

The TIRR Polypropylene Orthoses^{1 2}

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Until very recently, the development of new types of lower-limb orthoses which meet the specific needs of individual patients has been largely ignored, owing, partially, to the lack of understanding of the bio-mechanical principles involved in ambulation. As a result only about four basic types of conventional braces were used for a wide variety and degree of diagnostic conditions. In many cases more control than was needed was applied, resulting in atrophy of normal, or near normal, muscles when they were not permitted to be active.

In 1968 a research and development project, under partial sponsorship of the Social and Rehabilitation Service, was initiated in the Depart-

ment of Orthotics at the Texas Institute for Rehabilitation and Research (2) to create new design concepts and develop devices for the lower limbs that would meet more accurately the needs of individual patients with drop-foot conditions, mediolateral instability, and dorsi- and plantarflexion impairments. It was intended that the new devices would, in addition, be less noticeable and lighter in weight than the rather cumbersome conventional orthoses. Initially, effort was concentrated on patients with impairments below the knee. A group of five patients was selected: a hemiplegic with flaccidity; a hemiparetic with spasticity and sensory loss; a unilateral lower-limb paralytic (post-poliomyelitis) with muscular atrophy; a bilateral lower-limb paralytic with muscular disease (muscular dystrophy); and a paraplegic with spasticity secondary to spinal cord malformation (spina bifida). Special forms for recording data were developed for evaluation of the effectiveness of the new devices as they were conceived. A videotape recording system was used to provide an opportunity to compare the

¹Grant Number 23-P-55233/6-02, SRS, DHEW; R & T Center Number (Grant Number 16-P-56813/6-09) SRS, DHEW

²This paper is based on a presentation made at the Fourth Symposium on External Control of Human Extremities, Dubrovnik, Yugoslavia, 1972.

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ambulation patterns of these patients with their conventional orthosis, without any orthotic equipment, and with each new device as it was developed (3).

EVOLUTION OF THE DESIGN

The design developed early in the project involved a posterior spring. In this early design, a precision fitted arch support of stainless steel was attached to a posterior heel spring that followed closely the contour of the bulge of the gastrocnemius muscle. It terminated proximally with a small band below the knee

This device was applied to sixteen patients with diagnoses including post-poliomyelitis, Guillain-Barre syndrome, and hemiplegia. In all cases, the orthosis gave the patient the needed stability and dorsiflexion assistance. Comparison of videotaped recordings of their ambulation without assistance, in their previously used conventional orthoses, and with the new orthoses supported the judgment that the new device was effective. Unfortunately, mechanical failures of the spring steel material were experienced continuously, particularly in the arch support, at the



FIG. 1 Various stages of the development and evolution of the TIRR Polypropylene Orthosis. The device on the extreme right is the first approach taken; the one on the extreme left is one version of the latest design.

(Fig. 1, extreme right). Because the arch support fitted inside the shoe, the patient was allowed a choice of shoes, and the device was less noticeable than conventional braces. It provided approximately 20 deg. of dynamic flexion-extension of the foot, in addition to good medio-lateral stability about the ankle.

attachment points of the posterior spring where it divided posteriorly to the malleoli, and at the mid-portion of the posterior spring itself. Despite efforts to eliminate breakage by using various means of attachment and methods of hardening the steel, the difficulties persisted. The average lifespan of the devices was increased

only to an average of 300,000 impacts.

It was concluded that the design principle should be retained, but a more suitable material had to be found. Various laminations of nylon and polyester resins reinforced with polypropylene screen weaves of varying sizes were employed. Better durability was achieved initially, but the laminations failed after four to six months of use.

In the meantime sheet polypropylene became available (9) (10) (11) (12), and experiments were undertaken using that material. It was evident, however, that drop-foot orthoses constructed of unreinforced polypropylene were too flexible to provide sufficient dorsiflexion assistance. After considerable experimentation, the idea of incorporating corrugations strategically in the material evolved. This method provided additional strength and stability in stress areas, especially in the transition from the shoe insert or arch support portion of the malleoli



FIG. 2 The TIRR Polypropylene Orthosis at the beginning of the stance phase.

area (Fig. 1, extreme right). Success was finally achieved using this method, thus increasing the structural strength and stability without adding unnecessary weight in the form of reinforcing materials (Fig. 1, extreme left, and Fig. 2) (4) (5) (6).

INDICATIONS

The polypropylene orthosis is indicated for most patients with drop-foot impairments and instability where conventional "short leg braces" would be prescribed. In addition, where the weight of conventional braces has contraindicated their use, the lightness (approximately four ounces) of the corrugated polypropylene device has made it possible to assist safely a number of patients who otherwise would be unable to ambulate independently. The orthosis is contraindicated only for patients with severe, uncontrollable spasms and for those with extreme and irreversible deformities of the foot-ankle complex.

APPLICATION

Application of the orthosis requires careful attention to detail but is not complicated. The first step is very important. When the cast is taken of the patient's foot-ankle complex, special care must be taken in positioning the foot in plantigrade position. Any skeletal malalignment should, when possible, be corrected manually. The cast is filled and dried using standard procedures. When dry, it is sculptured and any obvious malalignments or flaws are corrected, and stockinette is drawn over the cast to help provide a smooth finish (Fig. 3).



FIG. 3 Application of stockinette over the modified model.

To produce the corrugations in the polypropylene, 3/16" diameter teflon rods are nailed to the cast (Fig. 4),

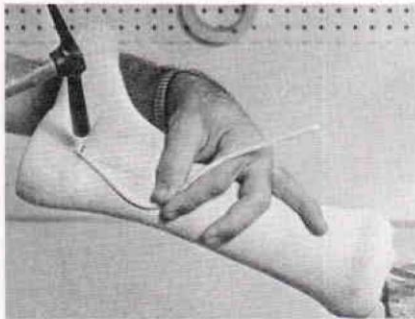


FIG. 4 Installation of teflon rod to provide corrugations.

originating at the calf band (which is two-thirds the distance from the plantar surface to the head of the fibula) both medially and laterally, curving downward, and meeting at the Achilles tendon. There they divide again to follow the division in the polypropylene which exposes the posterior aspect of the heel. They then follow the contour of the medial and lateral aspects of the heel posteriorly to the malleoli, and there they are tapered to a smooth finish (Fig. 5).

A full standard shoe insole is incorporated on the plantar surface of the cast corresponding to the patient's shoe size.

When the cast preparation has been completed, a sheet of 1/8" thick polypropylene is heated in an oven for ten minutes at 400°F. At this point, it becomes limber, like cloth, and will stretch readily over a model. The polypropylene is first folded over the posterior aspect of the cast and then stretched over the

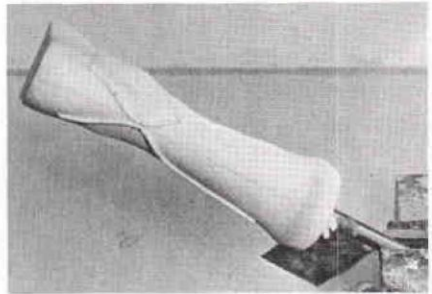


FIG. 5 Teflon rods in place.

heel portion (Fig. 6). A seam is formed on the anterior surface by pinching the two aspects of polypropylene together.

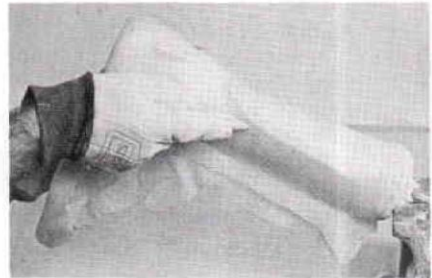


FIG. 6 Application of heated polypropylene from the model.

After the material has been folded over the cast, the surface of the polypropylene is smoothed, using a bluntly pointed instrument to impress thoroughly the corrugation pattern into the material along the edges of the teflon rods. After the polypropylene has set, it is pried open carefully and removed from the



FIG. 7 Removal of the molded polypropylene from the model.

cast (Fig. 7). The outline of the below-knee orthosis is drawn with a soft pencil or marking pen (Fig. 8).

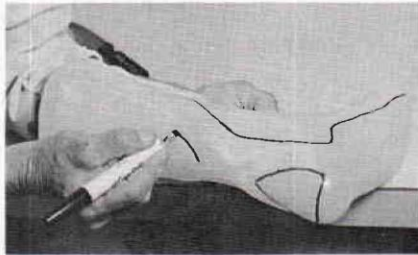


FIG. 8 Outlining the borders, or trim lines.

The excess plastic is then removed to give the final shape. All edges are

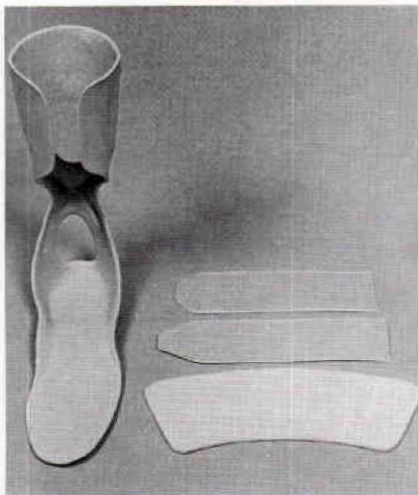


FIG. 9 Components of the TIRR Orthosis.

carefully sanded and smoothed. A light, padded insert with a tongue is then placed inside the calf portion, and a Velcro strap is attached for fastening the orthosis in position (Fig. 9).

The rigidity and/or flexibility of the device is regulated by selectively adjusting the width of the polypropylene cross-sectional area at the posterior junction, just above the heel. For the initial fitting, this area is purposely left wider than needed. It is gradually narrowed to provide the correct amount of dynamic dorsiflexion assistance needed by the

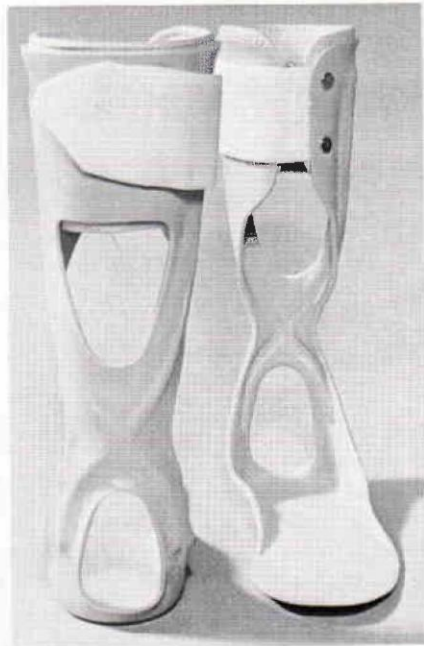


FIG. 10 Two views of the completed orthosis.

individual patient (Fig. 10). This "fine-tuning" of the device to the exact requirements for assistance needed by each patient enables the orthosis to meet a wide variety of patient disabilities while allowing maximum use of residual function.

RESULTS

At this time, 154 applications of the below-knee corrugated polypropylene orthosis have been made to patients with a wide variety of disabilities.

Forty-five percent of applications have been hemiparetic patients. Gait patterns of the hemiparetic using the

experimental orthosis as compared to the conventional brace show certain characteristic changes. Improvement is noted in gait rhythm, with changes in the swing phase of the affected extremity. Improved alignment control of varus and valgus instability at the ankle has been observed during the weight-bearing portion of the stance phase.

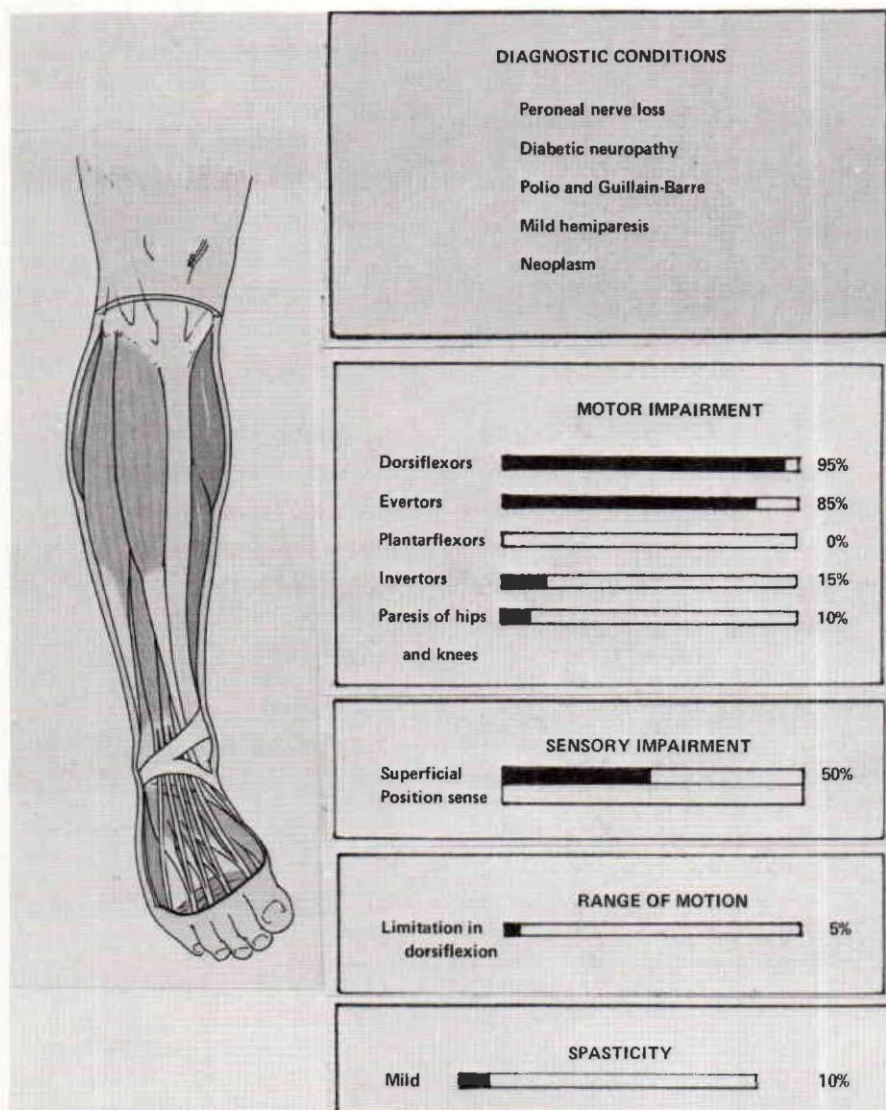


FIG. 11 CATEGORY I - Minimal impairment. Twenty-six of the first one hundred patients provided with the TIRR Orthosis fell into this category.

Fifteen percent of the case load have residual unilateral or bilateral weakness of the lower limb due to poliomyelitis or Guillain-Barre syndrome. For such disabilities, the light weight of the below-knee polypropylene device has been a great assistance in improving stability.

Forty percent of the patients represent other diagnostic conditions. Several patients with progressive disabilities were included in the research program; and it is felt that the experimental orthoses provided sufficient improvement to enable some patients to remain ambulatory longer, despite the

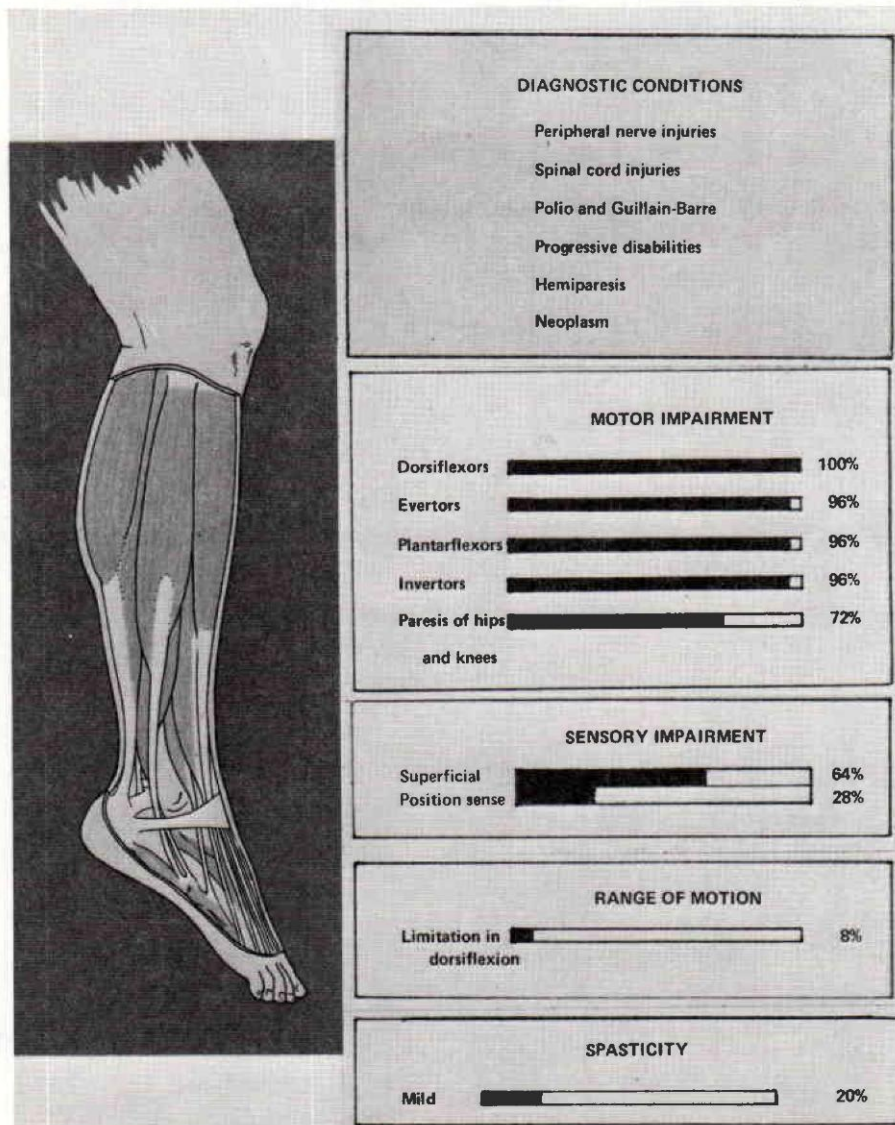


FIG. 12 CATEGORY II - Moderate impairment. Thirty-four of the first one hundred patients provided with the TIRR Orthosis fell into this category. Included were patients with progressive disorders such as muscular dystrophy and amyotrophic lateral sclerosis.

increasing severity of their disabilities. Ten patients with peroneal nerve loss due to trauma were fitted, and it was found that the experimental orthoses permitted them more flexibility than conventional bracing, allowing them to run, jump and participate in active sports.

Applications were made for a number of severely physically impaired children, including several with a diagnosis of spina bifida, one with congenital myopathy, and one

with arthrogryposis multiplex congenita. The mothers of these children report that the plastic orthoses cause much less wear and tear on clothing. Furthermore, where bladder control is poor, the nonabsorbent material of these devices is helpful in personal care.

APPLICATION WITH RESPECT TO PATIENT CLASSIFICATION

Regardless of specific diagnosis, however, the severity of the impair-

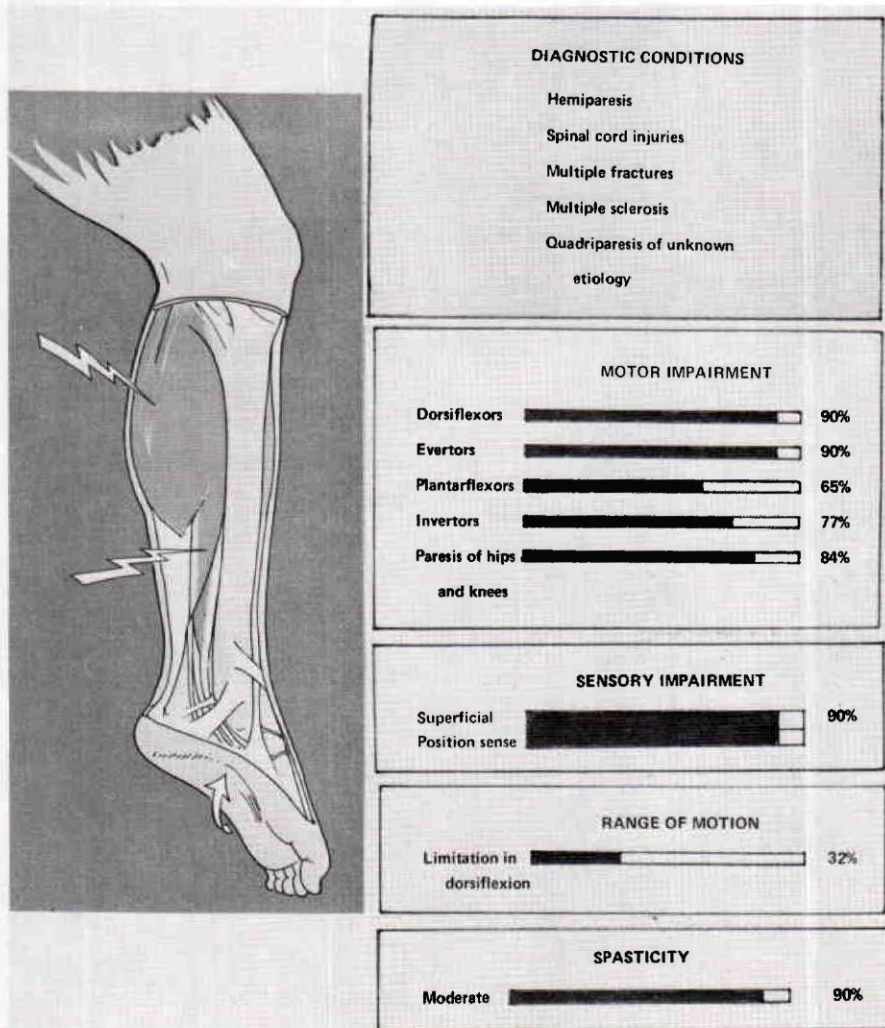


FIG. 13 CATEGORY III - Severe impairment. Forth of the First one hundred patients fell into this category.

ments represented by the first 100 patients fitted in the study tend to fall into three categories, with three overlapping, yet generally distinct, patterns of motor loss (1). These categories have been designated "Minimal", "Moderate", and "Severe" Impairment. A schematic presentation along with average degrees of impairment of each category are given in Figures 11, 12, and 13.

MINIMAL IMPAIRMENT

Twenty-six of the first 100 patients fell into the Minimal Impairment Group (Fig. 11). The major disabilities exhibited by most of these patients are impairments in the dorsiflexors and evertors, causing minimal to moderate impairment of mediolateral stability in 70% of these

patients. Although half of the patients show some sensory loss, in all cases the loss is spotty and includes only superficial modalities. Therefore there are usually no problems because the loss is substituted for effectively by remaining sense modalities and overlap. Joint mobility is within normal limits or is minimally limited. Where spasticity is present, it is very mild.

In matching the orthosis to the individual patient's condition, these orthoses were "programmed" for more flexibility and less rigidity than those for patients with more severe impairments.

Many of the patients of this group attained symmetrical gait patterns with the polypropylene orthosis. It enabled them to attain heel-toe

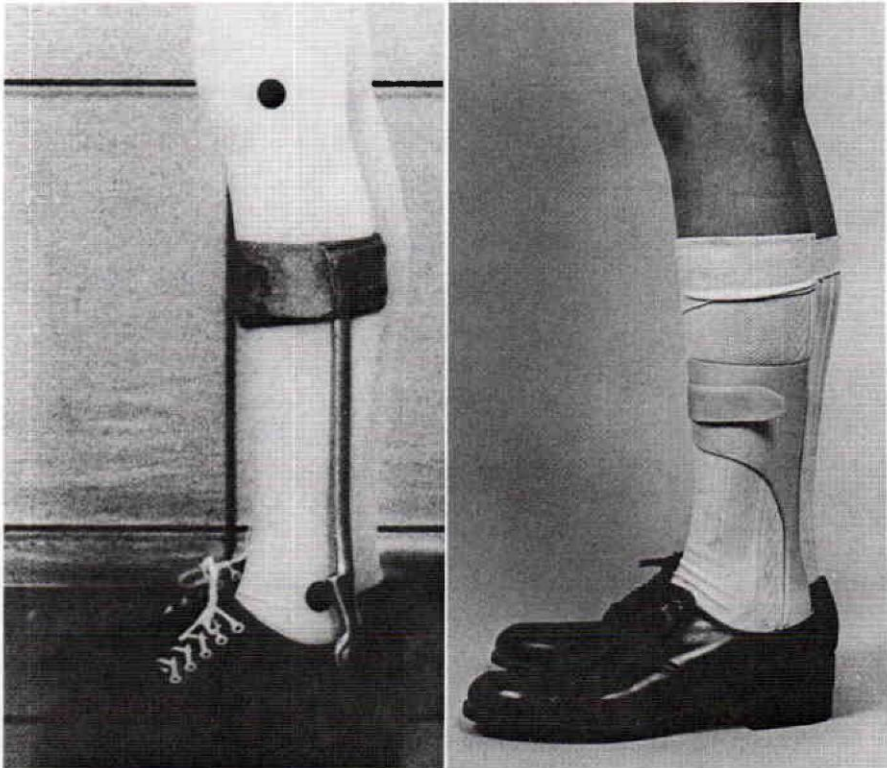


FIG. 14 Mild hemiparetic patient, age 12. Left - Conventional brace. Right - Corrugated polypropylene orthosis.

placement rather than flat-foot placement. The gait pattern exhibited by these minimally impaired patients does not differ markedly when comparing the polypropylene and the conventional orthosis, but the patients all preferred the polypropylene orthosis because of weight and appearance factors.

Typical of this group is a 12-year old girl with mild left hemiparesis secondary to cerebral thrombosis of the left middle cerebral artery, shown here with her old conventional brace and her new corrugated polypropylene orthosis (Fig. 14). Approximately two years ago when the polypropylene device was first applied, her left below-knee conventional orthosis was causing an increase of spasticity in her foot-ankle complex, possibly due to the weight of the device. With the new orthosis, she is able to ambulate further and more easily, averaging from a rating of "Fair" with the old brace to "Good" with the new orthosis⁴. She states that the orthosis is more comfortable than any she has used previously.

MODERATE IMPAIRMENT

The Moderate Impairment Group (Fig. 12) comprises 34% of the initial 100 applications. As shown, almost all of these patients have impairments of most of the principal muscle groups in the foot-ankle complex. The percentage and degree of sensory impairment is higher, with a significant number showing loss of position sense, and the frequency and severity of spasticity is also higher. Five of the patients in this group who suffered from progressive disabilities were unable to wear conventional bracing because the

⁴Grading Key developed for Functional Evaluation of Independence (8).

weight of the braces offset any positive gains.

One of these patients, a young lady age 32 with a diagnosis of

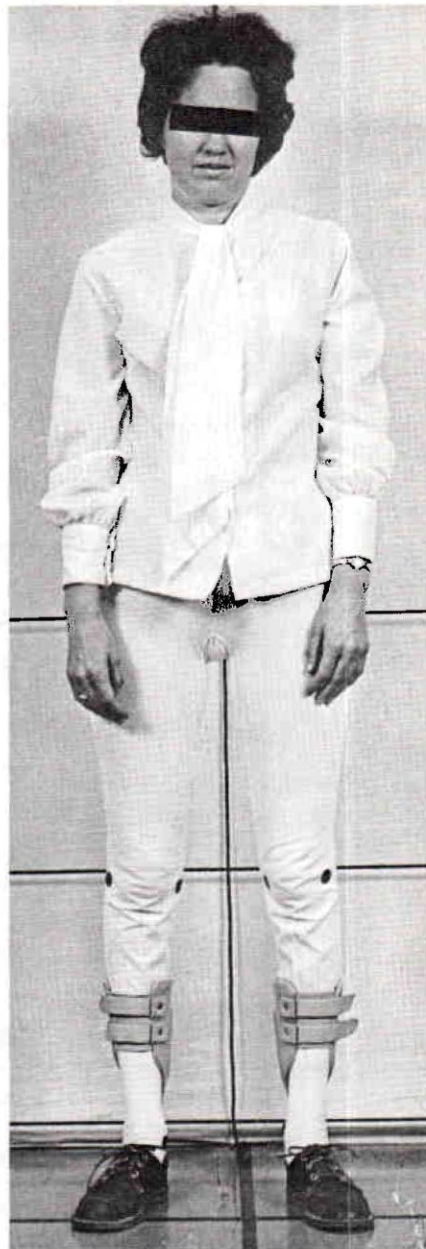


FIG. 15 Patient with Charcot-Marie-Tooth syndrome, age 32, with bilateral below-knee corrugated polypropylene orthoses applied.

Charcot-Marie-Tooth syndrome, was ambulating in the "Poor" range with no devices because the weight of conventional braces made ambulation almost impossible. Because of the progressive nature of her disability, the time was imminent when she would be confined to a wheelchair. Bilateral below-knee corrugated polypropylene orthoses (Fig. 15) were fabricated and fitted for her in November 1970, improving her ambulation grade at that time from the "Poor" to "Fair" range. She is still using the orthoses; and although her condition continues to deteriorate, she is still employed as a

medical secretary and still able to ambulate in the "Poor" range with the devices.

SEVERE IMPAIRMENT

The Severe Impairment Group (Fig. 13) comprises 40% of the original patient population for whom the polypropylene devices were adapted. These rather severely impaired patients usually show additional complications, as well as motor impairment. Patients in this group do not exhibit a clear-cut pattern of motor impairment, but a high percentage show weakness in hips and knees, as well as loss of the

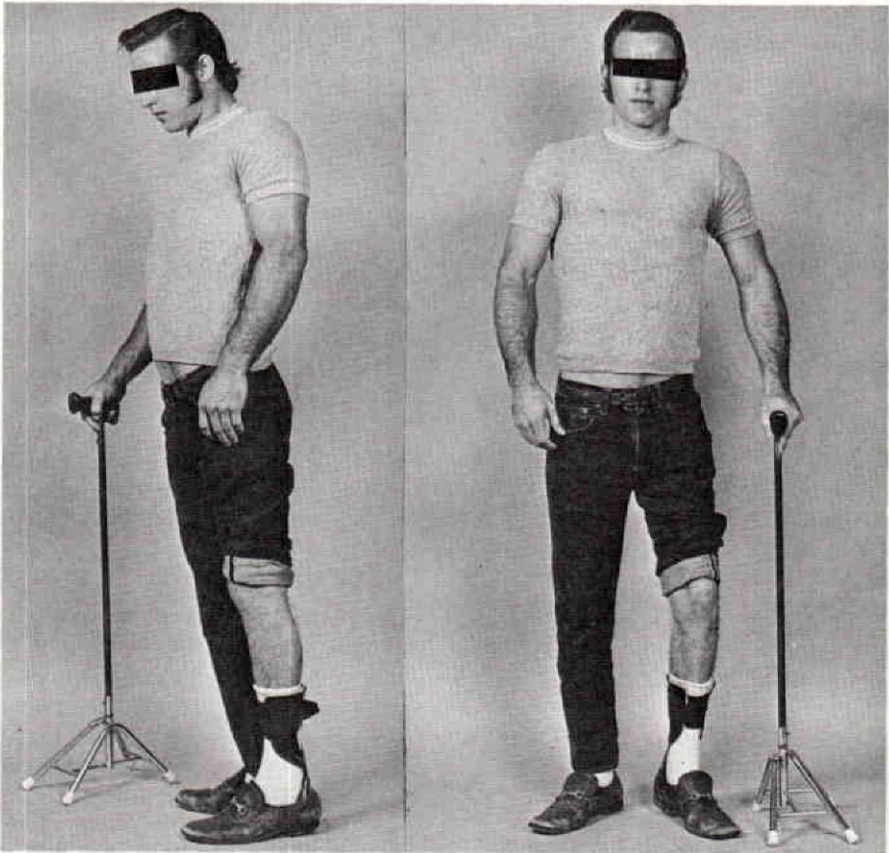


FIG. 16 Patient with incomplete paraplegia at T-6, age 21. Left - lateral view of corrugated polypropylene orthosis. Right - anterior view of corrugated polypropylene orthosis.

major muscle groups in the foot-ankle complex. The high proportion of sensory impairment complicated their motor losses. The majority of these patients whose etiology is cerebrovascular accidents have diffuse superficial sensory loss, as well as position sense loss, requiring the most careful follow-up of the contour-fitting polypropylene devices. Devices for patients in this category, in general, were provided with more rigidity to meet their biomechanical impairments.

In this group, spasticity is the largest additional complication, as the moderate and sustained clonus creates a deforming force which requires greater rigidity in the orthosis.

The limitations in range of motion noted in the chart were primarily of inability to reach plantigrade. There were also a number of patients who exhibited genu recurvatum. Other complications in this group include uncoordination, ataxia, synergistic movement, tremor, perceptual disability, and mental confusion, secondary to cerebral pathology.

An example of a severely impaired Group III patient is a young man, age 21, with a diagnosis of incomplete paraplegia at T-6 secondary to a gunshot wound (Fig. 16). In October 1970, bilateral above-knee conventional orthoses were prescribed for him. He experienced thereafter some motor return bilaterally, especially in the right lower limb. There remained moderate spasticity in the left leg and mild spasticity in the right leg. Mild tightness is found throughout the range of motion of both lower limbs, and severe limitations are recorded in dorsiflexion. He has bilateral drop-foot, complicated by skeletal

limitation in dorsiflexion on the left, and is dependent on a quad cane during stance phases of ambulation. A left below-knee corrugated polypropylene orthosis was prescribed and fitted for him in August 1971. Because of his severe disability, his gait is quite unstable, and his endurance is poor. However, the patient is satisfied with his orthosis because it is providing adequate support.

EVALUATION AND EDUCATION

Additional clinical evaluation of the corrugated below-knee polypropylene orthosis was conducted under the auspices of the National Academy of Sciences, Committee on Prosthetics Research and Development, at Moss Rehabilitation Hospital, Krusen Research Center, in Philadelphia. Two patients were fitted and clinically tested for effect on gait performance. Moss's preliminary report indicates that the new devices were effective in providing the necessary assistance for the patients.

At the request of the Committee on Prosthetics Research and Development, a course in fabrication and fitting of the below-knee orthosis was held at the New York University in January 1972, and in March 1972, that University included a one-week seminar in construction of corrugated polypropylene orthoses in their orthotic curriculum.

An *Instruction Manual for Fabrication and Fitting of a Below Knee Corrugated Polypropylene Orthosis* (8) has been prepared, giving in detail the necessary steps for construction and application of the device. This manual is available from the Texas Institute for Rehabilitation and Research.

DISCUSSION

Although successful prolonged usage of these below-knee devices is now a reality, adaptation demands that the orthotist perform a precision fitting process. Because the contour of the orthosis is critical to the function, application requires more care than is usually necessary for conventional orthoses. If the patient is hyperesthetic, a longer period of observation and initial adjustment of the orthosis is critical. Also, the same precautions are taken where there is reduced or lack of sensation in the lower limbs.

For the more severely impaired hemiplegic who has the functional use of only one hand, independent application and removal of the device can be very difficult, and in approximately 3% of the patients fitted to date, impossible.

According to the patient's reactions, any disadvantages of the polypropylene orthosis are exceeded by the following advantages:

1. the brace-shoe attachment has been eliminated;
2. the device is much lighter in weight than conventional braces;
3. ambulation is made easier;
4. it is less conspicuous; and
5. the assistance needed can be tailored to the individual patient and can be used without discomfort.

ABOVE-KNEE STUDIES

Efforts have been made to apply the design principles and material which were successfully used in the below-knee orthosis to above-knee devices. The fabrication and fitting methodology are similar to that used for the below-knee devices, except

orthotics and prosthetics

that a cast is taken of the patient's entire lower limb. The reinforcing corrugation is extended on the medial and lateral sides to just below the knee joint and is continued proximally to include the thigh area. Places where pressure points could occur are identified, and small discs are attached to the cast to produce indentations in the molded polypropylene at these points on the inner surfaces.

Above-knee devices have been fabricated and applied to eight patients. Six of these applications incorporated conventional prefabricated metal knee joints. Also investigated was the possibility of eliminating metal knee joints by using the polypropylene material itself. Flexible polypropylene hinges of special design have been tried in several applications with one successful adaptation. In this case, for a child with a diagnosis of spina bifida, the thigh and below-knee portions of the orthosis were joined using a narrow strap of polypropylene which acts as a hinge. This arrangement freely allows passive polycentric skeletal knee articulation and reduces the mechanical hindrance which can cause undesirable sliding motion, eliminating a common problem seen in conventional orthoses.

Means to provide adequate articulation still present an unsolved problem, locking the unstable knee. Efforts are being made to develop a different method of stabilizing the knee which will complement the experimental polypropylene hinge.

SUMMARY

As a result of three years of research and development in attempting to improve designs for

lower-limb orthoses, a device using polypropylene with corrugations has been developed for patients with "drop-foot."

By incorporating corrugations into polypropylene, which is extremely resistant to fatigue, the ratio between total flexibility and rigidity can be controlled selectively to match the specific deficits in the individual patient without the need for reinforcing materials. This orthosis may be considered as an analog of the ligaments, permitting musculo-skeletal functions while compensating for various deficits in the patient's biomechanical system.

In addition to providing the patient with dorsiflexion assistance and mediolateral stability of the foot-ankle complex, the TIRR orthosis has three distinct advantages over conventional devices:

1. The weight is much lower.
2. A permanent attachment between the shoe and the orthosis is not required.
3. The appearance is more acceptable to patients.

The TIRR device is indicated for all conditions where conventional below-knee orthoses would be prescribed. It also can be used effectively when the weight of a conventional brace would contraindicate its use, but where ankle stability and active dorsiflexion assistance would be helpful.

Contraindications for use are severe, uncontrollable spasms and severe, irreversible skeletal deformities of the foot-ankle complex.

ACKNOWLEDGEMENTS

Acknowledgement is made of the many reports and publications, in addition to those listed in this report, which have served as sources of

information and assistance for this project. Valuable contributions have also been received from the countless people who have participated in meetings and conferences during the past three years. These exchanges of ideas have stimulated the researchers and helped further this project.

Acknowledgement is also made to the entire professional and non-professional staff at Texas Institute for Rehabilitation and Research who contributed both ideas and service.

Special thanks are due to the entire staff of the Department of Orthotics for their full-time daily involvement in the furtherance of the project.

Finally, and most importantly, our grateful thanks are extended to the many patients who have cooperated with us in the clinical evaluation of our orthotic developments.

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