

The Design and Testing of a Gradient Pressure Sock for Control of Edema

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INTRODUCTION

Since the fit of a prosthesis on a residual limb influences skin condition, gait, comfort, and even whether or not the prosthesis will be worn, the stability of the limb size is critical. Even in a whole leg, prolonged standing without the 'pumping' action of the leg muscles leaves a poorly supported column of blood within the veins. "The amputated limb has virtually no muscle contraction to aid venous return."²¹ External pressure, when well applied, does facilitate venous return, reduces hemostasis, and provides comfort. Pressure must be sufficient to offset the increased hydrostatic pressure of trauma, standing, or straining and yet not interfere with arterial flow.² Poorly applied pressure may be injurious. Various investigators have charted the wide range of pressures obtained by elastic wrap and have cautioned against the harmful effects that could result from this edema control method.^{13,21} Isherwood states that "elastic wrap bandaging is unreliable and dangerous in terms of pressure and pressure distribution,"¹⁰ because pressure can become so great from too tight a wrap that a tourniquet effect results.

The use of tubular elastic bandaging results in more predictable and less pressure fluctuation, and requires considerably less skill in application. Especially for below-knee edema problems, Compressogrip[†] and similar products, including the Puddifoot method,¹⁵ have proven to be effective, inexpensive, easy to apply, and well liked.

However, as early as 1961, Beninson recognized that, "Pressure gradient dressings can, in

some instances, be used following surgery to hasten healing prior to application of the supports."¹ In 1971, Mooney, et al., stated that their study revealed postoperative residual limb care using plaster shell or plaster with pylon resulted in more successful prosthetic fittings than those using soft dressings.¹⁴ In 1975, Isherwood defined the requirements of a good dressing by stating that "as intracapillary pressure varies with dependency, the ideal bandage should provide a graded pressure which is maximum at the most dependent distal point, decreasing proximally."¹⁵

Shaping the residual limb is also recognized as a function of a shrinker sock. Available shrinker socks generally lack the shaping capacity, particularly at the distal end. Our objective, therefore, was to make a shrinker sock which would shape the distal end, have gradient pressure, and be accepted by wearers. This sock would not only accomplish the task of reducing post-amputation edema, but would also control fluids which might recur as the result of illness, injury, or any number of conditions. When any edema is uncontrolled, the tendency is not to wear the prosthesis.

In defining the size and shape of the residual limb, two studies were helpful. In the July, 1983 *Journal of the American Geriatrics Society*, Dr. Clark, et al., described ideal limb characteristics including length below knee (6-8 inches) and above knee (8-10 inches) and shape (cylindrical).⁴ A Swedish study actually measured 58 below-knee amputations. They found that 66 percent of the residual limbs were conical, 28 percent cylindrical, one percent bulbous, and five percent were other. The length in the supine position from the knee joint, i.e. the anterior rim of the medial condyle

[†] Available from Knit-Rite, Inc.

to the most distal part of the soft tissues at the end of the residual limb, was six inches (8 to 20 cm.).¹⁶ No average measurement has been found in the literature for above-knee residual limbs. This lack of information about residual limb measurements may result from the fact that, in spite of what researchers have said, wrapping has been the most universal method of residual limb reduction. It may be that prosthetists feel no two limbs are identical and each needs to be treated individually. Nevertheless, with cooperation and knowledge, general parameters can be established for socks which will exert the desired graded pressure over a limited measurement range so that standard sizes of socks can be readily available.

Although the benefits of using pressure as a prophylactic aid to reduce edema after amputation, or whenever edema develops in a mature stump, have been recognized for centuries, no precise definition of the amount of pressure to be used has been created. Part of the reason is that each researcher has used a different instrument for measurement, and although each instrument can be calibrated to a manometer, certain features of each instrument result in incomparable readings.^{3,7,8,11,12,17-21} Much of the research on using pressure to alleviate pain and ulcers in cases of deep venous insufficiency supports much higher mmHg readings than those indicated by the fairly limited research on wrapping and tubular elastic bandaging pressures.

Our request for information on instruments being used to obtain the pressures printed on packaging of various companies making pressure garments only revealed the use of the Kompritest II (Figure 1). We secured that instrument and found it gave readings 15-20 mmHg higher than the CTC 250 we had been using (Figure 2). We pursued this with Midwest Research Institute[‡] and received the following explanation:

Both devices accurately measure pressure imposed upon their respecting sensing elements.

[‡] Midwest Research Institute is a professional not-for-profit corporation doing contract research for business, industry, government, individuals and groups.

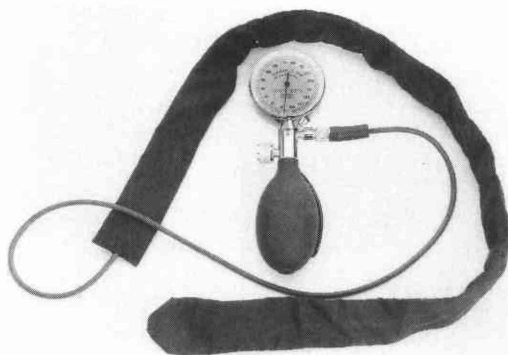


Figure 1. Kompritest II for measurement of pressure values of elastic stockings.

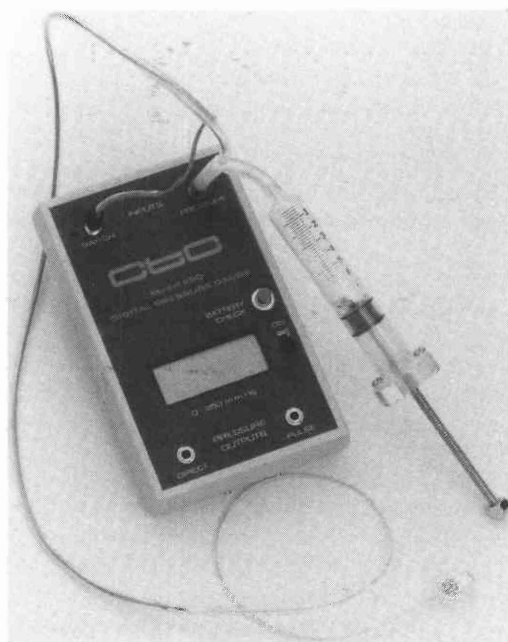


Figure 2. CTC 250 Digital Pressure Gauge.

When placed under an elastic fabric, the devices produce different readings because the Kompritest II (K-II) device distends the elastic fibers surrounding the bulge of its inflated bladder and thus produces a local increase in pressure over the measurement site. This local pressure increase observed using the K-II accounts for the difference between values produced by the two devices, and suggests that the CTC device is the more accurate of the two for measuring the pressures exerted by elastic fabric.⁵

Although some instruments have misrepresented pressures on the high side and some researchers have advocated unusually low pressures,⁹ a 1985 study by Hendricks and Swallow used stockings "designed to exert graded compression from 24 mmHg pressure at the ankle to 16 mmHg pressure at the calf." They admit that "the optimal amount of compression at the ankle and calf necessary to heal and prevent stasis leg ulcers is not known at this time." Their explanation of the value of external compression therapy is that "it compresses the superficial veins and prevents extravasation of fluid into the subcutaneous tissues . . .," thus reducing "swelling of the leg as measured by total leg volume and by lower extremity circumference measurements."⁶ The study by Varghese, et al., obtained similar results with similar pressure readings using the CTC instrument. To date, capillary and arteriolar blood pressure have not been related for the purpose of establishing pressure values that would reduce edema; nor has the difference between

new or mature residual limbs been studied. Different pressure readings have been observed over bony areas versus fleshy areas.²²

PROCEDURES

Since our aim was to develop a sock which would be fashioned to give greater pressure distally, less pressure proximally, and have a rounded toe to shape the distal end, the flat, V-bed type machine was employed. Figure 3 is a close up of the carriage and the needle bed where needles are picked up or dropped according to machine programming so that widenings or narrowings (fashionings) can be made. All standard prosthetic socks are full-fashion knit in this way, with gradual widenings up both sides of the sock. To give even greater rounding, a new widening for the toe was programmed. On circular machines, as used for most currently available shrinkers, widening can only be achieved by loosening

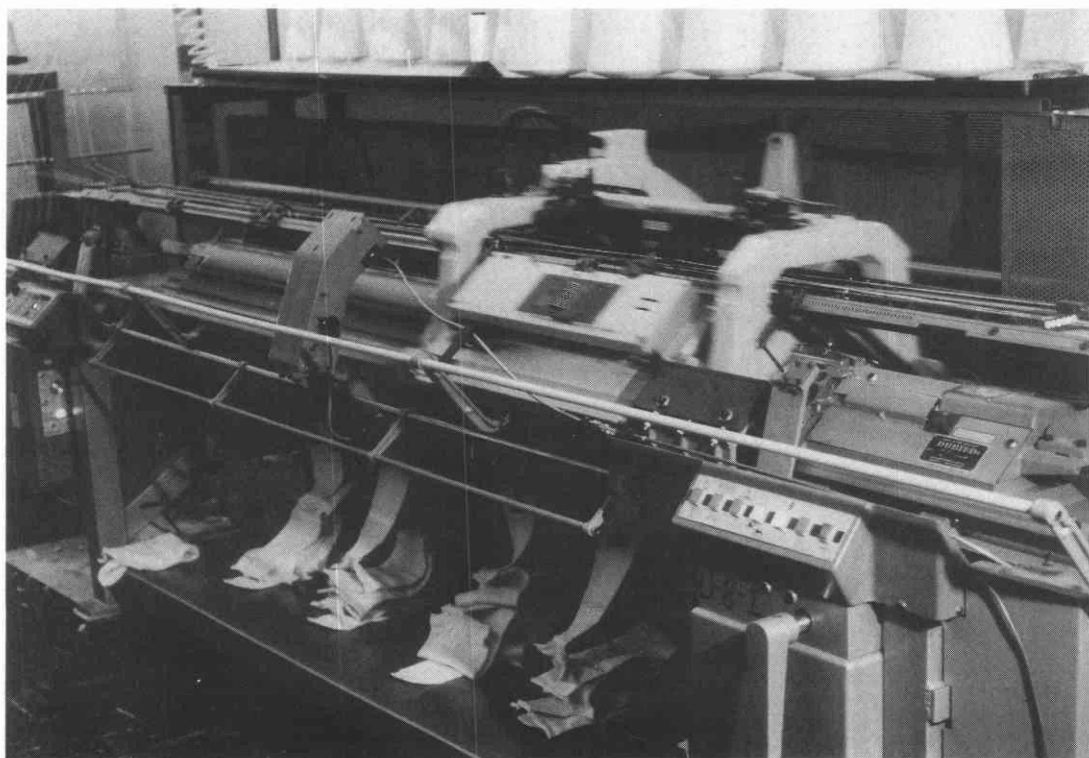


Figure 3. Needle bed of knitting machine where widenings and narrowings can be made.

EXPERIMENTAL SIZE RANGE Regular Taper Shrinker					
Size	Length (inches)	Flat Width		Fits Circumferences	
		Top (inches)	Toe (inches)	Top (inches)	Toe (inches)
Narrow	10" 12" 14"	5"	3"	13"-14"	9"-11"
Medium	10" 12" 14"	6"	4"	15"-17"	12"-14"
Wide	10" 12" 14"	7"	5"	18"-20"	15"-17"

Table 1.

the knitting tension. Knitting a rounded toe on a circular machine is not possible.

The yarn to be used for this sock needed firmness in its stretch so that the desired pressures could be obtained. Softness, strength, and washability were also considered important. A corespun yarn was selected, with Lycra spandex being the core and Avril rayon being the covering.

Attempts were made to obtain postoperative edemic residual limb measurements from various facilities. Not enough measurements were obtained to make any generalizations. Therefore, our knowledge was combined with that of the Knit-Rite production manager to formulate an experimental size range (Table 1).

Specifications were made for the knitting machines so that the desired pressures would be obtained when tested over a steel cylinder (Figure 4) at the Fits Circumference measurements. Heavy pressure was defined at the top of the effective range, i.e. 25-30 mmHg for the distal pressure and 15-20 mmHg for the proximal pressure. The recognition that some patients could not tolerate heavy pressure, and that some researchers suggested less pressure for nighttime wear, led to the development of a sock having distal pressure in the 15-20 mmHg range and proximal pressure in the 10-15 mmHg range. Socks were identified with color stitching at the top: green for heavy

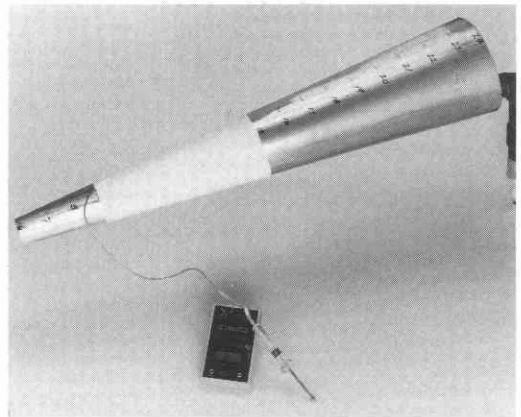


Figure 4. Testing cylinder with pressure sensing device in position.

pressure and gray for medium pressure. The increase in pressure caused by the increased stretch over the range was measured to be no greater than the allowed variance. Shrinker socks were sent to many prosthetists who indicated that they would use them and return evaluation forms.

RESULTS

Forty-five evaluations were returned representing 43 patients. All but three of these evaluations were for below-knee amputees (Table 2). Of the 42 below-knee evaluations, 17 had

**ACTUAL BK
CIRCUMFERENCE
MEASUREMENTS**
Measurements from distal end

1"	3-4"	6-8"	Top
8		11	13 $\frac{1}{8}$
8 $\frac{1}{4}$	7	9 $\frac{5}{8}$	12
8 $\frac{1}{2}$	11 $\frac{3}{8}$		14 $\frac{1}{2}$
8 $\frac{1}{2}$	12 $\frac{1}{2}$	15 $\frac{1}{2}$	14 $\frac{1}{2}$
8 $\frac{3}{4}$	10 $\frac{1}{2}$		
9	7 $\frac{1}{2}$	9 $\frac{1}{2}$	10
9 $\frac{1}{4}$	10	10 $\frac{3}{4}$	
9 $\frac{1}{2}$	10	12	
9 $\frac{1}{2}$	11 $\frac{3}{4}$		14 $\frac{1}{2}$
9 $\frac{3}{4}$	12	12	
9 $\frac{7}{8}$	12 $\frac{1}{2}$		15
10 $\frac{3}{8}$	12 $\frac{1}{2}$	13 KC	
10 $\frac{1}{2}$	11 $\frac{3}{8}$	14	14 $\frac{1}{2}$
10 $\frac{1}{2}$	10 $\frac{1}{4}$	12 $\frac{1}{4}$	13
10 $\frac{7}{8}$	11 $\frac{1}{4}$		
10 $\frac{7}{8}$	11		
11	12 $\frac{1}{4}$	14 $\frac{1}{4}$	13 $\frac{3}{4}$
11 $\frac{1}{8}$	11 $\frac{3}{4}$	14 $\frac{5}{8}$	14 $\frac{1}{2}$
11 $\frac{1}{2}$	13	14 $\frac{1}{4}$	16 $\frac{1}{2}$
11 $\frac{1}{2}$	13	14 $\frac{1}{4}$	16 $\frac{1}{2}$
11 $\frac{1}{2}$	12	13 $\frac{3}{4}$	12 $\frac{1}{2}$
11 $\frac{1}{2}$	13	14 $\frac{1}{4}$	14 $\frac{1}{2}$
12	14	15 $\frac{1}{2}$	15 $\frac{1}{2}$
12 $\frac{1}{8}$	13 $\frac{1}{4}$	15	15 $\frac{3}{4}$
12 $\frac{1}{4}$	13 $\frac{3}{4}$	16	17
12 $\frac{1}{2}$	15 $\frac{1}{2}$	17 $\frac{1}{2}$	15
12 $\frac{1}{2}$	13 $\frac{1}{2}$	15	17 $\frac{1}{2}$
12 $\frac{1}{2}$	12 $\frac{7}{8}$	14 $\frac{1}{2}$	14 $\frac{3}{4}$
12 $\frac{1}{2}$	12 $\frac{3}{4}$	14 $\frac{1}{4}$	
12 $\frac{3}{4}$	13	15	
13	13 $\frac{3}{8}$	16 $\frac{1}{2}$	16 $\frac{1}{4}$
13	15	16 $\frac{1}{4}$	15 $\frac{1}{2}$
13 $\frac{1}{2}$	13 $\frac{3}{4}$	15 $\frac{3}{4}$	16 $\frac{1}{2}$
13 $\frac{1}{2}$	13 $\frac{1}{2}$	15 $\frac{1}{2}$	17 $\frac{1}{2}$
13 $\frac{3}{8}$	13 $\frac{3}{4}$	13 $\frac{1}{4}$	13 $\frac{3}{4}$
14 $\frac{1}{2}$	16 $\frac{7}{8}$	18 $\frac{1}{2}$	20 $\frac{1}{4}$
14 $\frac{3}{4}$	16 $\frac{3}{4}$	17	17 $\frac{1}{4}$
15 $\frac{7}{8}$	16 $\frac{1}{2}$	18 $\frac{3}{8}$	19 $\frac{3}{4}$
16	15		16

Table 2.

toe measurements ranging in circumference from eight inches to 11 inches; 18 had toe measurements ranging from 11 $\frac{1}{8}$ inches to 13 $\frac{5}{8}$ inches; four had toe measurements ranging from 14 $\frac{1}{2}$ inches to 16 inches; and three did not give measurements (Table 3).

The significance of grouping the measurements in this way was so they would correspond with the size range we had developed for testing purposes. A smaller toe circumference measurement was encountered than had been anticipated, but the actual toe sizing ranges could be compared with the experimental toe sizing ranges in the narrow, medium, and wide. Top measurements were ranged as they corresponded with toe measurements in each size (Table 3). Note, the actual tester range of top circumference measurements was both larger and smaller than the experimental sizing range for the narrow and the regular, but was only smaller for the wide (Tables 1 and 3).

Pressure measurements were again taken which defined ranges of each size as reported for the wearers. Figure 5 shows pressure measurements of heavy shrinker socks at circumferences one inch from the distal end. These pressures should relate to pressures exerted on those fitted with the narrow, the medium, and the wide as indicated by the rectangles. Our KU study indicated laboratory pressure measurements over steel cylinders are approximately ten percent higher than pressure measured on patients, or control volunteers making these pressures in agreement with our criteria, if the larger circumference in each specified Fits Circumference range is the cut off point; therefore, if 11 inches is the larger suggested circumference, 11 $\frac{1}{8}$ circumference inches would be fit with the next size unless greater pressure is desired.

Figure 6 shows pressure measurements of heavy shrinker socks at circumferences six to eight inches from the distal end. These pressures should relate to pressures exerted on those fitted with the narrow, the medium, and the wide as defined by the rectangles. These pressures are less than the distal end pressures. However, particularly in the narrow size, some readings were at the 20 to 25 mmHg level. Since some wearers' residual limbs were exceeding the suggested range in top circumference measurement and were obtaining greater proximal pressure than might be desired, patterns were made using the measurements given for each limb. These were grouped by shape. As a result of comparing these shapes and listening to comments from several facilities, a double tapered shrinker was developed. Comparison to the regular taper is shown in Figure 7

RANGED BELOW-KNEE CIRCUMFERENCE MEASUREMENTS (inches)		
Toe 1" from Distal End (as close as possible)	3-4" from Distal End	Top 8" from Distal End
8 - 11 11 $\frac{1}{8}$ - 13 $\frac{3}{8}$ 14 $\frac{1}{2}$ - 16	7 - 12 $\frac{1}{2}$ 12 $\frac{3}{4}$ - 15 15 - 16 $\frac{7}{8}$	9 $\frac{5}{8}$ - 14 $\frac{5}{8}$ 11 $\frac{3}{4}$ - 17 $\frac{1}{2}$ 17 - 18 $\frac{5}{8}$

Table 3.

where the dotted lines represent the regular tapered sock and the three toe lengths represent the 10, 12, and 14 inch sock lengths.

When knitted, the regular taper and double taper can be compared as in Figure 8. The toe is the first consideration for fit using the Fits Circumference range as the guide. Then, if the top circumference exceeds the recommended limit of the regular range, a double taper should be ordered or at least considered.

Figure 9 shows pressure measurements of medium pressure shrinker socks at circumferences one inch from the distal end. These pressures should relate to pressures exerted on those fitted with the narrow, the medium, and the wide as indicated by the rectangles. These pressures met our criteria for a sock with medium pressure of 15 to 20 mmHg. Figure 10 shows pressure measurements of medium pressure shrinker socks at circumferences six inches to eight inches from the distal end. These pressures should relate to pressures exerted on those fitted with the narrow, the medium, and the wide as defined by the rectangles. These pressures were lower than our criteria when circumferences were less than our sizing guide. This was not considered to be a problem unless a lack of pressure caused slippage. Where circumferences were more than our sizing guide, the pressures of the narrow exceeded our criteria as did those of the heavy shrinker sock. As for the heavy shrinker sock, when the top circumference exceeds the Fits Circumference recommendation, the double taper is recommended to get the advantages of gradient pressure.

Evaluation forms revealed that both green top, heavy compression socks, and gray top, medium compression socks, were used for day and night wear. Four testers used two socks: heavy compression for daytime wear and me-

dium compression for nighttime wear. Seventy percent of the testers wearing the heavy compression felt the tops stayed up adequately; 65 percent of the testers wearing the medium compression socks felt the tops stayed up adequately. Night-time was the most difficult time. To one tester who complained in detail about the roll down, we sent him a shrinker with a turned down zigzagged stitched top. He liked this top, but it was not pursued for fear the doubled top would cause greater pressure proximally. Some trials indicated the shrinker should come up proximally past the patella and that if it comes a little higher, it is less likely to roll.

All but one of the testers using the heavy compression felt that the shrinker was improving the shape, decreasing the edema, and/or maintaining the limb. One tester, who felt the heavy pressure was not adequate, used both heavy and medium socks at the same time and still felt the need for greater pressure. The prosthetist noted this was a young man with a high pain level and a drive to get back on his legs. Sixty-four percent of the testers using the medium compression felt the shrinker was maintaining the limb's size and shape. Thirty-five percent of the respondents felt the pressure of the medium compression sock was not sufficient. Most of the amputees using the experimental shrinker socks were new patients who lost a leg because of vascular disease, usually diabetes. Any undue pressure over the residual limb serves as an excuse to take the shrinker off; therefore, medium pressure may help to start the process of controlling edema so that heavy pressure will eventually be tolerated as needed. Some of the shrinkers were worn over Ace® bandaging and some comments were made about using Ace® bandaging some of the time.

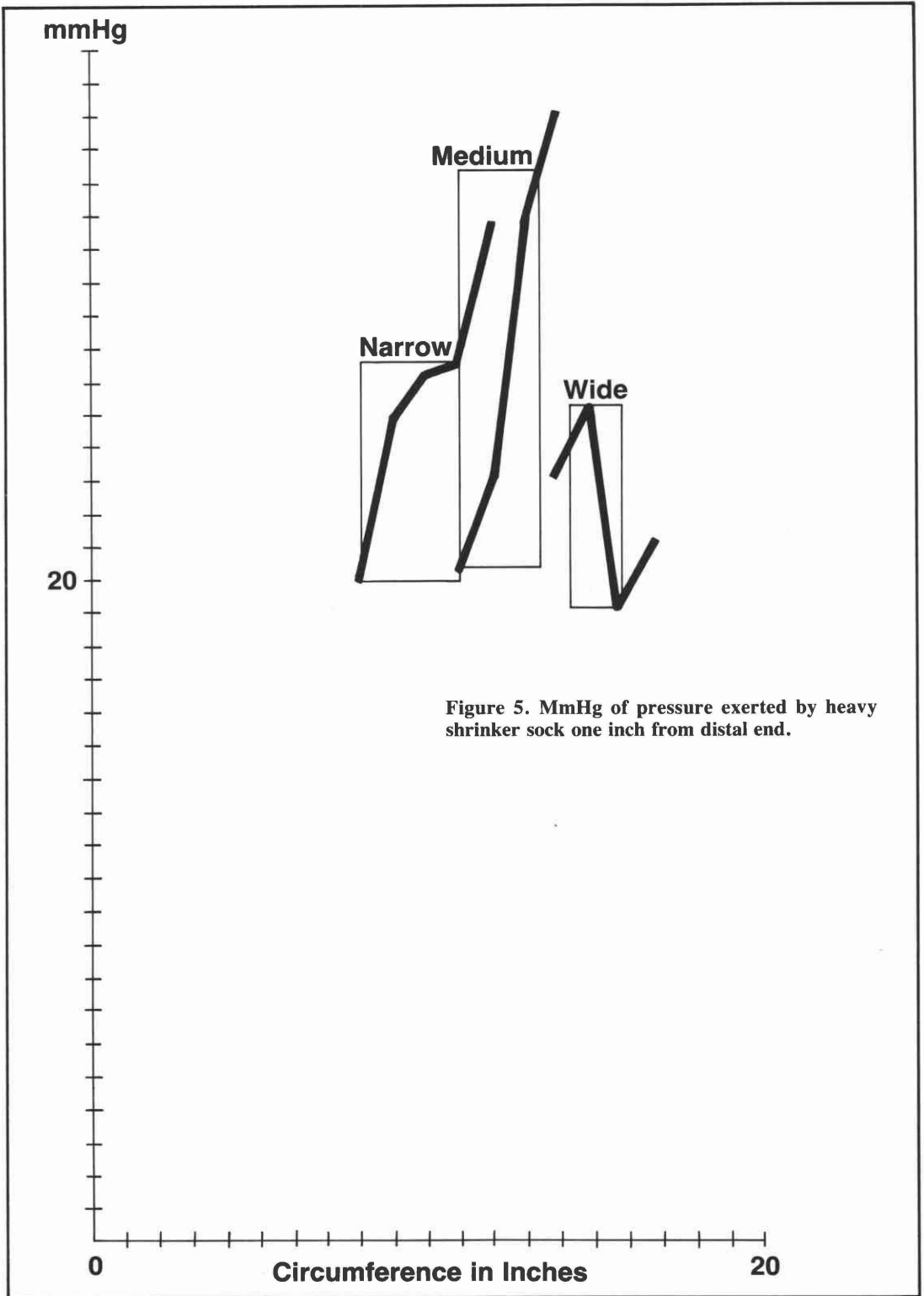
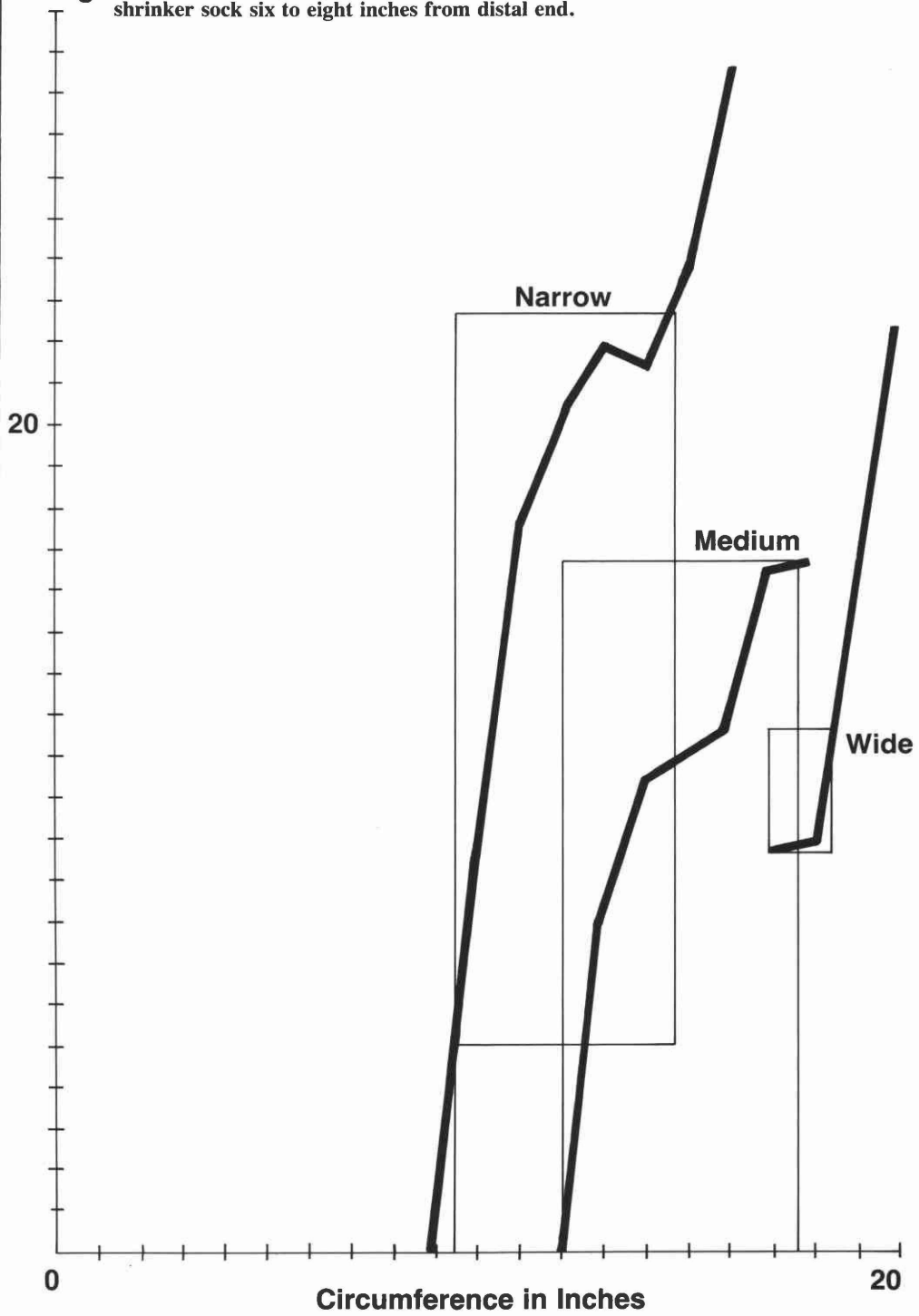


Figure 5. MmHg of pressure exerted by heavy shrinker sock one inch from distal end.

mmHg Figure 6. MmHg of pressure exerted by heavy shrinker sock six to eight inches from distal end.



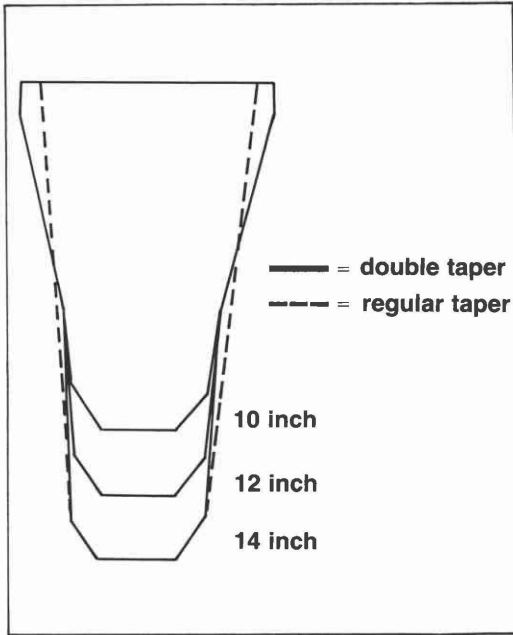


Figure 7 (left). Scale of regular and double taper.

Prosthetists' comments revealed that the experimental shrinkers were effective in shaping the distal end, hugging the anatomy, and giving good overall suspension. The distal end support was positive as long as the patients applied the shrinker firmly. Some residual limbs are very bulbous initially following surgery. This depends on the patient's physique, the surgical technique use, and the amount of edema. Previous experience indicates a bulbous residual limb will, in time (six to 12 weeks post-surgery), become slowly cylindrical, and a cylindrical amputation will become cone-shaped.

Thirty percent of the wearers said they had not washed their shrinker sock which may have meant that they were wearing it continuously. Five percent did not answer the question. Of the 65 percent who did wash their shrinker, none mentioned any washing problems.

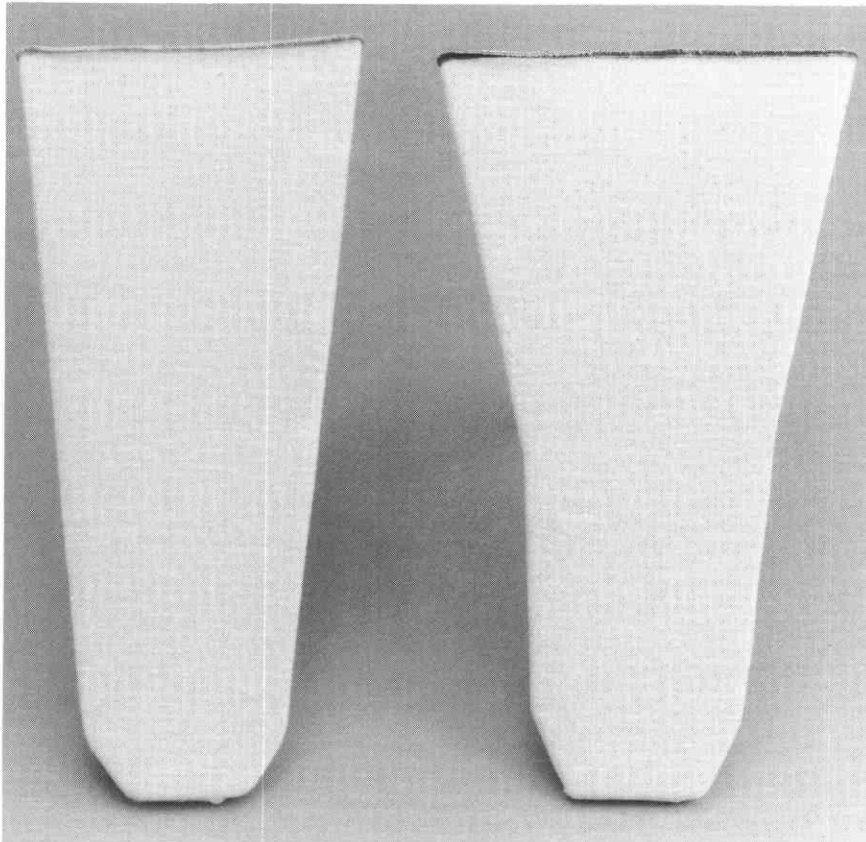
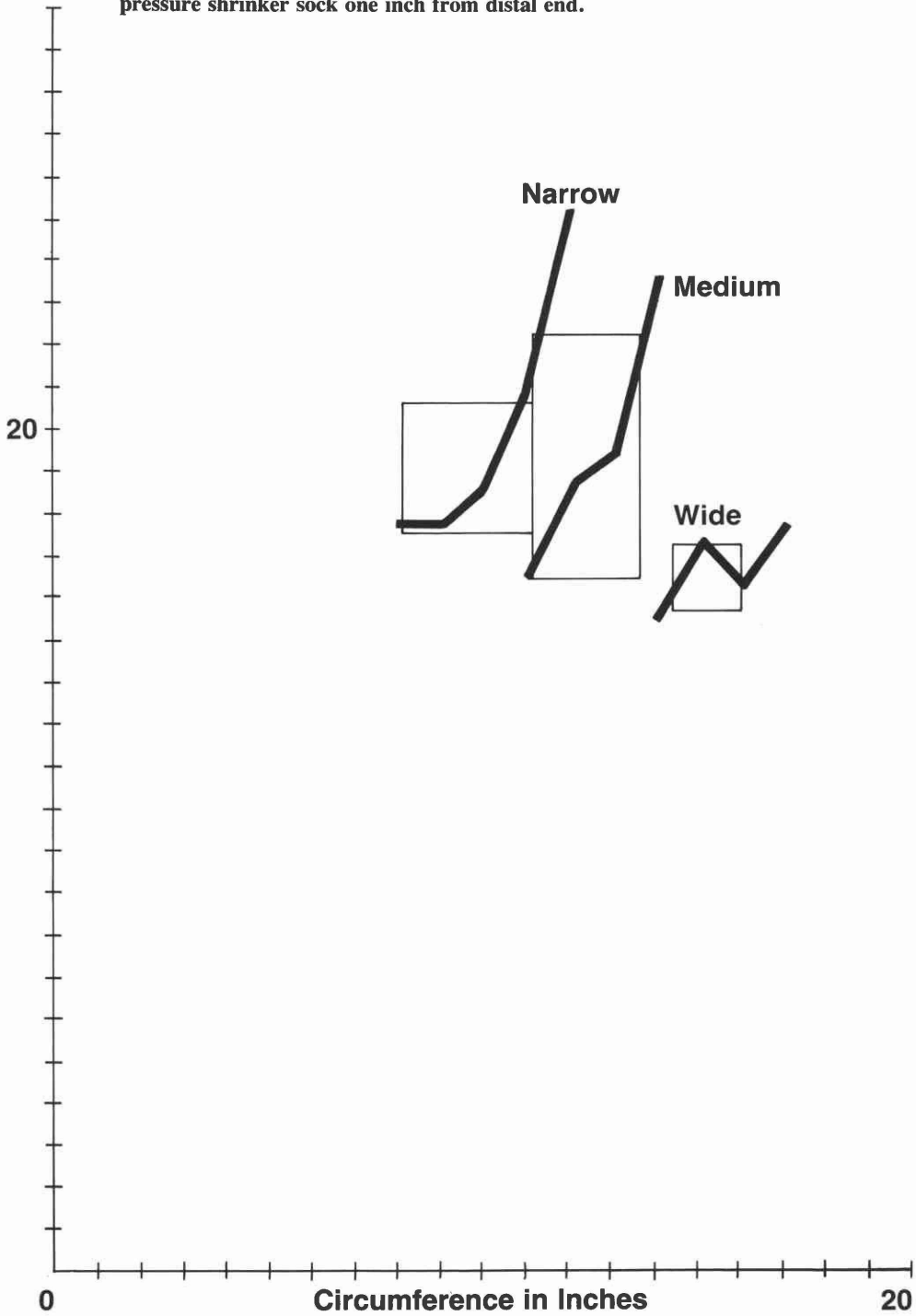


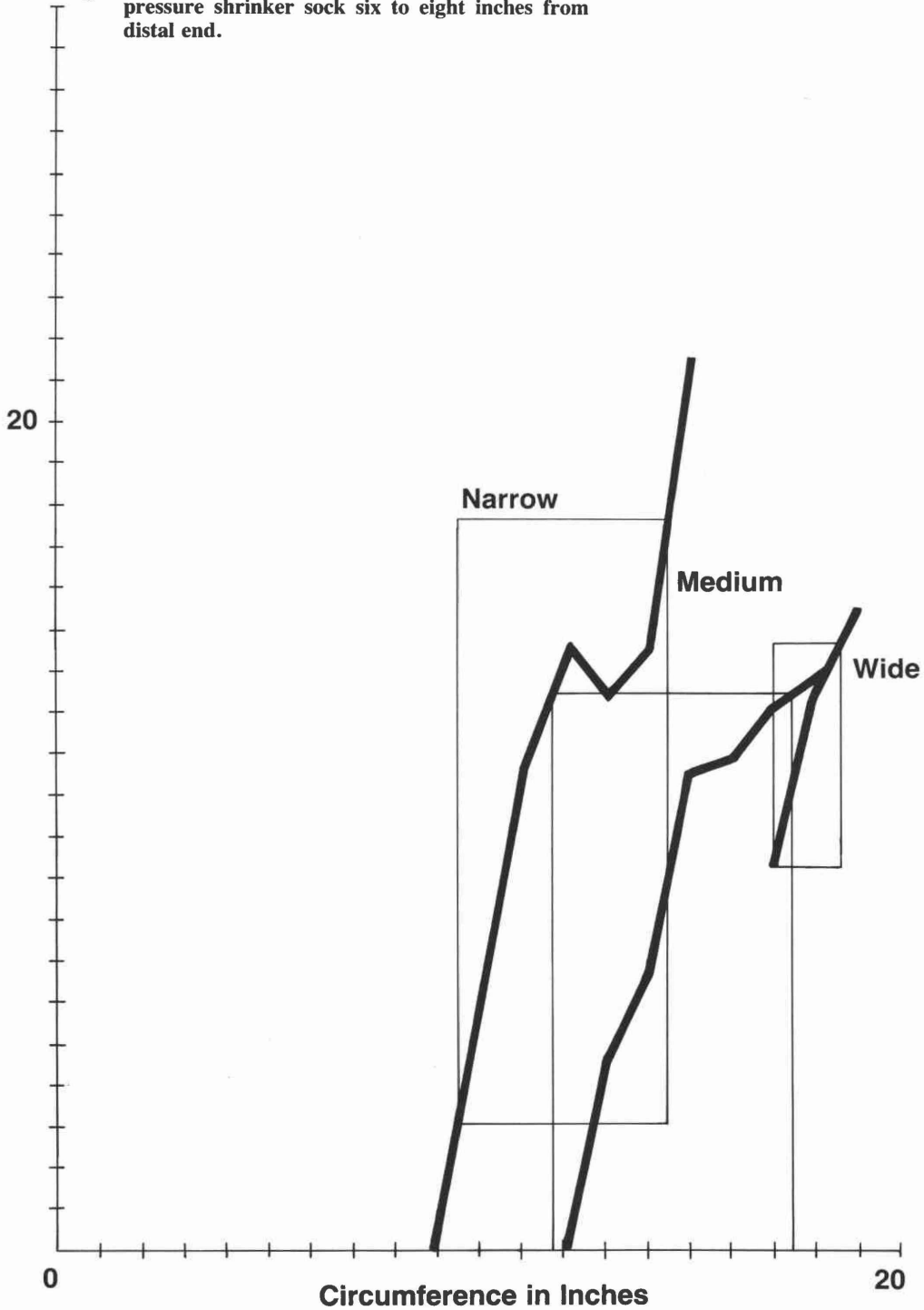
Figure 8. Comparison of regular and double taper shrinker sock (14 inch length).

mmHg Figure 9. MmHg of pressure exerted by medium pressure shrinker sock one inch from distal end.



mmHg

Figure 10. MmHg of pressure exerted by medium pressure shrinker sock six to eight inches from distal end.



In answer to the question, "Is the sock easy to apply", 100 percent of the testers said, "Yes." One said, "Very." In answer to the question, "Is the sock comfortable?", all but one tester replied positively. This one tester was having some orientation problems. Other comments were "Feels good," "Feels great, except at first when a little tender."

CONCLUSIONS

Evaluation forms for a new below-knee shrinker sock revealed it was comfortable, easy to put on, stayed up on most but not all wearers, gave desired shrinking and shaping in the heavy compression, and some shaping and residual limb maintenance for 65 percent of the medium compression wearers. When pressure was greater and the sock was fitted longer, proximally past the patella, roll down was less of a concern. Analysis of residual limb measurements and pressure measurements determined that both the heavy and the medium compression shrinker socks did exert greater pressure distally than proximally, and that wider circumferences than those recommended at six or more inches from the distal end could be accommodated by the double tapered sock.

This study did not offer the opportunity to study above-knee shrinkers, but they are being custom made in order to gain knowledge of fit and support. The same fabric used in the below-knee shrinkers can be cut and sewn to make above-knee socks. To meet the needs of shrinking stumps, below-knee shrinkers can be altered with a sewing machine stitch if the sock is not to be used for walking. If the sock is to be used for weight bearing, it can be returned to be altered with a flat seam according to specified markings, or a smaller size can be fitted.

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