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In-Vitro Evaluation of Intranasal Splints: Assessing Insertion Mechanics, Structural Integrity, and Airway Support for Post-Surgical Nasal Recovery in Nasal Phantom Model

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Abstract

Background: Intranasal splints are medical devices used after nasal surgeries (like septoplasty and rhinoplasty) to stabilize the nasal structures, maintain airway patency, prevent tissue adhesion, and support healing. Typically made from flexible materials like silicone, they help reduce discomfort and support the recovery process. Intranasal splints are widely used in post-operative nasal surgeries such as septoplasty, rhinoplasty, and nasal fracture repairs to maintain nasal airway patency, prevent tissue adhesion, and support efficient healing. These splints, often composed of medical-grade silicone, are designed to stabilize the septum while minimizing patient discomfort and nasal obstruction.

Objective: This study aims to evaluate the ease of insertion, structural integrity, and airway support of different nasal splint designs—Bi-Valve, Airway, and Pre-Cut—through an in-vitro simulation using a physical nasal model.

Methods: A simulated nasal environment was developed to assess the insertion mechanics, stability, and airflow properties of the splints under conditions mimicking post-surgical healing. The splints were evaluated for their ability to maintain airway patency, prevent posterior dislodgement, and minimize insertion-related stress. Performance parameters such as positioning accuracy and airflow resistance were analyzed to predict their viability.

Results: The findings indicate that all three splint designs exhibit excellent flexibility and stability while ensuring minimal airway obstruction. The Bi-Valve splint demonstrated superior adaptability to nasal contours, whereas the Airway and Pre-Cut splints provided enhanced airflow due to their integrated airway tubes. Additionally, the presence of suture indicators facilitated secure fixation, reducing the risk of posterior displacement.

Conclusion: This study underscores the critical role of intranasal splints in post-surgical nasal recovery and highlights their design considerations for optimal clinical outcomes. The in-vitro simulations validate the effectiveness of these splints in maintaining airway patency and ensuring patient comfort, providing valuable insights for further refinement and clinical implementation.

Keywords: Intranasal splints, Nasal fracture repair, Posterior displacement, Nasal obstruction prevention, Nasal airway patency, in-vitro simulation, silicone splints, Nasal surgery recovery

Introduction:

Nasal surgeries such as septoplasty, rhinoplasty, and sinus surgery are routinely performed to address both cosmetic concerns and functional issues or to correct structural abnormalities [2]. The success of these surgeries relies on appropriate post-operative care, as various complications—including nasal blockage, septal hematoma, mucosal adhesions, scar tissue formation, infection, abscess formation, and septal instability—can occur if recovery is not adequately managed [8]. To reduce these complications and ensure optimal recovery, effective post-operative care is crucial [3,4].

Medical-grade silicone is widely used in the manufacture of internal nasal airway splints due to its favorable material characteristics, including flexibility, biocompatibility, durability, and non-reactive nature [1]. These properties allow the splints to conform comfortably to the nasal anatomy, maintain structural integrity during healing, and minimize tissue irritation or inflammatory responses.

The presence of foreign materials like nasal packing within the nasal cavity is often associated with significant pain and discomfort, especially during removal. Additionally, this removal process may induce secondary bleeding, which sometimes requires repacking. Nasal packing can also damage the nasal mucosa and lead to ciliary loss. For these reasons, there is a growing consensus in the literature that nasal packing should be avoided whenever possible. As alternatives, intranasal splints and septal suturing have gained increased clinical preference [12].

To support healing, prevent adhesions, and maintain airway patency during the post-operative phase, internal nasal splints are commonly utilized [5]. However, if not properly placed, or if insertion is difficult, the splints may fail to provide adequate support, thereby prolonging recovery [4]. This underscores the importance of post-operative care that includes both ease of splint insertion and assurance of functional stability [9].

The internal nasal splints used in this context are typically made from medical-grade silicone, selected primarily for its flexibility, softness, and compatibility with human tissue [10]. These splints are sterilized using ethylene oxide (ETO) to ensure sterility and minimize infection risk. Packaged as single-use devices in sealed containers, they are sutured in place during surgery to prevent dislodgement or aspiration. Their design supports the nasal cavity's structural alignment and allows for easy, effective insertion with minimal tissue trauma.

To assess the clinical reliability of intranasal splints, this study focuses on key performance parameters such as positional stability, resistance to dislodgement, and structural integrity. These factors reflect real-world surgical requirements and serve as objective metrics to evaluate the safety and effectiveness of splints during recovery.

Benefits of Internal Nasal Splints:

During the post-surgical recovery process, internal nasal airway splints provide several key benefits:

I. Enhanced Breathing:

Post-operative surgical interventions in the nose can expose patients to complications such as swelling or tissue obstruction, which may impair normal breathing. A nasal airway splint often contains an internal airway tube that maintains an open passage even when surrounding tissues swell. This design ensures proper and easier breathing during the critical recovery phase.

II. Structural Support:

Internal nasal airway splints provide crucial structural support to the healing nasal passages following surgery. They help stabilize the nasal septum and surrounding structures, preventing unnatural movement. This promotes proper alignment and supports favorable surgical outcomes.

III. Prevention of Adhesions:

Adhesions—such as those forming between the septum and adjacent nasal tissues—are common post-surgical complications caused by scar tissue development. Internal splints help keep healing tissues separated, reducing the risk of such adhesions and ensuring healing occurs in the correct anatomical positions [5].

IV. Comfort and Temporariness:

Made from soft, pliable medical-grade silicone, these splints are designed to minimize discomfort during use. Although intended for short-term application, they are easy to remove once the patient has reached an appropriate stage of recovery. Their temporary nature adds to overall patient comfort and convenience during the healing period.

Literature Review:

Over the years, nasal splints have undergone significant evolution, with early designs being rigid and uncomfortable, which frequently led to poor patient compliance [3]. Early splints were primarily intended to stabilize the nasal septum after surgery but were often intolerable to patients due to their rigidity.

Recent advancements in the design of nasal airway splints have focused on improving patient comfort by using flexible, biocompatible materials such as silicone and polyurethane. These newer materials reduce irritation and inflammation, promoting faster healing and better overall recovery [7]. Studies have shown that biocompatible materials significantly reduce inflammation and support the healing of nasal tissues, which has led to better compliance and improved post-surgical outcomes [11]. These innovations in material technology have made nasal splints more tolerable for patients and have enhanced the effectiveness of post-operative care in nasal surgeries.

Materials and Method:

These splints are designed using medical-grade silicone, which is intended to support the septum without obstructing airflow. It provides structural support and prevents nasal blockage by consisting of two separate pieces that are inserted into each nostril. They are designed with an airway tube that allows unobstructed nasal breathing, even during the postoperative period.

In this study, Bi-Valve, Airway, and Pre-Cut internal nasal splints were evaluated using a simplified in-vitro simulation model replicating the human nasal cavity. The splints were inserted into the nasal model following the same procedure used during surgery, replicating the post-surgical environment. The primary aim was to assess whether the splints could remain in place without shifting, as this is critical for effective airway support during the healing process.

The model allowed for an easy evaluation of the insertion technique and the splints' stability, without simulating the interaction with airflow or mucus. This study provided valuable insights into the performance of the splints, highlighting their flexibility, ease of insertion, and ability to provide support while minimizing discomfort.

In-Vitro Testing Methodology:

The performance of Internal Nasal Airway, Bi-Valve & Pre-cut Splints was conducted using a simple nasal simulation model. The model was designed using CT-derived anatomical data of an average adult nasal cavity the model was 3D-printed using medical-grade silicone to mimic mucosal softness and rigidity. The dimensions of the model were as follows: length 7 cm, width 3.5 cm, and height 2.5 cm. The simplified in-vitro Simulation model (Figure-1) replicates the human nasal cavity, designed to simulate post-surgical conditions for evaluating the insertion of nasal splints.

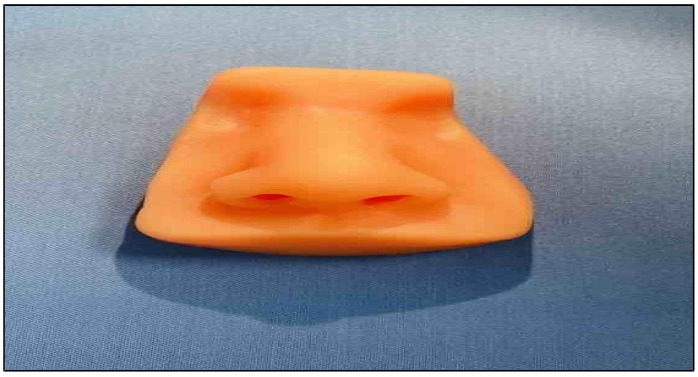

Figure 1: Experimental Setup of the Nasal Simulation Model for In-Vitro Testing

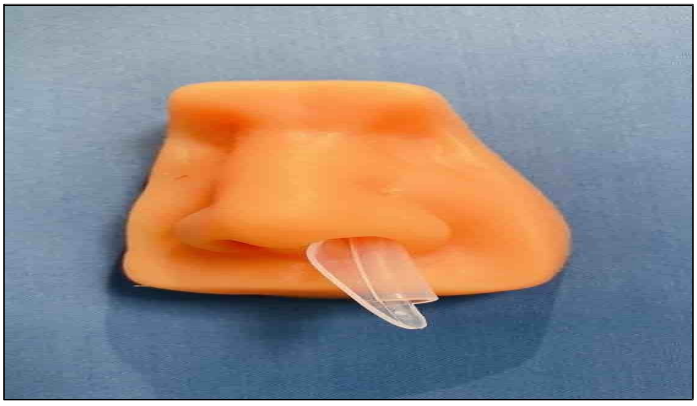

Figure 2: Insertion Process of Airway Splints into the Nasal Simulation Model for Evaluation

The airway splints are inserted into the simulation model (Figure-2), following the same procedure as during a surgical procedure, ensuring proper placement for airway support. The figure-3 represents the airway splints completely inserted into the model, effectively demonstrating their stable placement and accurate alignment within the nasal passages, ensuring optimal positioning for functionality.

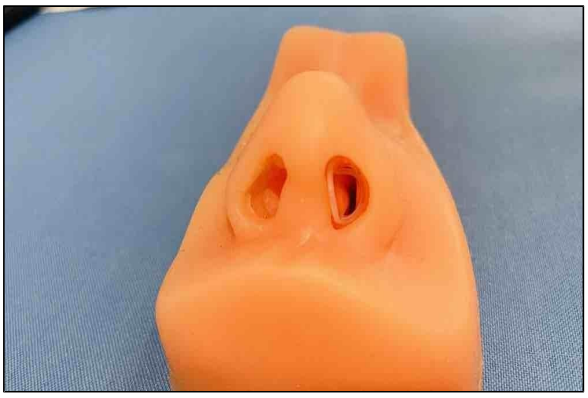

Figure 3: Complete Insertion and Placement of Airway Splints into the Nasal Simulation Model for Assessment

The Bi-Valve splints are inserted into the simulation model (Figure-4), replicating the surgical process and ensuring the splints are properly positioned to maintain structural support, highlighting their effectiveness in preserving nasal passage structure and ensuring they remain securely in place without shifting (Figure-5).

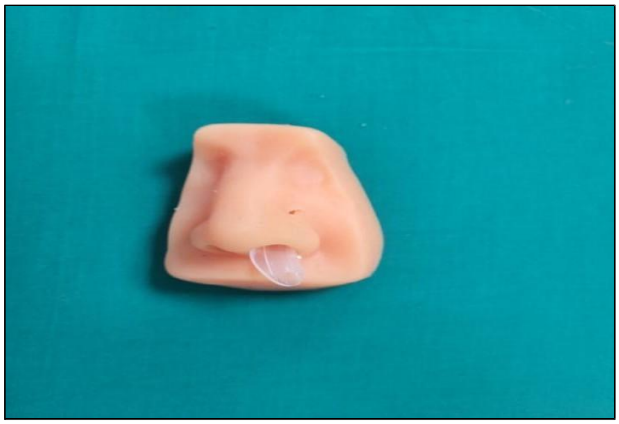

Figure 4: Insertion of Bi-Valve Splints into the Nasal Simulation Model for Evaluation

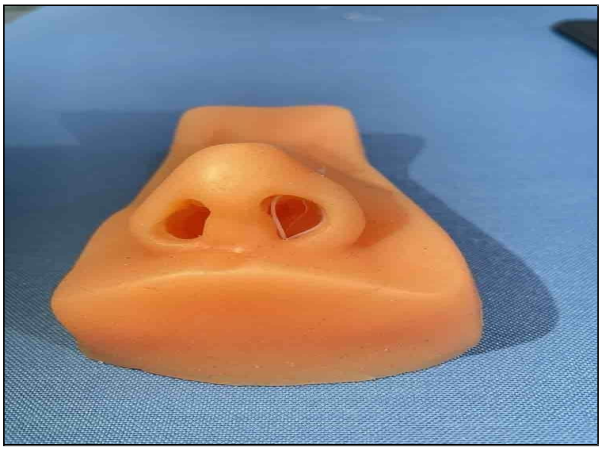

Figure 5: Complete Insertion of Bi-Valve Splints within the Nasal Simulation Model

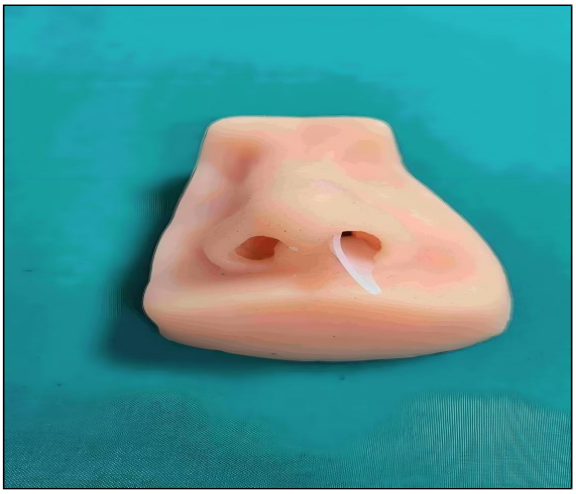

Figure 6: Insertion of Pre-Cut Splints into the Nasal Simulation Model for Assessment of Placement and Stability

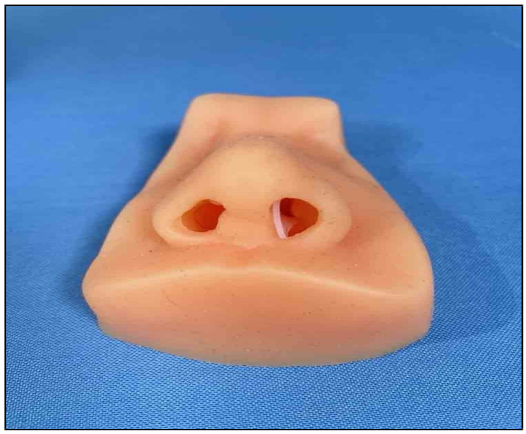

Figure 7: Complete Insertion of Pre-Cut Splints into the Nasal Simulation Model for Final Assessment

Figure-6&7 shows the Pre-Cut splints are inserted into the simulation model, designed to provide structural stability, prevent obstruction, and maintain proper airway support. Their design ensures that the model accurately reflects the conditions necessary for effective simulation, supporting both the integrity of the model and the proper functioning of the airway.

Result:

The simulation model successfully evaluated the ease of insertion and stability of the splints in a nasal cavity model. The splints were easily inserted and remained stable, effectively maintaining structural support. Although the model did not simulate airflow or mucus interaction, it provided valuable insights into the splints' ability to stay in place, ensuring proper support during the healing process.

Based on the defined performance justification criteria, all three splint types demonstrated acceptable performance, no structural deformation observed. The splints exhibited strong positional stability, resisting dislodgement under light force, and maintained anatomical alignment within the model. While patient comfort was not directly measured, the ease of insertion and flexibility suggests minimal discomfort. Additionally, the splints' designs ensured sufficient airway patency, fulfilling the predefined performance expectations.

All splints were inserted with no deformation or damage. The structural integrity of the silicone material used for the splints remained intact throughout the testing. The splints survived and retained its working shape throughout the test.

The reduced simulation model demonstrated that the intra nasal airway splints can be inserted without difficulty and are stably positioned within the nasal cavity. These splints demonstrated their ability to stay in their assigned location and with integrity without requiring the complex simulations of airflow, or mucus formation which is an indication of their appropriateness for the proposed application-intra nasal airway splints in nasal surgeries.

Trial Number	Nasal Splints	Test Sample Size	Ease of Insertion (Yes/No)	Material Damage Observed (Yes/No)	Stability (Yes/No)
1	Airway Splints	Length-74mm Width-27mm Thickness-1mm Diameter-10mm	Yes	No	Yes
2	Bi-Cut Splints	Length-64mm Width-42mm Thickness-0.50mm Suture Hole-1mmx7	Yes	No	Yes
3	Pre-Cut Splints	Length-74mm Width-27mm Thickness-1mm	Yes	No	Yes

Table: 1 Performance Evaluation of Nasal Splints

(Note:** Only one splint per type was tested, limiting the ability to assess reproducibility and variability. No repeated trials were conducted, so mean and standard deviation values are not available**).

Discussion:

The in-vitro test results of Internal Nasal Splints have been very promising with their use following nasal surgery, such as septoplasty and rhinoplasty, and even sinus surgery. These silicone-based splints facilitated easy placement, structural integrity, and stability in the nasal passages. These results tend to be congruent with the objectives of this study in appreciating the function and effectiveness of splints toward maintaining airway patency post-recovery.

One of the major problems post-nasal surgeries is maintaining the patency of the airway during the healing time. Conventional packing applied within the nostril or even external splints are stiff, and therefore irritate, discomfort, and cause tissue damage. The flexibility and biocompatibility of silicone ensure that the internal nasal airway splints provide structural support without irritating the nasal mucosa.

Although the mechanical testing has been done in this in-vitro study only by a simple model of a nasal cavity, thus not taking into consideration the complex conditions such as airflow dynamics, mucosal interaction, and also long-term effects. Although the simulation model has given insight into the ease of insertion and stability, as dynamic conditions such as airflow or mucus formation are not present, so further testing, especially in vivo or in more advanced models, is required to assess the full performance of the device in real-life clinical settings.

The splints are designed with an internal airway tube to keep nasal passages open, even with swelling, which commonly occurs after surgery. This feature is important in preventing nasal obstruction and allowing better airflow during the healing process. Additionally, the prevention of tissue adhesion and the minimization of scar tissue formation further support the role of the splint in improving recovery outcomes. The material is a medical-grade silicone, which is known to reduce inflammation and promote healing in the process.

However, several limitations must be acknowledged:

- The sample size was limited to a single splint per type, restricting statistical analysis and reproducibility of results.
- The model did not simulate dynamic airflow, mucus interaction, or long-term mechanical stress, which are relevant for clinical performance.
- Conclusions should be considered preliminary and interpreted with caution until confirmed by larger, more comprehensive studies including clinical trials.

Conclusion:

The in-vitro results confirm the splint's effectiveness in maintaining nasal airway patency, providing essential structural support, and enhancing patient comfort during the recovery process. The simulation model was made up of medical-grade silicone , the splint combines flexibility and biocompatibility, ensuring both safety and comfort, which are critical for postoperative applications. The simple simulation model utilized in this study successfully assessed the ease of insertion, positional stability, and structural integrity of the splint. However, further dynamic testing in more complex models and pre-clinical & clinical trials is necessary before its real-world application. Further studies will be essential to determine the long-term efficacy, patient comfort, and overall clinical utility of the splint. This research provides compelling evidence supporting the continued development of internal nasal splints, emphasizing their potential to address critical postoperative challenges such as tissue adhesion, nasal obstruction, and discomfort, while promoting optimal healing and recovery.

Although these in-vitro findings are promising, they are derived from a simplified simulation model. Therefore, further dynamic, long-term testing and clinical trials are essential to validate these results in real-world clinical settings.

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