

13-459

Evaluation of a modular palatal lift prosthesis with a silicone velar lamina for hypernasal patients

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## **ABSTRACT**

**Statement of problem.** Speech bulbs and palatal lift prostheses are used to improve oral-nasal balance in speakers with hypernasality resulting from velopharyngeal dysfunction. Fabricating such speech prostheses is often a protracted process and the nasopharyngeal impression can be uncomfortable for the client.

**Purpose.** The purpose of this study was to develop and test a modular palatal lift prosthesis with a silicone velar lamina that can be fabricated without a nasopharyngeal impression.

**Material and methods.** Six adult participants with different etiologies were treated with both a conventional palatal lift prosthesis and the new prosthesis. The outcome measures were nasalance scores, speech acceptability ratings, and participant responses on a questionnaire. Inferential statistical analyses were conducted with nonparametric Friedman tests and 2-tailed paired Wilcoxon Signed Ranks tests. The probability was set at  $P < .1$ .

**Results.** Among the 3 speaking conditions (no prosthesis, acrylic resin prosthesis, modular silicone palatal lift prosthesis), no differences were found in nasalance scores for the oral stimuli. For the nasal sentences, a numerically greater reduction was observed for the silicone than for the acrylic resin prosthesis. Speech acceptability was better with the modular silicone palatal lift prosthesis ( $z=2.032$ ,  $P < .05$ ) and the acrylic resin prosthesis ( $z=1.753$ ,  $P < .1$ ) than with no prosthesis. The questionnaire showed better subjective speech acceptability with the acrylic resin prosthesis ( $z=1.706$ ,  $P < .05$ ) and the modular silicone palatal lift prosthesis ( $z=1.706$ ,  $P < .05$ ) than with no prosthesis. Swallowing comfort was also numerically better for the acrylic resin prosthesis than for the modular silicone palatal lift prosthesis.

**Conclusions.** This study demonstrates the feasibility of a new design for a flexible and modular palatal lift prosthesis. The functional outcomes were comparable to those of the traditional design. While the overall results in this study favored the traditional prosthesis, the new design may be viable for patients who require alternative treatment solutions.

## CLINICAL IMPLICATIONS

A palatal lift prosthesis can be fabricated without a nasopharyngeal impression. The palatal lift extension is made from flexible silicone and can be detached for modification and replacement.

## INTRODUCTION

The velopharyngeal mechanism consists of a muscular valve, or sphincter, that includes the soft palate (velum), lateral pharyngeal walls, and the posterior pharyngeal wall.<sup>1</sup> One essential function of the velopharyngeal sphincter is to regulate the proportion of oral and nasal sound pressure and airflow in speech. The velum elevates and the pharyngeal walls may move inward at the level of the nasopharynx to close off the velopharyngeal tract for oral speech sounds. Proper oral-nasal balance in speech is important for the intelligibility and acceptability of speech.<sup>2</sup>

Velopharyngeal dysfunction may arise as a consequence of a congenital craniofacial syndrome, head and neck cancer, or neurogenic injury and may be caused by velopharyngeal insufficiency, velopharyngeal incompetence, or velopharyngeal mislearning. Speech characteristics common to velopharyngeal insufficiency and incompetence are hypernasality, nasal air emission, and the decreased intelligibility of speech due to weak consonant production.<sup>2,3</sup>

Velopharyngeal dysfunction may be treated surgically with pharyngeal flaps or pharyngoplasties.<sup>4</sup> However, surgery may not be appropriate for some speakers. The alternative but less commonly used treatment approach consists of velopharyngeal prosthetics. The current design of supportive prosthetic speech aids can be traced back to a seminal publication by Gibbons and Bloomer.<sup>5</sup> Two types of designs of velopharyngeal prostheses are commonly distinguished.<sup>6-8</sup> Palatal lifts are shoehorn-shaped prostheses that elevate the velum for closure. These devices tend to be mostly appropriate for speakers with neurogenic injuries who have a sufficiently long velum that does not elevate. Speech bulbs fill the velopharyngeal space and are often used for speakers with structural defects related to craniofacial syndromes or surgically

ablated pharyngeal cancer. The 2 designs may be combined to maximize the effectiveness of the prosthesis.<sup>6,9</sup> Current speech prosthesis shapes tend to follow the original design by Gibbons and Bloomer.<sup>5</sup> A number of researchers have aimed to incorporate a velar lamina that is adjustable inferiorly-superiorly by using a hinge,<sup>10</sup> Ni-Ti orthodontic wires,<sup>11</sup> or a wire spring.<sup>12</sup> Beder et al<sup>13</sup> attempted to make a generic button attached to a single connecting wire instead of an individualized velar attachment in order to reduce the number of appointments needed to make the prosthesis. The same approach, but with double wires, was applied by Shifman et al<sup>14</sup> and by Ueda et al<sup>15</sup> with double wires plus a palatal bar. This design had the advantage that the prosthesis could be fabricated quickly and easily. Since the button was supposed to fit every speaker, no nasopharyngeal impression was required. However, neither of these innovations has become standard clinical practice.

A speaker's response to a speech prosthesis can be variable, and not all speakers will be able to achieve consistent improvement.<sup>8,16</sup> In particular, some speakers will have difficulty tolerating the nasopharyngeal impression that is required to fabricate the velar lamina.<sup>16,17</sup> Wolfaardt et al<sup>18</sup> described a systematic approach to candidate selection, the technique of prosthesis fabrication, and the determination of subsequent need for speech therapy with the prosthesis.

Vogel et al<sup>19</sup> argued that rigid acrylic resin may predispose the speaker to tissue irritation or discomfort or stimulate a gag response. They proposed an alternative design using a velar lamina made from a 3-mm sheet of silicone rubber. The shape of the velar lamina was based on a complete nasopharyngeal impression. The lamina was made by grinding the silicone to the desired shape with a polishing disk. The silicone could be made paper thin at the edges, permitting the silicone to cling to the adjacent tissue without discomfort to the patient. The

prosthesis consisted of a removable dental appliance with a posterior rod with retention hooks. This metal rod supported the silicone velar lamina. Vogel et al<sup>19</sup> described how multiple shapes were produced for a single speaker to identify the ideal outline of the velar lamina. The lamina is attached to a steel extension at the end of the maxillary retainer. The authors estimate that a typical prosthesis has a life span of at least 6 months and usually fails because the steel extension perforates the silicone velar lamina. Ziegler & Vogel<sup>20</sup> demonstrated the usefulness of this speech prosthesis design with a group of 23 dysarthric speakers with different etiologies. They argued that the pliability of the extension reduced speaker discomfort during swallowing. Other teams have reported clinical studies with similar designs.<sup>21-23</sup>

The present study was inspired by both the idea of basing the velar attachment on a generic form proposed by Beder et al<sup>13</sup> and by Vogel et al's<sup>19</sup> idea to make a velar lamina from soft, pliable silicone material to reduce gagging and tissue irritation. The velar attachment of a speech prosthesis is situated in a dynamic region and may require repeated alteration over time. A more generic and modular prosthesis may permit easier prosthesis fabrication, easier prosthesis adjustment or replacement, and improve access to care. An additional benefit of a modular prosthesis design is that a nasopharyngeal impression may be avoided.

The purpose of this clinical study was to compare a palatal lift prosthesis with a generic flexible velar lamina fabricated from silicone to the conventional palatal lift prosthesis that incorporates a rigid velar lamina fabricated from acrylic resin. The outcome measures were nasalance scores, perceptual evaluations, and participant satisfaction.

## **MATERIAL AND METHODS**

### **Participants**

Approval for this study was granted by the University Health Network Research Ethics Board and the University of Toronto. A convenience sampling approach was used for the study. The recruitment phase for this study was 1 year. Over the course of this year, 6 consecutive speakers with hypernasality referred to the Dental Oncology Clinic at Princess Margaret Hospital in Toronto were enrolled in the study. The speaker demographics are detailed in Table I. Once a participant had been given sufficient time to adapt to the prostheses, he or she underwent a series of speech evaluations and completed a subjective feedback questionnaire.

### **Nasometric assessment**

The participants completed a nasometric assessment with and without the prosthesis to assess their resonance in different speaking conditions.<sup>24</sup> The Nasometer (Nasometer Model 6450; KayPENTAX) was used to obtain a measure called nasalance. The device uses 2 microphones to make separate recordings of oral and nasal sounds in speech. The sound pressure level from the nasal channel is divided by the added sound pressure levels from the nasal and oral channels and multiplied by 100 to obtain a percentage that expresses an individual oral-nasal balance in speech. The Nasometer was used to record each speaker reading the Zoo Passage (a text without nasal consonants) and the Nasal Sentences (a text loaded with nasal consonants).<sup>25</sup> Both these texts are commonly used in the assessment of resonance disorders. Participant 1 also recorded the Rainbow Passage,<sup>26</sup> a phonetically balanced text. However, this text was dropped from subsequent recordings to reduce the length of the procedure.

### **Speech acceptability**

Speech acceptability is a measure that assesses how far a speaker conforms to, or differs from, a socially accepted norm. It is a global measure of speech quality that aims to capture the intuitive reaction of listeners to a speaker. In order to assess speech acceptability without and

with the 2 prostheses, the sentence module of the computerized Test of Children's Speech (TOCS+) was used.<sup>27</sup> Twenty-one sentences of up to 6 words in length were recorded. All participants recorded the sentence module with and without the 2 prostheses. For the analysis of speech acceptability, 3 sentences were chosen from every speaker's recordings under all 3 conditions (3 without prosthesis, 3 with acrylic resin prosthesis, and 3 with modular silicone palatal lift prosthesis).

The recordings from all speakers were randomized using random numbers generated from atmospheric noise data ([www.random.org](http://www.random.org)) and embedded into a spreadsheet (Excel 2007; Microsoft Canada). To ascertain the listeners' ability to differentiate between normal and pathological recordings, 9 recordings from normal controls were mixed in with the participants' recordings, resulting in a total of 63 sound clips that were spread over 7 spreadsheets in an Excel file.

The sound clips were evaluated by 7 naïve and phonetically untrained listeners. The listeners worked through the spreadsheets at their own pace. To reduce possible ordering effects, the listeners received individual instructions as to which order to work through the spreadsheets. The spreadsheets were presented on a netbook computer (Acer Aspire One; Acer Canada) with high quality headphones (Ear Force DX12; Voyetra Turtle Beach). The listeners judged the acceptability of the recordings by using a 4-point rating scale (speech acceptability normal, mildly affected, moderately affected, severely affected).<sup>28,29</sup>

## **Questionnaire**

Participants used 5-point rating scales to assess their subjective comfort with their prosthesis and their subjective satisfaction with their own speech on a questionnaire. Four questions asked about subjective speech acceptability, gagging, and comfort of speech and

swallowing, and the participants answered the same questions for every condition (without prosthesis, with acrylic resin prosthesis, and with modular silicone palatal lift prosthesis).

### **Statistical analysis**

Because of the small and heterogenous speaker sample, statistical analysis was mostly limited to descriptive statistics. When inferential statistics were used, the conservative nonparametric Friedman test was used because of the small number of participants. For the same reason, the probability was set at  $P < .1$ . To further evaluate differences between the speaking conditions, 2-tailed paired Wilcoxon Signed Ranks test were used. An initial  $P < .1$  for the post hoc tests was assumed. Multiple post hoc comparisons were not Bonferroni-adjusted.<sup>30</sup>

### **Fabrication of the silicone speech prosthesis**

A prototype for the fabrication of the silicone velar lamina with an obovate outline was fabricated from galvanized sheet metal, wax (Baseplate Wax- pink regular No. 2; Kerr Dental Laboratory Products), and orthodontic wire (Tru-Chrome Stainless Steel Retainer Clasp Wire-Round 0.040 inch/18 gauge; Rocky Mountain Orthodontics). The prototype is shown in Figure 1. From this prototype, molds were made by using the 2 halves of a standard denture flask (No. 31 Ejector Flask; Buffalo Dental Manufacturing Co. Inc.) as the rigid outer shell of the mold. The denture flask halves were filled with a stone layer (Microstone; Whip Mix Corp.) that was covered with polyvinyl siloxane (PVS; Zhermack SpA) as the molding material to capture the details of the prototype. Petroleum jelly (Vaseline Original Petroleum Jelly; Unilever Canada Inc) was used as a separating agent. The molds were formed in a denture flask press (Reco Hydromatic; Reco Dental) under 6.9 MPa pressure. Upon polymerization of the PVS, the denture flask halves were separated and the prototype removed from the mold. An additional PVS

element for wire positioning was fashioned. Figure 2 shows one half of the molds with the velar lamina and the wire positioner.

To produce a silicone velar lamina, a 95-mm section of the stainless steel wrought wire was bent into a "U" shape with the arms of the U spaced 4 to 5 mm apart. The wire was then inserted into the PVS wire positioner and loaded into the matrix transfer mold. Two alternative silicones were identified as suitable to make a velar lamina. Elite Soft Relining (Zhermack SpA) has a Shore A hardness of 35. It is a room-temperature vulcanizing type of silicone and is advantageous because of its resiliency, biocompatibility, antifouling properties, and good dimensional stability. Negative qualities include low tear strength and poor resistance to mechanical and chemical abrasion. The manufacturer purports that Memosil 2 (Heraeus Kulzer) has a Shore A hardness of 72. It is a transparent addition silicone that has good dimensional stability, sufficient rigidity, and no disagreeable odor or taste. However, it possesses only moderate tear strength, which may shorten the life of the velar lamina. The selected silicone, Elite Soft Relining or Memosil 2, was dispensed around the "U" shaped wire in the half of the mold containing the wire positioner. The closed mold was placed in a denture flask press under a pressure of 6.9 MPa. Excess silicone around the lamina form was trimmed with scissors (Straight/Curved Iris Scissors; Hu-Friedy). Figure 3 shows the completed device for participant 4.

The velar lamina begins as a generic object that may be altered with scissors or a silicone cutting bur by the prosthodontist while working alongside a patient. When the definitive outline form has been achieved, the velar lamina is finished and polished to taper and smooth the periphery of the silicone. Since the velar lamina can be removed from the maxillary denture base, evaluating different configurations in a single patient visit is possible. To attach the velar

lamina, the retainer part of the prosthesis is fitted with 25-mm retention tubes that are symmetrically placed 2 mm on either side of the midline (Tru-Chrome Stainless Steel Tubing-0.032 inch/ 20 gauge; Rocky Mountain Orthodontics). The attachment wires of the velar lamina are bent outward so they diverge when inserted into the retention tubes. This divergence provides frictional retention by loading the wires as springs. To insert the velar lamina into, or remove it from the retention tubes, it is best to use pliers (Delicate Wire Twister 7 inch; Hu-Friedy). The velar lamina may be bent superiorly or inferiorly depending on how it needs to displace the soft palate.

## **RESULTS**

### **Nasometric assessment**

The nasometric measurements for the Zoo Passage are displayed in Table II. The Zoo Passage was used to assess the ability of the 2 types of prostheses to reduce perceived nasality, which was the desired effect. Due to a clerical error, the nasometry results for the Zoo Passage for participant 1 with the modular silicone palatal lift prosthesis were lost. By the time this error was noted, it was no longer possible to repeat the recording. Since this speaker also recorded the phonetically balanced Rainbow Passage, these results were included in the table. The 6 participants in the study had mean nasalance scores ranging from 21% to 67% when tested without a prosthesis. In participants 3 and 5, the conventional acrylic resin prosthesis resulted in a greater reduction of nasalance, while participants 1 and 6 achieved a better result with the modular silicone palatal lift prosthesis. For participant 4, the change with either prosthesis was minimal. Participant 2 showed a paradoxical response for both prostheses, resulting in an

increase in nasalance scores. A Friedman test for the 5 participants with complete data did not show a significant difference among the results for the 3 conditions.

The results for the Nasal Sentences are displayed in Table III. The Nasal Sentences were used to assess the ability to maintain nasal airflow in speech, so a reduction of nasalance was not desired. The 6 participants in the study had mean nasalance scores ranging from 57% to 76% when tested without a prosthesis. In participant 4, the conventional acrylic resin prosthesis resulted in greater reduction of nasalance, while participants 1, 3, 5, and 6 experienced a greater reduction in nasalance with the modular silicone palatal lift prosthesis. Participant 2 demonstrated a paradoxical increase in nasalance with both prostheses. However, this increase was smaller for the modular silicone prosthesis. A Friedman test did not show a significant difference among the results for the 3 conditions.

### **Speech acceptability ratings**

The results for the speech acceptability ratings by the 7 listeners are presented in Table IV. A Friedman test (corrected for ties) for the conditions without a prosthesis, with the acrylic resin prosthesis, and with the modular silicone prosthesis confirmed a difference that was at the cut-off for significance ( $Q=4.57$ ,  $P=.1$ ). A series of Wilcoxon Signed Ranks tests among the 3 conditions showed significantly better speech acceptability ratings with the modular silicone palatal lift prosthesis ( $z=2.032$ ,  $P<.05$ ) and the acrylic resin prosthesis ( $z=1.753$ ,  $P<.1$ ) compared to no prosthesis. No significant difference was found between the acrylic resin and modular silicone palatal lift prostheses.

### **Questionnaire**

The feedback questionnaire was completed by all participants except participant 6. For personal reasons that she did not elaborate on, participant 6 did not wish to answer the question

about her speech acceptability but answered the remaining questions. The data obtained from the feedback questionnaire are summarized in Table V. For speech acceptability, a Friedman test (corrected for ties) for the conditions without a prosthesis, with the acrylic prosthesis, and with the modular silicone prosthesis confirmed a significant effect ( $Q=4.90$ ,  $P<.1$ ). A series of paired Wilcoxon Signed Ranks tests among the 3 conditions showed better subjective speech acceptability with the acrylic resin prosthesis ( $z=1.706$ ,  $P<.05$ ) and the modular silicone palatal lift prosthesis ( $z=1.706$ ,  $P<.05$ ) compared to no prosthesis. Friedman tests showed no significant differences among the 3 conditions for gagging and subjective comfort of speech and swallowing. Numerically, swallowing comfort improved slightly with the acrylic resin prosthesis and deteriorated slightly with the modular silicone prosthesis.

## **DISCUSSION**

The purpose of the present study was to compare the new modular silicone palatal lift prosthesis to the conventional acrylic resin design. The goal of the research was to contrast and characterize the 2 devices. The group of research participants was small and heterogeneous, which was a limitation of the present study. The participants had velopharyngeal dysfunction related to oropharyngeal cancer, craniofacial syndromes, and neurological disease, all of which may respond differently to a palatal lift prosthesis. Only 6 participants could be enrolled over the 1-year recruitment period of the study, underlining the relatively rare prosthetic treatment of velopharyngeal dysfunction. As a result, a number of fundamental questions about palatal lift prostheses, for example, optimum placement and preferable contour, still do not have definitive answers.

The results of the nasometric assessment demonstrated that both prostheses reduced the nasalance scores for the Zoo Passage for 4 out of the 6 participants, but no significant differences were found among the 3 speaking conditions on a group level. The 6 participants showed heterogeneous responses, and participant 2 even showed a paradoxical increase of nasalance with both prostheses. The Nasal Sentences were used to assess the reduction of nasalance. Loss of nasal consonants can be an undesired effect. The results indicated that the reduction of nasalance scores for nasal consonants with the modular silicone palatal lift prosthesis was larger. Therefore, the results were equipoised for the Zoo Passage, and the acrylic resin prosthesis had numerically superior results for the Nasal Sentences.

The speech acceptability ratings by untrained listeners demonstrated that both prostheses led to improved speech acceptability. The lack of a statistically significant difference between the 2 appliances indicated that both devices had a similar effect for the participants' perceived acceptability of speech.

The feedback on the questionnaire indicated that the 5 participants who answered the question found their speech acceptability improved by either prosthesis. No significant differences were found for gagging and speech and swallowing comfort. However, interesting numerical differences were found in the subjective swallowing discomfort, which slightly improved with the acrylic resin prosthesis and slightly deteriorated with the modular silicone palatal lift prosthesis. This was an unexpected finding because the soft silicone should better accommodate pharyngeal constriction during swallowing. However, the participants commented that they could feel the tapered edges of the modular silicone prosthesis move up and down during swallowing and that this sensation was unpleasant. The design of the modular silicone palatal lift prosthesis was novel and could probably benefit from further refinement. The design

varied from the prosthesis described by Vogel et al<sup>19</sup> and Ziegler & Vogel<sup>20</sup> in a number of ways. Therefore, the outcomes for future speakers could be improved with more design experimentation.

Despite the experimental design of the modular silicone palatal lift prosthesis, the results were functional and comparable overall to the acrylic resin design. The modular silicone palatal lift prosthesis is simple and inexpensive to produce with the pressure molding process. A greater variety of standard molds could be made for different types of speakers. The modular design of the prosthesis enables the clinician to evaluate different shapes and sizes for the velar lamina. This makes the modular silicone palatal lift prosthesis potentially useful as a training device in speech therapy for an appropriate patient. In such an individual, the prosthodontist could make multiple end pieces of decreasing size for the speaker so that he or she could gradually improve velopharyngeal closure during speech. However, more research is needed to explore the potential of the modular silicone palatal lift prosthesis for speech therapy.

While the definitive devices were not weighed, the modular silicone palatal lift prostheses were probably lighter than the acrylic resin version, which may be an advantage of this design for speakers with large velopharyngeal defects. A final advantage of the new design is that the modular silicone palatal lift prostheses were made without the need for nasopharyngeal impressions. Nasopharyngeal impressions can be bothersome and traumatic for some individuals. The silicone appliance can eliminate this problem.

While the modular silicone palatal lift prosthesis may have a number of potential advantages, a number of initial disadvantages were observed that would warrant further improvement and research. Overall, the acrylic resin prosthesis provided better functional results. A particularly important factor was the slightly better participant comfort during swallowing.

However, the direct comparison of the 2 prostheses may not have been entirely fair. Five of 6 participants had pre-existing speech prostheses that they were accustomed to and that they had learned to tolerate. In comparison, the speech examinations and questionnaires were completed as soon as the participants had adapted to the modular silicone palatal lift prosthesis. Some of their evaluations might have improved over time. However, since the device was novel and untested, the research protocol did not include a longer-term follow-up. This also limited the participants' opportunity to use the modular silicone palatal lift prosthesis for everyday tasks such as masticating and eating.

While the production of the silicone lamina was found to be convenient, the design of the modular silicone palatal lift prosthesis requires a relatively bulky midline to cover the wire attachments. This area of bulk may not be suitable for every patient. In contrast, the sides of the silicone lamina are weak and provide little support. Since the margins of the lamina are tapered, the speaker may feel the edge and movement of the lamina. Since the participants were not given time to accommodate to the device over several weeks or months, and this discomfort might have eventually decreased.

While the lamina design is lighter than its traditional acrylic resin counterpart, the silicone design has the disadvantage that the prosthodontist cannot enter defects and engage soft tissue undercuts to enhance retention. Finally, silicone is more difficult to modify and polish than acrylic resin. Of the 2 silicone polymers used in the present study, the Memosil 2 appeared easier to finish. Over time, the silicone lamina may be more difficult to keep clean than the acrylic resin prosthesis. However, Vogel et al<sup>19</sup> and Ziegler & Vogel<sup>20</sup> did not report specific problems with the silicone material. Perhaps newly developed polymers for maxillofacial use such as polydimethyl siloxanes and chlorinated polyethylenes will have the mechanical and chemical

properties that are optimal for a modular palatal lift prosthesis.<sup>31</sup> Alternatively, the modular design of the prosthesis could also be adopted with acrylic resin end pieces that could be modified or augmented. This might enable the prosthodontist to polish the device and make the prosthesis lighter and thinner. Such a device could also be based on a posteriorly situated acrylic resin disk that would not require a nasopharyngeal impression, similar to the design originally proposed by Beder et al.<sup>13</sup>

## **CONCLUSIONS**

A design for a modular and flexible speech prosthesis with a silicone velar lamina is presented. An initial comparison of the new design and the traditional acrylic resin design demonstrated that the new device achieved functional results but did not surpass the conventional acrylic resin design. Nevertheless, individual speakers may benefit from alternative designs for speech prostheses. More research is needed to shed light on this important but under-researched field in prosthodontics.

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Table I. Overview of participants

Participant number	Sex	Age	Medical history	Pre-existing prosthesis	Number of study visits
1	F	38	Velopharyngeal dysfunction related to mandibulofacial dysostosis (Treacher Collins syndrome)	Yes	5
2	M	73	Velopharyngeal dysfunction related to ablation of oral carcinoma	Yes	7
3	F	32	Velopharyngeal dysfunction and oropharyngeal fistula related to ablation of oropharyngeal carcinoma	Yes	7
4	M	48	Velopharyngeal dysfunction related to ablation of oropharyngeal carcinoma	Yes	7
5	F	26	Congenital velopharyngeal dysfunction	Yes	6
6	F	66	Velopharyngeal dysfunction related to primary lateral sclerosis	No	5

Table II. Nasalance values for the Zoo Passage<sup>25 1</sup>

	No prosthesis	Acrylic prosthesis	Modular silicone palatal lift prosthesis	% reduction with acrylic	% reduction with silicone	More reduction/ less increase
Participant	59	47	MISSING	20%	-	-
1	(Rainbow: 57)	(Rainbow: 54)	(Rainbow: 38)	(Rainbow: 5%)	(Rainbow: 35%)	(Rainbow: Silicone)
Participant	52	64	61	-23%	-17%	Silicone
2						
Participant	47	28	41	40%	13%	Acrylic
3						
Participant	67	66	69	1%	-3%	Acrylic
4						
Participant	60	45	50	25%	17%	Acrylic
5						
Participant	21	10	9	52%	57%	Silicone
6						
Median	55.5	46	50			
Interquartile range	40.5- 61.75	23.5 - 64.5	25 - 65			

<sup>1</sup> For participant 1, results for the Rainbow Passage are also reported (see text)<sup>26</sup>

Table III. Nasalance values for Nasal Sentences<sup>25</sup>

	No prosthesis	Acrylic prosthesis	Modular silicone palatal lift prosthesis	% reduction with acrylic	% reduction with silicone	More reduction/ less increase
Participant 1	69	63	48	9%	30%	Silicone
Participant 2	59	71	65	-20%	-10%	Silicone
Participant 3	66	69	62	-5%	6%	Silicone
Participant 4	76	74	76	3%	0%	Acrylic
Participant 5	76	68	65	11%	14%	Silicone
Participant 6	57	55	51	4%	11%	Silicone
Median	67.5	68.5	63.5			
Interquartile range	58.5 – 76	61 - 71.75	50.25 67.75	–		

Table IV. Results for speech acceptability

Participant	No prosthesis	Acrylic prosthesis	Modular silicone palatal lift prosthesis
	Mean (SD)	Mean (SD)	Mean (SD)
1	2.90 (0.30)	1.10 (0.54)	1.62 (0.50)
2	3.00 (0.00)	3.00 (0.00)	2.95 (0.22)
3	2.00 (0.55)	0.05 (0.22)	0.52 (0.60)
4	2.10 (0.77)	1.57 (0.75)	1.57 (0.87)
5	1.67 (0.80)	0.76 (0.44)	1.14 (0.48)
6	2.29 (0.64)	2.62 (0.59)	2.29 (0.78)
Median	2.19	1.33	1.59
Interquartile range	1.92 - 2.92	0.58 – 2.71	0.98 – 2.45

Speech acceptability was rated on an equal appearing interval scale from 0 - 4 with the descriptors 0 = normal, 1 = mildly affected, 2 = moderately affected, and 3 = severely affected.

Table V. Results for the feedback questionnaire for the 6 participants. All items were rated were rated on a scale from 1 to 5 with 1 as the most favourable result, 3 as a neutral answer and 5 as the most negative result. Participant 6 chose to leave the answer about speech acceptability blank

	No prosthesis	Acrylic prosthesis	Modular silicone
	Median	Median	Median
	(Interquartile range)	(Interquartile range)	(Interquartile range)
Speech acceptability	5.00 (3.50 – 5.00)	3.00 (2.00 – 4.00)	3.00 (2.50 - 3.50)
	N=5	N=5	N=5
Gag/ choke	2.00 (1.00 – 3.00)	3.00 (2.00 - 4.25)	3.00 (2.00 – 3.50)
Speech comfort	3.50 (2.75 - 5)	3.00 (2.00 - 4.00)	3.50 (2.00 – 4.00)
Swallowing comfort	3.00 (1.00 – 4.50)	2.5 (2.00 – 3.50)	3.50 (2.75 - 5)

**LEGENDS**

Fig. 1. Velar lamina prototype with truncated oval outline form.

Fig. 2. Matrix transfer molding process with one half of mold with velar lamina and wire positioner.

Fig. 3. A, Conventional prosthesis for participant 4. B, Modular silicone palatal lift prosthesis with acrylic resin maxillary retainer.

Fig. 4. A, Participant 6 without prosthesis. B, With conventional acrylic resin prosthesis. C, With modular silicone palatal lift prosthesis.

Figure 1: Velar lamina prototype with a truncate ovate outline form.

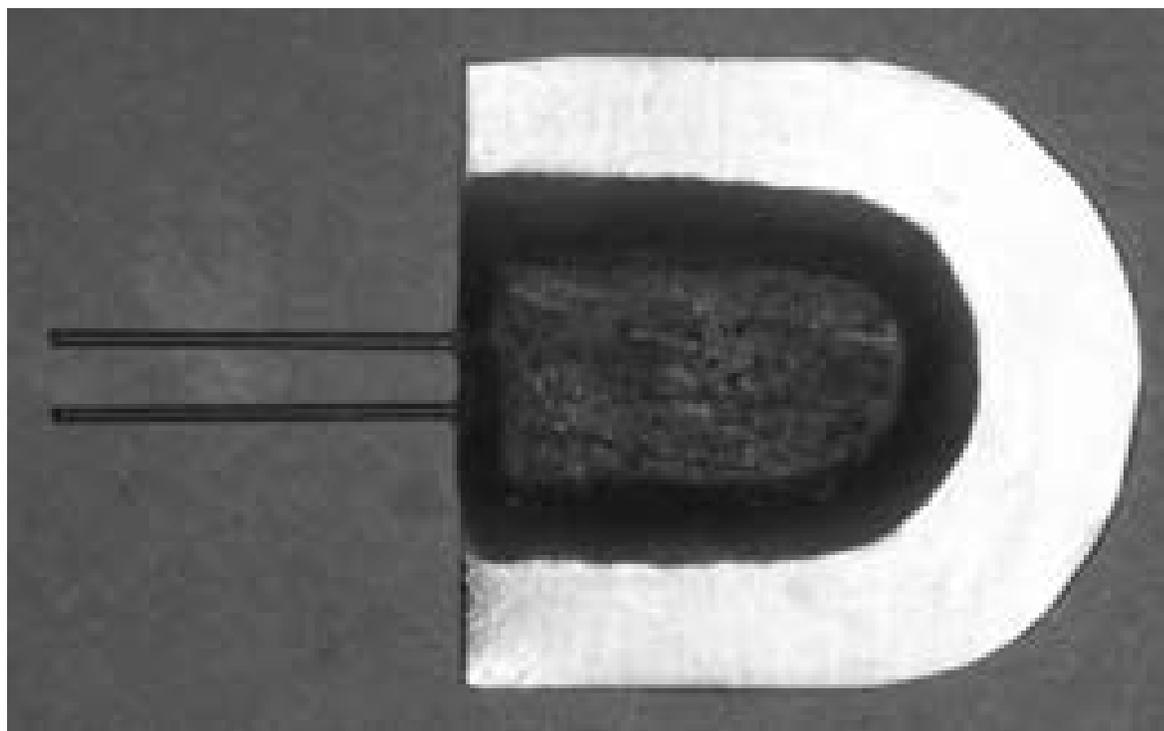


Figure 2: Matrix transfer molding process with one half of mold with velar lamina and wire positioner.

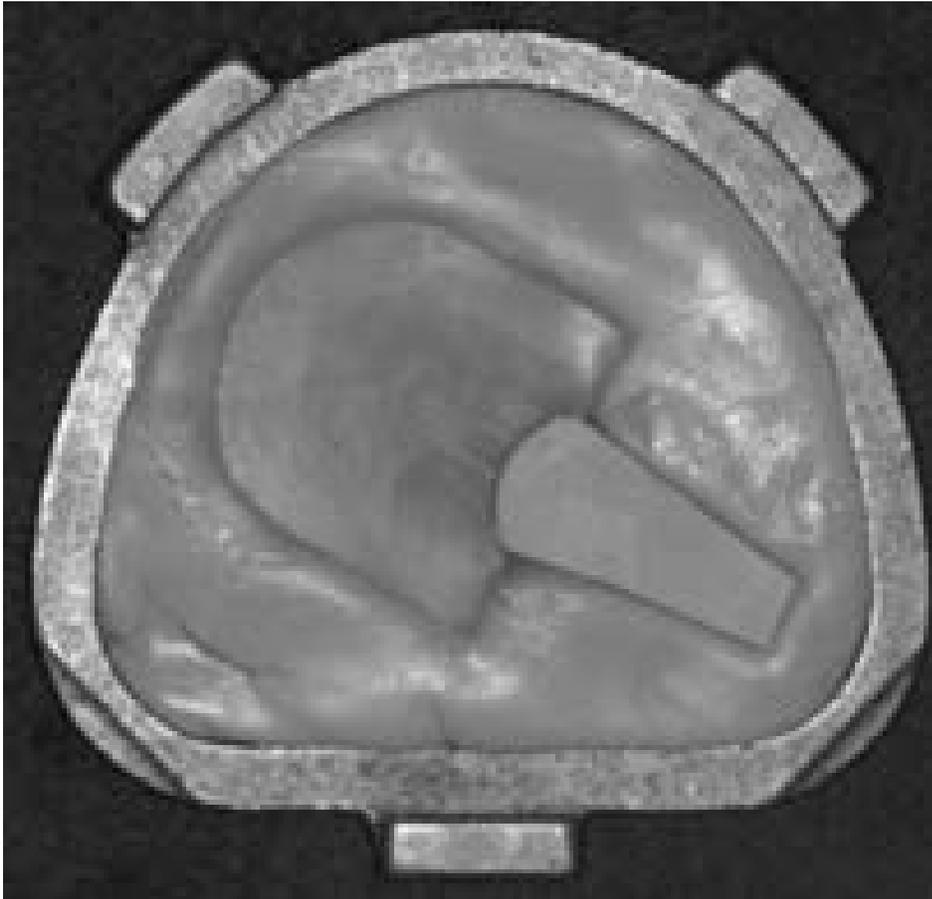


Figure 3. The conventional prosthesis for patient 4 is seen on the left. The silicone prosthesis with an acrylic maxillary retainer is shown on the right.

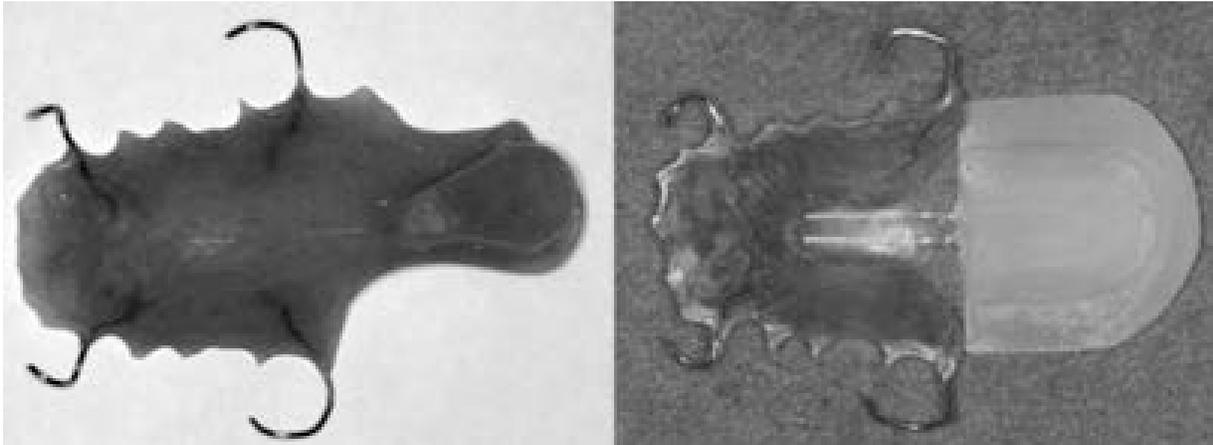


Figure 4. Patient 6 without prosthesis (left), with her conventional acrylic prosthesis (centre), and with the new silicone prosthesis (right).