SKELETAL EXTENSION DEVELOPMENT: CRITERIA FOR FUTURE DESIGNS[a]

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INTRODUCTION

The development of a protruding skeletal extension suitable for attaching a functional artificial limb has progressed through a number of design changes. Each change has been an attempt to solve identified and defined problems. A review of past mistakes and successes led to the establishment of the following criteria for future development of this device:

1. The device must be a skeletal extension penetrating the skin in such a manner that the normal loads are transmitted directly to the skeletal system and not through thick layers of intervening soft tissues.
2. These loads must be distributed in such a manner as not to damage the prosthesis, the bone to which it is attached, or any interfacial tissue ingrowth.
3. Both gross and microanatomical limitations must be kept in mind, so that the device neither restricts the circulation nor otherwise impedes tissue healing.
4. In its final application, the skeletal extension must be a functional unit that permits freedom of motion and causes no pain.

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5. Although not an absolute necessity, the design should permit minor adjustments to be made externally rather than requiring secondary operative procedures.

6. The device must have a surface suitable for tissue adhesion and/or ingrowth both at the bone interface and at the skin interface. The skin interface must prohibit the development of a sinus tract and/or inhibit bacterial invasion.

7. All materials used in fabrication must be compatible with interfacing tissues, must become functional for the purpose intended, and must not cause adverse systemic reactions.

8. The total end product must be readily sterilizable, using routine hospital procedures.

9. The device should be designed to permit easy application under standard operating room conditions.

10. Ultimately, the design should permit use of existing skeletal muscles to power external articulating mechanical joints. This, of course, demands development of an artificial tendon that will provide a strong tenacious interface with the musculotendinous portion of the existing skeletal muscles, penetrate the skin without allowing any entrance for bacterial invasion, and transmit the muscle's power to the load in an efficient manner.

Needless to say, none of our designs has met all of the above criteria. It is doubtful that the above list contains all the criteria necesary for the product's development. The list is simply being offered as a nucleus in the hope that other investigators will find it useful and add to it as new criteria are identified.

For discussion purposes, the problem areas can be grouped into the following general classes: 1. tissue interfacing, 2. model development, 3. animal models and surgical procedures, and 4. stresses in the bone.

TISSUE INTERFACING

Skin Interfacing

No other aspect of this program deserves nor has received more attention than has the interfacial attachment of the skin. The integument is the body's first line of defense against microbial invasion. In the presence of implanted foreign material, it becomes even more important to maintain the integrity of the skin.

Our experience with skin interfacing has been reported in several articles (1-16). Metals, plastics, and ceramics have been tried, utilizing a variety of surface topography, including solids, textiles, and foams. Some investigators have found carbon a useful skin interfacing material (17-18). No material has yet been found that is considered to be ideal, although Dacron and nylon velour fabrics bonded to a solid surface so as to form impervious laminates have offered the most suitable solution thus far.

Bone Interfacing

Numerous investigators have found various types of porous ceramics with satisfactory qualities that allow new bone ingrowth into the porous structure of the material (19,20). Other investigators have pointed out that adhesion of bone to a solid nonporous surface is also possible (21,22). Sintered metals that create a porous surface have also been used for application in this area (23,24). Surface ingrowth, however, appears quite different and often disturbed when presented with a dynamic load.

Since all models have violated one or more of the criteria outlined above, long-term successful implants have been few. For this reason, it would be impossible to judge the results of one type of bone interfacing material against the others. Better initial adhesion appears to be attained with porous surfaces, but even this conclusion might be invalidated by statistical scrutiny. It is possible that bone ingrowth and/or adhesion may eventually be an unnecessary requirement. Prospects for interfacing with the periosteum rather than with cortical bone are currently being investigated.

Musculotendinous Interfacing

Attaching an artificial tendon to the musculotendinous portion of a skeletal muscle is not particularly difficult technically, but to do it in a manner that will maintain the union under the repeated stresses of dynamic loading is a major problem. In our earlier attempts, we used nylon and Dacron velour bonded to the Dow-Corning artificial tendon made of Silastic® -covered Dacron tape (3). The velour served as a mechanism for attaining a strong attachment to the musculotendinous portion by allowing a wide surface area for tissue ingrowth. Very few implants were made using this model before it was obvious that tissue grew to both sides of the velour, causing the tendon to become immobilized. Since then, we have bonded Silastic® to the back of the velour, thus isolating it from tissue ingrowth except at the interface between the tendon and the velour (25, 26, 27). We have successfully designed an artificial tendon that has been used to replace the Achilles tendon of the goat. One of these replacements has maintained its function without incident for the past 15 months. The technique used in attaching the artificial tendon was quite simple and utilized, once again, the surface area ingrowth offered by nylon or Dacron velour fabric (Fig. 1).

Attaching the tendon to the muscle is one problem, bringing it out through the skin for external loading presents quite a different problem. As with the skeletal extension, the integrity of the integument must be maintained in a manner that prohibits bacterial invasion. The same technique was used, offering the skin a velour surface for sealing the wound. Repeated stresses created by flexing and extending the external joint soon tore the skin-velour interface. No satisfactory solution to this problem has yet been discovered.

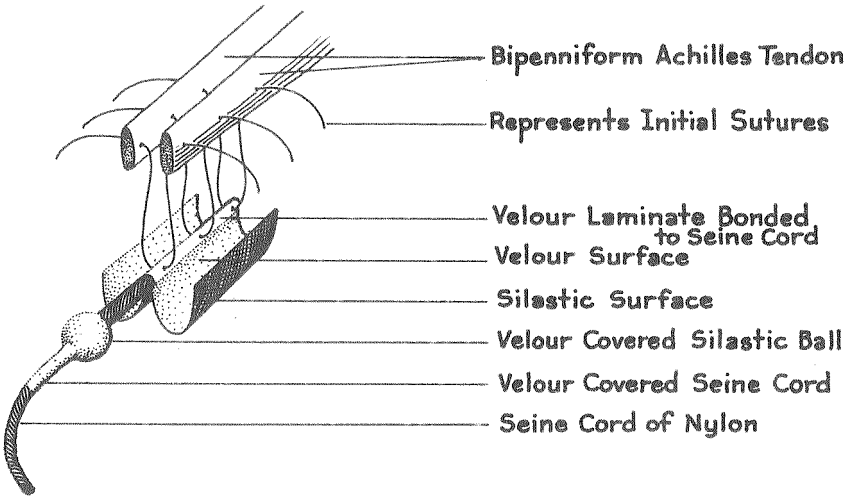

FIGURE 1.—The artificial tendon is shown with the initial suture placement orienting the artificial tendon between the bipenniform Achilles tendon. The Silastic®-covered velour flaps are next brought over the top of the tendon and the opposing edges approximated with a running inverting suture. Neither velour nor suture material is presented for surrounding tissue attachment; all that the adjacent surrounding tissues "see" is Silastic®, whereas the tendon surface "sees" only suture material and velour.

MODEL DEVELOPMENT

Intramedullary Rod Extension

Perhaps the simplest of all skeletal extensions utilized thus far has been an intramedullary rod held in position by friction. To keep the rod from being driven cephalad by the weight of the animal, a small plastic pedestal was molded to the rod to support the tibial stump. Later, a mortised joint between the tibial stump and the pedestal was incorporated to keep the shaft from rotating (Fig. 2). In the one horse that was utilized in these experiments, a crossbolt through the diaphysis and the shaft kept the shaft from rotating. However, after a few weeks the hole in the diaphysis became somewhat elliptical in reponse to these stresses. Nylon velour bonded to the surface of the pedestals served as an interface to support epithelial ingrowth and thereby reestablishing the skin's integrity.

Stainless steel was initially used as the axial rod, some having only a sandblasted surface. Sandblasted Vitallium® has also been used as an axial rod. Another surface was attained by stringing beads of porous ceramic (alumina) onto a stainless steel rod (12). In order to accommodate these thick-walled beads, the rod had to be made so small that mechanical failures resulted, causing us to abandon this approach (Fig. 3).

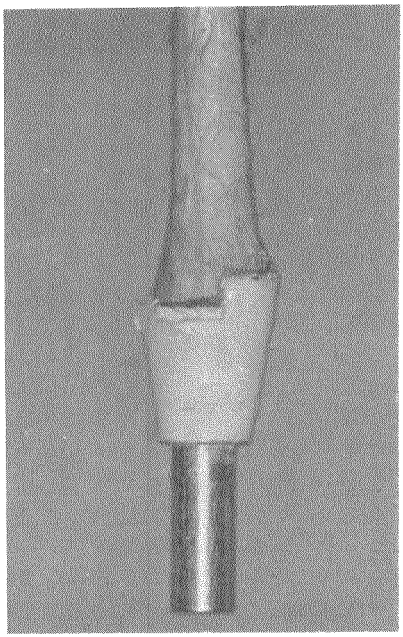

FIGURE 2.—Intramedullary rods can be coated with a variety of material. In each case, a pedestal is molded to the shaft to support the animal's weight and the pedestal is mortised to fit its counterpart, cut into the end of the bone. The completed mortise joint inhibits shaft rotation resulting from applied torque.

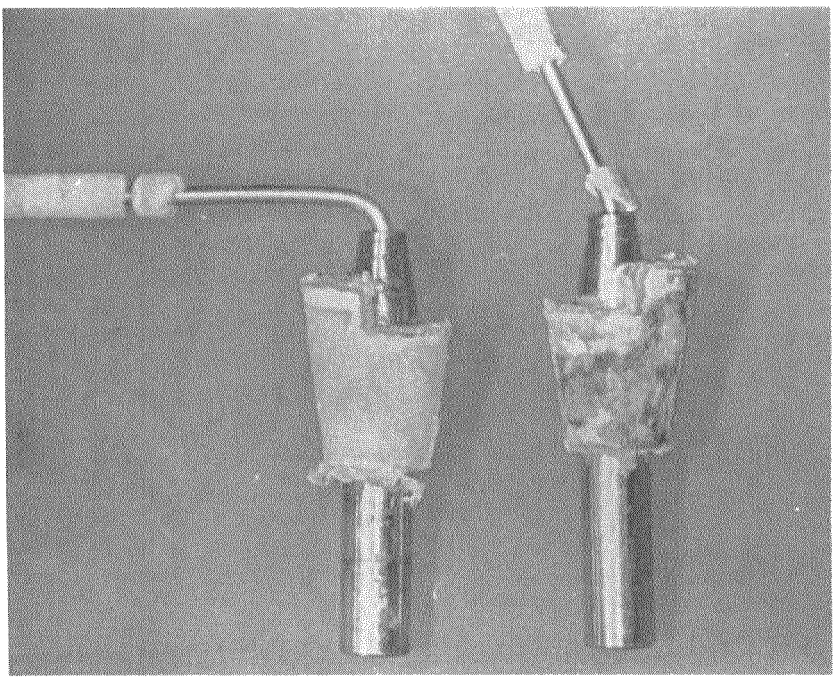

FIGURE 3.—Two intramedullary rods that became damaged as the animal tried to apply weight to the artificial limb. Construction of this device was by stringing beads of porous alumina onto the small stainless steel rod. Several of the ceramic beads were broken at the same time that the rod bent and pulled out of the intramedullary canal.

During cold weather, animals having a metallic skeletal extension seem to experience some pain, perhaps due to local heat dissipation. Other materials were tried, therefore, and these included composites of glass fibers and carbon fibers in a plastic matrix. The composites tried were apparently too brittle for this purpose, although it is quite possible special composite material design could alleviate this problem.

Some of the intramedullary rods were cemented *in situ* with polymethyl methacrylate (Surgical Simplex®). One surface was fabricated by making a slurry of polymethyl methacrylate and microspheres of urea. After removing the coated shaft from the mold, the cured surface was abraded to expose the urea microspheres. The exposed urea was then leached out by water, leaving a porous surface. (26)

Unexplained late failures caused by bone necrosis and/or osteomyelitis kept plaguing the program. One of the criticisms to the intramedullary approach was made by Dr. Fred Rhinelander, who suggested that we may be interrupting the bone's main circulatory supply. Following a technique outlined by Dr. Rhinelander, a series of femoral artery angiograms were made which revealed that the major blood supply to the cortical bone of the diaphysis is via the nutrient artery within the medullary canal (28, 29). Any intramedullary rod used as a skeletal extension would be liable to disrupt this blood supply, and certainly counterboring the canal would obliterate this source completely.

Supracortical Extension

Because of latent failures and angiographic data, which made the intramedullary approach less appealing, we designed a supracortical extension that left the intramedullary canal undisturbed. Three of these models were developed, all of which were based upon a cone-shaped distal tibia being fitted into a cone-shaped collet, which was compressed to the bone by a forcing cone driven by a jam nut. These stainless steel collets were altered in several ways so as to present to the bone a variety of surfaces: porous polymethyl methacrylate, Bioglass (University of Florida), Orthoplate carbon (General Atomic) and sintered porous stainless steel (Toronto Hospital).

A "pencil sharpener" type device was developed and used to prepare the distal tibia to accept the cone-shaped collets (Fig. 4). This device made a perfect cone so that a "machine fit" could be attained with the supracortical skeletal extension. The floor of the collets was stair-stepped to fit a mortise cut into the tibia's distal end to counter applied torsion.

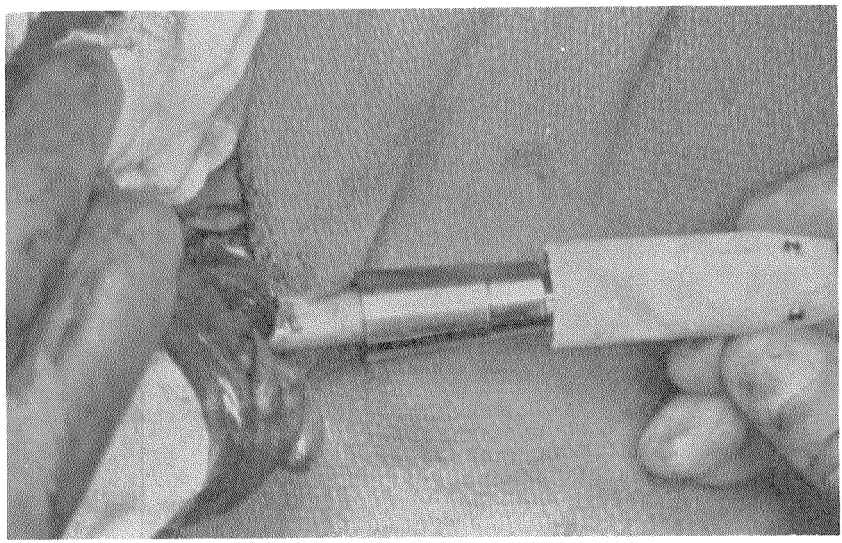

FIGURE 4.—The velour-covered forcing cone of the Mark I supracortical device is being placed over the collets. Prior to this maneuver, the bone had been amputated and made cone-shaped by a "pencil sharpener" type device. An Allen screw, countersunk into the base of the forcing cone and threaded to the collets, causes compression of the collets to the bone as the Allen screw is tightened.

The first supracortical device (Mark I) had a tightening mechanism that could not be approached subsequent to skin closure (Fig. 5). Since the shaved surface of the cortical bone undergoes the same healing process as a fracture, osteolysis and subsequent loosening of the collets occurred. This caused some loss of the devices because they would become wedged in fences, rocks, and loose soil and would thereby be extracted.

A second supracortical device was designed (Mark II) that would allow external readjustment of the collet's compression postoperatively (Fig. 6). A minor variation (Mark III) used a three-part collet having longitudinal cuts made so as to leave flexible tines in each collet (Fig. 7). This allowed a space for vascular growth between each tine and better distribution of the forces.

In order to standardize the procedure, a torque wrench was used, and 100 ft-lb selected as the torque applied at the time of installation. After 2 weeks, the wrench was again used to retighten the jam nut to the original 100 ft-lb. It is interesting to note that after this 2-week period, the remaining moment was only about 25 ft-lb. At the end of 6 weeks, a plateau of residual torque of about 70 ft-lb was reached.

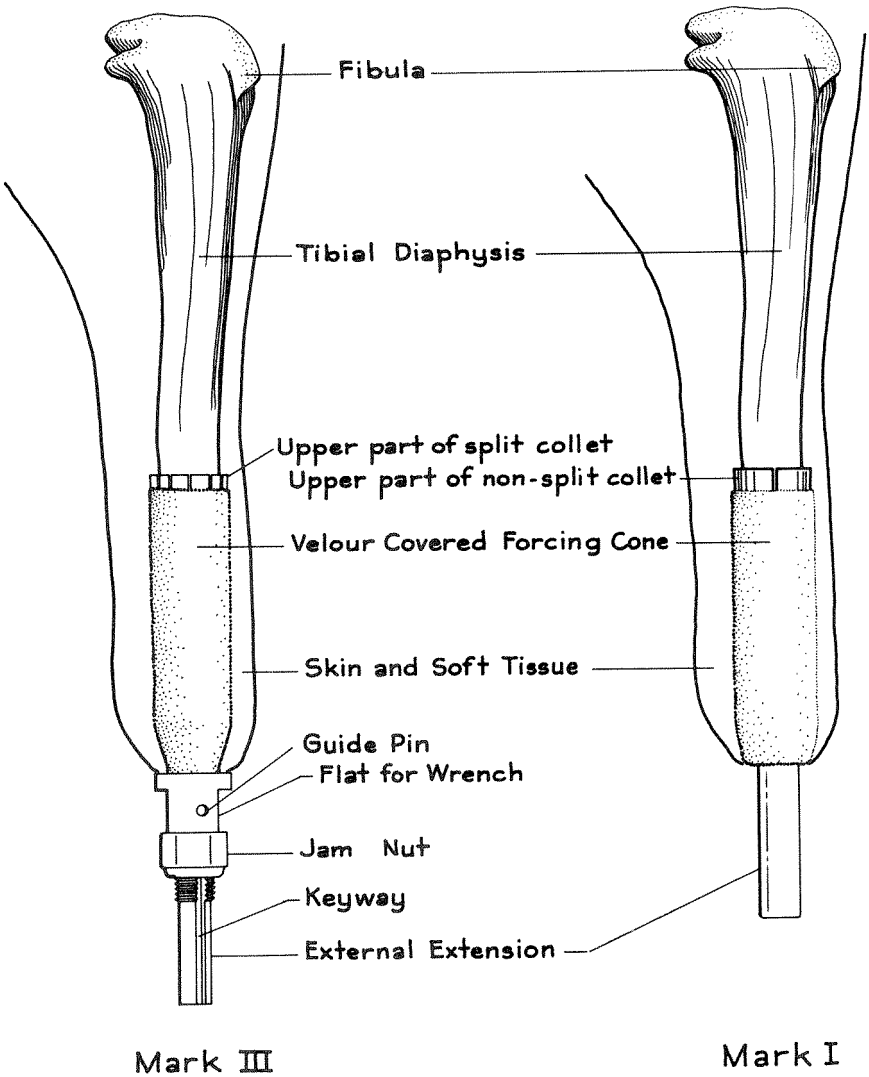

FIGURE 5.—Both the Mark III and Mark I are shown as they would appear installed. Two differences are apparent: the collet of the Mark I is a unit structure, whereas that of the Mark III is in three pieces (Fig. 6). The second difference is that the Mark I has a countersunk Allen-head screw in the base of the forcing cone, which is threaded to the collet. Tightening this screw causes compression of the collet to the bone. Once the external estension is screwed into place, the Allen screw is no longer accessible. The Mark III has an external jam nut that does the same thing as the Allen screw but remains accessible for external adjustments to be made periodically.

Artificial Tendon

Both the intramedullary and the supracortical extensions were designed to accommodate an articulating external joint controlled by exist-

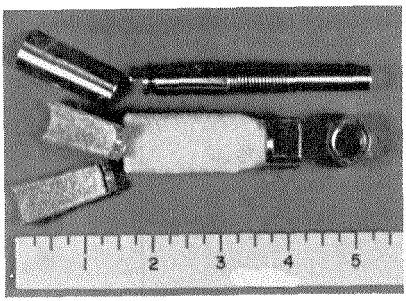

FIGURE 6.—The six separate pieces that make up the Mark II supracortical device. The collet is shown with two of the bone-interfacing surfaces facing the viewer. This particular interfacing material is porous polymethyl methacrylate.

FIGURE 7.—The slits cut into the three-part collet, creating tines, is the only difference between the Mark II and the Mark III. These Mark III collets have been coated with Orthoplate carbon by General Atomic Company.

ing skeletal muscles coupled by a skin-penetrating artificial tendon. Only the Achilles tendon has been used thus far because it presents a large object with which to work.[c] Being a bipenniform structure, it offers a method for strong mechanical attachment, initially, and a large surface area for subsequent reinforcement by tissue ingrowth into the artificial tendon.

The first artificial tendons were fabricated around the commercially available devices once manufactured by Dow Corning. These consist of narrow strips of Dacron tape covered with Silastic® . Using Dow Corning's Adhesive "A," a 4cm x 3cm piece of nylon velour, having a Silastic® backing, was bonded to one end of a 15cm strip of the artificial tendon. Tissue from the natural tendon would eventually grow into the interstices of the velour. This expanded surface area accepts the applied forces with ease and no pullout or tearing has yet occurred at this interface.

In order to come through the skin, velour was used at the point of exit so that skin integrity was maintained. When the artificial tendon was used in conjunction with the fitting of a skeletal extension, a modification in the initial skin incision was made. Instead of excising a triangular piece of skin over the heel, the skin was divided between the tibia and the Achilles tendon (Fig. 8). After suturing the artificial tendon to the

[c]The tendo calcaneus Achillis is derived from two extensor muscles, the gastrocnemius and and the soleus. The tendon starts as a septum between the two heads of the gastrocnemius and as a lamina on the deep surface of each head. The laminae and head fuse with the broad aponeurosis that covers the dorsal surface of the soleus. The aponeurosis has fibers arising from its posterior surface that pass obliquely to be inserted in a bipenniform manner on the deep surface of the tendon of Achilles. These fibers gradually converge into a heavy fibrous band that is inserted into the calcaneus. The Achilles tendon is perhaps the strongest tendon in the body.

Achilles, the opposing skin edges can be approximated so as to create a pantaloon-type structure (Fig. 9). The skin tunnel forming one leg of the pantaloon serves as a bellows to take up the slack necessary for tendon contraction and extension without actually sliding through the skin. Near the point where the artificial tendon exits through the skin, a ball 1cm in diameter is formed around the artificial tendon, using Adhesive "A" (Fig. 1). Nylon velour covers the ball. A stab wound in the skin allows the narrow artificial tendon to penetrate the integument, but the velour-covered ball to which the skin grows causes skin extension rather than tendon slippage. Late failures have been caused by the ball pulling through the skin. Using a slightly different technique, we hope to alleviate this problem in the future.

FIGURE 8.—Demonstration of the initial skin incision used when a skeletal extension implant is combined with an artificial tendon implant.

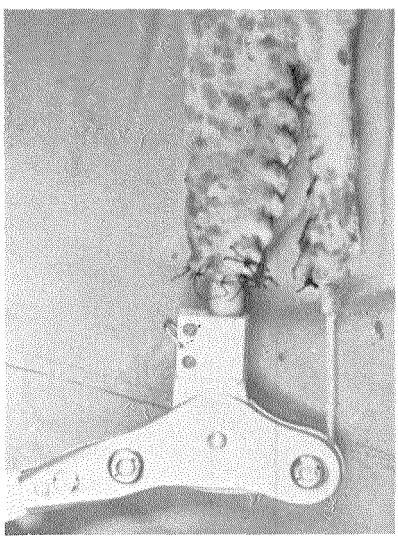

FIGURE 9.—External articulating ankle operated by artificial tendon exiting through one leg of the pantaloon. The flexor tendon, made of a rubberband, is not shown in place.

Breakage of the Dow Corning tendon caused all of the failures except one, which failed at the velour-Silastic® interface, leaving the velour still attached to the tissue. Testing this tendon on an Instron Universal Testing Machine revealed a break strength of around 80-100 lb. One might readily calculate that a goat of this weight could hardly be expected to keep the artificial tendon intact, considering the foot has about a 3:1 lever that applies force to the tendon. The remaining mystery is how the one implanted artificial tendon still manages to survive without breaking.

A commercial seine cord made of nylon and having a break strength of 350lb was located at one of the local sporting goods stores. The surface of the cord was washed, dried, and coated with Adhesive "A"® . After being cut into appropriate lengths, the cords were fabricated into tendons as previously described. Although none of these tendons have broken or pulled loose from their musculotendinous attachments, slippage through the skin is an unsolved problem.

ANIMAL MODELS AND SURGICAL PROCEDURES

The canine was the animal model initially used to develop a permanently attached artificial limb. For these procedures, the canine was a dismal failure because this animal would under no circumstances leave the wound alone during healing. His incessant gnawing and licking at the wound soon had the prosthesis partially or completely evulsed.

Both the horse and the goat have proved to be superior models for these experiments. Since the initial capital costs and subsequent upkeep for goats are both much less than for horses, our selection has favored the goat. Goats are very active animals—accustomed to jumping from pinnacle to pinnacle—and these habits have necessitated our "over-engineering" some of the implant devices.

Spanish and crossbred Angora goats are purchased in groups of 15-20, as needed, from neighboring ranches; these pasture selections usually net goats weighing from 25-35 kilograms. All animals undergo a 2-week period of quarantine and are drenched with thiabendazole immediately after delivery. Males are castrated and pregnant females are separated from the remaining herd until their newborn kids are weaned.

Goats selected for surgery are isolated from the herd and have the left hind leg X-rayed. Two days prior to surgery, all food is withheld and the evening prior to surgery, water is also withheld. Because these animals are ruminants, this type of preoperative regimen is mandatory to keep them from bloating and vomiting during anesthesia.

Sedation in the form of acepromazine, 1.0mg/2.5kg, and atropine, 1.5mg/kg of body weight is given I.M. (intramuscularly) 30 minutes before induction of anesthesia. With the animal in this tranquil state, the left hind limb is clipped with electric hair clippers from below the ankle to above the knee.

The animal is then led into the operating room and secured to the operating table in the left lateral position. An indwelling venous catheter is placed into the left jugular vein and kept open by 5 percent dextrose/normal saline. Intravenous sodium pentobarbital is then administered at a dosage of 2.0-2.5mg/kg of body weight through a "Y" in the intravenous setup until the lid reflex diminishes and the jaw muscles relax.

After this preliminary induction, the endotracheal tube is inserted into the trachea, the balloon inflated and the animal placed on endotracheal

halothane at a 5 percent flow rate until Stage III, Plane III is reached. The flow rate is then reduced to 2 percent for maintenance. Respirations are monitored by the rebreathing bag and the electrocardiogram displayed on an oscilloscope. During induction, a second assistant has coated the clipped leg with Nair® and after waiting a period of about 10 minutes, the remaining hair is removed by scraping with a tongue depressor and 4 x 4 gauze sponges.

The leg is then scrubbed with Betadine® solution, rinsed in 70 percent alcohol and allowed to air dry. During this drying period, the leg is grasped by the hoof and held away from the operating table. The prepared area is then sprayed with Rezifilm® and allowed to dry. Sterile, dry, skin towels and drapes are used to cover the unprepared parts of the animal in a standard fashion.

An initial circumscribing skin incision, 3cm below the ankle, is first made and a second incision is started over the Achilles tendon about 3½cm above the heel, extending distally toward the primary circumscribing incision and making about a 30 deg angle with the anterior border of the Achilles tendon. An identical incision is made on the medial side, thereby forming a triangular piece of skin, which is dissected free from the underlying tissues and discarded. The discarded skin contains the calloused heel through which we prefer not to enter with the knife blade.

Sharp dissection of the remaining skin is allowed to proceed cephalad until a medium-sized skin flap has been raised. This flap is then grasped with a lap sponge and pulled cephalad, gently tearing the skin from the subcutaneous tissues. Hemostasis is accomplished by clamping and ligating the divided vessels using $\overline{00}$ chromic catgut. Dissection of the skin flap is continued to the junction of the upper and middle one-third of the tibia.

Attention is then directed to the transverse crural ligament, which is transected, exposing the dorsalis pedis artery. This artery is divided and ligated with $\overline{00}$ chromic catgut. The Achilles tendon is then transected near its musculotendinous origin, allowing for the division and ligation of the posterior tibial artery. Remaining tendons are likewise transected to gain access to the underlying periosteum. After elevating the periosteum on the distal one-third of the tibia, the tibia is amputated with a bone saw just proximal to the distal tibial epiphysis.

Up to this point, all of our operative procedures have been the same. Due to variations in the methods of attaching the several models to the tibia, the subsequent operative techniques were individually designed to accommodate these differences.

Our initial model used an intramedullary rod having an incorporated morticed pedestal made of plastic. Nylon velour bonded to the pedestal's surface served to anchor the skin and new tissue ingrowth. Regardless of the composition of the intramedullary rod, in each instance the tibia was

treated the same by first counterboring to the depth and diameter necessary to accommodate the rod and tailoring the distal tibia to fit the pedestal mortise. The mortise was designed to prevent axial rotation of the intramedullary rod.

With the supracortical devices, the distal tibia was treated somewhat differently. No reaming of the intramedullary canal was necessary, which preserved the nutrient arteries within the canal. The distal end was coned by using a pencil-sharpener-type device until a tight fit was obtained with the cone-shaped collets. As before, the distal tibia was tailored to fit a mortised floor within the collet. A forcing cone applies compression to the bone-collet interface by torque on the jam nut. The forcing cones had nylon velour bonded to their outer surface, permitting the skin attachment.

Skin closure was fairly standardized, regardless of the model used. A running suture of $\overline{\text{ooo}}$ black silk is used to close the posterior incision, and a $\overline{\text{oo}}$ silk purse-string suture approximates the skin to the velour covered pedestal or forcing cone. If subcutaneo us oozing appears to be a potential problem, a sterile dry dressing is applied and held in place with an elastic bandage. This is usually unnecessary and all that is normally done is to apply a second coating of Rezifilm® and secure the external extension.

The external extension has taken on several forms. The most complicated of these was one which had an external articulating joint designed to accommodate the artificial tendon extension. However, the simplest and most satisfactory extension has been a straight pylon with a rubber hose secured to its distal end. This piece of rubber serves as both a hoof to give adequate traction and as a shock absorber.

Most of the animals walk on the prosthesis immediately after awakening from anesthesia. One animal managed to clear a 5½-ft-high (1.7m) corral fence on the afternoon of the day of surgery. Her presence has since eluded us, except for brief visual sightings by numerous individuals working on the several thousand acres of pastureland adjacent to the goat pens.

Some goats are reluctant to bear weight for several days after surgery. Why some animals show evidence of pain and others do not is somewhat puzzling. Any animal that begins to limp or favor that leg is sacrificed. These late developments of obvious pain are almost invariably due to osteomyelitis or bone necrosis.

STRESSES IN THE BONE AND SUPRACORTICAL EXTENSION

Stresses in the bone and skeletal extensions are produced by forces acting on the end of the extension as the goat walks, runs, and jumps. Although we do not know the magnitudes and directions of the peak forces that occur, we do know the types of forces to expect. We can,

therefore, show the reactions and stresses in the bone and skeletal extension for these expected forces.

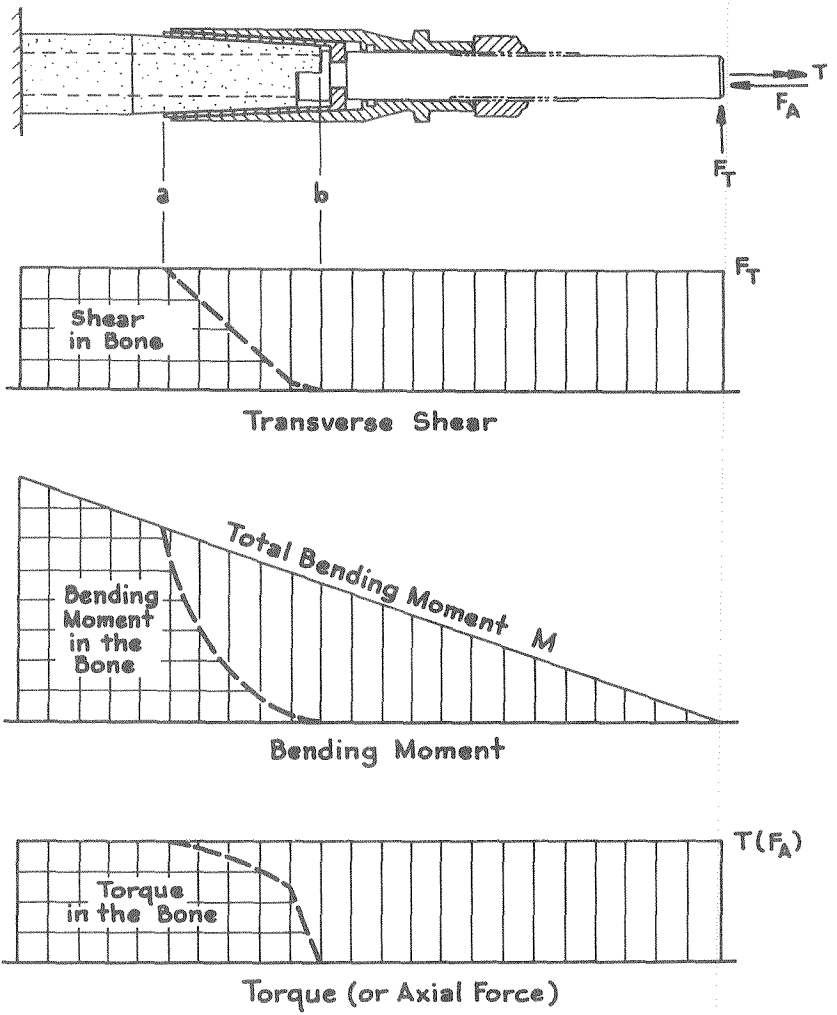

FIGURE 10.—Force diagram showing the applied and transmitted forces occuring with the Mark II or Mark III devices attached to the tibia.

Figure 10 shows some of the forces that occur. These include axial and transverse forces, F_A and F_T respectively, as well as an applied torque T. The torque is produced by an offset at the end of the extension associated with an articulating foot. An offset might also cause a concentrated moment at the end of the extension, but its value will be low, compared to

the moment produced by the transverse force F_T, so the concentrated moment has been omitted.

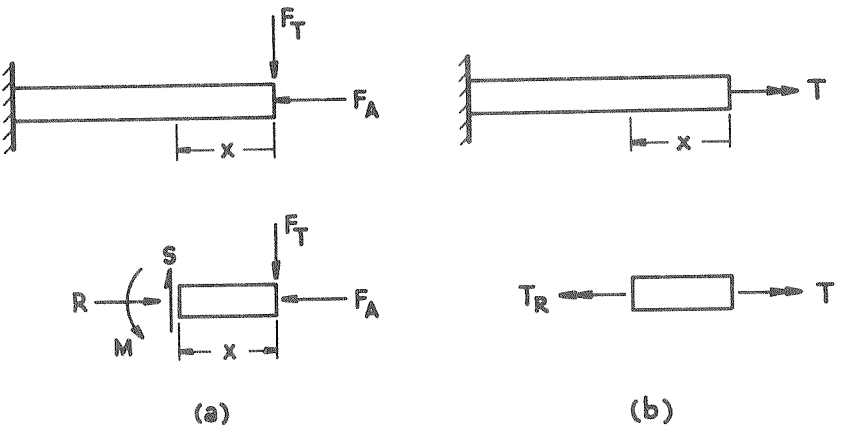

FIGURE 11.—Basic forces acting upon a cantilever beam. This diagram is used to illustrate the distribution of forces in the bone and supracortical extension.

To understand the reactions in the leg and skeletal extension produced by the applied forces, consider the simple cantilever beam of Figure 11. In part a, axial and transverse forces are acting on the end of the beam. If the beam is cut at any section, a distance X from the end of the beam, internal reactions R, S, and M are required for equilibrium. Values of R, S, and M are obtained by summating forces and moments in the plane of the forces and requiring that the summation equal zero. By this procedure we obtain:

$$\Sigma \text{ axial forces} = 0{:}F_A - R = 0; \text{ therefore } R = F_A$$
$$\Sigma \text{ transverse forces} = 0{:}F_T - S = 0; \text{ therefore } F_T = S$$
$$\Sigma \text{ moments} = 0{:}\ M - (F_T X) = 0; \text{ therefore } M = (F_T X)$$

Notice that the axial force R and shear force S will be the same at all sections along the beam, but that the bending moment M varies with the distance X.

For clarity, the applied torque is shown separately in part b. It is obvious that the torque reaction T_R is equal to the applied torque T at all sections along the beam.

In this same manner, the force diagrams for the leg were established (Fig. 10). The ordinate of each diagram represents the magnitude of the force in the bone or skeletal extension determined from an equilibrium balance at all points along the leg. Although it is easy to determine

the distribution of the total forces, computing the distribution of the forces in the various components (in the bone and parts of the skeletal extension) is difficult. At point a of Figure 10, the forces must be reacted totally by the bone, and at point b, they must be reacted totally by the skeletal extension. In between a and b, the distribution of the forces is a function of the relative stiffness of the parts and the bond between them. To date, we have only estimated load transfer between the skeletal extension and the bone. Our estimate is given by the dashed lines in the force diagrams of Figure 10. We have assumed that the transverse force F_T varies linearly between the bone and the prosthesis. Because the bending moment is a direct function of the transverse load (as explained in the discussion of Fig. 11), setting the distribution of F_T also sets the distribution of M. The distribution of the torque T, and axial force F_A, are similar and so are shown together in the last diagram. For these two forces, a more abrupt load transfer occurs because of the direct load path from the bone through the mortised shaft.

The magnitude of these forces has not been established, so peak stresses could not be calculated. However, stresses in the bone were determined for unit values (1N) of the forces. To compute the torque, a 25mm offset from the axis of the shaft was assumed (this is reasonable for a goat's foot), which yields a torque of 0.025N-m. The resulting stress distributions for each force are given in Figure 12. Stresses are the maximums at each cross-section through the long axis of the bone. Some of the stresses can be combined to compute the maximum stress for all loads, but to do so requires that we know both the magnitudes and phasing of the loads. So, only stresses produced by the individual loads were computed.

The most obvious conclusion to be reached from Figure 12 is that bending stresses predominate in the bone. This will probably be true even if the ratio of the loads (F_A and F_T) is not unity, as is true for the stresses in Figure 12. Another important point is the peak in the stresses at the upper end of the skeletal extension. The peak occurs because the taper in the bone starts outside of the collet. This condition can be avoided if the bone is not bigger than the inside diameter at the end of the forcing cone. This would require that either the cone be oversized to match the diameter of the largest bone expected or that the cone be carefully matched to each recipient of the prosthesis. This condition can be avoided by designing a prosthesis which requires no bone modification.

The force diagrams and stresses of Figures 10 and 12 were determined for forces applied to the skeletal extension in the direction indicated by Figure 10. Normally, the magnitudes of the stresses will be the same for a reversal of the load with only the signs changing; however, this is not true for the axial load in this case. If it is reversed to produce tension in the prosthesis, the primary load path is no longer through the shaft to the bone, but all of the axial tensile load will be transferred through the bond

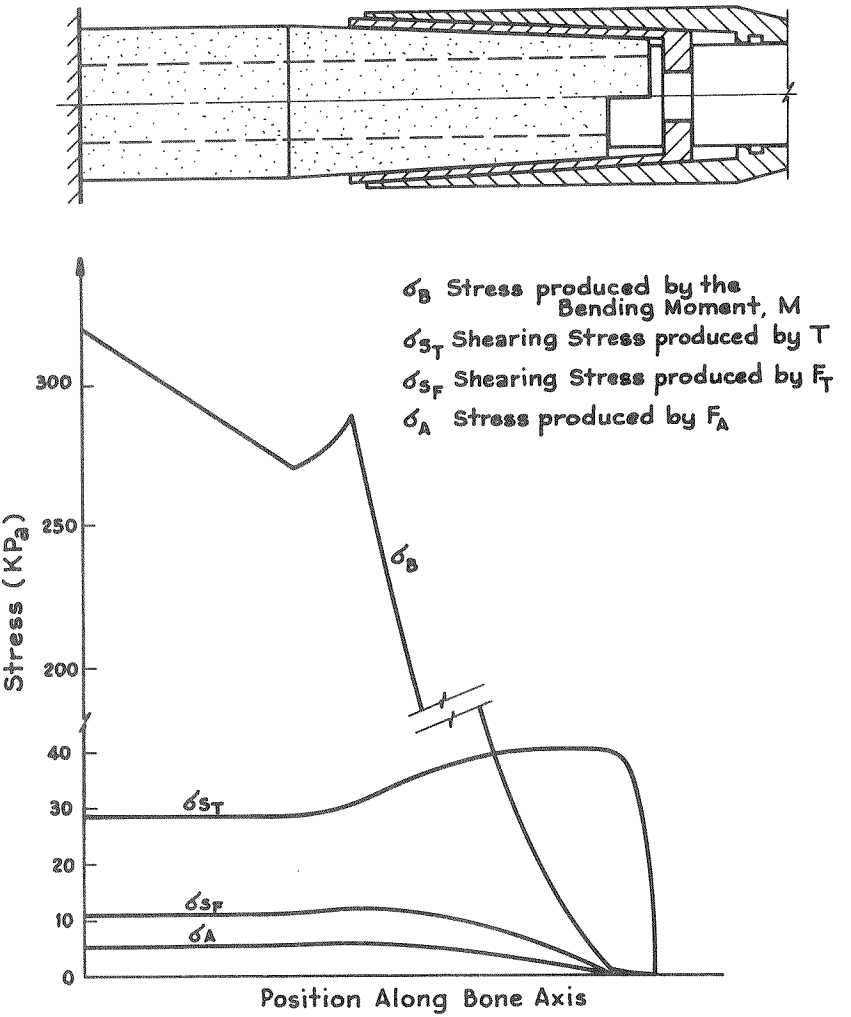

FIGURE 12.—Stresses in the bone produced by unit forces acting on the end of the skeletal extension. The stresses are computed using distribution of forces shown in Figure 10.

between the bone and the collet of the skeletal extension. Tensile forces will be created in the bond as shown in Figure 13, with the magnitude of the tension being proportional to the sine of the forcing cone angle θ. For the cone angle of 3deg in the current prosthesis, the tensile load in the bond is equal to 5.23 percent of the applied load. Because of the large bond area of approximately 1600mm^2, tensile stresses in the bond will be low. For example, the unit tensile load of 1N used in earlier calculations will produce a tensile stress in the bond of .032kPa, if the stresses are uniform throughout the bond. Additional tensile stresses will be produced

in the bond by bending in the prosthesis, but these stresses will depend upon the relative stiffness of the bone, skeletal extension, and bond material. The magnitude of these tensile stresses has not been calculated.

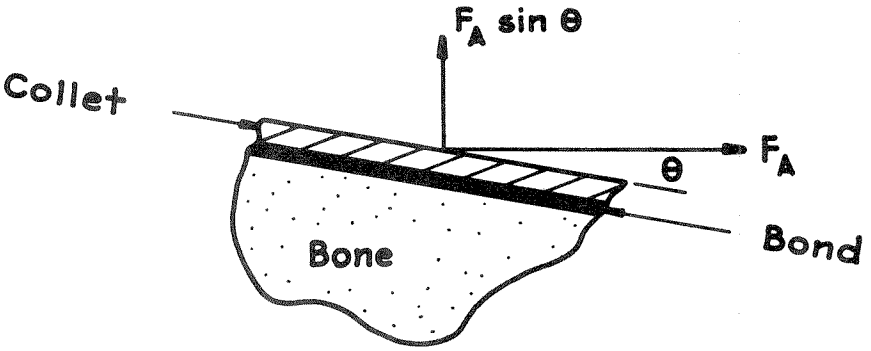

FIGURE 13.—Tension in the bond produced by tensile forces on the skeletal extension are a function of the cone angle θ.

RESULTS

Since March 1973, a total of 51 goats have had the left hind leg amputated and replaced with one of four skeletal extension models. Table 1 shows the individual results. Those animals alive at the time of tabulation have their weeks-in-place figure in italics. The first 27 of this group had an intramedullary rod implanted. Discounting eight early technical failures lasting only a week or less, the legs remained in place from 4 to 33 weeks on the 19 remaining animals and had an average time in place of 12 weeks. Six of the 27 goats had, in combination with the skeletal extension, an exteriorized artificial tendon implanted to the Achilles tendon. During this same time period, one animal had only the Achilles tendon replaced by an artificial tendon, and she remains completely free of any outward signs that such a procedure was done.

Three models of the supracortical device have been used as implants on 24 additional goats. This group contains five early technical failures, one escapee, and five who are alive and well. Of the remaining 13 animals, the average time in place is only 11 weeks. One of this group had, in combination with the skeletal extension, an Achilles tendon replacement. After 4 weeks, she jumped a fence, breaking the prosthesis and shearing the Silastic® bond between the velour and the seine cord.

These data might suggest that changing the design from an intramedullary rod to a supracortical device did not accomplish a thing. So far as time in place is concerned, this is true; however, no bone necrosis was seen, and only one case of ostemyelitis was observed. This compares with five such cases in the preceding group. The problem with the

TABLE 1[a]

Goat No.	Procedure	Results	Weeks in place
11	Intramedullary rod (I.R.) of steel held with Surgical Simplex® (PMM)	Steel rod broke due to defect. Sacrificed	25
12	Ceramic I.R. held with PMM	I.R. bent and pulled out. Sacrificed	5
14	I.R. ceramic over steel	Rod bent. Sacrificed	1
15	Ceramic I.R.	I.R. bent and pulled out. Sacrificed	1
16	I.R. with tapered shank	Bone fractured during insertion I.R. unstable. Immediate sacrifice	0
17	I.R. with tapered shank	Bone fractured during insertion, causing gradual bone necrosis. Sacrificed	8
20	Velour tendon used to replace Achilles tendon	Excellent—no perceptible limp Alive and well	*64*
21	Tapered I.R. with ceramic beads	Bone necrosis. Sacrificed	21
9	Tappered I.R. with cramic beads	Anesthetic death	0
10	I.R. coated with porous P.M.M.	Mortise fractured. Sacrificed	8

[a]Individual Results: animals alive at the time of tabulation have their weeks-in-place figure in italics.

Table 1 (*continued*)

Goat No	Procedure	Results	Weeks in place
25	I.R. coated with porous PMM	Canal too large for prosthesis. Sacrificed	8
26	I.R. coated with porous PMM	Died during kidding	6
24	I.R. coated with porous PMM	Broke leg in jumping. Sacrificed	4
23	I.R. coated with porous PMM	Mortise broke allowing rod to turn.	4
27	I.R. coated with porous PMM	Caught leg in fence, tore skin. Skin-velour infection. Sacrificed	4
29	I.R. coated with porous PMM	Osteomyelitis. Sacrificed	33
28	I.R. coated with porous PMM	Rod fell out. Sacrificed	4
30	I.R. coated with porous PMM	Bone necrosis. Sacrificed	13
31	I.R. coated with porous PMM	Goat had kid after 3 months. bone necrosis—aggravated by nursing? Sacrificed	14
33	I.R. made of fiber glass coated with porous PMM	Vomited and aspirated in recovery room	0
32	I.R. coated with porous PMM plus Achilles tendon implant	Tendon broke. Sacrificed	4

Table 1 (*continued*)

Goat No	Procedure	Results	Weeks in place
35	I.R. coated with PMM plus Achiles tendon implant	Tendon broke. Sacrificed	4
34	I.R. coated with porous PMM plus Achilles tendon implant	Tendon broke. Sacrificed	24
36	Carbon reinforced I.R. coated with porous PMM	Prosthesis lost in pasture, never found. Sacrificed	9
37	I.R. with porous PMM plus Achilles tendon implant	Tendon broke. Sacrificed	12
38	I.R. with porous PMM plus Achilles Tendon implant	Died of poisonous snake bite	21
39	I.R. with porous PMM plus Achilles tendon implant	I.R. fell out. Probably caught in fence. Sacrificed	1
40	I.R. with porous PMM	Leg fractured. Sacrificed	12
41	Supracortical endoprosthesis (Mark I) porous-PMM-coated collets	Osteomyelitis. Sacrificed	8
42	Supracortical endoprosthesis (Mark I) porous-PMM-coated collets	Prosthesis became loose. Sacrificed	2

Table 1 (*continued*)

Goate No.	Procedure	Results	Weeks in place
43	Supracortical endoprothesis (Mark I) porous-PMM-coated collets	Prosthesis became loose. Sacrificed	16
44	Poor fit at surgery, Mark I	Prosthesis became loose. Sacrificed	0
45	Mark I with Achilles implant	Jumped 4 ft fence. Broke prosthesis and pulled tendon loose. Reoperated	4
46	Mark I and porous-PMM-coated collets	Prosthesis came off, leaving velour still attached to skin.	22
47	Mark I with sand-finished collets	Died of intestinal parasites and/or drenching	4
48	Mark I with sand-finished collets	Goat jumped 5½ ft board fence P.M. of surgery. Whereabouts now unknown.	?
49	Mark I with silica granules in PMM	Prosthesis lost in pasture. Sacrificed	12
50	Mark I with silica granules in PMM	Forcing cone came off, leaving collet still attched. sacrificed	25
51	Mark I with Bioglass-coated collets	Prosthesis loosened. Sacrificed	4
53	Mark I with porous PMM	Painful coupling. Sacrificed No osteomyelitis seen at autopsy.	8
54	Mark II with porous PMM	Caught leg in fence, pulled out prosthesis. Sacrificed	13

Table 1 (*continued*)

Goat No.	Procedure	Results	Weeks in place
55	Mark II with porous PMM	Poor operative fit. Sacrificed due to non-healing.	1
56	Mark III (three split collets) coated with porous PMM	Delivered 4-legged kid 5 mo. postoperative Mother and kid still alive and well	*24*
57	Mark III (three split collets) coated with porous PMM	Prosthesis lost in pasture. Scrificed	23
58	Mark II with porous Lexan collets coated with porous PMM	Alive and well	*18*
59	Mark III coated with porous PMM	Alive and well	*12*
60	Mark II Lexan collet with perforations	Prosthesis came off, leaving Lexan collet attached to bone. Sacrificed	0
61	Mark III with porous PMM surface	Bone too small, Prosthesis removed 1st postoperative day. Sacrificed	0
45	Previous implant: Mark III with porous PMM—reamputation	Alive and well	*6*
62	Mark III with Orthoplate carbon surface	Forcing cone key migrated, causing fracture of mortise. Sacrificed 2nd day post operative.	0
63	Mark III with Orthoplate carbon surface	Prosthesis came off 3rd post operative day. Sacrificed	0
64	Mark III with porous sintered stainless steel	Alive and well	*4*

supracortical device seems to be an inability to overcome those forces in extension. Apparently this will always be a problem with a cone-shaped device. A new design is currently being readied to replace the present model.

SUMMARY

Experience with an intramedullary skeletal extension and a supracortical extension has been reviewed. Criteria for possible use in future developments have been outlined. Tissue interfacing with the material used in fabricating these devices were briefly discussed, stressing the importance of maintaining the skin's integrity. An artificial tendon, which attempts to bring the external mechanical ankle joint under the direct control of existing skeletal muscles, was described. Three animal models were reviewed and our reasons given for selecting the goat. Preoperative preparations, anesthesia, and the surgical procedures were described in some detail. A tabulation of the procedures done on 52 goats (Table 1) shows little difference between the intramedullary rod and the supracortical devices when only the times in place are compared. However, the supracortical devices showed no bone necrosis and produced only one case of osteomyelitis. With the intramedullary rod, five cases of necrosis and/or osteomyelitis were seen. The cone-shaped supracortical devices are somewhat vulnerable to forces in extension.

ADDENDUM

The problems surrounding the use of the supracortical prosthesis have led us toward a "supraperiosteal" approach. The unit is similar to the Mark III supracortical design but differs in having a two-part collet with straight walls, a forcing cone with straight walls and an elastomer swaging unit between the collete and the periosteum (Fig. 14 and 15). The elastic swaging socket is made of precast Silastic® and contains a nylon velour lining to interface with the periosteum. Velour likewise covers the forcing cone for the purpose of interfacing with the skin.

Since nylon velour may not be the most appropriate material for interfacing with periosteum, other materials will be investigated for this purpose. These will include Proplast®, polyurethane foam, and porous polyethelene. In order to keep avenues open for vascular development at the interface, it was proposed by Dr. Fred Rhinelander that these porous interfacing materials be laid in the precast socket in linear strips so as to form channels between them. It will be interesting to compare the results of this approach with results when the cavities are completely lined with an interfacing material.

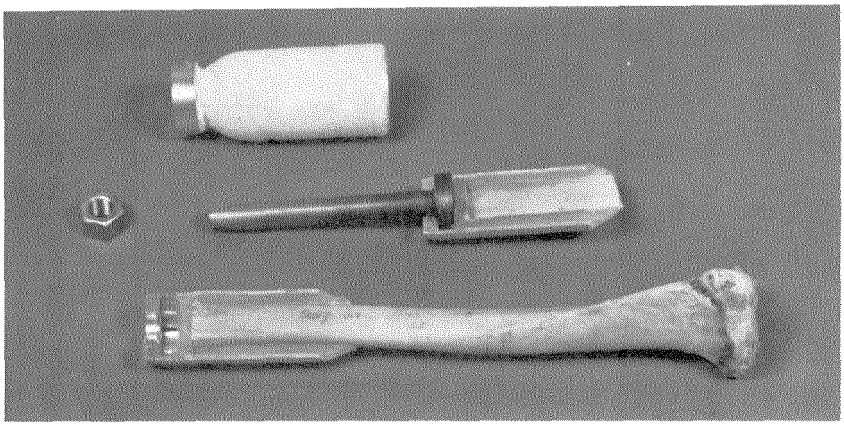

FIGURE 14.—Top portion of the assembly shows the velour-covered forcing cone and beneath this is the jam nut with the swaging ram in place in one-half of the collet. The other half of the swaging socket contains the amputated tibia used as a casting model.

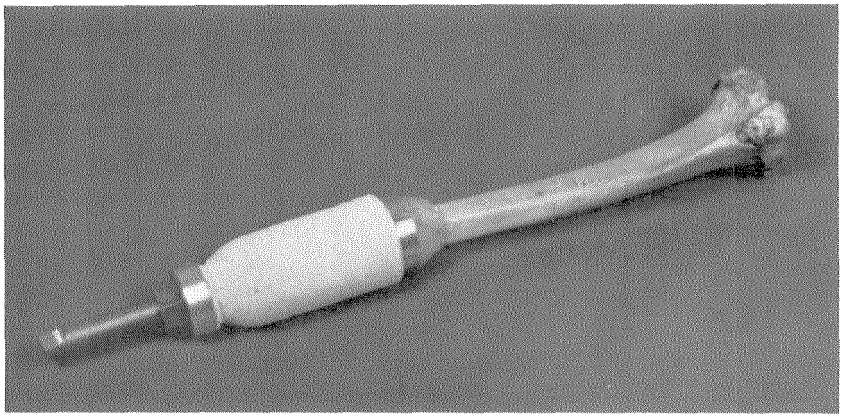

FIGURE 15.—The supraperiosteal prosthesis as it would appear implanted on the distal end of an amputated tibia (goat).

The supraperiosteal approach using a velour-lined elastic swaging socket offers several attractive solutions to some of the problems encountered with previous designs. The circulation of the bone arises from two sources, the intramedullary (nutrient artery) and the periosteum. If both of these sources are left relatively undisturbed, healing of the interface should progress more rapidly, and the resulting new tissue should remain healthy. Since the bone is not a perfectly round structure, it offers more resistance to shear stresses at the interface which arise from torque forces applied along the axis of the skeletal extension, provided that the precast cavity matches the bone rather closely. Also, the magnitude of

transverse forces will be diminished by the elastomer at the junction of the bone and the proximal end of the prostheses where there is currently a tendency to place the diaphysis in shear.

In order to obtain an accurate fit in a precast socket, we have X-rayed the intact hind limb of those animals brought to sacrifice during the past few months. The intact tibia is manually stripped of all soft tissue, allowed to dry and numbered according to its X-ray. An animal selected for operation is likewise X-rayed, and the X-ray compared with those on file. The appropriate tibia is then selected for use as the model in making the cavity of the precast elastic swaging socket. Raw Silastic® is molded into each half of the bipart collet and the tibial model is placed between them. This portion of the assembly is then placed into the forcing cone, using the jam nut of the swaging ram to compress the Silastic® around the bone. Excess extruded Silastic® is removed and the entire assembly is placed in the oven to vulcanize.

After vulcanizing, the forcing cone is removed and a razor blade cut, directed between the two collets and down to the bone, divides the elastic swaging socket into two halves, allowing removal of the bone. The Silastic® is not removed from the collets, but both halves are left in their respective relationships from then on. At this point, the cavities are lined with velour, using Dow Corning's Adhesive "A," and returned to the oven for curing.

During implantation of the device, an "H" gage is used to determine the appropriate site of amputation. This assures us a standard distal diameter and a better fit throughout the remaining tibial shaft. So far, only two prototype implants have been done and both of these were surprisingly simple—taking much less time to do than any previous model. Both animals are using the prosthesis and appear to have little reluctance to bear weight on the device.

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