

IHI Call Days | Call 12

Interdisciplinary Consortium for Resorbable Metallic Implants (InCReMI)

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Link to the IHI brokerage platform:

- [Proposal sharing tool](#)
- [Participant profile](#)

Group webpage: <https://ingrid.fjfi.cvut.cz/>



Challenges and objectives

Secondary surgeries to remove permanent implants

- Consume the time of surgical teams
- Increase healthcare costs
- Lower patient comfort

Hypersensitivity reactions, Metal-induced allergies

- Nickel hypersensitivity on the rise
- Sometimes suspicious reasons for the Ti implant rejection

e.g., hallux valgus

If conventional implants are replaced by magnesium-based implants, society could save up to 11.9 Mio € (Germany, 2015)

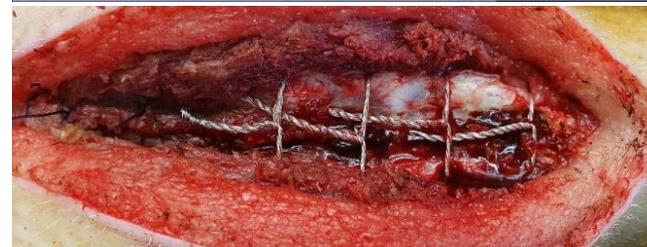
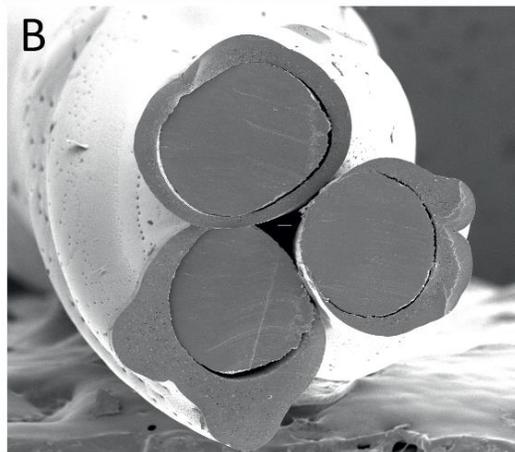
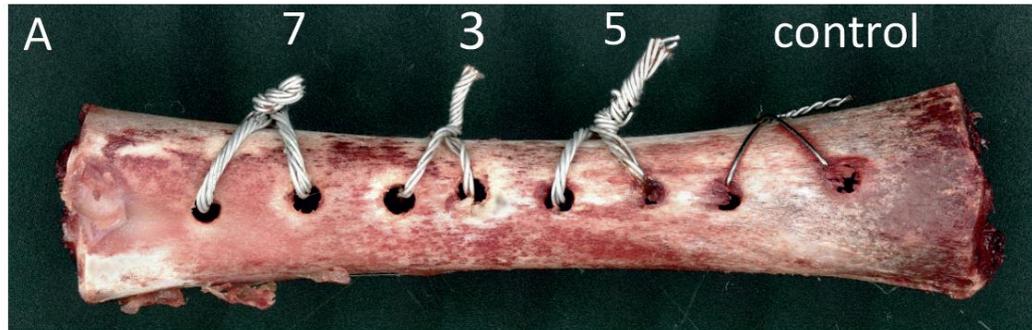
H. Klauser

Internal fixation of three-dimensional distal metatarsal I osteotomies in the treatment of hallux valgus deformities using biodegradable magnesium screws in comparison to titanium screws
<https://doi.org/10.1016/j.fas.2018.02.005>

Challenges and objectives

Mg-based biomedical implants

(e.g.) cerclage strands for hand reconstructive surgery, possibly sternal fixation



Challenges and objectives

Fractured approach to the problem - Topic 2 (SO2)

- Adoption of radically new solutions is **too uncertain** for the industry.
- The pathway to market and CE is **too expensive** for universities.
- Certification of **Class III** medical devices is **too difficult** for researchers and SMEs.



Challenges and objectives



Fractured approach to the problem - Topic 2 (SO2)

- Adoption of radically new solutions is **too uncertain** for the industry.
- The pathway to market and CE is **too expensive** for universities.
- Certification of **Class III** medical devices is **too difficult** for researchers and SMEs.
- We need mathematicians, physicists, metallurgists, biologists, medical experts, surgeons, regulatory experts, market analysts, representatives from notified bodies, investors, ... to work together for the development of resorbable implants.
- We need to find out how to cooperate and valorize knowledge **effectively**.

Our approach to solve the problem

Pre-competitive joint development

Stage 1 (Years 1-2)

- Identify Mg implant (Class III) that would greatly benefit a group of patients **AND** is difficult to commercialize effectively (not worth it revenue-wise).
- Manufacture the **pilot implant prototype** and distribute to all partners.
- Start EU-wide parallel development and discussions.
- Formulate **regulatory strategy** and identify obstacles for market adoption.

Our approach to solve the problem

Pre-competitive joint development

Stage 2 (Year 3-4)

- Jointly adapt Stage 1 solutions to a Stage 2 **superior implant prototype**.
- Obtain a fixed design, manufacturing route, and regulatory strategy.
- Perform all the needed in vitro and in vivo tests.

Stage 3 (Year 5)

- First-in-human trials on the Stage 2 prototype.
- **Consortium members start their follow-up competitive efforts.**

Is our project suitable for IHI?

We need private-public partnership

- Universities don't have the capital and experience to push to market.
- Industry can't afford to dig deep for groundbreaking solutions.

We need different industry sectors

- Medical device manufacturers ensure **supply chains** and **large-scale production**.
- AI and digital pathology companies enable advanced **in vitro** and **in vivo** analysis.
- **SMEs** in modeling, data, and cybersecurity secure optimization and data handling.
- Regulatory bodies and consultants steer **compliance and certification**.

Outcomes and Impact

- Universities and SMEs gain experience in the **development of Class III** devices.
- Networks between the **private and public sectors** are established.
- Networks between **different industry sectors** are established.
- Specific feedback is given to the regulatory bodies.

- A much-needed implant **that would not be pursued by the industry otherwise** is prepared for **first-in-human trials**.

Expertise and resources

- Czech Technical University in Prague (CTU), Czechia
- Centre National de la Recherche Scientifique (CNRS), France
- Norwegian University of Science and Technology (NTNU), Norway
- Institute of Physics of the Czech Academy of Sciences (FZU), Czechia
- University of Lille – UMET (UMET), France
- Charles University (CUNI), Czech Republic
- Institute of Materials and Machine Mechanics (UUMS), Slovak Republic
- MEDIN, a.s. (MEDIN) [**industrial partner – large enterprise**], Czech Republic

- We need: **industrial partners** and **SMEs**, **clinical institutions**, **notified bodies** and **regulatory consultants**, **investors**, **lawmakers** and **policy makers**, ...

Thank you for your attention

I will be around and happy to discuss

