Clinical Evaluation of the Engen Plastic Hand Orthosis

Hector W. Kay, M ED.[1]

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, or restoration of function, or both. 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 has continued to be of paramount importance. On-going efforts in this regard have been maintained not only at GWSF but also at Rancho Los Amigos Hospital and other institutions *(1,2).*

As part of Research Project VRA RD-1564, Thorkild J. Engen, Project Director, Baylor University College of Medicine, Houston, Texas, in 1959 initiated the development of a plastic hand orthosis having the basic configuration shown in Figure 1 (3). 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 then be adapted to meet individual needs. The Engen orthosis is made in four sizes: large, medium-large, medium, and small; and for both right and left hands. Because the orthosis is fabricated of polyester resins, it can be remolded upon application of heat.

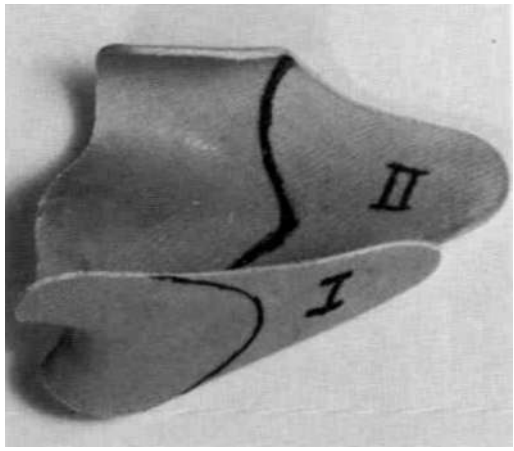


Fig. 1. Basic Engen plastic hand orthosis being prepared for individual application.

[1] Assistant Executive Director, Committee on Prosthetics Research and Development, National Research Council, 2101 Constitution Ave., N.W., Washington, D.C. 20418.

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. The plastic shells originally submitted to New York University for a laboratory evaluation program were made of fiberglass and polyester resins *(9).* 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 provide wrist support and to provide prehension.

Three versions or adaptations of the Engen plastic hand orthosis were selected as the subject of the field evaluation: 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 *(3).* 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 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-l levels, peripheral neuropathy (ulnar and median nerves), or hemiplegia.

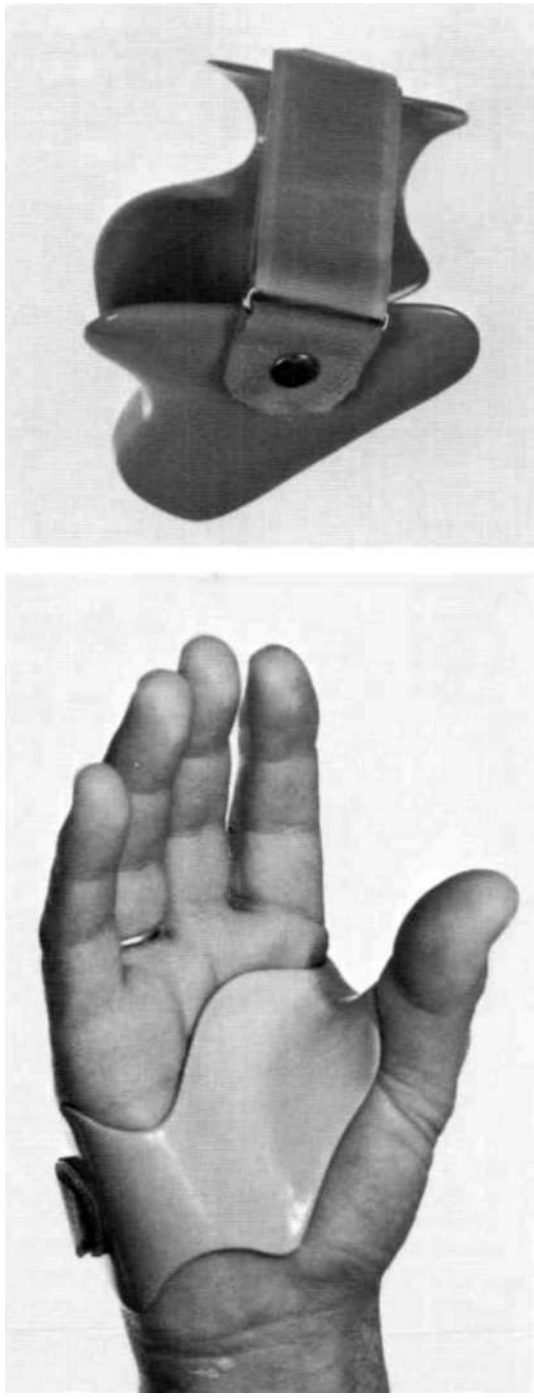


Fig. 2. Two views of the short opponens orthosis.

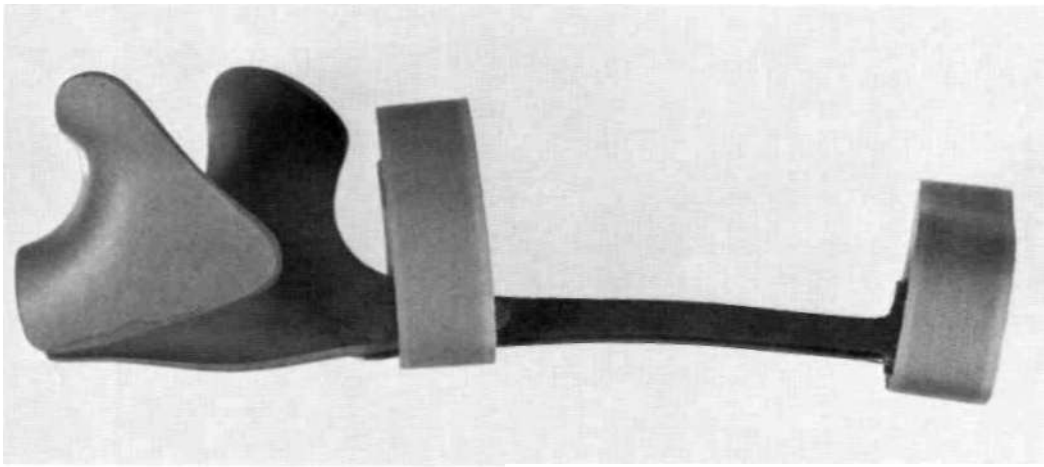
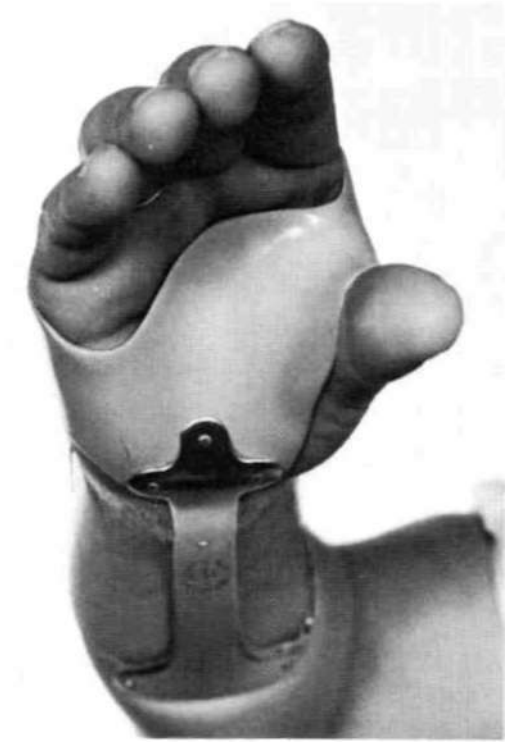


Fig. 3. Two views of the long opponens orthosis.



LONG OPPONENS ORTHOSIS

This adaptation (3) 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 or ulnar nerves, or both, and the radial nerve, or hemiplegia, are said to be suitable candidates for this device.

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

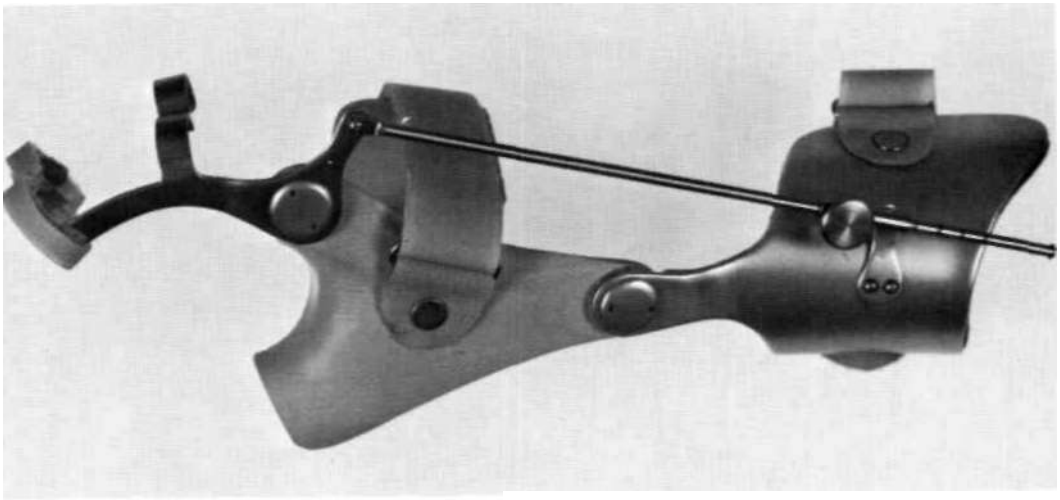
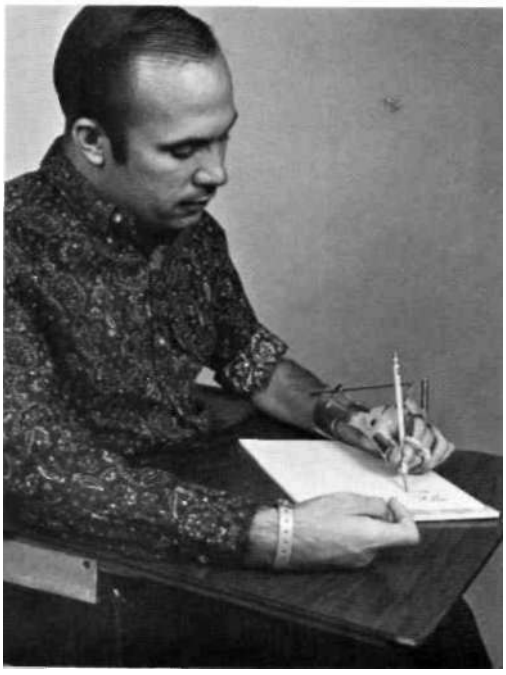


Fig. 4. Two views of the reciprocal orthosis.



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, N. C. (Frank W. Clippinger, Jr., M.D.; Bert R. Titus; Felton Elliott).
2. Georgia Warm Springs Foundation, Warm Springs, Ga. (Edward Haak, M.D.; H. G. Bowden).
3. Highland View Hospital,[2] 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, Ill. (James F. Kurtz, M.D.; Vladimir T. Liberson, M.D.; Walter J. Piotrowicz, CO.).

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 to 8, 1966 (orthotists, four days; physicians, one day). Instructional material and fitting check lists were prepared by the developer *(5,6,7,8),* 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.

[2] 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.

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 (8).

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.

PATIENT FITTINGS

The Sample

During the period of the evaluation program, 22 patients were fitted with the Engen Plastic Hand Orthosis. Distribution in terms of the three adaptations under study were: short opponens orthosis, 7; long opponens orthosis, 3; and reciprocal units, 12.

Moreover, data was 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.

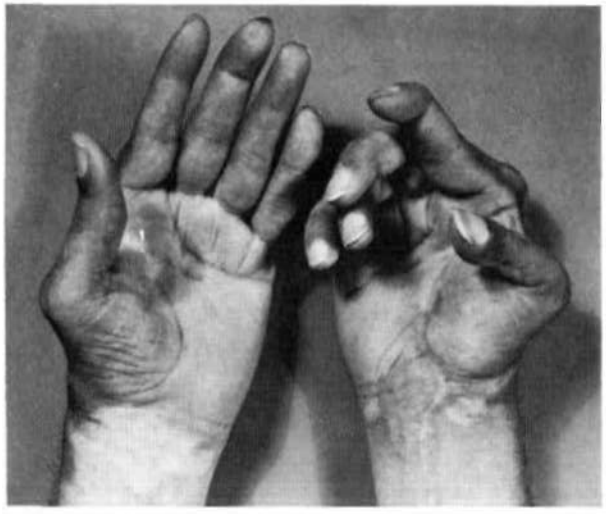
In the total of 70 fittings reported, 18 were with short opponens, 10 with long opponens, and 42 with reciprocal units, roughly a 2:1:4 ratio. Whether this ratio could be extrapolated to the general population is not known.

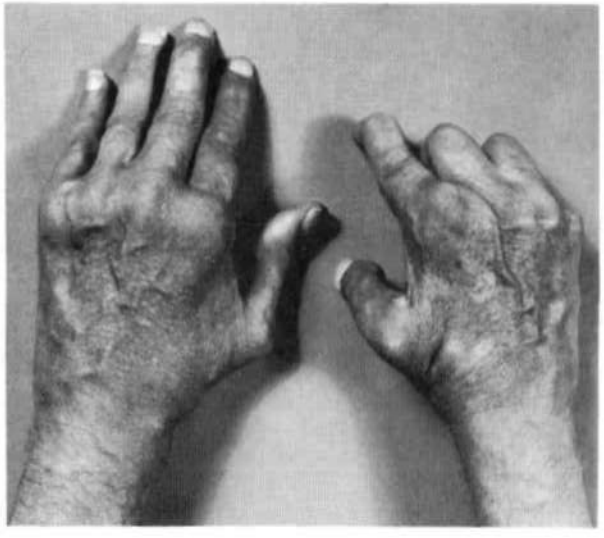
Typical conditions for which the three versions of the EPHO[3] were applied were: (1) short opponens orthosis: rheumatoid arthritis of the hands (Fig. 5); quadriplegia (to prevent deformities and support the hand in a position of function pending fitting of reciprocal units); contraction deformity of 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).

Outcomes

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

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





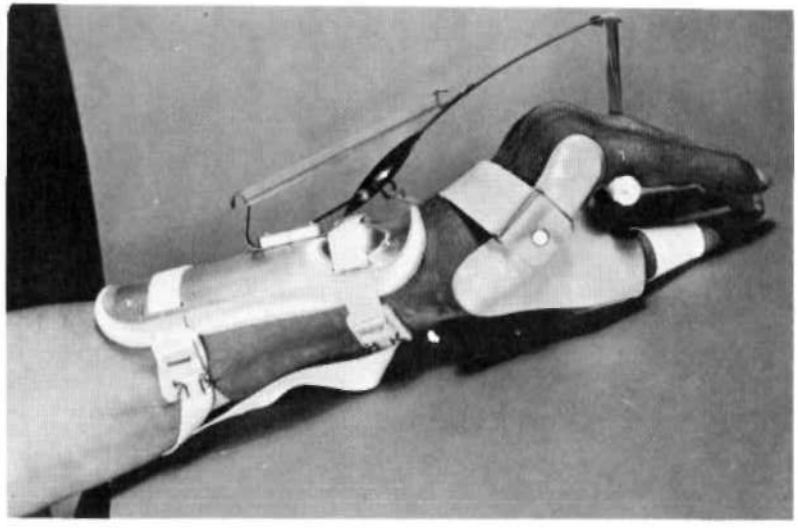


Fig. 5. *Left*, palmar and dorsal views of patient's arthritic hands. *Above*, left hand fitted with Engen short opponens orthosis and Thomas outrigger splint.

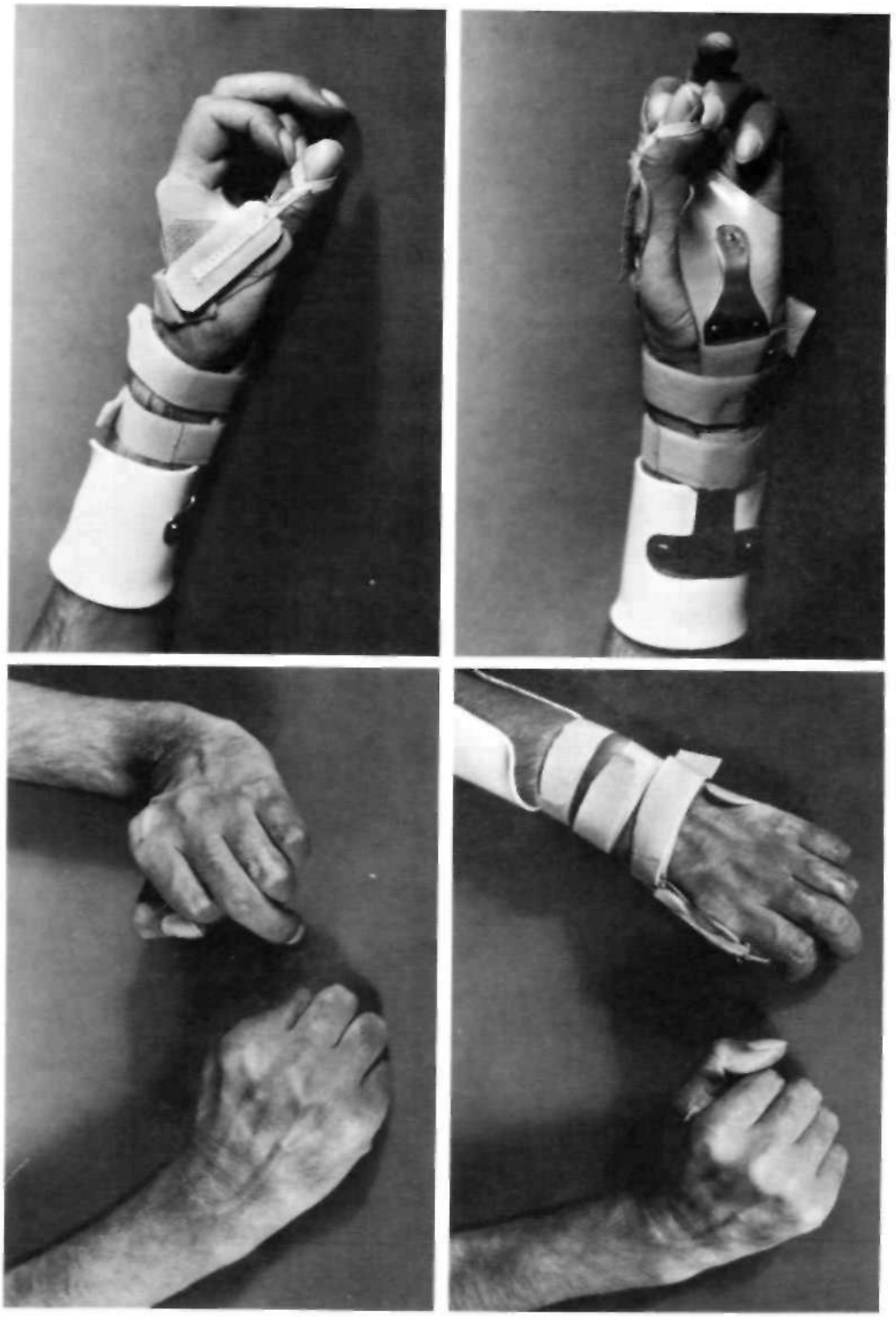


Fig. 6. Patient fitted with Engen long opponens orthosis as stabilizing device.

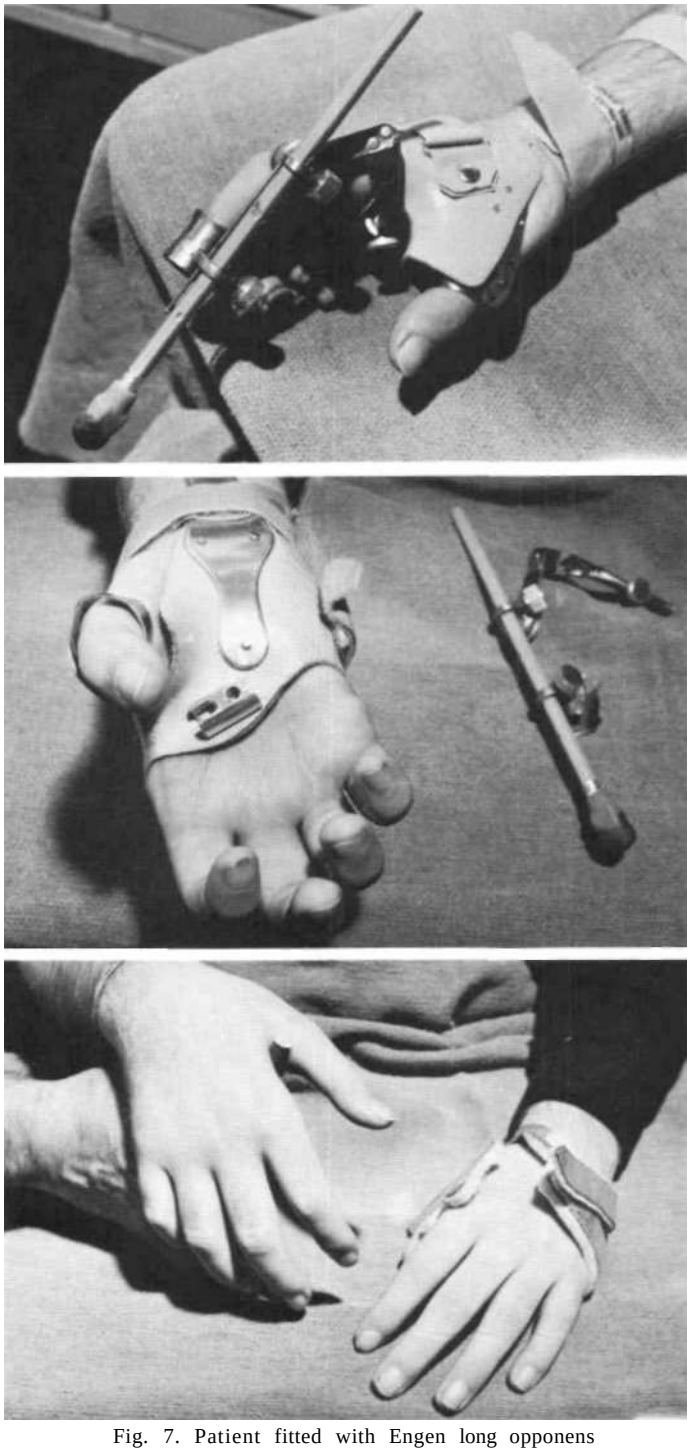


Fig. 7. Patient fitted with Engen long opponens orthosis with attachment for self-help devices. Note atrophy of thenar cleft.

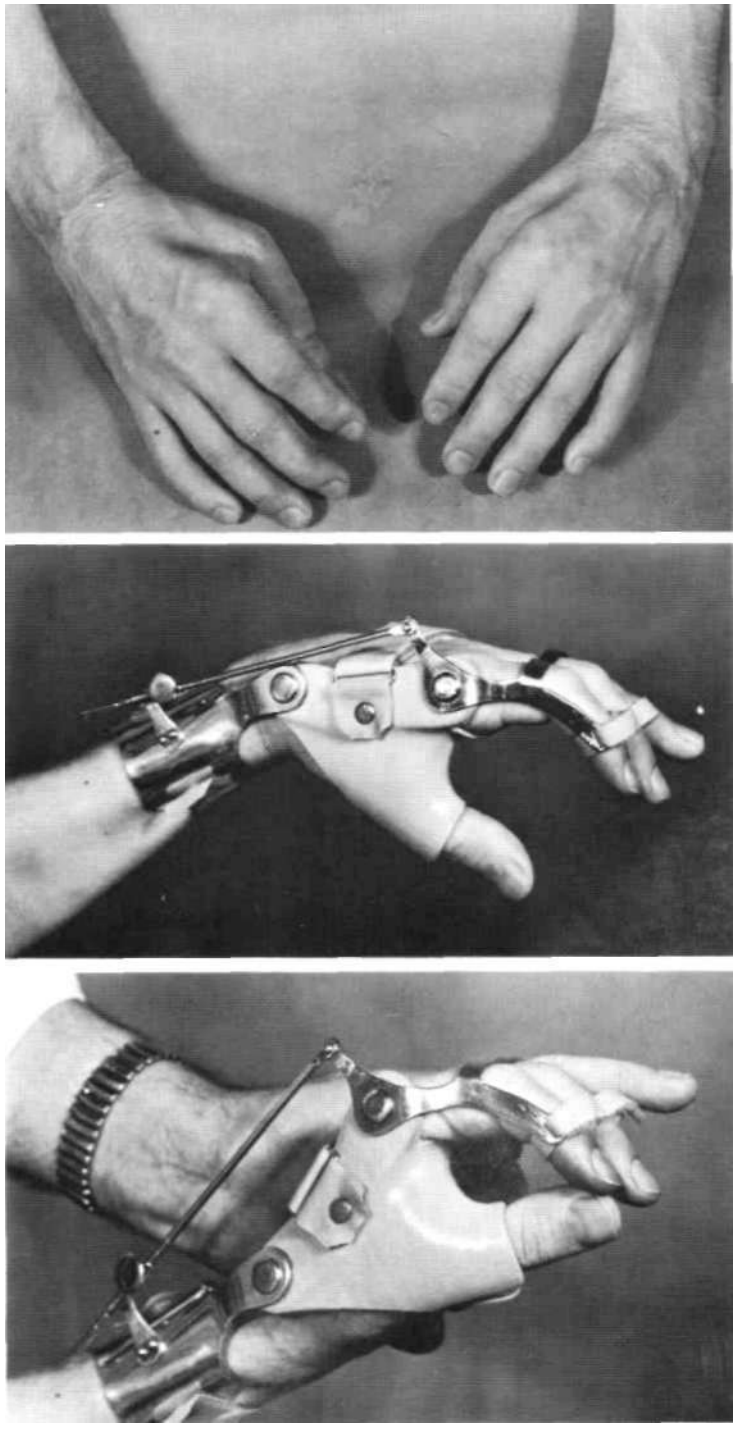


Fig. 8. Patient fitted with reciprocal unit.

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 a tolerance to pain that was average.

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 conditions were 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 were 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 page-turning, 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 Royalite 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 six and a half 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

larger 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

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 techniques 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: (1) proper selection of patients, including consideration of motivational factors; (2) meticulous care in application and follow-up of the devices; and (3) 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 set forth above were re-affirmed 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 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 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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