Annals of R.S.C.B., ISSN:1583-6258, Vol. 25, Issue 1, 2021, Pages. 2175 - 2184
Received 15 December 2020; Accepted 05 January 2021.

A Study of Usefulness of Nasalspacer in Post Endoscopic Middle Meatus Patency

G.C. Vijaya Sai[1], S. Rajasekaran[2], M. K. Rajasekar [3]
[1,2,3] Department of Otorhinolaryngology, Sree Balaji Medical College & Hospital,Chromepet, Chennai
* rajasekar.k@bharathuniv.ac.in

ABSTRACT

Middle meatal (MM) scarring is reported as being one of the most common postoperative complications of endoscopic sinus surgery. The incidence of postoperative synechiae ranges between 4% and 27%. The severity of scarring varies widely from mild, significant synechiae to clinically obstructive disease requiring further surgical intervention. Incomplete surgery, poor tissue respect, injury to the both sides of the mucosa, poor technique, poor postoperative care cannot be replaced by placing the stent in the middle meatus

Keywords: Middle meatal (MM) scarring, stents, endoscope, sinus cavity

INTRODUCTION

In an attempt to decrease the frequency of this complication, various surgical techniques and Middle meatal stents have been designed and used. Some authors advocate suture medialization or controlled synechiae medialization of the middle turbinate. Others believe partial middle turbinate resection to be beneficial in decreasing the rate of synechiae formation. Some advocate placing stents within the ostiomeatal complex. Others place synthetic sponges (ie, Ivalon, Merocel).

However, many questions linger regarding stenting of the Middle meatus : Are stents truly beneficial? What is their exact purpose or function? Are they to be used solely as Middle meatal spacers? Can they catalyze or delay wound healing? Do they promote hemostasis? Other questions pertain to the stent shape and size, whether the stent biomaterial is important, and whether surgical technique influences synechiae formation. The purpose of this study is to explore some of these questions.

MATERIALS AND METHODS

The present study "A study of usefulness of nasal spacer in post endoscopic middle meatus patency " was done in the Department of Otorhinolaryngology Sree Balaji Medical College & Hospital Chennai, Tamil Nadu from March 2014 to October 2015.

Source of Data

Patient for the study were selected from those who underwent endoscopic sinus surgery for chronic sinusitis in the Department of Otorhinolaryngology Sree Balaji Medical College & Hospital Chennai, Tamil Nadu.

Inclusion Criteria

Age Group: 15-45 years of age (young and middle aged adults)
Patient underwent endoscopic sinus surgeryfor chronic sinus infection.

Exclusion Criteria

Extremes of age
Malignancy
Immuno deficiency
Extensive polyposis, Post-surgical patients (No previous nasal or sinus surgery)

Sample size

In this study 30 patients operated for chronic sinusitis by functional endoscopic sinus surgery using general anaesthesia.

METHODOLOGY

Preoperative patient Evaluation

In this study patients were pre operatively evaluated by Diagnostic Nasal Endoscopy
X-ray paranasal sinuses (Occipitomental or water's view)
CT-PNS

Annals of R.S.C.B., ISSN:1583-6258, Vol. 25, Issue 1, 2021, Pages. 2175 - 2184
Received 15 December 2020; Accepted 05 January 2021.

Axial & Coronal

Diagnostic Nasal Endoscopy

Prior to surgery, the patient should ideally undergo diagnostic nasal endoscopy to review the anatomy and pathology, to ensure that there has been no acute exacerbation, and, if indicated, to take cultures to guide intraoperative and postoperative antibiotic therapy. During the preoperative endoscopy, access to the ethmoid cavity is re-evaluated. If the 4mm 0° telescope cannot be introduced to the anterior attachment of the M.T. because of septal deviation, then it will be evident that at least a limited septoplasty will be required at the time of surgery. Appropriate informed consent can then be obtained. At the same time, the patient can be re-evaluated, both by patient preference and by objective evaluation, for suitability for local versus general anesthesia.

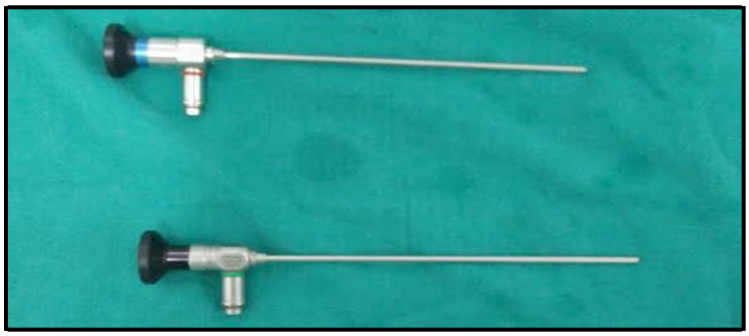


Figure 3: Endoscope

Preoperative CT Evaluation

In this study preoperative CT - PNS has been taken for all the patients

Site	Evaluation
Skull base	Slope, height, erosions, areas of relative thickening and Thinning
Medial orbital wall	Integrity, erosion, shape, infundibular size, and uncinate Position
Ethmoid Vessels	Position of anterior and posterior ethmoid vessels relative to skull base
Posterior ethmoid	Vertical height
Maxillary sinus medial wall	Infraorbital ethmoid cells, accessory ostia
Sphenoid sinus	Relative sizes, position of intersinus sep tum, relationship to carotid arteries, optic nerves
Frontal recess and	Frontal sinus pneumatization, frontal recess size, agger

Infraorbital ethmoid cells, accessory ostia

Sphenoid sinusRelative sizes, position of intersinus sep tum, relationship to carotid arteries, optic nerves
Frontal recess and Frontal sinus pneumatization, frontal recess size, agger
frontal sinusnasi and supraorbital ethmoid pneumatization, frontal sinus drainage

Annals of R.S.C.B., ISSN:1583-6258, Vol. 25, Issue 1, 2021, Pages. 2175 - 2184
Received 15 December 2020; Accepted 05 January 2021.

PROFILE OF SPACER Ivalon[30], Merocel[31]

Constructed of a unique hydroxylated polyvinyl acetal (PVAc) sponge developed by the pioneer of modern PVAc products. PVAc sponge has been used around the world in a variety of medical applications for over forty years. PVAc packings are lint and fiber free. They provide a unique combination of exceptional liquid absorption and wicking characteristics with high tensile strength.

Nasal and Sinus Packings are designed to combine unsurpassed fluid control with enhanced patient comfort. These packings are designed with an integral, smooth and porous outer surface. This surface enhances patient comfort by reducing the risk of rebleeding and adhesion during removal. The highly absorbent hydroxylated polyvinyl acetal (PVAc) inner sponge is extremely soft and pliable, providing optimum patient comfort.

Integral smooth outer surface reduces adhesion. Soft, pliable sponge enhances patient comfort. Double - compressed and rounded edges ease insertion. Fiber - free PVAc construction will not introduce lint fibers into the surgical site. Atraumatic removal Highly absorbent sponge provides fast and effective fluid control, absorbs upto 25 times its weight in fluid. Complete range of products to suit individual surgical needs. Extremely strong, will not tear or shred during use. Easily trimmed with scissors to achieve a custom shape or size.

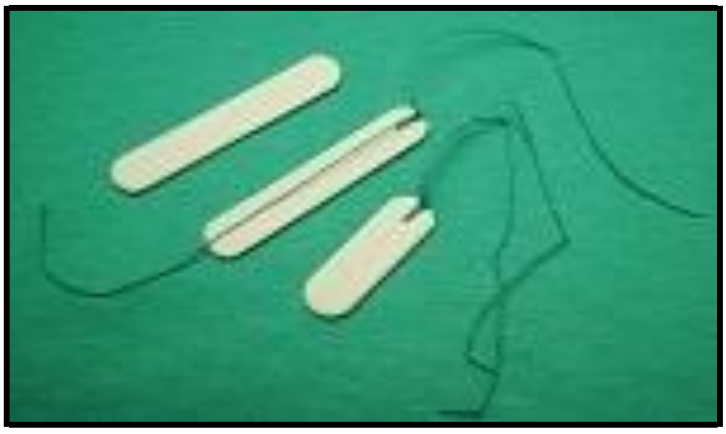


Figure 4: Showing the Ivalon Nasal Pack

Procedures

- In this study no turbinates were removed.
- Spacer kept intraoperatively removed on the 6th Postoperative Day.

Postoperative Care

Post-operative care begins at the conclusion of the surgery with placement of packing material. The study pack is made of polyvinyl acetal, which is a highly absorbent, inert material. The pack is inserted to stent the middle turbinate medially and to provide pressure, as well as a surface to promote coagulation. The packs are left in place for several days after surgery to help prevent lateralization of the middle turbinate and formation of synechiae from the turbinate to the lateral wall, and to facilitate hemostasis. The packs may be removed 6 days after surgery.

On the night of surgery, the patient is encouraged to remain at rest. For the first 10 days after surgery, the patient is limited to nonstressful activities. The recommendation is to avoid active exercise, lifting of more than 5 kg lb, and sexual activity. After this, the patient is advised to return gradually to normal activity levels. Nose blowing and sneezing are discouraged for the initial postoperative period until the cavity is remucosalized. This helps to avoid the potential complications of pneumocephalus and orbital emphysema.

Medications are prescribed for pain, infection control, and control of inflammation. Pain medication is tailored to the needs of the patient. Most commonly, acetaminophen is sufficient. Antibiotics are administered for a minimum of 2 weeks after surgery. Empiric selections include amoxicillin / clavulinic acid, clarithromycin, or ciprofloxacin to cover the usual bacteria and Staphylococcus aureus that may

Annals of R.S.C.B., ISSN:1583-6258, Vol. 25, Issue 1, 2021, Pages. 2175 - 2184
Received 15 December 2020; Accepted 05 January 2021.

colonize the packs and lead to toxic shock syndrome. If active infection is found at surgery, then cultures are taken, and as soon as the results are available, the antibiotic regimen is adjusted to cover the cultured bacteria. In cases of severe infection, a prolonged course of antibiotics is indicated; in selected cases, intravenous antibiotics may be administered.

Once the packs are removed, the patient is started on nasal irrigations, nasal saline spray. The irrigations begin with normal saline administered with a 20 cc syringe twice each day and continued until the cavity is healed and crusting subsides. Once the cavity is healed, the formulation of the irrigation can be changed if significant mucosal edema is found. The recommended formula is adapted from Parsons and approximates 3% buffered saline. This may be created at home by adding 3 tsp of salt and 1 tsp of baking soda to 230 ml of boiled water. This hypertonic solution may help resolve mucosal edema by drawing the fluid out of the tissue by osmotic pressure. In the interim between the two irrigations, the patient is instructed to use a commercially bottled nasal saline drops every 2 to 3 hours. An essential part of all ESS is the postoperative cleaning of the sinus cavity. The normal follow - up routine is to clean the sinus cavity at the first post operative visit following removal of the packs, one week after pack removal, and again 4 weeks after pack removal. Additional follow up visits maybe scheduled depending on the needs of the individual patient.

At each cleaning, the sinus cavity is completely debrided of all blood clot, mucus, and inspissated secretions. The regenerating or healing mucosa is preserved with care taken to minimize trauma to the site. Areas of granulation tissue and regenerative mucosal cysts are debrided using suction, and any synechiae are removed sharply. These procedures are uncomfortable for the patient, but with good topical anesthesia and decongestion, combined with gentle, careful technique, almost all patients can be coached through these procedures.

The importance of quality postoperative care cannot be over emphasized. Failure to achieve the desired debridement puts the patient at risk for stenosis, synechiae, and poor outcomes. On the contrary, successful cleaning and debridement will almost always result in normal healing and excellent results. Post operative video nasal endoscopy. On the day of pack removal, 6th post operative day One week after pack removal One month after pack removal Surgery was only decided on if patient signs and symptoms failed to respond to an aggressive trial of medical therapy (>3 weeks of antibiotics in addition to mucolytics, decongestants). Ivalon stent was placed in the middle meatus.

During each post operative visit patients were evaluated via nasal endoscopy for the presence of synechia e and or granulation tissue between the middle turbinate and the lateral nasal wall. Patients were assessed as well for possible stent - related morbidity, specifically nasal obstruction, headache, and infection. Such symptoms and signs were only considered to be stent related if present before the first postoperative visit. Patients were required to attend at least 2 of the 3 postoperative visits to be included in the study.

RESULTS

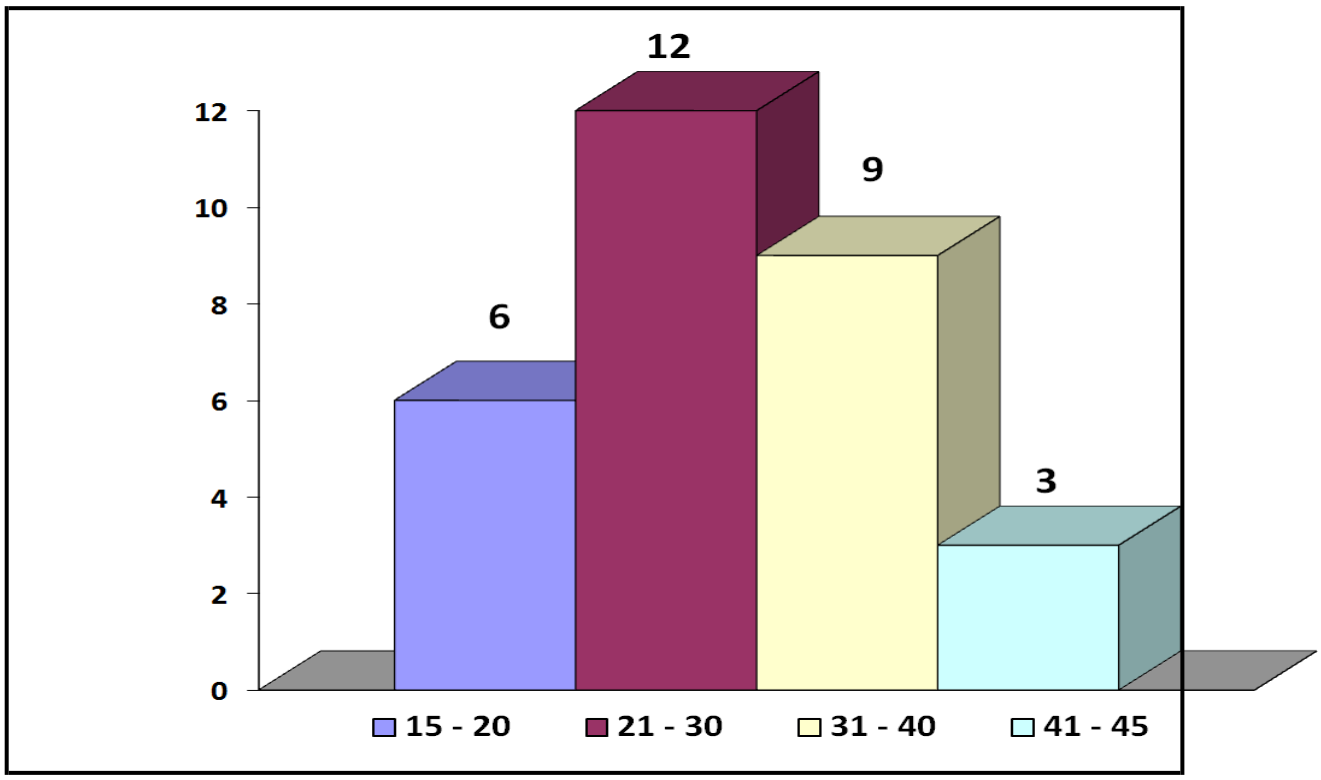
In the study population of 30 chronic sinusitis patient undergoing functional endoscopic sinus surgery in both sexes almost equally with a mild male preponderance 57% males and 43% females within the specified age group of 15-45 years which includes young and middle age adults.

Among the 30 patients in study population 6 patients 20% between the age group of 15-20,12 patients40% between the age group of 21-30,9 patients30% between the age group of 31-40, 3patients10% between the age group of 41-45. (Table 1) & Figure (5).

Age	No. of Patients
15 – 20	6
21 – 30	12
31 – 40	9
41 – 45	3

Annals of R.S.C.B., ISSN:1583-6258, Vol. 25, Issue 1, 2021, Pages. 2175 - 2184
Received 15 December 2020; Accepted 05 January 2021.

Table 1: Age distribution of operated patients in the study population in the study population



Age
Figure 5: A graphical representation showing the age distribution of the patients from 15 -45 years of age in The study population
Among the 30 patients in study population 17 patients 57% are male and 13 patients 43% in females (Figure 6)

Sex of the Patients	
Male	**Female**
17	13

Table 2: Gender distribution of the operated patients in the study population

Annals of R.S.C.B., ISSN:1583-6258, Vol. 25, Issue 1, 2021, Pages. 2175 - 2184
Received 15 December 2020; Accepted 05 January 2021.

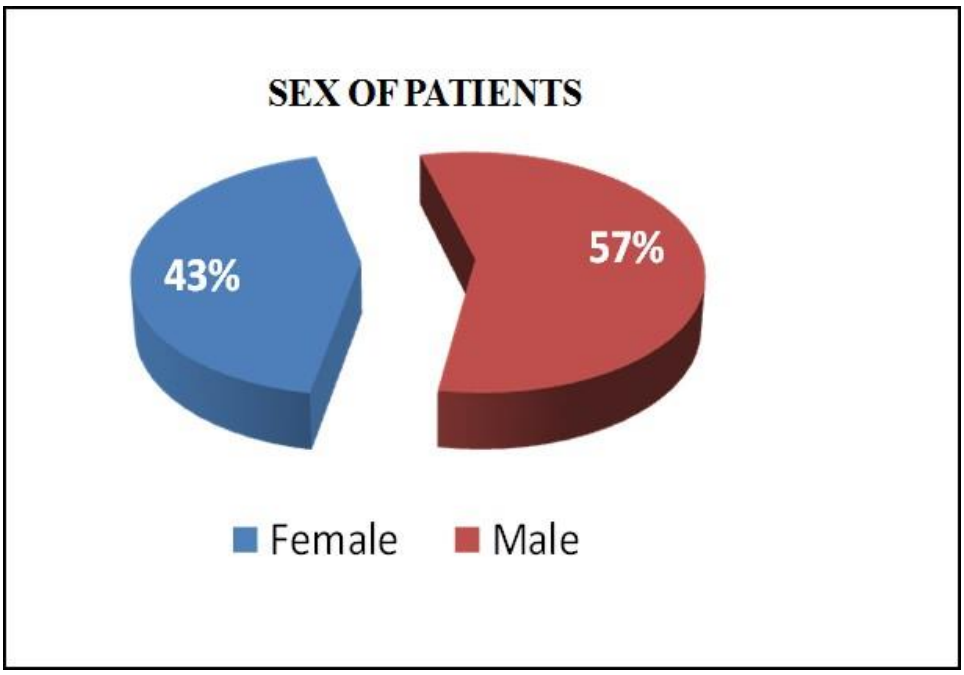


Figure 6: A Pie diagram showing the gender distribution of the operated patients in the study population

Postoperative Findings	**Visit 1, 6th Postoperative Day, Pack removal**	**Visit 2 1 week after Pack removal**	**Visit 3 1 month after pack removal**
Packing injury	Absent	Absent	Absent
Oedema	3	Absent	Absent
Post-Operative reactionary Hemorrhage	Absent	-	-
Post-Operative Secondary Hemorrhage	Absent	Absent	Absent
Blood clot in middle meatus	Absent	Absent	Absent
Granulation	Absent	1	Absent
Post-Operative Infection	Absent	2	Absent
Crusting	Absent	2	Absent
Middle Meatus / turbinate collapse	Absent	Absent	Absent

Annals of R.S.C.B., ISSN:1583-6258, Vol. 25, Issue 1, 2021, Pages. 2175 - 2184
Received 15 December 2020; Accepted 05 January 2021.

Stenosis of a surgically enlarged maxillary antrostomy	Absent	Absent	Absent
Latcralisation of the middle turbinate	Absent	Absent	Absent
Adhesion / synechiae	Absent	2	Absent
Contracture	Absent	Absent	Absent
Scar formation	Absent	Absent	Absent

Table 3: Post operative complications seen during follow up in the study population in the study population
For the 2 patients, with adhesion it was clinically insignificant during the follow-up period and therefore not lysed. Operative infection developed inpatients, missing few doses of oral antibiotics. One patient developed temporary granulation tissue in the middle meatus. In the study population Stent Related Morbidity seen in 8 patients out of 30 patients. Nasal obstruction seen in 10% of patients, Headache seen in 10% of patients and Infection seen in 8% of patients.

Stent Related Morbidity	**No. of Patients**
Nasal Obstruction	3
Headache	3
Infection	2

Table 6: Showing the stent related morbidity in operated patients in the study population in the study population

Annals of R.S.C.B., ISSN:1583-6258, Vol. 25, Issue 1, 2021, Pages. 2175 - 2184
Received 15 December 2020; Accepted 05 January 2021.

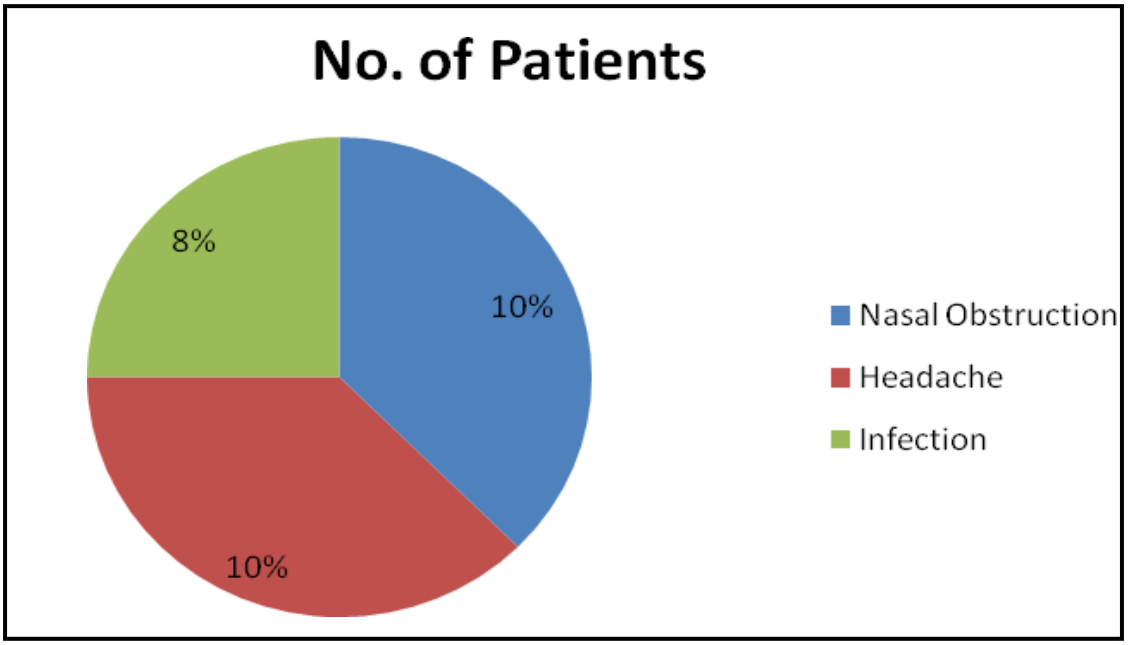


Figure 7: A Pie diagram showing the stent related morbidity in operated patients in the study population.

DISCUSSION

This study was conducted on 30 patients who underwent endoscopic sinus surgery for chronic sinusitis in the Department of Otorhinolaryngology Sree Balaji Medical College & Hospital Chennai, Tamil Nadu during the period from March 2014 to October 2015. Although various surgical techniques and middle meatal stents have been designed to help decrease the rate of Synechiae formation following endoscopic sinus surgery, there have been no prospective studies comparing any of these methods. Middle meatal spacers have shown benefit in decreasing middle meatal adhesions. Gaskins 32 reported a Synechiae rate of 10.0% for the nonstented side and 6.7% for the stented side. Zhao33 also stated that middle meatal spacer may reduce adhesions following ESS.

Data from our study supports the literature consensus that middle meatal stents 34,35 seem to be efficacious. Synechiae rate of 6.6% was observed in our study. Postoperative nasal edema will enlarge the middle turbinate beyond its normal size, therefore requiring that the stent extend past it's anterior and inferior edges for best functional results. The antero inferior aspect of the middle turbinate and the lateral nasal wall form an anatomic bottleneck to the MM, which during the period of postsurgical edema, is prone to Synechiae formation due to contact of deepithelialized mucosal edges.

In addition, the surgical technique may play a significant role in reducing the rate of Synechiae. Minimally Invasive Sinus Technique (MIST) 36,37, a surgical model that is effective in treating all stages of chronic sinus disease, does not disturb the maxillary birth ostium. No maxillary antrostomy is performed, and nasal mucosa and nasal turbinates are always preserved. Furthermore, the powered microdebrider tends to result in a more delicate and precise dissection within the nasal cavity. These procedural modifications minimize surgical trauma in the MM. No previous study has reported the incidence of Synechiae following MIST. We have also noted that Synechiae, when present following MIST, arc rarely clinically significant. This observation may directly relate to the naturalposition/ orientation of the maxillary birth ostium. In most patients, the maxillary birth ostium is oriented either obliqu ely or horizontally, thereby minimizing the risk of a lateralized middle turbinate causing obstruction. MM antrostomy, however, creates a parasagittal opening, which is favorably positioned to become occluded from a lateralized middle turbinate or edematous it middle meatus.

The granulation tissue, postoperative infection and adhesion resolved by the time of subsequent visit. Many factors contribute to nasal obstruction in the immediate postoperative period, including

postsurgical edema, atopy, and infection. The only disadvantage of the Ivalon pack is its cost effective. Findings noted during the visit after 1 week of pack removal in the study population.
Space maintained
No collapse
Smooth epithelialisation
No obvious edema
No obvious infections
Ostial secretions suction cleared
Findings noted during the visit after 1 month of pack removal in the study population.
No scarring
No lateralization

Ostium normal
No granulation tissue
The findings of this study are significant, because it introduces several new concepts and confirms others : Middle meatal stents are beneficial following sinus surgery and can minimize Synechiae. A bio inert stent is well tolerated postoperatively and eliminates the need for middle meatal debridement.

CONCLUSION

All 30 patients included in the study were packed with middle meatal spacers following Functional Endoscopic Sinus Surgery. Out of 30 patients in the follow up 20 patients (70%)had no post operative complications.10 patients (30%) had mild complications like postoperative infection, oedema, synechiae, crusting, granulation. We observed that middle meatal spacers are effective in preventing post operative complications after Functional Endoscopic Sinus Surgery. If proper surgery is done and middle meatus spacer is used, it definitely reduces postoperative infection, scarring, synechiae formation, contracture of middle meatus antrostomy and recurrence of disease.

Funding: No funding sources
Ethical approval: The study was approved by the Institutional Ethics Committee

CONFLICT OF INTEREST

The authors declare no conflict of interest

ACKNOWLEDGMENTS

The encouragement and support from Bharath University, Chennai is gratefully acknowledged. For provided the laboratory facilities to carry out the research work.

REFERENCES

[1] Mosher HP:The surgical anatomy of ethmoid labyrinth. Amer Aca Ophthal Otolaryngol. 1929; 376 -410.
[2] Lynch RC . The technique of a radical frontal sinus operation which has given me the best results. Laryngoscope. 1921; 31: 1 –5.
[3] Van Alyea OE: Nasal Sinuses: An Anatomic and clinical consideration, ed 2 Baltimore, Williams & Wilkins Co. 1951.
[4] Hopkins HH: Improvements on or relating to optical systems. UK Patent 1 534 541. Filed April 30, 1975.
[5] Kennedy DW, Zinreich SJ, Rosenbaum AE, et al: Functional endoscopic sinus surgery: Theory and diagnostic evaluation. Arch Otolaryngol 1985;111:576.
[6] Messerklinger W : Endoscopy of the nose. Urban and Schwarzenberg, Munich,1978.
[7] Wigand ME: Transnasal Ethmoidectomy Under Endoscopic Control. Rhinology 1981;19: 7-15.
[8] Naumann H. Pathologische Anatomie der chronischen Rhinitis und sinusitis. Proceedings VIII international congress of Otorhinolaryngology. Amsterdam. Exerpta Medica. 1965. p. 80.
[9] Stammberger H. and Wolf G: Headaches & Sinus disease. The endoscopic approach. Ann. Otol Rhinol. Laryngol, 1989; 97: 3-23.

[10] Stammberger H, Endoscopic endonasal surgery: concepts in treatment of recurring rhinosinusitis, part2, Surgical technique .Arch Otolaryngol 1986;94:147-156.
[11] Keros. on the practical value of differences in the level of lamina cribrosa of the ethmoid. Z Laryngol Rhinol Otol.1962;41:808 -13.
[12] Toremalm NG. The Mucociliary activity of the upper respiratory tract.Rhinology.1975.
[13] Mercke U, Hakanson CH, Torelman NG. A method for standardized studies of mucociliary cactivity. Acta Otolaryng. 1974; 78: 118 -123.
[14] Aust R et al. Elimination of contrast medium from the maxillary sinus. Acta Otolaryngol 1976May-Jun;81: 468-74.
[15] Kaluskar SK. Endoscopic Sinus Surgery. A practical approach, Springer-Verlag Berlin, Heidelberg, Newyork.1997.
[16] Sachdeva S. Endoscopic Dacryocystorhinostomy. Delhi journal of Ophthalmology 1999;7(2):30-32.
[17] Kuhn FA, Citardi MJ. Advances in postoperative care following functional endoscopic sinus surgery. Otolaryngol Clin North Am. 1997; 30: 479–490
[18] Citardi MJ, Javer AR, Kuhn FA. Revision endoscopic frontal sinusotomy with mucoperiosteal flap advancement: The frontal sinus rescue procedure. Otolaryngol Clin North Am. 2001; 34: 123 –132.
[19] Biedlingmaier J F, Rothman M. Histopathology and CT analysis of partially resected middle turbinates. Laryngoscope 1996; 106:102 -104
[20] Davis WE, Templer JW, LaMear WR, Davis WE, Jr, Craig SB. Middle meatus antrostomy: patency rates and risk factors. Otolaryngol Head Neck Surg. 1991; 104:467–472
[21] Kinsella JB, Calhoun KH, Bradfield JJ, Hokanson JA, Bailey BJ. Complications of endoscopic sinus surgery in a residency training program. Laryngoscope. 1995; 105:1029–1032.
[22] Ramadan HH, Allen GC. Complications of endoscopic sinus surgery in a residency training program. Laryngoscope. 1995; Apr; 105(4): 376 -79.
[23] Swanson PB, Lanza LC, Vining EM, et al.The effect of middle turbinate resection up on the frontal sinus. Am J Rhinol 1995; 9:191-195.
[24] Vleming M, Middelweerd RJ, De Vries N. Complications of endoscopic sinus surgery. Otolarygol Head Neck Surg 1992;/118:/617 -22.
[25] Bolger WE, Kuhn FA, Kennedy DW. Middle turbinate stabilization after functional endoscopic sinus surgery: the controlled synechiae technique. Laryngoscope. 1999; 109: 1852-1853.
[26] Shikani AH. A new middle meatal antrostomy stent for functional endoscopic sinus surgery.Laryngoscope 1994;638-41.
[27] Thronton RT.MT stabilization technique in endoscopic sinus surgery. Arch Otolaryngol Head Neck Surg1996; 122:869-72.
[28] Parsons DS, Stivers FE, Talbot AR. The missed ostium sequence and the surgical approach to revision functional endoscopic sinus surgery. Otolaryngol Clin North Am 1996;29(1):169 –183.
[29] Thaler ER. Post operative care after endoscopic sinus surgery. Otolaryngol Head neck surgery. 2002; Oct; 128(10): 1204-06.
[30] Ivalon surgical products, M-Pack worldwide LLC. 1040 OCL parkway,Endora,KS-66025 USA. Merocel surgical products, Medtronic, Xomed, Jacksonville, FL,32216 USA.Gaskins RE. Scarring in endoscopic ethmoidectomy. Am J Rhinol. 1994; 8: 271 -274.
[31] Zhaox, Grewal A, Briel M, Lee JM.A. Systemic review of non absorbable, absorbable and steroid - impregnated spacers following endoscopic sinus surgery. Int forum allergy Rinol. 2013;3(11):896 -904.
[32] Lee JM, Grewal A. Middle meatal spacers for the prevention of synechiae following endoscopic sinus surgery: A systemic review and meta analysis of randomized control trails. Int Forum Allergy Rhinol. 2012; 2(6):477-86.
[33] Weitzel EK, Wormald PJ. A scientific review of middle meatal packing/stents. AM. J Rhinol.2008:22(3); 302-307.
[34] Peter J. Catalono MD, Eric J Roffmen MD. Evaluation of middle meatal stenting after minimally invasive sinus techniques (MIST) Otolaryngol Head Neck, Surg, June 2003 Vol.128. No.6 875-881.