UNITISS: Competence Development in Catheter Design for Reduced Clinical Complications

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EUROMAT Warsaw, 23rd September 2015
Catheterisation procedures

• Urinary catheterization – urethra - bladder

• Coronary catheterization – artery:
  - Femoral artery access
  - Radial artery access (up to 54% of *PCIs)

*Percutaneous Coronary Intervention*
Clinical complications
In Transcatheter Cardiovascular Intervention

Acute:
• Haemorrhage
• Radial spasm (up to 40% of RA procedures)
• Tears in the intima layer
• Dissections in the media layer

Chronic:
• Occlusion (hyperplasia/stenosis)
• Medial calcification
• Adventitial inflammation/necrosis

• Good evidence for mechanical origins:
  – Mechanical interaction of the catheter and/or guidewire with the blood vessel wall

Growing awareness within the medical and medical equipment manufacturing communities


Sobolewski & ElFray: Cardiac catheterization: consequences for the endothelium and potential for nanomedicine, WIREs Nanomed Nanobiotechnol 2014. doi: 10.1002/wnan.1316
Understanding Interactions of Human Tissue with Medical Devices

Competence development in the design of high-end catheter-based medical devices* for minimal clinical complications and patient trauma

- FP7 People (Marie Curie, IAPP)
- 4 years, March 2012 – Feb 2016
- 146 man-months of staff exchange
- Partners:

*for coronary interventions
UNITISS project strategy

**Gathering knowledge, creating focus**
- Reviews of catheters, catheter materials, complications & interactions
  - Specific focus of UNITISS

**Developing design knowledge**
- Reverse engineering of catheters
- Evaluation of catheter internal friction points
- Tribological evaluation of coatings for catheters

**Developing and testing potential solution spaces**
- Lubricious antimicrobial catheter coatings
- Catheter steerability improvement options
- Catheter contact & pressure sensing & control options

**Materials & Methods**
- Methods to evaluate blood vessel tissue damage
- Mechanical properties of tissue materials
- Friction & tissue damage experiments

**Modelling**
- Biomechanical modelling catheter interactions
- Lubrication modelling catheter interactions

**Future device development**

Highlighted in this talk
UNITISS work programmes

- Summarised examples
- Details in various F3 oral and poster presentations
Catheter tip friction & tissue damage experiments

Investigation of conditions and forces leading to *mechanical trauma*

Evaluation of friction forces and tissue damage due to interaction of a catheter tip with ex-vivo porcine aorta

Tissue damage evaluation by ATR-FTIR

Ex vivo porcine aorta

Catheter tip

Tissue holder

Tip is based on Philips catheter tip and guidewire

CETR UMT-2 Tribometer
Methods to evaluate blood vessel tissue damage

Objectives:

• Investigation of different techniques for their suitability to evaluate blood vessel tissue damage from tribological tests on ex vivo porcine tissue
• Development of protocols for evaluating structural tissue damage

Techniques:

• Silver nitrate staining (endothelium integrity)
• Raman Spectroscopy
• ATR-FTIR spectroscopy
• Optical/confocal microscopy with SHG
• Optical Coherence Tomography
• SEM
• Metabolic assays-LDH release
• Histology (collagen condition)

Most promising

Jacek Wojnowski: poster F3.2 Tuesday; Luciana Bostan: F3.2 Tuesday AM2
Modelling of catheter-blood vessel interaction

**Objective:** Develop models to enable investigation and optimisation of catheter design parameters

- **FE model:** biomechanical model of catheter interaction & tissue damage mechanisms
- **Lubrication model:** Soft Elasto-Hydrodynamic Lubrication model to investigate effects of catheter design on catheter-blood vessel friction and shear forces, also providing input to FEM model

*Chris Noble  
Willem Potze*  
*F3.1, Thursday AM1*
Coatings for catheters

- Understanding friction behaviour and friction-lifetime of hydrophilic coatings for catheters
- In vitro tribological testing in simulated catheterisation conditions
- Development of lubricious antibacterial Chitosan and fatty acid-based coatings
- Benchmark against commercial coatings

Summary

• Growing awareness within the medical community of the need to reduce clinical complications associated with catheterization procedures
• Predominant root cause: mechanical interactions with the blood vessel wall
• UNITISS brings together experts from a range of relevant disciplines to develop a competence in catheter design for reduced clinical complications through:
  – Materials and methods development
  – Modelling of device interactions with the blood vessel wall
  – Developing and testing solution spaces that can be integrated into device designs
Acknowledgements

Contributions from:
• **Univ. of Sheffield** UK: Luciana Bostan, Sheila MacNeil, Roger Lewis, Matt Carré, Chris Noble, Oliver Burke
• **West Pomeranian Univ. of Techn. Szczecin PL**: Jolanta Baranowska, Miroslawa ElFray, Piotr Sobolewski, Agata Niemczyk, Malgorzata Nachman, Joanna Piwowarczyk, Jacek Wojnowski, Pawel Michalski
• **Philips Research** NL: Kiran Dellimore, Willem Potze, Nicole Smulders, Arjan Mank

*This work was supported by EU Marie Curie Industry-Academia Partnerships and Pathways: UNITISS, Understanding Interactions of Human Tissue with Medical Devices, FP7-PEOPLE-2011-IAPP/286174.*
EUROMAT-UNITISS presentations

- Tues. AM1: 1304 Malgorzata Nachman “Comparison of frictional and mechanical properties of human skin and synthetic materials in dry and moist skin conditions”
- Tues. AM2: 1457 Luciana Bostan “Measurement of load-induced changes in pig aorta fibre organization by non-invasive imaging as a model for detecting the tissue response to endovascular catheters”
- Tues. AM2: 2365 Chris Noble “Replicating diseased aorta mechanical properties via enzymatic digestion and glutaraldehyde treatment”
- Wed. AM2: 1835 Oliver Burke “Feasibility Assessment of Concepts for a Controllable Stiffness Catheter”
- Wed. PM1: 1483 Peter Sobolewski “Transradial access for cardiac catheterization: new biomaterials challenges”
- Wed. PM1: 1886 Steve Franklin “UNITISS: Competence Development in Catheter Design for Reduced Clinical Complications”
- Wed. PM1: 1924 Agata Niemczyk “Amphiphilic chitosan derivatives as multifunctional coatings for catheters”
- Thur. AM1: 1248 Willem Potze “Elasto—Hydrodynamic Lubrication in Catheter—Blood Vessel Contact”
- Thur. AM1: 1379 Chris Noble “A combined experimental-computational method for estimating friction during soft tissue perforation”
- Poster P1: 1666 Jacek Wojnowski “Evaluation of porcine aorta damage using FTIR spectroscopy”
- Poster P1: 2120 Pawel Michalski “Application of FTIR spectroscopy for the identification of blood vessel tissue damage by catheters - statistical interpretation of the results”
- Poster P2: 1469 Zing Siang Lee “In situ Damage Evaluation of Porcine Aorta Tissue using Standard Confocal Microscopy”
- Poster P2: 1729 Zygmunt Staniszewski “Pressure sensitive silicone composite for minimum invasive applications”