BioImplant ITN – Developing Next Generation Bioabsorbable Materials for Medical Implants

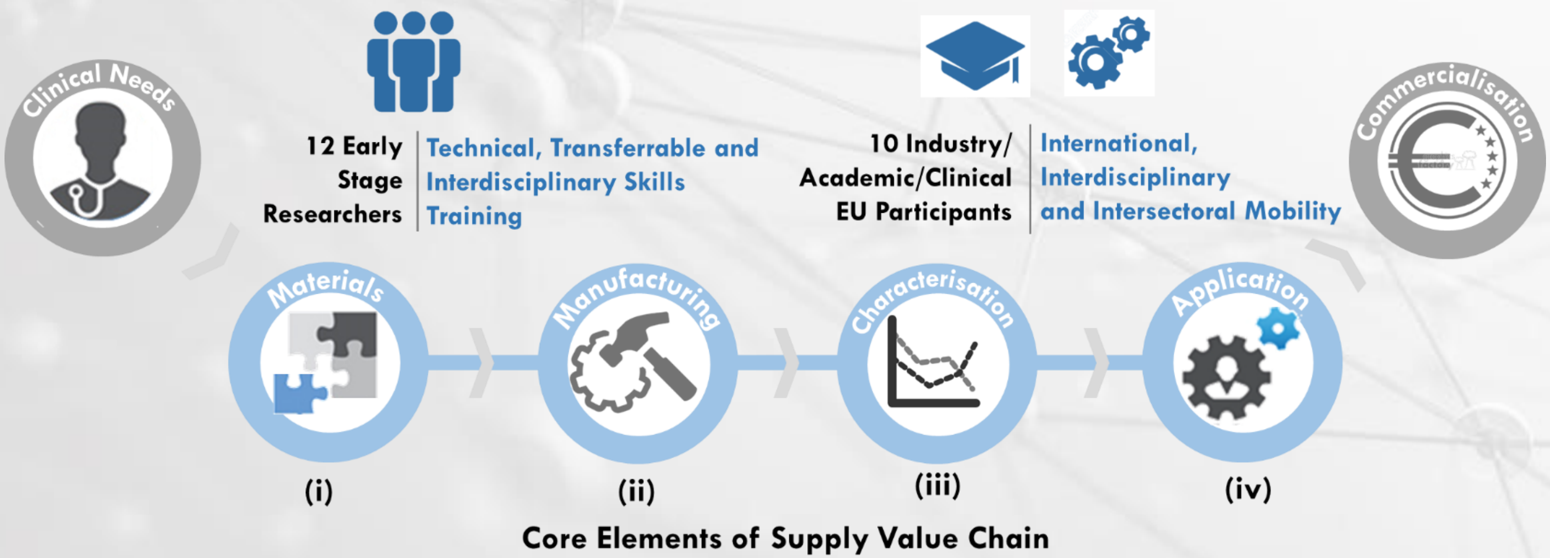
This project has received funding from the European Union's Horizon 2020 research and innovation programme under the Marie Skłodowska-Curie grant agreement No 813869

OÉ Gaillimh
NUI Galway

1. Background

BioImplant ITN

<u>Programme Vision:</u> The programme vision of the BioImplant ITN is to deliver **technical, interdisciplinary and transferrable skills training** to the ESR community (12 researchers in total) **throughout all areas of the medical device development Supply Value Chain.**



Integrated Research and **Training programme** centred on ‘Supply Value Chain” of Medical Implant Development

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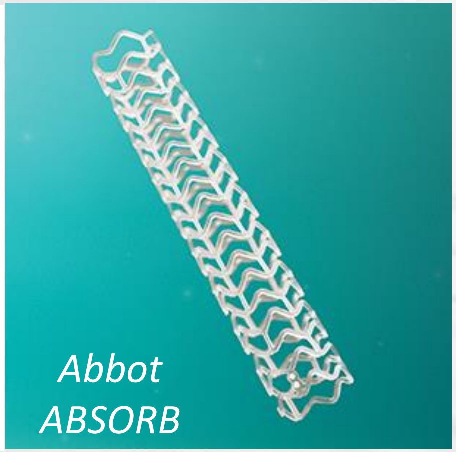
Motivation

Polymers:

❌ *Mechanical Properties* ✅ *Slow degradation*



THE LANCET

Comparison of an everolimus-eluting bioresorbable scaffold with an everolimus-eluting metallic stent for the treatment of coronary artery stenosis (ABSORB II): a 3 year, randomised,

Cardiovascular Business
STRATEGIES IN ECONOMICS, PRACTICE & TECHNOLOGY

Abbott pulls troubled Absorb stents from worldwide market

tctMD/the heart beat News Conferences Slides & More Top

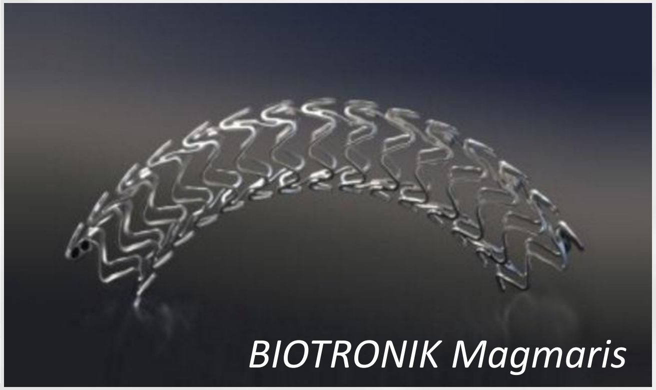
NEWS • INTERVENTIONAL

No More Absorb BVS: Abbott Puts a Stop to Sales

The company announced its intention to stop selling the bioresorbable scaffold in all countries but said follow-up of existing studies will continue.

Magnesium:

✅ *Mechanical Properties* ❌ *Rapid degradation*



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Research Objectives

Scientific Vision: Develop and implement improved bioabsorbable materials for vascular and orthopaedic implant applications

OBJ-1	**Enhance** the mechanical properties of **polymer-based** bioabsorbables through novel processing technologies.
OBJ-2	**Control** degradation rates of **magnesium-based** bioabsorbable materials through innovative polymer and ceramic coating technologies.
OBJ-3	**Develop** novel **composite-based bioabsorbables** material that exhibit superior mechanical properties to traditional polymers.

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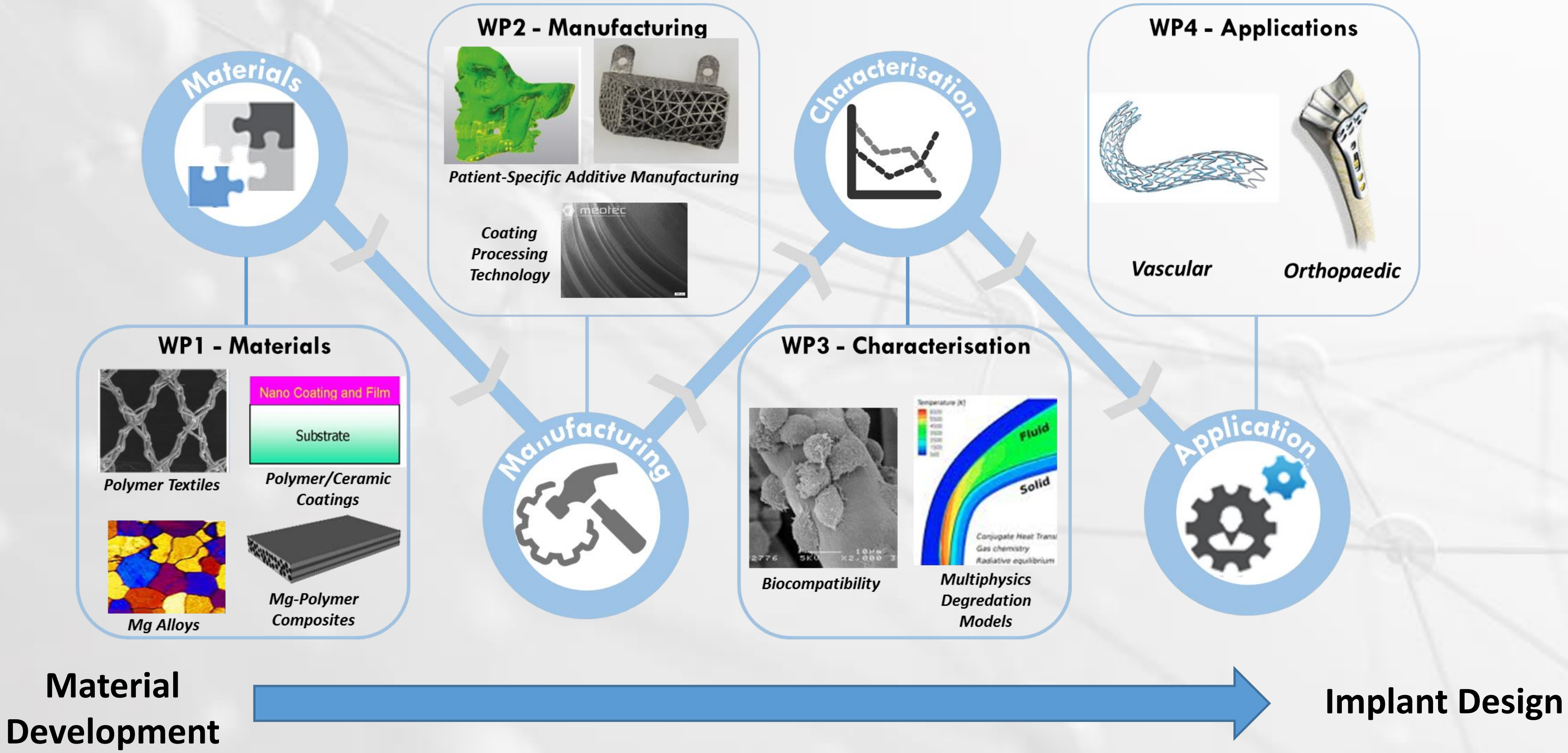
Integrated Research & Training

Research programme centred on ‘Supply Value Chain” of Medical Device Development



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Who are we?

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Partner Organisations

uc3m Universidad Carlos III de Madrid

UNIKLINIK RWTH AACHEN

TECHNISCHE UNIVERSITÄT DARMSTADT

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BioImplant ESRs

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NUI Galway OÉ Gaillimh | meotec

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Swati Nandan
NUI Galway OÉ Gaillimh | Vascular Flow Technologies

Flavia Caronna
NUI Galway OÉ Gaillimh | ITA GmbH

Agenese Luchetti
RWTH Aachen University | Boston Scientific

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Clara Hynes
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Wahaaj Ali Rizvi
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Carolina Costa
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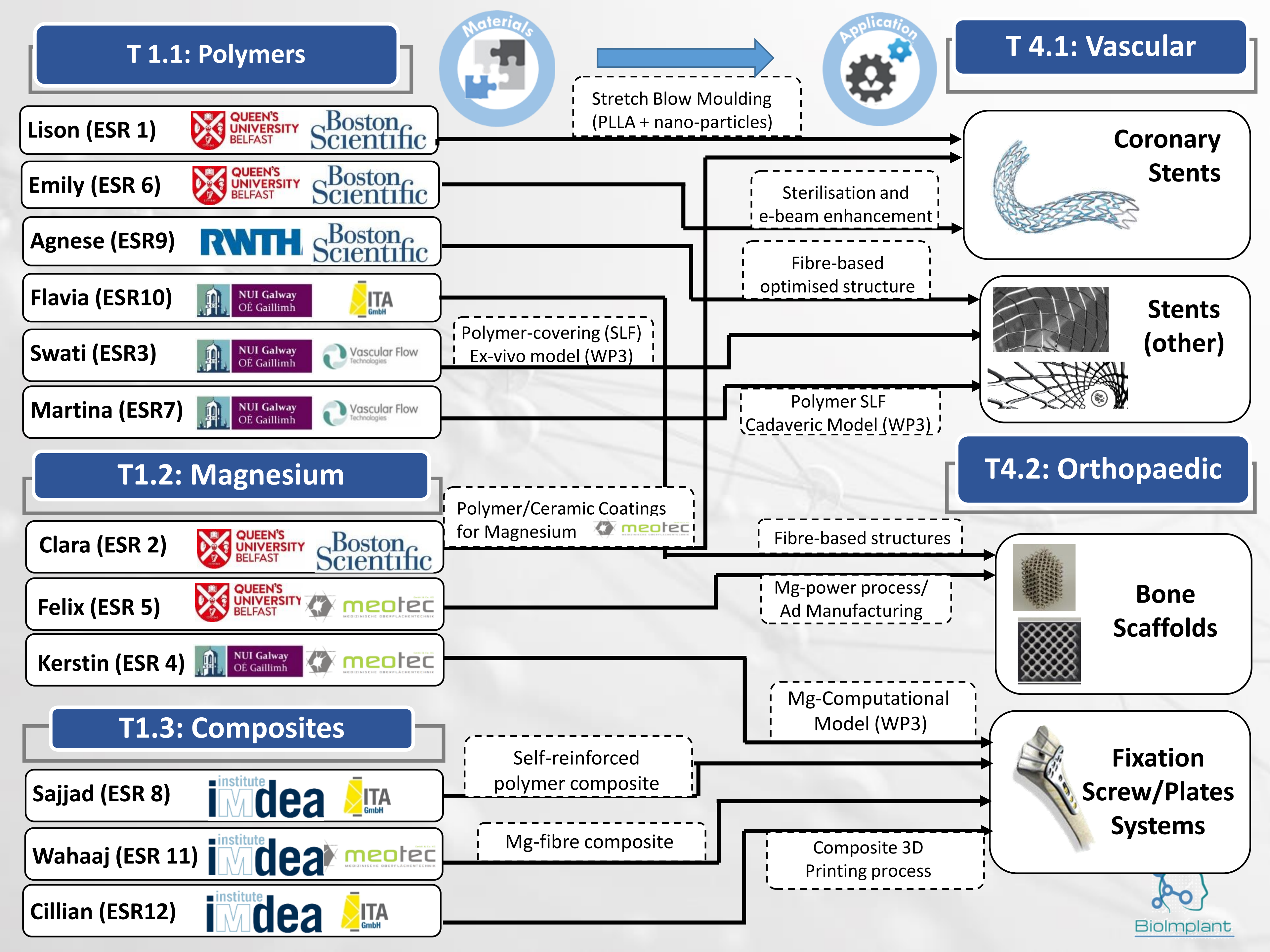
2. Project Roadmap



T 1.1: Polymers
Lison (ESR 1)
Emily (ESR 6)
Agnese (ESR9)
Flavia (ESR10)
Swati (ESR3)
Martina (ESR7)
T1.2: Magnesium
Clara (ESR 2)
Felix (ESR 5)
Kerstin (ESR 4)
T1.3: Composites
Sajjad (ESR 8)
Wahaaj (ESR 11)
Cillian (ESR12)
Materials
Application
Stretch Blow Moulding
(PLLA + nano-particles)
Sterilisation and
e-beam enhancement
Fibre-based
optimised structure
Polymer-covering (SLF)
Ex-vivo model (WP3)
Polymer SLF
Cadaveric Model (WP3)
Polymer/Ceramic Coatings
for Magnesium
Fibre-based structures
Mg-power process/
Ad Manufacturing
Mg-Computational
Model (WP3)
Self-reinforced
polymer composite
Mg-fibre composite
Composite 3D
Printing process
T 4.1: Vascular
Coronary
Stents
Stents
(other)
T4.2: Orthopaedic
Bone
Scaffolds
Fixation
Screw/Plates
Systems
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3. Training Programme

Training Objectives

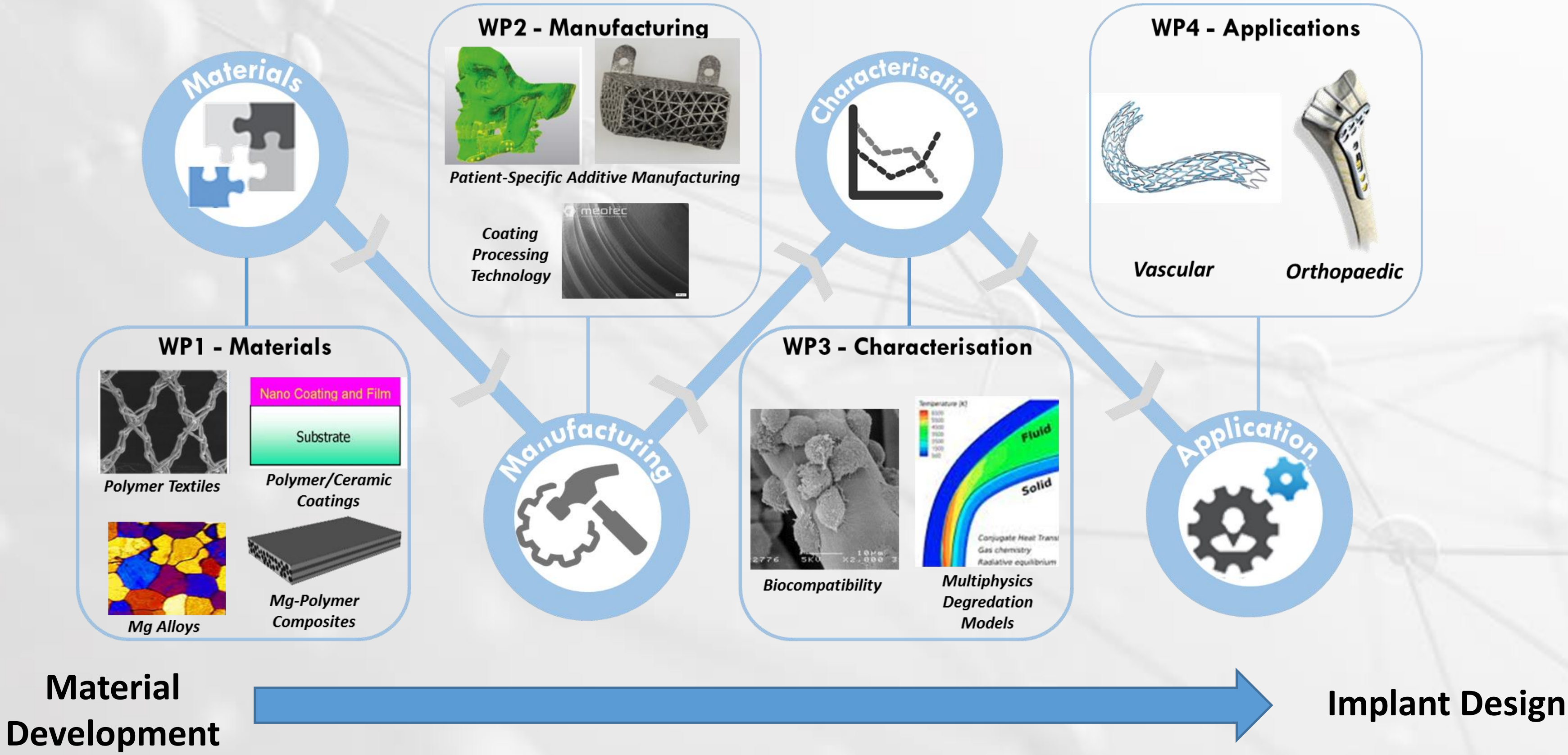
Training Vision: Provide world-class training to a new generation of highly skilled early-stage researchers in the area of biomaterial and medical implant development

OBJ-1	Develop **core technical skills** to ESRs throughout all elements of the Supply Value Chain through **hands-on research**
OBJ-2	Provide **advanced technical skills** training on advanced topics in all core elements of the Supply Value Chain through **network-wide training** events
OBJ-3	Promote **key transferable skills** to ESRs in areas such as communication and dissemination through network-wide training events to enable ESRs to **excel in both academic and non-academic environments**
OBJ-4	Provide network-wide training on **interdisciplinary aspects** of medical implant development, such as clinical engagement and entrepreneurship
OBJ-5	Promote **international mobility of ESRs** through inter-sectoral placement and secondment opportunities between participating countries

Impact: Enhance career development and employability and promote development into leading innovators in medical implant technologies.

Integrated Research & Training

Research programme centred on 'Supply Value Chain" of Medical Device Development



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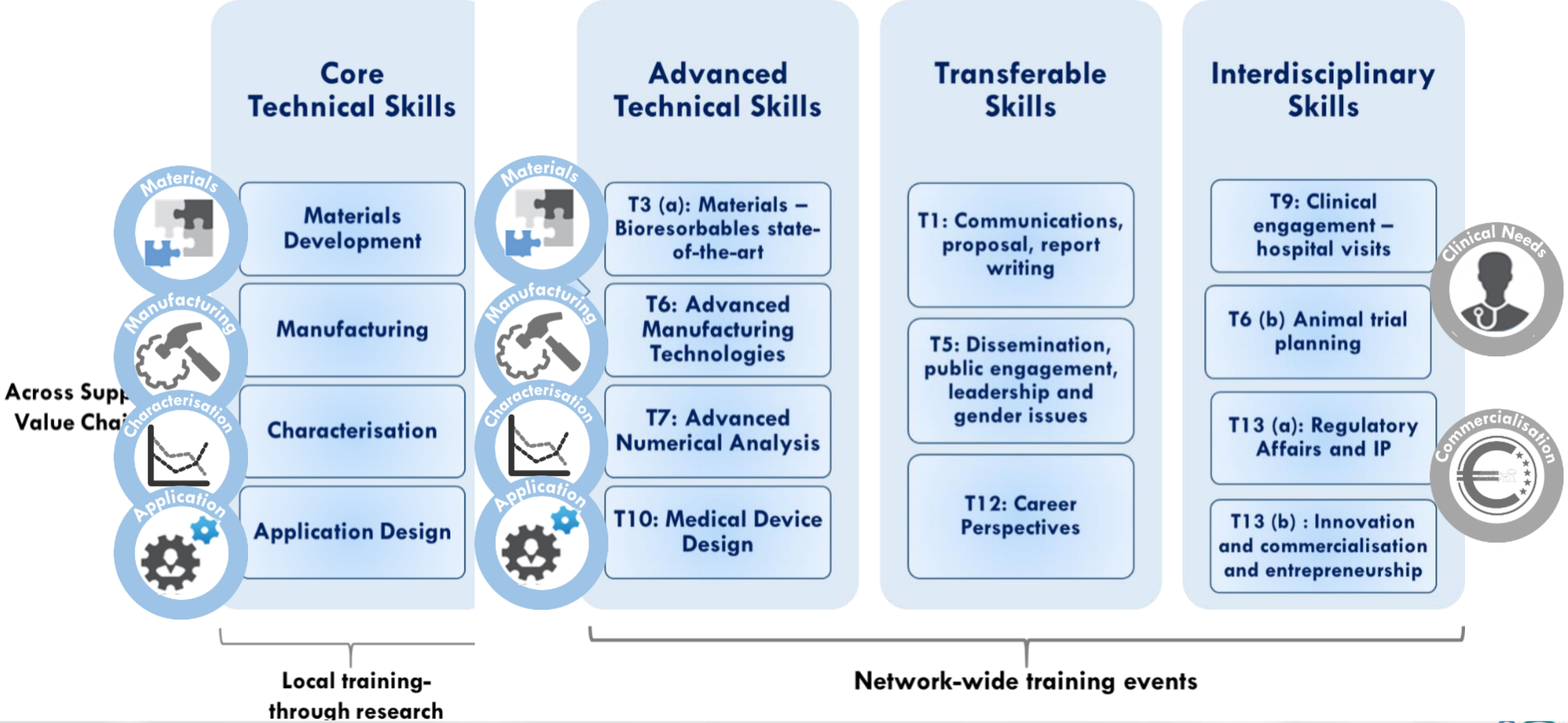
Training – Skills Development

Training programme centred on 'Supply Value Chain" of Medical Device Development



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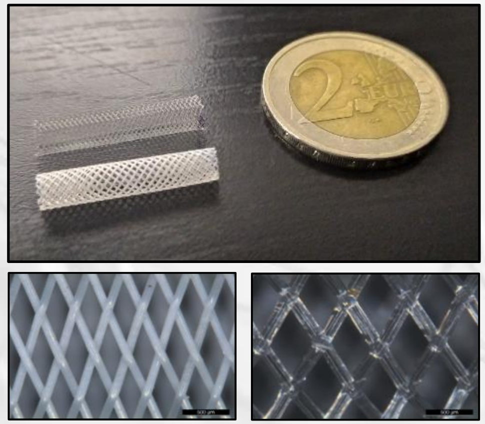
3. Results

Development of next generation bioresorbable polymer stent

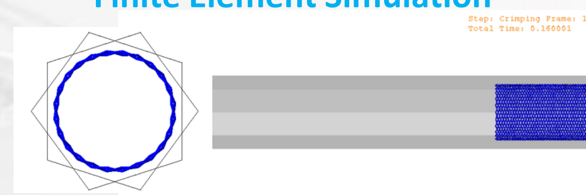
Manufacturing

Polymeric Braided Bioresorbable Stents



- **Experimental Characterization**

- **Finite Element Simulation**



Project main steps

- In-house manufacturing of PLLA braided stents
- *In-vitro* mechanical characterisation
- Development of a computational model to study stent mechanical performance in patient-specific scenarios
- Study of the degradation behaviour *in-vitro*

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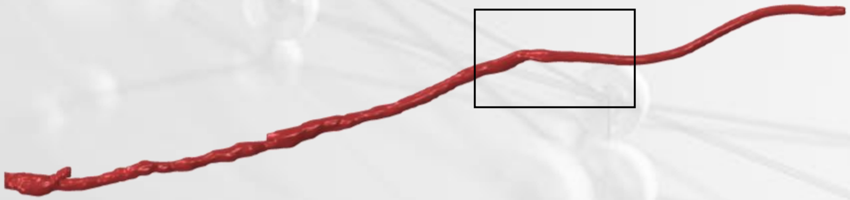
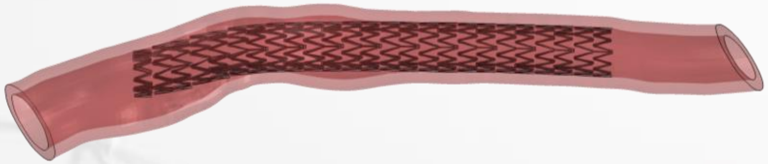
Improving Stenting Treatment for Superficial Femoral Arteries

- Development of computational patient-specific modelling for prediction and planning of stenting procedure

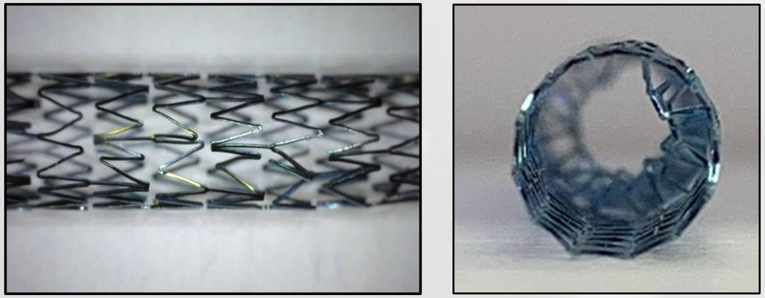


Vessel reconstruction from imaging [1, 2]

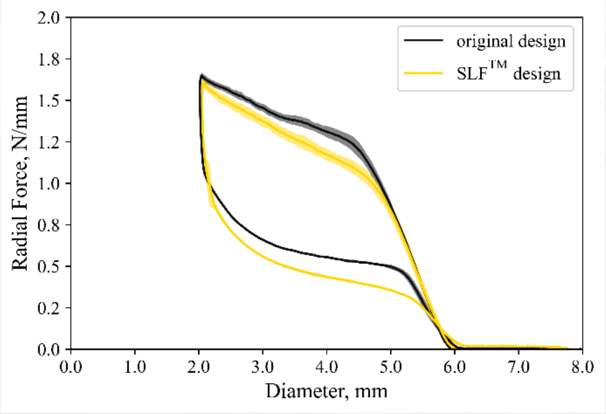


Finite Element modelling of device implantation and prediction of relevant clinical outcome (e.g., lumen gain)

- Development of Spiral Laminar Flow SLF™ technology on a self-expanding stent to recover the natural pattern of blood flow for improved long-term outcomes



Views of SLF™ technology applied on self-expanding stent



Radial compression behaviour of original and SLF™ designs

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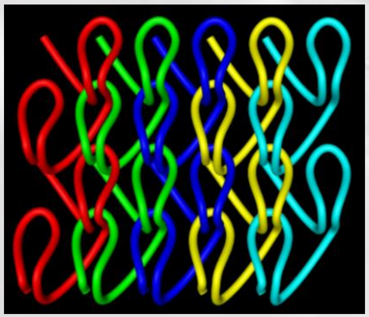
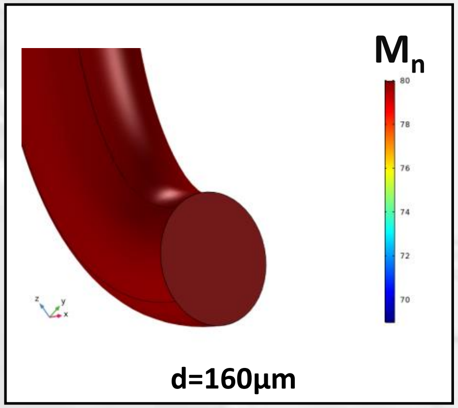
[1] Colombo et al., Scientific Reports. 1–12 (2021)
[2] Colombo et al., Medical Engineering and Physics. 75, 23–35 (2020)

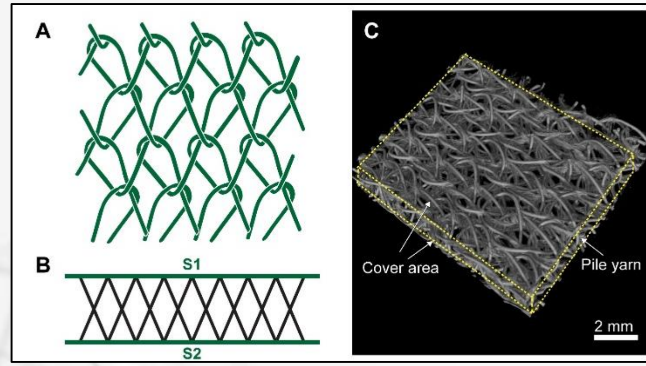
Development of a bioabsorbable polymeric textile scaffold for bone tissue engineering

MODELLING



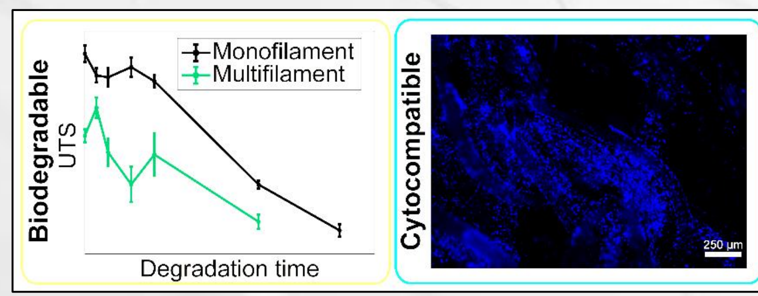


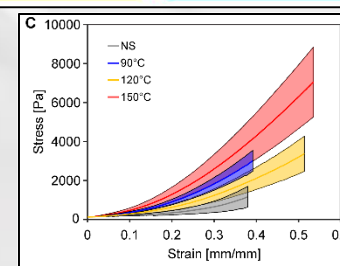
MANUFACTURING



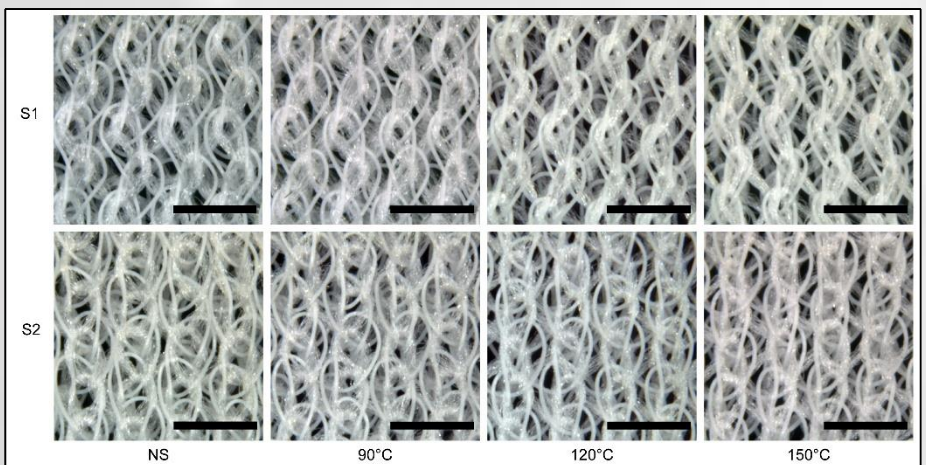
Bioabsorbable polyesters: PLA and P4HB

CHARACTERIZATION





OPTIMIZATION



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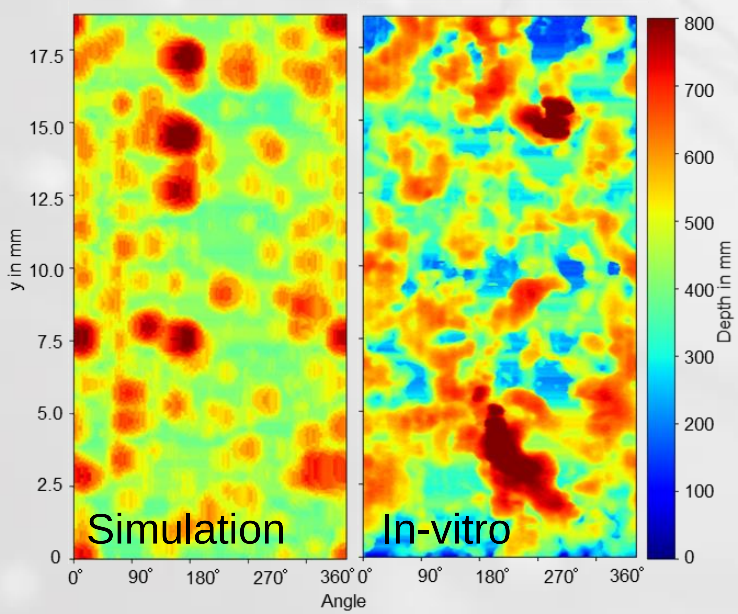
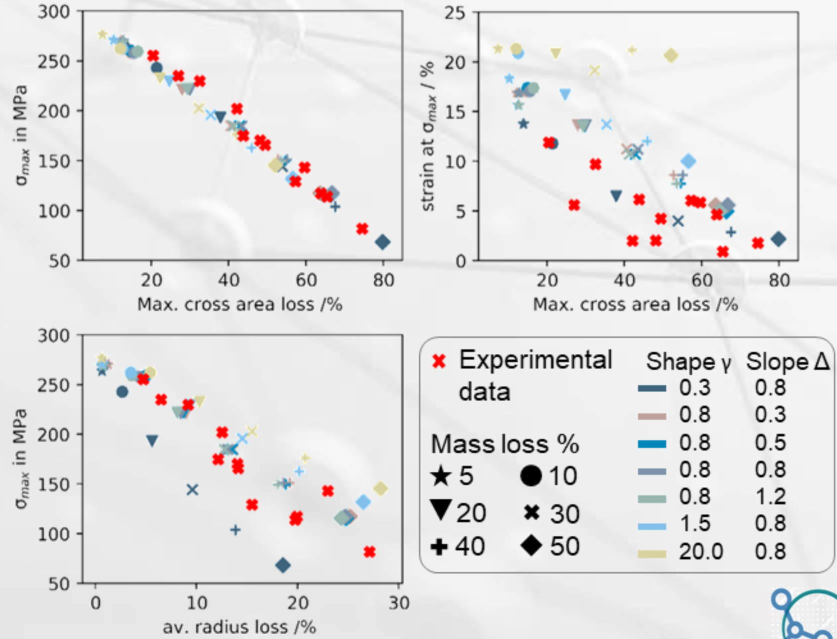
Numerical modelling of Magnesium degradation

Phenomenological and mechanical fitting of magnesium degradation

Phenomenological tracking by automated surface tracking (PitScan[1])



Mechanical integrity fitting by surface features



[1] van Gaalen, Kerstin, et al. "Automated ex-situ detection of pitting corrosion and its effect on the mechanical integrity of rare earth magnesium alloy-WE43." *Bioactive materials* 8 (2022): 545-558.

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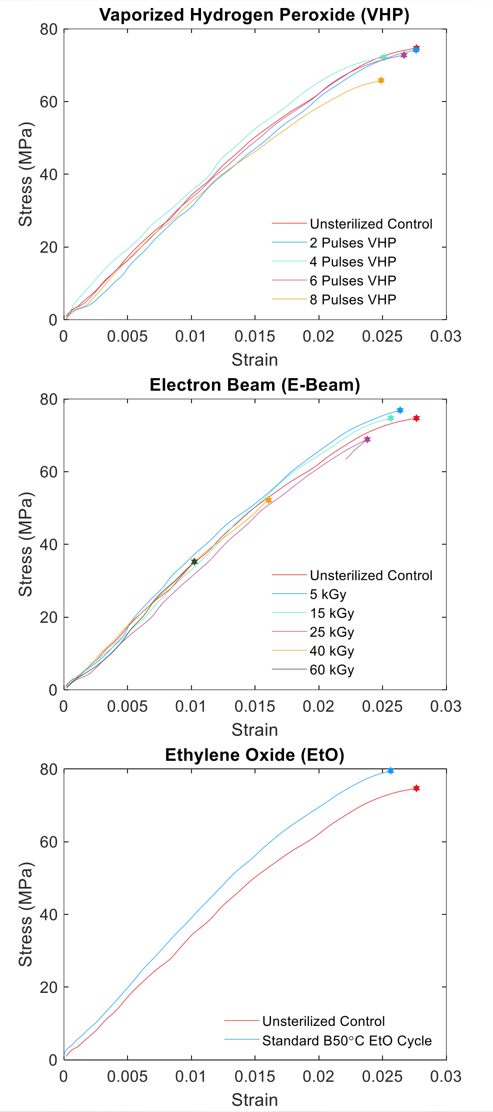
ESR 6: Sterilization of PLLA

- Understanding changes caused to Poly (L-lactide) (PLLA) during sterilization is a critical prerequisite to determining device performance.
- There is also a need to broaden available sterilization modalities within the medical device industry.
- This study aimed to evaluate the effects of vaporized hydrogen peroxide (VHP) sterilization on PLLA against two common sterilization techniques (e-beam and EtO) and assess its suitability as a novel, alternative sterilization modality.
- VHP produced comparable if not superior results to EtO and e-beam and is supported for use with PLLA based bioresorbable medical devices.



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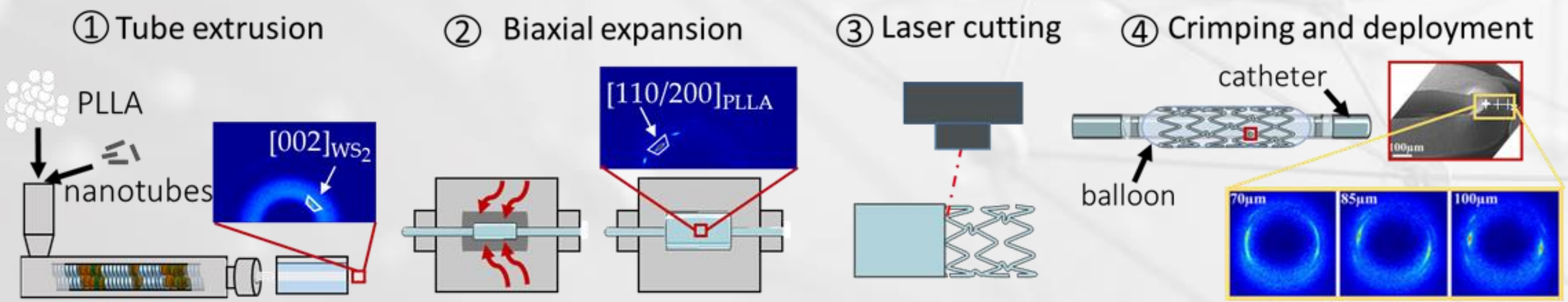
Investigation of a nanocomposite material and improvement of manufacturing process for stronger bioresorbable stents

- Production of neat and nanocomposite PLLA bioresorbable stents
- Characterisation at **each step of the stent manufacturing process**
- Study the **effect of the nanoparticle addition** on the PLLA microstructure
- Study of the **effect of processing parameters** (during extrusion, biaxial expansion and crimping) on the microstructure and mechanical properties of the stent prototypes



Main steps of a PLLA bioresorbable stent manufacturing process and characterisation of the microstructure by Wide angle x-rays scattering

Lison Rocher l.rocher@qub.ac.uk

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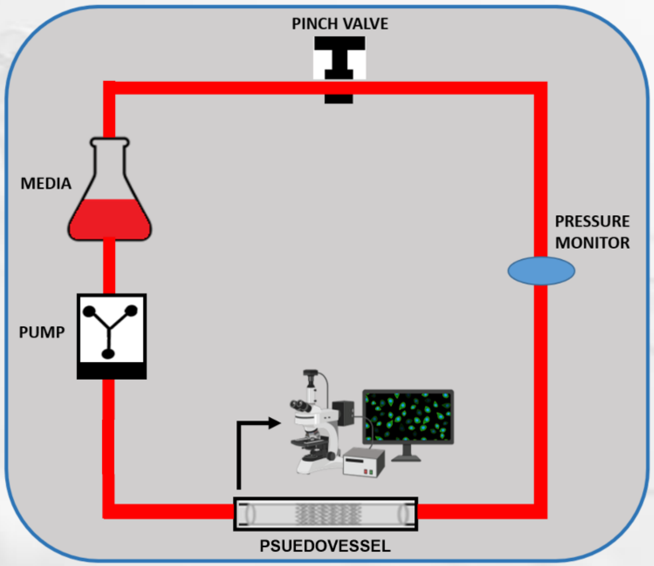
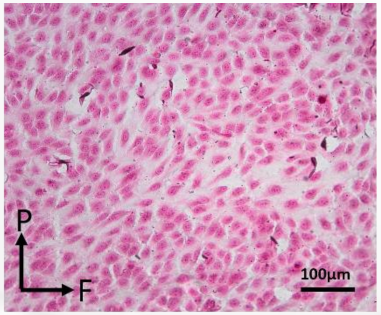
Project: Design and optimization of spiral laminar flow stents for peripheral artery applications to provide optimal flow and mechanical performance

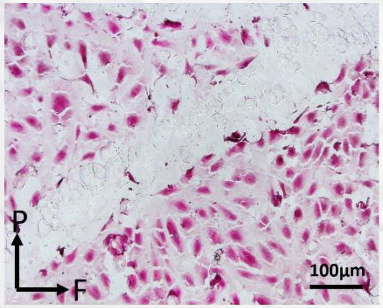
- Development of an *in vitro* bioreactor to evaluate functional performance of varied stent designs providing conditions comparable to native peripheral arteries

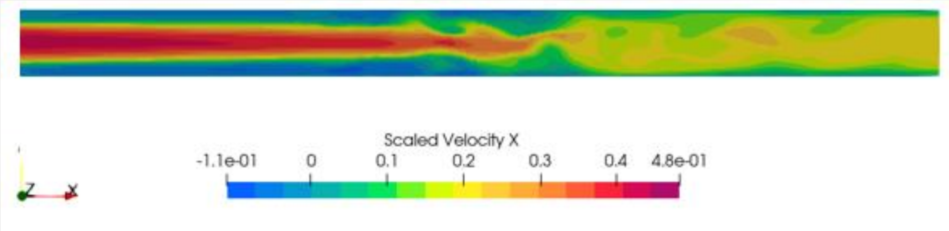
- Verification of the bioreactor design through Computational Fluid dynamic studies (CFD)

- Incorporation of Vascular Flow Technologies, UK (VFT) Spiral Laminar Flow for self-expanding nitinol stents through CFD studies to improve patency of peripheral stents









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