A BASIC STUDY IN
SEMI-BURIED IMPLANTS AND OSSEOUS ATTACHMENTS
FOR APPLICATION TO AMPUTATION PROSTHETIC FITTING

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INTRODUCTION

An improved means for the attachment of an external prosthesis to an amputated extremity is most desirable today as it was when this project was begun and conceived in 1952. The basic work for this project was delayed by military service until 1956. It was made possible through a grant from the Orthopaedic Research and Education Foundation and a grant from the Veterans Administration (Research Grant V1005M–5278). The general philosophy was that if it were possible to penetrate the integument of an amputated extremity by means of a permanent semi-buried implant, and through this means attach the external prosthesis to an osseous prosthesis, that is a prosthesis attached to bone, redundant external harnessing might be eliminated. Additional problems such as dermatitides, telescoping of the socket, rotational problems, and obtaining proprioceptive sense could be in part eliminated.

The concept of tissue acceptability of semi-buried materials was first conceived after reviewing materials done on orbital implants by Dr. William Stone, Jr., an ophthalmologist at that time of the Massachusetts Eye and Ear Institute. The project was divided into three phases: Phase I was designed to explore the possibilities of bringing various foreign materials through the integument, leaving them in a semi-buried state. Phase II was development of the osseous attachment of foreign material which would be permanent. Phase III, which was not carried out (beyond a few pilot experiments) was the development of an external prosthesis to be attached to Phase I and Phase II.

The project was carried out on 29 mongrel dogs with one exception, a Capuchin monkey. The years covered were from 1956 until 1969. The investigation was done with the intent that specific investigation procedures be carried out, not in quantity, but that each one be given

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a sufficient length of time to either prove or disprove its merit. Some of the experimental animals have been kept for as long as 5 or 6 years. No special care was afforded the animals other than the usual small animal hospital techniques of proper preoperative medication and anesthesia, aseptic techniques in the operating room, attention to wounds, general animal care and vaccination, medication for parasitic diseases, etc. Occasional applications of topical antibiotics were used in certain specific cases by the doctor of veterinary medicine, but the author does not feel that this had a major bearing in the overall outcome of any specific case. The age of the animals varied from maturing pups to middle aged dogs. One animal (Dog #3, Phase I) was known to have a concurrent lymphoma.

PHASE I. RESULTS OF BRINGING VARIOUS FOREIGN MATERIALS THROUGH THE INTEGUMENT AND LEFT IN A SEMI-BURIED STATE

Foreign material which is perforated and placed in the subcuticular level of the dog may remain for periods of 2 to 3 years. It is very evident that relatively stiff material inserted through the skin into the subcutaneous tissue and the underlying muscle, and thus subject to differential motions and loads, is not tolerated well and is extruded by the host in a very short number of weeks or months. Epithelium will grow through the interstices of the perforated material, and although not giving a material-to-tissue physiologic attachment may give a reasonably tight mechanical attachment. All materials seemed to have gradually extruded over a period of months and years, even though they have appeared grossly non-infected superficially. It was noted that in various materials there would be a period where the cutaneous implant junction was free of exudate for a period of weeks or months and then a small granulomatous reaction would occur. Other implants were grossly non-acceptable to the host and were extruded rather rapidly with gross foreign body reaction.

Microscopically, the least reactive material seems to be silicone rubber. It has the disadvantage in the fact that the material is friable and fractures leaving a minimal tab externally. We felt that its practical application was nil. Vitallium wire screening seems to be acceptable for longer periods of time than Teflon. In those instances where it was well accepted for longer periods of time, the failure of the material outside the skin was the drawback. Various procedures carried out to prevent this were not effective. Dacron mesh of the larger interstices has the advantage of being one of the most readily acceptable foreign materials in the semi-buried state and has the advantage of being reasonably resistant to external fragmentation.

In one of the experiments, Dog #26, stress was placed on the semi-buried implants, in this case Vitallium screening, by the application of...
lead sinker weights. These did not seem to affect the course of the implants in an adverse way. The weights were approximately 10.6 gm. It was thought by the author and many of his collaborators that an approximation of the flexibility of the implant to that of the skin would be optimum. However, in the case of fine-wire, open-mesh Vitallium screening this does not seem to be essential.

Particular note should be made of the fact that despite the presence of gross infection and stress on the prosthesis, the subcuticular prosthesis was often the only attachment that the combined skeletal and subcuticular prosthesis had to the extremity particularly long after the osseous attachment had failed. This attachment was gross due to projections of fibrous tissue growing between the interstices of the semi-buried implant extending from the skin to the subcutaneous tissue.

Materials used in Phase I were as follows: Tantalum wire screening, vulcanized silicone rubber, Teflon, Teflon and titanium, Vitallium screening, Dacron mesh and a Teflon “jelly fish” or central plug with perforated strips extending subcuticularly. A detailed description of the materials is too voluminous for this summary.

**PHASE II. OSSEOUS ATTACHMENT OF FOREIGN MATERIAL**

**Materials Used in Osseous Attachment**

1. **Stainless Steel**

   This was a stainless steel intramedullary prosthesis, tri-pronged, shaped somewhat like three opposing “Rush” nails, the most proximal prongs constructed so that they would diverge in the proximal metaphysis of the tibia. To this were attached two disks of tantalum wire mesh. Attachment was obtained by means of dental plastic. The proximal tantalum wire mesh was placed subperiosteally; the prongs were placed intramedullarily.

2. **Titanium**

   This was a tri-pronged similarly constructed intramedullary prosthesis which was made of titanium. There was attached to the collar of this a subperiosteal cylindrical cup measuring 3.8 centimeters with circular perforations. The prongs were placed in the medullary canal, and the cup was placed over the distal end of the tibia.

3. **Titanium**

   This was a tri-pronged intramedullary prosthesis made with perforated tri-radiate, sandblasted, subperiosteal strips. These strips were placed beneath the periosteum with minimal amount of periosteal stripping.
4. **Titanium and Teflon**

This was a tri-pronged intramedullary insert with a perforated Teflon disk at the collar and “ladders” of Teflon that were placed in the muscular components of the leg.

5. **Teflon Button**

This was a button made of Teflon placed in the medullary canal, the button having a hollowed out, perforated, threaded medullary component and a perforated collar. This was followed later by the attachment of an inverted Teflon, thimble shaped, perforated, subcuticular, semi-buried addition.

6. **Room Temperature Vulcanizing Silicone Rubber**

Freely poured “globs” of room temperature vulcanizing silicone rubber were poured into the previously drilled medullary canal with three radially drilled holes from the medullary canal through the periosteum. The silicone rubber would run into the inverted medullary canal in the tibia or radius, as the case may be, and out through into the soft tissue forming small irregular buttons of rubber outside the periosteum in the soft tissues. Somewhat analogous to rivet heads, these were the means of mechanically holding the silicone rubber in place.

7. **Teflon Mushroom**

A Teflon plug with a feathered stem was inserted into the medullary canal. The distal end of this was larger than the medullary canal and hemispherical in shape. This was referred to as a Teflon mushroom.

8. **Modified Teflon Mushroom**

This was a modified Teflon mushroom in which the extraosseous portion was much flattened in its vertical diameter and broadened in its lateral diameter with a feathered intramedullary stem.

In summary of Phase II of this experiment it will be seen that most of the insertions were made into the tibia; however, in one instance a radius was used and in one experiment four metatarsals were used.

After this experiment had been commenced it was found that one of the major problems in the orthopedic care of a child amputee was the overgrowth of the long bone. Dogs #1 and #17 show this well. This bone overgrowth would occur with regularity in the dog and would lead to the ulceration of the previously healed closed amputation stump. It has been brought to the author’s attention that the doctors of veterinary medicine usually choose to disarticulate an extremity of the proximal joint, either should or hip, rather than to amputate. It is very interesting in the one case which had a bilateral trans-metatarsal amputation (Dog #30), which was referred to the author for treatment,
to find that there was a rather marked bone overgrowth in all four metatarsals on both sides with extreme ulceration over the amputation stump bilaterally. These stumps had been previously revised by doctors of veterinary medicine. In experiment categories number 4, and 5, it was hoped that this tendency to overgrowth of the amputated bone distally could be used effectively through the utilization of a perforated collar which would allow the overgrowth of bone to perforate the interstices of the collar and fully help attach the prosthesis. However, it was found that no true osseous overgrowth occurred beyond the prosthesis, although apparently there was an attempt at new bone growth into the interstices but not through the perforations. It was universally found that a prosthesis with a collar which remained in place would prevent overgrowth of new bone distally. Parietal periosteal new bone would form and attempt to overgrow the prosthesis or engulf same, but this would be halted. As in the experiments of Dr. Stone on corneal transplants (in which eye tissue would not grow beyond a critical height of projection or "nubbin") there seemed to be a critical point beyond which new tissue, in this case periosteal bone, ceases to grow. The author does not have, from this limited experiment, a specific figure to indicate the distance/diameter index for further peripheral growth.

In all cases it was found that as long as the prosthesis was left buried and no external bending movement applied to the prosthesis by way of exteriorized extension with or without weight bearing, the prosthesis would remain unaltered. There would be a progressive peripheral periosteal new bone formation which would, in turn, mature and develop to normal trabecular pattern. However, in a matter of weeks after the attachment of an external prosthesis in which bending or axial stresses were applied to the bone attachment of the internal prosthesis, a regular pattern of intramedullary endosteal bone absorption around the prosthesis would occur with periosteal new bone formation occurring to reinforce the osseous structures at this point.

In the cases treated with the room temperature vulcanizing silicone rubber, which were actually mechanically attached only by means of the extension of the very flexible materials through a drill hole in the cortex and outside the periosteum, no absorption was seen. The bone, however, would hypertrophy peripherally, but distal overgrowth and exostosis were aborted. Extensive subperiosteal intramedullary operative damage could not be tolerated concomitantly. It has been the opinion of the author that probably about one-third of the cortical blood supply came from the periosteal vessels and two-thirds from the endosteal vessels. It would appear that if the periosteum is not overly traumatized, a small amount of medullary material may be removed in the distal end of the long bone without causing a ring sequestrum to
form. However, if both the periosteum and the endosteum are damaged by the surgical technique, a ring sequestrum will very frequently occur. Although it was found that in one case the room temperature vulcanizing silicone rubber did prove to be quite successful, in others there were great technical difficulties with too much or too little viscosity of the material, difficulty in handling, etc., because of temperature variations and ineffective control measures, i.e., hemostasis and so forth at the time of the pour. A technique, however, has been developed by Doctors Charles H. Frantz, Alfred B. Swanson, and James R. Glessner, Jr., in their use of vulcanized silicone rubber intramedullary plugs or osseous attachment for amputees.

In those cases in which there was an osseous attached prosthesis, as well as an attached subcuticular semi-buried prosthesis, there was failure in each case ultimately. The failure would occur in some instances because of osseous prosthesis failure. This was occasioned by endosteal absorption of bone around the prosthesis allowing the prosthesis to gravitate distally. This in turn would allow the formation of a seroma which would become secondarily infected either from a hematogenous or a direct contact infection through a subcuticular breakdown. The osseous prosthesis failure often preceded the subcuticular detachment by weeks and months.

One of the most significant findings of this work was the fact that a prosthesis that had been inserted intramedullarily and covered the end of the long bone would not only abort distal overgrowth, but would allow the animal to walk on the extremity without apparent pain or skin breakdown. The dog being a quadruped, it was thought that possibly the reason for lack of skin breakdown was in part due to the fact that the extremity could be held up and not used part of the time. Consequently, in the case of the seventh type of experiment and also in the eighth, the opposite hind extremity was first put in a hip sling to prevent it from reaching the ground for periods of time during the day, and then the opposite or normal hind extremity was disarticulated at the hip. In the case of Dog #16, there was a successful three-legged gait, the hind leg being the one in which there was a terminal mushroom plug of Teflon with feathered stem. The dog successfully walked on this without breakdown for over 6 years. It might be interesting to note that this dog was an extremely obese animal.

In all cases, periosteal new bone formation occurring peripherally on the long bone became mature, and no additional periosteal new bone or signs of osseous irritation were noted.

On dissecting one of the more successful animals noted in Category 6, Dog #10A, it was found that a fibrocollagenous capsule formed over the hemisphere of silicone rubber at the end of the extremity. There was hypertrophy of the skin with keratinization. A very shiny, smooth
lining was found beneath the fibrocollagenous capsule. This had the same appearance as an acetabulum from which a successful cup or mold arthroplast has been removed. In the case of this animal, a yellow material was found free in this space between the silicone rubber and the capsule, and this was felt to be a hemosiderin breakdown product. The bone around this silicone rubber implant remained viable.

**SUMMARY AND FINAL CONCLUSIONS**

It may be possible in the future to penetrate the integument by means of some material such as the Dacron mesh and indirectly attach to bone or to use this attachment for the harnessing of a prosthesis, provided the material is perforated and placed in a subcuticular layer. A satisfactory method for end-bearing on a long bone has been shown in experimental animals by the use of a flattened and mushroom shaped, feathered stem, Teflon implant. Some physiologic observations having to do with the effect of increased stress on the osseous prosthetic juncture as the cause of its destruction are pointed out. The need for close attention to preserving the blood supply of the distal end of the long bone is reemphasized, and it is suggested that, even in controlled cases, a delay period be employed between the time of the amputation and the time of insertion of the prosthesis. This has been arbitrarily fixed at 6 weeks, as this would seem to be the period of maturity of periosteal new bone in the average dog.

It is hoped that some of these observations may be of benefit, and that those who are able will find a means of integumental penetration which may be permanent and osseous attachment which may be permanent. Phase III of this experiment is predicated on successful completion of Phase I and Phase II, and it has not been embarked upon.

Techniques developed here may be of benefit in other integumentary penetration procedures such as dialysis, cardiac pacemaker installations, etc.