Development and Evaluation of a 3D-Printed Middle Turbinate Splint: A Pilot Clinical Study

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Abstract

Objectives: Adhesion of the middle turbinate (MT) to the lateral nasal wall can lead to synechiae in the middle meatus, potentially compromising the effectiveness of surgical treatment for chronic rhinosinusitis. This study aimed to develop an anatomically shaped MT splint using three-dimensional (3D) computer modeling and biocompatible elastic resin printing.

Methods: The study was conducted at the Sverzhevskiy Otorhinolaryngology Healthcare Research Institute of Moscow Health Department, Moscow, Russia and approved by the Institutional Review Board. Computed tomography data from 50 adults (25 men and 25 women) were analyzed to determine splint dimensions. A 3D model was designed and printed from a biocompatible elastic resin with a Shore hardness of 50A using a Formlabs Form 3BL printer. The device was evaluated in a pilot cohort of 20 adults (12 men and 8 women) after bilateral sinus surgery; the splint was placed in one nasal cavity for 2 weeks. Nasal endoscopy and patient-reported outcomes were assessed on postoperative days 7, 14, 30, and 60.

Results: The splint comprised two irregular polygon-shaped plates with rounded corners connected by a bridge. When positioned in the nasal cavity, it extended below the inferior margin of the MT. Rates of purulent discharge and crusting did not differ significantly between the splinted and non-splinted sides (all $p>0.05$). On the non-splinted side, adhesions in the middle meatus were observed in 3 patients (15%) at postoperative days 7 and 14 and in 5 patients (25%) at 1 and 2 months. No adhesions occurred on the splinted side during follow-up; the between-side difference was significant at 1 and 2 months ($p=0.047$). Patient-reported pain/discomfort, nasal breathing difficulty, and nasal discharge did not differ significantly between sides (all $p>0.05$). No local or systemic adverse reactions were observed.

Conclusions: A 3D-printed anatomically shaped MT splint was safely used in this pilot cohort and was associated with a lower frequency of postoperative adhesions. Larger controlled studies with longer follow-up are needed to evaluate its clinical efficacy and long-term safety.

Keywords: splint, synechiae, surgery of the paranasal sinuses, FESS, middle nasal turbinate, 3D printing, additive technologies, computed tomography

Introduction

Endonasal surgery of the paranasal sinuses is commonly performed within the framework of functional endoscopic sinus surgery (FESS), which has become a standard approach in rhinologic practice because

of advances in endoscopic techniques and surgical experience. Chronic rhinosinusitis, including cases associated with nasal polyposis, remains one of the principal indications for FESS, and recent regional data continue to highlight the clinical burden of this condition and the need for effective perioperative management strategies.[1] Despite its minimally invasive nature, FESS may be associated with postoperative complications, among which synechiae are among the most common. Reported rates of postoperative synechiae after FESS range from 1% to 43%.[2]

The anatomical narrowness of the middle meatus and common nasal passage, surgical trauma to the nasal mucosa, and postoperative mucosal edema predispose patients to synechiae formation.[3] Surgical modification of the size and shape of the middle turbinate (MT) for example in patients with polypoid changes or hypertrophy, may create an extensive mucosal wound surface and further increase this risk. Synechiae after FESS most commonly develop in the middle meatus; however, they may also occur in the common nasal passage at the level of the middle or inferior turbinate.[4] Although synechiae may not always cause symptoms, they can impair sinus drainage and ventilation, contribute to recurrent sinusitis and compromise the outcome of the primary procedure, potentially necessitating revision surgery.[5]

Several strategies have been proposed to prevent postoperative synechiae, each with specific advantages and limitations. Routine postoperative toilets of the surgical cavity does not reliably reduce the risk of adhesion formation and may cause additional mucosal trauma.[6] Nasal packing of the middle meatus with various materials has also been used; however, packing may cause patient discomfort, require removal, and does not provide an anatomically tailored barrier between the MT and the lateral nasal wall.[6] A systematic review and meta-analysis by Valentine et al. found that middle meatal spacers may reduce the incidence of synechiae compared with no spacer, particularly nonabsorbable spacers, although substantial heterogeneity among studies limited firm conclusions.[7]

Reviews comparing absorbable and nonabsorbable nasal packing after FESS have reported lower synechiae rates with absorbable materials (4.6–8.0% vs 8.0–35.7%), and absorbable packing has also been associated with lower adhesion rates than no packing at 6–8 and 12 weeks after surgery.[8] Nevertheless, none of these approaches completely eliminates the risk of synechiae, and their reported efficacy remains inconsistent because of methodological heterogeneity and the absence of an anatomically customized design.[9]

Another preventive strategy is medialization of the MT by fixation to the nasal septum using sutures or specialized devices, including conchopexy and turbinate-septal suture technique.[10] Prospective and retrospective studies have shown that suture medialization can reduce MT lateralization and synechiae formation compared with no fixation.[11] However, excessive medial displacement particularly in combination with excessive packing pressure, may promote adhesions between the MT and the nasal septum. Such adhesions can also narrow the middle meatus, impair sinus ventilation and drainage, and have been associated with a greater likelihood of revision surgery.[12] Moreover, medialization techniques do not provide a physical barrier between the MT and adjacent mucosa, and their effectiveness may depend on surgical technique and disease extent.

Silastic splints are another commonly used option and have been shown to reduce middle meatal adhesions after endoscopic sinus surgery.[13] However, conventional silastic splints were primarily developed for septal surgery and are not anatomically tailored to the geometry of the MT. Consequently, they may not completely isolate both the medial and lateral surfaces of the MT.

Existing systematic reviews also highlight heterogeneity and limited high-quality evidence across packing and spacer strategies [7-9]. Therefore, an anatomically customized device that isolates both surfaces of the MT and can be fabricated in a standardized, reproducible manner may address an important unmet clinical need.

To date, anatomically customized intranasal splints designed specifically for the MT have not been described. Favorable outcomes have been reported for similar devices fabricated intraoperatively; however, this approach is time-consuming and lacks standardization.[6] Three-dimensional (3D) printing offers a promising method for the rapid prototyping of medical devices. To our knowledge, this is the first study to describe a systematic, anatomically based approach to designing an intranasal MT splint using 3D-printing technology. The aim of this study was to develop an anatomically shaped MT splint using additive manufacturing and to evaluate its safety in a pilot clinical setting.

Methods

The study consisted of three stages: (1) computed tomography (CT)-based assessment of middle turbinate (MT) anatomy, (2) design and three-dimensional (3D) printing of an anatomical MT splint prototype, and (3) a pilot clinical safety assessment of the device.

At the first stage, anatomical parameters of the MT were evaluated using CT scans of the nasal cavity obtained from a retrospective cohort of 50 adults aged over 18 years (mean age, 34.6 ± 5.9 years; 25 men and 25 women). Patients with congenital craniofacial abnormalities, chronic rhinosinusitis, MT pneumatization, or a history of facial bone fractures were excluded.

The following parameters were measured:

1. Size A: length of the medial surface of the MT. This measurement was obtained in the axial plane at the level of the most prominent part of the anterior margin of the MT, from the anterior to the posterior border of its medial surface, as shown in Figure 1.

2. Size B: length of the lateral surface of the MT. This measurement was obtained in the sagittal plane passing through the MT, from the anterior margin to the vertical portion of the basal lamella, as shown in Figure 2.

3. Size C: height of the anterior portion of the MT. This measurement was obtained in the coronal plane angled 20° anteriorly relative to a line perpendicular to the floor of the nasal cavity, from the inferior to the superior border of the MT, as shown in Figure 3.

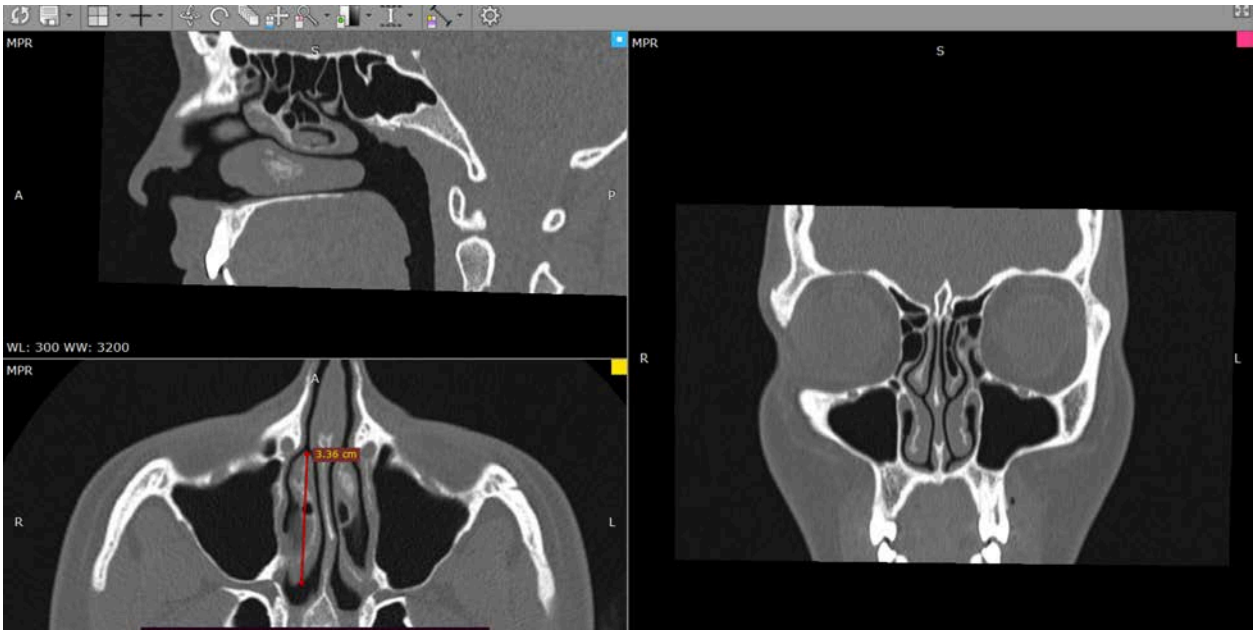

Figure 1: An example of measuring the length of the medial surface of the MT (size A)

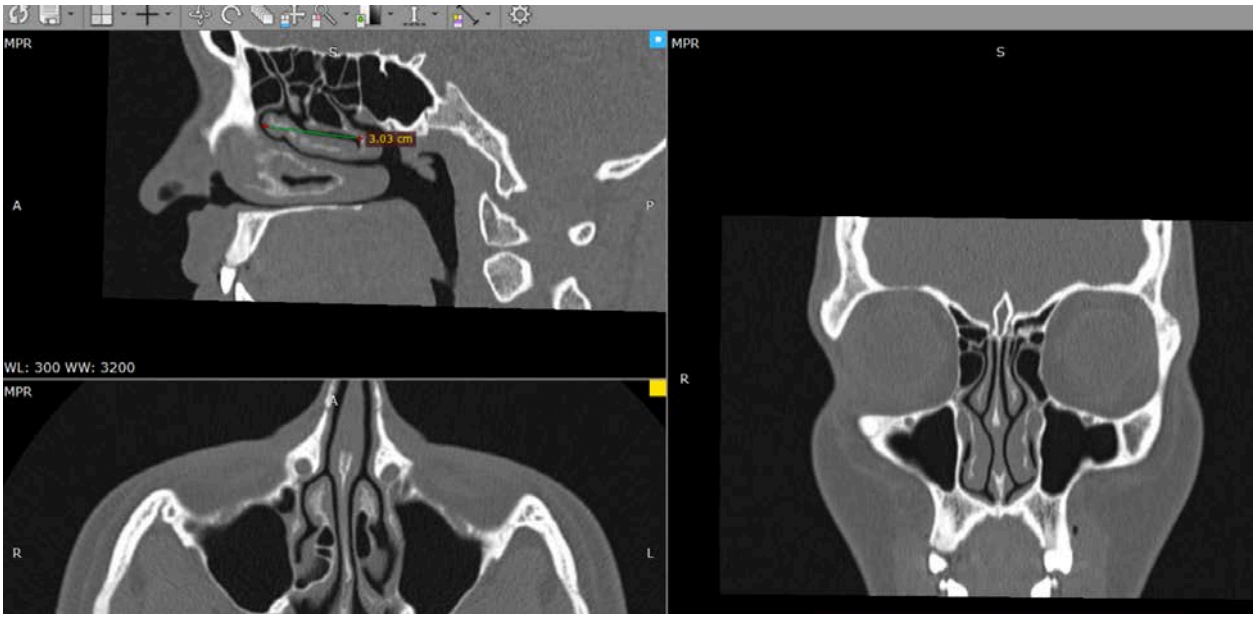

Figure 2: An example of measuring the length of the lateral surface of the MT (size B)

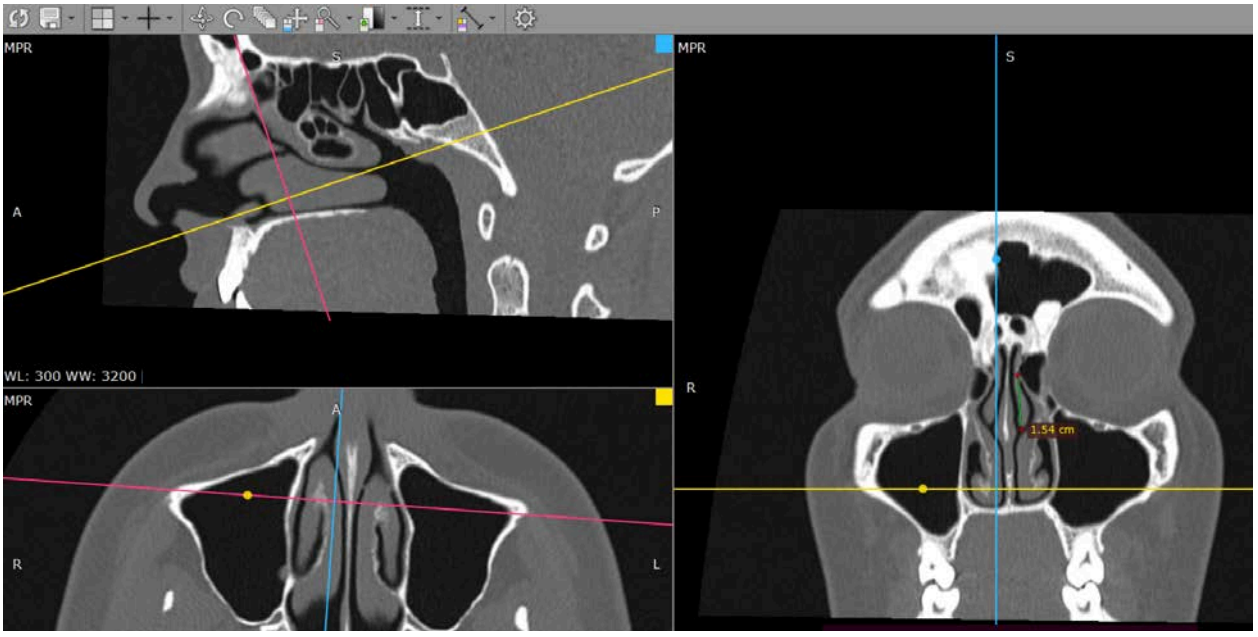

Figure 3: An example of measuring the height of the anterior part of the MT (size C).

Measurements were performed using RadiAnt Dicom Viewer software (Medixant, Poznań, Poland). Multislice CT data were acquired with a slice thickness of no more than 0.5 mm in the axial plane and reconstructed using multiplanar reconstruction.

For all variables, mean values and standard deviations were calculated for the total cohort and separately for men and women.

At the second stage, the anatomical measurements were used to design a 3D model of the MT splint prototype. The splint was designed de novo on the basis of the CT measurements described above and was not reconstructed from an individual patient's CT scan. The plate height was derived from the mean value of size C, with a small additional margin to ensure coverage of the anterior portion of the MT. For the symmetrical version, plate length was based on the minimum observed value of size B with an additional margin to cover the MT surface while avoiding contact with the basal lamella. For the asymmetrical version, the lateral plate length was based on size B, whereas the medial plate length was based on the mean value of size A, with an additional margin. This design strategy was intended to

produce a standardized splint that accommodated anatomical variation across patients rather than a patient-specific device.

The 3D model was created using DesignSpark Mechanical software ver. 5.0 (RS Group, London, UK). The model was exported in STL format and processed with PreForm software ver. 3.49 (Formlabs, Somerville, MA, USA) for slicing and generation of support structures, with a touchpoint size of 0.35 mm.

The splint was printed on a Formlabs Form 3BL stereolithography (SLA) printer (Formlabs) at a layer thickness of 0.1 mm and a printing temperature of 35°C using Biomed Elastic 50A Resin (Formlabs), a biocompatible elastic resin with a Shore hardness of 50A. Supports were removed mechanically after printing. The resin volume required to produce one splint was 0.42 mL without supports and 3.17 mL including supports. Printing time was 3 hours and 20 minutes for a batch of 1 to 8 splints printed simultaneously. The Form 3BL build platform accommodated up to 40 splints in a single layer; printing a maximum batch required 10 hours and 30 minutes, which allows efficient batch fabrication of multiple splints.

Based on the manufacturer's retail price of BioMed Elastic 50A Resin ($349 per 1 L cartridge), the estimated material cost was approximately $0.15 per splint excluding supports and $1.11 per splint including supports. Equipment costs, labor, and additional consumables (e.g., isopropyl alcohol for post-processing) were not included because these costs vary substantially by institution and setting.

After printing, the splints were washed in isopropyl alcohol for 20 minutes and post-cured at 60°C for 20 minutes in accordance with the manufacturer's protocol.

The third stage was a blinded, randomized, split-nose pilot study involving 25 patients with chronic rhinosinusitis who had indications for FESS. All patients underwent routine preoperative laboratory testing, CT of the paranasal sinuses, and nasal endoscopy at admission.

The study was conducted in accordance with the Declaration of Helsinki and approved by the Institutional Review Board of the Sverzhevskiy Otorhinolaryngology Healthcare Research Institute of the Moscow Health Department (protocol No. M12/4, July 29, 2022). Written informed consent was obtained from all participants.

The inclusion and exclusion criteria are presented in Table 1. Patients who did not attend the scheduled 1- and 2-month postoperative visits were excluded from the final statistical analysis (loss to follow-up). The study workflow, including enrollment, side randomization, intervention, follow-up, and the final analysis population, is shown in Figure 4.

Table 1: The inclusion and exclusion criteria.

Inclusion criteria	Exclusion criteria
Age over 18 years	History of surgical treatment of the nose or paranasal sinuses
Diagnosis of chronic bilateral sinusitis, with or without polyps	Hypertrophy of the MT
Little or no effect from medical therapy (local/systemic corticosteroids, saline irrigation, systemic antibacterial therapy)	Need to perform septoplasty and/or surgery on the inferior turbinate
Minimum planned surgical volume: bilateral rhinoantrostomy and ethmoidotomy	Pregnancy
—	Confirmed systemic inflammatory or oncological disease
—	Severe concomitant somatic pathology

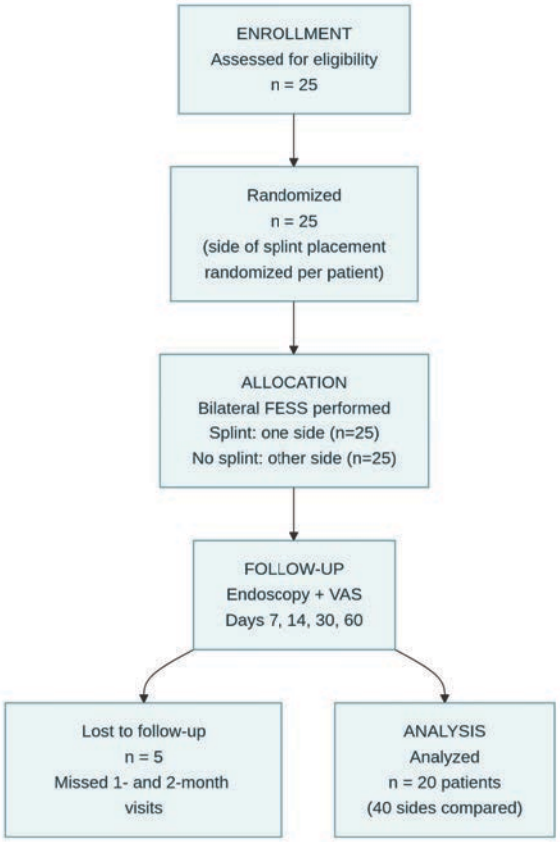

Figure 4: Study flow diagram.

Before surgery, computer-generated randomization was performed (http://www.random.org) to select the nasal side for splint placement.

All patients underwent surgical treatment under general endotracheal anesthesia. At the end of the surgical procedure, after completion of the required bilateral surgical intervention, the symmetrical splint was placed in the randomized nasal cavity using the technique described below (see Results section). The device was not trimmed or otherwise modified intraoperatively in any patient. All surgical procedures were performed by one experienced surgeon to reduce variation in operative technique and mucosal handling.

Patients were discharged on on postoperative day 2. Oral systemic antibacterial therapy and saline irrigation were prescribed for 7 days. On the day of discharge, gentle nasal toilet was performed using an aspirator.

The splint was removed without local anesthesia 14 days after surgery. Endoscopic follow-up was performed on postoperative days 7, 14, 30, and 60. Endoscopic assessments performed at 1 and 2 months after surgery, after removal of the splint, were conducted by physicians who were blinded to the side of splint placement. Endoscopic assessment included the presence and location of synechiae in the middle meatus, purulent discharge, crusting, mucosal edema, and the presence and character of nasal discharge.

Patients independently rated symptoms separately for each nasal cavity using a 10-point visual analog scale (VAS), where 0 indicated no symptoms and 10 indicated the greatest possible symptom severity. The assessed symptoms were pain or discomfort, difficulty with nasal breathing, and nasal discharge. Signs of systemic and local allergic reactions were also assessed. Postoperative microbiological cultures were not obtained because patients received postoperative antibacterial therapy, comparable studies used a similar approach, and no infectious complications occurred.[6,13]

Statistical analysis was performed using IBM SPSS Statistics software, ver. 26 (IBM Corp., Armonk, NY, USA). Paired ordinal variables from the splinted and non-splinted nasal sides were compared using the Wilcoxon signed-rank test. Binary variables were compared using Fisher's exact test. A two-sided p-value of less than 0.05 was considered statistically significant.

Results

The mean value of size A was 39.6 ± 5.8 mm (range, 27.6–54.7 mm), that of size B was 31.6 ± 5.1 mm (range, 22.1–41.6 mm), and that of size C was 13.1 ± 1.9 mm (range, 9.5–17.1 mm) (Table 2).

Table 2: The values of the determined sizes A, B, and C (n=50).

	Dimensions, mm average±standard deviation		
	A	**B**	**C**
Males, n=25	41.9±5.8	33.1±5.6	13.4±1.8
Females, n=25	37.5±5.0	30.2±4.2	12.8±1.9
Total, n=50	39.6±5.8	31.6±5.1	13.1±1.9

Values for men and women are presented separately in Table 2. The mean size A was 41.9 ± 5.8 mm in men and 37.5 ± 5.0 mm in women; the between-group difference was 4.4 mm (p=0.006). Mean size B was 3.1 mm greater in men than in women (p=0.044). Mean size C differed by less than 1 mm between sexes and was not significantly different (p>0.05).

Based on the anatomical analysis described above, a 3D model of the MT splint was created as shown in Figure 5. The splint comprised two parallel, irregular polygon-shaped plates with rounded corners connected by a bridge. Each plate had a thickness of 0.7 mm. The height of the plates was 15 mm, slightly exceeding size C. When the splint was placed in the nasal cavity, the plates extended slightly below the inferior margin of the MT. Plate length was selected to cover the MT surface and extend slightly beyond its anterior margin while avoiding contact with the basal lamella. For the symmetrical version, both plates were 25.1 mm long, which was 3 mm greater than the minimum observed value of size B. This configuration could be used in either nasal cavity. An asymmetrical version could also be used, with a 25.1-mm lateral plate and a 42.6-mm medial plate, corresponding to 3 mm more than the mean value of size A. However, in some patients, the longer medial plate may contact the choana and cause discomfort.

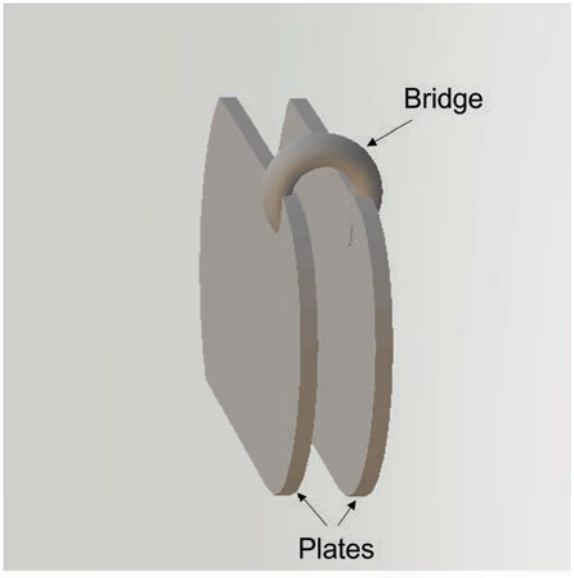

Figure 5: A 3D model of the splint prototype for the MT.

The symmetrical prototype manufactured from biocompatible elastic resin using 3D printing is shown in Figure 6.

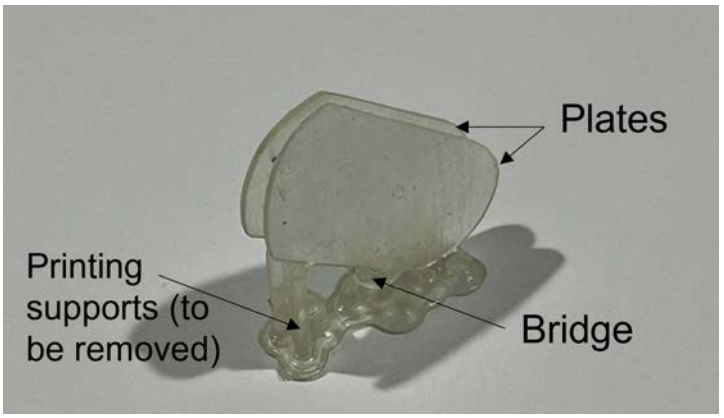

Figure 6: A prototype splint for the MT was made on a 3D printer. The splint is fixed on the supports necessary for the printing process (later removed).

After the surgery of the paranasal sinuses or MT, the splint was inserted into the nasal cavity with its posterior edge directed toward the choana. It could be introduced using bayonet or angled forceps, surgical forceps, or another surgical instrument.

The splint was positioned with one plate lateral and the other medial to the MT, thereby enclosing the MT between the two plates. The inferior edges of both plates were placed below the inferior margin of the MT, and the anterior edges were positioned anterior to the MT anterior margin. The bridge was aligned with the anterior attachment point of the MT axilla, providing stabilization at this anatomical landmark.

Once correctly positioned, the splint was secured to the MT with a single absorbable suture (Vicryl 4-0). The suture passed through both plates and the body of the MT at the level of the bridge and was tied using a simple interrupted technique, to prevent displacement during the postoperative period. Figure 7 shows the splint positioned intraoperatively in the right nasal cavity.

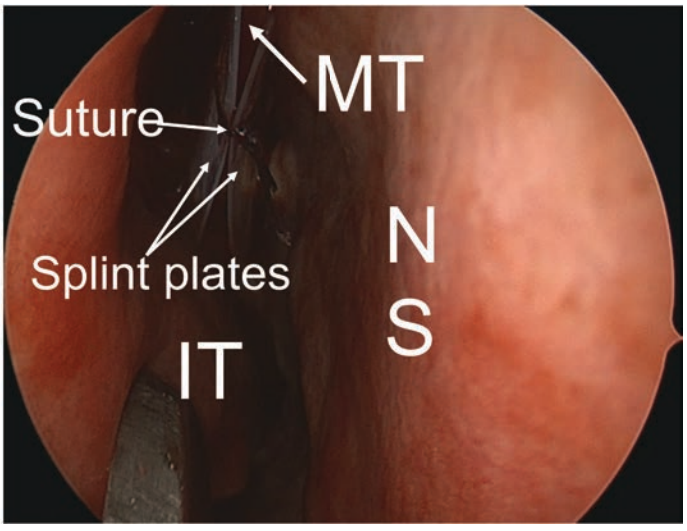

Figure 7: The splint for the MT is installed in the nasal cavity on the right (intraoperative endophoto). NS – nasal septum; MT – middle turbinate; IT – inferior turbinate.

In patients with a narrow nasal passage, suturing after placement could be technically difficult. In these cases, the suture could first be passed through one plate, then through the MT body, and finally through the second plate before insertion of the splint into the nasal cavity. The splint could then be positioned as described above, and the suture tied to secure the device.

The dimensions of the splint could be modified intraoperatively by trimming the plates with scissors or other appropriate instruments.

Twenty-five eligible patients underwent surgery with splint placement. Five patients (20%) were excluded from the final analysis because they did not attend the scheduled 1- and 2-month postoperative follow-up visits; reasons for non-attendance were relocation or scheduling conflicts unrelated to the intervention. Therefore, 20 patients completed the full follow-up protocol and were included in the final statistical analysis.

The median age was 35 years (range,18–61). Twelve patients were men and eight (40%) were women. The symmetrical splint was placed in the right nasal cavity in six patients (30%) and in the left nasal cavity in 14 patients (70%).

Endoscopic findings are summarized in Table 3. The splinted and non-splinted sides did not differ significantly in the occurrence of purulent discharge or crusting at any follow-up visit (all p>0.05). On postoperative day 14, before splint removal, crusting was observed in 10 patients (50%) on the splinted side and in 8 patients (40%) on the non-splinted side (p>0.05).

Table 3: Endoscopic assessment of the nasal cavity of patients in the postoperative period.

Parameter	Timepoint	Splint n(%)	No splint n(%)	p-value	Risk difference
Purulent discharge	7 days	0 (0%)	1 (5%)	1.000	-5%
	14 days	0 (0%)	1 (5%)	1.000	-5%
	1 month	0 (0%)	0 (0%)	1.000	0%
	2 months	0 (0%)	1 (5%)	1.000	-5%
Crusts	7 days	12 (60%)	11 (55%)	1.000	+5%
	14 days	10 (50%)	8 (40%)	0.751	+10%
	1 month	0 (0%)	2 (10%)	0.487	-10%
	2 months	0 (0%)	0 (0%)	1.000	0%
Adhesion	7 days	0 (0%)	3 (15%)	0.231	-15%
	14 days	0 (0%)	3 (15%)	0.231	-15%
	1 month	0 (0%)	5 (25%)	0.047	-25%
	2 months	0 (0%)	5 (25%)	0.047	-25%

Adhesions in the middle meatus were observed on the non-splinted side in 3 patients (15%) on postoperative days 7 and 14 and in 5 patients (25%) at 1 and 2 months. No adhesions were observed on the splinted side throughout follow-up. The between-side difference in adhesion frequency was statistically significant at 1 and 2 months after surgery (p=0.047). Trends in purulent discharge, crusting, and adhesion formation are presented in Figure 8.

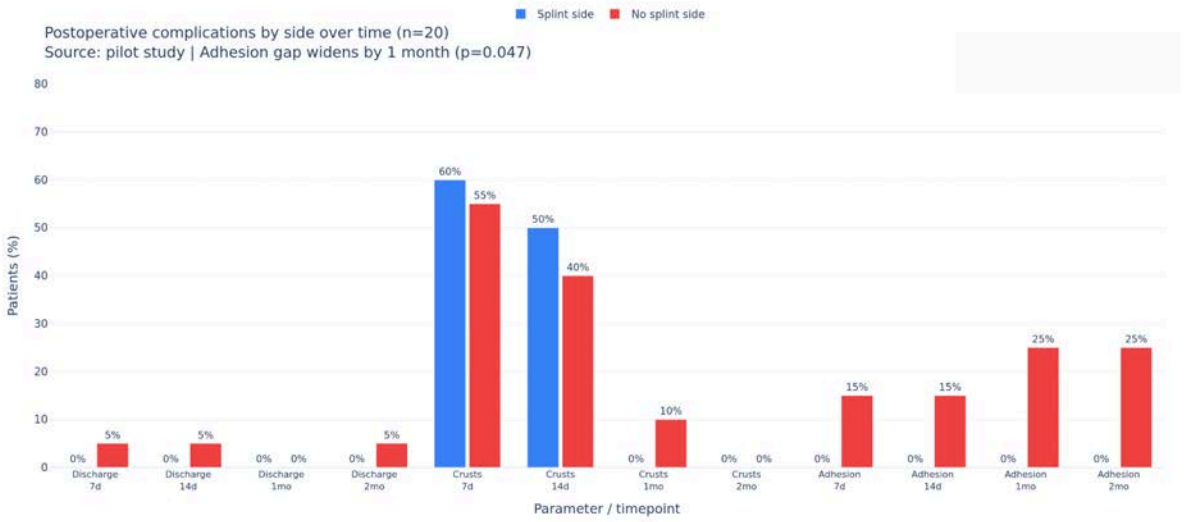

Figure 8: Postoperative complications by side over time.

Patients reported no significant differences between the splinted and non-splinted nasal sides in pain or discomfort (Table 4; all p>0.05). Splint removal caused no additional discomfort; no epistaxis occurred and no nasal packing was required after removal. Median VAS scores for pain or discomfort, nasal breathing difficulty, and nasal discharge are shown in Figure 9; interquartile ranges are provided in Table 4.

Table 4: Complaints of patients in the postoperative period.

Parameter	Timepoint	Splint Me (25–75)	No splint Me (25–75)	p-value	Median difference (effect size)
Tenderness/discomfort	7 days	2 (1–3)	2 (1–3)	0.157	0
	14 days	1 (0–4)	1 (0–2)	0.404	0
	1 month	0	0	0.496	0
	2 months	0	0	0.562	0
Difficulty in nasal breathing	7 days	3 (1–5)	2 (1–4)	0.112	+1
	14 days	2 (1–3)	1 (0–5)	0.320	+1
	1 month	1 (0–2)	2 (0–3)	0.282	-1
	2 months	0	1 (0–2)	0.527	-1
Nasal discharge	7 days	3 (1–6)	4 (2–7)	0.374	-1
	14 days	2 (1–4)	2 (1–5)	0.489	0
	1 month	1 (0–3)	2 (0–4)	0.204	-1
	2 months	1 (0–2)	1 (0–2)	0.453	0

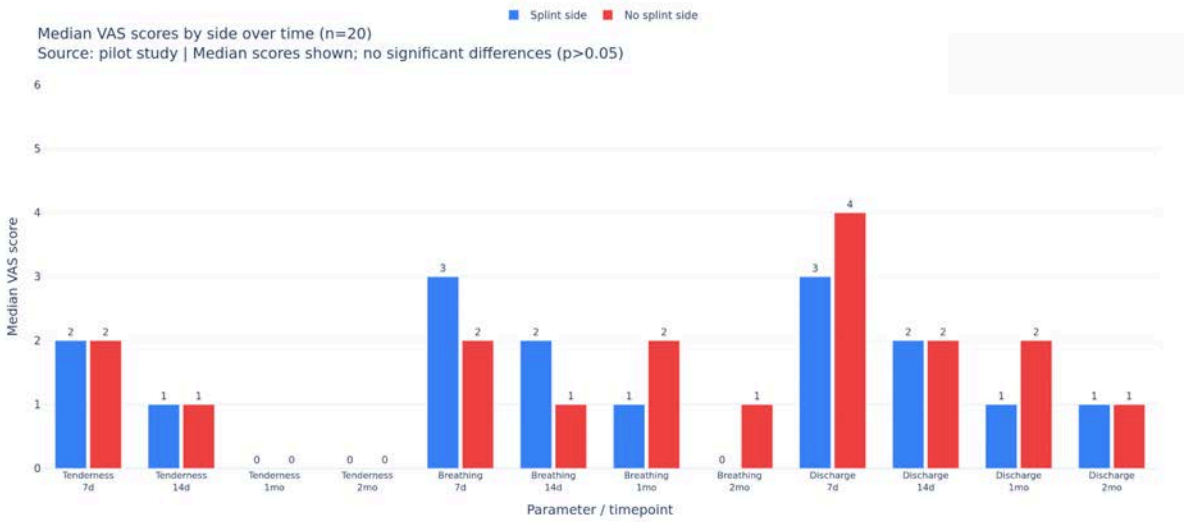

Figure 9: Median VAS scores by side and timepoint.

At postoperative day 7, the median VAS score for nasal breathing difficulty was 3 (interquartile range, 1–5) on the splinted side and 2 (interquartile range, 1–4) on the non-splinted side (p>0.05). Median VAS scores for nasal discharge were 3 (interquartile range, 1–6) and 4 (interquartile range, 2–7), respectively (p>0.05). At postoperative day 14 and at 1 and 2 months, no significant between-side differences were observed for any patient-reported outcome (all p>0.05). No local or systemic adverse reactions were observed.

Discussion

This study evaluated anatomical characteristics of the MT in an adult Eastern European population and used these measurements to develop a standardized 3D-printed intranasal splint. The findings showed substantial interindividual variability in MT dimensions. The medial and lateral dimensions of the MT were greater in men than in women, whereas the height of the anterior portion of the MT did not differ significantly between sexes. These findings support the use of an anatomically informed design while also indicating that a single standardized device may not be suitable for every patient.

The proposed splint was designed to isolate both the medial and lateral surfaces of the MT from adjacent mucosa. This differs from many currently used middle-meatal spacers and conventional splints, which primarily maintain separation between the lateral surface of the MT and the lateral nasal wall.[7] By providing a physical barrier on both sides of the MT, the device may reduce the opportunity for postoperative adhesion formation, including in situations associated with substantial mucosal trauma, such as partial MT resection or excision of pre-existing synechiae. However, the present clinical cohort excluded patients requiring direct MT surgery; therefore, this potential application should be evaluated specifically in future studies.

The use of 3D printing enabled rapid fabrication of the prototype from a biocompatible elastic resin. The complete workflow, from digital design to a ready-to-use splint, could be completed within several days. In institutions with established additive-manufacturing infrastructure, this approach may allow standardized production of splints with reproducible dimensions. However, the current prototype was designed as a standardized rather than patient-specific device, and its fit may be limited in patients with marked anatomical variation.

No local or systemic adverse reactions were observed during the 2-month follow-up period. In particular, no visible local mucosal changes attributable to contact with the splint were identified. Preoperative allergy testing for the resin was not performed because the manufacturer does not disclose the complete chemical composition of the material and no validated allergy test is available for this specific resin. The absence of observed allergic reactions in this small cohort is reassuring but does not establish long-term biocompatibility or exclude uncommon adverse events. Larger studies with longer follow-up are needed to evaluate the material's local tissue response and immunologic safety profile.

To our knowledge, this is the first report describing the use of 3D printing to manufacture an intranasal splint intended for direct contact with the nasal mucosa. The absence of clinically apparent local reactivity in this study suggests that the material may be suitable for short-term intranasal use; however, it should not be considered equivalent to medical-grade silicone without direct comparative testing.[6]

The observed clinical findings are consistent with previous reports that intranasal splinting can reduce synechiae formation after FESS. Baguley et al. reported a lower incidence of middle-meatal adhesions with silastic splints than with no splinting.[13] In the present study, no adhesions were detected on the splinted side, whereas adhesions were observed on the non-splinted side in 25% of patients at 1 and 2 months. The difference between sides was statistically significant at both time points ($p=0.047$). In addition, endoscopic assessments at 1 and 2 months were performed after splint removal by physicians blinded to the side of placement, which reduces the risk of detection bias for the main later postoperative outcome.

Unlike suture-based medialization techniques, such as conchopexy or turbinate-septal suture,[10,11] the proposed device does not merely reposition the MT. Rather, it separates both its medial and lateral surfaces from surrounding mucosa. This feature may help prevent adhesions regardless of the direction of postoperative turbinate displacement. In contrast to steroid-eluting implants, such as PROPEL,[5] the device provides mechanical separation without local drug delivery. It may therefore represent a simpler and potentially less costly option; however, its clinical benefits and cost-effectiveness relative to established splints, spacers, and steroid-eluting implants require direct comparison.

Routine use of a specialized intranasal splint may not be justified for all patients undergoing FESS. Its use may be most appropriate in selected cases involving extensive trauma to intranasal structures and an increased risk of synechiae formation, such as extensive surgery on the MT or wide excision of adhesions. In uncomplicated FESS with limited mucosal trauma, the additional cost and procedural complexity of splint placement may outweigh its potential benefit.

Establishing a dedicated 3D-printing laboratory solely to produce this device may not be practical for most institutions. However, centers that already have additive-manufacturing infrastructure for medical applications may be able to incorporate production of the splint into existing workflows. The reported material cost was low, although the present estimate did not include printer acquisition, maintenance, labor, sterilization, post-processing, or other consumables; therefore, it should not be interpreted as the total cost per device.

This pilot study has several limitations that should be considered when interpreting the results. First, the sample was small, and five of 25 enrolled patients were excluded from the final analysis because they did not complete the 1- and 2-month follow-up visits. Second, although split-side randomization controls for many patient-level factors, it cannot fully account for side-specific differences in disease severity, surgical extent, or intraoperative mucosal trauma. Third, the use of systemic antibacterial therapy and saline irrigation in both nasal cavities may have influenced postoperative healing and potentially reduced the observable difference between sides.

Fourth, follow-up was limited to 2 months and was insufficient to establish long-term effectiveness in preventing synechiae or MT lateralization. Fifth, the early endoscopic assessments, performed while the splint was still in place, could not be fully blinded; only the 1- and 2-month assessments after splint removal were performed by blinded evaluators. Finally, the study was designed primarily to assess feasibility and short-term safety rather than to provide definitive evidence of clinical efficacy. The statistically significant reduction in adhesions should therefore be interpreted cautiously.

Future controlled studies should include larger samples, longer follow-up, blinded outcome assessment at all feasible time points, and stratification by baseline disease severity and surgical extent. Comparative studies against established middle-meatal spacers, silastic splints, packing materials, and steroid-eluting implants would clarify the relative clinical value of this device. Studies should also evaluate the device in patients at increased risk of synechiae, particularly those undergoing extensive MT surgery or adhesion excision.

Conclusions

This study examined the anatomical characteristics of MTs in adult males and females to develop various intranasal devices, including splints for the middle nasal passage and MT. On the basis of our data, we developed the anatomical shape of an intranasal splint for MTs, comprising two parallel plates connected by a bridge, designed to isolate both the medial and lateral surfaces of the MT — an advantage over existing devices that isolate only the lateral surface. The additive technologies allowed us to make a prototype product suitable for rapid use, with the full workflow from digital design to a ready-to-use device completed within days.

In this pilot split-side study, short-term use of the splint was not associated with local or systemic adverse reactions or increased patient-reported discomfort. No adhesions were observed on the splinted side, whereas adhesions occurred on the non-splinted side in 25% of patients at 1 and 2 months after surgery; this between-side difference was statistically significant. However, given the small sample size and limited follow-up, these findings should be interpreted cautiously.

Larger controlled studies with longer follow-up are needed to confirm the clinical effectiveness, long-term safety, optimal indications, and cost-effectiveness of the device, particularly in patients at high risk of postoperative synechiae.

Disclosure

The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

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