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The role of using the submucosal conchoplasty technique for the management of concha bullosa in decreasing the postoperative middle meatus synechia formation after endoscopic sinus surgery: A randomised controlled trial

Short title:

The role of the submucosal conchoplasty technique in improving the postoperative middle meatus outcome after ESS

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Abstract

Objective:

The study aimed to compare the applicability of the classic lateral lamellectomy versus the submucosal conchoplasty techniques in managing the concha bullosa during and after ESS.

Methods:

The study randomly divided fifty-six patients with bilateral concha bullosa into two groups. One group had the submucosal conchoplasty technique, and the other had the lateral lamellectomy technique. The study compared the intraoperative findings, including the time required for each technique, the amount of intraoperative bleeding, and the postoperative endoscopic outcome of the middle meatus and middle turbinate stability.

Results:

Submucosal conchoplasty was significantly more time-consuming than the lateral lamellectomy technique (p-value: 0.001*). The difference in the intraoperative amount of bleeding (p-value: 0.086*). The lateral lamellectomy group showed a higher rate of synechia formation in the middle meatus (p-value: 0.012*).

Conclusion:

Submucosal conchoplasty is a proper technique for managing concha bullosa with better postoperative endoscopic outcomes.

Keywords:

Turbinate, Sinusitis, Endoscopic sinus surgery, Randomised control trials

Introduction:

Concha bullosa is the pneumatization of the middle turbinate. It is one of the most common anatomic variations of the lateral nasal wall after the agger nasi and the deviated septum [1]. Fadda et al. [2] documented a prevalence of 49.3% for concha bullosa; Maru and Gupta3 reported a prevalence of 42.6%, and Bolger et al.[3] showed a prevalence of 53.6% [4].

Large concha bullosa causes a crowded nose and obstruction of the middle meatus, resulting in obstruction of the ventilation and mucociliary drainage of the anterior paranasal sinuses group, including the maxillary, anterior ethmoid, and frontal sinuses. Also, concha bullosa can result in headaches or facial pain seen in the peri-orbital region due to its contact with the septum or the lateral nasal wall [5].

Nevertheless, there is no consensus on which method should be adopted or which side of the concha bullosa should be removed to promote the individuals' nasal and olfactory functions. These methods include crushing the middle turbinate, medial versus lateral laminectomy, or transverse resection [6].

The concept of middle turbinate resection may expose the patient to various complications, including increased postoperative synechia formation. Also, complete middle turbinate resection increases the risk of olfactory affection and atrophic rhinitis making it challenging to identify anatomical landmarks in revision cases [7,8]. Although the classic lateral lamellectomy technique is less traumatic and more conservative than the full-thickness resection, it still has the risk of synechia formation, mostly if done with ESS. While Canon et al. reported no synechia formation during isolated concha bullosa procedures, Dogru et al. reported synechia formation up to 27% when combined with osteo-meatal complex intervention [9].To prevent full-thickness middle turbinate resection complications, the submucosal resection technique,

including removing prominent bone while leaving the overlying mucosa intact, was reported [10].

The study aimed to assess the difference between the lateral lamellectomy and the submucosal conchoplasty techniques for managing concha bullosa regarding operative time, intraoperative applicability, and turbinate stability. We also compared the postoperative endoscopic outcome of both techniques.

Patients and Methods:

A prospective study of fifty-six patients undergoing primary endoscopic sinus surgery for chronic rhinosinusitis (CRSsNP) failed the maximal medical therapy [11]. Participants were gathered from the outpatient clinic at our tertiary care facility between October 2018 and April 2020.

The study included patients above 18 years who were diagnosed with chronic sinusitis based on the 2012 European Position Paper on Rhino-sinusitis and Nasal Polyps's criteria (EPOS 2012) [12] and presented by bilateral concha bullosa (112 operated conchae). We excluded smokers and individuals with polyps, primary ciliary dyskinesia, nasal masses, and revision cases. Sample size calculation was performed using the Kelsey formula [13]. A minimum of one hundred ten operated conchae was required to detect a difference (Alpha 0.05, 80% power) in the rate of postoperative synechia formation, according to the study conducted by Semih Karaketir et al.[9].

All participants in our research provided informed written consent. The study was performed following the principles established in the Declaration of Helsinki with the approval code of the hospital's Ethics Committee MKSU50-9-22

The authors documented the characteristics of the participants'. In addition, the nose and paranasal sinuses were scanned with HRCT before surgery and evaluated using the Lund Mackay score [14].

Surgical procedure:

According to the radiological score, the same surgeon (A.E.) performed primary bilateral endoscopic sinus surgery on all patients, including middle turbinate conchoplasty, middle meatal antrostomy, ethmoidectomy, and frontal sinusotomy with or without sphenoidotomy.

The concha bullosa was operated on at the beginning of the surgery to ease access to the middle meatus using one of two validated approaches, including the submucosal conchoplasty and the lateral turbinectomy techniques. The sample size was divided into two equal groups (28 patients with 56 operated conchae each). One group had submucosal conchoplasty, and the other group had lateral lamellectomy. The method distribution was determined using a computerized block randomization system (Excel sheet randomization). Regarding the submucosal conchoplasty technique, the concha was locally infiltrated with adrenaline with a concentration of 1:200,000. The mucosa was incised by blade 15 starting from the axilla posteriorly up to the attachment with the basal lamella. The mucosa covering the lateral lamella was dissected using the freer dissector. The lateral lamella was removed using a through cut forceps then the mucosa was repositioned. The bony skeleton of the medial lamella was preserved. (Figure 1)

Regarding the lateral lamellectomy technique, the concha was locally infiltrated with adrenaline with a concentration of 1:200,000; the sickle knife was used to open the concha then the scissor was used to remove the lateral lamella with its covering mucosa in one block. (Figure 2)

Multiple intraoperative measurements were considered, including the time of the technique (calculated using the monitor's stopwatch) and the amount of bleeding (calculated using the Fromme Ordinal Scale) [15].

No middle meatus packing was applied. Systemic antibiotics and steroids (0.5 mg/kg prednisolone) were given for two weeks after the surgery. The patients were instructed to use

local nasal irrigations (2 ml of budesonide 0.5 mg/ml mixed with 250 ml of normal saline) two times daily for a month postoperatively. Patients were followed up at the end of each month throughout the-six-month follow-up period.

The study assessed the clinical symptoms before and after the surgery through the Sinonasal outcome test 22. (SNOT 22) [16]. The patient's olfaction was tested using water as a control liquid (colorless and odorless) to exclude malingering and phenyl ethyl alcohol of 90% concentration (colorless and odorous). The solutions were placed in separate bottles and numbered 1 and 2. Both the examiner and the patients were unaware of the nature of the liquids within the bottles. A visual analoge score (VAS) was used for olfaction assessment ranging from grade (1 - 10). The patients were instructed to assign a score of (1) if they could not smell the odour at all and a score of (10) if they could smell the odour clearly. This examination test was done preoperatively and at the end of the sixth month postoperatively. The patient was blinded regarding the type of concha intervention in both nasal cavities [17].

The study used two established endoscopic scores. Patients were evaluated with the Lund-Kennedy endoscopic score (LKES) before the surgery as a baseline evaluation and at the first, third, and sixth months after the surgery. The LKES consists of five terms (polyps, discharge, edema, scarring and crusting) graded on an ordinal scale from 0–2 for each side. For polyps (0) none, (1) confined to middle meatus, (2) beyond middle meatus. For discharge (0) none, (1) clear and thin, (2) thick and purulent. For edema, scarring and crusting (0) absent, (1) mild, (2) severe [18]. To compare the endoscopic features of the frontal recess in the two techniques, peri-operative sinus endoscopy (POSE) was conducted during the operation and again one, three, and six months later. In POSE, the frontal recess/sinus was scored as patent/healthy (0), edema/narrowed (1), or severely inflamed/infected/obstructed (2)[19]. Furthermore, the study evaluated the state of the middle turbinate six months postoperatively and categorized it as

either healthy (0), partial lateralization (1), or severe lateralization (2) using the POSE score to evaluate and compare the two methods included in the study.

The study was single-blinded, as the patients were unaware of which technique was used. However, the investigator could not be blinded due to the nature of the technique. Therefore, two authors (A.E.) and (S.E.) conducted the postoperative endoscopic assessment in two separate settings.

The SPSS 23 program was used to analyze the results of this study. After applying the normal distribution tests, the quantitative data were analyzed using the T-test of significance or Wilcoxon Signed Ranks test. The LKES scores were compared using paired and unpaired T-tests. The study compared the olfactory function before and after surgery using the Wilcoxon Signed Ranks test. The qualitative information was analyzed percentages using the Fisher test. The Fisher test was used to compare the degree of intraoperative bleeding and postoperative synechia of both groups.

Results:

The study included fifty-six patients (25 males, 31 females) aged (34.68 ± 12.48 years old) between October 2019 and April 2021. No major perioperative complications were documented regarding both techniques.

By the end of the sixth month after the surgery, the overall SNOT 22 score had significantly improved (67.48 \pm 12.589 preoperatively vs. 29.66 \pm 15.687 postoperatively, p-value = 0.001*).

Both operated groups showed significant improvement in the olfaction score postoperatively (p-value = 0.001^*). There was no significant difference between both groups in olfaction score net change (postoperative – preoperative) (4.14 ± 1.268 vs. 3.57 ± 1.372 , p-value = 0.111 submucosal conchoplasty group and the lateral lamellectomy group, respectively).

The operative time (minutes) required was significantly higher in the submucosal conchoplasty group $(11.86 \pm 2.075 \text{ vs } 6.29 \pm 1.703, \text{ p-value} = 0.001^*).$

The two groups had no significant difference regarding the amount of intraoperative bleeding of both techniques according to the Fromme Ordinal Scale (Fisher Exact test: 6.111, P-value: 0.086).

Considering LKES, the differences observed between the two groups throughout the followup period were variable. (Figure 3)

There was no detectable distinction between the study groups at the baseline assessment time. $(3.91 \pm 0.793 \text{ vs. } 4.09 \pm 0.695, \text{ p-value} = 0.208$, for the side of submucosal conchoplasty and the side for lateral turbinectomy, respectively)

It was significantly higher in the lateral lamellectomy group at the 1st-month interval (4.23 \pm 1.191 vs. 4.86 \pm 1.034, p-value = 0.004*). (Table 1)

At the 3-month and 6-month intervals, however, neither group differed significantly from the other group $(2.55 \pm 0.952 \text{ vs. } 2.73 \pm 0.981, \text{ p-value} = 0.331, \text{ third month})$ and $(2.84 \pm 1.398 \text{ vs. } 2.98 \pm 1.368, \text{ p-value} = 0.586, \text{ sixth month})$ for the side of submucosal conchoplasty and the side for lateral turbinectomy, respectively.

<u>At the six-month interval</u>, both groups' LKES scores had increased significantly from their baseline score (p-value = 0.001^*). (Table 2)

Regarding the middle turbinate POSE score in the sixth month, there was a statistically significant difference between both groups, with the lateral lamellectomy group showing more synechia formation (Fisher test: 8.568, d.f.: 2, p-value: 0.012*). (Table 3)

Discussion:

Concha bullosa is a common anatomical variant, but a large concha may contribute to many nasal problems, including nasal obstruction and sinusitis. Also, the large concha bullosa narrows the middle meatus and hinders endoscopic accessibility during surgery. So, it is essential to properly manage this anatomical variation at the beginning of the operation to have good access to the middle meatus. The turbinate mucosa plays a vital role in nasal function, such as humidification, temperature control, sensation of airflow, and olfactory perception [7].

Although endoscopic lateral lamellectomy is the standard modality for its management, postoperative adhesions with the subsequent failure of ESS may occur. Sigston et al., in their study, designed a modification to the partial lateral turbinectomy technique to decrease the postoperative exposed raw area by using the concha's lateral posterior pedicled mucosal flap after extracting its bony lamina (Submucosal conchoplasty technique) [20].

The submucosal conchoplasty has the advantage of preserving the mucosa with its whole function. Although there was no significant difference between both techniques regarding intraoperative bleeding, we observed that the concha's feeding blood supply of the concha bollusa was more liable to be injured during the excision of the lateral lamella of the middle turbinate at its posterior stump in the traditional technique. Fortunately, this bleeding can be easily controlled by bipolar cauterization of the bleeding stump. This injury was less liable to occur with the submucosal turbinectomy technique because it included submucosal resection of the bony lamella with no mucosal tearing. The literature reported an increase in blood loss during and after middle turbinate excision [21]. It was also reported that the transection of the arterial supply along the posterior portion of the middle turbinate could lead to bleeding during full-thickness middle turbinate resection [22]. Also, we observed that the bony surface of the lateral lamella was rough with adherent mucosa, which made the mucosal dissection challenging and time-consuming to some extent. Although the time difference between both techniques was statistically significant, it was practically unimportant relative to the time needed for the whole surgery. Another disadvantage of the submucosal technique is that the repositioned mucosa of the lateral lamella may be repeatedly injured by the suction device during the operation or accidentally reflected during the application of the middle meatus pack.

The lateral turbinectomy group showed higher crusts and reactionary polyp formation rates than the submucosal conchoplasty group at the 1st-month follow-up interval. Due to the increased surface area of the exposed bone, crusts were found primarily along the line of turbinate resection. This bone exposure induces more granulations and prolongs the time needed for complete healing. However, there was significant postoperative edema on the side with submucosal conchoplasty than with lateral turbinectomy on top of the preserved repositioned mucosal surface of the middle turbinate. Fortunately, these findings were temporary since they were eliminated once the recovery process was complete, and no unfavorable consequences correlated.

The lateral lamellectomy group showed an increasing rate of synechia formation during the follow-up period and so did the POSE score. The rate at which synechia formed between the middle turbinate and the lateral nasal wall was significantly higher in the lateral lamellectomy group due to the more surface area exposure of the opposing raw tissues. The lateral lamellectomy group showed a postoperative synechia rate of 28.6%, while the submucosal turbinectomy group showed 7.1%.

According to POSE at the final assessment, only one case of the submucosal turbinectomy group showed grade 2 synechia formations restricted to one side only. It was due to the

accidental reflection of the repositioned mucosa during the merocel pack application at the end of the operation. This patient showed persistent symptoms and was a candidate for revision surgery. Regarding the lateral lamellectomy group, four patients showed complete middle meatus obliteration (one patient was bilaterally presented and three patients were unilateral). Only two of them showed persistent symptoms and needed revision surgery.

One limitation of the study is that the net endoscopic scores combine the concha and ethmoid sinus interventions. Future studies should include the concha bollusa surgery as a separate endoscopic intervention from other sinus surgery procedures.

13

Conclusion:

Submucosal conchoplasty is a proper technique for managing concha bullosa with better postoperative endoscopic outcomes and no significant perioperative comorbidity.

Declarations:

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References:

- 1 Dasar U, Gokce E. Evaluation of variations in sinonasal region with computed tomography. World J Radiol. 2016;8:98-108.
- 2 Fadda GL, Rosso S, Aversa S, Petrelli A, Ondolo C, Succo G. Multiparametric statistical correlations between paranasal sinus anatomic variations and chronic rhinosinusitis. ACTA otorhinolaryngologica italica. 2012;**32**:244-51
- Maru YK, Gupta Y. Concha bullosa: Frequency and appearances on sinonasal CT.
 Indian J Otolaryngol Head Neck Surg. 1999;52:40-4
- 4 Bolger WE, Butzin CA, Parsons DS. Paranasal sinus bony anatomic variations and mucosal abnormalities: CT analysis for endoscopic sinus surgery. Laryngoscope. 1991;101:56-64
- 5 Kumral TL, Yıldırım G, Cakır O, Ataç E, Berkiten G, Saltürk Z, et al. Comparison of two partial middle turbinectomy techniques for the treatment of a concha bullosa. Laryngoscope. 2015;125:1062-6
- 6 Apuhan T, Yıldırım YS, Şimşek T, Yılmaz F, Yılmaz F. Concha bullosa surgery and the distribution of human olfactory neuroepithelium. European Archives of Oto-Rhino-Laryngology. 2013;**270**:953-7
- Nurse LA, Duncavage JA. Surgery of the inferior and middle turbinates. Otolaryngol
 Clin North Am. 2009;42:295-309
- 8 Soler ZM, Hwang PH, Mace J, Smith TL. Outcomes after middle turbinate resection: revisiting a controversial topic. The Laryngoscope. 2010;**120**:832-7

- 9 Semih Karaketir M.D., Yavuz Uyar M.D. & Tolgar Lütfi Kumral M.D. (2018) Surgical Techniques for the Treatment of Concha Bullosa: A Systematic Review
- French C, Goyal P. Submucosal resection of the middle turbinate. Otolaryngol Head
 Neck Surg. 2012;147:116
- Dubin MG, Liu C, Lin SY, Senior BA. American Rhinologic Society member survey on
 "maximal medical therapy" for chronic rhinosinusitis. Am J Rhinol. 2007;21:483-8
- 12 Fokkens WJ, Lund VJ, Mullol J, Bachert C, Alobid I, Baroody F, et al. EPOS 2012: European position paper on rhinosinusitis and nasal polyps 2012. A summary for otorhinolaryngologists. Rhinology. 2012;50:1-2
- 13 Kelsey JL, Whittemore AS, Evans AS, Thompson WD. Methods in observational epidemiology. New York: Oxford University Press, 1986
- Hopkins C, Browne JP, Slack R, Lund V, Brown P. The Lund-Mackay staging system for chronic rhinosinusitis: how is it used and what does it predict?. Otolaryngology— Head and Neck Surgery. 2007;137:555-61
- 15 Fromme GA, MacKenzie RA, Gould Jr AB, Lund BA, Offord KP. Controlled hypotension for orthognathic surgery. Anesthesia & Analgesia. 1986;**65**:683-6
- 16 Hopkins C, Gillett S, Slack R, Lund VJ, Browne JP. Psychometric validity of the 22item Sinonasal Outcome Test. Clinical otolaryngology. 2009;34:447-54
- 17 Khafagy Y, Ghonim M, Elgendy A, Elzayat S. The impact of bolgerization versus partial resection of the middle turbinate on frontal sinusotomy patency outcome: A randomised controlled study. Clinical Otolaryngology. 2021;46:954-60
- 18 Lund VJ, Kennedy DW. Staging for rhinosinusitis. Otolaryngology-head and neck

surgery. 1997;117:S35-40

- 19 Wright ED, Agrawal S. Impact of perioperative systemic steroids on surgical outcomes in patients with chronic rhinosinusitis with polyposis: evaluation with the novel Perioperative Sinus Endoscopy (POSE) scoring system. The Laryngoscope. 2007 ;117:1-28
- 20 Sigston EA, Iseli CE, Iseli TA. Concha bullosa: reducing middle meatal adhesions by preserving the lateral mucosa as a posterior pedicle flap. The Journal of Laryngology & Otology. 2004;118:799-803
- Nyquist GG, Anand VK, Brown S, Singh A, Tabaee A, Schwartz TH. Middle turbinate preservation in endoscopic transsphenoidal surgery of the anterior skull base. Skull base.
 2010;20:343-7
- 22 Lee HY, Kim HU, Kim SS, Son EJ, Kim JW, Cho NH, et al. Surgical anatomy of the sphenopalatine artery in lateral nasal wall. The Laryngoscope. 2002;**112**:1813-8

Table legends:

 Table (1): Shows a detailed assessment of the postoperative LKES regarding the 1st-month

 interval follow-up.

 Table (2): Shows the level of significance regarding LKES and POSE scores changes

 between both groups.

Table (3): Shows the differences between both groups regarding postoperative synechia formation according to the POSE score at the sixth-month interval.

Figure legends:

Fig (1): Shows intraoperative endoscopic views of the right nasal cavity using 0 angled 4 mm nasal endoscope illustrating the submucosal conchoplasty technique.



Fig (1A): incision of the mucosa.



Fig (1B): dissection of the mucosa.



Fig (1C): removal of the lateral lamella.



Fig (1D): repositioning of the mucosa

Fig (2): Shows intraoperative endoscopic views of the right nasal cavity using 0 angled 4 mm nasal endoscope illustrating the lateral turbinectomy technique.



Fig (2A): opening of the concha using the sickle knife.

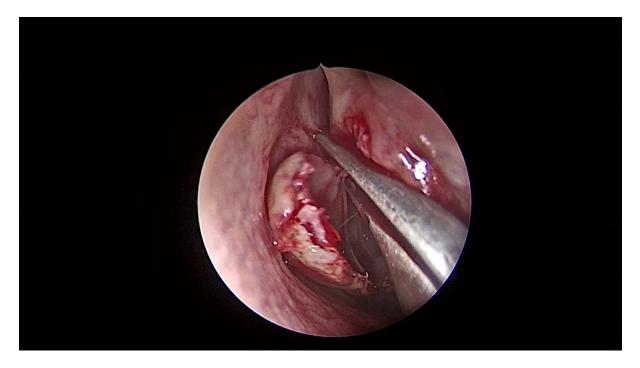


Fig (2B): Excising the lateral lamella using the scissor.

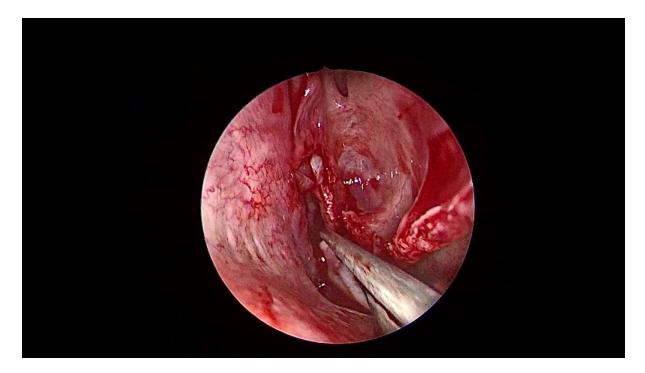


Fig (2C): removal of the posterior attachment of the concha.

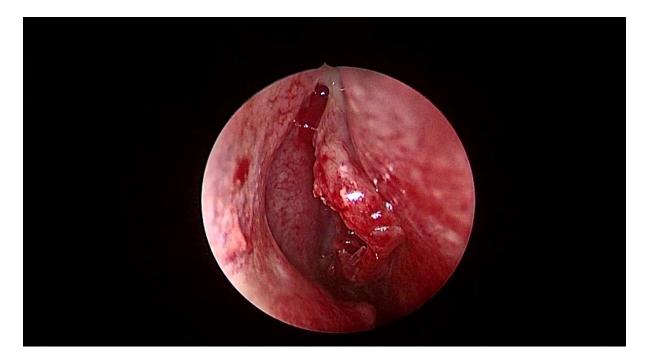
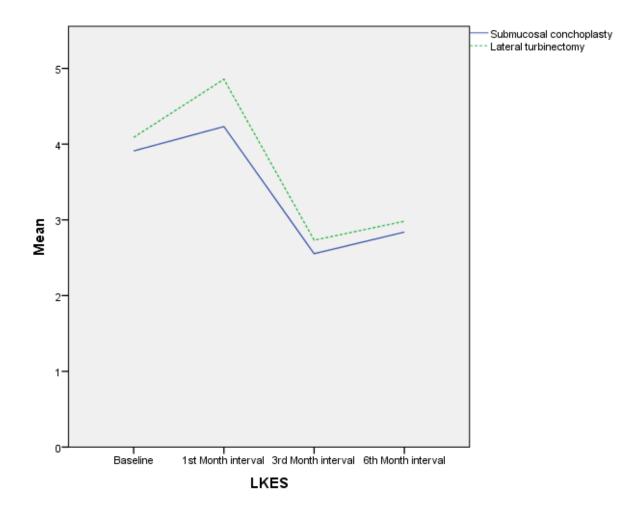


Fig (2D): Panoramic view.

Fig (3): Shows the results of the LKES at the different follow-up intervals.



*: significant difference < 0.05

Table I: Shows a detailed assessment of the postoperative LKES regarding the 1st-month interval follow-up.

	Procedure	Ν	Mean	SD	SE	T-test	P-value
Edema	Submucosal conchoplasty	56	1.64	0.483	0.065	4.262	0.001*
	Lateral lamellectomy	56	1.27	0.447	0.060		
Polyps	Submucosal conchoplasty	56	0.30	0.464	0.062	3.570	0.001*
	Lateral lamellectomy	56	0.63	0.489	0.065		
Discharge	Submucosal conchoplasty	56	0.59	0.596	0.080	0.947	0.346
	Lateral lamellectomy	56	0.70	0.601	0.080		
Crusts	Submucosal conchoplasty	56	1.27	0.447	0.060	5.773	0.001*
	Lateral lamellectomy	56	1.75	0.437	0.058		
Scarring	Submucosal conchoplasty	56	0.41	0.496	0.066	1.133	0.260
	Lateral lamellectomy	56	0.52	0.504	0.067		

*: significant difference < 0.05 according to independent sample t-test, SD: standard deviation, S.E.: standard error of the mean

		Ν	Mean	SD	SE	T-test	P-value
conchoplasty	Baseline	56	3.91	0.793	0.106	4.988	0.001*
	6th Month	56	2.84	1.398	0.187		
Lateral lamellectomy	Baseline	56	4.09	.695	0.093	5.399	0.001*
	6th Month	56	2.98	1.368	0.183		

 Table II: Shows the level of significance regarding LKES and POSE scores changes

 between both groups.

*: significant difference < 0.05 according to independent sample t-test, SD: standard deviation, S.E.: standard error of the mean

Table III: Shows the differences between both groups regarding postoperative synechiaformation according to the POSE score at the sixth-month interval.

		POSE middle turbinate					
		0	1	2	Total	Fisher test	P-value
Submucosal	Count	52	3	1	56		0.012*
conchoplasty	% within group	92.9%	5.4%	1.8%	100%	8.568	
Lateral	Count	40	11	5	56		
Lamellectomy	% within group	71.4%	19.6%	8.9%	100%		
T. 4 1	Count	92	14	6	112		
Total	% within group	82.1%	12.5%	5.4%	100%		

*: significant difference < 0.05 according to the Fisher test.