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Pulmonary Patency Stent

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BIOMEDICAL

Pulmonary Patency Stent

CAPSTONE DESIGN EXPO 2016

Introduction

PROJECT OBJECTIVE

With 1.2 million new cases/year worldwide, lung cancer is one of the fastest growing diseases. Patients with these malignancies in the central airways often experience significant breathing difficulties due to occlusion of the airways. One common palliative treatment option for this is a stent placement procedure using the Boston Scientific Tracheobronchial Stent (partially covered). While patients often experience immediate symptom relief, long term use can result in the formation of granulation tissue around the uncovered portions of the stent causing re-occlusion of the airway.

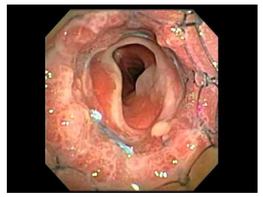

Figure 1. Granulation tissue formation at the end of an Ultraflex stent. The lumen is occluded and the green retrieval loop is completely buried in the tissue.

The objective of this project is to design and prototype a modification to the Ultraflex partially covered stent in order to reduce granulation tissue and maintain airway patency.

DELIVERABLES

- A detailed design of stent coating and deliverable drugs
- Working prototype of pulmonary patency stent (modified Ultraflex Tracheobronchial Stent)
- Data quantifying extent of granulation tissue reduction

DUE DILIGENCE

Drug-eluting stents have been commonly used in the coronary space. However, paclitaxel is relatively new to airway stents. Choong et al. (2006) showed that paclitaxel maintains patency over time in dog airways, using a paclitaxel-eluting bypass stent meant for treating emphysema.

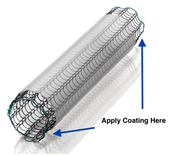

Figure 2. Design for Coating on Ultraflex Tracheobronchial Stent.

Test Methods

REDUCTION OF CELL ATTACHMENT

22 x 22 mm glass coverslips were coated with a paclitaxel-SIBS coating and placed in cell culture media with lung cancer cells. After 4 days, a Hoechst stain was performed on these coverslips to visualize the cell attachment compared to uncoated coverslips.

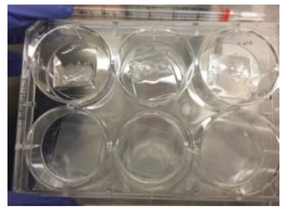

Figure 3. Coated coverslips.

PACLITAXEL CYTOXICITY

Cytotoxicity of paclitaxel was tested against lung cancer cells. However, results of the MTT assay were inconsistent.

RELEASE KINETICS

Release kinetics of paclitaxel from the drug-eluting coating was tested using UV-Vis spectrometry. A 1 cm^2 portion of a coated stent was placed in PBS buffer on a rocker and aliquots were taken at certain time points. The absorbance at paclitaxel's peak of 227 nm was recorded.

COATING STABILITY

Coating stability on the stent nitinol material was tested by placing a 2 cm^2 portion of a coated stent in PBS buffer on a rocker. The weight of the stent and coating was measured at various time points to detect coating degradation. Results showed that the weight did not decrease over 2 weeks.

Design

CONSIDERATIONS

- Reduce granulation tissue
- Adhesion of Coating to Stent
- Localization of Drug Response
- Controlled Release of Drug

FINAL DESIGN

Our final design consists of a paclitaxel-SIBS coating that is placed on the uncovered ends of a Boston Scientific Ultraflex Tracheobronchial Stent by using a dip coating method. This allows application of the coating at the uncovered stent ends, the areas most susceptible to granulation tissue formation.

Results

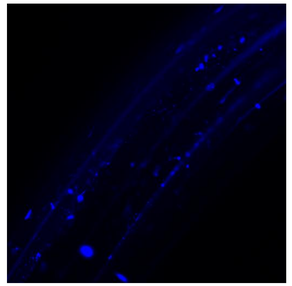

Figure 4. Hoechst Stain image of cells on an uncoated stent piece.

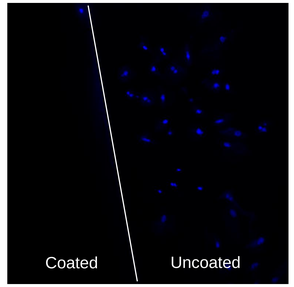

Figure 5. Edge showing reduced cell attachment on coated side (left).

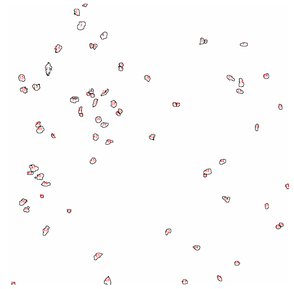

Figure 6. Image J software for cell counting.

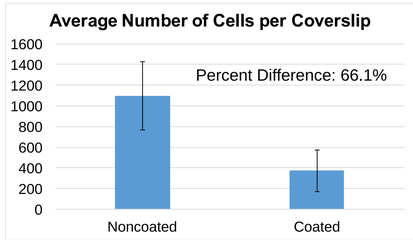

Figure 7. Cell Count of Coated and Uncoated Coverslips.

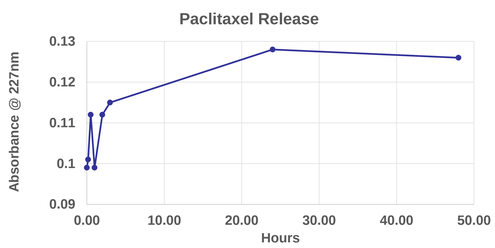

Figure 8. UV-Vis absorbance of paclitaxel released over time.

Conclusion

We have shown that the SIBS-paclitaxel coating is effective in reducing cell attachment in-vitro, the coating is stably adhered onto the stent in a moving environment, and that paclitaxel is steadily released from the coating. This is promising for future in-vivo testing.

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VCU School of Engineering

Make it real.

VIRGINIA COMMONWEALTH UNIVERSITY