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EFFECTS OF FLEXIBLE ACRYLIC OBTURATOR VERSUS HEAT CURED ACRYLIC OBTURATOR ON SPEECH QUALITY OF CHILDREN WITH CONGENITAL CLEFT PALATE

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ABSTRACT

Background: Clefts patients require multidisciplinary treatment as they suffer from several problems as feeding, speech, psychological and esthetic problems. Speech disorders and hypernasality are major problems in cleft patients that have negative consequences for speech intelligibility of affected patients. Prosthetic rehabilitation seeks to restore an effective separation of the oral and nasal cavities. Beyond this basic function, it is desirable to understand the degree to which an obturator restores speech to a functional level. This understanding can be gained through objective clinical measurements that include acoustical evaluation of the patient's resonance balance of oral versus nasal speech.

Purpose: To compare the effect of conventional heat cured obturator (Device A) versus thermoplastic injection molded (flexible) acrylic obturator (Device B) on hypernasality during oral and nasal sounds; and speech intelligibility of children with congenital cleft palate.

Methods: A clinical trial study was conducted in which twelve children with cleft palate were rehabilitated each with two obturators; one constructed with heat cured acrylic resin and the other from flexible acrylic resin after a complete oral rehabilitation of participating children. Speech ability was assessed by nasometric assessment, and auditory perceptual evaluation.

Results: Both obturator types showed varying degrees of reduction in hypernasality and maintenance of intraoral pressure as well as significant improved speech intelligibility. However, the thermoplastic obturators (Device B) showed significant reduction in hypernasality during oral and nasal sentences.

Conclusions: Both types of obturators improved speech intelligibility. However, Thermoplastic injection molded obturators were superior to heat cured ones in improving speech quality in children with cleft palate, probably due to better adaptation of the thermoplastic resin.

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INTRODUCTION

Cleft lip and palate (CLP) are common congenital defects which represent a heterogeneous group of disorders affecting the lips and oral cavity and are generally divided into two groups; cleft lip with or without palate (CL/P) and isolated cleft palate (CP). These defects are associated with many problems including cosmetic deformities, dental abnormalities, difficulties in speech and swallowing, as well as hearing problems. They also affect the psychology of the affected child, which can lead to lifelong unfavorable outcomes for health and social integration[(1,2)]. Cleft lip with or without cleft palate anomalies are the 4th common congenital birth defects, with a worldwide reported prevalence of 1 in every 500 to 1000 births[(3,4)]. In Cairo governorate, Egypt, a prevalence of 3.85 per 1000 living births was found in one year from 2011 to 2012[(5)].

Typically, children with CLP need multidisciplinary care which starts from birth to adulthood. Care for children born with CLP generally includes many disciplines such as nursing, plastic surgery, maxillofacial surgery, prosthodontics, speech therapy, otolaryngology, audiology, orthodontics, pediatric dentistry, psychology, and genetics counseling[(4, 6, 7)].

Controversies still exist regarding how and when to intervene in the correction of CL/P, yet planning must be started soon after birth as early management is essential[(3,4,8)]. Surgical correction usually starts with primary surgeries to correct cleft lip and cleft palate most often during the first months and first year of life, respectively. This is called primary palatal surgical repair or primary palatoplasty[(7,9)]. However, early palatal repair can sometimes cause persistent palatal fistulae between the nose and mouth. The incidence of such oro-antral fistulae following primary palatal repair can be as high as 60%[(10-12)]. Large fistulae do not have enough soft tissue adjacent to the surgical site for raising a flap and closing the fistula. An alternative to surgery will be a palatal obturator until secondary correction can be performed[(13)]. Another drawback of early palatal closure is the high risk of maxillary and midfacial growth limitation[(7,12)]. Thus, another approach for CL/P management is the two stage palatoplasty in which early repair of the soft palate and / or lip is done at one stage followed by hard palate repair at a later stage at 4 to 14 years of age. This delay allows for a better midfacial growth and significantly reduces the width of the hard palate cleft which simplifies its closure without the need for extensive dissection[(7,14)]. Children planned for a two stage palatoplasty will also require rehabilitation with a palatal obturator to improve feeding and speech until the time of the hard palate repair[(15)].

Children with a palatal fistula whether after primary palatolasty or requiring a two stage palatoplasty will suffer from an oro-nasal communication that is in addition to missing teeth will have adverse effects on the child's chewing abilities, appearance and speech (ability to speak intelligibly). This will usually negatively impact the psychology of the child. It has been shown that patients with craniofacial defects often feel more positive about themselves after prosthetic treatment[(15)].

During speech a palatal fistula will decrease the intraoral air pressure, air escapes during production of high pressure constants causing sound distortion and an increase in nasal airflow. Loss of intraoral air pressure is compensated for by increasing the respiratory effort and developing compensatory articulations, which occur by abnormal articulations and deviant tongue placements (midpalatal stops to occlude the fistula) causing sound distortions during speech. In addition, an increased nasal resonance for non-nasal speech is encountered (hypernasality). The final result is a reduction in speech intelligibility [(3,13, 16)]. It is essential to identify whether air escape is through an anterior palatal fistula or a posterior pharyngeal opening as in cases of velopharyngeal dysfunction (VPD) before deciding the treatment plan. If an anterior palatal fistula is the major cause of air escape, then a palatal obturator can help in developing a normal speech. It covers the fistula, reduces hypernasal speech and re-establishes normal air flow during speech. Thereby, contributing to normal speech production and assists speech therapy in correcting compensatory articulations[2,13]. If the major cause is VPD then a palatal lift appliance can address the problem[13]. The main aim of treatment is the achievement of intelligible speech of pleasing quality and the human ear is the final judge in determining whether a satisfactory result has been achieved[16].

Flexible acrylic resin was introduced since 1950 for fabricating removable partial dentures. The application of nylon-like materials to the fabrication of dental appliances has been seen as an advance in dental materials. This material generally replaces the metal, and the pink acrylic denture material used to build the framework for standard removable partial dentures. Flexible dentures are an excellent alternative to conventionally used methyl methacrylate dentures, which not only provide excellent aesthetics and comfort but also adapt to the constant movement of the oral tissues[17-21]. Retention and adaptability of flexible dentures were reported to be significantly better than conventional acrylic dentures. This may be attributed to the physical properties of the flexible acrylic which allows effective engagement with undercuts and close adaptation to the supporting tissues. Flexible dentures can be extended into deeper soft-tissue undercuts to gain further retention without risking the health of the supporting tissues or creating pain and difficulty during denture removal or insertion[21,22].

Flexible dentures may be used in rehabilitating anomalies such as ectodermal dysplasia, or cleft patients. The therapeutic use of thermoplastic materials has increased drastically in the late decade. This new procedure, during which a fully polymerized basic material is softened by heat (without chemical changes) and injected afterwards, has opened up a new challenge in making dentures. The excellent tissue-friendly and mechanical characteristics of these basic materials can only be made to last by an exactly executed and reproducible technology. However, with the development of new elastomers and copolymer alloys, it is certain that there will be many new clinical applications for thermoplastic resins in dentistry[20-23]. Yet, it is not known from the current literature, whether palatal obturators made of injection molded flexible acrylic resin with their reported improved retention and adaptability can be more effective in sealing an oro-antral fistula compared to heat cured obturators, thus, contributing to better speech improvement or not.

Recognizing that children with clefts and other craniofacial anomalies have special needs, the American Academy of Pediatric Dentistry endorsed the current statements of the American Cleft Palate-Craniofacial Association that states that, to provide optimal cleft/craniofacial care, it is crucial that patients' management is best provided by an interdisciplinary team of specialists. Pediatric dentistry plays an important role in creating the foundation of appropriate oral care and overall nutrition. Phases of cleft care such as surgery, orthodontics, and prosthodontics can be more effective and less complex as well as less time consuming and less costly if the teeth and oral cavity are maintained in a healthy state[4]. Thus, cleft patients should begin seeing a pediatric dentist since 6 months of age. Visits should be made on a regular semiannual basis, and treatment should include oral prophylaxis, oral hygiene instruction, fluoride application, and dental restorations as needed. The pediatric dentist should be aware of ongoing cleft treatment and should cooperate with the cleft team[1,24]. However, for years the role of pediatric dentists was mostly limited to preventing and treating dental diseases in the primary and mixed dentitions[4]. This role can be expanded to include appliances as palatal obturators as they require simple construction procedures in contrast to palatopharyngeal appliances so that feeding and speech are improved until definitive palatal closure can be achieved. This will have a great impact on the growing child psychology as well as quality of life.

Objectives:

The objective of the present study was to compare the effects of heat cured and injection molded flexible acrylic resin obturators on speech quality of children with congenital cleft palate.

PATIENTS AND METHODS

Participants

Twelve children (4 females and 8 males) aging 5-7 year old participated in the present study. Patients had non-syndromic unoperated or operated congenital cleft palate defect with a palatal fistula which compromised feeding ability and speech as reported by parents, Figure(1). After obtaining an ethical approval from the ethical committee of the Faculty of Dentistry, Ain Shams University, Cairo, Egypt, all parents and patients were informed about the purpose of the study and written signed consents and assents were obtained from parents and children, respectively. An experienced speech pathologist confirmed the presence of hypernasal speech, compensatory articulations and compromised speech intelligibility mainly due to the palatal fistula and not due to a VPD. Social, medical, and dental histories, as well as clinical examination were performed and results were recorded. All subjects had normal health conditions, normal hearing thresholds, and normal intellectual capacity. None of the children had speech or obturator therapy before the study.

Obturators construction

Before construction and placement of the palatal obturators, comprehensive preventive and restorative care was done for all participating children. Stainless steel crowns had to be fitted on maxillary primary molars of all children even if they were sound as examination revealed that primary molars had no or minimal buccal undercuts to retain a removable obturator, Figure (2). Two children had to be rehabilitated under general anesthesia due to uncooperativeness. Once favorable dental conditions to support the obturators were reached, maxillary and mandibular primary impressions were made for each child using heavy consistency

Fig. (1) Congenital cleft defect in the hard palate in a 7 year old child.

Fig. (2) The same child in figure(1) after fitting stainless steel crowns to maxillary primary molars and fluoride varnish application (DuraShield, Sultan Healthcare, USA).

polysiloxane rubber base (Xantopren, Kulzer, Germany), Figure(3). Special trays were constructed using cold cure acrylic resin (Acrostone, Egypt), and then secondary impressions were made using a one-step medium consistency vinylsiloxanether impression material (Identium Medium, Kettenbach, Germany).The secondary impressions were poured twice; first time using conventional stone suitable for heat cured acrylic resin, and the second time using special (expansion stone) for constructing the injection molded (flexible) obturators to compensate for volumetric contraction during cooling process. Acrylic teeth were added when needed in both types of obturators. Thereafter, all children were fitted with two obturators; one constructed using heat cured acrylic resin (Acrostone, Egypt), (Device A), and one constructed using injection molded thermoplastic acrylic resin (Biodentaplast material, Bredent, Senden/ Witzighausen, Germany), (Device B), Figure(4). Patients and parents were blinded for the type of obturators.

Fig. (3) Primary impression made with heavy consistency rubber base impression material.

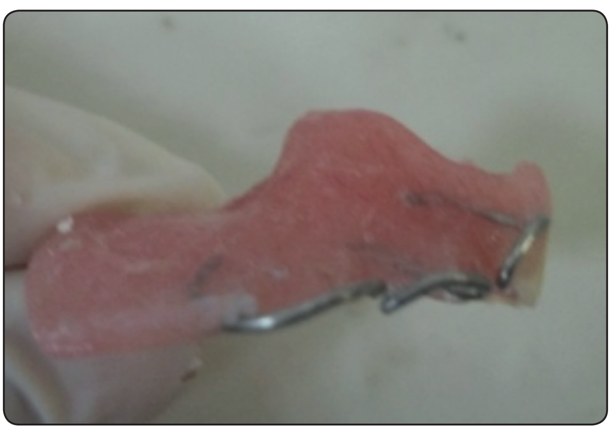

Fig. (4) A finished Injection molded flexible obturator.

Speech Assessment

Speech assessment of both obturators was done immediately at the same day after adjusting both obturators for each patient at the Phoniatric Unit, ENT Department, Ain-Shams University Specialized Hospital, Cairo, Egypt. Speech sound records were evaluated using two methods: objective method by using a nasometer (Kay Elemetrics, model 6200, USA) which provides an acoustic measure of movement of the vibrational energy through the vocal tract[25,26] to assess oral and nasal sentences production and subjective method using Auditory Perceptual Assessment[3,16] to assess speech intelligibility.

Speech recording and nasometric assessment

Nasalance scores were determined using a nasometer (Kay Elemetrics, model 6200 USA) to assess oral and nasal sentences production. Speech sample of each child was audio recorded in an acoustically treated room using a Computerized Speech Lab (CSL Hardware, Model 4500 USA). The latest generation CSL hardware, Model 4500, is an input/output recording device for a PC, which complies with the rigorous specifications and features needed for reliable acoustic measurements. Children were seated in an upright position and allowed to talk freely in a microphone fixed 20 cm from the patient mouth while describing 3 given pictures. Afterwards, children were instructed to repeat a predetermined sentence three times to take the average frequency between the three readings. For oral sentence assessment, children were instructed to repeat “3Ali Ra7 Yel3ab Kora”. While for nasal sentence assessment, children were instructed to repeat “Mama Betnayyem Manal”.

Speech sample recordings were done in three situations for each child; without obturator, with device A, and with device B.

Auditory Perceptual Assessment

Auditory perceptual analysis was done to assess speech intelligibility. The recorded speech samples were evaluated by 2 experienced phoniatricians at the Phoniatric Unit, ENT department, Ain-Shams University Specialized Hospital, Cairo, Egypt. During the listening task, each speech sample was rated on a score sheet. Randomization of each child speech samples (without obturator; and while wearing devices A and B) was done before scoring to eliminate any order defect[16]. Speech samples were classified according to the following 6- point speech intelligibility scale[16], which addresses speech intelligibility judgments according to the understanding of speech sounds (phonetic characteristics) and the speech outcome meaning, where 1 represented normal speech intelligibility, and 6 represented severely impaired speech intelligibility.

1. **Normal**: normal speech.
2. **Mild**: intelligibility is mildly impaired, yet speech sounds and meaning can be understood.
3. **Mild to moderate**: speech sounds can be partially understood, and meaning can be fully understood.
4. **Moderate**: some difficulty in understanding speech sounds, with some impaired understanding of meaning.
5. **Moderate to severe**: great difficulty understanding speech sounds, and understanding of meaning is very impaired.
6. **Severe**: speech sounds and meaning cannot be understood.

Results were evaluated by calculating the means of both phoniatricians for each patient in the three situations.

Statistical analysis

Statistical analysis was performed by Microsoft Office 2013 (Excel) and Statistical Package for Social Science (SPSS) version 20. The significant level was set at $P \leq 0.05$. Kolmogorov-Smirnova and Shapiro-Wilk tests were used to assess data normality. Anova for repeated measures was used and adjusted using Bonferrioni correction to assess significance between the three groups.

RESULTS

Data was found to be normally distributed.

Oral sentences

Anova for repeated measures revealed significant differences among studied groups. The mean value for nasalance score for Oral sentences was significantly lowest (the best) with device B (27.5000±6.12372) followed by device A (46.6667±12.11060). Control (no obturator) had the significantly highest (the worst) mean value for nasalance score for oral sentences (62.500±7.58288), Table (1).

TABLE (1) Mean and standard (Std) deviation values for nasalance scores for oral sentences without (control) and with different obturator types.

Device	Mean (%)	Std. Deviation	N	P value
Control	62.500	7.58288	12	
Device A	46.6667	12.11060	12	<0.001*
Device B	27.5000	6.12372	12	

: Significant at $P \leq 0.05$

Nasal sentences

Anova for repeated measures revealed significant differences among studied groups. The mean value for nasalance score for nasal sentences was significantly lowest (the best) with device B (30.8333 ± 8.01041) followed by device A (51.6667 ± 9.30949). Control (no obturator) had the significantly highest (the worst) mean value for nasalance score for nasal sentences (68.3333 ± 7.52773), Table (2).

TABLE (2) Mean and standard (Std) deviation values for nasalance scores for nasal sentences without(control) and with different obturator types.

Device	Mean (%)	Std. Deviation	N	P value
Control	68.3333	7.52773	12	
Device A	51.6667	9.30949	12	0.000*
Device B	30.8333	8.01041	12	

: Significant at P ≤ 0.05

Speech intelligibility

Anova for repeated measures revealed significant differences among studied groups. Simple main effect with Bonferrioni correction revealed no significant difference between device A (2.5000±0.54772) and device B (1.6667 ± 0.81650), Table (3).

TABLE (3) Speech intelligibility in the three groups:

Device	Mean	Std. Deviation	N	P value
Control	3.3333	0.51640	12	0.001
Device A	2.5000[a]	0.54772	12	
Device B	1.6667[a]	0.81650	12	

Similar letters indicate no significant difference at P ≤0.05

DISCUSSION

Palatal obturators are typically short-term prosthetics used to close defects of the palate that may affect speech production or cause nasal regurgitation during feeding. Following surgery, there may remain a residual oro-nasal opening in the palate, alveolar ridge, or labial vestibule. A palatal obturator may be used to compensate for hypernasality and to aid in speech therapy targeting correction of compensatory articulation caused by the cleft palate[13, 27].

The basic requirements of a prosthetic obturator are support, retention and stability. Acrylic resin needs to be well adapted over the palate as well as the palatal defect and well supported by existing teeth to optimize retention and stability[28]. The objective of prosthesis extension is to provide resistance to vertical and horizontal displacement. The extension should not contact the nasal septum or the turbinates. One way of overcoming the retention problem is to obtain accurate reproduction of undercut areas. The quality of retention of the obturator prosthesis is dependent on direct and indirect retention provided by any remaining teeth, defect size, availability of tissue undercut around the cavity, and the development of muscular control[29,30]. In the present study, children had only primary dentition, and preoperative assessment revealed that primary maxillary molars had minimal or no undercuts to support the prosthesis. Thus, stainless steel crowns had to be fitted to all molars as maximum number of posterior abutments must be used to avoid the disadvantages of a cantilever and improve support[31].

Historically, speech characteristics have been an integral part of any description of the sequlae of cleft palate which was evident in the preoperative assessment that included an evaluation by a speech pathologist to confirm that the major source of air escape is through the palatal defect and not a VPD, as in the latter condition a palatopharyngeal prothesis will be required to address the problem[13,16].

Appliances made of injection molded acrylic resin were reported to have better adaptability to the fitting surfaces than those made of heat cured acrylic resins. It was reported that injection molded system has better adaptation compared to heat cured resin. The authors attributed this better adaptation of the injection-molded system to several factors such as: the fluid resin has smaller particles than the conventional acrylic resin, the polymerization temperature is lower, the injection molded technique does not form a resin film between the two halves of the flask, and no displacement of the two halves of the flask occurs during resin packing(32). This can improve appliance retention and patient acceptance. Improved adaptability and retention of a palatal obturator will improve sealing of the palatal fistula which can lead to better speech and feeding and can augment and simplify future speech therapy. Therefore, the present study sought to compare palatal obturators made of heat cured and injection molded flexible acrylic resin regarding speech changes in children with congenital palatal clefts. Speech assessment was done directly after adjusting the finished obturators to make sure that speech improvements were the result of the obturator's ability to seal the palatal defect and not due to the child's accommodation to the prosthesis.

In the present study, all assessments of spontaneous speech intelligibility demonstrated improvement with the use of a prosthesis in all patients. This finding is in agreement with results reported in the literature(16,33-35). Intelligibility is the final product of speech that can be impaired by hypernasality, audible air emission, lack of oral pressure and articulation errors. Hypernasality is a resonance disorder that has negative consequences for speech production and intelligibility of afflicted individuals so palatal obturators contribute to a greater extent in reduction of this hypernasilty(16). This was evident in our study where both types of obturators improved speech intelligibility with no significant difference between them, since both obturators decreased air escape to the nose.

Oral and nasal sentences production was also significantly better with the palatal obturators, this indicates that the presence of a prosthesis significantly maintained intraoral pressure and decreased hypernasality and contributed to the observed intelligibility enhancement. This also comes in agreement with previous studies that assessed different speech appliances and reported that with the elimination of hypernasality more intraoral pressure was created(16,35). These improvements were significantly better with injection molded flexible obturators compared to heat cured ones, which may be related to the better adaptability of flexible resins as previously reported(32).

CONCLUSIONS

Within the limitations of this study, it can be concluded that speech intelligibility improved with rehabilitation with a palatal obturator. Obturators made of injection molded flexible acrylic resins significantly produced better oral and nasal sentences and may be more useful in assisting future speech therapy. Rehabilitation of children with congenital clefts with palatal obturators can be a routine procedure in pediatric dentistry as it does not require complex construction procedures as in cases of appliances needed for velopharyngeal dysfunction, thus, contributing to the enhancement of social interactions and quality of life of those children.

Further studies are needed assessing the combination of speech therapy with palatal obturators made of flexible acrylic resin.

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