

Septal Crossbar Graft versus Spreader Graft for Nasal Septal Deviation: A Triple-Blind Randomized Clinical Trial

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Abstract

Introduction:

Nasal septal deviation (NSD) is a common problem that often requires surgical correction. Although spreader grafts are widely used in septorhinoplasty, evidence directly comparing them with septal crossbar grafts remains limited. This study aimed to compare these two techniques in patients with primary NSD.

Materials and Methods:

In this triple-blind randomized clinical trial, 68 patients were recruited from November 2024 to March 2025 and randomly assigned to undergo open septorhinoplasty using either a septal crossbar graft (n=34) or a spreader graft (n=34). Anatomical and functional outcomes were assessed preoperatively and six months postoperatively by measuring septal deviation angle correction via computed tomography and the Nasal Obstruction Symptom Evaluation (NOSE) questionnaire, respectively.

Results:

Both techniques produced significant improvements in septal deviation and NOSE scores at six months (all $p < 0.001$), which were comparable between groups ($p > 0.05$). The mean NSD correction was $11.32 \pm 2.57^\circ$ for septal crossbar graft and $12.76 \pm 3.84^\circ$ for spreader graft. No postoperative complications were observed. Surgical duration was significantly longer with septal crossbar graft (3.72 ± 0.44 vs. 2.02 ± 0.52 hours, $p < 0.001$). Multivariate regression analysis showed a significant independent effect of surgical technique favoring the septal crossbar graft while surgical duration imposed a significant negative impact concerning the anatomical correction.

Conclusion:

Both techniques provide safe and effective anatomical and functional improvements in patients with primary NSD. Although adjusted analyses favored the septal crossbar graft for septal correction, it was neutralized by its longer operative time, should be considered during surgical planning.

Keywords: Nasal septal deviation, Open septorhinoplasty, Septal crossbar graft, Spreader graft

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Introduction

Nasal septal deviation (NSD) is a common condition with varying degrees of severity characterized by the displacement of the nasal septum, which can lead to significant health and quality of life issues, including impaired olfactory function, reduced productivity, sleep disturbances, and sinusitis (1-4). While non-surgical treatments may offer temporary relief, septoplasty is often necessary for long-term improvement, especially in cases where the deviation causes significant obstruction and related symptoms (5,6).

Effective surgical intervention can lead to substantial improvements in nasal patency and quality of life, underscoring the importance of addressing NSD with empathy and clinical precision (6,7).

Various surgical techniques have been developed to address NSD, each with its own set of advantages and limitations. The spreader graft technique is widely used in rhinoplasty to reconstruct the nasal mid-vault, improve nasal airway obstruction, and enhance aesthetic outcomes. It is considered the gold standard for maintaining nasal patency and has been shown to provide consistent functional and aesthetic results (8,9). On the other hand, the septal crossbar graft technique, introduced in 2003, is notable for its ability to correct crooked noses by combining staggered septal incisions with a spreader graft on the concave side of the deviation. This method is praised for its effectiveness in straightening the septum and providing lasting stability, although it has undergone modifications to address certain procedural challenges (10,11). While both the crossbar graft and spreader graft techniques are clinically viable for treating nasal septal deviation, there is a notable gap in the literature on direct comparisons of their efficacy, safety, and patient outcomes. Existing studies often focus on aesthetic and functional outcomes of spreader grafts without any of them directly contrasting these two specific techniques (12,13). Non-randomized studies addressing the use of septal crossbar grafts, while informative, are insufficient due to potential confounders that can skew results, such as patient selection bias and variations in surgical skill (14). Thus, a randomized clinical trial is essential to provide robust evidence by minimizing these biases and offering a clear, head-to-head comparison. Furthermore, it is

also important to evaluate their relative effectiveness, particularly in terms of patient satisfaction and the durability of results. By figuring out which technique offers superior outcomes, surgeons can make more informed decisions, potentially improving patient satisfaction and surgical success rates. The current study was conducted to address the anatomical and functional outcomes of spreader grafts versus septal crossbar grafts for septorhinoplasty in patients with primary NSD.

Materials and Methods

The current triple blind randomized parallel group clinical trial has been designed and conducted to assess and compare the outcomes of using the spreader graft technique or septal crossbar graft technique for septorhinoplasty to address patients with primary NSD. All procedures performed in this study involving human participants were by the ethical standards of the Institutional and/or National Research Committee and with the 1964 Helsinki Declaration. The study was approved by the Research Ethics Committees of School of Medicine, Shahid Beheshti University of Medical Sciences with the registration number of IR.SBMU.MSP.REC.1403.396 as well as the Iranian Registry of Clinical Trials with registration number of IRCT20241021063450N1. This study was conducted in Taleghani hospital, Tehran, Iran, a tertiary medical center affiliated to Shahid Beheshti University of Medical Sciences. The participants were recruited from patients with NSD requiring surgical intervention referring to the ENT clinic from November 2024 until March 2025 according to the predetermined inclusion and exclusion criteria:

Inclusion criteria:

- Age between 20 and 40 years
- Willingness to participate in the study and full satisfaction
- Diagnosis of NSD with indication for surgical treatment

Exclusion criteria:

- history of nose surgeries
- history of nasal trauma
- Refusal for follow-up evaluations
- Systemic conditions affecting wound healing
- Coagulation disorders
- Uncontrolled medical problems

- Contraindications for the general anesthetics

The sampling method in the present study was convenient and consecutive sampling. The number of participants required for each study group was calculated based on the main dependent variables, and the largest number of

$$n = \frac{(Z_{1-\alpha/2} + Z_{1-\beta})^2 \times 2 \times \sigma^2}{(\mu_1 - \mu_2)^2} \quad n = \frac{(1.96 + 0.84)^2 \times 2 \times (5.2)^2}{(3.72)^2} = 31$$

Randomization and Allocation

After assessing the patients in accordance with the inclusion and exclusion criteria, a written signed informed consent was obtained from the eligible patients. Then, a unique number was assigned to each patient entering the study by a third party (ENT clinic secretary) in order of their recruitment time. These numbers were used for the randomization process through a computer-generated sequence; that is, the numbers assigned to individuals were randomly arranged by the computer, and the first and second half of the numbers in this sequence were assigned to group A and B, respectively. A third party (ENT clinic secretary) was assigned to keep the allocation concealment via sealed, opaque envelopes for each of the participants, having their specific numbers written on the surface of the envelopes and the randomization results (allocated to either group A or B) placed inside them. At the time of intervention, the envelopes containing the allocation results were given to the patients matched by their assigned number and were opened by the person responsible for the intervention application, so that the patients remain blinded to the outcome of their allocation to group A or B. In the present study, the participants, their caregivers, along with the research team including the data recording staff and the data analysts, were all kept blind to the group each participant was allocated to. After all interventions, data collection, follow-up, and data analysis were carried out, the third party responsible for maintaining the allocation concealment (the clinic secretary) disclosed the allocation results to the research team (group A was treated using the septal crossbar graft technique for septorhinoplasty, group B was treated via septorhinoplasty with spreader graft technique). This procedure ensured that the

samples was obtained based on the nasal septum deviation variable. In accordance, the number of participants for each group was estimated to be 31, and considering the 10% probability of sample loss, 34 patients were considered in each group. The sample size was calculated based on the outcomes of the study of Chen et al (15) using the following formula:

principles of randomization and blinding could be well observed, ensuring the integrity maintenance of the study throughout.

Intervention

All the participants in the current study were treated with open septorhinoplasty under generalized anesthesia. Though, concerning the implemented surgical techniques, the septal crossbar graft technique was determined as the surgical technique for the participants in Group A, while the patients in Group B were treated via the spreader graft technique. Both procedures followed standardized surgical techniques and performed by the same surgeon to ensure consistency.

Spreader graft technique: The intervention in the spreader graft group (group B) began with a conventional septoplasty that left the caudal and dorsal portions of the L-strut intact by at least 1 cm in width. The entire deviated septal cartilage was then excised as a vertical block, creating a full-thickness defect between the cranial and caudal portions of the septal cartilage. This allowed the surgeon to freely move both edges of the remaining cartilage and determine the craniocaudal length of the septal cartilage defect. This measurement was necessary to determine the length of the spreader grafts, which was determined by adding 2 cm to the length of the cartilage defect. The proximal length of the spreader graft was sutured to the cranial portion of the septal cartilage with two 4/0 Polydioxanone (PDS) sutures, and the distal length was sutured to the caudal portion in the same manner. All four sutures were passed in a horizontal mattress through the superior and lateral cartilages of both sides, the spreader grafts on both sides, and the remaining septal cartilage. At the end of this procedure, the septal gap remained unchanged, and septal integrity was provided

primarily by the spreader grafts placed on both sides.

Septal crossbar graft technique: The septal crossbar graft procedure was similar to the spreader graft in general; Yet they varied in certain specifications. The septal crossbar graft has been used to treat severe septal deformities as well as cosmetic surgical interventions. It combines staggered septal incisions with a spreader graft in the dorsal septum on the concave side of the deviation. It is used to straighten the septum and is said to be long-lasting and less affected by cartilage memory.

Post-op care

For both groups the nose was not covered with nasal packing. Instead, one-centimeter hypoallergenic tape was used, covering the nasal dorsum to prevent edema and was removed from the nose 7 days after the surgery. Additionally, all patients received antibiotics to prevent infection after the surgery (amoxicillin-clavulanic acid tablet 875/125 mg every 12 hours for 10 days).

Data assessments and outcome measures

Prior to the intervention, background information including age and gender, quantitative and qualitative severity of NSD and the severity of nasal obstructive symptoms were assessed and recorded. The severity of NSD and nasal obstructive symptoms were also recorded six months after the surgery. Moreover, the duration of the surgery and the postoperative complications were recorded.

To have a quantitative, objective and precise measurement of NSD severity, a computed tomography (CT) scan of the nose and paranasal sinuses was obtained from all patients prior to the intervention and 6 months after surgery. In accordance, the quantitative NSD severity was assessed by the measurement of the angle made between the line drawn from the crista galli to the most prominent deviation point of the nasal septum and the midline line (the line that extends from the crista galli to the median palatine suture).

For patient symptom assessment, the Nasal Obstruction Symptom Evaluation (NOSE) questionnaire, a valid and reliable scale provided by Awan et al., was completed for all patients at baseline and six months after

surgery. Accordingly, five symptoms were evaluated and scored from 0 (no problem) to 4 (severe problem) and then the scores were summed to attain the total NOSE score (16).

The anatomical NSD correction was considered the primary outcome, while the functional improvement (evaluated via the NOSE questionnaire) and postoperative complications were considered as the secondary objectives.

Statistical Analysis

All statistical analyses were conducted using SPSS version 27. Descriptive statistics were initially performed for all study variables. The normality of continuous data was assessed using the Shapiro–Wilk test. Normally distributed continuous variables were compared between groups using the independent-samples t-test, whereas non-normally distributed continuous variables were analyzed using the Mann–Whitney U test. Within-group comparisons of normally distributed continuous variables were conducted using paired-samples t-test, as non-normally distributed variables were performed using the Wilcoxon signed-rank test. Categorical variables were compared between the two groups using the chi-square test. Multivariate regression models were considered to adjust confounders. A two-sided P value of <0.05 was considered statistically significant.

Results

Patient enrollment

From November 2024 until March 2025, 263 patients were evaluated for eligibility to participate in the current study. In accordance with the previously estimated sample size, 68 patients were included and randomly assigned to either of the study groups in a 1:1 ratio, who were treated with open septorhinoplasty using septal crossbar graft or spreader graft techniques. The flow diagram of this trial is presented in (Figure 1).

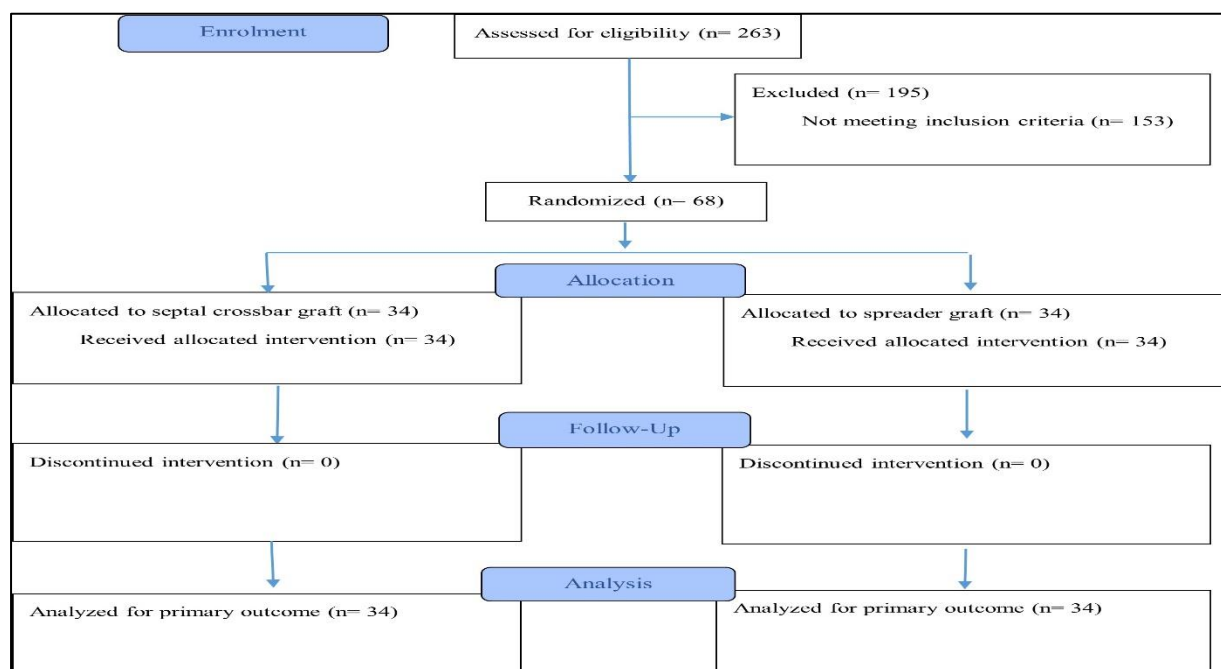


Fig 1. The flow diagram of the current study from patient enrollment to their inclusion for primary outcome analysis.

Baseline evaluation and duration of surgery

The baseline assessment results of the patients are reported in (Table 1). By comparing the data assessed at baseline between the groups, no significant differences were found (p -value >0.05). The mean duration of the surgery was 2.87 ± 0.98 hours for all participants.

Considering the study groups, the mean surgery duration for septal crossbar graft group was 3.72 ± 0.44 hours, while the mean duration for patients in the spreader graft group was 2.02 ± 0.52 hours, expressing a significant difference between the study groups (p -value <0.001).

Table 1. Baseline characteristics and duration of surgery in the study groups. Abbreviations: SD: standard deviation, NSD: nasal septal deviation, NOSE: the Nasal Obstruction Symptom Evaluation questionnaire

	Total	Septal crossbar graft	Spreader graft	p-value
Age (year (mean $\pm$ SD))	25.44 $\pm$ 3.24	26.03 $\pm$ 3.65	24.85 $\pm$ 2.69	0.13
Gender (female (%))	49 (72.1)	25 (73.5)	24 (70.6)	1.00
NSD (degree (mean $\pm$ SD))	12.93 $\pm$ 3.66	12.79 $\pm$ 3.89	13.06 $\pm$ 3.46	0.76
NOSE score (mean $\pm$ SD)	14.04 $\pm$ 2.76	13.94 $\pm$ 3.05	14.15 $\pm$ 2.47	0.76
Surgery duration (hour (mean $\pm$ SD))	2.87 $\pm$ 0.98	3.72 $\pm$ 0.44	2.02 $\pm$ 0.52	<0.001

Primary outcome evaluation

As reported in Table 2, the results of the current study demonstrated that using either of the spreader graft or septal crossbar graft techniques ended in significant improvement in terms of NSD (p -value <0.001).

By comparing the NSD change between the study groups, no statistically significant difference was found (p -value = 0.07).

Secondary outcome evaluations

Considering the functional results, both groups demonstrated significant improvements according to the NOSE score changes (p -value <0.001). The comparison of study groups in terms of NOSE score change did not elicit a statistically significant difference (p -value = 0.10). In addition, no complications were observed or reported postoperatively, including infection, significant hemorrhage, saddle nose deformity, etc.

Table 2. Changes in NSD and NOSE score among the study groups.

	Study groups	
	Spreader graft	Septal crossbar graft
Baseline NSD (Degree (mean $\pm$ S`D))	12.79 $\pm$ 3.89	13.06 $\pm$ 3.46
Follow-up NSD (Degree (mean $\pm$ SD))	0.03 $\pm$ 0.17	1.74 $\pm$ 1.52
p-value ^a	<0.001	<0.001
NSD change (Degree (mean $\pm$ SD))	12.76 $\pm$ 3.84	11.32 $\pm$ 2.57
p-value ^b	0.07	
Baseline NOSE score (mean $\pm$ SD)	13.94 $\pm$ 3.05	14.15 $\pm$ 2.47
Follow-up NOSE score (mean $\pm$ SD)	0.56 $\pm$ 0.78	1.97 $\pm$ 1.86
p-value ^a	<0.001	<0.001
NOSE score change (mean $\pm$ SD)	13.35 $\pm$ 2.94	12.32 $\pm$ 2.17
p-value ^b	0.10	
NSD change in men (Degree (mean $\pm$ SD))	13.11 $\pm$ 4.80	12.2 $\pm$ 3.32
NSD change in women (Degree (mean $\pm$ SD))	12.64 $\pm$ 3.54	10.96 $\pm$ 2.17
p-value ^b	0.75	0.20
NOSE score change in men (mean $\pm$ SD)	13.89 $\pm$ 2.36	11.40 $\pm$ 2.11
NOSE score change in women (mean $\pm$ SD)	13.16 $\pm$ 3.14	12.71 $\pm$ 2.11
p-value ^b	0.53	0.11
Pearson correlation between age and NSD change (p-value, r)	0.37, 0.15	<0.001, 0.61
Pearson correlation between surgery duration and NSD change (p-value, r)	0.01, 0.42	<0.001, 0.55
Pearson correlation between age and NOSE score change (p-value, r)	0.46, 0.13	0.74, 0.05
Pearson correlation between surgery duration and NOSE score change (p-value, r)	0.05, 0.32	0.11, 0.27

Abbreviations: SD: standard deviation, NSD: nasal septal deviation, NOSE: the Nasal Obstruction Symptom Evaluation questionnaire, ^a: paired-sample t-test, ^b: independent-sample t-test

Subgroup analysis of the main outcomes

The NSD changes in both study groups were compared between genders and the impact of age and surgery duration on the primary outcome was also evaluated. Either of the study groups showed no significant difference between genders regarding NSD changes (septal crossbar graft group: p-value = 0.570, spreader graft group: p-value = 0.099). In the Septal Crossbar Graft group, the Pearson correlation between age and nasal deviation change indicated no significant relationship, as well (p-value = 0.37). Though, there was a statistically significant positive correlation between age and nasal deviation change in the spreader graft group (p-value <0.001). Additionally, the correlation between surgery duration and nasal deviation change in both groups indicated a significant relationship, suggesting longer surgery duration being associated with a greater change in NSD (septal crossbar graft group: p-value = 0.01, spreader graft group: p-value <0.001). To control the

effect of confounding variables, a multivariate linear regression model was implemented to assess the impact of age, gender, and surgery duration on NSD improvement in both study groups. The results of the multivariate linear regression which are presented in **Table 3**, suggested a statistically significant effect of the surgical technique implemented for NSD correction in favor of septal crossbar graft (p-value <0.001). Meanwhile, surgery duration had a significant negative impact on NSD correction (p-value = 0.004). Still, no significant impact of age (p-value = 0.379) or gender (p-value = 0.587) was observed on the NSD correction. Concerning the subgroup analysis conducted on the functional outcomes, there were no significant gender-based differences between two groups in accordance with NOSE score changes (p-value >0.05). Consistently, no significant relationships between NOSE score change and age or surgery duration were observed in either of the study groups (p-value >0.05).

Table 3. Multivariable linear regression analysis evaluating the independent association of intervention type with postoperative septal deviation change after adjustment for baseline septal deviation, age, gender, and surgery duration.

Variable	Unstandardized Coefficient (B)	Standard Error	Standardized Coefficient (β)	t	P value
Constant	7.744	1.654	—	4.681	<0.001
Age	-0.033	0.038	-0.031	-0.887	0.379
Gender	0.136	0.249	0.017	0.545	0.587
Surgery duration	-0.827	0.278	-0.230	-2.976	0.004
Baseline septal deviation	0.931	0.038	1.002	24.641	<0.001
Intervention group	-3.156	0.521	-0.451	-6.058	<0.001

Model statistics: $R^2 = 0.938$, Adjusted $R^2 = 0.933$, $F = 188.548$, $P < 0.001$

Discussion

Comparison with Existing Literature

The spreader graft is widely recognized as a "gold standard" for maintaining nasal patency and improving aesthetic outcomes, with consistent functional and aesthetic results reported in the literature (13,17). In recent years, two systematic review studies have evaluated the outcomes of using spreader grafts in comparison with autospreaders or spreader flaps for the treatment of NSD. The study conducted by Keyhan et al which included 10 published studies and analyzed the outcomes of more than 500 patients revealed that both spreader graft and spreader flap techniques could provide favorable anatomical and functional improvements in patients with NSD, while the spreader graft provided superior satisfaction rates compared to the spreader flap (13). The findings of another systematic review conducted by Buba et al which compared the spreader grafts and autospreaders in terms of safety and functional outcomes suggested that both methods could generate comparable functional improvements in patients either treated with spreader grafts, autospreaders or both techniques combined (17). In line with these findings, other recently published randomized clinical trials confirmed the satisfactory aesthetic and functional results of spreader grafts, as well (18-20).

While high quality evidence is available confirming the safety and efficacy of spreader grafts, the safety profile and efficacy of septal crossbar grafts are not sufficiently evaluated, and the current literature lacks high quality evidence in this matter. The current study is one of the first efforts to investigate the outcomes of using septal crossbar grafts for NSD correction in a randomized clinical trial setting. The septal crossbar graft, introduced by Bocchieri in 2003, despite it being less addressed

in the literature compared to the spreader graft, has been praised for its ability to correct crooked noses by combining staggered septal incisions with a spreader graft, aiming for long-lasting straightening and harness the impact of cartilage memory (10,11,21-23). Consistent with the results of formerly published studies, the findings of the current study support the effectiveness of septal crossbar grafts in achieving favorable anatomical and functional improvements in patients with NSD.

Even though the outcomes of using spreader grafts or septal crossbar grafts for NSD correction are available, to the best of our knowledge, the results of employing these techniques have not yet been directly compared. Accordingly, this study directly addresses a notable gap in existing literature.

It should be noted that while the direct comparison of septal crossbar grafts and spreader grafts showed no statistically significant differences in terms of NSD correction and NOSE score change, when data adjustment for confounders was made by conducting a multivariate regression analysis, a significant effect of the employed surgical method on NSD improvement was found, favoring the septal crossbar graft technique. This suggests that while generally equivalent, the septal crossbar graft technique might offer a subtle advantage to achieve better NSD correction in specific patients. This inconsistency might be explained by the fact that septal crossbar grafts require longer durations of surgery to be performed, due to the complexities involved in the process of implementing this technique. In the current study, using septal crossbar graft was associated with significantly longer surgery durations. Accordingly, it could be interpreted that while septal crossbar graft technique shows superiority when confounding variables are

controlled, its need for longer surgery duration to conduct poses limitations to this technique, hindering it from generating superior outcomes.

Clinical Implications

Despite the comparable and favorable efficacy of the techniques, some points should be taken into consideration. As mentioned previously, the multivariate regression analysis results suggested the septal crossbar graft technique to provide greater NSD improvements. On the other hand, these results showed a negative impact of longer durations of surgery on NSD improvements. Notably, patients treated with septal crossbar graft experienced significantly longer durations of surgery, which might be the reason behind the comparable NSD changes in the direct comparison of the study groups. The significantly longer surgery duration associated with the septal crossbar graft technique is a practical consideration for surgical planning. A systematic review and meta-analysis study aiming to address the association of surgery duration with complications suggested higher occurrence of complications when surgery exceeds a 2-hour threshold and steadily increase as the surgery prolongs (24). Moreover, longer surgery duration could lead to longer hospital stay and patient dissatisfaction (25-27). Longer operative times can also impact operating room availability, healthcare costs, and patient exposure to anesthesia (28). It is important that the surgeons consider the strengths and limitations of these techniques as they aim to provide the best available treatments for their patients.

The participants of the current study experienced no significant postoperative complications, regardless of the surgical method used for their treatment. The absence of significant postoperative complications in both groups is reassuring and supports the safety profile of both techniques when performed by an experienced surgeon under standardized conditions. This provides further confidence in their clinical application, as the previously published studies confirmed the safety of these techniques (17,29).

Strengths of the Study

The study was conducted in a triple-blind, randomized controlled trial setting, providing the highest level of evidence to compare the two surgical techniques with lower rate of biases. In addition, using both objective (CT

scan measurements of NSD angle) and subjective but validated (NOSE questionnaire) outcome measures made the evaluation of both anatomical and functional improvements available. All surgical procedures were performed by a single surgeon using standardized techniques, reducing inter-operator variability and improving the internal validity of the findings. The sample size was also properly calculated regarding the primary outcome to ensure sufficient statistical power. Moreover, all the participants in the current study properly received their allocated intervention, none of the study participants were lost to follow-up, and their data was meticulously recorded, leaving no missing data. These methodological strengths lead us so we could report outcomes with acceptable reliability and internal validity and interpretations made accordingly.

Limitations

Despite the strengths, the current study has some limitations that should not be overlooked. First, the six-month follow-up period, while adequate for initial assessment, may not be sufficient to express long-term stability, potential recurrence of deviation, or the full impact of "cartilage memory". Given the septal crossbar graft's reported advantage of being "long-lasting and less affected by cartilage memory", longer follow-up durations should be considered to evaluate the efficacy of these techniques in terms of outcome sustainability and adverse results. Second, the current study was conducted at a single medical center. While this could improve consistency of the outcomes, it could limit the generalizability of the findings. Accordingly, studies with longer follow-ups, and implementing multi-center design are recommended to provide more generalizable results and to address the long-standing outcomes of using spreader graft or septal crossbar graft techniques for NSD correction.

Conclusion

The outcomes of the current study demonstrated that both methods could yield favorable anatomic and functional corrections according to evaluations made by imaging studies and NOSE scale. Although the multivariate regression analysis results suggested the septal crossbar graft to be the

superior technique able to make grater anatomical correction, this advantage seemed to be confounded by longer duration of surgery required to perform this technique, as the direct comparisons of study groups showed no significant differences. These findings should be considered for surgical planning and choosing the optimal surgical method to address NSD.

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Ethical Approval

All procedures performed in this study involving human participants were by 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 and were approved by the Research Ethics Committees of School of Medicine, Shahid Beheshti University of Medical Sciences with the registration number of IR.SBMU.MSP.REC.1403.396 as well as the Iranian Registry of Clinical Trials with registration number of IRCT20241021063450N1.

Author Disclosure Statement

No conflicting financial interests exist.

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