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Original article

Liquid Silicone Injection Moulding: Revolutionizing Nasal Splint Development for Improved Patient Outcomes

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Abstract

Maintaining a healthy nose is critical to overall well-being, especially for individuals undergoing rhinoplasty or septoplasty, where nasal splints play an important role in promoting recovery and minimising postoperative bleeding. This study looks at the potential of liquid silicone resin (LSR) in the manufacture of nasal splints, with a particular focus on the LSR moulding method. LSR, which is known for its easy flowability, precision and fast drying, proves to be an ideal material for the development of internal nasal splints. The use of LSR not only improves the quality of the resulting products, but also speeds up the manufacturing process. Laboratory-scale tests have been conducted to verify the safety and effectiveness of nasal splints produced using LSR moulding technology. The field of LSR moulding continues to evolve, positioning liquid silicone injection moulding as the primary method for manufacturing nasal splints and other medical devices. This study provides valuable insight into the versatile applications of LSR and paves the way for innovative solutions for nasal health. By exploring the possibilities of LSR in the manufacture of nasal splints, this study provides a comprehensive understanding of the potential advances in medical device manufacturing, contributing to continued progress in the field.

Keywords: ***Nasal Health, Liquid Silicone Resin (LSR), Nasal Splint Manufacturing, LSR Injection Moulding Technique and Medical Device Manufacturing.***

1. Introduction

Intranasal splints are important medical devices designed to provide support, stability, and dimentional stability to the structures of the nasal cavity. The implantation of these devices into the nasal cavity serves as a therapeutic intervention for addressing various issues arising from nasal surgery, trauma, or deformities. The nasal cavity, a complex structure nestled within the nose, undertakes multifaceted functions such as air filtration, humidification, and sense of smell. The division of the nasal cavity into two sides is achived by the nasal septum, a structure made of cartilage and bone. Typically, intranasal splints are implanted in the nasal septum and lateral nasal walls, strategically positioned to stabilize the nasal structures and promotes optimal healing.

This research study focuses on the development of three different types of nasal splints: Airway nasal splints, pre-cut nasal splints and bi-valve nasal splints, each targeting specific applications in nasal surgery. Nasal surgery, especially rhinoplasty and septoplasty, is aimed at correcting nasal deformities, improving breathing and correcting functional or aesthetic problems. Following these procedures, intranasal splints play a crucial role in preventing adhesions, maintaining the desired nasal shape and reducing the risk of postoperative complications, including bleeding.

Traditionally, intranasal splints have been developed using materials such as metal, rubber or silicone. However, the advent of Liquid Silicone Resin (LSR) injection moulding technology has ushered in a new era in the manufacture of intranasal splints. LSR is characterised by its ease of flow, precision and rapid curing, making it an exemplary material for the development of these splints. The flexibility of LSR enables intricate designs that accurately replicate the nasal anatomy, resulting in excellent product quality. Its biocompatibility minimises the risk of adverse reactions and its fast-curing speeds up the manufacturing process.

The advantageous characteristics of LSR injection moulding technology provide surgeons versatile and reliable options, making LSR increasingly preferred in the medical field. This preference not only contributes to enhanced outcomes in nasal surgeries but also positively influences patient recovery. The ongoing evolution of LSR injection moulding technology continues to redefine intranasal splint manufacturing, offering innovative solutions in nasal health and further advancing surgical interventions.

2. Materials and Method

2.1 Selection of Material for Nasal Splints:
The development of the nasal splints commenced with a consideration of the material to be employed. The optimal choice, identified as Liquid Silicone Resin (LSR); (Silicone 4340), was selected based on its well-established properties of flexibility, biocompatibility, and durability.

2.2 Analysis of the Mechanical Characteristics of LSR:
To gain a comprehensive understanding of how LSR affects the functionality and design of nasal splints, an in-depth analysis of its mechanical characteristics was conducted. Leveraging the inherent elasticity and flexibility of LSR, the material was strategically employed to achieve a personalized fit, minimizing discomfort by molding the splints to the unique shape of the nose.

2.3 Biocompatibility Evaluation:
In addition to assessing its mechanical properties, the biocompatibility of silicone was evaluated. This analysis focused on highlighting the material's potential to reduce the likelihood of negative reactions, rendering LSR suitable for extended usage during critical postoperative recovery phases.

2.4 Development of Intranasal Splints

2.4.1 Liquid Silicone Injection Molding (LSIM) Process:
The manufacturing process for nasal splints utilized the Liquid Silicone Injection Molding (LSIM) technique, a refined method designed to ensure precision and consistency throughout the development process.

2.4.2 Components Mixing:
Liquid Silicone Rubber was provided in two separate components; a base compound and a curing agent. These components were meticuleoulsy blended in precise ratios of 1:1 to initiate the curing process, a critical step in achieving the desired material properties.

2.4.3 LSIM Equipment Setup:
The LSIM process employed specialized equipment, including an injection molding machine tailored for liquid silicone rubber. This machine, equippied with a barrel and a plunger, mirrored the configuration of traditional injection molding machines used for thermoplastics.

2.4.4. Mold Design and Preparation:
Integral to the process were mold design and preparation. A metal mold with two halves (cavities) was employed, conforming to the desired shape and specifications of the nasal splints. To ensure convenient removal of the cured silicone component, we applied a release agent consisting of a blend of 2 parts isopropyl alcohol and 1 part dish soap.

2.4.5 Injection Molding Procedure:
The injection molding procedure commenced with the closure of the mold. Liquid silicone rubber was then injected into the mold cavity under high pressure ranging from 150-220 bar, ensuring complete cavity filling and precise replication of the mold's shape.

2.4.6 Curing Process and Post-Curing:
Heat treatment ranging from 150 to 220 °C was applied to the mold to initiate the curing process, activated by the addition of the peroxide, Metallic oxides, Acetoxysilane, Sulfur systems, Urethane crosslinkers, etc. Curing times varied but were comparatively quick. Some applications may require post-curing to enhance specific material properties.

2.4.7 Part Removal:
Following the completion of the curing process, the mold was opened, and the cured silicone part, now shaped to match the mold, was extracted. Through this consistent process, three distinct types of splints were developed: Airway splints, Pre-cut splints, and Bi-valve splints. The only variation among these splints lay in the mold cavity, as each type required a specific shape corresponding to its intended purpose. Airway, pre-cut, and bivalve nasal splints are depicted in the figure 01, 02 and 03 serve different purposes and are typically implanted at various locations within the nasal cavity, depending upon the medical application. A brief overview of each type of intranasal splints with their general placement has also been illustrated below.

2.4.8 Morphology of Nasal Splints:
The morphology of nasal splints viz. Desired dimention, formation of bubble in the splints etc were systematically integrated throughout the LSIM process. These measures ensured the production of high-quality, precise components with excellent part-to-part consistency, thereby guaranteeing the reliability of the developed nasal splints. The versatility of the injection molding process made it particularly suitable for producing nasal splints with intricate designs, thin walls, or complex geometries.

Figure 1: Internal Nasal Airway Splints

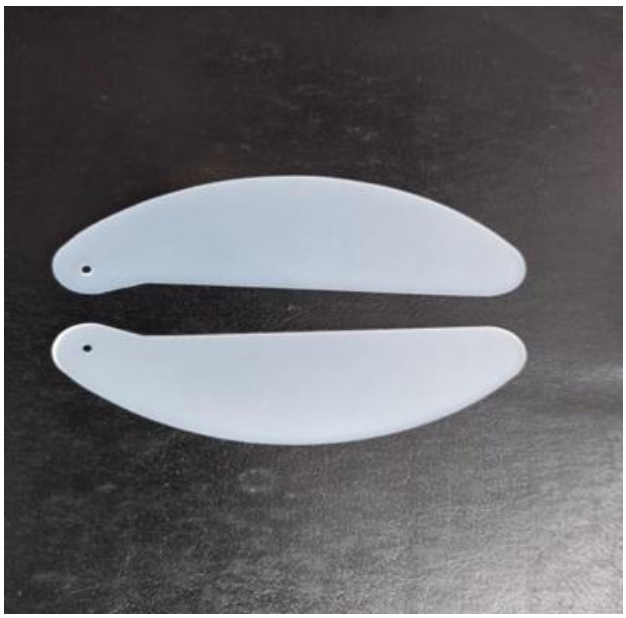

Figure 2: Internal Nasal Pre-Cut Splints

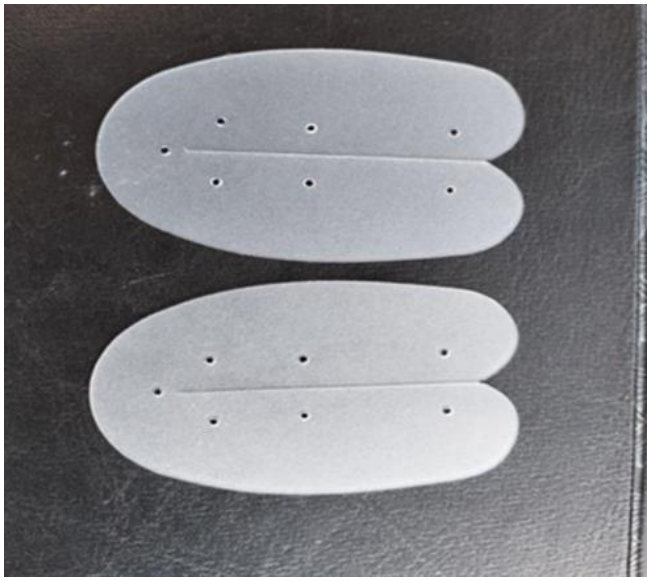

Figure 3: Internal Nasal Bi-Valve Splints

1. Internal Nasal Airway Splints Airway Nasal Splints:
Purpose: Nasal airway splints are used to maintain patency and prevent collapse of the nasal airway.

Implantation: These splints are often placed within the nasal passages to support the nasal airway. They are often used in cases of nasal valve collapse or other conditions that can lead to airway obstruction.

2. Pre-Cut Nasal Splints:
Purpose: Pre-cut nasal splints are usually pre-shaped or cut to a specific size and are used to support and stabilize to the nasal structure.

Implantation: These splints are tusually inserted into the nasal passages to support and maintain the desired shape after procedures such as septoplasty or rhinoplasty. The pre-cut design helps to avoid the need for extensive customization during the surgical procedure.

3. Bivalve Nasal Splints:
Purpose: Bivalve nasal splints are hinged splints that are designed to open and close. They provide structural support while allowing for easy removal or adjustment.

Implantation: Bivalve splints are often used when where temporary support is required, such as after nasal surgery. The hinged design facilitates easy insertion and removal, and the splints may be adjusted to accommodate changes in the nasal structure during the healing process.

The specific placement of nasal splints can vary depending on the surgeon's preference, the patient's anatomy, and the surgical procedure being performed. Surgeons may choose the type of splint and its placement based on the individual characteristics of the patient and the goals of the surgery. Advancements in medical technology and surgical techniques may also influence the selection and positioning of nasal splints. As such, it's recommended to consult with a qualified healthcare professional for specific information tailored to a particular medical scenario. Nasal splints come in various types, including airway splints measuring 74x27mm, bivalve splints measuring 64x42mm, and pre-cut splints also measuring 74x27mm. These splints are adaptable and can be trimmed to fit the size of the patient's nose. Typically, nasal splints are employed following procedures such as septoplasty or crrecting a deviated septum. Composed of flexible silicone material, these splints are inserted into the nasal cavity post-surgery to provide support to the septum, helping maintain the integrity of the bridge between the nostrils.

3. Results and Discussion

The mechanical properties of the nasal splints were evaluated through various tests to assess their suitability and safety for internal use within the nostrils.

Firstly, the hardness of each splint was assessed using the ASTM D 2240 Shore A method to evaluate its flexibility, considering its insertion into the nasal cavity. All splints demonstrated a hardness within the acceptable range (45-55 Shore A), indicating their appropriate flexibility for this purpose.

Secondly, tensile strength, which is crucial for assessing the splint's resistance to force during removal, was measured using an ASTM D 412-compliant universal tensile load testing machine. Results revealed that all splints exceeded the minimum requirement, ensuring their safety during removal procedures.

Additionally, elongation at break, which determines the maximum stretching capacity of the splints before rupture, was evaluated. The elongation values at 100%, 200%, and 300% were measured to demonstrate the splints' ability to withstand stretching forces.

Furthermore, tear strength, an essential parameter considering the suturing process within the nostrils, was determined using the ASTM D 624 Type C testing method. All splints exhibited tear strengths exceeding the minimum threshold, indicating their suitability for internal use.

Moreover, the modulus at different elongation percentages (100%, 200%, and 300%) was measured to understand the splints' stiffness at various levels of stretching. Results indicated that all splints met the specified modulus requirements, ensuring their structural integrity under stretching conditions.

Finally, additional parameters such as continuous temperature limits and specific gravity were assessed to ensure the splints' compatibility with physiological conditions and materials' consistency, respectively. All splints met these criteria, further confirming their suitability for nasal application.

Overall, the results demonstrate the satisfactory mechanical properties of the nasal splints, validating their potential for effective use in rhinoplasty and septoplasty procedures. The mechanical properties of all internal nasal splints, including the Bi-Valve Splint, Pre Cut Splint, and Airway Splint, evaluated through bench-scale testing, are presented in Tables 01, 02, and 03, respectively.

Table 01: Mechanical Properties of the Internal Nasal Airway Splints

No	Physical Properties	Test Method	Unit	LL	UL	Observation	Pass/Fail
1	Hardness	ASTM D 2240	Shore A	45	55	51	PASS
2	Tensile Strength (Min)	ASTM D 412	Kg/cm2	50	-	58.32	PASS
3	Elongation at Break (Min)	ASTM D 412	%	300	-	385	PASS
4	Modulus @100%	ASTM D 412	Kg/cm2	15	-	18.24	PASS
5	Modulus @ 200%	ASTM D 412	Kg/cm2	30	-	32.31	PASS
6	Modulus @ 300%	ASTM D 412	Kg/cm2	45	-	50.76	PASS

7	Tear Strength (Min) - (Type C)	ASTM D 624	Kg/cm	12	-	13.7	PASS
8	Continuous Temperature limit	-	°C	-40	220		PASS
9	Specific Gravity	-	g/cm³	1.1	-	1.425	PASS

Table 02: Mechanical Properties of the Internal Nasal Pre Cut Splint

No	Physical Properties	Test Method	Unit	LL	UL	Observation	Pass/Fail
1	Hardness	ASTM D 2240	Shore A	45	55	51	PASS
2	Tensile Strength (Min)	ASTM D 412	Kg/cm2	60	-	73.21	PASS
3	Elongation at Break (Min)	ASTM D 412	%	300	-	410	PASS
4	Modulus @100%	ASTM D 412	Kg/cm2	20	-	28.69	PASS
5	Modulus @ 200%	ASTM D 412	Kg/cm2	40	-	47.53	PASS
6	Modulus @ 300%	ASTM D 412	Kg/cm2	60	-	68.82	PASS
7	Tear Strength (Min) - (Type C)	ASTM D 624	Kg/cm	12	-	20.84	PASS
8	Continuous Temperature limit	-	°C	-40	220		PASS
9	Specific Gravity	-	g/cm³	1.1	-	1.425	PASS

Table 03: Mechanical Properties of the Internal Nasal Bi-Valve Splints

No	Physical Properties	Test Method	Unit	LL	UL	Observation	Pass/Fail
1	Hardness	ASTM D 2240	Shore A	45	55	51	PASS
2	Tensile Strength (Min)	ASTM D 412	Kg/cm2	70	-	86.23	PASS
3	Elongation at Break (Min)	ASTM D 412	%	300	-	412.83	PASS
4	Modulus @100%	ASTM D 412	Kg/cm2	20	-	31.2	PASS
5	Modulus @ 200%	ASTM D 412	Kg/cm2	40	-	58.47	PASS
6	Modulus @ 300%	ASTM D 412	Kg/cm2	60	-	75.12	PASS
7	Tear Strength (Min) - (Type C)	ASTM D 624	Kg/cm	12	-	23.6	PASS
8	Continuous Temperature limit	-	°C	-40	220		PASS
9	Specific Gravity	-	g/cm³	1.1	-	1.425	PASS

Conclusion

In conclusion, this research highlights the crucial role of nasal splints in enhancing postoperative outcomes for rhinoplasty and septoplasty patients. The investigation into liquid silicone resin (LSR) for nasal splints development underscores its numerous advantages, including fluidity, precision, and rapid curing properties, which contribute to both improved product quality and streamlined it's development processes. Through rigorous bench-scale testing, the safety and efficacy of LSR-based nasal splints have been confirmed, with mechanical properties meeting or exceeding industry standards. Additionally, assessments of parameters such as continuous temperature limit and specific gravity further validate the compatibility and reliability of these splints within physiological conditions. Overall, this study provides valuable insights into the potential of LSR-based nasal splints to advance nasal health and it's manufacturing. By offering a comprehensive understanding of their mechanical characteristics and performance, this research contributes significantly to the continual progress of the field, benefiting patients undergoing nasal surgery. Our forthcoming research article will be on the clinical implementation of these splints, bridging the gap between research findings and practical medical application.

Abbreviations

LSR: Liquid Silicone Resin
LSIM: Liquid Silicone Injection Molding

Declaration by Authors

Ethical Approval and Consent to participate

Approved

Consent for publication

None

Competing interests

None

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None

Authors' conflicts

The Author declare no conflict of work

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