



CLINICAL STUDY

ASSESSMENT OF IDEAL DURATION OF INTRANASAL SPLINT USE AFTER SEPTOPLASTY: A PROSPECTIVE RANDOMIZED CLINICAL STUDY

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SUMMARY

Amaç: Literatürde ideal nazal splint çıkarma zamanı konusunda fikir birliği yoktur ve bu konuda sadece birkaç randomize prospektif çalışma yapılmıştır. Çalışmamız hasta memnuniyeti, koku alma fonksiyonu, mukosilyer aktivite, nazal hava akımı ve komplikasyon oranlarını karşılaştırarak septal cerrahi sonrası ideal nazal atel kullanım süresini bulmayı amaçlamıştır.

Yöntemler: Septoplasti operasyonu geçiren hastalar nazal splint çıkarma sürelerine göre rastgele üç gruba ayrıldı. Grup 1, 2 ve 3'te ameliyat sonrası üçüncü, beşinci ve yedinci günlerde splintler çıkarıldı. Hasta konforunu görsel analog skala (VAS) ve Nazal Obstrüksiyon Semptom Değerlendirme (NOSE) skorlarını kullanarak değerlendirdik, nazal hava akımı pik nazal inspiratuar hava akımına (PNIF) göre ölçüldü. Mukosilyer aktiviteyi bulmak için sakarin testi ve koku alma fonksiyonunu değerlendirmek için Connecticut Chemosensory Clinical Research Center (CCCRC) koku testi kullanıldı. Erken ve geç komplikasyonlar da değerlendirildi.

Bulgular: Gruplar arasında VAS skoru, PNIF skoru, mukosilyer aktivite veya komplikasyon oranı açısından anlamlı fark yoktu. Nazal dolgunluk değerlerine göre grup 1 diğerlerine göre istatistiksel olarak daha kötü puanlara sahipti, ancak grup 2 ve 3 arasında fark yoktu. Tampon çıkarıldığı gün yapılan koku testinde ise en düşük puan grup 1 de gözlendi.

Sonuç: Literatürde septoplasti sonrası burun içi atellerin ne kadar süre kullanımda kalması gerektiği konusunda bir fikir birliği yoktur. Biz çalışmamızda koku testinde ve NOSE skorlarında grup 1 de alınan kötü sonuçlar nedeniyle septoplasti sonrası erken dönemde özellikle üçüncü gün ve öncesinde nazal splintlerin çıkarılmasını önermemekteyiz.

Keywords: Septoplasty, nasal splint, patient comfort

SEPTOPLASTİ SONRASI İDEAL İNTRANAZAL SPLİNT KULLANIM SÜRESİNİN DEĞERLENDİRİLMESİ: PROSPEKTİF RANDOMİZE KLİNİK ÇALIŞMA ÖZET

Aim: In the literature, there is no consensus about the ideal nasal splint removal time, and only a few randomized prospective studies on this subject have been conducted. Our study aimed to find the ideal duration for nasal splint use after septal surgeries by comparing patient satisfaction, olfactory function, mucociliary activity, nasal airflow, and complication rates.

Methods: Patients undergoing a septoplasty operation were randomly divided into three groups, defined by their nasal splint removal time. Splints were removed on the third, fifth, and seventh postoperative days in groups 1, 2, and 3, respectively. We evaluated patient comfort using visual analog scale (VAS) and Nasal Obstruction Symptom Evaluation (NOSE) scores, while nasal airflow was measured according to the peak nasal inspiratory air flow (PNIF). The saccharine test was used to find the mucociliary activity, and the Connecticut Chemosensory Clinical Research Center (CCCRC) odor test was used to assess olfactory function. Early and late complications were also assessed.

Results: There were no significant differences among the groups in terms of VAS score, PNIF score, mucociliary activity, or complication rate. Regarding the nasal fullness values, group 1 had statistically worse scores than did the others, but there were no differences between groups 2 and 3. Another significant difference was observed for the odor test on tampon removal day, with group 1 having the lowest scores.

Conclusion: There is no consensus about how long intranasal splints should remain in use after a septoplasty. However, we do not recommend splint removal on the third day and before after a septoplasty, as the worst odor results and NOSE scores were seen in group 1.

Anahtar Sözcükler: Septoplasti, nazal splint, hasta konforu

INTRODUCTION

In otolaryngological practice, septoplasty is one of the most common surgical procedures,

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and it can be used alone or in combination with sinus surgery and rhinoplasty surgery. Nasal tampons are often preferred by surgeons after a septoplasty to control bleeding and prevent hematomas, perforations, and intranasal synechiae.^{1,2} The nasal tampon materials that are used after septal surgery include polyvinyl acetate (Merocel), biodegradable synthetics, polyurethane foam (BSPF NasoPore), Vaseline-impregnated gauze bandages, and intranasal splints.^{3,4}



Despite their advantages, it is known that intranasal splints-which are used as nasal tampons-cause discomfort in patients and cause pain and bleeding during removal.^{5,6} The ideal time at which nasal tampons and intranasal splints should be removed is still controversial. Without a consensus in the literature, it has been observed that the length nasal splint use varies between one and seven days.^{7,8} As such, in the current study, we aimed to find the ideal duration of nasal splint use by comparing patient satisfaction, olfactory function, mucociliary activity, nasal airflow, and complication rates according to splint removal time.

MATERIAL and METHODS

Subjects

This study was carried out prospectively in a tertiary otorhinolaryngology clinic from January 2018 to January 2019. Ethics approval was received from the local ethics committee (date: 2018; no. 10). Written informed consent was obtained from each patient participating in the study. In total, 84 patients undergoing a septoplasty operation due to nasal septum deviation were included. Patients with chronic sinusitis, nasal polyps, a concha pathology, or systemic disease were excluded from the study. All patients underwent detailed otorhinolaryngologic examinations, and the septal deviations of the patients were classified according to the criteria published by Rao et al.⁹

The study's power analysis and sample size calculation were performed using the G*Power software, version 3.1.6 (Heinrich-Heine-Universität Düsseldorf, Düsseldorf, Germany). For an effect size of 0.4 and alpha error probability of 0.05, a minimum of 28 patients per group was required to ensure a study power of 90%. Patients were randomly divided into three groups, defined by the nasal splint removal time. A computer-generated randomization allocation table was used to determine the groups. Splints were removed on the third, fifth, and seventh postoperative days in groups 1, 2, and 3, respectively, and each group consisted of 28 patients.

Surgical procedures

All patients were operated on under general anesthesia by the same surgeon (O.B.). Preoperatively, 2 ml of 1% lidocaine hydrochloride (HCL) and epinephrine (1:100,000) were used for local hemostasis, by injection into the caudal septum. After a right Killian incision, the septal mucoperichondrial flaps were elevated. The deviated septal cartilage and bony deviations of the vomer and ethmoid perpendicular plate were removed. The incision was sutured with 3-0 absorbable sutures (VICRYL RAPIDE; Ethicon Inc., Brunswick, NJ, United States). Nasal splints (Doyle Intranasal Airway Splint; Medtronic, Minneapolis, MN, United States) were placed each side of the nasal cavity and fixed to the septum with 3-0 non-absorbable sutures (Prolene; Ethicon Inc., Brunswick, NJ, United States). All patients were given 1 g ampicillin/sulbactam intravenously during surgery and a 300 mg cefdinir tablet daily for 7 days after surgery.

Measurements

The visual analog scale (VAS) was used to assess patients' pain before the removal of the splints in all three groups (0-10, with 0 indicating no pain and 10 indicating severe pain). The Nasal Obstruction Symptom Evaluation (NOSE) was used to measure the severity of the nasal obstruction symptoms experienced by the patients. The scale's 5 questions were scored on a 5 -point scale according to the level of complaint (4 = severe, 3 = moderate, 2 = mild, 1 = minimal, and 0 = absent).¹⁰ The NOSE was done preoperatively and at two days after the removal of the nasal splints.

A saccharin test was used to evaluate the nasal mucociliary clearance time. The test was performed in both nasal cavities, and the two values were averaged.¹¹ The test was applied preoperatively, on the nasal splint removal day, and at two months after the operation. Specifically, the test was performed while patients were in the sitting position; a quarter of a saccharine tablet was placed 1 cm medially and posteriorly into the anterior attachment of the inferior concha. The test carried out at an environment free of dust or breezes, and the



patients were told not to bend their heads forward, to sneeze, or to sniff. The time when the patients felt the taste was recorded.

The peak nasal inspiratory flow (PNIF) measurement was done using a Youlten PNIF meter (Clement Clarke International Ltd., Harrow, United Kingdom) to assess the nasal obstruction level in the preoperative period, on the nasal splint removal day, and at two months after the operation. The PNIF measurement was performed with masked peak flow meter covering the nose and mouth of the patients after 15 minutes of resting while in a sitting position. Each patient was told to exhale deeply and, after the mask was applied, to inhale quickly and deeply through the nose. This activity was repeated three times, and the highest value obtained was recorded. The results were shown in liters per minute (L/min).¹²

We also investigated the effect of nasal splint use duration on odor function. The Connecticut Chemosensory Clinical Research Center (CCCRC) test was applied to this end, which consists of a butanol threshold test and odor identification test; an average value of the two tests was obtained and accepted as the final result (normosmic: 6.00-7.00, mildly hyposmic: 5.00-5.75, moderately hyposmic: 4.00-4.75, severely hyposmic: 2.00-3.75, anosmic: 0-1.75).¹³ A locally validated CCCRC odor test was performed for each patient in the preoperative period, on the nasal splint removal day, and at two months after the operation.

Finally, complications were divided into two groups: complications seen in the first two months after the operation were identified as "early complications," while those occurring beyond this point were identified as "late complications."

Statistical analysis

SPSS 15.0 for Windows (IBM, Armonk, NY, United States) was used for the statistical analysis. The descriptive statistics analyzed included the number and percentage for categorical variables, and the mean, standard deviation (SD), minimum, maximum, and median for numerical variables. A one-way analysis of variance (ANOVA) test was used for the comparison of numerical variables in two

independent groups under normal distribution conditions. The Kruskal-Wallis test was used when no normal distribution condition was observed. The Mann-Whitney U test was used for subgroup analyses, and these results were interpreted using the Bonferroni correction. Ratios of the groups were compared using chi-squared analyses. The statistical significance level (alpha) was accepted as $p < 0.05$.

RESULTS

In this study, there were 20 male and 8 female patients in group 1, who had a mean age of 31.3 ± 11.1 years. Group 2 consisted of 19 male and 9 female patients, with a mean age of 31.7 ± 11.2 years. Last, group 3 consisted of 18 male and 10 female patients, with a mean age of 33.7 ± 9.8 years. There was no significant difference between the groups in terms of age or gender ($p = 0.420$, $p = 0.145$). There was no significant difference in septum deviation types between the groups ($p = 0.054$). There was also no significant difference between the three groups in terms of VAS score ($p > 0.05$) or PNIF ($p > 0.05$) score, as shown in Table 1. A substantial improvement was observed in the patients' PNIF scores after surgery, compared to the preoperative period.

The NOSE results of group 1 were statistically higher than those of group 2 ($p = 0.005$) and group 3 ($p = 0.026$). However, there was no difference statistically between group 2 and group 3 ($p = 0.487$). Group 1 had the worst scores related to nasal fullness (Table 2). There was no statistically significant difference in the saccharine test scores between the three groups. It was observed that the saccharine test time was longer on nasal tampon removal days, and the mucociliary clearance improved at the long-term control (Table 3).

There was no statistically significant difference in the preoperative and two-month control of the odor test results between the three groups. The only statistically significant difference in relation to the odor test was found in that performed on the tampon removal day ($p = 0.002$); the relationships between group 1 and group 2 ($p = 0.002$) and between group 1 and group 3 ($p = 0.001$) were significant. Group 1 had the lowest scores overall (Table 4).



There was no statistically significant difference in the complications observed among the three groups. In terms of early complications, a septal hematoma was detected in 1 patient in group 1, but this complication was not observed in any patients in the other groups. The patient with the hematoma was given parenteral antibiotic therapy, and the hematoma was

drained. Early bleeding was seen one patient in each group, but treatment with tampons was not required. In terms of late complications, synechiae were observed in 2 patients, one in group 1 and one in group 2, while septal perforation was observed only in group 1.

Table 1. Peak nasal flows.

	Group 1	Group 2	Group 3	
PNIF*	Avg. ± SD	Avg. ± SD	Avg. ± SD	p
Preoperative	87.6 ± 28.1	93.1 ± 31.5	76.2 ± 26.2	0.074
Nasal tampon removal day	93.6 ± 42.1	110.7 ± 28.8	109.7 ± 42.8	0.148
Two-month control	117.9 ± 37.1	126.4 ± 42.2	116.2 ± 33.6	0.775

*PNIF: peak nasal inspiratory flow, L/min.

Table 2. Obstruction scale.

	Group 1	Group 2	Group 3	
NOSE*	Avg. ± SD	Avg. ± SD	Avg. ± SD	p
Preoperative	69.4 ± 24.6	68.7 ± 20.8	70.2 ± 20.4	0.896
Postoperative	32.0 ± 23.7	28.1 ± 23.5	45.8 ± 24.1	0.011

*NOSE: Nasal Obstruction Symptom Evaluation.

Table 3. Mucociliary activity.

	Group 1	Group 2	Group 3	
STS*	Avg. ± SD	Avg. ± SD	Avg. ± SD	p
Preoperative	12.1 ± 8.0	10.9 ± 6.9	9.7 ± 5.0	0.521
Nasal tampon removal day	19.8 ± 17.6	16.7 ± 11.6	18.9 ± 12.3	0.790
Two-month control	10.1 ± 7.2	11.9 ± 9.1	13.9 ± 14.9	0.133

*STS: saccharine test score, min.



Table 4. Olfactory function.

	Group 1	Group 2	Group 3	
CCCRC* odor test	Avg. ± SD	Avg. ± SD	Avg. ± SD	p
Preoperative	5.88 ± 1.33	5.79 ± 1.04	5.92 ± 1.07	0.814
Nasal tampon removal day	5.74 ± 2.04	6.87 ± 0.57	6.94 ± 0.22	0.002
Two-month control	6.87 ± 0.48	6.94 ± 0.22	6.83 ± 0.51	0.702

*CCCRC: Connecticut Chemosensory Clinical Research Center.

DISCUSSION

There is no consensus in the literature on the ideal removal time for nasal splints, and only a few randomized prospective studies have been done on this subject that include the assessment of patient comfort and complications. As such, unlike other prospective studies, the current study examined mucociliary clearance, nasal airflow, and olfactory functions to achieve an ideal nasal splint removal time.

While we could not identify a significant difference between the groups in the assessment of VAS scores, the results in group 1 related to nasal fullness were found to be worse than those of the other groups. There are various opinions in the literature regarding pain and nasal fullness scores in connection with nasal splints. We think that the poor result in NOSE scores is due to the edema seen in the early surgical period and early removal of the splint cannot prevent this edema. For example, Lubianca-Neto et al. reported that patient discomfort and postoperative pain were lower in the 24-hour nasal splint removal group compared to the 48-hour nasal splint removal group.¹⁴ Karatas et al. analyzed the effect of nasal splint removal at the fifth, seventh, and tenth day after surgery; they reported a significant increase in the VAS pain scores in the first three days after splint removal and a decrease after the third day in all groups.¹⁵ Ozdogan et al. found no significant difference in the pain and nasal fullness levels among the groups they studied.¹⁶ In an analysis of 106 cases, Campbell et al. found an increase in postoperative pain and a decrease in nasal

synechiae in the group whose nasal splints were removed on the seventh day after surgery.¹⁷

In patients with a deviated nasal septum, the mucociliary clearance time is prolonged due to cilia loss and seromucinous gland decline on the concave side.¹⁸ It has been thought that septoplasty may have a positive effect on mucociliary clearance time but that nasal splint use may cause mechanical trauma to the nasal mucosa, thereby decreasing cilia levels and, hence, having a negative effect on the mucociliary clearance time.¹⁹ One study reported that early postoperative results should be evaluated to investigate the effect of nasal splint use on olfactory function and ciliary activity.²⁰ In another study, transseptal suturing and nasal splint use were compared, and no difference was found in relation to mucociliary clearance time or olfactory function.²¹ In the current study, while there was no significant difference in the saccharin test levels between the groups, it was observed that the long-term results were better than those seen in the early period following surgery.

Dösen et al., in their study examining the results of septum surgery, observed that the bilateral PNIF results improved in the postoperative period.²² In our study, a significant increase was observed in the postoperative PNIF results, but no significant difference was found between the groups. Further, on the day of splint removal, we observed that the olfactory function results in group 1 were worse than those in the other groups, but there was no difference between the groups in the long-term results.



Various opinions have been reported in the literature regarding the complications that may occur due to nasal splints. In our study, there was no significant differences in the complication rates between the groups. Acar et al. reported biofilm formation on the nasal tampons of septoplasty patients after 48 hours, and this might cause early postoperative infection.²³ In another study, it was concluded that the nasal splint removal period could be extended up to ten days without increasing the risk of early complications; in addition, the patient tolerance results were good and the postoperative late complications were reduced when the nasal removal period was extended.¹⁵ Aksoy et al. could not find any difference between the first- and fifth-day splint removal groups in terms of complications, and they recommended early splint removal due to patient comfort results.⁷ Another study found no significant difference in the complication rates or patient comfort results between the third-, fifth-, and seventh-day nasal tampon removal groups, and they suggested nasal tampon removal on the fifth postoperative day as their clinical routine.¹⁶

CONCLUSION

As supported by the literature, we conclude that early postoperative results are more useful in determining the optimal nasal tampon removal time and in observing the effect of nasal tampon use. Early removal of the splint is important for patient comfort. However, it is thought that the reason for the worst odor results and NOSE scores to be seen in the first group is due to the edema observed in the early surgical period. Removing the splint on the 3rd day does not benefit the patient because this edema cannot be prevented when the splints are removed in the early period. Therefore, we do not recommend removing the splint on the 3rd day. Instead, it is recommended to remove the nasal splints on the fifth or seventh postoperative day.

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