with four axially compressible plates spanning a range of axial stiffnesses. These plates were implanted on unilaterally osteotomized canine femora for periods of 8, 16, and 24 weeks. At the end of each implantation period the femora were excised and the plates removed from the experimental bones. Pairs of femora were tested biomechanically under nondestructive four-point bending in twenty-four planes about the longitudinal axis of each bone to evaluate the polar distribution of flexural rigidities. A normalized measure of healing, stiffness index, was calculated for each pair as the ratio of the flexural rigidity of the experimental bone to that of its contralateral control. Femora treated with plates having intermediate axial stiffness exhibited significantly superior healing. Healing advanced with time at a diminishing rate toward a steady state that was approached asymptotically.

Acknowledgements

First, foremost and always, to my wife, Michelle, thank you for your support, your understanding, and often putting my needs ahead of your own. I can't imagine how I will ever be able to return these gifts, but I will try.

To my supervisor, Donald Russell, it's a small world, isn't it? How fortunate for me that fate would have our paths cross again so that you could guide me through this little project. Your thoughtful insight, quiet encouragement and wise advice nudged this sometime wanderer back onto the correct path.

To my mentors, Dr. Hans Uthoff and Amnon Foux, deepest thanks for providing the impetus and means to pursue this work. Between the two of you there is almost 100 years of knowledge and experience in medicine, engineering and scientific research that I had the immense privilege of drawing upon. I sincerely hope that you consider this work to reflect well on you both.

My many colleagues at the National Research Council of Canada; Robin Black, Lloyd McSheffrey, Bob Taylor, Serge Bouchard, Ken Tierney, and Donald Raizenne; and at the University of Ottawa; Brigitte Eiselt and Clare Booth; are gratefully acknowledged for their technical assistance and warm friendship.

Finally, the financial support of the Medical Research Council of Canada and the National Research Council of Canada is gratefully acknowledged.

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List of Symbols

Symbol	Description
ACP	Axially Compressible Plate
AR	Area Ratio
DCP	Dynamic Compression Plate
EI	Flexural Rigidity
F	F-test Statistic
GFMM	Graphite Fibre Reinforced Methylmethacrylate
k	Axial Stiffness
LC-DCP	Limited Contact Dynamic Compression Plate
LDPE	Low Density Polyethylene
LVDT	Linear Variable Differential Transformer
p	Probability of Incorrectly Rejecting the Null Hypothesis
PCP	Point Contact Plate
PFRP	Polar Flexural Rigidity Profile
PMMA	Polymethylmethacrylate
SEM	Standard Error of the Mean
SI	Stiffness Index
SI_{∞}	Asymptotic Value
t	Healing Time
σ_p	Constant Stress Applied for Creep Testing
θ_H	Position of Screw Holes

Symbol	Description
$\theta,$	Position of Plate
θ_{st}	Position of Stiffness Index
τ	Time Constant

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CHAPTER 1: INTRODUCTION

1.1 Problem Statement and Thesis Summary

Fractured long bones treated with rigid internal fracture fixation plates are prone to bone atrophy (weakening due to loss of bone mass) and refracture subsequent to plate removal. The incidence of refracture has been reported to be as high as 20% ⁴⁰. It has been generally believed that the problems of bone atrophy and refracture can be minimized by treating long bone fractures with internal fixation plates having reduced rigidity. Several authors have postulated that the degree of *axial* rigidity is the most important factor influencing the healing of plated long bone fractures ^{8,9,17,55,56}. However, this hypothesis has never been tested.

The purpose of this work was to determine the effect of plates with selectively reduced axial stiffness on the healing of osteotomized (ie. cut surgically with a saw) canine femora (plural of femur), and to test the hypothesis that fracture healing is improved with such plates. Axially compressible plates (ACP's) were designed for this purpose. These ACP's consisted of metal plates, polymer inserts and metal bone screws. Selective reduction of axial stiffness was achieved by interposing the polymer inserts between the shanks of the bone screws and the slots in the plates.

An important note is the fact that the terms *rigidity* and *stiffness* were often given the same meaning in the literature. For example, the phrase *axial*

rigidity was commonly used with reference to internal fixation plates when the phrase *axial stiffness* would have been technically correct. Therefore, the *axial stiffness* of plates in this work refers to the phrase *axial rigidity* in the literature.

Four types of ACP's were manufactured to provide a range of axial stiffnesses. It was hypothesized that optimal fracture healing would be observed with plates near the centre of this range. The ACP's were implanted on osteotomized canine femora for periods of 8, 16 and 24 weeks. At the end of the implantation periods, the femora were excised, the ACP's were removed from the femora, and healing was assessed biomechanically under nondestructive four-point bending.

Chapter 1 is an explanation of internal fracture fixation plates and basic bone mechanics. This includes an overview of the development of plates from their introduction in 1886 to the modern rigid plating systems used in orthopaedic surgery today. Plates are intended to treat fractured bone, so an understanding of basic bone mechanics is essential. This topic is covered with a discussion of the structure, mechanical properties, and healing mechanism of bone. Being familiar with plates and basic bone mechanics, an analysis of the benefits and problems associated with rigid plates as a treatment for fractured bones is then presented. The problems of bone atrophy and refracture associated with rigid plates have been the impetus for a great deal of research. Consequent alternatives to rigid plates that have been offered as solutions to bone atrophy and refracture are discussed.

One of the alternatives discussed in chapter 1 suggested selective reduction of the axial rigidity of plates as a solution to bone atrophy and refracture. This alternative served as the rationale for this work and is the subject of chapter 2 along with the ACP. Selectively reducing the axial stiffness of plates is defined as a problem, while the ACP is proposed as the solution. The design of the plates, inserts and screws for the four ACP's is presented. The assembly and function of the ACP's is also explained.

Selective reduction of axial stiffness was the primary design criterion for the ACP's. Therefore, it was necessary to verify that this design criterion had been satisfied through a series of mechanical tests. Tensile testing of the ACP's to measure their axial stiffnesses is described. The ACP's were also subjected to nondestructive four-point bending to test for differences amongst their bending stiffnesses, and these bending tests are described. Torsional stiffnesses were analyzed to check for differences amongst the ACP's, and this comparison is explained.

Having established that the primary design criterion of selective reduction of axial stiffness had been satisfied with the ACP's, the fracture healing experiments were initiated. These experiments are the subject of chapter 4. Osteotomized canine femora were selected as the fracture model. The selection of animals for these experiments and the duration of the implantation periods for the ACP's are explained. A description of the surgical techniques used to osteotomize the canine femora and implant the ACP's is included. After the

implantation periods had elapsed, biomechanical test methods were used to measure the degree of healing achieved by the femora. These test methods and the analysis methods used to interpret the results are explained. The results of the biomechanical testing are listed and discussed.

During the course of the fracture healing experiments, it was observed that the biomechanical test methods did not account for the presence of screw holes in the femora. Therefore, a supplemental testing program was initiated, and this is the subject of chapter 5. The purpose of this supplemental testing program was to determine the effect of screw holes on the flexural rigidity of femora and factor this effect into the results obtained from plating with the ACP's. A description of the testing methods, a listing of the results, and a discussion of the results pertaining to this supplemental testing program are presented.

Finally, chapter 6 contains a discussion of the conclusions drawn from this work and chapter 7 offers recommendations for future work on the topic of ACP's.

1.2 Origins and History of Internal Fracture Fixation Plates

Metallic plates used to treat fractured bones act as internal splints that approximate the bone fragments and stabilize the fracture. Such plates are usually positioned on the tension side of the fracture and fastened to bone with metallic screws. Bagby ⁵ presented a thorough historical review of internal

fracture fixation plates, and this review is summarized below.

Internal fracture fixation plates were introduced by Hansmann ²⁰ in 1886. His plate was intended to be removed at the first sign of stable fracture healing. Therefore, the plate was designed with a right angle at one end that protruded through the skin and screw heads that also protruded through the skin as illustrated in figure 1 ⁵.

Subsequent improvements to internal fracture fixation plates were made by Lambotte ²⁹, Sherman ³⁰, and Lane ⁴² in 1909, 1912 and 1914, respectively. These three plates, also illustrated in figure 1, were stronger than Hansmann's plate, and they displayed a greater degree of biocompatibility ⁶. Sherman's plate was the first to be made from a stainless steel alloyed with Vanadium ⁶. Lane's plate was made from weaker material such that it could be bent to conform to the contour of a bone. This plate design also included more severe stress concentrations than Sherman's ⁵. Therefore, Lane's plate proved to be inferior to Sherman's ^{5,6}.

Slotted plates were first reported by Townsend and Gilfillan ⁴⁷ in 1943. All previous plate designs had round screw holes. An illustration of the Townsend and Gilfillan plate is shown in figure 2. This plate was fastened loosely to the bone and the fragments were approximated manually before the screws were tightened ^{5,6}. Being thin and flexible, several such plates were stacked one upon the other when greater strength was required ⁵. Eggers ¹⁴ reported a plate in 1946 that had rather long slots as shown in figure 2. This

Hansmann (1886)

FIG. 1-A

Lambotte (1909)

FIG. 1-B

Lane (1914)

FIG. 1-C

Sherman (1912)

FIG. 1-D

Figure 1: Early Fracture Fixation Plates (from Bagby, 1977)

Townsend and Gilfillan (1943)

FIG. 2-A

Eggers (1948)

FIG. 2-B

Collison (1950)

FIG. 2-C

Figure 2: Slotted Plates (from Bagby, 1977)

plate was implanted with loose screws and relied on muscle contraction to approximate the fragments ^{5,6}. Collison reported a similar plate in 1950 ^{5,6}. The slots were shorter than Eggers' and bevelled for conical screw heads as illustrated in figure 2 ^{5,6}. It is doubtful that any of these slotted plates achieved improvement over the Sherman plate ⁶.

Danis ¹² introduced the concept of compression to internal fracture fixation in 1949. The term *compression* in this sense referred to the compression applied to the fragments by the plate as part of the surgical procedure, as opposed to compression applied by muscle contraction or weight bearing. An axially oriented screw shown in figure 3 was used to force the fragments together under compression. Unfortunately, the head of this screw was very close to the bone and thereby difficult to tighten ⁵. Venable ⁵³ attempted to solve this problem in 1951. The compression screw was oriented obliquely to make it more accessible for tightening as shown in figure 3 ⁵. Unfortunately, the junction proved to be unstable between the compression screw and the bone screw against which it was threaded to generate the compressive force ⁵. In 1952, Boreau and Hermann ³⁴ reported a plate in two halves that was joined in the middle by a turnbuckle shown in figure 3. Compression was achieved by drawing the two halves together with the turnbuckle, but the stability of this assembly was insufficient ⁵. All three compression plates were awkward and ineffective ⁶. None of them became popular with surgeons ⁵.

Danis (1949)

9

FIG. 3-A

Venable (1951)

FIG. 3-B

Boreau and Hermann (1952)

FIG. 3-C

Muller (1961)

FIG. 3-D

Figure 3: Compression Plates (from Bagby, 1977)

A modification of the Danis plate was also made by Müller in 1961 ³⁴. An external compression device similar to a vice was positioned at one end of the plate as illustrated in figure 3 ⁵. Sufficient compression was readily achieved with this external compression device. However, an extra long incision was required to accommodate the presence of this device which was removed at the end of the surgical procedure ⁵. Müller's screws were also an improvement over those used with the Danis plate ⁶. This plate was considered a significant improvement over the Danis plate and was widely used into the 1980's ⁶.

Bagby and Janes ⁷ were the first to report a self-compressing plate in 1958. This was to become known as the "Bagby plate". Self-compression was achieved through a modification of the bevelled slots introduced by Collison ^{5,7,38}. The bevel was replaced by a vertical wall at the end furthest from the midsection of the plate in each slot as shown in figure 4 ^{5,7,38}. The screws were threaded into bone such that the conical heads bore against the vertical walls as they were tightened ^{5,7,38}. This forced the fragments together under compression without the use of extraneous screws or devices.

However, self-compressing plates did not become widely available until the early 1970's following the introduction of the dynamic compression plate (DCP) by Perren et. al. ³⁸ in 1969. The DCP operated on the same principles as the Bagby plate but employed the slight modifications shown in figure 5. Spherically countersunk slots replaced the bevelled slots, but the vertical wall was retained at the end furthest from the midsection of the plate in each slot.

Figure 4: Self-compression Plate (from Bagby, 1977)

Figure 5: Concept of Dynamic Compression Plating (from Perren et. al., 1969)

Screws with spherical heads replaced the screws with conical heads. The DCP was also made from commercially pure titanium. These modifications resulted in a plate that offered more rigid fixation, precision fitting screws, and screws with greater fastening strength ⁶. In the intervening years the DCP has become the standard treatment for internal fixation of bone fractures with plates. Curiously, modern DCP's are generally made from an implant grade stainless steel ^{1,36}.

1.3 Bone: A Living Engineering Material

Bone is an engineering material. Like other more traditional engineering materials, bone is a material from which structures and mechanisms are constructed and its primary function is to support loads and transmit forces. However, bone is living which distinguishes it from other traditional engineering materials. This gives bone the unique ability to adapt to its environment and even repair itself subsequent to suffering damage. A thorough understanding of the structure, mechanical properties and healing mechanism of bone is essential to effectively design and evaluate any man-made device intended to assist or accelerate the capacity of bone to repair itself.

1.3.1 Structure of Bone

Long bones are load bearing structures in the limbs of the body that are designed to act as rigid levers for muscular action. They consist of a diaphyseal shaft with epiphyseal widenings at each end as illustrated in figure 6. The

Figure 6: Structure of Long Bone (from Cowin et. al., 1987)
Cross section of human femur illustrating cortical bone and cancellous bone.

diaphysis is composed of dense material called cortical bone ^{10,11,18,32} with a specific gravity of about 2 ^{10,11}, whereas the epiphyses are composed of a three-dimensional branching mesh called cancellous bone ^{10,11,18,32}. The diaphysis can be described roughly as a thick walled hollow cylinder, the walls of which taper off toward the ends of the bone to become a thin shell surrounding the cancellous bone within the epiphyses ¹⁸. Within the diaphysis is a hollow space called the medullary canal that is filled with bone marrow ^{18,32}. Cortical bone assumes three forms in the adult human body: woven, lamellar, and haversian ¹¹. Woven bone is usually only present subsequent to a fracture ¹¹. It is an immature and disorganized form of cortical bone, whereas lamellar and haversian bone is highly organized ¹⁸. The diaphyseal shaft consists of three regions or "envelopes": the periosteal envelope, the haversian envelope, and the endosteal envelope. Two of these, the periosteal and endosteal envelopes, are composed of lamellar bone while the remaining envelope is composed of haversian bone ^{10,11}.

The periosteal envelope forms the outer circumferential layer of the diaphysis as illustrated in figure 7. It consists of concentrically arranged lamellae, each having a thickness of about 200 μm ^{10,11}. Each lamella consists of a layer of poorly organized bone tissue sandwiched between two layers of highly organized bone tissue. Interfaces between lamellae contain an array of ellipsoidal shaped cavities called lacunae which contain bone cells. Numerous fine canals called canaliculi extend from the lacunae to form a vascular net. On

Figure 7: Microstructure of Cortical Bone (from Cowin, 1989)

This drawing of a cross section of a long bone illustrates the three envelopes of cortical bone with the haversian envelope contained within the periosteal and endosteal envelopes. The microstructure of lamellar bone is shown above and that of haversian bone is shown below.

the outer surface of the diaphysis the periosteal envelope is wrapped in a fibrous membrane called the periosteum^{18,32}. This membrane contains dormant cells that become active in the formation of bone in the event of a fracture¹⁸.

The endosteal envelope forms the inner circumferential layer of the diaphysis^{10,11}. Its microstructure is identical to that of the periosteal envelope. This envelope is also covered by a similar membrane as that described for the periosteal envelope called the endosteum.

Occupying the space between the periosteal and endosteal envelopes is the haversian envelope. As illustrated in figure 7, the structural unit of this envelope is the osteon^{10,11,18} which is about 200 μm in diameter and 10 to 20 mm in length^{10,11}. Osteons consist of concentrically arranged laminae, each having a thickness of 3 to 7 μm ^{10,11}. The interfaces between these laminae consist of an array of lacunae and a vascular net similar to that seen in lamellar bone. Each lamina consists of parallel collagen fibres wound into a helical geometry as shown in figure 8^{10,11,18}. The fibres in adjacent laminae are oriented roughly perpendicular to one another¹⁸. These collagen fibres are impregnated with mineral crystals at regularly spaced intervals along their length. At the centre of each osteon is the haversian canal which is occupied by a blood vessel.

Cortical bone is a composite material that consists of organic and inorganic components. The organic components include the cells and approximately 1/3 of the extracellular matrix^{10,11}. It is these organic

Figure 8: Microstructure of Osteon (from Cowin, 1989)

components, particularly collagen, that contribute to bone's tensile strength. The inorganic components include hydroxyapatite crystals primarily and inorganic mineral salts such as calcium phosphate, calcium hydroxide and calcium carbonate. They account for approximately 2/3 of the weight of cortical bone or about half its volume ¹⁸. It is these inorganic components that contribute to the hardness of bone and its strength in compression.

1.3.2 Mechanical Properties of Bone

Cortical bone is a heterogeneous, anisotropic, nonlinear viscoelastic material ^{10,11,18}. Its mechanical properties are dependent upon many biologic variables such as age, sex, pathologic state, and method of preservation of specimens prior to mechanical testing ^{11,18}. In order to simplify the modelling of cortical bone, the assumption has been made that cortical bone is an anisotropic linear elastic material. This assumption suffices in most situations involving physiologic strains and strain rates ^{10,11}, and the constitutive equation can be expressed as follows:

$$\sigma_i = c_{ij}\epsilon_j$$

where σ_i is the stress tensor, ϵ_j is the infinitesimal strain tensor, and c_{ij} is the elasticity tensor ¹¹.

A typical stress-strain curve for cortical bone under pseudostatic tension is shown in figure 9. However, figure 10 illustrates the dependence of cortical bone stress-strain response on strain rate. Figure 11 illustrates how the elastic modulus can vary at different locations on the same bone.

Figure 9: Typical Stress-Strain Response of Cortical Bone (from Cowin et. al., 1987)

This graph illustrates the typical stress-strain response of cortical bone loaded in tension at a strain rate of 0.01 s^{-1} .

Figure 10: Dependence of Stress-Strain Response on Strain Rate (from Cowin et. al., 1987)

Figure 11: Dependence of Elastic Modulus on Location (from Cowin, 1989)
 This graph shows the elastic modulus to vary at different locations around the circumference of the human tibia where P = posterior, PL = posterolateral, AL = anterolateral, A = anterior, AM = anteromedial, and PM = posteromedial.

The mechanical properties of bone are also dependent upon the mode and direction of loading. An average value for the elastic modulus of the human femur in tension is 18 GPa, and this is larger than the corresponding value in compression ¹⁸. However, the values for strain at failure, 1.85%, and ultimate strength, 170 MPa, in compression are larger than the corresponding values in tension of 1.41% and 124 MPa, respectively ¹⁸. Even larger differences are seen when comparing other modes of loading such as shear and torsion. The dependence of the response of cortical bone to the mode of loading is a function of its composite structure ¹⁸.

Creep and relaxation experiments conducted on cortical bone confirm that it is a viscoelastic material ^{10,11,18}. Figure 12 is an example of the creep behaviour of cortical bone under a constant stress (σ_p) of 60 MPa. It has also been demonstrated that creeping cortical bone recovers completely from the deformed state after removal of the load, and that this recovery is time-dependent ¹⁰. According to the theory of linear viscoelasticity, there should be no dependence of the relaxation function on the imposed strain during a creep test. However, cortical bone has been found to exhibit a mild dependence ¹¹. This is evidence of nonlinear viscoelastic behaviour.

1.3.3 Healing Mechanism of Bone

The natural healing mechanism of fractured long bones occurs in two phases: the phase of union, and the remodelling phase. Subsequent to a fracture, areas of dead bone develop at the fragment ends in response to the

Figure 12: Typical Creep Response of Cortical Bone (from Cowin, 1989)

interrupted local blood supply ³¹. This makes direct union at the fragment ends impossible at this early stage. Therefore, the phase of union is initiated by the response of the periosteal envelope to generate an anchoring callus on either side of the fracture ⁵¹ which is eventually joined by a bridging callus ^{31,51}. This callus is composed of woven bone that is laid down in a rather tangled manner. The purpose of this callus is to bridge the fracture gap and immobilize the fragments. As this periosteal callus formation proceeds, the endosteal envelope also contributes to the healing process by generating a similar callus that may bridge the fracture gap or seal off the medullary canal ⁵¹. It is generally believed that a small amount of motion between the two fragments is required to stimulate callus formation ^{31,51}, and that a direct relationship exists between the magnitude of this motion and the quantity of callus generated ³¹.

The remodelling phase begins once the fragments ends have been sufficiently approximated and immobilized by the callus generated during the phase of union ^{31,51}. Cells called osteoclasts tunnel through the zone of dead bone at the fracture site along a path parallel to the longitudinal axis of the bone. These tunnels are soon occupied with a blood vessel. Cells called osteoblasts line the walls of the tunnels with new bone to complete the formation of a new haversian system. This remodelling proceeds until the fracture site is completely replaced with new bone and healing is complete.

However, the process of remodelling is not restricted to fracture healing. As illustrated in figure 13, normal healthy bone is in a constant state of

Figure 13: Remodelling of Cortical Bone (from Fung, 1993)

This drawing of a cross section of cortical bone illustrates osteoclastic resorption of bone and osteoblastic apposition of bone.

remodelling as osteoclasts remove old bone and osteoblasts lay down new bone ¹⁸. It is this mechanism of remodelling that gives bone its ability to adapt to its mechanical environment. Julius Wolff ⁵⁴ was the first to advance this concept of functional adaptation in 1874, and it has since become known as Wolff's law. Subsequent experiments involving long term immobilization of load bearing limbs and resulting in bone mineral loss, osteoporosis (loss of bone mass as pores through the cortical thickness), and cortical thinning have confirmed Wolff's law ¹⁸. Therefore, form follows function whereby osteoclastic activity removes old bone (resorption) from regions with a low stress state while osteoblastic activity deposits new bone (apposition) in regions with a high stress state. The resulting bone structure is very complex but highly optimized.

1.4 Benefits and Problems Associated with Rigid Internal Fixation Plates

The modern standard for internal fixation of bone fractures with plates is the DCP. Introduced in 1969 by Perren et. al. ³⁸ from the Laboratory for Experimental Surgery, Swiss Research Institute at Davos, DCP's are currently manufactured and sold worldwide by a multitude of orthopaedic companies. Generally, this method of treating bone fractures has enjoyed a high degree of success ^{55,57}. The benefits of dynamic compression plating over conservative treatment of fractures (ie. plaster casts) include superior realignment of bone fragments, reduced hospital stay, early mobilization of surrounding joints, and the absence of a cumbersome and uncomfortable external support. This means

that the patient can resume normal activities sooner and avoid lengthy rehabilitation of stiff joints and atrophied soft tissue.

However, the initial surgical intervention required to implant DCP's continues to be a disadvantage of this treatment, and it is unlikely that avoiding such surgery will ever be possible. A second surgical procedure is also required to remove the plate after the fracture has healed, because plates and screws interfere with the normal physiology of bone ^{21,33,49}. Uthoff and Finnegan ⁵⁰ recommended that DCP's be removed as soon as the fracture is united.

Several other disadvantages are consequences of the mode of fracture healing under the rigid internal fixation generated by DCP's. During the phase of union, rigid fixation suppresses the osteogenic potential of the periosteal envelope. Hence, no external callus develops ^{17,48,50,51,55}. Indeed, this was the result intended by the designers of the DCP ³⁸, because it was believed that the presence of external callus was a sign of instability that would lead to resorption of the fragment ends ³⁶. However, it is common practice to monitor the growth and subsidence of the external callus in a conservatively managed fracture to decide when healing has progressed sufficiently to remove a plaster cast. Radiography is used to monitor the callus, so this decision is somewhat subjective. Unfortunately, the absence of an external callus under rigid fixation makes radiographic assessment of fracture healing impossible ^{17,48,50,51,55}. Despite the qualitative nature of radiography, this eliminates the most effective means available to physicians for assessing the progress of fracture healing.

Rigid fixation also delays the process of union since healing must rely on the activity of the haversian envelope for direct bone growth across the fracture site ^{17,51,65}. In the absence of radiographic information, Müller et. al. ⁵⁰ recommended plate removal after 18 to 24 months of implantation which is far longer than the time required for healing under conservative fracture management. According to Uthoff and Dubuc ⁴⁹, osteotomized canine femora continued to show histologic evidence of small, local gaps in the fracture site after 24 weeks of healing under rigid plates.

The disadvantage of rigid internal fixation that has received the most attention in the literature is osteoporosis and thinning of the cortex (cortical bone) beneath the plate. Even if it is assumed that perfect healing of the fracture is achieved under rigid fixation, osteoporosis and cortical thinning render the bone weaker than it was prior to being fractured. Two processes have been identified in the literature as potential causes for osteoporosis and cortical thinning: shielding of bone from stress by rigid plates, and interference of plates with the cortical blood supply.

The phrase *stress shielding* has come into common use in the literature to describe the effect of rigid plates on the state of stress in bone. A transfer of stress to the rigid plate causes a reduction in the state of stress to below normal physiological levels in the underlying bone. According to Wolff's law ⁵⁴, bone reacts to the reduced state of stress by eliminating unneeded material through a remodelling process whereby osteoclastic activity surpasses

osteoblastic activity. Stress shielding and the consequent remodelling leading to osteoporosis and cortical thinning has been well documented in animal studies ^{2,3,9,17,24,26,28,39,45,48,49,51,52,55-57}. The results of a finite element model of a rigidly plated intact bone reported by Woo et. al. ⁵⁷ also supported the concept of stress shielding.

In addition to stress shielding, it has also been suggested that osteoporosis is caused by the interference of plates with the cortical blood supply. Lack of blood leads to bone death. Osteoclastic activity removes the dead bone which results in osteoporosis. Gunst ¹⁹ measured decreased blood flow under rigid plates by local injection of dye into the cortical blood supply. Later, Jacobs et. al. ²³ conducted a similar experiment that supported Gunst's findings. Later still, Smith et. al. ⁴³ measured a small reduction in blood flow caused by the presence of plates. However, he also suggested that the techniques employed by Gunst and Jacobs et. al. measured interstitial fluid flow in the cortical bone and not actual blood flow.

Tepic et. al. ⁴⁶ claimed that interference of plates with cortical blood supply creates zones of dead bone that cannot contribute to the healing process thus slowing it down. Unfortunately, no data were ever presented to substantiate this claim. Perren et. al. ³⁷ claimed that interference with blood supply can cause zones of dead bone, disturbed bone healing, and the spread of infection. He also claimed that interference with blood supply was responsible for osteoporosis under DCP's early in the healing process ³⁶.

However, he did not elaborate on the consequences of this early osteoporosis and no data were presented to support his claims. Apparently, the effect of the plate is temporary as the blood supply under the plate recovers completely in time ³⁶. Gunst ¹⁹ measured such a recovery within 4 weeks of plating.

Delayed union, osteoporosis and cortical thinning have been identified as causes of refracture after plate removal ^{13,22,49}. This is a serious disadvantage of treating fractures with the rigid internal fixation plates in common use today. The incidence of refracture has been reported to be as high as 20% ⁴⁰. Ironically, the general trend has been to solve this problem by making plates more rigid ^{55,56}. However, many alternatives to rigid internal fixation plates have been reported in the literature as solutions to the problems of delayed union, osteoporosis and cortical thinning.

1.5 Alternatives to Rigid Internal Fixation Plates

Suggestions in the literature for solving the problem of osteoporosis and cortical thinning under rigid plates fall into two groups: those that advocate reducing the contact area at the plate/bone interface, and those that advocate reducing the rigidity of plates.

1.5.1 Reduction of Contact Area at the Plate/Bone Interface

Reducing the contact area at the plate/bone interface was intended to minimize the interference of plates with the cortical blood supply. This concept was first put into practice with the introduction of the Limited Contact Dynamic

Compression Plate (LC-DCP) by Perren et. al. ³⁷ in 1990. Portions of the plate's undersurface were cut away to decrease contact with the bone. Swiontkowski et. al. ⁴⁴ measured greater cortical blood flow under LC-DCP's than under DCP's, but there was no significant difference in the osteoporosis observed under both plate types.

In 1992, Tepic et. al. ⁴⁶ reported on the Point Contact Plate (PCP) that made minimal point contact with bone. Destructive four-point bending tests of sheep tibiae showed that stronger healing was obtained with PCP's compared to DCP's, but no data were reported on the relative rigidities of the two plates. In the same year, Kregor et. al. ²⁷ compared the effect of LC-DCP's and PCP's on cortical blood supply. After 12 weeks there was no difference in cortical perfusion (penetration of blood vessels into cortical bone) between the two plates.

Uhthoff et. al. ⁵² reported on a comparison between two types of rigid plates in 1993. Both plate types had identical mechanical properties but different contact surfaces: a radiused full contact surface, and longitudinal rails for reduced contact. A higher degree of cortical thinning was observed under the full contact plate, but no significant difference in flexural rigidity was observed between the bones plated with the full contact plates and the bones plated with the railed plates. It was concluded that osteoporosis and cortical thinning were consequences of two processes: interference of the plate with cortical blood supply, and stress shielding. However, interference of the plate

with cortical blood supply was found to be temporary, whereas stress shielding prevailed over the long-term and was found to be the dominant factor.

In 1991, Nunamaker et. al. ³⁶ reported plating bones with a technique called luting. Plate luting involved interposing a layer of polymethylmethacrylate between the bone and the undersurface of DCP's to provide complete contact at the plate/bone interface. The intention of this plate luting was to prevent loosening of plates as a consequence of cyclic loading *in vivo*. However, there was no significant difference in osteoporosis of intact bones plated with the luting technique compared to intact bones plated in the standard manner.

From the contradictory reports in the literature it is difficult to decide whether or not plates interfere with the cortical blood supply. Even if it is assumed that plates do interfere with the cortical blood supply, the reports in the literature do not explain how strongly this problem contributes to osteoporosis, cortical thinning or the risk of refracture.

1.5.2 Reduction of Internal Fixation Plate Rigidity

Reducing the rigidity of internal fracture fixation plates was intended to minimize stress shielding. This has been achieved by changes in plate material, changes in plate dimension, or both. Titanium alloy (Ti-6Al-4V) has been used as an alternative material to stainless steel. In 1981, Uhthoff et. al. ⁴⁸ used radiologic and histologic techniques to assess the healing of osteotomized canine femora plated with stainless steel and titanium alloy DCP's having identical dimensions. The elastic modulus of the stainless steel was 200 GPa

while that of the titanium alloy was 110 GPa. Therefore, the titanium plates were less rigid than the steel plates. After 24 weeks of implantation the titanium plates showed radiologic evidence of callus formation. Also, the steel plates induced more cortical thinning than the titanium plates. This report was followed up by a similar longer term study ⁵⁰. After 60 weeks of implantation, both plates induced cortical thinning, but significantly more cortical thinning was observed under the steel plates than under the titanium plates. Upon removing both plate types after 8 weeks, all osteotomized bones remodelled and eventually regained their normal structure and mass.

Foux et. al. ¹⁷ reported a biomechanical evaluation of the healing of osteotomized canine femora treated with three different plate types in 1993. The plate types were stainless steel DCP's being the most rigid, titanium alloy DCP's, and 1/3 tubular stainless steel noncompression plates being the least rigid. The 1/3 tubular stainless steel plates had a cross-section corresponding to 1/3 of the circumference of a tube. After 24 weeks of implantation, there was no significant difference amongst the flexural rigidities of bones plated with the three plate types. This was attributed to the flexural rigidities of the plates which were believed to be too low to provide sufficient fracture stabilization.

In 1994, Sei et. al. ⁴¹ reported results of implanting three types of noncompression titanium plates on osteotomized rabbit tibiae. All three plates were identical except in their thickness, the thickest plate being the most rigid and the thinnest plate being the least rigid. After 24 weeks of implantation, the

two thinner plates induced significantly less cortical thinning than the thickest plate. Also, under destructive three-point bending the maximum energy stored in bones treated with the thinnest plate was significantly higher than the maximum energy stored in bones treated with the thickest plate.

Fine graphite fibre reinforced methylmethacrylate (GFMM) resin composite plates were reported by Akeson et. al. in 1975 ², again in 1976 ³, and also by Woo et. al. in 1977 ⁵⁷. The first report by Akeson et. al. discussed treating osteotomized canine femora with stainless steel noncompression plates and less rigid GFMM noncompression plates, both with identical dimensions. After 4 months of implantation, biomechanical testing to destruction indicated that there was no significant difference between the strength of bones treated with steel plates and bones treated with GFMM plates. However, significantly more osteoporosis was induced in the bones treated with steel plates than those treated with GFMM plates.

The two subsequent reports on the use of GFMM plates were conducted on intact canine femora, so healing was not a factor. Both reports concluded that plates shield bone from stress and that this causes a remodelling process leading to cortical thinning beneath the plate. This stress shielding effect was more pronounced under rigid stainless steel plates, because cortical thinning was observed to be greater than under the GFMM plates and bone structural properties were observed to be lower than under the GFMM plates. However, there was no difference found between the material properties of bones treated

with the steel plates and those treated with the GFMM plates.

In 1979, Bradley et. al. ⁸ reported on results of treating osteotomized canine femora with noncompression plates made from three different materials: stainless steel, a graphite-polysulfone composite, and a glass-epoxy composite. By varying the dimensions of the plates and adjusting the lamination patterns of the composite material, a wide range of flexural rigidities was achieved for these plates. Bending tests to destruction indicated an inverse relationship between the structural properties of the bones and plate rigidity. Such a relationship was also observed between the material properties of the bones and plate rigidity.

Carbon fibre reinforced carbon composite plates were used by Claes ⁹ and the results of this investigation were reported in 1989. The effect of these plates on intact canine femora were compared with stainless steel plates having the same dimensions. Greater osteoporosis and cortical thinning was observed in the bones plated with the more rigid stainless steel plates. Also, the mechanical properties of the bones plated with the stainless steel plates were found to be inferior to those plated with the carbon fibre reinforced carbon composite plates.

Forty human forearm fractures were treated with carbon fibre reinforced epoxy resin composite plates in a clinical study reported by Ali et. al. in 1990 ⁴. In 20% of the patients there was no radiologic evidence of external callus development, and in 5 cases there was an unexplained tissue reaction to

the plates. However, all fractures united and there were no refractures or mechanical failures of the plates.

Plates made from fibre reinforced composite materials are rarely used in clinical practice today and few reports of their clinical use exist in the literature ⁴¹. It has been suggested that fibre reinforced composites have not become popular as plate materials for the following reasons: control of plate dimensions is difficult during manufacturing; mechanical properties of the material vary considerably even if plate dimensions can be controlled; mechanical properties of the material can change *in vivo* as a result of dissolution, hydrolysis and oxidation; and plates made from such material cannot be bent to conform to the shape of bones ⁴¹.

In 1987, Jasmine et. al. ²⁴ reported *in vitro* cyclic compression testing of intact canine femora plated with a low density polyethylene underplate interposed between DCP's and bone. It was expected that such an underplate would cause loosening of the plate under the cyclic loading. This plating configuration was compared against DCP's without underplates mounted on intact canine femora and loaded in a similar manner. After 100,000 cycles, the assemblies with underplates were found to be significantly looser than the assemblies without underplates. It was reasoned that such loosening would reduce the effect of stress shielding *in vivo*.

Silicon was the material used for an underplate in a report by Korvick et. al. ²⁶ in the same year. Standard DCP's were mounted on an instrumented

aluminum tube with and without the underplate. Results of four-point bending tests indicated that there was no difference in the stress shielding effect of the two configurations. However, the area of contact between the DCP and the tube was greater with the underplate, and contact pressure between the DCP and the tube was lower with the underplate. After 27 weeks of implantation, DCP's with the underplate induced less osteoporosis in intact canine femora than DCP's without underplates.

It appears quite clear that reducing the rigidity of internal fracture fixation plates helps reduce the effect of stress shielding. However, changing the material a plate is made from or altering its dimensions affects the structural properties of the plate in all planes of loading. The mechanics at the plate/bone interface are complex, and the effect of interposing a polymeric underplate at this interface has not been fully characterized. Therefore, it is unclear exactly how the rigidity of a plate should be reduced to achieve the most effective healing of fractured bones and minimize remodelling activity that leads to osteoporosis and cortical thinning.

Several authors have expressed the opinion that the axial rigidity of plates is the dominant factor associated with stress shielding of plated bones. In 1979, Bradley et. al.⁸ claimed that mathematical modelling of a plated bone indicated the strain at the fracture site was unaffected by the flexural rigidity of the plate while being greatly influenced by the axial rigidity of the plate. It was recommended that further research be pursued with plates having reduced

axial rigidity.

Woo et. al. ⁵⁶ reasoned in 1983 that immediately after plating of a fractured bone the neutral axis of the plate/bone assembly is located along the plate, and the plate is the only structure resisting bending and torsional loads. Later as healing progresses and the fracture gap is closed with bone, the neutral axis shifts toward the bone and the plate resists axial loads primarily. Therefore, it was suggested that a plate with moderate bending and torsional rigidities would provide the stability required during the phase of union while the same plate having reduced axial rigidity would minimize stress shielding during the remodelling phase. It was also claimed that the results of a finite element analysis isolated axial rigidity as the dominant factor affecting stress shielding ⁵⁵.

Both Claes ⁹ in 1989 and Foux et. al. ¹⁷ in 1993 reported that they agreed with the reasoning of Woo et. al. ⁵⁶. Claes suggested that plates made from carbon fibre reinforced carbon composite material could be designed with sufficiently high flexural and torsional rigidities to provide stable fixation and sufficiently low axial rigidity to minimize stress shielding. Foux et. al. postulated that a direct relationship exists between the mechanical status of healing and the flexural rigidity of plates, while an inverse relationship exists between the mechanical status of healing and the axial rigidity of plates.

There was strong agreement in the literature that axial rigidity is the dominant factor affecting stress shielding and that plates with reduced axial

rigidity would improve fracture healing. However, this hypothesis has never been investigated with a plate having selectively reduced axial rigidity. The design of such a plate is the subject of chapter 2.

CHAPTER 2: DESIGN OF THE AXIALLY COMPRESSIBLE PLATES

2.1 Definition of the Problem

Two opposing criteria must be satisfied for effective healing of a fractured bone treated with an internal fracture fixation plate. First, the bone fragments must be reassembled and held together^{8,51,55,57}. This demands that the plating system provide rigid fixation. Second, stress shielding of the fractured bone must be avoided to stimulate healing and allow the bone to return to its original shape, size, and strength in accordance with Wolff's law^{8,51,55,57}. This requires a plating system of reduced rigidity.

It has been suggested in the literature that the degree of *axial* rigidity is the most important factor influencing the healing of plated bone fractures^{8,9,17,55,56}. However, data generated with plates having selectively reduced axial rigidity do not appear to have been reported in the available literature. Therefore, the hypothesis that fracture healing is improved with plates having reduced axial rigidity has never been tested. In order to test this hypothesis it was necessary to solve the problem of simultaneously satisfying the two opposing criteria for effective fracture healing in a single plate design that selectively reduced the axial rigidity while maintaining high flexural and torsional rigidity.

2.2 Proposed Solution

The purpose of this work was to determine the effect of plates with selectively reduced axial stiffness on the healing of osteotomized femora to test the hypothesis that fracture healing is improved with such plates. Beagle dogs were chosen as the animal model, and axially compressible plates (ACP's) to fit beagle femora were designed for this investigation. They consisted of three components: stainless steel plates, polymer inserts, and stainless steel screws. The ACP's addressed both opposing criteria for effective healing with plates: high flexural and torsional stiffness for fracture stabilization, and reduced axial stiffness to control stress shielding. Foux¹⁵ is credited with the concept of the ACP which is documented in a United States Patent.

The optimal axial stiffness for an internal fracture fixation plate was not known. Therefore, the ACP's were manufactured to provide a range of axial stiffnesses. It was hypothesized that optimal fracture healing would be observed with plates near the centre of this range.

An important fact was that the terms *rigidity* and *stiffness* were often given the same meaning in the literature. For example, the phrase *axial rigidity* was commonly used with reference to internal fixation plates when the phrase *axial stiffness* would have been technically correct. Therefore, the *axial stiffness* of plates in this work referred to the phrase *axial rigidity* in the literature.

2.3 Design of the Plates

Three plate types were designed and manufactured from 316 LVM implant grade stainless steel. These plates are illustrated in figure 14. Engineering drawings of these plates are assembled in appendix A.1. All three plate types had six holes through their thickness. The plates differed only by the shape of these holes. Plate type A had spherically counterbored 3.5 mm diameter round holes. The distance between the centres of the two inner holes was 14 mm. The remaining holes were equally spaced by 8 mm.

Plate type B had square-shouldered slots, each slot being radiused at both ends. The distance between the centres of the two radii in each slot was 0.75 mm. Each slot was oriented such that its longitudinal axis coincided with the longitudinal axis of the plate. The width of the slots was selected for a snug fit with the shank of a bone screw having a major diameter of 3.5 mm. Plate type C had similar square-shouldered slots, but the distance between the centres of the two radii in each slot was 1.50 mm. Distances between slots were measured from the centres of the radii furthest from the midsection of the plate. The two inner slots were 14 mm apart in both slotted plate types. The remaining slots were equally spaced by 8 mm. Therefore, the spacing of the slots in plate types B and C was identical to the spacing of the round holes in plate type A.

All three plate types were 56 mm long and 9.5 mm wide. The bottom surface of all plates was contoured to approximate the radius of the canine

Figure 14: Three Plate Types

The three plate types used for the axially compressible plates are shown in this photograph, from top to bottom: plate type A with spherically countersunk round holes, plate type B with 0.75 mm slots, and plate type C with 1.50 mm slots.

femora. All cross-sections without screw holes had an area of 48.2 mm^2 , a flexural rigidity about a tangential centroidal axis of 17.3 Nm^2 , a flexural rigidity about a radial centroidal axis of 177.2 Nm^2 , and a torsional rigidity of 74.6 Nm^2 .

Assuming the canine femora could be modelled as uniform hollow cylinders with an outer radius of 4.7 mm and an inner radius of 2.7 mm, the structural properties of the bones were compared to those of the plates listed above. The cross-sectional area of the femora was 46.5 mm^2 with a moment of inertia of $3.42 \times 10^{-10} \text{ m}^4$ and a polar moment of inertia of $6.83 \times 10^{-10} \text{ m}^4$. The moduli of elasticity and rigidity for canine femora have been reported to be 20.10 GPa and 4.68 GPa, respectively ¹¹. Therefore, the flexural rigidity of the femora about a tangential centroidal axis was 6.86 Nm^2 which was 2.52 times smaller than the corresponding value for the plates, and the torsional rigidity of the femora was 3.20 Nm^2 which was 23.31 times smaller than the corresponding value for the plates. This comparison showed that the plates were considerably more rigid in bending and torsion than the femora.

2.4 Design of the Inserts

Inserts were designed in two sizes to fit snugly into the slots of plate types B and C. As illustrated in figure 15, these inserts took the form of a long, flat washer with three crescent shaped cushions protruding from the bottom surface. The inserts were manufactured by numerically controlled milling. Insert

Figure 15: Insert

This photograph shows an example of an insert for the axially compressible plates. Three crescent shaped cushions protrude downward from the long washer on top.

size was determined by the thickness of the cushions, and compressibility was directly related to cushion thickness. A round screw hole through the washer was positioned directly adjacent to each cushion. Engineering drawings of the inserts are assembled in appendix A.2.

The inserts were made of two polymer materials: low density polyethylene (LDPE) and polymethylmethacrylate (PMMA) which is commonly known as plexiglass. These materials were chosen for their proven biocompatibility and for the difference in their compressibility. The elastic modulus of the LDPE was approximately 0.20 GPa while that of the PMMA was approximately 3.10 GPa.

Three insert types were selected from the four possible combinations of insert size and material to provide a range of axial stiffnesses. Insert type I was made from PMMA and fit into plate type B. Insert type II was made from PMMA and fit into plate type C. Insert type III was made from LDPE and fit into plate type C.

2.5 Design of the Screws

Standard 3.5 mm cortical bone screws with hexagon socket spherical heads¹ were purchased for use with plate type A. These screws, shown in figure 16, were made from 316 LVM implant grade stainless steel. Thread lengths of 14 mm, 16 mm, 18 mm, and 20 mm were selected to accommodate

¹ Synthes (Canada) Ltd., Mississauga, Ontario

Figure 16: Standard Cortical Bone Screws

This photograph shows an example of the standard cortical bone screws used in orthopaedic surgery. Note the special thread profile and the spherical shape of the undersurface of the head.

bones of various diameters.

Custom cortical bone screws were designed for plate types B and C, and they were also made from 316 LVM implant grade stainless steel. Their thread specifications were identical to those of the standard 3.5 mm cortical bone screws. However, as seen in figure 17, these custom screws were manufactured with cross slotted flat heads and a 3.30 mm length of unthreaded shank immediately beneath the heads. The unthreaded shank was intended to bear against the cushions protruding from the inserts.

2.6 Assembly and Function of the Axially Compressible Plates

As shown in figure 18, the inserts fit into plate types B and C such that the washer rested flat along the top surface of the plate with the cushions snugly in the slots. Two inserts were required for each plate. Care was taken to ensure that the cushions of each insert were positioned at the ends closest to the midsection of the plate in each slot. In this manner, a round screw hole remained empty in each slot at the end furthest from the midsection of the plate.

Upon insertion of a bone screw through a plate, the washer served to reduce friction between the bottom surface of the flat head and the top surface of the plate. Within each screw hole, half of the unthreaded shank was surrounded by the metallic walls of the slot, and the remaining half bore against the compressible cushion. Therefore, motion of the screws was confined to the

Figure 17: Flat Head Cortical Bone Screws

This photograph shows an example of the custom flat head cortical bone screws used with the axially compressible plates. Note the unthreaded shank immediately below the head that is intended to bear against the cushions of the inserts.

Figure 18: Assembly of the ACF

This photograph shows an exploded view of the plates, inserts, and screws of an axially compressible plate that illustrates how they are assembled and fastened to a femur. When implanted, the cushions of the inserts fit completely into the slots in the plate, and the screws are threaded down such that the heads make contact with the top surface of the plate.

longitudinal axis of the plate toward its midsection.

A total of four ACP's were selected from the five possible combinations of plate type and insert type. Plate type A which did not employ inserts served as the stiffest ACP and was referred to as ACP #1. The remaining three ACP's employed inserts and were selected by decreasing axial stiffness (ie. increasing axial compressibility). Plate type B and insert type I combined for ACP #2. Plate type C and insert type II combined for ACP #3. Finally, plate type C and insert type III combined for ACP #4.

The standard of rigid internal fixation with plates in modern orthopaedic surgery is the DCP. However, DCP's were not included in this investigation. Instead, a noncompression plate (ACP #1) was selected to provide the most rigid fixation. This decision was made in an effort to limit variables in the experiments. The three other ACP's were not designed to induce self-compression of the fragments, nor were they intended to sustain compression applied to the fragments by an external device during the implantation procedure. Therefore, it was decided that the effect of self-compression should not be superimposed on the results of one plate out of four.

Selective reduction of axial stiffness was the primary design criterion for the ACP's. The intent of the design described above was to satisfy this criterion. However, it was necessary to verify this experimentally. Mechanical verification testing of the ACP is discussed in chapter 3.

CHAPTER 3: VERIFICATION TESTING OF THE AXIALLY COMPRESSIBLE PLATES

3.1 Measurement of Axial Stiffnesses

The axial stiffness of the four ACP types was also termed *axial compressibility*, hence *axially compressible plates*. This phrase was chosen because it described the function of the polymer inserts: to serve as compressible cushions that reduced the axial stiffness of the stainless steel plates. Nominal axial stiffnesses of the four ACP types were measured experimentally under nondestructive tensile load to verify that a range of axial stiffnesses had been achieved with the design of the ACP's.

An ACP was mounted between two fixtures made from cold rolled steel round stock. These fixtures were then fastened to the upper and lower crossheads of an Instron model TM tabletop materials testing machine as shown in figure 19. Drawings of this apparatus are assembled in appendix A.3.

The perpendicular distance between the inner surfaces of the two parallel arms extending from one end of each fixture was selected to accommodate the thickness of an ACP and two spacers. Two sets of spacers were prepared for the tests: one set for ACP #1 and another set for ACP's #2, #3 and #4 to account for the washer portion of the inserts. The function of the spacers was to position the plates within the arms such that the longitudinal axis of the fixtures coincided with the centroidal axis of the plate. A small tolerance of

Figure 19: Testing of ACP in Tension

This photograph shows the axially compressible plate mounted between two fixtures and tested in tension. Spacers that position the plate properly within each fixture are visible. In the background a linear variable differential transformer (LVDT) fastened across the gap between the two fixtures measures the elongation of the plate.

0.15 mm maximum existed between the spacers and the inner surfaces of the arms to minimize friction.

There were three holes through both arms on each fixture. These holes were spaced according to the spacing of the holes and slots in the ACP's. Six smooth pins with a diameter equal to the diameter of the unthreaded shanks of the flat head screws were inserted through these holes and through the holes/slots in the ACP's to hold the ACP's in the fixtures. Within the slots of ACP's #2, #3 and #4 the inserts were oriented such that the cushions occupied the ends of the slots furthest from the midsection of the plate. This orientation of the inserts was exactly the opposite of what was required for implantation. However, such an orientation was necessary for the inserts to be compressed by the pins under the tensile load applied to each ACP.

During each test the load was measured by an Instron CT tensile load cell mounted on the upper crosshead of the Instron machine. Elongation was measured with a linear variable differential transformer (LVDT) mounted across the gap between the two fixtures. Since the longitudinal axis of the fixtures coincided with the line of action of the load, the spacers ensured that the line of action of the load coincided with the centroidal axis of the plate to prevent eccentric loading of the plate during a tensile test.

These tensile tests resulted in compressive deformation of the inserts that simulated an actual plated bone assembly subjected to a compressive force. However, there was a difference in the friction forces between the *in*

vitro and *in vivo* cases. Despite the moist surroundings and the design considerations intended to reduce friction at plate interfaces, some friction may occur *in vivo*. This was not accounted for in the design of the tensile test system due to lack of information on the friction parameters *in situ*. Therefore, the measured values of axial stiffness for the ACP's were considered nominal values.

Initially, ACP's #2, #3 and #4 were subjected to a series of pseudostatic load cycles to a maximum of 500 N that were intended to precondition the polymer inserts. A constant crosshead speed of 0.5 mm/min was used during the loading and unloading portions of the cycle. Fifteen to twenty load cycles were required for preconditioning. As ACP #1 did not employ inserts preconditioning was not necessary. Subsequent to preconditioning, each ACP type was subjected to 10 separate pseudostatic tensile tests at a constant crosshead speed of 0.5 mm/min to a maximum load of 500 N. Axial stiffness (k) was calculated as the slope of the load/elongation curve generated from each tensile test. A mean value of axial stiffness was calculated for each ACP type and listed in table 1.

The axial stiffness data were analyzed statistically. The minimum sample size was ten and a p value (the probability of incorrectly rejecting the null hypothesis) less than or equal to 0.05 was considered significant. One-way analysis of variance indicated that the data had 3 degrees of freedom and a residual of 36. A large value of 331.97 corresponding to a p value of zero was

ACP #	SLOT LENGTH (mm)	INSERT MATERIAL	AXIAL STIFFNESS ($\times 10^6$ N/m)	BENDING STIFFNESS ($\times 10^5$ N/m)
1	0.00	-	13.91	77.72
2	0.75	PMMA	8.39	74.82
3	1.50	PMMA	4.26	75.59
4	1.50	LDPE	1.64	77.95

Table 1: ACP Axial Stiffness and Bending Stiffness

Values of axial stiffness and bending stiffness for the four axially compressible plates are listed in this table. The insert materials were polymethylmethacrylate (PMMA) and low density polyethylene (LDPE).

calculated for the F-test statistic. The results of the one-way analysis of variance were summarized as follows: $\{F(3,36) = 381.97, p = 0.000\}$. Therefore, significant differences existed amongst the four ACP types on the basis of axial stiffness. Further analysis with the Student-Newman Keuls test for pair-wise post hoc comparison indicated that each ACP type was significantly different than the other three on the basis of axial stiffness. Therefore, ACP #1 was significantly stiffer than ACP #2, ACP #2 was significantly stiffer than ACP #3, and ACP #3 was significantly stiffer than ACP #4.

3.2 Measurement of Bending Stiffnesses

The bending stiffnesses of the four ACP types were measured experimentally under nondestructive four-point bending. Each ACP was fastened to a steel "bone" with the appropriate bone screws. This assembly was then positioned on a frame for fixation of the steel "bone" ends in two coaxial cups as shown in figure 20. The centre section of the plate was aligned with the centre of the potting frame, and the top surface of the plate was facing exactly upward. Bismuth alloy was used to embed the steel "bone" ends in the cups. This procedure was referred to as "potting". Please refer to section 4.3 for details of the potting procedure, the bismuth alloy, and the four-point bending apparatus.

After proper fixation in the cups, the entire assembly of cups, plate and

Figure 20: ACP Positioned in Potting Frame

This photograph shows an axially compressible plate positioned in the potting frame with the steel "bone" ends potted with Bismuth alloy in the cups in preparation for bending testing.

steel "bone" was positioned on a base that rested on an Instron CCT compression load cell in the Instron machine. Internal fracture fixation plates are fastened to the tension side of fractured bones. Therefore, the cups were rotated to the 180° position such that the top surface of the plate faced exactly downward. Load was applied at four loading points on extensions of the cups through a loading frame fastened above to the moving crosshead of the Instron machine. Deflection of the assembly was measured by a LVDT positioned directly under the midsection of the plate. Testing of the ACP's in bending is illustrated in figure 21.

Initially, ACP's #2, #3 and #4 were subjected to a series of pseudostatic load cycles to a maximum of 500 N that were intended to precondition the polymer inserts. A constant crosshead speed of 0.5 mm/min was used during the loading and unloading portions of the cycle. Ten to twelve load cycles were required for preconditioning. As ACP #1 did not employ inserts preconditioning was not necessary. Subsequent to preconditioning, each ACP type was subjected to 10 separate pseudostatic bending tests at a constant crosshead speed of 0.5 mm/min to a maximum load of 500 N. Bending stiffness was calculated as the slope of the load/elongation curve generated from each bending test. A mean value of bending stiffness was calculated for each ACP type and listed in table 1.

The bending stiffness data were analyzed statistically. The minimum sample size was ten and a *p* value less than or equal to 0.05 was considered

Figure 21: Testing of ACP in Bending

This photograph shows an axially compressible plate positioned in the testing machine and subjected to bending. The plate has been rotated to the tension side of the steel "bone" such that the plate is facing downward. Weights are seen hanging off the left and right ends of the bending apparatus to counterbalance the weight of the cups and Bismuth alloy.

significant. One-way analysis of variance indicated that no significant differences existed between the four ACP types on the basis of bending stiffness $\{F(3,36) = 0.92, p = 0.440\}$. Consequently, further analysis was not necessary. Therefore, bending stiffness of the ACP's was eliminated from the experiments as a variable.

3.3 Comparison of Torsional Stiffnesses

All four plate types had identical cross-sections and were made from the same material, so the torsional stiffnesses of all four plate types were equal. In section 2.3 it was stated that the torsional rigidity of the plates was 23.31 times greater than the torsional rigidity of the canine femora. Also, all four ACP's were assembled such that any torsion applied to the healing femur was resisted via metal on metal contact between the plate and the screws. It was reasoned that any differences amongst the torsional stiffnesses of the ACP's were negligible relative to the large difference between the torsional rigidities of the plates and femora. Therefore, torsional stiffness of the ACP's was eliminated from the experiments as a variable. The comparisons of the bending and torsional stiffnesses indicate that selective reduction of axial stiffness was achieved with the design of the ACP's.

Based on this finding, the decision was made to proceed with experiments where the ACP's would be used to treat bone fractures. These experiments are the subject of chapter 4.

CHAPTER 4: EXPERIMENTAL DESIGN, BIOMECHANICAL TESTING, AND DATA ANALYSIS

4.1 Selection of Animals and Time Periods for Implantation

Dogs were selected for the animal study because their bone structure is haversian like that of humans. See appendix A.5 for the ethical acceptance of this animal study by the Animal Care Committee. A total of seventy-two mature beagles being under two years of age and having an average weight of 11.3 kg (± 1.2 kg) were used in the experiments. These animals were randomly divided into twelve groups of six according to ACP type and implantation period. Three implantation periods were selected to monitor the progress of healing with time: 8 weeks, 16 weeks, and 24 weeks. Therefore, each ACP was implanted in six dogs for each of the three implantation periods as illustrated in figure 22. The 8 and 24 week periods corresponded to the ends of the phase of union and remodelling phase, respectively ⁴⁹. The 16 week period was selected as an interim point in time to observe the progress of healing.

4.2 Surgical Procedure

After prepping, draping and under general endotracheal anesthesia with pentothal-halothane, a lateral incision was made in the skin and the femur approached between the vastus lateralis and biceps muscles. After judicious local stripping of the periosteum, a drill guide was clamped to the anterolateral

Figure 22: Experimental Design

An organization chart of the experimental design is displayed to show the numbers and groupings of animals according to implantation period and axially compressible plate type.

surface of the femur. This drill guide, a photograph of which is shown in figure 23, was designed to ensure that all six holes were drilled parallel to one another and normal to the anterolateral surface of the femur. The holes were drilled through both cortices (all the way through the bone). After drilling all six holes, the drill guide was removed, the holes were tapped with a manual bone tap, and a transverse osteotomy (surgical cut through bone) was performed at the midplate position with an oscillating saw. The drill guide was also designed to compensate for the 0.4 mm thickness of bone removed by the saw blade. This allowed both fragments to be brought into good contact upon fastening the plate to the bone. Compression was not applied to the bone fragments during surgery. The femora were quite straight along the anterolateral aspect, so the plates were not bent to conform to the shape of the bones. All six bone screws were tightened with a torque driver. A tightening torque of 0.113 Nm was used to fasten ACP's #2, #3, and #4. This torque magnitude was selected to permit sliding of the screw heads along the top surface of the plate while providing sufficient fixation of the osteotomy. A tightening torque of 0.170 Nm was used to fasten ACP #1. Only one plate was implanted in each dog, and the corresponding femur was referred to as the experimental bone. The contralateral femur was left intact to serve as a control bone. At the end of surgery the wounds were closed in three layers and each dog received one intramuscular injection of penicillin G 500,000 IU.

The dogs were kept in large stalls and had unlimited access to standard

Figure 23: Drill Guide

This photograph shows the drill guide used to ensure proper spacing and direction of the screw holes drilled into bone. The drill guide is shown mounted on a bone with a drill bit for cortical bone in the foreground.

dog food and water. All dogs limped slightly during the first week and occasionally one intramuscular injection of oxymorphone 0.5 mL was needed to sedate them. Wound healing occurred *per primam* in all and no infection was noted.

4.3 Biomechanical Testing and Data Analysis Methods

Both the experimental bone and the contralateral control bone from each dog were tested biomechanically according to a modified Polar Flexural Rigidity Profile (PFRP) testing and analysis method ¹⁶. The method described in the publication by Foux et. al. involved nondestructive three-point bending, while his modified method involved nondestructive four-point bending. The biomechanical testing apparatus and the analysis software used in this work were designed and written, respectively, by Foux.

A schematic of the four-point bending apparatus is shown in figure 24. Both ends of each individual bone were rigidly fixed into two coaxial potting cups to form a single beam. This beam was simply supported by a base at four pivots on extensions of the potting cups. This base rested on an Instron CCT compression load cell having a range of 0 to 890 N. A loading frame was fastened above the beam to the moving crosshead of an Instron model TM tabletop materials testing machine. Bending loads were applied to the beam at four loading points on extensions of the potting cups. A LVDT was positioned to measure the centre deflection of the beam under the bending loads.

Figure 24: Schematic of Four-Point Bending Apparatus

4.3.1 Preparation of Bones for Polar Flexural Rigidity Profile Testing

At the end of the implantation periods the dogs were euthanised and both femora were excised. Plates were then removed from the experimental bones. A torque driver equipped with a dial gauge was used to remove all screws and measure loosening that may have occurred during the period of implantation. A retightening torque equal to the initial tightening torque at implantation was applied to each screw. During this retightening each screw was observed to note any rotation of the head. If rotation was observed then the screw was threaded until the head stopped rotating, even if the applied torque exceeded the initial tightening torque. This torque was read off the dial gauge and recorded. Finally, the torque required to remove each screw was read off the dial gauge and recorded. All femora were preserved in neutral buffered formalin solution and tested within 16 weeks.

In preparation for testing each bone was carefully stripped of all soft tissue. Each experimental bone was placed along side its contralateral control and the position of the osteotomy site was transferred to the control bone with a lightly scribed line. The bones were then ready to be positioned for fixation in the cups on the custom potting frame shown in figure 25. A triple prong clamp mounted at the centre of the frame was used to suspend the bone between the cups.

Proper positioning of a bone required three criteria to be satisfied simultaneously: the osteotomy site must be centred between the cups, the

Figure 25: Femur Positioned in Potting Frame

This photograph shows a femur positioned in the potting frame in preparation for potting in the cups. The bone is centred manually in the triple prong clamp, and proper rotational positioning is achieved with the sliding wedge shown to be in contact with both femoral condyles.

longitudinal axis of the bone must coincide with the longitudinal axis of the cups, and the anterior aspect of the bone must be facing directly up. The osteotomy site was visible on all experimental bones, and it existed as a scribed line on the control bones. Therefore, the osteotomy site was centred by hand directly under the central prong of the clamp. Two "V" shaped notches in the two outer prongs helped align the longitudinal axis of the bone with the longitudinal axis of the cups. Considering the irregular cross-sectional geometry along the length of the femora, it was impractical to identify the longitudinal axis mathematically. Therefore, the alignment of the longitudinal axis of the bone with that of the cups was approximated by eye. To ensure that the anterior aspect of each bone was facing directly up, the horizontal surface of a sliding wedge was pushed up into contact with the femoral condyles until both condyles were seen to be in good contact with the wedge. This was defined as 0° for the PFRP testing. Once proper positioning of a bone had been achieved, the clamp was tightened to hold the bone firmly.

Bismuth alloy² having a Brinell hardness of 12 and a melting temperature of 47 °C was used to fix the bone ends rigidly in the potting cups. This alloy can be melted very easily in the laboratory with hot water, and it returns to a solid state upon cooling to room temperature. Volume change of the alloy upon cooling from a liquid to a solid was only -1.4%. After positioning the bone properly in the potting frame, one cup was filled exactly to the brim with molten

²CERROLOW-117, Cerro Metal Products, Bellefonte, PA, USA

alloy and the alloy was allowed to cool to a solid state. Molten alloy was then poured into the remaining cup in the same manner and allowed to cool to a solid state. Figure 26 illustrates a potted bone end. Subsequent to testing the bone ends were easily released intact from the encasing alloy with a stream of hot water. The bone tissue was not damaged or altered by the hot water, and the same quantity of alloy was reused throughout the testing program.

4.3.2 Polar Flexural Rigidity Profile Testing Method

After potting a bone in the cups, the entire beam was carefully removed from the potting frame and transferred to the base of the four-point bending apparatus in the Instron machine as shown in figure 27. Testing of each bone was conducted in twenty-four planes of bending at 15° angular increments about the longitudinal axis of the cups. Starting at 0° , a pseudostatic nondestructive load to a maximum of 98 N was applied to the beam at a fixed crosshead speed of 0.5 mm/min. This generated a maximum bending moment of 2.0 Nm and a maximum bending stress in the bone of 27.53 MPa, assuming a hollow cylindrical cross-section having an outer radius of 4.7 mm and an inner radius of 2.7 mm. Specific data for the yield stress of canine cortical bone was not found in the literature. However, the tensile yield stress in the longitudinal direction for bovine cortical bone has been reported to be 141 MPa while that for human cortical bone has been reported to be 115 MPa¹¹. Therefore, it was assumed that the maximum bending stress was well below the yield stress of any of the femora being tested. During the test, load data from the load cell

Figure 26: Potted Bone End

This photograph shows one end of a femur potted in a cup with Bismuth alloy.

Figure 27: PFRP Testing of Femur

This photograph shows a femur mounted in the testing machine and subjected to bending. Load is applied by a moving crosshead above the bending apparatus and measured by a load cell upon which the apparatus rests. A LVDT positioned under the midsection of the bone measures deflection.

and centre deflection data from the LVDT were digitized and recorded by a computerized data acquisition system. Data collection was controlled by LABTECH NOTEBOOK³ software at a frequency of 40 Hz.

The Instron controller was set to reverse the direction of the crosshead at the maximum load of 98 N. This released the load from the bone and marked the end of the test at 0°. Two clamps on each cup were then loosened and a single index pin in each cup was removed allowing both cups and the bone to be rotated through a 15° increment about their common longitudinal axis. Rotation was measured off a scale on the outer surface of one cup. The cups were locked in this new position by reinserting the index pins and retightening the clamps. Testing was repeated in this manner through a complete revolution at 15° increments in a total of twenty-four planes of bending. The test at 360° was a repeat of the test at 0°. Upon subsequent analysis, if the result of a test at 360° was found to differ from that at 0° by more than $\pm 5\%$, then the bone was retested.

All bones were tested in pairs, because the results of an experimental bone were compared with those of its contralateral control. The experimental bone was assumed to be more fragile than the control, so it was always tested first. If the experimental bone was damaged during preparation or during testing then there was no need to test the control.

Just prior to removing the experimental bone from the Instron machine

³LABTECH NOTEBOOK Version 4.13, Laboratory Technologies Corporation, 255 Ballardvale Street, Wilmington, MA, USA, 1986

after a complete PFRP test, the position of the plate on the femur was measured. A smooth 7 cm long pin having a diameter of 2.5 mm was inserted into one of the screw holes furthest from the osteotomy site and through both cortices. The diameter of this pin was equal to the minor diameter of the bone screws, therefore the fit was snug in the screw holes. Rotating the pin to the vertical position corresponded to the plate position which was read directly off the scale on one cup. This measurement was repeated by inserting the rod into the other screw hole furthest from the osteotomy site. A mean plate position was calculated from the two measurements.

4.3.3 Polar Flexural Rigidity Profile Analysis Method

Twenty-four data files corresponding to tests in twenty-four planes of bending were recorded for each bone. The data from an experimental bone and its control served as input for the PFRP analysis software written by Foux. Complete analysis of the data from a pair of bones occurred in three stages. First, a linear stiffness value was calculated by the software from the load and deflection data in each file. Second, these stiffness values were used to calculate the flexural rigidity (EI) in each plane of bending. Third, a plot of the results was generated.

The cross-sectional geometries of the canine femora were irregular and varied along their lengths. Practical nondestructive techniques do not exist to quantify the cross-sectional geometry of bone. Therefore, the femora were modelled as homogeneous beams having uniform cross-sectional geometry. The

cups were also modelled as homogeneous beams having uniform cross-sectional geometry. Beam theory was applied to this model, illustrated in figure 28, to calculate the apparent flexural rigidity of the femora, $(EI)_{bone}$.

The tensile elastic modulus of canine femora has been reported to be 20.1 GPa ¹¹. The cups were made from stainless steel having a tensile elastic modulus of 190 GPa. Also, the cross-sectional area of the cups was about 50 times larger than that of the femora. Based on these facts it was assumed that $(EI)_{bone} < (EI)_{cup}$. Therefore, $(EI)_{bone}$ could be calculated from an equation of the elastic curve for the deflection of a beam in static bending. The general form of this equation was written as follows:

$$(EI)_{bone} = q(P/y) \quad (1)$$

where P/y was the linear stiffness calculated from the load/deflection data, and q was a function of the length of the beam and the positions of the loading and support points (ie. the mode of bending). The specific form of equation 1 for four-point bending of the model shown in figure 28 includes an expression for q :

$$q = (bL^2/16)(1-(4a^2/L^2)) \quad (2)$$

where q is a function of the lengths L , a , and b of the model.

The twenty-four $(EI)_{bone}$ values obtained for each bone were of elliptical distribution in a plane normal to the longitudinal axis of the bone. An elliptical regression routine in the software fit an ellipse to these twenty-four data points. This ellipse described the flexural rigidity characteristics about a complete

Figure 28: Model of Potted Femur

Beam theory was applied to the model shown here to calculate flexural rigidity values from the load/deflection data collected during bending testing.

revolution of a tested bone and was referred to as a PFRP. The PFRP's of an experimental bone and its contralateral control were plotted on the same polar coordinate system for comparison. Figure 29 illustrates a typical PFRP plot. In figure 29 the plane of bending at 0° was labelled "anterior". The magnitude of $(EI)_{\text{bone}}$ was represented by the distance of the data points from the centre of the ellipse and their angular position was measured from the 0° position in a clockwise direction about the origin. The data points were included on the plots to observe the fit of the ellipses, and the position of the plate (θ_p) was indicated with a line. Due to the left/right symmetry of a pair of bones, the PFRP of the left bone was shown as its mirror image.

Foux et. al. ¹⁶ reported four healing efficiency parameters calculated from the ellipse parameters defining the two PFRP's from a pair of bones. However, one of these parameters, the stiffness index (SI), contains the information given by the other three. Therefore, the other three healing efficiency parameters were disregarded in the current investigation. The SI was a quantitative measure of the mechanical status of the healing experimental bone. It was defined as the ratio of the flexural rigidity of the experimental bone, $(EI)_{\text{exp}}$, to that of its control, $(EI)_{\text{con}}$, both in the same plane of bending, θ_{SI} , that yields the minimum value of this ratio, and expressed as:

$$SI = \{(EI)_{\text{exp}} / (EI)_{\text{con}}\}_{\text{min}} \quad (3)$$

In other words, the software calculated a ratio $(EI)_{\text{exp}} / (EI)_{\text{con}}$ at every angular position about the origin and searched for the angular position at which the

Figure 29: Typical PFRP Plot for Plated Femora

Both polar flexural rigidity profiles from a pair of femora are plotted on the same polar coordinate system. The circular data points and the solid ellipse represent the control bone while the starred data points and the dashed ellipse represent the experimental bone. A line running from the origin to the perimeter of each ellipse identifies the semi-minor axis of each ellipse. Notice how the ellipse representing the experimental bone is smaller and rotated toward the position of the plate. The position of the plate is listed in the side bar to the right. Values for stiffness index and position of stiffness index are also listed at the bottom of the side bar. Please note that "AR" appearing at the bottom of the side bar does *not* refer to the angle ratio calculated in this work.

value of this ratio was minimum. That minimum ratio was selected as the stiffness index.

The calculated values of SI were normalized with respect to the control bone and, therefore, independent of variations amongst the seventy-two dogs. Nonunion of the bone fragments was indicated by $SI = 0$. When $0 < SI < 1$, the flexural rigidity of the experimental bone was less than that of the control bone in the weakest plane of bending (θ_{SI}). The flexural rigidity of both bones was equal in the plane θ_{SI} when $SI = 1$. However, the flexural rigidity of the experimental bone was greater than that of the control bone in any plane other than θ_{SI} . When $SI > 1$ the flexural rigidity of the experimental bone was greater than its control in all planes of bending. The values for SI and θ_{SI} were also listed on each PFRP plot.

Foux et. al.¹⁶ reported using the PFRP method to test ten pairs of intact bones. The mean SI calculated for these bones was 0.97 with a standard deviation of ± 0.05 . This value was slightly less than unity due to left/right variability between the femora of the same animal. Therefore, in the current investigation a mean SI of 0.97 was used to represent perfect healing.

4.3.4 Calculation of the Angle Ratio

Subsequent to the analysis of the biomechanical testing with the PFRP software, an angle ratio was calculated to measure the closeness of the position of SI (θ_{SI}) to the position of the plate (θ_p). This ratio was expressed as:

$$AR = \theta_{SI} / \theta_p \quad (4)$$

where $AR = 1$ indicated coincidence of θ_{SI} with θ_p .

4.3.5 Analysis of the Dependence of the Healing Process on Time

Time zero was defined at the instant the plate was completely fastened to the experimental bone during surgery. Healing could begin at that instant. However, without the plate holding it together the experimental bone was cut into two halves. Therefore, at time zero the PFRP of the experimental bone degenerated to a point and SI was equal to zero in all planes of bending

It was assumed that the stiffness index would increase with time as healing progressed. It was also assumed that the healing process would eventually subside and that SI would achieve a corresponding steady state value. Typical of many biological processes, a high rate of change is observed initially that diminishes with time toward a steady state which is approached asymptotically. Therefore, the healing process was modelled by the following exponential relation:

$$SI = SI_{\infty}\{1 - e^{-(t/\tau)}\} \quad (5)$$

The stiffness index (SI) changed with the healing time (t). Two constants defined the healing process: SI_{∞} was the asymptotic value of SI, and τ was the time constant of the healing process. The value of the time constant was such that $t = \tau$ when the value of SI was 63.2% of SI_{∞} , and $t = 3\tau$ when SI was 95.0% of SI_{∞} . Equation 5 was used to fit a curve to the mean values of SI for the four ACP's plotted against time (ie. 8, 16, and 24 weeks). Constants SI_{∞}

2

PM-1 3½"x4" PHOTOGRAPHIC MICROCOPY TARGET
NBS 1010a ANSI/ISO #2 EQUIVALENT

and r were calculated with an iterative curve fitting routine in the SigmaPlot⁴ software package. Convergence of the fitting process was dependent upon the absolute value of the difference between the square root of the sum of squares of the residuals from one iteration to the next being less than the tolerance value of 0.0001.

4.3.6 Statistical Analysis Methods

Parametric statistical methods were used to analyze the effect of the two independent variables, axial stiffness and healing time, on the dependent variable, SI. Main effects and interaction between the two independent variables were investigated via two-way analysis of variance. In the event that no significant interaction between the two independent variables was found, a separate one-way analysis of variance was conducted on each of the two independent variables. In the event that significant differences were found by the one-way analysis of variance, the data were investigated further using the Student-Newman-Keuls test for pair-wise post hoc comparison. The minimum sample size for a group was five and a p value less than or equal to 0.05 was considered significant.

⁴ SigmaPlot for Windows Version 1.0, Jandel Scientific, P.O. Box 7005, San Rafael, CA, USA, 1993

4.4 Results of Biomechanical Testing and Data Analysis

4.4.1 Results of Measurements of Bone Screw Loosening

A total of 432 cortical bone screws were removed from the femora at the end of the implantation periods. Only twenty-seven or 6.25% required retightening. Of these, twenty-one were observed in the 24 week implantation period, two were observed in the 16 week implantation period, and four were observed in the 8 week implantation period. Only fifteen or 3.47% of the bone screws were removed with a torque less than the initial tightening torque. Of these, eleven were observed in the 24 week implantation period, none were observed in the 16 week implantation period, and four were observed in the 8 week implantation period.

4.4.2 Results of Stiffness Index Calculations

A total of seventy-two ACP's were implanted. However, values of SI were calculated for seventy-one pairs of femora, because one experimental bone corresponding to ACP #1 and implanted for 8 weeks was accidentally broken during PFRP testing. Therefore, this group had a sample size of only five instead of the intended six. All seventy-one PFRP plots were compiled in appendix A.4. The data were condensed by calculating a mean value of SI and standard error of the mean (SEM) for each of the twelve groups. These results are listed in table 2.

The results of a two-way analysis of variance indicated that there was no interaction between the two independent variables, axial stiffness and

ACP #	STIFFNESS INDEX (SI)			
	0 Weeks	8 Weeks	16 Weeks	24 Weeks
1	0	0.67 $\pm$ 0.03	0.74 $\pm$ 0.05	0.70 $\pm$ 0.03
2	0	0.73 $\pm$ 0.03	0.76 $\pm$ 0.02	0.80 $\pm$ 0.04
3	0	0.75 $\pm$ 0.02	0.76 $\pm$ 0.03	0.85 $\pm$ 0.05
4	0	0.68 $\pm$ 0.01	0.73 $\pm$ 0.02	0.72 $\pm$ 0.03

Table 2: Stiffness Index Results

This table lists mean values of stiffness index with standard error of the mean for the experimental femora plated with the four axially compressible plates for 8, 16 and 24 weeks of implantation. At time zero the stiffness index is zero by definition.

healing time $\{F(6,59) = 0.880, p = 0.516\}$. Further one-way analysis of variance indicated that significant differences of SI existed between groups with respect to axial stiffness $\{F(3,67) = 4.3915, p = 0.0070\}$ and also with respect to healing time $\{F(2,68) = 3.1399, p = 0.0496\}$. Therefore, the statistical analysis was continued by using the Student-Newman-Keuls test for multiple pair-wise comparisons. With respect to axial stiffness, ACP #3 had a significantly larger SI than ACP #1, ACP #2 had a significantly larger SI than ACP #4, and ACP #3 had a significantly larger SI than ACP #4. However, no significant differences in SI were found between ACP #1 and ACP #2, between ACP #1 and ACP #4, nor between ACP #2 and ACP #3. With respect to healing time, SI at 8 weeks was significantly larger than at time zero, and SI at 24 weeks was significantly larger than at 8 weeks. No significant differences in SI were found between the healing times of 8 weeks and 16 weeks, nor between 16 weeks and 24 weeks.

4.4.3 Results of Angle Ratio Calculations

The mean values of AR and standard errors of the mean (SEM) were calculated for each of the twelve groups. These results are listed in table 3.

The results of a two-way analysis of variance indicated that there was no interaction between the two independent variables, axial stiffness and healing time $\{F(6,59) = 1.122, p = 0.361\}$. Further one-way analysis of variance indicated that no significant differences of AR existed between groups with respect to axial stiffness $\{F(3,67) = 2.1949, p = 0.0967\}$ nor with

ACP #	ANGLE RATIO (θ_{SI} / θ_P)		
	8 Weeks	16 Weeks	24 Weeks
1	0.98 $\pm$ 0.03	0.85 $\pm$ 0.14	0.97 $\pm$ 0.03
2	0.99 $\pm$ 0.08	1.06 $\pm$ 0.07	0.98 $\pm$ 0.07
3	0.80 $\pm$ 0.10	0.95 $\pm$ 0.07	0.98 $\pm$ 0.02
4	1.00 $\pm$ 0.03	1.09 $\pm$ 0.05	1.00 $\pm$ 0.04

Table 3: Angle Ratio Results

This table lists mean values of angle ratio with standard error of the mean for the experimental femora plated with the four axially compressible plates for 8, 16 and 24 weeks of implantation.

respect to healing time $\{F(2,68) = 0.4570, p = 0.6351\}$. Therefore, multiple pair-wise comparisons were not necessary. The overall mean value for θ_{SI} was 68.5° (SEM = 1.99° , $n = 71$) and that for θ_p was 70.2° (SEM = 1.27° , $n = 71$).

4.4.4 Results of Analysis of the Dependence of the Healing Process on Time

Two constants, SI_∞ and τ , were calculated from a curve fit of equation 5 to the mean SI for each ACP plotted against time (ie. 8, 16, and 24 weeks). In all four cases the tolerance value was satisfied and the fitting process converged. These constants are listed in table 4. A curve for each ACP was plotted using the values for SI_∞ and τ in equation 5. These plots are illustrated in figure 30.

The four values of the constant SI_∞ corresponding to each ACP were also plotted against k . A cubic spline interpolation routine in the SigmaPlot software package was used to draw a smooth curve through these points. This plot is illustrated in figure 31. The mathematical maximum value of SI_∞ on this curve coincides with $k = 5.0 \times 10^6$ N/m.

ACP #	ASYMPTOTIC VALUE (SI_{∞})	TIME CONSTANT IN WEEKS (τ)
1	0.72	2.88
2	0.78	3.16
3	0.81	3.31
4	0.72	2.85

Table 4: Asymptotic Values and Time Constants

This table lists asymptotic values and time constants of stiffness index for the experimental femora plated with the four axially compressible plates.

Figure 30: Stiffness Index Plotted Against Time

Vertical bars indicating standard error of the mean at each data point are shown on the graph.

Figure 31: Asymptotic Values Plotted Against Axial Stiffness

4.5 Discussion

The effect of internal fracture fixation plates with reduced axial stiffness on the healing of osteotomized canine femora was investigated. It was hypothesized that fractures treated with plates having reduced axial stiffness would exhibit improved healing. It was also hypothesized that optimal fracture healing would be observed near the middle of a range of axial stiffnesses. Four custom axially compressible plates were designed and manufactured for this investigation. The stiffest plate was ACP #1. The remaining ACP's had increasing degrees of axial compressibility with ACP #4 being the most compressible.

Compared to ACP #1, the axial stiffness of ACP #2 was 39.7% lower, that of ACP #3 was 69.4% lower, and that of ACP #4 was 88.2% lower (table 1). All four ACP's were designed with the same cross-section and external dimensions. All plates and screws were made from the same material. The same surgical technique was employed to implant all ACP's. Verification testing confirmed that bending and torsional stiffnesses of the ACP's were eliminated from the experiments as variables. Therefore, axial stiffness was isolated as the only variable amongst the four ACP's as was intended by their design.

Fracture healing was assessed biomechanically. Several methods exist to measure the mechanical integrity of a healing bone including strength testing to destruction in bending, torsion, tension or compression. The PFRP method employing nondestructive four-point bending was chosen for this investigation.

It offered several advantages over the more common destructive methods. Differences amongst the dogs may have been a source of error in the experiments. However, this possible source of error was eliminated during the calculation of SI by using the intact contralateral femur from each dog as its own control. Destructive testing yields information in only one plane of loading, so the value of this information is highly dependent on the chosen plane of loading. On the other hand, PFRP testing yielded information in multiple planes of loading about the entire circumference of a bone. Although PFRP testing did not measure the strength of bone directly, a linear correlation between the bending stiffness and strength of bone has been reported ²⁵. Therefore, SI was considered representative of the strength of a healing bone where larger values of SI represented greater strength. Finally, bones remained intact subsequent to PFRP testing for further biological evaluation by histologic and histomorphometric methods that might otherwise have been impossible after destructive testing.

Significant differences were found in the results for SI on the basis of axial stiffness. This fact confirmed that plates with reduced axial stiffness had a significant influence on the healing of osteotomized canine femora. Superior fracture healing was observed after plating with ACP #2 and ACP #3 compared to ACP #1. Both ACP #2 and ACP #3 were more compressible than ACP #1. This supported the hypothesis that fractures treated with plates having reduced axial stiffness would exhibit improved healing compared to stiffer plates.

Superior fracture healing was also observed after plating with ACP #3 compared to ACP #4, and ACP #3 was stiffer than ACP #4. This supported the hypothesis that fractures treated with plates having an intermediate axial compressibility would exhibit optimal healing.

All four plates were implanted for periods of 8, 16, and 24 weeks to monitor the progress of healing with time. Significant differences were found in the results for SI on the basis of healing time. Therefore, time had a significant influence on the healing of osteotomized canine femora. Fracture healing of the osteotomized bones had progressed significantly after the first 8 weeks and also from 8 to 24 weeks. Therefore, healing improved with time. However, there was no significant difference in the progress of healing from 8 to 16 weeks and also from 16 to 24 weeks. This suggested that the healing process was slowing down from 8 to 24 weeks and validated the assumption in the model expressed by equation 5 that the rate of healing would diminish with time.

Figure 30 illustrates the dependency of the healing process on time and its response to the four ACP's. It is seen in figure 30 that the slopes of all four plots were steep between time zero and 8 weeks. This rapid increase in SI coincided with rapid healing of the experimental bones. It was reasoned that this initial 8 week period corresponded with the duration of the phase of union. After 8 weeks, however, the slopes of all four plots became very shallow. According to the time constants calculated from equation 5, bones plated with

ACP #1 achieved 95% of SI_{∞} after only 8.64 weeks (ie. $t = 3\tau$). The same was true for ACP's #2, #3 and #4 after only 9.48, 9.93 and 8.55 weeks, respectively. This validated the assumption in the model expressed by equation 5 that a rapid improvement in healing would occur initially. After 24 weeks the actual values of SI for the four ACP's listed in table 2 were very close to their respective asymptotic values, SI_{∞} , listed in table 4. This validated the assumption that the healing process would approach a steady state. Therefore, it was also reasoned that the remodelling phase of healing began after 8 weeks.

The value of SI_{∞} for ACP #3 was the highest. That of ACP #2 was only slightly lower, and the plots representing these two ACP's appear close together in figure 30. The values of SI_{∞} for ACP #1 and ACP #4 were the same, and these plots also appear close together in figure 30. However, there was a noticeable separation between the two pairs of curves that illustrated the beneficial effect on healing of plates with reduced axial stiffness over stiff plates. This space also illustrated that optimal healing was achieved with an intermediate axial stiffness.

Figure 31 shows the four values of SI_{∞} plotted against axial stiffness. This plot illustrated the range of axial stiffnesses spanned by the four ACP's and their effect on the final state of healing of the experimental bones. Although ACP #3 resulted in the best healing, the peak of the curve did not coincide with the axial stiffness corresponding to ACP #3, but at $k = 5.0 \times 10^6$ N/m which was between ACP #2 and ACP #3. However, the curve is rather flat

in the vicinity of the peak at $k = 5.0 \times 10^6$ N/m. This suggested that optimal healing may have been achieved with a plate having an axial stiffness between those of ACP #2 and ACP #3, but not necessarily corresponding exactly to $k = 5.0 \times 10^6$ N/m.

Inferior healing was observed with ACP #1. It was reasoned that the high stiffness of this plate shielded the underlying bone from stress. Therefore, the bone adapted itself to the reduced state of stress according to Wolff's law. The remodelling process tended toward resorption of bone in response to the presence of the plate.

Inferior healing was also observed with ACP #4. It was reasoned that there was a limit to how much the axial stiffness of a plate should be reduced. It would appear that this limit was exceeded and ACP #4 was unable to provide adequate fracture stabilization in the axial direction.

Whether or not the statistically significant differences in performance amongst the four ACP's observed in this work would produce clinically significant differences in the practice of orthopaedic surgery is not known. An extensive clinical trial in either animals or humans would be required to gain this knowledge. Perhaps the results of this work could be used as a step in the direction toward designing plates that produce clinically significant improvements over DCP's.

Of interest, however, was a similar study reported by Foux et. al.¹⁷ in 1993 on the healing of femoral osteotomies in beagles treated with three

different plate types. One of the plate types was a stainless steel DCP. Five of these stainless steel DCP's were implanted for 24 weeks and the corresponding pairs of femora were subsequently tested in nondestructive three-point bending according to the PFRP method. These plates generated a mean SI of 0.50 compared to a mean SI of 0.85 for ACP #3 after a similar 24 week implantation period. In fact, ACP #3 generated a mean SI of 0.75 after only 8 weeks of implantation. This result was far superior to that generated by the stainless steel DCP's after 24 weeks of implantation.

No significant differences were found in the results for AR on the basis of axial stiffness nor on the basis of healing time. For all seventy-one experimental bones the weakest plane of bending, θ_{SI} , coincided almost perfectly with the position of the plate, θ_p . This was illustrated on the PFRP plots for every pair of bones where the PFRP of the experimental bone was observed to rotate toward the position of the plate. All four ACP's subjected the experimental bones to various degrees of stress shielding depending upon their axial stiffness. Therefore, it was suggested that the bones sensed the reinforcing effect of the plates and remodelled in accordance to Wolff's law. Consequently, healing was more intense in the planes perpendicular to the position of the plate. Moreover, this response was established very early as no change in AR was observed beyond the 8 week period. In fact, it was reasoned that a deviation of the value of AR from unity would never be observed as long as the ACP's remained fastened to the experimental bones.

A similar argument could be made about the steady state of healing achieved by the experimental bones and expressed as SI_{∞} . As long as the ACP's remained fastened to the experimental bones, their steady state values would be limited to those listed in table 4. However, the PFRP testing and analysis method did not account for the screw holes that remained in the experimental bones upon removal of the plates. Corresponding screw holes were never drilled into the control bones. Therefore, the effect of screw holes on the flexural rigidity of the experimental bones was not known. A supplementary test program to investigate this effect is the subject of chapter 5.

CHAPTER 5: INFLUENCE OF SCREW HOLES ON THE FLEXURAL RIGIDITY OF BONE

5.1 Purpose

The PFRP biomechanical test method did not account for the presence of screw holes in the experimental bones. Corresponding screw holes were not drilled into the control bones prior to PFRP testing of a pair of bones. Therefore, the screw holes may have had an effect on the flexural rigidity of the experimental bones, and this effect may have been superimposed on the results of the PFRP testing. A supplemental biomechanical testing program was conducted to determine the nature and magnitude of the influence of the screw holes on the flexural rigidity of canine femora plated with the ACP's. However, it should be noted that this supplemental testing program was conducted on dead bone, so the influence of bone remodelling in the vicinity of the screw holes on the flexural rigidity of live bone was not accounted for.

5.2 Biomechanical Testing

Six control bones, three left bones and three right bones, were selected at random from those tested previously. Aside from the revisions to be described below, the bones were remounted and retested exactly in accordance to the PFRP test method described previously.

Each femur was tested in its intact state first. Subsequent to this first PFRP test, the beam consisting of the intact bone and the cups was removed from the Instron machine and remounted on the potting frame. The beam was rotated to the 70° position where the same drill guide described previously was then centred over the femur and used to drill six 2.5 mm diameter holes through both cortices. Drilling the holes is shown in figure 32. The 70° position was selected for the screw holes, because the mean position for all seventy-one ACP's was also 70°. All holes were tapped with a 3.5 mm manual tap.

With the femur still potted in the cups, the beam was repositioned in the Instron machine and retested. Thus, each femur served as the control bone in its intact state, and as the experimental bone in its drilled state. Both PFRP's from the same bone were plotted on the same PFRP plot. A typical example is shown in figure 33 where the bone in its intact state was represented as the solid ellipse, and the bone in its drilled state was represented by the dashed ellipse. Since both PFRP's were from the same bone, the analysis software was edited such that neither PFRP was shown as its mirror image. Note that "PLATE DIRECTION" in figure 33 refers to the position of the screw holes.

A stiffness index was calculated for each bone. An angle ratio was then calculated to measure the closeness of the position of SI (θ_{SI}) to the position of the screw holes (θ_H). This ratio was expressed as:

$$AR_H = \theta_{SI} / \theta_H \quad (6)$$

where $\theta_H = 70^\circ$.

Figure 32: Drilling Holes in Femur

Subsequent to the first PFRP test, the drill guide is clamped onto the potted intact femur with the three prong clamp on the potting frame. Holes are drilled in preparation for a retest of the femur in the drilled state.

Figure 33: Typical PFRP Plot for Femora with Screw Holes

Both polar flexural rigidity profiles from a single femur are plotted on the same polar coordinate system. The circular data points and the solid ellipse represent the bone in its intact state while the starred data points and the dashed ellipse represent the bone in its drilled state. A line running from the origin to the perimeter of each ellipse identifies the semi-minor axis of each ellipse. Notice how the ellipse representing the bone in its drilled state is smaller and rotated toward the position of the screw holes. The position of the screw holes is listed as "PLATE ANGLE" in the side bar to the right. Values for stiffness index and position of stiffness index are also listed at the bottom of the side bar. Please note that "PLATE DIRECTION" on the plot refers to the position of the screw holes and "AR" appearing at the bottom of the side bar does *not* refer to the angle ratio calculated in this work.

5.3 Results

The results for SI, θ_{SI} , and AR_H are listed in table 5. The mean SI for all six bones was 0.82 (SEM = ± 0.01 , $n = 6$) with a mean θ_{SI} of 69° (SEM = ± 1.39 , $n = 6$). The mean AR_H for all six bones 0.99 (SEM = ± 0.02 , $n = 6$).

5.4 Discussion

Despite the absence of plates, there was almost perfect coincidence between the position of SI and the position of the screw holes. In other words, the greatest reduction of flexural rigidity occurred in the plane of bending occupied by the screw holes. This observation was also made of the experimental bones plated with the ACP's, because by definition the position of the ACP's was also the position of their screw holes. Therefore, the screw holes had a stronger influence on the rotation of the PFRP's belonging to the experimental femora than the stress shielding effect of the ACP's and any subsequent remodelling. However, all bones plated with the ACP's had identical screw holes and significant differences in SI were found amongst those same bones. Therefore, despite the effect of screw holes, the ACP's had a significant influence on the healing of the experimental femora.

The previous PFRP testing program showed that the best healing was achieved with ACP #3 after 24 weeks of implantation where the mean SI reached 0.85 (SEM = ± 0.05 , $n = 6$). According to a t -test where $p = 0.05$ was considered significant, there was no significant difference in SI ($p =$

FEMUR #	STIFFNESS INDEX (SI)	POSITION OF STIFFNESS INDEX (θ_{SI})	ANGLE RATIO (θ_{SI} / θ_H)
1	0.77	68°	0.97
2	0.78	67°	0.96
3	0.83	75°	1.07
4	0.82	66°	0.94
5	0.85	71°	1.01
6	0.84	67°	0.96
MEAN	0.82	69°	0.99
SEM	±0.01	±1.39°	±0.02

Table 5: Effect of Screw Holes

This table lists values of stiffness index, position of stiffness index and angle ratio, and their respective mean values with standard error of the mean for the femora with screw holes. Angle ratio was calculated with a value for the position of the screw holes (θ_H) of 70°.

0.599) between these femora and the drilled femora of the supplemental test program. This is illustrated on the graph in figure 34 where the curve representing ACP #3 rises up to meet the line representing the femora with screw holes. Screw holes were shown to reduce the flexural rigidity of normal intact canine femora to $SI = 0.82$, and the best healing observed with the ACP's was limited to $SI = 0.85$. If normal intact bone is considered to have an SI of 0.97^{16} , then the difference between the SI achieved with ACP #3 after 24 weeks and the SI of normal intact canine femora is approximately equal to the amount by which screw holes reduce the flexural rigidity of normal intact canine femora.

Therefore, a healing bone can never be as strong as it was prior to fracture until the screw holes fill with bone. Also, healing of the experimental bones plated with ACP #3 after 24 weeks had indeed achieved the level of a normal intact bone. Finally, the researcher wishing to measure the strength of bone in bending need only test in the direction of the screw holes to be certain that the weakest direction has been chosen.

The conclusions drawn from this entire work follow in chapter 6.

Figure 34: Stiffness Index Plotted Against Time

This graph is identical to that shown in figure 30 except for the addition of a line indicating the value of the mean stiffness index for the femora with screw holes. Vertical bars indicating standard error of the mean at each data point are shown on the graph.

CHAPTER 6: CONCLUSIONS

Axially compressible plates were designed to test the hypothesis that fracture healing is improved with plates having selectively reduced axial stiffness. Four types of such ACP's were manufactured to provide a range of axial stiffnesses. They were implanted on osteotomized beagle femora for periods of 8, 16 and 24 weeks.

Axial stiffness had an influence on the healing of the osteotomized canine femora, because significant differences were found amongst the SI values for the bones plated with the four ACP's. The two ACP's having intermediate axial stiffness generated better healing than the stiffest ACP and the most compressible ACP. Therefore, fracture healing was improved with plates having selectively reduced axial stiffness compared to fracture healing with stiffer plates. However, an excessive reduction in the axial stiffness of plates did not improve fracture healing. This finding confirmed the hypothesis that plates near the centre of the range of axial stiffnesses would generate optimal healing. This finding also supported two theories: overly rigid fixation shields the healing bone from stress resulting in remodelling that weakens the bone, and unstable fixation prevents complete union of the fragments.

Time also had a significant influence on the healing of the osteotomized canine femora. This influence of time was observed to be strongest during the early stages of healing when the rate of healing was greatest. However, the

rate of healing diminished rapidly and time virtually ceased to be a factor after only 8 weeks. Eventually, the healing of the plated bones attained a steady state. This dependence of the healing process on time was accurately modelled by the exponential relation in equation 5. Therefore, the healing of osteotomized bones treated with internal fracture fixation plates is a first order biological process.

Healing of the osteotomized bones was limited to a maximum value of $SI = 0.85$ after 24 weeks of implantation with ACP #3. However, it was shown that screw holes reduced the value of SI for intact bones to 0.82. Therefore, taking the effect of screw holes into account, perfect fracture healing was achieved with ACP #3 after 24 weeks of implantation.

Two opposing criteria must be satisfied for effective healing of a fractured bone treated with a plate: the fragments must be approximated and stabilized, and stress shielding of the bone must be avoided. Considering the excellent healing that was achieved with ACP's #2 and #3, it must be concluded that the two opposing criteria for effective fracture healing were satisfied with these plates.

Recommendations for future work on the topic of ACP's follow in chapter 7.

CHAPTER 7: RECOMMENDATIONS

This investigation presented a biomechanical assessment of the fracture healing of bones treated with plates having selectively reduced axial stiffness. Although bone is an engineering material, it is also a living organ that is under the influence of many biological factors. Therefore, biomechanical methods alone cannot completely explain the mechanisms of fracture healing. The canine femora used in this investigation should also be assessed by radiologic, histologic and histomorphometric methods. An attempt should then be made to correlate information obtained from such a biological examination of the fracture healing to the results of the biomechanical assessment. Any correlation that might be established between the biomechanical and radiologic assessments of fracture healing would have highly significant clinical relevance.

Analysis of the results presented in figure 31 suggested that optimal healing may have been achieved with an axial stiffness between that of ACP #2 and ACP #3 in the vicinity of $k = 5.0 \times 10^6$ N/m. It may be of benefit to investigate the effect of plates with such an axial stiffness on fracture healing in an animal model to confirm or deny that optimal healing can be achieved. Although perfect healing was achieved with ACP #3 after 24 weeks of implantation, it is possible that plates with a truly optimal axial stiffness may generate perfect healing more rapidly.

The standard of rigid internal fixation with plates in modern orthopaedic

surgery is the DCP, but it was decided that the effect of self-compression should not be superimposed on the results of this investigation. Consequently, the DCP was not included. However, the effect of plates with selectively reduced axial stiffness has been elucidated in this investigation. Therefore, plates with selectively reduced axial stiffness should be compared directly with DCP's in the same investigation using an animal model.

If it is proven by a direct comparison with DCP's that fracture healing is significantly improved with plates having selectively reduced axial stiffness, then efforts should be made to design an ACP for clinical use in humans. It must be understood that the current ACP's were designed to investigate a specific hypothesis and were not intended for use in humans in their current form. It would be necessary that an ACP for humans be designed with a much smaller profile. It would also be necessary that the dimensions and materials of such an ACP be selected to sustain safely the physiological loads exerted at the particular location within the human body it was intended for.

The axial stiffnesses for the ACP's in this investigation are given as absolute values. In themselves, these values cannot be used to design an ACP for humans. However, if these axial stiffness values were normalized with respect to the canine femora they would be useful in the design of an ACP for humans. Therefore, efforts should be made to accurately model the ACP/bone interaction mathematically with the objective of calculating a normalized stiffness or normalized load sharing parameter.

A significant disadvantage of rigid internal fixation of fractures with plates such as the DCP is the risk of refracture subsequent to removal of the plate. The ACP was designed to address this disadvantage. However, two other significant disadvantages of plating as a treatment for bone fractures persist: the initial surgical intervention required to implant the plate, and the second surgical intervention required to remove the plate. A possible means to avoid the second surgical intervention is plates made from bioresorbable materials that dissolve after the fracture has healed. Unfortunately, modern bioresorbable materials do not have the strength required to treat long bone fractures.

In the meantime, bioresorbable materials may be suitable as inserts for ACP's. The current ACP's maintain the same level of axial stiffness throughout the implantation period. However, bioresorbable inserts offer the potential to provide intermediate axial stiffness initially that diminishes with time as healing progresses. Such a time dependent axial stiffness may accelerate the healing process and eliminate the effects of stress shielding.

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APPENDIX A.1
DRAWINGS OF PLATES

APPENDIX A.2
DRAWINGS OF INSERTS

AC-SI-228A

.118 RAD. DRILL # 28 (.140) DIA. 3 HOLES.

NOTES:

1. MATERIAL: PLEXIGLASS SHEET
2. REMOVE BURRS AND SHARP EDGES
3. SURFACE FINISH TO 63√ ALL OVER.

National Research Council
Canada
Electrical
Engineering Division
Ottawa, Canada
K1A 0R8

Conseil national de recherches
Canada
Division de genie électrique
Ottawa, Canada
K1A 0R8

DESIGNED BY
K. S.

CHECKED BY
ONE

APPROVED BY
ONE

AS ABOVE

ONE

ONE

CURVED BUSHING # 3

ONE

ORTHOPAEDIC ENGINEERING

2X FULL

14 DEC. 1969

AC-SI-228A

AC-91-827A

.145 RAD. DRILL # 28 (.140) DIA. 3 HOLES.

NOTES:

1. MATERIAL: PLEXIGLASS SHEET
2. REMOVE BURRS AND SHARP EDGES
3. SURFACE FINISH TO 63√ ALL OVER.

	National Research Council Canada Electrical Engineering Division Ottawa, Canada K1A 0R8	Conseil national de recherches Canada Division de genie electrique Ottawa, Canada K1A 0R8	DESIGNED BY K. E.	MATERIALS AS ABOVE	PART NAME CURVED BUSHING / B	DRAWN BY EX FULL
			CHECKED BY DNE	DATE 14 DEC. 1989	PROJECT ORTHOPAEDIC ENGINEERING	AC-91-827A
			APPROVED BY 			

APPENDIX A.3

**DRAWINGS OF TENSILE AND BENDING TEST APPARATUS FOR
VERIFICATION TESTING OF ACP's**

TENSILE TEST APPARATUS

TITLE: TENSILE TEST APPARATUS, UPPER X-HEAD FIXTURE		MATERIAL: COLD ROLLED STEEL	
PROJECT: AXIALLY FLEXIBLE PLATE		TOLERANCES: ± 0.003 UNLESS SPECIFIED OTHERWISE	
ACAD FILENAME: C:\ACAD\DWGS\AFP\TENSILE.DWG		SCALE: N/A	DATE: 27/10/93
DRAWN BY: A. YEADON	CHECKED BY: D. RUSSELL	QUANTITY: 1 PER UNIT	DRAWING NO.: AFP-001-002

TITLE: TENSILE TEST APPARATUS, SPACERS		MATERIAL: COLD ROLLED STEEL	
PROJECT: AXIALLY FLEXIBLE PLATE		TOLERANCES: ± 0.003 in. UNLESS SPECIFIED OTHERWISE	
ACAD FILENAME: C:\ACAD\DWGS\AFP\TENSILE3.DWG		SCALE: N/A	DATE: 27/10/03
DRAWN BY: A. YEADON	CHECKED BY: D. RUSSELL	QUANTITY: 2 PER UNIT	DRAWING NO.: AFP-001-003

TITLE: TENSILE TEST APPARATUS UPPER LVDT BRACKET EXTENSION		MATERIAL: 0.075 in. COLD ROLLED STEEL SHEET	
PROJECT: AXIALLY FLEXIBLE PLATE		TOLERANCES: ± 0.003 in. UNLESS SPECIFIED OTHERWISE	
ACAD FILENAME: C:\ACAD\DWGS\AFP\TENSILES.DWG		SCALE: N/A	DATE: 30/03/94
DRAWN BY: A. YEADON	CHECKED BY:	QUANTITY: 1 PER UNIT	DRAWING NO.: AFP-001-006

BENDING TEST APPARATUS

NOTE:
THREADED SLEEVES TO BE PRESS FIT INTO HOLES IN
STEEL BONE. SEE DRAWING AFP-002-003.

TITLE: THREADED SLEEVE		MATERIAL: BRASS	
PROJECT: AXIALLY FLEXIBLE PLATE		TOLERANCES: ± 0.003 In.	
ACAD FILENAME: C:\ACAD\DWGS\AFP\SLEEVE.DWG		SCALE: N/A	DATE: 10/08/04
DRAWN BY: A. YEADON	CHECKED BY: D. RUSSELL	QUANTITY: 6	DRAWING NO.: AFP-002-005

TITLE: UPPER MOUNTING ADAPTOR		MATERIAL: ALUMINUM	
PROJECT: AXIALLY FLEXIBLE PLATE		TOLERANCES: +/- 0.003 in.	
ACAD FILENAME: C:\ACAD\DWGS\AFP\MOUNT1.DWG		SCALE: N/A	DATE: 04/08/94
DRAWN BY: A. YEADON	CHECKED BY: D. RUSSELL	QUANTITY: 1	DRAWING NO.: AFP-002-001

TITLE: LOWER MOUNTING ADAPTOR		MATERIAL: ALUMINUM	
PROJECT: AXIALLY FLEXIBLE PLATE		TOLERANCES: +/- 0.003 in.	
ACAD FILENAME: C:\ACAD\DWGS\AFF\MOUNT2.DWG		SCALE: N/A	DATE: 04/08/94
DRAWN BY: A. YEADON	CHECKED BY: D. RUSSELL	QUANTITY: 1	DRAWING NO.: AFF-002-002

APPENDIX A.4**PFRP PLOTS**

8 WEEKS IMPLANTATION

AFP #1

ANTERIOR

ANTERIOR

8 WEEKS IMPLANTATION

AFP #2

3

PM-1 3½"x4" PHOTOGRAPHIC MICROCOPY TARGET
NBS 1010a ANSI/ISO #2 EQUIVALENT

ANTERIOR

8 WEEKS IMPLANTATION

AFP #3

ANTERIOR

8 WEEKS IMPLANTATION

AFP #4

 

ANTERIOR

16 WEEKS IMPLANTATION

AFP #1

 

16 WEEKS IMPLANTATION

AFP #2

 

16 WEEKS IMPLANTATION

AFP #3

16 WEEKS IMPLANTATION**AFP #4**

24 WEEKS IMPLANTATION

AFP #1

4

OF/DE

4

PM-1 3 1/2"x4" PHOTOGRAPHIC MICROCOPY TARGET
NBS 1010a ANSI/ISO #2 EQUIVALENT

24 WEEKS IMPLANTATION

AFP #2

ANTERIOR

24 WEEKS IMPLANTATION

AFP #3

24 WEEKS IMPLANTATION

AFP #4

APPENDIX A.5

**ETHICAL ACCEPTANCE OF ANIMAL RESEARCH REPORT OF THE ANIMAL
CARE COMMITTEE**

ETHICAL ACCEPTANCE OF ANIMAL RESEARCH REPORT OF THE ANIMAL CARE COMMITTEE

CONFORMITÉ À L'ÉTHIQUE EN MATIÈRE DE RECHERCHE SUR LES ANIMAUX 226 RAPPORT DU COMITÉ DE PROTECTION DES ANIMAUX

Required for all Applications Proposing Research Involving Animals

Obligatoire pour toutes les demandes concernant des recherches sur des animaux

Funds from the Medical Research Council of Canada may not be used for research involving animals unless the research proposed has been found acceptable by an Animal Care Committee appointed and operating in accord with the Guide to the Care and Use of Experimental Animals of the Canadian Council on Animal Care (CCAC) (Vol. 1 (1980), Vol. 2 (1984)).

Les fonds que le Conseil de recherches médicales du Canada a accordés ne peuvent servir à des recherches sur des animaux à moins que le Comité de protection des animaux établi et dirigé conformément au Manuel sur le soin et l'utilisation des animaux d'expérimentation (vol. 1 (1980), vol. 2 (1984)) du Conseil canadien de protection des animaux (CCPA) n'ait convenu que la recherche proposée répond aux normes établies par le CCPA.

(The completed form must be received by Council not later than sixty (60) days after the deadline date for the receipt of the application. If the form is not provided within this period, the application will not be considered.)

(Le formulaire dûment rempli doit être reçu par le Conseil au plus tard soixante (60) jours après la date limite de réception de la demande. Si le formulaire n'est pas fourni au bout de ce délai, la candidature ne sera pas étudiée.)

STATEMENT FROM THE INSTITUTION* IN WHICH THE RESEARCH WILL BE PERFORMED

DÉCLARATION DE L'INSTITUTION* OÙ SE DÉROULERA LA RECHERCHE

The Animal Care Committee established by

Le Comité de protection des animaux établi par

University of Ottawa

(Institution* in which the research will be performed)
(Institution* où se déroulera la recherche)

has examined the protocol for the research funds entitled:

a étudié le protocole de la recherche intitulée:

EFFECT OF AXIAL PLATE RIGIDITY ON FRACTURE HEALING AND REMODELING

(Use the same title as on the application submitted to the Council)
(Utiliser le même titre que celui indiqué sur la demande présentée au Conseil)

MA 10037

MRC Grant Number
CRM n° de subvention

submitted by

soumise par

Drs. Uhthoff, H.K., Johnson, F., Wyss, U., Goosen, M., McAuley, J.P.

(Name(s) of applicant(s) as appearing on the application submitted to the Council)
(Nom(s) du(des) candidat(s) tels qu'ils apparaissent sur la demande soumise au Conseil)

and found the proposed protocol involving animals to meet the standards of the Canadian Council on Animal Care, and that the facilities in which the animals will be housed and used comply with the CCAC requirements.

et a convenu que le protocole proposé sur des animaux répond aux normes établies par le Conseil canadien de protection des animaux, et que les installations qui abriteront les animaux qui serviront à l'expérimentation sont conformes aux exigences du CCPA.

Date. October 15, 1993

Signatures:

(Signature)

Dr. J. Hinke, Chairman

(Print name of Institution's Representative for Research Involving Animals) / (Noms en lettres moules du délégué de l'institution* en matière de recherche sur des animaux)

Applicant(s) / Candidat(s)

October 15/93
Date

*Institution includes universities, hospitals, research institutes or companies

*Par institution, on entend les universités, les hôpitaux, les instituts de recherche ou les compagnies

END

2 2 1 1 - 9 6

FIN