ORIGINAL ARTICLE

Clinical outcome and patient satisfaction using biodegradable (NasoPore) and non-biodegradable packing, a double-blind, prospective, randomized study

Pawel Krzysztof Burduk a,*, Małgorzata Wierczowska a, Blazej Grześkowski b, Wojciech Kaźmierczak c, Katarzyna Wawrzyniak d

a Nicolaus Copernicus University, Faculty of Medicine, Otolaryngology and Laryngological Oncology Collegium Medicum, Toruń, Poland
b University Hospital, Department of Otolaryngology and Laryngological Oncology, Bydgoszcz, Poland
c Nicolaus Copernicus University, Faculty of Medicine, Department of Pathophysiology of Hearing and Balance System, Toruń, Poland
d Nicolaus Copernicus University, Faculty of Medicine, Department of Anesthesiology and Intensive Therapy Collegium Medicum, Toruń, Polônia

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KEYWORDS
FESS surgery; Biodegradable packing; Patient satisfaction; Mucosal healing; Follow-up

Abstract
Introduction: Nasal packing after endoscopic sinus surgery is used as a standard procedure. The optimum solution to minimize or eliminate all disadvantages of this procedure may be accomplished using biodegradable packs.
Objective: The aim of this study was to compare patient satisfaction and clinical outcome associated with absorbable and non-absorbable packing after FESS.
Methods: In total, 50 patients were included in a prospective, double-blind, randomized trial. One side was packed with polyurethane foam, while the opposite side was packed with gauze packing. On the 2nd, 10th, and 30th postoperative day, the patients were questioned with the aid of a visual analog scale. The standardized questionnaires for bleeding, nasal breathing, feeling of pressure, and headache were used. The presence of synechiae, infection, or granulation was noted and recorded with the video-endoscopy.
Results: A significant difference according to lower pressure was found in the NasoPore group compared to the controls on day ten after surgery. The NasoPore packing had lower scores with respect to postoperative nose blockage on the 2nd and 10th days. Mucosal healing was better for the NasoPore group, both at day ten and 30 compared with the control group.

* Corresponding author.
E-mail: pburduk@wp.pl (P.K. Burduk).
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Conclusion: The overall patient comfort is higher when using NasoPore compared to non-resorbable traditional impregnated gauze packing. Intensive saline douches applied three to four times per day are mandatory after the operation to prevent synechiae formation and fluid resorption by the packing.

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Introduction

Chronic rhinosinusitis is a very common disease, and the success of treatment is dependent on effective surgery and postoperative care. Endoscopic sinus surgery (ESS) has become the gold standard for the treatment of inflammatory, benign and selected malignant pathology.\(^1\)\(^,\)\(^2\) The main principles are re-establishing ventilation and drainage without scarring, synechiae, and obstruction.\(^3\)\(^-\)\(^5\) To achieve these results, the middle meatus is often packed. This procedure should stabilize the middle turbinate, prevent synechiae formation, and act as a hemostatic agent.\(^3\)\(^-\)\(^7\) However, nasal packing can be a source of pain, nasal obstruction, bleeding, and discomfort during pack removal.\(^5\)\(^,\)\(^6\) These disadvantages are mostly compared with non-absorbable nasal packing.\(^3\)\(^,\)\(^5\)\(^-\)\(^9\)

Recently, different absorbable biomaterials have become available for use as middle meatus packing after functional endoscopic sinus surgery (FESS).\(^3\)\(^-\)\(^8\)\(^,\)\(^10\) These kind of packs do not need to be removed and therefore improve patient comfort after surgery.\(^3\)\(^-\)\(^4\)\(^,\)\(^7\)\(^-\)\(^8\)\(^,\)\(^10\) The material prevents synechiae formation and stabilizes the middle turbinate. It starts to dissolve within a few days and can be washed out or suctioned from the nose.\(^5\)\(^,\)\(^8\)\(^,\)\(^10\)

NasoPore (Polyganics – Groningen, The Netherlands) is a biodegradable synthetic polyurethane foam, which was used in the current work. The polyurethane bonds provide strong initial compressive mechanical properties, whereas the hydrophilic component takes-up the water or blood and is gradually fragmented. The aim of this study was to compare patient satisfaction and clinical outcome associated with the absorbable and non-absorbable packing after FESS.

Methods

Study design

A prospective, double-blind, randomized trial; one side was packed with polyurethane foam after bilateral sinus
surgery while the opposite side was filled with packing composed of traditional impregnated gauze strip. This study was approved by the Bioethics Committee of the Nicolaus Copernicus University (KB 326/2013) and written informed consent was obtained from all participants.

A total of 50 patients were included from the Dep. of Otolaryngology and Laryngological Oncology. The mean age was 47.5 years (±9.8); 22 female and 28 male patients were included. The inclusion criteria were chronic rhinosinusitis (CRS) with or without nasal polyps according to the EPOS guidelines and symmetrical pathology between the nasal cavities based on computed tomography (CT) scan. The study included 38 patients with CRS with nasal polyps and 12 without nasal polyps. The exclusion criteria were septoplasty, turbinate surgery, or known intolerance to polyurethane. In each case, bilateral surgery was performed to the same extent. The research was approved by the local ethics committee and informed consent was obtained before the study. The patients were computer-randomized to packing the right or left side with NasoPore and the other side with gauze strip. In all cases, the packing was placed in the middle meatus at the end of the surgery.

**Surgery**

The surgery was performed under general anesthesia by one surgeon. To minimize bleeding and optimize the surgical field, the procedure used premedication with clonidine and total intravenous anesthesia (TIVA), as described previously. Preoperatively, all of the patients received intravenous antibiotics (cefuroxime 1.5 g). At the end of the surgery, the surgeon was informed by the nurse of which side to use the NasoPore, which was randomly assigned. The opposite side was packed with non-resorbable gauze strip pack. Standard 4 cm NasoPore and 4 cm long gauze strip with an ointment (Fig. 1) were used. The procedure utilized 2 g Oxycort ointment (1 g contains 310 mg of hydrocortisone and 30 mg of oxytetracycline, as well as the base – Jelfa, Poland). The patients and the observer were not informed of which side had received the NasoPore or gauze packing.

**Figure 1** NasoPore (A) and gauze strip (B) packing.
Follow-up

On the 2nd, 10th, and 30th postoperative day, a physician other than the operating surgeon questioned the patients with the aid of a visual analog scale (VAS) and performed nasal endoscopy. The non-absorbable packing was removed on the 10th day after surgery. The data collection was analogous to comparable studies, using standardized questionnaires for each side for the following parameters: bleeding, nasal breathing, feeling of pressure, and headache. The parameters were determined using a VAS with possible values ranging from 0 (no symptoms) to 10 (maximum symptoms). The presence of synechiae, infection, granulation, or re-epithelialization was noted and recorded with the video-endoscopy on both sides on the 10th and 30th day after surgery. After discharge, all patients used an antibiotic (clarithromycin, 1000 mg daily for 10 days, nasal steroids (fluticasone furoate) once daily, and nasal saline douches up to three to four times daily).

Statistical analysis

Statistical analysis was performed with Statistica software, v. 10 (StatSoft Inc.) The parameters were compared using the Wilcoxon signed rank test, McNemara test, and Shapiro–Wilk’s test. The level of significance was defined as $p < 0.05$. The study population was calculated for error inherent in a test result. The power analysis of the investigation group was 80%.

Results

Fifty patients were randomized and 100 sinus cavities were treated. The absorbable packing was put in 27 right sides and 23 left sides of the nasal cavities. The non-absorbable packing was put accordingly in 23 right and 27 left sides of the nasal cavities. Forty-nine patients completed the study. This was due to one patient refusing to attend follow-up, as he felt well. The VAS results for pressure, nose blockage, headache, and nasal pain are shown in Table 1. A significant difference according to pressure was found between the NasoPore and control sides on day 10 after surgery ($p < 0.04$). The patients reported lower filling of nose pressure on the NasoPore side. No differences were observed on the 2nd and 30th days post-surgery. The NasoPore packing had lower scores with respect to postoperative nose blockage (4.26 vs. 4.73, $p < 0.04$) on the 2nd and 10th days (1.81 vs. 2.29, $p < 0.02$; Table 1). The results were significant. However, there was no significance on the 30th day (0.45 vs. 0.68, ns). Nevertheless, slightly lower scores for headache and nasal pain were recorded for the NasoPore group during the follow-up visits, but the results were not significant (Table 1).

Assessment of bleeding on packing removal demonstrated no differences. Minimal bleeding without any future intervention was observed for one case in each group.

Forty-nine subjects returned for the assessment of mucosal healing on the 10th and 30th days after operation. Endoscopic observations of wound healing after surgery revealed blood crusting, edematous swelling, and epithelialization. Mucosal healing (re-epithelialization) was better for

Figure 2  NasoPore at the end of surgery (A) and resorption process at 2nd, 10th, and 30th day (B–D), as well as some remnants of dressing after ten days post operation (E) and synechia formation (F).
the NasoPore group, both on day ten and 30, compared with the control group (p < 0.001, p < 0.06). At 10th day the re-
epithelization in study group was 68.1% and reached over
95.7% at 30th day. The endoscopic view at 10th day was
very satisfactory compared to control group, where only
32.7% of the operated field showed epithelization. In both
groups at the 30th day, the re-epithelization level was over
90%, pointing to complete healing. Nevertheless, the re-
epithelialization in the control group achieved a satisfactory
level on the 30th day (90.2%). In this study, synechiae for-

tation was observed in three of the NasoPore group and two of
the control group (Fig. 2). No significance was observed
(Table 2). In one case of non-resorbable packing, on the 30th
day of follow-up, infection with mucopurulent discharge was
found.

Resorption of the absorbable packing was fluent in most
cases (Fig. 2). In three cases, some remnants of the dressing
on the 10th day were noted, which could result in synche-
i formation in the late follow-up (Fig. 2). In these cases, the
patients did not adhere to the recommendation of regular
(three to four times per day) nasal douches.

**Discussion**

The most important considerations after FESS operations
are patient comfort, minimizing bleeding, reduction of dis-
comfort associated with nasal packing, and proper mucosal
healing. As the non-resorbable (removable) nasal packing

<table>
<thead>
<tr>
<th>Table 2</th>
<th>Results of synechiae, infection, and re-epithelization between groups.</th>
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<tbody>
<tr>
<td></td>
<td>Synechiae</td>
</tr>
<tr>
<td></td>
<td>N</td>
</tr>
<tr>
<td>Day 2</td>
<td></td>
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<tr>
<td>n = 50</td>
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<tr>
<td>Day 10</td>
<td>0</td>
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<td>n = 49</td>
<td></td>
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<tr>
<td>Day 30</td>
<td>3</td>
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<td>n = 49</td>
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</tbody>
</table>

N, Nasopore; C, Control; ns, not significant; n, number of patients.

on anesthetic (oxytetracycline and hydrocortisone). The ointment was used
to prevent the adherence of the packing to the mucosa.

The post-operative feeling of pressure was higher in the
control group than on the NasoPore side. On post-operative
days two and 30, this observation was not statistically signif-

icant. On day ten, the feeling of pressure was greater on the
control side, resulting in a significant difference (p < 0.04).

In the authors’ opinion, this was caused by resorption of the
NasoPore, and by stable gauze strip packing and the for-
mation of blood clots around the gauze material. Patient
comfort appears to be improved by the resorbable pack-
ing. The same observations have been reported by other
authors.4,5,10

Parameters including nose blockage, headache, and nasal
pain were generally lower for the NasoPore group than the
control group. On day ten, a statistically significant reduc-
tion of nose blockage (p < 0.02) in the NasoPore group was
observed. This was caused by resorption of the packing
with lea debridement in the middle meatus compared to
high secretion and edema mediated by the gauze pack-
ing on the other side. However, although there were no
statistically significant differences for the observed param-
eters during the follow-up, patient comfort appeared to be
much better in the NasoPore group. The same observations
were made by other authors comparing the usage of differ-
ent absorbable and non-resorbable packing materials.3,5,6,10

The study has demonstrated that NasoPore does not signif-
ically reduce the risk of post-operative bleeding. The
same results were observed for other resorbable and non-
resorbable nasal packing materials.5-7,9,10

The present study did not find any statistically significant
differences between the packing materials used with regard
to synechiae formation or infection.5,10 Otherwise, if the
patient did not respect the necessity of intense nasal rinsing
in early post-operative period, the formation of synechiae
would be highly likely. The partially dissolvable pack and
all debridement should be suctioned out or washed out if
remaining in place for longer than ten days. The remnants
of the NasoPore could form a bridge between the middle
turbinate and the lateral nasal wall as a point of synechiae
formation.8 On the other hand, some absorbable materia-
lars or its remnants could be incorporated into regenerating
mucosa or activate osteogenesis, leading to synechiae for-
mation. This process is responsible for slower mucosal
healing, as described by Shoman.5 The present study found a
significantly better re-epithelialization process in the Naso-
Pore group on day ten (p < 0.001) and nearly complete
epithelialization 30 days after surgery (95.7%). It is thought that removing the non-absorbable packing could cause local mucosal bleeding and a prolonged phase of blood crusting, which delays epithelialization. Nevertheless, the difference almost disappeared by the late follow-up visit (p < 0.06). The same results were observed by Shoman.3
Overall, the NasoPore packing results in better patient comfort and a better healing process after FESS surgery.

Conclusion
Using a resorbable NasoPore packing after FESS, the feeling of pressure and nose blockage in the early post-operative period were significantly reduced. The overall patient comfort was higher compared to non-resorbable traditional gauze strip packing. The wound healing was better when using NasoPore, but future investigations are required. Intensive saline douches, three to four times per day, are mandatory after the operation to prevent synchiea formation and fluid resorption by the packing.

Conflicts of interest
The authors declare no conflicts of interest.

Acknowledgments
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References