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Custom nasal obturator for velopharyngeal dysfunction: A dental technique

ABSTRACT

Removable nasal obturators provide a treatment option for a range of patients presenting with velopharyngeal dysfunction without eliminating the possibility for future surgery, speech therapy, or the provision of other devices. The presented technique describes the fabrication of a 1-piece silicone nasal obturator to reduce hypernasality and nasal airflow errors without causing significant hyponasality. The obturator has minimal visibility and minimal risk of inhalation.

INTRODUCTION

Velopharyngeal dysfunction (VPD) is characterized by the leakage of air into the nasal cavity during speech, resulting in hypernasality,¹⁻³ nasal emission,^{2,4} facial grimacing, and decreased vocal intensity.² VPD may be associated with velopharyngeal insufficiency, where the soft palate anatomy is insufficient (seen in patients with a cleft palate), or velopharyngeal incompetency, where the soft palate anatomy is normal but the innervation and movement of the soft palate is impaired (seen after neurological conditions such as stroke or traumatic brain injury).^{2,5}

Conventional treatments include surgery to repair, re-repair, or lengthen the soft palate,^{2,6} palatal lifting devices for patients with incompetence,² or oral obturators for patients with severe palatal insufficiency.^{2,7} Stock and custom-made rigid nasal obturators using 1-way nonreturn valves have been reported.^{8,9} While these devices have been reported to be successful,⁹ when designing the present device, the inclusion of a valve was found to increase hyponasality because of the complete occlusion of the expiratory airflow from the nasal cavity during speech. In

addition, the small components of the valve are a potential inhalation risk. The principal maxillofacial prosthetist (C.R.) at Guy's and St Thomas' Hospital, London, UK designed a 1-piece, silicone nasal obturator which aimed to reduce hypernasality and features of VPD in speech, had no small parts (reducing inhalation risk), was custom in design, and was color matched to the patient's skin to reduce visibility.

Patients diagnosed with cleft or noncleft were assessed by the Evelina London Cleft multidisciplinary team (MDT) and, if deemed suitable (exhibited features of VPD in speech such as hypernasality, nasal emission, nasal turbulence, and cleft speech characteristics) were referred to the nasal obturator clinic. Working with the cleft MDT, the principal maxillofacial prosthetist (C.R.) designed and manufactured the device after consent to treatment.

TECHNIQUE

1. Examine the nasal vestibules for evidence of fistulas and undercuts that could impact the recording of an impression and apply a thin layer of petroleum jelly to the internal surfaces of both the left and right nasal vestibules to facilitate impression removal.
2. Record an impression of the patient's nasal vestibules with a soft silicone impression material (Co-Form Soft; Technovent), cartridge gun, and nozzle. Record each side individually to ensure straightforward removal before reinserting them together and joining them with additional silicone material (Coform Soft; Technovent). Instruct the patient to mouth breathe throughout to prevent inhaling or dislodging the impression material. Use a silicone swatch guide (custom manufactured by using a randomized database of skin shades on the department's e-skin system; Spectromatch) to identify a suitable silicone color to match the patient's skin tone.

3. Trim the impressions to create a flat surface at the top of both vestibules (Fig. 1). Pour the middle section of the impression in a Type IV dental stone (Orthostone; Bracon), ensuring extension past the mid-point of both the left and right nasal vestibule and beyond the impression to permit the later addition of location grooves. Once set, trim the stone to produce flat, smooth surfaces on all sides (do not trim the anatomic surfaces of the impression) and add location grooves on both sides (Fig. 2). This section forms the internal walls of the nasal vestibules.
4. Apply a separator (Unifol; Bracon) to the stone and pour the 2 side sections of the mold to form the outer surfaces of the nasal vestibules: 1 part for the left side, 1 for the right (Fig. 3). Once set, open the mold and smooth the anatomic surfaces with hand tools to remove the air blows and surface roughness caused by nasal hairs or secretions (Fig. 4). Scribe, in reverse, the letters J and Я into the mold to identify the left and right side of the nasal obturator (Fig. 4).
5. Assemble the 3 stone sections and hold in place while applying 2 to 3 washes of molten wax (Anütex Modelling Wax; Bracon) to the mold (Fig. 5). The final wax thickness should be approximately 0.5 mm, and a cavity should be kept through the center to maintain an airway. Trim the wax so that the nasal obturator stops within the nasal vestibule and link a bar in wax between the left and right side of the wax pattern (Fig. 5).
6. Add location grooves to the top surfaces of the stone (Fig. 5). Apply a separator (Unifol; Bracon) to the stone and fill the mold with autopolymerizing acrylic resin (Opacyl PMMA; WHW Plastics) by using the sprinkle technique.¹⁰ Fill the remaining airways on both sides extending the acrylic resin to join the 2 sides (Fig. 6) before processing for 20 minutes at 44 °C under 0.2-MPa pressure.
7. With a fret saw, cut halfway through the acrylic resin along the mid-line of the nose (Fig. 6). Carry out the final separation of the 2 sections with a knife to provide a controlled fracture of the

final thickness of acrylic resin so that the 2 sections can be relocated without a gap, creating a sealed mold (Fig. 7). Remove all wax from the mold with boiling water and apply a separator (Unifol; Bracon) to the stone sections. Color match a biocompatible silicone (LSR-4330 Silicone Elastomer; Factor II) to the preselected skin tone, pack the mold, secure with G-clamps, and polymerize under 0.2-MPa pressure at 70 °C for a minimum of 3.5 hours.

8. Remove the nasal obturator from the mold, remove all flash, and disinfect, ready for fitting (Fig. 8). Arrange a joint appointment between the principal maxillofacial prosthetist (C.R.) and the speech and language therapists (SLT) (A.B.) to fit the device.

9. On inserting the nasal obturator (Fig. 9), a small amount of petroleum jelly may be used to help ease placement; however, excessive amounts may reduce retention. Assess the nasal obturator for fit and color match to the surrounding skin, ensuring the silicone lines the nasal vestibules without a gap from a poor fit or nasal flare, as this will allow excess air to escape that will affect the patient's resonance and speech. Have the specialist SLT screen for speech with the patient wearing the nasal obturator by using a speech sample which includes 4 sentences from the Great Ormond Street Speech Assessment (G.O.S.SP.ASS).¹¹

10. Create holes (approximately 1 mm) in the flat superior surface of the nasal obturators (indicated in Fig. 8) by using a cylindrical metal rod. Reinsert the obturator and reassess speech by using the assessment outlined previously in Step 9. If the speech assessment reveals significant hyponasality, the holes can be increased in size with scissors, and the speech reassessed with the same protocol. This adjustment process aims to minimize hyponasality and improve oral resonance in speech. During this stage, assess nasal airflow and patency while the patient wears the device. Airflow will be reduced but not to the point of making the patient feel congested. The required size of the holes will vary depending on individual speech assessments.

11. Demonstrate the insertion and removal of the nasal obturator to the patient and allow the patient to practice until comfortable with the process. Assess speech and video record, by the specialist SLT, using the full G.O.S.SP.ASS assessment¹¹ and advise the patient when to use the nasal obturator. Provide written instructions on cleaning, storing, and wearing the nasal obturator to the patient and parent or guardian if applicable.

12. Review the patient within 1 month and every 3 to 6 months in the maxillofacial prosthetic clinic, depending on how the patient is managing the device, to evaluate the fit, color, condition of the device, and silicone. Reassess speech 6 months after the initial fit with the specialist SLT. Remake the device when necessary because of silicone deterioration, damage, color fading, or patient growth. When providing devices to children, new impressions and devices may be required periodically as the child grows; timing will depend on the individual's growth.

DISCUSSION

Nasal obturators benefit patients by providing an alternative treatment for VPD in addition to traditional prosthetic speech devices. Disadvantages of the device include that they may not work for every individual or may be poorly tolerated. The silicone used was selected because its medical testing was at a higher level than other maxillofacial prosthetic silicones that are recommended for external use only.

SUMMARY

The presented nasal obturator design reduces hypernasality and the features of VPD in speech, reduced visibility, and the patient is at minimal risk of inhalation. Future development of the fabrication method involves 3D printing of the mold from cast scanning or from a CT scan or

direct printing of the silicone prosthesis. Speech outcome data and patient reported outcome measures could also be considered for future studies.

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FIGURES

Figure 1. Impression of nasal vestibules showing superior surface of impression of both airways, trimmed flat (*red arrows*).

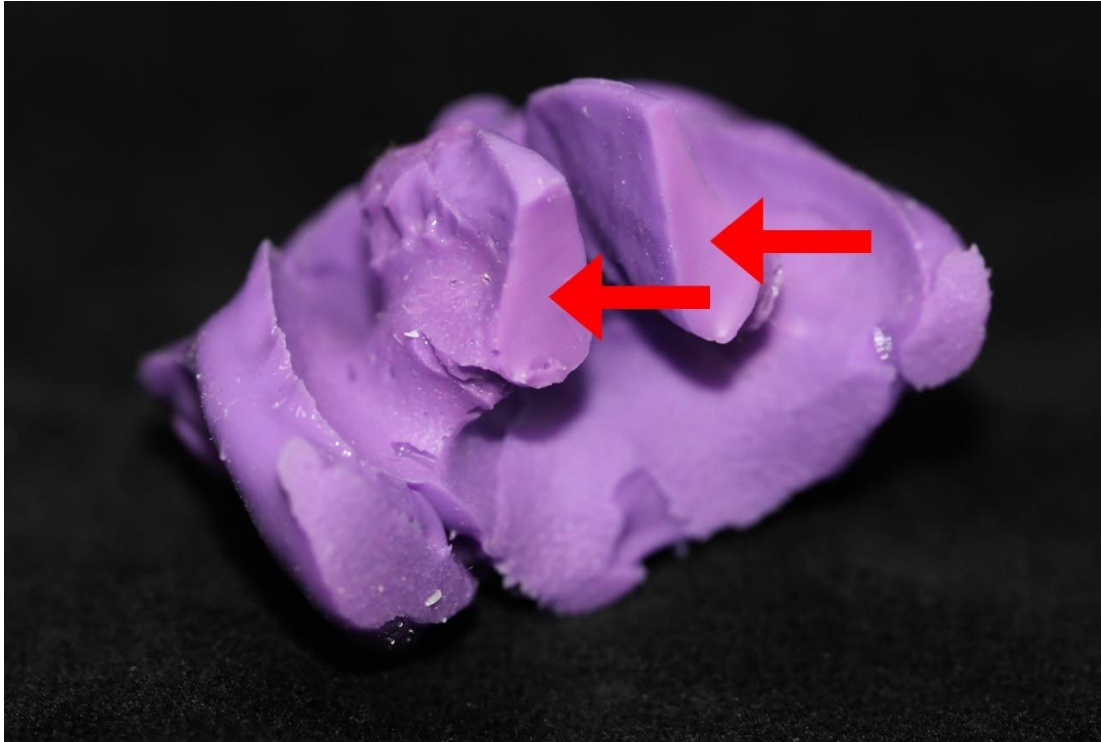


Figure 2. First section of dental stone mold poured between nasal vestibules, trimmed, smoothed with location grooves added.

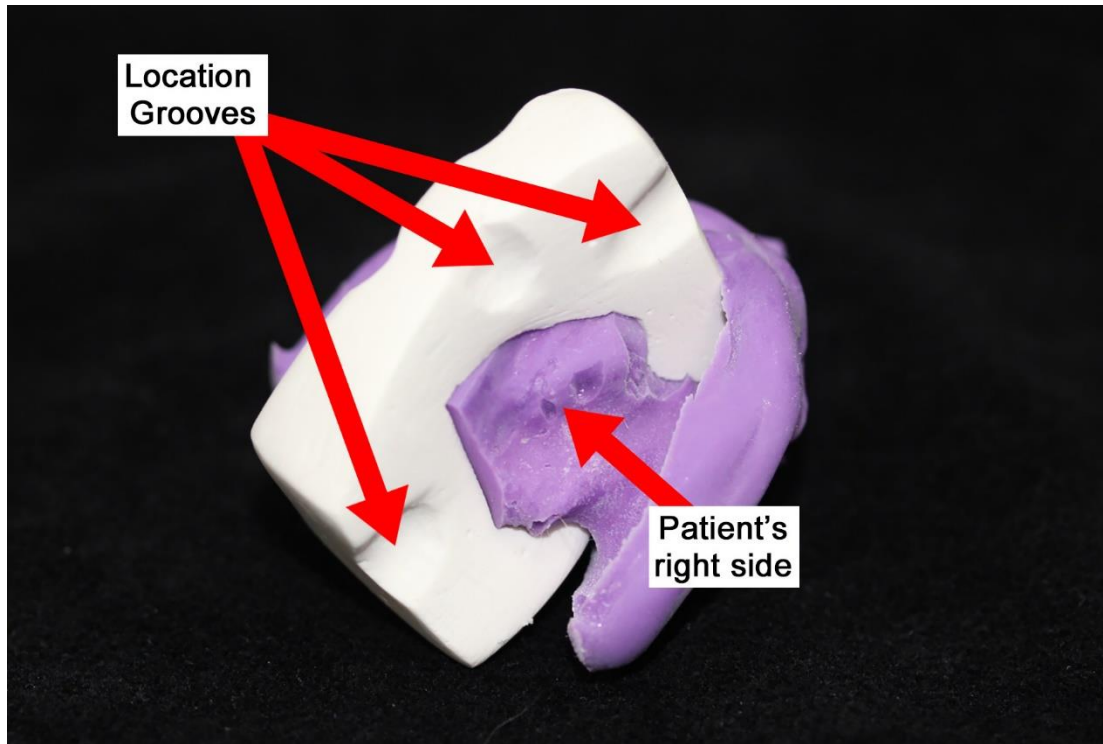


Figure 3. Three sections of stone mold; middle section initially poured with two side sections forming outer surfaces of nasal vestibules.

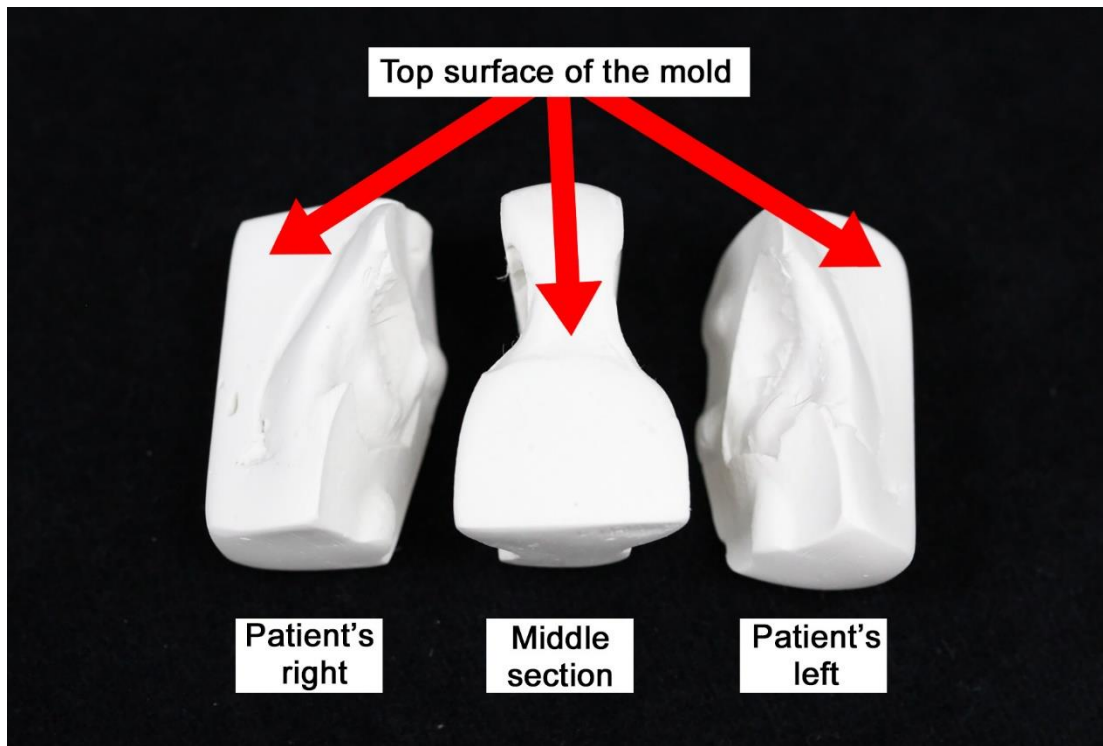


Figure 4. Internal surface of one side of mold showing rough surface from air bubbles, mucus, or hair, followed by smoothed final mold with letter L scribed in reverse for orientation.

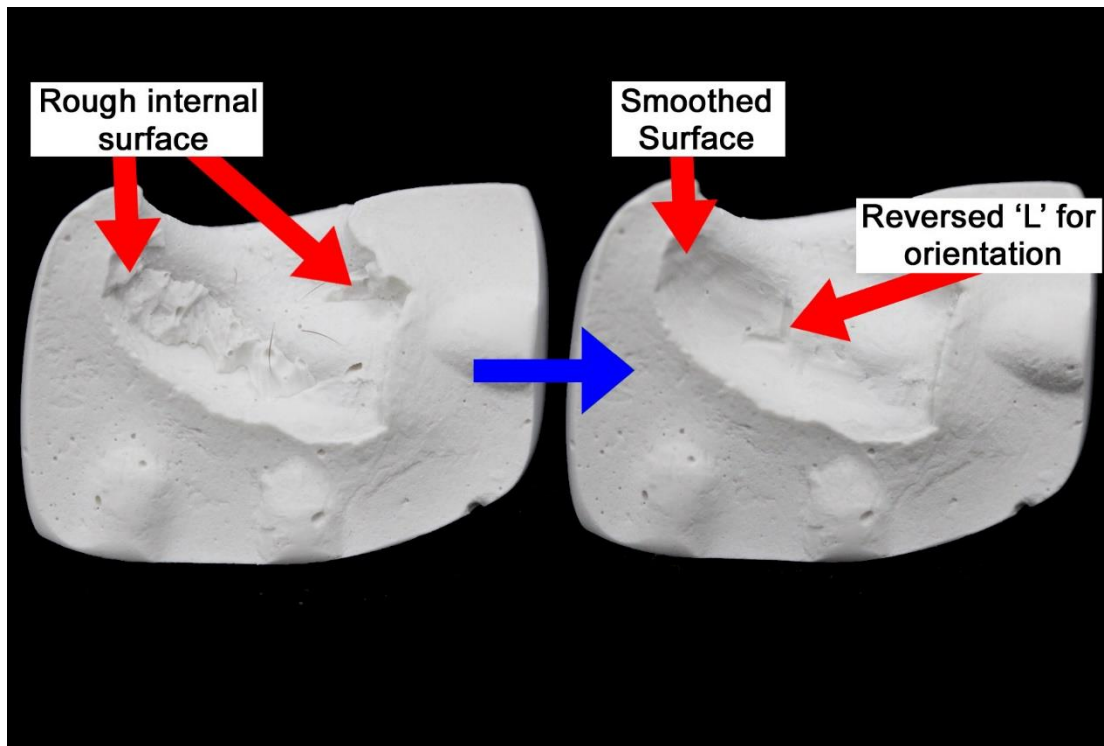


Figure 5. Three stone mold sections located together with wax nasal obturator formed, including joining bar. Shows location grooves in stone for location of acrylic resin section.

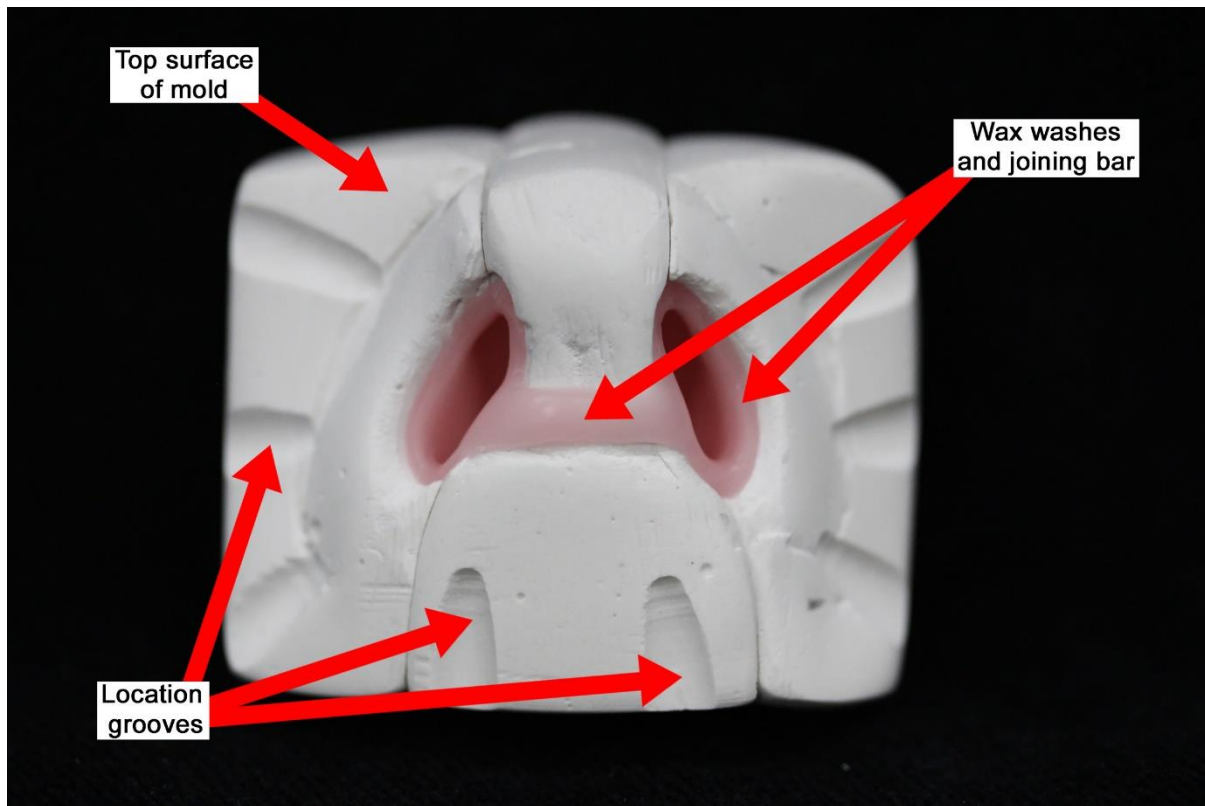


Figure 6. Showing extent of acrylic resin section over top surface of mold, joining two airways, creating final section of mold. Angulation of saw cut to separate acrylic section into two parts.

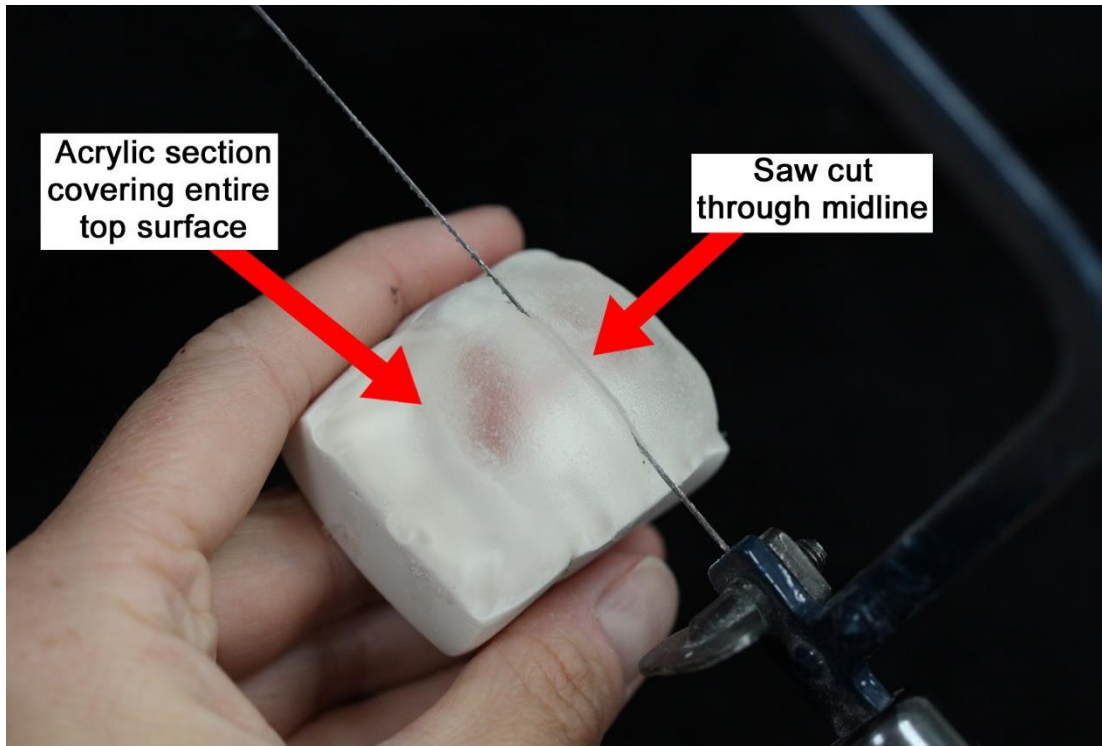


Figure 7. Final (5-part) mold, opened, before removing wax. Showing start of saw cut with final thickness of acrylic resin fractured to separate.

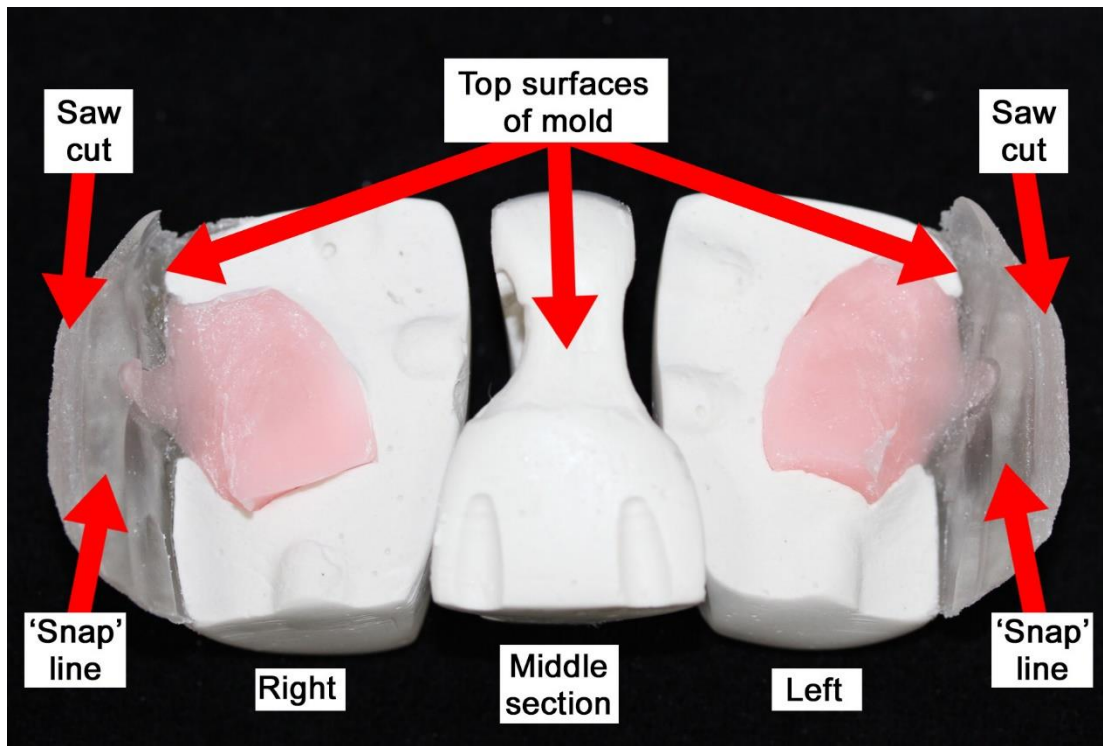


Figure 8. Left - definitive nasal obturator on middle section of mold. Right - definitive nasal obturator with *red circles* indicating location of holes to be created in flat superior surface on both sides of nasal obturator during fitting appointment.



Figure 9. Nasal obturator in situ.

