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ORIGINAL CONTRIBUTION

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Outcomes of force-directed balloon-assisted endoscopic septoplasty: a retrospective analysis with a new technique and device

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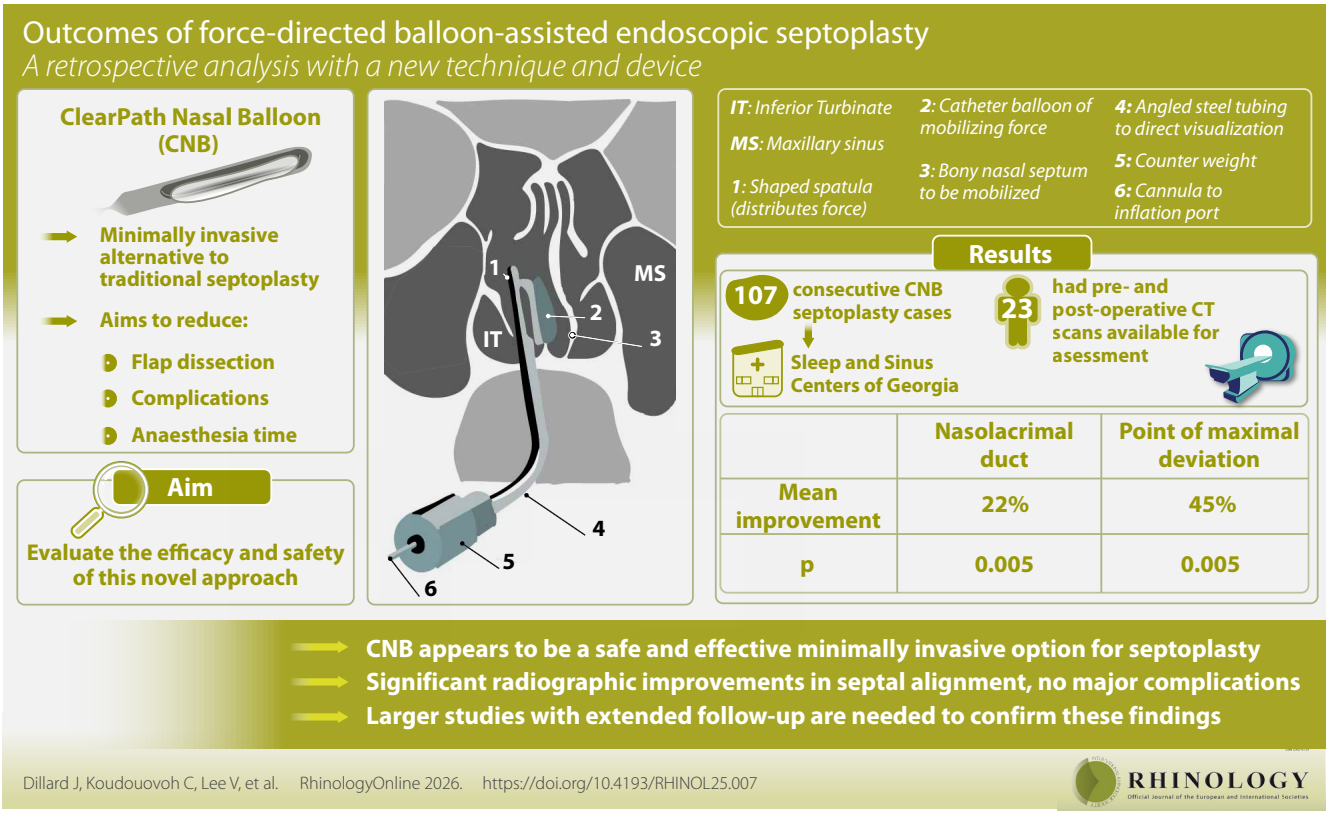

Abstract

Background: Balloon-assisted endoscopic septoplasty using the ClearPath Nasal Balloon (CNB) offers a minimally invasive alternative to traditional septoplasty, aiming to reduce flap dissection, complications, and anesthesia time. This study aims to evaluate the efficacy and safety of this novel approach.

Methods: This retrospective review analyzed 107 consecutive CNB septoplasty cases at Sleep and Sinus Centers of Georgia. Of these, 23 patients had pre- and post-operative CT scans available for assessment. Septal alignment was measured by the distance from the septum to the nasal sidewall at key anatomical landmarks, including the pyriform aperture (PYR), point of maximal deviation (PMD), and nasolacrimal ducts (NLD), using RadiAnt DICOM software. Postoperative CT scans were also assessed for complications. Statistical analysis was performed with paired t-tests.

Results: Results showed a mean improvement of 22% at the nasolacrimal duct and a 45% improvement at the point of maximal

deviation (PMD), both statistically significant (p = 0.005). When a Wilcoxon Signed-Rank Test was used, statistically significant improvements were found for all three anatomical landmarks. No major complications such as septal perforation or synechia were observed.

Conclusion: The CNB technique appears to be a safe and effective minimally invasive option for septoplasty, providing significant radiographic improvements in septal alignment with no major complications in this cohort. However, larger studies with extended follow-up are needed to confirm these findings and determine long-term durability and broader applicability of this novel approach.

Key words: balloon-assisted endoscopic septoplasty, clearpath nasal balloon (CNB), septoplasty, nasal obstruction, deviated nasal septum, nasal surgical procedures

Introduction

Septoplasty is a common otolaryngologic procedure, with over 250,000 performed annually in the United States. Traditional septoplasty requires mucoperichondrial flap elevation and resection of cartilage or bone, often necessitating suturing or packing and carrying risks such as perforation, hematoma, or synechia. Endoscopic septoplasty, developed in the 1990s, improved visualization and access but retained these limitations. Hydrostatic balloon systems received FDA-approval in 2019 for endoscopic nasal surgery. The CNB incorporates a force-directed spatula that redistributes pressure, mobilizes the septum, and minimizes contralateral trauma. This design may reduce flap elevation and mucosal injury. This study evaluates CNB-assisted septoplasty outcomes and safety as a minimally invasive alternative to traditional septoplasty.

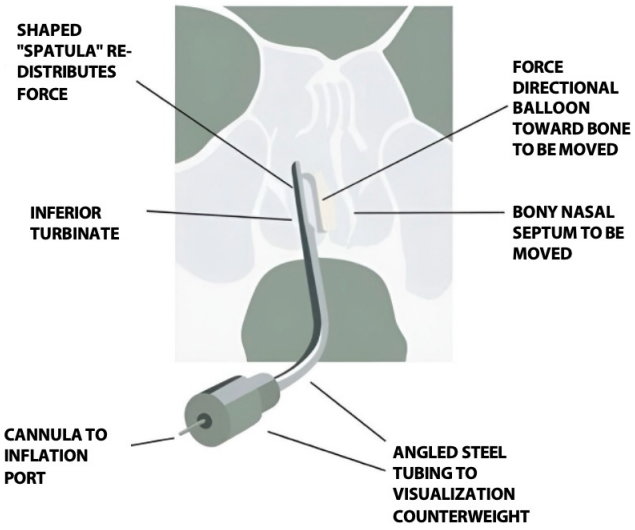

Figure 1. ClearPath nasal balloon model diagram. This diagram of the ClearPath Nasal Balloon (CNB) design for force-directional septal realignment. The shaped distal 'spatula' distributes balloon pressure evenly across the targeted bony septum, thereby allowing the surgeon to mobilize the septum while simultaneously minimizing unintended stress on adjacent lateral nasal structures. An angled steel shaft optimizes endoscopic visualization and serves as a counterbalance. The integrated cannula connects to the inflation port to allow controlled balloon expansion.

Methods

This retrospective case series evaluated 107 consecutive patients who underwent CNB-assisted septoplasty over five years at Sleep and Sinus Centers of Georgia. The procedure was offered as a less invasive alternative to flap-based septoplasty for patients with nasal obstruction, impaired drainage, headaches, or sleep-related complaints. Exclusion criteria were limited to incomplete clinical, imaging, or survey data. Among 107 patients, 23 had both pre- and post-operative CT scans, and 43 completed SNOT-22 surveys.

The CNB system applies directional hydrostatic pressure via a balloon and curved spatula, mobilizing septal deviation while often reducing or avoiding mucoperichondrial flap elevation (Figure 1). It does not address the cartilaginous septum or septal spurs. CT scans were obtained preoperatively to evaluate sinus pathology, guide surgical planning, and assess structural causes of obstruction, and postoperatively in patients with persistent sinus complaints. CT scans were reviewed using DICOM. Septal alignment was measured at the PYR, NLD, and PMD. Although alignment varies by patient, the nasal tip and spine remain constant in axial CT, ensuring consistent measurements. Data were standardized as ratios, with 1.0 indicating midline symmetry.

Statistical analyses were initially performed using paired t-tests. When non-normality was identified, results were reanalyzed using Wilcoxon signed-rank tests. SNOT-22 scores measured qualitative outcomes. Interobserver reliability was assessed using Pearson correlation.

Results

Of 107 patients undergoing CNB-assisted septoplasty, 23 patients had both preoperative and postoperative CT scans.

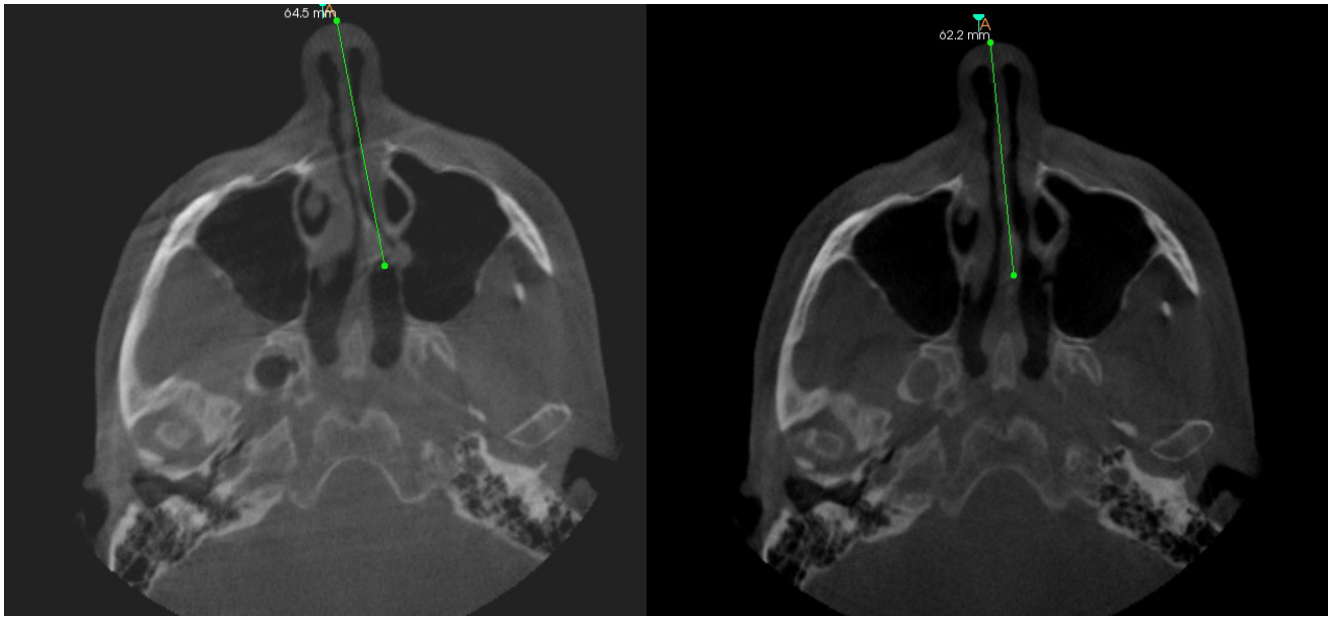

Figure 2. Pre-operative and post-operative axial CT shows septal deviation at PMD. Pre-operative (left) CT scan shows significant septal deviation with a PMD of 65.60 mm from the midline. Post-operative (right) scan demonstrates improved septal alignment following CNB-assisted septoplasty.

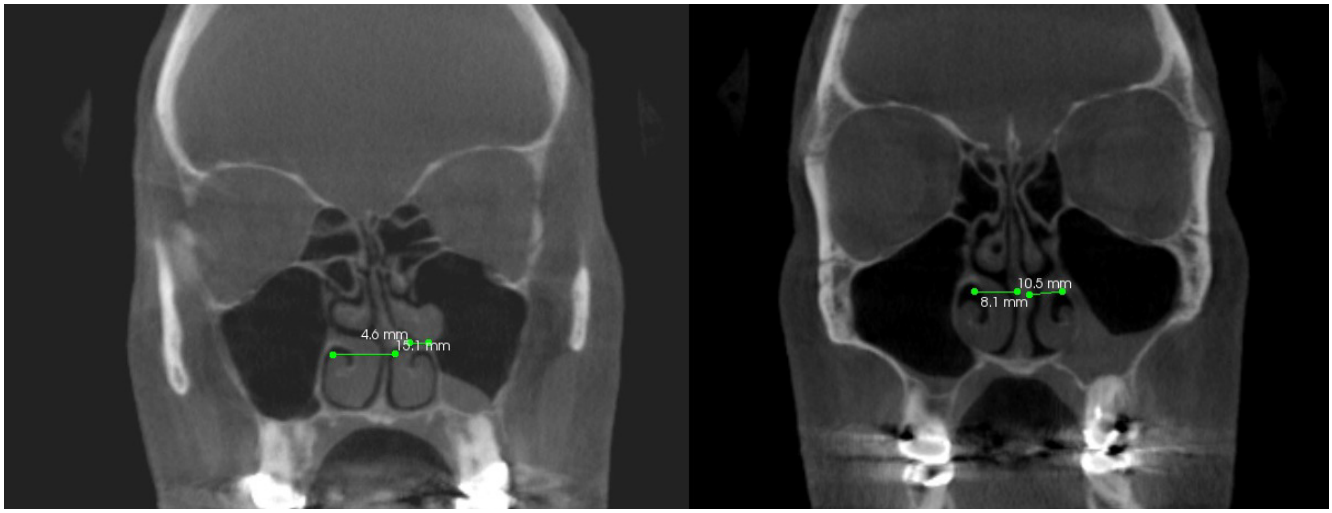

Figure 3. Pre-operative and post-operative coronal CT shows septal deviation at PMD. Pre-operative (left) CT shows septal deviation, while post-operative (right). Coronal CT images demonstrating preoperative (left) and postoperative (right) measurements at the point of maximal deviation (PMD). All measurements were obtained at a consistent anatomic level using a fixed reference point at the tip of the nasal spine or cartilage tip of the nose. Values were converted to ratios, with 1.00 indicating perfect midline symmetry, to allow for direct comparison between time points. CT demonstrates a 38% improvement in alignment after CNB-assisted septoplasty.

No major intraoperative or postoperative complications were identified, including perforation, hematoma, mucosal injury, infection, or need for conversion to traditional septoplasty.

At the NLD, mean symmetry improved postoperatively by 22% (p=0.0047). At the PMD, symmetry improved by 45% (p=0.0038). The PYR showed smaller gains (0.77 to 0.89), which were significant for one observer but not the other. Interobserver reproducibility was excellent (Pearson r>0.98, p<10-15; Tables 1-2 and Figures 2-5).

When stratified by baseline deviation at the PMD, mean improvement was 45% in severe (n=10), 48% improvement in moderate (n=11), and 27% in mild (n=2), yielding a weighted overall mean of 45%. Overall, 18/23 (78%) achieved ≥30% improvement and no patients worsened (Figure 4).

Of the 107 patients in the cohort, 43 (40.2%) completed the Sinonasal Outcome Test-22 (SNOT-22) at their one-month follow-up. Scores improved from 58.7 to 44.8, a 23.8% reduction (p=0.02). The largest improvements were in nasal congestion (-3.8), headache/facial pressure (-3.2), and sleep quality (-1.5) (Table 3 and Figures 6-7).

Table 1. Summary of efficacy measurements of CNB in endoscopic septoplasty.

Measurement	Pre-Operative Measurement (%)	Post-Operative Measurement (%)
NLD Mean Ratio	66.23	87.81
Standard Deviation NLD	27.10	11.50
PMD Mean Ratio	37.69	82.69
Standard Deviation PMD	19.90	16.00

Table 2. Summary of Wilcoxon signed-rank and Pearson correlation analyses for symmetry ratios for all three anatomic landmarks.

Wilcoxon Signed Rank Test	P value (Observer 1; Observer 2) (significance <0.05)	Pearson "r" Value	Pearson "p" value	W value (Observer 1; Observer 2)
PYR	0.021; 0.064	0.9954	9.69×10^{-24}	82; 91
NLD	0.0027; 0.0031	0.9899	5.15×10^{-16}	53;52
PMD	0.00001;0.00005	0.9847	3.21×10^{-15}	122;128

Table 3. SNOT-22 outcomes before and after CNB-assisted septoplasty, including mean change, variability, and percent improvement.

SNOT-22 Symptom Category	Total SNOT-22 Score
Pre-Operative Mean SNOT-22	58.72
Post-Operative Mean Snot-22	44.77
Pre-Operative Standard Deviation	28.67
Post-Operative Standard Deviation	26.32
Percent Change (%)	23.76

Table 4. Baseline demographic and clinical characteristics of patients undergoing CNB-assisted septoplasty (n=23).

Demographic Category	Value
Average Age (years)	42.7 years
Sex (M/F)	Male: 12 (52.2%) Female: 11 (47.8%)
BMI (kg/m^2)	26.4 kg/m^2
Smoking Status (yes/never/former)	Yes: 3 (13%); Never: 18 (78.3%); Former: 2 (8.7%)
Rhinosinusitis Symptoms (>12 weeks nasal obstruction)	65% (15/23 patients)
Hypertension (BP >130/80)	56 % (13/23 patients)
Asthma	8.7% (2 patients)

Discussion

CNB-assisted endoscopic septoplasty is a safe and effective minimally invasive approach for correcting septal deviation, achieving significant improvements in septal alignment and patient symptoms. In our cohort, patients reported improvements in nasal congestion, facial pressure, and sleep quality, with a 24% mean reduction in SNOT-22 (1). These results parallel outcomes reported in larger registries (2). For example, the Swedish registry found 81% of patients with severe nasal obstruction improved at 12 months, suggesting CNB may achieve similar results through a less invasive method. Importantly, no major complications such as septal perforations or orbital injuries occurred.

Endoscopic septoplasty was popularized in the 1990s, and balloon sinus dilation introduced in 2006 provided a low-morbidity alternative to traditional sinus surgery (3-5). Balloon sinus procedures expanded rapidly, with Medicare data showing a 486% increase from 2011-2017, before plateauing after 2018 due to coding changes (6,7). The CNB device was developed within this minimally invasive trend. Using a high-pressure (10 atm) noncompliant balloon on a curved spatula, it applies directional force to mobilize deviated septal cartilage while shielding the opposite side. This reduces contralateral pressure, preserves mucoperichondrium and vascular supply, and minimizes flap elevation, sutures, or packing.

Traditional septoplasty carries risks including septal perforation, cartilage necrosis, and orbital injury, and outcomes vary across patients and centers (8). In the UK National Comparative Audit, SNOT-22 scores improved from 42 to 25.5 in three months but with an 11.4% revision rate, while a Nordic registry reported ~25% persistent obstruction (9,10). A Dutch study noted modest but fairly inconsistent improvements (11). By comparison, CNB produced uniform improvements in radiographic symmetry and symptoms. Improved alignment may also enhance visualization and reduce complications in sinus and skull-base procedures, where poor visualization is a recognized contributor to adverse events (12). Hydrostatic balloon techniques have been shown to reduce surgical trauma, preserve cartilage viability, and are feasible in neonates and skull-base procedures (13-16).

Conclusions

Balloon-assisted endoscopic septoplasty using the CNB significantly improved septal alignment at key anatomical landmarks without postoperative complications. Both objective and subjective outcomes were favorable, though interpretation is limited by the small sample size, retrospective design, and absence of a control group. Larger prospective studies with long-term follow-up are needed to confirm durability and establish CNB's role in standardizing septoplasty outcomes.

List of abbreviations

BMI: Body Mass Index; DICOM: RadiAnt Digital Imaging and Communications in Medicine; CNB: ClearPath Nasal Balloon; CT: Computed Tomography; NLD: Nasolacrimal Duct; PMD: Point of

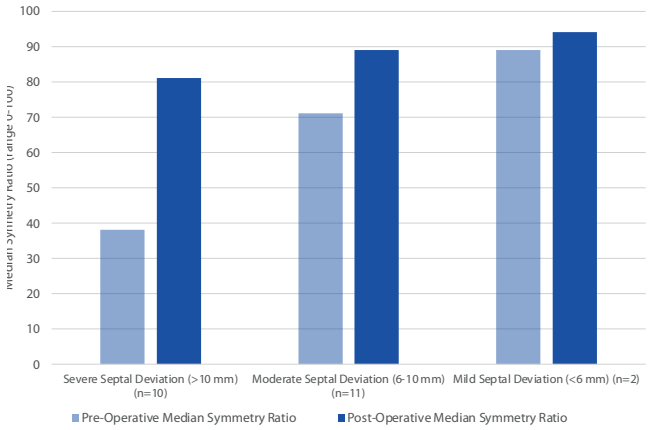

Figure 4. Post-operative septal alignment stratified by baseline deviation severity. Post-operative septal alignment stratified by baseline deviation severity. Severe deviations (>10 mm) demonstrated the largest proportional correction, though all groups showed significant improvement.

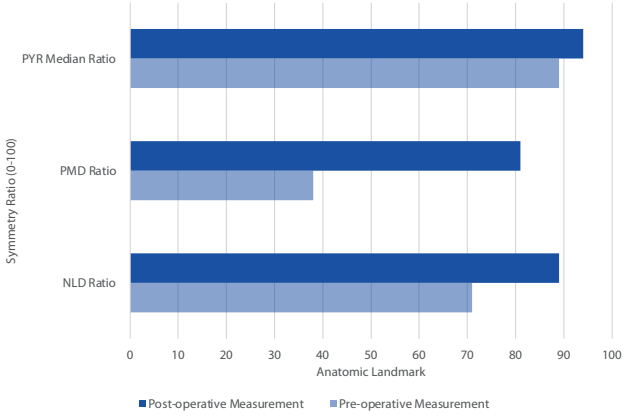

Figure 5. Comparison of pre- and post-operative symmetry ratios for nasolacrimal duct and point of maximal deviation. Pre- and post-operative symmetry ratios for the nasolacrimal duct and point of maximal deviation. Endoscopic septoplasty yielded improved mean ratios and reduced variability, reflecting enhanced nasal symmetry.

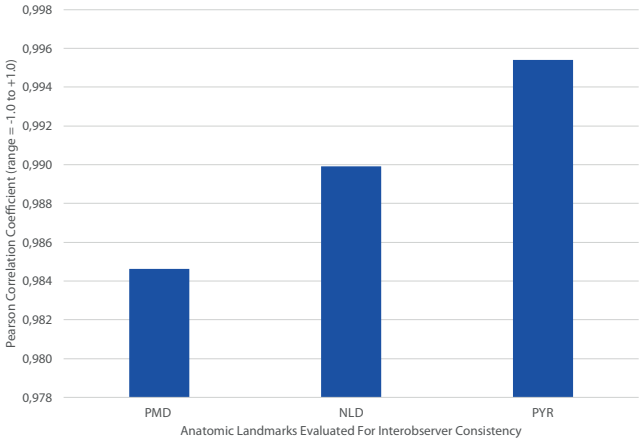

Figure 6. Wilcoxon signed-rank test demonstration high correlation between observers across anatomic landmarks. Inter-observer agreement on septal deviation measurements across anatomic landmarks. Strong correlations confirm reliability and reproducibility of the analytic method.

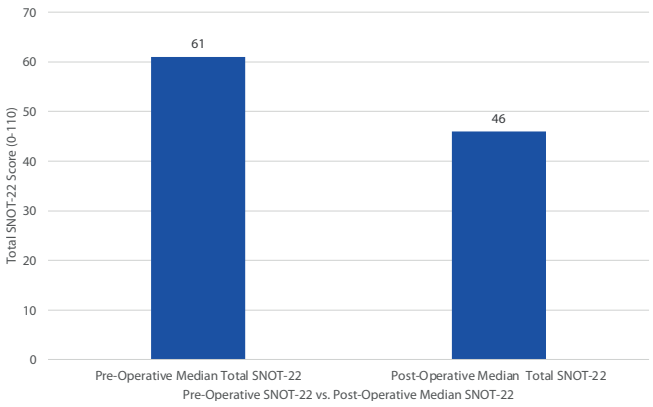

Figure 7. Summary of SNOT-22 improvements following endoscopic septoplasty Using the CNB. SNOT-22 outcomes before and after endoscopic septoplasty using the CNB technique. Post-operative scores showed reductions in symptom burden and variability demonstrating clinical efficacy.

Maximal Deviation; PYR: Pyriform Aperture; SNOT-22: Sinonasal Outcome Test-22.

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Authorship contribution

JD collected the patient data, drafted and finalized the manuscript. CK performed statistical analysis. JKF designed the study, reviewed the data, provided clinical oversight, and critically revised the manuscript for important intellectual content. VL, CB, RS read and approved the final manuscript.

Ethics approval and consent to participate

This study was approved by Sterling Institutional Review Board (Sterling IRB, protocol #12419). The requirement for informed consent was waived due to the retrospective design and use of de-identified patient data.

Consent for publication

Not applicable.

Availability of data and material

Due to patient confidentiality and institutional restrictions, the imaging datasets (DICOM CT scans and SNOT-22 scores) analysed during this study are not publicly available. Qualified and reasonable requests for access may be directed to the corresponding author and will require approval from the Sleep and Sinus Centres of Georgia, USA.

Conflict of interest

The authors declare that they have no competing interests.

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