

Tubular orthoses

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Abstract

A method of constructing orthoses and other patient devices using nylon tubing and clip-together standard components is described. This permits the rapid assembly of custom orthoses that can be evaluated before prescription in a clinical setting. These orthoses have been successfully used for the control of thoracic spinal flexion, hip abduction, elbow extension, shoulder abduction, cervical spine stabilization and pressure sore relief. Advantages over existing orthoses include reduced weight, improved comfort and cosmesis, low cost and increased speed of provision. Examples of these orthoses are shown, together with details of their structure, function and clinical results.

Introduction

A new approach to the construction of orthoses has been developed. The basis of this construction is the interlinking of plastic tubes to provide a strong and lightweight framework. These tubes are linked to form structures to which pads, straps and other surfacing elements can be fastened. These form the interface of the orthosis with the body and so allow the framework to control the motions of the various body segments.

The orthoses have been successfully applied in the management of spinal injuries, arthritis, head injuries, burns and congenital disabilities. Examples of these applications will be discussed, including structural considerations, the current

status of each orthosis and the areas of application. The management principles and plans for this new approach to orthotics will also be considered, together with the advantages offered to the patient and to the clinical community.

Structural considerations:

The structural principles common to all Tubular Orthoses include selected directional rigidity; use of tensile elements to increase the strength-to-weight ratio; three-point counter-loading where appropriate; and the use of contra-lateral body stabilization. The result is lightweight yet strong structures giving support in the directions needed and not restricting movement when not desired. Tubular Orthoses use the body to maximize support and stability of the device.

The use of plastic tubing for the construction of orthoses is advocated. High strength-to-weight ratio is achieved through this configuration and material. Rigid nylon bushing stock is used. Lengths are pre-cut in $\frac{1}{2}$ " (12.5mm) increments from 2" (50mm) to 2' (600mm) in the sizes of $\frac{3}{8}$ " (9mm) O.D. $\frac{1}{4}$ " (6mm) I.D.; $\frac{1}{2}$ " (12.5mm) O.D. $\frac{3}{8}$ " (9mm) I.D.; and $\frac{5}{8}$ " (15mm) O.D. $\frac{1}{2}$ " (12.5mm) I.D. These are interlinked by various components that function as T junctions, hinges, ball and socket joints, crossovers, C clips, rings, end plugs, cable ties and clamps. A selection of these is illustrated in Figure 1.

The result is a system of tubes and linkages that can be plugged together to permit rapid assembly and adjustment of a wide range of orthoses and patient devices. Six orthoses have entered the clinical trials stage using this system and these will now be described.

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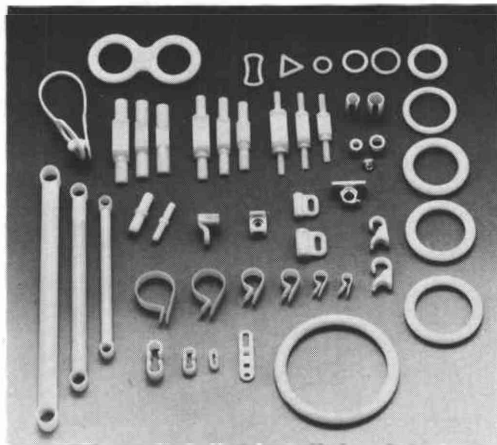


Fig. 1. An array of components is shown. The 3 sets of 3 linkages near the top of the figure are the T junctions, which are folded over and inserted into the tubes. A variety of additional components are presently being moulded, including ball and socket joints, lap hinge joints and cross-overs.

The orthoses

a) *The cervical orthosis*

(i) Structure and function

This orthosis is designed to provide control of flexion and extension of the cervical spine. This is achieved by support on the soft tissues under the mandible and over the upper portion of the chest; at the occiput and across the shoulders. Rigidity is controlled by the closeness of fit and by the position of the vertical tubes. The orthosis is constructed from short lengths of $\frac{3}{8}$ " (9mm) nylon tube ranging in length from 4" (100mm) posteriorly to 2" (50mm) anteriorly. These are linked by T junctions to flexible clear PVC tubing at the superior and inferior perimeters of the orthosis. Closure anteriorly is achieved with $\frac{1}{4}$ " (6mm) nylon rod that plugs into the two anterior tubes. A breastplate ring and a chin support are heat formed in three sizes to accommodate a range of patients. A small chin cup is clipped to the chin support rod to complete the structure. Fabrication and fitting time is of the order of 30–45 minutes. The weight of the orthosis is 110 g. An example of the orthosis, without a chin cup, is shown in Figure 2.

ii) Clinical results and plans

Ten patients have been fitted in the preliminary clinical trials of this orthosis. These comprise 7 arthritis, 1 cerebral vascular accident, 1 spinal cord injury and 1 'whiplash' injury

patient. Of these patients 8 continue to wear the device on a regular basis. One arthritis patient complained of soreness under the chin. The whiplash injury patient had tenderness at the occiput due to her injury, consequently she only wore it when riding in a car. However, the other 8 patients continue to wear their collars on a regular basis. For example, the spinal cord injury patient, (a chipped facet or slipped disc at C6 resulting from a skiing accident,) wore his collar at least 15 hours a day for two weeks immediately after his accident. The cerebral vascular accident patient had resulting muscle weakness on the right side. This was compounded by narcolepsy resulting in a postural problem of the head drooping to the right side. the collar was fitted primarily for posture control, enabling the patient to communicate more readily and to use a typewriter. The majority of patients had either rheumatoid or osteo-arthritis of long standing. Prime advantages cited by the patients over their existing Plastazote collars were coolness, reduced weight and increased rigidity. The preliminary trials of this device are now complete and extended clinical trials will now be conducted. These will include controlled studies



Fig. 2. The cervical orthosis showing the vertical $\frac{3}{8}$ " (9mm) nylon tubes linked by T junctions to the superior and inferior lengths of PVC tubing. A curved chin piece of $\frac{1}{4}$ " (6mm) nylon rod is inserted into the top of the two anterior tubes and a chin cup is clipped onto this. A circular curving section of $\frac{1}{4}$ " (6mm) rod forms the breastplate.

on arthritis with radiological determination of atlanto-axial stabilization; provision of the collars for emergency care; and expansion of use in rehabilitation for posture control.

b) *The spinal extension orthosis*

i) Structure and function

This orthosis is designed to resist flexion of the thoracic spine. The orthosis also encourages extension which aids in resisting lateral and rotary motion of the spine. The resistance to flexion by the structure is achieved by three point application of forces. Sternal and pubic area pressures are counterbalanced by a lumbar pressure area. This is achieved by linking pressure surfaces at these three points with structural beams constructed from the plastic tubes. An outline of the forces involved is given in Figure 3. This three-point loading system is common to many orthoses. Immobilization of the thoracic spine is achieved by keeping the spine in extension. Additional support is given to the abdominal muscles by the ring network shown in the anterior view in Figure 4. This support in turn braces the spine in a similar manner to a corset.

The orthosis is constructed from plastic tubular rings; two large ones on the ventral

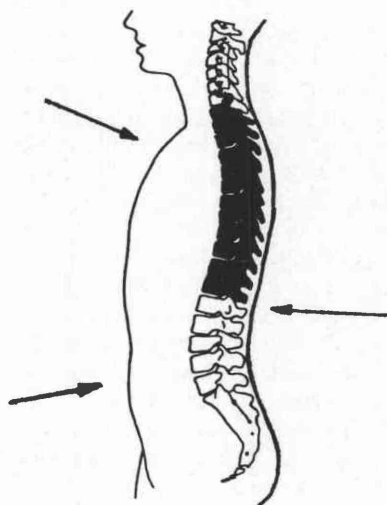


Fig. 3. The three-point force application of the spinal orthosis. The two anterior forces are balanced by the posterior force, with the objective of stabilizing the thoracic vertebra (shaded).

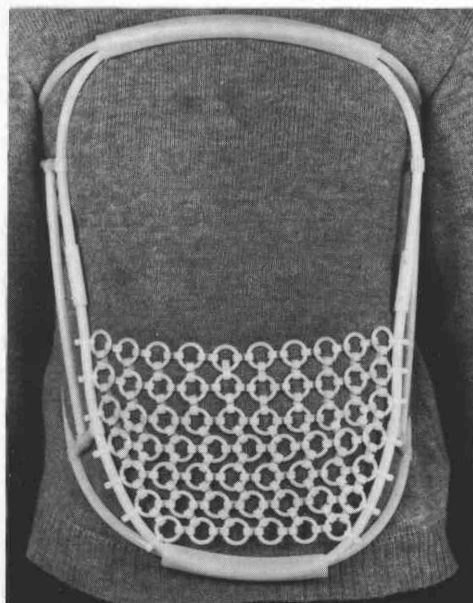


Fig. 4. This anterior view of the spinal orthosis shows the two concentric ventral rings joined at the top and bottom. A meshwork of fine nylon rings pulls the abdominal muscles up and in to aid in supporting the spine. Larger rings are used dorsally to enclose the lower back.

surface and several small ones (2" (50mm) diameter) on the dorsal surface. (The dorsal rings used are the same as those shown on the shoulder abduction orthosis in Figure 6). The two ventral rings are concentric and the smaller internal ring is distorted to press against the sternal and pubic areas at its upper and lower poles.

The small dorsal rings hook onto the larger ventral ring at each side of the body and they are detachable at these points for application and removal of the orthosis. When the cross-linked lateral sections of the ventral rings are pulled towards the body, they are pulled into the sagittal plane and so they are more able to aid in resisting flexion. The rings can be pulled away from the anterior superior iliac spines or be shaped around the breasts. The weight of the orthosis is 350 g.

(ii) Clinical results and plans

Forty-seven orthoses were fitted to patients in a clinical trial to obtain design information and to determine the correct prescription criteria for this orthosis. Consequently all the patients that

were referred for fitting by physicians were fitted, regardless of the appropriateness of the orthosis. Even with this "take-all" approach, a 50% success rate was achieved. That is, 50% of all the patients referred accepted and continued to wear the orthosis until their spinal problem was resolved. The most successful users of the orthosis were those in the 15 to 40 age range who had suffered a spinal injury and needed an intermediate support after the removal of a plaster cast. The most unsuccessful cases were those patients suffering from arthritis of the spine, osteoporosis of the spine, or with intractable lower back pain.

The prescription criteria can thus be defined as: enhancement of stability of the spine and control of thoracic flexion for those patients having suffered recent trauma to the spine. Application will be most successful at the removal of a standard body cast when the patient is entering a more active stage of the rehabilitation process. The orthosis can reduce the time spent in a plaster cast and it can be used for pool therapy during rehabilitation. It will also provide support during showering and bathing. The orthosis is now ready for wide use and commercial availability will now be established.



Fig. 5. Lateral view of the abduction orthosis showing the anterior and posterior suspension loops. These are secured to the limb by Velcro straps to the thigh. The three-tube beam can be seen clearly maintaining the hips in abduction.

c) *The hip abduction orthosis*

(i) Structure and function

This orthosis is designed to maintain the hips in abduction and to permit the continuation of normal activities of daily living. Abduction of the hips is achieved by pushing the knees apart with a rigid tubular beam. This beam is held in place by loops of plastic tubing, anteriorly and posteriorly, that also suspend the orthosis from the waist. An example of the orthosis is shown in Figure 5.

The major functional part of the orthosis is the beam positioned between the distal medial surfaces of the thigh and resting just proximal to the superior medial aspect of the condyles of the knees. The function of the rest of the orthosis is to hold this beam in place, and so each part of the orthosis is constructed to different standards of rigidity. The beam is constructed of three $\frac{1}{2}$ " (12.5mm) O.D. $\frac{3}{8}$ " (9mm) I.D. longitudinal struts that are cross-linked with additional short struts. At the ends of this beam are pads that rest on the thighs. These pads are free-pivoting on the end cross-linking struts and therefore are self-aligning. The anterior and posterior tubes of the beam are open-ended to allow the long $\frac{3}{8}$ " (9mm) suspension tubes to be plugged into them. The suspension tubes are continuous from the anterior beam tube, up the lateral aspect of the thigh, over the iliac crest and down the thigh again to plug into the anterior beam tube on the contralateral side. This arrangement can be seen clearly in Figure 5. The length of these tubes is adjustable where they plug into the cross-beam. These suspension tubes are held together with a waist strap and by additional straps around the proximal third of the thigh. The total weight of the abduction orthosis is 350 g.

iii) Clinical results and plans

Abduction tubular orthoses have been provided to two patients. The first patient was an eight year old child suffering from Legg-Perthes disease. This child has now used the orthosis for 24 months with continuing success.

The second patient was a four year old child who required hip stabilization following hip surgery. The orthosis was fitted shortly after surgery and it was used for two weeks post-operatively. This application was not a complete success, however, as the orthosis did not stabilize the hips adequately against rotation. Perineal care and toileting were facilitated by the orthosis

for this patient and it was suggested by therapists that this could be a prime function of the orthosis for spastic adults.

Although the clinical trials of the abduction orthosis have been limited to two patients, it is felt that potential uses of the orthosis can be defined. They are: hip abduction management in Legg-Perthes whilst permitting ambulation and other activities of daily living for the child; perineal care management for the spastic child and adult; management of burn injuries; and post-operative stabilization of the hip. Preliminary clinical trials will be expanded to these areas in order to refine the design and prove the clinical viability of the device.

d) *The shoulder abduction orthosis*

i) Structure and function

The function of this orthosis is to maintain the shoulder in an abducted position whilst the patient is ambulatory or confined to bed. The orthosis is constructed using $\frac{1}{2}$ " (12.5mm) O.D. $\frac{3}{8}$ " (9mm) I.D. tubing. Two curved sections of tubing run up the lateral aspect slightly anterior and posterior to the pelvis, the shoulder and the distal portion of the arm. This curve is given by a heat gun and can be seen clearly in Figure 6.

The angle of abduction is determined by the length of the two straight supporting tubes running from the pelvis to the distal portion of the arm. A mesh work of small rings provides a comfortable and stable cushion over the lateral

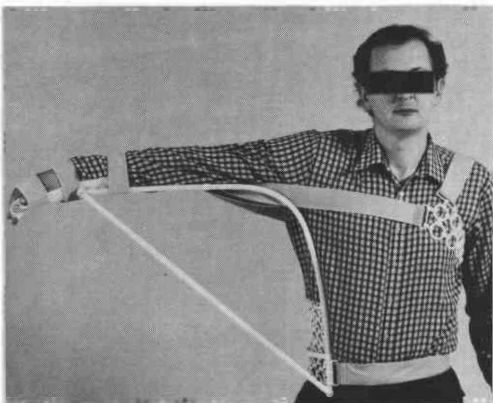


Fig. 6. The shoulder abduction orthosis is shown here on an ambulatory subject. The meshwork of rings provide comfortable pressure distribution areas under which additional padding can be inserted if desired. The angle of shoulder abduction can be altered rapidly by use of differing lengths of the straight supporting tubes.



Fig. 7. The shoulder abduction orthosis is shown on a patient confined to bed shortly after skin graft surgery. This orthosis was used whilst the patient was both prone and lying on her side.

superior aspect of the pelvis and the supporting tubes are bridged at this point by a short curving tube. The wrist/hand is supported and cushioned by a thermoplastic resting splint and secured by straps. The main strapping support is anchored to a cross-bar mid-way along the arm. Two straps run anteriorly and posteriorly to the contralateral axilla and up over the shoulder. A meshwork of rings secures the orthosis comfortably using this contralateral stabilization. A waist band provides additional security. The weight of the orthosis is 620 g.

ii) Clinical results and plans

Two patients have been fitted with this orthosis. They both had severe burns to their back, axilla and lateral abdomen as well as elsewhere on the body. One patient was ambulatory and one patient was confined to bed (Fig. 7).

Acceptance by the ambulatory patient was not good, but this could be attributed to a widely fluctuating level of co-operation. The orthosis for the patient confined to bed was constructed by the leading author working from measurements supplied by the therapist, who then fitted the orthosis in the operating room after the patient had received a skin graft to the

axilla. Adjustments to the angle of abduction were made quickly and easily in the recovery room with the use of shorter lengths of straight supporting tubes.

Wide application of this device is anticipated for burns cases, where the considerations of ease of sterilization, adjustment and access to the wounds are paramount. Clinical trials of this orthosis will be extended to post-surgical management of the shoulder as well as further burns cases.

e) *The elbow extension orthosis*

i) *Structure and function*

The function of this orthosis is to resist further flexion and reduce flexion contractures of the elbow. It is constructed of $\frac{3}{8}$ " (9mm) O.D. $\frac{1}{4}$ " (6mm) I.D. nylon tubing and a mesh of rings at the elbow. A slight curve is imparted to the lower tubes with a heat gun and the correct length of cross-bracing tubes is selected to give the desired angle of elbow flexion (Fig. 8).

Straps at the proximal and distal ends of the orthosis hold the arm into it. Additional padding of artificial sheepskin can be used to protect the elbow, although this is omitted from the figure for clarity. Pronation/supination can be controlled by the addition of a thermoplastic wrist/hand splint if necessary.

ii) *Clinical result and plans*

Six elbow extension orthoses have been fitted to patients with various types of neurological

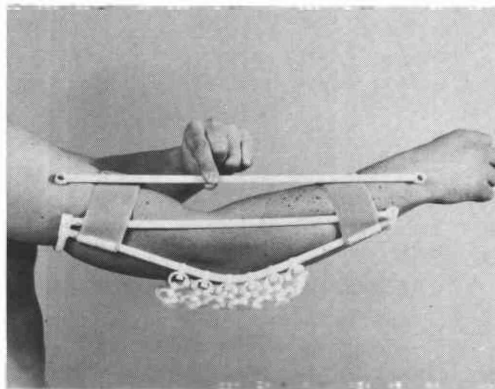


Fig. 8. The elbow flexion control orthosis is shown holding the elbow almost fully extended. The angle of flexion can be varied by using different lengths of straight tube from wrist to axilla, as shown. This tube can be pulled off and replaced quickly without any tools. The elbow is shown hanging free in the orthosis whereas a sheepskin pad is usually used.

damage. These comprise 3 head injury patients and 3 spinal cord injury patients. The head injury patients were tonic and they were fitted 8 to 10 months after injury. They had spastic flexion contractures of the order of 30–45 degrees. Regular methods of bracing had been tried and proven to be either of insufficient strength or to be otherwise inappropriate. For example, one patient had an intravenous block that prevented the use of plaster and another patient required a lightweight orthosis for daily use. The three spinal cord injury patients all had C5/C6 lesions with flexion deformities of the elbow ranging from 15 to 45 degrees. The orthoses in these cases were used on a 2 hours on, 2 hours off basis and one patient used the orthosis for sleeping in conjunction with a wrist pronation splint. The orthoses were used for an average of 2 weeks except for the patient who needed his for extended daily use.

The plans for this orthosis include an extension of the clinical trials to further cases of neurological damage and to other areas such as burns and serial casting of juvenile rheumatoid arthritis.

f) *Pressure sore relief frames*

i) *Structure and function*

The objective of this application was to explore non-standard orthotic uses of the Tubular Orthoses system in order to demonstrate the versatility of the system. Frames constructed of $\frac{1}{2}$ " (12.5mm) and $\frac{3}{8}$ "



Fig. 9. This pressure sore relief frame allowed the patient to sit in a wheelchair without weight being borne on the decubitus ulcers of his heels. The straps acting as slings were adjusted to provide correct clearance and positioning of his feet and legs. Gradual improvement in the condition of his heels has been observed over a period of 2 months.

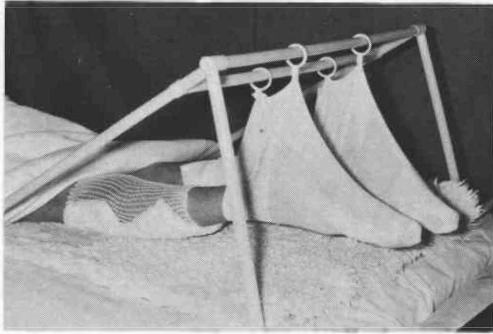


Fig. 10. Pressure sore relief frame used daily by this paraplegic patient in order to remove pressure from the anterior surface of the lower portions of his legs. He had an existing plantar flexion deformity and this did not worsen with extended use of this frame. Marked improvement of his pressure sores was achieved after alternative methods applied over a period of 8 months had failed.

(15mm) nylon tubing were used to manage cases of pressure sores in the lower limb. The function of the first orthosis was to relieve the weight of the legs from the heels of a wheelchair bound patient (Fig. 9).

The frame consists of vertical and horizontal supports to which straps are attached. These form slings for the calf and for the distal portion of the foot in conjunction with a Plastazote footplate. The heel hangs free and is unloaded. Additional protection for the toes is given by extension of the frame anteriorly.

The second patient fitted needed pressure relief to the anterior of his lower legs whilst lying prone. This was necessary as the patient, a paraplegic, also had severe pressure sores at the sacrum. A triangular based frame with cross-struts was constructed using $\frac{5}{8}$ " (15mm) tubing (Fig. 10). A stainless steel rod was inserted inside the top cross-tube to give additional rigidity.

The patients feet were suspended using prosthetic stump sheaths attached by nylon clips to the tubes. This permitted selective positioning. The ankles appear to be more plantar-flexed than was the case due to the position of the feet within the sheaths. The anterior aspects of the lower portions of the legs were clear of the bed, although this does not show clearly in the figure.

ii) Clinical results and plans

Two patients have been fitted with these frames. The second patient with the anterior leg sores showed marked improvement of these

sores after a 4 week period of use. The frame was used whilst the patient was prone for 2 hour intervals during the day with mobilization of the ankles at each time of application and removal. There was an initial plantar flexion deformity of 25 degrees and this did not show any worsening over the trial period.

The patient with the heel relief frames had decubitus ulcers of the heel due to peripheral vascular disease. He spent all of his time either in a wheelchair or in bed. Fitting of the frames resulted in a gradual improvement of his ulcers over a period of six weeks. For both of these patients alternative techniques over a period of 9 to 12 months had failed to resolve their problems. The pressure sore relief frames did give improvement of their pressure sores, they were rapid to construct (30-45 minutes) and easy to fit and adjust. Future plans include extension of the technique to other types of pressure sores, to burns cases and to post-surgical management of the lower limb.

Discussion

The construction techniques of Tubular Orthoses allow a diversity of orthoses to be constructed from the same basic components. Prototypes have been constructed of an upper limb orthosis to manage the MCP joints post-operatively, a resting frame for protection of the knee, and an ankle-foot orthosis for use as a dorsi-flexion assist. Although these devices have been tried on ourselves, they have not yet entered the clinical trial stage and no prescription criteria can be defined. However, it is anticipated that many diverse applications of the Tubular Orthotic approach will emerge as the technique is accepted.

The patients, the prescribing physicians, the orthotists and the therapists involved in fitting Tubular Orthoses have responded positively to these new devices. The patients who had had experience with other types of spinal and cervical orthoses remarked on the lightness of the orthoses, the coolness and the improved appearance. Some patients indicated that greater comfort was experienced than with their existing orthoses. Most frequently expressed was the coolness of the cervical orthosis, compared to existing all-enclosing orthoses. The orthotist participating in the trials of the spinal orthoses was very enthusiastic and supportive of this new device. The elbow and shoulder orthoses have

been well-received by therapists, who appreciate the ease of making angle adjustments and the facilitation of access to the skin. Although the trials of the abduction orthosis have been limited, the appropriateness of the design was well demonstrated by the eight year old child. She was able to compete in her school sports day and to carry out other normal activities of a child her age. The pressure sore relief frames demonstrate that custom devices can be readily fabricated from standard tubular components and it is anticipated that a wide variety of these types of frames will emerge. Co-operating physicians gave a response that varied from enthusiasm and a willingness to continue prescribing the orthosis to that of a neutral opinion because of a lack of sufficient experience with the orthoses.

The advent of Tubular Orthoses presents an opportunity to develop a family of orthoses that will set new standards for orthotics. The management principles defined by Tubular Orthoses are those of speed of provision and adjustment of improved orthoses through the use of mass-produced interchangeable components. The adjustable nature of the orthoses permits them to be fitted in a clinical setting, so reducing the need for repeat visits at the initial fitting stage. In these ways the labour costs of supplying an orthosis are reduced. The material costs are reduced by the use of inexpensive standard nylon or polyethylene tubing readily available from plastics distributors. Additional inexpensive plastic

junction components are being designed and moulded and these will be commercially available. These materials and techniques allow the orthoses to be quickly adjusted, thus allowing them to be used for evaluation purposes in the clinic before prescription. The exploitation of modern materials such as thermoplastics and modern techniques such as injection moulding can greatly enhance the field of orthotics to the benefit of patient and clinician alike.

Development and clinical trials of Tubular Orthoses are continuing and as the preliminary clinical trials are completed for each orthosis, instructional literature and journal articles will be prepared. This will include fabrication and fitting procedures, together with prescription criteria and biomechanical analyses of the function of each orthosis. In parallel to these activities will be the closer examination of the containment and interface requirements, resulting in a comprehensive modular exoskeletal system.

Acknowledgements

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