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Original articles

Can a pharyngeal bulb prosthesis eliminate hypernasal speech in individuals with hypodynamic velopharynx?

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ABSTRACT

Purpose: to investigate the effectiveness of a pharyngeal bulb prosthesis to eliminate hypernasality in patients with operated cleft palate presenting with diagnosis of hypodynamic velopharynx.

Methods: twenty patients with cleft palate, ages 11-40 years, presenting hypodynamic velopharynx participated in the study. Patients had their speech audio recorded twice, with and without prosthesis, simultaneously with nasometry. Three speech-pathologists rated the presence and absence of hypernasality. Perceptual and nasometric data without and with prosthesis were compared, using the McNemar Test ($p<0.05$).

Results: three (15%) patients presented hypernasality without prosthesis and normal resonance with prosthesis, 3 (15%), normal resonance without prosthesis and hypernasality with prosthesis, 9 (45%), hypernasality without and with prosthesis, and 5 (25%), normal resonance in both conditions. Nasometry (≤27% cut off): 1 (5%), presented scores >27% without prosthesis and <27% with prosthesis, 2 (10%), scores <27% without prosthesis and >27% with prosthesis, 17 (85%), scores >27% in both conditions, and 1(5%), scores <27% in both conditions. The comparisons between the results were not significant ($p=1.000$).

Conclusion: the pharyngeal bulb prosthesis alone is insufficient to eliminate hypernasality of patients presented with hypodynamic velopharynx. To this purpose, the combination between the prosthesis and speech therapy is required.

Keywords: Cleft Palate; Velopharyngeal Insufficiency; Palatal Obturators

INTRODUCTION

Hypernasality is the main speech symptom of operated cleft palate patients presenting with velopharyngeal dysfunction (VPD)[1]. The success in eliminating hypernasality by a physical procedure (surgery or bulb) depends on the movement of the pharyngeal walls during speech. Patients with hypodynamic velopharynx (HV) usually combine velopharyngeal insufficiency and mislearning, leading to the need of a combination of physical procedure and speech therapy[2,3]. Usually they present with a large velopharyngeal gap size (greater than 50% of the resting velopharyngeal space) with limited movement of the velopharyngeal structures during speech[4]. Surgical prognosis for HV is not good since the repair of the structural problem (with a wide pharyngeal flap, for example), without addressing the functional behavior of the velopharyngeal function, would not eliminate hypernasality[3]. Prosthetic treatment, in these cases, is an alternative for the management of VPD when combined with speech therapy[2].

A pharyngeal bulb prosthesis is a removable maxillary prosthesis that consists of an oral section composed of a cast partial dental prosthesis framework with a perforated palatal extension (intermediary section) to support the posterior section (pharyngeal bulb). The role of the bulb is to fulfill the gap and promote velopharyngeal closure. The prosthesis is an alternative approach to treat patients with HV, although its fabrication might be somewhat complex due to the absence or limited movement of the pharyngeal walls. The dentist and speech-language-pathologist working as a team face the challenge of tailoring a bulb to fulfill the velopharyngeal gap without promoting over or under obturation[4].

Patients with HV present inadequate sensory stimulation of the passage of air/acoustic energy in the pharynx, which would somehow explain the limitation of movements of velopharyngeal structures during speech. The presence of the bulb in the nasopharynx can stimulate the movement of the pharyngeal walls affecting the pattern of velopharyngeal activity, especially when the movement of the pharyngeal walls is limited[2,3].

This study aimed at investigating the effectiveness of a pharyngeal bulb prosthesis to eliminate hypernasality in patients with operated cleft palate presenting with HV. It is hypothesized that the prosthesis alone is not effective to eliminate hypernasality for those cases.

METHODS

This research was approved by the institutional review and ethical board of the Craniofacial Anomalies Rehabilitation Hospital with University of São Paulo (Hospital de Reabilitação de Anomalias Craniofaciais da Universidade de São Paulo -HRAC/USP) (4.249.745 SVAPEPE-CEP 2020), Brazil. Informed consent was obtained from all participants.

The HRAC/USP is a comprehensive hospital specializing in the treatment of patients with cleft lip/palate (CLP) and other craniofacial anomalies, which includes a service of speech appliances. The universe for the current study was the group of patients who underwent primary palatal surgery and presented with VPD with poor prognosis for secondary surgery. At HRAC/USP, patients presenting with characteristics of HV during nasoendoscopy are referred first to prosthetic treatment in steady of surgery, combined with speech therapy. This conservative approach aims to improve their prognosis for a future surgery[3].

Participants

Participants were carried out prospectively, using convenience sampling consisting of patients presenting with consistent hypernasality, with or without compensatory articulation, referred to prosthetic management of VPD. To qualify for the study group, they had to meet the following criteria: a) operated syndromic or non-syndromic cleft palate, or cleft lip and palate (with or without fistula in the hard palate, but not in the soft palate); b) velopharyngeal insufficiency after primary palatal repair, or surgical resection of a failure pharyngeal flap; c) ineligibility for secondary velopharyngeal surgery due to characteristics of HV; d) no moderate or severe hearing impairment.

Twenty participants (11 males/9 females) with repaired cleft lip and palate or cleft palate only, age 10 to 45 years (median 26 years), fulfilled the inclusion criteria (Table 1). The rationale for them to undergo prosthetic treatment is because they had large velopharyngeal gap with poor movement of the pharyngeal walls (HV). The sample size of 20 was determined empirically and not based on a formal sample size calculation.

Table 1. Distribution of participants by age, gender, cleft type, occurrence of syndrome and compensatory articulation, before the fabrication of pharyngeal bulb prosthesis

Participant #	Age (y)	Gender	Cleft Type	Syndrome	CA
1	34	F	BCLP	N	Y
2	33	M	BCLP	N	N
3	40	F	BCLP	N	Y
4	28	M	ULCP	N	N
5	31	M	UCLP	N	N
6	26	M	UCLP	N	N
7	24	F	BCLP	N	Y
8	23	F	CP	N	Y
9	24	M	CP	Fetal Alcohol	Y
10	34	M	CP	N	Y
11	36	M	UCLP	Optiz G/BBB	N
12	22	M	UCLP	N	N
13	22	F	UCLP	Noonan	N
14	32	F	UCLP	N	Y
15	12	M	UCLP	N	Y
16	11	F	CP	N	N
17	23	M	CP	N	N
18	29	F	BCLP	N	Y
19	28	F	UCLP	N	Y
20	25	F	CP	N	Y

Captions: F = female; M = male; UCLP = unilateral cleft lip and palate; BCLP = bilateral cleft lip and palate; CP = cleft palate; CA = compensatory articulation; Y = yes; N = no

Pharyngeal bulb prosthesis

Pharyngeal bulb prosthesis was fabricated by an experienced dentist and speech-pathologist of the institution (Figure 1). The impression of the bulb was established during diagnostic therapy using nasoendoscopic biofeedback (Olympus ENF-P4). Diagnostic therapy in this situation refers to a stimulability testing which uses strategies for the manipulation of intraoral air pressure at the time of articulation assessment aiming to increase the movement of velopharyngeal walls and therefore the velopharyngeal closure with the bulb.

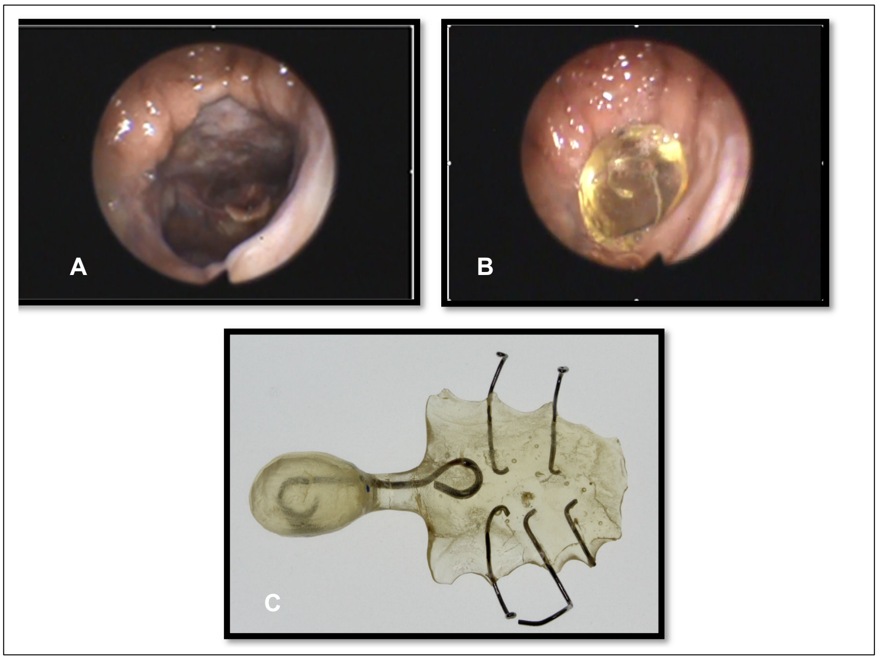

Figure 1. A) Nasoendoscopic view of the nasopharynx during the emission of vowel /a/; B) Nasoendoscopic view of the nasopharynx during the emission of vowel /a/ with the bulb in place; C) view of the pharyngeal bulb prosthesis

Audiorecordings

Participants were recorded twice (without and with prosthesis), sitting in a comfortable chair in a silent room. A set of 5 sentences in Brazilian Portuguese, containing oral sounds was used as stimulus: *Papai caiu da escada (Dad fell off the ladder), Fábio pegou o gelo (Fabio took the ice), O palhaço chutou a bola (The Joker kicked the ball), Tereza fez pastel (Tereza made pastry), A* árvore *dá frutos e flores (The tree bears fruits and flowers)*. The sample was repeated after the evaluator and recorded on audio simultaneously to nasometry. A digital tape recorder Marantz (PMD660) and a Sennheiser E935 microphone, positioned 20 cm from the patient´s mouth, were used for recordings.

The recordings were transferred to a personal computer and files were saved in *.wav format. The 40-speech-sample-recordings (20 with and 20 without prosthesis) were randomly edited using the *Praat Program version* 5.3.63[5] into a pen-drive for the rating task. In addition, 20% (8 pairs of sentence sets) of the recordings were randomly duplicated for intra-rater comparison.

Auditory-perceptual rating

Three female-certified Brazilian Speech Pathologists, with over 5 years of experience with evaluation of cleft speech served as raters. They were not aware of the purpose of the study nor were they familiar with any of the participants. They were also blinded to the conditions of the speech samples they were rating, i.e., whether the recordings were done with or without prosthesis. Hypernasality was rated as present (rating score 1) or absent (rating score 0), based on recordings of the sentences set.

Each rater received a pen-drive containing a file with the randomly edited 28 pair of speech recordings plus a file containing the manual of instructions about the rating task, as well as a link to get access to the Google Form where they should complete with their ratings. The raters rated the recordings individually using their own personal computer and headphone.

Nasalance scores

The nasalance scores were obtained using the Nasometer Model 6200-3 (software version 30-02-3.22, Kay Elemetrics, Lincoln Park, NJ), after reading the same set of 5 sentences used on the audio recordings, first without the prosthesis and then with it.

Statistical Analysis

a) Intra and inter-rater´s agreements with and without prosthesis: the ratings were compared between the three raters using Kappa. Interpretation of Kappa (κ) scores can be done according to Landis and Koch:[6] Poor=$\kappa < 0.00$; Slight=κ:0.00-0.20; Fair=κ:0.21-0.40; Moderate=κ:0.41-0.60; Substantial=κ:0.61-0.80; Almost perfect=κ:0.81-1.00.
b) Perceptual ratings of hypernasality with and without prosthesis: were calculated using the McNemar Test, considering the equal results of all raters or of at least two raters. Ratings of zero = no hypernasality and ratings of 1 = with hypernasality.
c) Nasalance scores with and without prosthesis: were compared using the McNemar Test. Results were categorized using the cut off value of 27% for hypernasality, based on the normative values for Brazilian Portuguese[7]. Scores ≤ 27% suggest no hypernasality and scores >27%, presence of hypernasality.
d) Agreement between the perceptual ratings of hypernasality and nasalance scores: were calculated using Kappa statistics.

The level of significance was set at 5% ($p < 0.05$).

RESULTS

Reliability

The overall intra-raters´ percentage agreement was 79% (substantial) -R1 = 100%: almost perfect; R2 = 62%: substantial, and R3 = 75%: substantial. Inter-rater´s percentage agreement for each pair of raters were, respectively: R1 vs. R2 = 45% (moderate) and 50% (moderate), R1 vs. R3 = 80% (substantial) and 50% (moderate), and R2 vs. R3 = 65% (substantial) and 75% (substantial).

Perceptual ratings

Out of the 20 participants, 12 (60%) were rated with hypernasality and 8 (40%) without hypernasality when they were not using the prosthesis. With the prosthesis on, 12 (60%) were rated with hypernasality and 8 (60%) without hypernasality. Comparing the results with and without prosthesis, 3 (15%) eliminated hypernasality with the prosthesis, 3 (15%) only presented hypernasality with prosthesis, 9 (45%) presented hypernasality with and without prosthesis, and 5 (25%) did not present hypernasality in any of the two conditions. The comparison of the ratings with and without prosthesis were not significant (McNemar Test, p=1.000). See Table 2.

Nasalance scores

Without prosthesis, 19 (95%) presented scores between 31% and 70% (mean = 47%), which is indicative of hypernasality (>27% cut off) and 1 (5%) score of 20%, indicative of no hypernasality (≤27% cut off). With the prosthesis in place, 17 (85%) presented scores between 32% and 61% (Mean = 46%), indicative of hypernasality (>27% cut off), and 3 (15%) between 19% e 24% (Mean = 21%), indicative of no hypernasality (≤27% cut off). The comparison of the results with and without prosthesis was not significant (McNemar Test, p=0.500). See Table 2.

Table 2. Hypernasality ratings and nasalances scores (%), obtained without (W/o) and with (W/) speech bulb prosthesis for all participants

Participant #	Hypernasality Rating		Nasalance Score (%)	
	W/o Bulb	W/ Bulb	W/o Bulb	W/ Bulb
1	1	1	20	19
2	1	1	39	51
3	1	0	34	49
4	0	0	32	33
5	0	0	44	32
6	0	0	31	24
7	1	1	44	39
8	1	1	41	41
9	1	0	43	20
10	1	1	56	52
11	1	1	69	56
12	0	0	70	61
13	1	1	35	33
14	1	1	44	43
15	0	0	48	46
16	0	1	64	60
17	1	0	55	52
18	0	1	40	37
19	0	1	51	55
20	1	1	45	42
Total	T: 0= 40% 111= 60%	0= 40% 1= 60%	Mean=43%	Mean= 42%

Captions: 0 = No hypernasality, 1 = presence of hypernasality, W/o = without W/= with

Agreement between perceptual ratings and nasalance scores

Eight (40%) participants presented with agreement between perceptual ratings and nasalance scores, without (Kappa = -0.098, p=0.402) and with (Kappa = 0.186, p=0.306) prosthesis, and 12 (60%) did not. The results were not significant (kappa = 0.186).

DISCUSSION

The comparison between the results, with and without prosthesis, confirmed the initial hypothesis for 85% (# 2, # 3, # 4, # 5, # 7, # 8, # 10, # 11, # 12, # 13, # 14, # 15, # 16, # 17, # 18, # 19, and # 20) of the 20 participants, according to the nasalance scores, and for 45% (# 1, # 2, # 7, # 8, # 10, # 11, # 13, # 14 and # 20), according to auditory-perceptual-ratings. The success in eliminating hypernasality through a physical procedure (surgical or prosthetic), depends on the movement of the pharyngeal walls during speech, which does not occur in individuals with HV[8].

One of the most challenging tasks in the fabrication of a pharyngeal bulb prosthesis in patients with HV is the impression of the bulb, due to the large gap size and the poor movement of the pharyngeal walls during speech[3]. The bulb to be manufactured needs to be large to fulfill the gap, but far enough from the pharyngeal walls in rest to allow nasal breathing and nasalization of the nasal sounds, and close enough to be touched by the walls during oral sounds production. This "plug-function" of the bulb shows that the success of this functionality depends on the movements of the pharyngeal walls. In other words, the competence of the velopharyngeal mechanism with the presence of bulb occurs when there is function of the pharyngeal muscles against the bulb[3,4,8].

Patients with HV might present with inadequate sensory stimulation of the passage of air/acoustic energy in the pharynx, which somewhat could explain the limitation of the movements of the velopharyngeal structures during speech. Studies have shown that the constant use of a pharyngeal bulb can stimulate the movement of the pharyngeal walls, therefore affecting the pattern of velopharyngeal activity[3,4]. It is likely that the participants of the present study had had the opportunity to obtain stimulation in their pharyngeal walls after the constant use of the prosthesis combined with speech therapy. However, these data were not collected, since the purpose of the study was only to investigate the effectiveness of the bulb to eliminate hypernasality right after the fabrication of the prosthesis.

Although individuals diagnosed with HV have in common large gaps with limited movement of the velopharyngeal structures, to understand the causes that lead them to present this picture is quite complex, especially when there is no change in the pattern movement of these structures in the presence of a bulb. Understanding the reason why some individuals are not successful in the prosthetic treatment of VPD is not an easy task. Many factors, isolated or combined with each other, related to phonetics, physiology and even prosthetics, may be involved. In addition, the presence of compensatory articulation affecting a smaller or greater number of sounds, the dental conditions (lack of dental elements, malocclusion), the heterogeneity of the palatal conditions (fistula, cleft type), the velopharyngeal characteristics and history of speech therapy among individuals with HV could also explain the differences in the results.

The decision making to refer a patient for a pharyngeal bulb requires the interdisciplinary work among speech pathologists, prosthodontists and plastic surgeons, and its fabrication requires a trans-disciplinary work between the dentist and the speech-pathologist[8]. In the present study, the indication of the bulb occurred after a clinical and nasoendoscopic speech assessment. The impression of the bulb was also made using nasoendoscopy, under diagnostic therapy to get the most possibility of an "ideal bulb size". Nasoendoscopy, as a complementary tool in the rehabilitation of VPD is essential for the impression of a bulb, since it allows the dentist to shape the bulb according to the velopharyngeal gap size. As a pharyngeal flap must be tailor-made for velopharyngeal function a bulb has also to be tailor-made for the fulfilling of the different types of gaps[4].

Several authors agree that hypernasality and/or nasal air emission that persist after surgical correction are functional changes resulting from the inadequate use of the velopharyngeal mechanism and, therefore, should be treated by means of speech therapy[9]. Learning errors, such as compensatory articulations, in the use of velopharyngeal structures can directly affect the pattern and amount of movement of these structures. Thus, individuals who articulate with compensatory articulation do not require the movement of the pharyngeal walls, even if the bulb is in place, therefore being unable to eliminate hypernasality. Another likely explanation for the limited movement of the pharyngeal walls is the habit of the individual to impound low subglottic and intraoral pressure for speech. Hypernasality and/or audible air emission in individuals with HV might act as functional compensatory responses to the inadequate "rearrangement" of the speech articulation gear.

The lack of agreement between the obtained nasalance scores and the auditory-perceptual ratings in the present study might somewhat be explained by the nasometer's own limitation in "capturing hypernasality" related to the information that the evaluators used to assess hypernasality. Many studies have shown that the acoustic effects of nasalization are not constant among individuals, nor among different speech sounds, nor among different gap sizes[9,10]. The nasometer is not able to measure all the spectral information that is available to the listener, as well as variables related to suprasegmental factors such as intensity and vocal tone, phonetic context and/or individual articulatory characteristics[11]. Many participants of the present study presented with audible nasal air emission, associated or not with facial grimace, and this fact might have caused impact on nasalance scores. Individuals with audible nasal air emission and mild hypernasality may have higher nasalance scores because the nasometer cannot distinguish aerodynamic energy from acoustic energy. Although the nasometer does not capture the physical correlate (nasal air emission) of hypernasality, it is possible that for some individuals the nasalance scores agree well with the listener's judgments in some circumstances[10]. That is, for some patients the nasometer is efficient to agree with the listener, but not for others, or to be efficient for one type of speech sample, but not for another. It is up to the clinician to decide how much nasalance can be useful or not for some patients.

The difference between face-to-face speech assessment vs. recording ratings also deserves consideration. The studies by Kuehn and Moon[12] and Sweeney and Sell[13] showed better speech results when the evaluation was carried out in person because the evaluator gathers all the visual information and the individual characteristics present in the speech disorders. The authors emphasize the importance of studies using speech recordings for auditory-perceptual assessments, but recognize that these can offer numerous limitations for the assessment. The use of recordings allows the achievement of inter and intra-rater reliability measures, which contributes to greater scientific credibility of the results[10]. However, it is necessary to be aware that the recordings can capture ambient noise or still not detect enough acoustic information to allow the evaluator to identify the presence of weak intraoral pressure, leakage of non-audible nasal air, and errors related to speech production. The combination of mild hypernasality with some vocal alteration (low intensity of voice, breathiness, hoarseness etc.), for example, could also mask hypernasality, to the point that it be evaluated as absent, especially if the evaluation was done through an audiorecording[10]. Imatomi[14] pointed out that experienced evaluators in the occurrence of hypernasality tend to minimize it when the patient presents vocal disorders. Several studies agree that that vocal changes have been recognized as a factor that can influence the perception of hypernasality[15,16]. As those variables were not controlled in the present study, it is difficult to predict whether they influenced results, therefore, it is suggested that they should be controlled in future studies. Sommerlad et al.[17] found similar results, demonstrating that the evaluators of their study also did not find hypernasality to be present in the speech recordings of patients before surgery. The authors attributed this fact to the possibility of patients presenting with mild or inconsistent hypernasality that may not have been captured in the recordings. The "blind" evaluation has the disadvantage that there is no direct interaction between the evaluator and the patient, in addition to the loss of sound quality in the recordings, especially when the patient has mild or inconsistent hypernasality and audible nasal air leak, which is not always they are captured in the recordings.

No patient in the present study underwent prosthetic treatment for VPD, unless they were symptomatic and had evidence of hypernasality, as well as nasoendoscopic evidence of the HV. However, it was curious to note that some were evaluated as having eliminated speech hypernasality when using the prosthesis, some with no hypernasality in both conditions (with and without prosthesis), and some with hypernasality only when using the prosthesis. It is difficult to assign a specific reason to justify such findings, in addition to those previously discussed. Minor degrees of turbulence or nasal air emission, which are clinically detectable, can be masked, depending on the quality of the recording and reproduction and the loss of visual cues[10].

The relationship between the gap size and the degree of hypernasality has received much speculation for many years, but no study has been successful in demonstrating a correlation between these two variables. Considering that the ratio between oral and nasal impedances can affect the perception of hypernasality, and that this ratio can be influenced by several factors (i.e., amount of effort, configuration of the articulators, size of the vocal tract), then it is fact to expect that the presence of the bulb in the nasopharynx would somewhat influence this impedance relationship in individuals with HV.

Some studies have compared speech resonance, with and without pharyngeal bulb prosthesis. Pegoraro-Krook et al.[8] reported that most of their participants eliminated hypernasality using pharyngeal bulb. It is important to point out they did not present HV. Their referral for bulb occurred while they were on a waiting list for secondary surgery. This means that they all had good prognosis for the surgery, and therefore, good prognosis for the pharyngeal bulb as well.

The lack of agreement between the obtained nasalance scores and the auditory-perceptual ratings was a limitation of the present study. In order to understand the role of a bulb on the speech and its relationship with the velopharyngeal function, further studies on nasometry and perceptual evaluation of hypernasality of patients wearing pharyngeal bulbs are recommended.

CONCLUSION

The pharyngeal bulb prosthesis alone is not able to eliminate speech hypernasality of individuals diagnosed with HV. To this purpose, the combination of a speech therapy program is required.

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