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ORIGINAL REPORT

The Role of Spreader Grafts in Reduction Septorhinoplasty: A Randomized Clinical Trial With Quality of Life Assessment

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ABSTRACT

Objective: To evaluate the impact of spreader grafts in reduction septorhinoplasty on quality of life (QOL) outcomes.

Trial Design: Randomized clinical trial (RCT).

Methods: Individuals over 15 years old with nasal obstruction were evaluated for functional and aesthetic septorhinoplasty from October 2018 to October 2022 at a facial plastic surgery clinic of a tertiary university hospital in Brazil. Participants were randomly allocated to subjects with or without spreader grafts. Primary outcome: Relative changes in specific Nasal Obstruction Symptom Evaluation in the Portuguese language (NOSE-p). Outcomes were assessed at least 6 and 12 months postoperatively (PO ≥ 6 and PO ≥ 12 m). The participants and those assessing the outcomes were blinded to group assignment.

Results: A 50 patients were included, 25 randomized to each group, mainly Caucasians with moderate/severe allergic rhinitis symptoms. Mean age was 32.89 ± 13.36 years and 68% were female. Septorhinoplasty improved specific quality-of-life scores irrespective of using spreader grafts ($p < 0.001$). There was no difference between subjects submitted or not to placement of spreader grafts in NOSE-p score in PO ≥ 6 m (−60.0 vs. −66.6%; $p = 0.37$); ROE in PO ≥ 6 m (71.83 vs. 79.56; $p = 0.35$), NO-VAS in PO ≥ 6 m (13.00 vs. 8.00; $p = 0,35$), NOSE p in PO ≥ 12 m (−53.14% vs. −68.33%; $p = 0.28$), ROE in PO ≥ 12 m (76.33 vs. 79.53; $p = 0.645$), NO-VAS in PO ≥ 12 m (13.00 vs. 11.50; $p = 0.60$).

Conclusions: Reduction septorhinoplasty was associated with improvement in quality of life regarding nasal obstruction irrespective of using spreader grafts in a 7.88-month follow-up.

Level of Evidence: 2.

Trial Registration: ClinicalTrials.gov identifier: (NCT0449946).

1 | Introduction

Septorhinoplasty is among the most commonly performed facial plastic and reconstructive surgeries. Despite being among the most commonly performed facial surgeries, septorhinoplasty has a relatively high revision rate, reflecting its inherent complexity [1]. The most common patient complaint in primary cases is a dorsal hump, followed by too large a nose, bulbous tip, and nasal airway obstruction [2]. One of the main concerns in rhinoplasty is precise dorsal hump

reduction. This reduction can cause major aesthetic and functional complications, such as insufficient support of the nasal midvault. Consequences such as open roof deformity, inverted-V deformity, irregularity of the dorsal aesthetic lines, and collapse of the internal nasal valve (INV) are described after reduction of the dorsal hump [3].

The gold standard for midvault reconstruction after dorsal reduction is the spreader graft (SG), advocated for the first time by Sheen [4]. Spreader grafts, however, can occasionally turn into a time-consuming process that requires cartilage harvest [3] and a worry of widening the dorsum in some cases when applied only preventively. On the other hand, a significant development in recent years has been the renaissance and rebirth of preservation rhinoplasty, a technique that seeks to preserve both the nasal bones and upper lateral cartilage, thus maintaining an intact osseocartilaginous nasal dorsum. This approach is particularly driven by concerns over the amputation of upper lateral cartilage during traditional reduction rhinoplasty [5].

There is no consensus in the literature on the impact of spreader grafts, and although evidence is limited, it suggests effectiveness for functional and aesthetic outcomes [6, 7]. As reduction rhinoplasty is common in daily practice and there are still gaps in the literature regarding the effectiveness of spreader grafts in standardized quality-of-life outcomes, we conducted this randomized clinical trial with the aim of evaluating the role of spreader grafts with a quality-of-life outcome for nasal obstruction.

2 | Materials and Methods

2.1 | Trial Design

This was a pragmatic, single-center, randomized [1:1] and parallel-group clinical trial comparing quality-of-life outcomes of primary septorhinoplasty with versus without spreader grafts. Participants and those who applied the questionnaires assessing outcomes were blinded to group assignment.

2.2 | Settings and Participants

The study was undertaken in a tertiary care and university hospital in southern Brazil. Eligible participants were aged ≥ 15 years old and candidates for functional and aesthetic primary septorhinoplasty with nasal obstruction. Exclusion criteria were: (1) absence of nasal obstruction; (2) previous sinus surgery; (3) symmetric or asymmetric insufficiency of the middle third that would require graft placement; (4) nasal valve insufficiency as the sole cause of obstruction; (5) craniofacial anomalies; (6) nasal or sinus tumors; (7) augmentation rhinoplasty; (8) concurrent procedures such as sinus surgery, turbinate reduction, otoplasty, or blepharoplasty.

Written informed consent was obtained from all patients before study enrollment. The protocol was registered at ClinicalTrials.gov (http://clinicaltrials.gov) as NCT0449946. The research protocol was approved by the Ethics and Research Committee of Hospital de Clínicas de Porto Alegre (registered #91672218.4.0000.5327).

2.3 | Randomization

A randomization sequence was generated using an online service by an independent researcher. Patients were randomized into groups with 1:1 allocation and random block sizes of 10. The allocation sequence was concealed from those involved in enrolling and assessing participants. During anesthesia induction, the surgeon (ROM) telephoned a contact who was independent of the recruitment process for allocation consignment.

2.4 | Data Collection

At study enrollment, each subject completed a brief questionnaire to provide baseline data, included in Table 1 and three questionnaires: Nasal Obstruction Symptom Evaluation in the Portuguese language (NOSE-p) [8], Rhinoplasty Outcome Evaluation (ROE) [9, 10] and degree of nasal obstruction and annoyance, assessed by visual analogue scales (NO-VAS). Clinical preoperative evaluation included history, physical examination with the Cottle maneuver, and nasal endoscopy with a Storz telescope 0° (Karl Storz, Tuttlingen, Germany).

2.5 | Interventions

All patients underwent primary septorhinoplasty. During anesthetic induction, the patients were randomly allocated to the surgery with or without spreader grafts. Procedures were performed using open or endonasal reduction rhinoplasty access, all separating the upper lateral cartilage from the septum and lowering the cartilaginous and, later, the bony septum. Appropriate dorsal profile alignment, reduction of dorsum, lateral, and medial osteotomies were performed in all procedures. Nasal tip adjustments with grafts were present in most of the cases. No patient underwent preservation rhinoplasty.

2.6 | Reduction Septorhinoplasty With Spreader Grafts Versus Reduction Septorhinoplasty Without Spreader Grafts

Patients in the first group underwent surgery with the placement and attachment of bilateral grafts taken from septal cartilage in the middle third of the nose (typically within the range of 1.0 to 1.5 cm in length and 3–4 mm in width) using 5.0 polydioxanone (PDS) suture. In the control group, no graft was placed in the middle third.

2.7 | Primary Outcome

Primary outcome was the relative change [delta (Δ)] in a disease-specific quality-of-life questionnaire for assessing outcomes in nasal obstruction in trials, the NOSE-p [7]. A score of 0 means

TABLE 1 | Baseline characteristics.

Characteristics	With spreader grafts *n* (%) or mean (SD)	Without spreader grafts *n* (%) or mean (SD)	*p*
Sex (female)	18 (72)	16 (64)	$p = 0.76$
Age, years	36.26 (±12.72)	29.52 (±13.38)	$p = 0.74$
Caucasian	24 (96)	23 (92)	$p = 1.00$
Postoperative follow-up (month)	8.55 (±2.72)	7.19 (±1.77)	$p = 0.06$
Open Approach	16 (64)	16 (64)	$p = 0.77$
Previous nasal trauma	7 (28)	4 (16)	$p = 0.49$
Nasal symptoms			
Rhinorrhea	11 (44)	10 (40)	$p = 1.00$
Nasal sneezing	15 (60)	14 (56)	$p = 1.00$
Nasal itching	15 (60)	8 (25)	$p = 0.09$
Allergic rhinitis (AR)			
Intermitent	9 (36)	5 (20)	$p = 0.34$
Persistent	16 (64)	20 (80)	$p = 0.34$
Moderate/severe AR symptoms	21 (84)	22 (88)	$p = 1.00$
Current use of topical nasal corticosteroid	16 (64)	15 (60)	$p = 1.00$
Self-reported chronic disease	10 (40)	8 (32)	$p = 0.77$

Note: Number expressed as *n* (%), unless otherwise specified. AR, allergic rhinitis. For categorical variables, Pearson chi-square was used; for continuous variables, *t*-test for independent samples was used.

no problems with nasal obstruction and a score of 100 means the most severe problem possible with nasal obstruction [7, 11].

2.8 | Secondary Outcomes

2.8.1 | Rhinoplasty Outcome Evaluation (ROE)

ROE scale [12] is a quality-of-life questionnaire validated in Brazilian Portuguese for use in rhinoplasty patients. Higher scores indicate greater patient satisfaction.

2.8.2 | Nasal Obstruction Visual Analogue Scales (NO-VAS)

The NO-VAS for nasal obstruction used in the present study was a 100 mm long scale, with 2 anchors—structured in words: "without nasal obstruction" and "nasal obstruction maximum"—at each end to express the extremes of the perception of the symptom. The patients were instructed to place an "X" on the straight line of the scale and tag was converted to 0 to 100.

2.9 | Follow-Up

Outcomes were blindly assessed preoperatively and at 1, 3, 6, and 12 months postoperatively by trained researchers to apply the questionnaires NOSE-p, ROE, and NO-VAS. An annual follow-up was encouraged for all patients.

2.10 | Sample Size

Sample size was calculated using the G*Power software, version 3.1.9.2, considering a power of 80%, a significance level of 5%, and an effect size of 0.24. Sample size was calculated to detect a reduction of 20 points in NOSE-p score, using as reference the studies from our population [9, 10]. There was a total sample size of 38 subjects, 19 in each group. For possible losses and refusals, 25% was estimated, resulting in 25 individuals in each group.

2.11 | Statistical Methods

Statistical analyses were carried out using the Statistical Package for the Social Sciences version 20.0 (SPSS, Chicago, Illinois, US). Categorical variables were described by frequencies and percentages. The normality of the variables was checked using the Kolmogorov Smirnov test. Quantitative variables with normal distribution were reported as mean ± standard deviation and those with asymmetric distribution by the median and 25th and 75th percentiles. Categorical variables were associated using the Chi-square test with Yates correction or Fisher's Exact test. Quantitative variables with normal distribution were compared using Student's *t* test for independent samples and within groups using Student's *t* test for paired samples. Variables with asymmetric distribution were compared between groups using the Mann–Whitney test and within groups using the Wilcoxon test.

A significance level of 5% was considered for the comparisons.

3 | Results

From October 2018 to October 2022, potentially eligible patients were screened from the outpatient Facial Plastic Surgery Clinic at the Hospital de Clínicas de Porto Alegre. Out of 118 screened patients, the first 50 subjects who fulfilled the entry criteria and consented to participate in the protocol were included. After randomization, 4 patients from each group did not complete the minimally required 6-month follow-up visit (Figure 1).

The study population was predominantly composed of Caucasian patients with moderate to severe persistent allergic rhinitis symptoms. Mean age was 32.89 ± 13.36, and 68% were female. Age seemed to be more advanced in the septorhinoplasty with spreader graft group; however, there was no statistical significance between groups ($p = 0.74$), nor between history of nasal trauma and female sex ($p = 0.49$ and 0.76, respectively). The open approach was distributed exactly the same way among groups (64% in each group). All other baseline clinical characteristics were similar between groups (Table 1).

3.1 | NOSE–p Score

The Δ relative change of NOSE-p scores between groups was % −60.00 (−93.3 to −23.8) in the SG group and − 66.66 (−97.36 to −34.28) in the control group in the PO ≥ 6 m ($p = 0.37$) and— 53.14 (−92.50 to −22.66) in the SG group and − 68.33 (−100.00 to −37.14) in the control group in the PO ≥ 12 m ($p = 0{,}28$) (Figure 2). The median (IQR) NOSE-p scores were significantly lower postoperatively in the PO ≥ 6 m and PO ≥ 12. No difference was found in postoperative PO ≥ 6 m NOSE-p 25.00 (5.00 to 55.00) in the SG group versus 20.0 (2.5 to 47.5) in the control group ($p = 0.448$) (Figure 3) and in the postoperative PO ≥ 12 m NOSE-p 37.50 (5.00 to 50.00) in the SG group versus 17.50 (0,00 to 41.25) in the control group ($p = 0.320$).

3.2 | Rhinoplasty Outcome Evaluation (ROE) Scale

The mean (± SD) ROE scale scores were significantly higher postoperatively in both groups: 28.5 (±16.40) in preoperative versus 71.83 (±18.72) in PO ≥ 6 m in the SG group [$p < 0.001$]

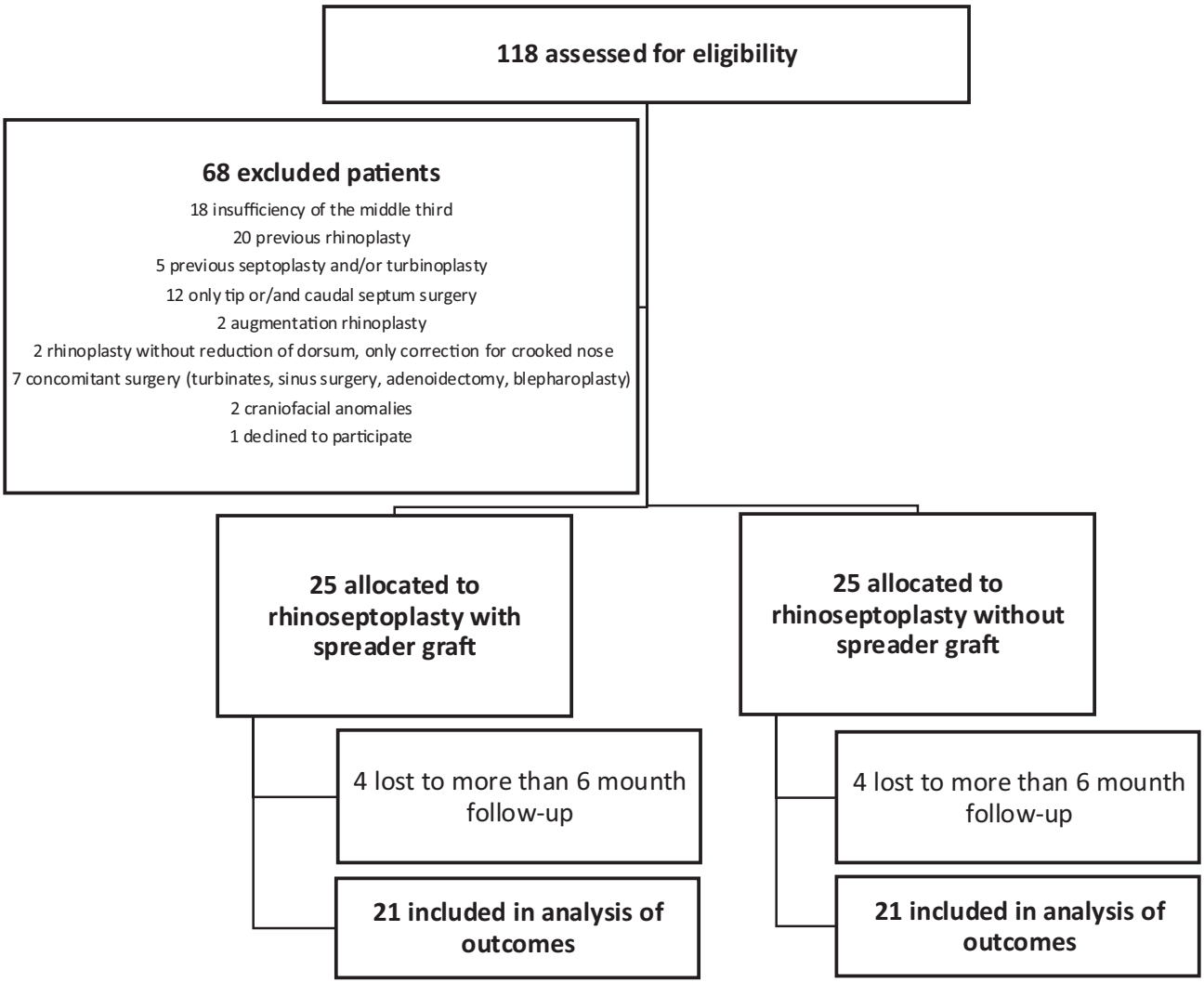

FIGURE 1 | Study flow diagram.

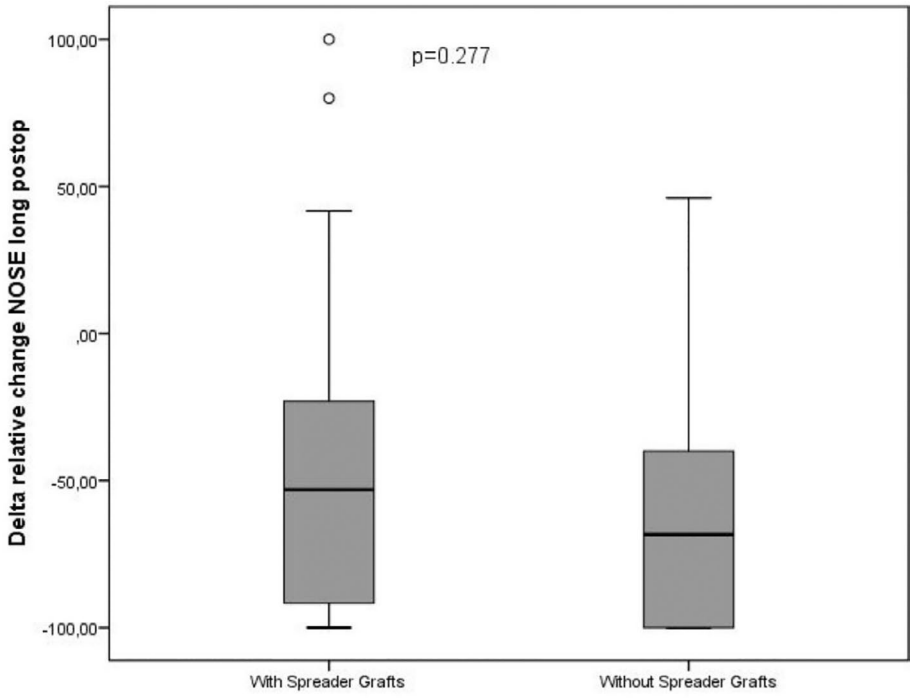

FIGURE 2 | Box whisker plots of the Δ relative change of NOSE-p scores in the group with spreader grafts and without spreader grafts, respectively.

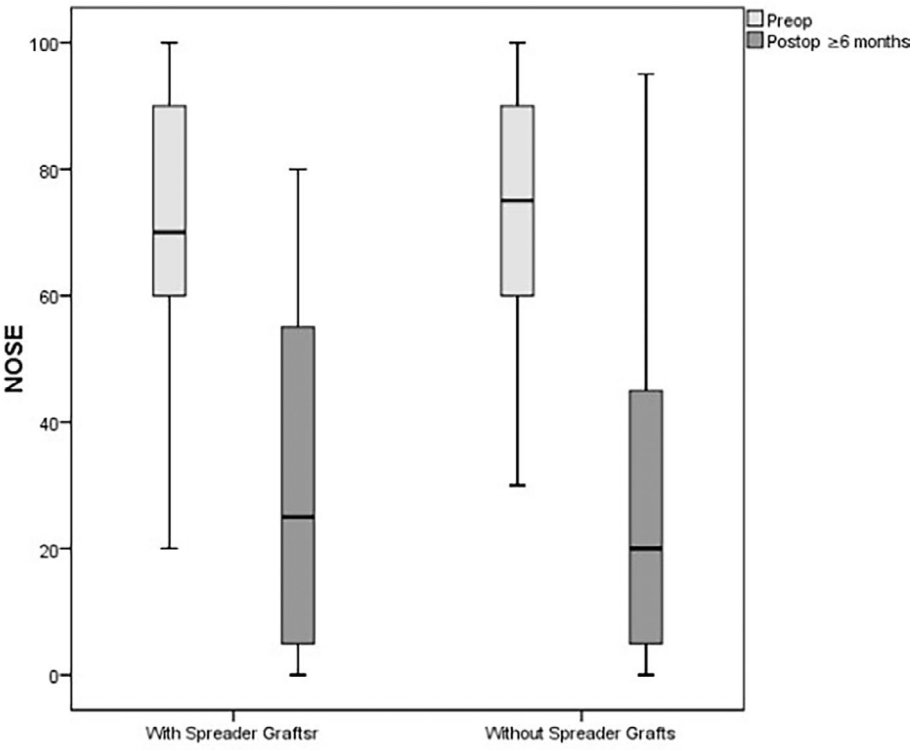

FIGURE 3 | Box whisker plots of pre and 6 months postoperative nasal obstruction symptom evaluation portuguese scale with spreader grafts and without spreader grafts, respectively.

and 31.67 (±16.84) versus 79.56 (±13.75) PO = 6 m in the control group [$p < 0.001$]. No significant difference was found between groups ($p = 0.135$). In PO ≥ 12 m the mean (± SD) ROE scores were also significantly higher postoperatively in both groups: 28.5 (±16.40) in preoperative versus 76.33 (±23.62) in the SG group [$p < 0.001$] and 31.67 (±16.84) versus 79.53 (±22.75) PO ≥ 12 m in the control group [$p < 0.001$]. No significant difference was found between groups ($p = 0.645$) (Figure 4).

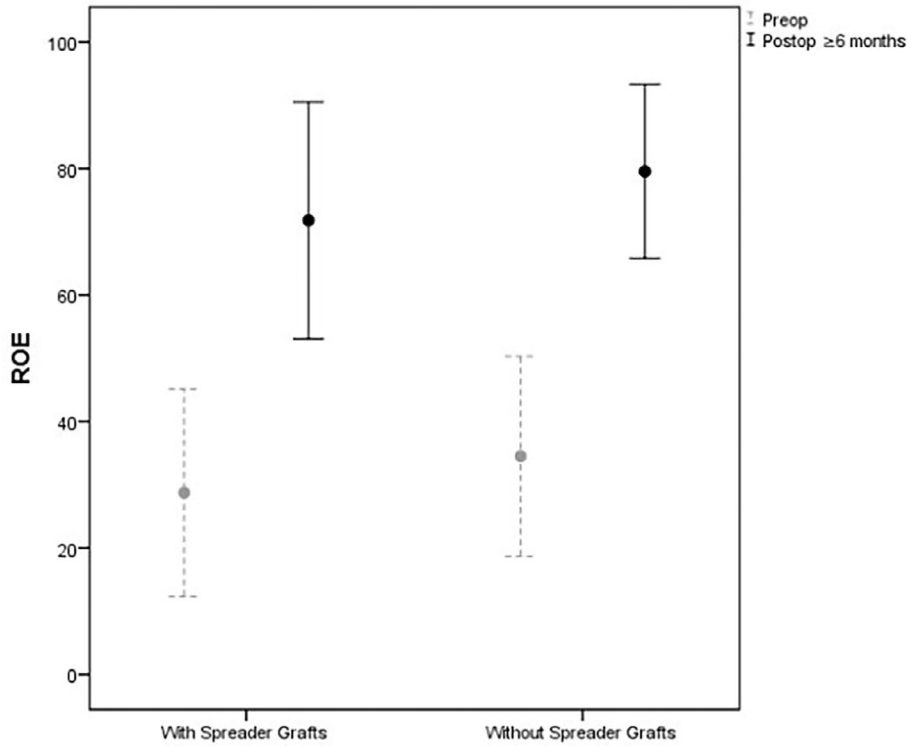

FIGURE 4 | Mean plots and standard deviation of preoperative and ≥6 months postoperative ROE score of patients with spreader grafts and without spreader grafts, respectively.

3.3 | Nasal Obstruction Visual Analogue Scales (NO-VAS)

Degree of nasal obstruction using *Nasal Obstruction Visual Analogue Scales (NO-VAS)* from PO ≥6 m in the SG group versus controls had no significant difference between groups, with median 13.00 (5.25 to 69.00) versus 8.00 (5.00 to 30.00), respectively; [$p = 0.36$]. In the control group, the NO-VAS decreased significantly from before surgery 64.00 (35.00 to 70.00) to PO ≥6 m 8.00 (5.00 to 30.00) [$p = 0.002$]. No significant difference was found in NO-VAS in the intervention group comparing the pre-operative median 53.5 (41.75 to 78.00) with the PO ≥6 m median 13.00 (5.25 to 69.00) [$p = 0.052$]. (Figure 5). NO-VAS PO ≥12 m median was significantly lower postoperatively in both groups: from 53.5 median before surgery (41.75 to 78.00) to 13.00 (5.50 to 47.00) in the PO ≥12 m of the SG group ($p < 0.008$) and 64.00 (35.00 to 70.00) to 11.50 (5.25 to 30.00) in PO ≥12 m of the control group ($p = 0.001$).

3.4 | Complications

There were no complications directly related to the use of SG or absence that resulted in reoperation. Four patients (16%) from the intervention group were reoperated after ≥1-year follow-up. In the control group, one (4%) was reoperated, with no statistical difference between groups ($p = 0.349$). Other complications were reported in both groups, such as one bleeding and three minimal septal perforations in the control group (Table 2).

4 | Discussion

Internal nasal valve (INV) is an essential area for adequate nasal breathing. It is formed laterally by the caudal edge of the upper lateral cartilage, medially by the dorsal septum, and inferiorly by the head of the inferior turbinate [13]. Our group previously had performed randomized clinical trials to evaluate the impact of inferior turbinate reduction (partial inferior turbinectomy [9] and submucosal diathermy of inferior turbinate [10]) on the QOL of patients undergoing septorhinoplasty. The next step of our search for evidence, in the field of rhinoplasty in pragmatic trials, was focused in the midvault area. The question to be answered in this trial was: "For patients undergoing reduction septorhinoplasty, do spreader grafts improve QOL outcomes compared to those without spreader grafts?". To study this question ethically in a trial, the leading exclusion criteria was any symmetric or asymmetric insufficiency of midvault. In those cases, the graft placement, such as SG, is often mandatory and the objective of the trial was to study the role of prevention, rather than treatment, of midline grafts in nasal obstruction.

Our sample of patients reflected a pragmatic setting for rhinoplasty surgeons, including patients undergoing rhinoplasty for various indications such as aesthetic-functional or functional septorhinoplasty. Open or endonasal surgery was considered a question of access and not of surgical technique, and its choice varied not by the use or lack of spreader grafts (since patients were randomized after access planning) but by greater or lesser manipulation of the nasal tip.

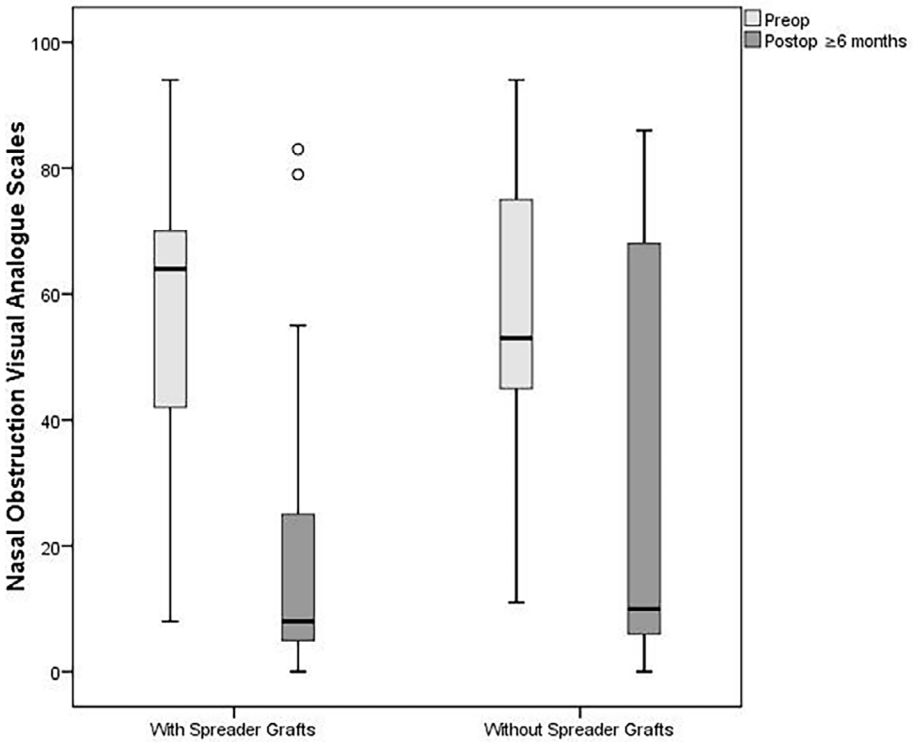

FIGURE 5 | Box-and-whisker plots of preoperative and 6-month postoperative nasal obstruction visual Analogue scales (NO-VAS) for patients with and without spreader grafts, respectively.

TABLE 2 | Complications and reoperated cases in the sample.

Patient no.	Spreader grafts	Complication/ reoperation	Cause	Treatment
1	Yes	Revision surgery in 3rd year follow-up	Aesthetic for residual dorsal hump	Open rhinoplasty, spreader grafts maintained
2	No	Epistaxis in first postoperative period	Anterior epistaxis	24-h nasal packing
3	Yes	Revision surgery in 1st year follow-up	Aesthetic residual dorsal hump	Closed rhinoplasty, spreader grafts maintained
4	No	Revision surgery in 1st year follow-up	Functional for enlarged turbinates	Turbinectomy
5	No	Minimal septal perforation	—	—
6	Yes	Revision surgery in 2nd year follow-up	Aesthetic and functional for reduction of naso-labial angle and crooked nose	Open rhinoplasty, spreader grafts maintained and placement of another spreader graft on the right side
7	Yes	Revision surgery in 1st year follow-up	Functional for deviated SEG	Open rhinoplasty, spreader grafts maintained, refixation of SEG
8	No	Minimal septal perforation	—	—
9	No	Minimal septal perforation	—	—

Abbreviation: SEG, septal extension graft.

The high incidence of concurrent allergic rhinitis in our population could be a confounding factor, but we can assume that the equality between the groups due to randomization helped not to impact the results.

A recent systematic review and meta-analysis [14] compared the outcomes of spreader grafts and autospreader flaps (AF) in the context of midvault reconstruction after dorsal hump removal. A 52 studies were included in the qualitative analysis: 45

observational studies, 6 randomized clinical trials (11.5%), and 1 non-randomized clinical trial (1.9%). Additionally, of the 52 studies, only 19 reported NOSE scores, as was performed in our study, which used QOL outcomes with validated instruments instead of nasal obstruction and nasal airflow measurements. In the meta-analyses, the overall preoperative and postoperative change in the NOSE score was—23.9 (95% CI, − 26.7 to—21.1) points. The changes in the NOSE scores before and after surgery were similar in all groups:—27.1 (95% CI, − 36.2 to—18.0) points for AF; − 26.5 (95% CI, − 30.4 to 22.6) points for SG, and for those in which none of them was used, the scores were—19.9 (95% CI, − 24.3 to—15.5) points. The ANOVA for summary data (Tukey's HSD Post hoc Test) showed no differences between groups, AF group versus no graft ($p = 0.7578$), AF versus SF group ($p = 0.9948$), and SG group versus no graft ($p = 0.6608$). Standlee et al. [15] retrospectively compared pre- and postoperative NOSE scores of patients who underwent septoturbinoplasty to those who underwent open septorhinoplasty with spreader graft placement. The results of this study demonstrated that rhinoplasty with spreader grafting achieved a greater and more robust reduction in NOSE scores than septoturbinoplasty alone. Since it was a retrospective and non-randomized study, potential biases are more likely to occur. On the other hand, in our RCT, the NOSE-p scores were also significantly lower postoperatively than before surgery in both groups, which indicates better nasal obstruction-specific QOL, and no difference was found in postoperative NOSE-p between the SG group versus no graft ($p = 0.448$).

The RCTs including spreader grafts available in the literature to date have: (1) either used autospreader grafts versus spreader grafts with an outcome focused on VAS and acoustic rhinometry [6] or rhinomanometry [16]; (2) either compared autospreader grafts, spreader grafts, and no grafts, with an aesthetic outcome (Face-Q rhinoplasty module) [1]; (3) either compared spreader grafts, the mattress suture technique, and no graft with a Functional AlSarraf standardized questionnaire [17] or (4) compared VAS of patients with or without spreader grafts [18]. Therefore, this is the first RCT that studied quality-of-life outcomes with the NOSE score that compares spreader grafts with midvault reconstruction versus control without spreader grafts.

Our choice not to use objective measures in nasal obstruction was because the current literature discusses that quantitative measures do not necessarily correlate with patient symptoms [19, 20]. As such, we focus the analysis of our outcomes on validated QOL-specific questionnaires: the NOSE and ROE scales.

One limitation of our study is the relatively short follow-up. Some authors that studied the natural history of nasal patency following functional rhinoplasty believe that the improvement in functional rhinoplasty may as well be maximally achieved in an early follow-up. A study from 2017 [21] showed that the scores at 1 to 2 months postoperatively are not significantly different from > 12 months, implying that the breathing improvement in functional rhinoplasty may as well be fully achieved as early as 1 month postoperatively. On the other hand, we believe that our findings of no difference among groups in NOSE scale could change in long follow-ups because the consequences associated with valve insufficiency usually appear after years of follow-up. In this specific study, we did not set out to find this answer. Our cohort is encouraged to maintain annual follow-up at our outpatient clinic so that we can have longer-term analyses for further evaluations.

The ROE scale scores were significantly higher postoperatively in both groups ($p < 0.001$) and no significant difference was found in the PO ≥ 6 m and PO ≥ 12 m ROE score between patients allocated to septorhinoplasty with or without SG. In aesthetics, measured through the ROE scale, deformities are clearly represented by the inverted "V" associated with valve insufficiency, which usually appears after years of follow-up; therefore, in the future, we can have long-term answers in our cohort. Concerning an aesthetic penalty of widening the nasal dorsum, our study demonstrated higher ROE scales postoperatively also in the SG group, in agreement with Fuller et al. [22] This prospective level 3 of evidence study compared preoperative and postoperative Face-Q Satisfaction With NOSE scores in patients undergoing functional septorhinoplasty (FSRP) using spreader grafts, and observed a significant improvement in both aesthetic and functional indicators of the NOSE during 12 months of follow-up.

The absence of differences between groups in NO-VAS follows the same logic as the NOSE; there was no difference in the decrease of nasal obstruction after rhinoplasty among groups in our 7.59 ± 2.36 months follow-up, and it could change in a long follow-up because of the consequences associated with valve insufficiency.

Spreader grafts have potential advantages, such as reconstruction and preservation of nasal valve angle, better stability of nasal structure, and restoration of dorsum aesthetics, but can also have potential disadvantages, like widening of nasal dorsum, graft displacement, and a time-consuming process [23]. In our cohort, there were no complications directly related to the absence of SG, probably due to exclusion criteria, since our medical staff kept routinely indicating spreader grafts in cases of symmetric or asymmetric insufficiency of the middle third. On the other hand, we observed that none of the patients in the SG group complained about widening of the dorsum or graft displacement. The revision rate of the intervention group compared to the control was 16% versus 4% ($p = 0.349$), which is a similar result to the revision rate in the literature (4% to 15.5%) [24]. One patient (2%) of the sample had epistaxis. The incidence of bleeding as an early complication in rhinoplasty (within the first week after surgery) is reported to range between 0.2% and 6.7% [25]. Minor septal perforations of all patients were asymptomatic, but their incidence (6%) was higher than in the literature (ranging from 0% to 2.9%) [25], probably due to the complexity of septum deviation of a population ass.

Another fact about this RCT in a tertiary hospital was that the COVID-19 pandemic started during the period of enrollment, surgeries, and follow-up of the patients. This led to a one-year suspension of elective septorhinoplasties and a nearly 2-year restriction of elective surgical rooms at Hospital de Clínicas de Porto Alegre, a reference center in southern Brazil for care of severe COVID-19 cases. Outpatient care was also quite restricted, which posed challenges to the follow-up of study patients, especially in the first year of the pandemic, and it eventually required that six-month consultations of many patients be postponed. That is the reason why we used a mean follow-up of 7.59 (±2.36) months on the data of PO ≥ 6 m. Further, we assigned four losses

due to COVID issues related to transportation into the appointments or fear of attending a hospital care unit.

Concerning sample size, when it was calculated, the forecast was up to 25% of losses and refusals. In fact, it was 16% of losses, less than we had anticipated. When we compute our primary outcome with the NOSE values actually found in our sample, with standard deviations of approximately 25 points with 21 patients in each group that have been followed up 6 months, we can detect a difference between groups of 20 points with a power of approximately 72%. If we increase the difference of the NOSE values between groups to 25 points with standard deviations of approximately 25 points, seeking an even more clinically relevant difference between the groups, the power of the sample turns to 88.61%.

Since the results of post-operative NOSE were similar between groups, even though larger samples may detect statistically significant differences for the group with or the group without SG, they could have uncertain clinical relevance.

5 | Conclusion

Our study focused on a trial with high methodological quality that addressed primary reduction septorhinoplasty using QOL-related outcomes. It is the first RCT that uses a NOSE scale to directly compare a group with spreader grafts versus a group without such grafts. Our findings demonstrate that reduction septorhinoplasty was associated with nasal obstruction-related improvement of quality of life irrespective of using spreader grafts in a 7.88-month mean follow-up. More studies are necessary to analyze longer-term effects of SG in nasal obstruction-specific QOL.

Conflicts of Interest

The authors declare no conflicts of interest.

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