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16. Abstract

This report describes the test program which was conducted on percutaneous (through the skin) multielectrode connectors.

Percutaneous connectors are required in medical research to provide an interface for the external control and monitoring of human neurological and other biological functions. The connectors enable direct placement or monitoring of electrical signals in the body for precise control of muscle and joint activity, pain, and metabolic processes.

Experience with multipolar connectors is relatively limited and early designs have not met many performance and production requirements for practical medical use. A feasible design and a fabrication process have been established through this study. Demonstration units were produced and delivered which are considered an engineering starting point. The design utilizes an ultra-pure carbon collar to provide an infection free biocompatible passage through the skin. It provides reliable electrical continuity, mates and demates readily with the implant, and is fabricated with processes and materials oriented to commercial production. Further development is required to refine its design and fabrication for commercial production.

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By Laurence A. Myers

Prepared by:
ADRIAN INDUSTRIES, INC.
Titusville, Florida 32780

FOR

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION
DESIGN ENGINEERING DIRECTORATE
KENNEDY SPACE CENTER, FLA. 32899

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Laurence A Myers
ADRIAN INDUSTRIES, INC.
Titusville, Florida 32780

PREFACE

Advances in medical science related to the nervous system have progressed to a point where some body functions can be controlled from outside the human body. Signals from within the body can also be utilized to control external devices. Some controls are effected without penetrating the skin, while others require direct access to internal parts. In some cases a permanent internal access through the skin is desired. Such access, if it is permanent and infection free, could be used to control many neuromuscular and biological functions.

With the development for NASA of an ultra-pure carbon material, a biocompatible method of providing a permanent infection free passage to the interior of the human body is available.

Covered in this report are the detail design and fabrication of multielectrode connectors.

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PERCUTANEOUS MULTIPLE ELECTRODE CONNECTOR DESIGN PARAMETERS AND FABRICATION

By Laurence A. Myers
Adrian Industries, Inc.

SUMMARY

This work was performed for the National Aeronautics and Space Administration, John F. Kennedy Space Center. The technical representative was Mr. William G. Franklin of Systems Engineering Division, Design Engineering Directorate.

The contract was funded by the Technology Utilization Office of NASA Headquarters in support of Rancho Los Amigos Hospital, Downey, California.

Multielectrode connectors previsously used did not have all the desired attributes. The purpose of this study is to establish design criteria for building a device that will meet the requirements of a permanent multielectrode connector. This connector will be used as a basis for establishing design guidelines for production and function.

Covered in this report are the results of basic tests conducted. These tests provided data that were used for designing multielectrode connectors. An outline of the fabrication sequence for the selected design is also presented.

It is concluded that a connector can be designed that is completely satisfactory. Also that the connector can be manufactured in large quantities at a relatively low cost. This can be accomplished as a result of more development.

INTRODUCTION

Stimulation of a muscle through the use of an external electrical source, and electromyograms, have been known for several years. An electromyogram is the combined effect of the electrical fields of all muscle fibers in a muscle observed on a pair of electrodes placed outside the muscle (reference 1). Synthesis of peripheral neuromuscular systems (reference 2) require constant development of basic electrical hardware. These hardware aid in the recording and operational functions necessary for advancement in the state of the art of medical science.

Synthesizing of peripheral neuromuscular systems (reference 2), which are the local organization of neurons, muscles, skeletal elements, and associated sense organs, which made the basic functional blocks employed by the higher levels of the nervous system in the execution of motor acts directed by its command signals, requires constant development of basic electrical hardware to aid in the recording and operating functions necessary for advancement of the state of the art. (reference 2)

Since 1968 Rancho Los Amigos Hospital, Downey, California, and others have been investigating the use of several biocompatible substances as percutaneous (through the skin) implant material. The purpose of the percutaneous implant, discussed in this report, is to provide a means whereby bioelectrical signals can be fed into or taken from the human body. These electrical signals would either monitor, control, or suppress neurological signals (reference 3) that are associated with the human nervous system. Control of joint and muscle activity, control of pain through local electrical stimulation, and precise monitoring of metabolic functions utilize percutaneous devices. The adaptation of an electrically controlled mechanical arm to a human (reference 4) is dependent on the successes of percutaneous connectors.

The development of reliable percutaneous multielectrode (2-wire and 3-wire) electrical connectors to be used as skin implants is vital to current medical research. Unipolar (single-wire) connectors are promising, but many applications require two or more electrical paths through the skin for optimum results.

Previous connector designs using springs or sliding surfaces were not sufficiently reliable in a multipolar configuration. They were too tight (difficult to release) or too loose (demate accidentally). Designs using split magnets as connectors require precision grinding and polishing of the mating surfaces.

This report outlines the results of design parameter studies and improvements made to the John F. Kennedy Space Center (KSC) concept for multielectrode connectors shown in figure 1.

GENERAL DESCRIPTION

The percutaneous multiple electrode connector discussed here is a tripolar connector. The physical features of a bipolar connector are identical except for the omission of one electrode.

Figure 1 shows the KSC design concept of the multielectrode connector. It consists of a service half that is connected to the external electrical signal monitor or supply, and the implantable portion that remains permanently attached to the human body. The implantable portion consists of the outer shell made of vitreous carbon and an insulating layer that insulates the outer shell from the electrodes. The electrodes are placed on top of the insulating layer. Then another insulating layer is placed over the electrodes to insulate them from the cylindrical magnet which is cemented in place and provides the holding force for the service half of the connector.

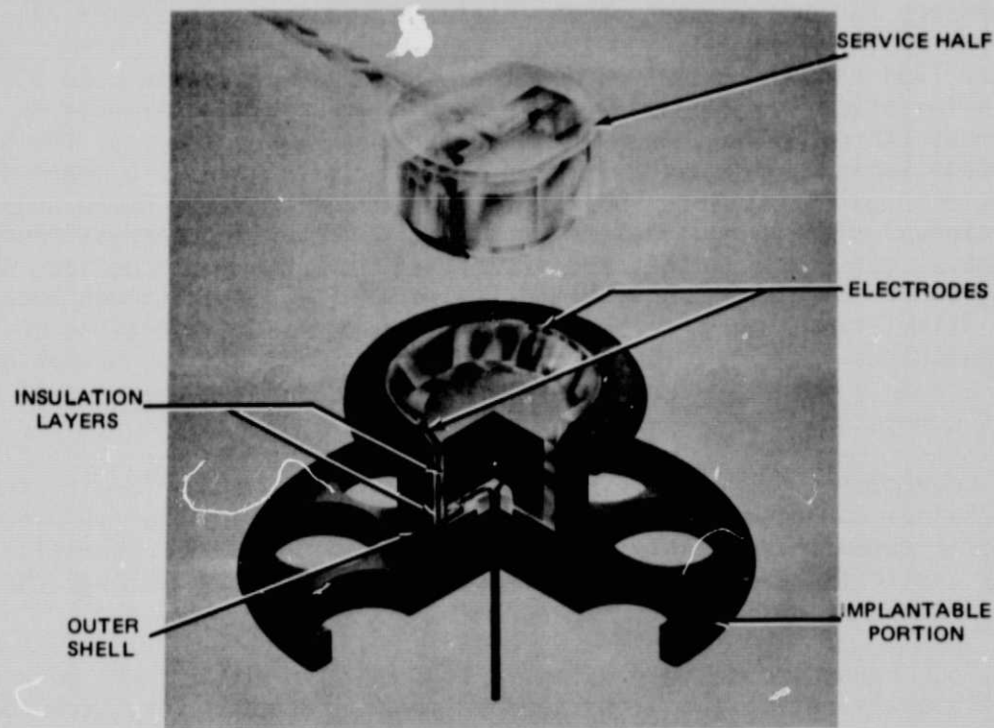

Figure 1. Initial KSC Design Concept of a Multielectrode Connector

Coiled stainless steel insulated wires are attached to the conductors of the implantable portion and provides the placement or reception of an electrical potential from a distant junction.

The force holding the two connector halves together is provided by magnets made from samarium cobalt material. Construction of the service half begins with placement of the magnet in a contoured mold and a nonconductive resin is poured over the magnet. The solidified resin, which takes the shape of the mold, provides grooves for the placement of precontoured conductors. The conductors are cemented in place. Wire leads are connected, and the unit encapsulated.

Although this design provided good electrical contact with an easy disconnect feature, delamination of the conductor from the resin occurred. One solution to the problem of delamination in the service half was forming the ends of the foil conductor. The ends were bent 120 degrees and buried in the resin. This solution, though ideal for the service half, could not be implemented in the implantable portion due to lack of space.

The design criteria required high reliability, ease of cleaning, and connection in semidarkness and proper contact orientation. Therefore, it was necessary to know more about the required or acceptable force to hold the parts together. The optimum conical angle to achieve proper stability (mating of the service and implant portions without intermittent electrical continuity) and the desirable combination of magnet diameters to achieve adequate holding force was also required. Simple tests were conducted on magnet diameters versus air gaps between the magnet surfaces. Several conical angles versus the lateral force required to pull the service half from the implantable portion were also investigated.

As a result of the above research, an arbitrary design was chosen. Then connectors were built to conform to the physical dimensions which are required to obtain the values recorded in the test data.

Experiments were conducted in two areas. First, break-away forces for various magnet sizes and air gaps were measured and recorded; second, an evaluation of taper angles was conducted.

MAGNETIC ATTRACTION

The test apparatus for the magnet attraction study consisted of a balance scale arranged as shown in figure 2. The service half magnets were mounted in a plastic holder through which a flexible cord was attached, and the other end of the flexible cord was connected to the scale. The magnet for the implantable portion was also mounted in a plastic holder but fixed to the table immediately below the service half. The weights of the flexible cord, magnet, and plastic holder were balanced out. The gap between the magnets was derived by placing known thicknesses of brass shims between the faces of the magnets. Known weights were carefully added until the magnet force was exceeded. Several magnet diameters and magnet lengths were tested in combination. Results of the test were plotted and is shown in figure 3. A tabulation of the combinations used is shown in table 1.

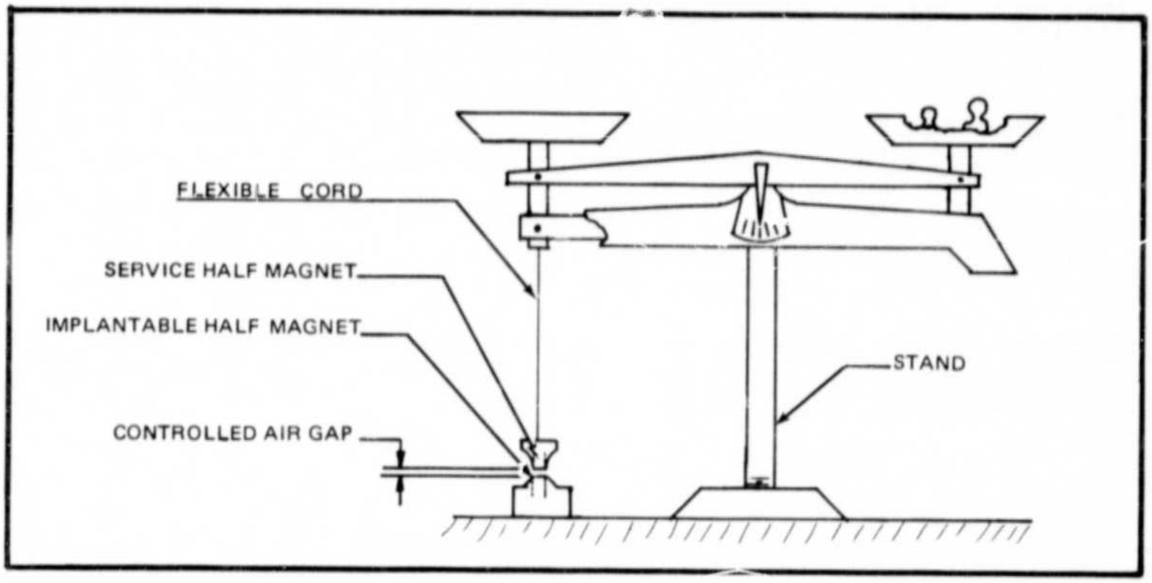

Figure 2. Test Apparatus for the Measurement of Magnet Force versus Air Gap and Magnet Diameters

TABLE II UPPER AND LOWER MAGNET DIMENSION COMBINATIONS

	UPPER MAGNET ASSEMBLY		LOWER MAGNET ASSEMBLY	
CURVE	DIAMETER	LENGTH	DIAMETER	LENGTH
1	4.06	1.91	4.06	1.27
2	*	2.54	4.06	1.27
3	4.65	1.27	4.65	2.54
4	*	2.54	4.65	2.54
5	4.65	2.54	4.65	2.54

* MAGNET TAPERED TO 3.68 MM ON MINOR DIAMETER AND 4.65 MM ON MAJOR DIAMETER.

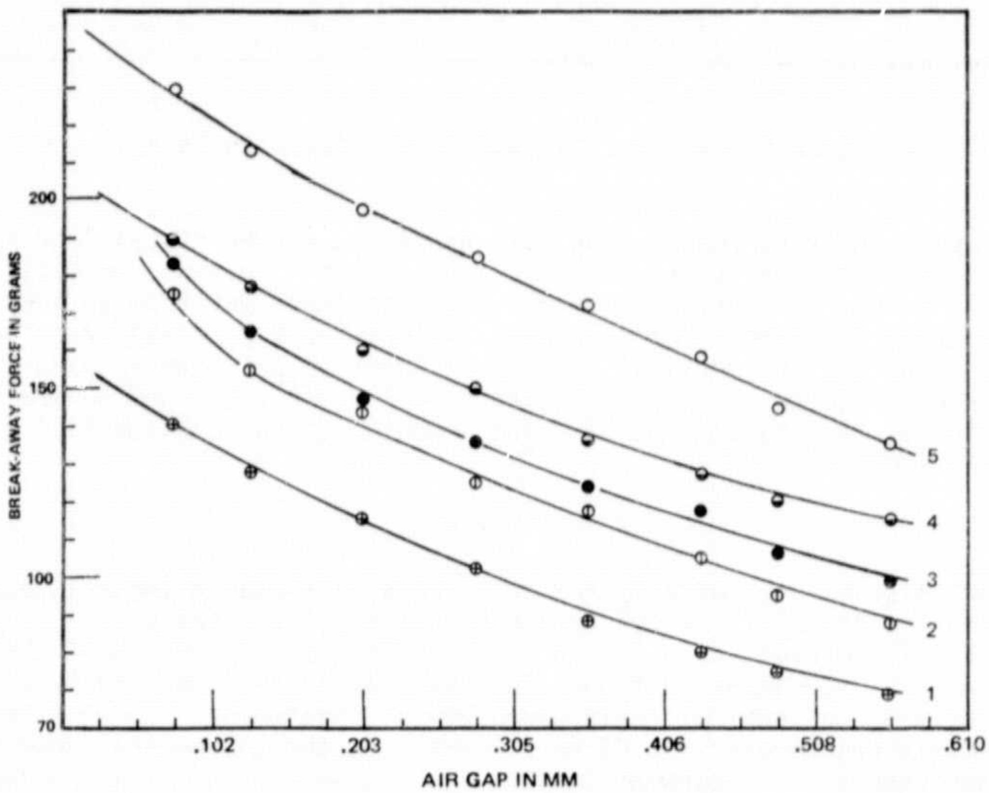

Figure 3. Plot of Magnetic Force versus Air Gap for Different Magnet Sizes

TAPER EVALUATION

A study of seven conical angles was made comparing theoretical with actual load to disengage.

The test specimens were made of brass with the service half machined to fit the lower half at controlled engagement depths. A constant height above the lower half of 4.7 mm was maintained.

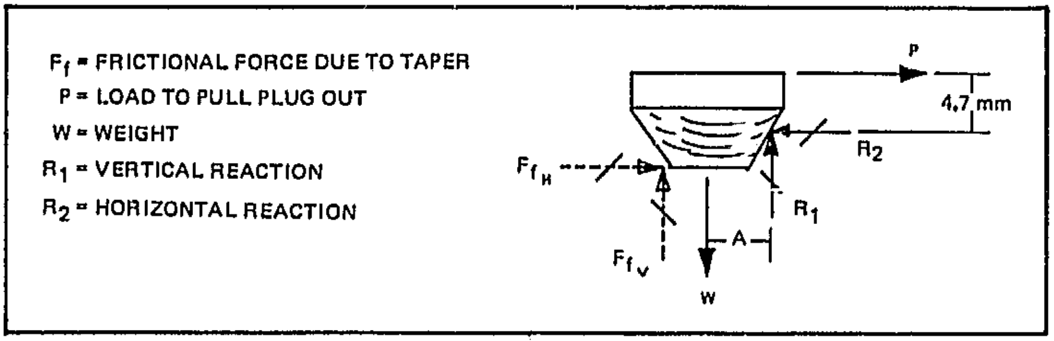

Figure Horizontal Load versus Taper Angle

To compare the test result with some baseline, a theoretical load P_c was calculated which neglected the frictional force. This was necessary to establish from the curves how much variation there was from an ideal pull-out without friction. For this calculation, the horizontal frictional force (F_{fh}) and the vertical frictional force (F_{fv}) shown in figure 4 were considered to be zero. The reactive loads P_c, R_1, and R_2 are the only forces that balance W. Summing moments at the reaction will give the value of:

$$P = WA/4.7 \text{ mm}$$

A tabulation of the force P_c for each angle is shown in table 11 and plotted in figure 5. Values obtained from the tests are also tabulated in table 1 and plotted in figure 5. The trend of the curves of the two sets of test specimens in figure 5 shows that there is a direct relationship between the conical angle and depth of engagement. Curve A used a plug depth engagement of 2.03 mm. Curve C is the theoretical load and is independent of engagement depth. Curve B used a plug depth engagement of 1.016 mm.

TABLE II TABULATION OF PLUG LOADS

ANGLE	DISTANCE A	P_C CALCULATED	P_B MEASURED	P_A MEASURED
10°	2.38 mm	28.7 GRAMS	PLUG BINDING OCCURRED	
15°	2.56 mm	31.0 GRAMS	50 GRAMS	75 GRAMS
20°	2.76 mm	33.0 GRAMS	47 GRAMS	69 GRAMS
25°	2.81 mm	34.0 GRAMS	36 GRAMS	60 GRAMS
30°	3.19 mm	38.5 GRAMS	43 GRAMS	52 GRAMS
35°	3.44 mm	42.0 GRAMS	43 GRAMS	53 GRAMS
40°	3.77 mm	45.6 GRAMS	47 GRAMS	50 GRAMS

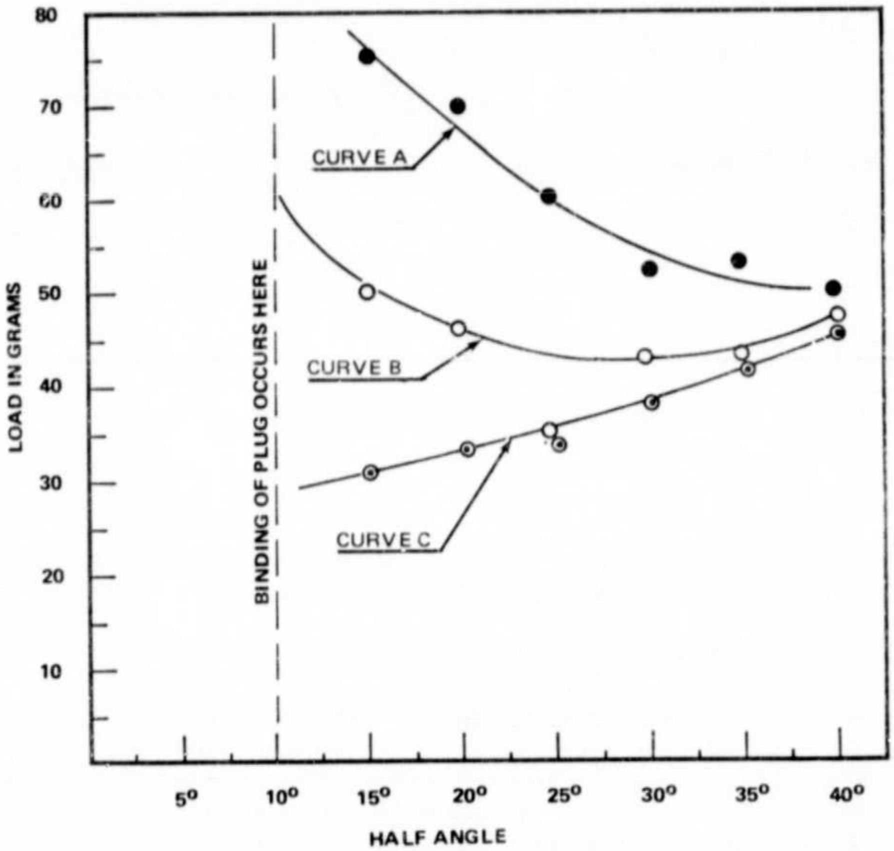

Figure 5. Plot of Conical Angle versus Horizontal Load P to Pull Plug out of Lower Half

SERVICE HALF ANGLE SELECTION

The angle selected through the use of the plot was 20 degrees. This angle would correspond with the test weight of 57 grams on a curve that would be between curves A and B of figure 5. This angle is twice that which caused plug binding. Therefore, the 20-degree point would seem to lie approximately midway between the binding angle and 45 degrees, where service half instability occurred. Corresponding to the selected point on figure 5 was a depth of engagement of the service half cone into the implantable portion.

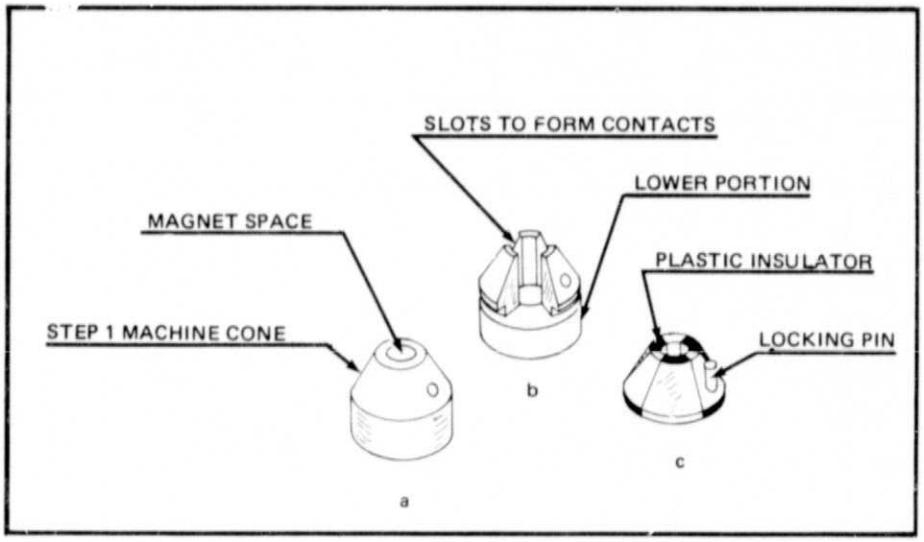

Figure 6. Fabrication Sequence for Service Half

Since Curve A was engaged to a depth of 2.03 mm and Curve B to a depth of 1.02 mm. then the engagement depth for the selected point would be 1.52 mm.

SERVICE HALF FABRICATION SEQUENCE

Fabrication begins with machining the 20-degree angle onto a cylindrical brass stock, then drilling parallel to the longitudinal axis a hole to receive the locking pin and service half magnet (figure 6a). The apex of the cone is cut off so that a magnet air gap of approximately 0.64 mm will result when the service half is inserted into the implant portion.

Figure 6b shows the next step where slots are machined to form the contacts and a groove made to allow for mechanical holding of the plastic insulator formed in subsequent steps. The part is deburred, cleaned, and gold plated. After plating, the part is placed in a mold that holds the contact angle at precisely 20 degrees while the part is injection molded to insulate the contacts and hold them in place while the lower portion of figure 6b is cut off, leaving the three contacts isolated but secured in place.

The final sequence places the locking pin in position (see figure 6c). Then conductor leads are soldered in place and the joints encapsulated. Finally, the upper half magnet is cemented in place to complete the assembly of the upper half.

IMPLANTABLE HALF FABRICATION SEQUENCE

The lower half fabrication begins with reducing the outside diameter of a solid brass stock, to fit loosely in the inside diameter of the cavity in the outer shell (see figure 1). A hole is drilled in the center of the stock to accommodate the lower half magnet, then a 20-degree angle is machined on the inside diameter to match the angle of the upper half.

The part just completed is shown in figure 7a. In figure 7b, slots are machined to form the conductor contacts, then a locking groove is machined. The part is then deburred, cleaned, and gold plated. A special molding fixture holds the contact segments while in the injection molding machine so that no distortion will take place during the molding sequence.

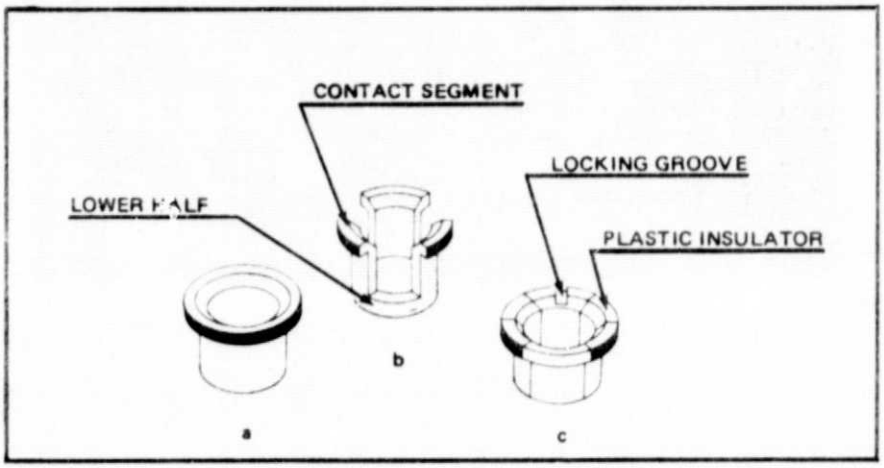

Figure 7. Fabrication Sequence for Lower Half

When the part is removed from the molding fixture, the lower half is cut off to isolate the three contacts. The part now appearing as shown in figure 7c is then inserted into the cavity of the outer shell, cemented in place, and baked to solidify the epoxy used for cementing the cuter shell to the contact assembly. An insulation check is made at this point to ensure that at least cne megohm resistance exists between the contacts and the outer shell. The coiled stainless steel conductor wires are joined to the plated contacts through the use of a conductive epoxy. When the epoxy is cured, a biocompatible epoxy seals the stainless steel conductors and the conductive epoxy joint from damage. Finally the lower half magnet is inserted, and its depth of insertion is controlled to obtain the proper air gap between the magnets.

Figures 8 and 9 show the fully assembled units magnified.

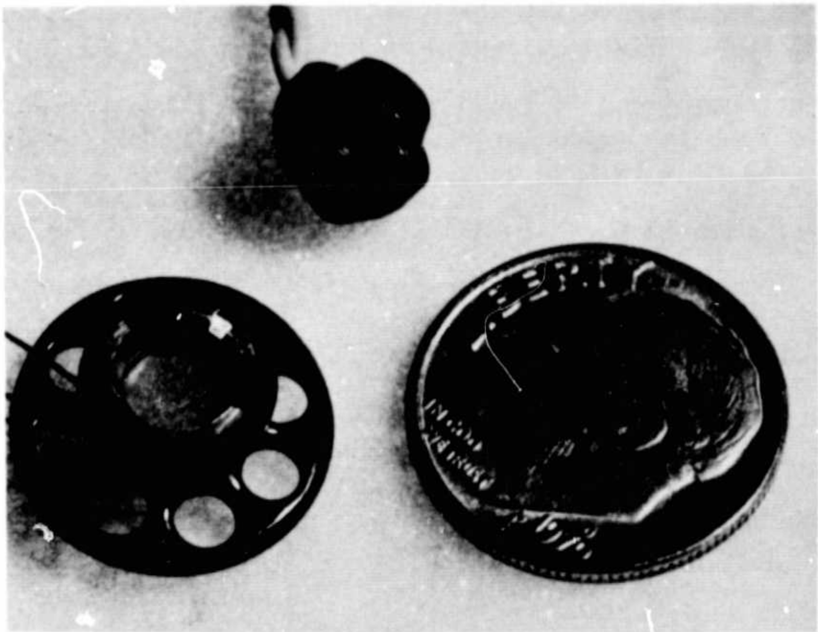

Figure 8. Upper and Lower Half Magnified 2.5 Times Showing Completed Assemblies

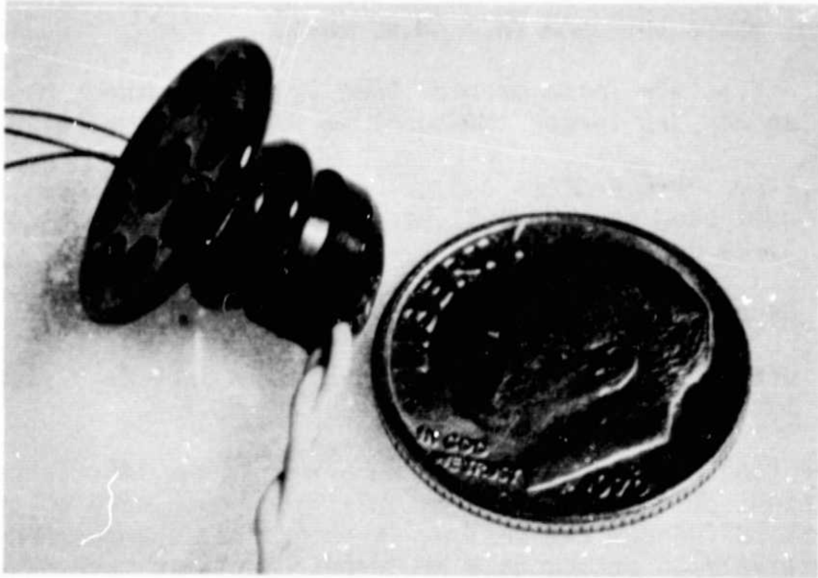

Figure 9. Upper and Lower Half Magnified Two Times, Showing Units Mated and Implantable Conductors from Lower End

CONCLUSION

No previous studies or data could be located to compare to these findings. Connectors of this type have not been in use long enough to obtain design criteria or experience to determine what combinations of magnet diameters, taper, and attractive force give the best connector design.

The final design chosen to establish a baseline design is only the first try for a multielectrode connector. It was to fall in the midrange of the data obtained in these tests. Then a known model could be evaluated by the ultimate user and decisions made regarding functional behavior and necessary improvements.

Tooling developed for fabrication of the connector chosen was intended for development of a workable connector design. Future success of a percutaneous connector will depend upon reliability and cost. Much more work must be undertaken to refine the connector design. This requires finding the optimum combination of parameters that will be most cost effective to produce in large quantities.

This study based upon the test shows that:

1. Attractive force greater than 150 grams cannot be obtained with an air gap larger than 0.51 mm for the magnet size used.

2. From 35-40 degrees conical angle, the divergence of load P to pull plug from base is not as pronounced as that of angles from 15-25 degrees.

3. Decreasing taper angle provides increased stability.

4. Greater depth of engagement provides increased stability of the mating parts and increased separation force.

The above findings agree with the behavior of the fabricated models. It is the intent of this study to establish how much each of the above parameters influences the design, in order that changes can be made easily and effectively to accommodate new requirements as more experience is gained on desirable features for percutaneous connectors.

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