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Comparison of 3D Printing and Traditional Hand Orthosis Fabrication

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Abstract

Traditional methods of custom orthosis fabrication are prone to challenges and limitations. Three-dimensional (3D) printing has been piloted with lower extremity orthotics and worthy of exploration with upper extremities. The aim of this study was to compare three-dimensionally printed wrist immobilization splints to conventionally made orthoses in terms of fabrication, comfort, and functionality. Three healthy participants with no history of wrist or hand conditions were recruited to be fitted for conventional and 3D-printed wrist immobilization splints. A sequential mixed-methods study design was conducted to explore comfort, fabrication, and functionality. An ethnographic study was conducted afterward to further understand the fabrication process of 3D-printed orthotics. The Quebec User Evaluation of Satisfaction with Assistive Technology and a Splint Analysis form was used to assess comfort. The function was assessed using the Jebsen-Taylor Hand Function Test. A five-point satisfaction Likert scale was used to evaluate fabrication. Although the results were not statistically significant due to the small sample size, 3D-printed orthotics appear to provide some benefits over traditional methods.

Keywords: Hand/wrist orthotics, customized hand orthotics, conventional, three-dimensional printing, comfort, fabrication, functionality

1. Introduction

Orthoses, also known as splints, are external devices that serve to prevent or support movement to help correct many orthopedic maladjustments through immobilization. Orthotics describes the services associated with assessing, fabrication, and fitting of orthoses to the patient (Howell et al., 2021).

Instability of the joint may result in direct injuries, including bone fractures, dislocation of joints, and/or soft tissue injuries such as muscle strains or ligaments sprains. Impairments of the hand and wrist can occur in neurological, neuromuscular, and musculoskeletal disorders (Althoff & Reeves, 2020; Oud et al., 2021). Examples of common chronic conditions within these categories include spinal cord injuries (SCI), multiple sclerosis (MS), cerebral palsy (CP), and cerebrovascular accidents (CVA). Common limitations surrounding neurological disorders can be spasticity or contractures. Muscle weakness and sensory loss are common due to neuromuscular disorders. Pain, joint deformity, and decreased grip strength are linked to musculoskeletal disorders (Oud et al., 2021).

These limitations can drastically limit functional performance throughout the day (Zheng et al., 2020). Due to the chronic nature of several of these diagnoses, comfort is a priority in order to promote better compliance with wearing the orthotic and sticking to treatment with patients, which improves outcomes. Customized orthoses are commonly fabricated for individuals with chronic hand and wrist impairments; however, adherence to wear schedules and treatment protocols are often neglected (Cole, Robinson, Romero, & O'Brien, 2019; Zheng et al., 2020).

Occupational therapists (OTs) often assess those who are in need of customized orthoses, as the condition they are facing often impairs function. Multiple studies suggest custom-made orthoses and orthotic services can be an effective strategy in improving movement, participation, and overall quality of life (Portnova et. al, 2018, Toth et. al, 2020). Each injury that requires an orthosis is unique in terms of how the joints should be stabilized and protected to promote optimal healing. An improperly fitted orthosis may generate opportunities for delayed healing and/or contribute to further injury (Zheng et al., 2020).

The process of fabricating a conventional orthosis can pose several problems. Fabrication of the conventional thermoplastic hand and wrist orthosis can be laborious, time-consuming, and prone to extensive production time, mixed functional outcomes, and lead to decreased satisfaction due to inaccuracy of fit and discomfort (Oud et al., 2021). Conventional hand-made orthoses cannot fully match the curve of the wrist and hand. Inaccurate size, insufficient strength of the material, and inadequate support for the wrist and hand may lead to inadequate stretching (Zheng et al., 2020). Addressing these issues might promote an increase in user satisfaction and fit, as well as lead to better compliance and adherence to the orthotic protocols.

An emerging alternative is the potential use of three-dimensional (3D) scanning of the contours of the body, paired with 3D printing or orthoses. This technology has the potential to contribute improvements in orthoses fabrication accuracy (Oud et al., 2021; Portnova et al., 2018; Toth et al., 2020; Zheng et al., 2020). The purpose of the present research study was to compare the differences in comfort, fabrication, and functionality between 3D-printed and conventional hand orthoses.

1.1 Research Question

The present study was guided by the following research question: does a wrist orthosis fabricated using 3D scanning and printing lead to improved fit and functionality, when compared to traditional methods? The authors hypothesized that 3D-printed wrist orthoses would improve patient's comfort and functionality when compared to traditional thermoplastic custom-made devices. The authors also hypothesized that the time needed to make an orthosis using this technology would be significantly different than using traditional methods.

2. Literature Review

Since 2010, 3D printing has exploded in popularity due to increased availability of technology and decreased costs. In health professions, 3D printing has become a powerful tool due to the customizability and ability to control the production and fabrication of the items needed, eliminating the wait time and unavailability of needed parts from manufacturers around the world. Three-dimensional printing has opened the door to new innovations and provided health professionals new power to create customized items that did not exist prior, enhancing the quality of care and expected outcomes (Ventola, 2014).

Many aspects such as design, function, comfort, and appearance impact orthotic treatment outcomes. Several studies have shown that 3D-printed orthoses are often comparable and occasionally even more effective than traditional orthotics in terms of fabrication process, comfort/fit, and functionality (Oud et al., 2021, Portnova et al., 2018, Toth et al., 2020, Zheng et al., 2020).

2.1 Functionality

Functionality has been measured using multiple standardized tests, including grasp, strength, range of motion (ROM), standardized evaluations, and performance in various activities of daily living (ADL). Common outcome measures of functionality have included the Patient Rated Wrist Evaluation (PWRE) and the Jebsen-Taylor Hand Function Test (JHFT). Studies that used the JHFT concluded that there were no statistically different results when comparing 3D-printed orthoses and traditional orthoses. The JHFT was administered after wearing the 3D-printed orthoses and the average time to complete the assessment was lower than at baseline (Portnova et al., 2018). The studies that used the PWRE as an outcome measure had mixed results. There was no significant difference between the 3D-printed orthoses and the traditional orthoses in terms of functionality (Kim et al., 2018). However, Graham et al. (2020) concluded that 3D-printed orthoses had improved functionality compared to traditional orthoses.

Other standardized outcome measures of functionality have consisted of the Box and Blocks test, pinch dynamometry, and the Manual Function Test. When using these outcome measures, all participants showed improvement in function when using a 3D-printed orthosis. (Portnova et al., 2018, Toth et al., 2020). One possible explanation for this is that the 3D-printed orthoses may have had a more accurate fit compared to the conventional orthoses. This leads to higher patient orthosis wearing adherence, further contributing to improvement in function.

2.2 Fabrication

Fabrication consists of several factors such as cost, material, production time, fit and accuracy. In a study of developing anti-spastic orthoses for stroke patients, a combination of 3D printing technologies and nitinol, a mix of nickel and titanium metal, material was used to create anti-spastic wrist orthoses for home-use. It was found that not only did the orthoses provide ease of assembly and use, but also a cost-effective alternative to traditional methods (Toth et al., 2020).

In another study, researchers sought out to explore optimal 3D-printing materials for creating good quality, cost-effective wrist-hand orthoses (Górski et al., 2020). Polylactic acid (PLA) and acrylonitrile butadiene styrene (ABS) presented the best designed results at low cost (Górski et al., 2020). More specifically, the PLA material presented the highest strength, least expensive, and most versatile qualities that would be possible to process on any deposition modeling or fused filament fabrication printer (Górski et al., 2020).

Production time also plays an important factor in the feasibility of 3D-printed orthoses. A study by Oud (2021) found that the mean time for 3D-printed orthoses was 112 minutes, and 239 minutes for conventional orthoses (Oud et al., 2021), suggesting a 127-minute difference with 3D printing providing a quicker production (Oud et al., 2021). In addition to production time, fitting time was another aspect of this study that also showed 3D-printed orthoses having a decreased mean time of 5 minutes versus the conventional fitting time of 10.3 minutes (Oud et al., 2021).

2.3 Comfort

Comfort is a priority in regard to promoting orthoses wear compliance and successful outcomes (Cole, Robinson, Romero, & O'Brien, 2019; Zheng et al., 2020). A comparative study assessed the traditional vs 3D-printed orthotics using a self-designed questionnaire with one domain being comfort (Oud et al., 2021). Comfort included fit, material feel, and transpiration. Results suggested the 3D-printed orthoses resulted in improved comfort only (Oud et al., 2021).

In another study, prosthetics and orthotics students were tasked with creating 3D-printed orthotics for SCI patients and completed a self-designed survey which included items related to comfort (Portnova et al., 2018). Following the use of the orthotics, the participants scored comfort with a mean of 7.7 out of 10 (Portnova et al., 2018). However, in a study most closely resembling the present one, Zheng et al (2020) found no difference in comfort levels between 3D-printed and traditionally fabricated orthoses.

While the literature is mixed on the benefits of 3D-printed orthoses, it appears to suggest that 3D scanner and printer technology are capable of improving the accuracy of the fit of orthoses to the patient's contours. This may lead to improved comfort and function, which ultimately may impact adherence to wear schedules, treatment protocols, and thus improved outcomes.

3. Methodology

A sequential mixed-methods study was conducted. Participant perspective qualitative and quantitative data was gathered initially to address functionality, comfort, and fabrication in 3D-printed orthoses compared to traditional orthoses made with thermoplastic. Ethnographic qualitative data was also gathered from the study authors to describe the fabrication process when creating 3D-printed and conventional orthoses.

Conventional orthoses were designed and modified from heat-moldable plastics, more commonly known as thermoplastics. The 3D-printed orthotics shape was captured by using 3D-scanning, designed and modified with *SketchUp* computer aided design software, and printed on a *Fusion3* 3D-printer using high-temperature PLA.

3.1 Participants

The present study was approved through the Pace University IRB committee and performed in accordance with the principles stated in the Declaration of Helsinki. A convenience sample of Pace University graduate students entering their second year of an Occupational Therapy Master's Program were recruited for study participation. All participants provided informed written consent. Participants of this pilot study consisted of three healthy individuals (3 females) with no hand or wrist diagnoses. This was a within-subjects design, in which each participant served as their own control, trialing both the 3D and traditional orthoses. The exclusion criteria were any hand or wrist diagnosis, or sensory impairment impacting the ability to express pain, discomfort, or skin irritation.

3.1 Interventions/ Outcome Measures

Within the literature review, common outcome measures were used to assess comfort, functionality, and fabrication in similar research. The following assessment and evaluation tools were used to measure outcomes.

3.2 Participant Function

Hand and wrist function were evaluated through the 7 subtests of the Jebsen-Taylor Hand Function Test (JHFT), which includes writing, card-turning, manipulating small objects, and simulated feeding. This test is timed with a lower score indicating higher function. The JHFT was chosen due to its prior use in research studies as it has been shown to have good to excellent test-retest reliability (Sığırtmaç & Öksüz, 2020).

3.3 Participant Comfort

The outcome measures to assess comfort consisted of the Quebec User Evaluation of Satisfaction with Assistive Technology (QUEST 2.0) and the Splint Analysis form. The QUEST 2.0 measures device comfort on a five-point Likert scale. The QUEST 2.0 has been shown to demonstrate good test-retest stability [(ICC 0.82, 0.82, 0.91) (Wessels & De Witte, 2003)].

A Splint Analysis form assessed user satisfaction, regarding comfort of both orthotics. Subjective questions were posed to the participants assessing any noticeable skin irritations, discomfort, proper support of eminences and contours, and appearance of the orthosis. Validity and reliability of the Splint Analysis form has not been directly assessed; but is used as a standard evaluation in an accredited graduate level occupational therapy program to assess student orthoses fabrication outcomes for academic purposes.

3.4 Fabrication

Fabrication time and cost was assessed during each session with the participants. The time necessary for completing the 3D scanning and printing, as well as traditional orthosis fabrication, were measured and compared. Cost was measured by calculating the type and amount of material being used for both the 3D-printed and traditional orthotic. Labor and device costs were also included.

3.5 Procedures and Data Collection

Following a brief explanation of the study procedures, participants were measured/scanned and fitted for both a 3D-printed and a conventionally fabricated wrist immobilization orthosis. Participants attended two sessions. During the first session, the participant's hand was scanned with the use of a hand-held 3D scanner. Immediately following, the participant was fitted for a traditional orthotic made of thermoplastic material. During the second session, participants were fitted for the 3D-printed and traditional orthoses and outcome measures were gathered to assess comfort and functionality. Between these two participant sessions, the clinician/authors finalized the fabrication of the traditional orthosis which had been started in the initial session. During this period of time, the 3D-printed orthosis was also created by 1) processing the scanner file, 2) creating the orthosis design from a negative imprint of the scanned model, 3) generating the ready-for-print file through the slicing software, and 4) 3D-printing the final orthosis device.

3.6 Data Analysis

Descriptive and nonparametric statistical analyses were conducted using SPSS (IBM.inc) statistics package through a Wilcoxon signed-rank test. Cohen's D was also calculated to measure effect size to provide context in the absence of a large enough sample size to make meaningful inference from resulting p-values. Frequencies were used to determine the outcome of the surveys and comparison of fabrication domains.

4. Results

Table 1 shows the results of a Wilcoxon signed-rank test, comparing the results from Questions 1-8 on the QUEST 2.0. A Wilcoxon signed-rank test examined the results of user satisfaction (comfort) of the 3D-printed orthotic and the traditional thermoplastic orthotic. No significant difference was found in the results ($p > 0.1$). User satisfaction between the 3D-printed orthotic was not statistically significantly different from the traditional thermoplastic orthotic satisfaction.

Table 1. Results of the QUEST 2.0 scores comparison

Quest 2.0	*p-value*	*Z-value*	3D-printed *M(SD)*	Traditional *M(SD)*
Q1- Dimensions	1	-	4(1)	4(1)
Q2- Weight	0.317	-1	5(0)	4.67(0.58)
Q3- Adjusting	0.157	1.414	4.33(0.58)	5(0)
Q4- Safe/secure	0.157	-1.414	4.67(0.58)	4(1)
Q5- Durability	1	-	4.67(0.58)	4.67(0.58)
Q6- Easy	1	0	4(1.73)	4(1)
Q7- Comfortable	0.655	-0.447	4.33(1.15)	3.33(2.08)
Q8- Effective	0.157	1.414	3.67(0.58)	4.33(.058)

Note. Table 1 represents a Wilcoxon signed rank test to compare user satisfaction in comfort.

$*p<0.1$

Table 2 describes the results of the Splint Analysis score form. All participants indicated 'yes' to all questions suggesting that both the traditional and 3D-printed orthoses achieved the basic criteria for fabrication outcomes.

However, a ceiling effect has been observed suggesting the Splint Analysis score form lacks the specificity needed to measure differences between fabrication methods.

Table 2. Splint Analysis score comparison

Evaluation Areas	3D	Traditional
The wrist has adequate support	Yes	Yes
The orthosis allows full thumb motions	Yes	Yes
The orthosis allows full metacarpophalangeal (MCP) joint flexion of the fingers	Yes	Yes
The orthosis provides wrist supports that allows functional activities	Yes	Yes
The orthosis does not cause impingements or pressure sores	Yes	Yes
The orthosis does not irritate bony prominences	Yes	Yes

Note. The Splint Analysis form consists of subjective yes/no questions.

Table 3 shows the results of a Wilcoxon signed-rank test, comparing scores on the Jebsen Hand Function test. This test used timed scoring procedures; thus, lower mean and standard deviation scores imply better performance. While the 3D-printed orthosis resulted in lower timed scores (M = 49.45) compared to the traditional fabrication method (M = 55.36), the differences were not statistically significant (Z = 0.535, p > 0.1). However, the small sample size of n = 3 suggests that rejecting the null hypothesis in this would likely result in a Type II Error. The Cohen's d verifies this assumption as several subtests suggest moderately large ($d > 0.5$) effect sizes for the areas of writing, feeding, and total scores.

Table 3. Jebsen Hand Function Test (JHFT) comparison

Subtest	*p-value*	*Z-value*	3D-Printed *M(SD)*	Traditional *M(SD)*	Cohen's *d*
Writing	0.593	0.535	12.88(3.19)	16.79(7.58)	0.67
Simulated Page Turning	1	0	5.39(0.83)	5.58(0.35)	0.3
Lifting small common objects	1	0	8.14(2.54)	8.56(1.37)	0.21
Simulated Feeding	0.285	1.069	11.19(4.81)	13.82(2.95)	0.66
Stacking Checkers	0.593	0.535	3.40(1.08)	3.81(0.76)	0.44
Lifting large light objects	0.593	0.535	4.36(1.08)	4.43(0.33)	0.09
Lifting large heavy objects	1	0	4.09(0.65)	4.1(0.32)	0.02
Total	0.593	0.535	49.45(13.33)	55.36(8.86)	0.52

Note. Table 3 represents a Wilcoxon signed rank test to compare functionality. Lower mean scores indicate improved timed performance.

Table 4 describes the fabrication time for each orthosis. The added complexities associated with 3D-scanning, computer aided-design preparations, and printing resulted in significantly longer fabrication times than traditional orthosis fabrication. The PLA material used for printing costs approximately $20-40; while the thermoplastic material is approximately $50-60 per (1/8‘' x 18" x 24") sheet. Additional tools are needed for traditional fabrication methods, such as heat pans, heat guns, scissors, etc., but poses significantly lower costs that the 3D-scanner and printer which in the case of the present study totaled approximately $9,000 combined.

Table 4. Fabrication Time

Participant	3D	Traditional
1	8h 40m	18m
2	8h 20m	21m
3	7h 50m	22m

Note. Table 6 represents the time used to create each orthotic, measuring the fabrication process of the 3D-printed splint and thermoplastic splint.

5. Discussion

The present study resulted in no statistical significance due to the small sample size and lack of power. However, the difference in means and Cohen's *d* calculations suggest there were some benefits found with user functionality and fabrication of 3D-printed orthoses. Participants using the 3D-printed orthosis were found to have improved writing and simulated feeding functionality; however, this occurred at the expense of significantly increased fabrication time and cost associated with 3D-related technologies.

Zheng et al. (2020) described the importance of a properly fitted orthosis for the promotion of healing and prevention of further injury. The 3D-printed orthosis appeared to result in a more accurate fit, meaning that the surface of the orthosis more accurately reflected the contours of the hand, wrist, and forearm in a way which does not seem easily achieved with a traditional fabrication method. Furthermore, the traditional fabrication method required the clinician to make 'adjustments' to ensure a proper fit.

Proper fit and comfort play an additionally important role in assuring adherence of wear schedule, since an orthosis can only be effective if it is applied consistently according to the therapist recommendations (Oud et al., 2021). While the 3D-printed orthosis appears to provide increased contour accuracy, it is not clear that this benefits the comfort or eventual adherence to usage. Despite the 3D-printed orthoses increased contour and fit accuracy, the present authors acknowledged that this fabrication method would also likely need adjustments for an effective fit in a real case scenario. Making adjustments to a 3D-printed splint is significantly more challenging as the material does not easily bend or flare when focused heat is applied. Furthermore, it cannot be simply cut with scissors if the material needs trimming, as with thermoplastic materials.

Furthermore, while the traditional orthoses appeared to require more adjustments to ensure a proper fit, the time saving over the 3D-printed fabrication method nullified this issue. The 3D-printed orthoses fabrication required a multiple step process consisting of 3D-scanning the participant's hand, using computer aided design (CAD) software to create the orthosis design, slicing software processing to prepare the design for printing, and printing of the actual orthosis. The CAD software design process was particularly labor intensive, time consuming, and required knowledge and expertise not typical of a clinician's general practice skills.

These findings suggested that 3D-printed orthoses are theoretically capable of resulting in comparable or better fitted orthoses which may lead to improved comfort and function. The 3D-scanning and printing technologies can be used as an alternative to traditional fabrication methods, and in some ways may be beneficial depending on the specific needs of the client. However, the time, technology cost, and decreased adjustability associated with 3D-fabricated orthosis does not appear to render it a viable alternative to traditional fabrication methods for the typical clinical setting.

It is possible that 3D-related technologies will continue to evolve leading to a closing of the gap between fabrication methods. However, traditional methods continue to be most feasible given the present productivity and economic landscape of the clinical setting.

5.1 Limitations

There were several notable limitations in this research. The sample size was too small for inference of generalizability, and as stated previously most likely resulted in a Type II error in terms of assuming the differences were not statistically significant, as suggested by the Cohen's *d* calculations. Rather, these results described the feasibility of using 3D-scanning and printing of orthoses and pilot this technology within a small cohort.

The study authors served as the fabricators for both orthosis methods. The authors were also the data gathers for all outcome measures. The participants were healthy occupational therapy students and did not present with any hand diagnoses.

5.2 Contribution

Previous research suggests that 3D-printing and scanning technology can have a positive impact on orthosis fabrication (Oud et al., 2021). The present study found that this technology can improve the accuracy of matching the contours to the hand, and thus improved fit. Theoretically, improved fit and comfort should lead to improved adherence to wear schedules. While the present study was not able to make inferences on improved patient adherence to wear schedules, the 3D-printed orthosis presented with several limitations that appear to make it prohibitive to be used in a conventional clinical setting. These included: time to fabricate, technology cost, and limited adjustability to orthosis once completed. While 3D-scanning and printing have the potential to improve the orthosis fabrication process, presently, the technology is too complex for realistic clinical use.

6. Conclusion

No statistically significant differences were found between the 3D-printed and traditionally fabricated orthoses in terms of comfort and function, although the effect size calculations suggest the former improves the functionality when compared to the latter as measured by the Jebsen Hand Function Test. These findings indicated that although there was not enough difference for statistical significance due to the small sample size, 3D-printed orthoses appeared to improve the accuracy of the fit to the surface of the hand/wrist/forearm.

While 3D-scanning and printing technologies may improve the fit of the orthoses, the time, cost, and learning curve associated with using the technology appears to be not feasible for realistic general clinical use. Productivity and cost-containment requirements of the present economic healthcare landscape are likely to require that these technologies significantly improve the efficiency of orthosis fabrication before they can be adapted within the general clinical setting.

Competing Interests Statement

The authors report there are no competing interests to declare.

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