SERVIZIO SANITARIO REGIONALE
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Istituto Ortopedico Rizzoli di Bologna
Istituto di Ricovero e Cura a Carattere Scientifico

Elaborazione di un planning chirurgico ottimale in casi complessi: il parere del bioingegnere

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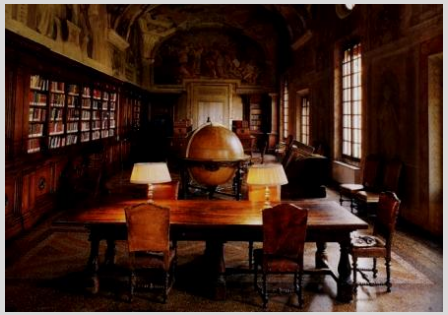
Movement Analysis Laboratory, IRCCS Istituto Ortopedico Rizzoli, Bologna, Italy

President (August 2021 – August 2023)
of the International Society of Biomechanics, founded on August 1973

TREDICESIMO CONVEGNO DI TRAUMATOLOGIA CLINICA E FORENSE
24-25 Novembre 2023
Palazzo dei Congressi - Salsomaggiore Terme

IRCCS ISTITUTO ORTOPEDICO RIZZOLI, Bologna



The Library, 1517

Opening, June 1896

Prosthetics-Orthotics since 1896

BORS at IOR, 1921

- More than **150 physicians**, **300 researchers**, **300 publications**/yy;
- **20.000 treated patients**/yy;
- **130.000 out-patient visits**/yy;
- **258.000 medical services**/yy on aggregate;

- **Research activities** (Labs) on biomechanics, biology, oncology, biotechnology, immunorheumatology, tissue regeneration etc.
- Three University **Clinics in Orthopaedics** and one in **Rehabilitation Medicine**

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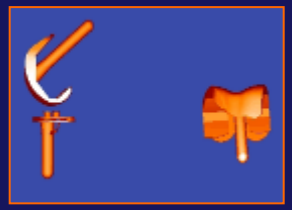
MOVEMENT ANALYSIS LAB

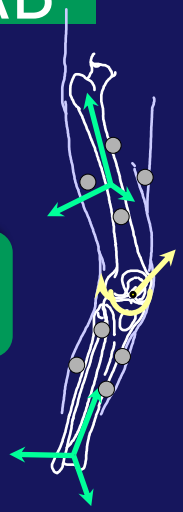
Pre-operative analyses

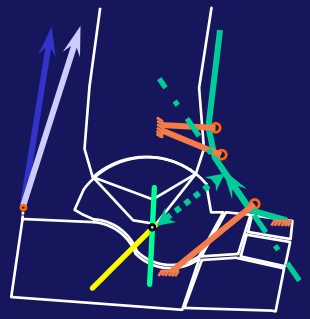
Post-operative assessments



3D FLUOROSCOPY

MOTION ANALYSIS



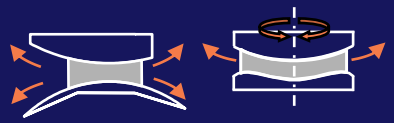


JOINT MODELLING

- Planning the correct surgery
- Supporting prosthesis implantation
- Monitoring functional performance
- Making earlier prognosis of failure
- Designing new prostheses

now custom-made, because of AM!

R.S.A



PROSTHESIS DESIGN

Intra-operative measures

SURGICAL NAVIGATION

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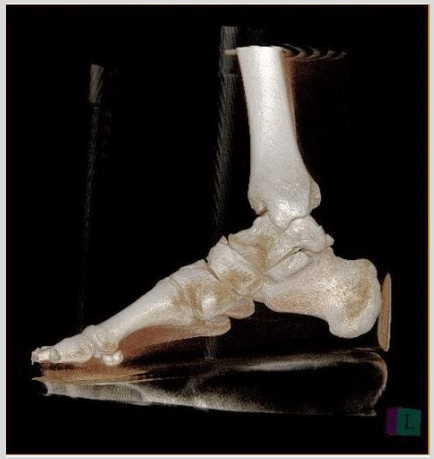
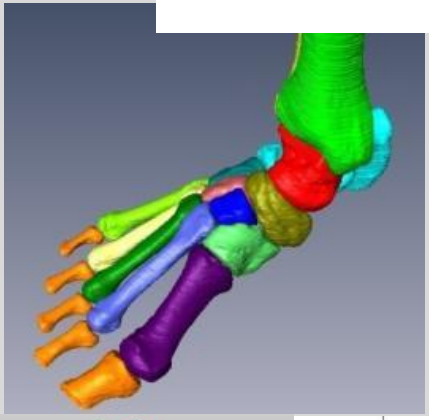
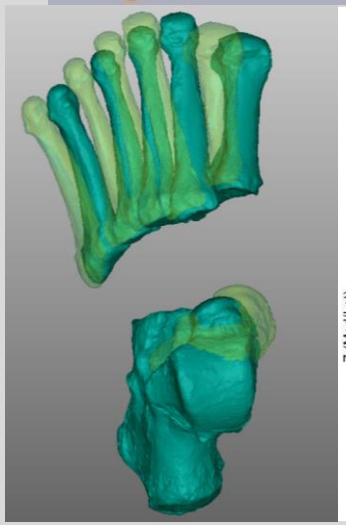
the Movement Analysis Lab

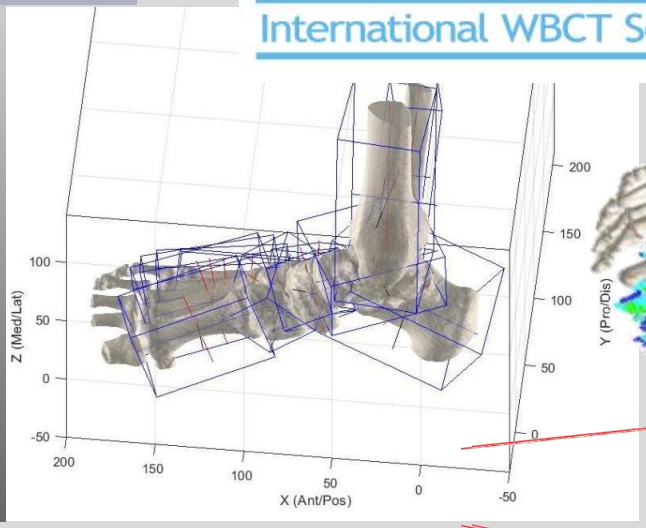
3D MODELS from WBCT scans

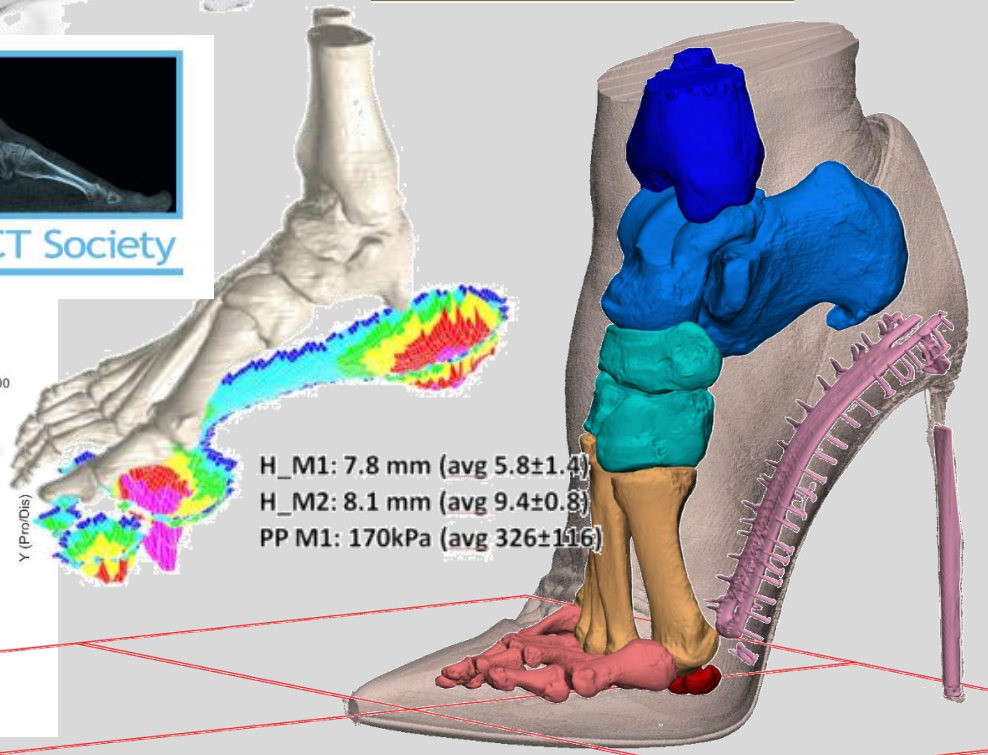




International WBCT Society

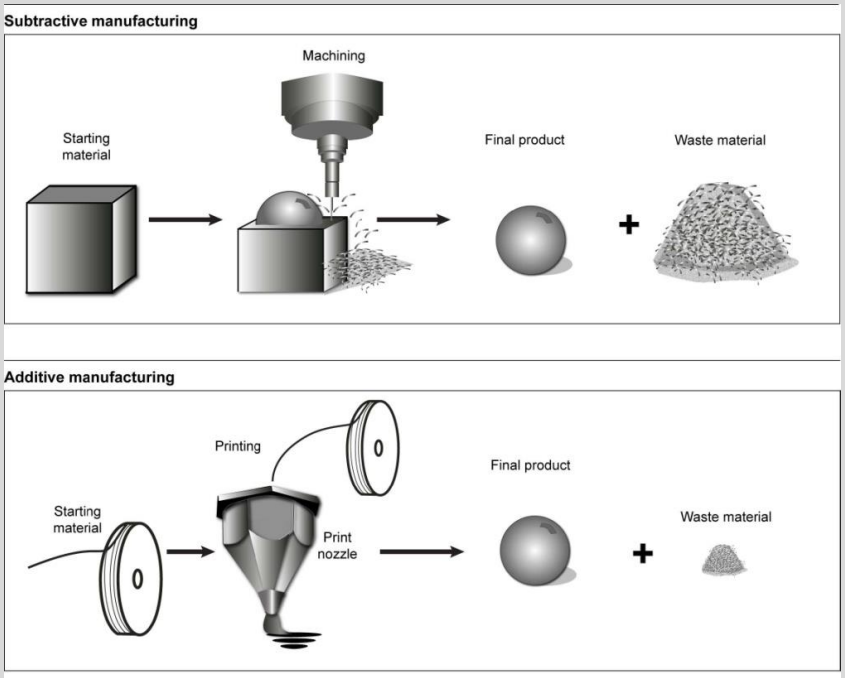






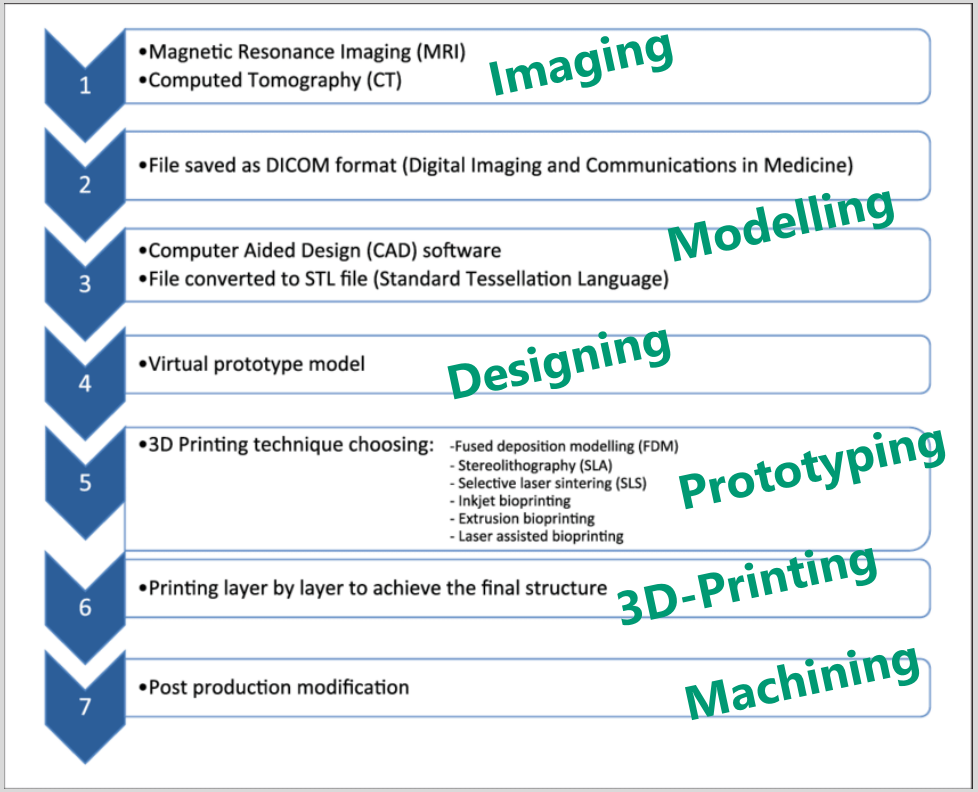
- **Leardini et al. Semin Musculoskelet Radiol 2019; Durastanti et al. Quant Imaging Med Surg 2021**
- **Caravaggi et al. Appl Sci 2021; Ortolani et al. Scien Rep 2021; Giacomozzi et al. Appl Sci 2021**

3D-PRINTING: Technology - Techniques

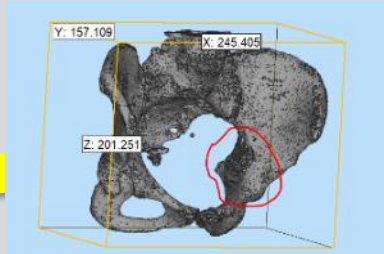


Subtractive
vs
Additive
manufacturing

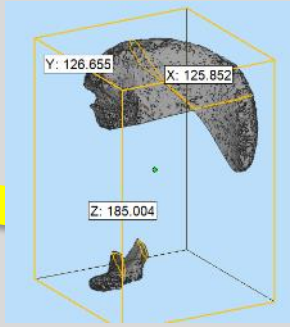
FlowChart



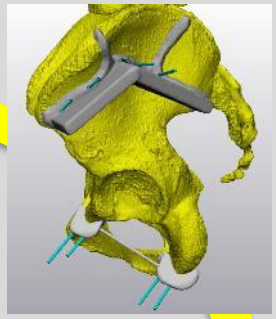
CUSTOM-MADE in Orthopaedics: the flowchart



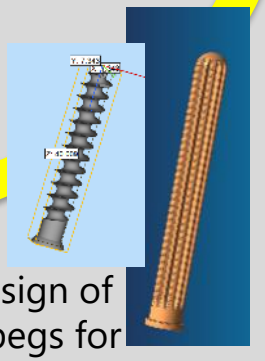
1. Imaging (DICOM files) the area to identify tissues > 3D models (STL files)



2. Definition of 3D resection planes (surgeon&engineer) >> healthy hosting tissues

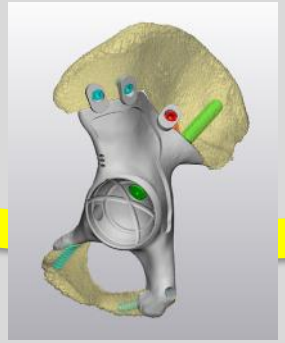


3. 3D design of cutting guides

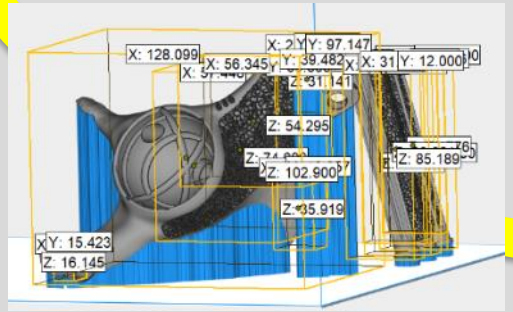


4. 3D design of screws/pegs for osteosyinthesis (primary fixation)

5. 3D general model of implant



6. Virtual check of the full assembly



7. Executive model for 3DP: metals (implant & accessories), polymers (cutting guides & biomodels)

8. Final physical check of the assembly

- **Ahmadpour, Leardini et al. Technovation 2023**

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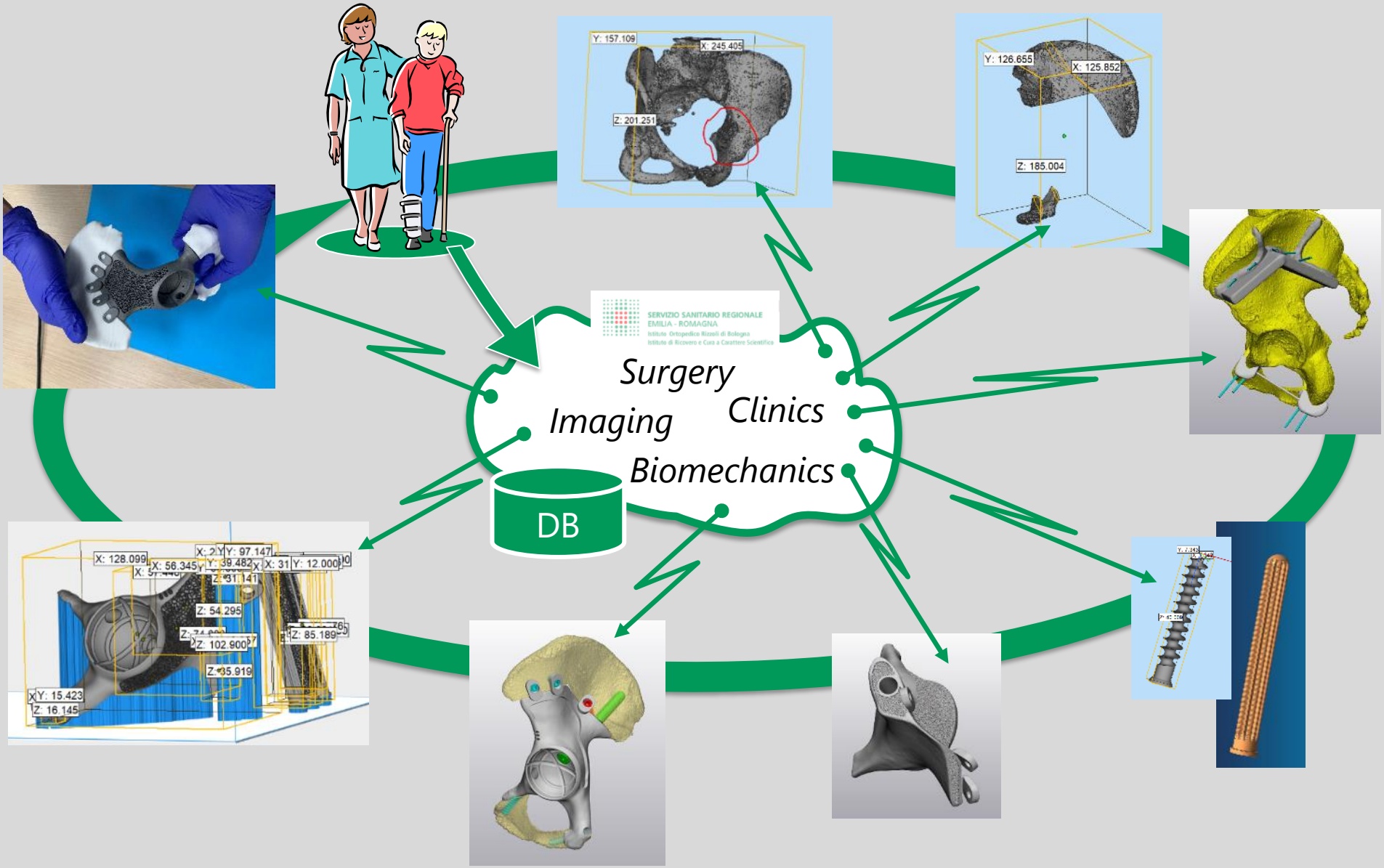
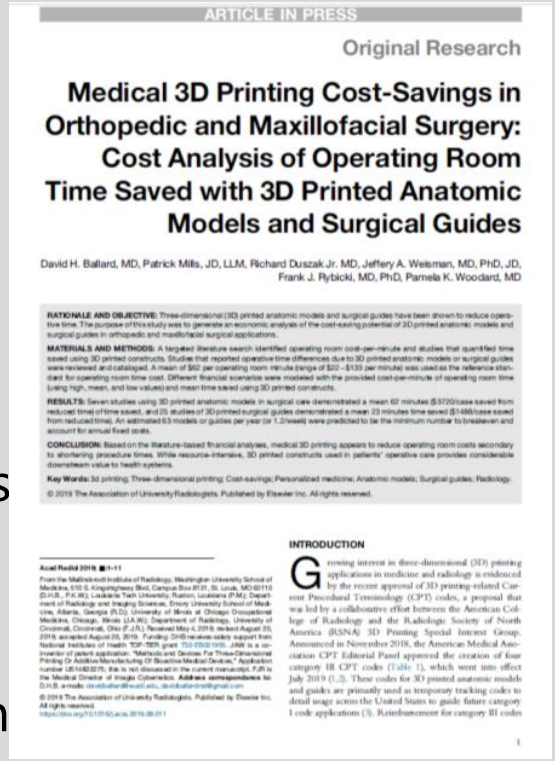
CUSTOM-MADE in Orthopaedics: IOR contributes



CUSTOM-MADE in Orthopaedics: why?

- Full 3D picture of each single patient condition
- Better accuracy and less bone removal
- No longer size related issues
- Minimal invasiveness
- Partial replacement / resurfacing
- Respect of natural patient physiology
- Shorter surgical time via customized fixation and tools
- Less invasive surgery, for shorter recovery
- Longer survivorship, and less failures and revisions
- Better Communication / Education / Training / Plannin
- Cheaper (?): manufacturing, stock, efficacy, operation-time, contentious …
- Less travelling, for patients, surgeons, implants … good for everybody



ARTICLE IN PRESS

Original Research

Medical 3D Printing Cost-Savings in Orthopedic and Maxillofacial Surgery: Cost Analysis of Operating Room Time Saved with 3D Printed Anatomic Models and Surgical Guides

David H. Ballard, MD, Patrick Mills, JD, LLM, Richard Duszak Jr. MD, Jeffery A. Weisman, MD, PhD, JD, Frank J. Rybicki, MD, PhD, Pamela K. Woodard, MD

RATIONALE AND OBJECTIVE: Three-dimensional (3D) printed anatomic models and surgical guides have been shown to reduce operative time. The purpose of this study was to generate an economic analysis of the cost-saving potential of 3D printed anatomic models and surgical guides in orthopedic and maxillofacial surgical applications.

MATERIALS AND METHODS: A targeted literature search identified operating room cost-per-minute and studies that quantified time saved using 3D printed constructs. Studies that reported operative time differences due to 3D printed anatomic models or surgical guides were reviewed and cataloged. A mean of $62 per operating room minute (range of $22–$133 per minute) was used as the reference standard for operating room time cost. Different financial scenarios were modeled with the provided cost-per-minute of operating room time (using high, mean, and low values) and mean time saved using 3D printed constructs.

RESULTS: Seven studies using 3D printed anatomic models in surgical care demonstrated a mean 62 minutes ($3720/case saved from reduced time) of time saved, and 25 studies of 3D printed surgical guides demonstrated a mean 23 minutes time saved ($1486/case saved from reduced time). An estimated 63 models or guides per year (or 1.2/week) were predicted to be the minimum number to breakeven and account for annual fixed costs.

CONCLUSION: Based on the literature-based financial analyses, medical 3D printing appears to reduce operating room costs secondary to shortening procedure times. While resource-intensive, 3D printed constructs used in patients' operative care provides considerable downstream value to health systems.

Key Words: 3d printing; Three-dimensional printing; Cost-savings; Personalized medicine; Anatomic models; Surgical guides; Radiology.

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INTRODUCTION

Growing interest in three-dimensional (3D) printing applications in medicine and radiology is evidenced by the recent approval of 3D printing-related Current Procedural Terminology (CPT) codes, a proposal that was led by a collaborative effort between the American College of Radiology and the Radiologic Society of North America (RSNA) 3D Printing Special Interest Group. Announced in November 2018, the American Medical Association CPT Editorial Panel approved the creation of four category III CPT codes (Table 1), which went into effect July 2019 (1,2). These codes for 3D printed anatomic models and guides are primarily used as temporary tracking codes to detail usage across the United States to guide future category I code applications (3). Reimbursement for category III codes

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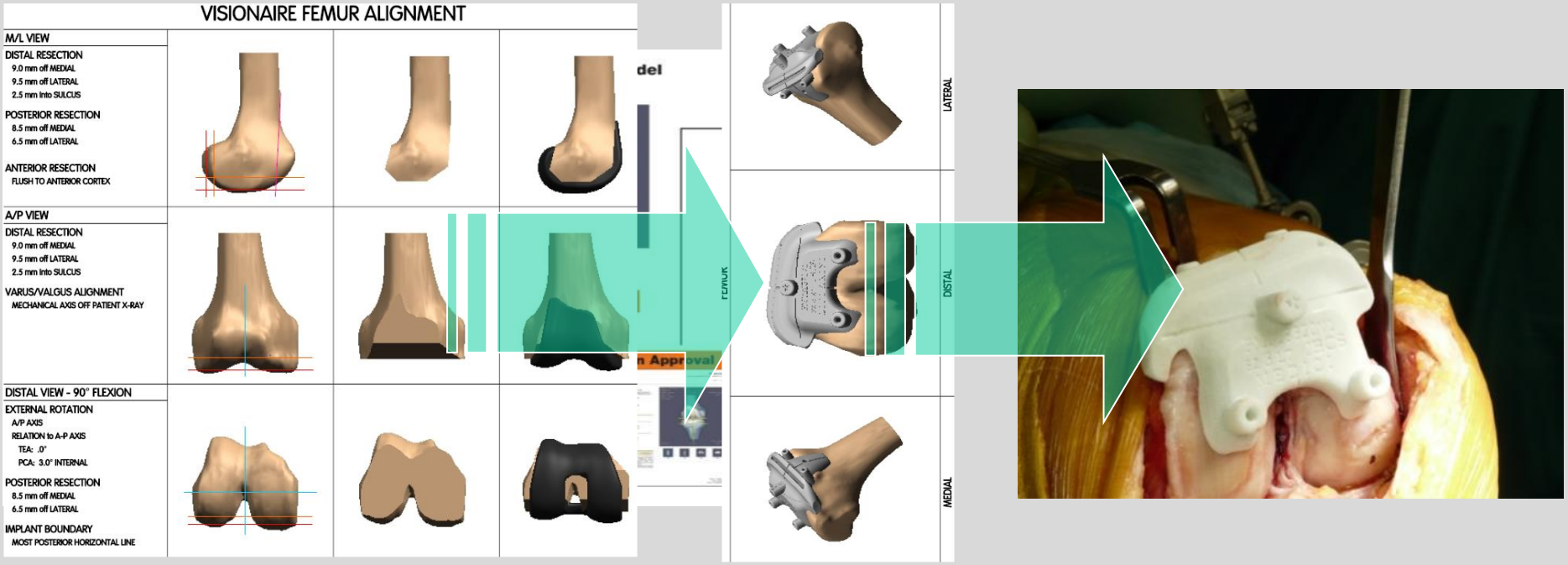
PSI in Total Knee Replacement

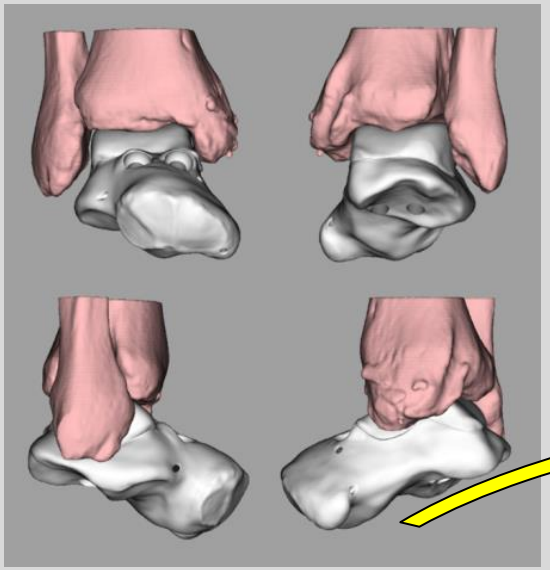
- 3D Printing of custom-fit cutting blocks for femoral & tibial resections, derived from lower-limb scans (CT, MRI)
- Faster, more accurate and cheaper (no additional instrumentation!) ?

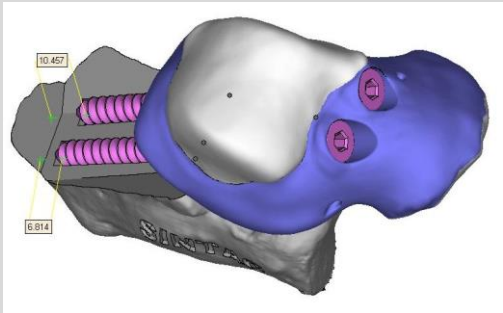


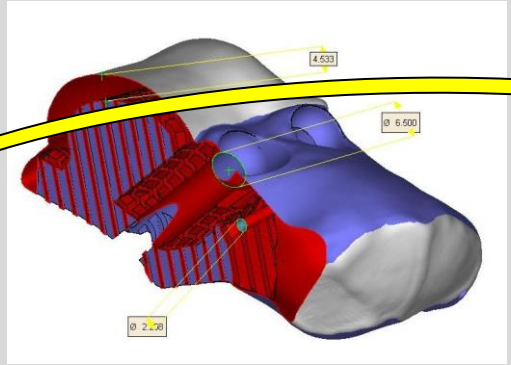
- **Belvedere et al. Int J Med Robot 2007**
- **Cenni et al. J Orthop Res 2014**
- **Ensini et al. Knee Surg Sports Traum Arthr 2014**

Massive Osteoarticular Reconstructions

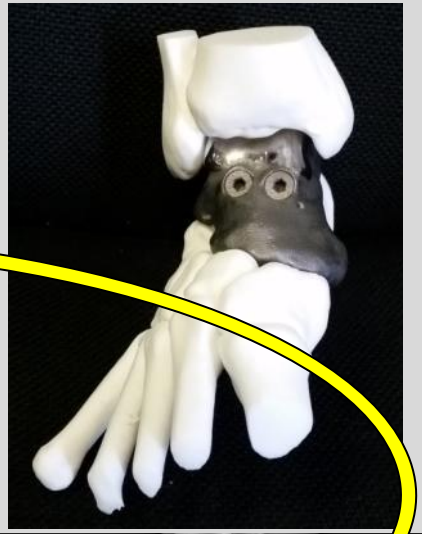
Custom-Made Total Talonavicular Replacement

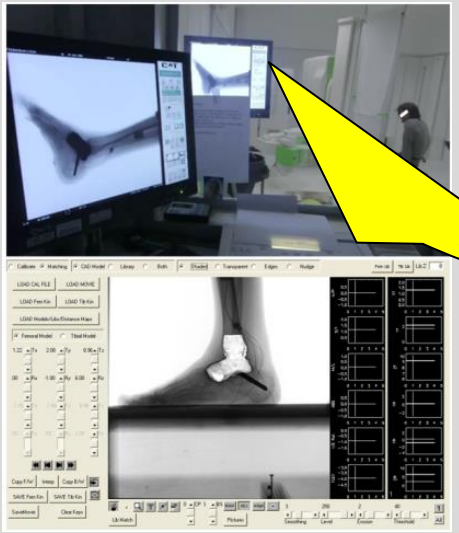


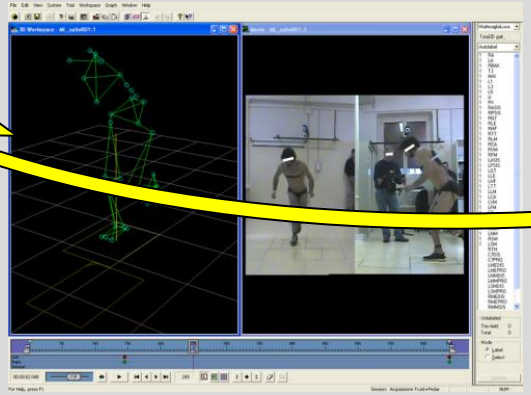




- From CT scans of the contralateral
- Prosthesis in cobalt-chrome alloy powder melting



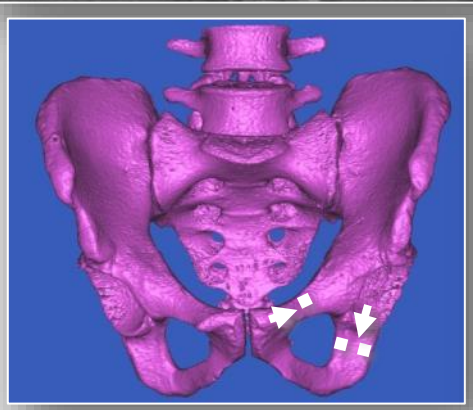


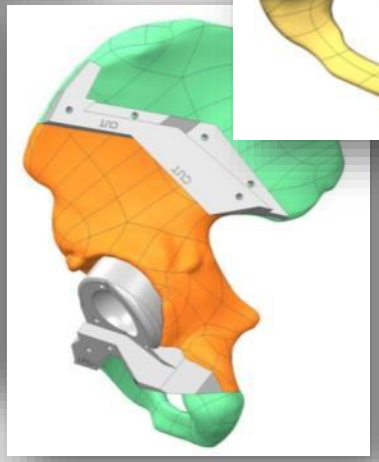


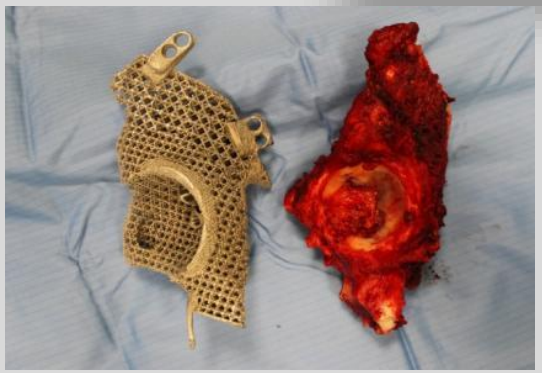
- **Giannini et al. J Foot Ankle Surg 2015; Belvedere et al. J Foot Ankle Surg 2017 & 2020**

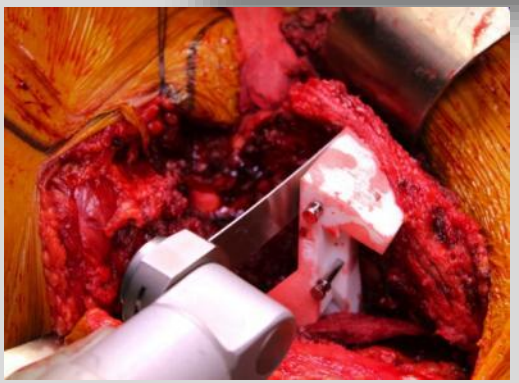
Pelvic Reconstruction in Oncology: the steps

Custom-made implants and guides for bone tumor surgery









- De Paolis et al. Orthopedics 2020

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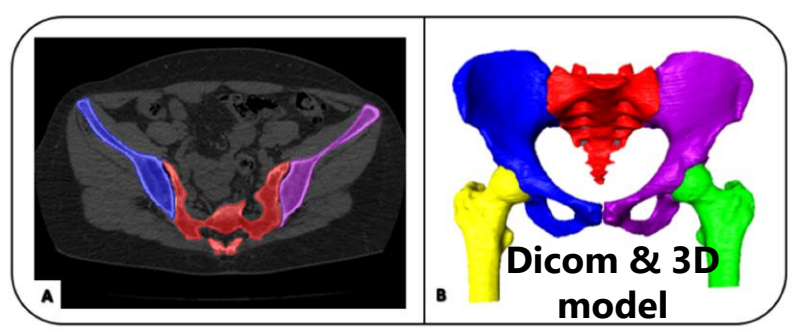
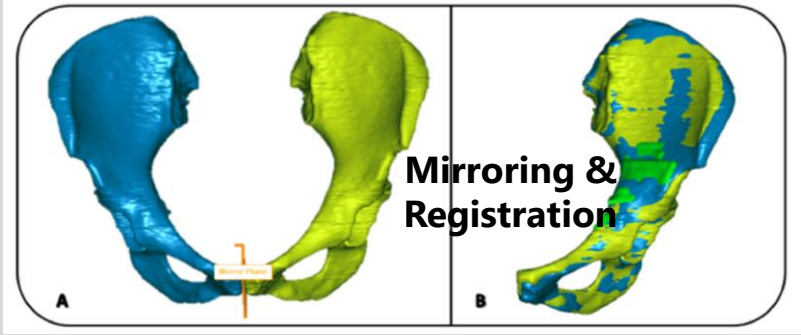
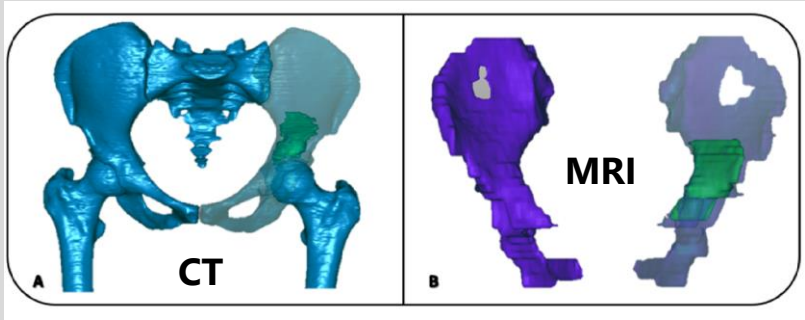
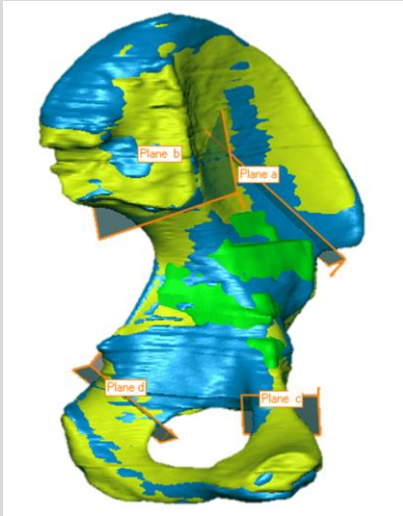
Pelvic Reconstruction in Oncology: modelling

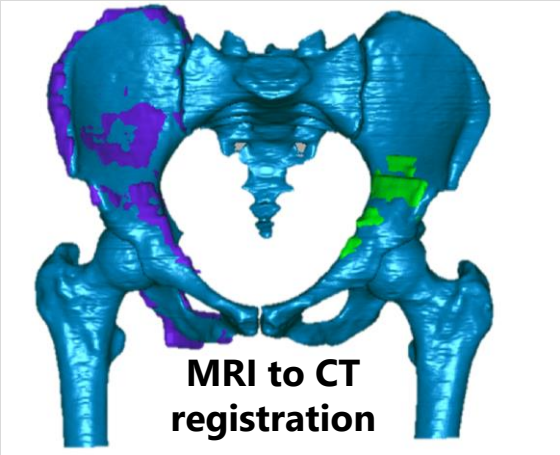


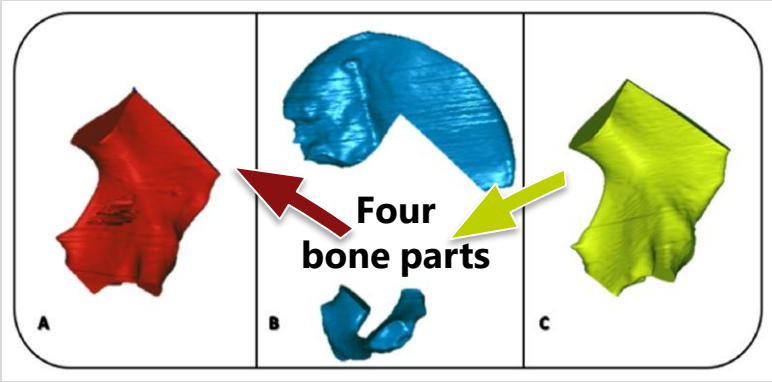




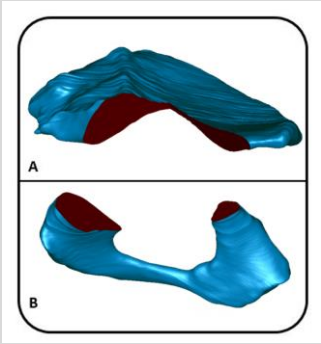


Virtual Bone-cuts





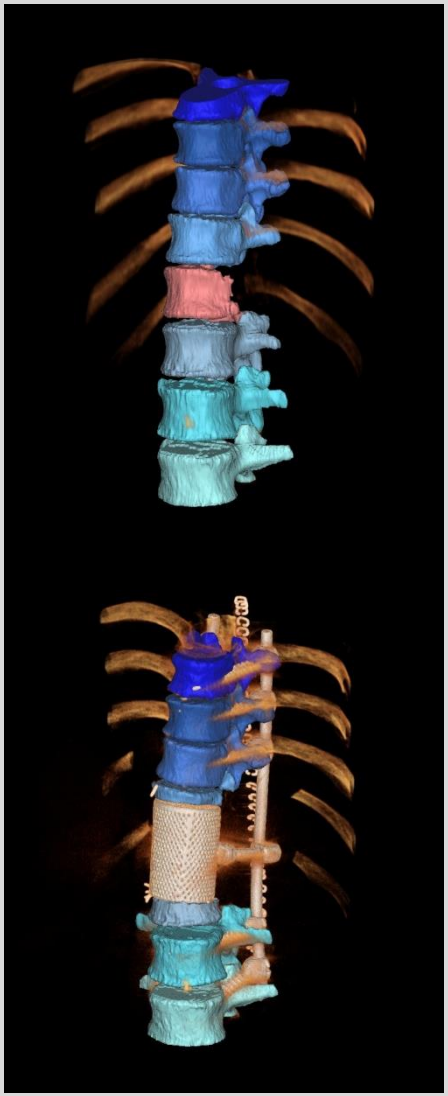
Bone section-areas

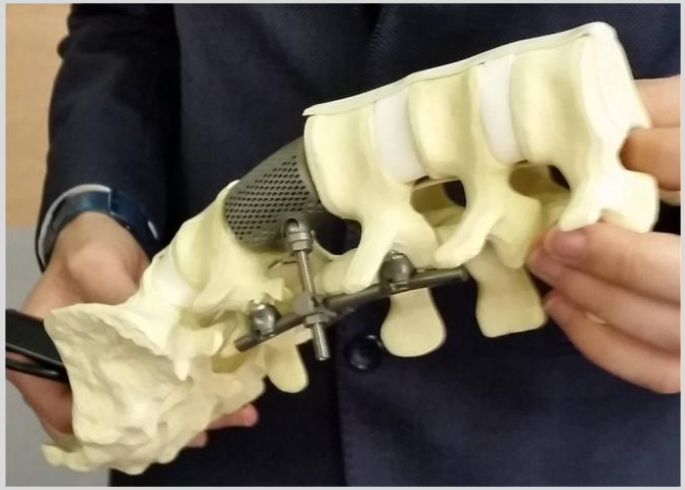


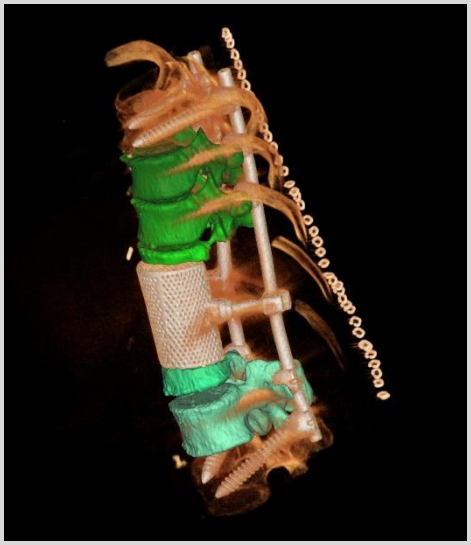
- Durastanti et al. Appl Sci 2022

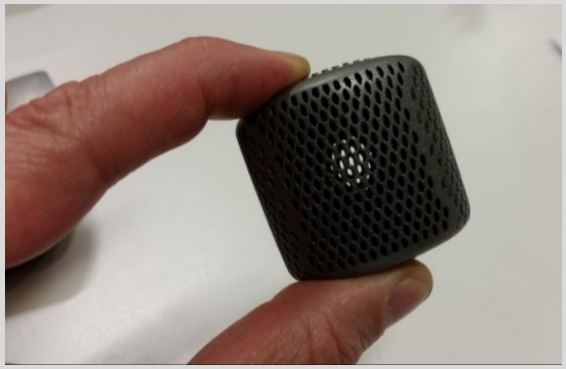
Vertebral Body Replacement

- Titanium alloy, lightweight (density 10%), also to favour bone ingrowth: 21 patients
- Surgical time from 12 – 30 hours, to 7 – 8 hours







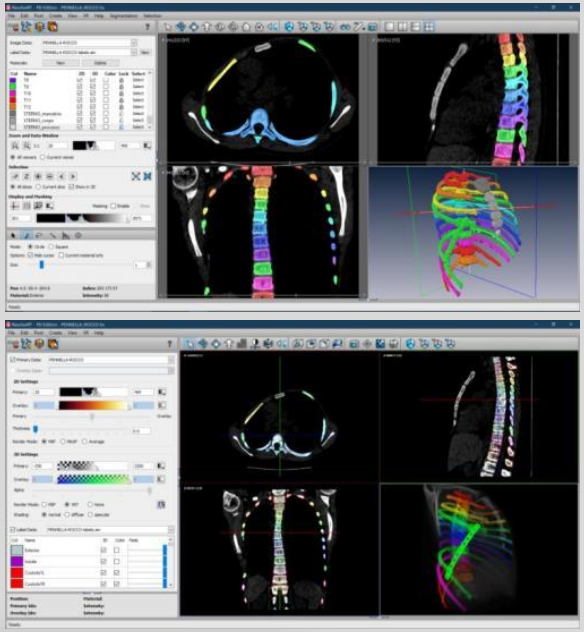


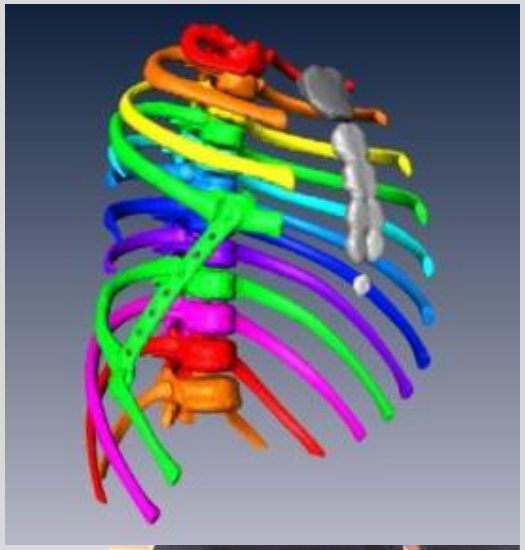
- **Girolami et al. Eur Spine J 2018; Girolami et al. Eur Spine J 2021**

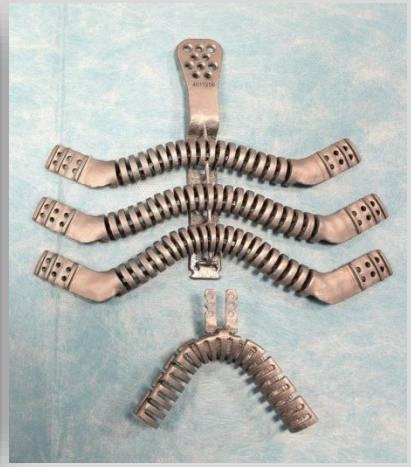
Surgery for Thorax/Sternum reconstruction

Patient-specific chest wall reconstruction implants

- After a wide resection for wide anterior chest wall defect



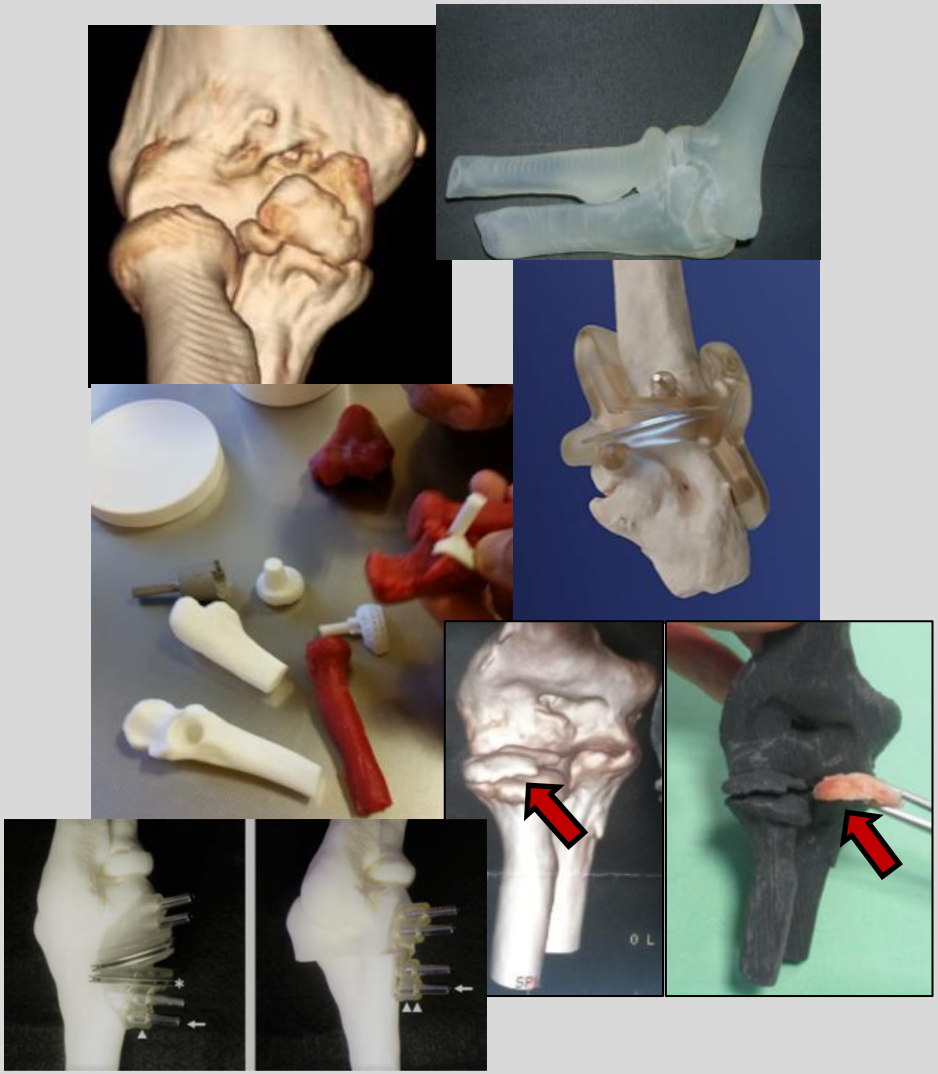




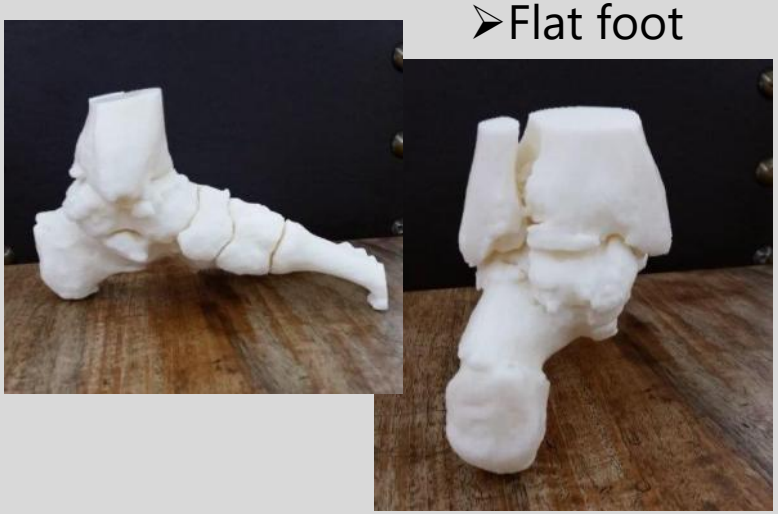
Biomodels, support to surgery & communications

Pre-op planning, surgical guides, training, patient communication …

➢Elbow arthritis and deformities



➢Flat foot



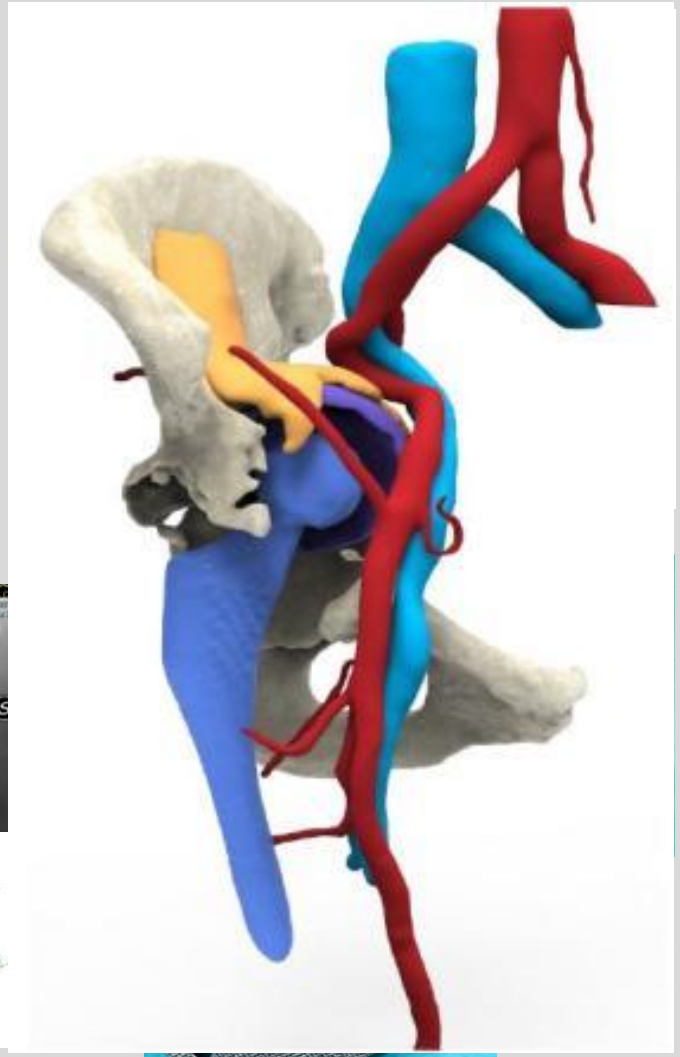
➢

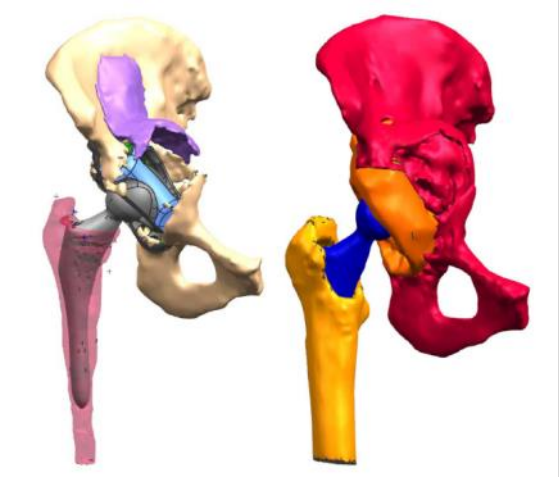
- **Belvedere, De Iure et al. Applied Sciences 2022**

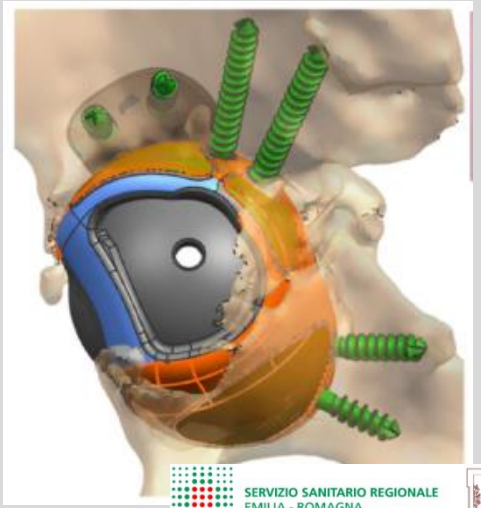
Hip Revision Surgery: role of biomodels

3D anatomical models and implants

- Full reconstructions after failures of THR, with massive bone loss

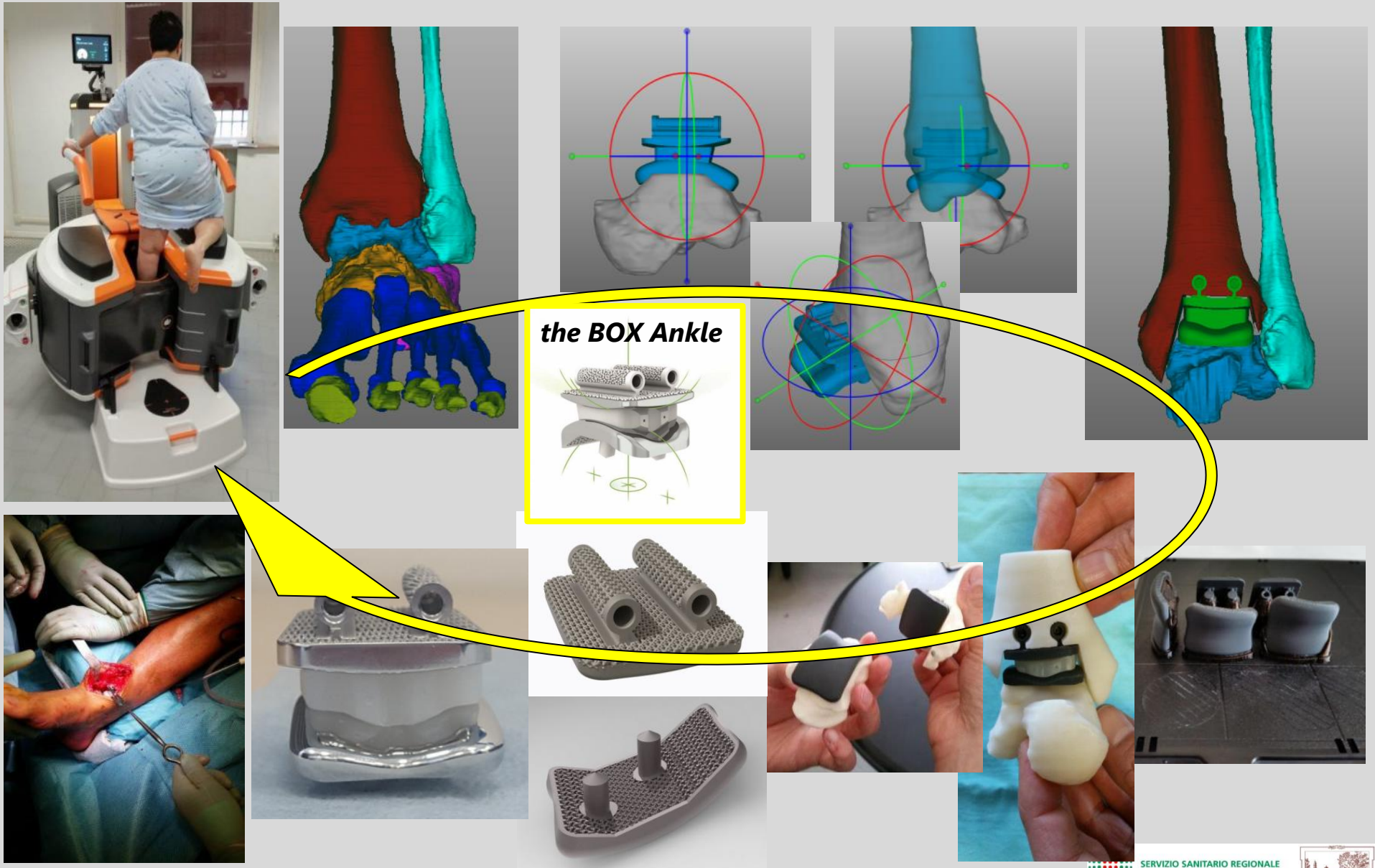






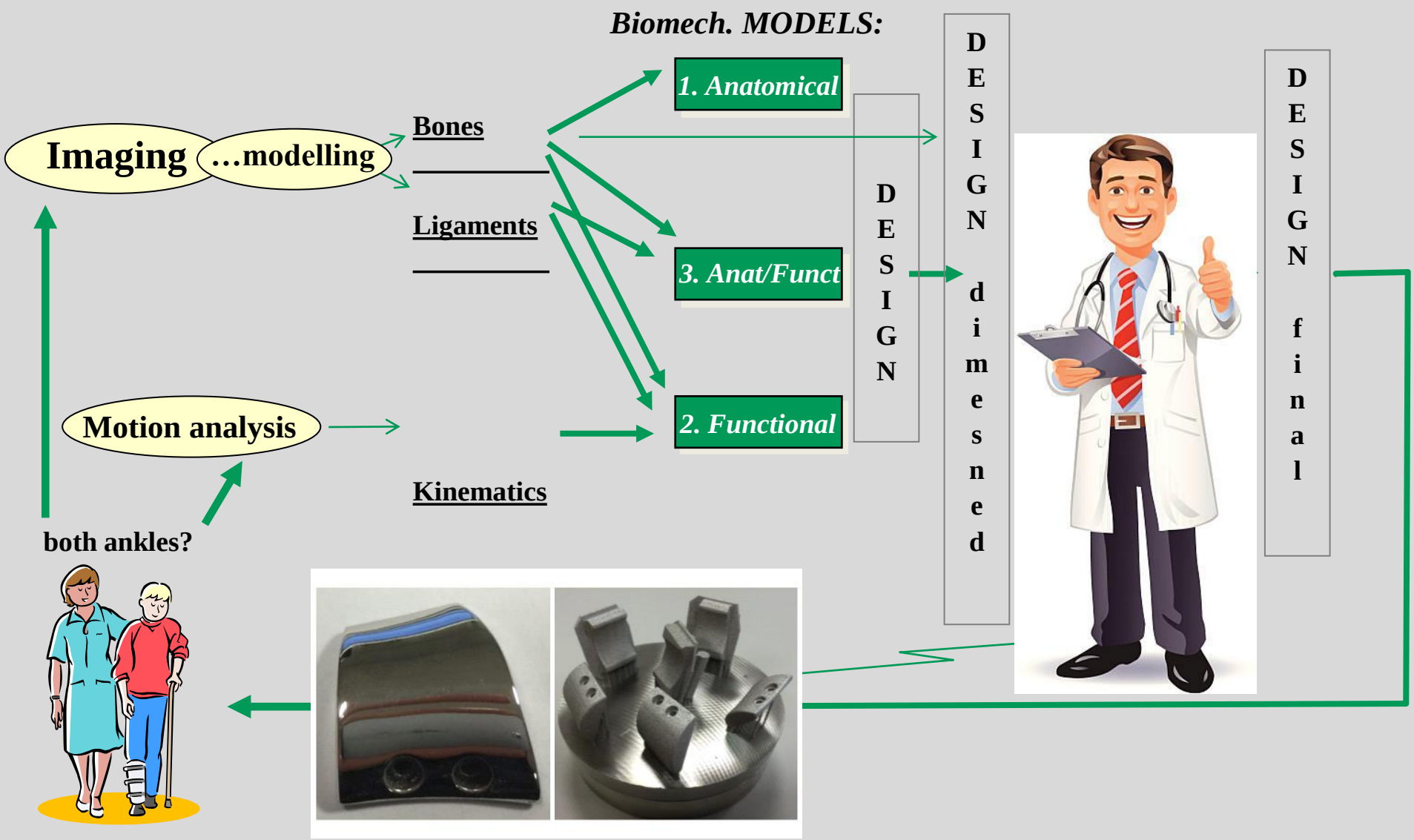
- **Castagnini et al. World J Orthop 2021**

Total Ankle Replacement: workflow for custom



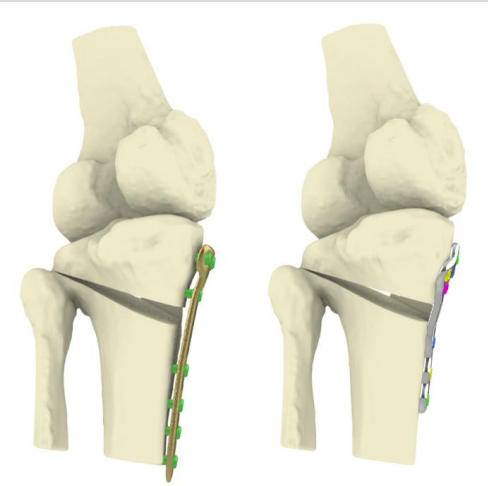
- Belvedere et al. JOR 2019; Faldini et al. J Orth Traum 2020; Ferraro et al. Clin Biomech 2021; Faldini et al. World J Orth 2022

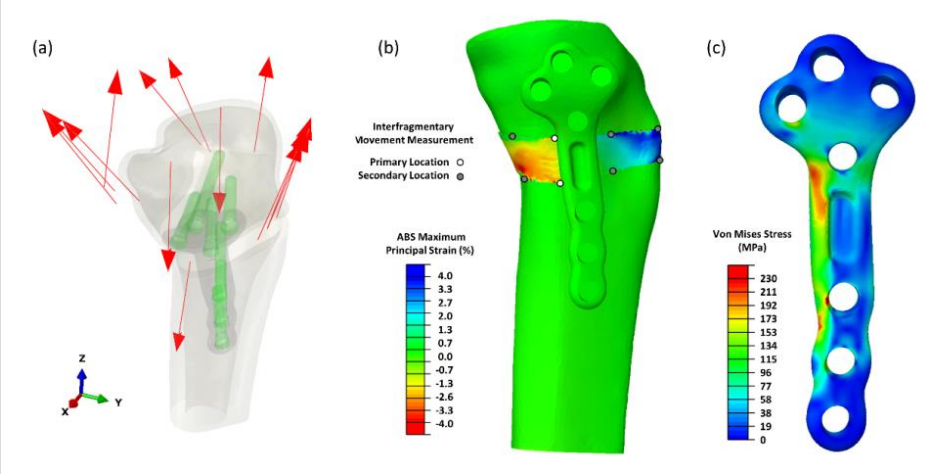
Total Ankle Replacement: options, preferences



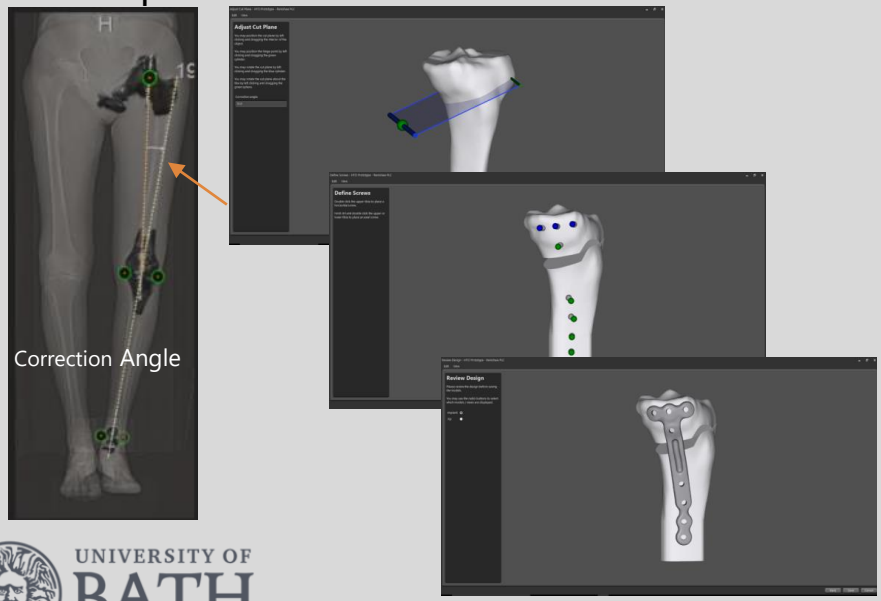
High Tibia Osteotomy: custom guide and plate

- Goal: 3D alignment correction, and perfect match of plate and screws



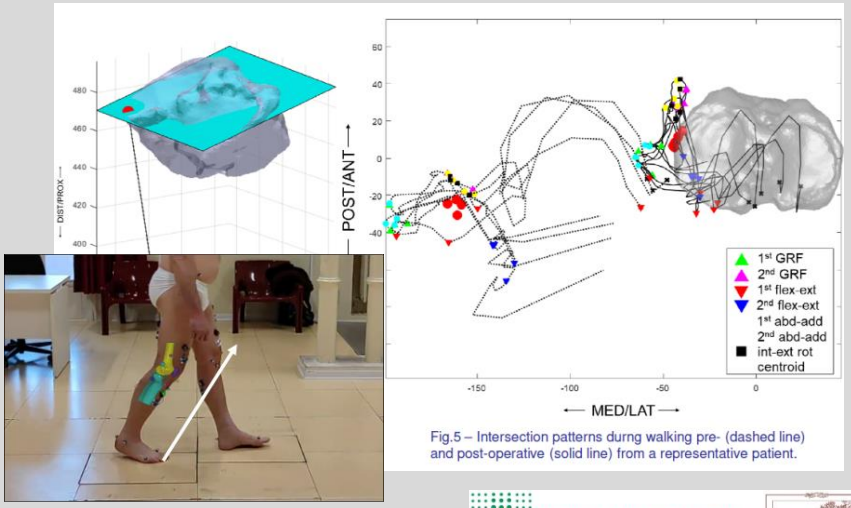


- 3D plan



- **MacLeod et al. Bone Joint Res 2018; MacLeod et al. Comm Med 2021**

- Medical-imaging combined with Gait-analysis



- **Ruggeri et al. Gait Post 2022; Belvedere et al. App Sci 2023 in review**

UNIVERSITY OF BATH

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Disciplines - Resources - Synergies

Via combination of multi- instrumental/disciplinary activities *NEEDS*:

- ✓ *Overall plan of the treatment*
- ✓ *Data capture (scans, medical imaging, …)*
- ✓ *Medical imaging analysis*
- ✓ *Geometrical modelling*
- ✓ *Biomechanical modelling*
- ✓ *Design of the device (clinical, surgical, techr*
- ✓ *Prototyping* *PRINTERS*
- ✓ *Implantation procedure, pre-op planning*
- ✓ *Final manufacturing (additive)* …
- ✓ *Final implantation*
- ✓ *Tests: Mechanical, Functional & Biological*

Organization / Administration: paradigm A

Hospital

Clinical assess.

Radiology

Surgery

Dicom images

Implant & Instrumentation

INDUSTRY

- Design refining
- 3D printing
- Finishing / Polishing / Sterilising
- Packaging / Tracking

Modelling

Design

Prototyping

Pre-op planning

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Organization / Administration: paradigm B

IOR
(Hospital & Research centre)

Clinical assess. — Radiology — Modelling — Design — Prototyping

Surgery

Pre-op planning

Implant & Instrumentation

Bone model & CAD of Implant

INDUSTRY

- Design refining
- 3D printing
- Finishing / Polishing / Sterilising
- Packaging / Tracking

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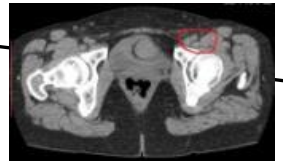
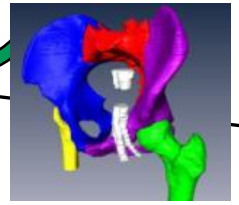
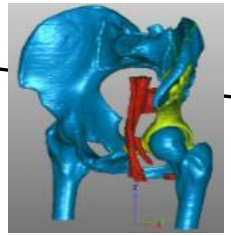
Organization / Administration: paradigm B

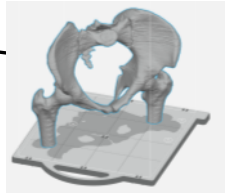
IOR
(Hospital & Research centre)

Clinical assess.









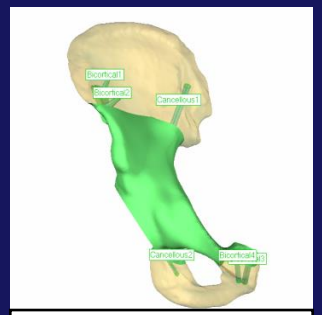
Implant & Instrumentation

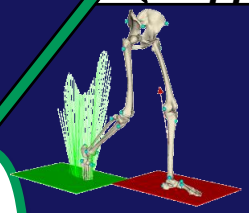
Bone model & CAD of Implant

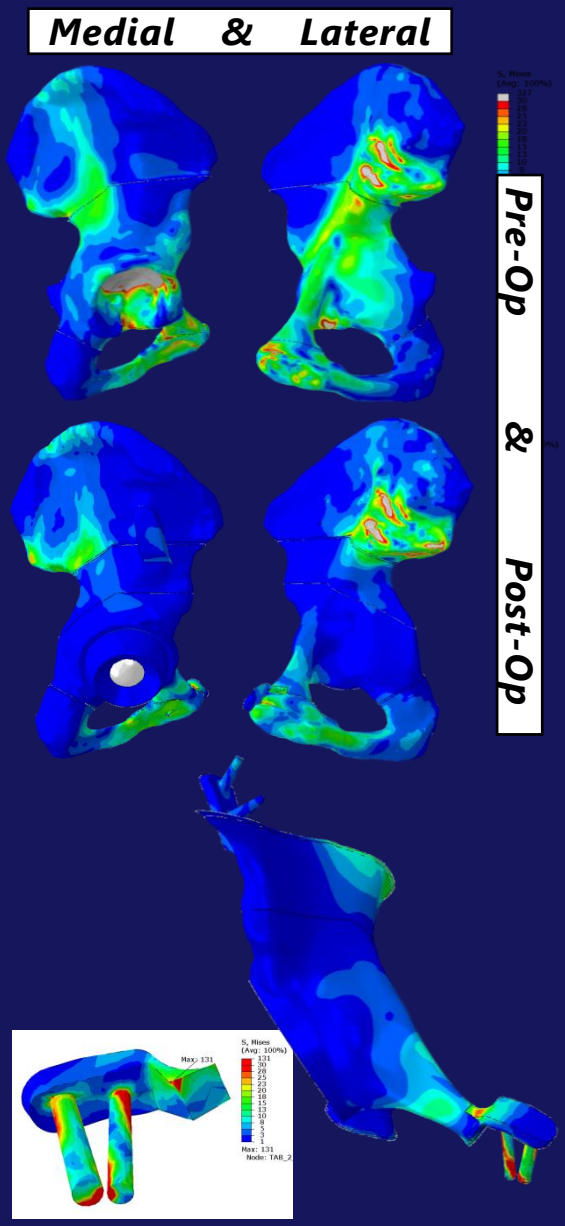
INDUSTRY

- Design refining
- 3D printing
- Finishing / Polishing / Sterilising
- Packaging / Tracking

Organization / Administration: B plus (+ Biomech!)





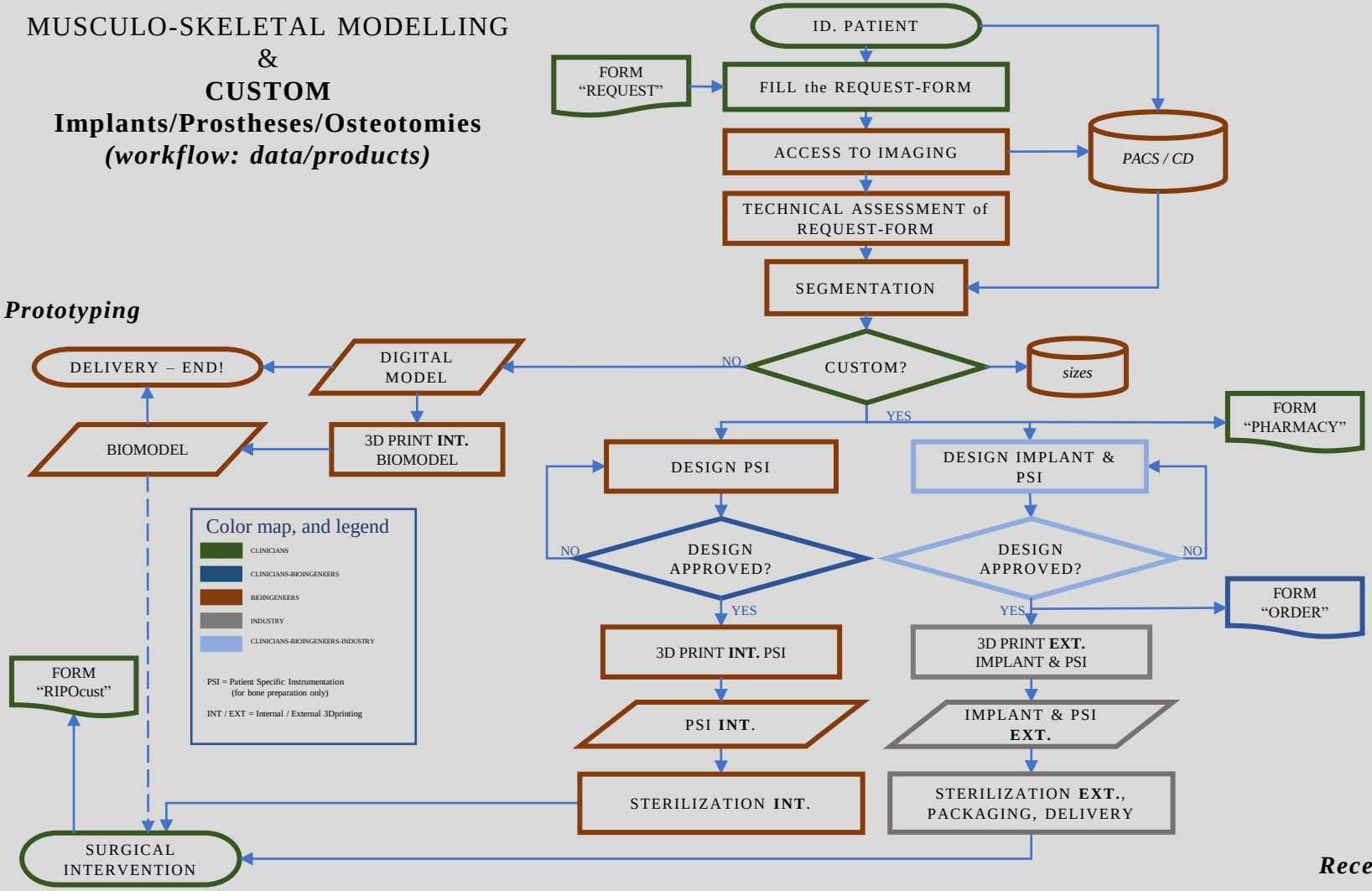


- *Zhu, Dunbar, Leardini, Fregly et al. Med Eng & Phys 2023*

‘Rizzoli-su-Misura’, the 3Dlab

FONDAZIONE ISTITUTO ORTOPEDICO RIZZOLI

MUSCULO-SKELETAL MODELLING
&
CUSTOM
Implants/Prostheses/Osteotomies
(workflow: data/products)



Receiving & Accepting

Modelling

Prototyping

Planning / Approval / Authorisation

Manufacturing: 3Dprinting & post-processing

Delivery

Reception & Surgery

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CUSTOM IMPLANTS in IOR
the lessons learned

- The Techniques / Tools:

☞ A fascinating value-chain involving many powerful **sw tools**;

☞ Implants are fine, but care to **implantation** (pre-op planning, PSI, etc.);

☞ Timing, quality, costs, … already impressive; and are **improving** rapidly.

- The Overall Concept:

☞ Tailoring does result in **better treatments**, addressing many patient-specific conditions and expectations: also in elective surgery, also in remote;

☞ Personalization includes experience & **expertise of the surgeon**;

☞ A **big value overall**? Now more expensive, but quicker;

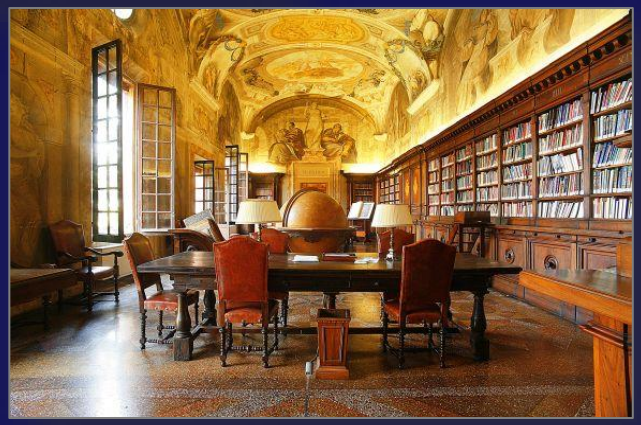
☞ Big value also in **planning, communication, education, training, learning-curve**;

☞ Potential revolutionary **new solutions** for the design (shapes, lattice, surfaces, fixation, interfaces, coating, …) .

- Professional:

☞ Strategic role of **multi-disciplinary teams**, and of collaboration between University – Research – Healthcare – Industry

Thank You



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