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Treatment of nasal septal perforations with a custom-made prosthesis

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Abstract We present the fabrication and clinical use of a custom-made nasal septal silicone button that can be inserted transnasally into a perforation of the nasal septum by the physician as an office procedure, or by the patients themselves in their home. Questionnaire and retrospective chart review were used to evaluate the efficacy of this prosthesis as treatment of disturbing symptoms from nasal septal perforation. The study included 41 patients (27 women) with a nasal septal perforation. The follow-up time ranged from 1 to 9 years. Symptoms investigated were nasal obstruction, crusting, feeling of dryness, pain, epistaxis, and whistling from the nose. The degree of experienced symptoms was estimated on a VAS-scale. The questionnaire was answered by 37 of the 41 patients. Fourteen patients were still using their button at the follow-up. Treatment with the prosthesis greatly diminished all the investigated symptoms. Also, use of the silicone button resulted in an improved quality of life. No case of infection was noted in connection with use of the silicone prosthesis.

Keywords Nasal septal perforation · Prosthesis · Silicone · Custom-made

Introduction

Nasal septal perforations (NSP) are a severe problem to many patients and present a distinct challenge to the otolaryngology-head & neck surgeon. The condition can be caused by trauma to the nose, extensive nasal surgery or chronic disease, although in many cases the cause remains idiopathic [1, 2]. In a population-based study from a Swedish community the prevalence of NSP was 0.9% among inhabitants over the age of 20 years [3]. Some persons with NSP have no symptoms at all from their perforation, whereas others have distressing symptoms affecting their quality of life. Nasal septal perforations can carry symptoms such as nasal crusting and recurrent epistaxis, pain and nasal obstruction. Conservative treatment with nasal saline douching and emollients can relieve symptoms and slow down the growing-pace of the perforation. Surgical repair of the perforation is the optimal treatment but it holds a risk of re-perforation. Also, local conditions in the nose or the patient's general state of health may render surgery of NSP difficult. Nonsurgical closure of nasal perforation can be achieved with a preformed or a custom-made prosthesis [1]. In a classic report from the Mayo Clinic in 1979 Facer and Kern describe the use of Silastic buttons inserted transnasally into a perforation of the nasal septum [4–6]. Initially the button they used was hand carved from a block of Silastic, but later they developed the first preformed nasal button with two flanged sides about 1 mm in thickness and a central 3 mm wide axle having a diameter of 5 mm. In the referred study the prosthesis remained in place in 70% of the patients at a follow-up 9 months to 6 years after the insertion. Commercially available prefabricated septal buttons are probably the most commonly used. They are cost-effective but although they can be modified they are limited by imprecise fit. Treatment with a custom-made prosthesis has been proposed since 1951 [7]. Several techniques have been described for making custom-made septal obturators. Kern et al. [4] described placing a piece of paper in one nasal chamber, while outlining the perforation via a cotton

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carrier dipped in thimerosal. Zaki [8] used mould material on a cotton swab or tongue blade to make an impression of the perforation from which a polished, heat-cured acrylic button was made. In 2006, Federspil and Schneider [9] describe the fabrication of a custom-made silicone button with the aid of an intranasal cast. Price et al. [10] suggested in 2003 the use of computed tomography for constructing nasal septal buttons.

In this report, we present a method of making a custom-made nasal septal prosthesis by using a detailed alginate mould of the perforation to fabricate a button in medical silicone. We also report the outcome of this treatment as revealed by a follow-up study.

Patients and methods

Patients

Treatment with a custom-made silicone obturator was initiated in 41 patients (27 women) with nasal septal perforation between February 1993 and February 2002 at the Department of Otorhinolaryngology, University hospital of Umeå, Sweden. Patients ages ranged from 13 to 82 years at the start of the treatment (mean age 46 years). Only patients with symptomatic perforations who had not been satisfactorily treated medically were included in the study. Also, only patients having a complete circumferential ridge of nasal septal tissue around the perforation were given treatment with a custom-made prosthesis. The mean value of the longest diameter of the perforations at the time of fabrication of the prosthesis was 11, 5 mm (range: 4–20 mm).

Technique

In a consulting-room with an ear, nose, and throat specialist and a dental prosthetist present, a cast of the patient's nasal septal perforation was made. The nose was topically anaesthetized, where after the perforation and adjacent parts of the nasal cavities including the nares were filled with alginate-mass after first placing tamponades in the posterior parts of the nose to prevent the mould mass to pass into the pharynx. Alginate was chosen as it is the impression material lest likely to traumatize the sensitive nasal mucosa and because it gives a very detailed template. The mould mass was first administered into one nasal cavity with a piece of moistened gauze in the perforation. After a few minutes the gauze was removed and the opposite nasal cavity was filled with mould mass. This manoeuvre made it possible to gently remove the cast in to halves without tearing them apart. The cast was then in multiple steps transformed into a plaster model of the perforation and the nasal cavity. From a wax model of the obturator a mould for the silicone material was made. A milled, platinum-cured silicone, MED-4032 (Nusil, Carpinteria, CA, USA) was used. The silicone was carefully worked, and also coloured to match the mucosa. The individually manufactured prosthesis (Fig. 1) has a handle for insertion and extraction. When the obturator is in place the handle is placed and hidden under the alar dome into which it fits exactly. Placement of the handle depends on whether the patient is right-or left-handed and on which nostril that provides most space. The silicone used is soft enough to allow the flange of one side of the button to be pushed trough the perforation when put in place. The physician or the patients themselves can fit the button into the perforation. The prosthesis was sent to the patient by post accompanied with a written instruction or it was received at a policlinic visit. All patients were recommended to remove and reinsert the button for daily cleaning. When needed, if lost, a new prosthesis is easily made as all models and moulds are saved.

Fig. 1 This picture shows a custom-made nasal septal prosthesis in medical silicone manufactured to be inserted from the patients' left nasal cavity. The prosthesis fit exactly in the nasal septal perforation and the central part of the button is thinned down to maximize breathing through the nose. When in place the handle will be hidden under the alar dome

Questionnaire

A questionnaire was mailed to all of the 41 patients, one to nine years after treatment with a custom-made button was initiated. The purpose of the questionnaire was to evaluate common symptoms found with NSP. Patients were asked to mark their responses both before, and after, button insertion. Symptoms investigated were nasal obstruction, crusting, feeling of dryness, pain, nose bleed and whistling from the nose. Furthermore, the impact the perforation as well as the treatment had on the patients quality of life was investigated, as was the patients experience of removing and reinserting the obturator. The severity of each symptom was estimated on a VAS-scale from zero to ten [11]. The patients were asked if they suffered from any chronic disease, and if they have had any surgery conducted in the nose or experienced any nasal trauma. Also, the patients were asked if they had experienced any problems during the treatment with the prosthesis, and patients who had ended the treatment, were asked the reason for this. The patients' medical records were also reviewed.

The investigation was approved by the Ethical Committee of the Umeå University Medical Faculty (02-199).

Results

The questionnaire was answered by 37 of the 41 patients. Twelve (32%) of the 37 patients reported a chronic disease. The reported chronic diseases were asthma (three patients), diabetes (two patients), sarcoidosis, Ehler Danlos syndrome, Bechterews disease, fibromyalgia, arthritis, cystic fibrosis, and systemic lupus erythematosus. At least 15 (41%) of the 37 patients were previously operated in the nose. Eight (22%) patients reported trauma to the external nose. The symptoms before initiating treatment of the nasal septal perforation are illustrated in Table 1. The most disturbing symptoms before treatment were nose bleed and a sense of irritation and dryness, which were both reported by 95% of the patients. Crusting was reported by 86%, obstruction by 81% and whistling by 78%. The least common symptom was pain, reported by 65%. Nearly all patients, 35 of 37 reported a negative effect on the quality of life from the nasal septal perforation with a mean value 6.8 on a VAS-scale from zero (no effect on the quality of life) to ten (severe effect on the quality of life).

Table 1 Nasal symptoms before treatment ($n = 37$)

Symptom	Number of patients	Mean negative value on a VAS-scale[a]
Irritation and dryness	35	8
Nose bleeds	35	5.8
Crusting	32	8.6
Obstruction	30	6.7
Whistling	29	6.7
Pain	24	4.3

[a] The VAS-scale is from 0 = not bothered at all by the symptom to 10 = very much bothered by the symptom

Fourteen patients (38%) still used their obturator after a follow-up time of 1–9 years. The effect the treatment had on the above-mentioned symptoms for the patients who were users of the prosthesis at the time of the follow-up is illustrated in Table 2. An improvement regarding the symptom of whistling was reported by 10 out of 11 (91%). The corresponding percentage for the following symptoms are put within brackets; epistaxis (71%), crusting (67%), pain (67%), irritation and dryness (62%), and obstruction (62%). The magnitude of the improvements is illustrated in Table 2. Only three users of the button reported impairment of symptoms. One reported impairment of crusting, one of obstruction and one of irritation and dryness. The improvement of the quality of life was as a mean of 6, 4 on a VAS-scale. Twenty-seven of the 37 patients found the insertion of the obturator into the nose easy and 10 found it difficult. For those who chose not to continue their treatment with the obturator the reasons for this were the following; difficulties to put the obturator into place (nine patients), discomfort when the obturator was in place (seven patients), and the fact that the perforation had grown to large for the obturator (five patients). One patient experienced after about 6 months of using the obturator a permanent healing of the edges of the nasal septal perforation with such an improvement of symptoms that she did not need any further treatment. One patient did not give any reason to why he had interrupted the treatment with the button. Two (5%) of the patients who answered the questionnaire reported complications with the obturator. For both these patients their obturator had been dislodged posteriorly within the nasal cavity and they needed medical help to have it removed. One patient did not answer the question regarding occurrence of complications and the remainder of the patients answered that no complications had occurred. We did not observe any signs of infection associated with use of the silicone prosthesis. Out of the 14 patients who used their obturators at the follow-up seven reported that they removed the button daily for cleaning, and seven that they did it once a week.

Discussion

Our results show that treatment with a custom-made obturator brought relief of disturbing symptoms from the nasal septum perforation in a majority of the patients who used

Table 2 Effect of treatment with custom-made nasal septal prosthesis on nasal symptoms

Symptom	Total number of patients	Improvement number of patients	Improvement mean value on a VAS-scale	Impairment number of patients	Impairment mean value on a VAS-scale	No change number of patients
Whistling						
Reported pre-treatment	11	10	7.8	–	–	1
Not reported pre-treatment	3			–	–	3
Nose bleeds						
Reported pre-treatment	14	10	6.9	–	–	4
Not reported pre-treatment	0	–	–	–	–	–
Crusting						
Reported pre-treatment	12	8	7.8	1	1	3
Not reported pre-treatment	2	–	–	–	–	2
Obstruction						
Reported pre-treatment	13	8	7.9	1	1	4
Not reported pre-treatment	1	–	–	–	–	1
Pain						
Reported pre-treatment	9	6	6.2	–	–	3
Not reported pre-treatment	5	1	2	–	–	4
Irritation and dryness						
Reported pre-treatment	13	8	7.9	1	10	4
Not reported pre-treatment	1	–	–	–	–	1

This table comprehend the 14 users of the prosthesis at the time of follow-up. The VAS-scale is for improvement from zero (no improvement) to ten (relieve of the symptom), and for impairment from zero (no impairment) to ten (significant impairment)

the obturator. A majority of these patients also experienced an improvement in their quality of life. According to Huizing and de Groot [12] septal prosthesis has proven to be an effective treatment in many patients and it is the only option when surgical closure is out of the question or has failed, and the patient does not get sufficient relief from conservative treatment. Patients who suffer from vasculitis and collagenous diseases may be poor candidates for surgery, but they can still be treated with an obturator. The same circumstances apply to persons who have had extensive rhinoplasty or severe nasal trauma, and thereby have damage of the vascular supply to the nose.

The experiences from the use of different obturators are varying [4, 10, 13, 14]. In general, disturbing symptoms of epistaxis and whistling are found to be improved, whereas nasal obstruction is more difficult to cure with an obturator. In a recent study a subjective all-over improvement regarding NSP symptoms by 83% was reported by users of a custom-made silicone button [9]. The use of custom-made obturators has earlier been reported especially in cases of very big perforations [4, 7, 10]. We have not found any study that compares preformed obturators with custom-made ones, but at least for patients with large perforations, perforations located far back or at the basal edge of the nasal septum, and perforations with irregular edges, the custom-made obturator is the only alternative. Since 1993 the obturator described in this study is the only one we have used to obtain prosthetic closure of nasal septal perforations irrespectively of their size.

The method we are presenting to fabricate buttons with the use of a mould gives an exact fit. The alginate cast gives a detailed imprint not only of the outline of the margins of the perforation, but also of the surface of the border. This results in prostheses with a perfect fit even when the border is broad or irregular. The button stays put in place because it is fitted against the perforation border and not because the flanges exert pressure on the remaining surrounding nasal septal wall. This, in combination with the soft medical silicone material with thin flanges, results in an obturator that gives a minimum of abrasion and irritation. We do not think that the use of computed tomography as described by Price et al. [10] will give a better image of the perforation than that accomplished by mould and cast. Most of our patients removed and reinserted the button themselves without problems. However, as a result of the actual study, it was brought to our attention that some patients had interrupted their treatment with the prosthesis due to difficulties to reinsert it. Following the study we changed our routines in that respect that we now initiate the treatment at the outpatient department by giving the button together with

detailed instructions for inserting and removing it to the patient and then allowing them to test the procedure at the hospital. We have not encountered any problems with infections despite the fact that not all patients followed our initial recommendation to clean the obturator daily and presently we recommend a weekly cleaning for those who remove and insert the button themselves. For patients who find it difficult to put the obturator into place, help is offered in the clinic to remove the obturator for cleaning and reinsertion at 3 months intervals.

Conclusions

In the care taking of a patient with symptomatic nasal septal perforation conservative treatment is the first choice. Also, if successful surgical treatment seems to be possible to perform, the patient should be referred to an ENT-surgeon with a vast experience in nasal surgery. The remainder of patients should be offered treatment with a nasal septal prosthesis, which preferably could be custom-made. The septal button described in this study is fabricated in soft medical silicon from a mould of the perforation resulting in a perfect fit. Treatment with this button greatly reduced disturbing symptoms such as bleeding and crusting caused by the nasal septal perforation. Furthermore, this custom-made nasal septal button is easy to handle and can be inserted and removed by the physician as an office procedure, or by the patients themselves in their homes.

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