

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

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GNB School 2022, Brixen-Bressanone

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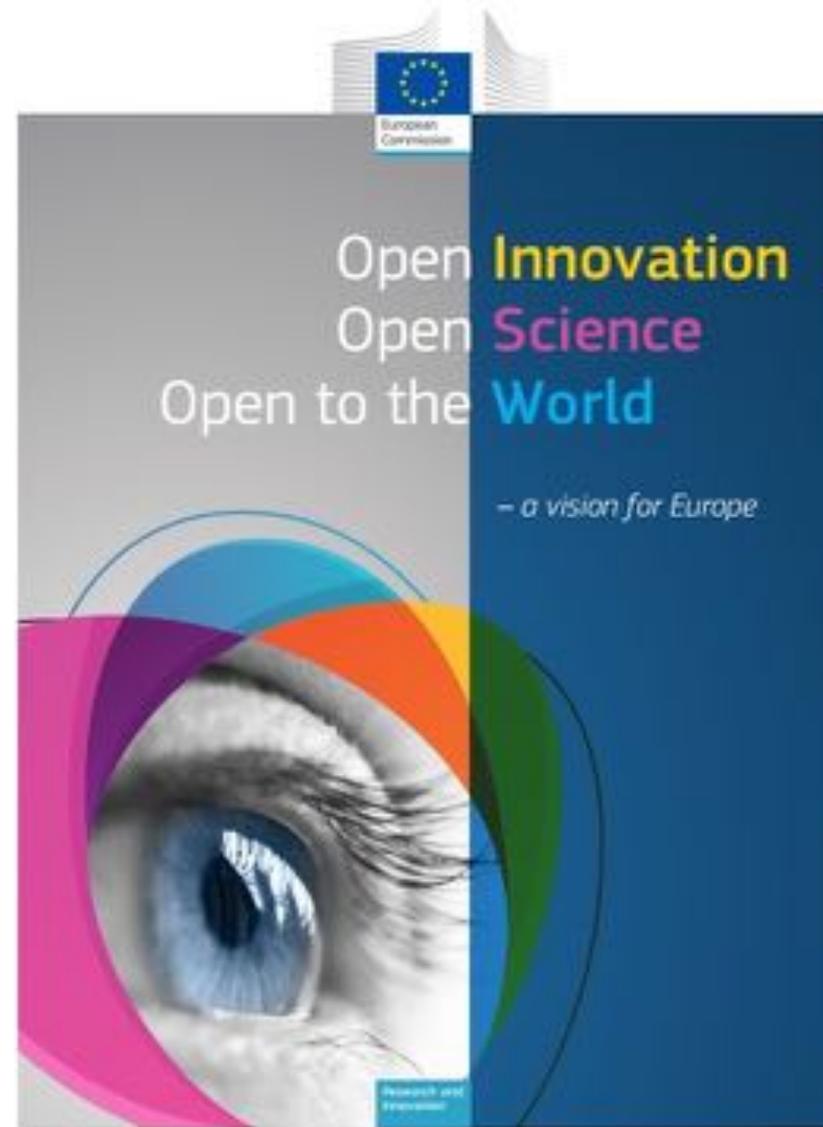
1.- Open science and open innovation

According to EU Commission'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

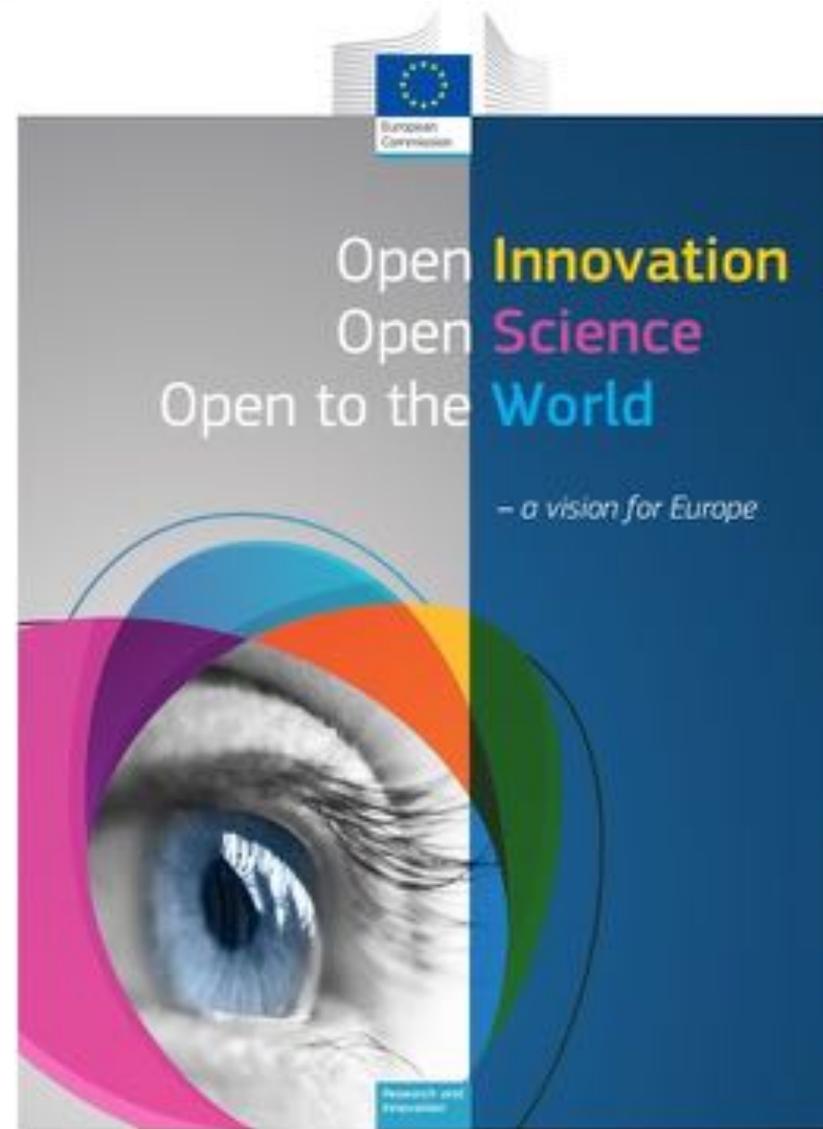
According to EU Commission's definition:

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”.

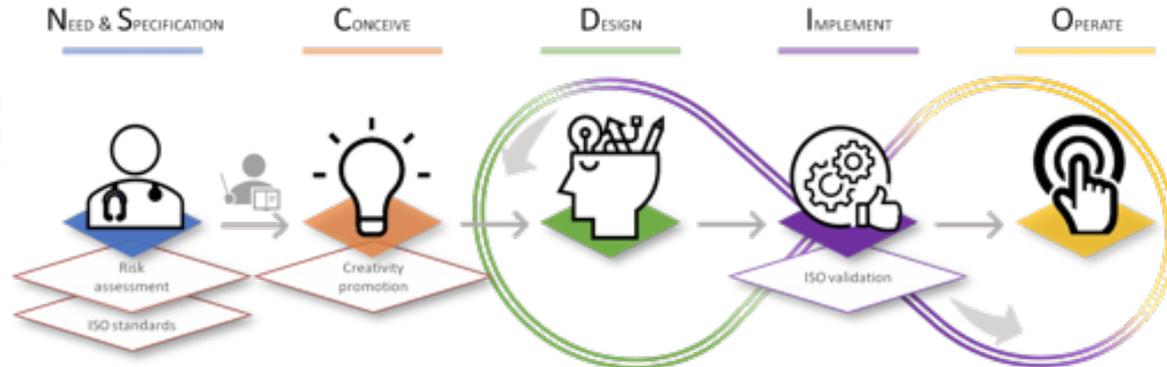
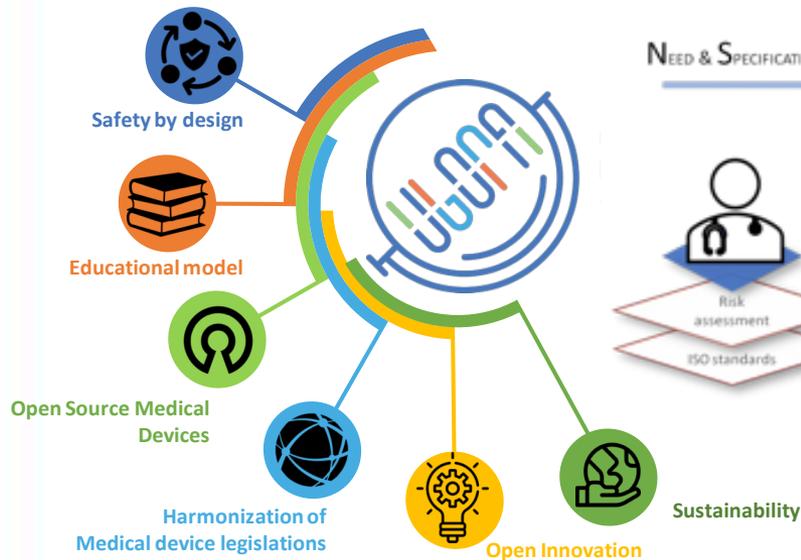
Source: Carmelo De Maria, Licia Di Pietro, Alice Ravizza, Andres Diaz Lantada, Arti Devi Ahluwalia, Open-source medical devices: Healthcare solutions for low-, middle-, and high-resource settings, Editor(s): Ernesto Iadanza, Clinical Engineering Handbook (Second Edition), Academic Press, 2020.

2.- Open-source medical devices

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

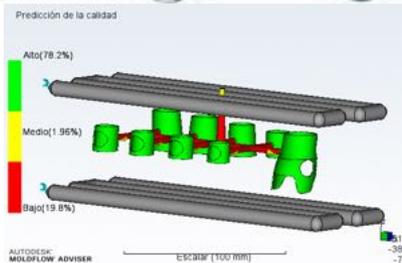
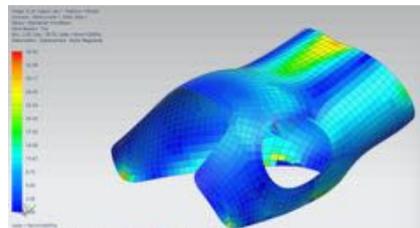
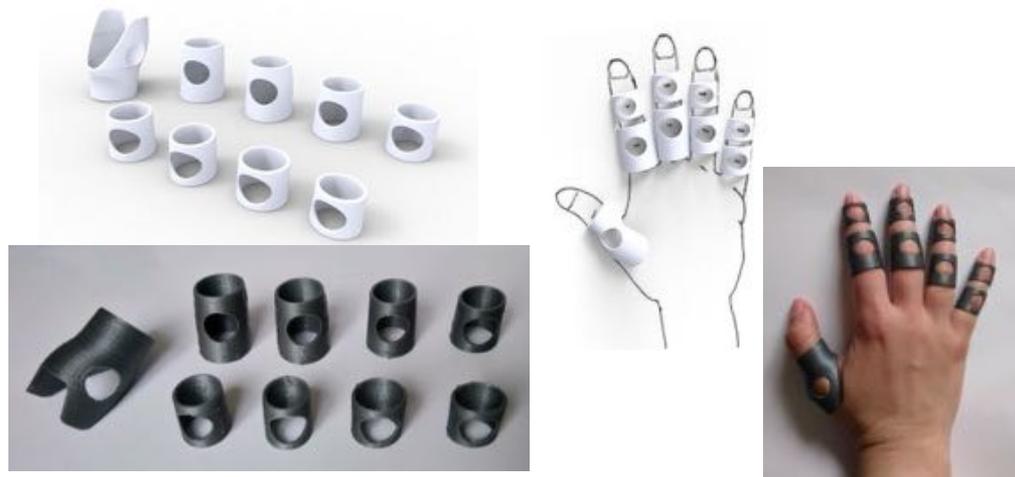
UBORA → Much more than a medical device “Wikipedia”

- 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.



2.- Open-source medical devices

Key enabling technologies for co-creating open-source medical devices:
UBORA → Example: modular multi-finger splint




OrthoKit
Modular Multi-Finger Splint Kit
Customizable treatment for finger fractures and sprains

USE BY
2028-09-07

GTIN 11111111
LOT RNR3LHYS

Keep away from sunlight

Keep dry

Non-sterile

OrthoKit
UBORA Design School
2018

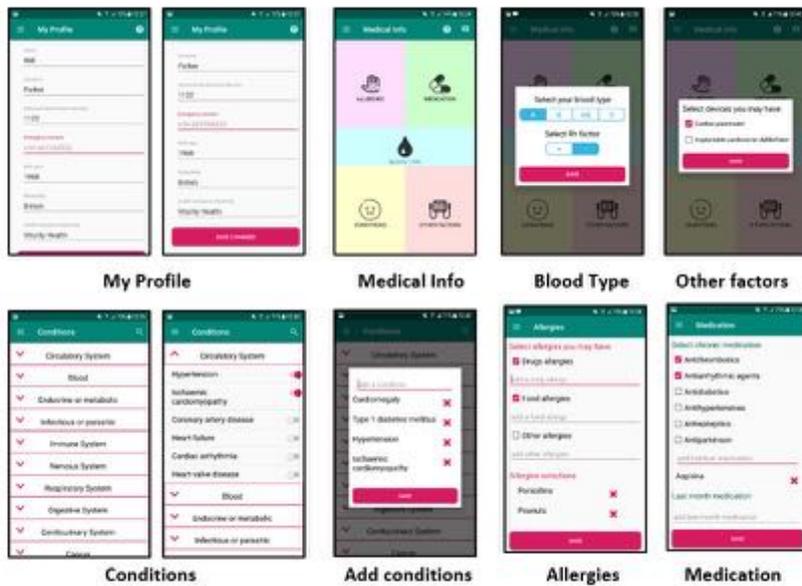
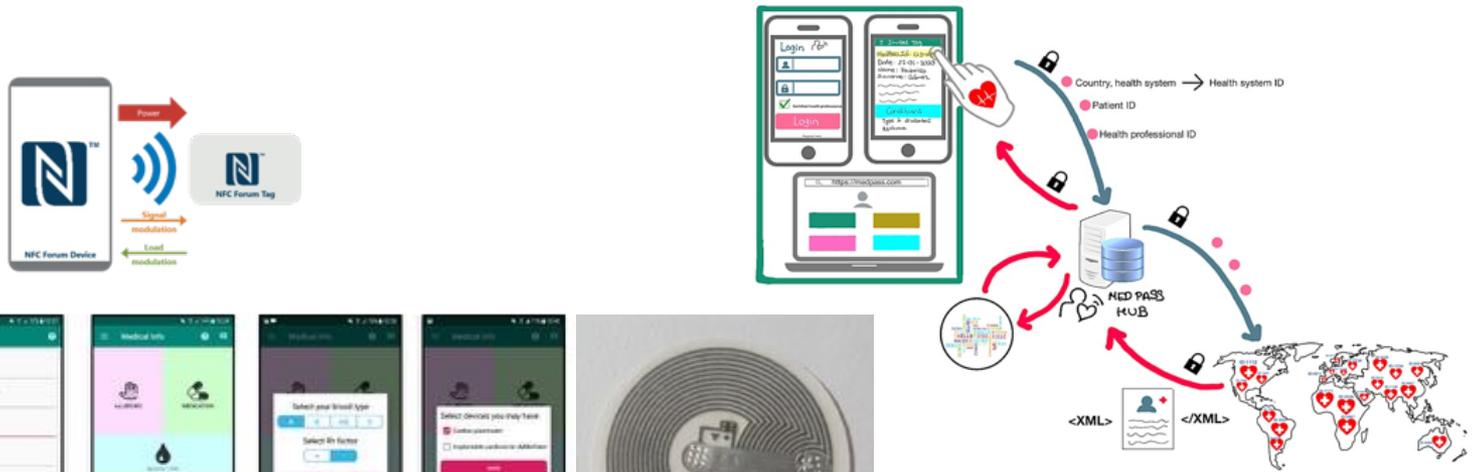
EC REP
info@ubora-biomedical.org



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



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



3.- Enabling design and manufacturing technologies

INDUSTRIALES
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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 tools
- ✓ 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 filament
- ✓ Affordable production technologies for massive impact

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

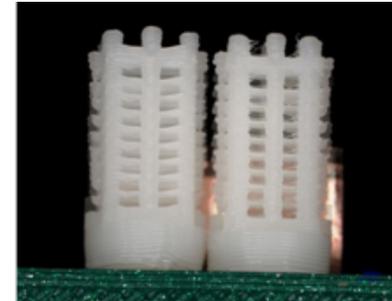
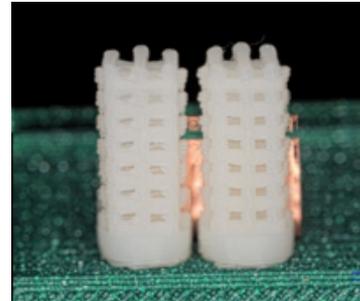
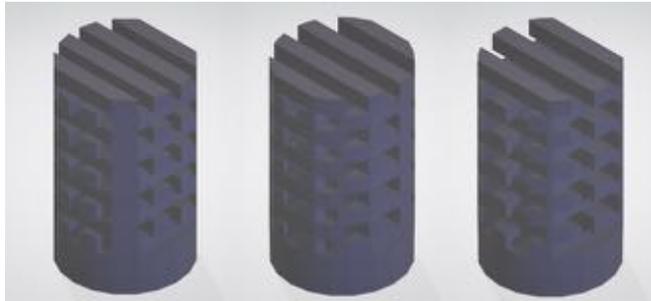


3.- Enabling design and manufacturing technologies

Case study I: Open-source software for biomaterials research

Reconstruction of tissue engineering scaffolds

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



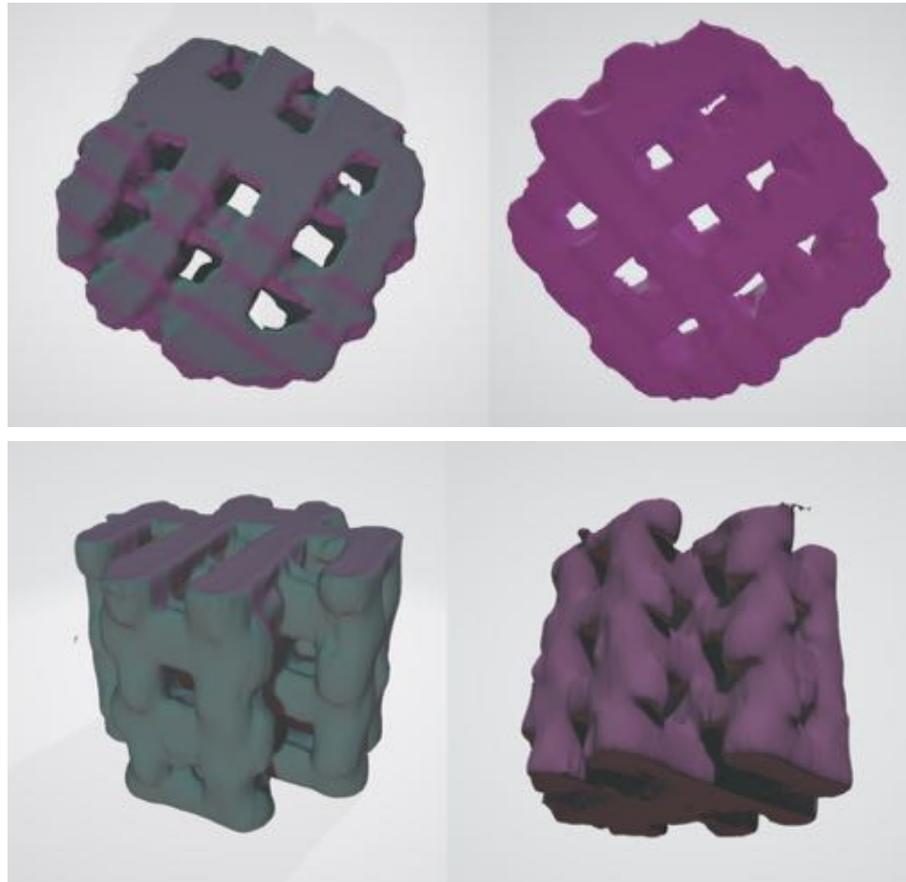


3.- Enabling design and manufacturing technologies

Case study I: Open-source software for biomaterials research

Reconstruction of tissue engineering scaffolds

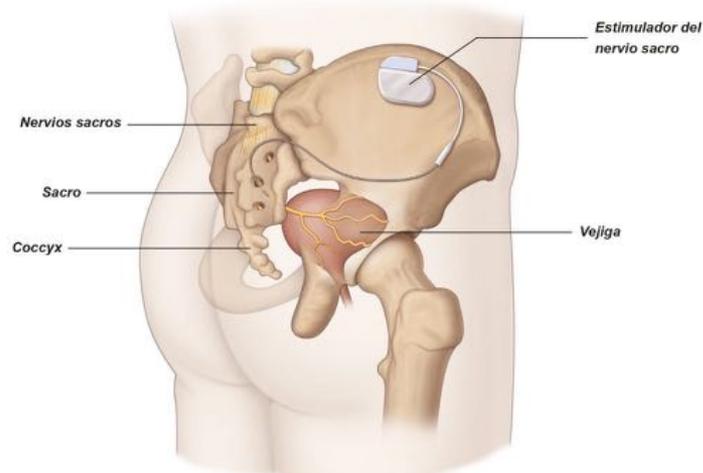
- ✓ 3D reconstruction for quality inspection purposes
- ✓ Slicer 3D



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



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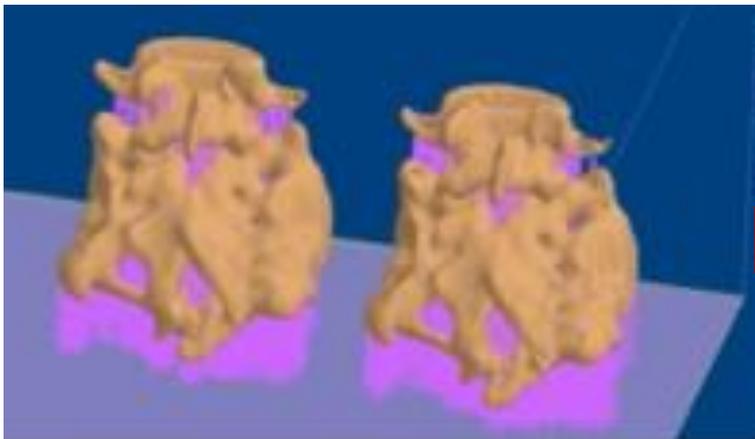




3.- Enabling design and manufacturing technologies

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

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

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- ✓ 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

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Abstract: Sacral nerve stimulation or sacral neuromodulation involves the implantation of a stimulating electrode lead through the sacral foramina. In patients with anatomical sacral anomalies, it can constitute a challenging procedure due to a lack of common reference points present in the normal anatomy. In this study, we present an innovative application of additive manufacturing for the planning of sacral nerve stimulation techniques and related surgical procedures in complex cases, and we verify that the use of personalized patient models may help to manage the presence of sacral anomalies. The use of novel alternative additive manufacturing technologies working with thermoplastic and thermoset polymers, including fused deposition modeling as bio-cast alternative and laser microthickening as industrial gold standard, is compared in terms of viability, precision and overall production costs. They pay special attention to safety, in terms of the bone reconstruction, which is necessary for adequately planning electrode insertion. Advantages and limitations of the alternative approaches are discussed and ideas for future developments and for solving current challenges are presented.

Keywords: surgical planning; additive manufacturing; rapid prototyping; fused deposition modeling; laser microthickening; sacral nerve stimulation; biomedical engineering; personalized medicine

1. Introduction

Sacral nerve stimulation (SNS) or sacral neuromodulation involves the implantation of a stimulating electrode lead through the sacral foramina, which stimulates the nerve and appears to modulate motor and sensory function locally and via central nervous activity. This has demonstrated a remarkable efficacy for the treatment of several colonic and urinary conditions, such as urinary retention, fecal incontinence, constipation, and other bowel dysfunctions [1,2].

However, in patients with anatomical sacral anomalies, it constitutes a challenging procedure due to the lack of common reference points present in the normal anatomy, which are essential to locate the appropriate sacral foramina and perform the standardized implantation technique. These reference points are clearly seen in simple oblique (anterior and lateral projections), computed tomography (CT) images and nuclear magnetic resonance images (MRI) and can be highlighted by simple visual inspection by surgeons during the interventions.

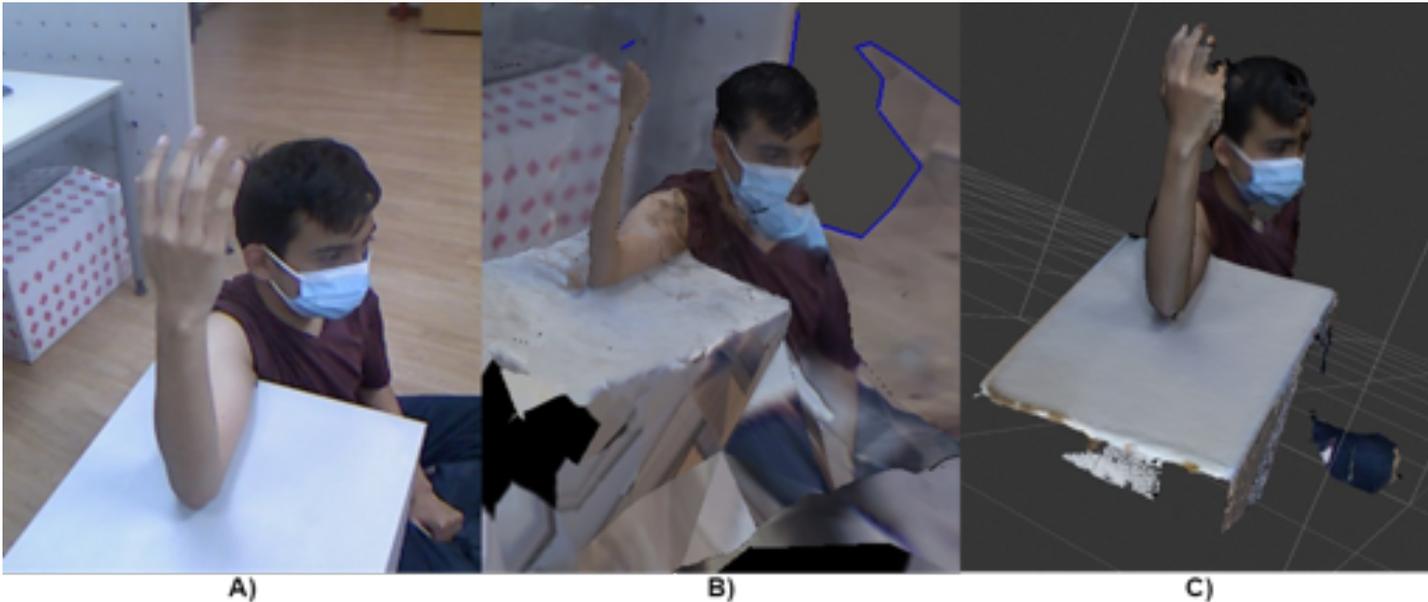
Current solutions for the more complex or anomalous sacral anatomy rely on intra-operative CT combined with neuronavigation, a very specific use of advanced technologies leading to higher and

Polymers 2020, 11, 361; doi:10.3390/polym11030361 www.mdpi.com/journal/polymers

3.- Enabling design and manufacturing technologies

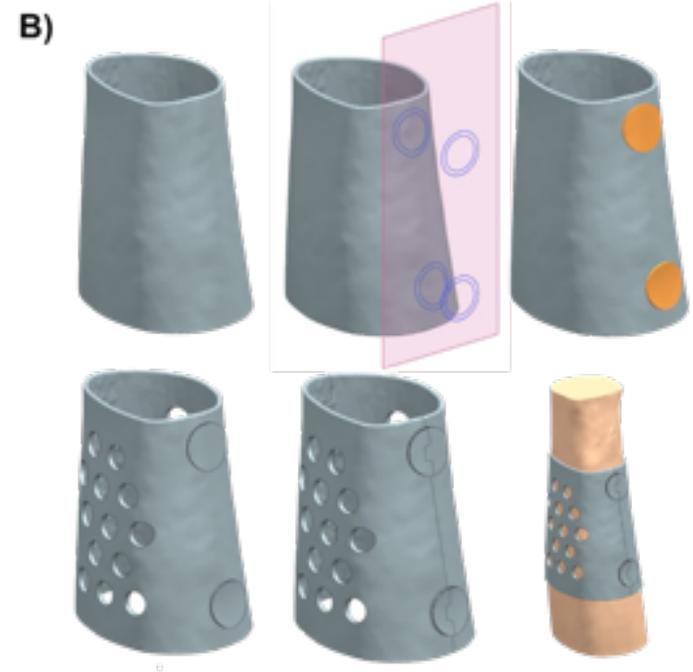
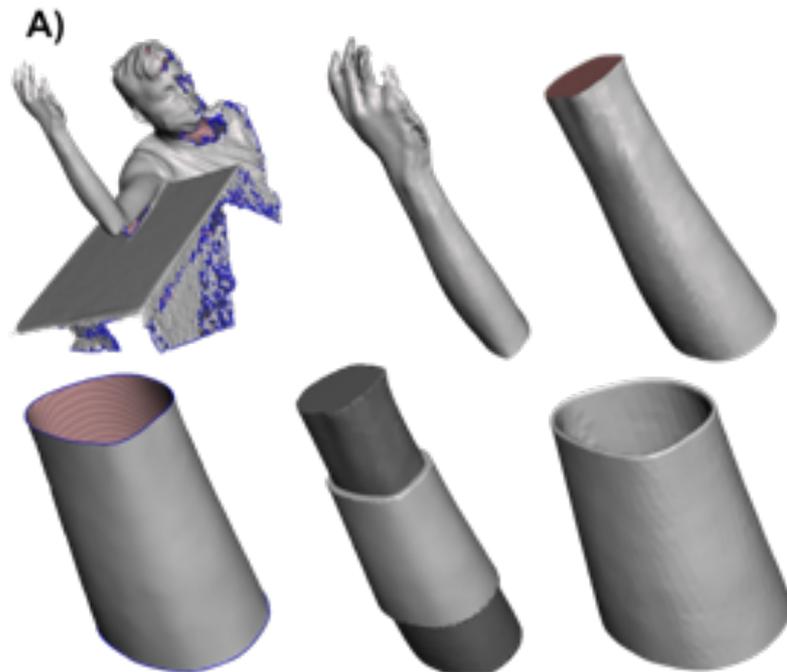
Case study III: Open-source hardware for design personalization Personalized articular splints

- ✓ MS Kinect open-source hardware or normal smartphone camera
- ✓ Optical scanning (C) and photogrammetry (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

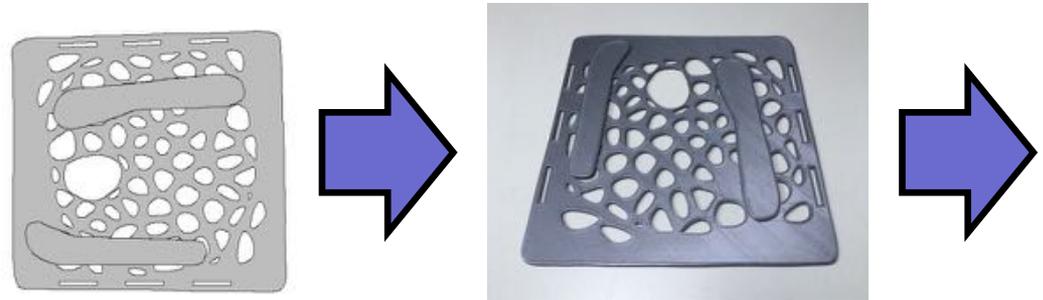




3.- Enabling design and manufacturing technologies

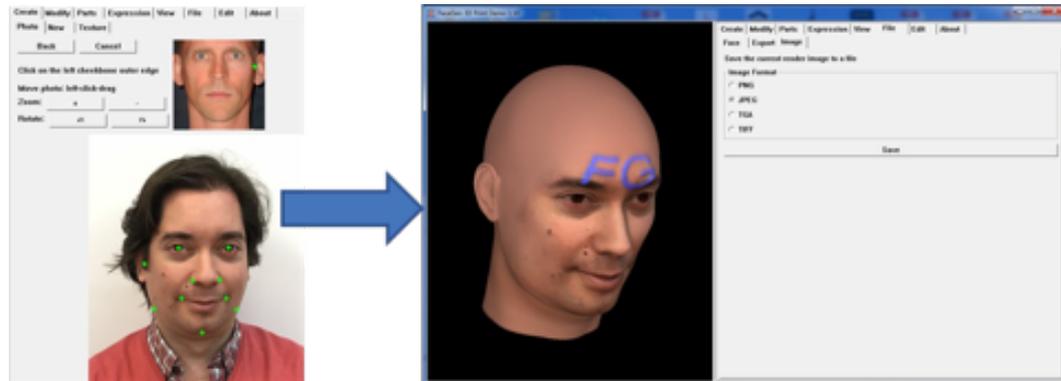
Case study III: Open-source hardware for design personalization Personalized articular splints

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

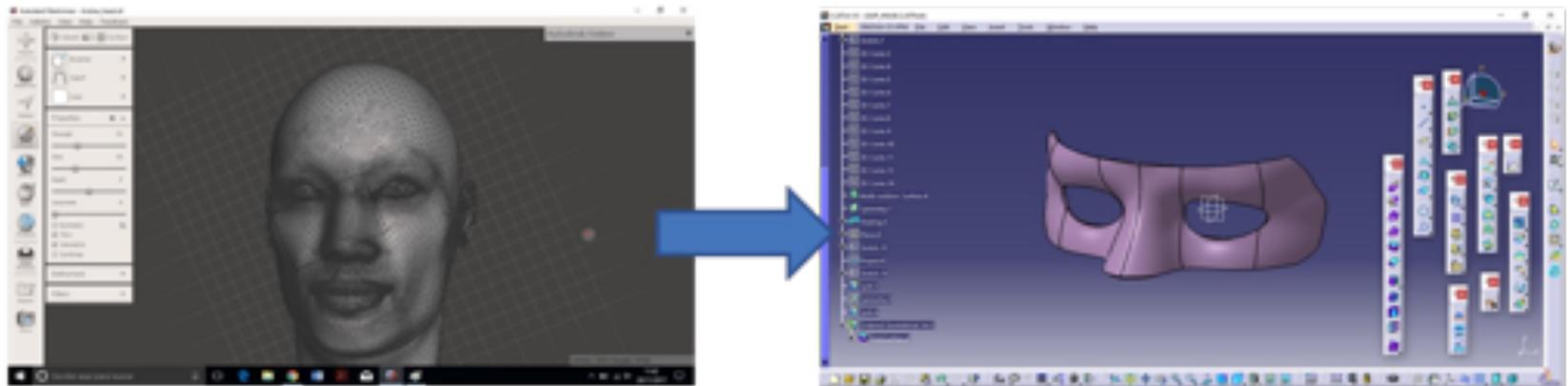


3.- Enabling design and manufacturing technologies

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



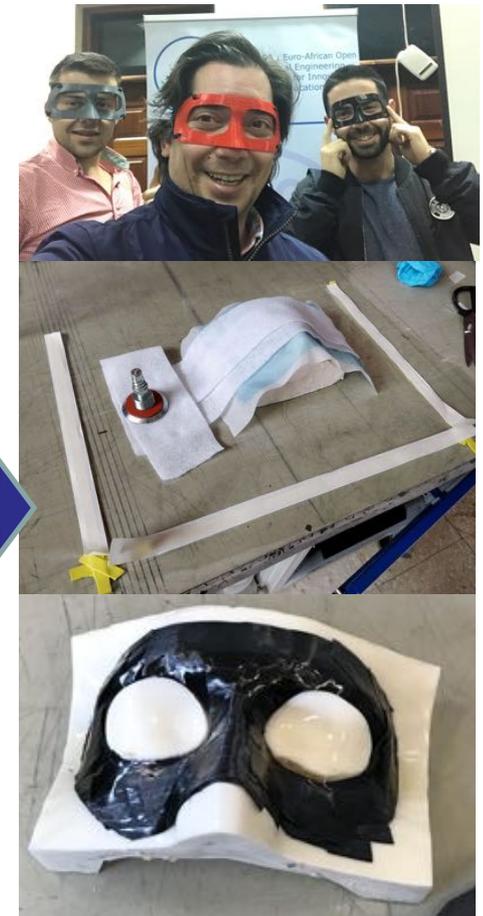
(FaceGen & Catia / NX)



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 photogrammetry for personalized devices Face protecting splints for safe sport practice



4.- Prototyping and production

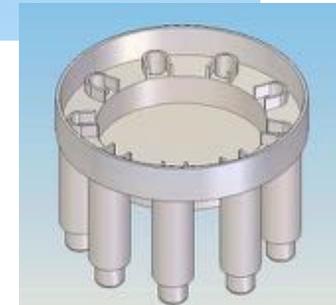
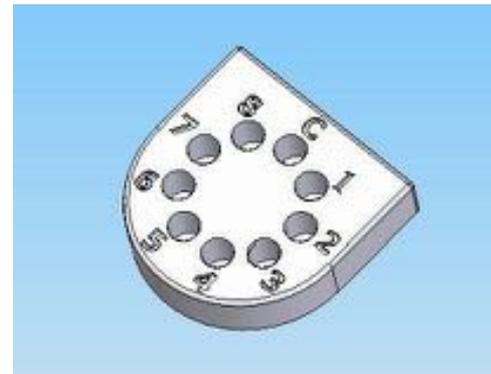
Case study V: Injection molding for massive production of medical devices Point-of-care testing system for urinary infection



Source: Wikimedia Commons, @Itsmemartin & @BiotechMichael.



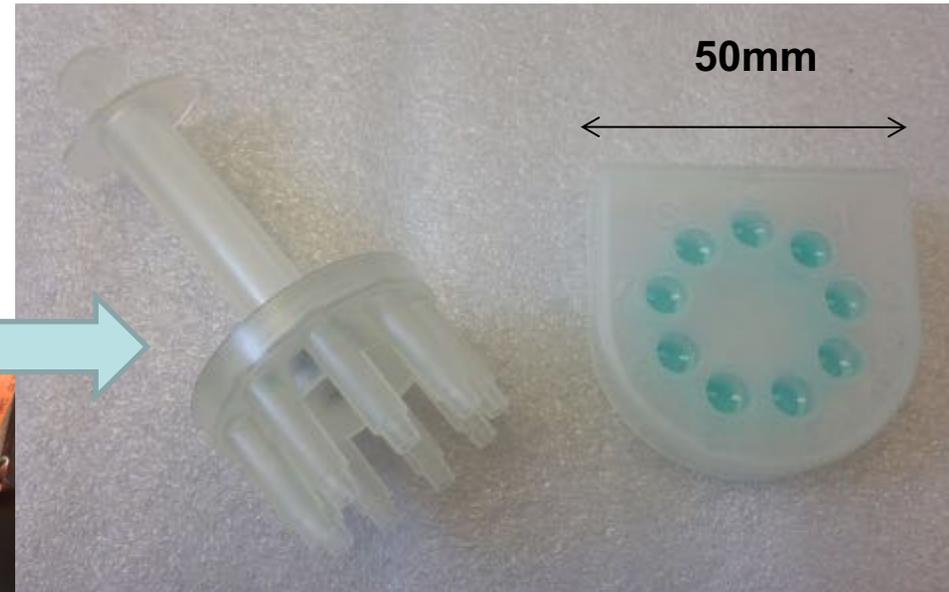
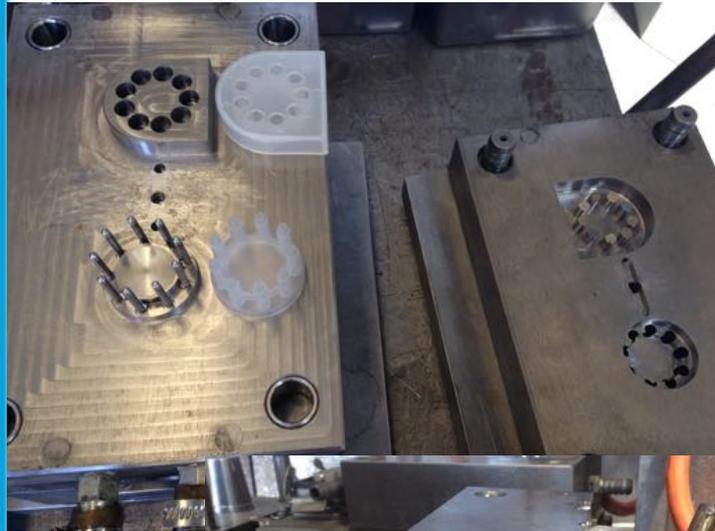
From ELISA 96-well plate to self-contained autonomous device



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

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

Jorge Jover-García¹, Jesús J. Gil-Torralba², Andrés Díaz-Lainada³, Pilar Lafont-Mogador⁴, Paloma Oliver-Sáez⁵ y Javier Colmenero-Rodríguez⁶

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⁵Servicio de Microbiología, Hospital Clínico Universitario, Valencia, España.

Los autores no tienen conflicto de intereses con el presente trabajo.
 El estudio ha sido financiado parcialmente por (CNPQ) (Comisión de Fomento de la Producción del Gobierno de Chile, y por el Hospital Universitario de La Ribera (Ibiza, Valencia) a través de una línea de investigación.

Recibido: 5 de abril de 2020 / Aceptado: 28 de julio de 2020

Resumen

Introducción: Las infecciones del tracto urinario (ITU) presentan una elevada prevalencia en el ámbito comunitario. Un rápido diagnóstico microbiológico es esencial para asegurar una terapia adecuada y efectiva. **Objetivo:** Evaluar un kit de antígenos rápidos (KAR*) en formato *point-of-care* para la detección rápida de ITU y sensibilidad antimicrobiana. **Materiales y Métodos:** El dispositivo KAR* se diseñó y desarrolló en colaboración con ingenieros técnicos y microbiólogos clínicos. Se evaluó en un estudio multicéntrico en el que participaron tres hospitales españoles. Para ello, se realizaron distintos ensayos *in vitro* con el fin de determinar la correlación del dispositivo con los técnicas microbiológicas de referencia. **Resultados:** Se ensayó un total de 406 muestras de orinas procedentes de pacientes con sospecha de ITU. El dispositivo KAR* proporcionó rápidos resultados (tiempo medio de positividad de 7,8 ± 1,3 h) con 97% de sensibilidad, 89% de especificidad y 97% de concordancia para la detección de bacterias significativas. Los porcentajes de especificidad para los antimicrobianos testados fueron: ciprofloxacino (97%), fusidomida (94%), cotrimoxazol (84%), ampicilina (80%) y amoxicilina/ácido clavulánico (57%). **Conclusión:** El dispositivo KAR* puede ser una herramienta útil para el diagnóstico de ITU en pacientes ambulatorios, especialmente en áreas de bajo nivel socio-económico.

Palabras clave: microbiología; pruebas en el punto de cuidado; infección urinaria; antibiograma.

Abstract

Background: Urinary tract infections (UTI) present a high prevalence in the community setting. Rapid and accurate microbiological diagnosis is essential to ensure adequate and effective therapy. **Aim:** To evaluate a rapid antigen test (KAR*) in point-of-care format for rapid detection of UTI and antibiotic susceptibility. **Methods:** The KAR* device has been designed and developed in collaboration with technical engineers and clinical microbiologists. Its evaluation has been carried out through a multicenter study in which three Spanish hospitals have participated. Thus, different *in vitro* tests have been implemented in order to determine device correlation with the reference microbiological techniques. **Results:** During the study period, a total of 406 urine samples from patients with suspected UTI were tested. The KAR* device provided fast results (mean positivity time of 7.8 ± 1.3 hours) with 97% sensitivity, 89% specificity and 97% agreement for the detection of significant bacteria. The percentages of specificity for the antibiotics tested were: ciprofloxacin (97%), fusidomide (94%), cotrimoxazole (84%), ampicillin (80%) and amoxicillin/clavulanic acid (57%). **Conclusion:** The KAR* device could be a useful tool for diagnosing UTI in outpatients, especially in areas of low socio-economic level.

Keywords: microbiology; point-of-care testing; urinary tract infection; antibiogram.

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Main conclusions: Shared dreams

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

“Enabling design and manufacturing technologies
for open-source medical devices”

***THANKS FOR YOUR
ATTENTION***

Prof. Dr. Andrés Díaz Lantada, *contact: andres.diaz@upm.es*
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UBORA: Euro-African Open
Biomedical Engineering
e-Platform for Innovation
through Education

