DEVELOPMENT OF A PERCUTANEOUS ELECTRICAL CONNECTOR

by

Albert F. Badeau

Bioengineering Division

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William A. Hyman

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Abstract

The major problems with percutaneous electrical conduits are biocompatibility and infection. A system has been designed to avoid such problems and has been tested both in vitro and in vivo. The project, carried out under the Texas A&M Undergraduate Fellows Program, involved the development of an electrical connector which does not permanently pass through the skin, and yet can provide electrical continuity when and for as long as it is needed.

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Introduction

Several methods of passing electrical energy through the skin are presently being used in medicine and biomedical research. The applications of percutaneous electrical current include powering, controlling or testing implanted devices (1, 2), bioelectric signal reception for the control of prosthesis (3, 4) or for diagnostic purposes, the stimulation of muscles in rehabilitation (5), and the stimulation of nerves for the alleviation of chronic pain (6, 7).

The passage of energy into or out of the body is accomplished transcutaneously if the skin is not penetrated by the coupling device. Transcutaneous coupling could involve the use of surface electrodes, induction coils (8), or telemetry systems (9). Percutaneous passage would involve a current conductor passing through the skin. Electrical coupling of this type could involve the use of needle electrodes or wires with various interfacing devices at the site of penetration (10, 11).

Transcutaneous coupling has the advantage of not breaking the body's first line of bacteriological defense. The devices, however, are typically expensive, electronically complex, and require precise alignment for effective use. Percutaneous coupling inherently has had the problem of infections around and gradual extrusion of the conduits or coupling device (12). A general approach to these problems has been to create a seal between the skin and conduit. This necessitates either tissue ingrowth into the implant or encapsulation of the implant with a synovial type membrane.

The concept of the design being presented here is to implant one or more receptacles whose leads would connect to (hypothetically) an

implanted device. The other part of the design is for a skin piercing plug which connects into the receptacle. If the device had a battery, only one receptacle would be required for intermittent recharging. If the device continuously required current, two receptacles could be implanted with their leads connected in parallel. Before the tissue begins to react unfavorably to a plug's intrusion, a second plug could be connected into the second receptacle. The first plug could then be removed, and the surrounding tissue allowed to recover, (See Figure 1).

The primary goal of the study was to determine whether a connector of this type described would be feasible. There existed the problem of creating an electrically secure connection in a highly conductive environment. Secondly, the insertion of the plug would have to be made without being able to see the receptacle. The solution of these problems was foremost in the criteria for a design. The first problem was investigated in vitro and then in vivo. The second was studied only in vivo.

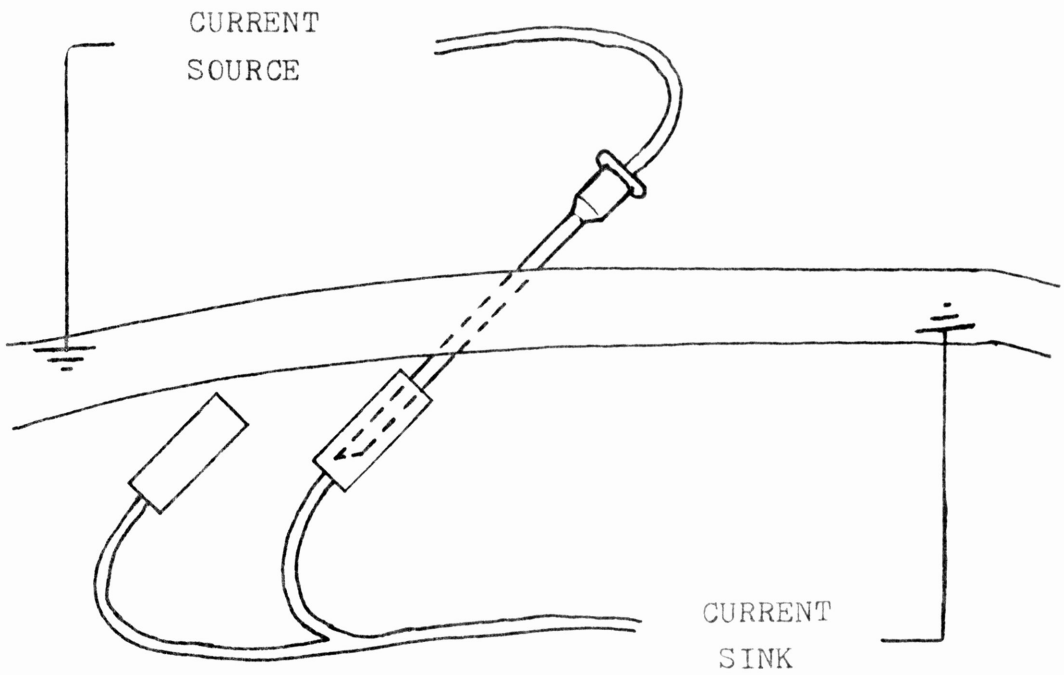

Figure 1: Two implanted receptacles with leads connected. Permanent conduction can occur since at all times the needle will be inserted into one of the two receptacles.

Design and Materials

The plugs were made from 22 guage intra-venous needles. All that was required was to insulate the upper portion, which would be outside of the receptacle but still inside the body. A bake-on epoxy was found to work well. Several applications produced a smooth, hard insulating covering which did not add appreciably to the needle's diameter.

The receptacles used were made from plexiglass rods, mainly because they were readily available and easily machined. In the final phases of the research the receptacle was 1/4" in diameter and 1/2" in length, (See Figure 2). It had a cone-beveled opening to guide the needle in toward a metal contact. The metal contact was tubular with an inner diameter slightly larger than the diameter of the plug. Separating the contact and the opening was a cavity which was to be filled with silicone grease. The silicone grease, having a high resistivity, acted to seal the connection as the needle passed into the metal contact.

Also designed was a bipolar connector. The plug would consist of two needle sections separated by an insulating cylinder. An insulated wire would run through the first section, then be soldered to the second. The receptacle would consist of two metal contacts and two silicone filled cavities, all contained in one plexigless rod, (See Figure 3). Bipolar or possible multipolar connecters could transfer current from more than one source. Several diagnostic signals could be transferred, for example, as could both a control signal and powering current for an implanted device.

The bipolar design was not tested because of difficulties encountered in the construction of a bipolar needle plug. The two needle

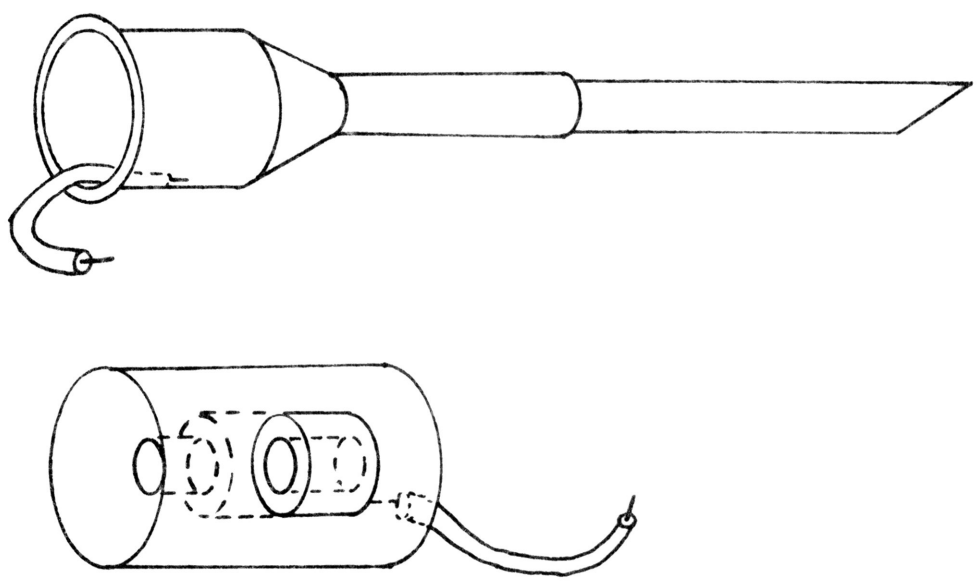

Figure 2: The incorporation of a silicone grease filled cavity into the design of the receptacle is essential for a watertight, insulating seal.

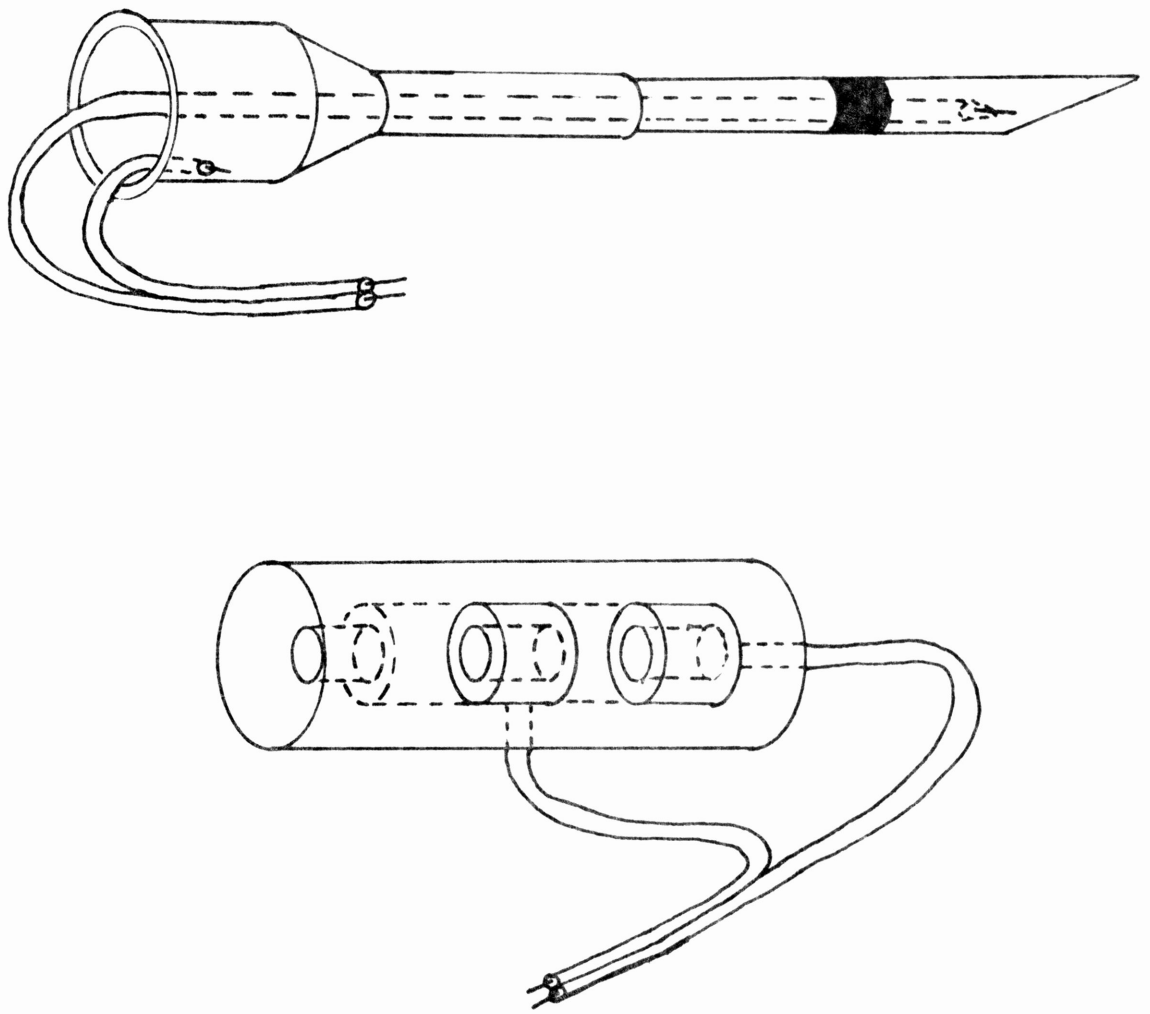

Figure 3: A bipolar version of the design permits two separate signals to be independently transferred.

sections could not be isolated electrically and still perform as a rigid unit. Further development will hopefully produce a bipolar needle that can be forced through the skin.

Methods for Testing

The electrical connector was first bench tested. The receptacle, with wire lead, was immersed in saline solution. The needle was then inserted, leaving the uninsulated upper portion above the saline. An ohmmeter was used to check the electrical continuity (zero resistance between the leads). An ECG electrode was then placed in the saline and the resistance between it and either of the connector leads was measured, (See Figure 4). The resistance measured was above 10 megaohms, the maximum resistance measureable by the meter used. This procedure checked for current leakage out of the connector.

Rabbits were used for the in vivo tests. The first implantation was of a single receptacle with 5" of insulated wire attached. Under steriel conditions, a subcutaneous tunnel was formed. The receptacle was pushed in, and the wire was anchored in place with permanent sutures. The wire left outside of the skin was coiled and taped over the surgical dressing. No tests were carried out on the first implantation because the device was extruded, due to the exposed wire, within three days of the operation. Extrusion of percutaneous devices and infection were two major problems which the design was to prevent. To avoid these problems in testing, a new connector was constructed. Two of the receptacles were connected with 4" of insulated wire. The implant was then dip coated with rubber to lessen possible tissue irritation or reactions.

For the first implantation, the silicone grease was injected into the receptacle before its sterilization. For the second implantation the silicone grease was injected through the needle plugs just prior to meter

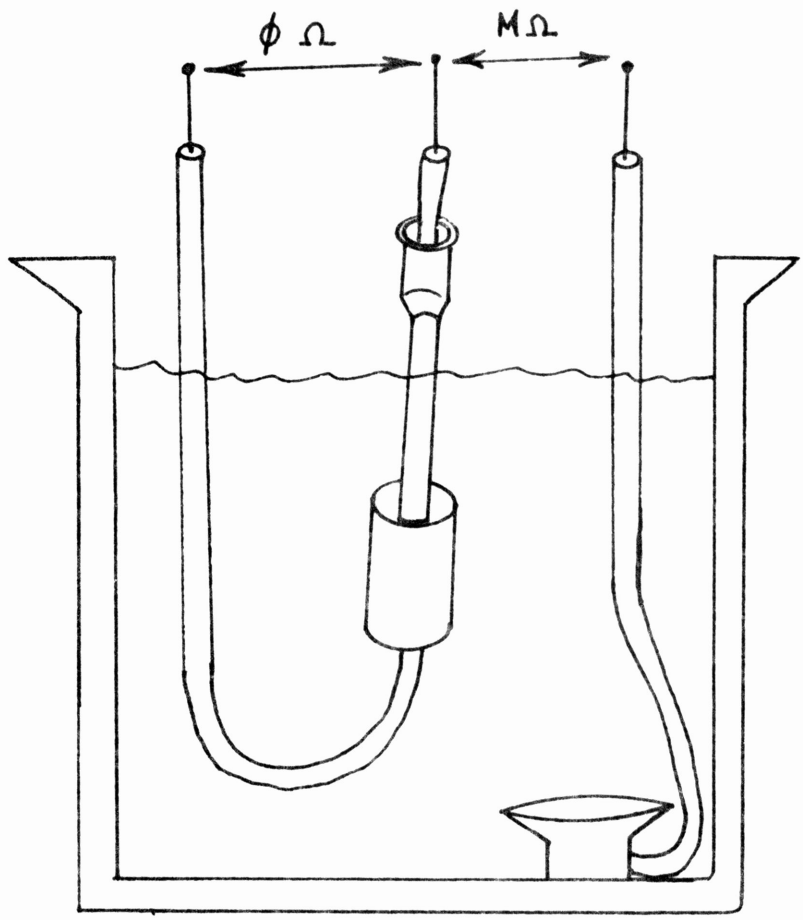

Figure 4: Saline solution simulated body fluids for the in vitro testing of the connector.

testing the connectors (one week post - operative). The needles were then pushed into the metal contacts and test were carried out. Electrical continuity was first confirmed. A resistance of 2 ohms between the needles indicated a good connection had been made. A third uninsulated test needle was inserted under the skin close to one of the receptacles, (See Figure 5). The resistances between both receptacles and the test needle were measured to be 5.4 megaohms. This indicated that current leakage was minimal. Leakage might also be detected using an ECG electrode properly applied over the receptacle. In this case the resistance through the skin would have to be subtracted from the measured resistance to obtain true indications of the connector's electrical security.

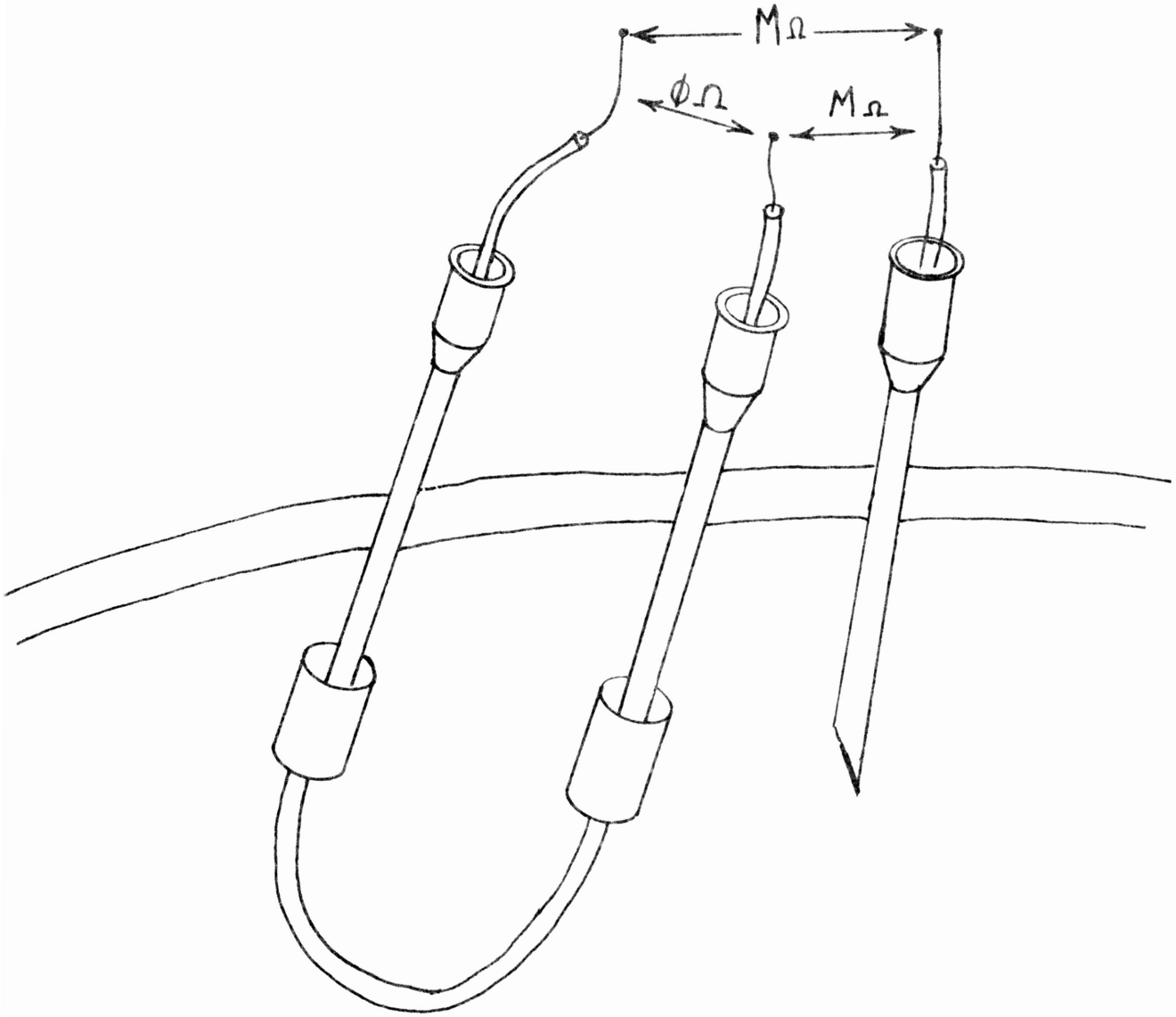

Figure 5: Leakage current out of the connector to an uninsulated subcutaneous needle was checked for during the in vivo tests.

Conclusion

The results obtained from the in vivo tests are very hopeful. The surgical procedure for implantation was simple. The insertion of the needle into the receptacle was also easily accomplished since the receptacles could be palpated through the skin. The security of the connector was acceptable as indicated by the high resistances from the inside of the connector to the outside body fluids.

Further research would include longer implantation periods with more of the described tests. With longer implantation, the materials used for the receptacle might require biocompatibility testing. As indicated earlier, biopolar and multipolar prototypes could also be tested.

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