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“Enabling Design and Manufacturing Technologies for Open Source Medical Devices”

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General index

1. Open science and open innovation
2. Open-source medical devices
3. Enabling design & manufacturing technologies
4. Prototyping and production
5. Shared dream

1.- Open science and open innovation

According to EU Commision's definition:

Open innovation:

"The basic premise of OI is to open-up the innovation process to all active players so that knowledge can circulate more freely and be transformed into products and services that create new markets, fostering a stronger culture of entrepreneurship.

A specific innovation can no longer be seen as the result of predefined and isolated innovation activities but rather as the outcome of a complex co-creation process involving knowledge flows across the entire economic and social environment."

1.- Open science and open innovation

According to EU Commision's definition:

Open science:

"New approach to the scientific process based on cooperative work and new ways of diffusing knowledge by using digital technologies and new tools. Spread knowledge through open access / open source.

Open science has the potential to strengthen and enhance science by facilitating more transparency, openness, networking and collaboration, and by fostering interdisciplinary research.

Open science, however, does not mean 'free science'."

2.- Open-source medical devices

Open-source medical devices: concept and potentials for transforming healthcare

"An open-source medical device is a medical device whose design and product development information are made publicly available so that anyone can study, modify, distribute, make, and sell the medical devices, and their related software or hardware, based on the initial available design and information. The design of the open-source medical device should be shared in a format conceived for enabling validation, verification and modification. Open-source medical devices rely on widely available materials and components, benefit from being designed according to international safety standards and processes aimed at guaranteeing patients' safety, take advantage of modularity, even being designed as inter-changeable and inter-operable kits, and rely on open e-infrastructures for information dissemination and promotion of collaboration.

FAIR (findable, accessible, interoperable, reusable) data principles are proposed for open-source medical devices. Persons or companies producing and commercializing open-source medical devices are obliged to attribute to the original designers and to make clear that such medical devices are not manufactured, sold, warranted, or otherwise sanctioned by the original designer".

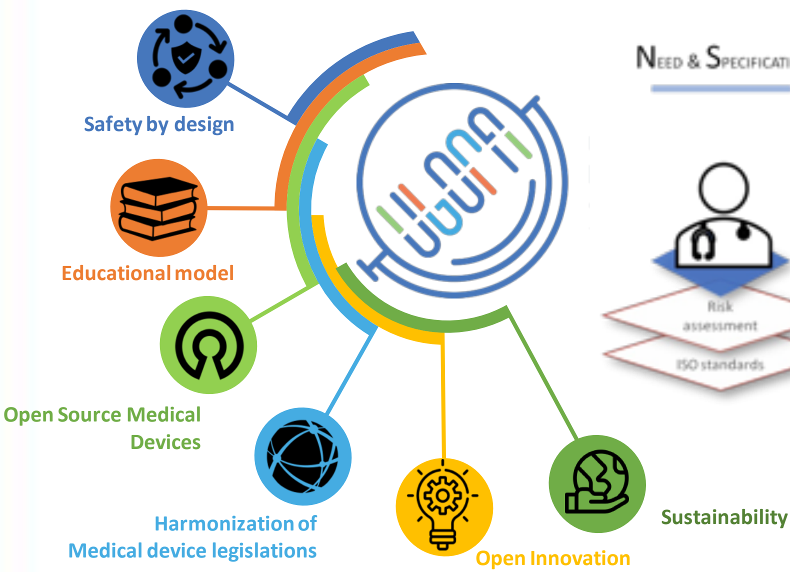
Source: Carmelo De Maria, Licia Di Pietro, Alice Ravizza, Andres Diaz Lantada, Arti Devi Ahluwalia, Open-source medical devices: Healthcare solutions for low-, middle-, and high-resource settings, Editor(s): Ernesto Iadanza, Clinical Engineering Handbook (Second Edition), Academic Press, 2020.

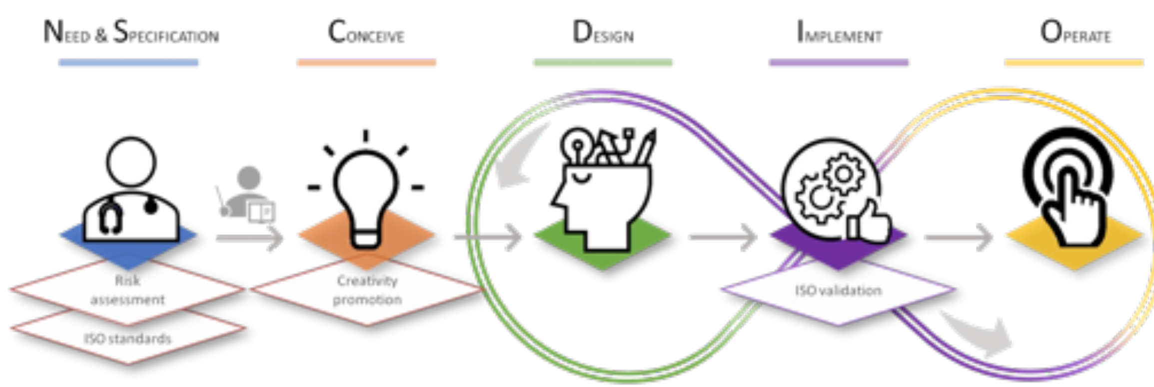
2.- Open-source medical devices

Key enabling technologies for co-creating open-source medical devices:

UBORA → Much more than a medical device "Wikipedia"

- **UBORA platform supports medical devices' developers to design and share their innovative medical technologies.**
- **Promotes systematic engineering design methodologies for safe medical devices.**
- **The infrastructure guides and helps with the medical device classification.**
- **The infrastructure guides and helps with the selection and application of standards.**
- **From specification to fund raising for impactful technologies.**
- **Working from a medical need towards validated prototypes.**





https://platform.ubora-biomedical.org/

2.- Open-source medical devices

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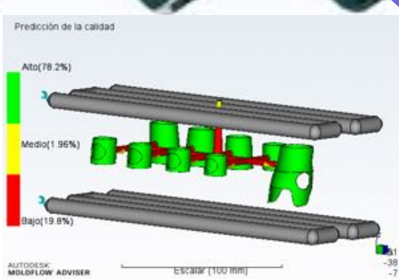
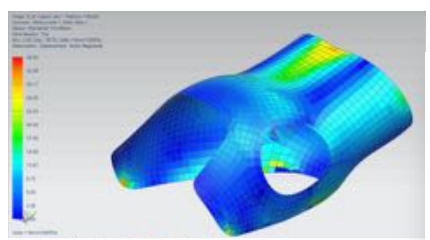
Key enabling technologies for co-creating open-source medical devices:

UBORA → Example: modular multi-finger splint



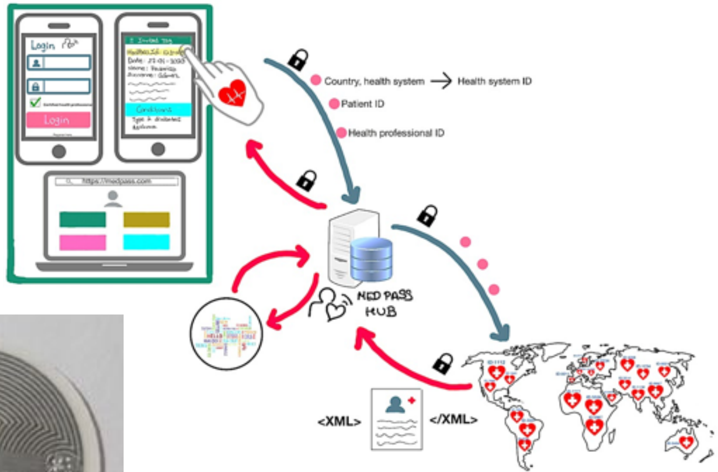


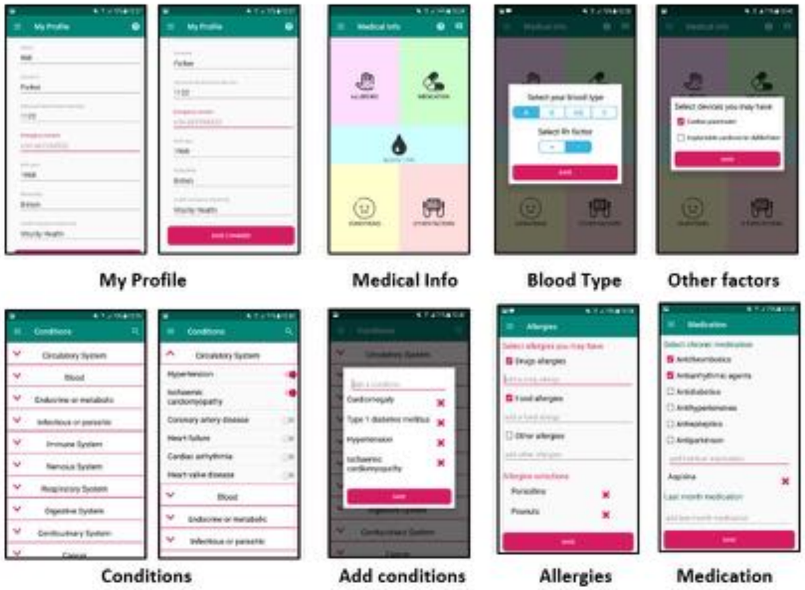
Designs: A. Holcomb, C. Dongmo, G. Abate, G. Marongiu, V. Palomino. Mentors: A. Díaz Lantada, A. Lapomarda

2.- Open-source medical devices

Key enabling technologies for co-creating open-source medical devices:

UBORA → Example: open-source medical passport






SoftwareX

Contents lists available at ScienceDirect

SoftwareX

Original software publication

An open source medical passport based on an Android mobile application and near-field communication

Andrea Quero Martín, Andrés Díaz Lantada

ARTICLE INFO

ABSTRACT

Designs and prototypes: A. Quero, A. Díaz Lantada

3.- Enabling design and manufacturing technologies

Key enabling design and manufacturing technologies for OSMDs:

Design resources including:

- ✓ Open-source (or affordable) hardware for obtaining medical images
- ✓ Open-source software for manipulating medical images
- ✓ Open-source computer-aided design resources
- ✓ Open-source simulation tools
- ✓ Open-source computer-aided manufacturing tolos
- ✓ Open-source archives and repositories (incl. UBORA)

Prototyping and manufacturing resources such as:

- ✓ Different rapid prototyping and rapid tooling technologies
- ✓ Open-source rapid prototyping electronics
- ✓ Open-source additive manufacturing tools (3D printers)
- ✓ Affordable 3D printers and recycling systems for fillament
- ✓ Affordable production technologies for massive impact

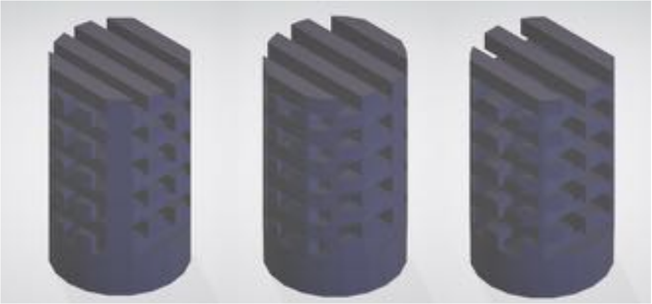
- ✓ Check chapter’s tables for the list of resources
- ✓ Understand differences between prototypes and products

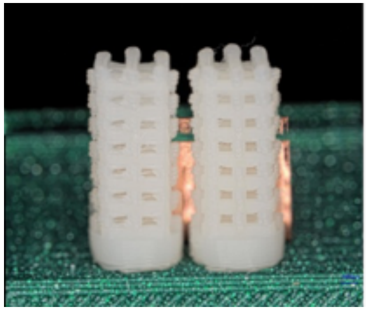
3.- Enabling design and manufacturing technologies

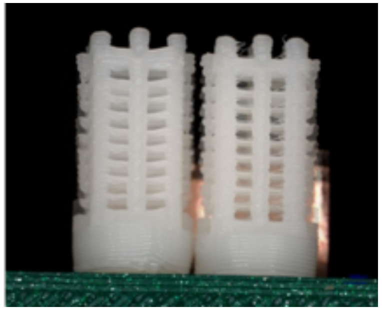
Case study I: Open-source software for biomaterials research

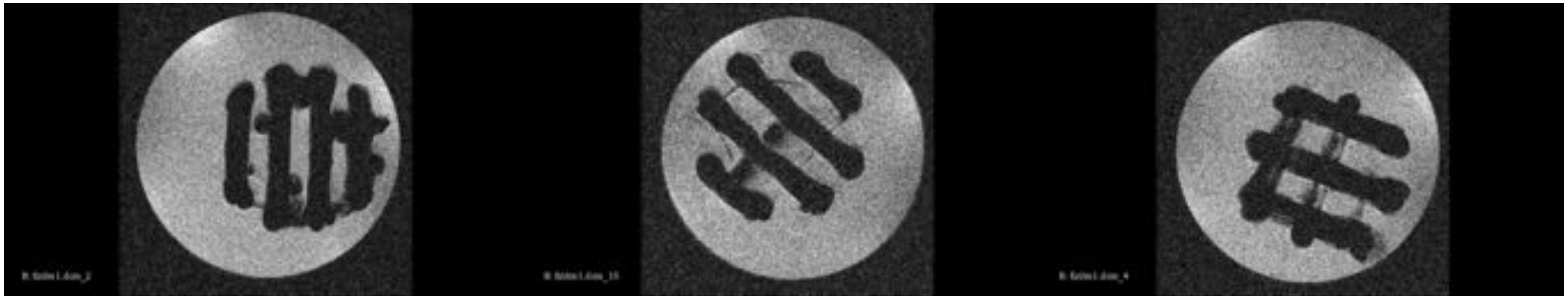
Reconstruction of tissue engineering scaffolds

- ✓ **Micromagnetic resonance imaging (acknowledgment: IMT-KIT, Prof. Korvink)**









3.- Enabling design and manufacturing technologies

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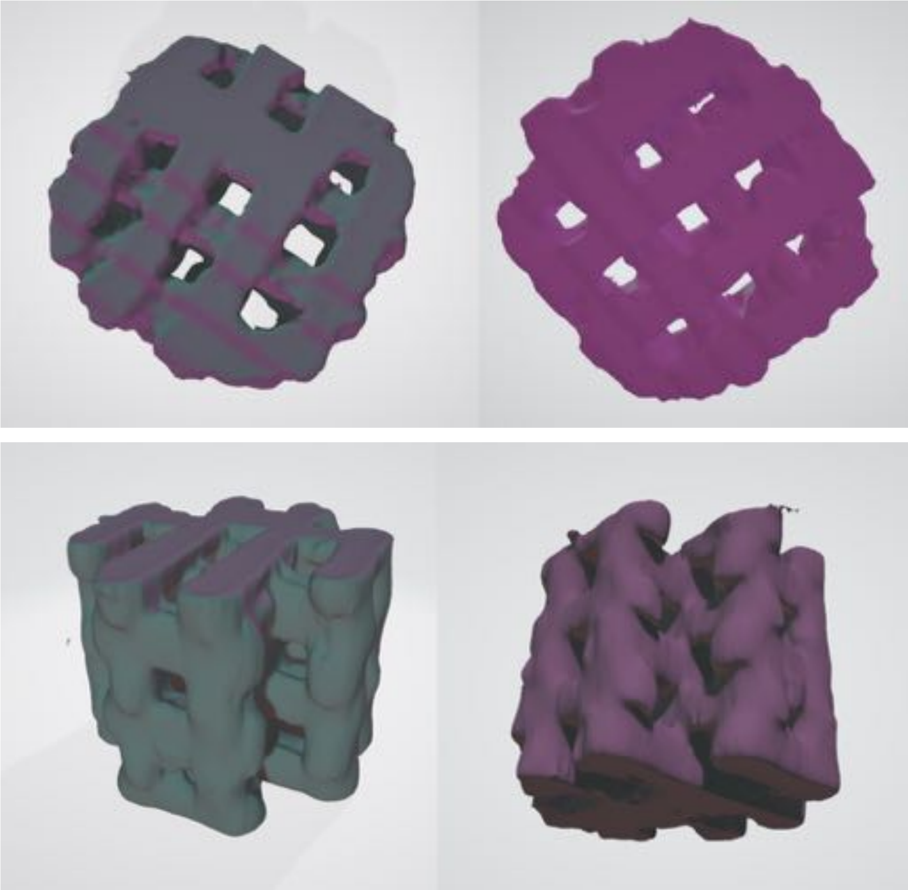
Case study I: Open-source software for biomaterials research
Reconstruction of tissue engineering scaffolds

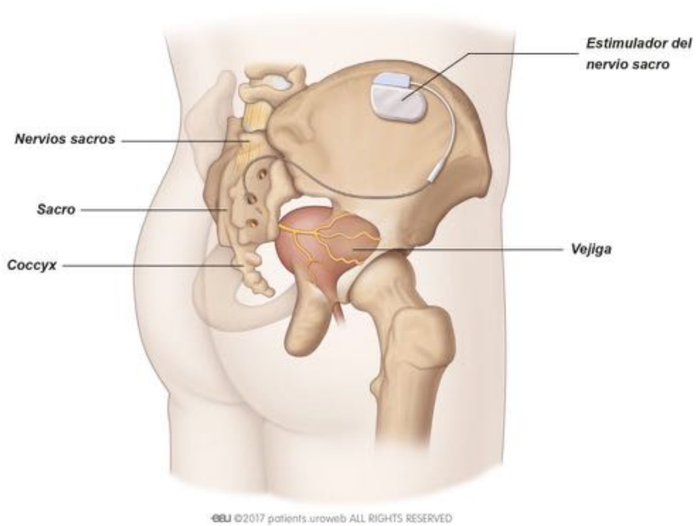
- ✓ 3D reconstruction for quality inspection purposes
- ✓ Slicer 3D



3.- Enabling design and manufacturing technologies

Case study II: Open-access software and rapid prototyping for surgical planning
Personalized model for sacrum agenesis

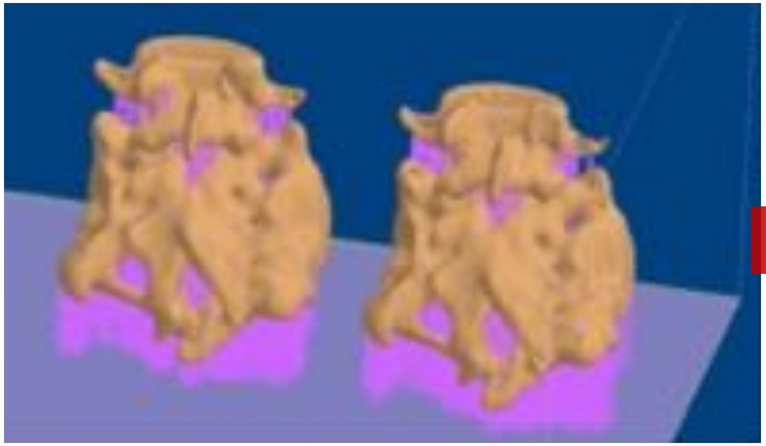
- ✓ Rare congenital defect
- ✓ Abnormal development of spine
- ✓ Treated by electrostimulation
- ✓ Challenging surgery

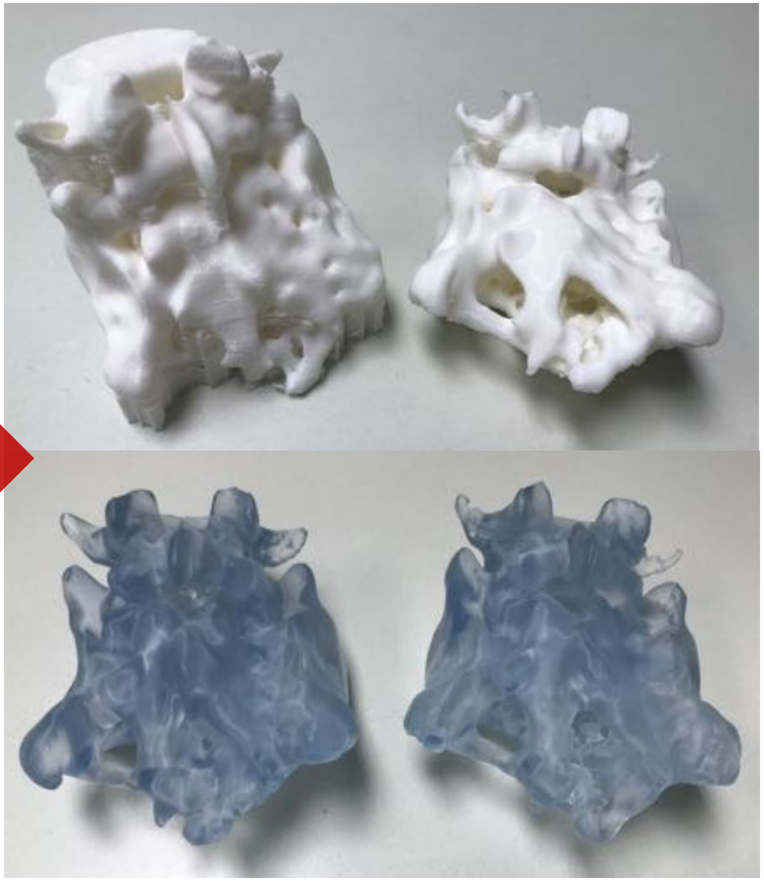


3.- Enabling design and manufacturing technologies

Case study II: Open-access software and rapid prototyping for surgical planning
Personalized model for sacrum agenesis

- ✓ Rapid prototypes obtained using open-access software tools
- ✓ Support to surgical planning





3.- Enabling design and manufacturing technologies

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Case study II: Open-access software and rapid prototyping for surgical planning

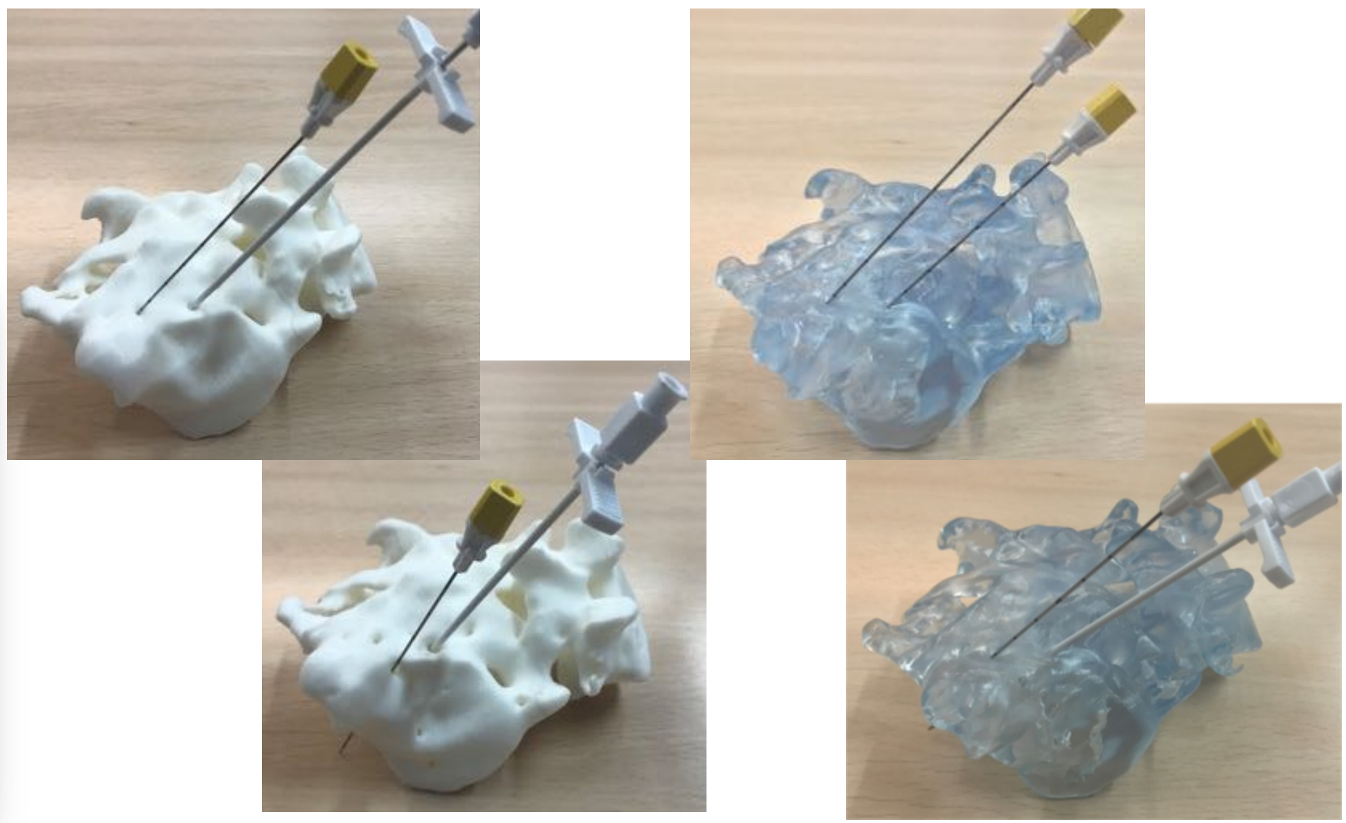
Personalized model for sacrum agenesis

- ✓ Rapid prototypes obtained using open-access software tools
- ✓ Support to surgical planning


polymers
MDPI

Article

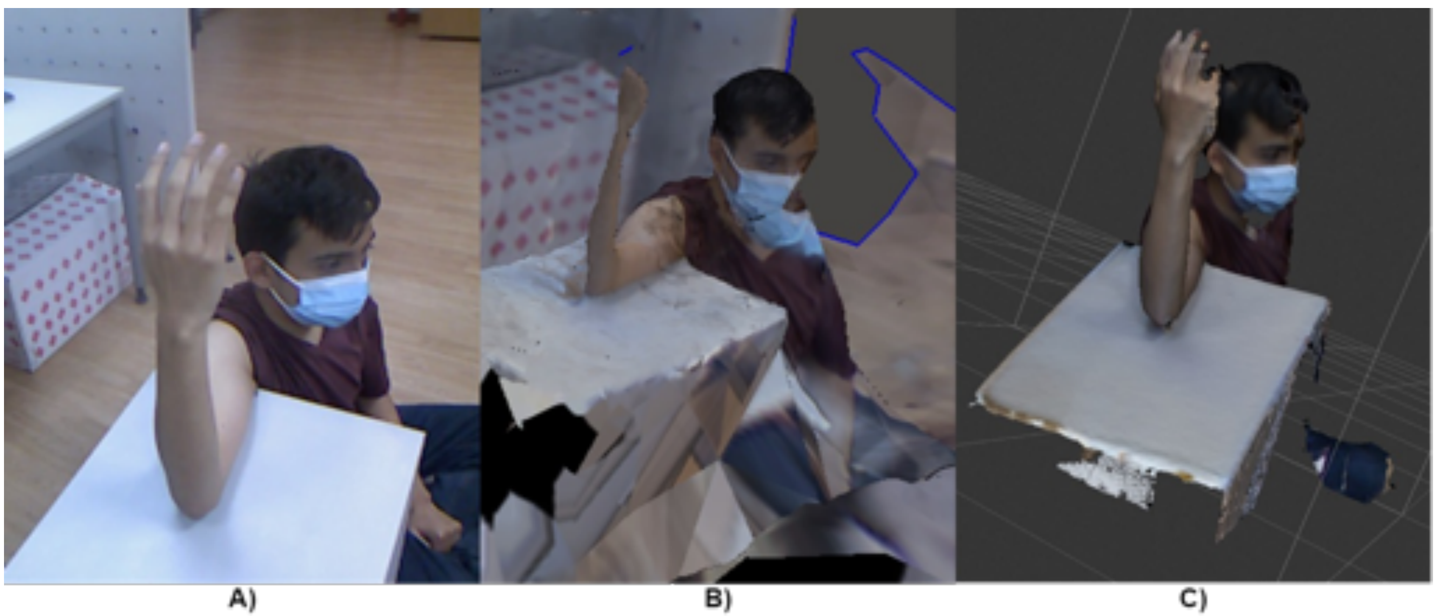
Surgical Planning of Sacral Nerve Stimulation Procedure in Presence of Sacral Anomalies by Using Personalized Polymeric Prototypes Obtained with Additive Manufacturing Techniques



3.- Enabling design and manufacturing technologies

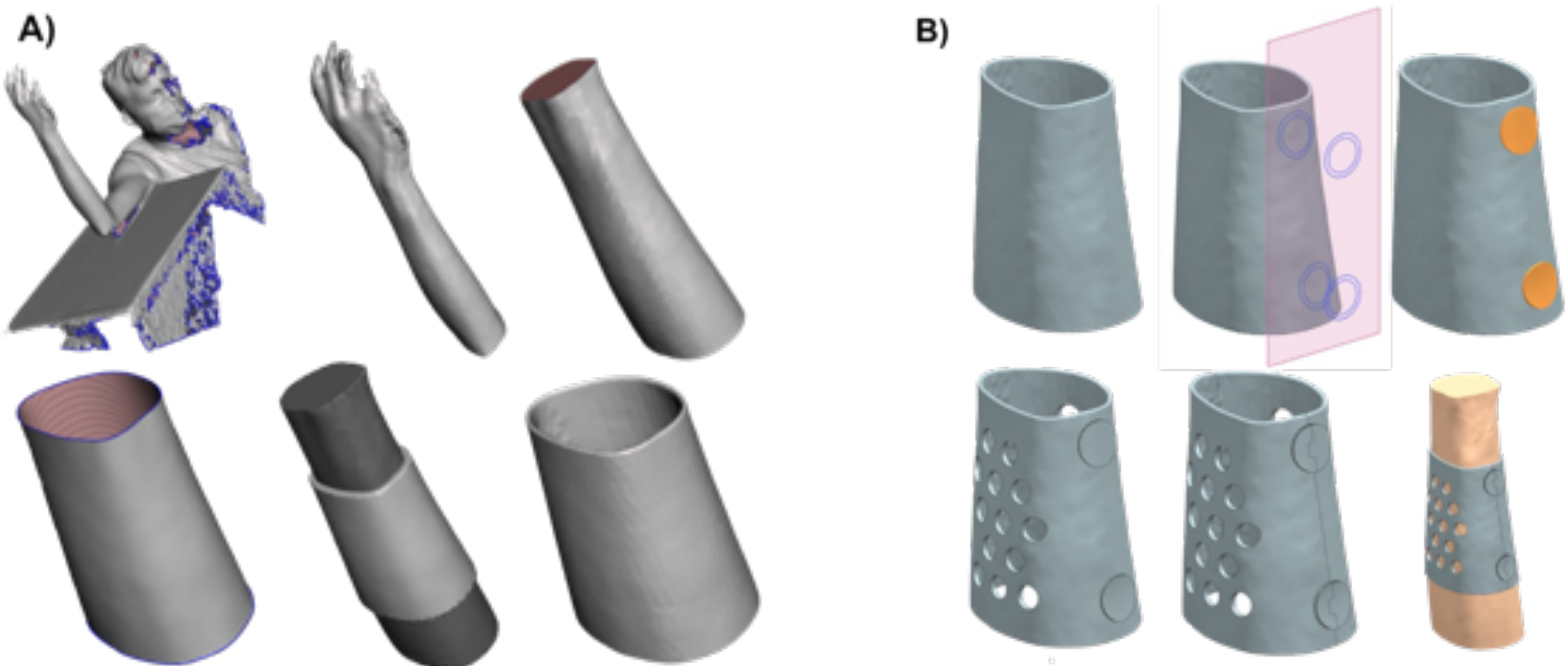
Case study III: Open-source hardware for design personalization
Personalized articular splints

- ✓ MS Kinect open-source hardware or normal smartphone camera
- ✓ Optical scanning (C) and photogrametry (B)
- ✓ MS Kinect Skanect 3D (C) and Meshroom (B)



3.- Enabling design and manufacturing technologies

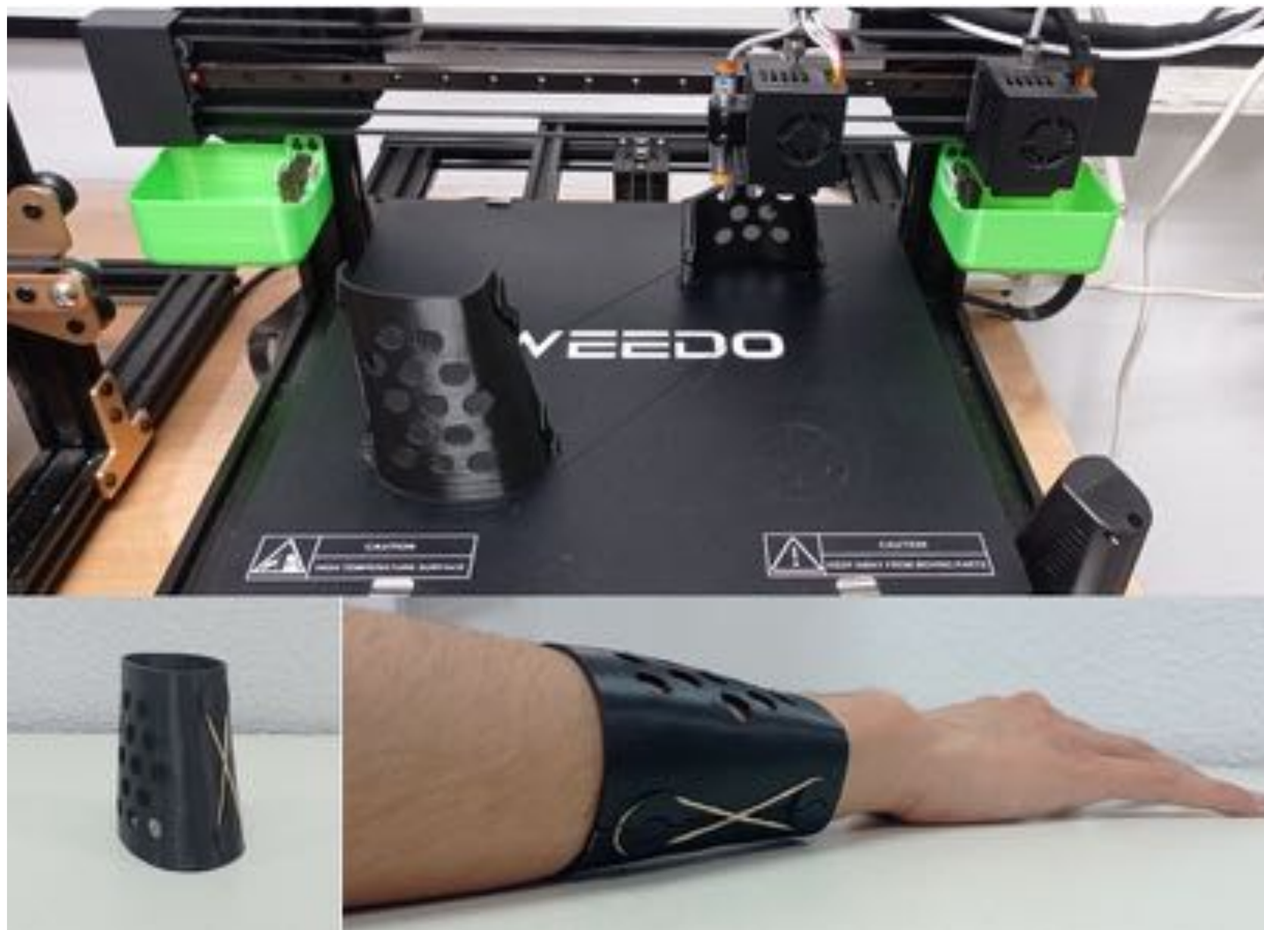
Case study III: Open-source hardware for design personalization
Personalized articular splints



3.- Enabling design and manufacturing technologies

Case study III: Open-source hardware for design personalization
Personalized articular splints

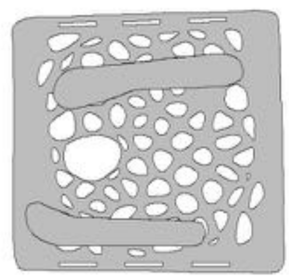
- ✓ **Rapid prototypes**
- ✓ **Personalized**
- ✓ **Ergonomic**
- ✓ **Safe materials**
- ✓ **PoC fabrication**



3.- Enabling design and manufacturing technologies

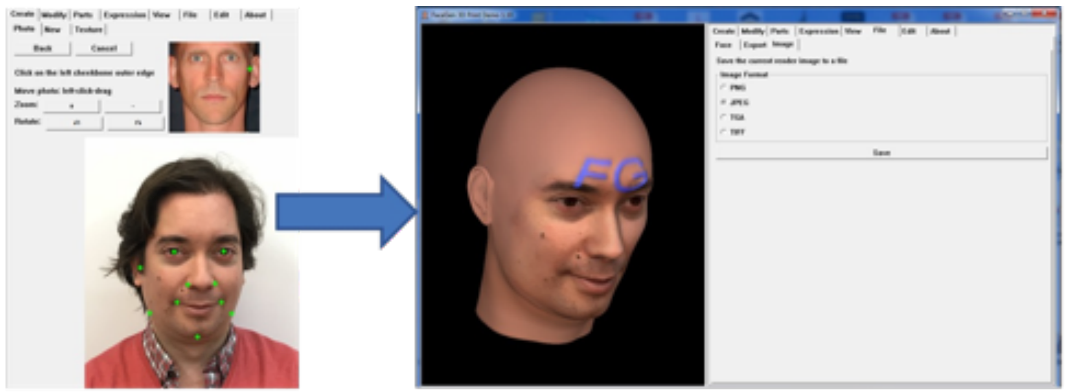
Case study III: Open-source hardware for design personalization
Personalized articular splints

- ✓ 4D printed alternative
- ✓ Increased productivity
- ✓ Personalized fit
- ✓ Enhanced ergonomics
- ✓ Minimal post-processes

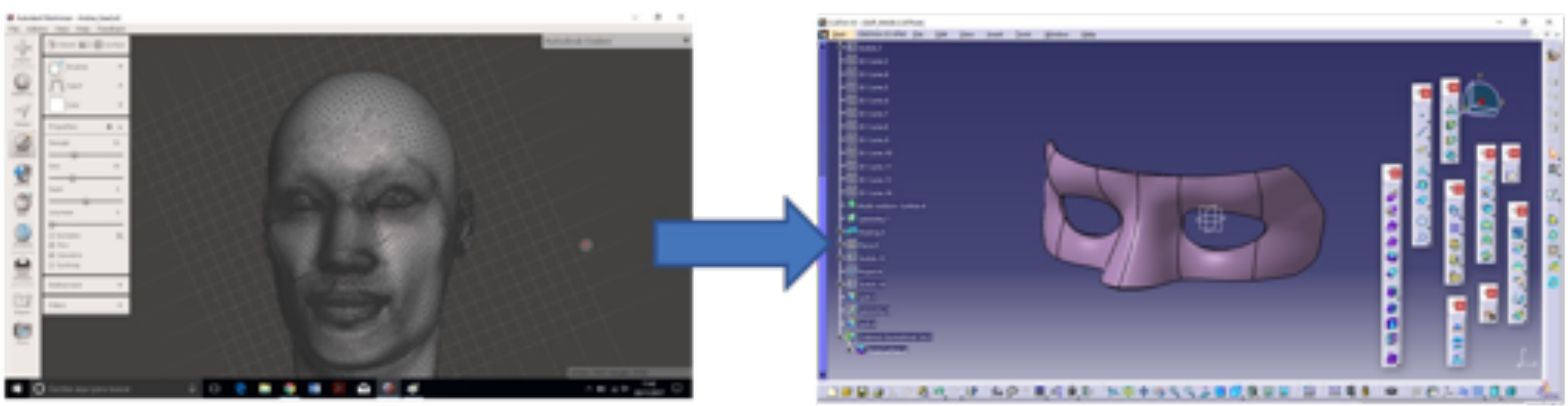


3.- Enabling design and manufacturing technologies

Case study IV: Open-source photogrametry for personalized devices
Face protecting splints for safe sport practice



(FaceGen & Catia / NX)



Meshmixer for correcting the mesh of stl files and further surface & solid based design tools

3.- Enabling design and manufacturing technologies

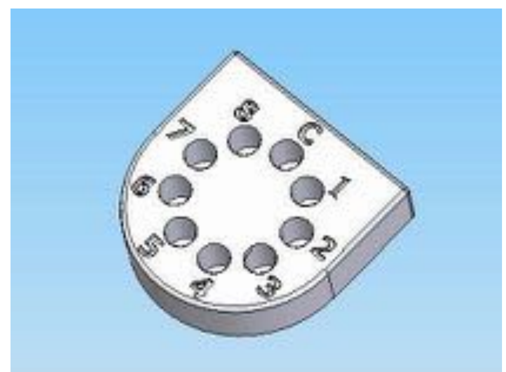
Case study IV: Open-source photogrametry for personalized devices
Face protecting splints for safe sport practice

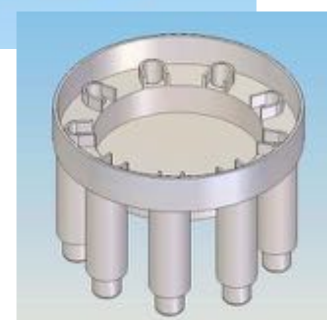
4.- Prototyping and production

Case study V: Injection molding for massive production of medical devices
Point-of-care testing system for urinary infection

Source: Wikimedia Commons, @Itsmemartin & @BiotechMichael.

Common problems: Resistance to antibiotics and difficult access to laboratories.
Need: Rapid antibiogram in the point of care.



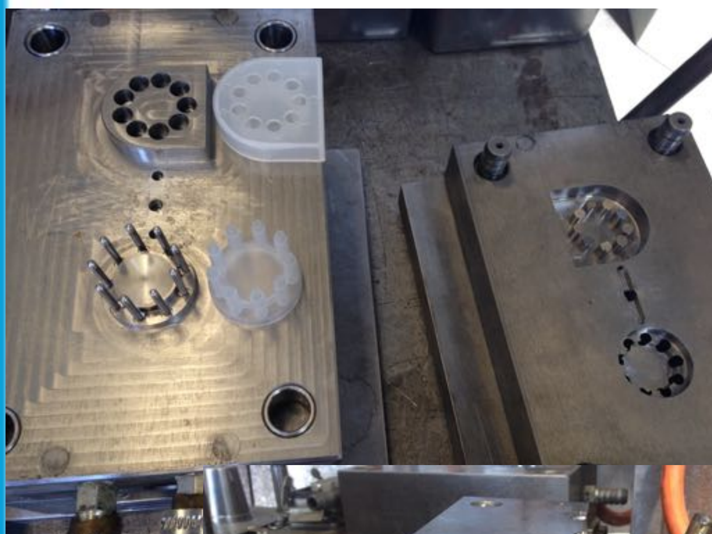


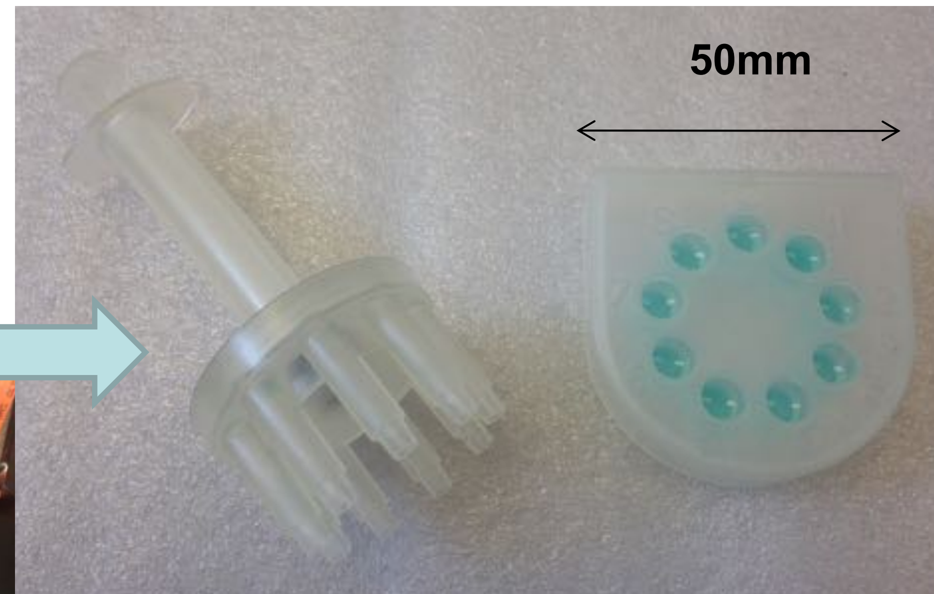
From ELISA 96-well plate to self-contained autonomous device

Acknowledgements: Diagnochip project, supported by CORFO, Government of Chile.
Design and protoytpes: UPM. Molds: Matriceria FERH. Microbiology tests: La Paz & La Ribera university hospitals.

4.- Prototyping and production

Case study V: Injection molding for massive production of medical devices
Point-of-care testing system for urinary infection





4.- Prototyping and production

Case study V: Injection molding for massive production of medical devices
Point-of-care testing system for urinary infection

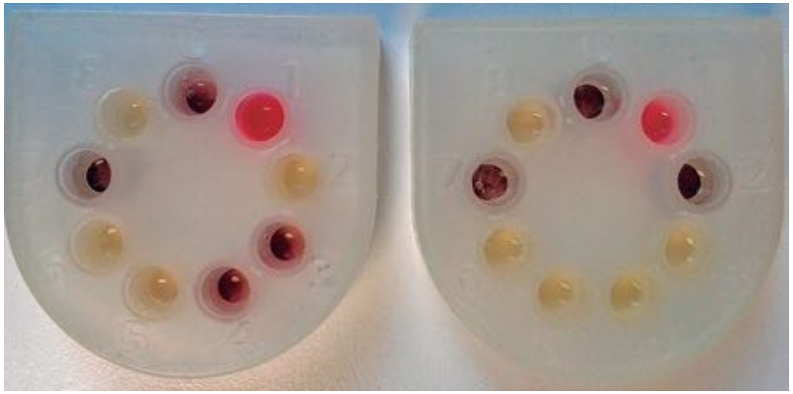
Laboratorio e Infectología

Validación de un dispositivo *point-of-care* para la detección rápida de infección urinaria y susceptibilidad antimicrobiana

Validation of point-of-care device for rapid detection of urinary tract infection and antibiotic susceptibility

Resumen

Abstract



Main conclusions: Shared dreams

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UBORA and the UBORA Community
Shared dreams summarized in the Kahawa Declaration

A look at a better future:

→UBORA as new collaborative model

→Towards a *"bottom-up"* medical industry

→Worldwide cooperation

→Biomedical engineering education for all

→Open and personalized solutions for free

→Accessible designs and prototypes

→Always open to suggestions and proposals

Some current challenges:

→Sustainable growth of UBORA

→Regulations and OSMDs

→Data management

→Privacy and traceability

→Security in e-infrastructures

→Ethics in co-creation

→Research capacity building

UBORA: Much more than a "Wikipedia" of medical devices

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http://ubora-biomedical.org/kahawa-declaration/

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THANKS FOR YOUR ATTENTION

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UBORA: Euro-African Open Biomedical Engineering e-Platform for Innovation through Education