2023

Utilization of Intraoral Scanners for Fabrication of Obturators for Patients Born with Cleft Lip/ Palate (CLP)

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Utilization of Intraoral Scanners for Fabrication of Obturators for Patients Born with Cleft Lip/ Palate (CLP)

A thesis submitted in partial fulfillment of the requirements for the degree of Master of Science in Dentistry at Virginia Commonwealth University.

By

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May 2021

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May, 2023

Acknowledgements

This study was supported by VCU CTSA Award (UL1TR002649).

I would like to thank my thesis committee- Dr. Williams, Dr. Shroff, Dr. Carrico, and Dr. Jayaraman for their guidance throughout this process.

I would like to thank my co-residents and the VCU Pediatric Dentistry faculty and staff for their love and support.

Lastly, I would like to thank my family- my parents, my brother, my in-laws, and my husband, for their patience, neverending positivity and encouragement, and unconditional love.

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Abstract

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Objective: The goal of this cross-sectional study was to assess the knowledge and attitude of providers regarding incorporating a digital scanner for impression taking in children born with cleft lip and/or palate (CLP). *Methods:* A survey was sent out to members of the American Association of Pediatric Dentistry (AAPD). The survey included questions regarding the providers' perception of incorporating digital intraoral scanners for impressions for fabrication of obturators. The survey also included questions about the providers' reservations in using this technology in practice, what their experience has been with the incorporation of this technology into practice, and what is the reason, if any, for not utilizing this technology for this purpose. *Results:* A total of 308 respondents answered the survey, with 58% identifying as female, 58% having greater than 10 years of experience in practice, 64% serving in private practice, and 43% currently treating patients with cleft lip and/or palate. The results of the study indicated that 73%

of respondents either agree or strongly agree that they are willing to dedicate the time and effort required to learn about digital technologies. Some commonly reported barriers were- cost, lack of training in residency, and limited use of digital scanners in a pediatric dental practice. Those who self-reported use of an intraoral (IO) scanner had significantly higher agreement with statements about the ease of digital technology ($p<0.0001$), increased accuracy ($p=0.0003$), increased efficiency ($p=0.0004$), increased predictability ($p=0.0002$), increased patient acceptance/tolerance ($p<0.0001$), and that it's worth the investment ($p<0.0001$). *Conclusion*: Our study has shown that practitioners in the US view digital scanning as a viable option for fabrication of obturators and that the major limiting factors seem to be cost and lack of training during residency. Our study has yielded promising results regarding incorporating digital dentistry to obtain impressions for obturators. We hope to encourage pediatric practitioners to employ digital dentistry and expand its use to treating children born with cleft and/or palate.

Introduction

Cleft lip and/or palate (CLP) is one of the most common congenital defects involving the orofacial region. According to the Centers for Disease Control and Prevention, about 1 in 600 babies are born with both a cleft lip and cleft palate in the United States.[1] The etiology of CLP is variable and multifactorial: it can be inherited genetically as an autosomal dominant condition, it can occur as a result of environmental factors such as maternal epilepsy, use of certain drugs (steroids, diazepam, phenytoin), or folic acid deficiency, and family history can play a part in it—having a first-degree relative with CLP increases the chances of inheriting the condition by a factor of 20%.[1] Cleft lip and palate also occur as a part of more than 100 syndromic conditions, including Down syndrome and Treacher-Collins syndrome.[2]

In a cleft condition, there is a communication between the oral cavity and the nasal cavity, and this lack of barrier leads to nasal regurgitation and feeding problems that could lead to malnourishment of the child and failure to thrive. A complete unilateral or bilateral cleft lip and palate patient has a severe nasal deformity, maxillary alveolar process rotation with a medial movement of the cleft side, and smaller alveolar segment that can affect the facial profile, appearance, and dental development.[3] The impact of physical deformities as a result of CLP can have long-term detrimental effects on the patient's growth and development as well as on the developing psyche. Alveolar surgical repair is therefore done early in life allowing the patient to feed, separating the oral from the nasal cavity, minimizing treatment at a later age, normalizing the tongue position, and guiding the growth of maxilla.[3] In order to understand the treatment

options for these patients, it is imperative to first discuss the growth and development of the palate and nasomaxillary complex.

During the first months of life, there is an exponential growth of the maxilla that is seen in infants.[5] In other words, the most postnatal growth change in the maxilla is seen during infancy and early childhood, when relative antero-posterior growth and maturation are most prominent.[5] When the maxilla grows, it undergoes ventral-caudal rotation and expansion, at the same time demonstrating an increase in width, length, and height.[6] Cleft lip and/or palate occur as a lack of fusion of the palatal processes, medial nasal processes, and the maxillary process (laterally).[7] Knowledge of the development of the face will prevent iatrogenic damage such as mucosal ulcerations or restriction of growth.[4] Treatment of patients born with cleft lip/palate is usually undertaken with a team approach. The craniofacial team typically involves plastic surgery, pediatric medicine, speech and language pathology, otolaryngology (ENT), pediatric dentistry, and orthodontics. Many craniofacial teams also involve other specialties, including psychology and genetics.[8]

The cleft palate is associated with a variety of potentially life-threatening problems such as- feeding difficulties, eustachian tube dysfunction, middle ear effusions and infections, hearing loss, speech disorders, deficient facial growth, velo-pharyngeal incompetence, and dental and orthodontic problems to name a few. Although the optimal timing for cleft palate surgery remains controversial, with every cleft team having its own protocol, there are some similarities.[9] Despite the differences in treatment modalities, there is uniform agreement that the surgical repair of the lip is to be done between 3 and 6 months of age and palate closure is usually done between 12 and 18 months of age.[10]

The consensus remains that the immediate aim of treatment in infants born with CLP is to restore feeding and eventually improve normal anatomy and function. Often, devices are needed to facilitate this process. Fabrication of these devices requires obtaining an impression of the tissue. An obturator, which is a prosthetic aid that seals the cleft to occlude the separation between oral and nasal cavities, is one of the most common type of these devices.[2] This communication between the oral and nasal cavities hinders the creation of negative pressure, which is necessary for feeding through suckling. As a compensatory mechanism, the baby presses the nipple between the tongue and the hard palate to squeeze out the liquids and milk. But if the cleft is large, the baby is not able to obturate it enough with its tongue and this leads to insufficient feeding. Moreover, this process is painful for the mother.[2] These palatal obturators/plates help in feeding as well as speech/language development.[11] Obturator devices can make a life changing impact on a child's and the family's lives physically, emotionally, and psychologically.

Benefits of an obturator include creation of a rigid physical platform towards which the baby can press the nipple and extract the milk, facilitate feeding, reduce nasal regurgitation, reduce the incidence of choking, and shorten the time of feeding.[2] The obturator also facilitates growth of palatal shelves towards each other by blocking the tongue from entering the defect. Correction of this tongue position also facilitates proper speech development. Obturators used for feedings will improve the ability of infants to attain suction and help the infant to feed adequately.[12] Obturators decrease the incidence of nasal regurgitation and nasal discharge, which decreases apprehension and time required for feeding.[12] Lastly, obturators prevent the passage of food into the nasopharynx, thereby reducing the chances of the infant acquiring infections

(particularly otitis media and nasopharyngeal infections).[13] It is necessary for the infant to have a sustained weight gain prior to surgery to correct the cleft lip and/or palate.[12]

Obturators have an overwhelming number of benefits, but they also have some problems such as- damage to the delicate oral mucosa from the appliance and frequent impression taking associated with growth and the changing anatomy of the infant[10], potential for festering fungal growth if oral hygiene is inadequate, associated hazard of conventional impression techniques, and lastly the cost associated with the fabrication of an obturator, as well as the time required to complete the process satisfactorily from the day the child is born until the last surgery required to restore form and function of the oral cavity and craniofacial complex.

Currently, impressions are being made using elastomeric materials such as alginate or polyvinyl siloxane. But there is an emerging body of research for using a digital scanner for this purpose. Digital intra-oral (IO) scanners were first introduced in dentistry in the 1980s.[14] Since then, advancements in dental technologies have popularized the use of these devices. Intraoral scanners consist of a digital camera that consecutively acquires thousands of pictures of the area to be impressed from different angles and compiles these 2D images into a single 3D reconstruction.[3] Today, digital scanners are used in fabrication of dentures, orthodontic appliances, and crowns, to name a few. Studies have shown that success can be achieved by extending this technology for Nasoalveolar Molding (NAM), Presurgical Nasoalveolar Molding (PNAM), and obturator appliances for patients born with CLP.[15]

Incorporating this technology in practice has long term implications in the field of CLP surgery in many ways. Implementations of a digital protocol reduces the time, cost, and invasiveness of the impression-taking process.[3] Impression taking in infants born with CLP is accompanied by some challenges, such as size of the infant's mouth, anatomical variations

depending on the severity of cleft, and a lack of cooperation as well as the inability to respond to commands.[2] But conventional impressions are accompanied by a unique set of drawbacks that are mitigated if digital impression techniques are used instead. With conventional impressions, it is imperative that dentists be well versed with basic life support measures (BLS)—and ideally pediatric advanced life support (PALS)—in order to handle airway emergencies if any were to happen. High volume suction should be available chairside to manage any regurgitation during the impression-taking procedure.[16] The conventional impression is made when the infant is awake and oriented, not under any type of anesthesia or sedation.[17] Crying during the impression procedure is seen as a positive sign because it indicates that the airway is patent and the infant is ventilating appropriately, whereas not crying may be a sign of airway blockage.[16] This restricts the process of impression taking to be done chairside and adds a contraindication to do it during general anesthesia. Some major advantages of intraoral scanners are discussed in detail below.

Efficiency in Time and Resources

A study by Gjelvold et al. evaluated differences on time, clinical condition perceptions of the dentist and patient on a VAS between digital and conventional impression techniques. The results of this study demonstrated that the digital technique was more efficient and convenient than the conventional impression technique.[18] The advances in digital technology reduce the number of appointments needed for fabrication of appliances and reduce chair time. A digital protocol could optimize the impression appointment because only three minutes, on average, are needed to acquire one dental arch reconstruction.[3] Additionally, a single operator is enough to obtain a high-quality impression, whereas traditional methods necessitate the need for a second operator in order to keep oral cavity dry, to mix impression materials and load them on to impression trays

to hand to the principal operator.[3] Moreover, with a digital scanner, impression taking can be done in a controlled environment under general anesthesia when indicated.[19] This saves on appointment frequency and time spent chairside just to obtain impressions. Finally, the ease of transfer from one cleft center to another ought to be considered when it comes to comparing digital versus conventional impressions. If the patient's family were to relocate, the impression data can easily be transferred between centers electronically. Whereas, with conventional impressions, transportation will be challenging and risky. If transportation of models is not feasible, impressions will need to be retaken, which is an unnecessary burden on the provider as well as the patient's time and a waste of materials to take impressions.

Safety

For some patients, conventional alginate impressions can be life-threatening due to the risk of impression fragment aspiration, which could lead to respiratory obstruction and acute cyanosis during the procedure. Done improperly, a conventional impression technique can cause ingestion of the impression material and subsequent regurgitation.[3] Due to this risk, a team of trained neonatologists, orthodontists and neonatal nurses must be present when an impression is taken. Hence, intraoral scanning followed by a digital workflow may prove to be a significantly better and safer treatment option. Furthermore, infections can be caused by any material that remains in the oronasal cavity after the impression has been taken.[20]

Patient Preference

Historically, adult patients are usually reluctant to take elastomeric impressions due to the awkward and uncomfortable nature of the process.[21] This process is much more stressful for a child who has never had dental work done before and does not know what to expect. Intraoral scanners are much more readily accepted by patients due to the size and ease of use. They're less invasive and less messy compared to elastomeric impression techniques. One study evaluated patient perceptions on digital intraoral scanning and polyether impressions with a VAS questionnaire. The results demonstrated that patients would prefer the digital workflow if they could choose between the two techniques in the future.[22]

Accuracy, Reproducibility, and Longevity of Impressions

Digital impressions reduce discrepancy and chance of error by eliminating factors such as material shrinkage, voids, tissue displacement during impression, variations in mixing, etc. Digital intraoral impression could be considered a valid alternative to conventional one.[23] Impression material stability over time, material working time, and inconsistencies in mixing are issues which do not exist in the case of optical impressions.

Reduction in Waste

Taking dental impressions involves the use of a silicone, plastic, or metal impression tray, which is filled with the mixed impression material and inserted into the patient's mouth.[21] Sometimes the impression material, depending on the brand and type, comes in individual pre-measured plastic packages. Once this process is completed, the tray and the material cannot be reused. Additionally, those impressions need to be poured in microstone, which also is sold

commercially packaged in pre-measured individual plastic bags; this adds up and generates a lot of waste. Not to mention, if the impression is inaccurate or if it fails to capture the full extent of the anatomical landmarks, it needs to be retaken, leading to the waste being generated in the dental office. Furthermore, by eliminating the need to pour impressions to make models, there will be a reduction in chances of loss of models or damage to the models during transportation. The elimination of stone models saves on storage of casts.

Patient Education Tool

Digital scans can be used as a tool for patient education. Scanning and displaying the scans on a screen, manipulating the scans, showing the parents a before and after treatment time lapse, and giving parents the opportunity to visualize treatment outcomes easily on the screen are just a few advantages to scanning those conventional impressions can't offer.[14,24] A recent study reviewed the perceptions of parents of 30 children born with cleft conditions by assessing VAS scores and concluded that digital models provided the parents with a better understanding of their child's condition.[25]

Methods

The use of digital technology seems to have several benefits as an alternative method for capturing impressions, especially in young children with CLP.[26] The goal of this study was to assess the knowledge and attitude of providers regarding incorporating a digital scanner for impression taking in patients born with CLP, what their experience has been with the incorporation of this technology into practice, and what is the reason, if any, for not utilizing this technology for this purpose. A survey was sent out to members of the American Association of Pediatric Dentistry (AAPD) that included questions regarding their perception of incorporating digital intraoral scanners for impressions for fabrication of obturators. This study was approved for distribution by Virginia Commonwealth University Institutional Review Board (ID: HM20023815).

The first section of the survey asked about the participant's demographics. Questions included participant's gender, specialty training, years since graduation from the most recent specialty program, region of practice, and work setting (private practice, community health center, community hospital, university hospital, or other). The last question of this section asked whether the participant is currently involved in the treatment of cleft lip/ craniofacial patients. If the participant said yes, they were taken to the next section, which asked specifics about the participant's treatment modality and opinions about digital technology. If the participant

answered no to the question, they were directed to the end of the survey, since the survey questions are tailored towards providers who are involved in the treatment of cleft/ craniofacial patients.

The second section of the survey asked about the age of the cleft/ craniofacial patients that the participant is involved in treating. The purpose of this question was to get an understanding about the type of appliances that the participant is fabricating in their practice. After answering this question, participants were asked if they currently used an intraoral scanner. If they answered 'yes', they were directed to answer questions about what procedures they used intraoral scanning for. If they answered 'no', they were asked what methods they currently used to make impressions, and what their reservations were with using intraoral scanners. All participants answered a set of opinion questions which had answers measured on a Likert scale.

Survey questions were based on existing literature that surveyed the use of digital technology for fabrication of appliances such as crowns, bridges, orthodontic appliances, and dentures. The literature is sparse on the use of digital technology for fabrication of obturators. There are a vast number of articles in the literature that discuss participant experience when digital technology was used to address their prosthodontic needs compared to conventional impressions.[27]

Statistical Methods

Differences in categorical responses were compared with chi-squared tests. Differences in agreement scores (5-point Likert scale) were compared between users and nonusers with t-test and based on treatment of general patients and those with CLP using paired t-test. Significance level was set at 0.05. SAS EG.8.2 (SAS Institute, Cary, NC) was used for all analyses.

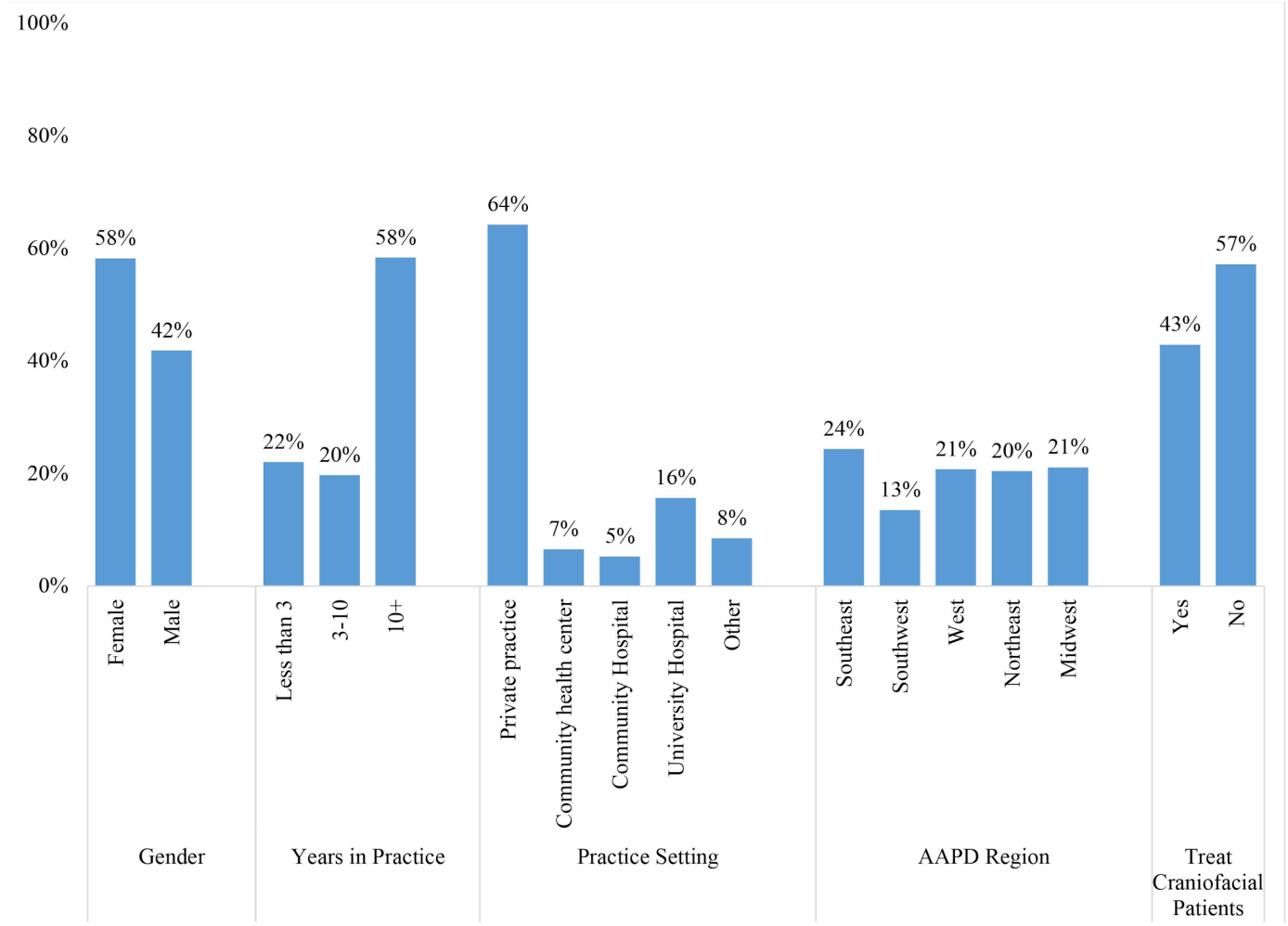
Results

A total of 308 respondents answered the survey, with 58% female, 58% with greater than 10 years in practice, 64% in private practice, and 43% who treat patients with cleft lip and/or palate. Complete demographics of respondents are provided in Table 1.

Table 1: Respondent Demographics

	n	%
Gender		
Female	178	58%
Male	128	42%
Years in Practice		
Less than 3	66	22%
3-10	59	20%
10+	175	58%
Practice Setting		
Private practice	197	64%
Community health center	20	7%
Community Hospital	16	5%
University Hospital	48	16%
Other	26	8%
AAPD Region		
Southeast	74	24%
Southwest	41	13%
West	63	21%
Northeast	62	20%
Midwest	64	21%
Treat Craniofacial Patients		
Yes	132	43%
No	176	57%

Figure 1: Respondent Demographics



Twenty-three percent self-reported to currently using an intraoral scanner in their practice. The only provider or practice characteristic significantly associated with self-reported intraoral scanner use was the AAPD region, with a greater percent of providers in the West (32%), Northeast (31%), and Midwest (25%) reporting IO scanner use compared to 12% of those from Southeast and 15% from Southwest (Table 2).

Table 2: Associations between Provider Characteristics and Use of Intraoral Scanners (n, %)

	Use IO	**No IO**	**P-value**
Self-Reported IO Scanner Use	71, 23%	237, 77%	

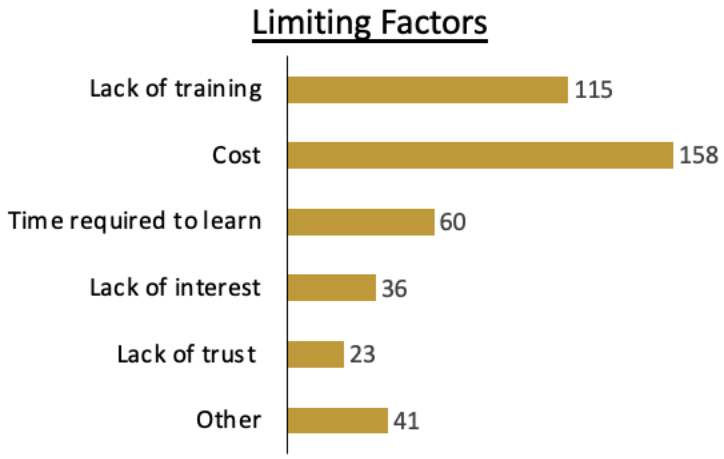
Gender				0.1146
	Female	35, 20%	143, 80%	
	Male	35, 27%	93, 73%	
Years in Practice				0.6451
	Less than 3	13, 20%	53, 80%	
	3-10	12, 20%	47, 80%	
	10+	43, 25%	132, 75%	
Practice Setting				0.4212
	Private practice	47, 24%	150, 76%	
	Community health center	2, 10%	18, 90%	
	Community Hospital	2, 13%	14, 88%	
	University Hospital	11, 23%	37, 77%	
	Other	8, 31%	18, 69%	
AAPD Region				0.0221
	Southeast	9, 12%	65, 88%	
	Southwest	6, 15%	35, 85%	
	West	20, 32%	43, 68%	
	Northeast	19, 31%	43, 69%	
	Midwest	16, 25%	48, 75%	
Treat Craniofacial Patients				0.3289
	Yes	34, 26%	98, 74%	
	No	37, 21%	139, 79%	
Note: IO- Intraoral Scanner; P-value from chi-squared test				

Among those who reported not using intraoral scanners, the most selected limiting factor for use of IO scanners was the cost (67%) followed by lack of training during residency (49%) (Table 3).

Table 3: Limiting Factors for Use of Intraoral Scanners among Non-Users (n=237)

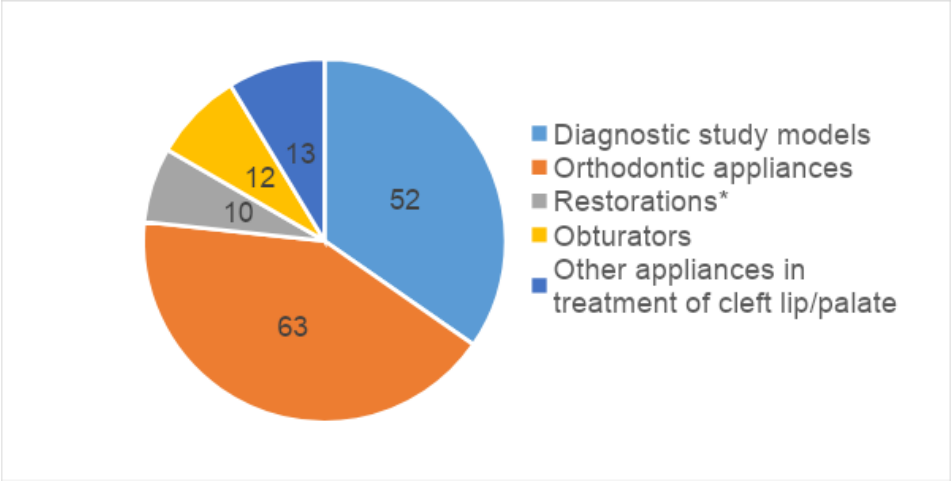
Limiting Factors	**n**	**%**
Lack of training in residency	115	49%
Cost	158	67%
Time required to learn about using intraoral scanners	60	25%
Lack of interest	36	15%
Lack of trust in technology (accuracy and reliability)	23	10%
Other	41	17%

Figure 2: Limiting Factors



The most common procedures indicated for IO scanner use were orthodontic appliances (89%) and diagnostic study models (73%). Less than 20% report using the scanner for restorations (14%), obturators (17%), or other appliances for treating cleft lip/palate (18%) (Figure 3).

Figure 3: Procedures Indicated for IO Scanner Use



When comparing practitioners who treat patients with CLP with those who do not, there was a significant difference in the use of IO scanners for diagnostic study models with those who

treat CLP indicating a significantly higher rate (94% vs 54%, p<0.0001). Those who treat CLP patients also indicated use of IO scanners for obturators at a higher rate (29% vs 5%, p=0.0101). Results are provided in Table 4.

Table 4: Procedures Indicated for Intraoral Scanner Use

Procedures	All Users (n=71)	Treat CLP (n=34)	No CLP Patients (n=37)	P-value*
Diagnostic study models	52, 73%	32, 94%	20, 54%	0.0001
Orthodontic appliances	63, 89%	31, 91%	32, 86%	0.7121
Restorations*	10, 14%	3, 9%	7, 19%	0.3115
Obturators	12, 17%	10, 29%	2, 5%	0.0101
Other appliances in treatment of cleft lip/palate	13, 18%	13, 38%	N/A	N/A

*P-value from Fisher's exact test; Restorations included crowns, veneers, inlays/onlays, dentures, bridges, implants

Those who self-reported use of an IO scanner had significantly higher agreement with statements about ease of digital technology (p-value<0.0001), increased accuracy (p=0.0003), increased efficiency (p=0.0004), increased predictability (p=0.0002), increased patient acceptance/tolerance (p<0.0001), and that it is worth the investment (p<0.0001) (Table 5).

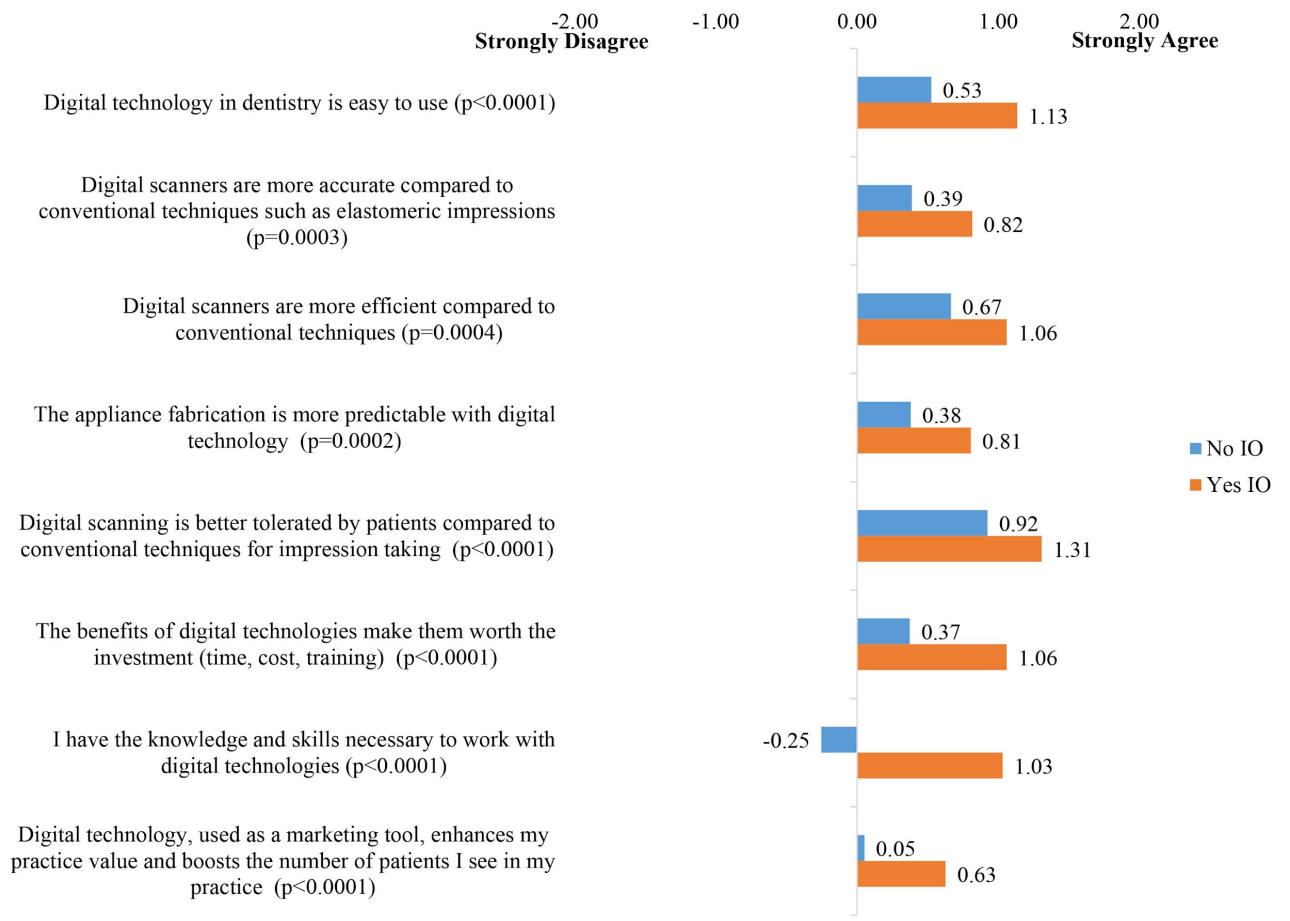
Table 5: Differences in Beliefs about Intraoral Scanner Use by Utilization

	Use Intraoral Scanner		
Statement	Yes (n=67)	No (n=213)	P-value
Digital technology in dentistry is easy to use	1.1, 0.67	0.5, 0.82	<0.0001
Digital scanners are more accurate compared to conventional techniques such as elastomeric impressions	0.8, 0.85	0.4, 0.66	0.0003
Digital scanners are more efficient compared to conventional techniques	1.1, 0.85	0.7, 0.76	0.0004
The appliance fabrication is more predictable with digital technology	0.8, 0.82	0.4, 0.64	0.0002

Digital scanning is better tolerated by patients compared to conventional techniques for impression taking	1.3, 0.58	0.9, 0.74	<0.0001
The benefits of digital technologies make them worth the investment (time, cost, training)	1.1, 0.72	0.4, 0.84	<0.0001
I have the knowledge and skills necessary to work with digital technologies	1, 0.87	-0.3, 1.2	<0.0001
Digital technology, used as a marketing tool, enhances my practice value and boosts the number of patients I see in my practice	0.6, 0.93	0.1, 0.88	<0.0001

***Values represent Mean, SD of agreement based on 5-point Likert scale with -2 indicating "Strongly Disagree" and 2 indicating "Strongly Agree"**

Figure 4: Differences in Beliefs about Intraoral Scanner Use by Utilization



Those who use IO scanners also had greater agreement with the statement that they have the knowledge and skills necessary to work with digital technologies (p<0.0001) and that use of digital technologies as a marketing tool enhances their practice and boosts the number of patients

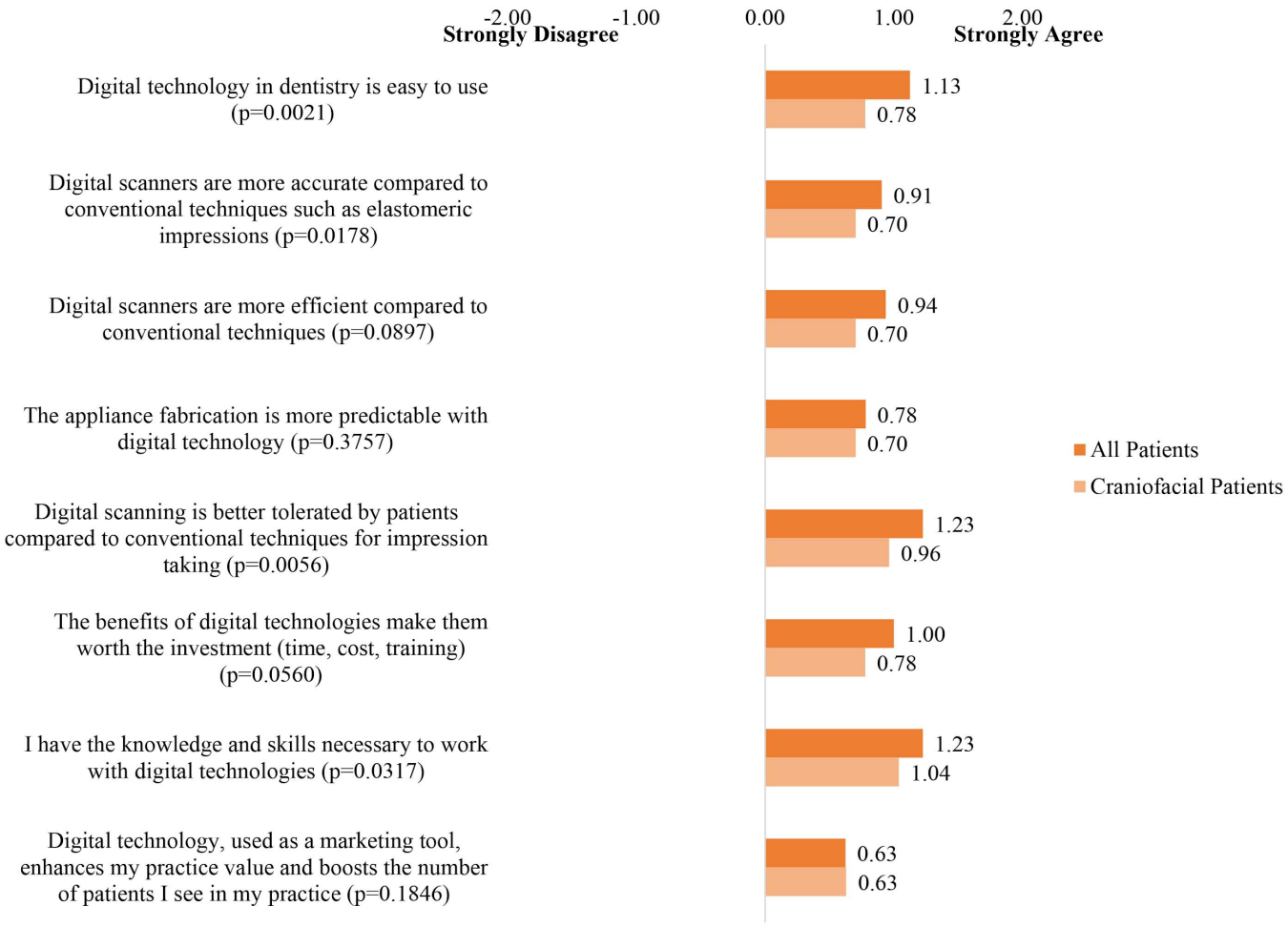
seen ($p<0.0001$). Respondents who reported treating patients with CLP and using IO scanners were asked the belief statements presented above a second time, specifically as it relates to impressing the maxillae of children born with cleft lip/cleft palate for fabrication of appliances. The purpose of doing this was to understand if providers felt any difference in scanning for cleft patients vs. all patients. Among the 27 respondents who reported using IO scanners, treating patients with CLP, and answered both sets of questions, there were significant differences in beliefs based on the differentiation of patients. Particularly, providers had lower agreement regarding the ease of use, accuracy, patient tolerability, value of investment, and their knowledge and skills for digital technologies (Table 6).

Table 6: Differences in Beliefs about Intraoral Scanner Use for Patients with CLP

Statement	All Patients	CLP Patients	**P-value**
Digital technology in dentistry is easy to use	1.1, 0.71	0.8, 0.85	0.0021
Digital scanners are more accurate compared to conventional techniques such as elastomeric impressions	0.9, 0.86	0.7, 0.99	0.0178
Digital scanners are more efficient compared to conventional techniques	0.9, 0.91	0.7, 0.91	0.0897
The appliance fabrication is more predictable with digital technology	0.8, 0.91	0.7, 0.87	0.3757
Digital scanning is better tolerated by patients compared to conventional techniques for impression taking	1.2, 0.50	1.0, 0.65	0.0056
The benefits of digital technologies make them worth the investment (time, cost, training)	1.0, 0.76	0.8, 0.97	0.056
I have the knowledge and skills necessary to work with digital technologies	1.2, 0.76	1.0, 0.92	0.0317
Digital technology, used as a marketing tool, enhances my practice value and boosts the number of patients I see in my practice	0.6, 0.91	0.6, 0.84	0.1846

***P-value from paired t-test; Values represent Mean, SD of agreement based on 5-point Likert scale with -2 indicating "Strongly Disagree" and 2 indicating "Strongly Agree"**

Figure 5: Differences in Beliefs about Intraoral Scanner Use for Patients with CLP



These responses indicate an increased level of difficulty when treating patients with CLP. Additionally, those who treat CLP patients were also asked their agreement with the statement: "Intraoral scanning is a viable option for fabrication of obturators for patients born with cleft lip/ palate." The average response was 0.77 (SD=0.80) indicating average agreement just below "Agree" on the Likert Scale. None of the respondents disagreed with the statement, but 44% were neutral. The remaining 56% agreed or strongly agreed that IO scanners are viable for patients with CLP.

Discussion

Modern dentistry is based on convenience and patient experience. There are a vast number of articles in the literature that discuss digital technology with conventional methods of impression taking from the point of view of the provider as well as the patient. A randomized control trial found that conventional impressions were more time-effective than the digital impressions. In terms of patient comfort, no differences were found between the conventional and the digital techniques.[27] A systematic review assessed whether digital scanning for implant-supported restorations is more time-efficient and convenient for the patient. This was one of the many studies that assessed patient preference. The results of this study suggested that digital scanning was found to be more time-efficient and convenient than conventional impression making for implant-supported restorations.[28] Previous studies have shown that patients have reported discomfort with conventional impressions, especially in the maxilla.

A study investigated the patient preference and clinical working time between digital impressions and conventional impressions in young orthodontic patients (10-17 years of age). The results showed that young orthodontic patients preferred the digital impression techniques over the alginate method, although alginate impressions required the shortest chairside time. Subjects of this study preferred intraoral scanners (51%) over alginate impressions (29%), because of the comfortable feeling and less queasiness.[29]

Before discussing the accuracy of digital impressions compared to conventional impressions and the implementation of digital scanning into practice, it is worthwhile to delve into the actual process of scanning. The most important structures that need to be scanned accurately are the maxillary tuberosity, the vestibule, and the labial frenulum.[30] In order to be reproducible, the scanner needs a defined reference point at where scanning is consistently started- this is the incisive papilla. If the scanning position is lost, the operator should go back to the incisive papilla or to the last completely scanned area. It is important to methodically scan the palate in the same way every time to circumvent any discrepancies. The authors recommend starting with the incisive papilla, the alveolar ridge, the tuberosity, and the vestibule on the right side.[30] The authors then recommend scanning the same structures on the left side in the same order before scanning the anterior maxilla and vestibule, which includes the labial and buccal frena. Finally, after the raw scan is acquired, it is refined via a post-processing tool for correction of any surface deformities.[30] When the design is done for the appliance, the insertion angle should be set as high as possible to block out any undercuts that could prevent its seating.

There have been concerns brought up regarding the accuracy of digital impressions as it affects the fit of an obturator in an infant's mouth. Empirical and clinical data has revealed that the retention of the obturator is not of critical importance in an infant because it can be held in place during activities that the baby performs on a regular basis such as sucking, swallowing, and the resting state by the tongue and by mouth closure.[2] During the first few months of life, most of the maxillary growth happens in the transverse plane, and so pressure points on the lateral vestibule should be periodically evaluated to prevent obstruction of growth and trauma to the oral tissue from the pressure.[30]

There is an emerging body of evidence for the incorporation of digital technology in pediatric dentistry. This is more so in relation to CLP patients than everyday use of digital dentistry for chairside applications, but it is nonetheless encouraging. A recent study evaluated the differences between conventionally impressed and digitally developed models for rehabilitation of cleft palate.[35] A digital model was derived, and 3D printed from the patient's CBCT scan. This model was compared to a digital scan of the same patient's conventional impression. Obturators were fabricated from both the casts and tested in vivo.[35] Factors that were evaluated were ease of insertion, need for trimming, seal, and retention of the obturator without stimulation, with vocal stimulation, and during swallowing.[35] The results of the study indicated that the accuracy of the impression within the cleft defect was higher in the digital impression than in the conventional impression. These results are promising in the field of craniofacial reconstruction and digital dentistry, but more research is needed to implement this technology into practice and refine the consistency of the technology. Another drawback of this study is that it was done on an adult patient. Extrapolating it to pediatric dentistry may yield unique results and is an avenue worth exploring.

A retrospective cohort study done in Switzerland investigated the safety and scanning time in newborns to preschoolers with CLP, both chairside and under general anesthesia. The authors also assessed the accuracy of 342 digital impressions that were taken for all 190 subjects.[19] These scans were done in a variety of patients presenting with different types of clefts including soft palate, soft and hard palate, unilateral and bilateral cleft lip and palate, cleft lip and alveolus, and isolated cleft lip. The median scan duration was 85.5 seconds for cleft palate and 50 seconds for cleft lip and nose, which is a significant difference compared to conventional impressions. The results also indicated that it took longer to scan for younger patients and infants

due to the size of the oral cavity and maneuvering required due to the large scanner head size. Lastly, it was also reported that the cleft type did not affect scan time or quality.[19]

Computer-aided design and computer-aided manufacturing, abbreviated as CAD/CAM, has been implemented in the treatment of CLP by several research groups.[31] There is some research to support the use of digital technology for fabrication of Nasoalveolar Molding (NAM) in patients with craniofacial anomalies. NAM is a presurgical treatment modality that is performed in newborns to prepare their cleft site for surgery.[32] A disadvantage of NAM is that it is time-consuming since it involves weekly adjustments and multiple impressions that need to be taken every time new plates are to be fabricated[32]. This also means that every time new impressions are taken, those impressions need to be poured and casts need to be fabricated and analyzed, which puts undue burden on the dental provider that could be reduced or altogether avoided by the introduction of digital technology. Despite the drawbacks, NAM is associated with promising long-term favorable results for the patient and a consecutive reduction of costs for the provider. According to a study, NAM treatment led to an estimated savings of between $491 and $4893 depending on the type of cleft.[33] Hence, a NAM appliance can be considered essential for the overall health and well-being of the patient and introduction of digital technology for fabrication of this pivotal appliance can make it more accessible and cost effective.

The challenge in implementing digital technology for pediatric impression taking is the lack of evidence in the field, as well as the lack of a feasible and efficient workflow.[34] The evidence base is limited in this field due to it being a new technology. A semi-automated method of generation of intraoral molding plates (RapidNAM) has been proposed for fabrication of feeding plates/ obturators and NAM devices.[31] Added to the use of a semi-automated production,

traditional impression methods (such as acrylic resin) can be added to the plates or appliances when and where necessary. Our pilot study demonstrated promising results and opened the avenue for extending this research to fabrication of other pediatric appliances.

There have been studies of successful implementation of a digital workflow for fabrication of a palatal plate for patients with Down Syndrome.[30] The software presented in the study does not require additional installation and designing of the appliance can be done with the provider's existing computer system. This makes the idea of implementing it into practice enticing to clinicians who may be hesitant due to the technical aspect. The results of this study showed that the palatal area was successfully scanned to create a virtual model and the plates that were fabricated were well-fitting. Two methods of fabrication of the palatal plate were discussed: additive and subtractive.[30] It was determined that the plate created via an additive mechanism fitted better than the one that was milled via a subtractive mechanism. These favorable results can potentially encourage practitioners who may be uncertain about the accuracy of a digital scan to adopt this technology.

A limitation of this study was the number of responses. The survey was sent via the American Association of Pediatric Dentistry (AAPD) ListServ to 10,890 members, of which 308 responded, making the response rate to be approximately 3%. One of the reasons for this low response rate could be due to the lack of use of digital technology in pediatric dentistry. The study results showed that although pediatric dentists in the US are routinely part of a craniofacial team, they are not involved in the fabrication of appliances for patients born with cleft lip and/or palate (CLP). Another reason for a low response rate could be the lack of training with digital technology in residency training programs and participants not being able to relate to the topic..

Our pilot study gave an idea of the perception and comfort level of pediatric dental providers across the US regarding digital technology. More research needs to be conducted in this area to get a more comprehensive idea of the comfort level of providers with using digital dentistry in pediatric dentistry in general, not specific to patients born with CLP. Another error in our study was sample selection. On a cleft team, orthodontists or plastic surgeons are the ones who typically fabricate obturators for patients. Hence, a way to increase response rate could be to send the same or a similar survey to members of the American Cleft Palate Association (ACPA) and to the American Association of Orthodontics (AAO) to get a more representative sample of providers involved with fabrication of obturators on a craniofacial team.

Despite the recent boom of digital dentistry, there are some hesitations that dentists have when it comes to implementing it in practice, as exhibited by results of the current cross-sectional study. A study by Farook et al. demonstrated that the primary reason for lack of use of digital scanning in pediatric dentistry is cost, and our pilot study has buttressed this finding.[36] Furthermore, there is a prevalent stigma associated with computer-aided design and digital dentistry that installation of these require professional computer setups. Even though these stigmas remain prevalent in dentistry, the younger generation of dentists appears to be more accepting of digital tools and images, as reinforced by the results of our study. Our hope is that this will lead to a paradigm shift in design professions and in dentistry, particularly pediatric dentistry.[37] Computers, and technology in general, are growing exponentially and getting better and more affordable. If the trend continues, more research will emerge, and ways to make modifications at the initial stages of digitization in practice will materialize to allow practitioners to perform computer-aided designs from their personal computers.[38]

Conclusion

Digital technology is increasingly used in dentistry in this time and age. Evidence supports the use of digital dentistry for fabrication of crowns, bridges, dentures, orthodontic appliances, and spacers. This technology is not utilized as much in pediatric dentistry as it is in other fields of dentistry, but literature supports extending its use to pediatric dentistry. Our study has shown that practitioners in the US see digital scanning as a viable option for fabrication of obturators and that the major limiting factors seem to be cost and lack of training during residency. Our study has yielded promising results regarding incorporating digital dentistry to obtain impressions for obturators. We hope to encourage pediatric practitioners to employ digital dentistry and expand its use to treating children born with cleft and/or palate.

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