A COMPARATIVE STUDY OF FRACTURE HEALING IN THE CANINE FEMUR FOLLOWING FIXATION BY SEVERAL DIFFERENT METHODS

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ABSTRACT

A COMPARATIVE STUDY OF FRACTURE HEALING IN THE CANINE FEMUR FOLLOWING FIXATION BY SEVERAL DIFFERENT METHODS

By

Carl Gordon Grant

This experiment was designed to compare the fracture healing which occurred following the use of 4 fixation methods employed to maintain the reduction of experimental femoral fractures in the dog. The healing which resulted was studied over experimental periods varying from 6 to 12 weeks. The methods compared were intramedullary nailing, intramedullary nailing with half Kirschner splintage, compression plating, and extracortical clamp fixation. The comparisons were made on the basis of physical findings, radiography and histology.

The right femur was surgically exposed and a transverse fracture of the mid-diaphysis was produced in 19 standard Beagles. Each experimental fracture was fixed using one of the methods previously dsecribed. The dogs were maintained postoperatively under controlled conditions for predetermined periods of time.

Clinical examinations were performed on all dogs at frequent intervals and radiographs were taken of the fractures postoperatively, at 4 weeks, at 8 weeks, and at the end of the experimental period. The dogs then were euthanatized and the healing fractures compared histologically.

Complete return to function of the operated limb was achieved by the compression plated animals within the first 3 weeks. Those treated with I.M. pins with and without the half Kirschner splintage required 6 weeks to achieve full function. This never was achieved by the animals in which extracortical clamps were employed.

Radiographs revealed that fractures treated with I.M. pinning with and without the assistance of the half Kirschner splintage healed through the development of the classical fusiform callus. By 10 weeks this callus was at the remodeling stage and the bones were nearly tubular after 12 weeks of healing. Compression-plated fractures could not be monitored radiographically since no significant changes could be observed during the healing. It was impossible also to monitor the extracortical clamp series since the device obscured the fracture area.

Histology revealed that bony union with cortical remodeling had occurred by 12 weeks in both the I.M. pinning series and by 8 weeks in the compression plating series.

The Sampson extracortical clamp in its present form was of no value as a fixation device for the treatment of mid-shaft fractures of the canine femur. Its design proved to be mechanically unsound for this purpose.

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INTRODUCTION

Bone differs from most other tissues in that its healing is really a process of regeneration which eventually restores the bone to its original form. This means that, in a fracture healing experiment in which bone specimens are examined at different times during the healing period, these samplings represent arbitrary interruptions in this continuous process. It is therefore possible to interpolate the events which would have occurred between the times at which examinations were performed. Fracture healing research is currently gaining new interest due to a number of recent advances which have been made regarding the histogenesis and morphogenesis of bone. Important among these is the new knowledge available on the function of the bone stem cell which is responsible for bone growth and for the reaction of the periosteum, endosteum and the cortical bone itself, to a fracture.

Other pertinent studies have shed new light on the orientation and quality of the histological elements of bone and their relationship to the mechanical strength of healing fractures. Such biomechanical studies are of particular interest in this field since the prime function of the skeleton is for support of the body, and the ultimate goal of fracture healing is to render the bone involved capable of regaining its load carrying capacity quickly.

More pertinent are the recent studies which have shown that the size and quality of the callus produced following a fracture is directly related to the stability of the fixation. Instability and movement in the region of the fracture invariably result in the production of a large immature callus, while stability permits the early development of a small mature callus spindle. Rigid fixation using compression plating techniques allows direct cortical healing to occur with no callus formation at all.

Small animal orthopedic surgery imposes some unique requirements upon fracture fixation devices. The ideal fixation device for fractures of long bones in animals should be simple to apply even on very small skeletal structures. It should involve relatively low cost, permit rapid and efficient healing, be well tolerated by the animal, and at the same time allow immediate ambulation.

Until recently, fracture treatment in animals employed mainly external splintage with the associated disadvantages of poor alignment control and poor toleration.

When internal fixation was perfected for human use in the 1940's its techniques were soon adopted by veterinarians. The use of such devices produced more favorable results, and were better tolerated by animals, resulting in simplified postoperative care. In the intervening years these techniques evolved to meet the needs of veterinary surgeons. While in human orthopedics the tight fitting Küntscher nail gained popularity, the veterinarians developed the intramedullary (I.M.) pinning technique using the round-bodied Steinman pin which usually did not fill the medullary cavity. Similarly, while medical men were able to use traction or full pin splintage with casts on their human patients, veterinarians turned towards such devices as the Kirschner splint for external skeletal fixation. The Steinman pin took advantage of the muscle tone to maintain alignment and worked well when used alone if the original fracture was stable enough to resist rotational forces and could maintain length. The Kirschner device was used to stabilize the fixation against these 2 weaknesses and could be used in conjunction with the pin.

All of these techniques have been proven by years of clinical experience in both disciplines. Within recent years the use of the compression plating technique was advanced by Swiss orthopedic surgeons (Muller *et al.*, 1963) and in the last few years veterinarians have added this method to their techniques available for fracture treatment. Unlike the equipment previously discussed, however, the mechanics and the histological healing dynamics following its use were documented in the dog by the original researchers who used this species in their experiments. At this time, however, very little clinical experience has been gained with compression plating in veterinary practice compared to the other methods of internal fixation. Thus it is apparent that more basic research is needed regarding such widely used devices as the I.M. pin and the half pin splintage in veterinary surgery, so that comparisons may be made with information already gained about similar devices used in human surgery and about compression plating, to provide a better understanding of fracture fixation.

Recently a device called the Sampson extracortical clamp was developed by Dr. A. Sampson.* This device appeared to potentially

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*Dr. Arnold Sampson, The Sampson Corporation, 214 South Craig Street, Pittsburgh, Pa.

possess the qualities of the ideal fixation device as previously described. It was simply clamped onto the periosteal surface of the fracture fragments. Its design suggested that it might be useful for efficient fixation of fractures where only limited exposure was available. Particularly intriguing was the opportunity which it seemed to offer for research into the potential value of extracortical fixation in general.

The present experiment was designed to compare the fracture healing which occurred following the use of four fixation methods employed to maintain reduction of an experimental femoral fracture in the dog. The methods investigated were: I.M. pinning with Steinman pins, I.M. pinning and half Kirschner splintage, compression plating and extracortical clamp fixation.

This comparison was made based on the following parameters;

1. The time and effort required to perform the surgical techniques and identification of possible problem areas related to the application of the devices.

2. The time required for a complete return to function of the operated limb and the ease with which this was achieved.

3. The type of fracture healing achieved as revealed by radiographic studies. Also, the stability of the fixation as revealed by the characteristics of the callus or changes in the reduction as demonstrated on radiographs.

4. The type and stage of healing achieved after a predetermined period of time as demonstrated by histologic studies of the fracture area.

Based on recent knowledge as discussed in the literature review to follow, the amount and type of callus was used to evaluate the efficacy of the fixation device in producing the desired results.

LITERATURE REVIEW

A. TISSUE ORIGIN OF BONE

Since man first turned his interest to fracture healing, there has been controversy over which tissue elements play the major role in this process. While Hippocrates believed that only bone marrow was capable of forming callus, Galen considered that the fracture fragments were joined together by some undefined cement-like substance which never developed into bone. Thus, research into the origin of callus began long before the development of the microscope and modern histological technique (Orr, 1953). These gross studies established early that bone was ensheathed in a membrane called the periosteum which possessed an outer membranous layer and an inner active layer. The relationship which the bark of a tree bears to the wood was soon compared with the periosteal layers and, hence, the term "cambium layer of the periosteum" (Ham and Harris, 1971). The callus was considered to be some type of effusion until Du Hamel, in the 16th century, proposed the "periosteal theory", designating that layer as the seat of the fracture healing process. In establishing this theory, he was the first to employ intra-vital bone staining techniques using, in this case, alizarin red (Ham and Harris, 1971). Keith, in his very inspiring book *Menders of the Maimed*, written in 1919, tells how a young surgeon Belchier noticed the red coloring in the bone of the pork which his host was carving. On enquiring, he found that his friend, a dye manufacturer, had fed the residue from madder root to his pigs after extracting the dye. Belchier

subsequently fed madder to experimental animals and showed that any new bone which formed while the madder was being fed was colored red. Du Hamel, learning of Belchier's work, fed the madder to experimental animals in which he had produced fractures, and demonstrated that the entire callus was colored red in contrast to the uncolored fragments which the callus was joining. He was also able to trace the origin of the red callus tissue to the periosteum. Almost 200 years passed before this same kind of study could be made in a more sophisticated way by means of autoradiography or radioactive tracer studies. Du Hamel's conclusion that periosteum was the source of callus began a great controversy which has lasted almost to the present. According to Keith, Hunter, a contemporary of Du Hamel, is an example of one who strongly opposed the periosteal theory, maintaining that new bone originated from the arteries which grew into the fracture area.

Many varieties of the old theories and a few new ones were proposed over the years, until the development of the microscope revealed new knowledge about the cell theory, at which time the controversy changed slightly. Thus, by the middle of the 17th century, Goodsir, studying bone microscopically, realized that it contained "self-acting units of living matter". Since he visualized periosteum merely as a limiting membrane, he felt that the repair of bone occurred through the action of these minute living units within the bone itself (Keith, 1919). This theory was to be further supported by the experiments of Gallie and Robertson (1920) and Ely (1922), who maintained that the periosteum definitely did not possess osteogenic powers. Ollier, however, also with the aid of the microscope, refuted Goodsir's theory and, showing that the deepest layer of the periosteum was cellular, used a series of clever experiments to demonstrate that it would indeed produce bone. This work provided the scientific basis for the principle that the periosteum was a two-layered membrane composed of an outer fibrous layer and an inner cellular layer which possessed osteogenic powers (Keith, 1919). Among those who refuted this idea was MacEwen (1912), who contended that the cells which gave rise to new bone were cells of bone and not of the periosteum, i.e., that the osteogenic layer of the periosteum really was part of the bone surface and not part of the periosteum. The important concept which all of this early work offered, however, was that the cells of the cambium layer, regardless of whether they belong to the periosteum or to the bone itself, represent a population of committed cells of a special ineage responsible for bone formation both in growth and repair (Ham, 1930).

B. FRACTURE REPAIR

During the last few decades an overwhelming majority of investigations have revealed that the periosteum is of prime importance in fracture healing and repair, although the endosteal cells in the haversian systems and those in the marrow cavity also seem to be involved (Ham and Harris, 1971). Different authors place different degrees of importance to these 3 tissue elements. Wehner (1920), Kolodny (1923), Koch (1925) and Cowan (1928) emphasized the major importance of the periosteal cells while McGaw and Harbin (1934) and others considered the endosteal cells and the undifferentiated cells of the bone marrow to be at least as important if not more so. From an overall view of the literature, one tends to conclude that all three layers are osteogenic but that the periosteum plays the dominant role (Lexer, 1924; Ham, 1930; Hertz, 1936). Ennecking (1948) proposed the novel idea that, while the periosteum and endosteum are the most important layers, the fibrous layer of the

periosteum can be transformed by metaplasia to possess osteogenic potential. This view may have been derived from the theories of bone induction which were being developed at that time. These began with Huggins' discovery in 1931 that bladder mucosa, when transplanted into the connective tissue of the abdominal wall, would cause metaplasia to occur in the connective tissue cells and induce them to form bone.

At present, the controversy seems to be fairly well resolved and a generally accepted view of the histologic dynamics of fracture healing has developed mostly from the works of Urist and McLean (1941, 1950), McLean and Urist (1955), Pritchard and Ruzicka (1950), and Ham and Harris (1971). With only minor differences these authors and most others working in the field generally agree with the following concepts:

C. THE BONE CELL FAMILY

Bone is one of those tissues in which the cells are highly differentiated to perform a number of specific and specialized functions. This level of differentiation is only obtained at the expense of a complete loss of reproductive capacity by these cells. Therefore, such a tissue must have a reserve of less differentiated cells of the same cell lineage associated with the fully differentiated ones to provide it with new cells to replace those that die or are destroyed. While such cells must remain undifferentiated enough to retain reproductive capacity, they must have differentiated sufficiently to be committed to the cell lineage which terminated with the creation of the mature cell of that tissue. These relatively undifferentiated cells are called "stem cells" and the stem cell of the bone cell family is the osteogenic cell. This self-perpetuating cell lineage is responsible for bone growth and bone repair (Ham and Harris, 1971; Tonna and Cronkite, 1961).

When a bone is fractured, these cells respond by active proliferation beneath the fibrous layer of the periosteum to form a cuff of callus around the fracture site which pushes the fibrous layer back as it grows. Simultaneously, a sparse internal callus forms from the endosteum and the undifferentiated cells of the bone marrow. The osteocytes in the original bone adjacent to the fracture site die as far back as the nearest anastomotic branch of haversian vessels. The callus is composed of trabecular bone at its proximal and distal attachment to the original cortex while, in its more central areas, remote from a satisfactory blood supply, it is composed of cartilage and fibrocartilage. The profuse proliferation of osteogenic cells in these more central areas of the callus have outgrown their blood supply causing a local decrease in oxygen tension which always causes the osteogenic cells to differentiate to chondroblasts and fibroblasts. As the fusiform callus cuff calcifies, there is a marked increase in strength and rigidity which produces full stability at the fracture site. This seems to cause a decrease in cell proliferation. Blood vessels can now penetrate the callus, and cartilage is replaced by trabecular bone through the process of enchondral ossification to form the "bony callus". This bony callus eventually is removed in the process of remodeling during which the bone returns to its original tubular form and strength. All of these tissue changes can be attributed to the activity of the "bone cell family" which is represented in the normal resting bone, by the osteogenic cell. This stem cell can differentiate depending on local conditions and initiating factors into any of the active members of the family which include osteoblasts, osteocytes, osteoclasts, chondroblasts and chondrocytes (Ham, 1969).

The osteoblasts are the cells which produce the new bone matrix. They can differentiate into osteocytes, the cells of living bone, when they become enveloped in the matrix which they produce. Chondroblasts and chondrocytes are the cells of cartilage which are analogous to the osteoblasts and osteocytes of bone (Ham, 1969).

The multinucleated osteoclasts, which are the cells associated with bone resorption, are often seen in histologic sections and lie within small depressions which they have created in bone surfaces (Ham, 1969).

All of these principles have been confirmed by the more sophisticated and precise tests which are being employed in current studies of bone physiology. These include autoradiography (Tonna and Cronkite, 1968), intravital fluorescent bone labeling (Frost, 1964; Harris *et al.*, 1962), microradiography (Jowsey *et al.*, 1965), and cell population dynamics (Till and McCulloch, 1961).

D. FRACTURE HEALING THROUGH CALLUS FORMATION

The factors which initiate healing by activation of the bone stem cells are unknown, as are the mechanisms which control the healing process. Some external factors which seem to affect osteogenic cell proliferation and, therefore, bone growth and healing are discussed in the literature. These include mechanical forces such as compression, tension, and shear forces, electrical phenomena such as intrinsic electrical potentials, and piezoelectric effects, as well as chemical controls and cell population events (Dickerson, 1970).

As previously stated, the osteogenic cells of the periosteum, endosteum and haversian lining can differentiate to produce either bone or cartilage depending on local conditions. In the presence of high oxygen tension they are stimulated to differentiate to osteoblasts and osteogenesis while under the reverse conditions they produce chondroblasts which in turn produce cartilage (Bassett, 1962). This explains why a normal early callus is composed of trabecular bone at its ends and surfaces, but cartilage and fibrocartilage in its deeper areas (Ham and Harris, 1971).

The size of the callus produced by a given individual with a given fracture is related somehow to the amount of movement and stability present at the fracture site. Thus, an unstable fracture fixation will result in the production of a voluminous amount of rapidly growing callus tissue while rigid fixation causes the reverse to occur. The large rapidly growing callus, because of its high content of cartilage and fibrous tissue, will form a softer union than the smaller, more mature callus which is more rigid (Yamagishi and Yoshimura, 1955). Either type of callus, formed by necessity to stabilize a particular fracture, will eventually undergo the changes which result in a fusiform, firm bony callus. The region of bony callus is probably as strong as the normal cortical bone but, since the woven bone of which it is composed is biomechanically inferior to compact bone, it is substituting quantity for quality. As the quality of the bone across the fracture gap improves due to an increase in the amount of lamellar bone and the subsequent remodeling to mature bone, the diameter of the fracture area will approach that of the normal cortical shaft (Segmüller, 1966). Thus, there is a definite sequence of events which occur from the time of fracture until complete regeneration of the fractured bone has occurred (Ham, 1930; Wray and Lynch, 1959; Rhinelander and Baragry, 1962; Geiser, 1963).

E. FRACTURE HEALING FOLLOWING RIGID FIXATION

Krompecher (1937), in his studies of embryonic bone formation, showed that new bone formation takes place in a neutral area which is free of mechanical stresses. He proposed the existence of an "angiogenic" type of bone formation. Based on this, Schenk and Willenegger (1963) postulated the osteogenic unit to be a capillary sprout surrounded by perivascular osteoblasts. Bassett *et al.* (1961) and Bassett (1962), using cultures of embryonic osteoblasts, were able to study the relationship of environmental factors to embryonic cell differentiation. In essence, it was found that subjecting them to compression caused the production of bone while substituting tension caused the production of fibrous tendon-like tissues. Osteoblasts under pressure in the presence of high oxygen tension formed new bone and, with a lack of oxygen, formed cartilage. Tension plus high oxygen concentration led to fibrous tissue formation. These results confirm the prior *in vivo* experiments performed by Nicole (1945) using a tubular bone in the dog. He showed that connective tissue placed under compression changed to cartilage and then to chondrogenic bone and that primary compression of bone produced chondrogenic bone immediately. Needham (1952) referred to the healing of bone as a "physiological regeneration" in response to injury. Schenk and Willenegger (1964), using the tetracycline labeling technique of Milch *et al.* (1957) and Frost *et al.* (1961), were able to quantitate the physiological changeover of compact bone. They were then able to measure the osteoblastic activity of a fractured limb and compare this to the opposite normal bone. In this way they clearly demonstrated the role played by compact cortical bone in fracture healing showing that very efficient osteoblastic activity can develop from haversian systems under certain conditions through a remarkable increase in the physiological regeneration rate. Schenk and Willenegger (1967) demonstrated this primary healing directly across the fracture site and also the formation of primary osteons within the fracture gap. This process was illustrated clearly by Olerud and Danckwardt-Lilliestrӧm (1968) using tetracycline labeling in conjunction with India ink techniques for portraying the capillary pattern. From these earlier studies developed the principles of fracture healing under rigid fixation. If the fixation provides adequate stabilization, the periosteum and periosseous tissues show only minimal activity and, thus, no external callus tissue is formed; but healing occurs directly from cortex to cortex across the fracture gap (Allgower, 1964). This is the kind of direct cortical healing which occurs following rigid fixation using the technique of the "Association for the Study of Osteosynthesis" (A.O.), and which has been termed "primary bone healing" by Müller *et al.* (1963, 1970). The term suggests that this is a new type of fracture healing as compared to healing through the production of callus. It is important to note that the direct cortical healing described above is just a manifestation of the response of the same osteoprogenitor cells, the osteogenic cells, to a change in external environment. In the case of rigid fixation the bone plate represents an attempt to neutralize the forces acting on the fracture site, thereby simulating the mechanical environment which would exist there if a mature bony callus were present. It seems that when the bending forces acting at the fracture site have been neutralized, either by bony callus or some mechanical fixation device, the signal is triggered to begin cortical healing and remodeling. This is accomplished by the cells of the bone cell family through an acceleration of the normal physiological mechanisms of bone production and resorption, which are continually working in balance in all living bone as part of its normal turnover pattern (Schenk and Willenegger, 1964; Ham and Harris, 1971).

F. EARLY HISTORY OF FRACTURE TREATMENT

Many principles which are basic to orthopedic surgery today were developed in an era prior to the microscope and the x-ray. The early orthopedic surgeons were ingenious in their development of large machines and devices for the reduction and immobilization of fractured limbs. Their work often resulted in the production of gross deformities and non-unions. Amputation was a frequent sequel to the fracture of a long bone. Part of the reason for their high failure rate was the fact that amost nothing was known about bone physiology. Nevertheless, some very outstanding figures emerged from the early years of the development of fracture treatment. Among them was John Hunter who, near the end of the 18th century, established the principle that "living tissues possess an inherent power for self-healing and the surgeon can only help by tending these powers" (Keith, 1919). Others, such as John Hilton, who taught a century later, strongly advocated the use of rest as the basis of therapy (Keith, 1919). He implanted this idea firmly into the thinking of a former student, Hugh Owen Thomas, who spent a lifetime developing his principles of conservative fracture treatment and the techniques and devices with which he applied them. Modifications of the Thomas splint continue to be used today in both human and veterinary orthopedics (Keith, 1919). He is described by Robert Jones (1913) as an "applied physiologist" using as his basis for treatment a complete knowledge of function. He advocated "resting" of the fracture area while attempting to maintain function in adjacent structures and to derive maximum mechanical advantage from them. Plaster of Paris was introduced

by Mathijsen in 1852 and was in wide use at that time (Orr, 1953). Closed reduction and conservative methods of treatment were universal then and the major controversy centered around the question of whether a fracture should be "rested" or "stimulated by passive movement" (Keith, 1919).

The use of open reduction began with the advent of aseptic surgery introduced by Lister in 1866 when he wired a fractured patella using operative techniques (Keith, 1919). It soon was complimented by the introduction of the x-ray by Roentgen in 1895 (Orr, 1953). Keith, in his book *Menders of the Maimed* (1919), describes how a dynamic orthopedic surgeon, Arbuthnot Lane, really began the use of open reduction with the repair of a tibial fracture using screws, and how it took him 15 years to make open reduction and "osteosynthesis" acceptable among his peers. The term osteosynthesis was coined by Lambotte of Antwerp in 1888, who was the first to use a bone plate which he applied to the repair of a tibial fracture. Around 1895, Lane designed the Lane bone plates and screws (Lane, 1909).

In 1910, when the British Medical Association met in London, they compared the results of 3 of the then current methods which were: (1) closed reduction with external splinting, (2) massage and mobilization, (3) direct open methods as advocated by Lane. The statistics showed that the non-operative methods gave better results in patients under 15 years of age, while open methods proved more satisfactory for people above that age. According to Keith, the principles of open reduction which Lane advocated were: (1) perfect reapposition of fractured fragments to allow adjacent parts to maintain their natural relationships, (2) minimal gap between fragments, (3) asepsis, (4) passive movement of

parts during the later stages of healing. These are principles which are recommended yet.

The Lane plating methods were greatly improved upon by many who followed him, including some American orthopedic surgeons such as Sherman (1912) of Pittsburgh and Clay Ray Murray of New York (Anderson, 1965). These people did a great deal of work on the design of plates and screws which vastly improved the ability of this equipment to resist breakage. The Sherman bone plate is still in general use. Stuck (1937) studied the electrolytic action generated by screws and plates of different alloys, and developed alloys of inert metals from such elements as cobalt and molybdenum. Key (1946) continued this work using cold rolled steel. Thus, materials used for implants were greatly improved.

Traction, using a device similar to the Balkan Frame, was first introduced by Bardenheurer of Cologne over 100 years ago and remains a popular method for fracture treatment (Keith, 1919). The Steinman pin originated as a transfixation pin for use in traction and was largely replaced during World War I by the Kirschner wire which reduced the number of pin tract infections associated with the larger Steinman pin (Magnuson, 1936). Lowen (1921) described the use of a round steel pin in the treatment of fractures of the femoral neck in children, the advantage being that it could be turned into the bone rather than pounded in with a mallet. This reduced the trauma to small bones, a point which may be significant in small animal orthopedic surgery.

Until the early 1940's, veterinary fracture treatment was predominantly conservative in nature and pins were only used in skeletal traction or in such skeletal fixation devices as the Stader splint (Nichols, 1943). In a thesis on fracture treatment in the dog, Nichols

(1943) gave an excellent detailed description of the methodology used at that time in the repair of every type of fracture commonly seen. Most of the techniques involved external splintage or skeletal splintage. The impression which this manuscript imparts is that the early veterinarians applied familiarity with skeletal and muscle interrelationships to the application of these splints to a much greater degree than do modern veterinarians. It seemed that with the great shift towards open reduction which occurred in human orthopedics in the early 1940's, veterinarians tended to favor surgical methods of repair and abandoned some of the finer details of closed reduction and external splintage which at that time had reached a fairly advanced level of development (Nichols, 1943).

G. INTRAMEDULLARY NAILING

Experiments with intramedullary (I.M.) fixation began and progressed during the first half of the century. Details of methods for I.M. fixation of bones were published by Nicolaysen (1897), Lambotte (1913), and Orr (1920). All of these men used thin nails for the I.M. fixation of small superficial bones such as the clavicle, metacarpals and femoral neck. The first use of large nails which filled the medullary cavity was credited to Groves (1916). Originally he experimented with the use of nails in the femoral neck, but he later introduced nails into the greater tuberosity for fractures of the humerus, and through the olecranon for fractures of the shaft of the ulna. He even used the retrograde method of introducing nails into the medullary cavity of the femur. However, like all of his predecessors, he did not use long nails which would seat in both metaphyses. Many other materials were used for nailing including bone pegs (Hogland, 1917). None of these devices was long enough and, when metal was used, it often caused a tissue reaction which resulted in bone resorption and loosening of the nail. With the development of biologically inert metals such as vitallium and stainless steel, and the successful nailing of the femoral neck by Smith-Petersen, came new interest in I.M. nailing (Smith-Petersen *et al.*, 1931). I.M. fixation using Kirschner wires was used by Danis (1949) and Lambrinudi (1940). Rush and Rush (1939) used Steinman pins. These last 2 methods included the practice of leaving the end of the pins outside of the skin.

The first effective method of I.M. nailing appeared with the publication of Küntschner's report (1940) on the results of I.M. nailing employing a long, strong "elastic" nail of his own design. It appeared in the German literature in the early months of World War II but was first seen by Allied surgeons working with prisoners of war in 1943. His clover-leaf nail was so designed to fill the medullary cavity completely, making contact with the narrow waist and lodging in both metaphyses. The clover-leaf design gave it an elastic-like grip on the walls of the medullary cavity. This method was so effective that within a short period of time the literature was flooded with reports describing the clinical use of it for fractures of every suitable bone in the body. While it was probably overused in these early days, the method has now developed into an important addition to the resources of fracture therapy (Soeur, 1946; Dickerson, 1970). Küntscher's most recent advance in his technique following the development of both open and closed methods of introduction was the practice of reaming of the medullary cavity prior to nail insertion (Küntscher, 1965). This method has been endorsed recently in a thorough study by Danckwardt-Lilliestrðm *et al.* (1970) using fractures of the rabbit tibia.

H. I.M. PINS IN VETERINARY MEDICINE

At the time that Küntscher developed his famous I.M. nail, veterinary surgeons were using mainly external splintage for fracture treatment (Nichols, 1943). Open reduction was applied infrequently and consisted either of wiring or plating, or the screwing of bone fragments. One of the earliest references to intramedullary fixation to be found in veterinary literature reports on the results of I.M. fixation in man (Wright, 1944). In this article, the American Army reported unfavorable results using I.M. nails in fractures of war casualties, osteomyelitis being the most frequent complication. In 1943, the first report appeared on the use of the Küntscher method of fixation in animals. The method was developed by Frick *et al.* (1948) at Kansas State Veterinary Clinic. Of the various methods tried, they endorsed the use of 3 Kirschner wires inserted into the medullary cavity. In 1948 Brinker was the first to report on the use of I.M. pins using 12 cases in dogs and cats. He employed Steinman pins and, in smaller animals, the pin from the Stader splint. Fractured bones treated included the femur, mandible and tibia. In the same year Bernard (1948) described the technique for using a Steinman pin introduced through the trochanteric fossa for closed I.M. nailing of the femur in dogs using Küntscher's method. Greene *et al.* (1950) gave a very complete summary of the indications and limitations of I.M. nailing in small animals and favored the practice after evaluating their results with 400 cases. Leighton (1950) described his new Leighton shuttle pin along with several case reports. This was a stainless steel double-pointed nail with a hole halfway along its length. It was inserted by open reduction into the medullary cavity of the proximal fragment with a wire suture passing through the hole. The fracture was reduced and the suture tightened with a special tool which drew the pin into the distal fragment. The suture was then removed and the pin left permanently in place. Carney (1952) reported on the use of the Rush nail in veterinary surgery. He described its history and technique and gave several favorable case reports on the use of this nail, with the hooked head and sled-runner point. Garbutt (1952) reported on the use of this nail which was inserted by open reduction for fractures of the distal shaft of the femur. Armistead (1954) described the influence of contact and compression on fracture union. His comments centered around the Eggers slotted plate which was one of the first used in human surgery (Eggers *et al.*, 1949). Brinker (1955) presented a complete discussion of his methods of treatment of fractures of the distal end of the humerus in small animals. He employed I.M. pins using various techniques often supplemented by the use of either a Thomas splint or a Kirschner splint. A report by Temizer (1956) described the use of heterogenous bone pins in the repair of fractures of the long bones in various species. In 1954, the Jonas splint was developed by 2 veterinarians after whom it was named. A number of subsequent articles appeared in the literature describing clinical cases where this splint was used for treatment of a variety of fracture types (Jonas and Jonas, 1957).

I.M. nailing has continued to be the most popular form of I.M. fixation used in dogs. From time to time reports have appeared describing the use of small Küntscher nails in small animals (Jenny, 1965), but these are not as suitable for small animal work as they are for human use. The Steinman pin continues to be the usual type used by veterinarians. A modification of I.M. nailing was developed by Hankes and Gorman (1968) at Colorado State Veterinary College. This was an indwelling prosthetic bone extender used to maintain length, while comminuted fractures of the femoral shaft underwent healing.

I. THE KIRSCHNER SPLINT

This splint represents a type of skeletal fixation which employs pins which cross the bone in a transverse direction and pass to the outside where they are joined together by a metal bar (Ehmer, 1947). The method probably had its earliest origin in the different forms of skeletal traction developed in human medicine. The Steinman pin (1907) and Kirschner wire (1909) both came into use in traction units and later for use in full pin splintage (Magnuson, 1936). The first half-pin splintage had been used by Clayton Parkhill in 1897 (Magnuson, 1936). But the real forerunner of the Kirschner device was the Roger Anderson half-pin splintage developed for human use in 1932. This was the first device of its kind to successfully allow patients early ambulation with comminuted fractures (Anderson, 1932). Stader (1937), a veterinarian, made a preliminary announcement of results achieved using his new Stader splint. This device was a reduction splint as well as a fixation splint, designed so that after the insertion of the pins into the bone, it could be adjusted to manoeuver the fragments into the reduced position, and then tightened to achieve permanent fixation. In 1942 a review was published by Shaar and Kreuz reporting successful use of the Stader splint for the treatment of human fractures. Reports have since appeared detailing the use of this splint in various types of fractures and in a wide variety of species (Lacroix and Mayer, 1944; Hutchings, 1945).

The Roger Anderson splint was modified for use in small animals (Ehmer, 1947). It is this device* which we employed in the second series of dogs in this experiment.

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*Kirschner Manufacturing Co., Rt. 2, Box 160, Vashon, Washington.

J. COMPRESSION PLATING

Bone plates were first introduced with the advent of open reduction and popularized by Lane (1909). Sherman tested different metals and a variety of modifications of the Lane plate and improved its design. The popular plate used in orthopedics until very recently has been this same Sherman plate made of stainless steel or vitallium.

The value of compression plating in providing rigid fixation and healing without radiological evidence of callus formation was recognized by Danis (1949). He described this direct healing of cortex to cortex in shaft fractures using the term "soudure autogene", which was translated to mean autogenous weld. His work was based on the experiments of Krompecher (1937), who had analyzed the effect of various mechanical conditions on fetal ossification as previously described in this review. Charnley (1948) had shown that compression across an osteotomy site augmented the healing process on metaphyseal bone.

On the basis of these and other studies (Altmann, 1950; Matzen, 1952; and others) it soon was concluded that rigidity of the fixation was the necessary element for the development of primary healing of a fracture. Within the succeeding few years, further research indicated clearly that the extent of callus formation was dictated by the stability of the fixation (Yamagishi and Yoshimura, 1955; Friedenberg and French, 1952; and others).

First experiments with compression plating techniques were carried out using sheep and rabbits, but these species were not considered suitable for such studies at that time due to the diverse structure of their cortical bone (Geiser, 1963). Schenk and Willenegger (1963) began to use dogs in their research and stated that these experiments promised to be more successful.

It is the work of all these researchers which stimulated the formation of the Association for the Study of Osteosynthesis (A.O.) (Müller *et al.*, 1963). This group has designed new implants based on the biomechanical principles of stability and compression and have developed the methodology for their proper use.

They showed that, in the light of Krompecher's work, adequate and permanent mechanical fixation of a meticulously reduced fracture zone was necessary to achieve direct cortical healing (Schenk and Willenegger, 1963). It was also demonstrated by use of strain gauge compression plates that the degree of compression within physiological limits did not affect the fracture healing (Perren *et al.*, 1969c). Many new and interesting studies are currently in progress in the field of compression plating and direct cortical bone healing (Allgöwer *et al.*, 1969). New fluorescent labeling materials have been developed for the study of fractures (Rahn and Perren, 1971). Some of the work in the area of intravital bone labeling as applied to direct cortical bone healing has already been reported (Schenk and Willenegger, 1967; Olerud and Danckwardt-Lillieström, 1968). Many new advances in this area are forthcoming (Rhinelander, 1970; Willenegger, 1971).

Numerous clinical reports have appeared in the recent literature with mostly favorable results, using rigid fixation (Naiman *et al.*, 1970; Ruedi *et al.*, 1971; and others). These techniques are presently being employed in small animal practice, and the A.O. group of orthopedic surgeons now has a veterinary section added to their regular instructional course.

Reports on the general use of compression plating techniques have appeared in the veterinary literature over the past few years (Sumner-Smith, 1970; Herron and Doonan, 1971). Many orthopedic manufacturers have compression equipment available for veterinary use.* In the Richards continuous strength plate** of the Hirschhorn modification the compression may be applied over the center of the plate rather than from the end which seems to be a distinct advantage where limited exposure is a problem (Hickcox, 1970; Horne, 1971). Compression plating is gaining increasing use in veterinary medicine, including application in large animals (Dingwall *et al.*, 1971).

K. EXTRACORTICAL FIXATION

This method of internal fixation involves the use of an implantable clamp which attaches to the surface of the bone fragments and holds them firmly in apposition.

Very few such devices have been described in the literature. Brown (1911) designed an extracortical clamp and tested it in fractures of the canine humerus. In his experiments the device failed, partly because of poor surgical technique, infection and loosening of the clamps before the fracture could gain adequate stability. Bevins and Sullivan (1956) reported the trial of a special extracortical clamp which was applied with compression forceps to the long bones of dogs and cats. It was used successfully in 9 cases of fractures including the radius, ulna and femur. It was also used in the treatment of comminuted fractures in conjunction with an I.M. nail. They reported that full use of the affected limb was achieved by the fourth day in several cases and after 3 weeks in the remainder. This clamp was designed to cover 2/3 of the

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*Zimmer, Warsaw, Indiana.

**Howmet Corp., Med. Div., 359 Veterans Blvd., Rutherford, N.J.

***Richards Mfg. Co., 1450 Brooks Rd., Memphis, Tenn.

bone circumference and had no spikes but had a smooth surface to contact the bone. This prevented the clamp from holding the fragments in distraction but allowed muscle tone to draw them together. In all 9 cases, the healing was satisfactory and the clamp was left permanently in place.

Lee and Blakemore (1964) developed and experimented with a stainless steel clip for the treatment of fractures of the iliac shaft. An uncomplicated surgical procedure was developed for its use. The clip was applied with a rubber-shod Rongeur forceps and was stapled extracortically across the fracture line. It was found to maintain reduction leading to early mobilization of the animal and rapid healing. This clamp was given clinical trials by local veterinary practitioners and the results were encouraging.

L. TETRACYCLINE LABELING

Since its discovery by Milch *et al.* (1957), this technique has come to play an indispensable part in the study of bone physiology and bone healing dynamics. The underlying principle involved is that tetracycline is deposited in those parts of the bone substance which are undergoing mineralization at the time of administration of the antibiotic. By recording the dates of injection of several consecutive tetracycline doses, the rate of bone regeneration can be determined by measuring the distances between consecutive labels as visualized under fluorescent microscopy (Frost *et al.*, 1961). Using specialized counting techniques and prescribed mathematical formulae, the turnover rate of cortical bone can be determined for a particular individual or a particular area of the skeleton (Frost, 1969).

This intravital staining technique using tetracycline has been employed to study the dynamics of fracture healing following rigid fixation under compression (Schenk and Willenegger, 1964; Olerud and Danckwardt-Lilleström, 1968). It was also used to measure the physiological turnover rate within normal cortical bone (Amprino and Marotti, 1964), and adjacent to a fracture during the healing period under rigid fixation (Schenk and Willenegger, 1967). Recently, callus formation following experimental fractures has been studied in animals using this technique (Coutelier, 1969; Lacroix, 1970).

MATERIALS AND METHODS

A. EXPERIMENTAL ANIMALS

Series 1 Intramedullary pin fixation - Dogs #1 to 4 inclusive. A 3/16 inch double-ended, trochar-pointed Steinman pin was introduced into the medullary cavity using the standard retrograde insertion technique and open reduction (Figure 6). Two dogs were euthanatized at 10 weeks and 2 at 12 weeks.

Series 2 Intramedullary pinning plus half Kirschner splint - Dogs #5 to 8 inclusive. The half Kirschner splint was used to supplement the pinning method described above (Figure 18). It was removed at 6 weeks. The I.M. pin was not removed until euthanasia. Two dogs were destroyed at 10 weeks and 2 at 12 weeks.

Series 3 Compression plating - Dogs #9 to 11 inclusive. The standard A.O. compression plating techniques and equipment were used (Figure 25). It was necessary to depart from the A.O. system in the application of the compressive force due to the lack of exposure available in these dogs. Instead of the A.O. compression device, a Bachaus towel clamp was modified to create compression across the fracture site during the plating procedure. A 5-hole plate was used on Dog #10 (Figure 28) and 4-hole plates on Dogs #9 and 11 (Figure 25). All dogs were euthanatized at 8 weeks.

Series 4 Extracortical clamp - Dogs #12 to 19 inclusive. This clamp (Figure 1) and inserter (Figure 4) were originally designed by Dr. A. Sampson for extracortical fixation of fractures of the long bones. It was applied to the cranial border of the femur in 4 cases (Figure 34) and to the caudal border (Figure 38) in the other 4 cases. The 8 dogs in this series were destroyed at 10 weeks.

A total of 19 male Beagle dogs were used in this project. They were housed in individual kennels at the Michigan State University Veterinary Clinic. For easier reference, the dogs were numbered from 1 to 19 (Table 1).

B. ANESTHETIC

Each dog was induced using thiamylal sodium* in a 4% solution given to effect, intubated, and maintained in a surgical plane of anesthesia with methoxyflurane** inhalant anesthetic. The inhalant was vaporized in oxygen, combined with an equal amount of nitrous oxide gas and delivered to the animal in a semi-closed anesthetic system.***

C. PREOPERATIVE PREPARATION

When the animal was fully anesthetized, the hair was clipped from the right hind leg, from the dorsal midline to the hock. The leg was scrubbed in a standard way with a detergent soap solution. It was dried and a germicidal skin preparation solution was applied to the entire clipped area and allowed to dry. The rules for aseptic technique were

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*"Surital", Parke, Davis & Company, Detroit, Mich.

**"Metafane", Pitman & Moore Co., Indianapolis, Ind.

***Ohio Heidbrink, Model 960, Madison, Wisc.

observed carefully as the dog was transferred to the operating table. A second application of germicidal solution was used on the area and allowed to dry. The surgeons followed a standard hospital scrubbing and gowning routine and draped the dog in preparation for aseptic surgery.

D. SURGICAL TECHNIQUE

A standard lateral approach to the shaft of the femur was used to expose the fracture site (Piermattei and Greeley, 1966). A skin incision was made along the craniolateral border of the shaft of the femur along a line between the greater trochanter and the patella. The subcutaneous fat and superficial fascia were incised and the skin margins undermined and retracted. A stab incision was made through the fascia lata at the cranial border of the biceps femoris muscle. This incision was lengthened to coincide with the skin incision. The vastus lateralis muscle was separated from the biceps femoris by blunt dissection and retracted cranially. The intermuscular connective tissue between these 2 muscles was dissected away to reveal the lateral border of the femur. The caudal border of the vastus intermedius which lies against the cranial border of the femoral shaft was retracted cranially with the vastus lateralis (Figure 2). In the 4 cases where the extracortical clamp was to be applied to the posterior border of the femur, the adductor muscle was reflected caudally. This was accomplished by elevating the periosteum from the caudal surface of the femur and reflecting it caudally with the adductor muscle attached (Figure 3).

The double action bone cutters were placed on the midshaft of the femur from cranial to caudal, and their blades tightened onto the bone lightly. The position of the blades was adjusted so that they were at right angles to the shaft in both planes. The instrument then was closed firmly and sharply, and if no rotation of the instrument was allowed during closure, a fairly uniform simple transverse fracture usually resulted. The form of the fracture so produced was such that when it was reduced, some degree of interdigitation occurred between the fragments which added rotational stability to the reduction (Figure 3). Following reduction, the fracture was fixed using one of the 4 methods outlined. The incision in the fascia lata was sutured with 000 medium chromic catgut* using a simple interrupted pattern. The skin incision was closed using non-absorbable suture material** also in a simple interrupted pattern. The dogs recovered from anesthetic in their individual cages and were kept in these cages during the course of the experiment. They were allowed into the runs only after some use of the operated limb was attained.

E. METHODS OF FIXATION

1. Intramedullary nailing. An 8-inch trochar-pointed stainless steel Steinman pin, 3/16 inches in diameter, was used to fix the fracture in the first series of 4 dogs. In all cases, the pin was introduced using a Kirschner hand chuck and the standard retrograde insertion method (Leonard, 1960). After the pin was inserted into the medullary cavity and was ready to be advanced distally across the reduced fracture site, the distal fragment was angled cranially a slight amount to allow the pin to penetrate more deeply into the trabecular bone in the caudal

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*Surgical Gut, Clinical Supply Corp., Mount Vernon, N.Y.

**"Tasalon", Coats and Clark, New York, N.Y.

part of the distal metaphysis (Brinker, 1965). Radiographs were taken to assure that axial and rotational alignment had been maintained and that the pin was within 1/4 inch of the articular surface but not into the joint (Figure 6). The pin was cut to an appropriate length and the skin closed over it. Closure was carried out as previously described and postoperative radiographs were taken. No supplementary fixation was applied to the leg. The reduction was maintained entirely by the I.M. pin.

2. Intramedullary pin with half Kirschner splint. The procedure for pinning was carried out in this series of 4 dogs using the same method as was described in the previous section. Before closure of the incision, however, 2 1/16 inch Steinman pins were driven transversely through the femur, 1 in each fragment, from the lateral to the medial cortex (Figure 18). They were driven through the skin adjacent to the incision line, through the underlying muscle and into the bone. They were allowed to pass through the opposite or medial cortex a distance of 1/8 inch. They passed through the bone obliquely in such a way that they made an approximate angle of 17 degrees with a line drawn perpendicular to it (Figure 18). They were placed in the same axial plane and approximately equidistant from the fracture line. With the reduction maintained, these pins were joined with Kirschner clamps to a common bar (Figure 18). The two pins thus became part of a single unit which reinforced the fixation against shortening of the bone or rotational displacement at the fracture site (Ehmer, 1947; Brinker, 1965). This is called half pin splintage. When the Kirschner splint was firmly secured, the routine skin closure was carried out. No supplementary fixation was added to these devices. The half Kirschner device was

removed 6 weeks postoperatively. The I.M. pin remained in place until the time of euthanasia.

3. Compression plating. The technique used in this series was essentially the A.O. method, with one slight modification (Müller *et al.*, 1970). Following reduction, a narrow A.O. compression plate of appropriate length was selected (Figure 25). The plate was contoured using the A.O. plate bender to correspond with the contour of the lateral surface of the bone as determined from the appropriate radiographic view or by trial at the fracture site. It was then placed in its final position on the lateral cortex of the distal fragment and clamped into position using the Verbrugge plate retaining forceps. One screw hole was drilled through both cortices of the distal fragment using the 4.5 mm. drill bit. The depth gauge was used to aid in selecting a screw of the proper length to pass through the hole in the plate, through both cortices of the bone, and to protrude 3/16 inch beyond the opposite cortex. This hole was then tapped using the 4.5 mm. bone tap. With the plate in the desired position, this screw was seated. The fracture was then reduced and held in place with a bone clamp. Beyond the proximal end of the plate, an anchor screw hole was made in the cortex of the bone on the same axis as the center of the plate. This was the screw which would normally be used to attach the compression device to the bone at a point proximal to the end of the plate.

In these experiments because of the length of the plates being used, compared to the relatively shorter length of bone which could be surgically exposed in Beagle dogs, a departure from the prescribed A.O. method of compression was employed. The compressive force was applied to the fragments using a modified Bachaus towel clamp. The sharp points were removed from the jaws of the clamp. One jaw was inserted into the anchor hole created for this purpose, the other into the nearest hole in the proximal end of the plate, and manual pressure was applied to the clamp, thus drawing the plate and attached distal fragment towards the trochanter and thereby creating a compressive force across the fracture site. This force was maintained until the screws could be inserted, attaching the plate to the proximal fragment. When the modified clamp was released, a compressive force was maintained across the fracture gap by an equal and opposite tensile force which existed in the plate. The mechanical system between plate and bone having been thereby established, the remaining screw holes were prepared as previously described and all screws were firmly tightened. The incision was closed in the previously described way.

Three dogs were employed in this series. A 4-hole plate was used on 2 of these and a 5-hole plate on the other (Figure 28a). No supplementary fixation was provided following surgery. The plates were not removed until after the dogs were euthanatized.

4. Extracortical clamp. This clamp was thought to be made of a pretreated, biologically inert, implantable metal (Figure 1). It was composed of 2 interlocking plates, each of which possessed 8 spikes on its inner surface. These plates were joined together by a sliding mechanism composed of 2 halves, one of which extended from each of the plates and which came together to form the third side of the complete clamp. With the clamp in position on the bone, the 2 plates were forced together by a special inserter, thereby clamping down medially and laterally on the previously reduced fragments (Figure 4). The inserter was especially designed for positioning and tightening of the clamp, and for seating

of the retaining screw which maintained the clamping effect after the inserter was removed.

Before the skin incision was made, a clamp of appropriate size was selected and secured in the inserter (Figure 4). After the standard fracture was created and carefully reduced, the clamp, in its position within the inserter, was placed over the bone so that the distal plate was against the medial surface of the bone and the proximal plate was against the upper, lateral surface. The sliding mechanism which joins the 2 plates was against the anterior surface of the bone. This was the position which previously had been described as the anterior clamping position and had been used in the first 4 dogs of the series (Figure 12). The large tightening nut was then screwed down, pushing the tightening plate with its attached proximal plate of the clamp downward, forcing it against the bone. In this way, the medial and lateral surfaces of the bone were squeezed between the plates of the clamp, the teeth of which penetrated the cortex. The adjustable sliding surface of the clamp was locked into this position by tightening the retaining screw using a screwdriver built into the inserter. The jaws of the inserter could then be opened and the inserter removed. The pressure which the inserter had created was then maintained by the clamp and retaining screw (Figure 3).

At this point the reduction was checked for stability by gentle manipulation. If it was considered to be secure, routine closure was performed and postoperative radiographs taken. If these showed the fixation to be satisfactory the dog was returned to its cage and allowed the same freedom as those in the other 3 series.

F. POSTOPERATIVE CARE

All dogs were cared for following surgery in a similar manner. They were all kept in identical cages in the same ward and allowed into the runs several times per day at cage cleaning time. Feeding and other general aspects of animal care were standardized. They were not given supplementary fixation to assist the experimental internal devices since an attempt was being made to simulate the type of aftercare that they would probably have received in a clinical situation. All of the dogs were examined clinically every second day during the first week and twice a week thereafter.

G. RADIOGRAPHIC EXAMINATION

A portable Phillips x-ray machine was used to monitor healing. A tube distance of 36 inches was used with the following technique:

K.V.P. - twice the thickness in cm. plus 45

Time - 0.12 seconds

A slow speed film was used with intensifying screens. The following schedule of radiographs was used for each dog:

1. Surgery. A lateral projection was taken to illustrate the experimental fracture in each case (Figure 17).

2. Immediate postoperative. Lateral (Lat.) and anteroposterior (A.P.) projections were taken to demonstrate the quality of fixation.

3. Four weeks postoperative. Lat. and A.P. projections were taken to check the progress of healing.

4. Eight weeks postoperative. Lat. and A.P. projections were taken prior to euthanasia.

5. Postmortem radiographs. Lat. and A.P. projections were taken immediately following euthanasia. They usually were taken with the fixation devices removed for a clearer visualization of the fracture site. Since all dogs were checked clinically at frequent intervals, radiographs also were taken between the prescribed times in the event that the stability of fixation became questionable.

H. CLINICAL EXAMINATION

Each dog was checked at regular intervals and records kept on their progress. After the general state of health was assessed, the dog was encouraged to walk and alterations in gait due to the surgery were recorded. The fracture site was then palpated for stability, callus size, and, where applicable, for any loosening of the fixation device. The fracture site was manipulated to determine the ease with which pain could be elicited, and the degree of rigidity which the healing fracture had attained.

I. TETRACYCLINE LABELING

Ten days prior to euthanasia, each dog was given a single intramuscular injection of 300 mg. of tetracycline antibiotic* for intravital labeling of new bone produced at the fracture site. This was expected to demonstrate the osteoblastic activity which was occurring at the time of administration of the antibiotic. It was also expected to show the

*"Liquimycin", Pfizer Co., Ltd., Agricultural Div., New York, N.Y.

amount of new bone which was laid down between the time of injection and death of the animal.

J. POSTMORTEM EXAMINATION

Each dog was euthanatized with pentobarbital sodium* given at the rate of 36 mg. per pound intravenously. Both femurs were removed and the soft tissue was quickly dissected from their surfaces. The fixation devices were removed and the operated bone radiographed. The bones were then placed in FAA fixative** and submitted to the histology laboratory.

K. HISTOLOGICAL TECHNIQUE

After 24 hours of fixation, the bones were sawed longitudinally in half, in the plane of the screw holes. One half was placed in 70% alcohol for use in preparation of undecalcified sections. The other half was placed in 10% buffered formalin to be used in the preparation of paraffin sections.

1. Undecalcified sections. This half of the femoral shaft was dehydrated in alcohols and embedded in methyl methacrylate. After hardening of the plastic was complete, the sections were cut on the Jung sliding microtome to a thickness of approximately 100 microns and mounted in Permount mounting medium.*** These sections were examined under the fluorescent microscope for tetracycline, which would label with a bright yellow fluorescence all new bone deposited on bone surfaces while the

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*"Toxital", Jensen-Salsbury Labs, Kansas City, Missouri.

**FAA fixative (Wisconsin) as recommended by the Dept. of Anatomy, University of Wisconsin, Madison, Wisc.

***"Permount", Fisher Chemical Specialty, Fair Lawn, N.J.

drug was in the blood stream (Figure 5). These undecalcified sections were also stained with 5% basic fuschin stain to demonstrate osteoid seams (see Appendix).

2. Decalcified sections. After 24 hours of fixation in FAA solution the bone was cut into sections and placed in "Cal-Ex" solution* for 24 hours for decalcification. The specimens were then washed and put through the alcohol series for dehydration. Amyl acetate was used for cleaning. They were then embedded and cut to a thickness of 7 microns, and mounted for staining.

Two routine stains were employed as a basis for the histological studies. These were hematoxylin and eosin stain, and Gomori's one-step trichrome, which stains collagen green, nuclei black and muscle fibers red (Figure 22). Further differentiation was required between fibro-cartilage and fibrous connective tissue so some of the slides were stained with azure A for metachromasia. This stained the cartilage deep purple (Figure 13). It also was helpful in staining mast cells whcih are also metachromatic. As a check on the Gomori trichrome stain, several slides were stained with hematoxylin-phloxine-saffron (H.P.S.) to assess the reproducibility of the trichrome (Figure 14). All of these stains are described in greater detail in the Appendix to this manuscript.

Several sections were examined under polarized light to demonstrate the presence or absence of metal granules which might indicate corrosion of the metal of the fixation device.

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*"Cal-Ex", Fisher Chemical Specialty, Fair Lawn, N.J.

RESULTS

The Sampson extracortical clamp maintained reduction in only 2 dogs out of 8 (Figures 37 and 39). All experimental fractures treated with the other 3 methods underwent satisfactory union (Table 2).

Fluorescence microscopy was also unsatisfactory because the tetracycline label was too light, being only slightly brighter than the autofluorescence of the bone. In some sections no label was visible. Bone samples were stored in FAA fixative. This is an acidic solution which was found to be capable of slightly decalcifying the specimens. This appeared to have removed the recently deposited tetracycline labels from most of the cortical bone in this experiment.

The results of this experiment will be described separately for the 4 series.

A. SERIES I - INTRAMEDULLARY PIN FIXATION

1. Surgical results. In all of the dogs, a satisfactory experimental fracture was produced. The surgical procedure involved in I.M. pinning using the retrograde method was found to be fairly simple and direct presenting few problems. It required less surgical time than any of the other 3 methods.

2. Clinical examination. On the day after surgery all of these dogs carried the operated leg while walking on the 3 normal legs. By the tenth postoperative day, all of the dogs used the leg from time to

time and would momentarily stand on it. By 4 weeks, they were all using the leg, though none used it fully. Six weeks elapsed before full use of the leg through a complete range of motion was achieved. The callus was palpable by 10 days and pain could be elicited by manipulation. By one month, however, it was larger, firmer and rigid, and manipulation elicited pain only when done vigorously. Just prior to euthanasia, no abnormality of gait could be discerned and a firm callus was easily palpated. No pain could be elicited on manipulation of the fracture site (Table 3).

3. Radiolcgical results. Radiographs taken during surgery revealed that satisfactory experimental fractures had been produced in all 4 animals, but that the method usually removed a small chip of bone from the anterior cortex. These fractures were all successfully reduced and fixed with I.M. nails (Figure 6). At 4 weeks a fusiform external callus of variable size was visible on all radiographs. The callus was moderately calcified and in 2 of the dogs this calcification crossed the fracture gap, while in the other 2 the radiographs suggested that bridging was just about to take place. The fracture line was visible in each case at 4 weeks (Figure 7). On the films taken at 10 weeks there was a suggestion of widening of the fracture gap due to resorption of the cortical ends of the bone fragments, but the overall calcification of the callus per se had increased in density and appeared to bridge the widened gap (Figure 8). In the 2 dogs which were euthanatized at 12 weeks, the final radiographs revealed that the fracture gap was bridged with calcified tissue but the fracture line was still faintly discernible. Remodeling of the callus was nearly complete as the shaft had almost returned to its original tubular form. At the time of euthanasia, the radiographs

demonstrated that there had been no shift in position of the reduction or the fixation device, nor was any shortening of the shaft evident. The radiographic findings throughout this healing period were well within the expected limits of normal physiological fracture healing. The sequence of radiographs for each dog followed the general description for the series as outlined above with only slight variations which are described below.

Dog #1 - The sequence of radiographs on this dog showed that the fracture was properly reduced and fixed and remained this way throughout the healing period (Figure 6). At 4 weeks a large fusiform callus was evident (Figure 7) which was larger and more dense on radiographs taken at 10 weeks following surgery (Figure 8).

Dog #2 - The reduction of the fracture fragments in this femur was satisfactory, but a slight over-riding of the cortices was evident. The healing progressed in a similar manner to the other dogs of the series except that only a slight amount of calcified tissue was demonstrated radiographically (Figure 9).

Dog #3 - The healing pattern as visualized radiographically up to 8 weeks was similar to that seen in Dog #1. By 12 weeks, however, the fusiform callus had nearly disappeared, and the fracture line was barely visible. The endosteal callus appeared to be still present.

Dog #4 - A larger callus was evident during the first 8 weeks of healing in this femur. By 12 weeks, the fracture site was still visible, as was a small callus spindle and the endosteal callus.

4. Histological results. Each animal which was destroyed at 10 weeks presented the histological appearance of a normally healing fracture, united by a spindle of callus tissue which was approaching the stage of pure "bony callus" (figures 10 and 11). While the external callus was composed of mature trabecular bone at its proximal and distal ends (Figure 12), closer to the fracture site the trabeculae were composed of less mature lamellar bone and woven bone (Figure 14). At the fracture site, the bridging, uniting, and endosteal areas of callus were composed of immature connective tissue, fibrocartilage, and hyaline cartilage. These tissues were being replaced at their periphery by trabeculae of woven bone, some of which still contained calcified cartilage cores which were seen to be metachromatic (Figures 13 and 14). Cement lines between the new bone of the callus and the original cortical bone were very obvious and represented the surfaces of attachment of callus to the original fragments (Figure 12). The endosteal callus was composed of a fine lattice of trabecular bone but its 2 halves still were separated by a small amount of hyaline cartilage (Figure 10). In the areas of trabecular bone, there was primarily osteoblastic activity in evidence with large numbers of plump osteoblasts covering all trabecular surfaces (Figure 13). On the surfaces of the bony callus, osteoclasis predominated, particularly toward the ends of the spindle where large osteoclasts in Howship's lacunae could be seen in great numbers (Figure 16).

At the ends of the original cortical fragments, the osteocyte lacunae appeared to be empty in patches for some distance back from the fracture surface. In these areas there was heavy resorption and cancellization of cortical bone (Figure 10). None of the slides of this series showed any signs of inflammation, degeneration or necrosis (Figure 14).

The 2 dogs which were euthanatized at 12 weeks showed no evidence of cartilage or connective tissue at the original fracture site but the fracture gap was bridged by bone (Figure 30). This bridging bone was still trabecular in form but the spaces between trabeculae were being filled in with lamellar bone as the bone became more compact in nature. An endosteal callus of lacy trabecular bone still filled the medullary cavity near the fracture site (Table 2).

Dog #1 - This specimen followed the general histological appearance of the series as a whole (Figure 10). Bony union had not yet occurred, as 2 triangular areas of cartilage remained in the center of each bridging callus, and these were joined to each other by a thin strip of fibrocartilage which threaded across the fracture gap. This thread of fibrocartilage was being replaced by trabeculae of woven bone through the process of enchondral ossification (Figures 10 and 13).

Dog #2 - This dog had reached a stage of healing only slightly advanced from Dog #1 (Figure 11). The bony trabeculae actually had crossed the fracture gap in one cortex while in all other areas the 2 fragments were still separated by cartilage and connective tissue elements as seen in the previous specimen.

Dogs #3 and #4 - These 2 dogs were euthanatized at 12 weeks following surgery. Due to the longer healing time, histological sections revealed that these 2 animals were at a more advanced stage of healing than the previous 2. They also had healed by callus formation, but the fragments now were joined by a uniting callus of solid trabecular bone. As previously stated, this trabecular bone was of a more dense lamellar type, and some of the trabeculae had closed in to form primary osteons which, by definition, were oriented in a transverse direction across the fracture gap, i.e., perpendicular to the secondary osteons of the mature cortical bone which were oriented longitudinally (Figure 30). Thus, the uniting callus was in the early stages of cortical remodeling. The bridging callus in Dog #3 still contained a small island of cartilage in its center. Endosteal callus was still present in both cases but at its ends farthest from the fracture, osteoclastic activity was evident on its trabecular surfaces. This activity would eventually have returned this bone to its original tubular form.

B. SERIES II - INTRAMEDULLARY NAILING PLUS HALF KIRSCHNER SPLINT

The first 2 dogs in this series were euthanatized at 12 weeks and the second 2 at 10 weeks postoperatively.

1. Surgical results. The entire procedure in all 4 animals was without complications and the fractures produced were quite amenable to this type of fixation (Figure 17). In Dog #6 the experimental fracture was slightly comminuted but a satisfactory reduction still was achieved.

The surgical procedure used in this series was found also to be simple and direct, posing no significant mechanical problems. The application of the half Kirschner device did add a small amount of surgical time to the operation and required a little more skill than did the I.M. pinning procedure alone.

2. Clinical examination. The clinical aspects of fracture healing in this series were essentially the same as in the previous series. Dog #6, in which a comminuted fracture was inadvertently produced, showed a return to function as early as the other dogs of Series I and II. This was probably due to the additional stability offered by the Kirschner splint (Table 3).

3. Radiological results. In general the callus formation seen in this series was identical to that of the previous series. Satisfactory fractures were produced in 3 of the dogs (Figure 17) and, in the fourth dog (Dog #6), the fracture produced was comminuted and fairly oblique. Reduction and fixation in this dog were difficult, and the final surgical result was not as satisfactory as in the other 3 of the series.

In general, at 4 weeks, an obvious fusiform callus was observed developing from both fragments but no bridging of the fracture gap was evident. The outer surface of the external callus exhibited the typical "lipping" of its edges at the fracture site, indicating that the calcification was about to cross the gap (Figure 19). Any indentations present at the fracture site due to imperfect apposition of the cortices now were being filled in and smoothed over with calcifying callus in preparation for the remodeling process. Endosteal callus was evident at this stage. At 10 weeks, all callus tissues had increased their radiodensity and the fracture gap was seen to be crossed by calcified tissue in some areas. The entire fracture separation had widened slightly at this stage (Figure 21). In the 2 animals which were euthanatized at 12 weeks, the fracture line was still visible, the external callus had decreased in size, the endosteal callus was no longer discernible, and any defects in the shaft resulting from the fracture or fixation were being filled in with dense callus tissue as remodeling began (Figure 20). Specific variations from this general description are outlined below.

Dog #5 - While a satisfactory fracture and reduction had apparently been achieved, a slight overriding of the cortical fragments remained visible through to the time of euthanasia (Figure 18). At that

time, the external callus had been removed almost completely as had the internal callus, leaving the bone nearly tubular in form. The fracture site, however, was still visible on radiographs (Figure 20).

Dog #6 - The experimental fracture produced in this dog failed to conform to standards. Misalignment and overriding of cortices were evident in postoperative films. After 4 weeks of healing, however, the repair had progressed, exhibiting a well calcified external callus and filling in of the cortical defects. By 8 weeks the remodeling had advanced even further tending to remove the artifacts produced by the poor reduction. At 12 weeks, most of the periosteal callus had been removed but the endosteal callus was still visible adjacent to the fracture site. The misalignment which had been obvious on the previous radiographs was less noticeable by this time.

Dog #7 - Radiographs of this animal showed no variation from the general description of this series as reported at the beginning of this section. At the time of euthanasia after 10 weeks of healing, a classical fusiform callus was visible radiographically but the 2 halves were still separated by the fracture line (Figure 21).

Dog #8 - The only variation from the general description which this animal showed was a slight interfragmentary telescoping seen on the postoperative radiograph. This was completely removed through the process of remodeling by the time the 10-week radiograph was taken. At that time the bone appeared to be almost tubular but the fracture line was still discernible.

4. Histological results. In this series all fractures were united with firm callus. In the dogs killed at 10 weeks, a thin intermittent band of cartilage wove through the callus at the fracture site (Figure 22). In the 12-week specimens, the callus was composed of mature trabecular bone at the periphery and immature woven bone trabeculae in the uniting and bridging callus (Figure 23).

The specimens of this series represented the early stage of bony callus in which the fragments had just been recently united by bony trabeculae and essentially all of the cartilage in the callus had been replaced by bone. A very rigid and vascular union had in this way been formed between the fragments.

Remodeling was a predominant feature of this callus, and all fixation artifacts present were covered with osteoclasts as were the callus surfaces and peripheral areas of the endosteal callus (Figure 16). At the fracture site, the abundance of osteoblastic activity which had been apparent in the older specimens of the previous series was also evident here. Since this was an early bony callus, a few cartilage cores still remained within some of the trabeculae of woven bone in the bridging callus (Figure 14). The tracts left by the Kirschner wires traversed both cortices in several slides and showed little evidence of tissue reaction to their presence. There was, however, a very small amount of periosteal new bone formed at the site where they had passed through the periosteum and a column of trabecular endosteal callus where t-ey had passed through the medullary cavity. The space which contained the I.M. pin was also visible as a hollow cavity lined with a fibrous membrane passing through the length of the medullary canal (Figure 22). Specific variations from this general description are outlined below (Table 2).

Dog #5 - Evidence of the fracture line was seen only as an area of cancellization in both cortices. Union had been accomplished entirely by bone with no cartilage or connective tissue elements present (Figure 23). There were just a few trabeculae of the very immature bone remaining, which illustrated the fact that this callus had recently been converted to pure bone, free of the more primitive connective tissue elements. The fusiform external callus had been nearly removed and the endosteal callus remained only because of the presence of the pin.

Dog #6 - This specimen was at the same stage of healing as the previous one, with pronounced osteoblastic activity between fragments, and osteoclasis occurring on the outer surfaces of the small spindle of periosteal callus which remained. One cortex had been fixed in a slightly overriding position. The histological section revealed that the ends of 2 fragments of this cortex were united in a side to side fashion, with new bone (Figure 24).

Dog #7 - This specimen possessed a fusiform periosteal callus and a substantial amount of endosteal callus (Figure 22). Bony union had not quite been achieved, as a thin band of cartilage could be seen weaving through the fracture site. Also, a small "V" of cartilage existed in both halves of the bridging callus. However, the densities of osteoblasts and osteoclasts and their relative locations suggested that bony union and subsequent remodeling were just about to begin. This was further substantiated with the basic fuschin stain which demonstrated the presence of osteoid on all trabecular surfaces, but none subperiosteally.

Dog #8 - This specimen presented the same histological features as the previous one. The tetracycline label was fairly prominent in this specimen and, together with the information from the basic fuschin stain, allowed one to conclude that the intense osteoblastic activity which was taking place in the area of the uniting callus had been active there for at least 10 days, i.e., since the tetracycline label was given (Figure 5).

C. SERIES III - COMPRESSION PLATING

1. Surgical results. The experimental fractures to be fixed with this method were all quite acceptable. No problems developed during surgery, although the center screw hole in Dog #9 was noticed to have passed very close to the fracture line (Figure 25). Also, in the same dog, the alignment of the screws was such that upon completion of the plating, a slight misalignment of the fragments was produced (Figure 27). The other 2 fractures were reduced and fixed in almost perfect apposition, but in Dog #10 one screw was again placed too close to the fracture line (Figure 28a).

This technique was the most time consuming of the methods used in this experiment. It also required more knowledge and mechanical skill to apply it properly. Slight errors of technique on the part of the surgeon manifested themselves in the form of deficiencies in the quality of fixation as seen in Dogs #9 and #10. In these 2 specimens, screw holes were placed too close to the fracture site, thereby losing some of their mechanical advantage and at the same time interfering with the healing process. But when the A.O. methods were followed explicitly, favorable results were achieved.

2. Clinical examination. In general, these dogs began to use the operated legs just a few days after surgery and, by the end of the first week, were walking on them with only the occasional sign of a limp. There was little pain on manipulation of the femur as early as 24 hours after surgery. By the end of the third week, the dogs had full use of the leg through the complete range of motion and no pain could be elicited on manipulation. Only the plate could be palpated in the fracture area (Table 3).

3. Radiological results. Postoperative films of the femurs of Dogs #9 and #11 showed the fracture line to have been almost eliminated (Figure 25). In Dog #9 the fragments were very slightly misaligned (Figure 25). The inner screw was seen to be very close to the fracture site in Dogs #9 and #10 (Figure 27). At 4 weeks, there was essentially no periosteal callus seen developing adjacent to the fracture site. The only callus seen on radiography was that caused by the filling in of a defect left by an avulsed bone chip, or that surrounding a screw which had been placed too close to the fracture (Figure 27). All 3 specimens contained a slight density in the marrow cavity which suggested the presence of endosteal callus (Figure 28a). At 8 weeks, only with closer examination was it possible to differentiate these bones from the normal contralateral ones, except for the obvious screw holes (Figures 28b and 29). These 8-week radiographs were taken after the plates had been removed at the time of euthanasia, and they illustrated that the plate really could obscure a few of the less significant radiological features (Figure 27). It was then possible to clearly visualize the thin periosteal callus which developed under the plate, and the entire fracture site which was visible at the time of death in all cases (Figure 28b). Individual cases are discussed below.

Dog #9 - Postoperative radiographs revealed the fracture line to be nearly completely obliterated, but one screw was seen to almost enter the fracture site (Figure 25). At 4 weeks, a periosteal callus had developed over the area between that screw and the fracture (Figure 26). All other areas were relatively free of this periosteal reaction throughout the healing period. At the time of euthanasia, the fracture line was still evident as was the original misalignment (Figure 27).

Dog #10 - In this animal, a 5-hole plate had been used. There were very few changes to be observed throughout the healing period. At 4 weeks a very slight periosteal "lipping" was seen at the fracture site on the cortex opposite the plate. There was the suggestion of endosteal callus. At the time of euthanasia, the slight periosteal callus had joined across the fracture site and, when the plate was removed, a very thin callus cuff was seen to surround the fracture area. Only a suggestion of the fracture line was discernible (Figure 28b).

Dog #11 - This fracture was seen to be slightly oblique with the usual small bone fragment missing from the anterior surface of the shaft. At 4 weeks, the defect was revealed to be filling in with calcified tissue. Postmortem radiographs, with the plate removed, revealed very little new information, except that the fracture line was still quite visible (Figure 29).

4. Histological results. The fracture union in this series had been effected essentially by trabeculae of immature woven bone (Figure 30). In Dog #11, a thin thread of cartilage passed from the periosteum of one cortex to that of the other through the fracture gap (Figure 32). This cartilage band was being crossed in several areas by bony trabeculae.

Thus, true primary healing had not occurred in this case. The same was true for Dog #9 in this series, where only several nests of cartilage remained in the fracture area but some of the uniting bony trabeculae still contained cartilage cores. Dog #10 showed the most advanced stage of healing of the 3 with full bony union across the fracture gap, no cartilage being present anywhere in the slide (Figure 30). Some of the trabeculae had grown sufficiently to fill in the spaces between them, thereby forming primary, horizontally oriented osteons. Therefore, this specimen was in the very early stage of bone remodeling.

As a group, all 3 dogs in the series are close to the stage of remodeling of the cortex, but only Dog #10 has reached this stage through direct cortical healing with no cartilage phase.

Necrosis of original cortical bone at the fracture site seemed to be limited to a very narrow zone immediately adjacent to the fracture. There, a few patchy areas with empty lacunae and deeper staining of the matrix represented the necrotic bone.

The original cortical bone lying between the threads of the screws remained alive during the healing period, except for a narrow band at the tips of the bony threads produced by the bone tap. These narrow bands in which resorption had occurred were filled with woven bone and occasional islands of cartilage, and were firmly cemented to the live, original cortical bone of the rest of the thread (Figure 33).

The cortex which was under the plate appeared to be consistently thinner than the opposite one and appeared to have undergone a degree of resorption and cancellization not visible on the one opposite the plate. A similar comparison using a cross section of the normal opposite femur taken in the same orientation did not show this effect to the marked degree that the operated femurs did. This ruled out the possibility that this difference in structure between these 2 areas of the shaft was normal. There were, however, normal variations in both cortical thickness and density, in different zones around the circumference in the normal controls, but not to the extent of the operated femurs (Figures 31a and 31b).

The plates were enveloped in a non-reactive fibrous tissue capsule in each case. There was no evidence of active inflammation or of corrosion of the metal. Screw heads and tips were often encased in a small amount of trabecular bone but seemed to cause no further reaction (Figure 33). This trabecular bone often followed the screw as it crossed the medullary cavity. Histological features of specific animals of this series are discussed below (Table 2).

Dog #9 - Although this fracture was being bridged by bony trabeculae, there were a few remnants of cartilage remaining at the fracture site. The cortical bone under the plate was covered by a thin layer of periosteal new bone which joined it at an apparent cement line along the entire length of the plate. Trabeculae at the fracture site were being reinforced with new lamellae while endosteal callus was being removed. The intense osteoblastic activity occurring on these trabeculae was made apparent by the large numbers of osteoblasts which were seen covering them at the fracture site (Figure 15). Basic fuschin stain demonstrated that these trabeculae were covered with a smooth layer of osteoid on all surfaces. This represented the early remodeling process.

Dog #10 - In this animal, primary bony union was successfully achieved. The section showed that the bone was essentially tubular, with union accomplished by primary osteons and nearly complete resorption of the endosteal callus. Some of these transversely oriented osteons were being crossed by longitudinal resorption cavities. Some of these cavities were being filled with lamellar bone during the formation of new, longitudinally oriented secondary osteons, heralding the beginning of the final phase of remodeling (Figure 30). The fracture site was represented on low power by only a narrow band of increased cancellization which crossed each cortex. When viewed under polarized light, these areas became much more apparent due to their relative disorientation of osteons, compared to the uniform, longitudinally oriented original cortical bone adjacent to them. Basic fuschin and tetracycline labeling demonstrated that an intense osteoblastic activity had existed at the fracture site for at least 10 days prior to euthanasia, when the antibiotic was injected.

Dog #11 - In this animal, bony union was interrupted by a cartilage band transversely crossing the fracture site. But this was being crossed in several areas by bony trabeculae which traversed the fracture gap. The trabeculae near this cartilage were composed of very immature bone while those further away were made of mature lamellar bone (Figure 32). A small amount of endosteal and periosteal callus existed mainly around the area where one screw appeared to mechanically interfere with the fracture.

D. SERIES IV - EXTRACORTICAL CLAMP

Six of the operations of this series were total failures. These failures resulted when the clamps loosened from one of the fragments, with subsequent loss of fixation. This occurred at various times during the first 2 weeks. It was usually the proximal fragment which slipped out of the grip of the clamp, thereby leaving both fragments free in the tissues (Figure 37).

The extracortical clamps were applied in the first 4 animals to the cranial border of the femur as previously described (Figure 34). When early radiological results began to show that these were failing, the remainder were subsequently applied to the caudal border hoping that this would give them a greater mechanical advantage (Figure 39). From the results, it was obvious that this innovation in technique offered no advantage. Each method produced one of the 2 successes attained in the series.

1. Surgical results. Apparent satisfactory fixation seemed to have been attained at the conclusion of each operation in this series. In several dogs, fixation with the clamp proceeded smoothly following satisfactory reduction, as the clamps were firmly applied to both fragments with the fracture line positioned exactly in the middle of each clamp. Each fixation was tested by gentle manipulation to demonstrate the holding power of the clamp in its final position. In these animals the method appeared to be an efficient one.

In most dogs, however, difficulty was encountered during surgery. Occasionally, problems developed while tightening the clamp onto the bone. It was found that if the clamp was in certain positions relative to the bone, too few spikes contacted the cortex of each fragment, thereby allowing the fragments to swivel within its grip. It was necessary in such cases to shift the device to a new position on the cortices and try again. The obscuring effect of the clamp and inserter posed mechanical problems from time to time (Figure 1). It was often difficult to tighten the retaining screw of the clamp because of the fickle nature of the screwdriver which was built into the inserter. In other instances, if the clamping device of the inserter was turned down with firm manual force to clamp the bone tightly, the plates of the clamp tended to spread apart slightly by deforming the third side of the clamp which contained the screw hole that the retaining screw must contact. When it came time to tighten the retaining screw to lock the clamp in position, the screw would not enter the hole with which it should have been aligned. This made it necessary to release the force of the inserter slightly, in order to allow the screw to fit, and this backing off procedure presented a further opportunity for a shift in reduction (Figures 1 and 4). In several instances, a misaligned screw was sheared off while attempting to tighten it.

In 2 of the dogs, postoperative radiographs revealed that the clamp had released the fragments, probably as a result of the gentle manipulation required for positioning the dogs on the radiographic table. In one animal, the clamp appeared to be well positioned in the lateral projection, but in the A.P. film, taken minutes later, it had separated. In both animals, the procedure was repeated, but they subsequently separated a second time prior to consolidation of the fracture.

One of the major problems which this clamp presented at surgery was that the fracture site and a long segment of bone on either side of it were obscured by the clamp from the time that it was placed over the bone (Figure 1). At that time the clamp was not yet tightened and so reduction could easily have been lost before fixation was completed. At most, all that one could visualize was a small part of the fracture site visible through the open end of the clamp (Figure 3). Therefore, since the fracture site and an important length of bone could not be seen, errors in reduction and axial alignment could easily be overlooked until postoperative radiographs were taken.

In the rare instances when no unpredictable problems such as these occurred, the clamping was found to be a simple and direct method of repairing a fracture and one which required very little time.

2. Clinical examination. None of the dogs in this series used the operated leg in the first weeks following surgery. By 4 weeks, none of the dogs would stand on the operated leg, including the 2 in which the clamps had successfully maintained the reduction. By 6 weeks postoperatively, the 2 successfully operated animals were standing gingerly on the operated legs. By the time of euthanasia, that leg was still being favored by each of these 2 dogs, but they were using it through a greater range of movements. None of the 6 failures used the operated leg up to the time of euthanasia and, in each animal, it was always tender on manipulation (Table 3).

3. Radiological results. Surgical radiographs verified that all experimental fractures were simple and transverse, a few tending to be slightly obliqued. Postoperative radiographs revealed that all final reductions and fixations were clinically acceptable with no obvious misaligned or malpositioned fragments (Figures 34 and 38). In Dogs #12, #14, and #19, the reductions appeared perfect on direct visualization prior to closure, but the postoperative radiographs demonstrated that a slight abnormal angulation had actually been produced (Figure 34). In Dogs #14, #18, and #19 the clamp became detached from the proximal segment within a very short time, making it necessary to repeat the surgical procedure.

The radiographs taken at 4 weeks postoperatively showed that 6 procedures out of the 8 were total failures. The clamp had released the reduced fragments and was either detached from one of them completely or allowed them to swivel freely. Therefore, only 2 fractures were healing successfully with clamp fixation (Figures 35 and 39). Of the 3 dogs referred to previously,which showed postoperative angulation (Figure 34), the one which did not have to be reoperated on was one of the 2 which held its reduction at 4 weeks. By this time, however, the angulation in this healing fracture had increased slightly (Figure 35). The other fracture which was still holding at 4 weeks was one which had been satisfactory throughout the postoperative period and remained so (Figure 39).

Both of these healing fractures possessed large well calcified calluses which, on the 4-week radiograph, was seen to approach, but not surround, the clamp (Figures 35 and 39). The radiographs revealed that one of these dogs had the clamp applied to the cranial border of the femur and the other dog to its caudal border. The fracture site was not being bridged in either case by calcified callus and both of these possessed a widened fracture gap, suggestive of impending delayed union.

In the 6 dogs in which the clamp had failed, there was total separation of the fragments in 5 dogs, while the swivelling effect was seen in one. In addition, the clamp remained firmly attached to the distal fragment in 5 dogs and to the proximal fragment in only one, indicating that the clamp held more tenaciously to the distal fragment than to the proximal one (Figure 37).

Radiographs of the 6 failures demonstrated an attempt on the part of the fractured limb to repair the discontinuity in the femoral shaft by the production of a very large callus which attempted to surround the entire area and to bridge the space between the 2 fragments with a side to side type of union (Figure 37).

At 8 weeks the overall impression remained the same. The 2 cases in which the reduction had not been lost had developed very large calluses indicating that the fixation was somewhat unstable (Figures 36 and 39).

The angular deformity which was present in one of these at 4 weeks demonsrated at 8 weeks a marked accentuation of the angle (Figures 35 and 36). The fracture site in this dog appeared to be solidified by the presence of a well calcified bridging callus. This callus did not encompass the clamp but seemed to be separated from it by a thin radio-lucent line (Figure 36).

The other successfully clamped fracture also possessed a large callus which was separated from the clamp by a similar line (Figure 39). There was a definite gap between fragments, but the fracture line itself could not be visualized while the clamp was in place.

In the 6 failures, large calluses were still growing out from each segment and seemed to be fusing to form a side to side synostosis (Figure 37). There was still a line of separation between them as shown on the 8-week radiographs. Observations on the individual animals are discussed below.

<u>Dog #12</u> - This was one of the dogs in which the clamp succeeded in maintaining reduction until the fragments could become united by the callus tissue. The slight angulation permitted in the reduction became accentuated over the healing period but appeared to have stabilized prior to the time of euthanasia as the mineralization of the callus increased (Figures 34, 35, and 36). Even though healing appeared to be progressing rapidly, by euthanasia time, a fairly severe angular deformity was inevitable.

Dog #13 - In this dog, the clamp failed within 10 days postoperatively, detaching from the proximal segment which was lying free in the tissues parallel to the distal fragment. A synostosis was developing between the ends of these 2 segments by 8 weeks (Figure 37).

Dog #14 - A slight angulation of the fixation could be discerned from the postoperative radiographs of this dog. A subsequent radiograph taken 10 days after surgery revealed that the clamp had swivelled on the proximal fragment while holding fast to the distal one. When the 4-week radiograph was taken, the clamp had detached completely from the distal fragment but remained attached to the proximal one.

Dog #15 - This fracture was well reduced and fixed, but the postoperative radiographs suggested that a slight rotational misalignment may have been present. The 4-week radiograph revealed that the clamp had become detached from the proximal segment and that a large callus was attempting to form a side to side synostosis between the 2 segments.

Dog #16 - Excellent alignment and fixation had been achieved in this animal as seen in the postoperative radiographs (Figure 38). This was the only other animal in which the clamp fixation held the reduction until clinical union could occur. The callus in this dog grew up to, but not over, the clamp from which it was separated by a fine radiolucent line. The fracture site was very clear and appeared to be widening, but a complete view of it was not possible because of the clamp (Figure 39). By the end of the experimental period, good alignment had been maintained and no shortening of the bone had occurred, but a large periosteal callus was present.

Dog #17 - The reduction and fixation performed on this dog were very satisfactory as viewed on the postoperative radiographs. At 10 days, it was decided to radiograph the dog and a slight angulation of the proximal segment was observed. At 4 weeks, radiographs revealed that the clamp had become detached from the proximal fragment and remained with the distal one. The 8-week films demonstrated the presence of a large callus joining the fragments in the random side to side fashion which has been described for the other failures. The clamp had become detached from the femur completely and was free in the tissues.

Dog #18 - A satisfactory fixation was seen on the postoperative film. On the second postoperative day, clinical signs indicated the need for an additional radiograph, and a severe angulation was revealed in the fixation. The dog was reoperated and the clamp was replaced in the correct position. The radiograph at 4 weeks showed that the clamp had become detached from the proximal fragment. It resembled all the other such animals in this series. In this dog, small areas of radiolucence could be seen on the proximal segment where the clamp had been, which may have represented the holes produced by the spikes.

Dog #19 - The surgical procedure performed on this dog was very satisfactory and the fixation was tested for stability as always, just prior to closure. In the lateral postoperative radiograph, the fixation appeared to be satisfactory, but the A.P. projection revealed that the clamp had swivelled, allowing the fragments to assume a right-angled position. Thus, the small amount of manipulation necessary to position the dog for this radiograph had caused the clamp to lose its grip in the cortical bone of the proximal fragment. The dog was reoperated and the clamp replaced as carefully as possible. Postoperative radiographs again revealed that a slight bowing of the reduced fracture had been produced. At 4 weeks postoperatively the radiographs showed that the clamp had again detached and subsequent radiographs told the same story as was seen with the other failures.

4. Radiological observations made on the clamp. Various views of the clamp, including end views seen after detachment, revealed that callus tissue never actually surrounded the clamp but did develop beneath it. There were many views to demonstrate that very few of the 8 spikes ever contacted the cortex when the clamp was attached to the diaphysis. Often a whole row of spikes on one or both of the plates did not touch the bone. Some of the end views demonstrated clearly that the spikes did not penetrate the cortical bone very deeply and that in each case the attachment depended on only several of the 16 spikes available. In several views, there appeared to be some lysis around one of the key penetrating spikes. There were other similar views where no such reaction was visible. In one case, a spike could be seen contacting the bone at the fracture site and thereby tended to interfere with the reduction, a fact which would not have been apparent at surgery.

5. Histological results. The type of fracture callus seen in most of the previous dogs was formed only in the 2 animals where the clamp was able to maintain the fixation. In the other 6 dogs, extreme malunion and a strong suggestion of delayed or non-union was the most prominent feature of the histological sections (Figure 42).

In the 2 successful operations, the callus which formed was much larger and far more juvenile than those observed in the other series of this experiment (Figures 40 and 43). They contained a relatively large amount of cartilage, fibrocartilage, and connective tissue in the region of the fracture, with no bony union of the fragments.

The bone sections from these 2 dogs revealed several major differences between them regarding their healing characteristics. In Dog #12, there was a severe angular deformity present and the fragments were uniting by cartilage and fibrocartilage (Figure 40). The other, Dog #16, appeared on radiography to be healing in a satisfactory way with good axial alignment. On histological section, however, a band of cartilage and connective tissue was seen to span the entire callus in the fracture area in a similar fashion to the previous slide (Figure 43). But in this animal, there was much less osteoblastic activity in the trabeculae adjacent to the cartilage which was surrounded in most areas by connective tissue between it and the new bony trabeculae. In the center of this cartilage band could be found areas of degeneration and pockets of an eosinophilic fibrinoid material. These areas revealed large amounts of dense fibrous tissue, calcified tissues, and increased tissue fragility. While the first slide, Dog #12, suggested the presence of more active callus maturation (Figure 40), the second one, Dog #16, suggested the possibility of delayed union or non-union with the early signs of pseudoarthrosis formation (Figure 43).

Of the femurs from the 6 dogs in which the clamp had failed, only 3 were sectioned for histologic examination since they all presented a similar picture of the development of a large soft callus and an attempt to form a synostosis (Figure 42). This large callus was rich in cartilage, fibrocartilage, supporting connective tissue, and trabeculae of woven bone. There were foci of previous inflammation characterized in these sections by proliferation of connective tissue and degeneration. A very wide band of cartilage elements invariably wove through the callus separating the fragments. These sections offered little information relative to this project. The specific specimens are now described in greater detail (Table 2).

Dog #12 - This was the first dog of the series in which the clamp allowed a reasonably satisfactory union to take place (Figure 40). It was this dog which developed the progressive angular deformity. This angulation was evident on gross inspection of the section. The fracture site was surrounded by a large callus which held the bones in their misaligned position and it was traversed by a thick band of cartilage which was actively being replaced by trabecular bone. In a few areas bony union was nearly accomplished. A hollow cavity, in the concavity of the angle which was at the anterior border of the femur, was lined by a connective tissue capsule in which the clamp had been invested (Figures 40 and 41).

Dogs #13, #14, and #15 - These animals represented failures of the fixation device and were discussed in the general description of the histology of this series (Figure 42).

Dog #16 - This case was the other of the 2 successful operations and appeared to represent an improvement over the previous one in that the satisfactory alignment was maintained (Figure 43). But as was discussed, there existed the strong possibility that if the dog had been allowed to live longer, a pseudoarthrosis may have developed at the fracture site. The cavity which contained the clamp was visible in cross section.

6. Histological observations related to the clamp. On both of the slides from the 2 successful fixations, the cross section of the encapsulated cavity which had contained the clamp could be seen (Figure 41). This

space was lined with a very dense and mature connective tissue capsule. Within one thickened area of this capsule which had moulded into the depression in the top of the clamp, was found a large number of macrophages which were laden with many black granules. With the aid of polarized light microscopy, the black granules were revealed to be metallic in composition and glowed brightly. This polarizing material was located only within macrophages and could not be found free in the tissues. This finding was in keeping with the gross appearance of most of the clamps recovered from the bone specimens following euthanasia. These were all observed to be severely corroded and, in some cases, breakage had occurred. There was no sign of acute inflammation around the clamp except for several small areas of necrosis in the adjacent connective tissue.

Table 1. Animal identification

	Dog Number	Clinic Case Number	Method of Fixation
Series 1	1	126575	I.M. pin
	2	126576	I.M. pin
	3	621	I.M. pin
	4	639	I.M. pin
Series 2	5	126675	I.M. pin plus 1/2 Kirschner
	6	126699	I.M. pin plus 1/2 Kirschner
	7	126856	I.M. pin plus 1/2 Kirschner
	8	127250	I.M. pin plus 1/2 Kirschner
Series 3	9	126734	Compression fixation
	10	126735	Compression fixation
	11	127366	Compression fixation
Series 4	12	126136	Extracortical clamp
	13	126137	Extracortical clamp
	14	126858	Extracortical clamp
	15	126857	Extracortical clamp
	16	127281	Extracortical clamp
	17	127349	Extracortical clamp
	18	127249	Extracortical clamp
	19	127392	Extracortical clamp

Table 2. Summary of histological results

Series and Dog Number	Healing Time (wks)	Healing Progress	Histological Description
Series 1	Intramedullary pin fixation		
1	10	Maturing soft callus	Early bony union with cartilage in periosteal callus
2	10	Maturing soft callus	Early bony union with cartilage in periosteal callus
3	12	Early bony callus	Lamellar bony union
4	12	Early bony callus	Lamellar bony union
Series 2	Intramedullary pin plus half Kirschner splint		
5	12	Early bony callus	Lamellar bony union
6	12	Early bony callus	Lamellar bony union
7	10	Maturing soft callus	Cartilage band through fracture
8	10	Maturing soft callus	Cartilage band through fracture
Series 3	Compression plating		
9	8	Primary healing, small areas of enchondral ossification	Bony union with isolated areas of cartilage in fracture site
10	8	Primary healing	Primary osteons cross fracture site
11	8	Maturing soft callus	Cartilage across fracture site

Table 2--cont'd.

Series and Dog Number	Healing Time (wks)	Healing Progress	Histological Description
Series 4 Extracortical clamp fixation			
12	10	Maturing soft callus	Large callus with cartilaginous union, angular deformity
13	10	Delayed union	No alignment of fragments
14	10	Delayed union	No alignment of fragments
15	10	Delayed union	No alignment of fragments
16	6	Threatened delayed union	Very inactive immature callus
17	8	Failure of fixation	No histological slides prepared
18	8	Failure of fixation	No histological slides prepared
19	6	Failure of fixation	No histological slides prepared

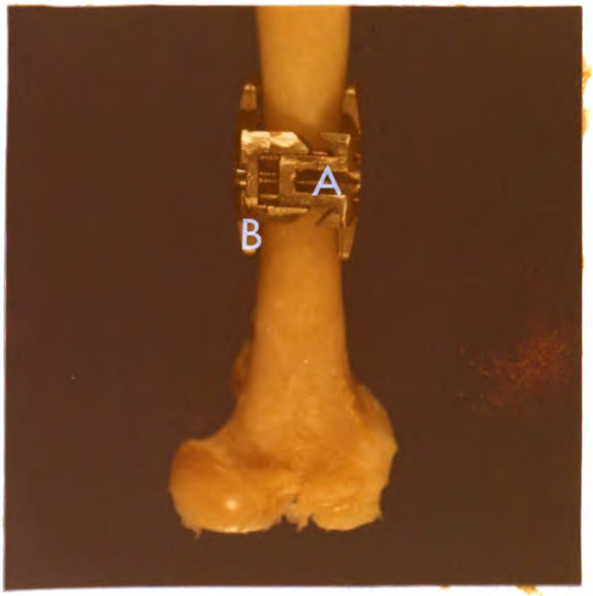
Table 3. Summary of clinical observations

	I.M. pin* (days)	I.M. pin + 1/2 Kirschner* (days)	Compression Plate* (days)	Extracortical Clamp	
				Successes** (days)	Failures (days)
Return of Operated Limbs to Function					
Began standing on operated leg	10	10	1	42	never
Occasional use	14	14	3	42	never
Functional use	28	28	7	never	never
Full use	42	42	21	never	never
Degree of Pain Elicted on Manipulation					
Tender	7	7	never	always	
Slightly tender	28	28	3		
Absence of pain	56	56	21		

*All dogs in the series.

**The 2 cases where the clamp maintained reduction through the healing period.

Figure 1. Right femur with mid-shaft fracture fixed with extracortical clamp. Note retaining screw (A) and clamping plates with spikes (B).



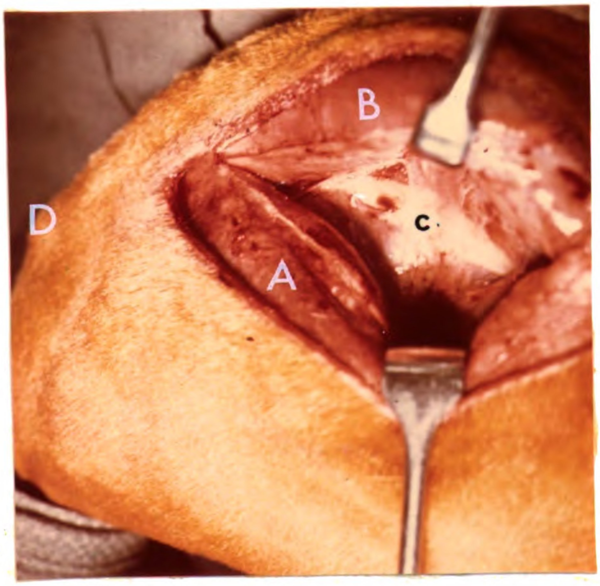
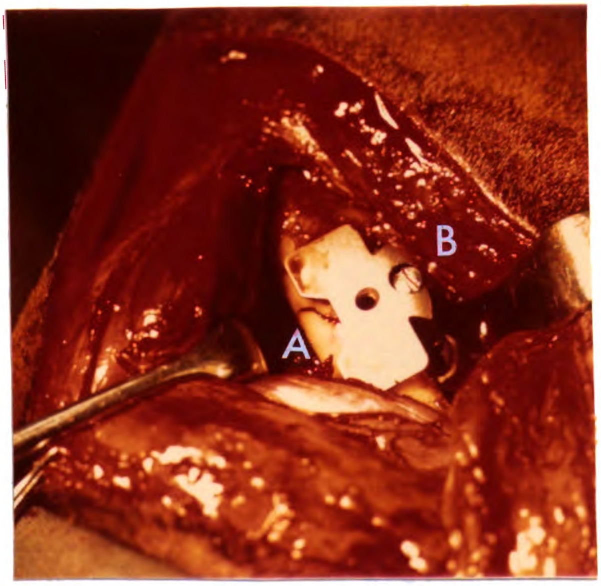


Figure 2. Surgical approach to femur. Biceps femoris m. (A), vastus lateralis m. (B), lateral femoral shaft (C), tibial tubercle (D).

Figure 3. Extracortical clamp in position fixing experimental femoral fracture. Cranial border of femur (A), biceps femoris m. (B).



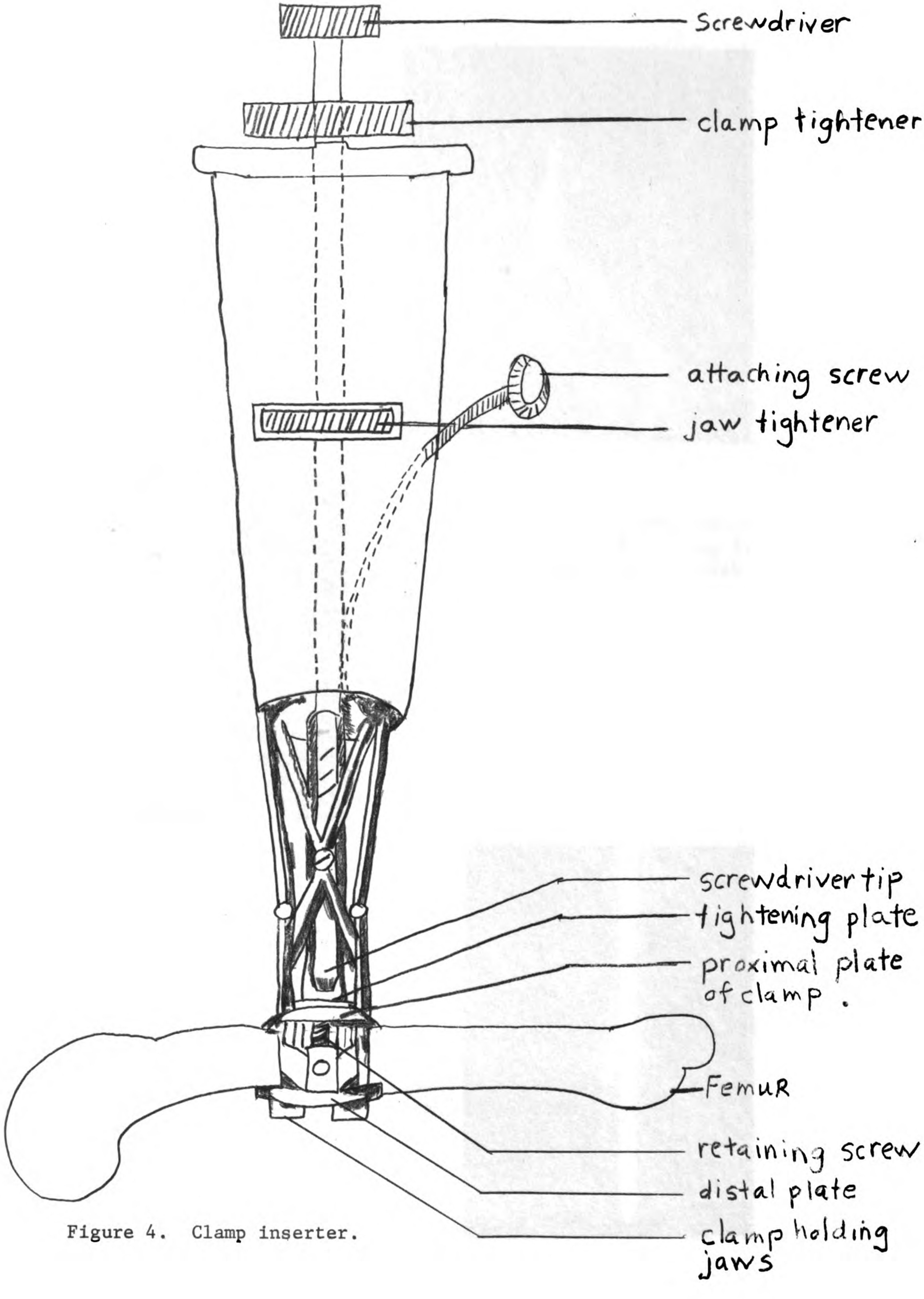


Figure 4. Clamp inserter.

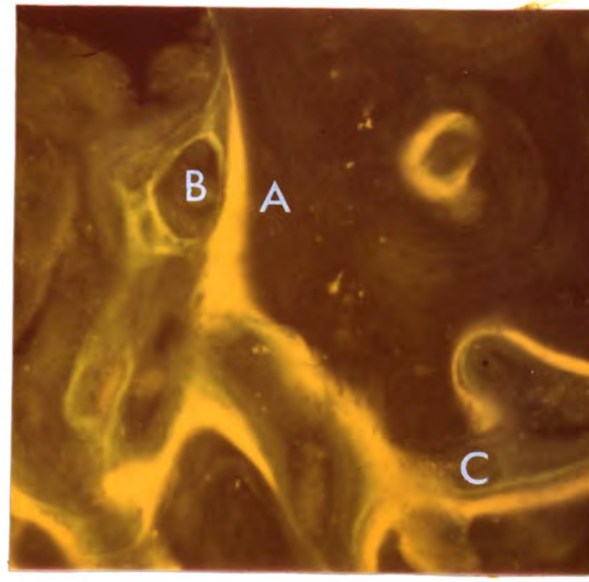


Figure 5. Tetracycline-labeled 10-week healing fracture site in Dog #8. Original cortical bone (A), trasnverse osteons (B), longitudinal osteon entering cortical bone (C). Tetracycline in newly formed bone fluoresces bright yellow in fluorescence microscopy.

Figure 6. Postoperative lateral radiograph of Dog #1. Reduction and fixation with Steinman pin.

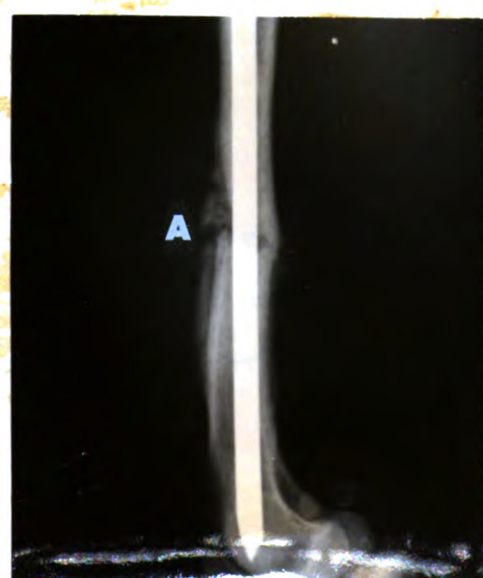


Figure 7. Lateral radiograph of Dog #1 at 4 weeks. Note calcified callus tissue forming spindle around fracture site and filling in defect in cranial cortex (A).

Figure 8. Lateral radiograph of Dog #1 of I.M. pin series at 10 weeks. Note increased density of fusiform callus, apparent widening of fracture gap, and early uniting callus.

Figure 9. Lateral radiograph of Dog #2 of I.M. pin series at 10 weeks. Note (1) calcification is limited to bridging callus and (2) slight misalignment of fragments.

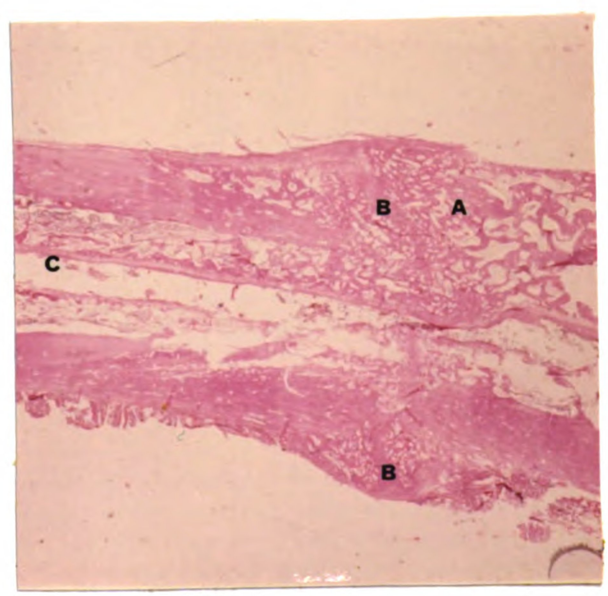


Figure 10. Longitudinal histological section through fracture site of Dog #1 after 10 weeks of healing with I.M. fixation alone. Callus is composed of mature trabecular bone (A) regressing to cartilage band through fracture site (B). Note thin fibrous capsule of pin tract (C) and lack of active inflammation. H & E stain; x 4.

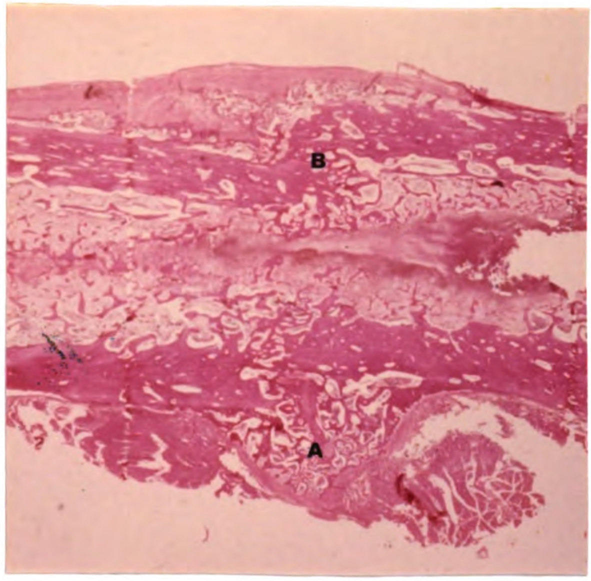


Figure 11. Longitudinal section through fracture in Dog #2 after 10 weeks of healing with I.M. fixation alone. Note bony bridging callus (A) on caudal surface and bony union of misaligned cortices (B) on cranial surface. H & E stain; x 4.

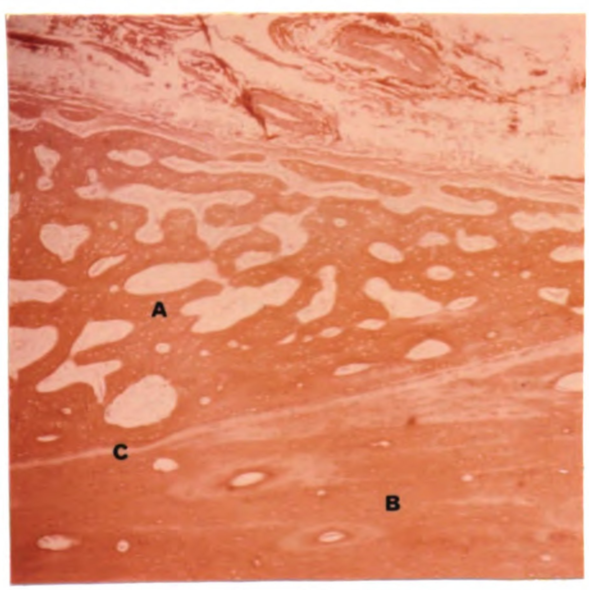


Figure 12. Histological section illustrating the tissue morphology at the end of a mature bony callus spindle. Note new trabecular bone (A) joined to original cortical bone (B) by cement line (C). H & E stain; x 25.

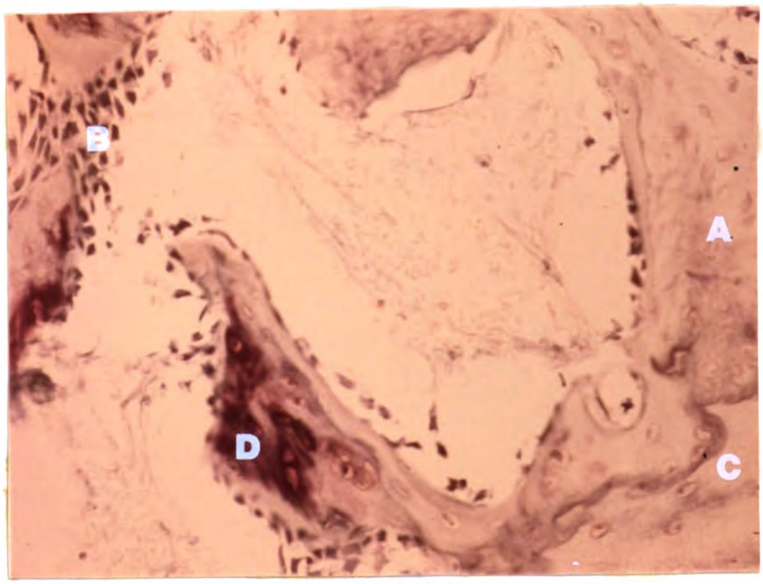


Figure 13. Microscopic view of fracture site in Dog #1. Trabeculae of new bone (A) in fracture gap lined with osteoblasts (B) cemented to original cortical bone (C) and containing cartilage core (D). Azure A metachromatic stain; x 120.

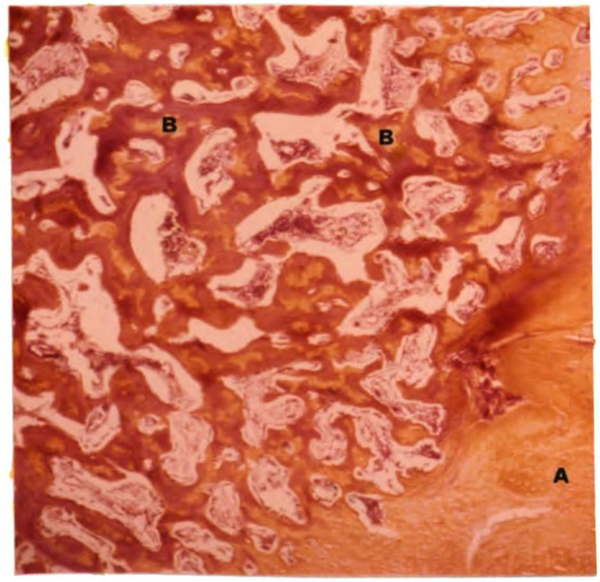


Figure 14. Example of immature callus seen in central areas of fracture site in Dog #2. Cartilage on right (A) undergoing enchondral ossification forming trabeculae containing cartilage cores (B). Callus matures towards left of illustration. H.P.S. stain; x 25.

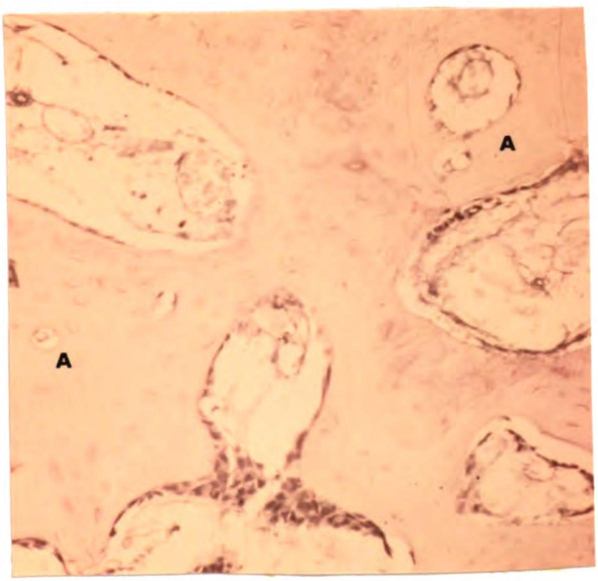


Figure 15. Osteoblastic enlargement of trabeculae at fracture site in Dog #3 forming early haversian bone (A). Azure A stain; x 120.

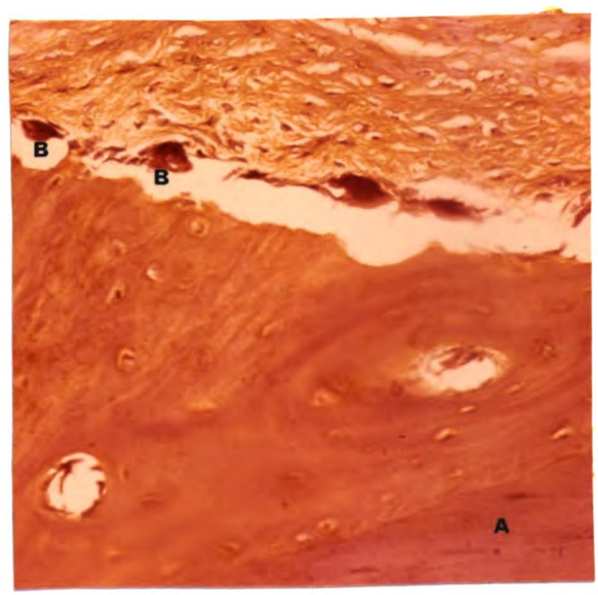


Figure 16. Osteoclastic resorption of peripheral areas of mature callus spindle of Dog #2. Original cortex (A), osteoclasts in Howship's lacunae (B). H.P.S. stain; x 120.

Figure 17. Lateral radiograph of experimental transverse mid-diaphyseal femoral fracture of Dog #5 taken during the experimental surgical procedure.

Figure 18. Postoperative A.P. radiograph of Dog #5. Note satisfactory fixation of fracture with I.M. pin and half Kirschner splintage.

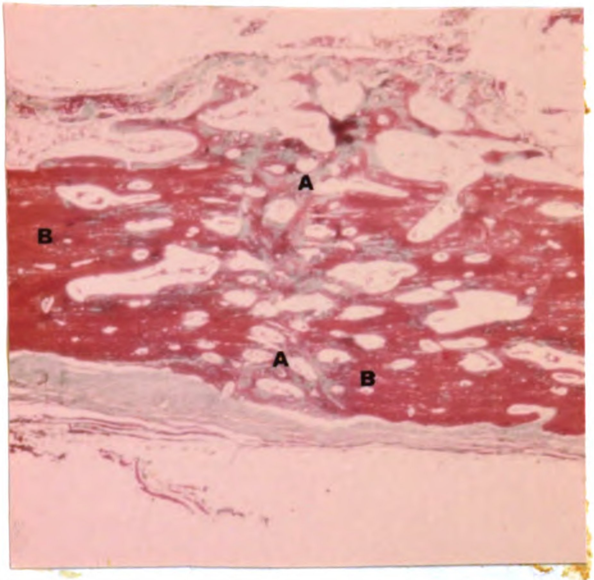
Figure 19. Lateral radiograph of Dog #5 at 4 weeks. Note widening of fracture gap and limited calcification of callus.

Figure 20. Lateral radiograph of Dog #5 at 12 weeks with I.M. pin and half Kirschner devices removed. Note disappearance of periosteal callus tissue. Fracture site is still visible.

Figure 21. Lateral radiograph of Dog #7 at 10 weeks with half Kirschner splint removed. Calcification of bridging callus is not complete. Fracture line is still visible with some uniting callus evident.

Figure 22. Longitudinal histological section of Dog #7 at 10 weeks. Note pin tract (A) and band of cartilage weaving through maturing callus (B). Trichrome stain; x 4.

Figure 23. Longitudinal section of one cortex of femur of Dog #5 at 10 weeks. Fragments are united by remodeling trabecular bone (A) which takes more blue stain than the red original cortex (B). Trichrome stain; x 10.



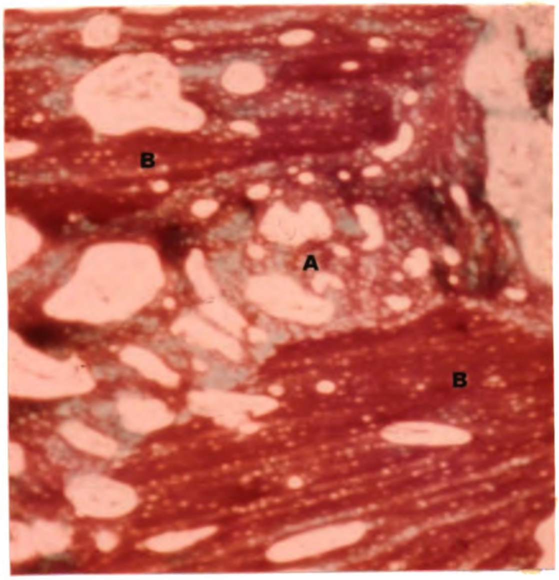
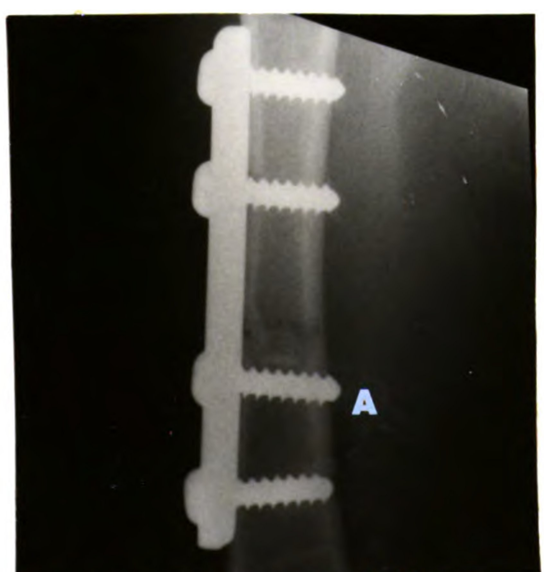


Figure 24. Fracture healing in Dog #6 at 12 weeks where misalignment produces a side to side type of union (A) between impacted cortices (B). Trichrome stain; x 25.

Figure 25. Postoperative lateral radiograph of Dog #9. Note that fracture line can barely be detected. Screw (A) has been positioned too close to fracture site.



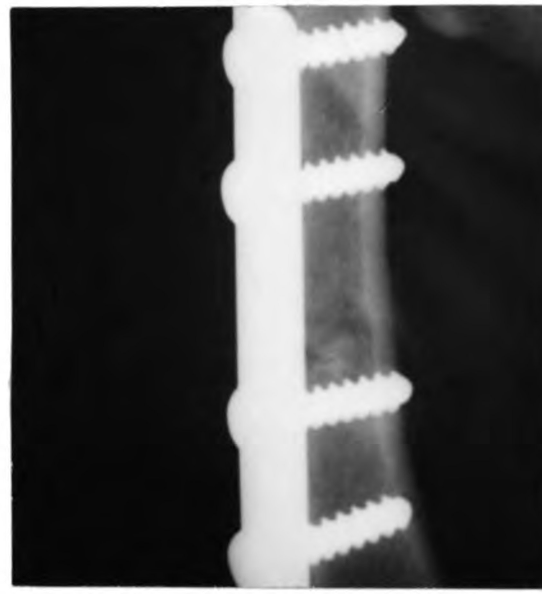


Figure 26. Lateral radiograph of Dog #9 at 4 weeks. Note slight periosteal reaction and endosteal callus.

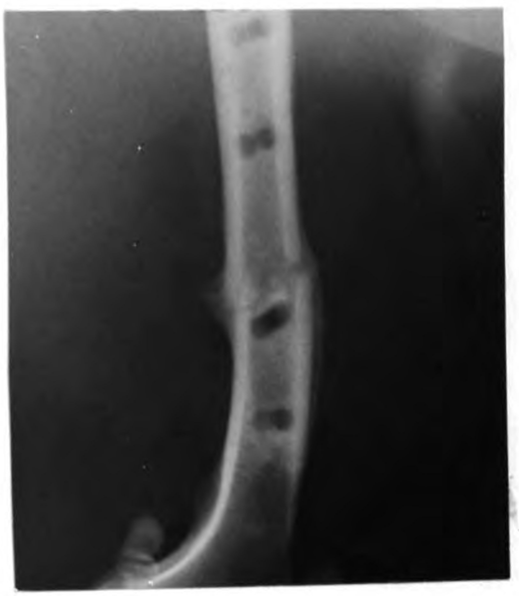


Figure 27. Lateral radiograph of Dog #9 at 8 weeks with plate removed. Note increased density of periosteal reaction.

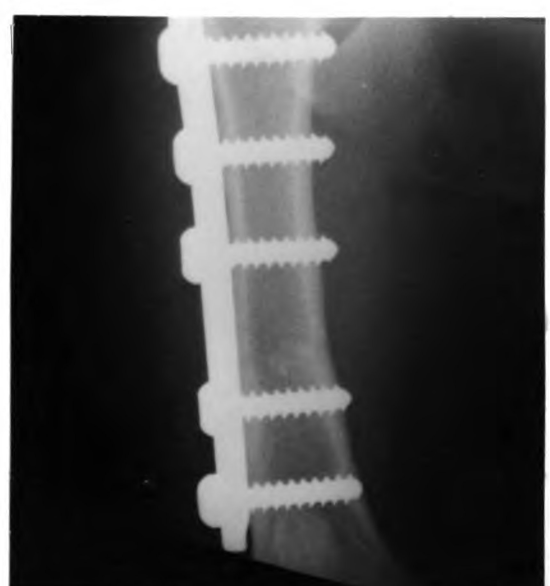


Figure 28a. Lateral radiograph of Dog #10 at 8 weeks. A trace of endosteal callus is still visible.

Figure 28b. Lateral radiograph of Dog #10 at 8 weeks with plate removed. Fracture is still discernible.

Figure 29. Lateral radiograph of Dog #11 at 8 weeks with plate removed. Fracture site is still visible.

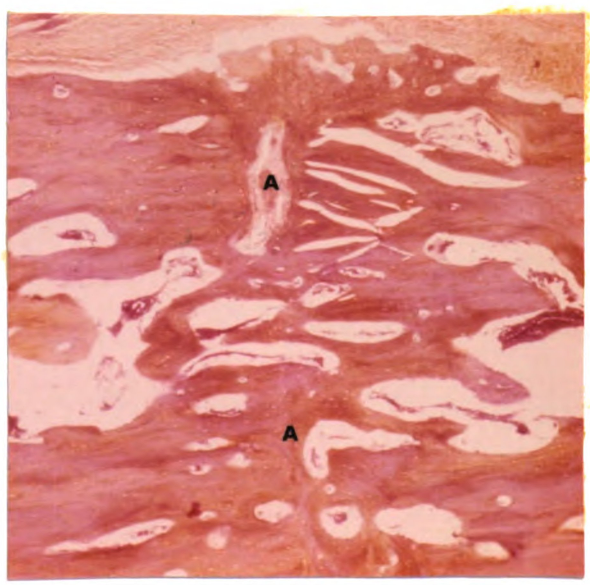


Figure 30. Longitudinal section of cortex under the plate in Dog #10. Note bony union with both longitudinally and horizontally oriented osteons. Also increased cancellization of original cortex on either side of fracture area (A). H.P.S. stain; x 25.

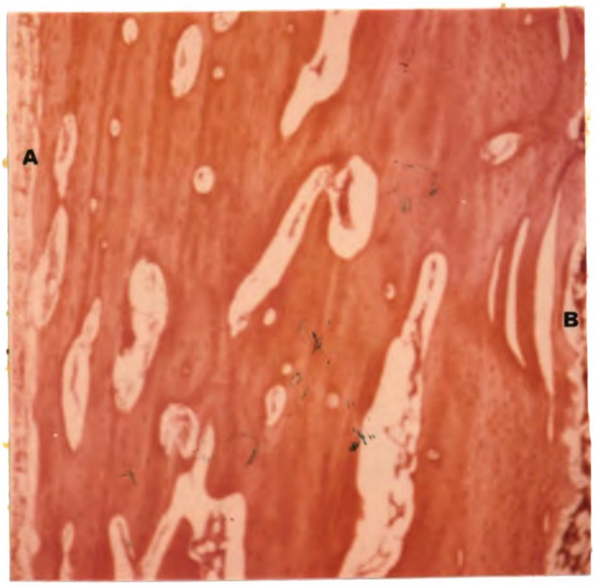


Figure 31a. Longitudinal section of the cortex under the plate in Dog #10. Periosteal surface is at (A), endosteal surface is at (B). The thickness of this cortex is only 2/3 of the corresponding area in the opposite cortex shown in Figure 31b. Note the increased cancellization. H & E stain; x 25.

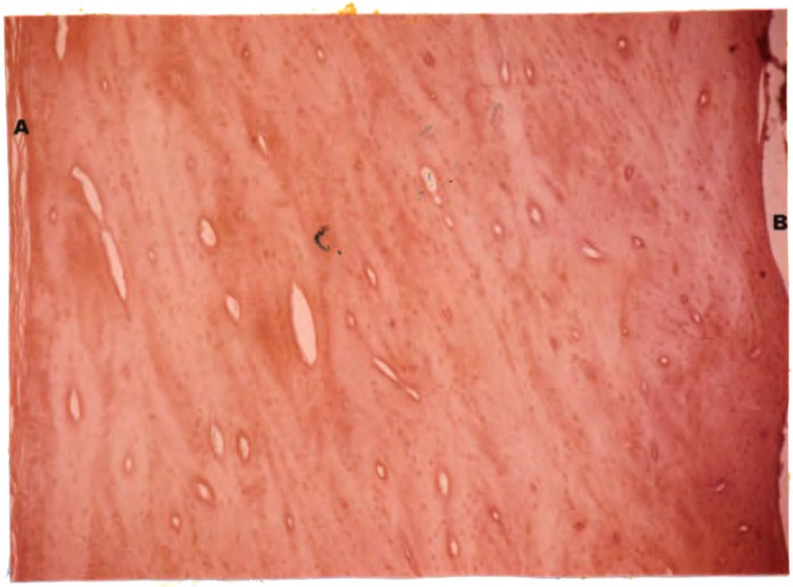


Figure 31b. Longitudinal section of the cortex opposite the plate in Dog #10. Periosteal surface is at (A) and endosteal surface is at (B). H & E stain; x 25.

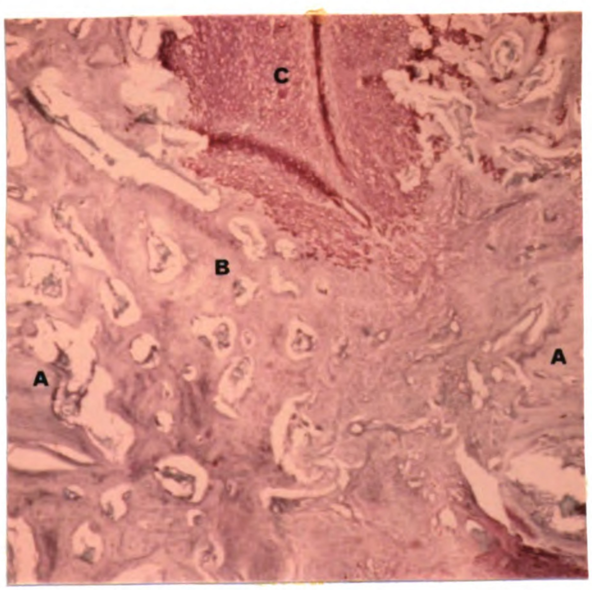


Figure 32. Longitudinal section of one cortex at fracture site in Dog #11. Note original cortex (A), trabecular bone of uniting callus (B), and cartilage in bridging callus (C). Azure A stain; x 25.

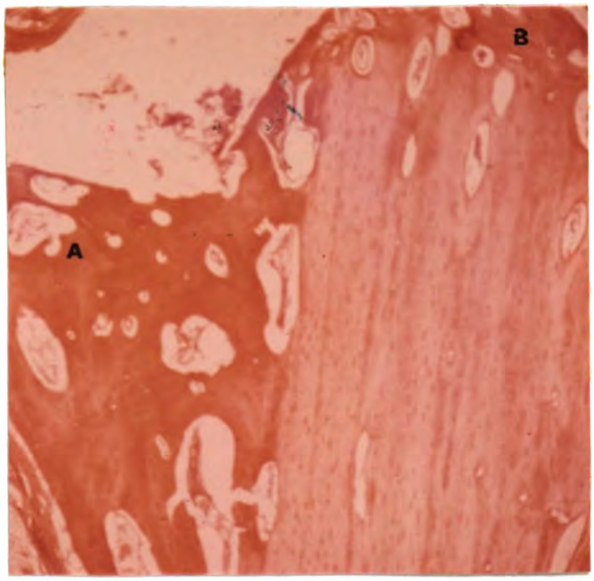


Figure 33. Screw hole through cortex in Dog #10. Note new bone surrounding shaft of screw (A) and at tip of cortical bone in space between adjacent threads (B). H & E stain; x 25.

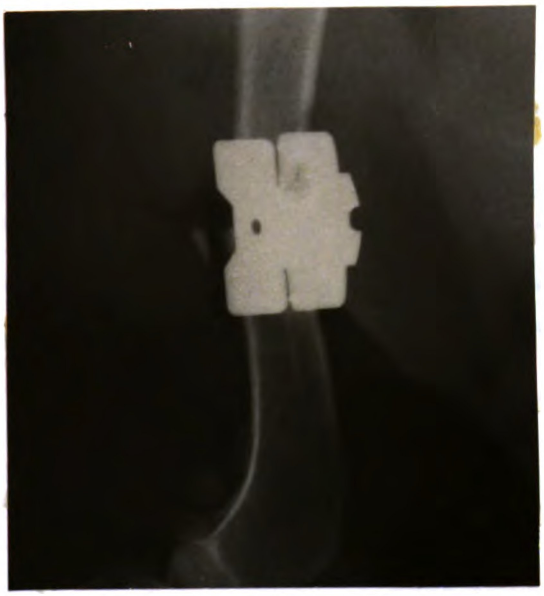


Figure 34. Postoperative lateral radiograph of Dog #12. Note slight angulation of reduction. Clamp is in cranial position on femur.

Figure 35. Lateral radiograph of Dog #12 at 4 weeks. Note calcification of periosteal callus. Callus does not cover the extracortical clamp. Note increased angulation of the reduction compared to the postoperative radiograph illustrated in Figure 33.

Figure 36. Lateral radiograph of Dog #12 at 8 weeks. Extracortical clamp continues to maintain reduction. The degree of angulation of the fixation has continued to increase compared with the 4-week film shown in Figure 35.

Figure 37. Lateral radiograph of Dog #13 at 10 weeks. Clamp has released proximal fragment. A synostosis is uniting the proximal and distal fragments typical of the 6 failures of Series 4.

Figure 38. Postoperative A.P. radiograph of Dog #16. Clamp is in caudal position. Note that the teeth of the clamp fail to penetrate the bone. Satisfactory reduction is maintained.

Figure 39. Lateral radiograph of Dog #16 at 6 weeks. Fracture site is surrounded by a large fusiform callus. Clamp continues to maintain satisfactory reduction.

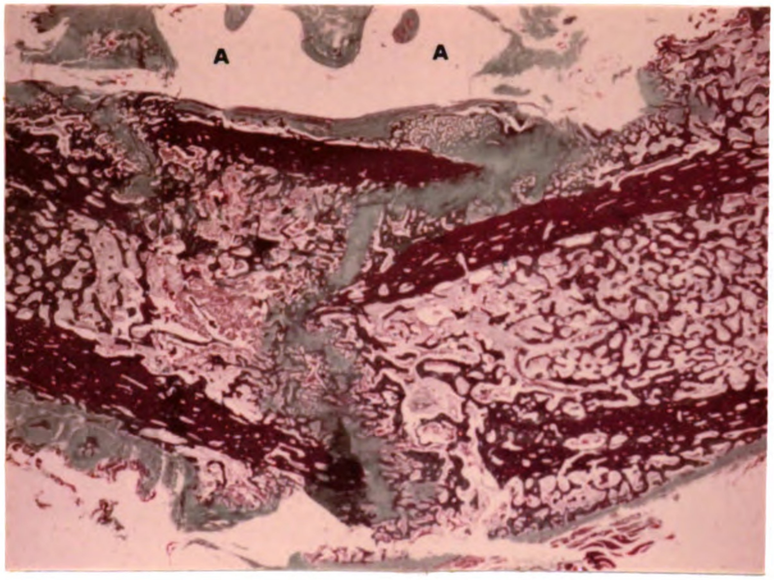


Figure 40. Longitudinal histological section of femur from Dog #12 showing angular malunion. Fracture is united by immature fusiform callus. Note cavity (A) in which the extracortical clamp was located prior to its removal. Trichrome stain; x 4.

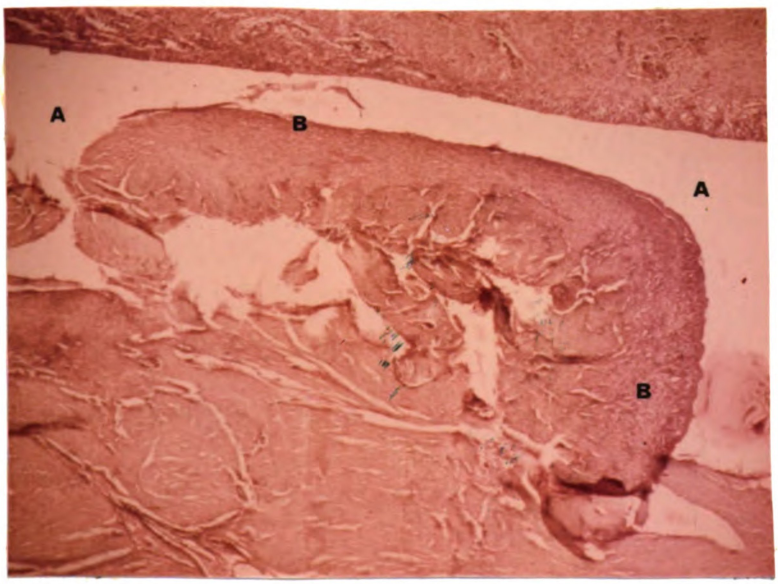


Figure 41. Cavity (A) which contained the clamp lined with dense connective tissue (B). H & E stain; x 25.

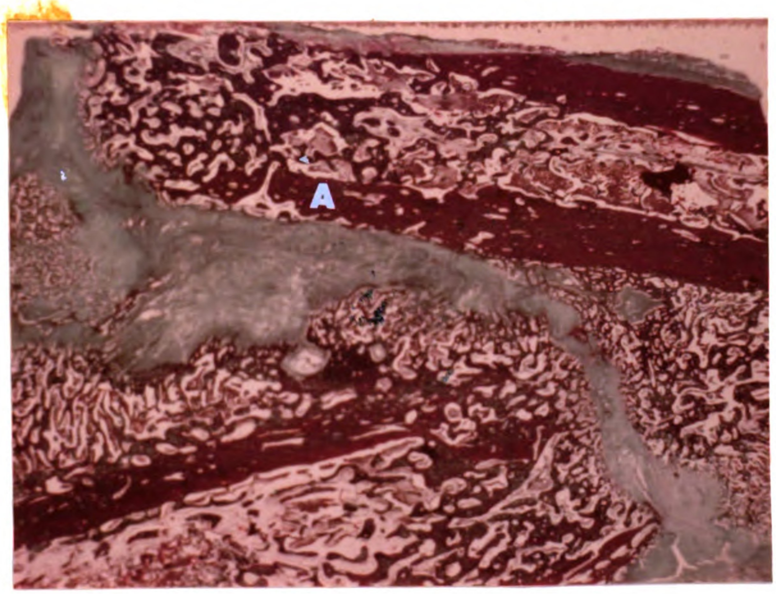


Figure 42. Longitudinal histological section of femur from Dog #13. Clamp released proximal fragment (A) a short time following surgery. Malunion with extreme overriding has been incorporated into a large immature callus. Note lysis of tip of proximal fragment. Trichrome stain; x 4.

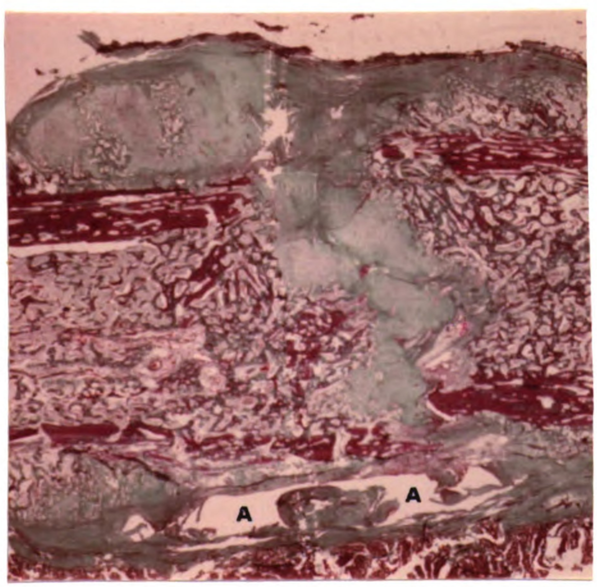


Figure 43. Longitudinal histological section of femur of Dog #16. Note that very satisfactory axial alignment of fragments still exists. Excessive hyaline cartilage separating the fragments strongly suggests delayed union. Note cavity (A) which contained the extracortical clamp. Trichrome stain; x 4.

DISCUSSION

A. SURGICAL TECHNIQUE

The I.M. pin fixation required a little more time to perform than an uneventful clamping procedure, but the technique presented a few inherent problems of technique in the hands of an experienced operator. The fixation was fully visible at surgery and its efficacy could be judged at the time of application which allowed any faults in the reduction to be corrected immediately. Rotational stability could not be maintained with this method alone unless the fracture fragments interdigitated.

When the half Kirschner splint was added to this method the time required was increased and the number of problem areas were compounded to a slight degree. But the design of the system was such that, again, in the hands of an experienced surgeon, the technique was predictable and not difficult to perform. The major problem area inherent in the method was concerned with the proper alignment of the pins on the bone. If this was not achieved, the splint itself could apply a considerable amount of force to the fixation causing axial or rotational misalignment (Figure 24). When properly applied, however, the system was as stable as the I.M. pin alone against bending forces, but possessed increased stability against rotational forces.

The compression plate method of fixation was found to be an exacting technique. It was always time consuming and capable of presenting a number of problems to the inexperienced operator. The fracture site was clearly visible from at least 2 points at all times, allowing for an evaluation of the procedure as it progressed. But for this technique to be most effective, perfect apposition of the fragments and the proper degree of compression applied across the fracture site were necessary. One problem inherent in plating of the femoral shaft was the large exposure required. This took time to prepare.

In principle, the extracortical clamp appeared to be an efficient and simple device to use in the fixation of a simple transverse fracture. In practice, this was the case, provided that no unforeseen problems were encountered during its application. In most cases, however, a considerable amount of time was spent attempting to achieve a solid fixation or in solving the mechanical problems which frequently developed in the inserter or in the clamp itself.

Many of the difficulties encountered in trying to attain a solid fixation could only have been solved by redesigning the clamp. It would have had to be made in such a way as to allow increased visualization of the fracture line and of a greater amount of the adjacent shaft of the bone. It was felt that if one could see the fracture site while the clamp was being tightened, minor adjustments could have been made during the procedure leading to a more satisfactory fixation on the first attempt. The plates of the clamp would also have had to be changed to give them greater ability to adapt to the topography of the bone, making contact with it over a greater area on both fragments. There was an additional number of mechanical changes which should have been made in both inserter and clamp to eliminate minor mechanical problems which tended to appear at critical moments during application.

The poor visibility of the fracture site resulted in the production of many borderline-type reductions which were not discovered to be such until postoperative radiographs were taken (Figure 34). When misalignments were found to exist postoperatively, the procedure often had to be repeated immediately, a situation that would be discouraging in clinical practice. The relative inefficiency of the clamp to maintain the fixation was another problem, which often made a repeat of the procedure necessary a few days following surgery.

B. RETURN TO FUNCTION (Table 3)

The fact that very early ambulation was achieved with the A.O. system gave it an important advantage. The dogs resumed a completely normal existence much earlier while normal function of muscles and joints of the operated leg was maintained. There was very little difference in the healing time between the I.M. pin series and the series in which the half Kirschner was added. This was probably due to the fact that the I.M. pin alone afforded these simple interdigitating fractures sufficient fixation for healing to proceed satisfactorily, rendering the added stability offered by the half Kirschner splint unnecessary. In Dog #6 of the second series, where a more complicated fracture was produced, the leg was being used as soon as any others of both the first and second series. This fracture probably did receive the benefit of the added stabilizing effect of the Kirschner splintage.

Satisfactory use of the operated leg was never accomplished by any of the animals of the clamp series. Even in the 2 animals in which reasonable alignment was maintained, the dogs seldom used the leg. This suggested that the stability offered by the clamp was very poor and allowed some movement at the fracture site when weight bearing was attempted, causing some discomfort to the animal.

C. FRACTURE HEALING

Bone is one of the few tissues of the body which can regenerate. Thus, when a bone is fractured, the healing process which ensues is really the method used by the body to affect the regeneration of a new bone, which will be identical to the original one. Fracture fixation is used to assist nature in this regeneration process. The more stable fixation devices seem to give the healing bone a head start over the less stable methods, to this end.

In this experiment, the first 2 fixation methods used were ones which had been proven by clinical experience. The healing process produced by these methods was at a comparable stage in all dogs. Some differences were present, but they were trivial. Obviously adequate fixation was afforded all fractures and fairly uniform results were attained. Had the fractures been more complex, the healing would probably have been more satisfactory where the half Kirschner splint was added.

In the compression plate series, after 8 weeks of healing, only one fracture healed by primary union (Figure 30). This was the most satisfactory result of the whole experiment. However, one dog from the second series presented an almost comparable histological picture after 12 weeks of healing (Figure 23). The other 3 dogs in the second series using the I.M. pin and the half Kirschner splint were uniformly very favorable at the time of euthanasia (Figures 22 and 23). The other 2 in the compression plate series were no better than these (Figure 32). This was due to the fact that small errors of technique were not tolerable using the A.O. method, and the resultant healing amplified these errors. In this experiment, the main error was placement of screws too close to the fracture site, which in one animal caused a slight distraction of the fragments. Primary healing did not occur in the 2 dogs where this happened, and at the time of euthanasia they resembled those of the previous 2 series. They had undergone, however, only 8 weeks of healing compared to 10 and 12 weeks for those of the other 2 series. Since the fractures produced did not lend themselves to perfect reduction, there were fewer contact areas compared to the number of gaps between fragments. Thus, the healing which resulted was essentially gap healing (Schenk and Willenegger, 1967). Sections taken through different parts of the fracture site may have revealed small areas of primary healing located in the contact areas which were not necessarily seen in the sections studied. Thus, if the advantages of primary healing were to be gained following rigid fixation with a compression plate, it was obvious that the technique had to be performed with extreme accuracy. This required a thorough knowledge of the A.O. principles plus experience with the technique.

Several special features of the healing following rigid fixation with compression plates were observed in this experiment. When the screws traversed the medullary cavity, they were surrounded by a network of trabecular bone. When the plates were removed, a similar network was found to have filled any spaces which had existed between the plate and the bone at the time of surgery. This represented the bone cell reaction to the presence of these implants and, if anything, it tended to strengthen the fixation (Figure 33).

Recently, Uhtoff and Dubec (1971) observed that the side of the cortex which was under the plate underwent an increased resorption from within haversian systems and from the endosteal surfaces. This thinning of cortical bone under the plate was observed in the 3 fractures of the plated series of this experiment. It is thought to be caused by the fact that bending moments to which the bone would normally be subjected are now being absorbed by the rigid plate.

The cancellization is thought to have a weakening effect on the cortex. This becomes particularly important after the plate has been removed, since the entire area which the plate had covered has become much weaker than the comparable part of the contralateral femur and is therefore predisposed to refracture (Figures 31a and 31b).

In the compression plated bone, a compressive force exists in the bone and across the fracture gap. In order to maintain this compression of bone, the plate contains an equal and opposite tensile force. If the plate is in tension in the longitudinal direction, it cannot, at the same time, bear any of the compressive forces which the bone receives due to body weight and muscle tone. These forces, therefore, must be carried by the bone itself and not the plate. The plate does, however, absorb most of the bending moments which are applied to the bone ends. Therefore the bone does not have to resist bending forces while the plate is present and it may be this fact which is responsible for the cancellization and thinning which occurs in that cortex most affected mechanically by the plate (Wolff, 1892; Burstein, 1970; Uhtoff and Duboc, 1971).

On the application of a compression plate, there is a gradient of compressive force which is created around the cortical circumference at the fracture site. Therefore, the side opposite the plated one may contain a gap between fragments even though the fragments per se are under compression. This gap must heal by the process of "gap healing" in which transverse primary osteons fill in the gap and are subsequently replaced by longitudinal secondary osteons. Since a difference does exist between these 2 sides of the bone regarding the healing process, it is important when radiographing a plated bone to take a view which shows the cortex under the plate as well as the opposite one (Figure 28a).

In the case of the extracortical clamp, an untried experimental device, relatively poor stability was imparted to the fracture. Thus, in Dog #12, in which the clamp had not detached, healing was progressing, but during the early weeks of the experiment, a slowly increasing angular deformity resulted (Figure 36). This was partly caused by a deformity which developed on the first day or so following surgery when the clamp was the only thing maintaining reduction. This caused a misalignment of forces across the fracture site tending to increase the angulation. The other outstanding factor was that the clamp was not maintaining firm stability. Thus a very large callus formed which, as expected, was rich in cartilage and connective tissue elements. In the presence of movement, ossification of these soft connective tissue elements could not occur properly. Therefore, the slow shift in the angle was allowed. In this case, the histology revealed that ossification was occurring and that the fracture would eventually be bridged by bony trabeculae (Figure 40). Thus, the fracture healing process may have overcome the deleterious effects which are often caused by a lack of stability. In Dog #16, the axial alignment was good. Still, the connective tissue elements predominated in the fracture gap.

When a fracture callus is in the process of ossifying, the hyaline cartilage is replaced through enchondral ossification by trabeculae of bone. Using a differential stain, the newly formed trabeculae close to the cartilage were seen to contain cartilage cores upon which new bone was being deposited (Figure 14). The superficial layer of cells was composed of osteoblasts (Figure 13). Further back from the cartilage, trabeculae with cores were being replaced by trabeculae of very immature woven bone, while still further back the trabeculae contained fairly mature lamellar bone. This is the picture of rapidly healing bone with active ossification of the callus (Figure 14). When fibrocartilage or frank fibrous tissue are found between the bony trabeculae and the hyaline cartilage of the callus core, some degree of retardation in the healing process is suggested. If a thick layer of mature fibrous tissue exists in this region of the callus, delayed union is implied. This was the type of healing which was seen in Dog #16 of the clamp series (Figure 43). The other "successful" healing in that series, Dog #12, presented a similar histological picture but retained more osteoblastic activity (Figure 40). There was no apparent reason for the delayed union which the histology suggested in Dog #16, but movement at the fracture site and instability of fixation seemed to be the causes. Therefore, from the histologic studies, it became apparent that even in the 2 "successful" cases, the clamp had failed to make normal fracture healing possible.

The poor progress of healing of these 2 clamped fractures from surgery to the time of euthanasia was not revealed by the radiographs. This was because only the external callus was visible with the clamp covering the fracture site where this delayed union could have possibly been seen. In a clinical situation with the radiographs as the only guide, the clamp could have been removed with disastrous results (Figures 36 and 39).

In none of the slides could contact between the clamp and bone be found. Since only one section was being observed in each case, there may have been areas where the clamp did contact bone, but this series of slides suggested that there was always an intervening layer of connective tissue between them (Figure 41). If this was so, then there was a strong possibility that lysis had occurred around the clamp, and the space so produced filled in with connective tissue. On the other hand, no contact areas between bone and spikes was found on the slides, but if the spikes were still embedded in the bone, but not too deeply, then the connective tissue layer may have only been filling a space which was present at surgery. Radiographs showed some spikes to be surrounded by a black line suggesting lysis of bone, while others did not show this. Therefore, the experiment was inconclusive regarding the question of whether lysis did or did not occur at points of contact between clamp and bone. If it did, and the resorbed bone was replaced with connective tissue, this would have accounted for some of the instability of fixation, with the connective tissue layer acting as a cushion.

All of the implants in this experiment were surrounded by a fibrous capsule. In the case of the pins and plates, this was represented only by a thin layer of loose connective tissue (Figures 10 and 11). The radiographs revealed that the clamp was surrounded by a thin dark line which separated it from the adjacent callus tissue (Figure 35). The histology clearly demonstrated that this line represented a dense, mature fibrous connective tissue capsule in which the clamp was invested (Figure 41). In some animals, macrophages were present in large numbers in this capsule. The suggestion was that perhaps a more acute reaction to the clamp had occurred at an earlier stage in the healing process and, if so, it could have caused bone resorption and subsequent connective tissue deposition.

The radiographs revealed that the callus never covered the outer surface of the clamp (Figure 35). This was because the periosteum was

beneath the clamp, so no periosteal new bone could be formed on its superficial surface.

D. EXTRACORTICAL CLAMP

The cause of failure of the clamp in this experiment was mainly a mechanical one. There were a number of deficiencies in the design of this fixation method, relative to fixation of femoral fractures. Some of these were major and others minor. It was probably only the major ones which were given the opportunity to express themselves, completely overshadowing the effect of any minor ones.

In its present form, the flat parallel plates of the clamp failed to contact the cortex with a sufficient number of spikes to hold the fragments. An additional important discrepancy in form was that the femoral shaft tapered towards the head end. Thus in a midshaft fracture, the proximal fragment would have a narrower cross section than the distal one (Figure 1). Therefore, the clamp released from the proximal fragment easily, since its jaws were prevented from closing tightly on it, being held open by the wider distal fragment. This was a prominent feature of the last series of this experiment (Figure 37).

The length of the clamp appeared to be an important weakness for fixation of this type of fracture. The plates could have been made much longer to allow more surface to contact bone. This would have allowed the clamp to resist a much greater bending moment with reference to the fracture site, and therefore would have increased the stability of fixation. The entire clamp could have been much sturdier to help it to resist springing of the plates when they were fully tightened onto the bone. This experiment strongly suggested that the unfavorable healing attained using the extracortical clamp equipment was caused by mechanical deficiencies inherent in its design. No conclusions could be made regarding the value of extracortical clamp fixation per se.

SUMMARY AND CONCLUSIONS

A comparative study was made of the fracture healing which resulted following the application of 4 different methods of internal fixation to mid-diaphyseal fractures of the canine femur.

Nineteen Beagle dogs of uniform size and age were used. Strict aseptic surgical technique was followed, using the standard lateral approach to the femur to expose the surgical site. A method was devised to create a reproducible, uniform, transverse experimental fracture in the mid-diaphysis of the right femur. These fractures were fixed using the 4 methods prescribed, in 4 series of dogs. The fixation methods employed were intramedullary nailing, intramedullary nailing with half Kirschner splintage, compression plating, and extracortical clamp fixation. Postoperatively, the dogs were maintained under controlled conditions for a predetermined period of time during which the progress of healing was monitored clinically and radiographically. The dogs were then euthanatized and the healing fractures compared histologically.

While the degree of difficulty in surgical technique was slightly greater when the half Kirschner splintage was added to the I.M. pinning technique, the effort required to apply the compression plates was greater still. The efficacy with which the methods augmented the healing process, however, increased accordingly. The extracortical clamp was probably the simplest and most expeditious technique of all when no complications arose, but frequent problems constantly developed both during surgery and immediately postoperatively, causing the procedure to lose value.

The compression plating technique allowed guarded use of the leg within the first week and full use of it within the first 3 weeks. This early ambulation appeared to promote a favorable physiological condition of the muscles and joints of the limb. The I.M. pinning, with or without the half Kirschner splintage, allowed the dogs to carefully walk on the operated leg by 4 weeks and to achieve full use of it by 6 weeks. The dogs of the extracortical clamp series were never able to fully use the operated leg throughout the experimental study (Table 3).

The healing resulting from the use of the half Kirschner splintage presented only little improvement over that obtained using the I.M. fixation alone. In both series, a solid callus was apparent on the radiographs after 4 weeks of healing, and it had increased in size and density by 8 weeks. At 12 weeks the callus was observed to decrease in size as cortical remodeling began. Histologically, bony union was achieved with these 2 methods some time between the tenth and twelfth postoperative week. The dogs of Series II would probably have healed more efficiently than those of Series I if the fractures produced had been more comminuted.

In the compression plating series, the healing could not be monitored radiologically, but the disappearance of the fracture line could be demonstrated. This event, however, was not indicative of the stage of healing. Histologically, bony union occurred by the eighth postoperative week, and the stage of cortical remodeling was most advanced in the plated fractures and comparable to the stage observed in the previous methods at 12 weeks.

This experiment clearly established that the Sampson extracortical calmp, in its present form, was of no value as a fixation device for treatment of midshaft fractures of the canine femur. In 6 cases out of 8 it failed to maintain reduction but released the fragments completely early in the experiment. The unpredictable results which it produced were demonstrated during application of the clamp, in the instability of the fixation produced, and in the undesirable healing pattern which resulted in the 2 animals in which the clamp remained in place. Radiology was shown to offer little indication as to the progress of healing except to illustrate mechanical failures of the fixation. Such failures occurred in 6 of the 8 dogs in the series, demonstrating that the design of the system was mechanically deficient. No conclusions were reached regarding the feasibility of extracortical fixation in general.

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APPENDIX

APPENDIX

HISTOLOGICAL STAINS EMPLOYED IN THIS EXPERIMENT

The following 4 staining methods were employed as described in the *Armed Forces Manual of Histologic and Special Staining Technics.*

A. Gomori's One-Step Trichrome Stain:

This is a trichrome differential stain which was used to differentiate muscle, collagen and nuclei. The muscle stains dark red, the collagen green, and the nuclei blue or black.

B. Hematoxylin, Phloxine and Safran (H.P.S.):

This is a similar differential stain and one which is used in routine histopathology. Hematoxylin is blue and stains nuclei blue to purple. Phloxine is red and stains muscle and cytoplasm of osteoblasts red or pink. Safran is yellow and stains cartilage yellow. Collagen takes on an orange color. The bone matrix is stained vermillion.

C. Alcian Blue, Hematoxylin, Phloxine and Safran:

The alcian blue stains acid mucopolysaccharides (AMP) and heparin blue. It has a histochemical affinity for these substances and therefore stains active cartilage blue. In this experiment it was used with H.P.S. to differentiate hyaline cartilage, fibrocartilage and young connective tissue. The connective tissue elements took the orange color of safran due to their collagen content. Cartilage elements were easily identified as they took up the alcian blue stain.

D. Metachromasia:

This is the ability of a pure dye in solution to manifest a second and possibly a third light absorption peak when induced to do so by substances called chromotropes. Metachromatic dyes are pure dyes which in the presence of certain chromotropes will exhibit the characteristic shifts in color. The commonest metachromatic dyes are toluidine blue and azure A. These were used in this experiment to differentiate the areas of cartilage from other tissues in the callus.

E. Basic Fuschin Stain:

This stain was applied to the ground sections of undecalcified bone at a strength of 5% in 30% alcohol. It was employed to demonstrate osteoid tissue and may be used in combination with tetracycline labeling. The tetracycline labeled any bone produced at the time the antibiotic was given. The basic fuschin stained the osteoid seam. Thus, the bone found between these 2 rings of stain was that produced betwen the time that the tetracycline was injected and the time of euthanasia (Villanueva *et al.*, 1964; Wei and Arnold, 1970).