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IN-HOUSE DEVELOPMENT AND FEASIBILITY AFFIRMATION OF A TRACHEAL T-TUBE DEVICE IN AIRWAY OBSTRUCTION MANAGEMENT

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ABSTRACT

Airway obstruction characterized by the inability to move air in or out of the lungs, can result from various factors such as inhaled foreign bodies, diseases, allergic reactions, or trauma, potentially affecting partial or complete airway passages. Airway obstruction poses a significant threat to ventilation, encompassing a spectrum from acute to chronic and congenital to acquired conditions, with potentially fatal consequences if left untreated. The most prevalent cause of chronic airway obstruction in adults is obstructive sleep apnea (OSA). Less yet common consequential causes contributing to laryngeal pathology and subsequent airway compromise include tuberculosis, sarcoidosis, granulomatosis with polyangiitis, and Behcet disease. Stents have proven effective in alleviating airway obstruction arising from malignancy, postinflammatory stenosis, tracheobronchomalacia, and tracheoesophageal fistulas. In response to these challenges, the current research introduces the tracheal T-tube as a solution for addressing airway obstructions. The Tracheal stent's T-tube design deviates from traditional straight tubes, facilitating simultaneous airflow to enhance mucus clearance and reduce the risk of airway blockages. The stent incorporates an adjustable distal limb, tailored to accommodate the unique anatomy of individual patients, ensuring optimal placement within the trachea. This approach significantly improves the effectiveness of addressing and preventing airway obstructions. To affirm the safety and efficacy of the tracheal T-tube, mechanical testing has been conducted, providing assurance of its feasibility as a reliable solution for managing airway obstructions. Therefore, this research highlights the development of tracheal T-tube aimed at improving patient outcomes and addressing challenges associated with airway obstruction.

KEYWORDS

Airway obstruction, Tracheal T-tube, Ventilation threats and Mechanical Testing.

INTRODUCTION

Tracheal stenosis, characterized by the narrowing of the airway, poses a significant challenge in respiratory medicine, often necessitating advanced interventions for effective management. Among the various therapeutic options available, the tracheal T-tube, a silicone stent shaped like the letter "T," emerges as a crucial device in addressing this intricate medical condition. Primarily employed in adults and adolescents, especially in the aftermath of tracheostomy surgery, the T-tube stent serves a dual purpose: providing temporary airway support during the healing phase and preventing the collapse of the airway, particularly crucial for patients with compromised tracheal walls or complex medical conditions that preclude long-term tolerance of traditional tracheostomy tubes.

The unique design of the T-tube stent imparts several advantages that contribute to its efficacy and widespread applicability. Unlike conventional straight tubes, the tracheal T-tube's distinctive T-shape enhances stability and reduces the risk of inadvertent dislodgement. Furthermore, its configuration facilitates easier suctioning and cleaning, minimizing the potential for mucus accumulation. An additional boon is the presence of a capped external limb, enabling patients to speak and swallow comfortably, thereby significantly enhancing their overall quality of life. Notably, the accessibility of the T-tube stent in India adds a layer of significance to its utility, offering a cost-effective and widely available treatment option for patients grappling with tracheal stenosis.

While the benefits of the T-tube stent are evident across various age groups, its advantages become particularly pronounced in younger adults and adolescents requiring airway support. In comparison to alternative stents, the T-tube stands out due to its biocompatible silicone composition, which minimizes tissue irritation and fosters a conducive environment for healing. Furthermore, the incorporation of 25% barium sulfate ($BaSO_4$) renders the T-tube radiopaque, ensuring visibility on X-rays. This feature not only facilitates precise placement but also allows for effective monitoring, addressing a crucial aspect of the therapeutic process.

In this research article, we delve into the multifaceted advantages of the tracheal T-tube, examining its role in managing tracheal stenosis across diverse patient populations. By developing its unique design and exploring its diverse benefits, and applications, we aim to contribute valuable insights to the evolving aspects of respiratory medicine, with a focus on optimizing patient outcomes and expanding the understanding of this essential medical device.

MATERIALS AND METHODS

Tracheal T-Tube Development through Injection Molding

Biocompatible Silicone as a Selective Material:

The Tracheal T-tube was developed from a specialized platinum cured biocompatible silicone *(Suresh Enterprises Dediyasan, Mehsana, Gujarat, India)* to prioritize patient comfort as well as to mitigate potential tissue irritation. The silicone, carefully chosen for its biocompatibility, ensured patient well-being by possessing inherent flexibility, allowing for natural movement while maintaining structural integrity. This unique characteristic significantly diminished the risk of tracheal wall damage, contributing to the overall safety and efficacy of the T-tube stent.

Radiopacity for Placement and Monitoring of Tracheal T-tube:

To achieve accurate visualization during placement and monitoring phases, a radiopaque material, Barium Sulfate ($BaSO_4$) Super Grade *(Suresh Enterprises Dediyasan, Mehsana, Gujarat, India)* was incorporated into the silicone matrix at a concentration of 25%. This enhancement served a dual function, elevating safety during placement procedures and improving imaging clarity for continuous monitoring. Consequently, this advancement contributed to enhanced procedural ease and precision, ensuring optimal performance throughout the tracheal T-tube's placement and monitoring processes.

Manufacturing Process Overview

The Tracheal T-tube went through a manufacturing process utilizing injection molding technology. This approach not only ensured product uniformity but also aimed to create a smooth, burr-free surface, minimizing the risk of tissue irritation. The injection molding process

was progressed through the planned stages.

Comprehensive T-tube Stent Design:
To begin with, a comprehensive design of the T-tube stent was developed, incorporating precise specifications. This design formed the basis for the entire manufacturing process, guaranteeing that every aspect of the final product adhered to the necessary standards. Specifically, the design promotes efficient mucus clearance, thereby lowering the risk of complications, such as pneumonia.

Engineered Dimensions for Respiratory Efficiency:
The T-tube's specific dimensions and geometry shown in Figure 01 and Table 01 were carefully engineered to enhance respiratory efficiency by optimizing airflow within the airway.

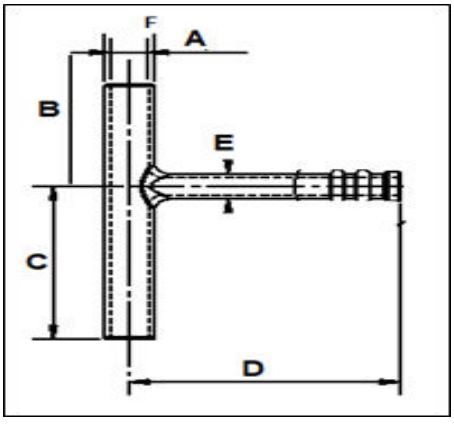

Figure 01 and Table 01 Depiction of Size Dimensions and Geometry of Tracheal T-Tube

Size	Dimensions(mm)					
	A	B	C	D	E	F
8	8	26	26	43	7	1
10	10	26	26	43	8.5	1
12	12	26	26	43	10.5	1
14	14	26	26	43	12.5	1

Injection Molding Technology
Mold Cavity Creation:
A mold cavity was created to replicate the design of the T-tube stent. This involved the use of advanced machining techniques to achieve the desired precision and accuracy. The mold cavity served as the negative impression of the final product and played a crucial role in shaping the T-tube during the injection molding process.

Material Injection and Shaping:
The chosen material, selected for its compatibility and durability, was then fed into the injection molding machine *(Bharaj hydraulic machine, Bharaj Machineries Pvt Ltd, Maharashtra)*. The injection molding machine heated the material to a precise temperature (150˚C - 190˚C) transforming it into a molten state ready for shaping. This molten material was then injected into the mold cavity with accuracy and with the controlled pressure (20 MPa (2900 psi) -50 MPa (7250 psi)).

Monitoring and Ejection:
As the molten material filled the mold, it assumed the exact shape and features of the T-tube design. The injection process was closely monitored to ensure consistency and accuracy in every detail. Once the material solidified within the mold, the newly formed T-tube was carefully ejected from the mold cavity.

Post-Molding Processes:
Post-molding processes were implemented to refine the T-tube further. This included the removal of excess material (flash) to achieve a desired smooth and burr-free surface. Quality control measures like Overall appearance, Flash removal, Burr formation, Critical dimensions, Tactile inspection and Tactile inspection were integrated at each stage to verify product uniformity and adherence to specifications.

The Tracheal T-tube, illustrated in Figure 02, has been effectively developed using injection molding technology, employing a blend of silicone and $BaSO_4$. Figure 03 displays the Tracheal T-tube achieved through the amalgamation of chosen materials (Silicone and $BaSO_4$) in addition with a milky white dye. The distinctive design and incorporation of biocompatible materials are expected to mitigate post-procedural complications, potentially improving patient outcomes and presenting the opportunity to lower overall healthcare expenses.

Figure 02 Silicone-Based Tracheal T-tube Developed In-House

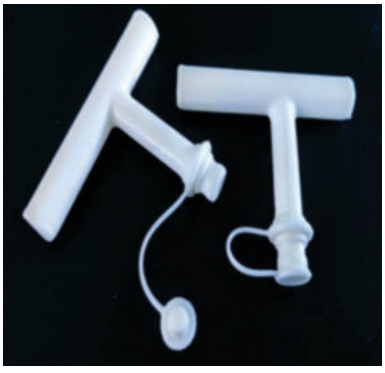

Figure 03 Tracheal T-tube Resulting from the Fusion of Silicone and $BaSO_4$ with Milky White Dye

Deployment Procedure of the T Tube
To facilitate smooth insertion, a water-soluble lubricant is applied to the distal end of the tracheal T-tube. Local anesthesia is administered to the trachea at the intended insertion site, followed by the creation of a small incision of sufficient size for the T-tube.

The T-tube is gently introduced into the tracheal incision, with careful advancement until the cuff is positioned just below the level of the vocal cords. Cuff inflation follows, securing the T-tube in place and creating an airtight seal by inflating it with an appropriate volume of air. To prevent accidental dislodgment, securing devices such as sutures or ties are employed. Confirmation of proper T-tube placement is achieved through visualization and, if necessary, imaging studies. Simultaneously, the patient's respiratory status is assessed, and continuous monitoring is undertaken to promptly identify any signs of complications throughout the procedure.

RESULTS AND DISCUSSION
A tensile property refers as the characterization of how a material responds to tension, particularly its reaction to stretching or elongation forces. These properties are fundamental for understanding a material's behavior when subjected to pulling or stretching forces.

In the case of medical devices, tensile properties holds significant importance for reasons related to performance, safety, and regulatory compliance. The key reasons for examining tensile properties in medical devices include material characterization, quality control, device design and performance, safety and reliability assurance, compliance with standards and regulations, and product liability and risk mitigation.

The testing standards are defined by ASTM D, a set of standards established by American Society for Testing and Materials (ASTM) International. In the context of this data, ASTM D 2240 and ASTM D

412 specifically address the hardness and tensile properties of elastomers, respectively. These standards outline test methods, units of measurement, and criteria for evaluating material performance. Researchers and industries frequently refer to these ASTM standards to ensure consistent and high-quality testing and characterization of materials.

Various ASTM methods are used for specific properties, such as ASTM D 2240 for Shore A Hardness and ASTM D 412 for Tensile Strength, Elongation at Break, and Modulus. The testing equipment can vary according to the requirements of each ASTM method. For instance, the Shore durometer, a handheld instrument, is used for ASTM D 2240, while a universal testing machine is typically employed for ASTM D 412. ASTM D 624, is employed to assess the tearing strength. A dedicated testing machine, specifically designed for tear testing, is utilized in this procedure. During the test, the specimen undergoes controlled tearing forces to evaluate its resistance to tearing. Adherence to detailed procedures outlined in the ASTM standards is crucial to guarantee accurate and repeatable results. Laboratories and testing facilities often utilize specialized equipment calibrated to meet ASTM specifications, emphasizing the importance of standardized testing in the development and manufacturing of medical devices. Here is the mechanical strength data of an aforementioned device illustrated in the table 02.

Table 02 Mechanical Properties Testing of the Tracheal T-tube

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	15	-	20.73	PASS
5	Modulus @ 200%	ASTM D 412	Kg/cm2	30	-	36.18	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	-	19.43	PASS
8	Continuous Temperature limit	-	°C	-40	220		PASS
9	Specific Gravity	-	g/cm³	1.1	-	1.425	PASS

1. Hardness

Hardness, as measured by ASTM D 2240 Shore A, was found to be within the specified limits. The observed hardness value of 51 falls between the lower limit (LL) of 45 and the upper limit (UL) of 55, resulting in a PASS.

This indicates that the material exhibits an appropriate level of hardness, meeting the criteria outlined by the testing standard.

2. Tensile Strength

The tensile strength of the material, determined by ASTM D 412, surpassed the minimum requirement of 70 Kg/cm². The observed value of 86.23 Kg/cm² indicates a robust tensile strength, exceeding the specified threshold and resulting in a PASS.

This suggests that the material possesses excellent tensile properties, crucial for applications demanding strength and durability.

3. Elongation at Break

The material's elongation at break, assessed through ASTM D 412, exceeded the minimum requirement of 300%. The observed value of 412.83% indicates a high level of flexibility and stretchability, meeting the specified standards and resulting in a PASS.

This implies that the material can endure significant deformation before breaking, making it suitable for applications where flexibility is a critical factor.

4. Modulus @100%, @200%, @300%

The modulus at different elongation percentages, evaluated by ASTM D 412, all fell within the specified limits. The material demonstrated a modulus of 20.73 Kg/cm² at 100%, 36.18 Kg/cm² at 200%, and 50.76 Kg/cm² at 300%, meeting the criteria and resulting in PASS for each measurement.

This indicates that the material maintains its structural integrity under different levels of deformation, making it suitable for a variety of applications.

5. Tear Strength (Type C)

The tear strength of the material, determined by ASTM D 624 Type C, surpassed the minimum requirement of 12 Kg/cm. With an observed value of 19.43 Kg/cm, the material exhibits a robust resistance to tearing and meets the specified standards, resulting in a PASS.

This suggests that the material can withstand tearing forces, making it suitable for applications where tear resistance is crucial.

6. Continuous Temperature Limit

The material's continuous temperature limit was evaluated to be between -40°C (lower limit) and 220°C (upper limit). As no specific observation value is given, the PASS indicates that the material can operate within this temperature range, meeting the defined criteria.

This suggests that the material can withstand a wide range of temperatures, making it versatile for various environmental conditions.

7. Specific Gravity

The specific gravity of the material, with a range of 1.1 to 1.425 g/cm³, was observed to be 1.425 g/cm³. This falls within the specified limits, resulting in a PASS.

This indicates that the material has an appropriate density, meeting the defined standards for specific gravity.

In summary, the comprehensive testing results demonstrated that the material meets or exceeds the specified criteria for various physical properties, indicating its suitability for intended applications.

CONCLUSION

In conclusion, the research introduces the tracheal T-tube as a promising solution for diverse airway obstructions, particularly in adults with conditions like OSA. Unlike traditional straight tracheal stents, the aforementioned tracheal T-tube's unique design, including an adjustable distal limb, accommodates individual anatomy while facilitating airflow. This enhancement aims to minimize the risk of airway blockages, addressing challenges associated with various conditions. Mechanical properties testing confirm the tracheal T-tube's safety and efficacy, indicating its feasibility as a reliable solution for managing airway obstructions. Hence, this research represents a significant advancement in airway management, highlighting the tracheal T-tube's tailored design and proven mechanical reliability as a promising solution. This exploration is essential in the process of establishing the tracheal T-tube as a valuable addition to the management of diverse airway obstructions.

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