Nanosharks: Creating a Biofilm-Resistant Tracheostomy Tube

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Executive Summary

Approximately 2 million people are affected by hospital acquired infections associated with tracheostomy every year only in the US. This project seeks to address hospital-acquired infections due to tracheostomies including bacterial tracheitis, ventilator associated tracheobronchitis, and ventilator associated pneumonia. Using Sharklet™, a micropatterned surface that prevents growth of bacterial biofilm due to irregular pattern and dimensions, we have developed a tracheostomy tube that will reduce significantly bacterial infections associated with the tube and that will prolongate the lifespan of the device.

Problem and Clinical Need

Current tracheostomy tubes in the market have a high incidence of causing tracheal infections including bacterial tracheitis and ventilator associated pneumonia and tracheobronchitis. These infections occur due to bacterial biofilms in the tube artificial airway. There is a need for tracheostomy tube that prevents bacterial biofilming, retains the mechanical properties of existing devices and cost effective.

This project aims to create a bacterial resistant tracheostomy tube to reduce the risk of infection for patients. This would reduce disease associated risks and costs.

Market Analysis

Based on the current market analysis, the target market for the product will be patients who have, or will undergo a tracheotomy. A study in 2004 revealed that there are about 6.5 million people in the United States living with tracheostomies and every year 2 million people get respiratory infections that require tracheostomy [1]. The global respiratory care market was worth about $8.8 billion in 2010 and is predicted to reach $13.5 billion by 2015 [3]. In particular, this product would be attractive for children as well as adults who experience severe discomfort during the procedure, in addition to patients who may experience adverse side effects due to antibiotics and intravenous treatments.

Novelty

This project utilizes the Sharklet™ pattern to reduce the formation of biofilm on tracheostomy tubes. As bacteria establish a biofilm, they send signals that promote increased bacterial growth. The Sharklet™ pattern reduces the formation of biofilm by creating an uneven surface at the micro-surface level thus preventing bacteria from communicating with each other. Some of the current devices in the market prevent bacterial growth, but none solve the bacterial biofilming. Although Sharklet™ is being investigated for use in urinary catheters, it's use in tracheostomy tubes is a novel application that would significantly reduce the risk of hospital acquired immunodeficiency disorders.

Anticipated Regulatory Pathway

Tracheostomy tubes are classified by the FDA as a Class 2 medical device. Our design follows previous tracheostomy tubes approved by the FDA, the anticipated regulatory pathway to follow would be a *510K* clearance, since our product is equivalent to a device already classified as Class 2 devices and will not cause any additional risks to be considered a new device .

Design Results

Our final prototype used photolithography to imprint the Sharklet™ pattern onto a PDMS film. The first step of the process involved transferring the pattern from a silicone film onto a coating with photoresist. The material was then exposed to ultraviolet light to cure the photoresist and etch the pattern onto a mold. A thin layer of PDMS was used to cover the mold such that the Sharklet pattern was printed across the film. The film was then wrapped around the existing tracheostomy tube and bound using UV curable glue.

Sterility tests were performed on the PDMS imprinted material using bleach, ethanol and UV light. The sterility methods were chosen based on the ease of access and frequency of use in hospitals. Of the the methods chosen, ethanol and UV light were found to leave the pattern on the PDMS material intact. Bleach was found to affect the material very slightly, due to its highly corrosive properties.

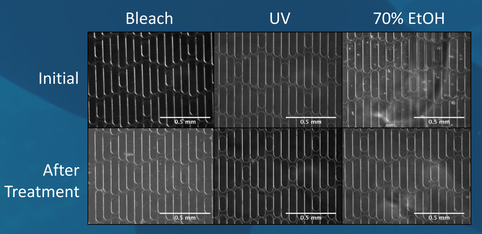

Figure 1: Sterility tests using bleach, UV and ethanol

Bacterial testing was performed using *Streptococcus pyogenes*. Pilot tests were performed on the Sharklet™ material to assess the effectiveness of the material in reducing bacterial growth. A polyurethane petri dish was used as a control for this experiment.

Sample	No Sharklet	Sharklet
1	710	15
2	695	45
3	1697	453
4	393	24
Average	873.7 +/- 567.9	134.2 +/- 212.8

Table 1: Results of bacterial testing

The bacterial tests were repeated on the etched PDMS material to assess the effectiveness of the final prototype, as well as when the PDMS was incorporated onto the tracheostomy tube using UV glue.

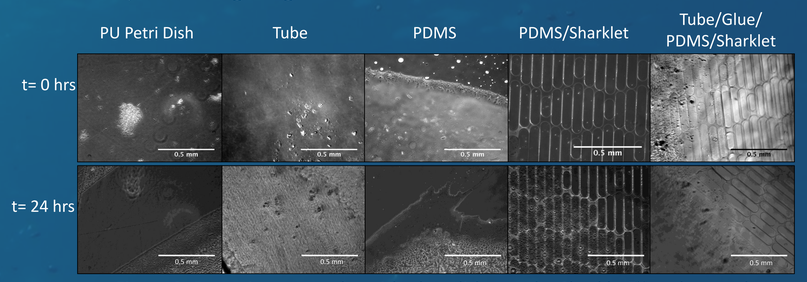

Figure 2: Bacteria test results with photolithography Sharklet™ and controls

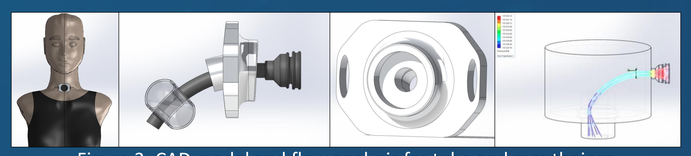

Figure 3: CAD model and flow analysis for tube and mouthpiece

Mechanical testing was performed on the Sharklet™ material to observe the Young's modulus of the material. The material was found to require about 40kN of force before failure.

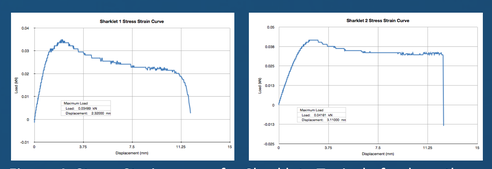

Figure 4: Stress Strain curves for Sharklet. Typical of polyurethane

For mass production we suggest a combination of micro injection molding a thermal rolling. Specialized injection molding techniques could be used to manufacture the tube with the Sharklet™ pattern imprinted in the outer layer of the tube and thermal rolling to imprint the pattern into the inner layer.

Estimation of Product Costs

Number of infections per year = 2 million
Cost of Injection Molding = $ 0.535/per tube*
Cost of Roller Imprint Technology = $ 0.69 (Average cost of thermal rolling)
Total Estimated Manufacture Cost = $ 1.225/ per tube
Proposed Cost = $ 65.00

The proposed cost was estimated following the cost of the other tracheostomy tubes in the market in order to establish a competitive price in the market and account for the cost to enter the product to market.

*Calculated from Custom Part Net

Conclusions

NanoSharks presents a viable, cost-effective option for patients to reduce the risk of hospital-acquired respiratory infections. The design of the tracheostomy tube not only minimizes the cost of treatment that would be incurred by the patient but also utilizes an innovative Sharklet™ pattern to reduce the formation of biofilm on the surface of the tube. Economically, incorporation of this design onto tracheostomy tubes would result in savings of $120 million per year in the global respiratory care market. For a single patient, the novel design would reduce treatment costs by more than 50%.

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