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ORIGINAL ARTICLE

The Role of Polyvinyl Alcohol and Mitomycin C in Prevention of Synechia after Endoscopic Sinus Surgery

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ABSTRACT

Background: Functional endoscopic sinus surgery (FESS) is a minimally invasive surgical procedure that opens up the sinus air cells and sinus ostia through endoscopic surgery, and has two main goals: maximum preservation of mucosa and secure communication between the nasal cavity and the paranasal sinus via natural channels .Despite the established efficacy of FESS for the treatment of chronic rhinosinusitis (CRS), recurrent symptoms developed in 1 - 36% of patients, necessitating revision surgery.

Methods: This is a prospective double blinded randomized study which was carried out on 30 patients (13 female and 17 male) ranging in age from 18 to 60 years with bilateral CRS with or without sinonasal polyposis. Duration of symptoms ranged from 5 months to 5 years. ESS had been done for all patients. The study period was from February 2017 to April 2018. All cases were selected from the outpatient clinic of Otorhinolaryngology department in Zagazig University hospital according to the inclusion criteria.

Results: Our results shows statistically insignificant difference between PVA packing side and traditional packing side, statistically significant difference between MMC packing side and traditional packing side and statistically insignificant difference between MMC side and PVA side for postoperative complication .

Conclusion: In patients undergoing ESS, using of MMC can significantly reduce the risk of synechia formation more than using PVA and traditional packs.

Keywords: FEES, mitomycin c, synechiaie, sinusitis, PVA

INTRODUCTION

Chronic rhinosinusitis is a common medical problem for individual seeking for medical care ^{1}. Endoscopic sinus surgery (ESS) is the most accepted choice for treatment of chronic sinus disease. By ESS we can: 1) maintain the sinus mucosa; 2) establish ventilation and drainage pathway of the sinus from the nateural opening 3) effectively remove the pathology^{2}.

One of the most common complications of EES is formation of postoperative synechiaie particularly in the middle meatus with incidence ranges from 1 % to 36% ^{3}.

Many types of nasal packing materials are used to prevent bleeding and adhesions after ESS. Nasal packs should be inserted and removed easily with minimal pain and discomfort, and should be effective to prevent postoperative

bleeding and adhesion. New packing materials are developed to reduce adhesion, decrease healing time and prevent shedding or tearing. Unopore, which is a sponge tampon coated by polyvinyl alcohol (PVA), is an expandable packing for use in rhinological surgery. This innovative surface treatment helps to reduce the possibility of adherence to tissue and of blood clotting within the sponge ^(4,5).

Mitomycin-C is an antibiotic which was isolated from the broth of streptomyces caespitosus. It can act as an alkylating agent which has the ability to inhibit DNA synthesis. Many studies have been performed to evaluate the effect of MMC on the scar formation after surgery, like airway restoration, choanal atresia repair, esophageal stricture and endoscopic sinus surgery. MMC usage will still at the research levels in Otorhinolaryngology ^(6,7).

PATIENTS AND METHODS

This prospective study was carried out on 30 patients (13 female and 17 male). Their age was ranging from 18 to 60 years with bilateral CRS with or without sinonasal polyposis. For all patients, ESS had been done. The study period was from February 2017 to April 2018. All patient were selected from the outpatient clinic of Otorhinolaryngology department of Zagazig University hospital .

The main object of the study was to compare the efficacy of polyvinyl alcohol and MMC in reducing adhesion formation after ESS. All operations were done in Zagazig University hospital. Institutional Research Board (IRB) approval was obtained prior to the study. A

Written informed consent was obtained from all participants. 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.

Exclusion criteria:

- patients with tumor, history of sino-nasal trauma, previous sino-nasal surgery, patients with maxillary sinusitis of dental origin, patients who had underlying systemic disease such as; cystic fibrosis, immune deficiency and ciliary movement disorder, patients with chronic specific inflammatory disease such as

rhinoscleroma, T.B, syphilis, history of bleeding disorders.

Preoperative questionnaire

- According to VAS score of 0-10, where "0" no symptom , "10" most severe symptom⁽⁸⁾.
- **Diagnostic nasal endoscopy** was done for excluding intranasal pathology to determine cases that may need additional surgical procedures .
- **CT scan:** The Lund-Mackay staging system was used. For each side, the total score of 0-12 was considered, and then the total score of 0-24 was obtained ⁽⁹⁾.

OPERATIVE PROCEDURES

Surgery was performed under general hypotensive anesthesia. ESS was done. Post-operative nasal packing was done as :

1. **Group (A) (10 Patients) (Fig1) :** one side was packed with Unopore PVA and other side with traditional packing.
2. **Group (B) (10 patients) (Fig 2) :** one side was packed with a cotton piece soaked in 1 ml of MMC in a concentration of 0.5 mg/ml in the middle meatus. Then after 5 minutes, the cotton pieces was removed and then then the nasal cavity was irrigated with 30 ml of sterile normal saline then was packed with traditional pack and the other was packed with traditional pack.
3. **Group (C) (10 patients) (Fig 3) :** one side was packed with Unopore PVA and other side was packed with a cotton piece soaked in 1 ml of MMC in a concentration of 0.5 mg/ml in the middle meatus. Then after 5 minutes, the cotton pieces was removed and then the nasal cavity was irrigated with 30 ml of sterile normal saline then was packed with traditional pack.

Postoperative follow up

After 48 h the packs were removed then follow up weekly for 4 weeks to ensure that healing was occurred.

Follow up schedule:

1. **Weekly for the first month:** in outpatient clinic, postoperative nasal endoscopy performed for inspection of the surgical site to ensure the outcome of the surgery.
2. **On 2nd week after surgery.** The ostium was examined for any evidence of stenosis or

discharge and any formed blood clots or crustations were removed.

3. **Then** , patients were examined after 3 weeks , then 6 weeks then finally after 12 weeks .
4. **And at the final evaluation** (after 12 week) : was done by
 - nasal endoscopic examination .
 - VAS with the same questionnaire .

Surgical outcome evaluation:

1- Subjective evaluation: VAS score with the same questionnaire.

2-Objective evaluation: nasal endoscopy examination.

STATISTICAL METHODS

The analysis was done using SPSS version 20 for Windows statistics software package (SPSS, Inc, an IBM Company; Chicago 2009). Data were expressed as mean \pm standard deviation (SD). P values < 0.05 were considered significant. Parametric tests such as the paired t test and 2-sample t test, Person correlation were applied for data that followed or were transformed to a normal distribution.

RESULTS

A total of 30 patient were included in this study , they were 13 female and 17 male ranging in age from 18 to 55 years with mean of **32.8 \pm 11.3** y, with bilateral chronic rhinosinusitis with or without sinonasal polyposis. Functional endoscopic sinus surgery had been done for all patients. Patient were divided in to 3 group : (Table 1)

Group I (10 patient; 3 female and 7 male) with mean of age 33.7years .

Group II (10 patient; 4 female and 6 male) with mean of age 30.8 years.

Group III (10 patient; 6 female and 4 male) with mean of age 32.8 years.

Presenting symptoms (VAS score) shows that; Anterior nasal Discharge, Posterior Nasal Drip, Olfactory affection, Nasal obstruction and Facial pain are statistically insignificant of three groups before treatment $p > 0.05$.

Preoperative endoscopic finding: shows that there is statistically insignificant difference of the 3 studied groups regard endoscopic finding $p > 0.05$.

Investigations findings: preoperative CT scan shows that there is statistically insignificant difference of studied groups regard preoperative CT finding $p > 0.05$.

Postoperative evaluation:

1.Comparison between pos-operative (VAS score) of the 3 groups :

Table 1 shows that Anterior nasal Discharge, Posterior Nasal Drip, Olfactory affection, Headache and Facial pain are statistically insignificant of three groups after treatment $p > 0.05$.

While post- operative VAS of Nasal obstruction is 2.6 of group I, 1.2 of group II finally group III VAS is 0.9 the difference statistically significant $p < 0.05$.

2.Objective evaluation: Endoscopic assessment

Group I

Table 2 shows that Scarring at PVA side is 50% at first month and second month decline to be 40% at third month but at traditional packing side is 70% at first and second month then increase to be 80% at third month.

Also this table shows statistically insignificant difference between PVA packing side and traditional packing side for post- operative complications $p > 0.05$

Group II

Table 3 shows that Scarring at MMC side is 30% at first month and second month decline to be 10% at third month but at traditional packing site is 60% at first month and 70% at second month then increase to be 80% at third month.

Also this table shows statistically significant difference between MMC packing side and traditional packing side for post –operative scarring at third month $p < 0.05$.

Group III

Table 4 shows that Scarring at MMC side is 30% at first month and 20% at second month decline to be 10% at third month but PVA side is 50% at first month and 40% at second month then decline to be 30% at third month.

Also this table shows statistically insignificant difference between MMC side and PVA side for post –operative complication $p > 0.05$.

Table(1):Comparison of Post -operative (VAS SCORE) Of studied groups .

Post- operative Variables	Group I (No= 10)	Group II (No= 10)	Group III (No= 10)	***p
	$\bar{X} \pm SD$	$\bar{X} \pm SD$	$\bar{X} \pm SD$	
Anterior nasal Discharge	1.8±1	1.1±0.9	1.6±1	0.35
Posterior Nasal Drip	1.1±1	1.7±1.2	1.6±0.84	0.35
Olfactory affection	5.8±3	2.6±2.4	4.5±3	0.09
Nasal obstruction	2.6±1.7	1.2±1.5	0.9±0.9	0.02(S)
Headache	1.3±1	2.1±1.4	1.7±1.5	0.43
Facial pain	1.2±1	1.6±1.3	1.1±0.6	0.56

Table(2): Comparison between PVA side and Traditional packing side at first month ,second month and third month post -operative occurrence of complication

Group I	First month (No= 10)		Second month (No= 10)		Third month (No=10)	
	PVA No (%)	TP No (%)	PVA No (%)	TP No (%)	PVA No (%)	TP No (%)
Scarring	5(50)	7 (70)	5(50)	7(70)	4 (40)	8(80)
Present	5 (50)	3 (30)	5(50)	3(30)	6 (60)	2 (20)
Absent						
*p	0.65		0.65		0.17	
Crust	4(40)	5(50)	4(40)	6(60)	5(50)	7(70)
Present	6(60)	5(50)	6 (60)	4 (40)	5 (50)	3 (30)
Absent						
*p	0.99		0.8		0.65	
Polypoid	4(40)	6(60)	3(30)	6(60)	4(40)	7(70)
Present	6 (60)	4(40)	7 (70)	4 (40)	6 (40)	3(70)
Absent						
*p	0.65		0.37		0.37	
MO restenosis	4(40)	7(70)	4(40)	8(80)	4(40)	8(80)
Present	6 (60)	3 (30)	6(60)	2 (20)	6(60)	2 (20)
Absent						
*p	0.37		0.17		0.17	

Table(3): Comparison between MMC site and Traditional packing site at first month ,second month and third month post -operative regard occurrence of complication

Group II	First month (No= 10)		Second month (No= 10)		Third month (No= 10)	
	MMC No (%)	TP No (%)	MMC No (%)	TP No (%)	MMC No (%)	TP No (%)
Scarring	3(30)	6 (60)	3(30)	7 (70)	1(10)	8(80)
Present	7 (70)	4 (40)	7 (70)	3(30)	9(90)	2 (20)
Absent						
*p	0.37		0.07		0.005(S)	
Crust	4(40)	6(60)	4(40)	6(60)	4(40)	6
Present	6(60)	4(40)	6 (60)	4 (40)	6(60)	(60)
Absent						4 (40)
*p	0.65		0.37		0.65	
Polypoid	3(30)	7(70)	3(30)	7(70)	2(20)	7(70)
Present	7 (70)	3(30)	7 (70)	3 (30)	8 (80)	3(30)
Absent						
*p	0.07		0.07		0.07	
MO restenosis	2(20)	7(70)	1(10)	8(80)	2(20)	6(60)
Present	8 (80)	3 (30)	9 (90)	20 (20)	8 (80)	4(40)
Absent						
*p	0.07		0.005(S)		0.17	

Table(4): Comparison between MMC site and PVA site at first month ,second month and third month post -operative regard occurrence of complication

Group III	First month (No= 10)		Second month (No= 10)		Third month (No=10)	
	MMC No (%)	PVA No (%)	MMC No (%)	PVA No (%)	MMC No (%)	PVA No (%)
Scarring	3(30)	5 (50)	2(20)	4(40)	1 (10)	3(30)
Present	7 (70)	5 (50)	80 (80)	60 (60)	9(90)	7 (70)
Absent						
*p	0.65		0.62		0.58	
Crust	3(30)	4(40)	3(30)	5(50)	3(30)	4(40)
Present	7(70)	6(60)	7 (70)	5 (50)	7 (70)	6(60)
Absent						
*p	0.99		0.65		0.99	
Polypoid	2(20)	3(30)	3(30)	4(40)	2(20)	4(40)
Present	8 (80)	7(70)	7 (70)	6(60)	8 (80)	6 (60)
Absent						
*p	0.99		0.99		0.63	

Group III	First month (No= 10)		Second month (No= 10)		Third month (No=10)	
MO stenosis Present	2(20)	4(40)	1(10)	3(30)	2(20)	3(30)
MO stenosis Absent	8 (80)	6 (60)	90 (90)	70 (70)	8(80)	7(70)
*p	0.63		0.58		0.99	

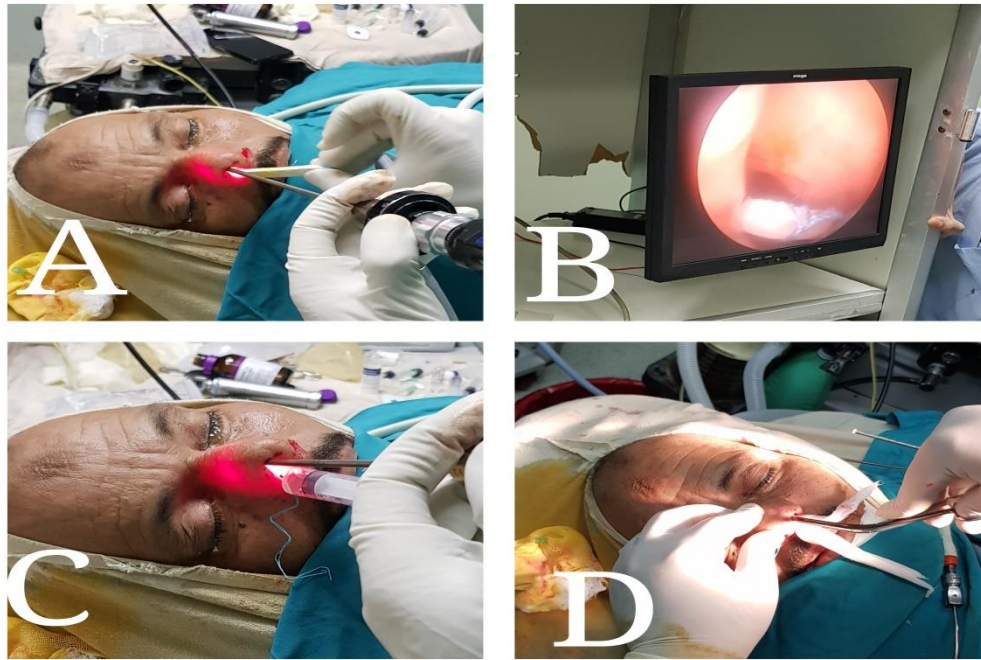


Fig.1 operative work for group A
A and B: introducing UNOPORE PVA pack in the middle meatus in rt side
C: irrigation UNOPOR with saline
D: introducing normal pack in the Lt side

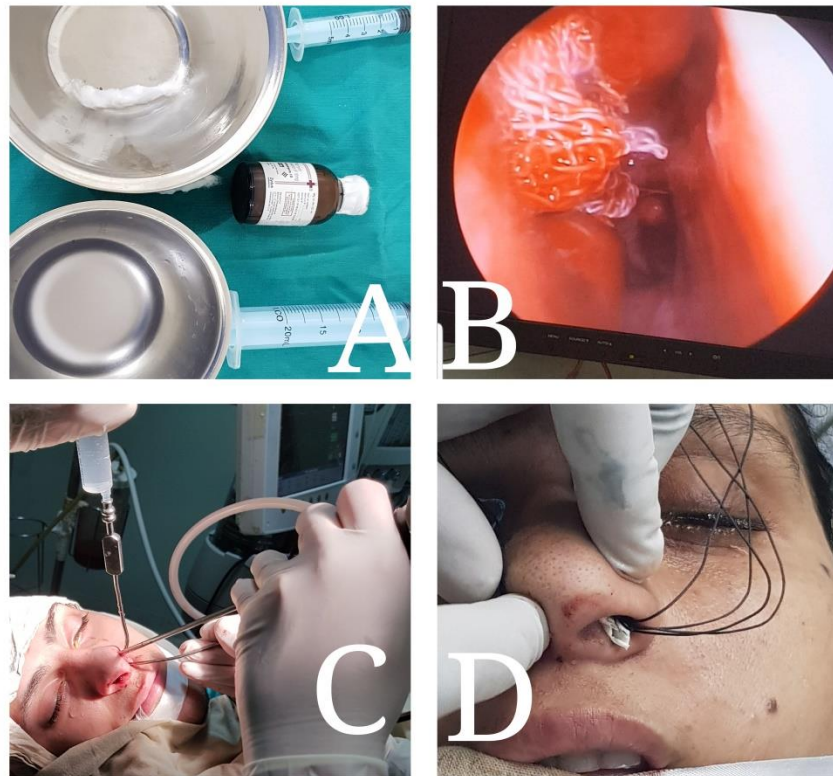


Fig.2 operative work for group B

A: preparation of the MMC solution **B:** a pack soaked in 1ml MMC introduced in the middle meatus for 5 minute **C:** irrigation with normal saline after removal of MMC pack **D:**introducing a traditional pack

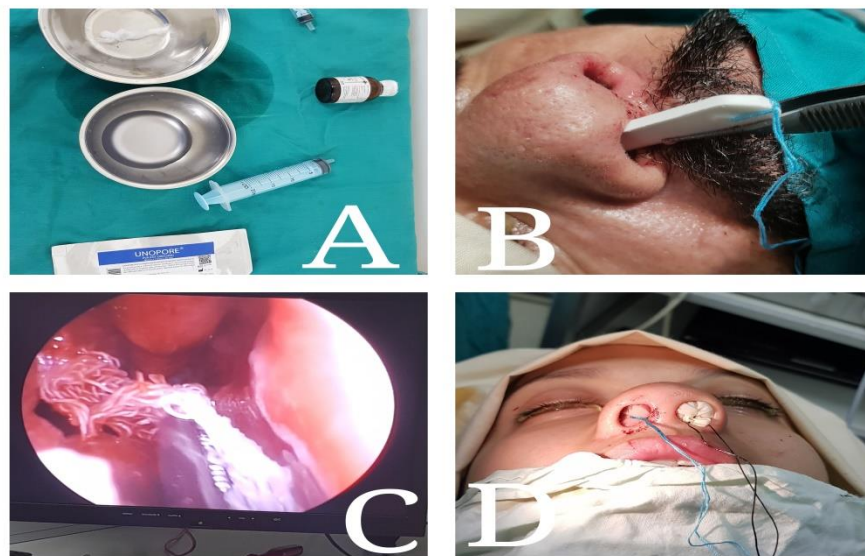


Fig.3 operative work for group c

A: preparation of MMC solution and UNOPRE PVA pack
B: introducing UNOPRE PVA in one side
C: a pack soaked in MMC introduced in middle meatus for 5 minutes
D: rt side UNOPRE PVA , lt side a traditional pack was introduced after removal of MMC soaked pack

DISCUSSION

Endoscopic sinus surgery (ESS) is the most accepted choice for treatment of chronic sinus disease. By endoscopic sinus surgery we can: 1) maintain the sinus mucosa; 2) establish ventilation and drainage pathway of the sinus from the natural opening 3) effectively remove the pathology⁽²⁾.

Synechia formation and ostial stenosis are the most common complication following ESS with a reported incidence of 1–36%⁽¹⁰⁾.

Adhesions are known to interfere with the normal mucociliary transport resulting in pooled mucous which is an ideal growth medium for a variety of microbial pathogens⁽¹¹⁾.

Nasal packs are widely used following nasal surgery and epistaxis. Ideally, nasal packs should be easy to insert and remove with minimal discomfort, and they should effectively prevent postoperative bleeding^(5, 12).

Knowledge of the properties of each material is essential for selecting the best device in each case. However, due to local market factors, availability, and actual differences in the effectiveness of the materials, the use of nasal packs varies in different countries. In Italy, for example, the expandable polyvinyl alcohol (PVA) nasal packs are the most popular⁽⁴⁾.

Polyvinyl alcohol (PVA) is a highly hydrophilic, non-toxic and biocompatible, semi-crystalline polymer with excellent properties such as strength, water solubility, gas permeability and thermal characteristics⁽¹³⁾.

Mitomycin-C can act as an alkylating agent which has the ability to inhibit DNA synthesis. Many studies have been performed to evaluate the effect of MMC on formation of the scar after surgery, like airway restoration, choanal atresia repair, esophageal stricture and endoscopic sinus surgery. The results of these studies till now are incongruent. So, MMC usage will still at the research levels in Otorhinolaryngology^(6, 7).

Overall, the rate of synechia formation after ESS differs from trial to trial, and the optimal

material for nasal packing is still a matter of debate.

In the present study, we adopted the formation of synechia and excessive granulation tissue in the middle meatus as the outcome variables to compare the effects of the 3 different materials (MMC, PVA, traditional pack).

According to endoscopic examination after one, two and three months: Using of PVA can reduce the risk of synechia formation more than using traditional pack and using of MMC can reduce the risk of synechia formation more than using PVA pack or traditional pack.

And there was a reduction in the degree of postoperative symptoms according to VAS SCOR in the 3 group.

One of the earliest studies was published by Kennedy in 1992, where in 97% of 120 patients reported improvement in symptoms (85% marked improvement) after ESS with a mean follow-up of 18 months⁽¹⁴⁾.

Kountakis followed a cohort of 158 patients for 12 months after ESS, reporting statistically significant improvements in patient visual analog scale (VAS) scores for Rhinosinusitis Task Force (RSTF) symptoms. Major RSTF symptom scores ranged from 4.5-5.7 (0-10 point scale) at baseline and improved to 0.3 to 0.9 after ESS, representing a greater than 80% change from baseline. SNOT-20 scores were also shown to improve by 77% after surgery⁽¹⁵⁾.

Granulation tissue formation is an essential stage during the mucosal healing process after ESS, and assessment of this process can indicate the healing status. Some authors have compared the wound-healing efficacies of absorbable packing and no packing in patients who had undergone ESS.

To assess the effect of different materials on synechia prevention, Miller et al. conducted a blinded randomized controlled trial to compare the effects of merogel and PVA packing in 7 patients who had undergone ESS. They found that the rate of synechia formation in both groups at 8 weeks after the operation was

approximately 8%, and the intergroup difference was not statistically significant^{16}.

Eliashar et al. found that packing was not necessary in all patients who underwent endoscopic sinus surgery. They proposed that it was possible to reduce patients' discomfort, and the cost of the procedure, by eliminating nasal packing^{17}.

Ji-Hun Mo et al. also suggested that packing could be safely used less frequently in cases of routine endoscopic sinus surgery^{18}.

On the other hand, Bugten et al. found an increasing incidence of adhesion in non-packed patients, in a randomised, clinical study. Most adhesions were observed in the middle meatus of the evaluated patients in the non-packed group, and could have been due to lateralisation of the middle turbinate, abrasion or mucosal inflammation^{19}.

In a study by Anand et al. on 29 patients with chronic rhinosinusitis resistant to medical treatment, MMC impregnated mesh and saline impregnated mesh randomly were used for each side of nasal cavity at the end of the surgery. In their study the main outcome measure was adhesions. They showed that the incidence of adhesion (9 cases of 29) between the two sides has no significant statistical difference^{4}.

In another study by Kim et al. on 20 patients, the effects of mitomycin C were evaluated on antrostomy size and were found to be effective only in the first month after surgery. But after 6 months (long term) follow up, MMC has no effect in reducing incidence of narrowing or obstruction of antrostomy. Also suggested that 70% of fibroblasts survive after a 5 minute MMC application (0.4 mg/ml) with an evidence of regrowth within 2 to 3 days^{20}.

Konstantinidis et al. assessed the efficacy of MMC using a two-stage application procedure allowing a more prolonged effect on the mucosa of the middle meatus. They reported that wound healing in the postoperative period after endoscopic sinus surgery is a prolonged and complex process mediated by several cell types. Although this period can be long and stenosis has been reported years after surgery, the first 6–8 weeks up to 3 months are the most

important. In their study intraoperative and postoperative use of topical mitomycin C in concentration 0.4 and 0.8 mg/ml applied over 5 min have been shown to decrease adhesion formation in patients undergoing functional endoscopic sinus surgery. This study shows the effect of mitomycin-C in prevention of synechiae formation and closer of ostiomeatal complex. They found the more the concentration of MMC, the better the result^{21}.

CONCLUSION

- In patients undergoing ESS, using of MMC can significantly reduce the risk of synechiae formation more than using PVA and traditional packs.
- The number of the patient is better to be increased for more statically accurate results in the same future studies.
- Postoperative CT scan should be done after 3 months to ensure the success of the surgery or the presence of complication.

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