Research and Development Project on Advanced Orthotic Devices for Adult Paraplegics

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Testing of the PACO III units got underway in April of 1978. At this time the modified wheelchair armrests for assisting a paraplegic in elevating himself have proven to be functioning satisfactorily. Minor adjustments were needed to compensate for wheelchair design differences between manufacturers. The universal adjustability in the orthotic design has functioned well in fitting the unit to individual paraplegics.

The self-locking knee locks, at present, are not functioning as well as hoped. Further evaluation into what can be done to remedy this problem with the existing design is being investigated. Also, a new design concept is being looked into. Contact has been made with Moog, Inc., a leader in the field of hydraulic controls.

Evaluation of Electrical Techniques for Stimulation of Hard Tissue Growth

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Electrical Osteogenesis—Basic Studies

The Orthopedic Research Laboratory (Syracuse VAH) has completed the in vitro phase of its testing of electrode materials. This project was undertaken to evaluate the electrochemical behavior of various metals which could be used for electrical stimulation of bone growth (Pt,Ag,Au,Ti,Ta,Pt-Ir,Ss-316L and Vitallium).

1. Current-potential behavior under steady-state conditions was measured in biological culture medium with fetal calf serum, under potentiostatic and galvanostatic conditions. The metals tested fell

into three approximate groups as measured by surface conductivity over the useful potential range. Pt and Pt-Ir were the most efficient interfaces; Ag, Au and Ss-316L were an order of magnitude lower in conductivity, and Ti, Vitallium and Ta were an order of magnitude still lower (Ta being by far the most inefficient interface). Thus it would seem that Pt and Pt-Ir would require the lowest interfacial potential to pass a given amount of cathodic current in vivo (Fig. 9).

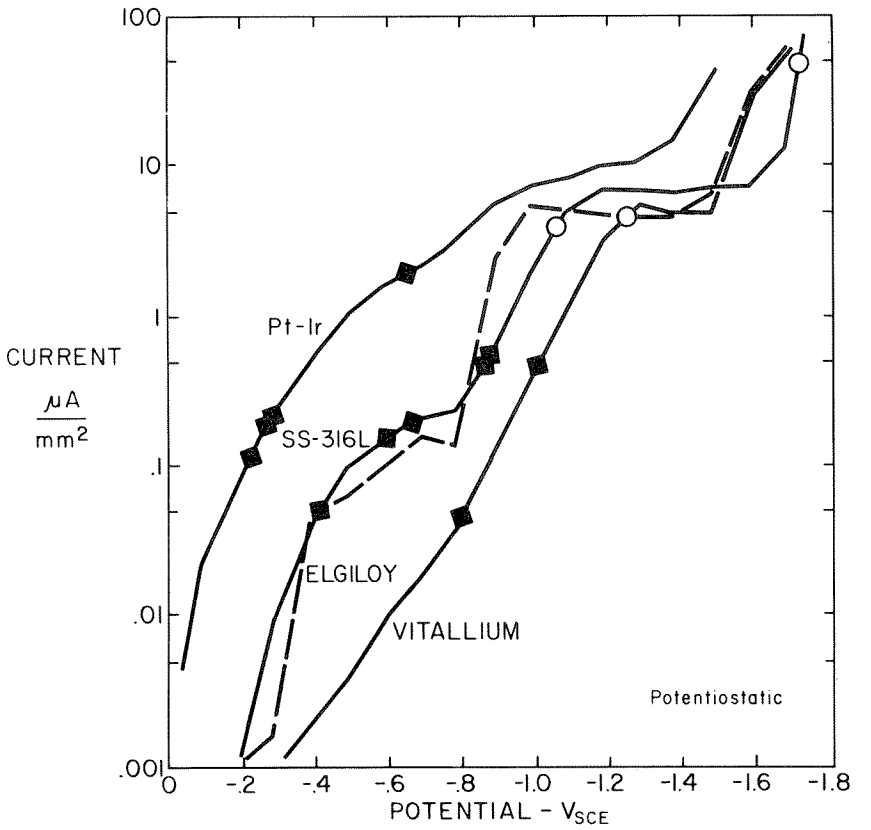

FIGURE 9.—Current-potential relationship for several metal alloy cathodes in cell culture medium (Dulbecco's, GIBCO, with 10 percent fetal calf serum added). The current density is determined at the geometric surface area of the metal and the potential is measured with respect to a calomel reference. Note the ten-fold differences between metals in the 0 to 0.8 V region in which the reduction of molecular oxygen occurs at the electrode. Above 0.8 V the electrode generates increasing amounts of hydrogen. The black squares indicate the conditions (and metals) at which electrical osteogenesis has been found to occur by several scientific groups. The open circles indicate conditions at which necrosis has been reported at such electrodes.

2. By changing the amount of oxygen available to the electrodes in these experiments, it was found, in the potential ranges below which deleterious hydrolysis would be expected, that the cathodic current is primarily transmitted by means of reactions involving chemical reduction of molecular oxygen; this is a factor which may be intimately related to the mechanism of action of electrical osteogenesis.

3. Simultaneously, in vivo experiments using rabbits are being completed in which the ability of these various metal cathodes to induce bone growth in the relatively uninjured femoral canal is being measured. Results thus far, at 500 nA constant current, seem to show that the cathode Pt is, in fact, an efficient promoter of bone growth. Further evaluation is in progress, and plans include the use of both higher and lower current levels. The implants used include a tiny transitorized constant-current DC circuit and battery. The encapsulation is in epoxy and silicone; this has been quite adequate for the 3-week duration of implantation used, although failure of the leads has been an occasional complication. Over 40 animals have been completed thus far.

Electrical Osteogenesis – Clinical Studies

Patients with resistant non-united fractures continue to be treated with the low-intensity direct-current system which has been successful in the past. These cases generally present in the orthopedic section of this hospital and are not solicited for. Thus far, 20 trials have been performed with a success rate of 75 percent. The median age of the non-unions was 2.5 yr and the mean follow-up time was 21 mo.

The use of anodic silver in the treatment of osteomyelitis in human patients continues on the same "as available" basis. Thus far, 14 patients have been treated, either using silver-impregnated nylon fabric or the solid silver wire as the bacteriostatic anode, depending on the nature of the lesion. The latter agent is used in conjunction with cathodic bone stimulation in fractures complicated by infection (a full description of the use of anodic silver in osteomyelitis is presently in press in the Journal of Bone and Joint Surgery).

Regeneration

Progress continues toward the international meeting on "Mechanisms of Stimulation and Control of Regenerative Growth and Its Clinical Application". This three day conference will be held in Syracuse in the Fall of 1979 and will be sponsored by the VA with assistance from the State University of New York (Upstate Medical Center). It will bring together recognized authorities in regeneration

and stimulation of bone growth to discuss the state of basic research and relate it to the future clinical application of regenerative phenomena.

Fracture Healing

Fundamental studies are in progress on the relationship of innervation to fracture healing. Using the rat fibula, the normal fracture healing sequence has been followed and documented. Preliminary work has indicated that denervation retards the rate of healing of long bone fractures and reduces the periosteal callus formation. The time between nerve resection and the fracture itself appears to be an important variable as well.

Acceleration of Bone Healing by Electrical Stimulation

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Work on this project continues. At present, we are utilizing a 16 mm defect in the ulna of beagles as a model non-union. Three stainless steel cathodes are placed, one in the defect center and one near the end of each bone fragment. An anode is placed subcutaneously. Each cathode is supplied separately with d.c. current in the range shown to produce new bone by Friedenburg, Brighton and other investigators. The object is to determine the importance of cathode location (in relation to pre-existing bone or bone elements) to the process of stimulating new bone formation in non-unions.

In Vivo Loading of Knee Joint Replacements

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Introduction

As stated in BPR 10-28 (Fall 1977), this project suffered an unfortunate setback in that the original dual condylar prostheses developed for telemetrized implantation were ruined during a commercial manufacturer's attempt to polish the devices to the necessary degree