EXTERNALLY CONTROLLED MOVEMENTS USING BIOMECHANICALLY PROGRAMMED ORTHOTIC DEVICES

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Summary

As a result of three years of research and developments improving designs for lower extremity orthotic devices, a corrugated polypropylene drop-foot orthosis was developed.

By using extremely fatigue-resistant polypropylene material with the developed corrugation technique, the ratio between total flexibility and rigidity can be selectively controlled to match the specific deficits in the individual patient without adding reinforcing materials. This material and technique permit optimum individualization in clinical applications. This orthosis is an analog of external ligaments, permitting muscular skeletal functions while compensating for various deficits in the patient's biomechanical system.

In addition to providing the patient with the necessary dorsiflexion assistance, including lateral and medial stability of the foot-ankle complex, this orthosis has three distinct advantages over conventional bracing methods:

1. Lightweight
2. Permanent shoe-brace attachment not required
3. Cosmetically acceptable.

The device is indicated for all conditions where conventional lower extremity bracing would be prescribed and used. It can also be effectively used in conditions where 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.

Until very recently, the development of new types of lower extremity orthoses which meet the specific needs of individual patients has been largely ignored, due partially to the complexity of the biomechanical principles involved in ambulation. This lack of research resulted in clinical usage of only four basic types of conventional braces for a wide variety and degree of diagnostic conditions, which in many cases resulted in overbracing.

In 1968 a research and development project, under practical sponsorship of Social and Rehabilitation Service, was initiated in the Department of Orthotics at Texas Institute for Rehabilitation and Research to create new design concepts and develop devices for the lower extremities which would more accurately meet the needs of individual patients with drop-foot condi-

tions, medial-lateral instability and dorsi- and plantar-flexion impairments. It was intended that the new devices would, in addition, be less noticeable and lighter in weight than the cumbersome conventional bracing methods. Initially, effort was concentrated on patients with below knee impairments, and a group of five patients was selected: a hemiplegic with flaccidity; a hemiparetic with spasticity and sensory loss; a unilateral lower extremity paralytic (post-poliomyelitis) with muscular atrophy; a bilateral lower extremity paralytic with muscular disease (muscular dystrophy); and a paraplegic with spasticity secondary to spinal cord malformation (spina bifida). Special data recording forms were developed to evaluate the usefulness of the new devices as they were concieved. A videotape recording system was devised to provide repeatable comparisons of these patients' ambulation patterns in their conventional braces, without orthotic equipment, and with each newly developed device as design and material improvements were made.

The orthotic design concept developed early in the project and was implemented with a posterior spring device. In this early orthosis, a precision fitted arch support of stainless steel was attached to a posterior heel spring that closely followed the contour of the gastrocnemius muscle bulge. In terminated with a small band below the knee. Because the arch support fitted inside the patient's shoe, this design allowed him a choice of shoes and was less visible than conventional braces. It provided approximately 20 degrees of dynamic flexion-extension of the foot, in addition to good medial-lateral ankle stability.

This device was applied to sixteen patients with diagnoses including postpoliomyelitis, Guillain-Barre syndrom, and hemiplegia. In all cases, the device gave the patient the needed stability and dorsiflexion assistance. Comparison of videotaped recordings of their ambulation without assistance, in their previously used conventional braces and with the new orthosis supported the judgment that the new device was effective. Unfortunately, however, mechanical breakdowns of the spring steel material were continuously experienced, particularly in the arch support at the attachment point of the posterior spring where it divided posteriorly to the malleoli, and at the mid-portion of the posterior spring itself. Depite efforts to eliminate breakage by using various means of attachment of methods of hardening the steel, the difficulties persisted. The average lifespan of the devices

was increased only to an average of 300,000 impacts, calculated by pedometer readings.

Therefore, it was felt that while the design principle should be retained, a more suitable material had to be found. Various forms of nylon laminated polyester resins reinforced with polypropylene screen weaves of varying sizes were employed. Better durability was initially achieved; however, it was found that the material delaminated after four to six manths of usage.

In the meantime it was found that the sheet polypropylene might have even better suitability for orthosis purposes, and experimentation was undertaken with that material. It was evident however, that drop-foot orthosis constructed of unreinforced polypropylene were too flexible to provide sufficient dorsiflexion assistance. After considerable experimentation, the idea of selectively corrugating the material evolved, similar in principle to the process of strenghtening sheet metal for construction purposes by corrugating it. This method provided additional strenght and stability in stress areas of the polypropylene, especially where it continued from the shoe insert or arch support portion and devided posteriorly to the malleoli (Fig. 1). 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. 2).

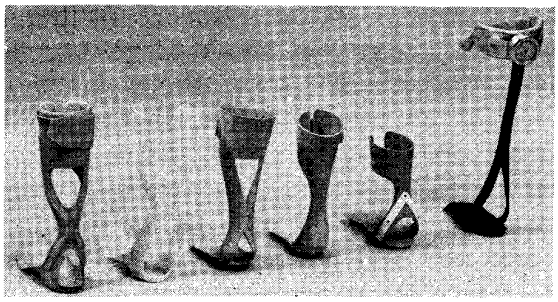

Fig. 1. Sequential development toward the below knee corrugated polypropylene orthosis

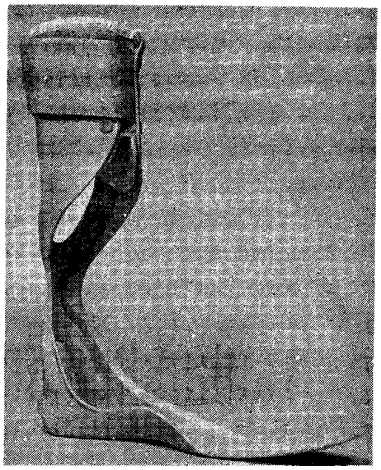

Fig. 2. The below knee corrugated polypropylene orthosis

This device 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 usage, the lightness (approximately four ounces) of the corrugated polypropylene device has made it possible to assist a number of patients safely 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 of the orthosis is exacting but not complicated. The forst step, however, is very important for successful adaptations. When the cast is taken of the patient´s foot-ankle complex, accuracy and care must be taken in positioning the foot in plantigrade position. Any skeletal malalignment should, is possible, be manually corrected. Thereafter, the cast is filled and dried using standard procedures. When dry, it is sculptured and any obvious malalignments or flaws are corrected.

To produce the corrugation imprint in the polypropylene material 3/16" round teflon rods are nailed to the cast, originating at the calf band (which is two-thirds the distance from the planta surface to the head of the fibula) both medially and laterally, curving downward, and meeting at the Achilles tendion. There they divide again to follow the division of the polypropylene which exposes the posterior aspect of the heel. Then they follow the contour of the medial and lateral aspect of the heel posteriorly to the malleoli, and there they are tapered to a smooth finish.

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" polypropylene is heated for ten minutes at $400^{\circ}F$ in an oven until it becomes limber, like cloth, and will stretch readily into three dimensional planes. The polypropylene is then folded over the posterior aspect of the cast and stretched over the heel portion with the seam assembled anteriorly by pinching together. (Fig. 3).

Once the material has been folded over the cast the surface of the polypropylene is smoothed. A bluntly pointed instrument is used to impress thoroughly the corrugation pattern into the material along the edges of the teflon rods. After the polypro-

Fig. 3. Draping the polypropylene over the cast, showing corrugation pattern of teflon rods for the below knee orthosis

Fig. 4. "Cross" area of orthosis above heel, where rigidity or flexibility of the device are biomechanically programmed to individual patient requirements.

pylene is set, it is carefully pried open and removed from the cast. The outline of the below knee orthosis is drawn with a soft pencil or marking pen. The excess plastic is then removed, giving the device its final shape. All edges are carefully power-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.

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 (Fig. 4). For the fitting, this area is purposely left too wide, then gradually narrowed to biomechanically program the correct amount of dynamic dorsiflexion assistance needed by the individual patient. This biomechanical 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.

At this time 154 patient applications of the below knee corrugated polypropylene orthosis have been made. A variety of disabilities are represented, and the percentage breakdown of diagnoses follows.

Forty-five percent of applications have been for hemiparetic patients. Gait patterns of the hemiparetic using the experimental orthosis as compared to the conventional brace show certain charateristic changes. Improvement is noted in gait rythm 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.

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

Forty percent 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 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 arthogryposis 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 nonabsorbant material of these devices is beneficial to personal hygiene.

Regardless of specific diagnosis, however, the severity of the impairments represented by the initial group of 100 patients included in the study tend to fall into three categories, with three overlapping yet generally distinct patterns of motor loss (Fig. 5).

The first group, representing 26% of the total (left side of Figure 5) typify minimal impairment, as detailed in Illustration 1 (Fig. 6). As shown, the major disabilities exhibited by most of these patients are impairments in the dorsiflexors and evertors, causing minimal to moderate impairment of medial-la-

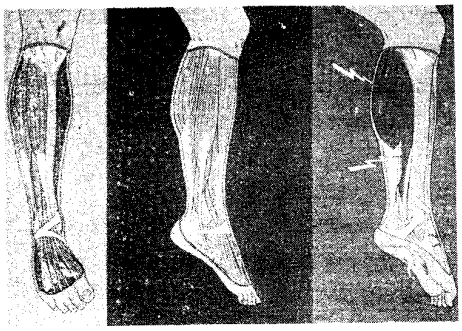

Fig. 5. Three general types of patient impairments: (a) group I, minimal impairment; (b)group II, moderate impairment; (c) group III, severe impairment.

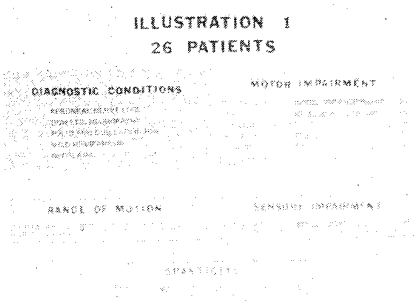

Fig. 6. Minimal impairment diagnostic and symtomatic chart.

teral stability in 70% of these patients. Although half of the patient show sensory loss, in all cases this is spotty and includes only superficial modalities, and therefore usually causes no problems as 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 biomechanically 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 placement rather than flat-foot placement. The gait pattern exhibits 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 for weight and appearance.

Typical of this group is a 12 years old girl with a diagnosis of 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.

7). Approximately two years ago when the polypropylene device was first applied, her left below knee conventional orthosis was causing an increse 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 orthosis*. She states that the orthosis is more comfortable than any she has previously used.

Fig. 7. Mild hemiparetic patient, age 12
(a) conventional brace
(b) Corrugated polypropylene orthosis

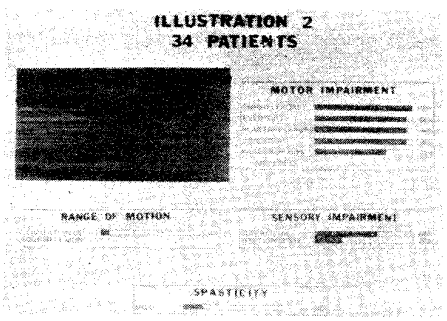

Fig. 8. Moderate impairment diagnostic and symptomatic chart

Group II, shown in Figure 6 center, can be termed moderate impairments, as detailed in Illustration 2 (Fig. 8). This group 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 sence, and the frequency and severity of spasticity is also higher. Five of the patients in this group who suffered from progressive distabilities were unable to wear conventional bracing because the weight of the braces negated any positive gain.

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

*Grading Key developed for Functional Evaluation of Independence, described in Bibliography, Final Report, September 1971.

of Charcot-Marie-Tooth syndrome, was ambulating in the Poor range with no devices because the weight of conventional braces made ambulation almost impossible (Fig. 9). Due to the progressive nature of her disability, the time was imminent when she would be confined to a wheelchair. Bilateral below knee corrugated polypropylene orthoses 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 continuous to deteriorate, she is still employed as a medical secretary and still able to ambulate in the Poor range with the devices.

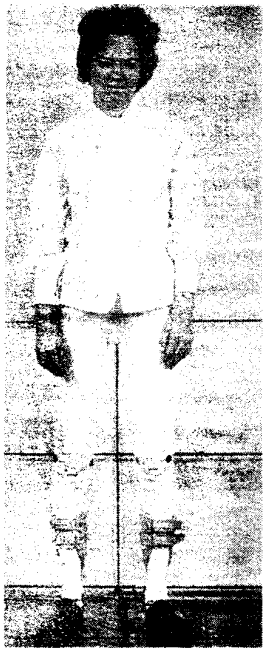

Fig. 9. Patient with Charcot-Marie-Tooth syndrome, age 32, with bilateral below knee corrugated polypropylene orthoses applied.

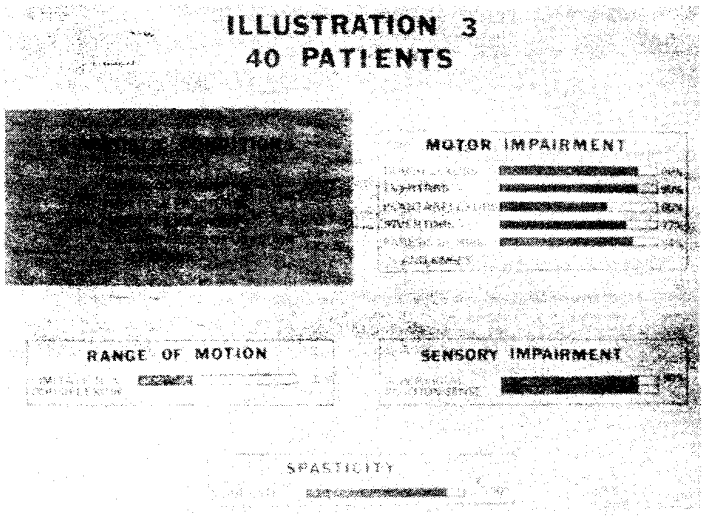

Fig. 10. Severe impairment diagnostic and symptomatic chart

Group III, shown at the right of Figure 6, comprises 40% of the original patient population for whom the polypropylene devices were adapted. These rather severily impaired patients usually show additional complications, as well as motor impairments, as shown in Illustration 3 (Fig. 10). Patients in this group do not exhibit a clear-cut pattern of motor impairment, but a high per-

centage show weakness in hips and knees, as well as loss of the 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. Their devices, in general, were programmed for more rigidity to meet their biomechanical impairments.

In this group, spasticity is the largest additional complication, as the moderate and sustained clonus create 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 incoordination, 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 gunchot wound (Fig. 11). In october 1970, bilateral above knee conventional orthoses were prescribed for him. He experienced thereafter some motor return bilaterally, especially in the right lower extremity. 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 extremities, 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. Due to 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.

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 Rehabilitaion Hospital, Krusen Research

Center in Philadelphia. Ten 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 New York University included a one-week seminar in construction of corrugated polypropylene orthoses in their orthotic curriculum.

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

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 so far fitted, 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. it increases ease in ambulation;
4. it is more attractive; and
5. it affords the individual patient the necessary assistance without discomfort.

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

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 that a cast is taken of the patient's entire lower extremity. The re-

inforcing corrugation is extended on the medial and lateral sides to adjust below the knee joint and continued again 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.

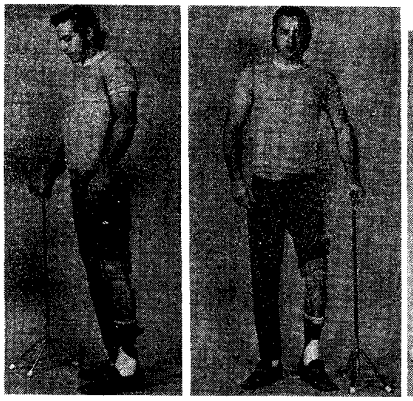

Fig. 11. Patient with incomplete paraplegia at T-6, age 21 (a) lateral view of corrugated polypropylene orthosis (b) anterior view of corrugated polypropylene orthosis.

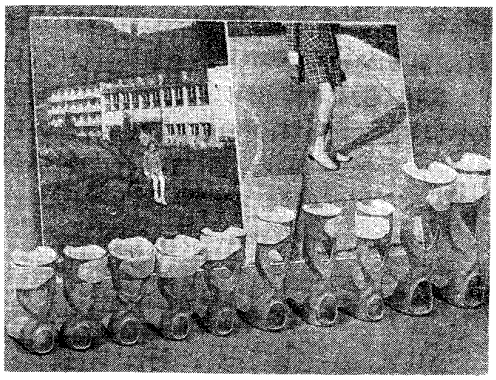

Fig. 12. Ten below knee corrugated polypropylene orthosis made at Texas Institute for Rehabilitation and Research for children with muscular distrophy at the Kamnik center.

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 metal 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 movements, eliminating a common problem seen in conventional bracing methods.

The above method of articulation still presents the unsolved problem of locking the unstable knee, and efforts are being made to develop a different method of stabilizing the knee which will complement the experimental polypropylene hinge.

During the past several years, collaboration has been active between the Institute of Clinical Neurophysiology in Ljubljana and the Texas Institute for Rehabilitation and Research in Houston. As a result of this collaboration, a number of below knee corrugated polypropylene orthoses have been made from casts taken on children in Kamnik, all with a diagnosis of muscular dystrophy (Fig. 12). Furtherance of international collaboration and exchange of ideas will doubtless prove to be of great value in improving health services for the many individuals in need of orthotic services.

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