Newsletter

Prosthetics and Orthotics Clinic

Vol. 5, No. 3 1981 Summer (Issued Quarterly)

PROSTHETIC SENSORY FEEDBACK LOWER EXTREMITY

Frank W. Clippinger, M.D.*
James H. McElhaney, Ph.D*
Maret G. Maxwell, Ph.D.*
David W. Vaughn, C.P.O.*
Grace Horton, R.P.T.*
Linda Bright, R.N.*

This is a progress report of a Duke University research project involving sensory feedback from lower extremity amputation prostheses.

It has been assumed for many years that replacement of sensory function in prosthetic limbs was a nearly impossible task. Developments in electronics have made possible small amplifier systems and usable transducers, but the basic difficulty remains that of getting the signals into the central nervous system in a fashion that is interpretable, comfortable, consistent, and convenient.

The problem has not been ignored and the obvious routes—auditory signal, electrical stimulation of intact skin, mechanical stimulation, and developments leading to solving the skin barrier with compatible percutaneous materials have been explored.

From 1969 to 1975, this laboratory developed the mechanism to produce sensation from upper limb prosthetic terminal devices. This system was built around the concept of proportional peripheral nerve stimulation by means of a surgically implanted, induction coupled radio receiver-pulse generator, driven by an external amplifier and transmitter that relayed frequency modulated signals, controlled by a strain gage transducer in the terminal device.

The conclusions from this study were:

(1) The system is feasible and signals can be interpreted with reliability relative to the stimulating activity.
(2) The brain interprets the signal as coming from the normal peripheral distribution of the nerve stimulated.
(3) Signal threshold and nerve excitability does not deteriorate with time, at least in this application.
(4) The implanted device is reliable, and durable, there having been no implant failures in twelve years.

In 1975, a grant was received from the National Cancer Institute to apply this technique to the lower limb amputee. This study is to determine whether sensory feedback, in addition to that provided normally from the stump-socket interface and terminal knee impact, is either useful or advantageous.

To date, 21 patients have been fitted with a lower extremity sensory feedback system, including below knee, above knee, and hip disarticulation amputees. The majority of these have been cancer patients.

The new amputee from malignancy presents a special problem. It is difficult to subject a person recently amputated for cancer to another surgical procedure to insert a stimulator implant. In addition, the amputation is followed by months of chemotherapy during which time wound healing is compromised and the patient does not feel well. Emotional factors must be considered also.

For this reason, it was necesary to develop a noninvasive system as well as the implanted nerve stimulator. After a brief unsuccessful trial with a skin vibrator, the auditory route was selected.

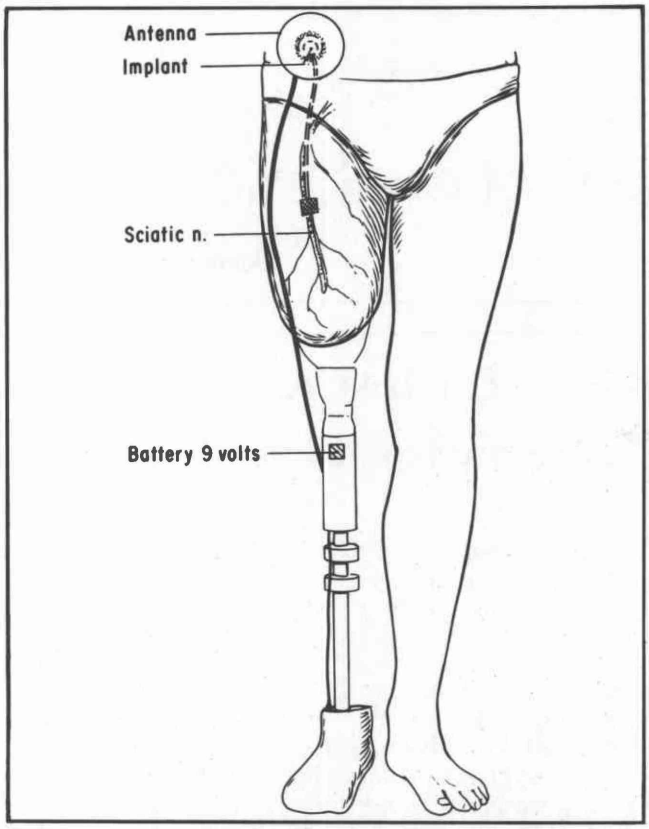
The electronic systems of both the implanted and auditory devices are similar. The system consists of a set of strain gages which measure anteroposterior and mediolateral bending moments incorporated into the below knee segment of the prosthesis utilizing an endoskeletal unit developed by the Department of Bioengineering at Duke, hybridized with Otto Bock endoskeletal prosthetic components.

In addition to the strain gages, a pressure activated piezo-electric crystal is imbedded in the heel of a SACH foot. This is activated on heel strike.

When the weight is balanced in mid stance or when the prosthesis is unloaded, as with the patient sitting, there is no signal produced by any of the transducers. The system is designed to provide proportional feedback as soon as weight is biased in any direction.

---

* Department of Surgery, School of Medicine, Department of Medicine, Department of Biomedical Engineering, School of Engineering, Duke University, Durham, N.C.



For the implant system, the signal to the nerve is frequency-modulated with the frequency of stimulus increasing from 0 to 90 Hertz proportionate to the load. With frequencies greater than 90 Hertz, a decrease in signal or complete loss of signal has been experienced routinely. Voltage is adjusted to a level that is comfortable for the patient. Threshold in these patients has varied between .5 and .9 volts.

Newsletter
Prosthetics and Orthotics Clinic

Editor: H. Richard Lehneis, Ph.D., C.P.O.
Editorial Board: Tamara Sowell, R.P.T.
Charles Pritham, C.P.O.
Charles Epps, Jr., M.D.

Managing Editor: Barbara Muller
Assistant Editor: Helene M. Murphy

Prepared by the American Academy of Orthotists and Prosthetists, 717 Pendleton St., Alexandria, Virginia 22314. Second class postage paid at Alexandria, VA and additional mailing offices. Subscriptions: Domestic: $10 per year. Foreign: $11 per year.

Chairman, Publications Committee:
H. Richard Lehneis, Ph.D., C.P.O.

The implanted receiver is identical to that used in the upper limb project except that four electrodes are placed around the sciatic nerve in the buttock rather than the two that were used for the median nerve in the upper limb project. The receiver is placed subcutaneously in the lower abdominal wall and the antenna is taped to the overlying skin. Only two electrodes are stimulated and the pair which produces the best response is selected. Electrode orientation is important and this is a compromise. The alternative would be to do the surgery with the patient awake which has obvious disadvantages.

In all patients, an interpretable signal was produced although the mental imaging, which was 90 percent correct in the upper limb, has been haphazard in the lower. No patient has reported that the stimulus or the mental image produced was uncomfortable, unpleasant, or confusing, however.

The auditory system uses the same external transducer unit, but the signal is fed to a hearing aid earpiece placed behind the ear without blocking the external auditory canal.

In that the end result of any sensory feedback is a subjective response, it is difficult to assay its effect in scientific terms.

A gait laboratory has been developed to analyze walking with and without the sensory feedback system. This provides computer-assisted analysis of force plate and segmental accelerometer data. This facet of the study has just started and at the moment, insufficient data analysis is available to be meaningful.

It is felt, however, that the subjective individual patient response will actually be more helpful in the long run. This is "quality of life" response and is voiced as statements like: "I can walk out in the driveway at night without worrying", "I feel better about going downstairs", "I can play basketball better with it turned on", "I can control the accelerator on my car far better".

Not all the subjects have found the system useful. Table I outlines the patients who have had the sensory feedback systems and their outcome. Most of those who have abandoned it, however, have had the auditory unit.

Conclusions

1. Sensory feedback systems in lower extremity amputees appear to have advantages. How much better the amputees are is still under investigation and whether the system is cost effective is still not determined.
2. The auditory system is somewhat confusing and cumbersome. It may end up being a good training apparatus but not appropriate for long term use.
3. The electronics package in the below knee segment of the prosthesis presents some problems related to the cosmetic cover which has to allow frequent access for adjustment and battery changes. An attempt is underway at present to replace the instrumented pylon with an instrumented ankle bolt.
4. Investigation is still needed to determine exactly what information is useful. Knee position, for instance, may be more useful information than the direction and magnitude of loading.

TABLE I

PATIENT	AGE	AMPUTATION	SIDE	DIAGNOSIS	SYSTEM	OUTCOME
D.B.	27	Hip Disart	Left	Osteogenic Sarcoma	Skin, then Auditory	Independent. Using prosthesis all day. Quit study because information not helpful enough. Decreased prosthesis wear and did not need for work as before.
J.B.	70	Above Knee	Left	Trauma	Auditory	Independent. Wears leg all day. Useful for walking without looking down.
R.C.	23	Hip Disart	Right	Osteogenic Sarcoma	Auditory	Chemotherapy and prosthesis discomfort prevents use of prosthesis more than 1-2 hours per day. Too soon to evaluate.
K.C.	23	Below Knee	Right	Trauma	Auditory	Quit study. Information not helpful. Device too much trouble.
M.D.	15	Hip Disart	Left	Osteogenic Sarcoma	Auditory	Quit study. Too many repairs. Useful for training but not helpful anymore. Wears leg all day.
B.D.	58	Below Knee	Left	Angiosarcoma	Auditory	Too soon to evaluate.
R.H.	58	Above Knee	Right	Liposarcoma	Auditory	Wore leg all day. Useful for walking without looking down, for increasing his confidence in walking, and lessening dependence on cane. Expired.
B.H.	26	Above Knee Knee Disart	Left Right	Trauma Trauma	Auditory	Wears leg all day. Too soon to evaluate.
J.L.	13	Hip Disart	Left	Osteogenic Sarcoma	Auditory	Independent. Wore leg during school one year, stopped wearing leg much for one year, and now is wearing leg during school. Device breaks down frequently but when working, it is useful for walking and playing sports, especially basketball because no need to look down.
S.O.	28	Above Knee	Right	Giant Cell Tumor	Auditory	Quit study because information not helpful, plus cosmesis of earpiece, cable, and prosthetic cover inadequate.
B.P.	18	Hip Disart	Right	Osteogenic Sarcoma	Auditory	Useful for walking without looking down but quit study because information not that helpful. Device required too frequent repairs, and it was too much trouble.
R.R.	29	Below Knee	Bil.	Trauma	Auditory Right BK	Quit study because information not helpful. (Identifies location of his leg by stump feeling and eye sight.) It was useful for walking without looking down, but not significant enough to keep device on prosthesis. Did not like cosmesis of earpiece, cable, and prosthesis cover and inconvenience of wiring under clothing.
J.W.	37	Hip Disart	Left	Malignant Fibrous Histocytoma	Auditory	Too soon to evaluate. Independent. Wears prosthesis 2 hours per day due to a fall and weakening due to chemotherapy treatments.
D.A.	12	Hip Disart	Right	Osteogenic Sarcoma	Implant	External Stimulator useful for lessening phantom limb pain postoperatively and one month before death. Useful for walking without looking down. Provided feeling that leg really was there. Independent and wore prosthesis all day until paralysis. Expired.
G.C.	34	Above Knee	Right	Trauma	Implant	First and second implant procedure failed. Third planned for 3-4-81. External stimulator useful for lessening phantom limb pain. Useful for walking without looking down. Not able to wear prosthesis because of continued stump pain and other physical problems. Only implant failure in series.
G.G.	16	Above Knee	Right	Osteogenic Sarcoma	Implant	External stimulator useful for lessening phantom limb pain. Quit study. Independent and wears leg all day. Useful for training but information not helpful anymore.