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Fit Comparison of Custom Casts Created Through Photogrammetry & FDM Rapid-Prototyping of Ipsilateral Versus Mirrored Contralateral Extremities

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Abstract: Approximately 185,000 amputations occur in the United States each year, and the number of amputations is much higher in the developing world. Though a generic prosthetic can restore some functionality, they are impersonal and a relatively poor fit may create an uncomfortable feeling. The purpose of this study is to compare the gap volume of custom casts created through photogrammetry and FDM rapid-prototyping of ipsilateral versus mirrored contralateral extremities. Based on the results of this study, the 3D-Scanning/CAD Modeling/3D-printing process offers a significant improvement over the current cast/ prosthetic production method for the rate of production, cost, comfort, subject satisfaction, material quality, and could be incorporated in small clinic settings for usage with minimal resource investment. **Keywords**: Cast, prosthetic, photogrammetry, FDM rapid-prototyping, mirrored extremities

INTRODUCTION

Approximately 185,000 amputations occur in the United States each year [1]. The Red Cross estimates that 40,000 prosthetists are needed across the developing world in order to meet

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demands; not only for new onset trauma but for congenital deficits/disorders as children will need frequent prosthetic replacements throughout life as they grow [2]. This demand further increases during wartime.

3D-Scanning/Modeling/Printing is a scalable process that is only limited by equipment as it does not take years to master a new prosthetic. The low cost of hardware makes the approach more accessible and ideal for the developing world and scalability [3]. The use of 3D printing to manufacture orthotics seems to have many potential benefits over traditional methods, and may exceed the quality of the parts produced by traditional methods [4].

Utilizing photogrammetry (3D-Scanning), computer-aided design (CAD) mirroring and alteration, and fusion deposition modeling (FDM) rapid-prototyping (3D-Printing), it is possible to create an inexpensive plastic prosthetic that is nearly identical to what a patient has lost (in form); as well as neatly matching the residual limb's complex surface anatomy to achieve a close fit with a minimal skin to material interface air gap. 3D-Printed casts may be considered as a substitute for traditionally used casts with clinically acceptable accuracy that can be used in diagnosis, treatment planning, and fabrication of prosthetic restorations [5].

Air trapping between a prosthetic and the patient's skin "can cause skin burn and blistering when it is heated while the prosthesis is loaded" [6]. A custom fit prosthetic should have the minimum amount of air gap possible fitting much closer as compared to a generic, thus it would be considerably more comfortable with less skin blistering.

Thermal discomfort was noted to be a leading cause of prosthetics patient complications; therefore, an ideal prosthetic socket should have the ability to control the residual-limb temperature [7]. Liners and/or ventilation channels could be incorporated in the design for patient comfort and improved tribology. 3D-Printing materials vary widely in material properties; the most common material Polylactic Acid (PLA) is a hydrophobic thermal insulator with a low melting point.

Utilizing human midline symmetry, an impaired extremity could be prosthetically restored to a static nearly anatomical ideal (in form), via mirroring of an intact scanned contralateral extremity. Regarding the 3D-printed accuracy of mirrored forearm casting, it is asserted that "The mirror technique offers relatively accurate patient data and minimises imaging difficulties for the patient", and "There is no [patient] complaint about the fitting issue by using the mirror technique". [8]. 3D-Scanning / CAD modeling / 3D-Printing on healthy subjects will enable us to theoretically & experimentally measure the magnitude of discrepancy of the underlying anatomy, and complex skin surface geometries of extremities of a direct fit cast compared to a contralateral mirrored fit

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cast. This will be done by measuring the amount of negative volume (gap) present after donning each, respectively. This will also reveal how close ideal human symmetry is in the upper distal extremity, and if there are any trends to handedness in size disparity.

Purpose of Study

The purpose of this study is to compare the gap volume of custom casts created through photogrammetry and FDM rapid-prototyping of ipsilateral versus mirrored contralateral extremities.

This comparison may demonstrate the advantages of utilizing relatively inexpensive recent innovations in 3D-Scanning, CAD modeling, and 3D-Printing, as a solution to make a better cast/prosthetic that fits more accurately, is more comfortable, and is true to anatomical form due to being generated from a scanned and mirrored contralateral extremity. Also, this study assesses the viability of contralateral scanning, mirroring, and printing of a region of an intact extremity to treat contralateral trauma as proof of concept, to encourage the export and reproduction of this methodology in the developing world where custom-fit casts/prosthetics solutions are in dire need.

Research Objectives

1. Assess gap fit (direct measurement of human anatomical surface boundaries) of 3D-scanned, modeled, and 3D-printed hand/wrist casts against subject anatomy, and show that it exceeds a non-custom generic's fit.

2. Survey healthy patients (subjects) on their preference (custom-fit wrist cast vs generic wrist cast): material comfort/pain, weight, stability/restrictive fixation strength, and overall cast preference (given cost difference & time), if they were in need.

METHODOLOGY

The following equipment was used for the study:

- 1. Computer Windows 11 x64, Intel i7-9700F, 32Gb RAM, with an NVIDEA RTX 2070
- 2. 3D Scanner Shining 3D Einstar Handheld 3D Scanner
- 3. 3D Printer Artillery Sidewinder X1 (v4)
- 4. 3D Printing Materials Blue OVERTURE Easy PLA (1.75mm)
- 5. Software Blender3D (v2.82.7), Ultimaker Cura (v4.13.1), EXStar (v1.0.6.0)

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- 6. The leading brand commercial Generic Wrist Brace (Medium/Large, L & R)
- 7. Etekcity Scale Weight capacity 11lbs (± 0.3 g accuracy)
- 8. Graduated Cylinder
- 9. "Gak" Quasi-solid material (Borax, Glue, Water, Coloring)

Also, additional research was conducted using Google Scholar, PubMed, and other relevant literature sources, with an extensive review of over 100 articles relating to: 3D scanning, 3D printing, prosthetics, orthotics, splints, braces, medical modeling, handedness size disparity, tribology, and amputee residual limb skin breakdown.

Study Design Due to not having access to a large population of amputee patients to fit for prosthetics, the upper extremities of healthy volunteer subjects (n=10) were utilized as proxies (Figure 1). This allows for modeling a form-fitted wrist cast over a specific complex region of distal anatomical geometry (with chirality), similar to a residual stump which would require fitting due to complex anatomical contours, but with the added benefit of a healthy symmetrical model as a control.

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Optical photogrammetry was used to 3D-Scan the hand/wrist (left & right independently), to generate CAD models for both distal upper extremities of a subject. Using CAD software (Blender) the scanned data was cleaned of noise aberrations and the model was reduced to cut off the region above the palmer crease, 1cm distal to the base of the hallux, and 1cm proximal to the base of the thenar eminence, to make a brace covering this region with the lateral border open 1cm for

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donning. A 1mm thickness of material was added to the outside of the scan, to make a form-fitting cast/shell for the wrist.

From the obtained models, a 3D-printed direct cast of this region and a mirrored version of the opposite side was generated. CURA was used to slice these objects into 0.2mm layers for 3D-Printing, then printed in Polylactic Acid (PLA) at 205°C. This was done for both sides (left wrist, left wrist mirrored, right wrist, & right wrist mirrored) making four casts per subject (n=40 total), effectively doubling the subject population group and allowing for midline symmetry comparison and analysis. From the obtained casts, an analysis of the fit accuracy was done by measuring the volume of the gap between the subject's skin and the created casts with a paired two-variable t-Test (direct ipsilateral cast versus mirrored contralateral casts percentage of gap fit).

The method for measuring gap fit percentage was done by using a quasi-solid ("Gak") to coat around the hand/wrist, applying the cast which would compress and displace the Gak causing it to flow out around the cast's edges and pack within the cast, removing the excess material, then collecting and weighing the Gak that was retained between the subject's skin & the cast. The weight of the Gak was measured, and then the volume retained was calculated via density, to give an objective approximation for the quality/accuracy of the fit by comparing relative volumes. Gak density was calculated via weighing a sample and measuring its water displacement (discarding samples after measurement to avoid altering the batch). From these measurements, the density of Gak was found to be 0.9324 (g/cm3).

Virtual models of the direct ipsilateral and mirrored contralateral sides were overlapped and the relative volumes were assessed digitally to predict the anticipated theoretical gap discrepancy, as done similarly by Jang et al. (2020) [9] by superimposing the models, and accounting for any possible boundary variability (figure 2).



Figure 2: Subject's 1 right wrist, and mirrored left wrist superimposed (Blender). Source: Authors

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The volume difference and ratio of a solidified cast between one side mapped to the mirrored contralateral, represents both a theoretical anticipated gap volume and a theoretical handedness size disparity assessment.

The difference between the virtually overlapped theoretical differences and the physically measured difference in gap volumes, yielded correlation data on how well anticipated virtual modeling results compare against 3D-printed results in reality. Comparing the direct ipsilateral versus mirrored contralateral gap volumes on the same subject's dominant versus non-dominant sides across the subject population would reveal if there is a trend in handedness size disparity (n=10).

Similar further investigation was done measuring the gap volume of cast/braces designed for the other subjects, on one male and one female subject (n=8) to assess whether or not there is a significant statistical difference in fit between a subject's personal scanned and printed custom form-fitting brace when compared to the printed casts intended for other subjects (grouped by sex), to evaluate for accuracy by gap fit percentage (comparing measured versus theoretical anticipated).

Subjects were also subjectively assessed (on a scale of 0 to 10) for: stability/restrictive fixation strength, worthwhileness/cast preference, comfort/pain, and weight, when given an option between the top-selling off the shelf generic cast versus their custom-fit 3D-scanned and printed cast. This data was compared to similar 3D-Printed casting studies with patient surveys preformed, like Chen et al. (2020), and Choi et al. (2021) [10-11].

A cost & time analysis (for both patient/subject and clinician) was also performed ex post facto based on the final tally of the study's materials, equipment used, time spent, and technique improvement/refinement during experimentation.

RESULTS

Fit Analysis

Comparing the weight of donned casts with gak filling all gaps (negative space) between the hands and the casts, to the cast alone prior without gak (table 1), gap volume was calculated, via the Gak density (0.9324 g/cm3).

Vol.13, No.1, pp.,41-62, 2025

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Website: https://www.eajournals.org/

Publication of the European Centre for Research Training and Development -UK

Table 1: Measured Gak (Quasi-Solid) Weight (g) / and Gap Volume (cm3). %Error of Direct & Mirrored Casts.

| | Right Wrist | Left Wrist Cast | Mirrored Right Wrist | Mirrored Left Wrist | | | | | |
|-----------------------------------|----------------|-----------------|---------------------------|--------------------------|--|--|--|--|--|
| Subject | Cast | On Left Wrist | On Left Wrist | On Right Wrist | | | | | |
| | On Right Wrist | (g) / (cm^3) | (g) / (cm^3) | (g) / (cm^3) | | | | | |
| | $(g) / (CM^3)$ | | | | | | | | |
| S1 | 6.6 / 7.082 | 9.4 / 10.086 | 8.7 / 9.335 | /.4 / /.940 | | | | | |
| S2 | 13.2 / 14.163 | 13.4 / 14.378 | 14.2 / 15.236 | 11.7 / 12.554 | | | | | |
| S3 | 11.3 /12.124 | 11.5 / 12.339 | 14.8 / 15.880 | 13.3 / 14.270 | | | | | |
| S4 | 15.6 /16.738 | 19.8 / 21.245 | 21.5 / 23.069 | 17.2 / 18.455 | | | | | |
| S5 | 23.4 / 25.107 | 29.1 / 31.223 | 37.6 / 40.343 | 27.6 / 29.614 | | | | | |
| S6 | 9.2 / 9.871 | 12.4 / 13.305 | 11.6 / 12.446 | 12.0 / 12.876 | | | | | |
| S7 | 13.4 / 14.378 | 12.0 / 12.876 | 16.1 / 17.275 | 12.4 / 13.305 | | | | | |
| S8 | 20.1 / 21.567 | 19.8 / 21.245 | 28.2 / 30.258 | 23.4 / 25.107 | | | | | |
| S9 | 15.8 / 16.953 | 11.8 / 12.661 | 21.9 / 23.498 | 15.8 / 16.953 | | | | | |
| S10 | 16.7 / 17.918 | 11.6 / 12.446 | 17.2 / 18.455 | 18.3 / 19.635 | | | | | |
| %Error of Direct & Mirrored Casts | | | | | | | | | |
| | Right Wrist | Left Wrist Cast | Mirrored Right Wrist Cast | Mirrored Left Wrist Cast | | | | | |
| | Cast | On Left Wrist | On Left Wrist (%Error) | On Right Wrist (%Error) | | | | | |
| | On Right Wrist | (%Error) | | 6 | | | | | |
| | (%Error) | | | | | | | | |
| S1 | 3.24% | 4.78% | 4.44% | 3.61% | | | | | |
| S2 | 5.67% | 5.78% | 6.10% | 5.06% | | | | | |
| S3 | 6.03% | 6.32% | 7.98% | 7.03% | | | | | |
| S4 | 6.58% | 8.56% | 9.22% | 7.21% | | | | | |
| S5 | 6.37% | 7.96% | 10.05% | 7.43% | | | | | |
| S6 | 5.56% | 7.29% | 6.85% | 7.13% | | | | | |
| S7 | 6.66% | 5.91% | 7.77% | 6.19% | | | | | |
| S8 | 6.39% 6.49% | | 8.99% | 7.36% | | | | | |
| S9 | 8.35% | 6.05% | 10.68% | 8.35% | | | | | |
| S10 | 6.23% | 4.76% | 6.91% | 6.78% | | | | | |
| Average | 6 | .25% | 7.26% | | | | | | |
| Standard | 1 | .23% | 1.74 | 1% | | | | | |
| Deviation (σ) | | | | | | | | | |

Note: Gak volume derived from calculated gak density 0.9324 (g/cm3). %Error was calculated by the measured gap volume divided by the total volume. Source: Authors

Vol.13, No.1, pp.,41-62, 2025

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Website: https://www.eajournals.org/

Publication of the European Centre for Research Training and Development -UK

The %Error as determined by measuring the retained gak volume, was found to be larger for the mirrored contralateral fit as compared to the direct ipsilateral fit by 1.01% on average; average %Error of a directly fit cast was found to be 6.25%, SD = 1.23%, while the average %Error of a mirrored cast was found to be 7.26%, SD = 1.74% (table 1).

Midline Symmetry Analysis

The mean difference between direct and the contralateral mirrored paired sides fitting showed a better fit for the directly modeled side, with M = 2.940 (cm3), and SD = 2.141 (table 2).

| Subject | Side Fit | Direct Fit (cm ³) | Mirrored Contralateral Fit (cm ³) | Difference (cm ³) | |
|---------------------------------|----------|-------------------------------|---|-------------------------------|--|
| S1 | Left | 10.086 | 9.335 | -0.751 | |
| S2 | Left | 14.378 | 15.236 | 0.858 | |
| S3 | Left | 12.339 | 15.880 | 3.541 | |
| S4 | Left | 21.245 | 23.069 | 1.824 | |
| S5 | Left | 31.223 | 40.343 | 9.120 | |
| S6 | Left | 13.305 | 12.446 | -0.858 | |
| S7 | Left | 12.876 | 17.275 | 4.399 | |
| S8 | Left | 21.245 | 30.258 | 9.013 | |
| S9 | Left | 12.661 | 23.498 | 10.837 | |
| S10 | Left | 12.446 | 18.455 | 6.009 | |
| S1 | Right | 7.082 | 7.940 | 0.858 | |
| S2 | Right | 14.163 | 12.554 | -1.609 | |
| S3 | Right | 12.124 | 14.270 | 2.146 | |
| S4 | Right | 16.738 | 18.455 | 1.717 | |
| S5 | Right | 25.107 | 29.614 | 4.506 | |
| S6 | Right | 9.871 | 12.876 | 3.004 | |
| S7 | Right | 14.378 | 13.305 | -1.073 | |
| S8 | Right | 21.567 | 25.107 | 3.541 | |
| S9 | Right | 16.953 | 16.953 | 0.000 | |
| S10 | Right | 17.918 | 19.635 | 1.717 | |
| | Average: | 15.885 | 18.825 | 2.940 | |
| Standard Deviation (σ) | | 5.783 | 7.924 | 2.141 | |

Table 2: Hand/Wrist Measured with Direct versus Mirrored Contralateral Fit.

Source: Authors

Direct fit of a scanned hand/wrist cast on a subject had a mean value of M = 15.885 (cm3), SD = 5.783 (cm3), whereas fitting the subject's same hand/wrist with their mirrored contralateral

Vol.13, No.1, pp.,41-62, 2025

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Publication of the European Centre for Research Training and Development -UK

extremity, M = 18.825 (cm3), SD = 7.924 (cm3). The paired-samples t-test revealed a significant difference between fitting the two sides, t (19) = -3.706, (p = 0.0015). There is a very high positive linear relation (Pearson correlation = 0.913) between direct and mirrored contralateral fitting, and Cohen's D = 0.424 implies a small to medium effect size in magnitude (table 3).

 Table 3: Same Hand/Wrist Fit, Direct Versus Mirrored Contralateral Fit.

| t-Test Paired Two Sample for Means | Direct Fit (cm3) | Mirrored Contralateral Fit (cm3) |
|------------------------------------|------------------|----------------------------------|
| Mean | 15.885 | 18.825 |
| Variance (σ^2) | 33.447 | 62.791 |
| Standard Deviation (σ) | 5.783 | 7.924 |
| Observations | 20 | 20 |
| Pearson Correlation | 0.913 | |
| Hypothesized Mean Difference | 0 | |
| df | 19 | |
| t Stat | -3.706 | |
| P(T<=t) one-tail | 0.0007503 | |
| t Critical one-tail | 1.729 | |
| P(T<=t) two-tail | 0.001501 | |
| t Critical two-tail | 2.093 | |
| Cohen's D | 0.4238 | |

Source: Authors

Thus, the direct scanning and cast recreation of a subject's extremity in terms of volume and surface geometry variation measured via gap volume of a hand/wrist is statistically significant in the difference from that of their mirrored contralateral extremity (hand/wrist), though the magnitude of the difference is small to medium.

Handedness

The scanned results showed that the subject's dominant hand/wrist volume had a mean increased size compared to the non-dominant hand/wrist M = 8.02 (cm3), with SD = 5.14 (cm3) and a mean increased size ratio compared to the non-dominant hand/wrist, M = 3.76%, with SD = 2.80%. Excluding subjects with past trauma respectively, M = 5.19 (cm3), SD = 2.81 (cm3) and M = 2.28%, with SD = 0.98% (table 4). Volume differences in handedness is more discernible with past trauma. Thus, there exists a larger dominant handedness disparity (by 2.28% to 3.76%).

Vol.13, No.1, pp.,41-62, 2025

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Website: https://www.eajournals.org/

Publication of the European Centre for Research Training and Development -UK

| Increased Size Ratio | |
|----------------------|--|
| | |
| 2.43% | |
| 3.71% | |
| 9.42% ^A | |
| 1.23% | |
| 4.31% ^в | |
| 1.25% | |
| 1.62% | |
| 3.31% | |
| 7.91% ^c | |
| 2.42% | |
| 76% (SD = 2.80) | |
| 28% (SD = 0.98) | |
| | |
| 76 28 | |

Source: Authors

Non-personalized Cast Fitting

Fitting casts not specifically designed for the subject showed a theoretical volume difference that matched the experimentally measured differences with an average % Error in males of 31.25%, and an average %Error in female subjects of 21.89% (including the undersized cast, 58.90%) (table 5).

Vol.13, No.1, pp.,41-62, 2025

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Table 5: Dominant Hand Cast Comparison for Male and Female Subjects

| | Male Subjects | | | | | | | |
|---|-----------------|----------------------|--------|--------|--------|--------|--------|--|
| Subject | S10 | | S8 | | S5 | | | |
| Measured: | | | | | | | | |
| Weight (g) | 1 | 6.7 | 42.1 | | 89.0 | | | |
| Volume (cm ³) | 17 | 7.918 | 45.172 | | 95.494 | | | |
| Extra Volume (cm ³) | | - | 27. | 253 | 77.575 | | | |
| Virtual: | | | | | | | | |
| Volume (cm ³) | 26 | 59.82 | 315.85 | | 368.90 | | | |
| Expected Difference (cm ³) | | - | 46 | .03 | 99.08 | | | |
| % Error | - | | 40. | 40.79% | | 21.70% | | |
| Average %Error | 31.25% | | | | | | | |
| | Female Subjects | | | | | | | |
| Subject | S3 | S6 | S9 | S1 | S7 | S4 | S2 | |
| Measured: | | | | | | | | |
| Weight (g) | 11.5 | 30.0 | 19.8 | 24.3 | 27.4 | 47.4 | 50.9 | |
| Volume (cm ³) | 12.339 | 32.189 | 21.244 | 26.073 | 29.399 | 50.858 | 54.614 | |
| Extra Volume (cm ³) | - 19.850 | | 8.906 | 13.734 | 17.060 | 38.519 | 42.275 | |
| Virtual: | | | | | | | | |
| Volume (cm ³) | 183.02 | 169.23 | 196.54 | 200.72 | 205.06 | 227.06 | 234.45 | |
| Expected Difference (cm ³) | - | -13.79 | 13.52 | 17.70 | 22.04 | 44.04 | 51.43 | |
| %Error | - | 243.94% ^A | 34.13% | 22.41% | 22.59% | 12.54% | 17.80% | |
| Average %Error | 58.90% | | | | | | | |
| Non-undersized Avg %Error | 21.89% | | | | | | | |
| A – Undersized cast didn't fit, causing large negative volume under palm. | | | | | | | | |

Note: Used subject S10 for reference male model and subject S3 for reference female model. Source: Authors

The average % Error for all subjects (excluding the undersized cast) was 24.57%. Thus, a generic cast not specifically designed for a subject will misfit (be undersized) by roughly 24.57% (21.89% Female, 31.25% Male, SD = 9.68%) of the theoretical virtually expected excess volume, or not fit entirely (if smaller).

Survey Results

Based on the average survey results and considering the totality of the qualitative feedback, the subjects found the custom hand/wrist casts to be stable/functional as a brace (8.25/10), very

Vol.13, No.1, pp.,41-62, 2025

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Website: https://www.eajournals.org/

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worthwhile/valuable (9.3/10), better than the leading commercially available generic brand cast (9.1/10), comfortable, but could be improved with flared edges (8.45/10), and very lightweight (9.8/10) (table 6).

| Subject | S1 | S2 | S3 | S4 | S5 | S6 | S 7 | S8 | S9 | S10 | Average |
|--|--|------|-----|----|------|-----|------------|----|-----|-----|---------|
| Stability / Restrictive Fixation Strength (RFS) | 8.75 | 7.75 | 9 | 6 | 7.5 | 8.5 | 8 | 9 | 9.5 | 8.5 | 8.25 |
| Worthwhileness / Value | 9.5 | 8.75 | 9.5 | 10 | 7.25 | 9.5 | 10 | 9 | 10 | 9.5 | 9.3 |
| Cast Preference | 6.5 | 10 | 10 | 10 | 8.5 | 8 | 9 | 9 | 10 | 10 | 9.1 |
| Comfort / Pain | 7 | 8.5 | 8 | 10 | 8.5 | 6.5 | 8 | 9 | 10 | 9 | 8.45 |
| Weight | 9 | 10 | 10 | 10 | 9 | 10 | 10 | 10 | 10 | 10 | 9.8 |
| Follow-up Survey Qualitative Feedback | | | | | | | | | | | |
| Stability/RFS: | "Fit well, didn't feel that restrictive.", "Didn't feel flimsy." | | | | | | | | | | |
| Worthwhileness | "Worth waiting for.", "Overall better than plaster casting, done previously on AFO (2-3 hours | | | | | | | | | | |
| Cast | "Custom, because it's hygienic/washable.", "Tailored to you.", "Generics irritate the skin, this | | | | | | | | | | |
| Comfort/Pain: | "Didn't feel too bad.", "Thumb & wrist felt constrictive.", "Should flare edges for comfort.", | | | | | | | | | | |
| Weight: | "So light!", "Really light!", "Lightweight!" | | | | | | | | | | |
| Survey Score Interpretation Notes: Stability / Restrictive Fixation Strength (RFS): Score of 0 means completely unstable or fragile, 10 is extremely stable & functions well as a hypothetical brace. Worthwhileness / Value: Score of 0 means useless, 10 means useful. Cast Preference: Score of 0 means a preference of a generic commercial cast, a score of 5 means ambivalence | | | | | | | | | | | |

Table 6: Follow-up Survey Results (Scale of 0-10).

Cast Preference: Score of 0 means a preference of a generic commercial cast, a score of 5 means ambivalence towards either cast, a score of 10 means a preference for the scanned & 3D-printed casts created for them personally.

Comfort / Pain: Score of 0 means very painful, score of 10 means very comfortable.

Weight: Score of 0 means heavy / encumbering, 10 means light.



DISCUSSION

Through hand/wrist cast creation, the accuracy of 3D-Scanning, CAD modeling, & 3D-Printing's ability to reproduce the surface boundary of a complex distal region was assessed through measuring the fit of both the ipsilateral hand/wrist directly and the contralateral mirrored extremity. The potential of modernizing the methodology of cast/prosthetic production was explored for the

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creation of custom fit solutions (3D-Scanning/CAD Modeling/3D-Printing) to help prosthetists in the developing world meet the dearth of roughly 40,000 prosthetists, and whether this alternative solution could meet or exceed the build quality in terms of overall performance, cost-effectiveness, comfort, and managing patient volume (patients per technician per year), relative to current typical prosthetic manufacturing of roughly one prosthetic producible per week [2].

Scanning Technology & Accuracy

Through the process of attempting accurate recreation, error is accumulated through every step in the procedure chiefly through the scanning & printing process. Multiple research studies have used various scanning methods depending on the desired target region, scanner cost & availability, and the fundamental technology employed by the scanner (optical, laser, CT, or MRI).

Aly and Mohsen (2020) [5], used optical scanning (Trios 3Shape), and found that "width overestimation was greatest in digital models due to arch distortion during cast scanning", a known scanning error phenomenon in dentistry. Despite the error being higher in scanning (average mean error of 0.06925, highest error of 0.142 SD or 0.38% of reference length,) they found their results were still within the clinically acceptable range (<5% for mean of dimensions).

Jang et al. (2020) [9] used an optical scanner (Comet LED 3D-scanner with 6- μ m precision), and noted that use of intraoral scanners is a major advance for dental offices, but echoes the results of Aly & Mohsen (2020) [5] that while the fit is within the clinically acceptable range (<120 μ m here), the marginal and internal RMS values were significantly higher than in stone casting, which avoids the digital intermediates of scanning and printing through direct surface casting.

Choi et al. (2021) used two different 2D & 3D scanning methods. The 3D scanned method was found to sometimes be frustrating for patients due to tracking loss during the scanning process [11]. Tracking loss is a common entry-level 3D-scanner issue due to a narrow visual window (restricted due to computational intensity) over an object with minimal or repeating feature details, or scanning in a poorly lit area. The 2D method employed by Choi et al. (2021) [11] used a flat trace or silhouette of the region, to model then print a similarly flat brace, then heated the brace to deform it directly to a 3D shape to fit to the affected region on the patient. What they discovered is that having patients maintain a static pose for scanning added an unexpected hurdle of scanning difficulty. Patient's reported pain, tremor, and exhaustion, all which lead to incomplete shape data. Choi et al (2021), note that these limitations could be overcome through "using expensive 3D scanners" [11]. Wang et al. (2018) overcame this dynamic patient movement issue by scanning static impressions made by the patients in clay [12]. Advancements in functional portable 3D-

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Scanning technology still have a long way to go, but as of September 2022, there is now an affordable commercial grade semi-portable scanner (EinStar 3D), available to the general public which overcomes many of the limitations noted by Choi et al. (2021) & Wang et al. (2017) [11-12], which requires a presently mid to higher end desktop computer [RAM (32Gb+), VRAM (6Gb+), graphics cards (NVidea 1060 GTX or above), & computational power (i7-11800H+)], to run it's with commercial grade scanning software. Taking into consideration the information described by other authors 3D-Scanning and fusion deposition modeling (FDM) rapid-prototyping (3D-Printing) were used in our study.

CAD Mirroring

When dealing with injury or defects, thanks to midline symmetry, mirroring can be a powerful tool to rectify the difference. Chen et al. (2017) mirrored 8 out of 10 of their casts from the contralateral non-fractured arm, and found that patients completed the entire clinical course with "superior clinical outcomes" [8].

Wang et al. (2018) [12] utilized midline symmetry to generate custom fit fingerboards from scanned hand imprints of a patient's non-contractured contralateral hands. They found that due to the customized design, it was more comfortable to wear, which lead to better compliance and "solved the defects of the traditional finger plates which could neither match hand types nor perform accurate orthopedics" [12].

Fit Analysis & Sources of Error

It was found that a direct ipsilateral scan of a hand is a more accurate fit, than any other rigid generic/non-fitted cast that deviates in virtual volume by $6.25\pm1.23\%$. The average %Error in modeling a distal extremity was 6.25% (SD = 1.23%), and the %Error in modeling a distal extremity based around that of a mirrored contralateral extremity was 7.24% (SD = 1.74%). In Zuniga et al. (2015) [13] work to fit a prosthetic 3D-hand, they photographed and then measured lengths in Blender, then compared that to direct measurements of the extremity. From this data, %Error was determined to be roughly 4.1% to 6.6%. This comparable yet smaller %Error, gives pause in the veracity of the measured results obtained from using the pseudo-solid (Gak) method for measuring gap volumes to assess the surface geometry difference, given the very accurately 3D-Scanned mapped surfaces (theoretically within ± 0.14 mm). Visually and tactically the directly scanned and donned casts empirically seemed to fit very snuggly.

Perhaps two sources of error potentially introduced here are:

Vol.13, No.1, pp.,41-62, 2025

Print ISSN: ISSN 2053-406X,

Online ISSN: ISSN 2053-4078

Website: https://www.eajournals.org/

Publication of the European Centre for Research Training and Development -UK

1) Gak surface tension & adhesive qualities may cause cast adherence, resisting being expressed out completely and thus leading to entrapment in non-rigid/boney regions due to compressibility of regional soft tissue deposits.

2) Variation of anatomical positioning (wrist flexion, ulnar wrist deviation, degree of pronation/supination, thumb radial & palmer ad/abduction, and flexion/extension), even within the same subjects in scanning vs measuring.

Assessing the fit of a cast crafted for a subject versus a direct cast of another subject, the volume difference measured was consistently smaller than the expected virtual difference by roughly 24.57% (21.89% Female, 31.25% Male) or roughly 9.8cm3 (tables 8, 9). This suggests that perhaps the measured volumes based on the weight of gak, should have a density closer to 24.57% times greater, or 1.179 (g/cm3) rather than 0.932 (g/cm3) (table 1). When submerged in water, the gak sinks (as expected for a density > 0.998) & begins to slowly dissolve, this brings concerns for a complex molecular change on submersion explaining the possible discrepancy. Considering this alternative density, if true, then all previously measured gap volumes will decrease in size (meaning closer fits), while simultaneously, all relative volumes and ratio comparisons would remain unchanged. Another way to think about this %Error is that the virtual model's expected difference can adequately predict the volume to be within 24.57% (SD 9.68%) of the measured volume difference (if not undersized).

Symmetry & Handedness

Symmetrical examination of direct fit of a scanned hand/wrist versus fitting the subject's same hand/wrist with their mirrored contralateral extremity revealed a significant difference between the gap fit of the two sides, with p<0.0015 (significance set at p = 0.05), with a very high positive linear relation (Pearson correlation = 0.913), and Cohen's D of 0.424 implying a small to medium effect size in magnitude (table 5). So, the left & right wrist/hands of individuals were found to be statistically different. Handedness analysis of the difference between a subject's left and right hand showed that the dominant hand/wrist volume had a mean increased size ratio compared to the non-dominant hand/wrist by 2.28% to 3.76% with a history of chronic trauma (table 7, figure 9). Thus, accounting for this volume difference by correspondingly enlarging or shrinking a prosthetic by roughly 3.0% of volume during the CAD modeling stage prior to 3D-Printing, should provide for closer replication for life (in the absence of an ipsilateral model). The proposed 3.0% factor would require further analysis for additional factors such as grip strength, age, occupation, sex, forced-handedness, ambidexterity, etc. to establish & identify better factor weights for anticipating

European Journal of Biology and Medical Science Research Vol.13, No.1, pp.,41-62, 2025 Print ISSN: ISSN 2053-406X, Online ISSN: ISSN 2053-4078 Website: <u>https://www.eajournals.org/</u>

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volume differences. Scharoun & Bryden (2014) [14] explored the topic of handedness, and noted conflictingly that right-handed individuals were on average 91-96% weaker on the left, with the difference increasing with age, while also noting that handedness could not be predicted from grip strength when it was sampled from an inventory of 16 different factors. According to Kaye & Konz (1986) [15] they found a similar 2.1% statistically significant difference in volume corresponding to handedness (n = 30, age 18-30).

Time & Cost Breakdown

A total of 20 scans were performed (discarding 5 failed early scan attempts that experienced movement / tracking loss, or incomplete scan detail), from which 40 hand/wrist braces models were designed & printed during the course of this experiment. Subjects required two visits, once for 3D-scanning, and then followed up cast for fitting typically two days to one week later, where the interim time was filled with CAD denoising and alteration/solidifying for 3D-printing.

1st Visit – Patient Scanning Visit. This initially took over 1hr with 2-3 scan attempts, which iteratively improved down to 10-15 minutes with experience and adapting/improving techniques typically requiring a single scan (roughly 5 minutes in duration for the subject to hold still regionally). Two adaptations were made:

1. To improve tracking loss complications, subjects were asked to keep their fingers together. Slight variation in relative finger positioning would cause tracking and alignment loss.

2. Improved hand positioning to better expose the interdigital space (slight webbing) between the thumb and fingers.

Clinician/Technician CAD work: Initially 8 hours, down to 3 hours with technique proficiency improvements in Blender. This time could be drastically improved with utilizing computer scripts or AI assistance.

Due to the goal of higher accuracy & smoothness/comfort, a smaller z-step was selected to be used (0.2mm using a 0.4mm 3D print nozzle), but a larger z-step of 0.4 to 0.6mm using a 0.8mm 3D-print nozzle could be utilized instead on current equipment to provide for faster prototyping (roughly 25% of the print time, $1hr \pm 15mins$), conferring moderately increased print strength, for minorly decreased smoothness/accuracy.

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2nd Visit – Patient Fit Testing. 5-10 minutes to fit, and make potential alterations (or start over). Only the first patient required alteration, due to the cast's thumb-hole being too distal, and thus just narrowly getting stuck at the interphalangeal joint.

In summation, the time to 3D-Scan/CAD/3D-Print for a single hand/wrist cast initially took roughly 15 ± 1 hours from start to finish, and through iterative experience and technique refinement, time without loss of quality, was halved to 7.5 hours (half an hour for the subject over two visits). A minimum time of roughly 2 hours or less is potentially possible utilizing a larger nozzle with a slightly larger 0.6mm z-step and CAD scripts, as described previously.

The total time spent creating 20 scans, and 40 3D-Prints was roughly 300 hours (an average of 30 hours/subject, with bilateral scans, and 4 cast prints) and cost roughly \$13.00 to \$97.50 depending on material used excluding the hardware cost (initial purchase & maintenance) and electricity. This may result in a dramatic improvement over the one prosthetic per week per prosthetist average estimate in the developing world [2].

Survey Feedback

Subjects report largely positive feedback during the study finding the casts to be stable/functional as a brace (8.25/10), very worthwhile/valuable (9.3/10), better than the leading commercially available generic brand cast or other past casting options experienced (9.1/10), comfortable, but needing improvement with flared edges (8.45/10), and very lightweight (9.8/10) (table 7). This echoes and exceeds nearly all positive survey dimensions seen in similar custom patient wrist/hand brace clinical studies surveying patients with similar dimensions assessed to this research study (table 7).

Vol.13, No.1, pp.,41-62, 2025

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Website: https://www.eajournals.org/

Publication of the European Centre for Research Training and Development -UK

Table 7: Follow-Up Survey Results from the studies of other authors (Scaled to a Scale of 0-10).

| Study | Choi et al. (2021) [11] 2D heat- molded | Choi et al. (2021) [11] 3D-printed | Chen et al. (2020) [10] | Chen et al. (2017) [8] | J.G. Salter (Author) (2024) | |
|-----------------|--|--|----------------------------|---------------------------|-----------------------------------|--|
| Stability/RFS | 8.1 ± 1.3 | 6.9 ± 2.2 | 9.22 ± 1.44 | 8.17 ± 1.5 | 8.25 | |
| Worthwhileness | 9.2 ± 1.2 | 8.8 ± 2.0 | Not Assessed | Not | 0.2 | |
| | | | | Assessed | 9.5 | |
| Cast Preference | 7.8 ± 1.6 | 6.6 ± 1.6 | 6.56 ± 2.15 | 7.67 ± 1.7 | 9.1 | |
| Comfort/Pain | 9.4 ± 0.8 | 6.4 ± 3.0 | 7.11 ± 1.61 | 8.17 ± 1.5 | 8.45 | |
| Weight | 9.4 ± 0.8 | 6.6 ± 2.0 | Not Assessed | Not | 0.8 | |
| | | | | Assessed | 9.8 | |

Survey Score Interpretation Notes:

Stability / Restrictive Fixation Strength (RFS): Score of 0 means completely unstable or fragile, 10 is extremely stable & functions well as a hypothetical brace.

Worthwhileness / Value: Score of 0 means useless, 10 means useful.

Cast Preference: Score of 0 means a preference of a generic commercial cast, a score of 5 means ambivalence towards either cast, a score of 10 means a preference for the scanned & 3D-printed casts created for them personally.

Comfort / Pain: Score of 0 means very painful, score of 10 means very comfortable.

Weight: Score of 0 means heavy / encumbering, 10 means light.

Source: Authors

Future Research

Though the results have proved mostly positive, additional improvements and alterations can be implemented to improve future versions and continue refinement and usability. Alternative materials should be explored / experimented with (Nylon, Nylon with Carbon Fiber, PLA with carbon fiber, ASA) for practicality, cost, availability, as well as other new emergent rapid prototyping thermoplastics or perhaps bound powder extrusion systems to make metal components. Hollow PLA parts could also be used to print negatives of desired parts, packed in sand, then cast in molten aluminum, for low-cost durable metal parts.

Cast specific improvements:

• Flared edges at borders to prevent scratching with shifting.

Vol.13, No.1, pp.,41-62, 2025

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Publication of the European Centre for Research Training and Development -UK

• Padding/spacing over boney prominences, else oversizing the cast by 1mm to allow for donning a soft elastic barrier material (cotton, nylon, etc).

- Velcro straps to adjust tightness.
- Faster modeling to drastically reduce CAD time. Utilizing computer scripts custom to Blender, else MeshMixer/Fusion360.

Prosthetic specific improvements:

• Modeling mechanical joints.

• Utilizing electronics/stepper motors or mechanical pulleys to restore some control & functionality.

These improvements were beyond the scope of this study, but worth investigation.

CONCLUSION

The obtained findings revealed that a direct ipsilateral scan of a hand deviated from matching the volume by $6.25\pm1.23\%$; whereas, when using the contralateral mirrored extremity, the fit was within $7.26\pm1.74\%$ of the volume - a minor difference of 1.01%, though statistically significant (p=0.0015) with small/medium impact (Cohen's D = 0.424). Thus the contralateral mirrored extremity should be considered distinct, but a viable substitute. Oversized rigid generic casts are predictably misfit by roughly $24.57\pm9.68\%$ of the virtual theoretically anticipated expected excess volume, thus a direct anatomical scan will be a more accurate fit than any other rigid generic/non-fitted cast. Handedness size disparity was determined to be between 2.28% to 3.76%. Subjects reported very positively on hand/wrist cast stability, worthwhileness, weight, comfort, and preferred it over a generic option. It was demonstrated that an individualized replica cast could be produced in under 8 hours, (potentially reducible to 2 hours with optimization) at roughly \$1 per cast, which if extrapolated to a full static lifelike forearm prosthetic would be under 48 hours, costing roughly \$10 to produce.

Therefore, the 3D-Scanning/CAD Modeling/3D-Printing process offers a significant improvement over the current cast/ prosthetic production method for the rate of production, cost, comfort, subject satisfaction, material quality, and could be incorporated in small clinic settings for usage in the developing world today with minimal resource investment.

European Journal of Biology and Medical Science Research Vol.13, No.1, pp.,41-62, 2025

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Recommendations

During the CAD modeling process, in the absence of a direct ipsilateral model, scale the mirrored contralateral model by a factor of roughly 3% to match handedness, for a truer to life fit/representation.

Limitation of Study

Subject pool was limited to healthy individuals, not ampute patient's (acquired or congenital) requiring prosthetics. So, a complex distal region of the hand/wrist was used in lieu of cojoining the boundary of a residual stump with an intact mirrored contralateral extremity.

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