Home exercise in the dart-throwing motion plane after distal radius fractures: A pilot randomized controlled trial

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Study Design: This is an intrasubject cross-sectional study.

Introduction: Upper limb injuries often require wearing an orthosis. Today, orthoses are custom-made by the clinician or purchased as an off-shelf product. Although 3D printing is a popular solution, the design and adjustment of an orthosis model according to patient-specific anatomy requires technical expertise, often unavailable to the clinicians.

Purpose of the Study: The purposes of this study were (a) to create software that receives input of anatomic dimensions of the finger and automatically adjusts an orthosis model for patient-specific 3D printing and (b) to compare preparation time, product weight, and user satisfaction of occupational therapy students between the manual method and the automatic 3D printing method.

Methods: A custom code allows the user to measure five anatomic measurements of the finger. The code adjusts a swan-neck orthosis model according to the patient-specific measurements and a fitted resized 3D-printable file is produced. We recruited 36 occupational therapy students (age 25.4 ± 1.9 years). They prepared two swan-neck orthoses for a finger of a rubber mannequin: one manually using a thermoplastic material and the other by 3D printing. The preparation time and orthosis weight were measured and the subjects filled out a user satisfaction questionnaire.

Results: The weight of the 3D-printed orthosis was significantly lower than that of the manual orthosis; however, the preparation time was longer. The subjects were more satisfied with the fit, esthetics, overall process, and product of the 3D-printed orthosis.

Conclusion: The creation of automated software for the patient-specific adjustment of orthoses for 3D printing can be the missing link for integration of 3D printing in the clinics.

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potential benefits of using exercises in the DTM plane, several research groups have manufactured orthosis devices to enable motion in the DTM plane.\textsuperscript{15-16} This orthosis was suggested as an optional treatment method after scapholunate repairs, carpal fractures, and other wrist injuries.\textsuperscript{15} However, Garcia-Elias et al\textsuperscript{12} suggested caution when using the DTM plane in individuals after recently repaired scapholunate injury. Despite the growing interest in orthoses enabling DTM, rehabilitation programs that incorporate the DTM have yet to be explored. Therefore, the aim of this study was to evaluate the rehabilitation outcomes after treatment in the DTM plane compared with outcomes after treatment in the sagittal plane after DRFs.

\section*{Methods}

\subsection*{Population}

We recruited 24 subjects after open reduction internal fixation (ORIF) of DRFs. As this is a pilot study, we recruited 12 subjects per group, based on a rule of thumb for pilot studies.\textsuperscript{19} The subjects were assigned to each group using a randomized sequence allocation method. The first 2 subjects assigned to the DTM group were immediately reallocated to the sagittal group, due to technical difficulties unrelated to the subjects in preparing the DTM orthosis. The main considerations for choosing this population were as follows: First, tears of the wrist ligaments are common in DRFs, with a prevalence of up to 69\% of DRFs.\textsuperscript{20} Therefore, we assumed that most of our subjects would have injuries to the one or more ligaments of the wrist. However, because the diagnosis is performed using radiographs, which were found to have moderate reliability in diagnosing ligament injuries after DRFs,\textsuperscript{21} we were not able to specify the extent of ligamentous injury. The second consideration was that DRFs limit the functionality of the individual. Because the DTM is deemed a “functional plane of motion”\textsuperscript{22,23} encouraging motion in this plane is hypothesized to increase functionality and might therefore be beneficial to individuals following DRF. Inclusion criteria were individuals aged 18 to 65 years. Individuals with previous orthopedic or neurological impairments of the upper limb or a cognitive impairment were excluded from the study. Patient eligibility was identified before the surgery by a committee of senior hand surgeons and these were approached by the researcher of this study. Subjects were enrolled from the department of hand surgery at the Sheba medical center, consisting of 7 hand surgeons. Ethical approval was obtained from the Helsinki Committee of the medical center (approval #2085-15-SMC). The study recruitment process and design are depicted in Figure 1. Eleven potentially eligible individuals were not enrolled in the study due to the following reasons: the presence of additional diagnoses, for example, other fractures (scaphoid or distal ulna fractures) or carpal tunnel syndrome, additional stabilization of the distal radius (screw, K-wire), bilateral fractures or a supplemental bone grafting.

\subsection*{Measures}

A personal questionnaire was filled out by the subjects (age, sex, hand dominance, and injured hand). The range of motion (ROM), pain levels and functional abilities were measured before and after the intervention of 12 hand therapy treatment sessions. A satisfaction questionnaire from self-training was collected as described in the following.

\subsection*{Range of motion}

The elbow and wrist active ROMs were measured during pronation-supination, flexion-extension, radio-ulnar deviation. In addition, the DTM plane angle of the wrist was measured according to Bugden’s\textsuperscript{24} proposed method of goniometric measurement of the DTM. Abduction and adduction, opposition, and flexion-extension were measured for the thumb and digits.

\subsection*{Pain levels}

The Patient-Rated Wrist Evaluation (PRWE) is a 15-item questionnaire designed to measure wrist pain and disability in ADLs. This questionnaire allows patients to rate their levels of wrist pain and disability from 0 to 10.\textsuperscript{25} A test-retest reliability study was conducted on patients with distal radius (n = 64) or scaphoid (n = 35) fractures. The test-retest reliability of the total PRWE score and pain subscale with patients with DRFs was excellent (ICC > 0.90).\textsuperscript{26}

\subsection*{Functional hand motor skills tests}

The Jebsen-Taylor Hand Function Test (JHFT) was conducted to assess fine motor skills, weighted and nonweighted hand function activities during performance of ADLs, and the effectiveness of treatment for varied hand conditions such as orthopedic and neurological disabilities (eg, upper limb fractures, spinal cord injuries, or hemiplegia). The seven subsets of the test represent a broad spectrum of hand function, which includes writing, turning over 3 x 5 inch cards (to simulate page turning), picking up small common objects, simulated feeding, stacking checkers, picking up large light objects, and picking up large heavy objects. To evaluate client performance, each subset is timed and can be compared with the established norms. Test-retest reliability for the items ranged from moderate to high (ranged from r = 0.60-0.99 (Pearson’s product-moment correlation).\textsuperscript{27} Correlation of the Jebsen Hand Function test is high with the overall Klein-Bell Scale score (Spearman’s r = -0.635) and Klein-Bell Scale—dressing subscale (Spearman’s r = −0.69), and moderate with Klein-Bell Scale—bathing/hygiene subscale (−0.57) and Klein-Bell Scale—eating.
Satisfaction from self-training

On completion of the intervention as described previously, both groups rated their overall satisfaction from the self-training home exercises, using a 5-point Likert scale (1, not satisfied to 5, extremely satisfied).34 This questionnaire was originally constructed in Hebrew and applied to individuals with chronic stroke with no significant cognitive impairment. In addition, the DTM group filled out the Quebec User Evaluation of Satisfaction with Assistive Technology 2.0 (QUEST 2.0) questionnaire, measuring the level of satisfaction attributed to assistive technologies, that is, the DTM orthosis. This questionnaire contains 27 variables which are scored in terms of perceived importance and satisfaction. For each assistive device being examined, approximately 30 min are required to administer the assessment. For the QUEST 2.0, the device subscale, services subscale, and total scores achieved good test-retest stability (ICC 0.82, 0.82, 0.91, respectively).36 The alternate-form equivalence (ICC 0.89, 0.76, 0.91, respectively) was lower for services. There were positive correlations between the QUEST 2.0 scores and the three Psychosocial Impact of Assistive Devices Scale dimensions. These correlations were fair to moderate (r > 0.80) test-retest reproducibility.52 High test-retest reproducibility has been shown among older American community-dwelling volunteers (mean age of 75 years) tested repeatedly over a 12-week period.34

Data collection and intervention

The evaluation and group allocation was performed one week after removing the cast, which was two weeks after the surgery. Each subject read and signed an informed consent form pretrial. Then personal information, upper limb ROM, pain levels, and functional hand motor skills tests were recorded by a certified hand therapist (CHT). To describe the sample, radiological measurements were performed up to one week before surgery and two weeks after surgery. One blinded surgeon quantified radial height, radial inclination, volar tilt, intra-articular step-off, and ulnar variance, both preoperatively and postoperatively.

All of the subjects in each group received 12 therapy sessions, 30 min each one, 2 to 3 times a week, during 6 to 8 weeks after the removal of the cast. Based on past studies, this length of time should allow patients to regain most of their wrist motion.37,38 Four blinded CHTs used conventional treatment techniques such as edema control, mobilization, and muscle strengthening during the sessions. Muscle strengthening incorporated active movement by working with elastic bands (Fig. 1A). Because the surgeons prohibited activity under resistance at least 6 weeks after the surgery, most subjects practiced movements under resistance only in the last week or two of sessions. During the last week or two of the sessions, both groups received treatment that incorporated active movement via an elastic band (eg, TheraBand). The resistance of the rubber band for both groups during the sessions was tailored to each participant according to his or her abilities and pain levels. The DTM group did not use the modified dart-orthosis during the sessions with the CHT. Both groups were instructed to exercise at home, 3 times a day, 10 min per exercise session. All participants were also encouraged to perform home activities and exercises according to personal occupational goals. The sagittal group activated the wrist mostly in the sagittal plane, whereas the research group activated the wrist also in the DTM plane, via the modified dart-orthosis.

Subscale (−0.45).28 The Jamar hand dynamometer was used to measure grip strength and the B&L Engineering pinch gauge to measure palmar pinch, key pinch, and tip pinch strength. Grip strength was measured with the elbow flexed at 90° and the forearm in neutral rotation. A single measure of grip strength was performed during assessment.26,30 The second handle position of the dynamometer was used throughout testing.11 Measurements of grip strength taken with the Jamar dynamometer have evidence for good to excellent (r > 0.80) test-retest reproducibility.12 High test-retest reproducibility has been shown among older American community-dwelling volunteers (mean age of 75 years) tested repeatedly over a 12-week period.34

FIG. 2. Both groups received treatment that incorporated active movement via a resistive orthosis or (A) working with elastic band. Home exercises of the dart throw motion (DTM) group included (B) an orthosis used, upgraded with a rubber band to provide guidance along the DTM plane via a rubber band.
dart-orthosis (Fig. 1B). All of the evaluations were performed by the same certified hand therapist, who did not treat the subjects. This therapist participated in a workshop led by Dr. Deborah A. Schwartz and was therefore qualified to manufacture the novel orthosis. The modified dart-orthosis was fitted to the subjects in the DTM group on their first evaluation session. They were instructed to use the orthosis at home. For each 10-minute exercise session, they were asked to perform 5 min of radial-extension under resistance and then 5 minute ulnar-flexion under resistance. In addition, this group was required to fill in a chart, stating that they practiced 5 minute of DTM movement, at the end of each practice session, throughout the intervention period. The evaluator (CHT) performed phone calls to both groups at least twice during the treatment period to follow-up on their progress and schedule the second evaluation. The DTM group was also asked if they were using the orthosis. Each subject received 2 to 4 phone calls from the researcher. The sagittal group was instructed to perform at home active wrist motion, similar to that practiced during the supervised therapy sessions. The prescribed instructions were similar to the exercises performed during the sessions. All measures (personal information, upper limb ROM, pain levels, functional tests and satisfaction) before and after tests were taken by the same evaluator.

Data analysis

For each subject, we calculated the residual deficit in all of the parameters between the evaluation after treatment and the evaluation at the baseline \( \left( \text{Percentage} = \frac{100 - \text{post}}{\text{pre}} \times 100 \right) \). For the pinch and grip strength tests, measured after treatment, we calculated the percentages of the values of the injured hand in relation to the uninjured hand \( \left( \text{percentage} = \frac{\text{injured}}{\text{uninjured}} \times 100 \right) \).

Descriptive statistics were used to describe the personal characteristics of the subjects in both groups (received treatment, age, sex, injured hand, hand dominance, radiological measurements, and QUEST). For the radiological measurements, we performed inter-group comparisons, for both pre- and post-surgery data. Based on the Shapiro–Wilk test, most variables were not normally distributed, so nonparametric tests were applied. We used the chi-square test for categorical variables and the Mann–Whitney test for numeric variables, when comparing parameters between groups. Significance was set at \( P < 0.05 \). Statistical analyses were performed in IBM SPSS software, v25 (IBM, Armonk, NY). Effect sizes for Mann–Whitney test were calculated according to Fritz et al.\(^39\).

Results

All of the subjects had ORIF surgery (19 subjects underwent surgery using the volar approach, 4 subjects with the dorsal approach and 1 subject underwent surgery with a dorsal-volar approach). Both groups were similar in their demographic and radiology data after surgery at the baseline (Table 1). In addition, the two groups had similar ROM, PRWE, and JHFT scores at the baseline. We compared the differences, calculated between baseline and post-treatment outcomes between the two groups. There were no statistically significant differences in the ROM (Table S1), pain, PRWE scores (Table S2), and JHFT scores between the groups (Table S2). Specifically, the percentage of difference in ROM of the wrist and forearm between the post- and pre-intervention evaluation time points was as follows (median and IQR): 150.0 (134.4–174.1) flexion, 191.7 (157.1–250.0) extension, 50.0 (25.0–100.0) ulnar deviation, 100.0 (0.0–200.0) radial deviation, 55.0 (37.5–95.0) radial extension, 100.0 (33.3–200.0) ulnar flexion, 56.3 (20.0–96.9) supination, and 16.0 (1.7–37.7) pronation. The PRWE score was improved by a median and IQR percentage of 33.8 (16.6–52.6). The Jebsen-Taylor test score was improved by a median and IQR percentage of 29.0 (14.1–34.4). After the intervention, the percentage between the injured versus the uninjured hand was as follows (median and IQR): 56.4 (35.4–65.8) grip strength, 66.7 (50.0–81.2) lateral pinch, 58.8 (42.9–72.0) tripod pinch, and 71.4 (50.0–83.3) tip-to-tip pinch.

The subjects in the DTM group reported significantly higher satisfaction comparison with those in the sagittal group after the intervention (Fig. 3). Their satisfaction was higher for measures of general satisfaction (DTM group: 3.4 ± 0.7, sagittal group: 2.5 ± 1.2, \( P = 0.030 \)), opportunity to self-train at home (DTM group: 3.5 ± 0.7, sagittal group: 2.3 ± 1.1, \( P = 0.005 \)), motivation to exert oneself due to self-training (DTM group: 2.8 ± 1.0, sagittal group: 2.3 ± 1.2, \( P = 0.009 \)), progressed function due to self-training (DTM group: 3.4 ± 0.7, sagittal group: 2.4 ± 1.1, \( P = 0.012 \)), and self-training contribution to the daily function (DTM group: 3.4 ± 0.7, sagittal group: 2.5 ± 1.2, \( P = 0.030 \)) (Fig. 3). We found no statistically significant differences in the grip and pinch strength percentages of the injured hand in relation to the uninjured hand following the intervention between the two groups (Table S3). In addition, the DTM group reported on the QUEST that the most important features that contributed to their satisfaction from the modified dart-orthosis that it was light-weight, easy to don, and durable over time.

Discussion

This is the first study to examine the effect of rehabilitation in the DTM plane after DRFs treated with ORIF in comparison with the conventional protocol treatment in the sagittal plane. For this purpose, we introduced a new dynamic orthosis at a relatively early time.
The main finding of this study was that most of the short-term outcome measures were similar between the treatment groups. The satisfaction levels from the treatment were higher among the DTM group. All treatment outcomes of both groups were similar to those in other clinics worldwide practicing early rehabilitation. The selected references detailed in the following incorporated similar intervention and had similar evaluation time points, as in the present study. Specifically, the interventions in the referenced studies included both outpatient hand therapy treatments in a clinic (30 minute twice a week) and instructions for home exercises (2-3 each day). Their first evaluation was approximately 2 weeks postsurgery and postintervention evaluation at 6 to 9 after surgery. In terms of ROM, after treatment, the median and IQR maximal wrist flexion was 52.5° (45.0°–60.0°). This was similar to other published wrist flexion degrees, for example, mean and SD of 52.7° ± 9.0 in 30 individuals aged 53.8 ± 14.1 years following volar approach ORIF surgery of DRF, and 44° ± 14.0 in 138 individuals aged 59 ± 16 years with DRF treated with ORIF. The maximal wrist extension of 50.0° (40.0°–55.0°) was also similar to other publications, for example, 54.67° ± 9.9°, 43° ± 16.0° (in 81 individuals aged approximately 52 years following volar approach ORIF surgery of DRF) and 56° ± 11.0°. This similarity was also noted for the pronation and supination ROMs. The rehabilitation outcomes were also comparable with current literature in the PRWE scores, as the PRWE scores after DRF rehabilitation was a median and IQR of 41.0 (17.4–60.7). These are similar to the mean and SD of 36.1 ± 13.9 in a study that included 48 individuals aged 54.8 ± 14.5 years following volar approach ORIF surgery of DRF. In addition, each of the seven items of the JJT measurements produced similar outcomes with the literature involving DRF rehabilitation. Finally, the grip strength values of 16.0 kg (9.2–30.2) agreed with the literature, as Quadlbauer et al reported grip strength of 12.3 ± 8.4 kg.

The likeness between protocols might explain the high similarity between the outcome measures. Because we chose to control only a singular factor, practicing in the DTM plane, the subjects received similar rehabilitation protocols of both surgery and rehabilitation. Regarding the method of surgery, both groups were recruited from a single facility, and therefore, the same surgical method of volar fixed-angle plating was administered, as is the protocol in our hospital (Table 1). Since our choice for including subjects who underwent volar fixed-angle plating and early active mobilization, as is the custom in our facility, the similarity in the outcomes of both groups might be expected. Broader criteria that might include several different treatment methods, surgical or nonsurgical, for example, fragment-specific fixations, external fixations, and various pinning techniques, as well as different rehabilitation methods, early versus late mobilization, might have affected the results. These have been previously shown to be a confounding factor. For example, significant differences in the rehabilitation outcomes measures were found between different surgical methods and rehabilitation protocols. In this study, the usage of the modified dart-orthosis was the only difference between the two rehabilitation protocols, so that it helped us to isolate the effect of exercising in the DTM plane. Since so, our results lead us to conclude that this isolated parameter does not hinder or accelerate the rehabilitation process, compared with the conventional treatment method.

The DTM group reported higher satisfaction from the self-training exercise compared with the sagittal group (Fig. 3). We assume that the significantly higher satisfaction rates in the DTM group could be explained with two reasons: First, while both groups received equal treatment time, the researcher asked the DTM group if they were using the modified dart-orthosis, thereby providing them with more attention compared with the sagittal group. Future studies should include a standardized script for the phone calls. Second, while all of the subjects were informed about
the novelty of the modified dart-orthosis, the awareness of the DTM group of the hypothesis for better rehabilitation outcomes might have elevated their subjective satisfaction from the treatment. Using the modified dart-orthosis to practice wrist movement could possibly contribute to the satisfaction from the treatment on the other hand, because the sagittal group improved without the DTM orthosis, the expense of the orthosis (approximately 180USD) was spared.

There were a few limitations to this study: First, the small sample size may not reflect the entire studied population. Second, it was difficult to track the amount of self-use of the modified dart-orthosis among the DTM group participants. Although this group was required to fill in a chart at the end of each self-training session at home, not all subjects complied. Therefore, the frequency of home exercises using the DTM orthosis might have been too limited to provide significant clinical outcomes. Third, the study was unblinded so that some experimenter bias might be expected and also the subjects were aware of their group assignment. Finally, the satisfaction questionnaire, although used by another researcher, has no reported validity. Future studies should involve higher frequency of usage of the DTM orthosis and may also compare the outcome measures between the usage of the DTM orthosis and the dynamic flexion-extension orthosis following DRFs.

The implications for occupational therapy practice are as follows:

- The clinician may choose between one of the treatment methods or devise a combination of both, depending on the abilities of the patient.
- Exercising in an alternate plane may contribute to the satisfaction of the patient.

Conclusions

The resemblance between both groups in outcomes does not favor one treatment method over the other. Therefore, we conclude that the similarities between the rehabilitation outcomes of both groups empower the liberty of the clinician to choose between the treatment methods or devise a protocol combining both methods. Individuals treated with the modified dart-orthosis were more satisfied with the modified dart-orthosis and the extra attention from the researcher. The clinician could therefore identify individuals less engaged in self-training exercises beyond the clinic sessions and hopefully promote their compliance by supplying them with the modified dart-orthosis. In conclusion, the higher satisfactory levels of the DTM group may point toward advantage of exercising in the DTM plane after DRFs by promoting better compliance to home exercise. Higher compliance would accelerate earlier return to function in recreational, occupational, and household activities.

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Supplementary data

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References