



Wrocław
University
of Science
and Technology

BREAKTHROUGH BIOMATERIALS for SMALL BONE DEFECTS REGENERATION

SUMMARY:

Bioactive elastomeric biocomposites with proven biocompatibility were developed and validated in laboratory scale on small animal model for application in regeneration of small bone defects.

The biocomposites **adapt in shape to the defect** and do not cause mechanical stress at the implantation site.

The biocomposites can be used as **implants for flat skull bone** defects regeneration.

For patients following **cranioplasty** procedures. They are an alternative to metallic meshes that prevent monitoring of bone healing with tomography.



HR EXCELLENCE IN RESEARCH



SUMMARY:

Biocomposites have applications as implant **materials for flat cranial bone regeneration and reconstruction.**

The suitability of the material has been verified in *in vivo* studies based on a flat cranial bone model in a rat animal model. Biocomposites can be manufactured as **Class III medical devices.** They are intended for **patients with defects in flat cranial bones related to cranial bone tumors, patients after craniotomy, patients scheduled for cranioplasty procedures, and patients with post-traumatic defects.**

The undertaking is funded by



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Problem & Solution

Problem:

1. Regeneration of small bone defect in flat skull bones – the defects are left empty or metallic meshes hindering postoperative diagnostics are used.
2. Bone tissue implants available on the market are **stiff** and **brittle**, and **difficult to precisely adjust to the shape of the bone defect**.
3. **Commercial implants do not provide comprehensive performance.**

Our approach to solve the problem:

1. We developed prototype implants for filling and regeneration of small defects of skull bones (positive *in vivo* tests on a flat skull bone model of rat). **They do not hinder postoperative diagnostics.**
2. The prototype biomaterials **can easily adapt to the shape of the bone defect and does not cause mechanical stress at the implantation site.**
3. The prototype implants are **biocompatible, osteoconductive** and exhibit **proregenerative activity**. They have potential to **exhibit mechanotransduction effect.**

What is the expected solution?

Introduction of the biocomposites to the market as **medical devices Class III** for use as filling materials in the regeneration of flat bones of the skull.

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The Mission

Current state



<https://e-meditrans.pl/>



Our solution



Problems 1-3 concern **patients after craniotomy** (e.g. removal of a brain aneurysm and brain tumor) and **patients qualified to cranioplasty surgeries**.

Developed prototype implants will ensure safe and faster regeneration and reconstruction of skull bone.

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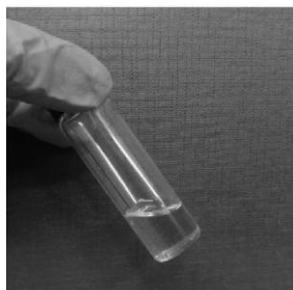
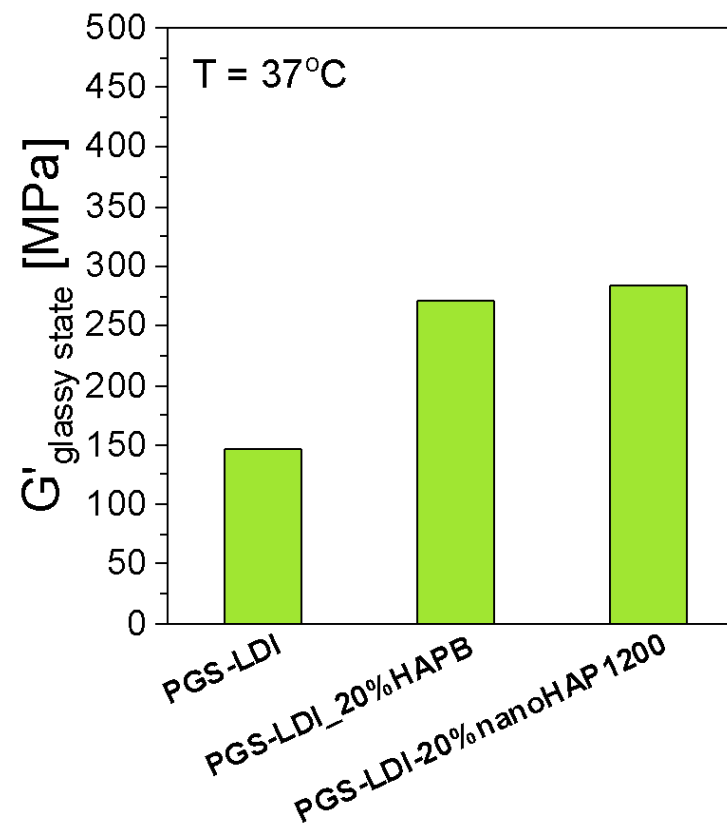
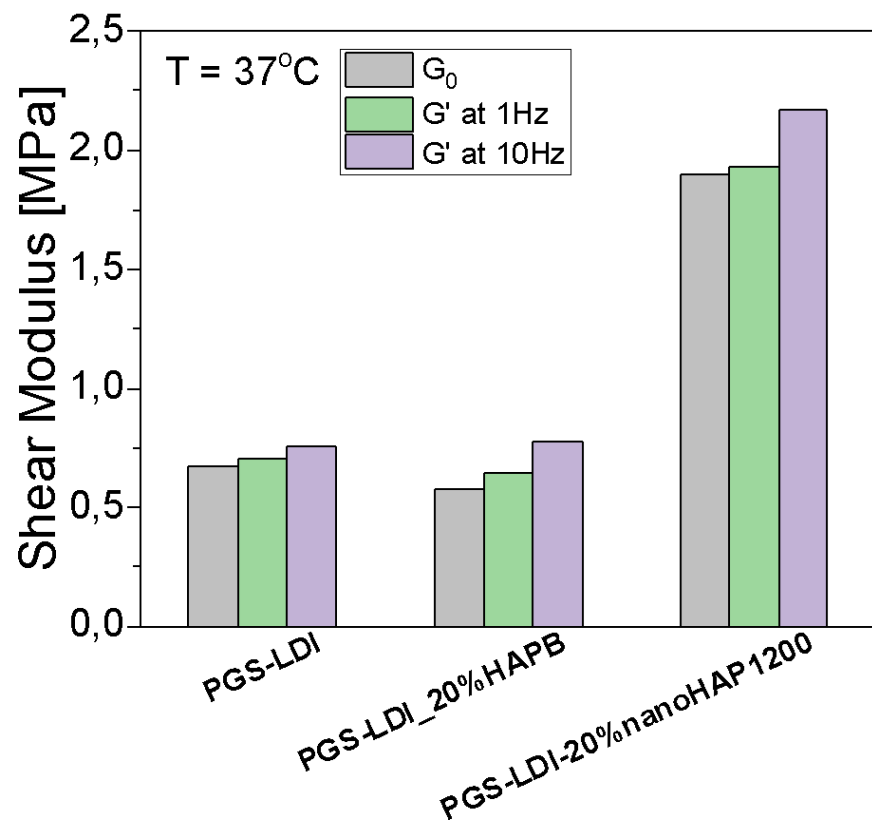
The Product

Elastomeric composite implants – prototype of medical device class III

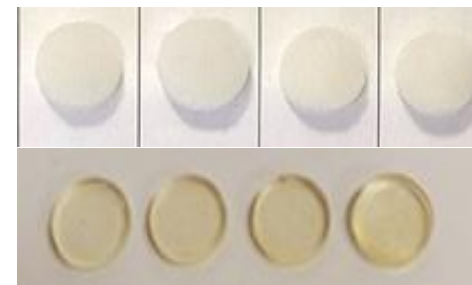


- The biocomposites **can be used to fill small defects of skull bones** (positive *in vivo* tests on a flat skull bone model of rat).
- The biocomposites **protect and accelerate bone tissue regeneration**.
- The elastomeric nature of the matrix ensures **easy adaptation of the material to the shape of the bone defect**.
- They **do not cause mechanical stress** at the implantation site.
- The biocomposites have proven **osteoinductive** properties and are **cytocompatible** at the cellular level *in vitro* and *in vivo* with respect to bone and normative cells, are **proadhesive** for bone cells.
- The biocomposites have proven **proregenerative** activity.
- The biocomposites have the potential to accelerate bone tissue regeneration through the **mechanotransduction effect**.

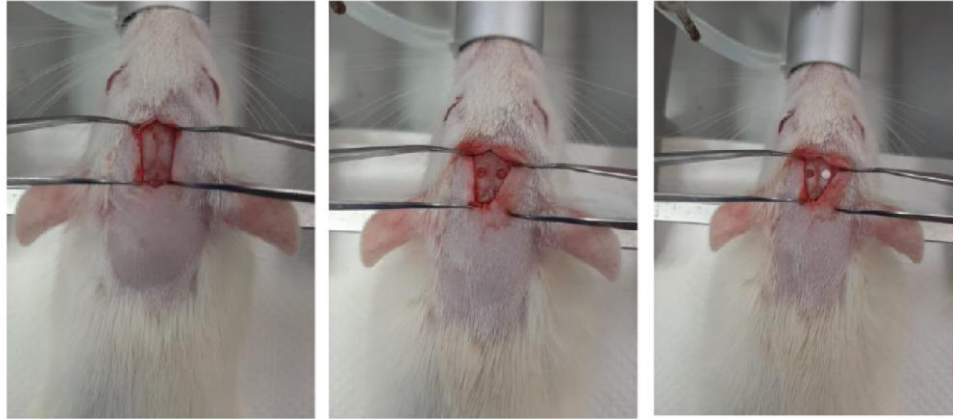
Elastomeric composites – Linear Viscoelastic Properties



crosslinking

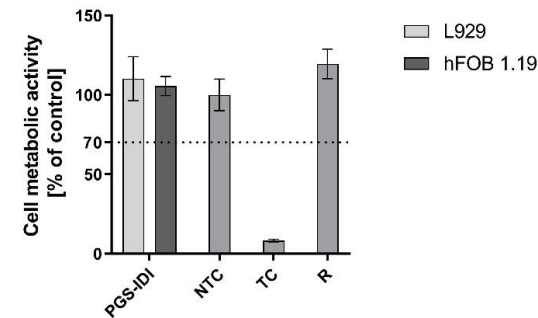


Porous and solid elastomeric bioactive polymer-ceramic composites for bone defect filling and bone tissue regeneration

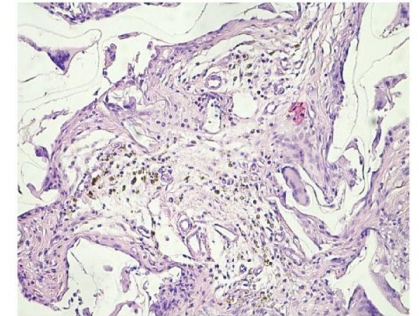


Cranial bone defect model – steps of biocomposite implantation.

a)



b)



The cytocompatibility against L929 fibroblasts and hFOB 1.19 osteoblasts in the MTT reduction assay (a). The typical histological appearance of the implanted material (b). The connective tissue covering the entire composite area, and formed proper vascularization.

INNOVATION / ADVANTAGES

- The **elastomeric nature** of the matrix ensures **easy adaptation of the material to the shape of the bone defect** and **does not cause mechanical stress** at the implantation site.
- The biocomposites have proven **osteoinductive** properties and are **cytocompatible** at the cellular level *in vitro* and *in vivo* with respect to bone and normative cells, are **proadhesive** for bone cells.
- The biocomposites have proven **proregenerative** activity.
- The biocomposites are not rinsed out of the body. Implantation studies have shown that after 60 days no signs of material disintegration and degradation can be seen.
- The composites can be used as a material for filling defects in flat bones.
- The biocomposites have the potential to accelerate bone tissue regeneration through the **mechanotransduction effect**.

Project Team

Key team members:



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Specialists in materials engineering, biomaterials engineering:

Małgorzata Gazińska - Management Committee Member (malgorzata.gazinska@pwr.edu.pl)

Konrad Szustakiewicz – Leader group (konrad.szustakiewicz@pwr.edu.pl)

Piotr Otręba - Intellectual property protection specialist (piotr.otreba@pwr.edu.pl)

Tomasz Marciniszyn - Commercialization specialist (tomasz.marciniszyn@pwr.edu.pl)



Specialists in biology and animal research

Karolina Rudnicka - Management Committee Member (karolina.rudnicka@biol.uni.lodz.pl)

Przemysław Płociński – Leader group (przemyslaw.plocinski@biol.uni.lodz.pl)



Cracow University
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Specialist in materials science

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Specialist in biomaterials engineering & ceramic materials

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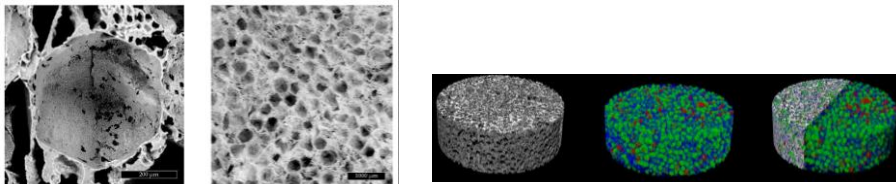
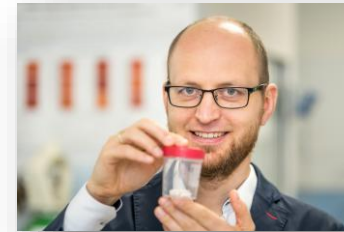


Specialist in molecular chemistry of peptides:

Sylvia Rodziewicz-Motowidło - Management Committee Member (s.rodziewicz-motowidlo@ug.edu.pl)



Project Team from WUST



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Project Status

Status of the project:

- "Multifunctional biologically active composites for applications in regenerative medicine of the skeletal system" OsteoRegNet (POIR.04.04.00-00-1607/18) of the Intelligent Development Operational Program TEAM-NET of the Foundation for Polish Science, funded by the European Union from the European Regional Development Fund, **project budget \$3.8 milion**
- "Multifunctional composite material with antimicrobial and pro-regenerative properties for bone tissue reconstruction" GlassPoPep (TECHMATSTRATEG 2/406384/7/NCBR/2019), financed by the National Centre for Research and Development); **project budget \$1.9 milion**



Keywords

Implants, Biomaterials, Polymer-Ceramic Biocomposites, Bioactive, Biocompatibility, Proregenerative, Osteoconductive, Elastomeric Composites, Bone Tissue Regeneration, Tissue Engineering

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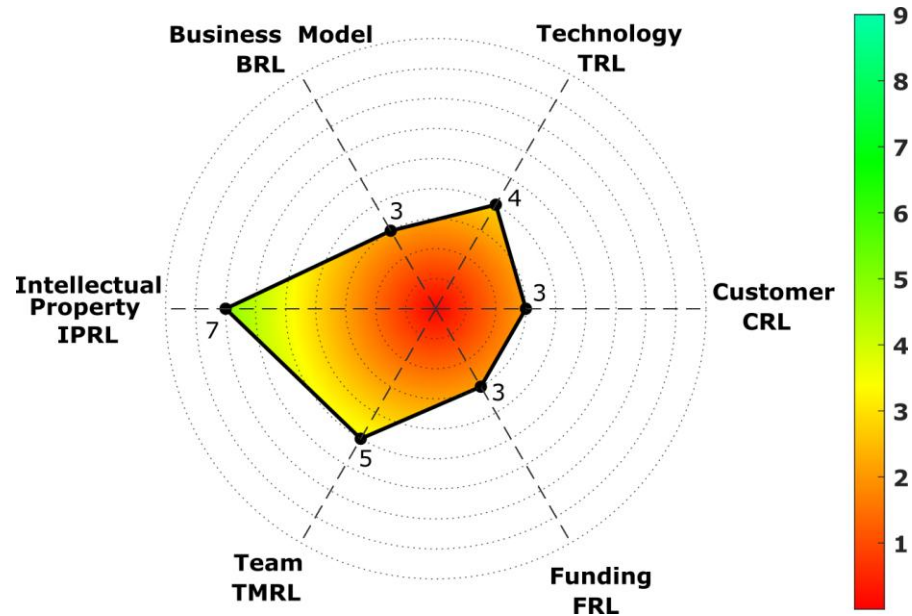


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Technology Readiness and IP Status



❑ **TRL** for medical devices: **4**

Concept of the implant material validated in operational conditions; materials tested *in vivo* on a small animal model with approval from the National Ethical Committee for Animal Experiments.

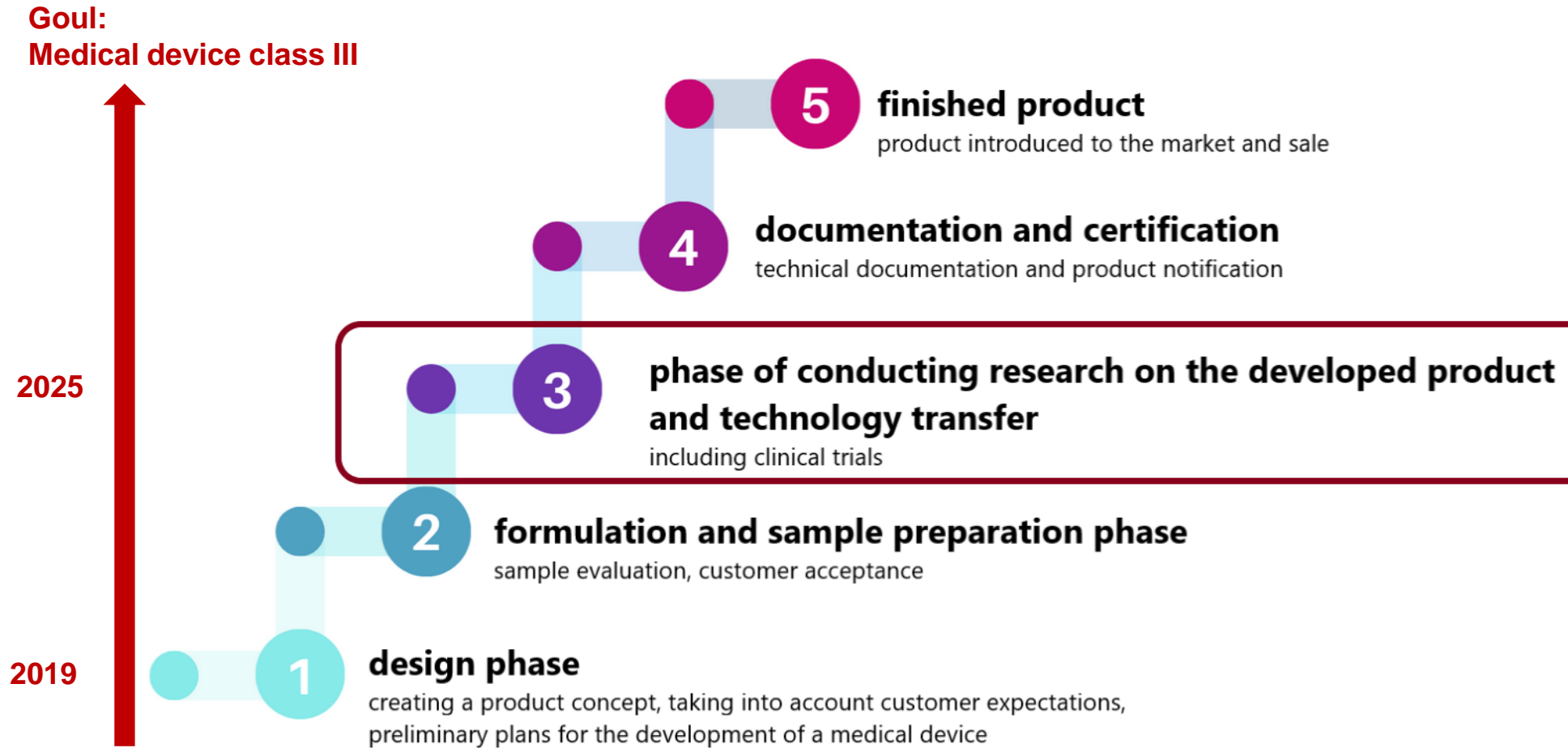
❑ **Three International Patent Applications, protection procedures in progress.**

❑ **Technology offers published** in the database of technological offers of the Technology Transfer Center of the Wrocław University of Science and Technology.



The invention "Porous and solid elastomeric bioactive polymer-ceramic composites for bone defect filling and regeneration" achieved Platinum Medal at the PRIX Eiffel International Invention Competition Paris, 2023.

Future development



The Market Opportunity



Prototype implants (Biocomposites) can be manufactured as **Class III medical devices**.

They are intended for **patients with defects in flat cranial bones related to cranial bone tumours, patients after craniotomy, patients scheduled for cranioplasty procedures, and patients with post-traumatic defects.**

The target market for these products includes **companies producing and marketing implant materials for flat cranial bones**, such as ChM Sp. z o.o., BHH Mikromed, Tricomed SA, and ReOss GmbH.

Desired Audience

Potential Applications and Prospective Buyers:

Biocomposites can be manufactured as **Class III medical devices**. They are intended for **patients with defects in flat cranial bones related to cranial bone tumors, patients after craniotomy, patients scheduled for cranioplasty procedures, and patients with post-traumatic defects**. The target market for these products includes companies producing and marketing implant materials for flat cranial bones, such as ChM Sp. z o.o., BHH Mikromed, Tricomed SA, and ReOss GmbH.

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The Ask

The next stages to commercialization are pre-clinical and clinical trials and certification of the biocomposites as class III medical devices. An investor interested in further joint research or purchasing a license is sought.

We are open for the scientific cooperation! We are interested in cooperation in evaluation of mechanotransduction effect with scientist from SV/US Universities:

Prof. Fan Yang, Department of Bioengineering, Stanford University,

Prof. Ovijit Chaudhuri, Department of Mechanical Engineering, Stanford University

We are interested in joint patent application in the US.

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