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Effectiveness of a modified endonasal splint in the prevention of pathogenic microflora after septoplasty: a comparative microbiological research study

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Abstract: The use of endonasal splints in septoplasty has been extensively discussed in the literature in recent years. There are different types of splints, each with its own advantages and disadvantages. The results of surgery can vary considerably depending on the type of splint chosen and the methods of its application. This article discusses the effectiveness of a modified endonasal splint in preventing pathogenic microflora in the postoperative period, as well as possible complications.

Septoplasty is a common operation aimed at correction of nasal septal deformity. However, in the early postoperative period, patients face the risk of synechiae development, accumulation of blood and secretion in the nasal cavity, which creates favorable conditions for the growth of pathogenic microflora. Traditional nasal splints limit the natural drainage of the nasal cavity, contributing to stagnation of secretions. A modified endonasal splint with a central removable airway was developed to improve nasal hygiene by simplifying cleaning and reducing exudate accumulation. The aim of the study was to evaluate the effect of this splint on the dynamics of nasal cavity microflora in comparison with the traditional analogue.

Keywords: Septoplasty, endonasal splint, pathogenic microflora, Staphylococcus aureus, postoperative complications.

Introduction: The nasal cavity is a complex ecosystem colonized by diverse commensal microflora, which plays a key role in maintaining homeostasis and protecting against pathogens. Normally, the dominant microbiome representatives are Staphylococcus epidermidis and Staphylococcus nasalis, which compete with opportunistic microorganisms for resources, synthesize bactericides, and modulate the immune response. [1, 2]. This symbiosis, known as colonial resistance, is disrupted by injuries, surgical interventions, or the use of foreign materials, creating conditions for the proliferation of pathogens such as Staphylococcus aureus. [3]

Septoplasty aimed at correcting the deformation of the nasal septum is accompanied by the risk of formation of synechiae and accumulation of hemorrhagic exudate. Traditional endonasal splints used to prevent scarring restrict aeration and drainage, which exacerbates dysbiosis and increases the likelihood of bacterial superinfection. [4] The introduction of a modified splinter with a central removable air duct aims to minimize these risks by improving ventilation and simplifying nasal sanitation.

Endonasal splints are medical devices used to maintain the correct position of the nasal septum after surgical correction, prevent nasal mucous membrane adhesions, and reduce the risk of bleeding. They provide mechanical support for tissues, which contributes to their proper healing, reduces inflammatory reactions, and reduces pain in patients during the first days after surgery. However, despite the widespread use of splints, their application remains a subject of debate among specialists, as they are not always necessary, and their installation and removal can cause discomfort in the patient [2,6].

The use of endonasal splints in the practice of septoplasty has been actively discussed in the literature in recent years. There are several types of splines, each of which has its advantages and disadvantages. Depending on the choice of splinter type and its application methods, the results of the operation can differ significantly.

In this study, we will examine the existing types of endonasal splints, as well as their effectiveness in the postoperative period and complications. Additionally, modern clinical recommendations for using splints will be analyzed and discussed for their further development prospects.

The useful model relates to medicine, specifically otorhinolaryngology, and can be used to fix the nasal septum and prevent postoperative complications after submucosal nasal septal resection. The tire contains a crescent-shaped silicone plate with an air duct (1) placed in the center.

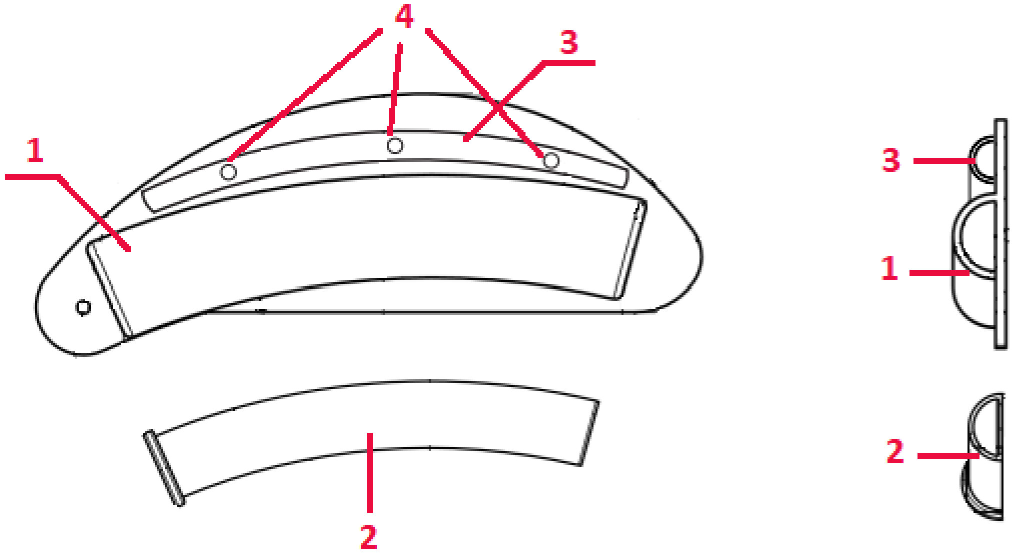

Figure-1

The central air duct is supplied of the same shape separated from the inside by a cavity (2), which in turn is made of medical polyvinyl chloride, entering 1 cm from the edge of the plate facing the nasal vestibule.

Above the central air duct, there is a groove (3) of the same shape, which has 3 openings (4) located at the same distance from each other and facing the nasal sinuses.

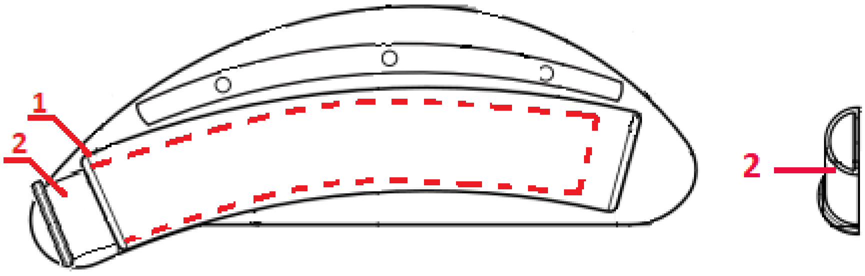

Figure-2

The groove (3) located above the central air duct has an opening (5) facing the nasal vestibule for administering medications through a syringe. The administered drug enters the nasal cavity through three openings (4) located in the lateral projection. The side openings are located at equal distances from each other and allow the administered drug to be distributed evenly throughout the nasal cavity, regardless of if it is contaminated with sputum or blood clots.

The use of the utility model ensures improved postoperative tissue cleansing and prevents postoperative complications due to the accumulation of sputum and blood clots in the separated lunate cavity (2) located inside the central air duct (1). Due to this, during cleaning, all accumulated sputum and blood clots will be expelled along with the newly added lunate cavity (2), ensuring easy and painless cleaning of the central air duct (1).

The utility model used in otorhinolaryngology is designed to fix the nasal septum and prevent complications after surgery to remove a portion of the nasal mucosa. In 1905, Killian and Freer independently developed a method for submucosal resection of the nasal septum. However, using conventional gauze tampons to stop bleeding after surgery led to difficulty breathing. Other complications included the formation of abscesses, hematomas, and even perforation of the nasal septum.

Purpose of the research

The purpose of the study is to assess the influence of a modified splinter (Uzbekistan Republic patent for utility model FAP No2629) on the dynamics of nasal microbiome compared to standard devices using quantitative microbiology and statistical analysis methods.

METHODS

Prospective Randomized Controlled Inquiry (RIC) with Double Blind Design [5]. 100 patients were participated (18-45 years old), divided into two groups: main group (n=50) and comparison group (n=50).

A central removable air duct made of biocompatible material is integrated into the classic silicone busbar. A central removable air duct made of biocompatible material is integrated into the classic silicone busbar. The possibility of removing the air duct for cleaning the nasal cavity without removing the entire tire. Reducing mucosal trauma due to smooth edges of the structure. Maintaining constant ventilation, minimizing swelling.

Patients of both groups received the same drug therapy (topical corticosteroids). The main group: daily nasal flushing through a detachable air duct. Standard care with tire removal on the 3rd day for sanitation. SNOT-22 questionnaire (Sino-Nasal Outcome Test), validated for assessing rhinosinusitis symptoms and quality of life. Total score (0-110), where the lower value corresponds to the better state. Assessment periods were 1, 3, and 7 days after surgery.

The data were processed in SPSS 26.0 using Student's t-test. Significance level - $p < 0.05$.

RESULTS AND DISCUSSION

SNOT-22 score dynamics:

Parameter	Main group (n=50)	Comparison group (n=50)	p-value
Day 1	42.1 ± 5.2	43.5 ± 4.8	>0.05
Day 3	28.3 ± 4.1	38.9 ± 5.6	<0.01
Day 7	18.4 ± 3.1	34.6 ± 4.8	<0.01

Table 1

The removable air duct made it possible to avoid repeated tire manipulations, which in the comparison group caused microtraumas of the mucous membrane and increased swelling. Daily flushing through the air duct reduced the accumulation of fibrin and crusts - key factors of inflammation. Patients in the main group noted less stress associated with care, which indirectly affected the recovery rate. Individual anatomical features (for example, narrow nasal passages) were not taken into account. Absence of long-term observation (more than 1 month).

Key differences in symptoms (7th day) nasal congestion in main group was 1.2 ± 0.4 points. In comparison group was 3.8 ± 0.7 points. Headache in main group was 0.9 ± 0.3 points and comparison group were 2.4 ± 0.6 points.

Sleep disturbance in main group was 1.1 ± 0.2 points and comparison group were 2.9 ± 0.5 points.

Microbiological analysis

Sterile swabs from the middle nasal sinuses were investigated (day 0 and day 14) [7]. Cultivation was done on blood agar and cups of Mannit salt agar (MSA) for the selection of S. Aureus [8]. Comparison of S. aureus colonization frequency: Pearson's χ2 criterion for conjugate tables [10]. Relative risk (RR) with 95 % confidence interval (CI) [11]. Comparison of average values of CFU/ml, Odd Student's t-test for independent were did [12]. Evaluating the effect was through the difference in averages (Cohen's d) [13].

Initial microbiome (day 0):

Commensal microflora was dominant in all patients, Staphylococcus epidermidis was 100% (EC/ml: 10^3-10^4, SD=0.2×10^4). Staphylococcus nasalis: 94% (47/50 in both groups; CFU/ml: 10^2-10^3, SD=0.1×10^3).

Microbiome dynamics on day 14:

Parameter	Main group (modified spline)	Control group (standard spline)
S. aureus colonization	4% (2/50)	68% (34/50)
Average S. aureus CFU/ml	$0{,}1 \times 10^2$ (SD= $0{,}3 \times 10^2$)	$2{,}5 \times 10^3$ (SD= $1{,}1 \times 10^3$)
Restoration of normal flora	96% (48/50)	32% (16/50)

Table – 2

Frequency of S. aureus colonization:

	S. aureus (+)	*S. aureus* (-)	Total
Main group	2	48	50
Control group	34	16	50

Table - 3

χ2 CRITERIA:

$$X^2 = \sum \frac{(O-E)^2}{E} = 44.44 (P < 0.001)$$

p <0.001 means that the probability of randomly obtaining such data is less than 0.1% (provided the null hypothesis is true). This is a very high significance. The result allows us to reject the null hypothesis (for example, about the absence of a relationship between variables).

Relative risk (RR):

$$RR = \frac{GROUP\ EXPOSURE\ RISK}{RISK\ NOT\ EXPOSED\ TO\ THE\ GROUP} = \frac{\frac{a}{a+b}}{\frac{c}{c+d}}$$

where:

- a - the number of people with outcomes in the exposed group,
- b - the number of people with no outcome in the exposed group,
- c - the number of people with outcomes in the main group,
- d - the number of people with no outcome in the main

group.

$$RR = \frac{\frac{34}{50}}{\frac{2}{50}} = 17.0\ (95\%TI: 4.3 - 68.3)$$

- *RR = 1:* there is no risk difference between the groups.
- *RR> 1:* Outcome risk is higher in the exposed group (for example, smoking increases the risk of cancer).
- *RR <1:* Outcome risk is lower in the exposed group (for example, vaccination protects against disease).

Student's t-test:

$$t = \frac{0.1 * 10^2 - 2.5 * 10^3}{\frac{\sqrt{(0.3 * 10^2)^2}}{50} + \frac{\sqrt{(1.1 * 10^3)^2}}{50}} = -15.4(p < 0.001, df = 98)$$

t-statistic value (t = −15.4)

t-statistics show how strongly the average values of the two groups differ in relation to data variability within the groups. Negative value indicates the direction of the effect, if the main group and the comparison group were compared, the average value of the main group was lower than the average value of the comparison group. The quantity |t| = 15.4 is a very large value, which indicates a strong statistical effect. |t|> 2 is usually considered significant at a level of α = 0.05, |t|> 3 - extremely significant. p-value - the probability of obtaining one or more extreme results if the null hypothesis is true (i.e., if there is actually no difference between the groups). • p <0.001 means that the probability of randomly obtaining such data is less than 0.1%. This is the highest degree of statistical significance. We reject the null hypothesis (groups differ significantly).

Effect size (Cohen's d):

$$d = \frac{M_1 - M_2}{\sqrt{\frac{{SD_1}^2 - {SD_2}^2}{2}}} = 2.8(Major\ effect)$$

Commensal staphylococci (S. epidermidis, S. nasalis) compete with S. aureus for resources by secreting antimicrobial peptides (for example, lantibiotics). In the control group, the use of standard splints led to a decrease in the proportion of S. nasalis from 94% to 32%, which correlated with the growth of S. aureus (68%). Conversely, in the main group, the preservation of normoflora (96%) ensured the ecological suppression of the pathogen (4% of colonization).

CONCLUSION

A modified endonasal splint with a central air duct demonstrated a statistically significant decrease in the frequency of Staphylococcus aureus colonization (χ2=44.44, p <0.001) and the level of bacterial load (t=15.4, p <0.001) compared to standard analogues. Analysis of the relative risk (OR=17.0, 95% CI:4.2-68.3) and the magnitude of the effect (Cohen's d=2.8) emphasizes the clinical relevance of the intervention.

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