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Comparative study of nasal septal retainer and nasal packing in patients undergoing septoplasty

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Abstract

Purpose Nasal packing is frequently used after septoplasty and some complications caused by nasal packing are unavoidable. A nasal septal retainer has recently been developed. We evaluated the safety and clinical efficacy of the retainer in septoplasty, and the subjective symptoms of patients with the retainer were compared with Merocel nasal packing.

Methods A prospective, randomized, controlled study was performed in patients who had undergone septoplasty. In total, 39 patients were randomized to receive Merocel ($n=17$) or the retainer ($n=22$) after septoplasty. The deviation of nasal septum and nasal mucosa was evaluated by endoscopy. The clinical efficacy and subjective symptoms were compared using the visual analog scale.

Results During the packing/retaining period, the mean scores of headache, nasal obstruction, epiphora, and facial pressure in the retainer group were significantly lower than in the Merocel group ($P<0.05$); the mean scores of nasal pain, nasal itching, rhinorrhea, dysphagia, and sleep disturbance in the retainer group were lower than in the Merocel group, but the difference did not reach statistical significance. On the removal of Merocel/retainer, nasal pain was significantly lower in patients with the retainer ($P<0.05$). In the retainer group, the incidence of grade 1 bleeding was 45.5%, and grade 0 bleeding was 54.5%. In the Merocel group, the incidence of grade 2 bleeding was 23.5%, grade 1 was 47.1%, and grade 0 was 29.4%.

Conclusions The nasal septal retainer is suitable for use after septoplasty with more beneficial effects than nasal packing.

Keywords Septoplasty · Nasal septal retainer · Nasal obstruction · Pain · Merocel · Nasal packing

Introduction

Patients commonly present at the otolaryngology department with septal deviation, and symptomatic deviations often require surgical treatment. The role of nasal cavity handling after septoplasty is to prevent postoperative bleeding and septal hematoma, avoid synechia formation, and optimize healing [1]. Nasal packing is a treatment which is widely used in many institutions. The use of packing can provide moderate pressure, eliminate the postoperative cavity in the septum, maintain the residual cartilaginous or bony framework, and promote physiological hemostatic and reparative processes [2]. Before novel packing materials appeared, petroleum-impregnated gauze was frequently used after septoplasty. Currently, Merocel (Medtronic Xomed Inc., Jacksonville, FL, USA) is a typical nonabsorbable packing material [3] and has a widespread use around the world [4]. Nasal packing is quite uncomfortable, affects the patient's quality of life, and lengthens the hospital stay [5]. In addition to the discomfort experienced during nasal packing, mucosal edema, irritation of nasal mucosa, and secondary bleeding have been reported in patients after removing Merocel [6–8].

To minimize the discomfort and improve the quality of life in patients after septoplasty, various treatment techniques have evolved over time, including silastic sheet insertion and trans-septal suturing. Although nasal packing was considered an effective method after septoplasty, the nonpacking method, including trans-septal suturing or septal splints, has equivalent outcomes with regard to postoperative bleeding, hematoma formation, septal perforation, residual septal deviation, and infection [3]. However, the nonpacking is less likely to induce pain, headache, and synechia and can

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be effective alternatives to nasal packing. Recently, a novel device, a nasal septal retainer (Changzhou Innovate Medical Instrument & Technology Inc., Jiangsu, China), has been invented. The nasal septal retainer is made of polycarbonate, and consists of 2 blades and 1 nut (Fig. 1). When the two blades close together, the retainer can provide mechanical pressure to the midline, so as to achieve the function of pressing the nasal septal mucosa. However, the relevant clinical research on the retainer has not been conducted. The device has been demonstrated to be safe and effective in our preliminary clinical observations. The retainer is convenient to use, requiring less than 10 s to put in place in most cases studied (Fig. 2). According to these characteristics, the nasal septal retainer can be used as a nasal cavity treatment device after septoplasty; however, the use of a nasal septal retainer in nasal septal surgery has not yet been reported.

In this study, we evaluated the safety and clinical efficacy of the nasal septal retainer in septoplasty, and the subjective symptoms and signs of the retainer were compared with Merocel packing.

Materials and methods

Patients and groups

This study was designed to be a prospective, randomized, controlled clinical study. The study protocol was approved by the Institutional Review Board (No. 2016–33) and written informed consent was obtained from all participating patients. Patients older than 18 years of age undergoing primary septoplasty were enrolled in this study. Patients who had a history of previous septoplasty, allergy, asthma, concurrent sinusitis, or systemic diseases were excluded. The patients were divided into two groups: the Merocel packing group and the nasal septal retainer group. On the day of surgery, a random envelope was selected to assign the patient to one of the groups.

Surgical procedure

In this study, all septoplasty procedures were performed under general anesthesia and by the same surgeon. A submucosal approach was adopted with a modified Killian or hemitransfixion incision. Depending on the location of the deviation, the deviated segment (cartilaginous or bony) was corrected with minimal excisions. Once the correction was deemed satisfactory, the elevated mucoperichondrial flaps were repositioned and the hemitransfixion incision was closed with stitches using 5–0 Vicryl. With regard to the management of hypertrophied inferior turbinates, we performed radiofrequency volumetric tissue reduction in all patients using a BONSS electrode (Bonss Medical Technology, Jiangsu, China). After all procedures, Merocel or retainer was placed in both nasal cavities along the floor of the cavity. The Merocel packs were irrigated with 10 mL of saline. In patients using retainers, the nut was screwed tight until the retainer was fixed in the nasal cavity (Fig. 2). On the 2nd postoperative day, Merocel or the retainer was removed.

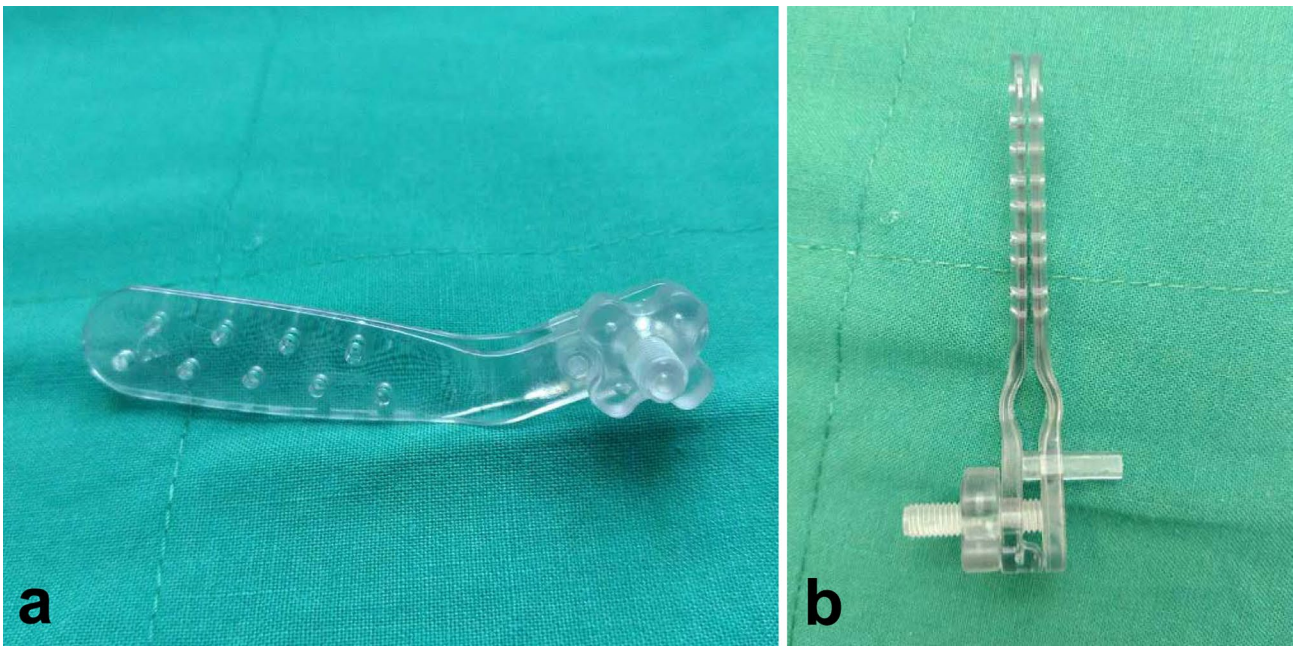

Fig. 1 Nasal septal retainer. **a** Side view; **b** view from above

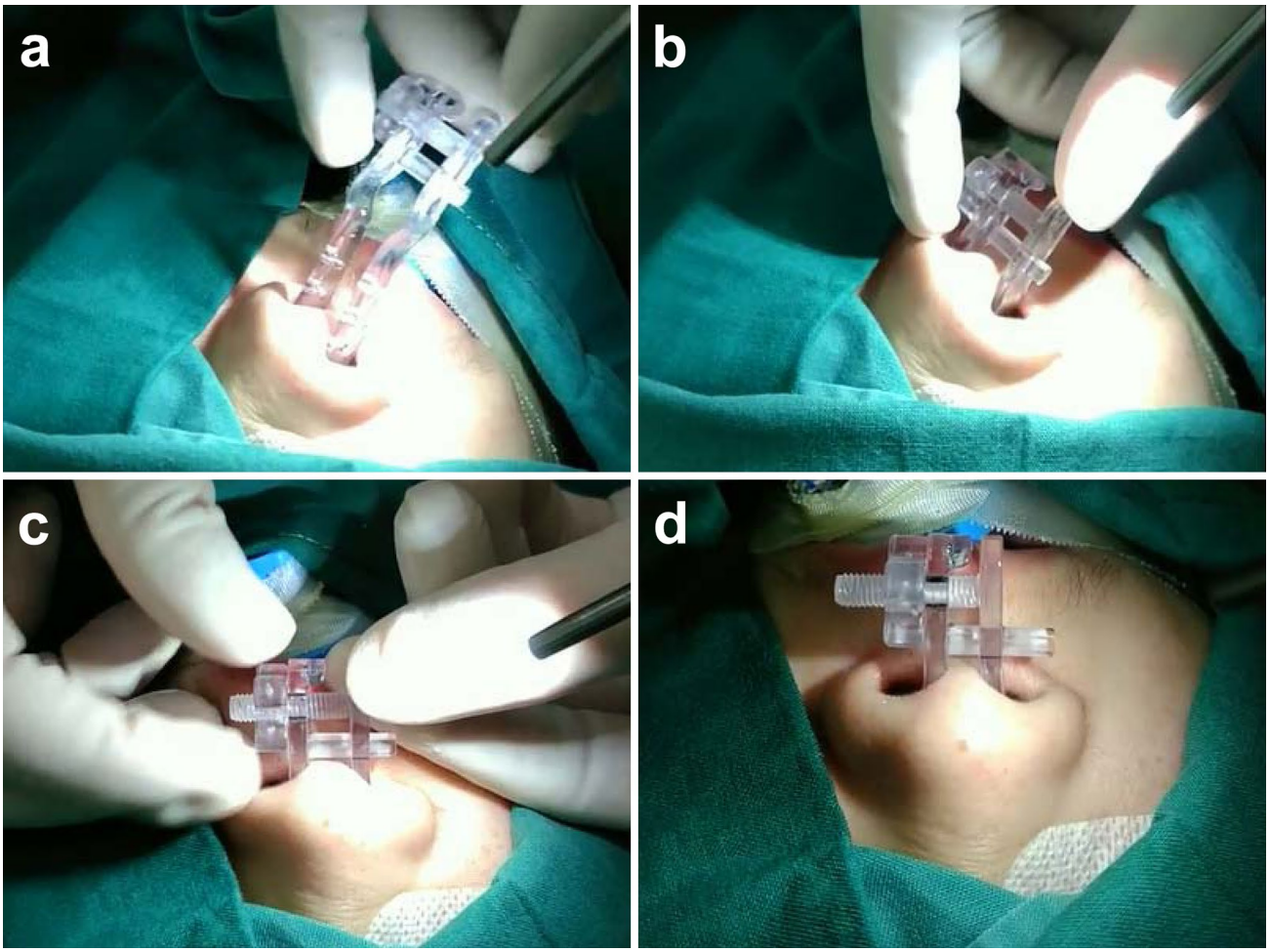

Fig. 2 Application steps for nasal septal retainer. **a** Unscrew the nut and place the two blades in parallel in both sides of the nasal cavity; **b** push the retainer into the deep part of the nasal cavity; **c** screw the nut until the retainer is fixed in the nasal cavity; **d** working position of the nasal septal retainer

Clinical curative effect evaluation

The safety and efficacy of the two treatments after septoplasty and the subjective severity of symptoms related to the treatments were the main indicators studied. To evaluate the degree of deviation of the nasal septum and the condition of the nasal mucosa, nasal endoscopy was applied before surgery, after removal of Merocel or the retainer, and 3 months after surgery. The clinicians who performed the endoscopy were blind to the treatment of nasal cavity the patients received after septoplasty. Surgical complications include bleeding, adhesion, and infection. The grading scale [8] for the complications is summarized in Table 1. The patients' subjective symptoms include the symptoms during the use of Merocel or the retainer and on removal of Merocel or the retainer, and consist of nasal pain, headache, pressure, nasal obstruction, anterior rhinorrhea, postnasal drip, dysphagia, and sleep disturbance. The severity of each symptom was graded using the visual analog scale (VAS) of 0 (none) to 10 (unbearable) as used previously [2, 6, 7, 9, 10].

Statistical analysis

The data are presented as mean ± standard error of the mean (SEM). Statistical analysis was performed using SPSS version 19.0 (IBM Inc., Armonk, NY, USA). To analyze the complications of the two treatments, a comparison of the Merocel and retainer groups during the observation period was done by Chi-square test. One-way analysis of variance (ANOVA) was used to determine the statistical significance of the subjective symptom comparisons. A P value < 0.05 was considered to be statistically significant.

Table 1 Grading scale for bleeding, adhesion, and infection after removal of Merocel/nasal septal retainer (see [6])

Grading scale	Specific description
Bleeding	
0	No bleeding
1	Minimal (confined to nasal cavity)
2	Moderate (bleeding out of nasal cavity)
3	Severe (required repacking)
Adhesion	
0	No adhesion
1	Mild (easy to detach)
2	Moderate (hard to detach)
3	Severe (required synechiolysis)
Infection	
0	No infection
1	Mild
2	Moderate (granulation)
3	Severe (perforation)

Table 2 Visual analog scale (VAS) scores [mean ± standard error of the mean (SEM)] during the use of Merocel or the retainer

	Mean VAS score	
	Merocel group	Nasal septal retainer group
Nasal pain	5.68 ± 1.31	3.15 ± 0.54
Headache*	5.88 ± 1.11	2.87 ± 1.15
Nasal obstruction*	9.65 ± 0.56	4.11 ± 1.32
Epiphora*	4.92 ± 1.58	1.78 ± 0.86
Nasal itching	3.13 ± 1.01	1.11 ± 0.39
Facial pressure*	6.20 ± 1.91	2.13 ± 0.84
Rhinorrhoea	4.10 ± 1.51	2.41 ± 1.37
Postnasal drip	4.14 ± 1.26	4.47 ± 1.22
Dysphagia	4.47 ± 1.24	3.10 ± 1.45
Sleep disturbance	5.98 ± 1.28	3.30 ± 0.98

*$P < 0.05$, statistically significant

Results

Between March and August 2018, 39 patients were included in this study. Of these, 28 were male and 11 female with ages ranging from 18 to 64 years. In the Merocel group (13 males and 4 females), the age of the patients ranged from 25 to 63 years with an average of 36 years (36.0 ± 10.3 years). In the retainer group (15 males and 7 females), the age of the patients ranged from 18 to 64 years with an average of 34 years (34.3 ± 9.9 years). There was no statistically significant difference in age or gender between the two groups.

All of the patients completed the evaluation on the subjective severity of symptoms and there was no follow-up loss until 3 months after surgery. During the use of Merocel or the retainer, no additional packing was required in either group to control bleeding. The mean VAS scores of headache (2.87 ± 1.15), nasal obstruction (4.11 ± 1.32), epiphora (1.78 ± 0.86), and facial pressure (2.13 ± 0.84) in the retainer group were significantly lower than in the Merocel group (5.88 ± 1.11, 9.65 ± 0.56, 4.92 ± 1.58, and 6.20 ± 1.91, respectively, $P < 0.05$) (Table 2). Although the mean scores of nasal pain, nasal itching, rhinorrhea, dysphagia, and sleep disturbance in the retainer group were lower than in the Merocel group, these differences did not reach statistical significance. These data indicate that the retainer may improve most postoperative discomfort symptoms in patients undergoing septoplasty, and treatment with a retainer is effective and superior to Merocel packing.

On the removal of Merocel/retainer, the score of nasal pain was significantly higher in the Merocel group. In the retainer group, the average VAS score of pain was 2.25 ± 0.49, whereas it was 5.25 ± 0.95 in the Merocel group ($P < 0.05$). In the retainer group, 10 cases showed grade 1 bleeding (45.5%), and 12 cases had grade 0 bleeding (54.5%). In the Merocel group, 4 cases presented grade 2 bleeding (23.5%), 8 cases grade 1 (47.1%), and 5 cases grade 0 (29.4%) (Fig. 3). There were no cases of grade 3 bleeding in either group. In the Merocel group, a local adhesion was observed in 1 case during the follow-up and this was resolved with a simple intervention. No septal hematoma or local infection was observed until 3 months after surgery (Fig. 4).

In terms of medical expense, we compared the cost of Merocel and the nasal septal retainer. The unit prices for Merocel and the nasal septal retainer are 136 and 630 RMB, respectively. Usually, a piece of Merocel is inserted into each nasal cavity after septoplasty. So the costings of Merocel nasal packing and the nasal septal retainer are 272 and 630 RMB, respectively. NasoPore, a high-expansion absorbable

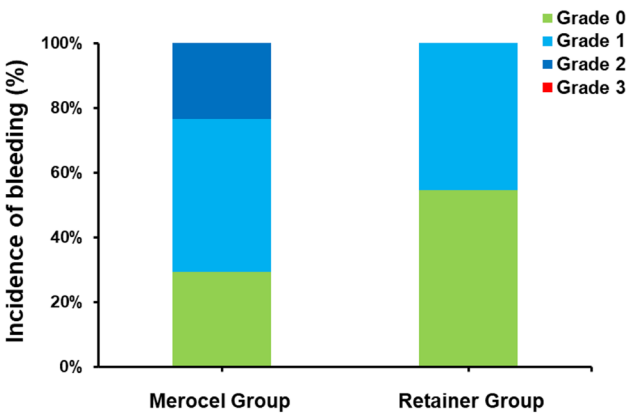

Fig. 3 Incidence and grading of bleeding on removal of Merocel/retainer in the Merocel and nasal septal retainer groups

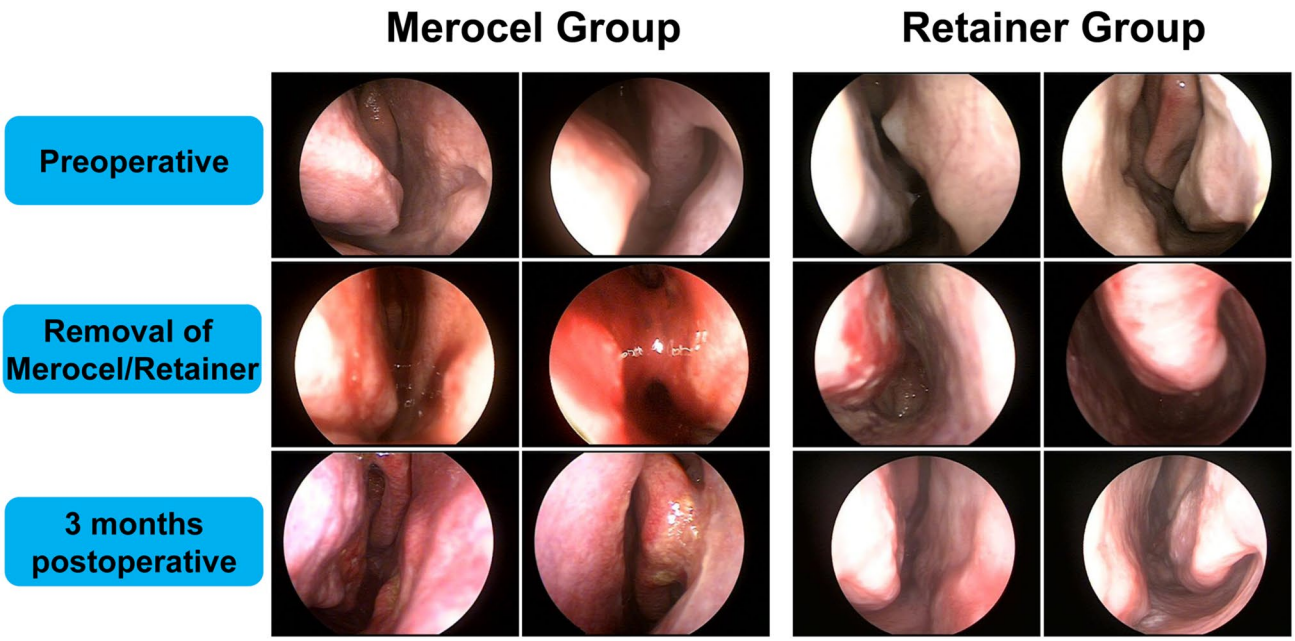

Fig. 4 Nasal endoscopy with a 0° nasal endoscope before surgery, after removal of Merocel/retainer, and 3 months after surgery. Representative images of endoscopy from patients in the Merocel and nasal septal retainer groups

material, is rarely used because of its costly price. In addition, the cost of sutures is very low and can be ignored.

Discussion

In the present study, our findings have preliminarily shown that the application of a nasal septal retainer in septoplasty is safe and effective. The purposes of nasal packing after septoplasty are to control bleeding, fix the elevated mucoperiosteal flaps, and prevent synechia formation and septal hematoma [11]. Unfortunately, complications caused by nasal packing, such as pain, septic shock syndrome, Eustachian tube dysfunction, middle ear effusion, and obstruction of the larynx, have been reported by many otolaryngologists [6, 7, 12, 13]. Although a variety of new packing materials have emerged to minimize morbidities, one shortcoming of nasal packing is unavoidable, namely, nasal obstruction. Nasal packing materials occupy the whole nasal cavity and obstruct nasal respiration. The direct and immediate discomfort is severe pain that patients experience while the packing is in place [1, 8, 14, 15]. However, the nasal septal retainer can exert an adjustable centripetal pressure on the elevated mucoperiosteal flaps without the support of the lateral nasal wall, and it also maintains nasal ventilation. This mode of action does not require all of the nasal cavity space and allows nasal breathing after surgery. This is the probable mechanism by which the retainer may relieve the headaches, nasal obstruction, epiphora, and facial pressure that are experienced by patients with nasal packing.

The smaller the contact area between the packing materials and the nasal mucosa, the easier it is to avoid complications. During nasal packing, Merocel is in contact with the mucosa of the nasal septum, lateral nasal wall, the bottom of the nasal cavity, and the olfactory area. The packing in these areas may obstruct the ciliated epithelial cells by 50–68%, which can affect mucociliary transport and olfactory sensation. As the Merocel is removed, there is a transient negative pressure in the nasal cavity, and friction between Merocel and the nasal mucosa increases. Accordingly, pain during pack removal is the most troubling complication [11]. In this study, the retainer only came in contact with a small portion of the nasal septal mucosa. Before removal of the retainer, the pressure between the blades had been released by loosening, so friction between the retainer and the corresponding nasal mucosa was very low. In addition, after placing the retainer, the space remaining in the nasal cavity offers the possibility for treatment and nursing of the cavity with nasal spray therapy or nasal irrigation.

Nasal packing exposes the patients to the risk of airway obstruction during anesthetic resuscitation [1]. Mouth breathing causes the jawbone to move closer to the anterior pharyngeal wall, and the tongue and hyoid to move backwards and narrow the pharynx [1]. Therefore, nasal packing constrains respiration during sleep and may reduce nocturnal arterial oxygen pressure levels [1]. Hypoxia is more severe in patients with packing because mouth-breathing is

insufficient, especially during sleep and anesthetic resuscitation. The use of the retainer may reduce the risk of respiratory distress related to anesthesia, even though it was not observed in our two groups of patients.

Trans-septal suturing and septal splints, as alternatives to nasal packing, are well-known in septoplasty [3, 16]. The early literature showed that trans-septal suturing was very effective and associated with less postoperative pain [1, 15, 17]. However, trans-septal suturing also has complication risks such as hematoma formation, blood oozing, and nasal obstruction with blood clots, particularly in a narrow nose [16]. It is also technically difficult in septoplasty using the available devices. It has been reported that the mean total operative time using septal suturing is about 43 min, and the mean time for closure with septal suturing is about 7 min [18]. Controversy surrounds the use of septal splints. It has been reported that using a septal splint could increase postoperative pain [19]. Cook et al. showed that there are no clear advantages to inserting intranasal splints [20]. Some septal splints need to be fixed with trans-septal sutures [21] and it is inconvenient to remove the splints. In the present study, the time required for placement of the retainer was less than 10 s. Sutures have a negligible cost. The medical expenses for Merocel and the nasal septal retainer are comparable, both of which are covered by the social health insurance in China.

Although the retainer showed better clinical efficacy than nasal packing, the results of observations in this study were limited to the selected patients. There are some limitations in the present study. More research is needed to elucidate the indications and complications of the application of the retainer, and the effect of systemic disease on bleeding. In addition, complete hemostasis during the operation is very important. The most likely site of bleeding is the front end of the nasal septum, approaching the foramen incisivum. If the deviation in this area needs to be corrected, it is important to ensure that there is no active bleeding before closing the incision.

Conclusion

In the present study, use of the nasal septal retainer produced a significant reduction in pain and nasal obstruction in patients after septoplasty, and improved the postoperative quality of life of patients. Application of the nasal septal retainer is convenient for topical drug therapy and the nursing care of patients undergoing nasal septum surgery or rhinoplasty.

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Compliance with ethical standards

Conflict of interest The authors declare that they have no conflict of interest.

Informed consent Informed consent was obtained from all individual participants included in the study.

Ethical approval All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki Declaration and its later amendments or comparable ethical standards.

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