CLINICAL EVALUATION OF THE SELF-FITTING MODULAR ORTHOSES BY SPASTIC PARAPLEGICS

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Abstract: This paper attends to present advantages and drawbacks of the so called Soft-suit technology in the rehabilitation of the spastic paraplegic patients. The favourable distribution of pressures, light weight, no pelivc band need, self-fitting, self-adjusting, self-lifting are the essential characteristics of the SFMO. The preliminary clinical evaluation with the SFMO laboratory prototypes provides the application possibilities of such an orthotic device by spastic paraplegics with the same indications and in the same manner as the long leg braces.

I INTRODUCTION

The self-fitting modular orthoses (SFMO) is an assistive device developped as a result of a new approach to the rehabilitation engineering, the so--called "Soft-suit technology" /1,2/ and biomechanical analysis of the man-machine systems /3,9/. The development of the modular, adaptive, active orthotic device is based on the logical control /4,5,6/ and the soft (elastic) man-machine interface /7,8,9/.

In the previous works /11/ the attention was devoted to the analysis of the man locomotion activities. Man's body and extremities, as well as the orthosis were treated as a multi-link, rigid system. The biomechanical analyses treat the man as a rigid link model, as well as the modules of the SFMO, but the connection is assumed to be elastic with damping elements. The first order elasticity is taken into account. Soft-suit fixation allows the distribution of pressures and forces and does not use the three point fixation principle. The elastic torques and forces are necessary for the real modeling of the hybrid biomechanical system.

The biomechanical structure assumed for the analyses (Fig. 1) is a complex hybrid system, consisting of the biological part of the system, the man's

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body and lower limbs, and the machine, orthoses modules. The eight-segment rigid kinematic chain is used as a model of the man, and the 5th class kinematic pairs with translation and rotation are provided for the SFMO modules (Fig. 2).
The Institute for rehabilitation "Dr Miroslav Zotović" in Belgrade has a thirty-years experience in rehabilitation of paraplegics, hemiplegics and other severly handicapped persons. Our experiences with lower limb extremity bracing are mainly unsatisfactory and we felt that new ideas in this field are necessary and wellcome.

A project of clinical and technical evaluation has been initiated in our Institute for various groups of patients with impaired functions of the lower limbs.

The first tested group is that of spastic paraplegics, and preliminary results are presented in this paper.

A part of the rehabilitation program for paraplegic patient is a training to stand or walk with lower limb braces. Standing is considered important due to the following reasons:

1) to minimize the development of osteoparesis of the long bones of lower limbs,
2) to stimulate the circulation,
3) to promote satisfactory renal and bladder function,
4) to prevent contracture in hip and knee joint,
5) to reduce spasticity.

Depending on the level of transversal lesions to the spinal cord i.e. when parts of trunk and lower limbs muscles are impaired, paraplegics can stand or walk between parallel bars only or with the crutches.

Some authors /12/ consider that the patient whose lesions is at the upper or mid-thoracis level (till Th 10) and who has a full invervation of upper extremity muscles and varying degrees of upper back, abdominal and intercostal inervation may be braced for standing and walking between parallel bars only.

The patient whose lesion is bellow Th 10, with full inervation of abdominal

and uper back muscles and respiratory reserve can expect to walk functionally with long leg braces crutches.

Functional walking is defined as a daily use of braces for practical mobility. Some recent follow-up studies /13/ about the paraplegics use of walking braces set some more severe criteria that hip hikers, full abdominal and lumbar back extensors are the minimum requirments for functional walking by paraplegics.

Obviously, the walking capabilities of paraplegics are limited, but those capable of walking with the braces and crutches greatly increase their possibilities in daily activities and at the working place.

II METHOD

We applied the SFMO to 14 patients with spastic paraplegia in the period from October 1, 1980. till May 1981.

One clinical function test included:

a) medical data (Appendix I) where the age, sex, weight, height, main diagnosis, other diagnosis of interest for locomotion, the number of the years and months since the injury/desease, neurologic level of injury, spasticity level, ambulation status, intellectual level, and motivation for bracing were registered,
b) clinical evaluation of the use of the SFMO (Appendix II). The time was measured how fast the patient was able to put on the orthoses, the duration of the necessary training in the use of the orthoses, control of the pressures on the skin (experimentally and clinically), testing of balance, ambulation with the SFMO and complications if any were noted,
c) the application process review. The application of the orthoses was described, step by step, pointing out special difficulties and the particular necessary individual adjustment. The time necessary for the complete application was registered too.

If the patient previously had been using the clasical long beg braces the functional results were compared with the SFMO.

After the test every patient was interviewed with respect to the advantages and drawbacks of the SFMO in comparison with the classical long leg braces or splints.

III RESULTS

The majority of our patients (11 out out of the total 14) suffered from the spinal cord injuries. The others were diagnosed as myelitis transversalis (two of them) and absecessus epiduralis (one). The male to female ratio was 10 : 4. The average age at the time of testing was 24. The average time since the injury amounted to 16 months. According to the level of muscle functions nine patients were classified in the first group (Th 2 - Th 10) and five (Th 11 - L 2) in second group. Their ambulatory state was as follows:
a) five standing between parallel bars,
b) seven walking between parallel bars (more than two lengths of the bars), and
c) two walking with long leg braces and crutches less than 50 meters.

The intellectual level and motivation for the use of the SFMO was average and above average.

Application of the SFMO. Except for the mechanical elements the conventional jeans and high shoes are all the patient needs. The adjustment of the trousers consists of patching the textil parts and Welcro tapes on the right posttion, and depatching of the inner side of the trouser legs. The trousers have to fit the patient very tight, so that the taylor's help is needed. This adjustment is the essential part of the application. If the fitting of trousers is uncorrect the possibility of use of the SFMO is extremily limited. The inserting of the pin in to the heel of the shoes is the only adaption of the shoes. The metal elements of the SFMO are prefabricated using self--fitting principle. According to the body forms the plastic pieces (patellar cap and pelvic support) have to be fitted. The light termo-plastic material is used for mentioned pieces.

Results of the clinical function tests show that two or three therapeutic sessions are sufficient for the patient to learn the mounting process of the SFMO.

During testings the patients needed 10-20 minutes for putting on the SFMO independently, or 5 minutes with the somebodys assistance.

The immediate use of the SFMO is possible if the patients were trained for standing or walking with splints or long leg braces.

The parametric pressure field of the man machine interface (Fig. 3.) by the application of the SFMO was measured and calculated.

Examination of the skin after the 6-hours use of the SFMO didn't show any sign of skin impairment.

Due to the rigidity reasons the classical orthosis give the better balance results in comparison with the SFMO.

All the patients were able to walk between the parallel bars (Fig. 4.) with the SFMO. The same two patients, who were trained to walk with long leg braces and crutches could walk with SFMO longer distances with four point gate type of motion.

IV DISCUSSION AND CONCLUSIONS

The SFMO could be applied as an orthotic device by spastic paraplegics with the same indications and in the same manner as the long leg braces.

The biomechanical approach to the construction of lower limb assistive devices provided the possibility of designing the orthosis as a lateral mechanism with the soft connections with the man's body. Such an interface leads to a favourable distribution of pressures. The over all sizes of the mechanical links are extremely small, and the weight of the whole system is under 3 kg.

As it was previously mentioned the prefabricated elements, conventional jeans and shoes makes possible cheap and fast application of the SFMO. The fixation problems of the knees arises from such an approach. It has been noticed that some antropometric measures (male and female, slim and fat etc.) have to be considered.

Because of the state of the art of used SFMO prototypes the process of fitting and adjusting for our 14 patients took a few weeks. The manufacturing of the classical braces takes at least three times longer in our conditions.

All the patients were tested with just two prototypes. This is important to mention because the patients weight varied between 47 and 65 kg, and the height from 1,60 to 1,85 m.

All the patients quickly learned the mounting and use of the SFMO.

SFMO does not require pelvic band.

The possibility of self-lifting, using additional device to the SFMO, is a new quality in orthotics which has not been achived by using existing system The self-lifting could be done only by paraplegics with upper-lumbar level of injury.

Having in view the opinions obtained from the interviews it was possible to conclude that patients were satisfied with design, weight and sizes of the orthoses and with the possibility of self-lifting. They were unsatisfied with "soft knees" (smooth knee flexion in the standing position) because of the feeling of instability. From our point of view this feeling results from short period of training and using the SFMO and the fact that the patients were habituated with rigid assistive devices (splints).

At the end we would like to point out briefly the advantages and drawbacks of the SFMO in bracing spastic paraplegics.

Advantages:

- low weight,
- soft interface,
- immediate application,
- self-lifting,
- prefabrication of mechanical elements,
- simple and cheap servicing,

- portability.

Shortcomings:

- the biomechanical requirments for the group of patients do not need all the possibilities of the SFMO,
- the technological level of the prototypes is unsuffucient,
- the variation in weight of the patient (more than 5 kg) requires the trousers adjustment for correct use,
- the fixation of knees is insatisfactory in the group of patients with intensive flexion spasms.

The authors are them-selves involved in such an investigation and hope that preliminary results reported here will encourage others to contribute in this aspect of clinical evaluation of the self fitting modular orthosis and in the biomechanical modeling of the man-machine systems.

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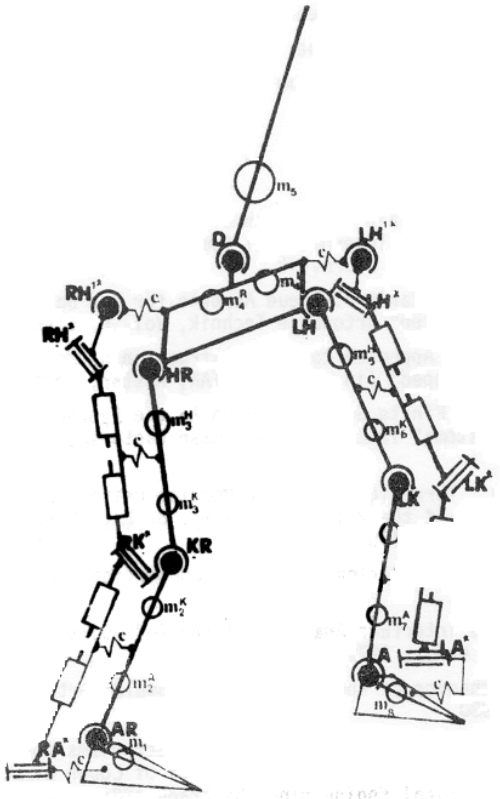

Fig. 1 The biomechanical model of the SFMO.

Fig. 4 Patients using SFMO in the Institute for Rehabilitation "Dr M. Zotović", Belgrade.

APPENDIX I

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MEDICAL DATA PAT.NAME ..... DATE .....

1. Age ..... Sex .....
2. Height ..... Weight .....
3. Main diagnosis .....
4. Other diagnosis related to locomotion (heart-failure, bone deformity, etc.) .....
5. Number of months/years since injury/desease .....
6. Ambulation set: a) whealchair
   b) standing between parallel bars with braces
   c) walking between parallel bars with braces
   d) walking with braces and crutches

7. Muscle function (note the level of injury. The patients are classified into two groups according to the classification by Ch.Longe /12/:I group- upper thoracal level (TH_2-TH_{10}): I I group middle thoracal -upper lumber level (TH_{11}-L_2)

   Level
   I Group
   II Group

8. Spasticity (A note was made also on the type of spasms ext. or fl.)

   Mild
   Medium
   Strong

9. Intellectual level

   Below verage
   Average
   Above average

10. Motivation for the use of the SFMO

    Below average
    Average
    Above average

APPENDIX II

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CLINICAL FUNCTION TEST PAT.NAME ..... DATE .....

1. The time for training to put on the SFMO (measured in therapeutic sessions) .....
2. Time for putting on the SFMO
   a) independently .....
   b) with assistance .....
3. Time of training for:
   a) walking between the parallels bars .....
   b) walking with crutches .....
4. Control of the pressure on the skin:
   a) experimentally (the pressures are measured using special pressure transducer. The temperature compensated Wheatstone circuitry is used for dynamic measuring during different patterns of motion. The simultaneous measuring of the 18 points is done. Using experimental data the pressure field of the man-machine interface is obtained in a function of time)
   b) examination of the skin after 6 hours of SFMO use:
5. Balance testing (standing between parallel-bars with both hands up for 5 sec.)
   good ○
   medium ○
   bed ○
6. Ambulation with the SFMO
   a) standing between parallel bars ○
   b) walking between parallel-bars ○
      (at least two lengths of the parallel bars).
      Two point gate ○
      Four point gate ○
   c) walking with crutches ○
      over 50 m ○
      less over 50 m ○

Notes of the examiner: .....