ORIGINAL CONTRIBUTION

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Silicone button in nasal septal perforation. Long term observations*

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SUMMARY

Objective: *To assess the long term survival rate of silicone buttons in nasal septal perforation and to improve selection criteria. To employ a symptom score that might also be used in comparative studies*

Methods: *Prospective and retrospective study of patients treated with commercially available silicone buttons in a tertiary treatment centre. The observation period of retained buttons was a minimum of four years.*

Results: *The removal rate in 45 patients was 67%, which is higher than in other studies probably due to the long observation period (mean thirteen years). Large perforations and those that are due to septal resection (Killian) are associated with a poor prognosis. Symptom score improvement for all symptoms except snoring was 55%, but for the main nasal symptoms it was 70%. Those who still kept the button were satisfied even though most of them would have preferred operation. Only 11% of all patients consider prosthetic treatment optimal.*

Conclusion: *Silicone button is an acceptable treatment for nasal septal perforation in a third of the patients. It is optimal only in a minority. Unfortunately results of surgery expressed in symptom score are not available for comparison. The present scoring system might be preferred.*

Keywords: nasal septum, perforation, prosthesis

INTRODUCTION

Nasal septal perforation (NSP) is an uncommon condition that often causes significant symptoms that may be difficult to treat [(1)]. Some favour prosthesis and others surgery [(2,3)]. We have used different modalities, but in this study we wanted to investigate the long term results of the commercially available silicone buttons (SB). There are already reports of the effects of both commercially and tailor - made SBs [(2,4-8)]. The minimum observation periods are, however, often short, even as low as one month. The purpose of this study was to examine the clinical data of the patients and the long term results (a minimum of four years) in order to assess the survival rate and to improve the selection of patients for this treatment. In addition we have used symptom scores to quantify the results in order to get a better evaluation of this option. Such scoring may later be used to compare surgery with prosthetic or symptomatic treatment.

MATERIALS AND METHODS

From 1981 to 2003, we have at Rikshospitalet HF treated some of our patients with symptomatic NSPs seven mm or more in diameter with the insertion of a SB. Smaller ones were all operated upon. Patients with NSP with a diameter of between seven and fourteen mm vertically underwent surgery if we thought it was feasible. We have excluded patients with nasal neoplasia, Wegeners granulomatosis and symptomatic septal deviation. The NSP was measured with a malleable pin (Figure 1). Only commercially available buttons with a diameter of three cm have been used. We often had to trim the SB to avoid irritating symptoms, but we tried to get a three to five

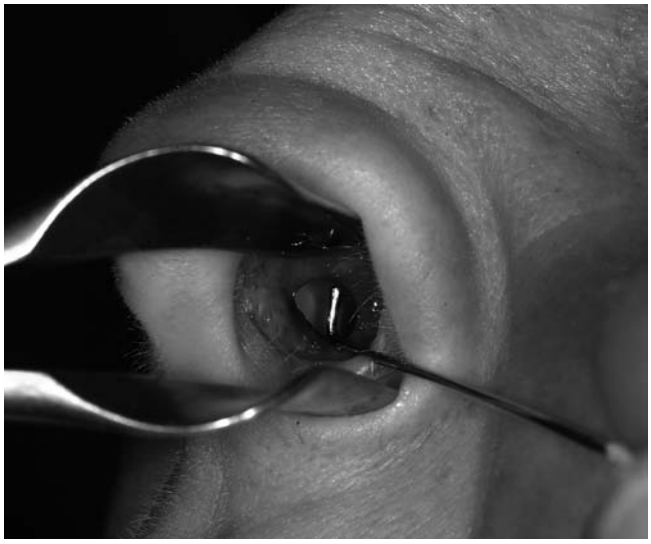

Figure 1. Measurement of NSP with a malleable pin.

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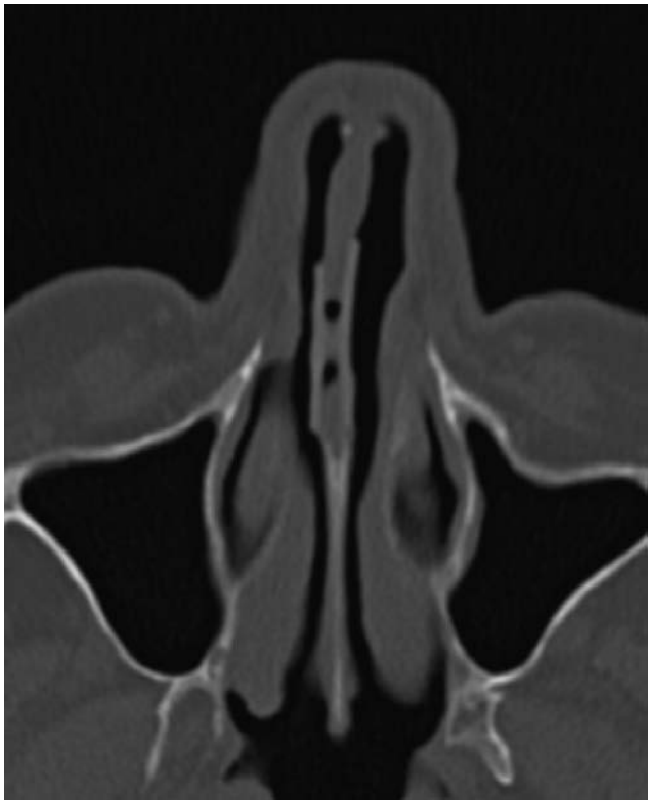

Figure 2. CT scan of SB in a patient with NSP in a slightly deviated septum.

mm extension of the flaps beyond the edge of the NSP. The insertions were made under topical anaesthesia.

Clinical data such as aetiology, symptoms, size and treatment (past and present) of the NSP have been registered consecutively at the time of treatment, at clinical examination six months post treatment and in addition at scheduled and unscheduled consultations for removal, change or inspection of the SB. In 1995 and 2007 questionnaires were sent to those patients in whom we presumed that the SB was still in place. In the latest questionnaire they were asked to rate their symptoms past and present on a four point scale (0= none, 1= mild, 2= moderate, 3=severe). In addition they were asked about their general satisfaction with the SB, use of topical treatment, preference for operation and whether they considered the prosthesis as inconvenient or embarrassing. A part of the material has been published previously [9]. The project was approved by the ethical committee of both hospitals.

RESULTS

Of 193 patients with symptomatic NSP, 47 (17 males, 30 females) were treated with the insertion of a SB. The age and gender distribution is shown in Table 1. Two patients were lost to follow up, one after 18 months and one after three years, both with the SB in place. The SB was removed within four years in 30 (67%), 11 males and 19 females, of the remaining 45 patients. In two thirds of them it was removed within two months. The number of patients who had the SB removed as related to size of the NSP are shown in Table 2. The reasons for these removals are also shown in the same table. Table 3 gives the number of retentions and removals related to initial cause of the perforation. The SB was retained in three patients with slight septal deviation (Figure 2), while in three others it was removed. 15 patients still kept the SB four years after the insertion. Two of them died eight and eleven years post insertion with the SB in place. The remaining 13 patients responded to the questionnaire. Their accumulated symptom scores past and present are shown in Table 4. Two of them were completely free of symptoms. The improvement in composite symptom score was 59% for all patients and all symptoms when snoring was excluded. The improvement was 70% for the main nasal symptoms (stenosis, crusting and bleeding). One patient had replaced the SB twice while the others still kept the original one. Five patients used symptomatic treatment such as ointment and saline spray. All 13 patients were satisfied with the treatment even though eight of them would have preferred surgery. Only five (11%) considered the insertion of a SB as optimal treatment.

Table 1. Age and gender.

Age	20-39	40-59	60-79	Total
Women	9	10	11	30
Men	7	8	2	17
Total	16	18	13	47

Table 2. Reasons for removal of silicone buttons within four years of insertion, related to size of perforation. Some patients are registered with more than one symptom. N= 30.

Vertical size (mm)	7-14	15-19	≥ 20	Total
Crusting	5	4		9
Stenosis	8	4	2	14
Bleeding	3	1		4
Pain	4		1	5
Infection		1		1
Dislodging	2	2	3	7
Secretion	1		1	2
Operation	2			2
No. of patients	15	10	5	30

DISCUSSION

The patients in this study were not randomly selected. Selection criteria are, however, not specified in other studies [2, 4-8]. We have found that the majority of removals of the SB takes place within two months of insertion which is also the finding in other studies. Removals however, may also take place after several years but many patients despite this, do not opt for a replacement. Removal of SBs in NSPs twenty mm or more in diameter is likely to happen with commercially available buttons. The results from the studies of Price et al. [7] and Barraclough et al. [8] imply that in these cases custom-made buttons should be used. Another alternative is to enlarge the NSP surgically as advocated by Eng et al. [10]. The prognosis was poor when septal resection (Killian) was the cause of the NSP. This may be due to insufficient straightening of the sep-

Table 3. Results of treatment with silicone buttons related to cause of septal perforation at 4 years. Two patients are lost to follow up after 18 months and 3 years with button in place.

Cause	Trauma	Septal resection (Killian)	Septo-plasty	Steroid spray/ ointment	Nose picking	Others	Unknown	Total
Removed	7	8	0	4	2	1	8	30
Retained	2	0	3	0	2	2	6	15
Total	9	8	3	4	4	3	14	45

tum. As septoplasty has replaced septal resection in the last 15-20 years, a larger percentage of NSPs is likely to be amenable to prosthetic treatment. In traumatic cases surgery should be the primary alternative.

The percentage of SB removal in this study was 67%. This is higher than in other publications. This may perhaps in part be due to the selection of patients. The removal rate decreased to 56% if we exclude patients with large NSPs and those in whom nasal septal resection (Killian) was the cause. Data from other studies are not specific enough to permit such comparison. There is, however, no reason to believe that such patients have been excluded in other studies. A more likely explanation is therefore that the longer the observation period lasts, the more SBs are removed.

There is a majority of females in this study as in the study of Pallanch et al. [4]. We have no indication suggesting that the results of treatment are age or gender dependant. This has not been discussed in other studies.

There are various ways to evaluate the results of treatment in those in whom the SB is retained. Osma et al. [5] favoured a two point scale (all or none); Brain [2] used a three point scale, while we have implemented a four point scale as earlier used by Luff et al. [6] and Barraclough et al. [8]. Such a four point scoring system is also widely used in the evaluation of the therapeutic effect of drugs in allergy. We have found a 59% improvement in all symptoms except snoring. This is of the same magnitude as those of Barraclough et al. [8]. Data from Osma et al. [5] using a two point scale showed an improvement of 75% in major symptoms. This is very comparable with our 70% improvement for the main nasal symptoms. However they noted 26.3% while we found a 63% improvement in crusting alone. We believe that the discrepancy can be explained by the difference in scoring scale. A more differentiated scoring system will give a more nuanced evaluation. Brain noted that 40% of the users were troubled by crusting. However, it is difficult to compare the results as no pre-treatment scores were given. Unfortunately the score of each individual symptom is not available in other studies [6,8]. In our opinion the use of the parameters SB retention or surgical closure is an inadequate measure of the success of therapy. Indeed, a surgically closed perforation or a retained SB may still cause symptoms.

Most of the patients, although generally satisfied with the SB, would have preferred surgery. However, we lack sufficient data regarding symptom scores, to give reliable advice in choosing between treatment options. Symptom scores for the different modalities would be useful in deciding which treatment to advise in a particular case. Our results indicate that SB has a place in the treatment of NSP.

Table 4. Total symptoms in 13 patients in whom the silicone button was retained for a minimum of 4 years

	Before	After	% improvement	% deterioration
Whistling	11	2	82	
Bleeding	20	2	90	
Crusting	27	10	63	
Stenosis	29	11	62	
Secretion	4	5		25
Pain	6	4	33	
Sneezing	8	8	0	
Foul smell	2	4		100
Infection	9	2	77	
Snoring	6	7		17

CONCLUSION

A third of the patients with NSP retained their SBs for four years or more. Slight septal deviation is not a contraindication to the insertion of SB. An important reason for removal was a large NSP. The removal rate was higher in patients with NSP caused by septal resection (Killian). If these two groups are excluded, the percentage of retained SBs increased to 44%. Symptom scores were obtained from 13 patients who had kept the SB for a minimum of four years. For combined scores of nasal stenosis, crusting and bleeding the improvement was 70%. We believe that commercially available SBs are useful in the treatment of NSP and may be a first line of treatment for some patients. SBs have to be custom made for large perforations. Our patients, however, favour operation. Symptom score data are lacking after surgical closure of NSP. We suggest that symptom scores are necessary in order to adequately compare treatment options. Surgical closure may still leave the patient with symptoms.

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