



Original Research Paper

The Implementation of CAD/CAM Technology for Feeding Obturator Fabrication in Cleft Lip and Palate Infants: A Systematic Review

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Creative Commons Attribution-ShareAlike 4.0 International License**Abstract**

Background: Infants born with cleft lip and palate (CL/P) face severe feeding difficulties. Conventional fabrication of feeding obturators relies on impression techniques that carry procedural risks and cause stress for both infants and parents. Recent advances in computer-aided design/computer-aided manufacturing (CAD/CAM) provide a digital alternative for obturator fabrication. **Objective:** This systematic review aimed to evaluate the clinical and technical outcomes of digital workflows compared to conventional techniques in fabricating neonatal feeding obturators. **Methods:** A systematic literature search was conducted in PubMed, Scopus, and Google Scholar. Nine studies met the inclusion criteria and were qualitatively synthesized. **Results:** Findings consistently demonstrated that digital workflows using intraoral scanning (IOS) and 3D printing provide significantly higher accuracy, better fit, and improved retention of feeding obturators. Moreover, digital fabrication markedly reduces physical and psychological stress for infants and parents. Clinicians also reported greater efficiency and safety with digital methods compared to conventional impression-based approaches. **Conclusion:** The digital workflow represents a safer, more efficient, and more accurate approach for fabricating feeding obturators in infants with CL/P. Wider adoption of this technique may support a paradigm shift in clinical practice, although further high-quality trials are needed to confirm long-term clinical and economic benefits.

Keywords: Cleft Lip and Palate; Digital Workflow; Obturator; Systematic Review.

Introduction

Cleft Lip and Palate (CL/P) is among the most common congenital craniofacial anomalies¹⁻⁴. The estimated national prevalence of CL/P in Indonesia continues to rise, from 0.08% in 2013 to 0.12% in 2018, with approximately 7,500 new cases each year^{5,6}. The negative effects of CL/P, however, do not end with the early feeding difficulties. Left unchecked or without proper care, children with CL/P often suffer from speech and language delay during adolescence and adulthood, leading to long-term social, emotional, and learning impairments^{7,8}. Early intervention is considered key in avoiding these problems, which has been

agreed upon internationally.⁷ The first step in this intervention is, however, the most obvious one; that of the infant's inability to feed.

The oro-nasal communication due to the palatal defect anatomically precludes an infant from producing the negative intraoral pressure required for suckling^{9,10}. This has several dire consequences: severe nasal regurgitation, prolonged feeding duration, choking and asphyxiation, and the risk of aspiration¹⁰⁻¹². The resultant undernutrition eventually becomes apparent with a failure to gain weight, which is often a requirement before the palate can be surgically repaired¹². Furthermore, undernutrition can contribute to stunting, a

public health issue that has long been a problem in Indonesia¹³⁻¹⁵. Feeding obturators, also called feeding plates, are prosthetic devices that serve as an artificial palate to close the cleft and separate the oral and nasal cavities^{11,12,16,17}. It can help an infant's tongue effectively compress a nipple, thereby allowing milk to express and improving nutritional intake¹². Obturators also offer a secondary orthopedic effect by supporting the growth of the palatal shelves and correcting improper tongue posture¹⁶.

Traditionally, these obturators are produced via a multi-step analog workflow that begins with an initial high-risk impression of the neonate's maxillary arch¹⁰. This is often distressing for both the infant and parents and has a high risk of airway compromise from the impression material^{10,18}. In addition, the impression may be inaccurate, leading to a poorly fitting prosthesis and return visits for adjustments or remake, prolonging the process and distress¹⁶. In parallel, CAD/CAM has been available since the 1980s and has consistently been refined and improved in the field of prosthodontics¹⁹⁻²¹. The streamlined digital workflow of digital data acquisition, computer-aided design, and automated manufacturing has shown to improve the speed, efficiency, and precision of prosthetic restorations²⁰.

This systematic review will assess the implementation of this digital workflow to the fabrication of feeding obturators for infants with CL/P in comparison to conventional techniques in clinical, technical, and humanistic outcomes.

Materials and Methods

Study Design

This study used systematic review method and conducted as per the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) 2020 statement.

Sample

The sample of the study was chosen by the guideline of PICOS Framework. The PICOS Framework was used to form a focused clinical question by breaking down the research question into the following five components: Population, Intervention, Comparison, Outcomes, and Study Design.

Table 1. PICOS Framework of the Study

Population:	Newborns and infants with cleft lip and/or palate (CL/P) who require feeding obturators for bottle feeding.
Intervention:	Fabrication of feeding obturators using complete or hybrid digital workflows with CAD/CAM technology involving IOS and digital design and 3D printing or milling.
Comparison	Fabrication of feeding obturators using conventional methods including physical impressions and manual laboratory procedures.
Outcomes	1) Technical/Clinical outcomes 2) Patient-centered outcomes 3) Burden of care.
Study Design	All study designs were included, including randomized controlled trials and comparative studies with in-vivo and in-vitro components and case series and case reports. No time restrictions were put on the search.

Data Collection Technique

A comprehensive search of all relevant literature was performed by the research team through the PubMed, Google Scholar and Scopus platforms with no time limitations. The search strategy was constructed with a combination of specific keywords with MeSH terms to identify all relevant articles related to ("CAD/CAM" OR "digital workflow" OR "3D printing") and ("feeding obturator" OR "feeding plate") and ("cleft palate" OR "cleft lip") and (infant OR neonate)

The initial database search identified 455 records for review. A total of 120 duplicate records were eliminated leaving 335 records which were screened by title and abstract to remove 290 irrelevant records. After the title and abstract screening, the research team requested full-text of 45 articles out of which five articles could not be retrieved. The remaining 40 full-text articles underwent the eligibility assessment against the PICOS criteria to eliminate articles not meeting inclusion criteria and resulted in 31 articles being excluded. PRISMA flow diagram which shows the four-stage process of the study selection process including the identification of the records, screening, assessment, and inclusion of the eligible studies (figure 1)²².

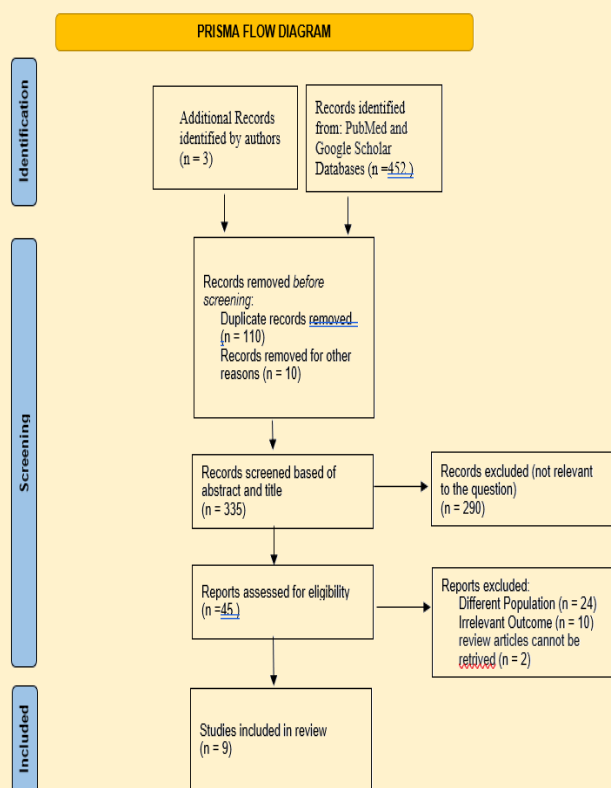


Figure 1. The PRISMA flow chart

Data Analysis Technique

A total of 9 studies were finally included in the review after the systematic search process. The studies combined in-vitro comparative studies, case reports, case series, and clinical trials. The

in-vitro comparative studies have different digital and conventional workflows being compared in terms of precision, efficiency, or other parameters. Data analysis was conducted using the Narrative Analysis technique. This technique involves summarizing the findings from the selected literature and presenting an overview and showed in the table to explain the relationships between variables relevant to the study focus.

Ethical Consideration

This study is a literature review and did not involve direct interaction with human participants, animal subjects, or collection of personal data. Therefore, ethical approval from an institutional review board was not required. All sources used were properly cited to ensure academic integrity, and the review process adhered to ethical principles of transparency, accuracy, and avoidance of plagiarism.

Results

Accuracy, Fit, and Retention

In-vitro studies provide consistent evidence that digitally fabricated feeding plates have better accuracy and fit than conventional ones. A study using micro-CT analysis reported a significantly smaller volumetric misfit for 3D-printed plates compared to conventionally molded plates¹⁸. Another in-vitro study showed that plates thermoformed from PET-G material and fabricated on 3D printed models had a significantly better fit and superior retention compared to conventional PMMA plates²³. Another randomized controlled trial also concluded that the digital impression technique provided outstanding surface detailing, accuracy, and adaptation of the feeding plate²⁴.

Process Efficiency (Time and Cost)

Time savings is a major benefit of the digital workflow as compared to the conventional workflow¹⁰. Studies comparing different

impression techniques reported that intraoral digital scanning was significantly faster than the conventional tray method for infants^{10,25}. A direct cost-effectiveness analysis for feeding obturators was not performed in any study. However, the high upfront cost of scanners and printers is the main barrier to their adoption²⁶.

Parental and Operator Preference and Satisfaction

Parents and operators also show a clear preference for the digital workflow. A systematic review of comparative studies reported that parents had a clear preference for digital over conventional impressions for their infants²⁷. The main reasons were the non-invasive approach of intraoral scanning which had no aspiration risk, and the procedure was perceived to be less stressful for the infant and the parents than conventional impressions¹⁰. Dental surgeons and dental technicians who use digital scanners have also reported greater efficiency, predictability, and patient tolerance with the digital method²⁷.

Discussion

This systematic review shows that the current evidence strongly suggests that the digital workflow of fabrication is superior to the conventional workflow in several important aspects and is well on its way to becoming an emerging standard of care. The most important advantage of the digital workflow is the avoidance of the high-risk conventional impression procedure¹⁰. The safety and reduced stress offered by the intraoral scanning technique is invaluable in this vulnerable neonatal population, and the expressed preference of the parents for the procedure is a strong humanistic argument in favor of its adoption^{23,27}. On the technical side, the results are also quite persuasive. Multiple studies have shown that 3D-printed obturators offer a more accurate and retentive fit, which is critical for

the appliance to function as an effective feeding aid^{18,23}. The time savings, especially in reducing laboratory turnaround times, also means that a critically needed appliance can be provided to a struggling newborn much faster with the digital workflow than with conventional methods¹⁶.

However, the evidence base has some concerning limitations. The included studies are almost all in-vitro, case reports, or case series which are informative but represent a lower level of evidence than long-term clinical trials. This is a significant gap in the evidence base as there are no long-term cohort studies tracking infants to compare definitive clinical outcomes like weight gain velocity, long-term craniofacial development, or success of subsequent surgical repair between the two methods.

In addition, there has been no formal cost-effectiveness or health technology assessment done for this application. The description of 3D printing as a “low cost” process in case reports is misleading in that the high initial capital costs for equipment are a major barrier to widespread use especially in low-resource settings^{11,26}. There are also significant barriers to the uptake of the digital workflow by individual clinicians and technicians such as the steep learning curve, lack of robust and standardized protocols, and the need for more materials to be certified for long-term, repeated intraoral use in infants (current materials are often only certified for short-term adult mucosal contact)²⁸⁻³¹. The future direction of this technology seems bright. The development of more standardized digital protocols perhaps using WHO’s “digital adaptation kits” (DAKs) framework may ensure a more consistent quality of care³². Artificial intelligence (AI) may be integrated in the future to automate the design process and further improve efficiency and consistency²⁰.

Table 1. Characteristics of Included Studies

Author(s) & Year	Study Design	Population/Sample	Intervention (Digital)	Comparison (Conventional)	Key Findings/Outcomes
Osman Akinci et al. (2025)	In-vitro comparative	3D models of bilateral, unilateral right, and left clefts (n=10 each)	3D additive manufacturing of feeding plates	Conventional compression molding (CM)	3D printed plates showed significantly better adaptation (less misfit) than CM plates for all cleft types ($p < 0.05$).
Singh et al. (2024)	Case Report	8-day-old infant with complete cleft palate	Novel self-retentive obturator	N/A (describes a new design)	The obturator was cost-effective, easy to use, and eliminated the need for extra retention aids.
Oday et al. (2025)	In-vitro comparative	3D printed models of infant maxilla (n=10)	Thermoformed PET-G and PET-G/EVA plates	PMMA plates	PET-G plates showed superior fit and retention compared to PMMA and PET-G/EVA plates ($p < 0.05$).
Nanduri et al. (2023)	Case Report	7-day-old infant with unilateral cleft	Digital intraoral impression for feeding plate fabrication	N/A (describes digital process)	Digital workflow was accurate, minimally invasive, and had good clinical acceptability.
Unnikrishnan et al. (2024)	Systematic Review	Infants with CLP	Digital impressions	Conventional impressions	Parents expressed a clear preference for digital impressions. Operators preferred digital for reduced stress.
Kapoor et al. (2021)	Case Series	Infants with cleft palate	3D printed bottle-attached obturator (D-cleft) made of PLA	Conventional obturator	D-cleft was effective, comfortable, and overcame disadvantages of conventional methods (brittleness, need for impressions).
Naveau et al. (2021)	Case Report	Newborn with unilateral cleft	Digitalization of existing tray, CAD design, 3D printing	Traditional fabrication	Digital workflow enables rapid and low-cost production of customized plates.
Krishnakumar, K. & Kalaskar, R (2025)	Randomized Controlled Trial	Neonates with CLP (n=30)	Digital Impression Technique (DIT)	Tray Impression Technique (TIT)	DIT was safer (no aspiration risk), faster, and produced more accurate impressions.
Divakar et al. (2025)	Narrative Review & Case Report	Infants with CLP	3D printed feeding plate and nasal stent	N/A	Highlights the use of CAD/CAM for presurgical nasoalveolar molding and feeding plates.

Conclusion

The study confirms that digital workflows using intraoral scanning (IOS) and 3D printing offer a safer, faster, more accurate, and well-accepted method for fabricating feeding obturators in infants with cleft lip and palate compared to conventional techniques. This approach reduces procedural risks and parental burden, supporting its potential as a new standard of care. However, high initial costs for IOS and 3D printing may hinder adoption among dentists. Therefore, further high-quality, long-term clinical trials are needed to validate both the clinical effectiveness and economic advantages of this digital paradigm shift in cleft care.

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Conflict of Interest Statement

The author(s) declare no commercial, financial, or personal conflicts of interest related to this research. All authors approved the final manuscript and consented to its publication in *Healthy Tadulako Journal*.

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