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USAARL REPORT NO. 74-1

CHRONIC TRANSDERMAL ELECTRODES

BY

COL William P. Schane, M.D.
Thomas L. Wachtel, M.D.

August 1973

U. S. ARMY AEROMEDICAL RESEARCH LABORATORY

Fort Rucker, Alabama 36360



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ABSTRACT

Five-tenths (0.5) mm diameter (20 mil) 80% platinum - 20% iridium wire was used to make chronically implanted transcutaneous electrodes for use in 14 subjects over a 19 week period.

The techniques of implantation and management are described.

The advantages and disadvantages of the implanted electrodes are discussed.

Suggestions are made to improve future applications.

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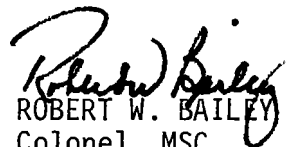

ROBERT W. BAILEY
Colonel, MSC
Commanding

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CHRONIC TRANSDERMAL ELECTRODES

INTRODUCTION

Since 1965 this Laboratory has been recording electrocardiograms of parachutists in free-fall.²² The electrodes used were 13 mm coin silver electrode discs set in plastic cups. Conducting bentonite and Type EC-2 EEG electrode cream were used as electrode pastes because of their relatively high viscosity and their resistance to being pumped out of the electrode cup by chest movement. The recordings were of readable clinical quality; however, a rash under the electrode which acted like dermatitis venenata was a common occurrence after the second or third successive day of electrode application. This rash has left several of our subjects with residual hyperpigmentation and/or superficial scarring.

In 1972, experiments were planned to extend our experience with the cardiovascular responses of parachutists during free-fall by studying a select group of 14 novice parachutists through their first 70 jumps. This would require nearly daily applications of chest electrodes over a number of months. To avoid the development of the rash seen since 1965, an alternate method of coupling the man to the recorder was sought.

After a review of the literature¹⁻²⁴ and some pilot studies to evaluate electrode performance in the free-fall environment, it was decided to use implanted electrodes of 0.5 mm diameter (20 mil) platinum-iridium wire.

This report describes the techniques used for implantation, and relates our experience with these chronically implanted electrodes.

METHOD

Eighty percent (80%) platinum - 20% iridium wire 0.5 mm in diameter (20 mil) was used to manufacture the electrodes. Wire of this diameter and composition is sturdy enough to withstand daily use, ductile enough for easy forming, yet stiff enough to resist inadvertent deformation.

In a pilot study two loops of wire were stitched subcutaneously at right angles to one another and to the skin plane. An ordinary white plastic button was slipped over the wire ends to act as a spacer, and the wire ends were then twisted to act as a connector post (Figure 1). Sufficient space was left under the button to allow for cleaning (Figure 2).

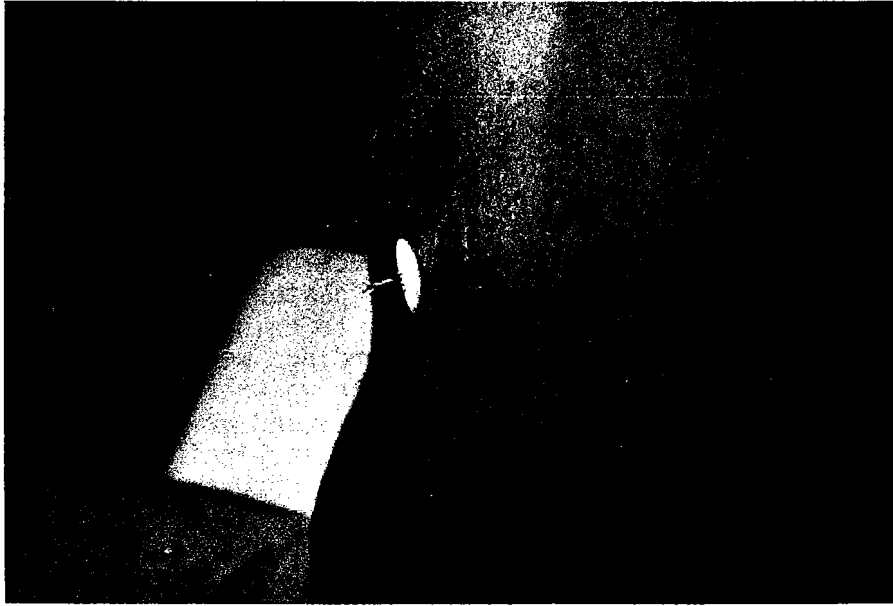


FIGURE 1

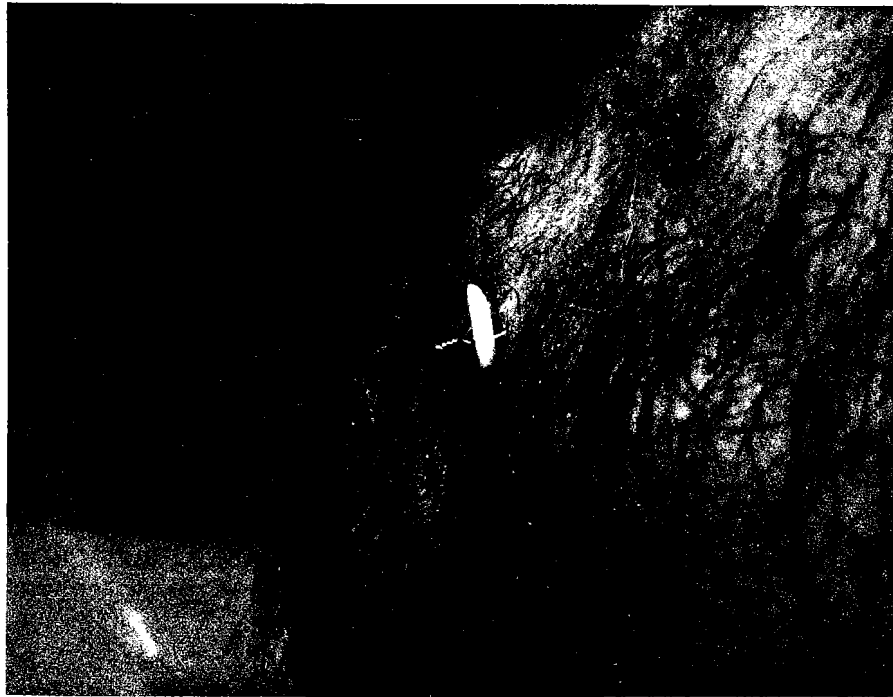


FIGURE 2

Three such electrodes were implanted--a reference electrode over the manubrium sterni, a recording electrode over the body of the sternum at the level of the insertion of the 5th costal cartilage, and a ground electrode in the anterior axillary line at the level of the 7th rib (Figure 3).



FIGURE 3

Since we were primarily concerned with cardiac rate and rhythm in subjects certain to be physically active, this electrode matrix was selected because it provided (1) a clear P wave, thus facilitating determination of rhythm; (2) a large R-S spike for rate counting; and (3) placement of the reference and recording electrodes over bony prominences to minimize electromyographic artifact.^{12 16 22}

To implant the wires, 1% lidocaine solution was infiltrated locally for anesthesia after appropriate surgical skin preparation. Then, a pinch of skin was elevated, and a disposable 18 gauge needle was passed through all layers of the two skin folds. Sterile platinum-iridium wire was threaded inside the lumen of the needle, and the needle was withdrawn, leaving the wire in the needle tract. The wire was then formed into a U shape, with the two wire ends protruding from the skin. The procedure was repeated 90° in the plane of the skin to the first implantation. An ordinary white plastic button was slipped over the wire ends to act as a spacer, and the wire ends were then twisted together.

These electrodes remained in place in one test subject for six weeks, with essentially no reaction, and no infection. They were given no special cleaning care. Because the wire tips were irregular, and protruded, they were generally kept covered with a small adhesive dressing to prevent the wire ends from catching on clothing, towels, wash cloths, etc. They were easily removed without local anesthesia like any other wire suture merely by clipping one end of each wire where it exited the skin and removing each wire individually.

The protruding wire ends of these electrodes proved to be a real nuisance; consequently, a revised electrode for use in the total subject population was designed to eliminate the projecting wire ends. The electrode was a rectangular loop 15 mm long by 7 mm wide, folded 90° at about the middle of its width into a three-dimensional figure (Figure 4). This shape permitted the electrode to lie flat against the skin after implantation (Figure 5). The loci, and method of implantation remained the same. The electrodes were bent to the shape shown in Figure 6 prior to threading the longer wire end through the disposable 18 gauge needle lumen. When the remaining wire end had been formed, the loop was closed with small eyelet loops, and a bead of epoxy was placed at the closing loops to prevent catching of the wire ends.

Three such electrodes were implanted in the thoracic skin of 14 subjects. The electrodes remained in place for 19 weeks.

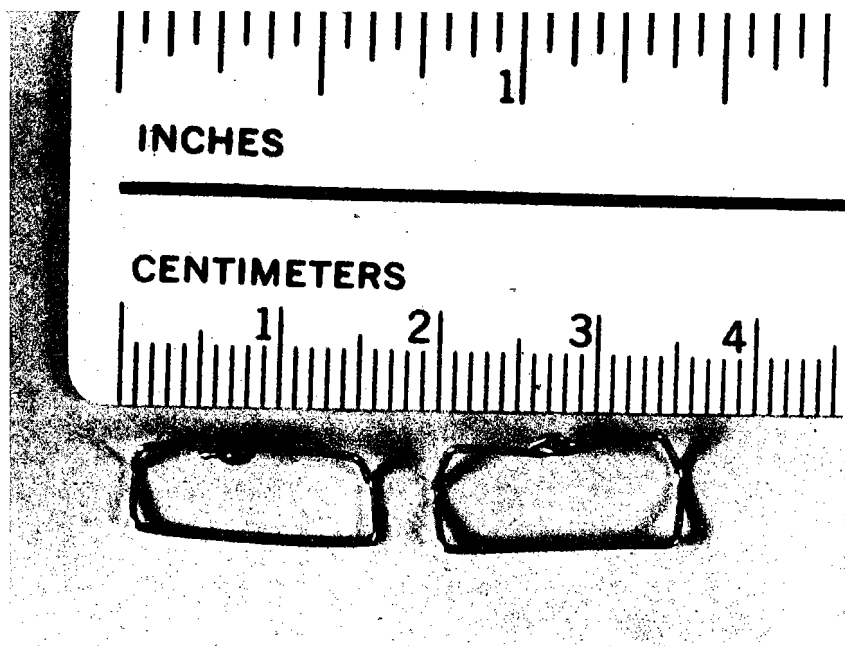


FIGURE 4

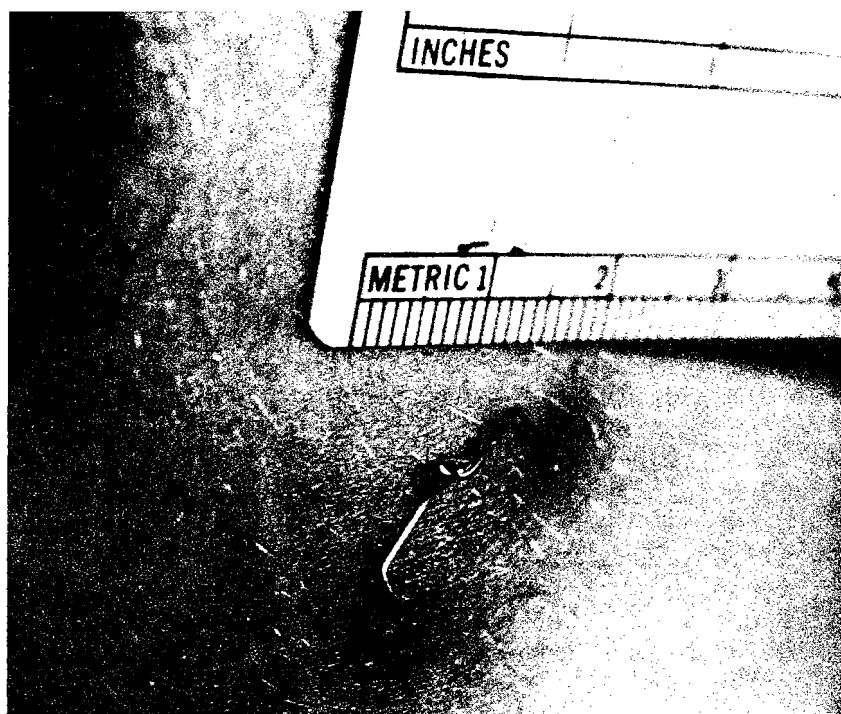


FIGURE 5

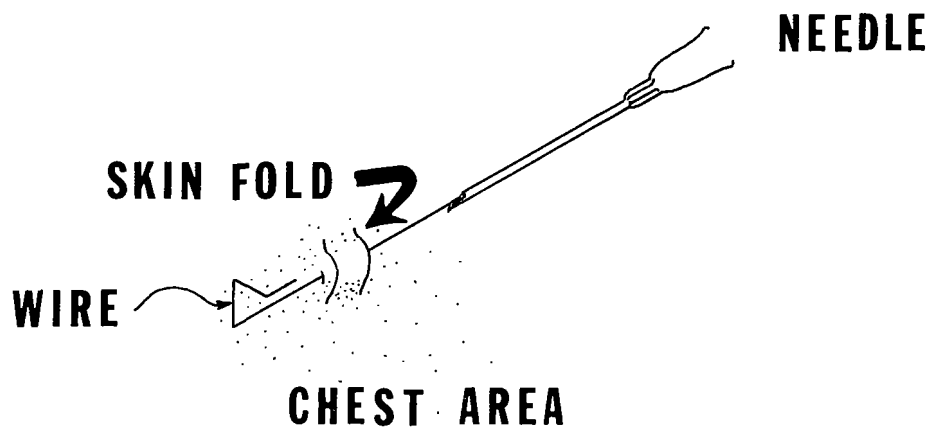


FIGURE 6

OBSERVATIONS

No difficulties of any kind were experienced with the electrodes in daily use for the first five weeks after implantation. In the sixth week, several subjects reported tenderness at the site of the electrode, and discharge from the skin punctures. Examination revealed mild erythema surrounding the implantation site; the discharge was gray and mucinous in appearance, but did not appear frankly purulent. Culture grew only normal skin flora. The subjects were instructed to apply hot, moist compresses three times daily to the electrode sites, and to remove all crusts from the wires where they exited the skin. They each were given 250 mg of tetracycline four times daily by mouth for five days. By the second therapeutic day, all evidence of inflammation had subsided, and the electrode sites appeared normal. During the 19 weeks of the study, eight subjects were treated at various times with this therapeutic regimen for complaints of swelling, tenderness, and discharge at the electrode sites. Three were treated on two occasions. Two subjects developed drainage tracts midway between the two wire exit orifices (Figure 7). Both responded to the described treatment program.

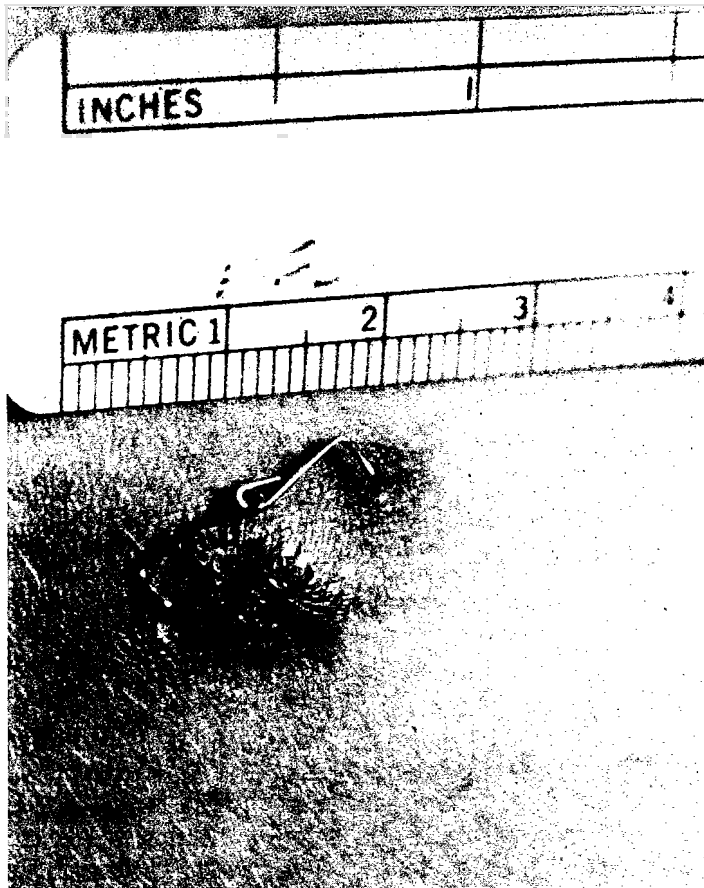


FIGURE 7

It was necessary to be careful that the electrodes were properly positioned at all times. If the electrode became canted in the tract

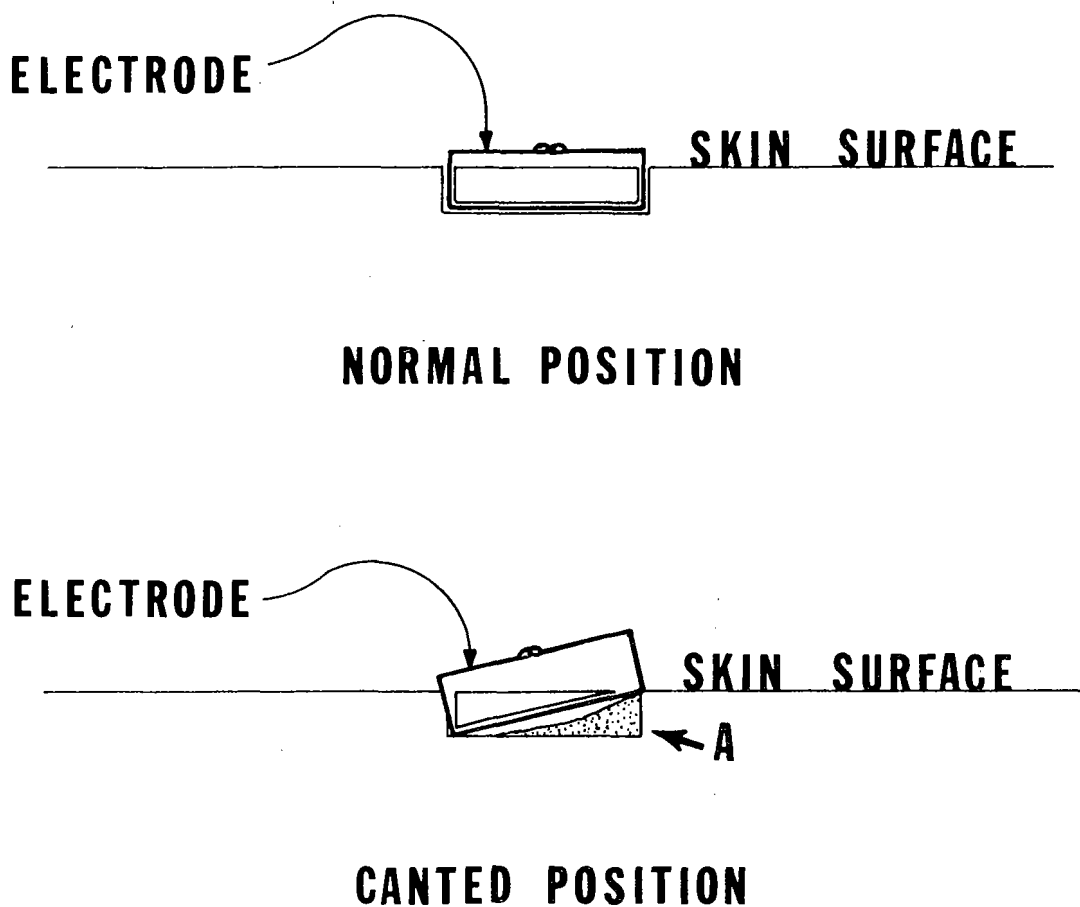


FIGURE 8

and remained in that position for as little as 24 hours, there was sufficient healing at A (Figure 8) to shorten the distance between the two skin penetrations, and the electrode then could not be replaced without making a short incision in the skin at A to permit replacement. Toward the end of the program, several electrodes were permitted to remain canted to follow their course. Orifice healing persisted at A and the wire migrated at about 1 mm/day toward the other skin puncture. In about 10-14 days, the electrode was painlessly extruded, eventually being held in place only by the superficial layers of epithelium.

In three instances electrodes were lost by avulsion: two in football games and one in a fight. In each case the avulsion wound was a clean slit that looked as though it had been cut with a scalpel. Each was closed with butterflies, and healed without incident.

Throughout the 19 weeks of study, each time the recorders were attached, resistance was read across all combinations of the three electrodes using a Triplett Model 310-C VOM. The inter-electrode resistance was regularly 25,000 ohms \pm 5,000 ohms. About 31 μ A passed through tissues during the measurement.

At the completion of the study, in four subjects the lateral chest electrode was removed by excision along with an ellipse of surrounding and underlying tissue. Subject A was selected because he had experienced frequent local reactions, B was selected because he was about average in his response to the implanted electrodes, C was selected because he had experienced minimal difficulty, and D was selected because he was black (though not a known keloid former).

The pathology cut sections are described as follows:

A: C. S. - There is an interruption of the epithelium with a sinus tract into a granulomatous process in the subjacent dermis. The center of the tract contains degenerating polymorphonuclear leukocytes. The wall of the tract is a mixture of neutrophiles, eosinophiles, histocytes, macrophages, lymphocytes, and foreign body giant cells. The wall of the tract is lined with an interrupted squamous epithelium. Another section is more chronic in nature, with fewer giant cells and histocytes, more lymphocytes, and immature fibroblasts lying down collagen. The entire lesion is surrounded by a thick rim of mature collagen. Some adnexa are surrounded by the inflammatory process. No bacterial colonies were seen.

Dermatitis, granulomatous, focal, solitary, foreign body, skin.

B: H. R. - Two sections are present, one with an intact epithelium and the other with 50% of the epithelium missing. There is a granulomatous process in the dermis with the core containing clusters of neutrophiles. The edge of the process is comprised of lymphocytes, histocytes, epithelioid cells, macrophages, and plasma cells. Some giant cells

are present. There are foci of lymphocytes and histocytes in several areas of the surrounding collagen capsule. These foci contain a moderate amount of phagocytized hemosiderin. No bacterial colonies were seen.

Dermatitis, granulomatous, focal, sub-acute, solitary, foreign body, skin.

- C: J. S. - Two sections are present. One contains a circular tract lined with a thick layer of squamous epithelium, secreting keratin into the center. Outside the tract are laminations of lymphocytes, histocytes, macrophages, and a few foreign body giant cells. These laminations are separated by fibroblasts and immature collagen. The other section is essentially the same but without the dermal inclusion cyst. No bacterial colonies were seen.

Dermatitis, granulomatous, sub-acute, foreign body, with dermal inclusion cyst, skin.

- D: D. H. - There is a dermal inclusion cyst, by history an epithelialized sinus tract with keratin in the center. Outside this tract are laminations of chronic inflammatory cells including lymphocytes, macrophages, plasma cells, epithelioid cells, and a few giant cells. These laminations are separated by young plump fibroblasts. A sprinkling of eosinophiles is seen. The overlying epidermis is acanthotic immediately over the lesion. No bacterial colonies were seen.

Dermatitis, granulomatous, focal, sub-acute, solitary, mild, with dermal inclusion cyst, skin.

Thus, microscopy showed considerable local reaction, mostly of a foreign body type, with infiltration of polymorphonuclear leukocytes (Figure 9), round cells, giant cells (Figure 10), and eosinophiles along the subcutaneous tract. There was evidence of epithelialization along the tracts of all the subjects, with some evidence of squamous epithelial debris in the tract (Figure 11).

The remainder of the electrodes were cut and removed without anesthesia much like any ordinary wire suture. All came out with no difficulty. After the wire was removed, a palpable subcutaneous tract could still be felt. Two months after removal of the electrodes, all subjects reported healing at the sites of implantation with no sequelae.

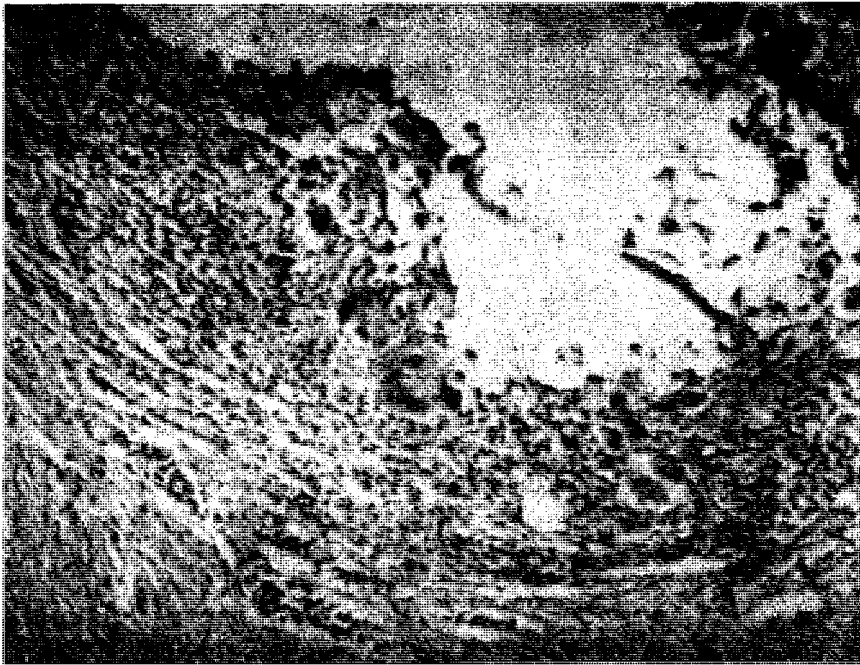


FIGURE 9

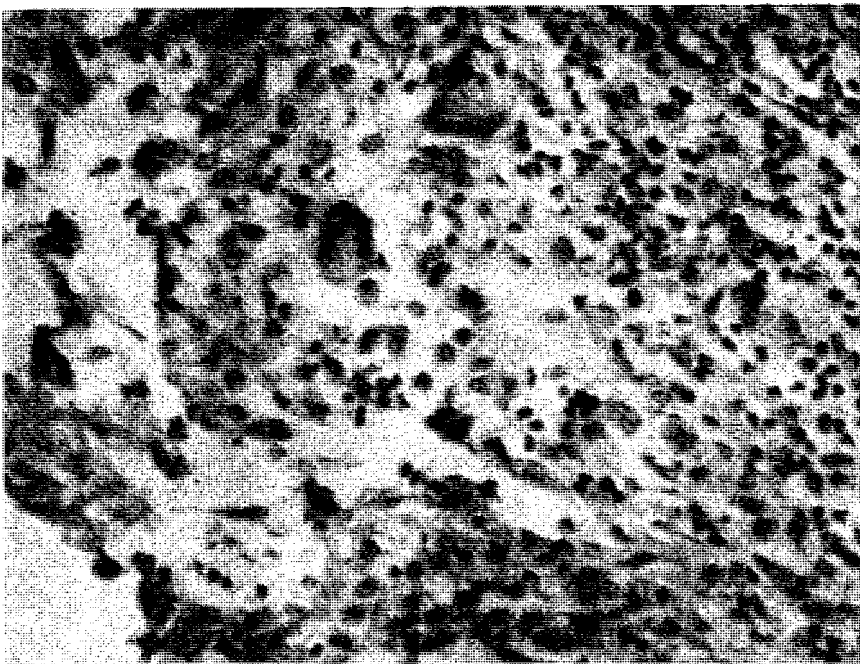


FIGURE 10

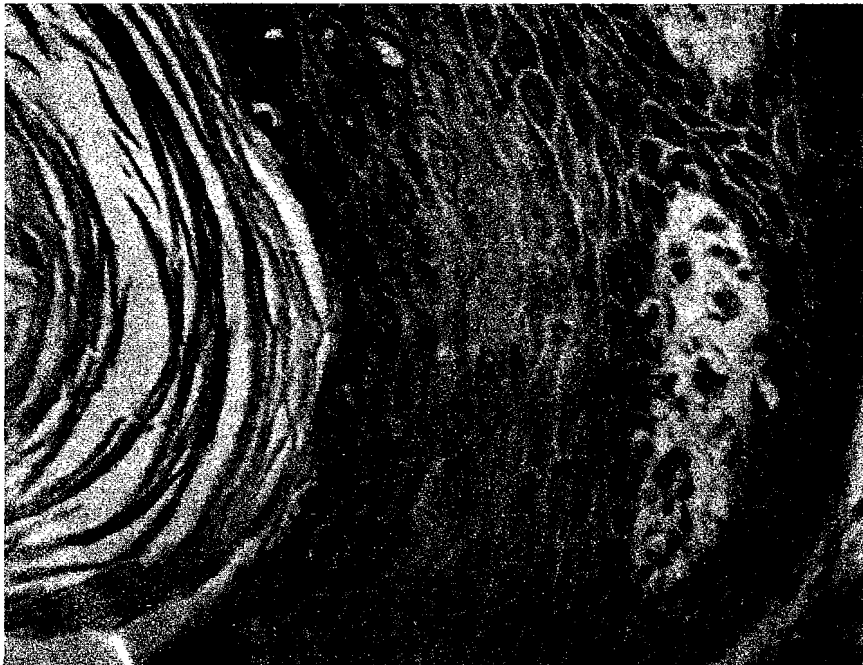
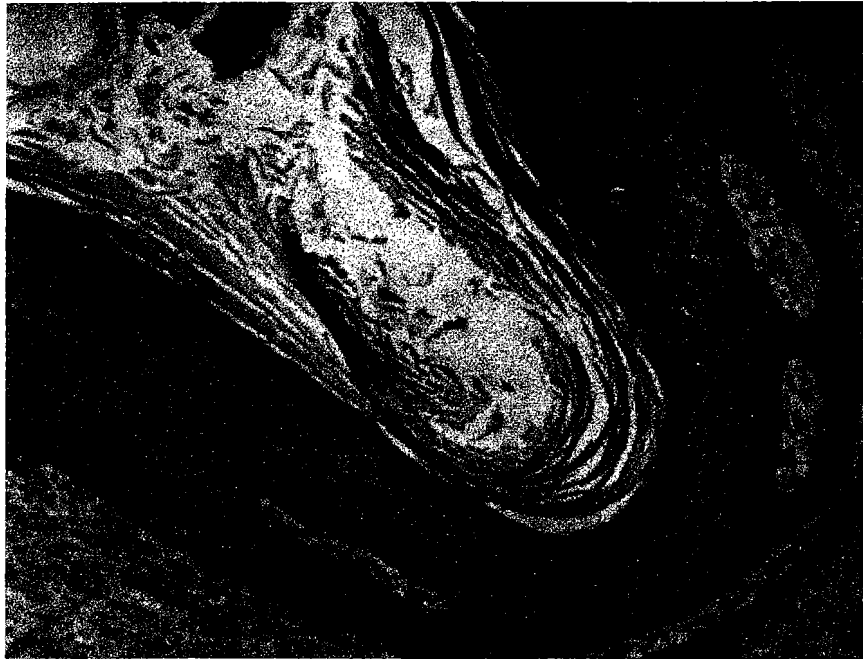


FIGURE 11

We had the opportunity to observe the electrode sites in one subject five months after electrode removal. At the manubrial site, two 1x1 mm nodules could be felt in the skin at the site of skin puncture. At the lateral thoracic site, there were two 2 mm diameter circles of hyperpigmentation at the site of skin puncture, with no palpable nodules. The electrode site over the lower sternal body could not be identified.

DISCUSSION

The technique of implanting electrodes offered several advantages for prolonged or repeated use:

1. It is a quick and simple process to attach the subject to the recorder. Attachment required only about one minute, and the subjects generally did it themselves. To adequately prepare the site and attach standard chest disc electrodes requires a minimum of five minutes per subject.

2. Implantation assured that the electrodes were always identically placed on repeated applications. Localization was excellent. There was no electrode movement in situ and no electrode paste to spread out on the skin to degrade localization. There was no baseline shifting due to battery effect at the electrode-skin interface. There were no changes in electrode capacitance, nor changes in impedance due to sweating. These are particularly important for long term recording, especially if one plans to compare wave forms of electrocardiograms derived from chest leads recorded on different days.

3. For chronic studies, our implanted electrodes were much cheaper than standard disc electrodes. During five months of experience a total of four dollars per subject was spent for the platinum-iridium wire. The three lead wires were made in our own laboratory for a total cost of one dollar per set (Figure 12). It is estimated that to make a comparable number of electrode applications using standard disc electrodes (3 electrodes/subject, 14 subjects, 70 days of test) would have cost \$139.80 for commercial disposable adhesive discs alone.



FIGURE 12

There are, however, certain disadvantages to implanted electrodes.

1. The major problem we noted was one of social acceptance. It took the subjects a week or so to adjust to the care that was desirable while bathing and when putting on or taking off their undershirts. They became objects of curiosity to other barracks-mates because they had "wires sticking out of their chests." The initial application of twisted wire over a button proved to be totally unsatisfactory; however, the eventual method developed was minimally incapacitating, and rarely caused difficulty.

2. Hyperkeratosis commonly develops at the point where the wires leave the chest (Figure 13).

3. Punctate suture scars may remain when the electrodes are removed.

4. There is possibility of local infection.

5. There is the possibility of electrode rejection; however, this can be minimized by adequate day by day care.

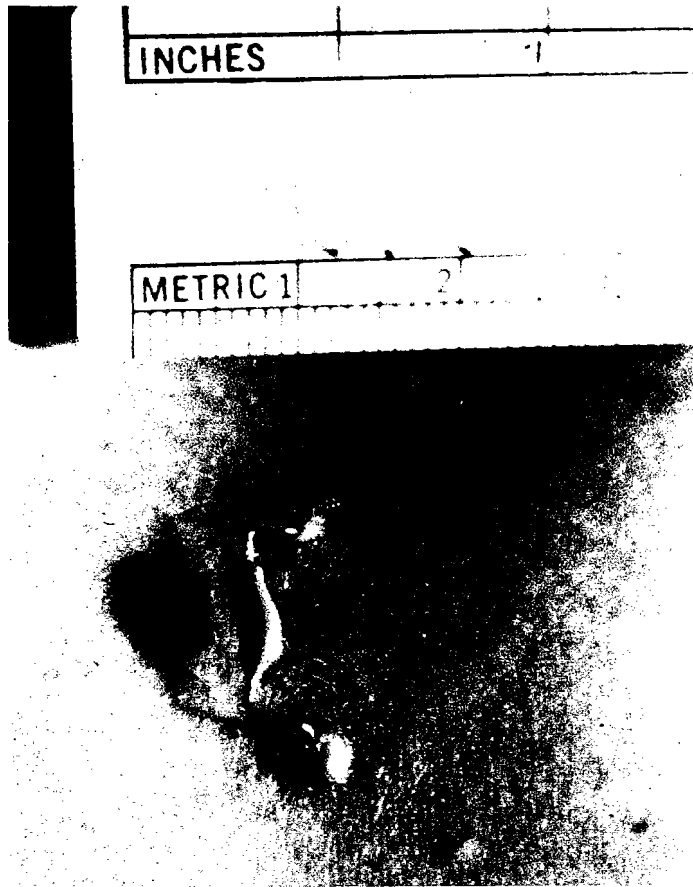


FIGURE 13

6. When epithelialization occurs along the electrode tract, desquamated epithelium sloughed into the tract becomes a disposal problem.

Two improvements are recommended for future use of such implanted electrodes:

1. The wire we used was hard drawn. In the process of hard drawing, the wire is bathed with lubricants which can be composed of soap solutions, graphite, and/or lubricant hydrocarbons. Prior to use, our wire was washed and steam sterilized. Since platinum is reported to cause no tissue reaction in dogs,¹⁵ and iridium is also relatively non-reactive in tissue, it is possible that the foreign body reactions described were due at least in part to residual surface materials deposited on the wire at the time of drawing. In the future, we plan to pay more attention to physical cleaning of the wire prior to implantation. The steps proposed are:

- a. An initial dip into dichromatic acid cleaning solution.
- b. Rinse.
- c. Wash with detergent and water in an ultrasonic bath.
- d. Rinse.
- e. Thorough lavage with chloroform.
- f. Final cleansing with live steam prior to sterilization.

2. To improve drainage from the subcutaneous tract, and thereby reduce the likelihood of inflammation along the tract caused by entrapped squamous debris, the subcutaneous length will be reduced from 15 mm to about half that length.

REFERENCES

1. Benda, G., "Needle Electrodes for Heart Rate Monitoring," Letters to the Editor, J. of Pediatrics, 80:160-161, January, 1972.
2. Blank, I. H. and Finesinger, J. E., "Electrical Resistance of the Skin - Effect of Size of Electrodes, Exercise and Cutaneous Hydration," Arch. of Neurol. & Psychiatry, 56:544-557, 1946.
3. Brettle, J., "A Survey of the Literature on Metallic Surgical Implants," Injury, 2:26-39, July 1970.
4. Burns, R. C., "Study of Skin Impedance," Electronics, 23:190-196, 1950.
5. Carmichael, E. A., Honeyman, W. M., Kolb, L. C., and Stewart, W. K., "A Physiological Study of the Skin Resistance Response in Man," J. Physiol., 99:329-337, 1941.
6. Cooper, K. H., "A Simple, Inexpensive Way to Monitor Electrocardiograms on an Actively Exercising Subject," Technical Documentary Report No. SAM-TDR-64-38, USAF School of Aerospace Medicine, Aerospace Medical Division (AFSC), Brooks AFB, TX, August 1964.
7. Floyd, W. F. and Keele, C. A., "Further Observations on Changes of Potential and E.M.F. Recorded from the Human Skin," From the Proceedings of the Physiological Society, J. of Physiol., 86:23P-25P, 1936.
8. Forbes, T. W. and Landis, C., "The Limiting A.C. Frequency for the Exhibition of the Galvanic Skin ("Psychogalvanic") Response," J. of Gen. Psychol., 13:188-198, 1935.
9. Geddes, L. A., DaCosta, C. P., and Wise, G., "The Impedance of Stainless-Steel Electrodes," Med. & Biol. Engng., 9:511-521, 1971.
10. Gesteland, R. C. and Howland, B., "Bridge for Measuring the Impedance of Metal Microelectrodes," Reprinted from The Review of Scientific Instruments, 30(4):262-264, April 1959.
11. Gesteland, R. C., Howland, B., Lettvin, J. Y., and Pitts, W. H., "Comments on Microelectrodes," Proceedings of the IRE, pp. 1856-1862, November 1959.
12. Gilson, J. S. and Griffing, R. B., "Continuous Electrocardiograms - Electrodes and Lead Systems," The Am. J. of Cardiol., pp. 212-215, August 1961.

13. Hanish, H. M., Neustein, R. A., Van Cott, C. C., and Sanders, R. T., "Technical Aspects of Monitoring the Heart Rate of Active Persons," Am. J. of Clin. Nutrition, 24:1155-1168, September 1971.
14. Hubel, D. H., "Tungsten Microelectrode for Recording from Single Units," Science, 123:349-350, 1956.
15. McFadden, J. T., "Tissue Reactions to Standard Neurosurgical Metallic Implants," J. Neurosurg., 36:598-603, May 1972.
16. Pacela, A. F., "Collecting the Body's Signals," Electronics, 40:103-112, July 10, 1967.
17. Patten, C. W., Ramme, F. B., and Roman, J., "The Flight Research Program ECG Techniques - A Rapid Method of Electrode Application," NASA Flight Research Center Technical Report, Edwards, CA
18. Prescott, J. W., Calatayud, J. B., Myers, T. I., and Pierpont, H., "Suture Electrodes: A Solution for Long-Term Bioelectric Recording," Abstract of a paper presented to 5th Annual Meeting of Society for Psychophysiological Research, Houston, TX, October 1965.
19. Robinson, D. A., "The Electrical Properties of Metal Microelectrodes," Proceedings of the IEEE, 56(6):1065-1071, June 1968.
20. Roman, J., "Flight Research Program III - High Impedance Electrode Techniques," a proposed publication, NASA Flight Research Center, Edwards, CA, January 1966.
21. Royal, O. L., "Use of Suture Electrodes for Continuous EEG Recording During Seven-Day Sensory Deprivation Experiments," Reprinted from the Proceedings, 76th Annual Convention, APA, pp. 629-630, 1968.
22. Schane, W. P. and Slinde, K. E., "Continuous EKG Recording During Free-Fall Parachuting," Aerospace Medicine, 39:597-603, June 1968.
23. Sosnow, M. and Ross, E., "Electrodes for Recording Primary Bioelectrical Signals," ASD Technical Report 61-437, Biomedical Laboratory, Aerospace Medical Laboratory, Aeronautical Systems Division, Air Force Systems Command, USAF, Wright-Patterson AFB, OH, September 1961.
24. Weinman, J. and Mahler, J., "An Analysis of Electrical Properties of Metal Electrodes," Med. Electron. Biol. Engng., 2:299-310, 1964.

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