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## ORIGINAL ARTICLE

# Effect of Absorbable Middle Metal Spacers in Prevention of Synechiae Following Endoscopic Surgery at Zagazig Faculty of Medicine Hospitals

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## ABSTRACT

**Background:** Medically refractory chronic rhinosinusitis treated with Endoscopic sinus surgery is a well-established for treatment of chronic rhinosinusitis with a symptomatic success rate ranging from 75% to 98%. Middle meatal dressings are commonly used to reduce postoperative complications. This study aims to study the effect of absorbable middle meatal spacers in preventing synechia following endoscopic sinus surgery.

**Methods:** A randomized controlled trial was carried out on 26 cases undergoing endoscopic sinus surgery for the management of bilateral chronic rhinosinusitis in the Otorhinolaryngology Department, Zagazig University Hospitals. With insertion middle absorbable spacers (Nasopore) in one side and insertion of non-absorbable ordinary pack in other side.

**Results:** Our results as regard to middle meatal dressing shows statistically significant difference between the absorbable spacers (nasopore) and non-absorbable ordinary pack as regards reduction of synechia and adhesion formation after endoscopic sinus surgery. Therefore, middle meatal packing with polyurethane foam (nasopore) is effective in reducing adhesion and synechiae after endoscopic sinus surgery. Endoscopic assessment of the patients 2 months after E.S.S revealed that adhesions mainly occurred on the non-absorbable ordinary pack, while middle absorbable spacers (Nasopore) side showed minimal adhesions mean P-value < 0.05 is significant.

**Conclusions:** A statistically significant difference had been reported between packing with Nasopore and ordinary pack at the middle meatus. So, packing with Nasopore is effective in reducing adhesions after endoscopic sinus surgery

**Keywords:** Endoscopic sinus surgery, Nasopore, Spacers, Synechiae.

## INTRODUCTION

Endoscopic sinus surgery (ESS) has become the standard surgical treatment for chronic rhinosinusitis and nasal polyps. The common complications of ESS include postoperative formation of synechiae in the middle meatus and nasal bleeding. The former is considered the most common complication of ESS, and the incidence of this complication ranges from 1% to 36%. [1] In the middle meatus, synechiae can

obstruct the usual sinus drainage pathway and contribute to recurrence of disease. Numerous strategies have been used to prevent postoperative synechia development, including (suture medialization, partial resection of middle turbinate, and middle meatal nasal packing). Nasal packing is the most effective way of preventing synechia. Conventional packaging items are non-absorbable materials, such as Vaseline gauze strip or expandable polyvinyl

acetate. New biodegradable packaging materials with different degrees of effectiveness have also been developed, such as Flo-Seal, MeroGel, Meropack, Nasopo and carboxymethylcellulose, but the effects of these packaging agents on mucosal healing and postoperative bleeding have not been observed. [2]

The most common complication after endoscopic sinus surgery (ESS) for chronic rhinosinusitis is middle meatal (MM) synechia. Several MM spacers were used to prevent the formation of synechia, with varying success in the literature published. A continuing controversy remains as to whether MM spacers reduce the risk of synechia after ESS. [3]

Many patients are packed with ESS products (Flo-Seal, MeroGel, Meropack, Nasopo and carboxymethylcellulose). Nevertheless, the packaging materials and the methods of their use vary among organizations, and there is still a lack of satisfaction with both the hemostatic and wound-healing effects and the nasal pain inflicted on the patient when the packaging is applied and removed. In Europe and the United States, it has been noted that post-ESS packing has a significant effect on the QOL (quality of life) and wound healing of the patient and it can be expected that work will be carried out in many countries on the packing materials applied into the nasal cavity following surgical procedures. [4]

Nasal dressings have been recommended widely to enhance wound healing and avoid more bleeding after ESS. Initial experience centered on reusable nasal packing materials; however, their profile of adverse effects such as pain/discomfort and mucosal injury has led to the development of absorbable biomaterials. Given these advances, there is still little agreement on the best option of nasal dressing or whether nasal dressings are needed at all. [5] Since 1969, absorbable nasal dressings have been used and since then several products have been advertised for their positive effects on hemostasis and wound healing. These products can be broadly categorized into materials derived from synthetics, plants, blood products or animals. The key reason for the regular use of absorbable

nasal packing materials is the regulation of wound healing processes, with the most common problem being adhesion formation. [6] This study aims to study the effect of absorbable middle meatal spacers in preventing synechia following endoscopic sinus surgery.

## METHODS

In 26 patients undergoing endoscopic sinus surgery for the treatment of bilateral chronic rhinosinusitis in the Department of Otorhinolaryngology, Zagazig University Hospitals, a randomized controlled trial was performed. With insertion middle absorbable spacers (Nasopore) in one side and insertion of non-absorbable onrdirny pack in other side and follow up by endoscope two weeks, one month, two months post operative.

### *Inclusion criteria*

Patients suffering from bilateral chronic rhinosinusitis of any age and sex.

### *Exclusion criteria*

Unilateral sinusitis. Previous nasal surgery.

### *Preoperative questionnaire*

The patient condition was subjectively assessed, and patients were asked to rate their symptoms on a 0-10 visual analog scale (VAS) where "0" indicates no symptoms present, "10" means the most serious symptom. The symptoms assessed included nasal obstruction, anterior nasal discharge and postnasal gout, facial pain, migraine, and reduction of the smell.

### *Objective analysis*

General assessment including vital signs, body built, mental function, chest, and heart examination.

### *Full ENT examination*

Including anterior rhinoscopy and endoscopic examination. Anterior rhinoscopic examination showing: Signs of chronic rhinosinusitis as mucous, swollen turbinate, congested mucosa and tenacious mucous in middle meatus (MM). Signs of allergic rhinitis as enlarged pale bluish turbinate and nasal polypi.

### *Diagnostic nasal endoscopy*

The Lund-Mackay endoscopic presence score was evaluated by giving the endoscopic findings score 0, 1, 2 or 3 as the following: Polyps: 0:

absence of polyps; 1: polyps in MM only; 2: polyps outside MM but not completely blocking the nose; 3: polyps that obstruct the nose entirely. Oedema 0: not present; 1: low; 2: serious. Discharge 0: no discharge; 1: thin, transparent discharge; 2: heavy purulent discharge. [7]

#### **Ethical Clearance**

Written Informed consent was taken from the patient to participate in the study. Approval for performing the study was obtained from Otorhinolaryngology Departments, Zagazig University Hospitals after taking Institutional Review Board (IRB) approval. The work has been carried out in accordance with the code of ethics of the world medical association (Declaration of Helsinki) for studies involving humans.

#### **Statistical analysis**

Data were collected, coded, revised, and entered to the Statistical Package for Social Science (IBM SPSS) version 20. The data were presented as number and percentages for the qualitative data, mean, standard deviations and ranges for the quantitative data with parametric distribution and median with inter quartile range (IQR) for the quantitative data with non-parametric distribution. Paired t-test was used in the comparison between two groups with quantitative data for before and after and parametric distribution and Wilxon Rank test was used in the comparison between two groups with quantitative data for before and after and non-parametric distribution

### **RESULTS**

This study showed conducted on 26 patients, 7 females (26.9%) and 19 male (73.1%) males) were with bilateral chronic rhinosinusitis ,with or without bilateral sinonasal polyposis ranging in age from 17 to 68 years with mean 37.9y, median 39.5 and standard deviation 15,86 ,undergo functional endoscopic sinus surgery had been done for all patients, 5 patients were missed during study and follow up.

#### **Clinical Presenting symptoms**

This study showed the presenting clinical symptoms in patient of our study are bilateral

nasal obstruction, nasal discharge, posterior nasal drip and facial pain. (Figure 1)

#### **Preoperative endoscopic findings:**

The preoperative endoscopic appearance score by Lund-Mackay staging system was used to evaluate both nasal sides and the mean score for each endoscopic finding was used as the following: Polypi mean score was  $2.30 \pm 0.73$  on nasopore side and  $2.30 \pm 0.73$  on ordinary pack side, oedema mean score was  $1.75 \pm 0.44$  on nasopore side and  $1.75 \pm 0.44$  on ordinary pack side, discharge mean score was  $1.65 \pm 0.49$  on nasopore and  $1.7 \pm 0.47$  on ordinary pack side.

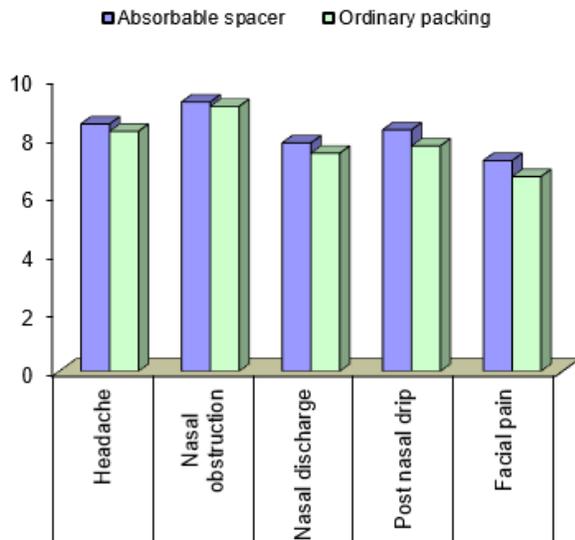
After follow up we found that there was statistically significant increase in pre operative in comparison to 2 weeks, 1 month and 2 months with polyp, oedema and discharge but there was statistically significant increase in 1 months with synechia and crusting in absorbable spacer group and gradual decrease in synechia with mean  $1.20 \pm 0.41$  after two weeks,  $0.90 \pm 0.41$  after one month,  $0.35 \pm 0.22$  after two month else there was gradual decrease in crusting and bleeding with mean  $1.35 \pm 0.44$  after two weeks,  $1.30 \pm 0.44$  after one moth,  $0.15 \pm 0.22$  after two month.

After follow up we found that there was statistically significant increase in pre operative in comparison to 2 weeks, 1 month and 2 months with polyp, oedema and discharge but there was statistically significant increase in 1 month with adhesion and increase in 2 weeks with crusting in ordinary packing group and marked increase in synechia with mean  $1.65 \pm 0.52$  after two weeks,  $1.22 \pm 0.67$  after one month,  $0.45 \pm 0.36$  after two months else there was gradual increase in crusting and bleeding with mean  $1.65 \pm 0.44$  after two weeks,  $1.55 \pm 0.58$  after one moth,  $0.20 \pm 0.11$  after two months.

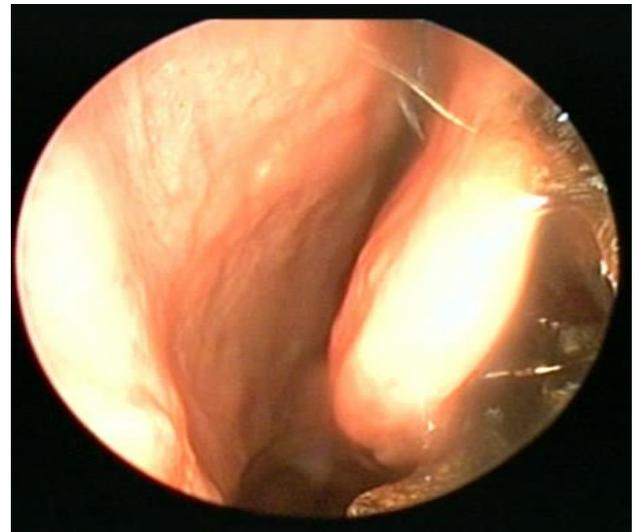
This study showed statistically significant decrease in absorbable spacer in comparison to ordinary packing with 2weeks postoperative endoscopic evaluation. There was statistically significant decrease in 2 weeks post operative in comparison to preoperative with endoscopic evaluation in absorbable spacer group. (Figure 2). This study showed statistically significant decrease in absorbable spacer in comparison to

ordinary packing with 1-month postoperative endoscopic evaluation. (Figure 3)  
This study showed statistically significant decrease in absorbable spacer in comparison to

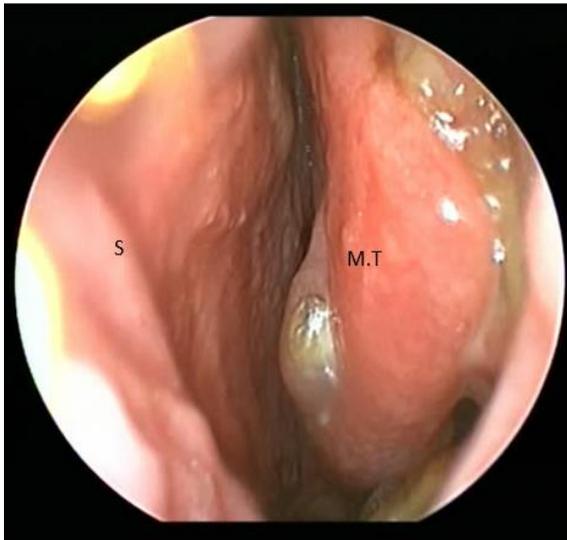
ordinary packing with 2month postoperative endoscopic evaluation (Figure 4).



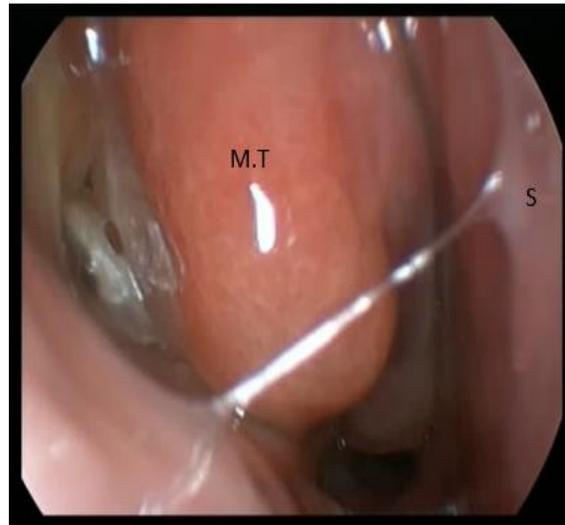
**Fig. (1):** Clinical presenting symptoms in our study.



**Fig. (2):** Left absorbable nasal side spacer (nasopore) two weeks postoperative with minimal crustion and synechiae (S=septum, MT=middle turbinate)



**Fig. (3):** Left absorbable spacer (nasopore) showing less synechiae one month postoperative by endoscope (S = septum, M. T= middle turbinate)



**Fig. (4):** Right middle meatus packed with absorbable nasal side spacer (nasopore) two months postoperative by endoscope with no synechiae (M.T=middle turbinate, S=septum)

### DISCUSSION

The theory of functional endoscopic sinus operation (FESS) is based on the principle of reversible mucosal disease and the principle of preserving ciliated respiratory epithelium flow pathways that constitute the optimal physiological state of healthy sinuses. [8] Surgery may fail for many different reasons, but chronic inflammation and polyposis, adhesion/synechiae formation, middle turbinate lateralization, and stenosis of the surgically expanded sinus ostia are common causes of suboptimal outcomes. [9]

The development of synechia and ostial restenosis follows ESS with a recorded incidence of 1–36%. This is expected to result from the closeness of two or more raw mucosal surfaces during wound healing. [10] In the operating room, avoidance of adhesion and synechia development starts (meaning we always take care to prevent of synechia during operation). Help me to prevent stenosis and synechiae by removing bone splinters and preventing mucosal scraping. The use of

traditional microdebridors also protects the mucosa and minimizes bone fragments and residual tissues. [11] In ESS, MM dressings were used to reduce the incidence of postoperative complications and improve surgical outcomes, namely by helping with local hemostasis, minimizing the development of synechia, and preventing middle turbinate lateralization. [12] Over time, the composition of dressings has evolved from non-resorbable fabrics such as vaselized gauze, Telfa pads, cotton latex finger cots, silastic sheets and Merocel sponges to biodegradable products such as Gelfilm, Merogel, hyaluronic acid gels, Floseal and cellulose gels. The transition from non-resorbable materials to resorbable materials was welcomed due to improved patient comfort and easy post-operative recovery. The polyurethane sponge (nasopore) is a new biologically inert, fully synthetic, biodegradable material for use in the sinonasal cavity. [13]

In this study, this drug appears healthy and biocompatible with no local granulations or synechia seen in the first 2 months of surgery

and no adverse systemic or regional effects such as allergies, discomfort, or excessive postoperative bleeding. This can partly be explained by the fact that it is fully artificial and lacks animal or plant proteins typically found in other dissolvable dressings. At least theoretically, these animal and plant products can serve as foreign antigens to the human immune system and therefore create more local tissue reactivity. Therefore, the polyurethane sponge easily dissolves into CO<sub>2</sub>, reducing the likelihood of a foreign body reaction or sinus obstruction and after 36-48 hours eliminating the need for postoperative removal. It has previously been proposed that the optimum retention time for MM dressing is 5 to 8 days. [14] Overall, the occurrence of synechia formation after ESS varies greatly from trial to trial, and the best product for nasal packing is still a matter of debate. Since none of the previous studies compared the effects of ordinary pack and Nasopore on synechia prevention after ESS, we analyzed our data and found a significant difference in their ability to reduce synechia formation among these materials. Granulation tissue formation is an important stage in the post-ESS cycle of mucosal healing, and evaluation of this process may indicate the healing status. Some authors compared the wound healing efficiencies of gelatin-based dressings (absorbable) and no packaging in patients with ESS, like NasoPore, (absorbable) which disappears by itself. An important difference is that gelatin-based dressings are of animal origin while NasoPore is artificial and thus biologically safe at 100 percent. In contrast, a gelatin-based dressing loses its compression strength when it gets wet, while Nasopore maintains its compression strength when wet while Nasopore is healthy and biocompatible materials such as gelatin film (Gelfilm) have been shown alone. [15] Another key consideration is the risk of infection with respect to MM nasal packaging (all types of pack absorbable or non-absorbable) or dressings. These dressings, especially when used as packaging material, may predispose a patient to sinusitis by acting as a medium for

pathogen colonization and multiplication and/or by obstructing sinus ostia. Different strategies have been adopted to alleviate this problem, including removing packs after few days, performing MM debridement, putting only the minimal amount of material needed to meet medical needs, and placing patients on prophylactic postoperative antibiotics. No case of sinusitis was reported in our study with the use of this new MM dressing (polyurethane foam) and our regular postoperative regimen consisting of 2 weeks of oral antibiotics and 4 weeks of nasal saline irrigation.

From the study results, polyurethane foam (nasopore) is highly biocompatible, well tolerated by patients, healthy and not associated with high incidence of postoperative problems such as bleeding or MM synechia [14]. We then embarked on a prospective randomized controlled trial to further study this new material to determine efficacy. The importance of MM dressings is an important issue as the prevalence of these postoperative complications leads to increased patient pain and health care costs, predisposes patients to chronic sinusitis and can adversely affect surgical outcome. The surgical outcomes in ESS remain conditional without excessive synechia formation on effective wound healing. [16] To assess the effect of nasal packing on wound healing, several parameters were used. In our research, we rely on clinical parameters including subjective evaluation by VAS and objective evaluation by C.T and endoscopic evaluation using Lund-MacKay grading system, other studies used the same parameters as selected [17] for the development of synechia, mucosal edema and infection as parameters for examination.

*Bugten, et al.* [18] In their analysis, endoscopic video recordings collected 1-8 weeks after surgery revealed seven (7/62) adhesions in the non-absorbable packaging group and 29 (29/54) adhesions in the control (non-packaging) group ( $p < 0.001$ ) and that agree with us on the value of mid-meat (MM) packaging.

In our study we compare one side packed with nasopore and other side with ordinary pack with 26 patients (17 male and 9 female) were with

bilateral chronic rhinosinusitis with or without nasal polyp ranging in age from 17 to 68 years. With follow up for two months by endoscope there is marked decrease in synechia in nasopore side after two months in polyposis group there was no polyp or recurrences, with decrease in synechia with more than 95% (mean decrease from  $1.20 \pm 0.41$  to  $0.35 \pm 0.22$  two month post operative) ( $P= 0.022$ ). decrease in polyp 80% (mean from  $2.30 \pm 0.73$  to  $0.45 \pm 0.12$  two months post operative) else bleeding and crustion decrease in 75% with decrease (mean  $1.35 \pm 0.44$  to  $0.15 \pm 0.22$  two months post operative) ( $P=0.002$ ) but in other ordinary nasal side we noticed recurrence of polps with obliteration of osteomeatal complex. With increase in synechia with 60% with increase in mean (from  $1.65 \pm 0.52$  to  $1.65 \pm 0.52$  after two months), else polyp mean ( $2.30 \pm 0.73$  to  $0.60 \pm 0.30$  after two months).

Miller, et al. [19] performed a blinded randomized controlled trial to compare the results of Merogel packing and Merocel packing in 40 patients who had undergone ESS. They found that the rate of development of synechia in both groups was approximately 8% at 8 weeks after the procedure, and the disparity between groups was not significant. In this study nasopore nasal side approximately 2% and statistically significant. In ordinary side group synechia approximately 14% and statistically significant.

Berlucchi et al. [20] said conducted a prospective randomized controlled study comparing the efficacy of Merogel at 2, 4 and 12 weeks after ESS in 66 patients with standard non-absorbable nasal packaging. At 4 and 12 weeks after the procedure, they observed lower rates of nasal synechia development in the Merogel group. In our study in contrast to Berlucchi et al. [20] found that non absorbable nasal packing has no role in decrease synechia and statistically insignificant ( $p < 0.001$ ).

### CONCLUSION

Many trials were done to reduce adhesion formation and many different materials had been used for synechia prevention, one of these materials is middle meatal spacers, one of them

is polyurethane foam (nasopore). Packing with polyurethane foam is effective in reducing adhesions after endoscopic sinus surgery. a statistically significant difference had been reported between packing with polyurethane foam and Ordinary pack at the middle meatus.

### Conflict of Interest

The authors of this manuscript declare no relevant conflicts of interest, and no relationships with any companies, whose products or services may be related to the subject matter of the article.

### Financial Disclosures

None.

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