Global Technology 2021 Virtual Expo

Post-Processing Effects and Prediction of Long-Term Performance for Bioresorbable Polymers for Vascular Stent Applications

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Problem Statement

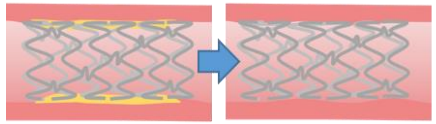
Bioresorbable polymer stents (BRS) represented a promising alternative to permanent metallic stents, however they experienced high rates of late-stage thrombosis attributed to mechanical and degradation properties. To achieve widespread clinical use, modifications to these properties as well as a better understanding of the influence of each processing step is required.

Key learning or achievement

The aims of this PhD project are to quantify the influence of sterilization on bioresorbable polymers used in BRS applications and explore opportunities for for post-processing material enhancements using e-beam treatment.

The current standard for treatment of coronary artery disease is permanent metallic stents. Bioresorbable stents were developed to reduce permanent stent complications and restore vessel function:

Permanent Metallic Stent

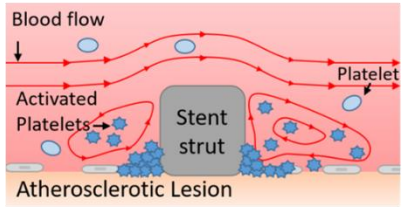


Long-term presence can lead to detrimental effects

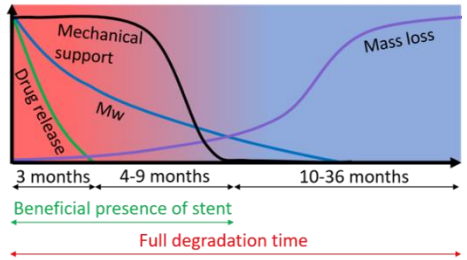
Bioresorbable Polymer Stent

Degrades with healing process, restoring vessel to natural state

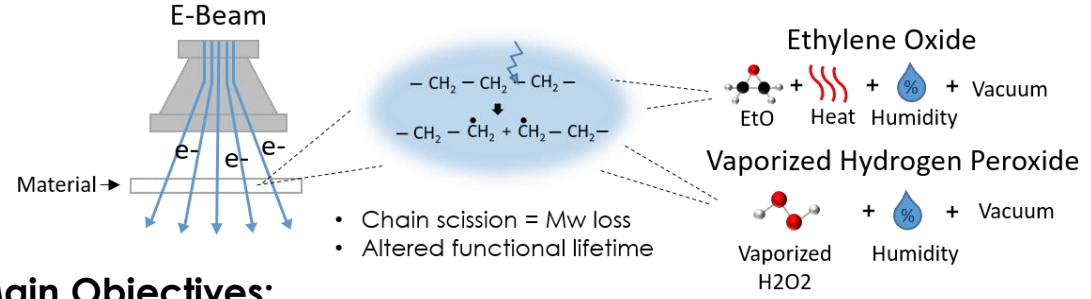
The use of bioresorbable stents is limited by their mechanical properties and degradation profile:



- Half the tensile and radial strength of metallic stents
- Need thick and wide struts to compensate, impairing the healing process



- Successful sterilization is a critical prerequisite for successful clinical application
- Additional considerations for bioresorbable polymers when choosing sterilization modality:
  - Moisture and temperature sensitive
  - Performance affected by change in molecular weight or overall structure



- Chain scission = Mw loss
- Altered functional lifetime

Main Objectives:

Quantify the influence of sterilisation on mechanical and degradation properties

Explore opportunities for post-processing material enhancements using e-beam treatment

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Sterilization Study:

- Purasorb PL38 medical grade PLLA (Corbion, Netherlands)
- Sheets of compression moulded material

Standard Sterilization Techniques		Potential Alternative
Electron Beam (e-beam)	Ethylene Oxide (EtO)	Vaporized Hydrogen Peroxide (VHP)
5 kGy	Standard B50°C Cycle	2 pulses
15 kGy		4 pulses
25 kGy		6 pulses
40 kGy		8 pulses
60 kGy		10 pulses

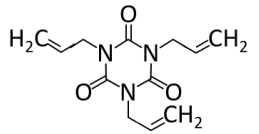
Key Outcomes/Findings:

- E-beam sterilization caused a dose-dependent decrease in material properties.
- Stability was observed in samples treated across the range of VHP doses indicating that it could be a viable alternative sterilization modality for use with PLLA.
- Obtained baseline data on properties and processing of Purasorb PL38 and examined the effects of e-beam irradiation to inform future material modification work.

Current Work: E-Beam Crosslinking

- The dominant response of PLLA exposed to e-beam is chain scission, enabling modifications to degradation profile
- To alter mechanical properties, a crosslinking response can be induced through the addition of a crosslinking agent which forms bonds between polymer chains when exposed to irradiation energy

Crosslinking Agent: Triallyl Isocyanurate (TAIC)



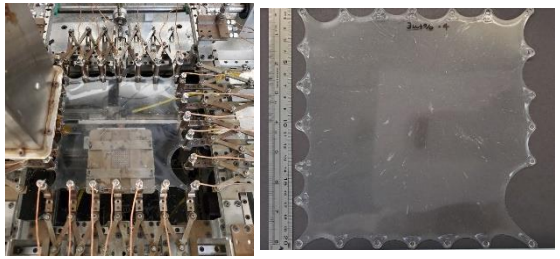
Material:	Purasorb PL 38 PLLA blended with TAIC at 0, 1, 3, and 5 wt%
Test Specimens:	Sheets of biaxially stretched material
E-Beam Doses:	10, 20, 30, 50, 100 kGy doses

Extrusion → Incorperate crosslinking agent

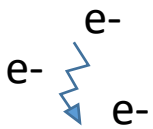
Compression Moulding → Flat sheets of material

Biaxial Stretching → Replicate stent processing history and thickness

Biaxially stretched sheet



E-beam crosslinking



Next step: characterisation

- Tensile testing
- DMA
- DSC
- FTIR
- Gel fraction
- NMR

BioImplant

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