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PLASTIC SPIRAL RETENTION CLIP FOR FES ELECTRODES

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The principles of functional electrical stimulation (FES) are well established (*1, 2, 3*), and both skin-surface electrodes and implanted electrodes have been used in recent years. However, both of these systems have produced problems.

The implants require surgery and, occasionally, post-surgical complications such as infection and peripheral nerve damage have occurred.

Non-surgical transcutaneous stimulation through the use of skin electrodes is an effective and useful approach, but it has had a major drawback. The electrodes are held in position customarily by an elastic knee cuff which is pulled over the knee and adjusted by the patient after a period of instruction and trial. The problem here is related directly to the tendency for the cuff to slip repeatedly and, thus, displace the electrodes as the patient walks. Frequent adjustment is required throughout the day, and unless the electrodes are repositioned properly the apparatus will not provide the function intended.

The authors have developed a plastic spiral electrode retention clip which eliminates the problem of slippage. The spiral retention clip (Fig. 1) is flexible and can be positioned easily by the patient without assistance. The manner of fabrication permits the patient to spread open the spiral and snap it into place on the limb and the electrodes will stay over their designated contact points. The clip does not cause constriction or discomfort to the patient. Figure 2 shows the Liberson Brief Pulse Stimulator [3] (*3*) with the Spiral Retention Clip for FES electrodes in place on a patient.

The distinctive features of this clip are:

1. It is simple to apply and position.
2. It does not slip.

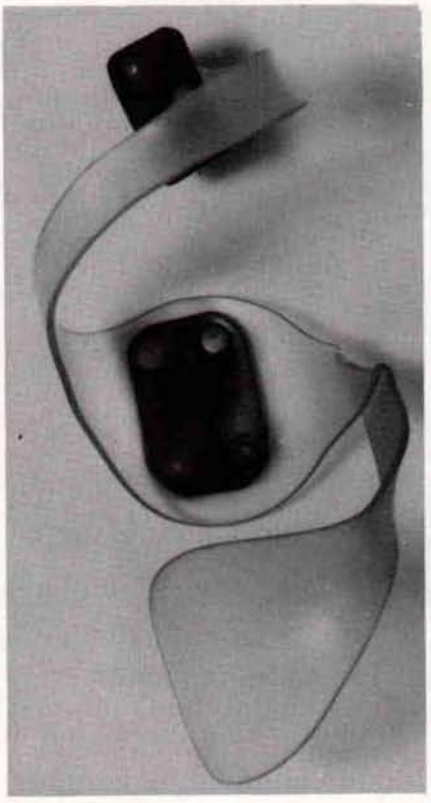

Fig. 1. The plastic spiral retention clip with electrodes in place.

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[3]The Liberson Brief Pulse Stimulator, referred to here, differs from other FES systems in that it employs simultaneous and balanced stimulation of both muscle (m. anterior tibialis) and nerve (n. superficial peroneal), to achieve optimum dorsiflexion and eversion of the foot during swing phase of walking.

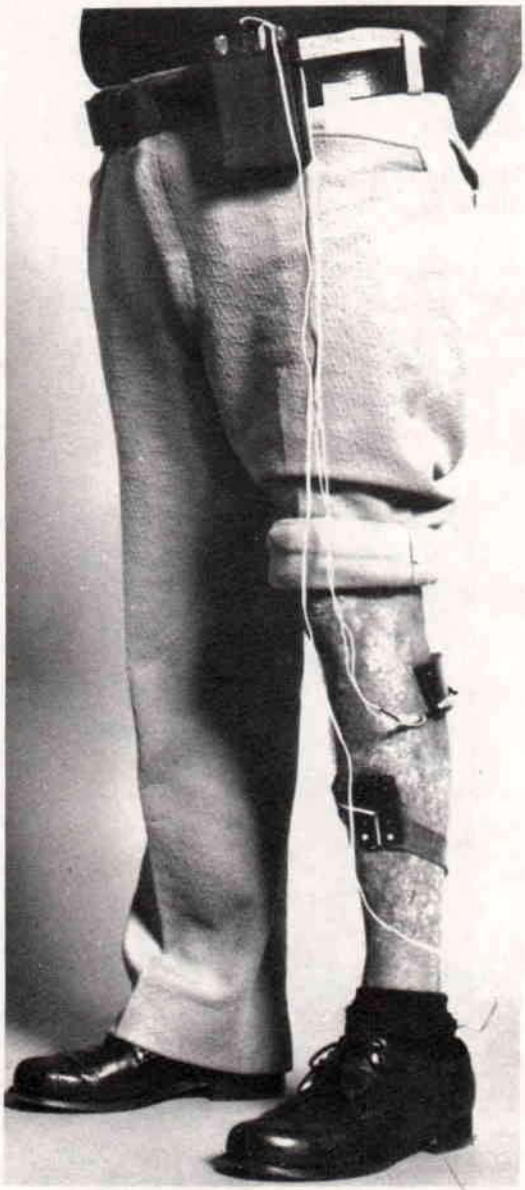

Fig. 2. The Liberson Brief Pulse Stimulator in use with the plastic retention clip.

CASTING

POSITIONING OF THE ELECTRODES

Position the smaller electrodes (overlying the superficial peroneal nerve) ½-in. distal and anterior to the head of the fibula and hold it in place with an elastic strap (Fig. 3). In the same manner secure the larger electrode (overlying the anterior tibialis muscle) ¾-in. lateral to the tibial crest at approximately the mid-shank level. The electrodes should be coated with conductive electrode gel.

Before connecting the electrode lead to the control module, set OUTPUT TIME to zero, and OUTPUT CONTROL to minimum. MODE SWTICH should be in center position. Connect electrode lead to OUTPUT-CHARGE plug. The system is then ready for checking.

The patient should be seated with the knee flexed to 90 degrees. Support the affected limb so that the foot is free to dorsiflex and plantarflex (Fig. 3). Set MODE SWITCH to TIMED position and OUTPUT TIME to approximately 3 seconds. Increase OUTPUT CONTROL gradually while observing the patient's reaction. The foot will begin to dorsiflex at ½ to ¾ of maximum output. If the foot is everting while dorsiflexing, shift the peroneal electrode slightly distal to the initial position. If sufficient dorsiflexion is not attained at maximum output setting, move the anterior tibialis electrode distally and laterally until optimum reaction is observed.

After the proper positions have been determined, trace the contours of the electrodes directly onto the patient's skin with an indelible marker (Fig. 4).

LOCATION OF THE DISTAL END OF THE SPIRAL

The most distal portion of the spiral should fall approximately 2 to 3 inches distal to the anterior tibialis electrode, and its anterior margin should fall just anterior to the medial midline of the shank. The clearance between the electrode and the distal end of the spiral should be as great as possible to facilitate donning the device, but at least 1 ½-in. superior to the medial malleolus. The distal end of the spiral should be between 1 ½ and 2-in. square. The positioning is marked as shown in Figures 3, 4, and 5.

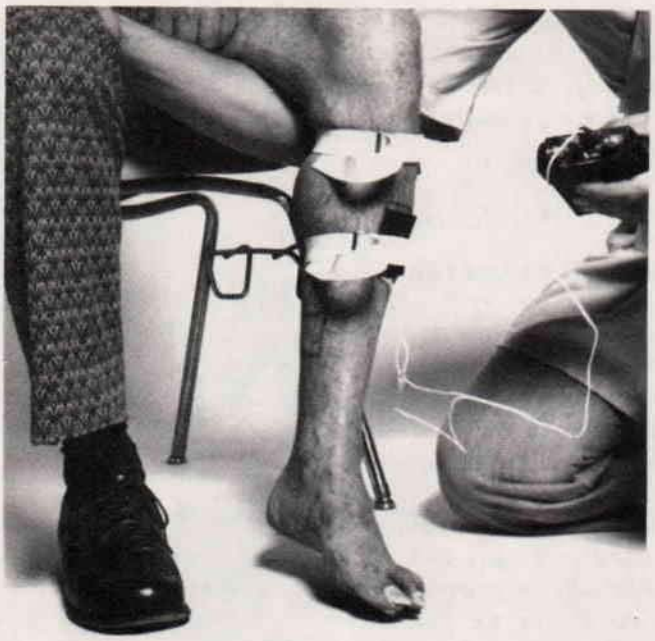

Fig. 3. Positioning the two electrodes on the surface of the leg.

Fig. 4. Outlining the positions of the electrodes.

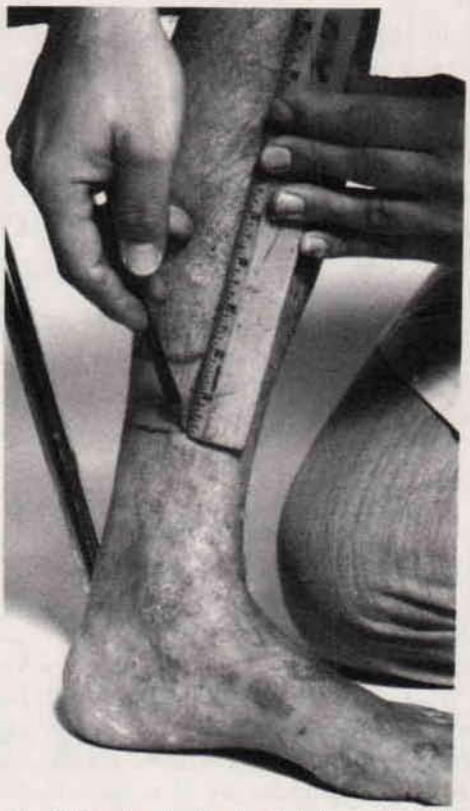

Fig. 5. Locating the distal end of the retention clip.

Mark the tibial crest and any other prominent areas, including any scar tissue or unusually pressure sensitive areas, so that contact of these areas with the clip can be avoided.

WRAPPING THE NEGATIVE MOLD

The patient is seated with the knee in 90 deg. of flexion.

A thin stockinet, i.e., elastic perlon tricot, tube gauze, or the equivalent, should be used as a separator, and should extend from a level just proximal to the patella to a level 1 or 2-in. inferior to the position marked for the distal end of the spiral.

Surgical tubing or Dacron tape inserted under the stockinet may be used to protect the patient while the cast is being cut for removal. Care must be taken in positioning the protective strip, so as not to obscure any of the indelible marks.

Four-inch wide elastic plaster bandage should be used for the initial wrap. It should be reinforced with a roll of four-inch wide ordinary plaster bandage before removal.

The wrap is begun distally and should continue proximally. The orthotist should mold an impression of the distal portion of the popliteal area posteriorly (Fig. 6).

Fig. 6. Making an impression of the shank to obtain a negative mold.

The negative mold is removed (Fig. 7), and after it has been determined that the indelible markings have been transferred, the mold is sealed and filled. A pipe should be inserted to facilitate cast modification and fabrication.

CAST MODIFICATION

The negative wrap is stripped, and the indelible markings on the positive mold are touched up (Fig. 8). Excess plaster in the area of the protective strip is removed. Care must be taken not to distort the contours of the cast during this procedure.

To prepare the electrode sites, retrace contours of the electrodes on the positive model, mark off a perimeter ¼-in. outside of the electrode marks, and remove approximately ⅛-in. of plaster from this area, following the parasagittal contours of the shank. If electrode marks have become obliterated, retrace contours.

Starting from the center of the posterior border of the peroneal electrode site, moving posteriorly and spiraling around the positive mold, draw a line connecting the centers of the two electrode sites. Continue the spiral postero-inferiorly from the posterior midpoint of the anterior tibialis electrode site to the distal end of the spiral already marked. Mark off a ¾-in. distance on each side and along the entire length of the connecting line (Fig. 9).

Remove ⅜ to ½-in. of plaster in the area delineated in the preceeding step (Fig. 10).

Fig. 7. Removal of the plaster wrap, or negative mold.

Retrace contours of the distal site.

Mark off a perimeter ¼-in. distance around distal end of spiral.

Remove plaster in this area to form a concavity with an apex ¼-in. deep.

Finish all modified areas with a fine sand screen.

Fig. 8. The indelible markings transferred from the stockinet need be touched up to ensure transfer to the positive model.

FABRICATION

PATTERN

Cut templates as shown in Figure 11 from cardboard.

Tape the cardboard templates for electrode sites in place on the positive model.

Tape the templates for the proximal spiral arm to the cast and to the electrode templates for the proximal spiral arm to the cast and to the electrode templates. Be certain that the templates are aligned intimately to the contours of the model (Fig. 12).

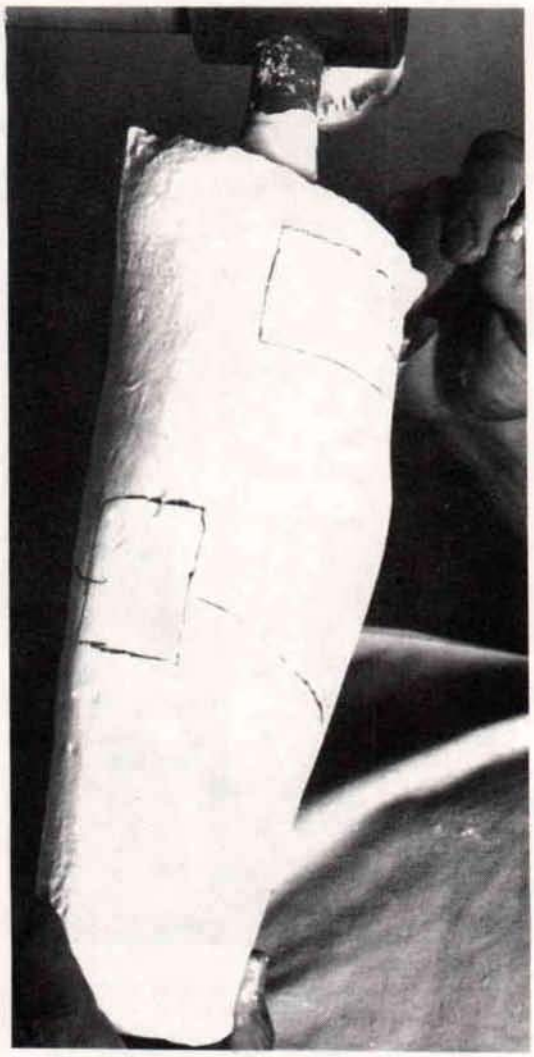

Fig. 9. Markings on the positive model to guide in the formation of the spiral retention clip.

Follow the same procedure for the distal spiral arm. The center of the distal end of the spiral should fall in the center of the concavity at the marked position at the distal end of the spiral.

Remove the pattern and transfer its outline onto cardboard. Round off the junctions between templates for electrodes and spiral arms to create a smooth flowing transition between all sections of the spiral, and cut out.

Use rubber cement to adhere the modified pattern to a piece of ⅛-in. thick Nyloplex, and cut along the edges. Smooth and polish all edges carefully.

MOLDING

Preheat the oven up to, but not exceeding, 215 deg. F. A heat gun may be used if no oven is available.

Place the Nyloplex in the oven for approximately 5 minutes, or heat until the entire piece is flexible.

When the plastic is ready for molding, lay the sheet on the model, being certain that the electrode pads correspond to electrode sites on the positive model.

Wrap an elastic bandage securely around the entire model, particularly over the channels for the spiral arms.

After the plastic cools remove the bandage.

Using a heat gun, spot heat and remold any area that is not intimate with the model. Particular attention should be given to transitional areas between the spiral arms and the electrode pads.

The orthosis is now ready for fitting.

FITTING

The design of the spiral clip is such that proper fit can be achieved in only one position on the limb.

After placing the cuff in position the skin should blanch uniformly under the entire length of the cuff except for the area over the tibial crest. Re-modify the positive model and spot heat the cuff to achieve intimate and uniform contact with the leg.

The electrodes may now be secured to the cuff using ⅜-in. non-metallic screws. Drill a ⅜-in. diameter hole in the center of both electrode sites to allow exit for the lead wires.

Connect electrode and foot switch leads to the control module. Place foot switch on inside heel pad of patient's shoe. Set MODE CONTROL to FOOT SWITCH and OUTPUT

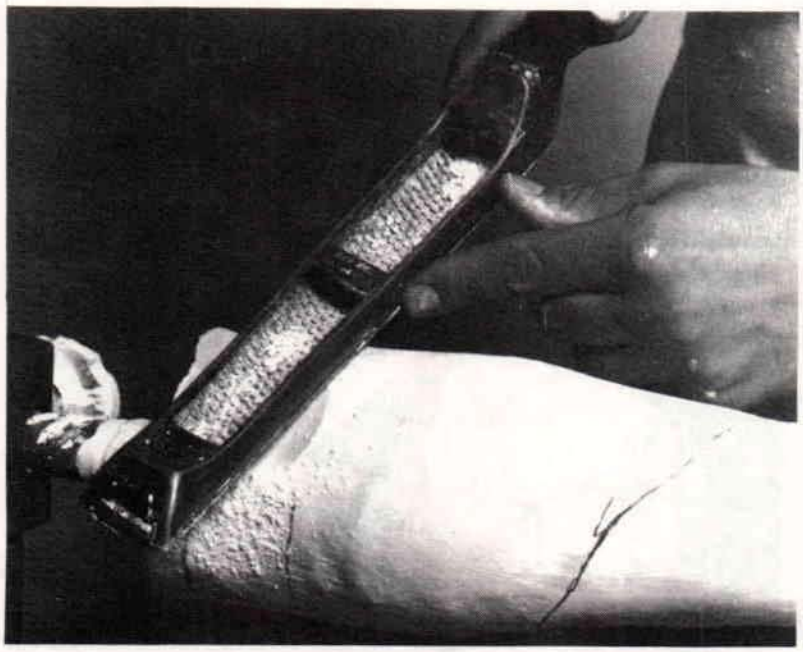

Fig. 10. Removal of plaster from the positive model.

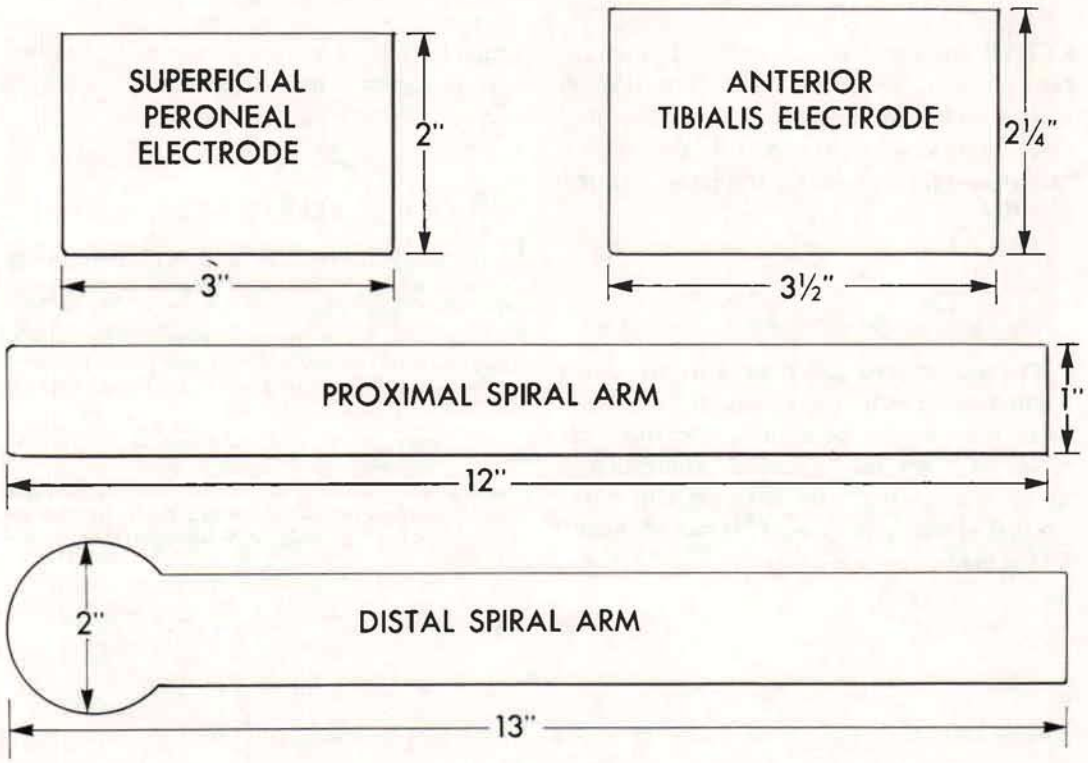

Fig. 11. Dimensions of templates for use in fabrication of the spiral retention clip.

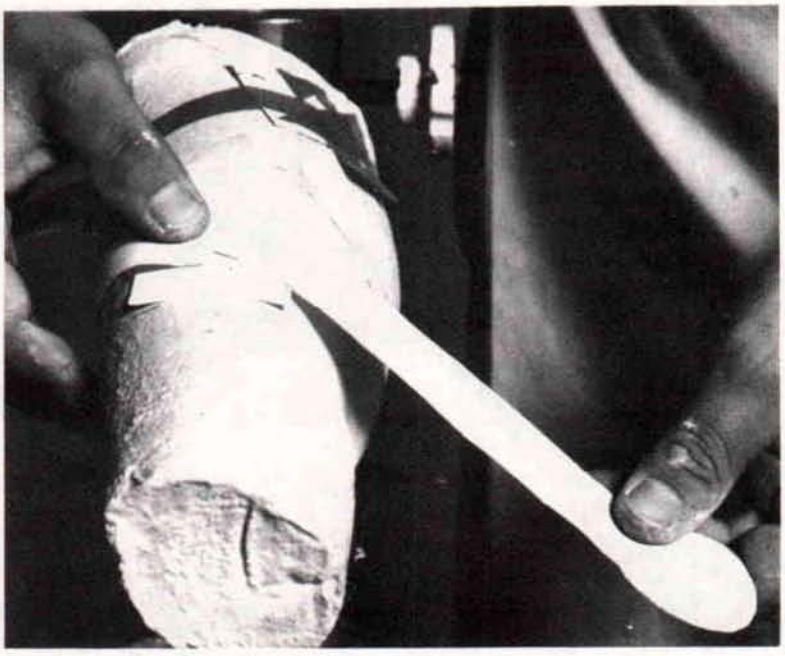

Fig. 12. Application of the templates to the positive model.

CONTROL to position determined during casting. Allow patient to ambulate. From heel-off to heel-strike the patient's foot will be in a dorsiflexed position. At heel-strike the circuit is broken and the foot is free to plantar flex into foot-flat.

SUMMARY

The authors have described a simple, easily applied device which will retain the electrodes in position on the lower-limb when the technique of functional electrical stimulation is used. The spiral plastic retention clip is not uncomfortable to the wearer. It can be donned by the patient without assistance; it is hygienic, requires little or no maintenance, is flexible, and in contrast to the previously employed elastic cuff method, does not slip.

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