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ORIGINAL RESEARCH

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The relationship between cleft palate repair technique and audiological outcomes: A retrospective cohort study

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Abstract

Objective: Otitis media with effusion is common in children with cleft palates. This study aimed to investigate the link between palatal closure techniques and audiological outcomes.

Methods: In this retrospective-prospective cohort study, we examined the relationship between palate repair techniques and hearing outcomes in children with cleft palates. From 2017 to 2022, 190 ears of 95 cleft patients were studied at the Cleft Lip and Palate Department of Shiraz University of Medical Sciences. Variables assessed included the surgical technique, cleft severity, auditory brainstem response (ABR) threshold, and tympanometry configuration.

Results: The mean ABR improved from a prepalatoplasty value of 39.51(11.62) decibels (dB) to a postpalatoplasty mean of 26.61(11.60) dB (Cohen's *d*: 1.12 [95% CI; 0.90–1.34]). Initially, 87.9% of the studied ears exhibited abnormal tympanometry, but this significantly decreased to 47% postsurgery (risk ratio: 4.43 [95% CI; 1.20–16.43]). When compared with Sommerlad intravelar veloplasty, the Nadjmi modified Furlow palatoplasty was associated with a notably lower mean ABR (β: −6.58 [95% CI: −10.43 to −2.73], p-value = .001) and a reduced frequency of abnormal tympanometry (odds ratio [OR]: −1.10; 95% CI: −1.85 to −0.36, p-value = .004). Factors like prepalatoplasty ABR, cleft palate severity, gender, and syndromic did not confound these findings.

Conclusions: Although the Nadjmi modified Furlow palatoplasty showed better results, our findings indicate a significant improvement in ABR and tympanometry outcomes for both techniques. Future randomized controlled trials are suggested to confirm the influence of palatal closure techniques on audiological outcomes.

Level of Evidence: 3b.

KEYWORDS

cleft palate, cleft severity, hearing loss, modified Furlow, palatoplasty, palatoplasty, Sommerlad intravelar veloplasty

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1 | INTRODUCTION

1.1 | Background

Orofacial cleft is the most prevalent congenital abnormality, occurring in ~1.6 per 1000 live births.[1,2] This condition presents a myriad of challenges to the affected individuals, ranging from aesthetic concerns to impediments in speech, eating, hearing, and social interactions.[3] One of the frequent complications, otitis media with effusion (OME), stands as the leading cause of conductive hearing loss in children with clefts. It tends to be both more prevalent and persistent compared with the general population.[4–7]

OME originates from the dysfunction of the eustachian tube, involving changes in para-tubal muscle architecture, tubal cartilage density, tubal curvature, and luminal diameter. These alterations facilitate inadequate ventilation and negative pressure within the middle ear cavity, culminating in OME and subsequent hearing loss.[6] Despite the proven effectiveness of cleft palate surgical repair in enhancing hearing outcomes and reducing OME occurrences, a considerable number of children continue to experience hearing impairments throughout their lives.[8,9]

Achieving optimal outcomes from cleft closure revolves around five fundamental objectives: fostering normal maxillary growth, averting fistula formation, ensuring normal speech development, restoring appropriate eustachian tube function, and realizing favorable aesthetic results.[10] Therefore, optimizing the primary palatoplasty surgery emerges as a crucial step in enhancing the management of orofacial clefts, setting the stage for improved patient outcomes.[11,12] While palatal surgeries have achieved promising cosmetic outcomes, they still face hurdles in remedying speech disturbances and persistent eustachian tube dysfunction. Although several studies have scrutinized the influence of surgical techniques on the hearing statuses of patients with cleft palates, the exact ramifications of defect severity and its subsequent recovery remain to be fully elucidated.[13–16] Notably, the Sommerlad and Nadjmi modified Furlow palatoplasty techniques have been correlated with the lowest incidence of OME and adverse hearing outcomes.[17]

1.2 | Objective

This study seeks to juxtapose the audiological outcomes of patients with cleft palates who have undergone Sommerlad intravelar veloplasty against those who received Nadjmi modified Furlow palatoplasty.[18,19]

2 | MATERIALS AND METHODS

2.1 | Study design and setting

The research was carried out at the Cleft Palate Department of Shiraz University of Medical Sciences, serving as a referral center for over 10 million individuals in southern Iran between 2017 and 2022. Recruitment began in June 2021, with data being gathered retrospectively from April 2017 to June 2021 and prospectively from June 2021 to March 2022. Dedicated clinical research assistants meticulously recorded data using a standardized electronic case report form. To ensure data accuracy and minimize inconsistencies or omissions, an extra researcher validated the data entries for a sample comprising 15% of the subjects. This study was conducted following the STROBE (Strengthening the Reporting of Observational Studies in Epidemiology) guidelines designated for retrospective-prospective cohort research.[20]

2.2 | Patient selection

We included patients with a cleft palate who had undergone either the Sommerlad intravelar veloplasty or the Nadjmi modified Furlow palatoplasty as their primary palatal surgery between April 2017 and March 2022. In order to maintain our focus on the hearing outcomes associated with primary palatoplasty techniques patients were specifically selected with a diagnosis of mild or moderate hearing loss (ABR thresholds 20–55 dB), while those presenting with severe hearing loss were excluded, aligning with our research objective to focus on a distinct patient demographic where ventilating tube placement was not clinically indicated. Also, we excluded patients who had experienced an upper respiratory tract infection within 3 weeks before the audiological test, those who had undergone a secondary palatoplasty or a re-repair surgery, individuals with incomplete records or without at least one follow-up visit, those with a prior history of myringotomy or hearing aid usage, those who had a ventilation tube insertion either prior to or during the palatal operation, and finally, those who were diagnosed with pure sensorineural hearing loss before the surgery.

2.3 | Data sources/measurements

We conducted a comprehensive review of the medical records of all patients who underwent primary palatoplasty in our center. To assess the severity of the palatal cleft, we employed the classification proposed by Veau et al. Patients were stratified based on the cleft's extent: soft palate only (Grade 1), clefts including both the hard and soft palate but not beyond the incisive foramen (Grade 2), complete unilateral clefts encompassing the soft palate to the alveolus, typically involving the lip (Grade 3), and bilateral complete unilateral clefts akin to Grade 3 (Grade 4).[21] Relevant data such as gender, birth date, severity of the cleft palate (graded from 1 to 4), the date of the primary palatoplasty surgery, syndromic status, and the specific surgical technique utilized were collated. Pre- and postpalatoplasty audiometric data were documented in alignment with the standards of the Academy of Otolaryngology—Head and Neck Surgery (AAO-HNS).[22] Given that most participants were under 2 years of age at the time of their palatoplasty, we opted for the sedated auditory brainstem response (ABR) and tympanometry tests to determine hearing

thresholds and assess the status of the middle ear. We administered standard dosages of oral sedatives, either diphenhydramine or promethazine, providing a noninvasive method to achieve the necessary sedation level for ABR, which is safer compared with intravenous sedatives. In this study, preoperative ABR assessments were consistently conducted 1 week prior to palatoplasty. Postoperative ABRs were performed 3 months following the surgery, and patients also underwent microscopic otoscopy evaluation 1 week after surgery, in accordance with the standard protocol at our center. These evaluations were performed both before the Sommerlad palatoplasty and after the initial stage of the Nadjmi modified Furlow palatoplasty.[23] We compared pre- and postoperative measures of both Sommerlad and the first stage of Furlow. This comparison was essential as the first stage of Furlow, involving reconstruction of the soft palate and tensor veli palatini muscle, significantly impacts Eustachian tube dysfunction, thereby influencing the results. All audiological tests were conducted on each ear separately, and the dates of these assessments were recorded. Furthermore, to ensure consistency in the testing process, all patients were examined within the same otolaryngologic clinic.

2.4 | Audiometric methods

The ABR threshold detection test utilized multiple click stimuli ranging between 0 and 100 dB HL, specifically targeting the 1–4 kHz range and with a focus on 4 kHz. We conducted the hearing assessment using the Eclipse from Intracoustic. The average hearing loss for each ear was calculated by taking the mean of hearing levels within the 0- and 100-dB range. The Clark classification was then used to categorize the ears into seven distinct hearing level groups: −10 to 15 dB was interpreted as normal hearing; 16–25 dB indicated minimal hearing loss; 26–40 dB represented mild loss; 41–55 dB was moderate; 56–70 dB signified moderately severe; 71–90 dB was viewed as severe, and anything above 90 dB was considered profound hearing loss.[24]

For tympanometry, an airtight probe connected to a tympanometer (sourced from GSI; Grason-Stadler, Eden Prairie, MN) was employed. For infants below 6 months, a 1000 Hz pure tone was used, while a 226 Hz pure tone was used for older children, applied at varying air pressure levels. Tympanograms were derived by contrasting the reflected energy with the initial energy. Using the Jerger–Liden classification system, tympanograms were then categorized into three distinct types: Type A, Type B, and Type C.[25] We defined abnormal tympanometry as the presence of a non-type A tympanogram.

2.5 | Surgical methods

The Sommerlad procedure, commonly referred to as the radical intravelar veloplasty, comprises a robust retro positioning of the velar musculature along with minimal incisions on the hard palate, tensor tenotomy, and repair of the levator muscle sling. The Furlow palatoplasty was modified by Nadjmi et al. in two primary ways: rejoining the levator muscle with a limited overlap of the myomucosal flaps and, in instances of more extensive clefts, deploying a buccal myomucosal flap to securely close the oral layer, avoiding undue tension and exposure of raw areas.[13,14] Each group of patients was treated by a senior surgeon of comparable expertise and qualifications.

2.6 | Ethical considerations

The ethical review committee at the Shiraz University of Medical Sciences granted approval for this study under the ethical number #18143-01-01-97. All procedures were undertaken in compliance with the appropriate guidelines and regulations. We ensured that all patient data were anonymized before analysis and that confidentiality was strictly maintained throughout the research process.

2.7 | Statistical analysis

Data entry was initially done in SPSS version 26.0 (SPSS Inc., Chicago, IL), followed by a detailed analysis. Qualitative data were represented through frequency and percentages, while quantitative data were described using mean (standard deviation [SD]), median, quartiles [Q1–Q3], and the interquartile range. Statistical comparisons among the various surgical techniques were conducted using either the Mann–Whitney or Pearson Chi-square tests.[26] McNemar's test has been used to compare ABR tympanometry results pre- and postpalatoplasty. Additionally, a generalized linear model (GLM) was employed for comparisons between the different surgical techniques in relation to ABR and tympanometry outcomes, with adjustments made for baseline values and demographic information. The comprehensive model included gender, cleft severity, and syndromic status as potential confounding variables. Statistical significance was denoted by a p-value of <.05, and all tests were two-tailed.

3 | RESULTS

3.1 | Participants

From 2017 to 2022, out of the 217 individuals initially screened, 95 patients (equivalent to 190 ears) met the inclusion criteria. Among these, 51 patients (53.6%) were male, with a median age of 13 months at the time of operation [Q1–Q3: 10–16; range: 3–152]. Syndromic characteristics were found in 15 patients (15.8%), accounting for 30 ears. On the other hand, 80 patients (84.2%) did not exhibit any co-existing diseases. Cleft palate severity was assessed, showing 36.3% with Grade 1, 52.1% with Grade 2, 10% with Grade 3, and 1.6% with Grade 4. The average prepalatoplasty ABR was 39.30 (with a SD of 11.90), and 167 ears (87.9%) displayed abnormal tympanometry. A detailed comparison of the baseline characteristics between Sommerlad intravelar veloplasty and Nadjmi modified Furlow Palatoplasty can be found in Table 1.

TABLE 1 Baseline demographic and surgical characteristics of patients.

Parameters		Total; ($N = 190$)	Sommerlad intravelar veloplasty; ($n = 142$)	Nadjmi modified Furlow palatoplasty; ($n = 48$)	*p*-Value
Operation age (month); Median [Q1–Q3]		13 [10.0–16.0]	13.0 [10.0–16.0]	12.0 [10.0–14.0]	.192[a]
Gender; *n* (%)	Male	88 (46.3%)	60 (42.3%)	28 (58.3%)	.053[b]
	Female	102 (53.6%)	82 (57.7%)	20 (41.7%)	
Cleft palate severity; *n* (%)	Grade 1	69 (36.3%)	57 (40.1%)	12 (25.0%)	.024[b,*]
	Grade 2	99 (52.1%)	65 (45.8%)	34 (70.8%)	
	Grade 3	19 (10%)	17 (12.0%)	2 (4.2%)	
	Grade 4	3 (1.6%)	3 (2.1%)	0 (0.0%)	
Syndromic; *n* (%)		30 (15.6%)	24 (16.9%)	6 (12.5%)	.470[b]
Prepalatoplasty tympanometry (abnormal); *n* (%)		167 (87.9%)	127 (89.4%)	40 (83.3%)	.573[b]
Prepalatoplasty ABR; mean (SD)		39.5 (11.6)	39.3 (11.8)	40.3 (11.0)	.592[a]

Abbreviations: ABR, auditory brainstem response; SD, standard deviation.
[a]Mann–Whitney *U* test.
[b]Pearson's chi-squared test.
*p-value <.05 considered as significant.

TABLE 2 Generalized linear model analysis examining the association between palatoplasty techniques and postpalatoplasty auditory brainstem response.

Parameter	Postpalatoplasty ABR Mean (SD)		β (95% CI)	*p*-Value
	Nadjmi modified Furlow alatoplasty	Sommerlad intravelar veloplasty		
Model 1 (adjusted for prepalatoplasty ABR)	21.53 (11.78)	28.12 (11.36)	−6.58 (−10.43 to −2.73)	.001*
Model 2 (adjusted for prepalatoplasty ABR, cleft severity)	21.86 (11.33)	28.02 (10.81)	−6.16 (−9.88 to −2.44)	.001*
Model 3 (adjusted for prepalatoplasty ABR, cleft severity, gender, syndrome)	21.66 (11.46)	28.08 (10.86)	−6.44 (−10.20 to −2.67)	.001*

Abbreviations: ABR, auditory brainstem response; CI, confidence interval; SD, standard deviation.
*p-value <.05 consider as significant.

3.2 | ABR outcomes

Following the analysis of data collected from 190 ears across 95 patients, a noteworthy enhancement in the mean ABR was observed, transitioning from a prepalatoplasty level of 39.51 (11.62) to a postpalatoplasty level of 26.61 (11.60).

Utilizing a GLM analysis, we sought to establish associations between postpalatoplasty ABR and various predictors, including prepalatoplasty ABR, gender, and syndromic status. Our findings indicated a lack of significant association between postpalatoplasty ABR and these predictors (prepalatoplasty ABR: p-value = .241, gender: p-value = .532, syndromic status: p-value = .222). However, distinct correlations were identified between postpalatoplasty ABR and both the palatal closure technique (p-value < .001) and cleft palate severity (p-value < .001). Notably, GLM analysis elucidated that both surgical methods significantly enhanced ABR outcomes (both p-value < .001). Postpalatoplasty outcomes favored the Nadjmi modified Furlow palatoplasty (21.58 ± 11.14) over the Sommerlad intravelar veloplasty (27.98 ± 11.14; β: −6.58 [95% CI: −10.43 to −2.73], p-value = .001). Further adjustments for potential confounders—namely, cleft severity, gender, and syndromic status—did not significantly alter these outcomes. Additionally, Grade 3 cleft severity demonstrated a higher ABR than Grade 4 cleft severity (β: −16.92 [95% CI: 3.73–30.10], p-value = .012; Table 2). Subgroup analysis comparing the efficacy of the two surgical techniques revealed varying outcomes across different cleft severity grades, with significant differences observed, particularly for Grades 2 and 3. However, due to a limited number of subjects, Grade 4 was excluded from the subgroup analysis (Table 3).

3.3 | Tympanometry outcomes

In the initial assessment, a striking 87.9% of examined ears exhibited deviations from normalcy in tympanometric readings. However, this prevalence markedly decreased to 47% during the subsequent postoperative observation period, showcasing a statistically significant

TABLE 3 Subgroup analysis of postpalatoplasty ABR stratified by cleft severity.

Cleft palate severity	Postpalatoplasty ABR mean (SD)		*p*-Value
	Sommerlad intravelar veloplasty	Nadjmi modified Furlow palatoplasty	
Cleft severity			
Grade 1	23.92 (9.18)	24.16 (7.63)	.934
Grade 2	28.69 (12.31)	20.81 (9.07)	.002*
Grade 3	40.00 (11.31)	20.00 (00)	.043*

Note: All comparison conducted by Mann–Whitney *U* test.
Abbreviations: ABR; auditory brainstem response; SD, standard deviation.
*p-value <.05 considered as significant.

TABLE 4 Generalized linear model analysis examining the association between palatoplasty techniques and postpalatoplasty tympanometry.

Parameter	OR (95% CI)	*p*-Value
Model 1 (adjusted for prepalatoplasty tympanometry)	−1.10 (−1.85 to −0.36)	.004*
Model 2 (adjusted for prepalatoplasty tympanometry, cleft severity)	−1.13 (−1.91 to −0.35)	.004*
Model 3 (adjusted for prepalatoplasty tympanometry, cleft severity, gender, syndrome)	−1.17 (−1.96 to −0.38)	.004*

Abbreviations: CI, confidence interval; OR, odds ratio.
*A p-value <.05 consider as significant.

reduction (p-value = .002). In postoperative microscopic otoscopy examination conducted by the senior surgeon, no tympanic membrane with perforation or adhesion was found.

To delve deeper into the intricate relationship between surgical methodologies employed and their impact on tympanometry results, GLM analyses were executed. Notably, the Nadjmi modified Furlow palatoplasty procedure exhibited a discernible association with fewer instances of abnormal tympanometry outcomes compared with cases where the Sommerlad intravelar veloplasty technique was employed (odds ratio [OR]: −1.10; 95% CI: −1.85 to −0.36, p-value = .004). Moreover, subsequent adjustments for potential confounding variables such as cleft severity, gender, and syndromic factors did not substantively alter these observed outcomes (Table 4).

Intra-group analysis indicated that both groups experienced statistically significant improvements in their tympanometry outcomes postoperatively, with p-values <.001 in comparison to their respective preoperative stages.

4 | DISCUSSION

OME in patients with cleft palate, with or without cleft lip, has been extensively investigated in recent years.[27] There remains debate over the optimal surgical technique and management strategies for cleft palate repair, particularly regarding their influence on middle ear function.[17] While consensus is not unanimous about the impact of primary palatoplasty on audiological outcomes, a significant body of research posits that palate repair can restore soft palate integrity, improve palatal muscle architecture, enhance eustachian tube function, and subsequently decrease the risk of OME.[28]

Téblick et al.[17] highlighted that among various palatoplasty procedures, Sommerlad and Furlow palatoplasty delivered the best outcomes concerning middle ear function. Nadjmi et al.[19] proposed a two-stage palatal repair technique, an adaptation of the Furlow palatoplasty. This method not only addresses limitations of the Furlow technique but also boasts more favorable outcomes in terms of speech, fistula formation, and maxillary growth. Studies by Lithovius et al.[13] and Carroll et al.[16] failed to establish a statistically significant relationship between the cleft palate type, the number of tube insertion surgeries, and the degree of hearing loss. However, Garcia-Vaquero et al.[29] noted that even in the absence of statistically significant data, individuals with Veau clefts graded 3 or 4 displayed a higher OME prevalence and more pronounced hearing loss. In contrast to these findings, our study identified a marked correlation between cleft palate extent and ABR results, with intergroup comparisons showing higher mean ABR thresholds for Veau clefts graded 2 and 3 than Grade 1. Notably, despite initial expectations, the mean ABR threshold was lower in Grade 4 than in Grade 1, a result which should be viewed with caution due to the limited number of participants in this category.[30]

Previous research has yielded mixed results concerning the influence of the primary palatoplasty method on audiological outcomes. Antonelli et al.[15] observed no discernible difference in hearing outcomes when comparing Furlow palatoplasty with Von Langenbeck repairs. Similarly, Lithovius et al.[13] reported that while double flap palatoplasty produced elevated mean pure tone averages, the lowest hearing loss rates followed Furlow palatoplasty, although the difference wasn't statistically significant. Carroll et al.[16] demonstrated a significant relationship between the cleft palate repair techniques (4-flap, Furlow, V-to-Y, and Von Langenbeck) and pure tone auduiometry (PTA) outcomes 6 years postrepair. While the Furlow technique was associated with the lowest PTA, indicating better hearing outcomes, it was applied only to soft and partial hard clefts by the surgeons in their study. They concluded that a modified Furlow technique is necessary to effectively close a complete hard palate cleft, suggesting that there remains room for improvement in the

outcomes of hard palate cleft repairs. Although no study directly compared Sommerlad intravelar veloplasty with Nadjmi's modified Furlow palatoplasty concerning audiological outcomes, D'Andrea et al.[31] proposed that early Sommerlad intravelar veloplasty, as opposed to Veau-Wardill-Kilner palatoplasty, might reduce persistent OME, thereby decreasing the need for ventilation tubes. Our results support the theory that the choice of palatoplasty technique significantly affects postoperative hearing thresholds. Both methods lowered mean ABR thresholds postsurgery (p-value for both <.001), but GLM analysis revealed that the Nadjmi modified Furlow approach led to a markedly superior ABR outcome compared with Sommerlad intravelar veloplasty.

Some studies have explored the relationship between cleft width and otologic outcomes in patients with cleft palate. For instance, a study by Martin et al.[32] suggested that patients with wider cleft palates may be more susceptible to severe eustachian tube dysfunction and otologic complications. Additionally, Wu et al.[33] indicated that wider preoperative cleft palates, which correlate with Veau classification, are associated with increased complications and poorer outcomes following cleft palate repair. However, to the best of our knowledge, there is no direct comparison in the existing literature that definitively evaluates whether cleft width or Veau classification has a greater impact on otologic outcomes.

Given the uneven distribution of patients across cleft severity grades, we undertook a subgroup analysis focused on postpalatoplasty ABR. Grade 4 cleft severity was excluded from this due to insufficient sample size. As summarized in Table 3, for Grades 2 and 3 Veau cleft severity, the Nadjmi Furlow technique corresponded with a reduced mean postpalatoplasty ABR compared with the Sommerlad intravelar veloplasty.

The Audiology Clinical Practice Guideline for Cleft Palate Patients indicates that palatoplasty surgery can positively impact audiological evaluations provided there is a minimum 3-month gap postsurgery.[29] Consequently, our study ensured a minimum 3-month interval between palatoplasty and audiological testing.

Like any retrospective cohort study, ours has limitations. The follow-up duration may be considered short, age-related hearing improvement was not factored in, and there was an uneven distribution of participants across the cleft severity spectrum. Nonetheless, our findings robustly support all the proposed hypotheses, suggesting they are not merely the result of statistical anomalies. We acknowledge that including patients with prior ventilation tubes in future studies, conducted through randomized, blinded clinical trials, could provide a broader and more comprehensive assessment of the outcomes of palatoplasty in a diverse patient population, with a specific focus on audiological aspects.

5 | CONCLUSION

In sum, our research suggests that the Nadjmi modified Furlow palatoplasty, in comparison to Sommerlad intravelar veloplasty, might offer improved audiological outcomes as gauged by ABR and tympanometry. Thus, in alignment with existing research, early intervention, continued follow-up, and judicious selection of the most effective surgical approach are advocated to enhance not just dental and orthodontic results but also hearing and speech outcomes. Such strategies can play a pivotal role in the holistic social development of children diagnosed with orofacial clefts.

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CONFLICT OF INTEREST STATEMENT

The authors declare no conflicts of interest.

DATA AVAILABILITY STATEMENT

The data that support the findings of this study are available from Dr. Sara S Nabavizadeh, upon reasonable request.

INFORMED CONSENT STATEMENT

Informed consent was obtained from all individual participants included in the study.

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