

CLINICAL AND TECHNICAL TESTING OF HAND ORTHOSES

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SUMMARY

The testing of hand orthoses sponsored by the Swedish Institute for the Handicapped at EFTO is performed according to the test instructions for each specific hand orthosis, wrist-driven, finger-driven, etc. The clinical testing follows a special routine where a medical record of the patient notes specific data regarding the hand orthosis: diagnosis, loss of function, sensitivity, social and psychological factors, vocation, etc.; various kinds of technical aids; application routine; training method. The improvement in function and patient independence is checked against the list of Activities of Daily Living.

Patients with active dorsal flexion in the wrist can often be helped by a wrist-driven hand orthosis. Six wrist-driven hand orthoses have been tested. The most important result is that wrist-driven hand orthoses must have adjustable grip width for the same dorsal flexion. Thus, four of the six orthoses were excluded. The two recommended are from Orthotic Systems, USA and from Jaeco Orthopedic Specialties, USA. Patients with drop-hand are prescribed externally powered hand orthoses. Three power units have been tested and two are recommended: Hosmer/Dorrance, USA and Een-Holmgren Orthopaedic, Inc., Sweden. The technical type test includes an examination and dimensional inspection, mechanical tests, climatic tests, and durability (extended life) tests.

One self-contained hand orthosis powered with the Een-Holmgren Actuating Unit has been tested and recommended for prescription.

Our test records are checked against our requirement specifications for each type of aid. When our requirements are fulfilled, the orthosis is recommended.

INTRODUCTION

Clinical and technical testing of orthoses for people with paralysed hands have been in progress at the Unit of Applied Orthotics (EFTO), Department of Rehabilitation Medicine, Central Hospital, Jönköping, Sweden, since 1971 at the request of and financed by the Swedish Institute for the Handicapped. EFTO was established by Dr L G Ottosson, former head of this clinic. He moved in 1976 to Regional Hospital, Linköping. We are grateful for the contribution he made to our work.

Evaluations of hand orthoses have been made at different times and different clinical centers. Most of them have in common a lack of test instructions which give the test methods and test routines. This makes it difficult to assess the test results. However, there are many valuable reports [1,2,3,4,5].

CLINICAL FUNCTION TESTING

The clinical function testing of hand orthoses is performed according to the test instructions for each specific category of hand orthosis, wrist-driven, finger-driven, etc. 6,7,8 . It follows a special routine where a medical record of the patient and specific aspects regarding the hand orthoses are noted. It is important that the patients are not permanently fitted with complicated technical aids before the possibilities of improving function by training have been utilized. An approximate evaluation of the training state has therefore been made before each application of an orthosis.

The majority of our patients had spinal cord injuries caused mostly by traffic accidents. A classification has been made of the level of injury:

<u>Lesion level</u>	<u>Muscle function</u>	<u>Orthosis</u>
C 4	Head movements Scapular movement Diaphragm respiration	Balanced forearm orthosis + externally powered hand orthosis
C 5	Shoulder joint motion Elbow flexion Supination	Externally powered hand orthosis
C 6	Latissimus dorsi Pectoralis Wrist extension	Wrist-driven hand orthosis

Fig 1

Classification of muscle function into level of spinal cord injury.

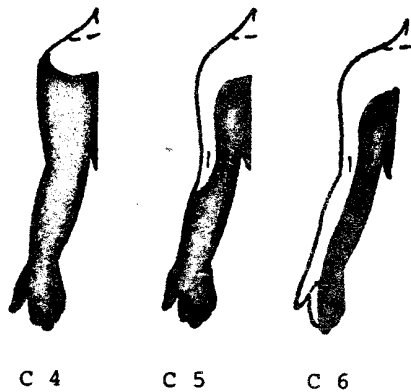


Fig 2

Sensitivity impairment for different levels of spinal cord injury.

In most cases of spinal cord injuries, the sensitivity impairment corresponds to the different levels of lesion according to fig 2.

Sufficient psychological adjustment, intellectual capacity, and motivation are important factors and were evaluated as being below average, average, or above average. The patient's living environment, occupational environment, and the like have been briefly described.

Usage of various kinds of technical aids was noted and the patient's function without an orthosis was estimated considering the neurological handicap.

The required time for the patient to put on the orthosis without help was estimated at the follow-up examination. Activities that the patient can perform only when using an orthosis were evaluated, but only such activities which are useful or valuable in activities of daily living, such as work, studies, hobbies, etc. Constructed test activities were considered to be of minor interest in this connection.



Fig 3

Jaeco's finger-driven band orthosis fitted with an Een-Holmgren actuating unit. The power unit is controlled by a rocker switch with built-in batteries. The orthosis is controlled by pro-supination.

Sometimes a patient can manage certain activities without technical aids, or with conventional aids, but with a hand orthosis he can considerably facilitate the activity in question. Such practical activities have been mentioned under this heading.

Finally, the amount of time that the patient generally used his orthosis was stated. Ex.: short periods several times a day, at every meal, in all two hours a day, etc.

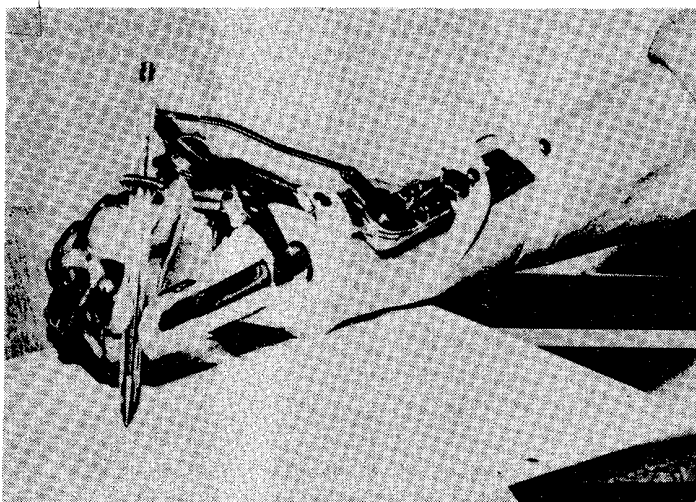


Fig 4

Jaeco's wrist-driven hand orthosis for writing.

The clinical testing of wrist-driven hand orthoses has proved that the best functional effect is obtained with an adjustable grip width for each degree of dorsal flexion. By appropriate adjustments it is possible to handle both large and small objects with maximum efficiency of wrist power and position for each particular object.

CLINICAL RESULTS

In total, 43 patients have been fitted with wrist-driven or electrically powered hand orthoses. Unfortunately, all of them have not been involved in the testing program. In 1973, however, a follow-up study of the first 15 patients fitted by us was made by the Institute for Gerontology in Jönköping [20]. They found that 9 of the patients were regular users of the orthoses.

Of 16 patients supplied with the Een-Holmgren actuating unit 9 are regular users, according to our own follow-up study.

TECHNICAL TYPE TEST

The technical type test includes inspection, mechanical testing with inspection of function and stability for different pinch forces, etc., shock tests, climate testing with change of temperature, and durability testing checking how many grips the orthosis can perform with a specified grip force and at different widths.

The application routine is checked.

Cosmetic aspects are assessed.

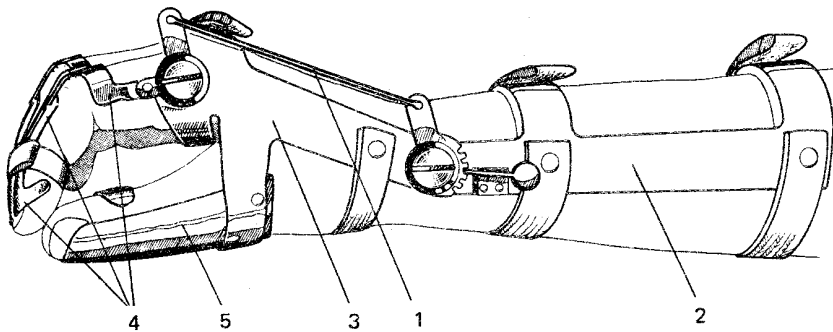


Fig 5

Wrist-driven hand orthosis.

- | | |
|------------------|-----------------|
| 1. Parallel bar | 4. Finger piece |
| 2. Forearm piece | 5. Thumb post |
| 3. Palm piece | |

Of nine commercially available wrist-driven hand orthoses the first six have been tested. The nine orthoses are:

1. Dorsi-flexion Prehension Splint from Hugh Steeper Ltd., England
2. Wrist-driven Flexor Hinge Splint from Orthomedics, USA
3. Reciprocal Wrist Extension Finger Flexion Orthosis from Orthotic Systems, USA
4. Flexor Hinge Hand Splint Wrist Actuated Less Adjustable Actuating Lever from Jaeco Orthopedic Specialties, USA
5. Flexor Hinge Hand Splint Wrist Actuated With Adjustable Actuating Lever from Jaeco Orthopedic Specialties, USA
6. Wrist Driven Flexor Hinge Hand Splint from Robin Aids, USA
7. Rancho Hand Splint from Hosmer/Dorrance, USA
8. Wrist Driven Prehension Orthosis from Sabolich Orthopedic Plastic Components Company, USA
9. Reziproke Handorthese from Johann Radl KG, Austria

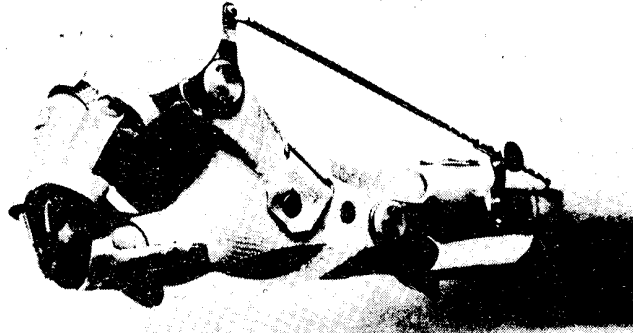


Fig 6

Reciprocal Wrist Extension Finger Flexion Orthosis, Orthotic Systems, USA.

Only two of these six orthoses have been recommended for prescription. These two are:

1. Reciprocal Wrist Extension Finger Flexion Orthosis, Orthotic Systems, USA
2. Flexor Hinge Hand Splint Wrist Actuated With Adjustable Actuating Lever, Jaeco Orthopedic Specialties, USA

The tests are described in EFTO-reports Nos. 6/73 and 8/77. No. 8/77 is in English [9,10].

A test of an orthosis need not necessarily include all the points listed. The extent to which partial inspection methods can be applied according to the experience gained is assessed for the different types of orthoses. Each category of orthosis has its own test instructions: Proposed test instructions for wrist-driven and finger driven hand orthoses, and for electrical power units for hand orthoses [6,7,8].

The test results are listed in a test record and are checked with the requirement specification for each category of orthosis. The requirement specification contains requirements and needs regarding the construction and design of the aid. A proposed requirement specification for wrist-driven hand orthoses is given in English in EFTO-report No. 7/77 [11].

The most important requirement in the testing of wrist-driven hand orthoses is that the orthoses must be able to grasp objects of different widths for each degree of dorsal flexion of the wrist. This requirement was fulfilled only by the two recommended orthoses.

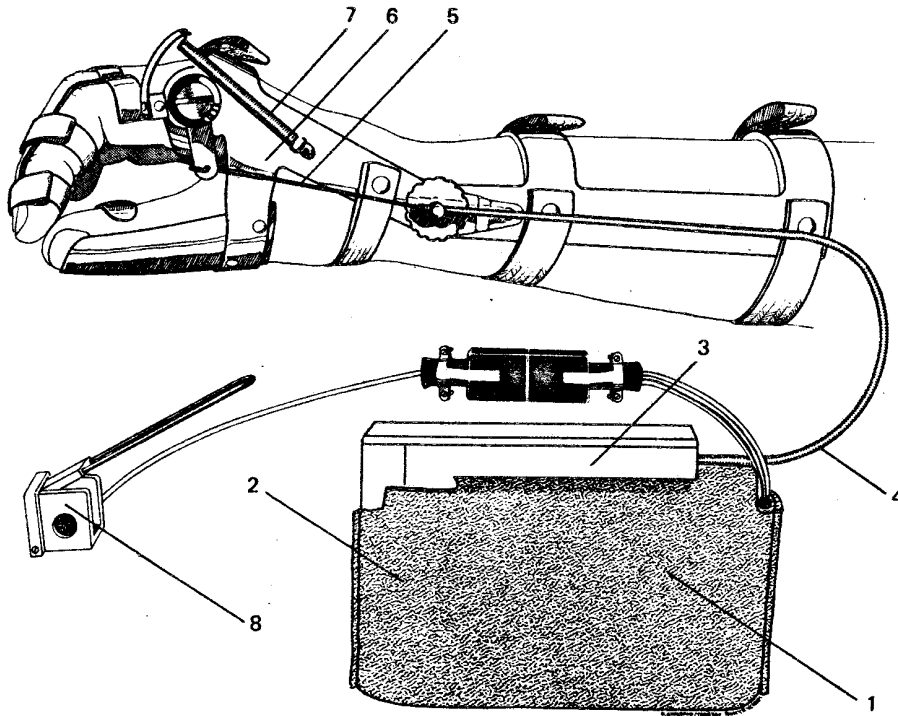


Fig 7

Hand orthosis with electrical power unit, Hosmer/Dorrance, USA

- | | |
|-----------------|------------------|
| 1. Battery | 5. Wire |
| 2. Motor | 6. Hand orthosis |
| 3. Winch | 7. Spring |
| 4. Bowden cable | 8. Control unit |

Finger-driven hand orthoses have been used with electrical power units to obtain externally powered orthoses. Two of three commercially available orthoses suitable for motorization have been tested and recommended:

1. Finger-driven Flexor Hinge Splint from Orthomedics Inc., USA
2. Flexor Hinge Hand Splint, Finger Actuated, from Jaeco Orthopedic Specialties, USA

There are four commercially available power units for hand orthoses. They come from:

1. Hosmer/Dorrance, USA
2. Viennatone, Austria
3. Een-Holmgren Orthopedic Inc., Sweden
4. Sabolich Orthopedic Plastic Components Company, USA

The test of the power unit from Hosmer/Dorrance together with the tests of finger-driven hand orthoses is reported in EFTO-report No. 2/74 (in Swedish) [12]. The clinical testing of the Een-Holmgren actuating unit has just recently been completed.

The power units from Hosmer/Dorrance and Een-Holmgren have undergone durability testing. They were run through a working period with the following cycle repeated:

full speed closing
2 sec. stall current
4 sec. rest
full opening
0.5 sec. rest

Three Hosmer/Dorrance power units were tested this way. They made about 100,000 grips when the test was stopped.

The Een-Holmgren actuating unit has been tested during the final development stage where the different details in its construction were decided. The last power unit which could be considered as a prototype but was nevertheless produced in a series of 30 units, was tested with very good results and its construction was decided according to this test. The Een-Holmgren actuating unit Mark II for 6 V has been tested the same way. This power unit has been manufactured in 50 pieces and the sample has been taken from the serial. The power unit broke down after a working period of about 30,000 cycles.

When defining lifetime in durability testing, it is important to know how much the orthosis is used. The lifetime defined must be related to the actual using time by the patient.

An important task for a testing unit like ours is to find out the connection between the theoretical specifications and actual values from the applications in practice. For about a year now 4 hand orthoses have been equipped with the "event counter system" from Karolinska Hospital [18]. Each patient wears a small counter which counts every opening of the orthosis.

The patients have used counters for a period of about 15 months each. On the average they have performed 21 grips per day. This means, if we expect the orthosis to withstand 50,000 grips, that it should function without breakdown for 6.5 years.!

The durability testing in the laboratory is probably far too severe. Our clinical experience reveals that we have had only one fault in the actuating unit after discharge of the 16 patients involved in the testing. A more common problem is that of cables and connectors which have been failing during the testing but with still not more than one fault per patient and year.

The Een-Holmgren actuating unit and the power source can be built into a self-contained hand orthosis. It is made of moulded plastic with a modular system for the finger piece, palm piece, and forearm piece, much inspired by the Engen modular system.

However, it is made of flexible plastic which becomes more flexible by the body temperature. In order not to lose the shape of the orthosis it is reinforced with stainless steel bars. Testing of this orthosis is still in progress.



Fig 8

The Een-Holmgren Compact Externally Powered Hand Orthosis can be controlled by two push-buttons on the orthosis or as here by an external control unit.

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