DEVELOPING A PERMANENTLY ATTACHED ARTIFICIAL LIMB

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INTRODUCTION

There is nothing new concerning the broad concept of having a permanently attached artificial limb. Our endeavor has been to determine if such a dream is feasible. We think it is.

Problems as complex as developing such a device must be approached by dividing them into small, well-defined problem areas and grouping these into sound research projects. The group of problems that must be given first priority are those pertaining to tissue interfacing.

This type of artificial limb would be designed around a direct skeletal extension protruding through the skin. A removable articulating joint would be affixed to the protruding portion. An external portion might also have the potential of being controlled by the primary skeletal muscles by way of artificial tendons exiting through skin tunnels.

To achieve the above, it is necessary to find solutions to the following four major problem areas:

1. Finding a material for skin interfacing that would create an absolute bacterial barrier, be tenacious in its attachment, and have the strength and durability for long-term function.
2. Developing a material and/or technique to interface with bone which would give long-term stability and whose mechanical impedance would closely match that of bone.
3. Developing techniques whereby artificial tendons could be strongly anchored to the musculotendinous portion of large skeletal muscles, then brought through the skin, and finally coupled to an external articulating prosthetic device.
4. Designing an external device which would be controllable by the artificial tendons and would incorporate sufficient shock absorbing techniques to protect the bone interface from trauma.

Before describing these problems in detail, it might be well to briefly outline the advantages that such a device would have over existing prosthetic devices:

1. Because the skeletal extension provides the weight-bearing element rather than interfacing with a cup and soft tissue, the total prosthetic device would be more stable.
2. This increase in stability should allow the wearer to perceive a more realistic and appropriate kinesthesia.
3. Since no forces are transmitted through soft tissue, there should be fewer soft tissue problems upon weight-bearing.
4. An important theoretical advantage would be the potential of bringing the amputated portion of the limb back under the control of existing skeletal muscles. There would be a tremendous advantage to the wearer in being able to flex and extend a simple joint. No longer would an above-knee amputee have to rely on gravity and total body attitude to produce a positive swing through.

SKIN INTERFACING

Many approaches have been used in an attempt to bring tubes, lead wires, conduits, and rods through the skin so as to prevent these exiting holes from becoming infected. Usually a sinus tract is formed which ultimately leads to either a cellulitis or an abscess.

Epithelial cells seem to have an inborn desire to be bound on their periphery by other epithelial cells. When a break in the integument occurs some cells are left with a side unsupported by other epithelial cells. As the repair process occurs, epithelium continues to grow until it reaches raw sides of other epithelium. If an obstruction is placed in its path, such as a tube or rod, the epithelium, unable to grow through or over the tube, proceeds deep into the tunnel until the deeper organs are encountered or until the object has become marsupialized. Such is the case of the carbon buttons shown in Figure 1. These buttons have been implanted for 7 months, during which time the wearer experienced little difficulty. However, upon removing these buttons it became apparent that they were no longer implanted but were residing in a completely marsupialized pouch. Biopsies taken from similar experiments corroborate these findings as clearly demonstrated by the photomicrograph shown in Figure 2.

During the 7-month implantation of the carbon buttons shown in Figure 1, electrical impedance measurements were taken. Little change in impedance could be demonstrated during this 7-month interval. For skin electrodes requiring long-term usage, carbon buttons appear ideal. However, for skin interfacing of the type required for deep penetration, carbon has little or no application.

The problem of skin interfacing was first brought to our attention to meet the needs of transmitting power through the chest wall in order to drive an artificial heart. Success in solving this problem using various

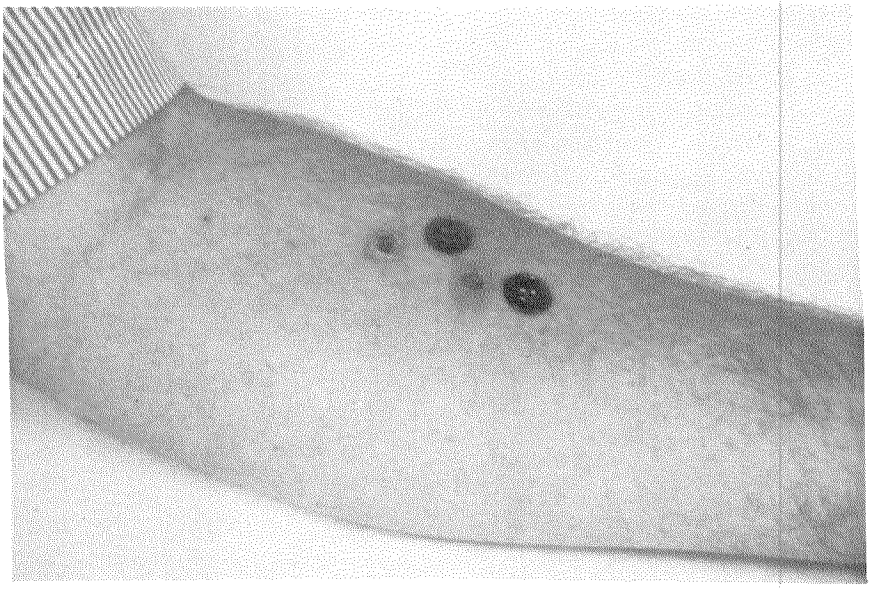

FIGURE 1.—Biocarbon buttons removed after 7 months' implantation. Notice absence of bleeding. Marsupialized pouch was found to be completely lined by squamous epithelium. Buttons were obtained through the courtesy of Mr. Jim Benson, Tarzana, California.

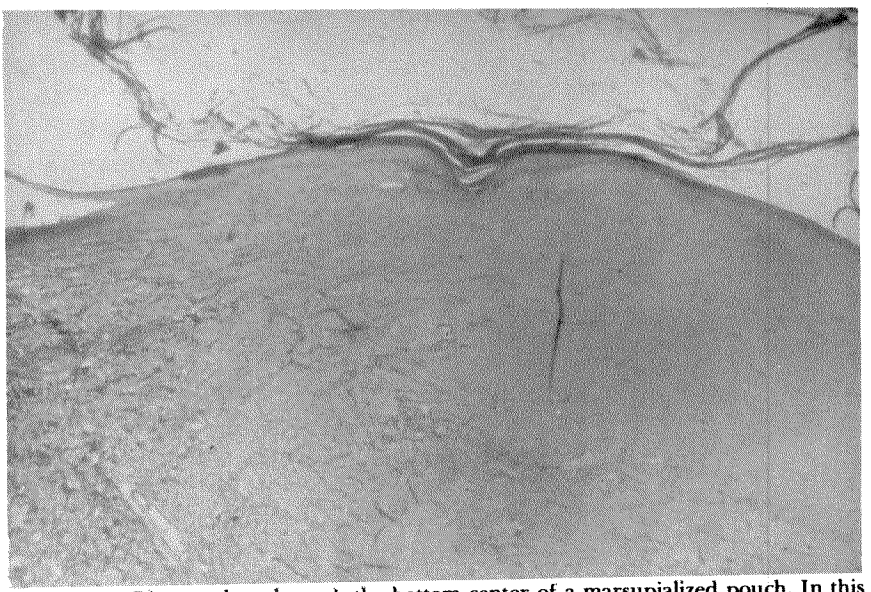

FIGURE 2.—Biopsy taken through the bottom center of a marsupialized pouch. In this case, the carbon button had been implanted for 12 months in the dorsum of a goat. Buttons were obtained through the courtesy of Dr. Jack Bokros, Gulf Atomic Research.

types of velour fabric led us into tangential problem areas, such as the development of a permanently attached artificial limb.

Many types of velour (Fig. 3) have been tried in an effort to find the one most suitable. A recent contract with the National Institute of Arthritis and Metabolic Diseases provided us the opportunity to test velours, foamed plastic, solid core rods, carbon buttons, and nonwoven fabric in a search for a suitable skin interface for the arteriovenous shunt used in hemodialysis.

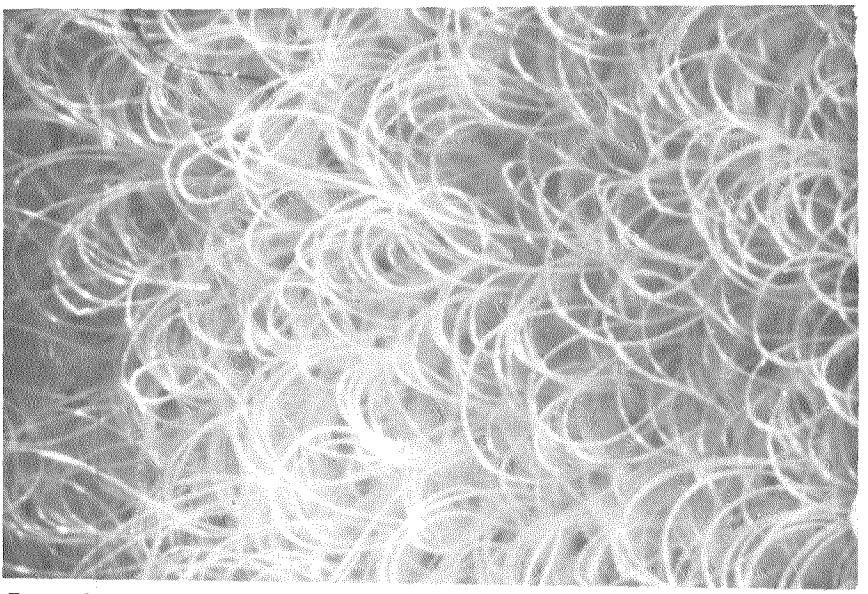

FIGURE 3.—Enlarged closeup of the velour-type weave. Notice the wicket-like construction of the monofilament weave which presents large interstices through which tissue can grow.

A summary of these findings are listed, and the materials bonded to the test rod and the results of these tests are shown in Table 1.

TABLE 1.—*Materials Bonded to Test Rod and Results*

Material	Results
. Nylon or Dacron velour	Excellent, only problem is eventual extrusion of rod—"Growth Phenomenon."
². Polypeptide with rough cast surface or nonwoven fabric	Good for short-term usage but is biodegradable.
³. Polyurethane foam	Good for short-term usage but not as predictable as nylon velour.
4. Nylon foam	Poor—probably due to closed cell construction of foamed material.
5. Vitreous carbon buttons	No wound infections seen but excisional biopsies demonstrated complete marsupialization of implant.
6. Solid uncoated Silastic rod (used as control)	Sinus tract invariably formed—easily withdrawn if retaining suture was removed.

It is obvious from Table 1 that of the materials tested to date, the only ɔnes to give satisfactory results are the velour fabrics. This is not meant ɛo imply that there is no need to continue our search for better materials.

Our methodology in obtaining the above tabulated data was to bond the test material to a solid core Silastic® rod that could then be implanted into the test animal. In order to more easily observe the test implant, the dorsum of the animal was selected. Goats, dogs, and pigs have been used as test animals. Of these, goats are easiest to care for and, since they ignore the implant site, more reliable data can be obtained. Figure 4 shows a test implant being biopsied after having been in place for several months.

One of the problems encountered using velour on the surface of these test implants was the tendency for the implant to "grow" —or rather, to be slowly extruded after a prolonged period of time. This "growth phenomenon" had a steady, predictable growth rate of approximately 1 mm. per month. Various theories were proposed to explain the extrusion of these implants. All but one have since been discarded.

Further experimentation and observation have convinced us that there are two factors involved. First is the fact that certain polymers are accepted by epithelial cells as "being" epithelial cells. The desire to have its bare side joining other epithelial cells is therefore satisfied. This must mean there has been a chemical wedding and not a simple mechanical entanglement of the tissues throughout the interstices of the fabric. Since the epithelium stops its search, no sinus tract is formed. Microscopic examination through an implant area (Fig. 5) demonstrated the relationship of each monofilament strand to adjacent cells. Secondly, there is microscopic evidence showing individual strands of velour en-

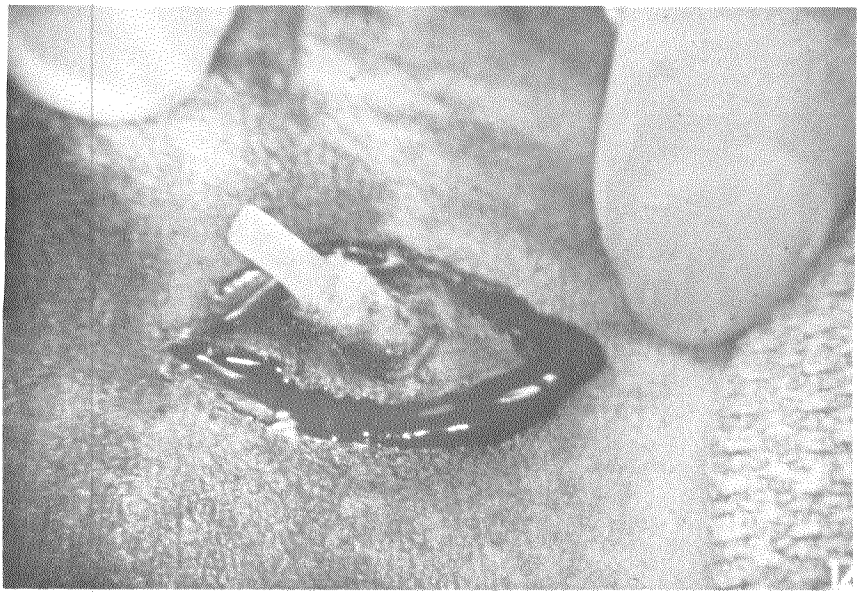

FIGURE 4.—Test implant demonstrating method of excisional biopsy. Note variations in shading of velour brought about by the "growth phenomenon."

trapped in the cornified layer of epithelium. Since the cornified layer represents nonviable, relatively inelastic, and certainly nonmoldable tissue, the natural question that comes to mind is, "How did it obtain this positional relationship?"

To answer this question, we have postulated a theory using known facts to explain the entire process. If the adjacent cells form a permanent chemical bond (perhaps due to the hydrogen bonding ability of the base polymer) to the surface of the monofilament strands, then it is safe to assume that if either the adjacent cells or the monofilament strands move, the movement is likely to occur together. This, of course, is dependent upon slow movement. A sudden departure from any fixed position would result in the tearing of tissue or breaking the monofilament strands. Cells forming the basal layer of the skin are composed of germinating immature epithelial cells. A natural course of events is for these basal cells to migrate toward the surface, gradually losing their cuboidal form to become the typical eliptical form of mature squamous epithelium. Finally, these cells die and become the cornified outer layer. A basal cell which has attached itself to the surface of a receptive polymer would, as it matures, have the same tendency to migrate toward the surface. Vector forces applied to the monofilament strand in this manner gradually carry it to the surface. As the individual cells become the cornified layer, strands of the monofilament velour should be demon-

strable as entrapments. Figure 6 is a photomicrograph of a biopsy site of nylon velour clearly showing monofilaments imbedded in the cornified layer of squamous epithelium.

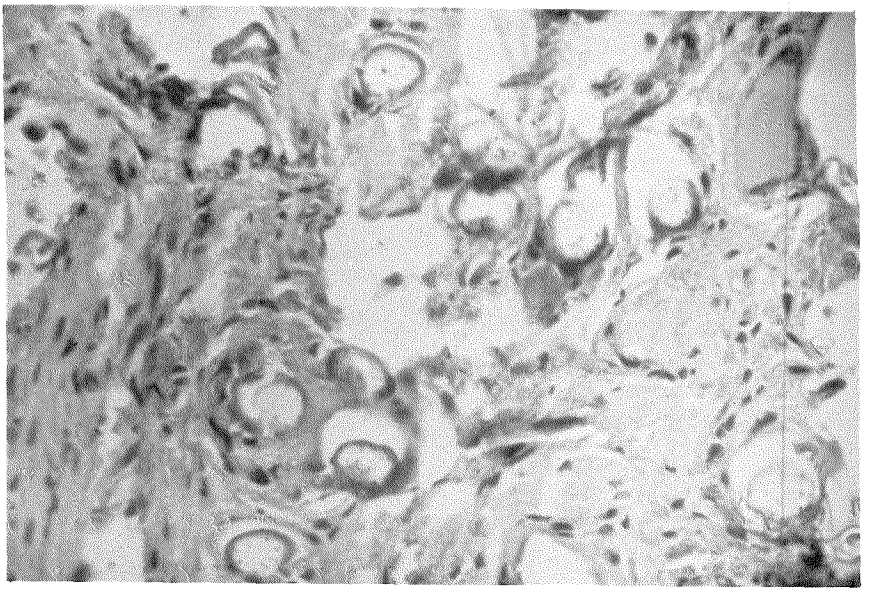

FIGURE 5.—Photomicrograph of implant site of velour fabric (nylon velour). The close relationship of the monofilament strands to adjacent cellular structure is apparent. The semilunar hiatus seen on one side of each strand is an artifact caused by the microtome knife encountering substances of varying mechanical impedance. Note that the hiatus is always on the same side—each strand having been pulled away from the tissue in the direction traveled by the microtome blade.

This would obviate a pessimistic outlook to the solution being sought if it were not for the fact that the maturation rate appears to be quite different at various anatomical sites. For instance, the site selected for these implants appears to be an order of magnitude greater than the ventral surface of the body. Why this should be true is conjecture, but it might have to do with the fact that the back is exposed to more direct rays of the sun and demands a more rapid sloughing rate than the ventral surface. A future experiment is planned whereby the implant procedure will be repeated but will alter the type of skin through which the test rod penetrates by first transplanting a full thickness homograft from the ventral surface of the animal to the dorsum and transplanting the excised dorsal portion to the ventral surface. Comparing the extrusion rates of these two implant areas should prove interesting.

Actual application of the velour technique to bring skeletal extension through the integument has not been impeded by the extrusion process.

This success might be explained on the basis of a short survival time, our longest being 14 months. Longer periods of time might expose extrusion problems. The skin maturation rate of the hind limb may be of the same order of magnitude as the ventral surface. In any event, the use of velour to create a bacteriostatic seal around the protruding skeletal extension has thus far been satisfactory and has presented no problems.

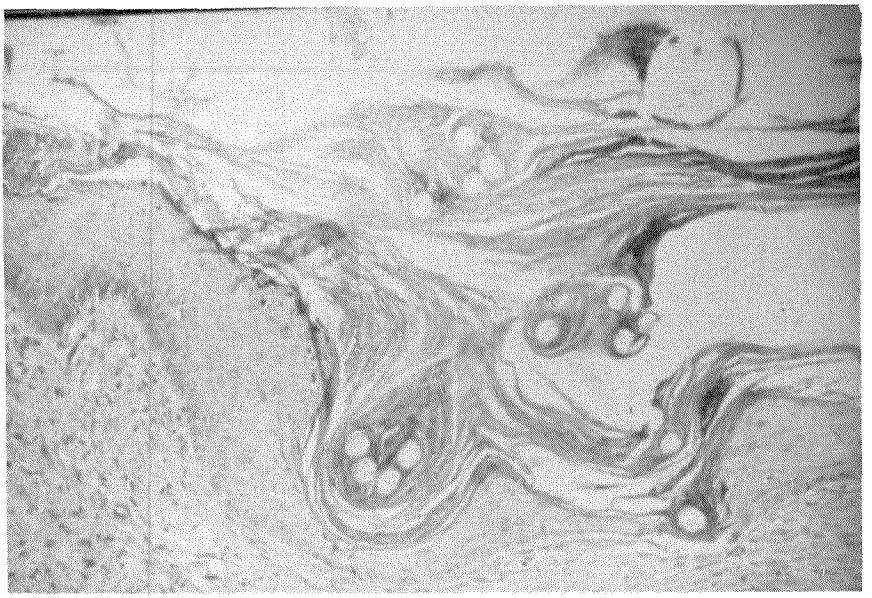

FIGURE 6.—Entrapped monofilament strands are demonstrable within the cornified layer. Natural migration of attached basal cells toward the surface during their maturation have carried the individual velour filaments along with them. This explanation postulates a permanent chemical bond between an adjacent basal cell and the surface of the polymer.

MUSCULOTENDINOUS SKIN INTERFACING

In order to bring the proposed alliance under direct control of existing skeletal muscles, a method is being proposed to couple the external articulating joint to the skeletal muscles using an artificial tendon. One end of the tendon would be sutured to the insertion end of the muscle. A skin-flap would be constructed to afford a bellow-type tunnel to accommodate the necessary travel and length change of the coupling. As the tendon exits through the tunnel end, a piece of velour fabric would be bonded to the artificial tendon's surface—thus preserving the bacteriostatic integrity of the skin. The distal end of the artificial tendon would then be mechanically affixed to the external prosthetic appliance.

Although all of the above appear theoretically possible, only portions have actually been attempted. A reel-type takeup to adjust tendon

tension has already been designed and fabricated into the articulating external device. An artificial tendon has been fabricated by modifying Dow Corning's original Silastic-covered Dacron tape. This modification consisted of sewing a triangular section of nylon velour to the proximal portion of the Dow Corning tendon (Fig. 7). The velour was sutured to the severed Achilles tendon of a goat: Holes bored into the calcaneus served to anchor the distal end of the artificial tendon. The velour presented a large surface area for fibrocytic ingrowth, adding strength to the union that would ordinarily depend upon simple sutures.

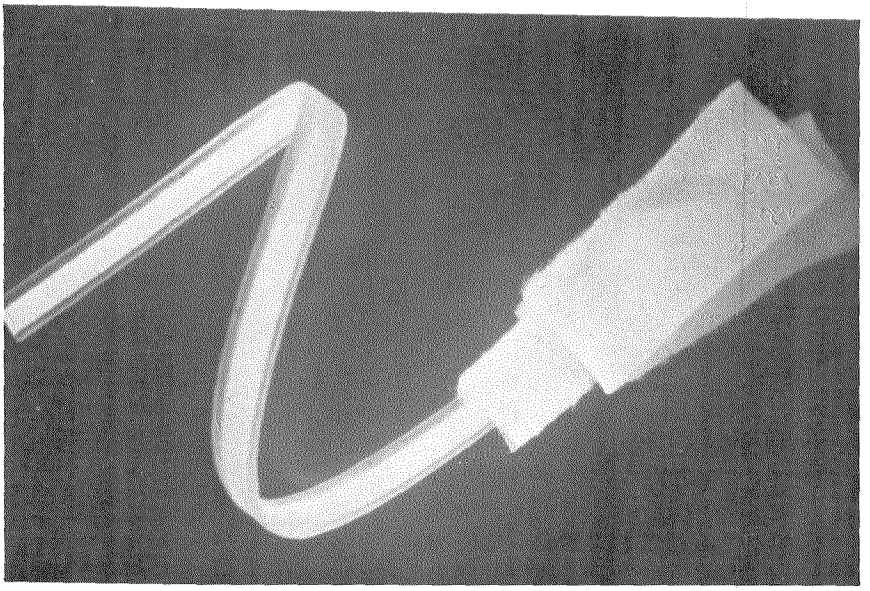

FIGURE 7.—Dow Corning's Silastic-coated tendon modified by sewing a piece of nylon velour to the proximal end. Fibrocytic ingrowth into the velour ultimately creates a union of such strength that the original sutures become unimportant.

This later experiment was designed to test the feasibility of developing a strong union between the artificial tendon and the musculotendinous portion of a strong skeletal muscle. Figure 8 shows an animal which has had the left Achilles tendon replaced by the method described in the preceding paragraph, The animal has no detectable limp, no contracture, and has complete freedom of motion as evidenced by her ability to maintain normal agility.

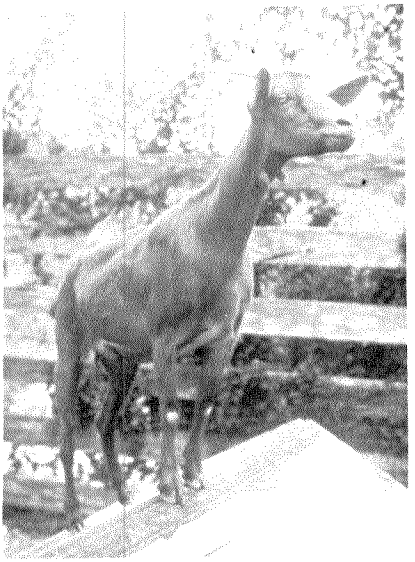

FIGURE 8.—Four months before this photograph was made, the Achilles tendon of the left leg was replaced by the artificial tendon shown in Figure 7. Agility was demonstrated by her ability to jump to the roof of her quarters just prior to the taking of this photograph.

A future experiment will be identical to the one described above, with the addition of developing a skin tunnel exiting to the exterior and penetrating the skin again near the proposed site of insertion. These experiments have been designed to prove the feasibility of anchoring an artificial tendon to its biologic counterpart with sufficient strength to maintain normal function and to prove the feasibility of bringing such a tendon to the exterior. No amputation of the limb is required for these studies.

BONE INTERFACING

The basic structure of the skeletal extension is an intramedullary rod driven into the amputated distal end of the goat's tibia. A polypropylene cone molded to the rod serves both as a weight-bearing pedestal and as a bond for the nylon velour to which the skin is sutured. Recently, this plastic cone has been redesigned to fit a mortice made in the tibia at the time of amputation (Fig. 9). This prevents rotation of the shaft and transmission of shear forces from being applied to the interface.

Transferring the forces of weight-bearing directly to a skeletal extension demands near perfect interfacing between the artificial device and the natural bone. Shear forces develop all along this interface and must be equally distributed over as wide an area as possible. Material selection for this interface should have an impedance match that would maintain the integrity of the interface.

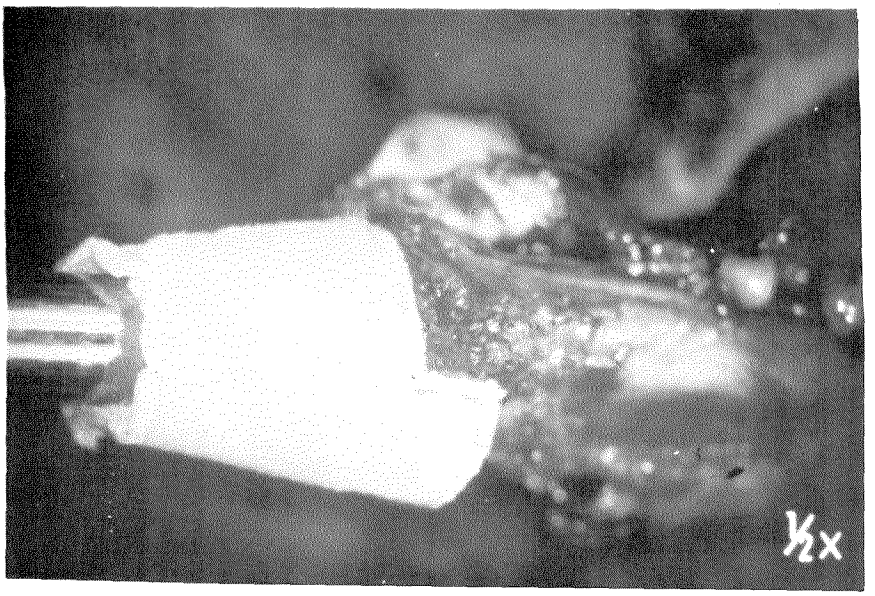

FIGURE 9.—A polypropylene cone molded to the shaft of the skeletal extension rod serves to accept the weight-bearing end of the tibia and to act as a bond for the velour fabric used to interface with the skin. In order to prevent torque to the shaft from being transmitted to the interface between the shaft surface and bone, a mortice between the cone and tibial end has been created.

To date, three types of interfacing have been tried. The first was a simple close fit using a sandblasted Vitallium rod. Eventually these rods became loosened by resorption of bone at the interface and replacement with a gelatinous layer of collagen. When this occurred, the pull strength of the device was severely weakened.

A second method was to use a metalic rod (either Vitallium or stainless steel) similar to the one described in the preceding paragraph but having lesser tolerances between the diameter of the rod and the intramedullary canal. Voids between the rod and the canal were filled with plastic adhesive (Surgical Simplex, North Hill Plastics, Ltd., London, England). For periods up to 7 months, this technique proved satisfactory. Late failures appear to be related to chronic osteomyelitis which could possibly be due to contamination of the surgical adhesive during mixing or to a break in aseptic technique during surgery.

A third method of establishing an interface with bone was to use porous ceramic as an outer surface on the intramedullary rod. Details of this construction were described in a previous report. Most of the failures using this technique were mechanical in nature (Fig. 10). Success depends upon new bone ingrowth into the porous ceramic (Fig. 11).

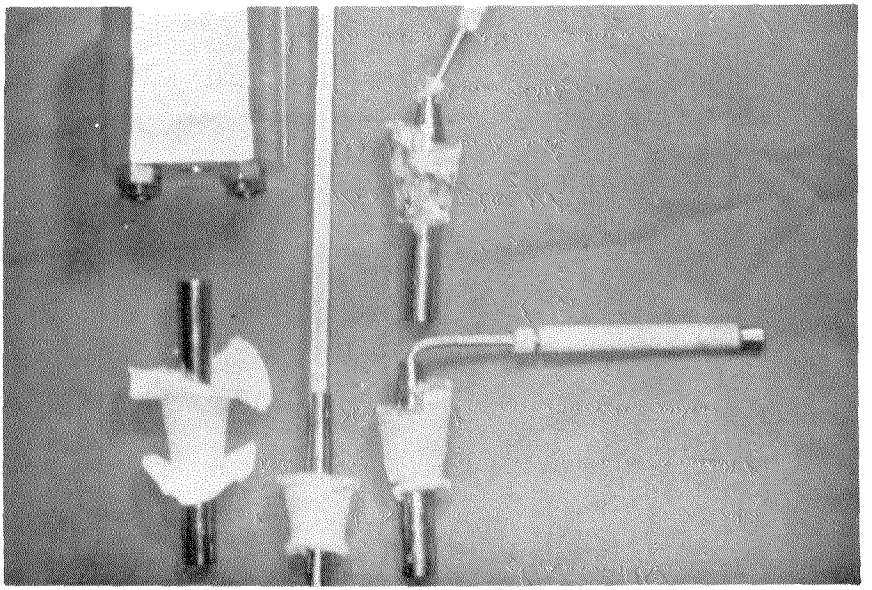

FIGURE 10.—Intramedullary rods. Top left is mold used to fabricate velour-covered pedestal shown at bottom left. Center rod made of stainless steel shows earlier form of the polypropylene pedestal. Later forms shown on the right have stair-stepped surface to accept morticed end of tibia. Mechanical failures of two of these devices are evident.

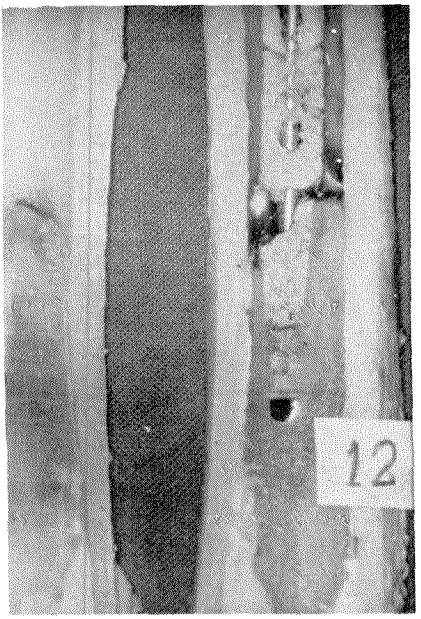

FIGURE 11.—Cross section cut through tibia exposing intramedullary rod, ceramic sections, and new bone ingrowth. New bone growth is more rapid at the distal end with no osteogenesis occurring at the isthmus. This is probably due to the anatomy of the circulatory system of long bones.

In all of these cases, velour has been permanently bonded to the surface of the pedestal which in turn serves as the interface for soft tissue ingrowth. A small skirt of velour at the distal base of the pedestal serves to anchor the skin (Fig. 12).

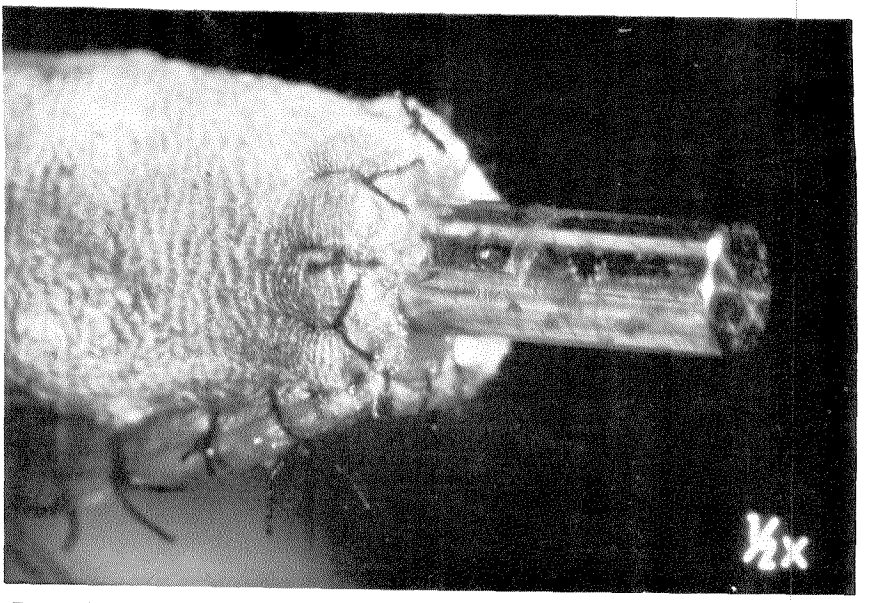

FIGURE 12.—Closeup of skin closure showing how interrupted sutures are used to approximate the skin edge to the velour skirt contained at the base of the pedestal.

EXTERNAL APPLIANCE

To date, only limited attention has been paid to the design of the external portion of the prosthetic device. An articulating structure having two reel-type takeup devices to adjust tendon tension has been designed. This remains untested since the tendon part of the research project is lagging. Most of the goats, having undergone amputation with implantation of an intramedullary extension, have had a simple pylon affixed to the projecting end. These have served well to test the skin and bone interfaces, and test animals quickly learn to use them without difficulty (Fig. 13).

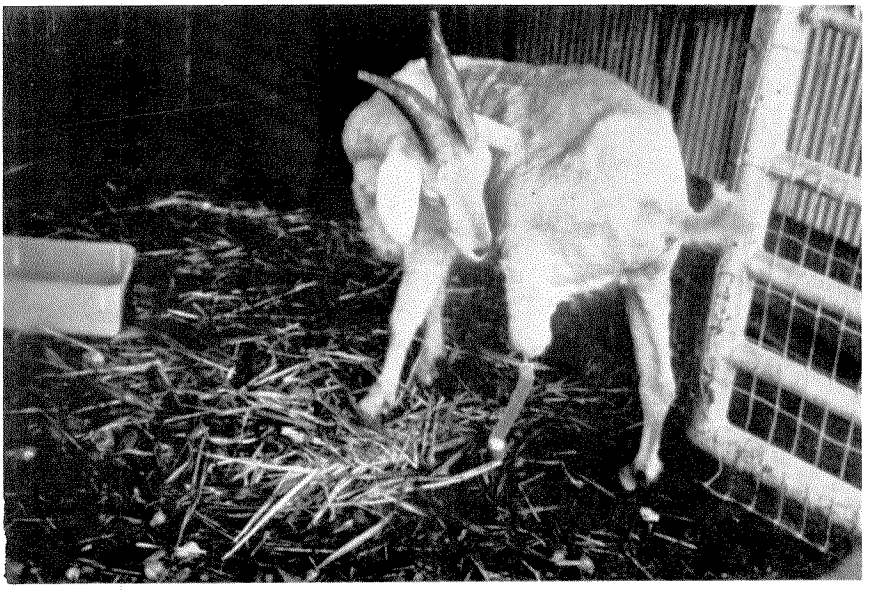

FIGURE 13.—Close inspection of the new leg apparently meets with approval.

SUMMARY

A permanently attached artificial limb is an achievable dream within the foreseeable future. The problems remaining to be solved are the interfaces which need to be maintained between the prosthetic device and bone, and between the prosthesis and the skin through which it protrudes. The interface between the bone of the limb and the metal rod placed in the medullary cavity is well on the road to solution by permitting bone ingrowth into a porous ceramic coating on the metal rod. The skin interface is a more difficult problem which we have approached through the use of nylon velour. This has thus far eliminated the problems of marsupialization which characterize the use of biocarbon interfaces and of extrusion as seen in some of our experimental rod implants. Bacteriostatic seal with nylon velour skin interface has been so good as to encourage our use of this same mechanism for artificial tendon and skin interface as we experiment with a means for connecting the muscles of the limb to the external portion of the prosthesis.