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A Pilot Study on 3D-Printed Impression Trays for Cleft Palate: A Digital Manufacturing Approach

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Abstract: Cleft lip and palate (CLP), affect approximately 1 in 756 births and require comprehensive, individualized treatment strategies. Among the first important interventions is the creation of impression trays for nasoalveolar molding (NAM) plates, which help separate the oral and nasal cavities in newborns. However, traditional tray fabrication methods are labour-intensive, imprecise, and unsuitable for mass production. This study investigates the use of reverse engineering and additive manufacturing (3D printing) to streamline and enhance the production of CLP impression trays. Seventeen tray models were digitally designed using 3D scanning and computer-aided design (CAD) tools and fabricated via stereolithography (SLA) technology using PLA photopolymer resin. The trays had an average consumable usage of 13.09 ml, a weight of 15.04 g, and a production time of approximately 2 hours and 30 minutes per tray. Descriptive statistics and correlation analysis indicated predictable relationships in the fabrication process, particularly between resin usage and tray weight. Batch production further reduces manufacturing times, demonstrating scalability. While CAD/CAM workflows significantly improve accuracy, customization, and reproducibility, challenges such as material optimization and cost barriers persist. Innovations like intraoral scanning hold promise for enhancing patient safety and comfort. This study highlights reverse engineering as an efficient and scalable solution for improving CLP treatment outcomes and clinical practices.

Keywords: impression trays, cleft palate, reverse engineering, CAD/CAM, additive manufacturing

1. Introduction

Orofacial clefts, including cleft lip and palate, occur in approximately 1 in 756 births and result from a disruption in the fusion of facial processes during early gestation. These conditions require long-term interdisciplinary care, and one of the first steps in treatment is creating an accurate impression for customized prosthetics, such as the NAM (nasoalveolar molding) plate, which helps separate the oral and nasal cavities [1-6]. Traditional methods of manufacturing cleft palate impression trays are labour-intensive and lack precision, making it difficult to mass-produce them for widespread clinical use. Advances in reverse engineering, including 3D scanning, computer-aided design (CAD), and additive manufacturing (3D printing), offer a promising solution to these limitations. These technologies enable the creation of accurate, reproducible, and efficient custom trays. Although research on digital tools for cleft treatment is growing, challenges such as material selection and cost efficiency remain. This study investigates the feasibility of using reverse engineering and additive manufacturing technologies to improve the production of cleft palate impression trays, aiming to develop a more precise, reproducible, and scalable solution for clinical application. The null hypothesis of this pilot study is that the use of reverse engineering and 3D printing

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does not significantly improve the efficiency, or scalability of impression tray production compared to conventional fabrication methods.

2. Experimental materials and methods

2.1. Data Acquisition

A total of 17 cleft palate impression trays were 3D scanned using the optical 3D scanner Revopoint POP 2 (Revopoint 3D technology Inc., Shenzhen, China). Each tray was placed on a compatible turntable with the posterior side facing downward, which resulted in only the anterior surface being captured, as the scanner was unable to detect the posterior side. Scanning parameters were optimized to capture the trays' intricate geometry (Fig. 1). The resulting meshes were exported in STL (Standard Tessellation Language) format for further processing.

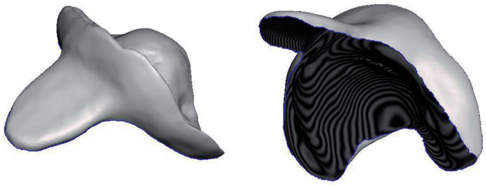

Figure 1: Scanned impression tray for newborns, the model renderings are taken from CAD software, where the models are displayed in a neutral grey colour.

2.2. Computer-Aided Design (CAD)

The meshes were edited using Meshmixer CAD software (Autodesk, Inc., San Rafael, CA, U.S.A.). Unnecessary elements were removed, and the tray handle and tray body were segmented. Both segments were extruded inferiorly by 3mm to enhance structural integrity. Subsequently, the models were united, smoothed, and uniquely numbered (Fig. 2). This process was repeated for all 17 trays.

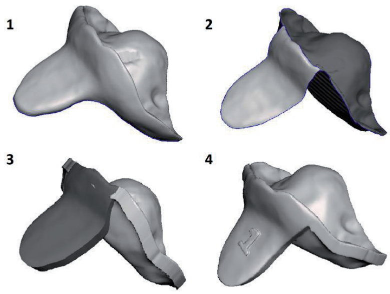

Figure 2: Impression trays from multiple views in the Meshmixer software (1 – unedited 3D scan, 2 – model separation, 3 – extrusion of surfaces, 4 – final 3D model).

2.3. Additive Manufacturing

PLA (polylactic acid) photopolymer resin was used for manufacturing of the individual impression trays via SLA (stereolithography) technology with a Creality Halot Max 3D printer (Shenzhen Creality 3D Technology Co., Ltd., Shenzhen, China). Each CAD model was prepared in Halot Box software (Shenzhen Creality 3D Technology Co., Ltd., Shenzhen, China), where support structures and printing parameters were defined (see Table 1) [7].

Table 1. Support settings and printing parameters

Support Settings		Printing Parameters	
Height from platform	6.00 mm	Layer thickness	0.05 mm
Density	50 %	Initial exposure	50 s
Tip diameter	0.80 mm	Exposure time	4 s
Support diameter	1.50 mm	Rising height	8 mm
		Motor speed	2 mm/s
		Turn off delay	4 s
		Bottom exposure layers	6

The final designs were sliced into layers and saved in the ".cxdlp" format for printing. (Fig.3)

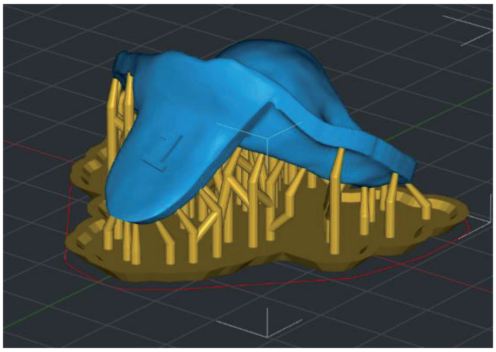

Figure 3. Impression tray prepared to be printed with support structures in the 3D printing software

3. Results

Each of the 17 trays (Fig. 4) was successfully manufactured. Table 2 summarizes consumable usage, weight, and print times. The average consumable usage per tray was 13.09 ml, and the average weight was 15.04 g. The average print time per tray was approximately 2 hours and 30 minutes, with variations due to tray geometry. The total cumulative print time for all trays was 40 hours, 58 minutes, and 28 seconds. In a theoretical batch scenario, the total printing could be reduced to the longest single print time, which was 3 hours, 18 minutes, and 18 second. To better understand the manufacturing consistency and efficiency, statistical analysis was performed.

Table 2. Consumable usage, weight, and print times of the trays.

Model number	Estimated consumable usage [ml]	Model weight [g]	Print time [hh:mm:ss]
1	11.79	13.56	02:55:14
2	10.06	11.57	02:11:03
3	16.29	18.73	03:18:18
4	11.86	13.64	02:51:15
5	11.58	13.32	02:02:05
6	12.25	13.97	02:16:52
7	13.72	15.78	02:15:27
8	14.73	16.94	02:15:39
9	12.26	14.10	02:15:27
10	13.04	15.00	02:03:13
11	12.27	14.11	02:19:08
12	14.58	16.77	02:42:15
13	12.78	14.70	02:09:12
14	13.05	15.01	02:19:08
15	12.55	14.43	02:18:02
16	16.05	18.46	02:26:19
17	13.62	15.66	02:19:51

Table 3. Descriptive Statistics.

Metric	Consumable (ml)	Weight (g)	Print Time (min)
Mean	13.09	15.04	144.41
Standard Deviation	1.61	1.86	20.38
Minimum	10.06	11.57	122.00
Maximum	16.29	18.73	198.00
Range	6.23	7.16	76.00
Coefficient of Variation	12.34 %	12.37 %	14.11 %

Table 4. Correlation Matrix.

Variable Pair	Pearson r	p-value	Interpretation
Consumable vs. Weight	0.9999	<0.001	Very strong correlation
Weight vs. Print Time	0.397	0.115	Not statistically significant
Consumable vs. Print Time	0.396	0.115	Not statistically significant

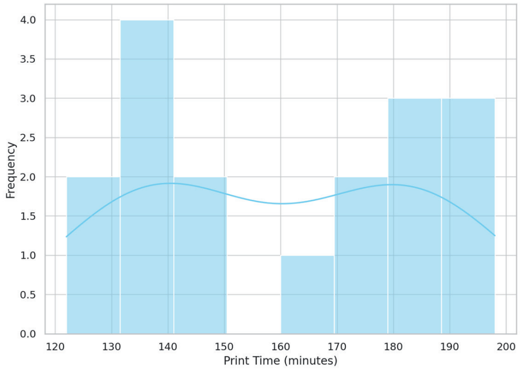

Figure 4. Distribution of print times for trays- Histogram showing the distribution of print times across 17 trays. Most trays were fabricated within a consistent time window of 2 to 2.5 hours.

Figure 5. 3D printed impression trays ready for sterilization process.

4. Discussion

This study demonstrates the feasibility of using reverse engineering for cleft palate impression trays, offering significant improvements over traditional methods. SLA technology proved reliable, with all 17 trays successfully fabricated. The process required an average consumable usage of 13.09 ml and tray weight of 15.04 g, while print times averaged 2 hours and 30 minutes.

Descriptive statistics (Table 3) show relatively low variance in print time (mean: 144.41 min, SD: 20.38), material consumption (mean: 13.09 ml, SD: 1.61), and tray weight (mean: 15.04 g, SD: 1.86), indicating a consistent and controlled manufacturing process. The near-perfect correlation between consumable use and tray weight ($r = 0.9999$, $p < 0.001$) further supports predictable material usage. While print time did not show significant correlation with weight or material, its low variance suggests it remains relatively stable.

These findings strengthen the argument for rejecting the null hypothesis, that reverse engineering and 3D printing do not significantly improve the efficiency, or scalability of impression tray production.

Surprisingly, although we expected print time to scale with object weight or material used, the data does not show a statistically significant correlation (Pearson $r \approx 0.396–0.397$, $p = 0.115$). This suggests that other factors such as geometry and complexity of the print, layer height, infill settings may influence print time more strongly than size alone.

4.1. Advancements in Nasoalveolar Molding Plate

A different approach involves collecting and scanning plaster casts of newborn patients with CLP to create a stock of prefabricated trays for conventional impressions. [8] However, the use of intraoral scanners represents an ideal advancement in nasoalveolar molding plate production, eliminating risks associated with traditional impression techniques, such as material aspiration or airway blockage. Despite their potential, intraoral scanners remain underutilized due to their high initial cost, limiting their availability in many hospitals. Wider adoption of this technology could significantly improve patient safety and comfort. [9], [10], [11], [12], [13]

By improving the precision and customization of impression trays, digital manufacturing could reduce the need for repeated fittings and adjustments, thereby shortening treatment time and enhancing patient comfort during the critical early stages of cleft palate management.

4.2. Benefits and Challenges of CAD/CAM Systems

CAD/CAM systems enhance customization and accuracy, allowing for better tray fit and patient outcomes. Digital workflows also enable rapid prototyping and iteration, particularly beneficial for complex cases. However, challenges such as ensuring uniform extrusion during CAD modeling and optimizing printing parameters persist, requiring careful calibration and expertise. [14]

Although initial investments in 3D printing equipment and training may be substantial, the reduction in labour intensity and material waste, alongside the scalability demonstrated through batch production, suggests long-term cost savings and greater accessibility for clinics.

While PLA resin showed promising mechanical properties, further research is required to optimize material biocompatibility, sterilization protocols, and long-term durability to ensure safety and efficacy in neonatal applications.

4.3. Limitations of the Study

Limitations of this study include the relatively small sample size and lack of direct clinical outcome data, which necessitates larger, longitudinal studies to fully validate these findings and assess patient-centred outcomes.

5. Conclusions

Reverse engineering and CAD/CAM systems provide a highly efficient and precise alternative for cleft palate tray manufacturing. Addressing current challenges and integrating innovations such as intraoral scanning have the potential to further optimize this process, ultimately improving outcomes for both patients and clinicians. This pilot study supports the adoption of digitally driven workflows for cleft palate impression trays, suggesting that these methods may outperform conventional approaches in terms of scalability.

Acknowledgments

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