

CLINICAL EVALUATION OF PROSTHETIC AND ORTHOTIC DEVICES AND TECHNIQUES

A PILOT PROGRAM

NATIONAL ACADEMY OF SCIENCES

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CLINICAL EVALUATION OF PROSTHETIC AND ORTHOTIC
DEVICES AND TECHNIQUES

REPORT OF A PILOT PROGRAM*
CONDUCTED BY THE
COMMITTEE ON PROSTHETICS RESEARCH AND DEVELOPMENT
DIVISION OF ENGINEERING-NATIONAL RESEARCH COUNCIL

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SUMMARY FINDINGS

The program of evaluation as planned and implemented in this study effectively identified the strengths and weaknesses of a selected experimental orthotic item.

When applied with care to suitable patients who were followed conscientiously after fitting, the three adaptations of the Engen Plastic Hand Orthosis, which were the subject matter of the evaluation, proved to be valuable additions to the armamentarium of devices available for treatment of hand disabilities.

CLINICAL EVALUATION OF PROSTHETIC AND ORTHOTIC DEVICES AND TECHNIQUES

A PILOT PROGRAM

BACKGROUND

Under Contract SAV-1053-67, between the Vocational Rehabilitation Administration and the National Academy of Sciences, which became effective September 1, 1966, the Academy agreed to conduct a Pilot Program for the clinical evaluation of prosthetic and orthotic devices under the aegis of the Committee on Prosthetics Research and Development.

Two orthotic items were selected as the foci of the pilot program--the Baylor (Engen) Hand Orthosis and the University of California Dual-Axis Ankle-Control System. Each of these items was to be evaluated through three to five treatment centers selected and recruited for that purpose. Subsequently the Veterans Administration Prosthetics Center Patellar-Tendon-Bearing Brace was substituted for the UCB device as the second item in the pilot program.

The present report presents the procedures and outcomes of the initial study, that of the Engen Plastic Hand Orthosis (EPHO). The results of the VAPC PTB Brace evaluation will be the subject of a later report. However, findings to date which reflect on the purposes of the field study are essentially the same as those presented here.

DESCRIPTION

The Engen Plastic Hand Orthosis was developed by Thorkild J. Engen, Director of the Orthotic Department, Texas Institute for Rehabilitation and Research, Houston, Texas, under Research Project RD-1564 with the Vocational Rehabilitation Administration. The development of this orthosis or hand splint was predicated on the assumption that preservation of hand posture is best maintained by support from the volar aspect rather than suspension. Various versions of the device are designed to hold the thumb in apposition and simultaneously to support the metacarpal arch. The aim has been to develop a standardized item (Fig. 1) shaped to conform to the natural contours of hands of various sizes. These



Fig. 1. Basic Engen Plastic Hand Orthosis being prepared for individual application.

standardized or shelf items are then adapted to the needs of individual patients. Initially, the orthosis was made in three sizes but an additional size was added in the course of the evaluation program. Thus, the sizes now available are small, medium, medium-large, and large; and units are available for both right and left hands. The Engen equipment was designed primarily for adult patients but the smaller sizes might also be suitable for older children.

The three versions or adaptations of the Engen plastic hand orthosis selected as the subject of the field evaluation were: the short opponens orthosis, the long opponens orthosis, and the reciprocal wrist-extension, finger-flexion unit. Additional modifications of the basic concept involving the use of external power were specifically not included in the study.

SHORT OPPONENS ORTHOSIS

The so-called short opponens orthosis is the simplest application or adaptation of the Engen equipment. It consists essentially of the basic hand shell with a retaining strap (Fig. 2). The prime purpose of this device is to maintain the thumb in apposition to the index and long fingers and to support the metacarpal arch. The functional goal is the



Fig. 2. Two views of the short opponens orthosis.

achievement of "three-jaw-chuck" prehension as distinct from "lateral" grasp. Patients said to benefit from this orthosis are those with neuromuscular disorders resulting in various degrees of muscle imbalance of the intrinsic and opponens muscle groups. Such patients would typically have spinal cord injuries at the C-7, C-8, and T-1 levels, peripheral neuropathy (ulnar and median nerves) or hemiplegia.

LONG OPPONENS ORTHOSIS

This adaptation consists essentially of the basic plastic hand shell with an attached extension arm which is stabilized on the forearm by appropriate straps (Fig. 3). Like the short opponens orthosis, this device is designed to prevent deformity and achieve "three-jaw-chuck" prehension if the necessary residual muscle movements are present and can be controlled. Patients with spinal lesions at the C-5, C-6 levels, peripheral neuropathy involving the median and/or ulnar nerves and the radial nerve, or hemiplegia, are said to be suitable candidates for this device.

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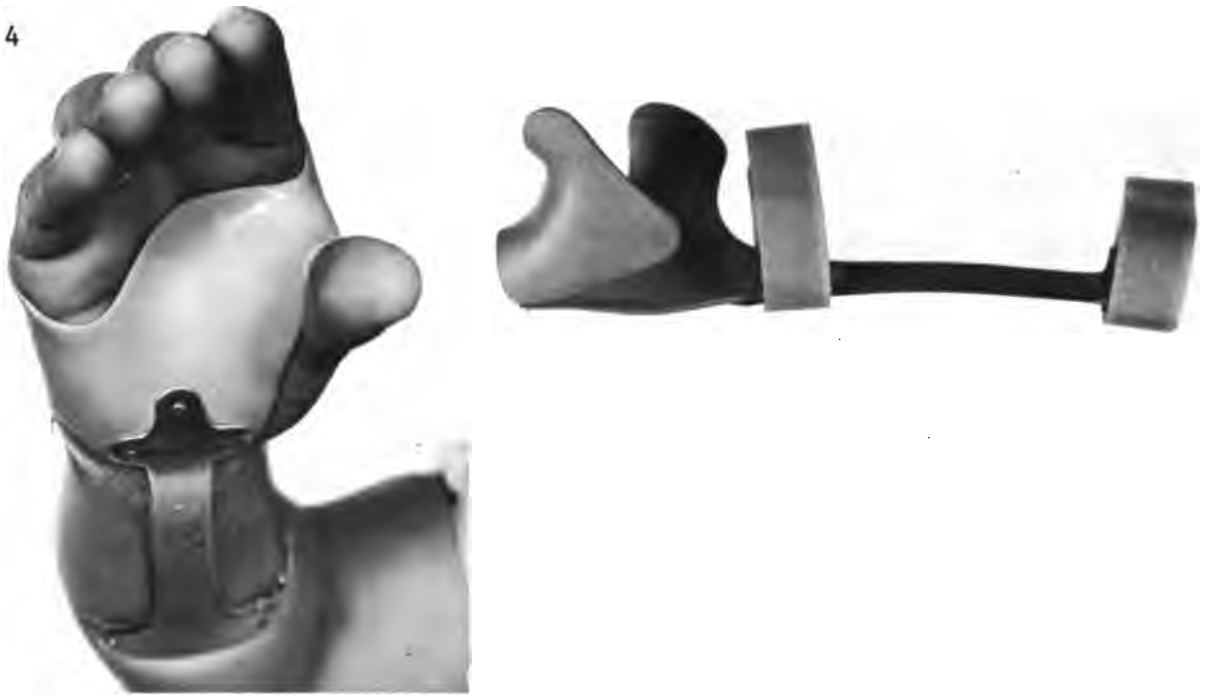


Fig. 3. Two views of the long opponens orthosis.



Fig. 4. Two views of the reciprocal orthosis.

RECIPROCAL WRIST-EXTENSION FINGER-FLEXION ORTHOSIS

This adaptation, which is the most complex of those studied, is designed to provide prehension when voluntary wrist-extension power is available (Fig. 4). Quadriplegic patients who retained innervation to the wrist extensor muscles are said to be appropriate subjects for this type of functional orthosis.

PROCEDURES

PARTICIPATING CLINICS AND PERSONNEL

As an initial step in the activation of the proposed field study, the Committee on Prosthetics Research and Development, through its staff and Subcommittee on Evaluation, selected five treatment centers known to be active and interested in the application of hand splints. These clinics were approached and each agreed to participate in the study. The institutions and personnel involved were:

1. Duke University Medical Center, Durham, North Carolina (Frank W. Clippinger, Jr., M.D.; Bert R. Titus; Felton Elliott)
2. Georgia Warm Springs Foundation, Warm Springs, Georgia (Edward Haak, M.D.; H. G. Bowden)
3. Highland View Hospital,* Cleveland, Ohio (Alvin A. Freehafer, M.D.; Arthur Guilford, Jr., G. A. Guilford and Sons)
4. Ohio State University, Columbus, Ohio (Marvin H. Spiegel, M.D.; Lawrence Czap; Charles W. Rosenquist, Columbus Orthopaedic Appliance Co.)
5. Veterans Administration Hospital, Hines, Illinois (James F. Kurtz, M.D.; Vladimir T. Liberson, M.D.; Walter J. Piotrowicz, C.O.)

**Unfortunately, the Highland View Hospital team had to withdraw prior to the commencement of the study. It was replaced by a team from Rancho Los Amigos Hospital consisting of E. Shannon Stauffer, M.D., and Dale Fries, orthotist. In the course of the study, Mr. Fries transferred to another position and was replaced by Mr. Charles Sigars.*

INSTRUCTION IN FABRICATION PROCEDURES

The study of the Engen devices was initiated by an instructional course in the three applications to be evaluated. This course was conducted by the developer and his staff at the Texas Institute for Rehabilitation and Research, Houston, Tex., from Dec. 5-8, 1966 (orthotists - four days; physicians - one day). Instructional material and fitting check lists were prepared by the developer (1,2,3), and used as the basis for the course. A special training session for Mr. Sigars was conducted December 4-6, 1967, after he joined the Rancho Los Amigos Hospital team.

THE STUDY PLAN

Concurrent with the recruitment and training of participating clinic personnel, the CPRD staff, in collaboration with the developer, and under the guidance of its Subcommittee on Evaluation, prepared the schedule and data-recording forms for the study (Appendix A).

Essentially, each clinic was requested to seek patients appropriate for applications of the Engen devices. Data related to the fittings would be recorded on the forms developed by the Committee on Prosthetics Research and Development. Each patient fitted was to be followed for a period of 12 months unless treatment was terminated prior to that time. The CPRD staff was to provide liaison with the field clinics as necessary during the course of the study.

RESULTS

TECHNIQUE TRANSFERABILITY

With a new fabrication or fitting technique which is said to yield excellent results in the hands of the developer, an important consideration is whether or not the skill and "know-how" involved in the applications can be successfully transferred to others.

In the present study the means of achieving this transfer were:

- 1) Written instructional material prepared by the developer;
- 2) A course of instruction which included practice in the fabrication of devices; and

3) Follow-up visits made by the developer to each participating facility. Problems encountered locally were analyzed and supplementary instruction given.

It was the consensus of the evaluation team as well as that of the participants that the fabrication techniques for the three EPHO adaptations under study were successfully transmitted by these procedures. Moreover, while the orthotists participating in the evaluation were selected and highly skilled, indications were that less skilled technicians could be satisfactorily taught by the same methods.

CLINIC COOPERATION

Five clinics were initially recruited as participants in the field evaluation program. When one of these clinics was forced to withdraw prior to the commencement of the study, a sixth institution was secured as a replacement. All clinics invited promptly accepted the invitation. No invitation to participate was rejected. This experience would indicate that the enlistment of treatment clinics to cooperate in field application studies conducted by the Committee on Prosthetics Research and Development presents no problems.

Nevertheless, it should be noted that despite their interest in research and in the item under evaluation, the essential business of these clinics is the treatment of patients. Hence, it is highly desirable that maximum stimulation, encouragement, and assistance be given the cooperating clinics in meeting the requirements of the field evaluation program. In the present study, the visits to the clinics by the developer and/or CPRD staff and members were of material assistance in this connection. Such visits should be a standard procedure in the clinical study program. Ideally they should be made 1) shortly after the commencement of the fittings at each individual clinic, and 2) at periodic intervals thereafter (perhaps on a quarterly basis).

PATIENT FITTINGS

A. The Sample

Twenty-two patients were fitted with the Engen Plastic Hand Orthosis during the period of the evaluation program. Distribution in terms of the three adaptations under study were: short opponens orthosis, 7; long opponens orthosis, 3; and reciprocal units, 12.

Moreover, data were available on an additional 48 patients distributed as follows: short opponens orthosis, 11; long opponens orthosis, 7; and wrist-driven reciprocal units, 30. These patients were fitted at Hines VA Hospital following the closure of the official phase of the study. Some findings of interest from these additional fittings are included.

In the total of 70 fittings reported, 18 were with short opponens, 10 with long opponens, and 42 with reciprocal units, roughly a 2:1:4 ratio. Whether this ratio could be extrapolated to the general population is not known.

Typical conditions for which the three versions of the EPHO* were applied were: 1) short opponens orthosis - rheumatoid arthritis of the hands (Fig. 5); quadriplegia (to prevent deformities and support the hand in a position of function pending fitting of reciprocal units); contraction deformity of the wrist; 2) long opponens orthosis - quadriplegia (as a stabilizing device pending reduction of contractures and fitting with a reciprocal unit)(Fig. 6); or as a base for the addition of self-help devices (Fig. 7); reciprocal units - quadriplegia (Fig. 8).

B. Outcomes

Results of the fittings in the five participating clinics were variable, success or failure being related primarily to three factors:

**Utilizing the basic Engen items as modules to which accessory equipment was added if indicated by the patient's needs.*



Fig. 5. Left, palmar and dorsal views of patient's arthritic hands. Above, left hand fitted with Engen short opponens orthosis and Thomas outrigger splint.





Fig. 6. Patient fitted with Engen long opponens orthosis as stabilizing device.



Fig. 7. Patient fitted with Engen long opponens orthosis with attachment for self-help devices. Note atrophy of thenar cleft.



Fig. 8. Patient fitted with reciprocal unit.

1. Proper Selection of Patients

In several of the clinics patients were selected under somewhat experimental circumstances, that is, either the motivation of the patients was less than optimal or the anticipated benefit to be derived from the Engen device was marginal. In these instances, the fittings typically proved to be failures.

2. Objectivity in the Evaluation of Outcomes

Two of the clinics participating in the study had devices of their own design which were "competitive" with the Engen items. Personnel of these clinics were of the opinion that the Engen devices provided no features superior to their own devices other than perhaps the telescoping rod on the reciprocal unit application.

3. Meticulous Care in Application and Follow-up

Although the Engen Plastic Hand Orthosis is essentially a prefabricated shelf item, it must be carefully tailored to the needs of the individual patient. This tailoring may involve: a) some reshaping of the plastic shell to accommodate atrophy or size discrepancy in the patient's hand; b) the addition of accessory finger pieces and other equipment to the basic Engen shell.

Moreover, since the condition of the patient's hand changes with time and with the use of the Engen splint, follow-up to maintain fit of the device is essential. This follow-up is obviously best accomplished when the patient is being treated on an in-patient basis, in-house orthotic facilities are available, and there is close cooperation between the disciplines involved in the care of the patient.

Where the foregoing conditions were satisfactorily met, excellent success was achieved in the fittings of the Engen devices. Selected cases which illustrate the applications and outcomes of the three EPHO modifications under study are presented below.

CASE PRESENTATIONS

SHORT OPPONENS ORTHOSIS

Case No. 1

A.M. was a 40-year-old male with a diagnosis of quadriplegia resulting from a physiologically incomplete lesion of the spinal cord at the C-5 level. A short opponens orthosis was prescribed for his right, dominant hand with a view to aiding in the restoration of function, and the prevention and correction of deformities. It was hoped that eventually Mr. M would be a candidate for a right reciprocal unit. The patient was described as having a motivational level of fair and an average degree of pain tolerance.

Mr. M was fitted with a medium-sized orthosis. The suitability of the preformed size and shape was rated as good and the ease of customizing and the clarity and completeness of the instructions for doing so were also rated as good. No special modifications of the shell were necessary for this patient.

A.M. was reevaluated at 1, 3, 6, 9, and 12 months following the initial fitting. The efficacy of the splint in achieving the objectives of the fitting was rated as good in all respects. The patient's performance in such activities as turning pages in a book and writing was rated as fair. The performance in feeding and using a toothbrush was cited as being poor. The patient's reactions to the orthosis were good with respect to fit, comfort, and cosmesis, and fair as regards function. During the course of his treatment the patient was given physical and occupational therapy and special instruction in the use of the Engen device. He was also given medication for spasticity which did not involve the hands.

The evaluation of the device with regard to this patient remained remarkably consistent throughout the entire 12 months of the test period except that the patient's own reactions to the functional assistance provided by the device declined from fair to poor from the third month on.

The outcome in this instance was considered to be excellent, but two other patients, D.R. and J.A., whose initial condition was remarkably

similar, withdrew from the study one and four months, respectively, after the initial fitting. In these two instances the restoration of function achieved with the orthosis was minimal and this factor, combined with low levels of motivation, resulted in the withdrawals.

Case No. 2

Patient N.E. was a 60-year-old male with a diagnosis of rheumatoid arthritis of some eight years duration. He was prescribed an EPHO short opponens orthosis for his right, dominant hand, the objectives being assistance in the restoration of function and the prevention and correction of deformities. His tolerance to pain was described as average, and his skin condition as thin, and his motivational level was said to be good.

N.E. was fitted with the large-sized EPHO shell. With regard to the fitting, the suitability of the preform size and shape was rated as good, as was the ease of customizing and the clarity and completeness of instructions. No special modification was necessary initially, but some five weeks later a Thomas outrigger suspension was applied to prevent further subluxation of the metacarpophalangeal (MCP) joints (Fig. 5). Mr. E was reevaluated at 1, 3, 6, 9, and 12 months following fitting and then left the clinic area taking the provided splint with him.

Initially the achievement of objectives involving the prevention and correction of deformities was rated as good, but the restoration of function as poor. Mr. E's performance in typical activities of daily living were all rated as poor. The patient's reactions to the device were good with respect to fit, comfort, and cosmesis, but poor as regards function.

As Mr. E continued to wear the experimental device his ratings in all performance activities were raised to fair, and finally to good in such activities as pageturning, writing, and feeding. The patient's rating of the functionality of the device gradually improved until finally it was reported as good.

In this fitting the outcomes appeared to be positive from the beginning with respect to the prevention and correction of deformities with gradually increasing benefit in the area of function.

LONG OPPONENS ORTHOSIS

Case No. 3

Patient J.K. was a 21-year-old male. His primary diagnosis was quadriplegia with a spinal-cord injury at the C-5, C-6 levels which was incurred some nine months prior to his inclusion in the evaluation program. He was fitted with an EPHO long opponens orthosis, medium-size, to the right hand which was less impaired than the left. His hands were atrophied, especially in the thenar-cleft area, and he had a slight lateral palmar drift on the (right) hand fitted. The patient's motivational level was said to be good and his pain tolerance average. The objectives of the fitting were restoration of function, and prevention and correction of deformities in the hope that he might eventually be fitted with a reciprocal orthosis.

The application of the device proceeded without difficulty except that the device was somewhat too large for the patient's atrophied thenar cleft area. The splint tended to displace itself into this area. Three weeks after the initial fitting a reduction in the cock-up angulation was recommended by the developer, together with the addition of a T-bar to abduct the thumb and a dorsal strap for better retention.

The patient preferred the EPHO splint to his previously worn Royallite device and requested that the EPHO be modified to include the self-aid attachments worn on the earlier splint. The device was subsequently reinforced with a monel metal piece and has held up well since that time. The patient's flexed lateral palmar drift was held in proper position by the orthosis.

At the one-month follow-up of this patient the ratings of outcomes were generally poor to fair with only the patient's reaction to the cosmesis of the device being designated as good. However, steady improvement occurred throughout the follow-up period, and by 9 months after initial fitting the device was rated as good in all characteristics specified in the evaluation program. Thus, in this instance, the outcomes of fitting the Engen plastic hand orthosis must be considered as excellent.

Case No. 4

On another patient, F.G., with a somewhat similar disability, the results of the fitting were considerably less positive. This patient was a 40-year-old male with complete transverse severance of the spinal cord at the C-6, C-7 levels. The injury to this patient had occurred some 6½ years prior to the present study and he had had a surgical transfer of the brachioradialis tendon to the wrist extensors on his left hand several years previously. The hand tended to go into marked radial deviation on voluntary extension of the wrist. He could raise his elbows and shoulders bilaterally. He had muscle spasms.

F.G. was fitted with a medium-sized long opponens orthosis and it was immediately noticeable that the splint would not hold the patient's marked radial deviation. At the developer's suggestion the cock-up angle of the splint was reduced to prevent creeping and a plastic clip added on the proximal medial side. A lateral Velcro strap was added to pull the ulnar side of the wrist toward the radial side, and an elastic sling was added to correct the flexion of the interphalangeal (IP) joint of the thumb. The patient was to be considered for a reciprocal orthosis if his contractures could be reduced. The patient's motivational level was rated as poor with respect to any type of splinting.

The outcomes of this fitting initially were also mixed and failed to show appreciable improvement, particularly with regard to function, over a 6-month follow-up period. The patient was then taken off the program at his own request.

RECIPROCAL WRIST-EXTENSION FINGER-FLEXION ORTHOSIS*Case No. 5*

Patient V.C. was a 42-year-old male who had sustained a spinal-cord injury at age 26. His primary diagnosis was "dislocation and compression of the spinal cord at the C-5, C-6 levels with complete paralysis." With no prior experience with orthotic devices, he was fitted with a reciprocal unit on his right, dominant hand. His motivational level was rated

as good but his pain tolerance was given as low. The objectives of the fitting were restoration of function and prevention and correction of deformities.

The fitting utilized a large reciprocal orthosis and finger pieces but a medium-sized forearm piece. The component sizes were considered to be good for this patient. However, the shape of the plastic shell did not provide good support for the arch of the hand or conform well to the thenar-cleft area. A thumb sling and a middle-finger IP stabilizer were added. A later review of this case indicated that the MCP and the wrist joints were incorrectly placed. With these conditions the patient had no desire to try and use the splint and did not wish to keep it. Replacement of the malpositioned joints effected a marked improvement in the function of the device and the patient's acceptance of it. This high level of performance and acceptance was maintained throughout the remainder of the patient's 12-month participation in the study. In this case, obviously the difference between success and failure hinged on the proper joint positioning, emphasizing the importance of this aspect of the fitting. This type of experience was repeated with a number of other patients in the evaluation.

Case No. 6

Patient W.M. was a 47-year-old male who sustained a spinal-cord injury approximately one year prior to being fitted with the Engen orthosis. His diagnosis was given as "compression of cord, level C-5, C-6 incomplete, C-7 complete." Mr. M's motivational level was said to be good but his pain tolerance was given as low. He was fitted with a reciprocal orthosis on his right, dominant hand, the objectives being restoration of function, and prevention and correction of deformities.

The initial application of the device seemed to proceed satisfactorily, the component parts being a large plastic shell, a large finger unit, and a large forearm piece. The sizes and shapes of the various components seemed to be appropriate. Three days later a "knuckle bender" was added because of tightness of the MCP joints and a modified Oppenheimer splint

was fitted to increase the limited range of wrist extension and thumb abduction.

A later review of this case indicated that the joint hinges had been incorrectly positioned and this deficiency was corrected. Again a dramatic improvement in the achievement of fitting objectives, functional level and patient acceptance, was evident, although this subject's function was not as good as that of the previous patient. This case again illustrates the importance of joint positioning and indicates the use of the Engen basic equipment as a module to which other accessories might be added.

SUMMARY AND RECOMMENDATIONS

THE EVALUATION PROCESS

The evaluation of the Engen plastic hand orthosis was part of a pilot study to determine the feasibility of field application studies conducted under the auspices of the Committee on Prosthetics Research and Development. The outcomes of the study indicate that protocols of the type used can be implemented without significant problems. Treatment clinics can be recruited to participate in such research, and personnel from these clinics can be trained in the fabrication and/or fitting procedures required for the study. Follow-up visits to the participating clinics by the developer or his representatives and by personnel of the evaluation agency are highly necessary for an effective program. Assistance in the clerical work relating to the provision of data may be necessary in some instances. Maximum neutrality and impartiality on the part of the participating clinics are highly desirable.

Specifically, in the present study it would appear evident that orthotists with prior experience and skill in the fabrication of hand splints can be taught to apply the EPHO variations successfully. In this connection the instructional manual and fitting checkout sheets developed in conjunction with the field study provided an excellent basis for the transfer of technique from developer to field orthotists. However, this

written material is not regarded as an adequate substitute for direct person-to-person instruction. Moreover, a follow-up visit to each of the clinics following initial fittings helps to insure that the techniques taught are being properly applied and assists in the solution of specific local problems.

The outcomes of the field fittings of the Engen equipment were mixed, positive results being related primarily to three factors: one, proper selection of patients, including consideration of motivational factors; two, meticulous care in application and follow up of the devices; and three, objectivity in evaluating outcomes. Where these considerations were observed, the successful outcomes achieved support the developer's claims for the device.

Fitting results for each subject in the study showed no significant changes after 6 months wear of the Engen device. Hence, consideration might be given to reducing the follow-up period in similar future studies from 12 to 6 months.

THE DEVICES

Prescription Criteria

The criteria for prescription of the Engen adaptations as described on pages 4, 5, and 6 of the Field Evaluation Protocol (Appendix A) were reaffirmed by the results of the field study. The following additional comments also emerged:

1. Short Opponens Orthosis

- a. has been found useful as a stabilizing splint in several instances of postsurgical management;
- b. has been used in providing patients with various self-help devices as attachments to the basic shell;
- c. with special modifications has been used in rheumatoid arthritic cases to help prevent ulnar and radial finger drift and align the fingers in proper position for finger prehension;

- d. has been used as the stabilizing splint pending evaluation for application of a reciprocal unit.
2. Long Opponens Splint with Extension Arm Support
 - a. has also been utilized for the same applications as the short opponens orthosis above.

SPECIFIC FINDINGS

Specific findings relating to the design and applications of the EPHO devices were:

1. Although the Engen Plastic Hand Orthosis is ostensibly a pre-fabricated shelf item, it must be carefully tailored to the needs of the individual patient. This tailoring may involve:
 - a. some reshaping of the plastic hand shell to accommodate atrophy or size discrepancy in the patient's hand;
 - b. the addition of accessory finger pieces and other equipment to the basic Engen shell.
2. In the installation of the EPHO reciprocal orthosis, great care must be exercised in the location of the joint axes.
3. Since the condition of the patient's hand changes with use of the Engen splint, follow up to maintain fit of the device is essential. This follow up is best accomplished when the patient is being treated on an in-patient basis, in-house orthotic facilities are available, and there is close cooperation between the disciplines involved in patient care.
4. The telescopic rod feature of the reciprocal unit was frequently cited as a most significant new characteristic of this type of orthosis.
5. Although definitely related to the level of experience gained in the application of the EPHO devices, saving of the orthotist's time was a significant feature of the system.

6. Some deficiencies in the design and materials of the EPHO were noted:

- a. The range of three sizes provided initially were considered inadequate but the addition of the fourth (medium-large) size virtually eliminated this problem.
- b. A very common problem was that of fitting the hand shell to atrophied thenar-cleft musculature. The likelihood that this problem would be encountered and measures for adapting the shell to meet it should be emphasized in the instructional material.
- c. Some problems were encountered with stripping and bending of the telescopic rods.
- d. Some tendency for the shells to revert to their original shape after heating and modification was reported. However, in general, the physical properties of the splints were considered adequate to last an indefinite period with proper care and maintenance.

In conclusion, the field evaluation of the EPHO adaptations clearly revealed that the devices are useful additions to the armamentarium of orthotic items available for the treatment of patients with disabilities of the hand. It is recommended that the outcomes of this study be forwarded to the prosthetics-orthotics schools with a view to the possible inclusion of instruction in this system as part of the orthotics curriculum.

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PLAN FOR FIELD EVALUATION
OF THE ENGEN PLASTIC HAND ORTHOSIS

INTRODUCTION

A primary function of the hand is prehension, the ability to grasp an object. While the hand can perform numerous types of grasp, of major importance is the type involving flexion of the index and middle fingers towards or against the opposing thumb to provide what is sometimes referred to as "three-jaw-chuck" prehension.

Temporary or permanent paralysis can impair or completely inhibit the function of hand, wrist, or entire upper extremity, and the ability to oppose the thumb to the flexing fingers may be lost. In these instances, various types of orthotic systems have been designed to achieve the goals of prevention or correction of deformities and/or restoration of function. A key feature of these systems is the stabilization of the thumb in opposition to the fingers.

Pioneering efforts in the area of hand splinting were undertaken at the Georgia Warm Springs Foundation where many types of assistive devices were developed to meet the needs of a large patient population having residuals of poliomyelitis. Although the number of polio patients has decreased in recent years, rehabilitative medicine has expanded to include patients with many other types of neuromuscular and skeletal disorders. A systematic method of hand splinting to meet the needs of these patients is still of paramount importance.

As part of Research Project VRA RD-1564, Thorkild J. Engen, Project Director, Baylor University College of Medicine, Houston, Texas, in 1959¹ initiated the development of a plastic hand orthosis. Based on the premise that preservation of hand posture is best maintained by support, rather than suspension, the device is designed to hold the thumb in the opposed position and simultaneously support the metacarpal arch. The aim has been to develop a standardized item shaped to conform to the natural contours of the hand which could be adapted to individual needs. At present this orthosis is made in three sizes: large, medium,

¹"A Plastic Hand Orthosis" by Thorkild J. Engen, Orthopedic & Prosthetic Appliance Journal, September 1959, pp 38-43.

and small; and for both right and left hands. Since it is fabricated of polyester resins, it is heat-remoldable for individual adaptability.

In the early stages of redevelopment, the Engen orthoses were fabricated of epoxy resins with and without fiberglass reinforcement. Ultimately these models were discarded because of breakage problems.² The plastic shells originally submitted to New York University for the laboratory evaluation program were made of fiberglass and polyester resins. The current shell is a polyester resin and nylon laminate prepared by means of a vacuum molding technique. With the new materials, the fitting technique is essentially unchanged; the orthosis is molded and modified by the orthotist as necessary to provide a custom fit.

In the course of development, attachments were devised or adapted to (a) provide wrist support and (b) provide prehension.

Wrist support is provided by an extension arm, essentially constituting a cock-up splint, with the plastic hand shell comprising the distal portion.

The second adaptation is a reciprocal wrist-extension/finger-flexion unit which provides prehensile motion and force (AOPA Journal, March 1960). Engen's reciprocal unit design is based on the concept originally presented by Bisgrove (Journal of the Association for Physical and Mental Rehabilitation, 1954). Although the components of the systems differ considerably, the mechanics are essentially the same. Changes in the angles of a classical floating four-bar linkage system produce prehension.

The overall plan for evaluation of the shell, known as the Engen Plastic Hand Orthosis (EPHO), and its extension arm and reciprocal unit adaptations, encompasses two major phases:

1. A laboratory study at New York University.
2. A field study to be conducted in selected clinics.

² *ibid*

The initial phase has been essentially completed by NYU and the results reported³. The present plan deals with the second phase and projects the fitting of selected patients on a field basis with:

1. The basic orthosis (plastic hand shell).
2. The orthosis with extension arm.
3. The orthosis with reciprocal unit.

For each type of application, a minimum of 10 and a maximum of 20 patients will be sought. For these fittings, the shells and all accessory components will be supplied by Mr. Engen. The components will be adapted to the needs of the patients by field clinic personnel in accordance with the fitting principles described and taught by the developer.

GENERAL CONSIDERATIONS

Participants

The five clinics and associated personnel, recruited to participate in the field study, are:

1. Duke University Medical Center, Durham, North Carolina (Frank W. Clippinger, Jr., M.D.; Bert R. Titus; Felton Elliott)
2. Georgia Warm Springs Foundation, Warm Springs, Georgia (Edward Haak, M.D.; and H. G. Bowden)
3. Highland View Hospital, Cleveland, Ohio (Alvin A. Freehafer, M.D.; and Arthur Guilford, Jr., G. A. Guilford & Sons)*
4. Ohio State University, Columbus, Ohio (Marvin H. Spiegel, M.D.; and Lawrence Czap) (Charles W. Rosenquist, Columbus Orthopedic Appliance Co.)
5. Veterans Administration Hospital, Hines, Illinois (Vladimir T. Liberson, M.D.; James F. Kurtz, M.D.; and Walter J. Piotrowicz--orthotist)

Instruction and Orientation

The study will be initiated by a course of instruction and orientation in the applications of the Engen devices. This course will be

³"Summary of Fittings--Engen Hand Orthoses" by Heidi Vorchheimer, Associate Research Scientist, Prosthetic and Orthotic Studies, Research Division, School of Engineering and Science, New York University, New York, New York, dated June 1966.

*team withdrew because of illness of Mr. Guilford's father

given by the developer at Texas Institute for Rehabilitation and Research, Houston, Texas, from December 5-8, 1966 (orthotists--4 days; physicians--1 day).

Followup and Data Collection

Following the introductory course of instruction, each clinic team will, in its local situation, seek patients appropriate for applications of the Engen adaptations. Data relating to fittings performed will be recorded on forms to be developed and provided by the Committee on Prosthetics Research and Development in collaboration with Mr. Engen (See Data Recording Forms I, II, and III). Each patient fitted will be followed for a period of 12 months unless treatment is terminated prior to that time. Reports on the progress of each case will be furnished to CPRD at one, three, six, and twelve months following fitting. A representative of CPRD will provide liaison with the field clinics as necessary during the course of the study.

Purposes

The general purposes of the field evaluation are to determine:

1. The contribution of the Engen hand orthosis and its adaptations to the treatment of disabled patients.
2. The adequacy of the materials and the method of assembly of the devices.
3. The clarity and completeness of the draft fabrication manual prepared by the developer.
4. Criteria for prescription of the three EPHO adaptations.

Method and Sample

The evaluation procedures and the specific patients involved will vary according to the intended purposes of the three adaptations of the Engen device:

1. Plastic Orthosis Alone

The primary purpose of the plastic orthosis is to maintain the thumb in opposition to the index and long fingers and to support the metacarpal arch. The functional goal is the achievement of "three-jaw-chuck," as distinct from lateral, prehension. Evaluation procedures primarily will involve clinical determination of the extent to which these objectives have

been achieved. Since the treated condition may change with time, the evaluation procedures will be applied periodically throughout the study.

Subjects for this application are found among patients with various kinds of neuromuscular disorders with variable degrees of resultant muscle imbalance of the intrinsic and opponens muscle groups. Such patients will typically have spinal cord injuries at the C7, C8, and T1 levels; peripheral neuropathy (ulnar and median nerves); or hemiplegia. Others who, in the opinion of clinic personnel, would benefit from the device would also be considered as prospective subjects (See Data Recording Form I).

2. Plastic Orthosis With Extension Arm

This adaptation is designed to support the hand and to prevent flexion deformity at the wrist; as well as to maintain the integrity of the metacarpal arch and position of the thumb. As with the short opponens orthosis, the goal in this case is deformity prevention and achievement of "three-jaw-chuck" prehension if the necessary controllable residual muscular movements are present. The study procedures will primarily involve clinical assessment of the extent of attainment of these objectives. Subjects for this application will typically be found among patients with spinal lesions at the C5, C6 levels; peripheral neuropathy involving the median and/or ulnar nerves and the radial nerve; or hemiplegia. Patients with other disabilities may be selected at the discretion of the participating clinics (See Data Recording Form II).

3. Plastic Orthosis with Reciprocal Unit

This adaptation is designed to provide prehension when voluntary wrist-extensor power is available. Therefore, quadriplegic patients who retain innervation to the wrist extensors would be appropriate subjects for this type of functional orthosis. However, subjects in the study would not be limited to this group.

Information concerning the levels of performance achieved with this device in relation to wrist-extensor strength and range of motion will be sought (See Data Recording Form III). Specific factors to be investigated will include:

- a. The range of opening of the device at different rod settings.
- b. The range of wrist motion necessary to achieve prehension.

c. Pinch force developed in relation to wrist-extensor strength and rod setting.

d. Functional achievement.

In order to simplify classification of patients' functional deficit, especially quadriplegics, secondary to cervical lesions, use of the method described below is requested. Indicate the appropriate group number on the Data Recording Form for both right and left extremities.

Group 1

Are able to position the upper extremities in space, but the fingers and thumbs are nonfunctional. Typically involve spinal cord lesions at the C-6, C-7 levels.

Group 2

Are able to position the upper extremities in space. The fingers and thumbs are nonfunctional and there is a total absence of wrist-extensor function. Typically involve lesions at the C-5, C-6 levels.

Group 3

Are only able to hike the shoulders. Typically involve lesions at the C-3, C-4, C-5 levels.

February 10, 1967

CLINICAL EVALUATION OF THE
ENGEN PLASTIC HAND ORTHOSIS

Notes on the Data Recording Forms

I. GENERAL

A. Three separate forms are provided:

Form I (buff) for the short opponens orthosis;
Form II (pink) for the long opponens orthosis;
Form III (green) for the reciprocal orthosis.

B. Parts A and B of the appropriate form should be completed at the time each patient is initially fitted and the form forwarded to CPRD.

Part C of additional forms should be completed after the device has been worn for one, three, six, and twelve months. Any changes in Parts A/B information should also be noted at these follow-up examinations: for example, changes in motivation, tissue condition, or fitting objectives. After each follow-up examination, the completed form should be sent to CPRD.

C. If sufficient space is not available on the forms for recording any item of information, additional sheets of paper should be attached.

EPHO

(Short Opponens Orthosis)

FABRICATION INSTRUCTIONS

1. Evaluate the patient.
2. Measure across the metacarpals (not including the thumb).
3. Select the proper shell size: Small 2-1/2" to 3"
 Medium 3" to 3-1/2"
 Large 3-1/2" to 4-1/4"
4. Check the thumb size of the selected shell on the patient.
5. Thumb trimline--trim just behind the distal joint of the thumb so that the thumb can bend freely; smooth the trimmed edge.
6. Check the ulnar "tab." If necessary, heat and close or open up as indicated for snug fit.
7. Proximal volar trimline--trim the palmar shell approximately 1/2" to 3/4" distal to the distal wrist-flexion line (on the "life line") so that the wrist can flex freely. Connect the proximal point of the trimline to the proximal thumb joint and ulnar "tab" with smooth curves.
8. Radial trimline--trim the shell radially 1/2" to 3/4" distal to the flexion line so that radial deviation of the hand is not restricted.
9. Distal volar trimline--the distal palmar shell is trimmed to allow for metacarpal phalangeal movements. Passive flexion of all fingertips to make contact with the thumb tip should be possible.
10. Sand trimmed edges.
11. Buff edges.
12. Heat, reshape, and further trim shell, if necessary. When heating, keep shell at least 3" from heat and do not burn finish.
13. Use cloth buffing on edges.
14. Position strap loop on the radial side so that the plastic shell acts as a shield, i.e., the loop comes below the trimline.
15. Mark hole for strap rivet in the center of the shell and drill with a #21 bit.
16. Provide deep countersink in the undersurface of the shell to seat the rivet.
17. With the patient's hand in the orthosis, adjust the Velcro strap so that the overlap is short of the loop by 1/4" to 1/2".
18. Drill hole for the ulnar strap rivet with a #21 bit. Hole is in the center of the ulnar "tab" about 1/2" from the end.
19. Punch hole and rivet strap in place.
20. Skive the end of the strap.

EPHO
WITH EXTENSION ARM
(Long Opponens Orthosis)

FABRICATION INSTRUCTIONS

1. Evaluate the patient.
2. Measure across the metacarpals (not including the thumb).
3. Select the proper shell size: Small 2-1/2" to 3"
 Medium 3" to 3-1/2"
 Large 3-1/2" to 4-1/4"
4. Select the appropriate forearm piece: small, medium, large.
5. Check the thumb size of the selected shell on the patient.
6. With shell on patient's hand, check the fit in the thenar cleft--
reduce or increase space if necessary.
7. Thumb trimline--trim just behind the distal joint of the thumb so that
the thumb can bend freely; smooth the trimmed edge.
8. Check the ulnar "tab." If necessary, heat and close or open up as in-
dicated for snug fit.
9. Radial trimline--trim the shell radially 1/2" to 3/4" distal to the
flexion line so that radial deviation of the hand is not restricted.
10. Distal volar trimline--the distal palmar shell is trimmed to allow
for metacarpal phalangeal movements. Passive flexion of all finger-
tips to make contact with the thumb tip should be possible.
11. Proximal volar flange--heat and mold to obtain desired hand position
(neutral or cock-up as prescribed).
12. Mark and fit the forearm piece so that the distal end supports the
palmar area of the shell.
13. Make reference marks on shell and forearm piece.
14. Drill holes in the hand shell and attach the forearm piece temporarily;
mark trimlines on volar flange.
15. Trim and buff all edges.
16. Rivet the forearm piece to the hand shell (heat the shell before apply-
ing the distal rivet).
17. Upholster the forearm piece with felt or leather.
18. Attach Velcro straps at the wrist and forearm.
 - a. Wrist--one hole is drilled in the center of the forearm piece with
a #21 bit right at the wrist joint.
 - b. Forearm--two holes are drilled with a #21 bit in the proximal flange.

Straps are attached to pass from the lateral to medial side of the
arm.

DATA RECORDING FORM I
FOR E.P.H.O. SHORT OPPONENS ORTHOSIS

Submitted by: _____ Physician
 _____ Orthotist

PART A--Initial Information to be Obtained by Physician

I. BASIC PATIENT INFORMATION

Name _____ Education level achieved _____
 Date of birth _____ Sex _____ Marital status _____ Wheelchair bound _____
 Occupation before disability _____ After disability _____
 *Primary diagnosis _____ Date of onset _____
 Side fitted with device: Rt. _____ Lft. _____ Dom. _____ Non-dom. _____ Both sides _____
 **Motivational level: Good ___ Fair ___ Poor ___ Previous usage of orthotic devices: Yes ___ No ___
 Any history of reconstructive hand surgery?: Yes ___ No ___
 If yes, specify _____
 Rx _____

II. PATIENT EXAMINATION

GENERAL CONDITION OF WRISTS AND HANDS

	<u>Skeletal Deformities</u>	
<u>Ankylosed or Fused Joints</u>	<u>Anatomical Deviations</u>	<u>Bony Defect, Absence or Abnormality</u>
If present, specify:	If present, specify:	If applicable, specify:
Rt. _____	_____	_____
Lft. _____	_____	_____

	<u>Soft Tissue Tightness</u>	
<u>If present, specify:</u>		<u>Range of Motion of Joints, if Abnormal</u>
Rt. _____		_____
Lft. _____		_____

	<u>Miscellaneous</u>	
***Residual Active Motion		<u>Residual Sensation</u>
Strong Weak Absent		Present Absent
Rt. _____		_____
Lft. _____		_____

Pain Tolerance: High ___ Average ___ Low ___; Tissue Swelling or Edema: High ___ Moderate ___ Low ___ None ___
 Skin Condition: If abnormal, specify _____
 Spasticity or Spasms: Yes ___ No ___; Functionally Limiting? Yes ___ No ___
 If circulatory insufficiency is present, specify: _____

III. OBJECTIVES OF FITTING

- A. Preservation of function _____
- B. Restoration of function _____
- C. Prevention of deformities _____
- D. Correction of deformities _____
- E. Other (e.g., support postsurgery) _____

*Include level of lesion if applicable and any secondary diagnosis (e.g., diabetes mellitus, rheumatoid arthritis, or peripheral vascular disease, etc.)
 **Rating of Good: responsive, alert; Fair: indifferent (neutral); Poor: apathetic, withdrawn
 ***Attach copy of patient's muscle test chart to data form

PART B--Fitting Information to be Provided by Orthotist

Date of Application _____

I. APPLICATION

A. Suitability of preform sizes: Good ___ Fair ___ Poor ___; B. Suitability of preform shapes: Good ___ Fair ___ Poor ___; C. Ease of customizing (time & effort): Good ___ Fair ___ Poor ___; D. Clarity and completeness of instructions: Good ___ Fair ___ Poor ___; E. Special modification necessary: Yes ___ No ___. If yes, specify _____

II. FITTING CHECKLIST (to be completed jointly by physician and orthotist)

Following adaptation of the orthosis on patient, the checklist below should be completed in order to record accuracy of fitting. Circle the appropriate response.

- 1. Thumb trimline permits distal joint flexion. Yes No
- 2. Thumb trimline supports thumb snugly without impingement. Yes No
- 3. The shell conforms well to arches of hand. Yes No
- 4. The shell conforms to the anatomy of the thenar cleft (web space). Yes No
- 5. The proximal volar trimline permits full wrist flexion while providing firm metacarpal arch support. Yes No
- 6. The distal volar trimline permits free digital motion; fingertips can be passively brought into contact with the stabilized thumb. Yes No
- 7. The ulnar "tab" conforms to the ulnar border of the hand and permits ulnar deviation without restriction. Yes No
- 8. The radial "tab" conforms to the radial border of the hand and permits radial deviation without restriction. Yes No
- 9. The ulnar strap is riveted approximately 1/2" below the rim and in the midsection of the ulnar "tab." Yes No
- 10. The radial strap is riveted in the midline of the radial "tab" and the loop is located below the trimline. Yes No
- 11. The thumb is satisfactorily aligned in opposition to the digits. Yes No
- 12. The patient can achieve finger-to-thumb-tip prehension. Yes No
- 13. After a half-hour of continuous wear, the skin shows no evidence of excessive pressure or other problems. Yes No

PART C--Follow-up Information to be Provided by Physician

Date _____

I. PATIENT EVALUATION WITH DEVICE

A. Extent of Achievement of Fitting Objectives

1. Preservation of function: Good ___ Fair ___ Poor ___; 2. Restoration of function: Good ___ Fair ___ Poor ___; 3. Prevention of deformities: Good ___ Fair ___ Poor ___; 4. Correction of deformities: Good ___ Fair ___ Poor ___; 5. Other (e.g., support postsurgery) _____ Good ___ Fair ___ Poor ___

B. Activity Performance

1. Page turning: Good ___ Fair ___ Poor ___; 2. Writing: Good ___ Fair ___ Poor ___; 3. Feeding: Good ___ Fair ___ Poor ___; 4. Hygiene and cosmetics (lipstick, razor, toothbrush): Good ___ Fair ___ Poor ___; 5. Other _____ Good ___ Fair ___ Poor ___

II. PATIENT REACTIONS

A. To fit: Good ___ Fair ___ Poor ___; B. To comfort: Good ___ Fair ___ Poor ___; C. To function: Good ___ Fair ___ Poor ___; D. To cosmesis: Good ___ Fair ___ Poor ___

III. THERAPY

A. Was physical therapy provided? Yes ___ No ___; B. Occupational therapy? Yes ___ No ___; C. Medication for spasticity? Yes ___ No ___; D. Specific instruction or training in usage of device(s)? Yes ___ No ___

DATA RECORDING FORM II

FOR E.P.H.O. LONG OPPONENS ORTHOSIS

Submitted by:

Physician

Orthotist

PART A--Initial Information to be Obtained by Physician

I. BASIC PATIENT INFORMATION

Name _____ Education level achieved _____
Date of birth _____ Sex _____ Marital status _____ Wheelchair bound _____
Occupation before disability _____ After disability _____
*Primary diagnosis _____ Date of onset _____
Side fitted with device: Rt. _____ Lft. _____ Dom. _____ Non-dom. _____ Both sides _____
**Motivational level: Good ___ Fair ___ Poor ___ Previous usage of orthotic devices: Yes ___ No ___
Any history of reconstructive hand surgery?: Yes ___ No ___
If yes, specify _____
Rx _____

II. PATIENT EXAMINATION

GENERAL CONDITION OF WRISTS AND HANDS

	<u>Ankylosed or Fused Joints</u>	<u>Skeletal Deformities</u>	<u>Bony Defect, Absence or Abnormality</u>
	<u>If present, specify:</u>	<u>Anatomical Deviations</u>	<u>If applicable, specify:</u>
		<u>If present, specify:</u>	
Rt.	_____	_____	_____
Lft.	_____	_____	_____

	<u>Soft Tissue Tightness</u>	<u>Range of Motion of Joints, if Abnormal</u>
	<u>If present, specify:</u>	
Rt.	_____	_____
Lft.	_____	_____

Miscellaneous

	<u>Residual Active Motion</u>			<u>Residual Sensation</u>	
	<u>Strong</u>	<u>Weak</u>	<u>Absent</u>	<u>Present</u>	<u>Absent</u>
Rt.	_____	_____	_____	_____	_____
Lft.	_____	_____	_____	_____	_____

Pain Tolerance: High ___ Average ___ Low ___; Tissue Swelling or Edema: High ___ Moderate ___ Low ___ None ___

Skin Condition: If abnormal, specify _____

Spasticity or Spasms: Yes ___ No ___; Functionally limiting? Yes ___ No ___

If circulatory insufficiency is present, specify: _____

III. OBJECTIVES OF FITTING

- A. Preservation of function _____
- B. Restoration of function _____
- C. Prevention of deformities _____
- D. Correction of deformities _____
- E. Other (e.g., support postsurgery) _____

*Include level of lesion if applicable and any secondary diagnosis (e.g., diabetes mellitus, rheumatoid arthritis, or peripheral vascular disease, etc.)

**Rating of Good: responsive, alert; Fair: indifferent (neutral); Poor: apathetic, withdrawn

*** Attach copy of patient's muscle test chart to data form

PART B--Fitting Information to be Provided by Orthotist

Date of Application _____

I. APPLICATION

A. Suitability of preform sizes: Good ___ Fair ___ Poor ___; B. Suitability of preform shapes: Good ___ Fair ___ Poor ___; C. Ease of customizing (time & effort): Good ___ Fair ___ Poor ___; D. Clarity and completeness of instructions: Good ___ Fair ___ Poor ___; E. Special modification necessary: Yes ___ No ___. If yes, specify _____

II. FITTING CHECKLIST (to be completed jointly by physician and orthotist)

Following adaptation of the orthosis on patient, the checklist below should be completed in order to record accuracy of fitting. Circle the appropriate response.

- 1. Thumb trimline permits distal joint flexion. Yes No
- 2. Thumb trimline supports thumb snugly without impingement. Yes No
- 3. The shell conforms well to arches of hand. Yes No
- 4. The shell conforms to the anatomy of the thenar cleft (web space). Yes No
- 5. The distal volar trimline permits free digital motion; fingertips can be passively brought into contact with the stabilized thumb. Yes No
- 6. The ulnar "tab" conforms to the ulnar border of the hand and permits ulnar deviation without restriction (when the straps are not fastened). Yes No
- 7. The radial "tab" conforms to the radial border of the hand and permits radial deviation without restriction (when the straps are not fastened). Yes No
- 8. The proximal volar trimline (volar flange) is molded to conform to the heel of the hand. Yes No
- 9. The proximal volar trimline (volar flange) holds the hand in a neutral or cock-up position as prescribed. Yes No
- 10. The extension arm conforms to the forearm and supports the hand. Yes No
- 11. The proximal and distal straps are attached to fasten from the radial side of the arm. Yes No
- 12. The thumb is satisfactorily aligned in opposition to the digits. Yes No
- 13. The patient can achieve finger-to-thumb-tip prehension. Yes No
- 14. After a half-hour of continuous wear, the skin shows no evidence of excessive pressure or other problems. Yes No

PART C--Follow-up Information to be Provided by Physician

Date _____

I. PATIENT EVALUATION WITH DEVICE

A. Extent of Achievement of Fitting Objectives

1. Preservation of function: Good ___ Fair ___ Poor ___; 2. Restoration of function: Good ___ Fair ___ Poor ___; 3. Prevention of deformities: Good ___ Fair ___ Poor ___; 4. Correction of deformities: Good ___ Fair ___ Poor ___; 5. Other (e.g., support postsurgery) _____ Good ___ Fair ___ Poor ___

B. Activity Performance

1. Page turning: Good ___ Fair ___ Poor ___; 2. Writing: Good ___ Fair ___ Poor ___; 3. Feeding: Good ___ Fair ___ Poor ___; 4. Hygiene and cosmetics (lipstick, razor, toothbrush): Good ___ Fair ___ Poor ___; 5. Other _____ Good ___ Fair ___ Poor ___

II. PATIENT REACTIONS

A. To fit: Good ___ Fair ___ Poor ___; B. To comfort: Good ___ Fair ___ Poor ___; C. To function: Good ___ Fair ___ Poor ___; D. To cosmesis: Good ___ Fair ___ Poor ___

III. THERAPY

A. Was physical therapy provided? Yes ___ No ___; B. Occupational therapy? Yes ___ No ___; C. Medication for spasticity? Yes ___ No ___; D. Specific instruction or training in usage of device(s)? Yes ___ No ___

DATA RECORDING FORM III
FOR E.P.H.O. RECIPROCAL ORTHOSIS

Submitted by: _____

Physician
Orthotist

PART A--Initial Information to be Obtained by Physician

I. BASIC PATIENT INFORMATION

Name _____ Education level achieved _____
Date of birth _____ Sex _____ Marital status _____ Wheelchair bound _____
Occupation before disability _____ After disability _____
*Primary diagnosis _____ Date of onset _____
Side fitted with device: Rt. _____ Lft. _____ Dom. _____ Non-dom. _____ Both sides _____
**Motivational level: Good _____ Fair _____ Poor _____ Previous usage of orthotic devices: Yes _____ No _____
Any history of reconstructive hand surgery?: Yes _____ No _____
If yes, specify _____
Rx _____

II. PATIENT EXAMINATION

GENERAL CONDITION OF WRISTS, HANDS, AND ELBOWS

	<u>Skeletal Deformities</u>	<u>Anatomical Deviations</u>	<u>Bony Defect, Absence or Abnormality</u>
	<u>Ankylosed or Fused Joints</u>	<u>Anatomical Deviations</u>	<u>Bony Defect, Absence or Abnormality</u>
	If present, specify: _____	If present, specify: _____	If applicable, specify: _____
Rt. _____	_____	_____	_____
Lft. _____	_____	_____	_____
	<u>Soft Tissue Tightness</u>		<u>Range of Motion of Joints, if Abnormal</u>
	If present, specify: _____		_____
Rt. _____	_____		_____
Lft. _____	_____		_____

Miscellaneous

*** Strength of Wrist Extensors (by Standard Manual Muscle Test)

Rt. Extensor Carpi Radialis: N G F P T O Rt. Extensor Carpi Ulnaris: N G F P T O
Lft. Extensor Carpi Radialis: N G F P T O Lft. Extensor Carpi Ulnaris: N G F P T O
Pain Tolerance: High _____ Average _____ Low _____; Tissue Swelling or Edema: High _____ Moderate _____ Low _____ None _____
Skin Condition: If abnormal, specify _____
Spasticity or Spasms: Yes _____ No _____; Functionally Limiting? Yes _____ No _____
If circulatory insufficiency is present, specify: _____

III. OBJECTIVES OF FITTING

- A. Preservation of function _____
- B. Restoration of function _____
- C. Prevention of deformities _____
- D. Correction of deformities _____
- E. Other (e.g., support postsurgery) _____

PART B--Fitting Information to be Provided by Orthotist

Date of Application _____

I. APPLICATION

A. Suitability of preform sizes: Good _____ Fair _____ Poor _____; B. Suitability of preform shapes: Good _____ Fair _____ Poor _____; C. Ease of customizing (time & effort): Good _____ Fair _____ Poor _____; D. Clarity and completeness of instructions: Good _____ Fair _____ Poor _____; E. Special modification necessary: Yes _____ No _____. If yes, specify _____

*Include level of lesion if applicable and any secondary diagnosis (e.g., diabetes mellitus, rheumatoid arthritis, or peripheral vascular disease, etc.)

**Rating of Good: responsive, alert; Fair: indifferent (neutral); Poor: apathetic, withdrawn

***Attach copy of patient's muscle test chart to data form

II. FITTING CHECKLIST (to be completed jointly by physician and orthotist)

Following adaptation of the orthosis on patient, the checklist below should be completed in order to record accuracy of fitting. Circle the appropriate response.

- | | | |
|---|-----|----|
| 1. Thumb trimline permits distal joint flexion. | Yes | No |
| 2. Thumb trimline supports thumb snugly without impingement. | Yes | No |
| 3. The shell conforms well to arches of hand. | Yes | No |
| 4. The shell conforms to the anatomy of the thenar cleft (web space). | Yes | No |
| 5. The proximal volar trimline permits full wrist flexion while providing firm metacarpal arch support. | Yes | No |
| 6. The distal volar trimline permits free digital motion; fingertips can be passively brought into contact with the stabilized thumb. | Yes | No |
| 7. The ulnar "tab" conforms to the ulnar border of the hand and permits ulnar deviation without restriction. | Yes | No |
| 8. The radial "tab" conforms to the radial border of the hand. | Yes | No |
| 9. The pivot sections for the finger and wrist joints are flattened and aligned at right angles to the axes of rotation. | Yes | No |
| 10. The wrist joint and index finger joint coincide with the anatomical joint axes (thus, the orthosis does not displace during reciprocal action). | Yes | No |
| 11. The fingerpiece and strap loop stabilize the index and long fingers in opposition to the thumb. | Yes | No |
| 12. The forearm piece fits snugly without impingement. | Yes | No |
| 13. The proximal anchor point for the telescopic unit is accurately located. | Yes | No |
| 14. With hand in neutral position, spring lock is in #4 position on telescopic rod (the distal groove on the rod is designated as position #1). | Yes | No |
| 15. The hand and forearm straps retain the orthosis snugly. | Yes | No |
| 16. Wrist extension produces satisfactory "3-jaw-chuck" prehension. | Yes | No |
| 17. After a half-hour of continuous wear, the skin shows no evidence of excessive pressure, abrasion, or other problems. | Yes | No |

PART C--Follow-up Information to be Provided by Physician

Date _____

I. PATIENT EVALUATION WITH DEVICE

A. Extent of Achievement of Fitting Objectives

1. Preservation of function: Good ___ Fair ___ Poor ___; 2. Restoration of function: Good ___ Fair ___ Poor ___; 3. Prevention of deformities: Good ___ Fair ___ Poor ___; 4. Correction of deformities: Good ___ Fair ___ Poor ___; 5. Other (e.g., support postsurgery) _____ Good ___ Fair ___ Poor ___

B. Activity Performance (indicate rod setting for each activity)

1. Page turning: Good ___ Fair ___ Poor ___; 2. Writing: Good ___ Fair ___ Poor ___; 3. Feeding: Good ___ Fair ___ Poor ___; 4. Hygiene and cosmetics (lipstick, razor, toothbrush): Good ___ Fair ___ Poor ___; 5. Grasp paper cup or glass: Good ___ Fair ___ Poor ___

C. Miscellaneous

1. Is patient able to apply and remove device unaided? Yes ___ No ___
2. Is patient able to change rod setting unaided? Yes ___ No ___
3. Adjustability Factors:

<u>Rod Settings</u>	<u>Related Finger Opening</u>	<u>Related Wrist Extension</u>	<u>Max. Pinch</u>
Most common _____	_____ " to _____ "	_____ ° to _____ °	_____ lbs.
Min. _____	_____ " to _____ "	_____ ° to _____ °	_____ lbs.
Max. _____	_____ " to _____ "	_____ ° to _____ °	_____ lbs.

II. PATIENT REACTIONS

- | | |
|---|---|
| A. To fit: Good ___ Fair ___ Poor ___; | B. To comfort: Good ___ Fair ___ Poor ___; |
| C. To function: Good ___ Fair ___ Poor ___; | D. To cosmesis: Good ___ Fair ___ Poor ___; |

- III. THERAPY A. Was physical therapy provided? Yes ___ No ___; B. Occupational therapy? Yes ___ No ___; C. Medication for spasticity? Yes ___ No ___; D. Specific instruction or training in usage of device(s)? Yes ___ No ___

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