

Patient comfort following FESS and Nasopore® packing, a double blind, prospective, randomized trial*

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Summary

Background: The use of nasal packing after functional endoscopic sinus surgery (FESS) is often associated with pain and a feeling of pressure for patients. The aim of the present work was to investigate a modern wound dressing made of polyurethane (Nasopore®) that makes removal of the nasal packing unnecessary and is focussed on patient comfort.

Methodology: Following bilateral FESS, after randomisation, one side was packed with Nasopore® while the other side was without packing as a control. The following parameters from 47 patients were determined daily in two centres from post-operative day 1 for the duration of the inpatient stay in a double-blinded setting: side-specific post-operative bleeding, nasal breathing and feeling of pressure as well as the general parameters sleep disturbance, headaches and general well-being. Which side patients considered subjectively the better was also recorded.

Results: No significant differences were determined between the two sides in terms of the rates of post-operative bleeding and nasal breathing. The feeling of pressure was slightly less on the side packed with Nasopore® on post-operative days 2 and 3. No trend could be observed regarding which side patients described as being subjectively better.

Conclusion: There were only slight differences in patient comfort between the Nasopore® side and the control. Because the feeling of pressure in the midface was significantly less and there were no complications, this suggests there is greater patient comfort when using Nasopore® compared to using no nasal packing.

Key words: endoscopic sinus surgery, FESS, nasal packing, patient comfort, polyurethane packing, Nasopore®

Introduction

Chronic rhinosinusitis is a common illness of great socio-economic significance. For cases that fail to respond to conservative therapy, functional endoscopic sinus surgery (FESS) is the standard therapy⁽¹⁾. However, the question of whether to use nasal packing after surgery is the subject of scientific discussion^(2,3).

There are many requirements for an optimal nasal packing. It should control post-operative bleeding, encourage wound healing or at least not impair wound healing, and be comfortable for patients. Practical and economic factors must also be

considered: the packing should be easy to insert and to remove and should have a favourable cost-benefit ratio^(4,5). Nasal packing can also cause considerable problems for patients. The use of conventional nasal packing means that nasal breathing is usually not possible and it can lead to a feeling of pressure, pain and sleep disturbances. With a pre-existing sleep apnoea syndrome, this can lead to dangerous reductions in saturation that require intensive monitoring⁽⁶⁻⁹⁾. Removal of the packing is for many patients the most unpleasant procedure during the entire inpatient stay⁽¹⁰⁾. Modern absorbable or self-dissolving nasal packing that does not require removal provides a solution

for many of these problems.

Nasopore®, a self-dissolving packing made from polyurethane foam (Polyganics, Groningen, the Netherlands), was used in the present work. The material is fragmented by repeatedly spraying with saline solution and is thus gradually flushed out. The aim of the study was to study patient comfort associated with the polyurethane packing in terms of the parameters post-operative bleeding, nasal breathing, feeling of pressure, headaches, general well-being and sleep disturbance compared to not using packing.

Materials and methods

Study design

In a double blind, randomised, multicentric, prospective clinical trial one side was packed with polyurethane foam after bilateral sinus surgery while the opposite side was not packed as a control.

A total of 52 patients were included in the period between October 2010 and July 2011 in the two study centres, the Ulm ENT university medical centre (University of Ulm, Germany) and the Munich-Großhadern ENT university medical centre (Ludwig Maximilian University, Munich, Germany). The mean age was 46 (\pm 11.6) years and 31 male and 16 female patients were included. The inclusion criteria were a surgical indication for chronic rhinosinusitis (CRS) with or without nasal polyps according to the EPOS guidelines⁽¹⁾, symmetrical pathology, aged 18 or more and the written consent of the patient. The exclusion criteria were serious underlying diseases, simultaneous septoplasty or turbinoplasty, the use of other foreign bodies such as septal films, coagulation disorders, cystic fibrosis, immune deficiencies and known intolerance to polyurethane. The discontinuation criterion was post-operative bleeding requiring intervention. Case number planning with a power of 80% (α = 0.05), assuming that the pressure on the packed side is 24% higher than on the unpacked side, yielded a necessary sample size of n = 40. The Lund-Mackay score was determined using pre-operative CT images to assess the severity of the chronic sinusitis. In the run-up to the trial, a positive vote was obtained from the ethics committee (University of Ulm medical centre, no. 141/10). In each case, bilateral surgery with generally symmetrical extent in accordance with the nomenclature of Simmen⁽¹¹⁾ was carried out.

Surgery

The surgeries were carried out under general anaesthetic by various surgeons in both study centres. To minimize bleeding and inflammation, patients received intraoperative an antibiotic, cefuroxime 1.5g and a dose of 250mg prednisolone. For the blinding, the OR nurse informed the surgeon only after the surgery was complete about which side was to receive the Nasopore® insert, which was randomised by computer. The opposite

side remained without packing as a comparison. Nasopore® Standard 8 cm (Polyganics, Groningen, the Netherlands) was inserted after moistening with NaCl. The middle nasal meatus was packed (Figure 1). The patient was not informed which side had received the Nasopore packing.

Follow-up treatment

For post-operative follow-up treatment, NaCl rinses were carried out by the patients themselves or during daily medical nasal care. The data collection was done analogously to comparable studies⁽¹²⁻¹⁶⁾ using standardised questionnaires for each side for the parameters post-operative bleeding, nasal breathing and feeling of pressure. The parameters headache, general well-being and sleep disturbance were collected without reference to side. The patients were also asked on which side they suspected the packing was and which side for them they felt was subjectively better. To evaluate the extent of bleeding, the ordinal scale of 0–4⁽¹³⁾ was used, whereby bleeding events evaluated as 3b and above would result in discontinuation of the study because this would require a further intervention (Table 1).

The remaining parameters were determined using a visual analogue scale (VAS) with possible values ranging from 0 (no symptoms) to 10 (maximum symptoms). An independent doctor who was not participating in the trial collected the data during the inpatient stay.

Statistical methods

The paired t-test was used and the calculation was done using WinSTAT for Microsoft Excel, version 2007.1 (R. Fitch Software, Bad Krozingen, Germany). A $p \leq 0.05$ was considered statistically significant.

Results

A total of 52 patients were included to the study. Because of a decision during surgery to carry out septoplasty, 5 patients were excluded. A total of 47 patients were included in the analysis. None of the remaining participants discontinued the trial.

Table 1. Grading for postoperative bleeding⁽¹³⁾.

Grade	Indication
0	No bleeding
1	Bloody secretion
2	Self-limiting bleeding
3	No-surgical intervention a) cool pack, control of blood pressure, xylometazoline spray b) packing
4	Surgical intervention

Table 2. Results of side-specific parameters.

	Bleeding			Nasal breathing			Pressure		
	Nasopore	control	p	Nasopore	control	p	Nasopore	control	p
Day 1	0.72 (± 0.65)	0.77 (± 0.63)	0.64	3.10 (± 2.58)	2.91 (± 2.20)	0.62	1.40 (± 2.17)	1.59 (± 2.16)	0.26
Day 2	0.48 (± 0.55)	0.48 (± 0.55)	1	3.08 (± 2.41)	3.36 (± 2.54)	0.52	1.57 (± 2.26)	2.13 (± 2.30)	0.02
Day 3	0.38 (± 0.49)	0.33 (± 0.47)	0.67	2.70 (± 2.54)	2.87 (± 2.46)	0.70	1.58 (± 2.03)	2.33 (± 2.27)	0.02

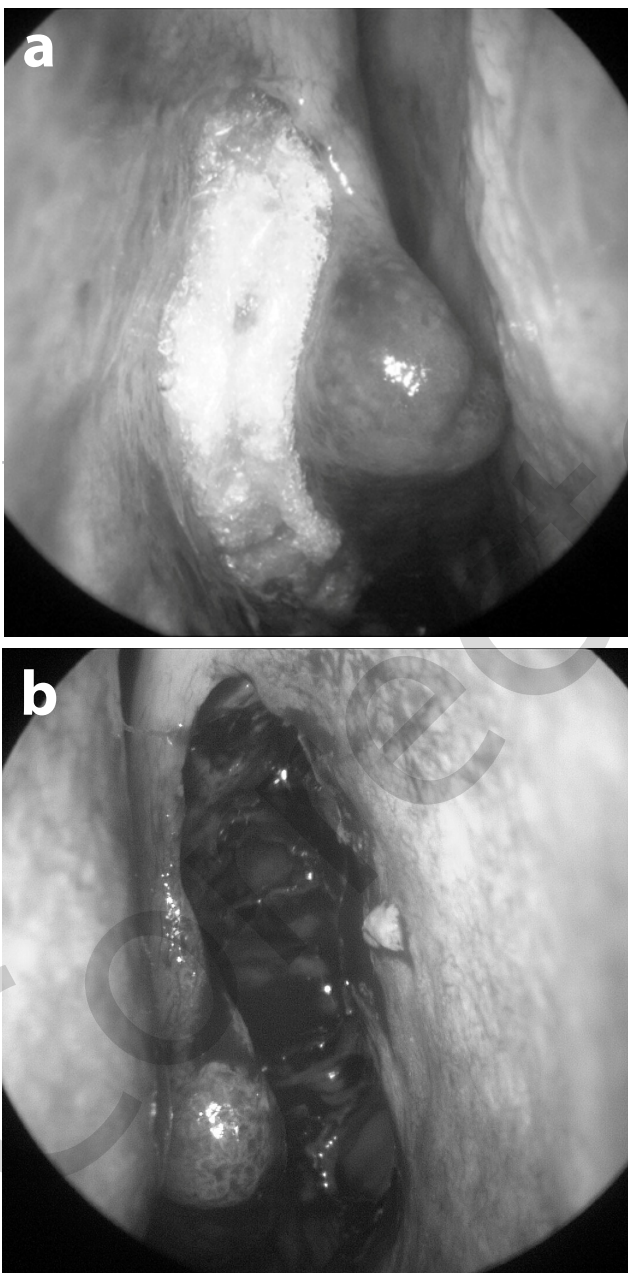


Figure 1. Situation at the end of surgery.
a) with Nasopore packing b) control without packing.

Table 3. Results of general parameters.

	Sleep disorder	Headache	General condition
Day 1	1.70 (± 2.52)	1.68 (± 2.53)	1.96 (± 2.00)
Day 2	1.80 (± 2.48)	1.77 (± 2.49)	2.19 (± 1.95)
Day 3	1.82 (± 2.43)	1.58 (± 2.23)	2.09 (± 2.17)

The indication for surgery was present for 10 patients due to CRS (mean Lund-Mackay score for both sides 9.0 (± 4.1)), for 21 patients due to CRS with polyposis (mean Lund-Mackay score for both sides 14.0 (± 3.7)) and for 16 patients due to CRS with polyps and acetylsalicylic acid intolerance (mean Lund-Mackay score for both sides 18.0 (± 4.0)).

The mean Lund-Mackay score per one side, on the side packed with Nasopore® was 6.8 (± 2.1) and on the opposite side was 7.3 (± 2.8). There was no significant difference between the sides (p > 0.05). For 39 patients (83%), an identical procedure on both OR sides according to the nomenclature of Simmen⁽¹¹⁾ was carried out. For 32 patients (68%), the surgery was a revision procedure. The Nasopore® was inserted on the right side for 22 patients and on the left side for 25 patients. On post-operative day 1, 47 patients were analysed, while due to discharges 46 patients were available on post-operative day 2 and 40 patients were still available for examination on post-operative day 3.

For both the mean severity of post-operative bleeding and nasal breathing, there were no significant differences between the two sides at any of the time points recorded. It must also be stated that the level of post-operative bleeding ranged on average on both sides between no bleeding and bloody discharge and was thus minimal. There was no significant difference for the feeling of pressure on post-operative day 1; however, the feeling of pressure increased on the unpacked side, resulting in a statistically significant difference on post-operative days 2 and 3.

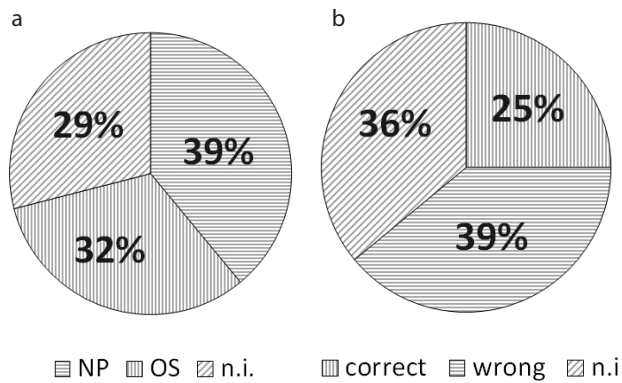


Figure 2. a) subjectively better side for the patients (NP = Nasopore®, OS = opposite side). b) assumed Nasopore side (n.i. = not identifiable).

(Table 2). The mean of the parameters not specific for a side are listed in Table 3.

The results of the subjectively better side for the patients on all three post-operative days and the side patients suspected had the Nasopore® insert are shown in Figure 2.

Discussion

The aim of the study was to assess patient comfort and in this context the severity of post-operative bleeding after FESS under randomised, unilateral use of Nasopore®. The observation period included the days of the inpatient stay. Nasal packing can be very unpleasant for patients and can have a negative impact on the overall subjective impression of sinus surgery^(2,5,10,17). As the golden standard in terms of patient comfort, the opposite side was not packed to prevent possible negative effects as a result of the foreign material. In the study, 47 patients were included, a number that is comparable to studies with similar objectives^(13–16,18–23). Overall, the case number is rated as adequate.

The severity of bleeding was assessed using an ordinal scale that has previously been used to assess post-operative bleeding with carboxymethylcellulose (CMC) nasal packing compared to no packing after FESS⁽¹³⁾. A significant difference between the Nasopore® side and the opposite side could not be detected at the times investigated. The mean severity of bleeding was between 0 and 1 on all 3 post-operative days recorded, which corresponds to 'no bleeding' or 'bloody discharge' and thus can be rated as very low in terms of extent. Overall, post-operative bleeding with correspondingly dry site at the end of surgery is a slight problem, meaning that in agreement with other studies packing can be omitted for reasons of bleeding control^(2,3). On the other hand, it was not reasonably possible to draw a conclusion about the haemostatic properties of Nasopore® on the basis of the available data.

In our patient collective, there was no difference in the nasal breathing between the Nasopore® side and the opposite side using a visual analogue scale (VAS). It must therefore be assumed that the Nasopore® packing of the middle nasal meatus after FESS did not have a negative effect on nasal breathing. This can supposedly reduce or even prevent complications such as sleep disturbances, tube dysfunctions or deterioration of a sleep apnoea syndrome. Studies to confirm this thesis, particularly in regard to sleep apnoea syndrome, should be done using modern packing materials. Post-operative monitoring in intensive care units of sleep apnoea patients may possibly become unnecessary as a result. The values determined in our patient collective in terms of nasal breathing on the Nasopore® side were 3.1 on post-operative day 1. A direct statistical comparison with other studies is not permitted because these were carried out using other protocols or follow-up treatment regimes. For orientation, however, the values for CMC from Leunig et al.⁽¹⁴⁾, who determined a value of 3.6 for nasal obstruction, and from Mo et al.⁽²²⁾, who determined a value of 4.9 for gauze or Merocel®, are cited. In a similar setting, Shoman et al.⁽¹⁶⁾ also determined a value of 4.1 for Nasopore® and 3.9 for Merocel® in the rubber finger stall using a VAS of 0–10 for the first post-operative week.

The post-operative feeling of pressure documented by the patients was higher on the unpacked side than on the Nasopore® side. On post-operative day 1, this observation was not statistically significant; however, the feeling of pressure increased on the unpacked side on post-operative days 2 and 3, resulting in a significant difference ($p < 0.05$). We suspect the symptoms were caused by increased crusting without packing, which in turn caused the increase in the feeling of pressure and the resultant significant difference. In terms of this parameter, patient comfort appears to actually be improved by the polyurethane foam. In our patient collective using a VAS on post-operative day 1, a value of 1.40 was determined on the Nasopore® side and of 1.59 on the opposite side. A similar evaluation of the feeling of pressure separately for each side had been described in previous studies even if using slightly different questionnaires^(12,14–16,24). Particularly for a feeling of pressure, it must be pointed out that a comparison on the basis of different post-operative analgesia standards and possibly different pain perception depending on socio-economic background means a comparison is not possible. In the comparison by Shoman⁽¹⁶⁾, which also investigated the feeling of pressure with Nasopore® after FESS and determined a value of 3.34 in the first week, shows precisely how difficult such comparisons are. To establish the reason for the discrepancy in the values it must be discussed whether the Merocel® or a different grade of firmness of the Nasopore® packing has any effect on the opposite side.

It must be generally stated that the values determined by us for

the feeling of pressure were low. Earlier studies by Buchanan et al. (25) and Karaman et al. (26) showed significantly reduced pain perception for patients after septoplasty who had been given Meroce® packing soaked with Bupivacaine. There is certainly potential here to reduce the feeling of pressure after FESS even further by using Nasopore® packing soaked with Bupivacaine (25,26). More et al. compared Nasopore® packing impregnated with triamcinolone to a steroid regime used post-operatively and showed the same efficacy (27). To what extent steroid-impregnated packing is beneficial compared to no post-operative steroid therapy and how this affects the post-operative feeling of pressure should be considered in further studies. More et al. compared Nasopore® packing impregnated with triamcinolone to a steroid regime used to treat early nasal polyposis after sinus surgery and showed the same efficacy (27). To what extent steroid-impregnated packing is beneficial compared to saline moistened Nasopore® concerning the patient comfort should be considered in further studies.

General parameters such as sleep disturbances or general well-being were also considered in the study. The patients estimated the sleep disturbance as 1.70 on post-operative day 1 and the general well-being was estimated as 1.96 on post-operative day 1. The identical points have already been investigated for carboxymethylcellulose (14) and for rubber finger stalls (12). Again, a direct statistical comparison of the studies is not permitted but for orientation, however, the following is noted: in the study of CMC the sleep disturbance was evaluated with a value of 2.2, the general well-being with a value of 2.3. Higher values (greater discomfort) were determined by Weber et al. (12) who determined a value of 5.0 for sleep disturbance and a value of 4.3 for general well-being. In the present study of Nasopore®, the parameter headaches was added, a parameter that has not yet been recorded separately for each side in other studies. On the scale from 0 to 10, a value of 1.38 was seen. In our study the patients were not able to indicate a clear favourite. The Nasopore® side was somewhat more often named as the better side than the unpacked side. About one-third of the

patients could not choose between either side.

The side with the Nasopore® insert could not be localised by the patients. Of all, 39% of the patients selected the suspected packed side incorrectly and 25% selected the correct side. That the Nasopore® nasal packing was somewhat more frequently incorrectly localised is a result of the reduced feeling of pressure which the patients probably suspected was rather on the unpacked side. About 36% of the patients could not identify either side as being the packed side.

Overall, there was no relevant difference between the side packed with polyurethane foam and the unpacked side after FESS. This results in a good level of comfort associated with Nasopore® after FESS.

Conclusion

In our study, there were few differences between the side packed with Nasopore® and the unpacked side. On post-operative days 2 and 3 there was a significantly reduced feeling of pressure on the Nasopore® side. Patient comfort can be assessed as high overall. Further studies to evaluate wound healing should be carried out. Likewise, in future it must be evaluated how much Nasopore® can impact patient comfort and wound healing as a carrier for medications such as local anaesthetics and steroids.

Authorship contribution

KGK: head of study, author

MR: data collection and analysis

MOS: concept of study

FS: sourcing of participants, investigations Ulm

UK: data collection Munich Großhadern

TB: investigations Munich Großhadern

MH: sourcing of participants Munich Großhadern

AL: head of study Munich Großhadern, concept of study

Conflict of interest

None to declare.

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