

MIMIMed@Lyon

Instrumented experimental organ models for the development and multi-scale testing of medical devices: A Lyon-based platform as an alternative to animal testing

Guilhem RIVAL

Electrical Engineering and Ferroelectricity Laboratory, INSA Lyon

LGEF

**Ingénierie
Matériaux
Polymères**

MatéIS
Matériaux
Ingénierie
et Structures
UMR 5510

LaMCoS
Laboratoire de Mécanique
des Contacts et des Structures
UMR 5259

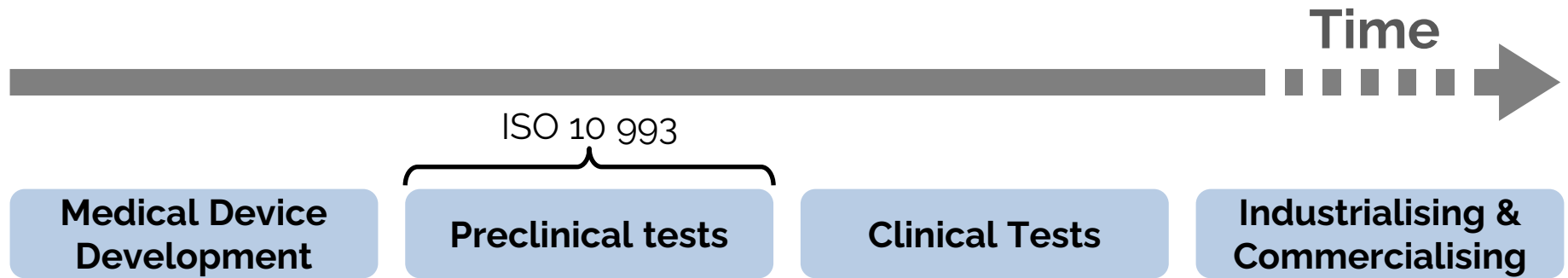
Lmfa

LMI
UMR5615

LTDS
Laboratoire de Tribologie et Dynamique des Systèmes

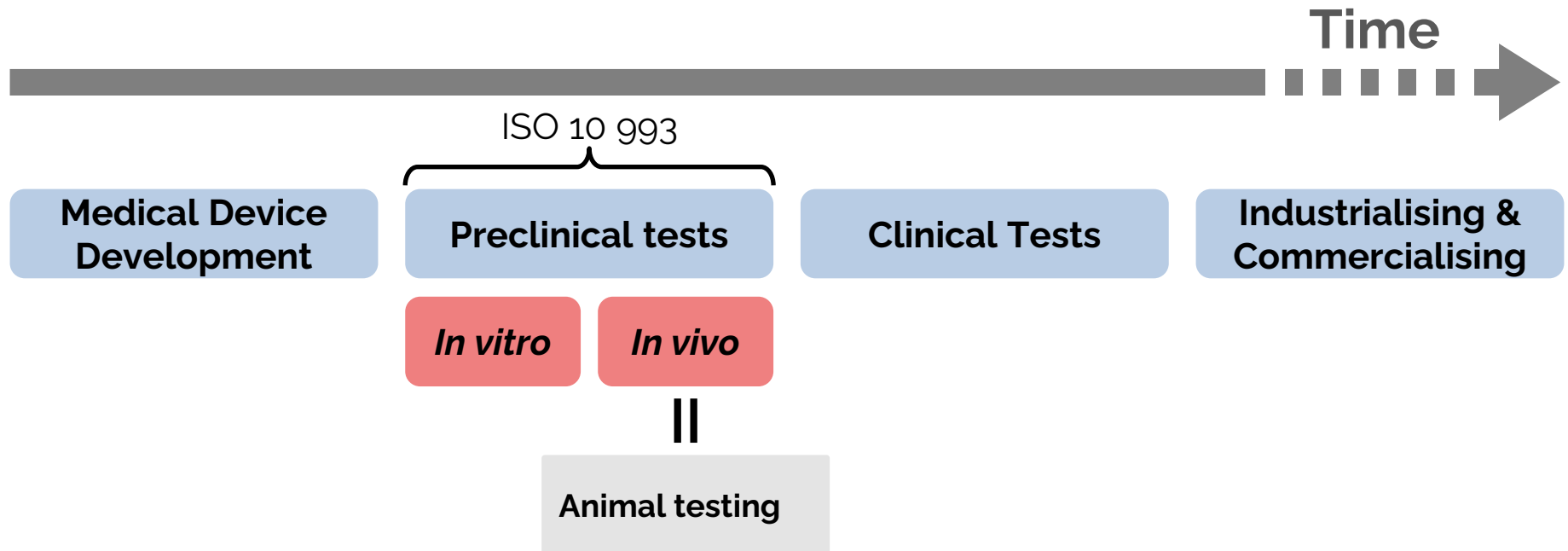
Context

Medical Devices: Evolving Regulations



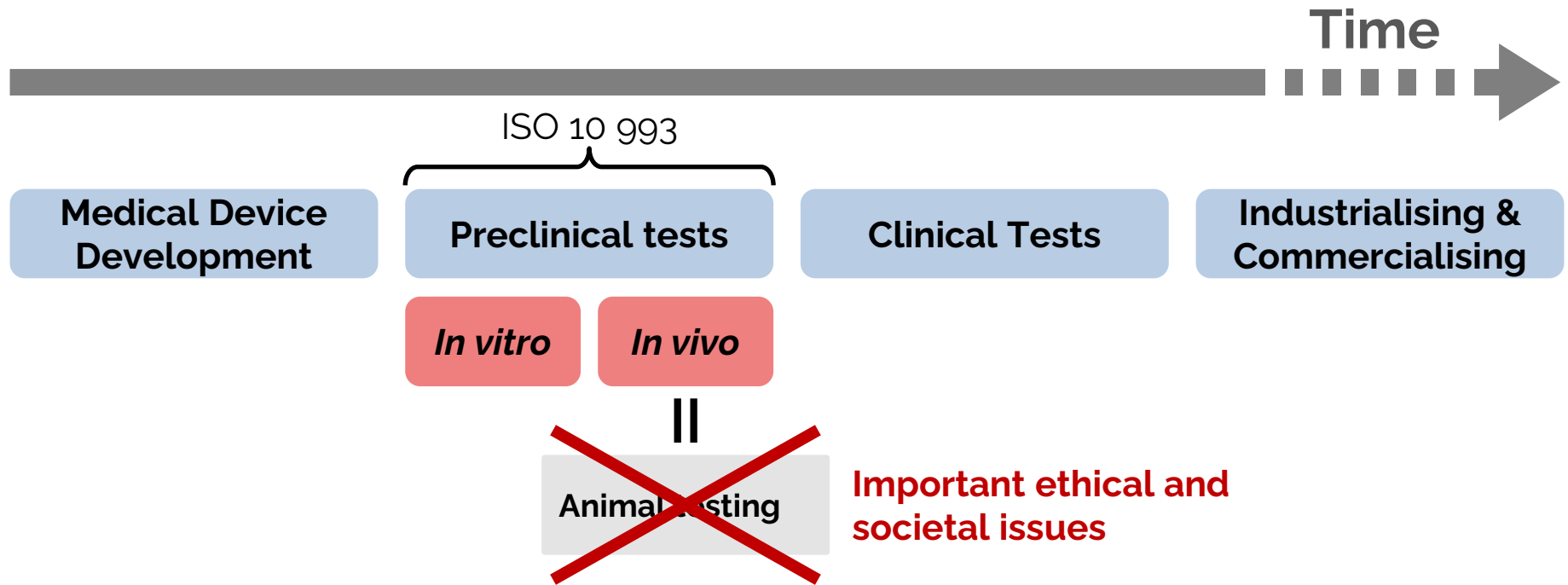
Context

Medical Devices: Evolving Regulations



Context

Medical Devices: Evolving Regulations



New European regulations aimed at limiting the use of animals via alternative methods

→ 4Rs principle: **Reduce, Reuse, Recycle and Restore**

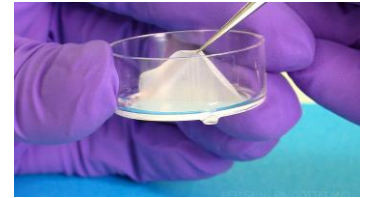
State of art

Alternative methods to animal testing?

Cosmetics field

Animal testing is forbidden!

- Development of representative matrices and model cells for testing
- Guided by reports from groups commissioned by the EU



EpiSkin, Lyon

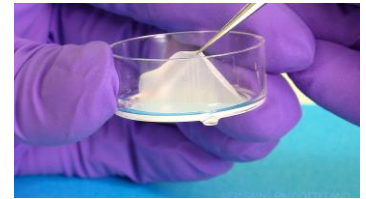
State of art

Alternative methods to animal testing?

Cosmetics field

Animal testing is forbidden!

- Development of representative matrices and model cells for testing
- Guided by reports from groups commissioned by the EU



EpiSkin, Lyon

Medical field?

Europe is mainly active in pharmacology

➔ No alternative methods yet for testing medical devices...

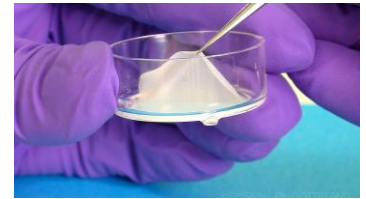
State of art

Alternative methods to animal testing?

Cosmetics field

Animal testing is forbidden!

- Development of representative matrices and model cells for testing
- Guided by reports from groups commissioned by the EU



EpiSkin, Lyon

Medical field?

Europe is mainly active in pharmacology

➔ No alternative methods yet for testing medical devices...

Issues: consideration of biomechanical interactions?

- Mechanical wear of medical devices (release of toxic products)
- Mechanobiology of biological tissues (inadequate responses)

Objective

Development of an experimental models platform,
representative of environmental conditions, for preclinical
testing of medical devices

Existing experimental models

Macro

**Mastication Simulator
(LMI)**



**Vascular Simulator
(LMFA)**



Micro

**Bio-Tribo-Reactor
(LaMCoS)**



- Reproduce variable chewing cycles
- Measurement of teeth displacement
- Simulation of the physico-chemical environment (Temp, pH, etc.)

Existing experimental models

Macro

**Mastication Simulator
(LMI)**



**Vascular Simulator
(LMFA)**



Micro

**Bio-Tribo-Reactor
(LaMCoS)**



HCL
HOSPICES CIVILS
DE LYON

- Use of a fluid simulating rheology of blood
- Pump to reproduce blood pressure and pulsation
- Image correlation to measure local fluid dynamics

Existing experimental models

Macro

**Mastication Simulator
(LMI)**

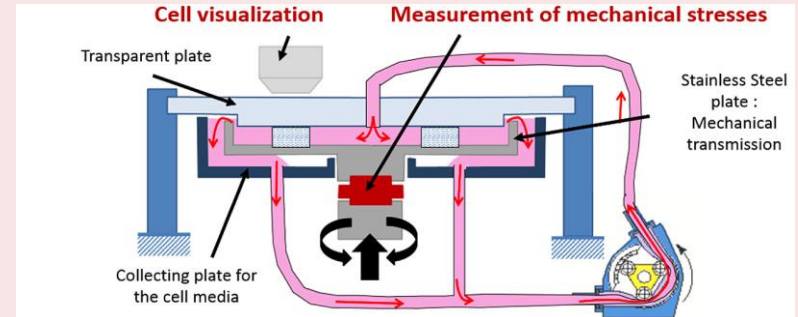


**Vascular Simulator
(LMFA)**



Micro

**Bio-Tribo-Reactor
(LaMCoS)**



- Interaction between medical devices and biological material under mechanical stress
- Control of the physico-chemical properties of the cell culture medium

Approach

Research areas: Multi-scale testing of medical devices

Multi-scale pre-clinical testing platform

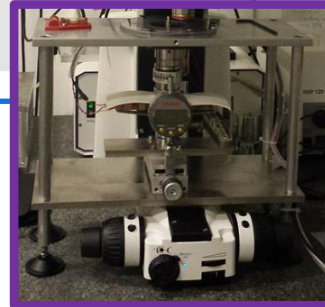
macro

Mastication Simulator

Vascular Simulator

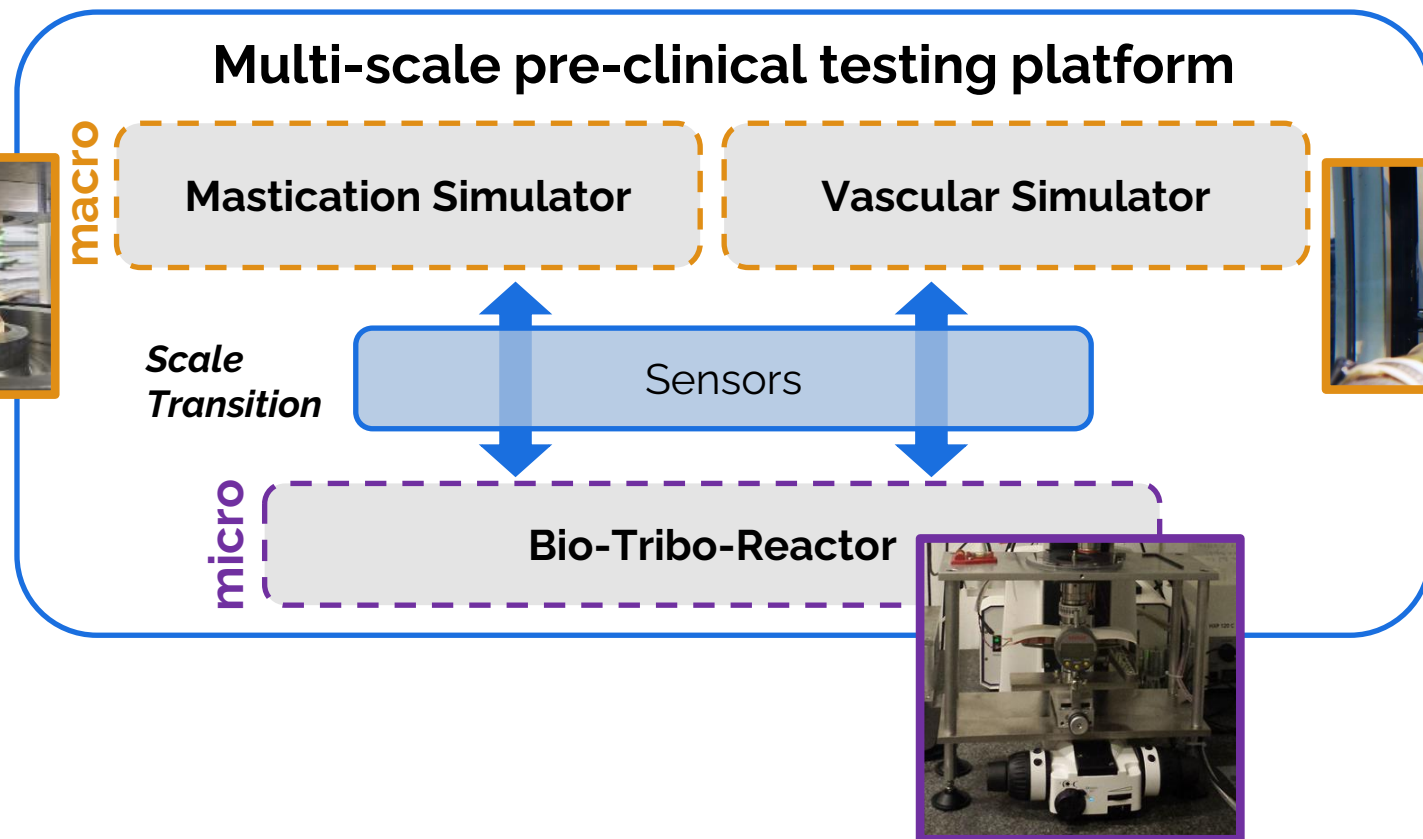
micro

Bio-Tribo-Reactor



Approach

Research areas: Multi-scale testing of medical devices



Retrospective planning

S1

S2

S3

S4

S5

S6

Task 1. Development and optimisation of electroactive sensors for the vascular simulator

Task 2. Instrumentation of the mastication simulator and validation over different chewing cycles

Task 3. Instrumentation of vascular simulator and validation with digital image correlation

Task 4. Scale transition in the bio-tribo-reactor to evaluate the biomechanical interactions with model medical devices

Retrospective planning

S1

S2

S3

S4

S5

S6

Task 1. Development and optimisation of electroactive sensors for the vascular simulator

Task 2. Instrumentation of the mastication simulator and validation over different chewing cycles

Task 3. Instrumentation of vascular simulator and validation with digital image correlation

Task 4. Scale transition in the bio-tribo-reactor to evaluate the biomechanical interactions with model medical devices

↑
Today

Task 1. Sensors for vascular simulator

Objectives and constraints

Develop **flexible sensors with high sensibility** that can be integrated inside or on top of **silicone tube used as model material for arteries** in the vascular simulator



Task 1. Sensors for vascular simulator

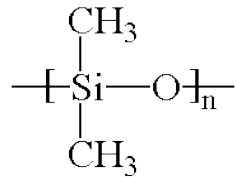
Objectives and constraints

Develop **flexible sensors with high sensibility** that can be integrated inside or on top of **silicone tube used as model material for arteries** in the vascular simulator



Elaboration of **Elastomer / Piezoelectric Particles** composite

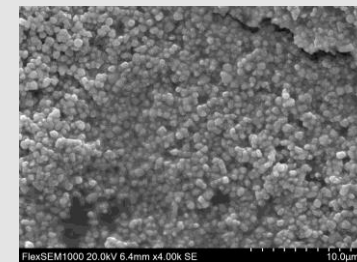
PolyDiMethylSiloxane (PDMS)



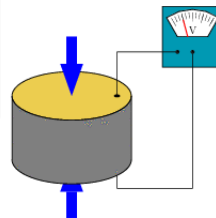
- Flexible
- Same material as silicone tube



Baryum Titanate (BaTiO_3)



- High piezoelectric response
- Lead free



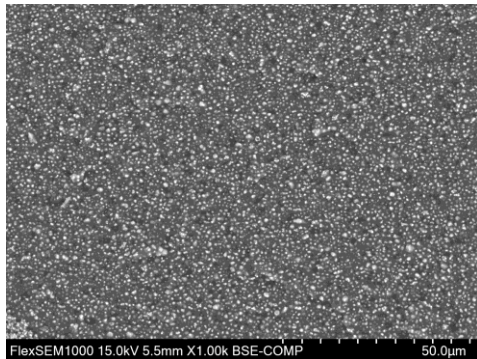
Task 1. Sensors for vascular simulator

Development and optimisation

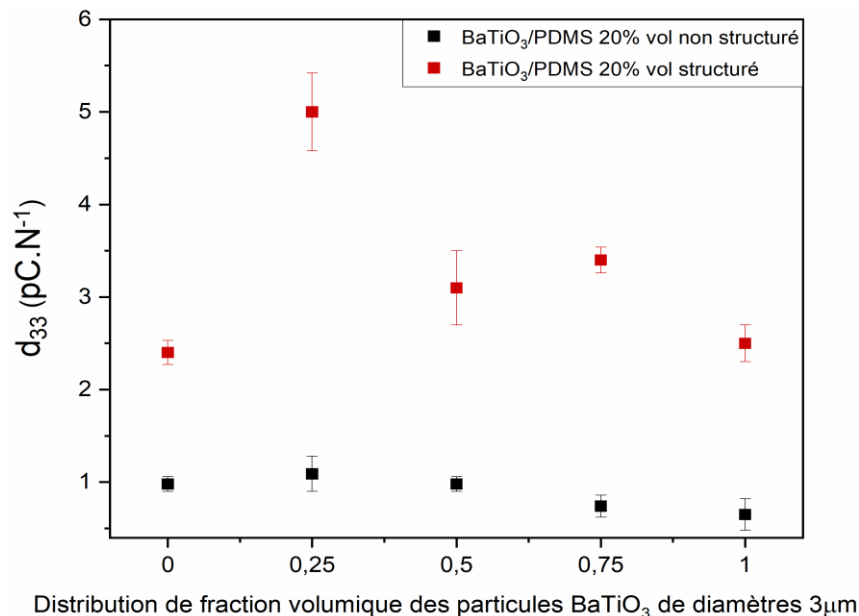
Optimisation axis

- **Bimodal distribution** of particles
- **Dielectrophoresis structuration** of particles

Random distribution



Piezoelectric coefficient



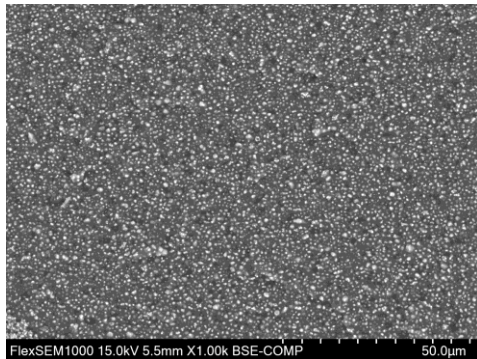
Task 1. Sensors for vascular simulator

Development and optimisation

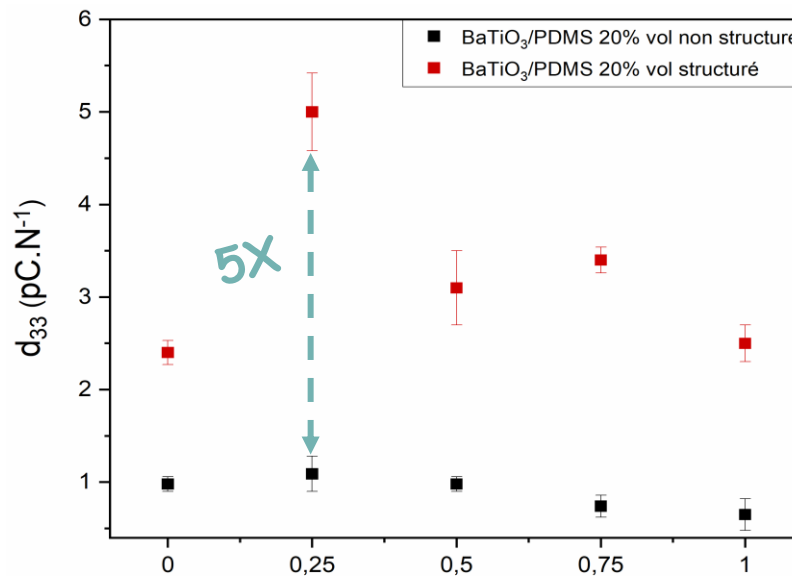
Optimisation axis

- **Bimodal distribution** of particles
- **Dielectrophoresis structuration** of particles

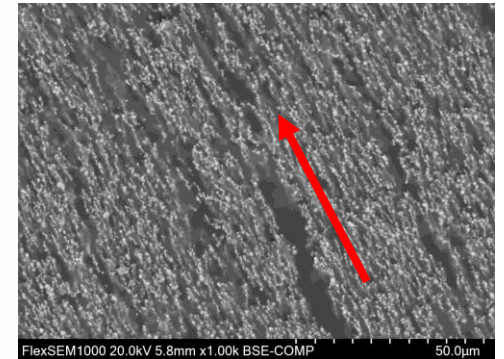
Random distribution



Piezoelectric coefficient



Structured distribution



Distribution de fraction volumique des particules BaTiO₃ de diamètres 3µm

Task 2. Instrumentation of mastication simulator

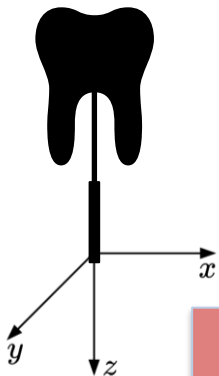
Objective

Measuring local tooth movements during representative mastication cycles

Integration of sensors in the roots of 3 teeth (canine, incisor and molar)

→ 3-axis movement tracking

Part used to record the movements of 3 teeth (prototype printed for validation)



Sensor installed (x axis)

Rod attached to the tooth

Locations of other sensors (y,z)

Conclusion

Technological Innovation

Developing a multi-scale pre-clinical tests platform
(national and international)

Testing **Medical Devices made in Lyon**

Partnership Development Santé@Lyon

Link between **research and clinicians**



Synergy of skills for a multidisciplinary problem

Long term...

- Standardise pre-clinical test protocols
- Extend the platform to other human biological systems
- Open up the platform to laboratories and industry