Presentazione progetti Health & Wealth
«Tecnologie per la Salute»
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UNIVERSITÀ DEGLI STUDI DI BRESCIA

RESHAPER: Reverse Engineering of Self-care and Healthcare Aids for Personalized Empowerment and Rehabilitation

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UNIVERSITÀ DEGLI STUDI DI BRESCIA

Multidisciplinar

Computer Science IT
Mechanical design
Law and regulation

Technological core

3D Scanning
Geometry Processing
3D Printing

Clinical target

Rehabilitation
Orthoses
Hand

From serial production to custom manufacturing

Our target application:

- Orthotic devices
  - Hand, fingers and wrist

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From serial production to custom manufacturing

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for Hemiplegic (post-stroke or) or tetra/paraplegic (spinal chord injury) patients

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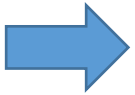
From serial production to custom manufacturing

Our target application:

➢Orthotic devices

- Hand, fingers and wrist

for Hemiplegic (post-stroke or) or tetra/paraplegic (spinal chord injury) patients



Immobilization orthosis

- Maintenance of proper hand and wrist posture
- Prevention of muscle and joint contracture
- Prevention of edema

- Custom additive manufacturing (3D printing) is *expanding* in orthopedic and rehabilitation applications
  - Improve comfort, compliance and tolerability
  - Reduce pain due to unfit devices

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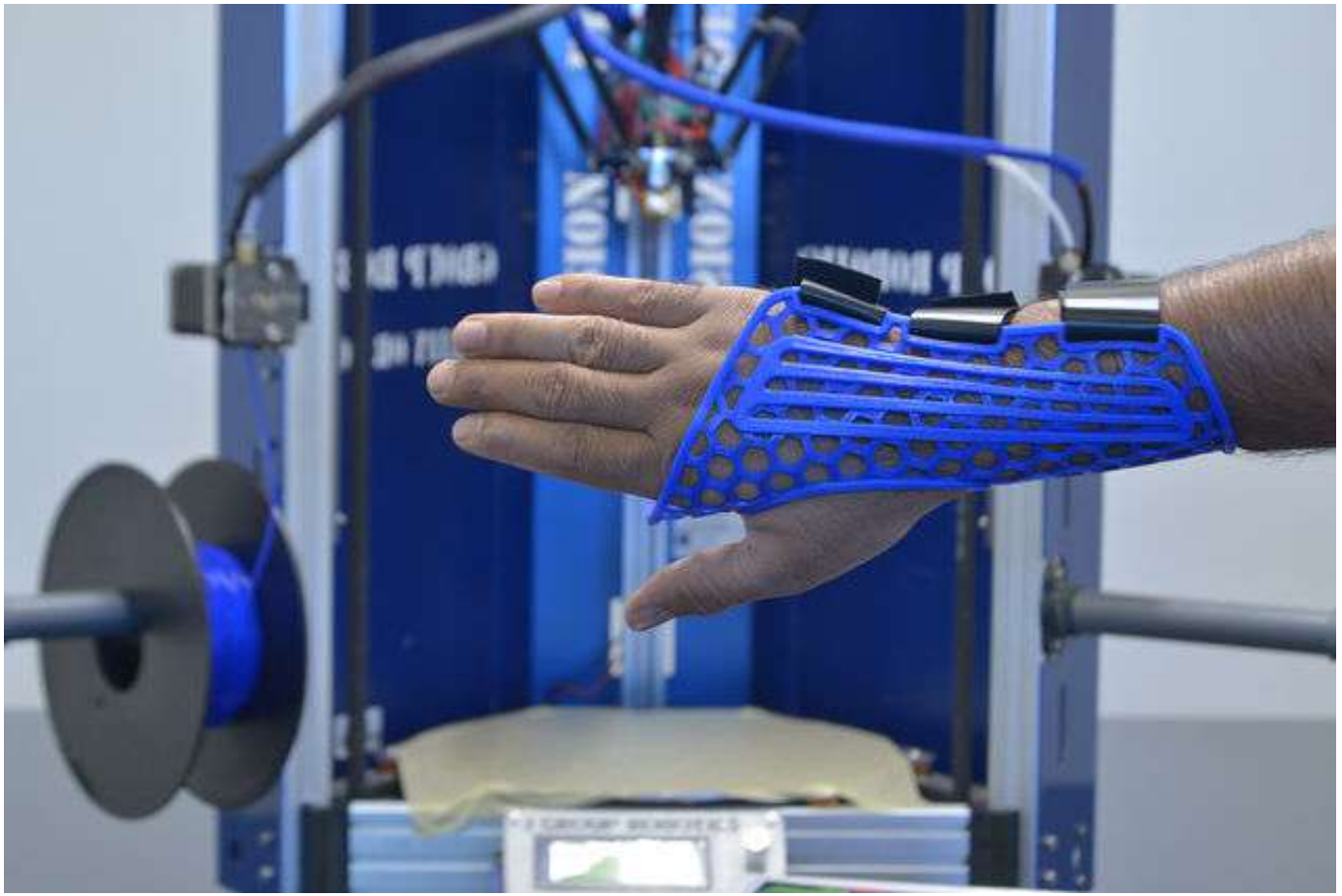
Personalized orthosis: *the 3D printing world*



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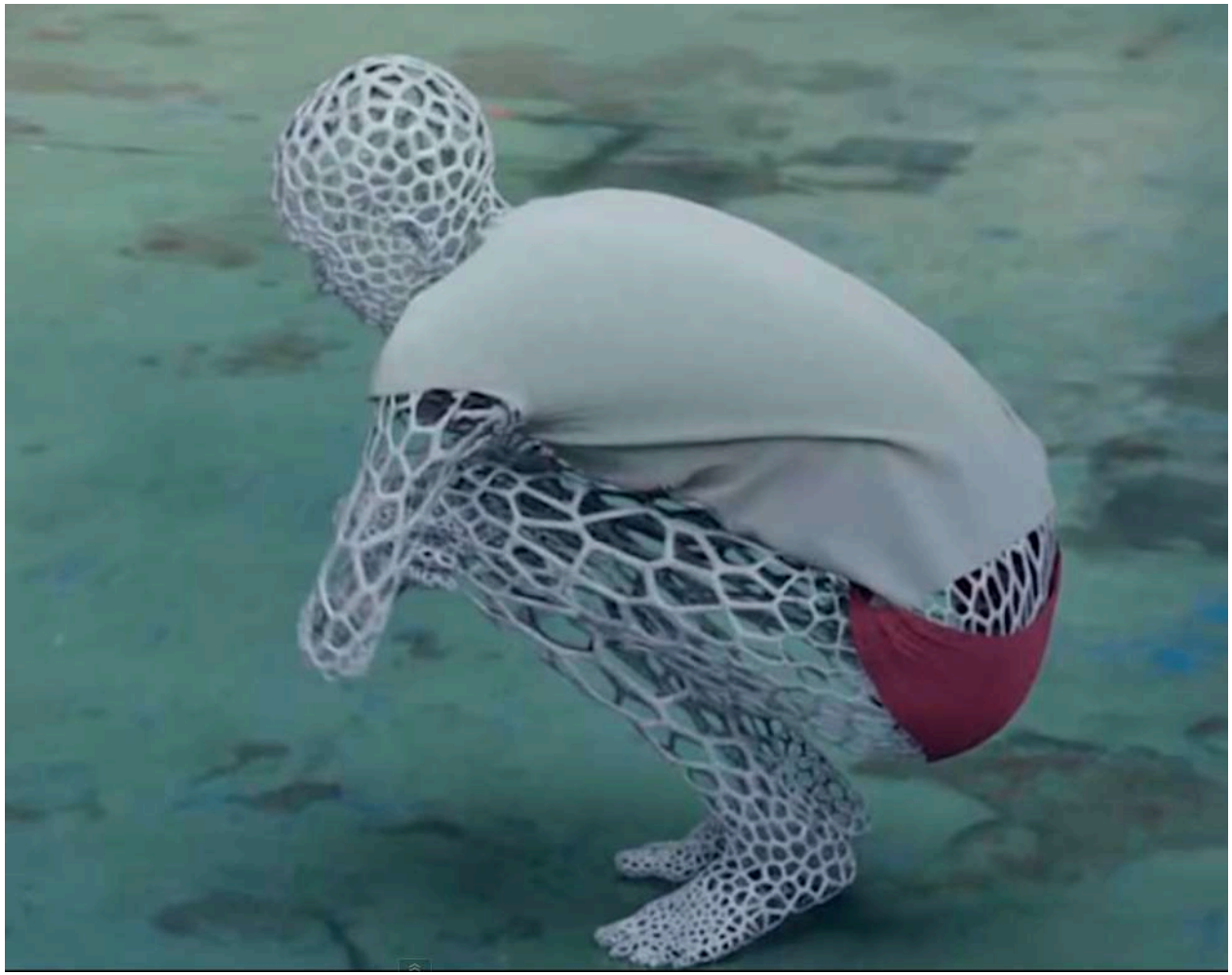
Personalized orthosis: many examples on the web

Personalized orthosis: **just 3D print it?**



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Personalized orthosis: The whole pipeline

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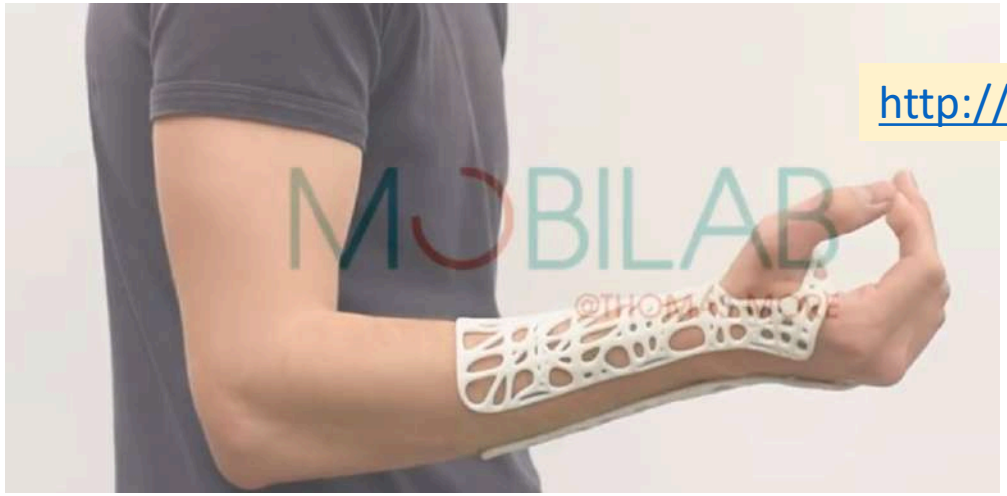
Personalized orthosis: many unaddressed issues



http://www.mobilab-research.be/efforth.html

Then why aren't these new techniques not yet adopted in the orthopaedic workshops?

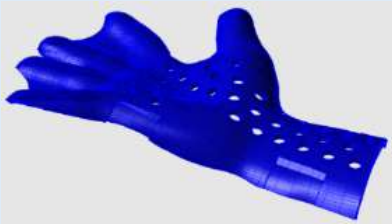
- One of the reasons for this is that **lead time, reproducibility and economic feasibility of the measuring and production processes** are not widely known.
- In addition, the **mechanical and functional properties of the final products** are not recognized for all the tools.
- Another reason is that **for some orthopaedic applications**, **intermediate steps in the process of 3D scan to printed final product are missing or inaccessible for orthopaedic businesses**.

- …we additionally found that **other main issues** also interest **the end-points** of the process: i.e. **3D anatomy scanning** and **3D printing** and **regulatory framework**

RESHAPER *reverse engineering* pipeline

Acquisition of the anatomy of the subject

Processing of the acquired geometry



3D printing of the orthosis

G. Baronio, S. Harran, and A. Signoroni, ***A critical analysis of a hand orthosis reverse engineering and 3D printing process***,
Applied Bionics and Biomechanics, 2016

[HTML] A critical analysis of a hand orthosis reverse engineering and 3D printing process

G Baronio, S Harran, A Signoroni - Applied bionics and biomechanics, 2016 - hindawi.com

The possibility to realize highly customized orthoses is receiving boost thanks to the widespread diffusion of low-cost 3D printing technologies. However, rapid prototyping (RP) with 3D printers is only the final stage of patient personalized orthotics processes. A reverse engineering (RE) process is in fact essential before RP, to digitize the 3D anatomy of interest and to process the obtained surface with suitable modeling software, in order to produce the virtual solid model of the orthosis to be printed. In this paper, we focus on the specific and …

☆ 99 Citato da 79 Articoli correlati Tutte e 9 le versioni »

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RESHAPER *issues requiring more attention and new ideas*

Acquisition of the anatomy of the subject

Acquisition of real patients involves challenging issues...

- **spasticity**: post-stroke, x-plegic subjects
- involountary/impaired **movements**

...after all **orthoses are not for healthy subjects**

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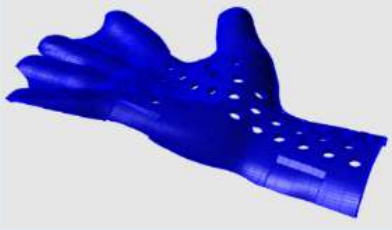
RESHAPER *issues requiring more attention and new ideas*

- Acquisition generates 3D meshes in output,
- 3D printing wants 3D meshes in input...

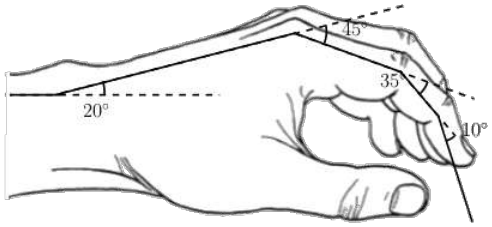
➔ we want to **avoid data domain conversions** (thus **avoiding ordinary CAD based design**)

User-driven design process entirely done in the mesh domain by setting up a dedicated **geometry processing toolbox and a versatile user interface**

Processing of the acquired geometry



We aim to introduce **added value** for clinicians (rehabilitation therapists) and enable **new kind of personalized orthosis design** and fabrication processes



New **mesh deformation approach** for **hand pose normalization and 4D orthosis design**

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RESHAPER *issues requiring more attention and new ideas*

Material selection and **3D printing**

- aware of patient **comfort** and **compliance** issues
- **mechanical properties**
- **accountability**, **medico-legal** and **device certification** aspects
- Integration with to **IoT** perspective

Various **feedbacks** toward the previous stages in terms of how the device fits patient and clinical needs

- suitable mesh accuracy for comfort
- mechanical resistance (crack tests on different materials)
- aeration patterns and aesthetics
- ...

3D printing of the orthosis

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RESHAPER Consortium

Reverse **E**ngineering of **S**elf-care and **H**ealthcare **A**ids for **P**ersonalized **E**mpowerment and **R**ehabilitation

- *University of Brescia*
  - **Information Engineering** Department
  - **Industrial and Mechanical Engineering** Dept.
  - **Justice and Law** department

  RESHAPER project co-funder

- *Open technologies Srl*

  RESHAPER project co-funder and scanning technology provider (real-timer scanner)

- *Fondazione Teresa Camplani – Casa di cura Domus Salutis*

  RESHAPER clinical partner – dott. Michele Scarazzato, dott. Luciano Bissolotti

- *Other technical/scientific contacts/collaborations*

  COOPERATIVA SOCIALE NIKOLAJEWKA - ONLUS

  PARTEC

  IDBN Italian Digital Biomanufacturing Network

  INAIL Centro Protesi

  dott. ing. Andrea Cutti

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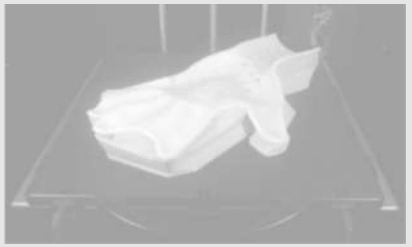
First step first... 3D hand modeling

Acquisition of the anatomy of the subject

Processing of the acquired geometry



3D printing of the orthosis

FOCUS → identification of suitable **acquisition procedures** for **3D hand modeling for both healthy and clinical subjects**

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3D Hand modeling: contact procedures

- High accuracy
- Low to moderate-cost

- Invasive methods
- Slow data collection
- Distortion of soft objects

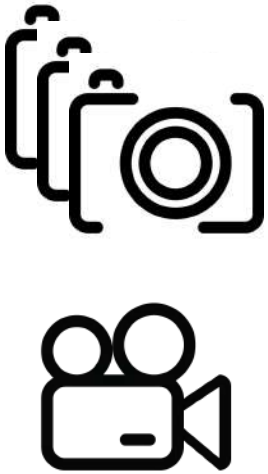
3D Hand modeling: ***non***-contact procedures

3D models

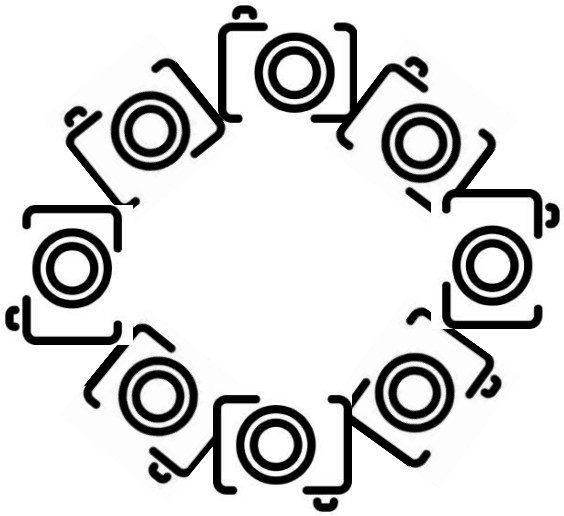
Passive systems

Active systems

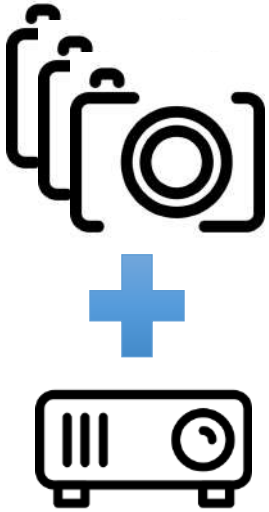
Multiple frames (SfM + MVS)



Multiview systems



Static



Real Time

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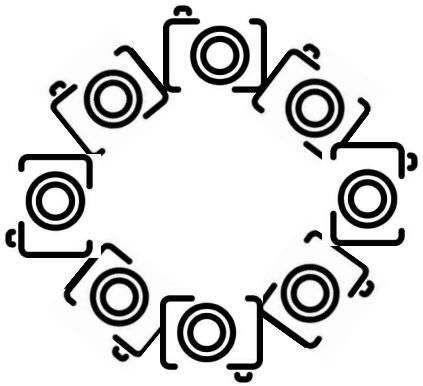
3D Hand modeling: ***non***-contact procedures

Passive systems (with possible active projection of markers)

- *Stereo-photogrammetry* → Multiple photos from different points of view and taken synchronously

  - 👍 Single shot data collection
  - 👍 No hand motion influence
  - 👎 Bulky and not easily transportable
  - 👎 Quite expensive
  - 👎 **Requires specific hand pose...**
    not feasible for many patients



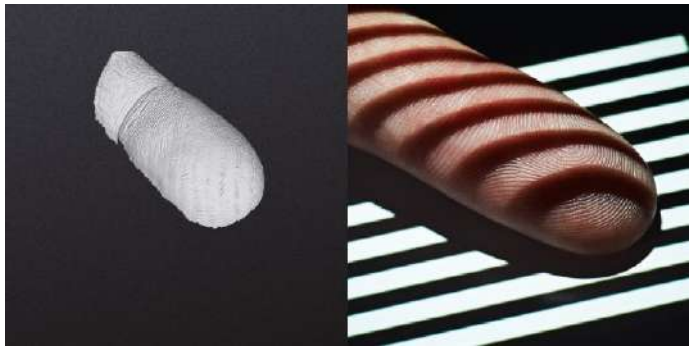
3D Hand modeling: ***non***-contact procedures

Active systems

- *Optical 3D scanner* → Use of **structured-light** to capture 3D views from different point of view to be merged in a single model

- **Acquisition flexibility**
- Incremental and controllable completion of the model with additional views
- High level of detail
- Hand held or transportable

- Acquisition can take minutes
- Expensive (with exceptions)
- **Hand motion influence** (with possible solutions)



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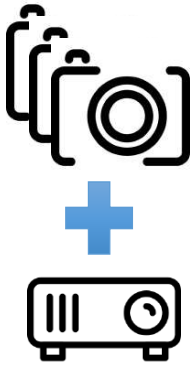
3D optical scanner comparison for hand modeling

Cronos 3D Dual, by *Open Technologies Srl*, Rezzato (BS), Italy



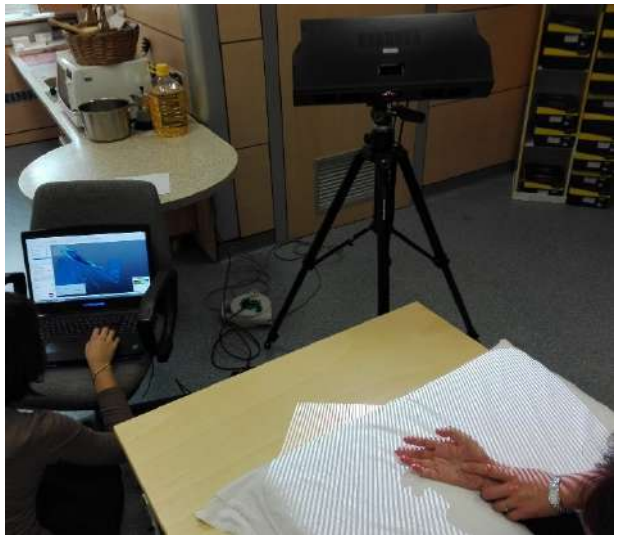
- **Static**
- used with a tripod

Insight3, by *Open Technologies Srl*, Rezzato (BS), Italy

- **Real-time**
- hand-held

Scanner technologies comparison

Cronos 3D Dual



Procedure

1. Hand positioning

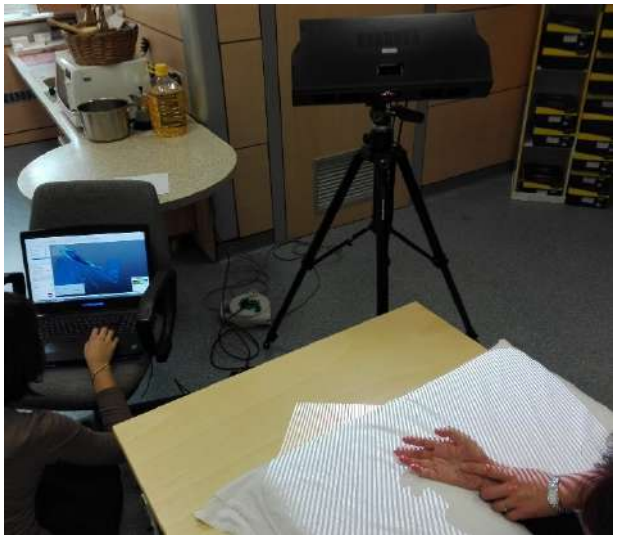
- Structured-light static scanner
- High accuracy (± 30-60 μm)
- Used on a tripod

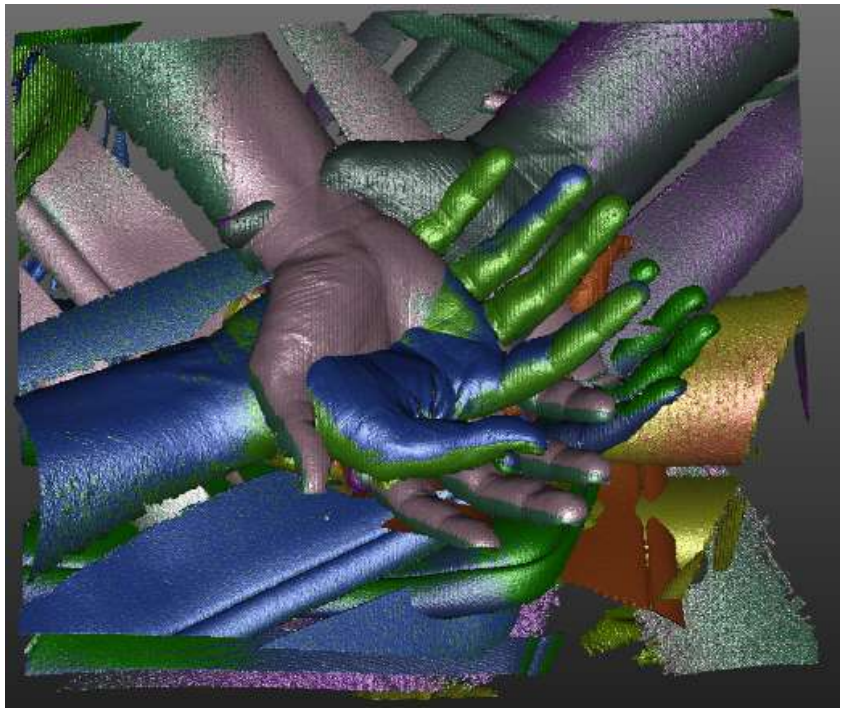
Scanner technologies comparison

Cronos 3D Dual

Procedure

1. Hand positioning
2. Acquisition from different viewpoints





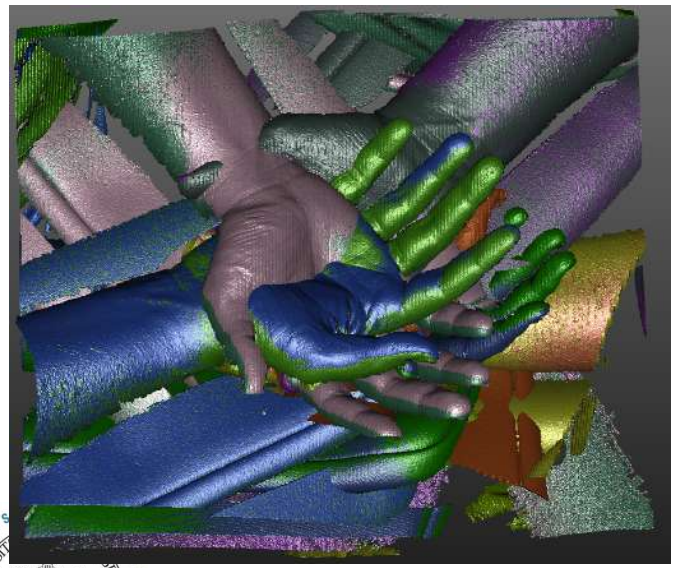
Scanner technologies comparison

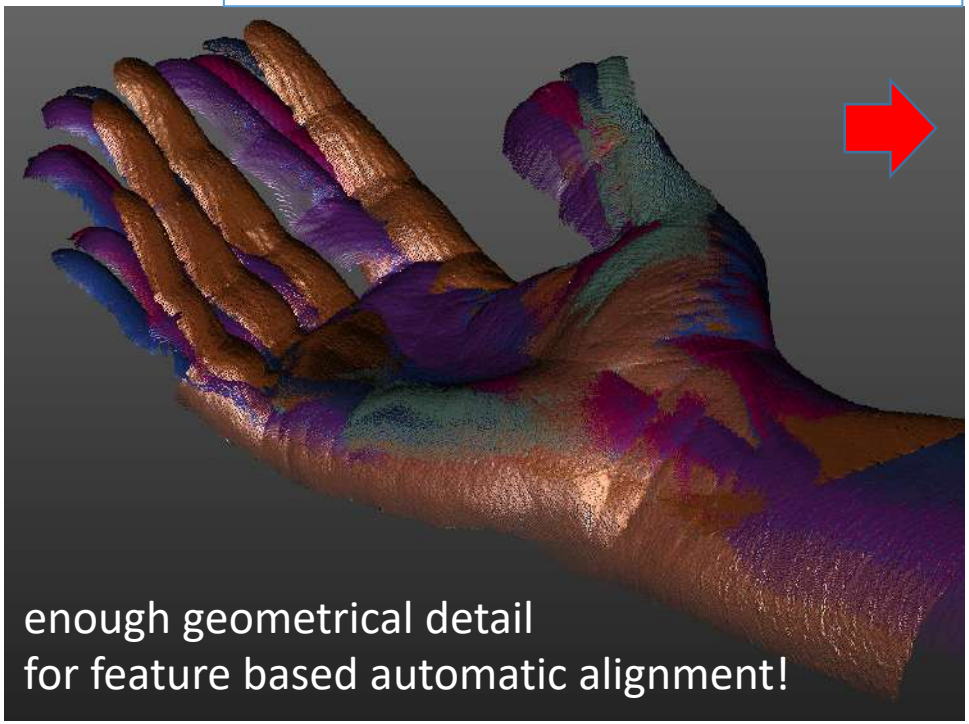
Cronos 3D Dual

Procedure

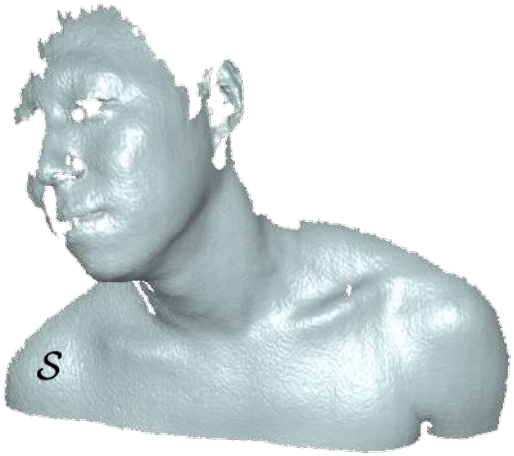
1. Hand positioning
2. Acquisition from different viewpoints
3. Automatic (3D feature based) multiview alignment

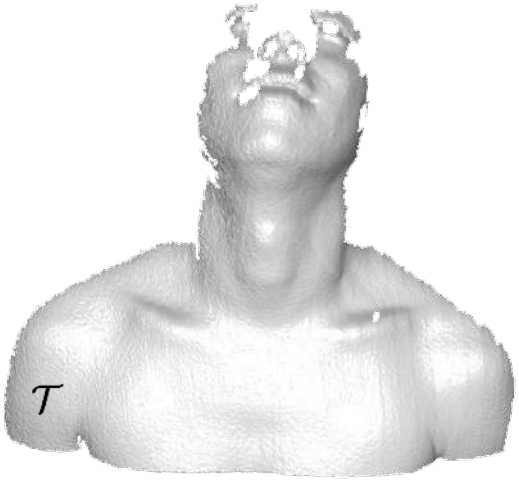
F. Bonarrigo, A. Signoroni and R. Leonardi, *A robust pipeline for rapid feature-based pre-alignment of dense range scans*, ICCV 2011



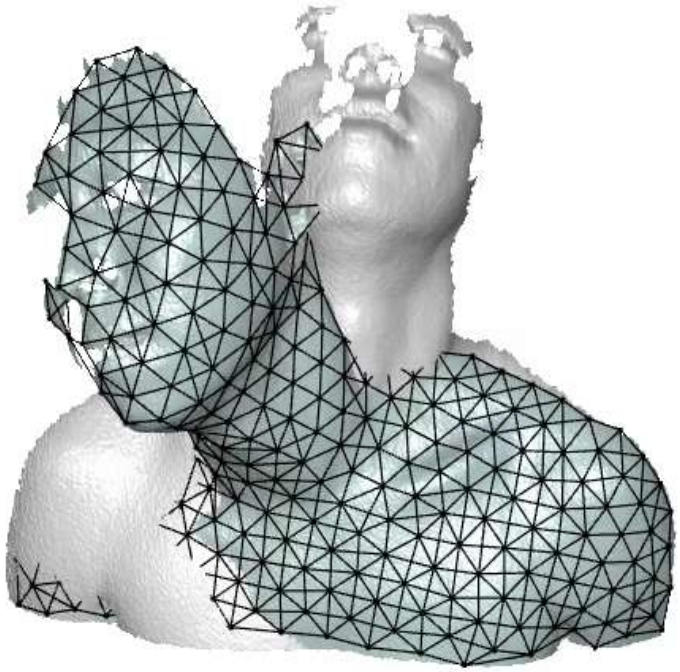


Deformable registration of “partial scans”



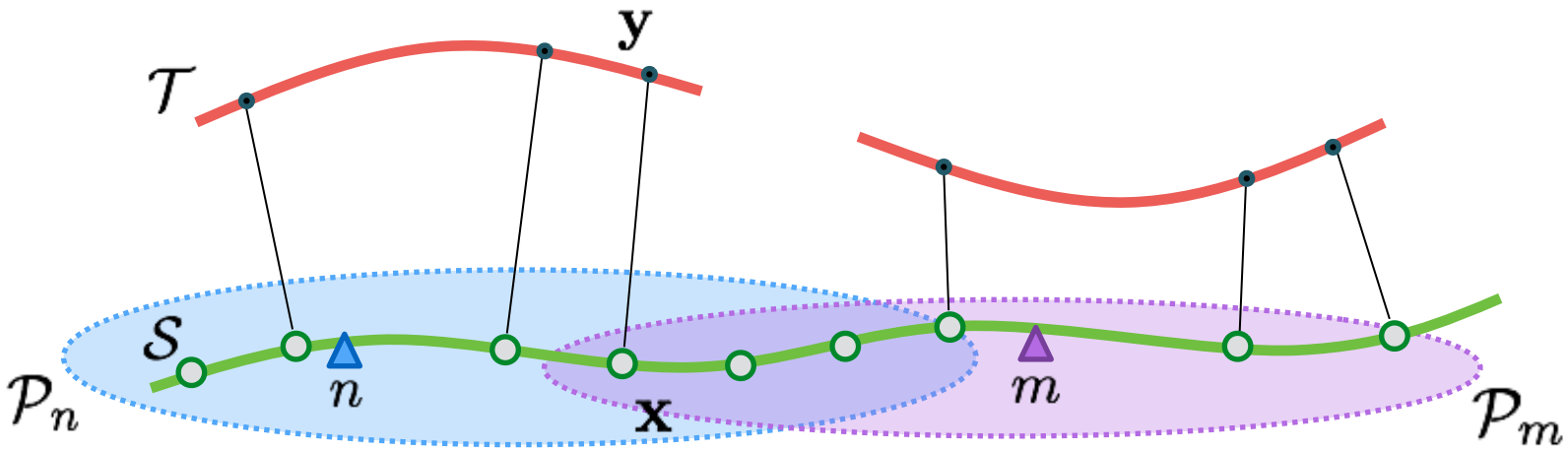


- Incomplete scan
  space deformation
- Large deformation
  nonlinear energy
- Complex geometry
  node subsampling
- Deform detailed scan
  interpolate node transforms



Deformable Registration
as-rigid-as-possible patch alignment

F. Bonarrigo, A. Signoroni and M. Botsch, *Deformable registration using patch-wise shape matching*, Graphical Models, 2014



$$E_{\text{fit}} = \sum_{n \in \mathcal{N}} \sum_{(\mathbf{x},\mathbf{y}) \in \mathcal{C}_n} \frac{\|\mathbf{R}_n\mathbf{x} + \mathbf{t}_n - \mathbf{y}\|^2}{|\mathcal{N}| \cdot |\mathcal{C}(n)|}$$

displacement penalty

$$E_{\text{def}} = \sum_{n \in \mathcal{N}} \sum_{m \in \mathcal{N}} \sum_{\mathbf{x} \in \mathcal{P}_n \cap \mathcal{P}_m} \frac{\|\mathbf{R}_n\mathbf{x} + \mathbf{t}_n - \mathbf{R}_m\mathbf{x} - \mathbf{t}_m\|^2}{|\mathcal{N}| \cdot |\mathcal{N}| \cdot |\mathcal{P}_n \cap \mathcal{P}_m|}$$

transform discrepancy penalty

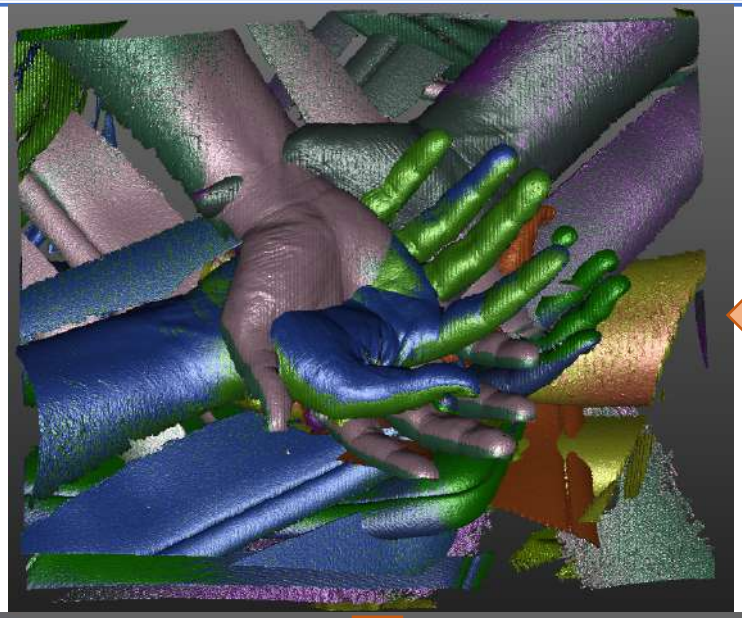
$$E_{\text{total}} = (1 - \lambda) \cdot E_{\text{fit}} + \lambda \cdot E_{\text{def}}$$

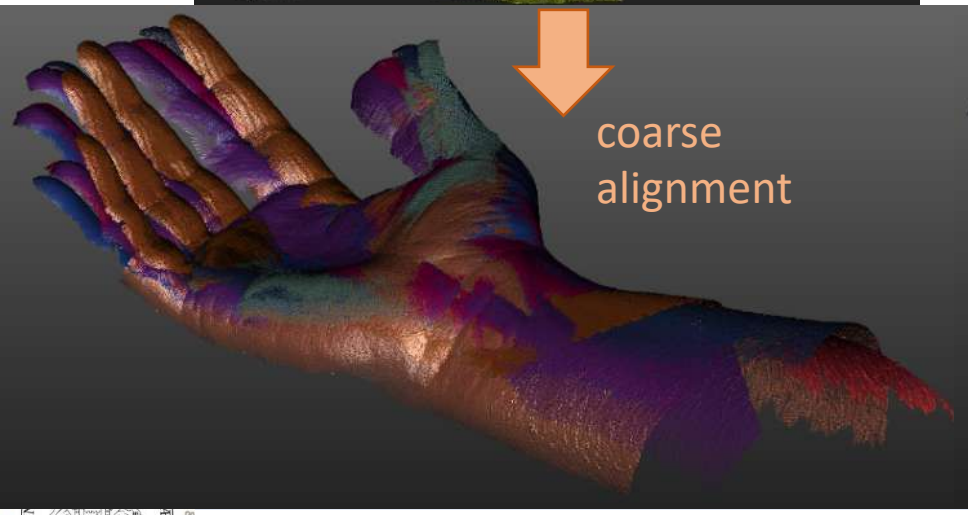
Deformable Registration
as-rigid-as-possible patch alignment

F. Bonarrigo, A. Signoroni and M. Botsch, *Deformable registration using patch-wise shape matching*, Graphical Models, 2014

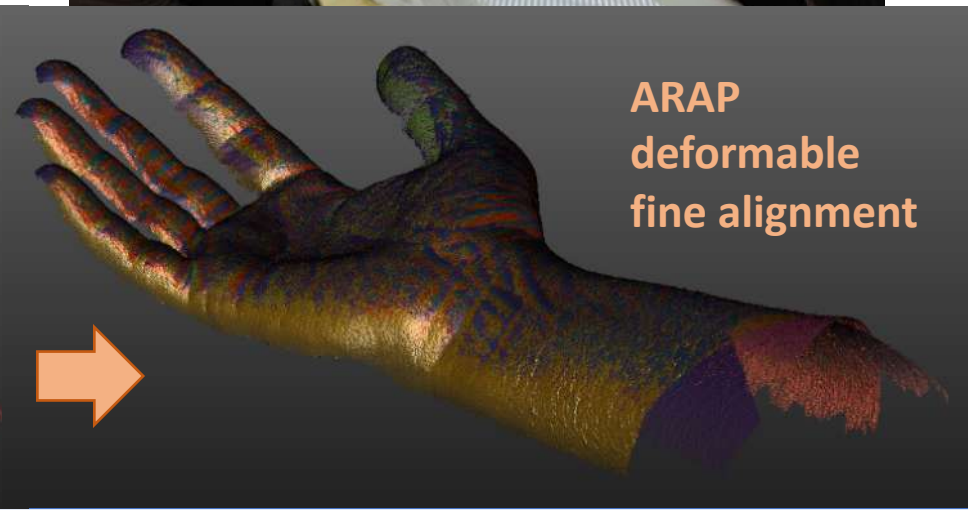
Iter = 10

Deformable Registration
ARAP alignment: **Hand Motion Compensation**



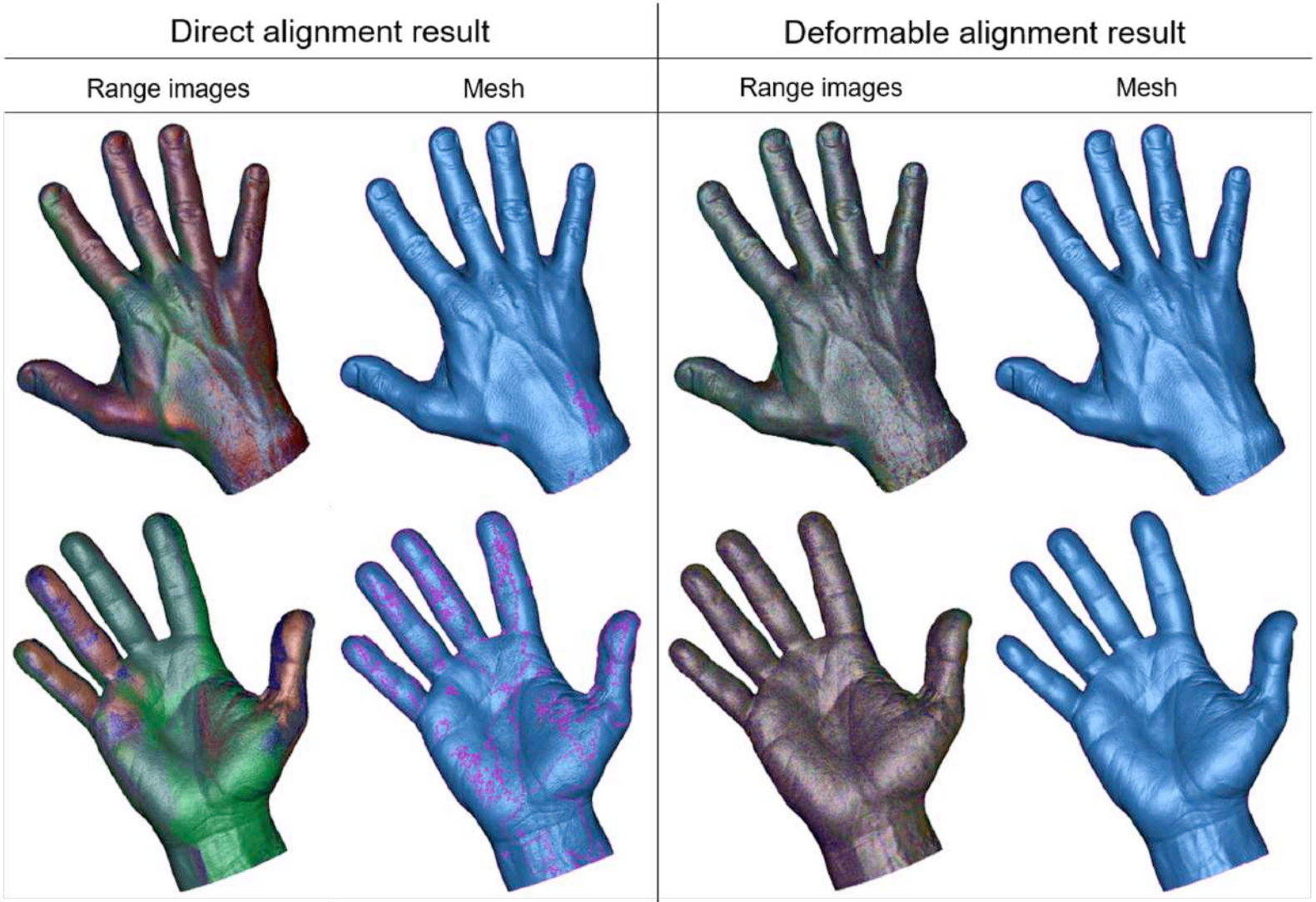


coarse
alignment



ARAP
deformable
fine alignment

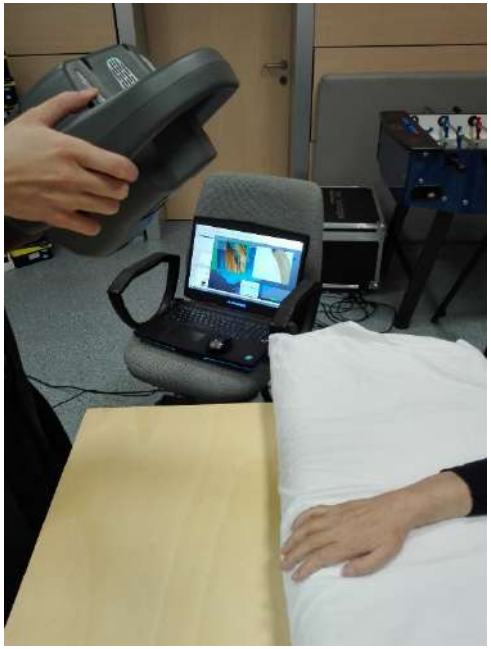
Deformable Registration
ARAP alignment: Hand Motion Compensation



Scanner technologies comparison

Insight3

- Real-time scanner (like a video-camera)
- Fixed structured-light technology (infrared range)
- Lower accuracy (± 0.25-0.5 mm)
- *Markerless* frame tracking



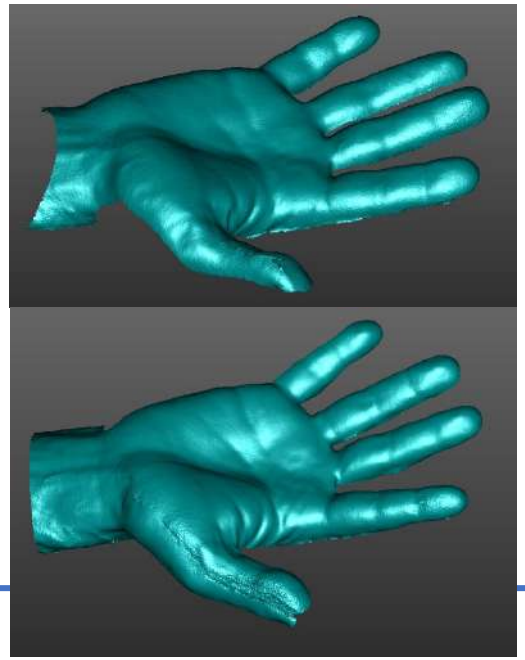
Scanner technologies comparison

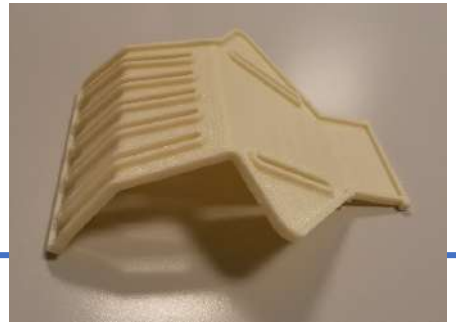
Insight3

Use or better design (as we are doing) of suitable and comfortable pose maintenance devices

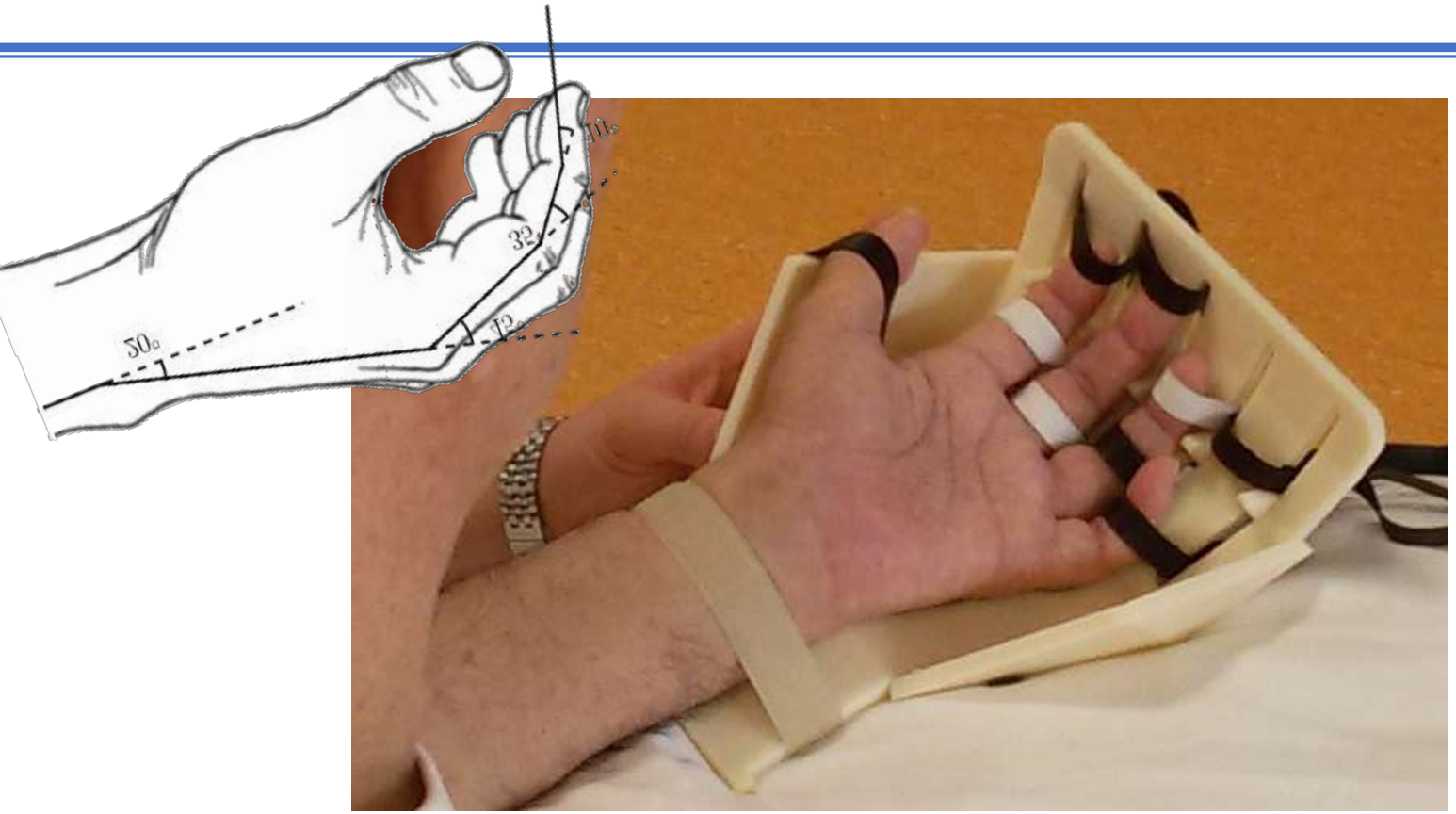
Procedure

1. Hand positioning
2. Scanner is moved slowly and smoothly around the geometry to be scanned
3. Real-time visual feedback (Optical RevEng software, Open Technologies Srl)
4. Influence of subject movements → immobilization needed





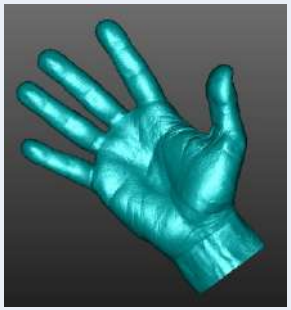
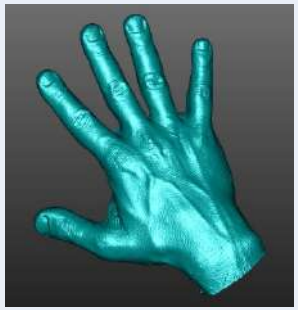
Hand-holding device



- our first 3D printed holding device in action on a post-stroke patient
- designed starting from anatomical landmarks and clinical parameters
- it allows acquiring enough anatomy to drive the orthosis design
- can be used also for dorsal side acquisition

Practical tests

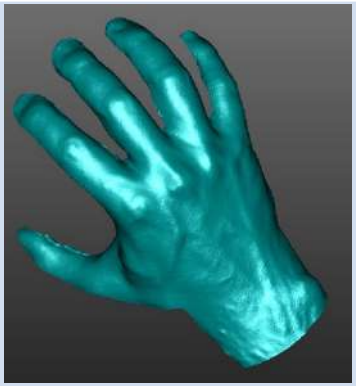
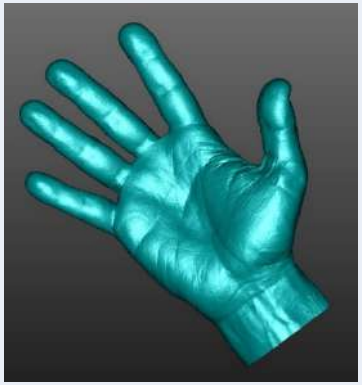
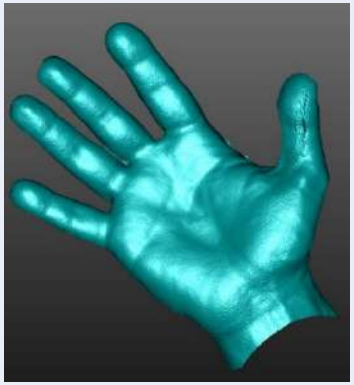
Experiments are a combination of:

Scanner		Scanned surface		Target	
Static	Real-time	Palmar side	Dorsal side	Volunteer	Patient
					

Aspects of major interest:

- Ease of use
- Total acquisition time
- Completeness and accuracy of the final geometry

Volunteers' hands

	STATIC SCANNER • 8 views • < 3 min • Deformable alignment needed	REAL-TIME SCANNER • ~ 1 min • Slight thumb movement in palmar side
Dorsal side		
Palmar side		

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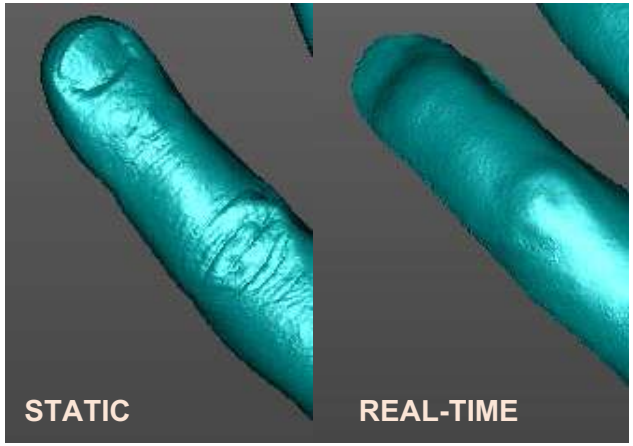
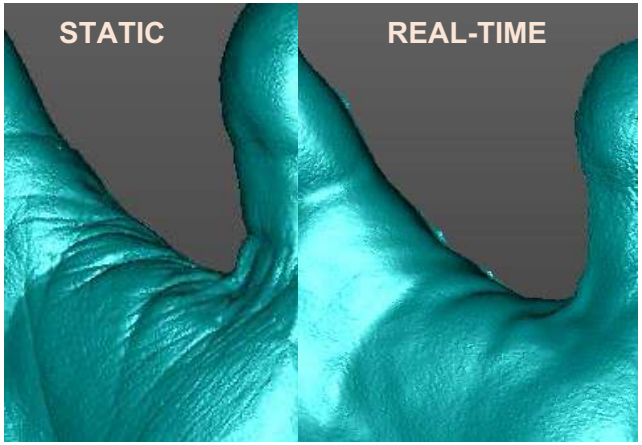
Considerations

Hand/fingers **scanning** for orthotic application is totally **suitable** with both scanner technologies.

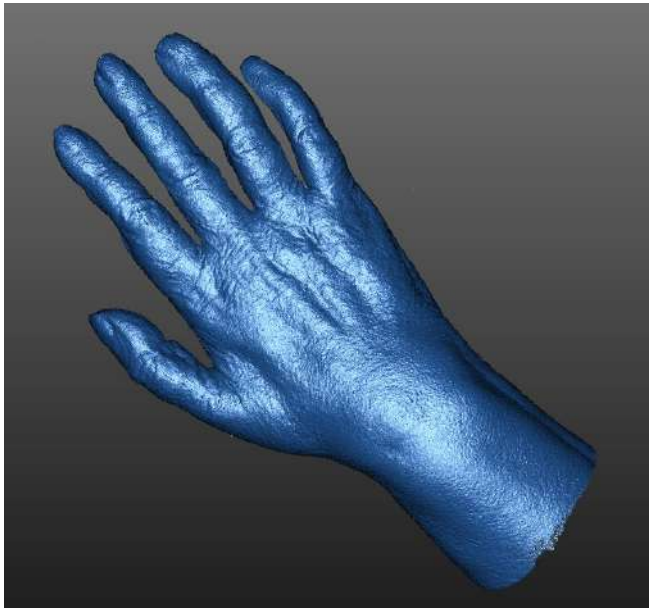
	Static scanner	Real time scanner
Acquisition time	+	+++
Comfort for the patient	++	+++
Movements influence	++	+
Level of detail of the mesh	+++	++





Patients' hands – dorsal side

Low spasticity → easy scanning and good results



Static scanner:

- 7 views
- ~ 4 min
- Deformable alignment not needed

Real-time scanner:

- ~ 2 min
- No movement artefacts

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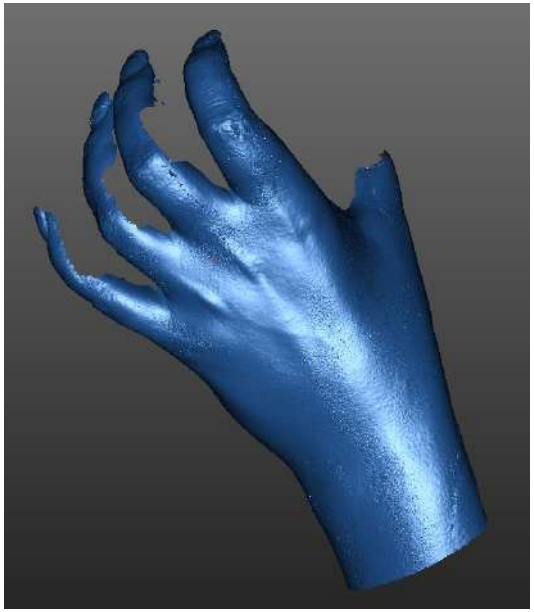
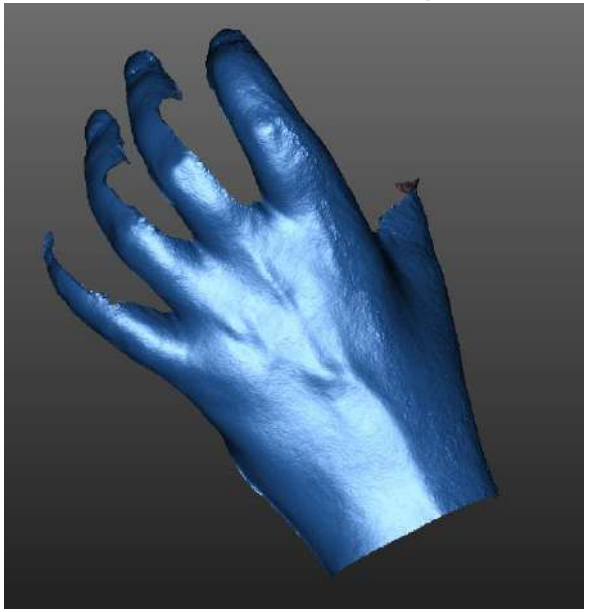
Patients' hands – dorsal side

- Low spasticity → easy scanning and good results
- Greater spasticity → use of immobolization splint → some lacking area



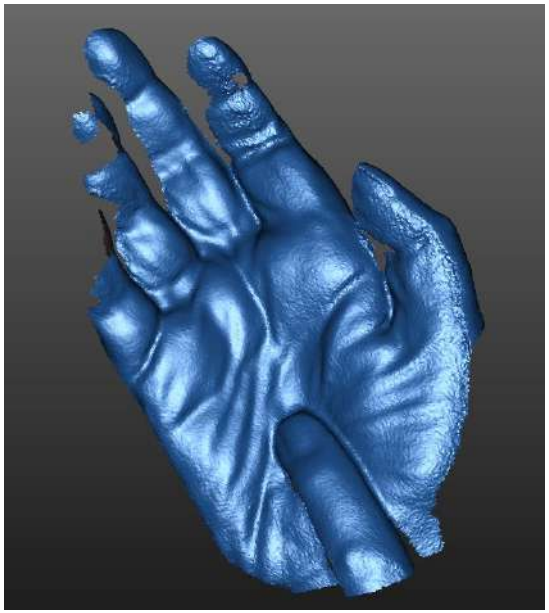
Static scanner:
- 12 views
- ~ 3 min
- Deformable alignment not needed



Real-time scanner:
- ~ 2 min 30 s
- No movement artefacts

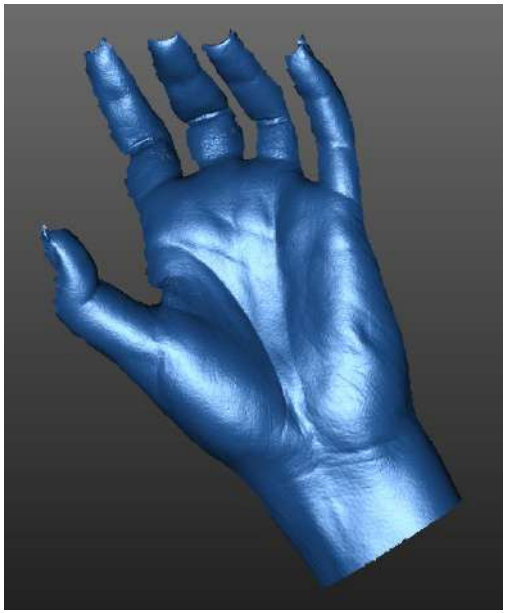
Patients' hands – palmar side

Problematic aspect: hand tends to close



Real-time scanner:

- ~ 2 min
- Visible thumb movements



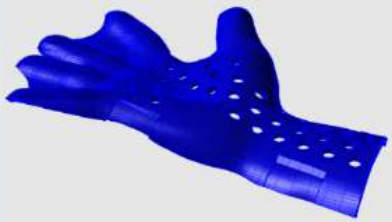
Static scanner:

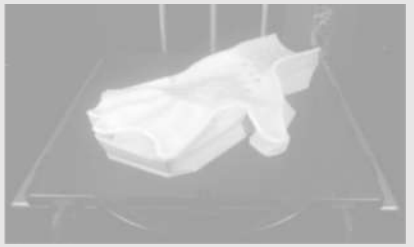
- 10 views
- ~ 3 min
- Deformable alignment needed

Second step... 3D hand “processing”

Acquisition of the anatomy of the subject

Processing of the acquired geometry





3D printing of the orthosis

FOCUS 1 → ***from the hand scanning to the orthesis***

FOCUS 2 → ***virtual deformable manipulation*** **and 3D model corrections for customizable and progressive therapy**

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FOCUS1: From the hand scanning to the orthesis

- Two possible ways

Personalized orthosis by device adaptation

1) Standard orthosis
2) Hand scanning
3) Size fit and adaptation

Personalized orthosis directly from the anatomy

1) Hand scanning
2) Direct mesh processing
3) Device production

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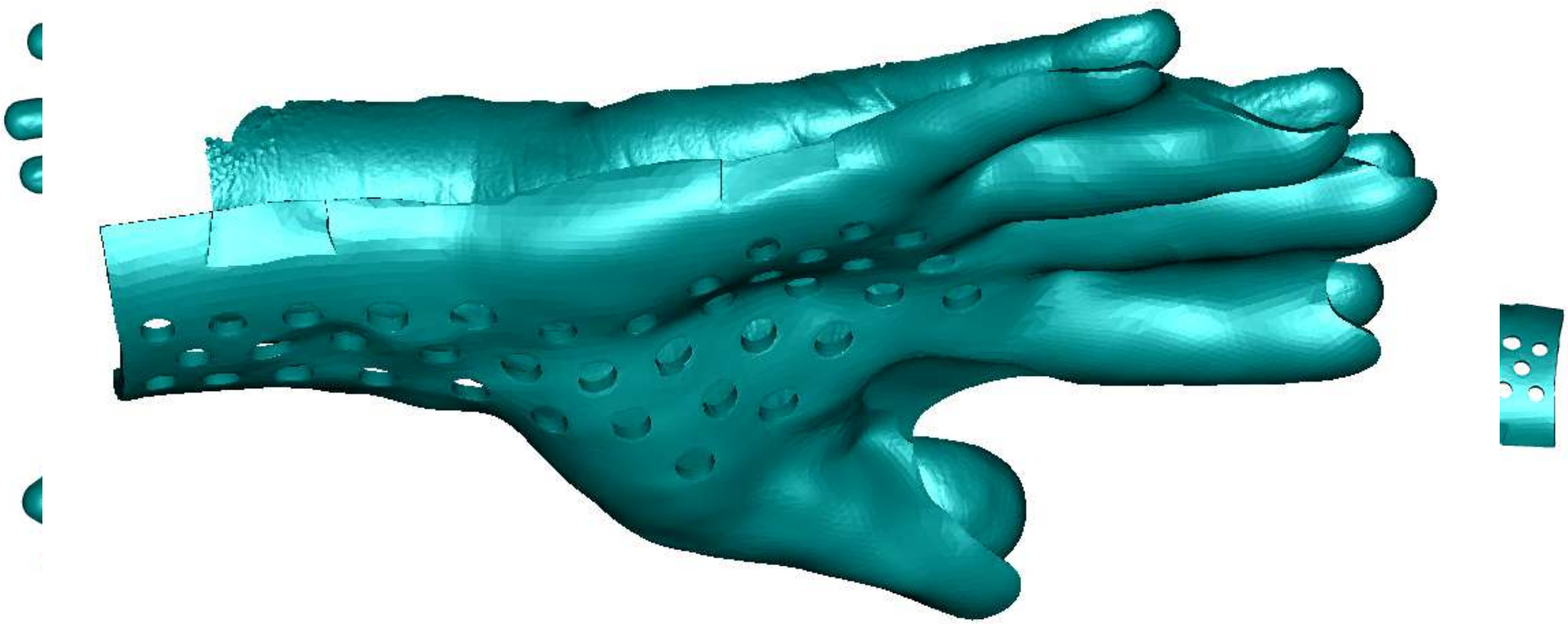
Personalized orthosis by device adaptation

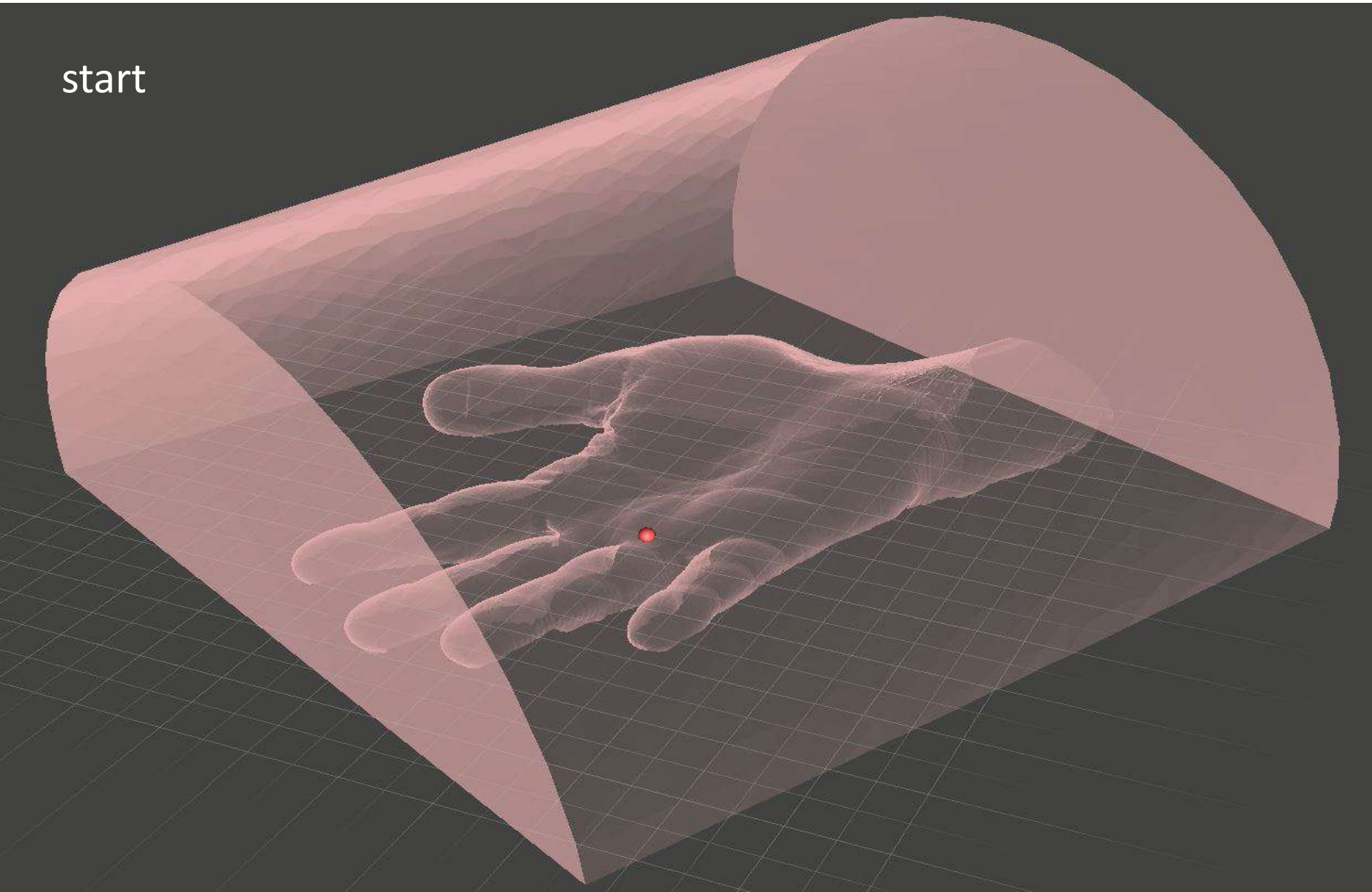
WRAPPING (i.e. deformation, see next focus):

STILL WORK IN PROGRESS

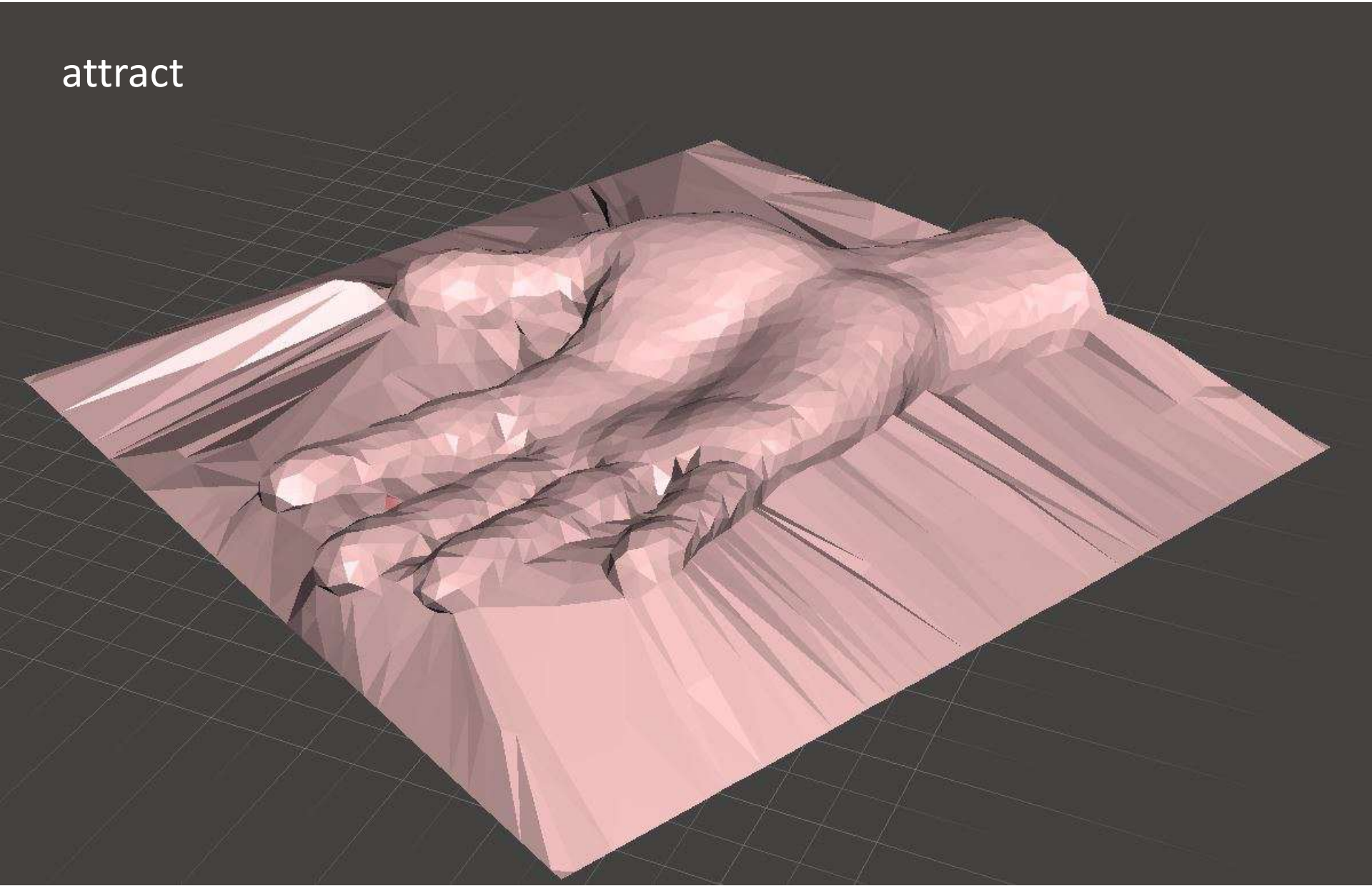
for adapting a mesh over another one



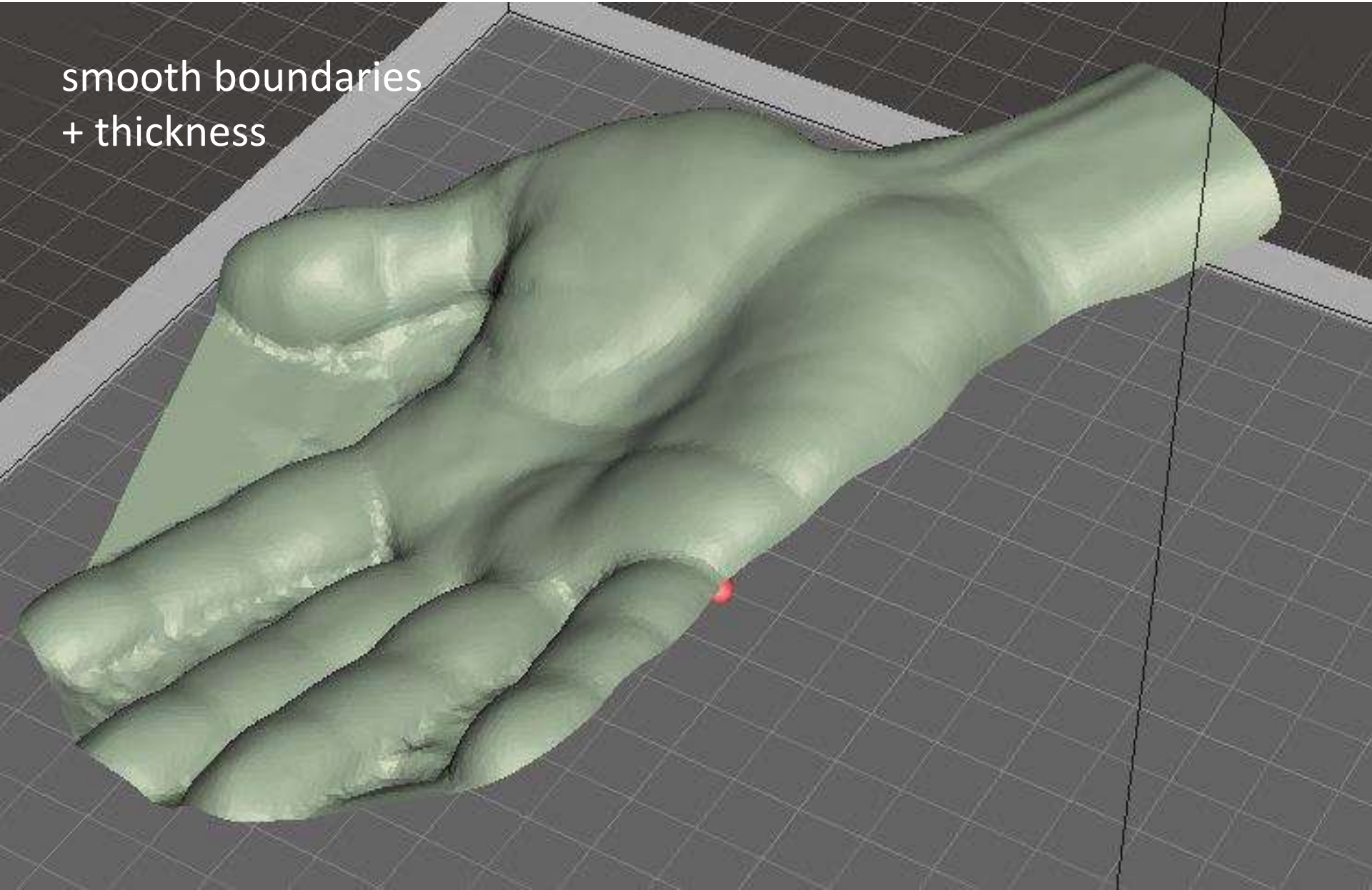
Personalized orthosis directly from the anatomy



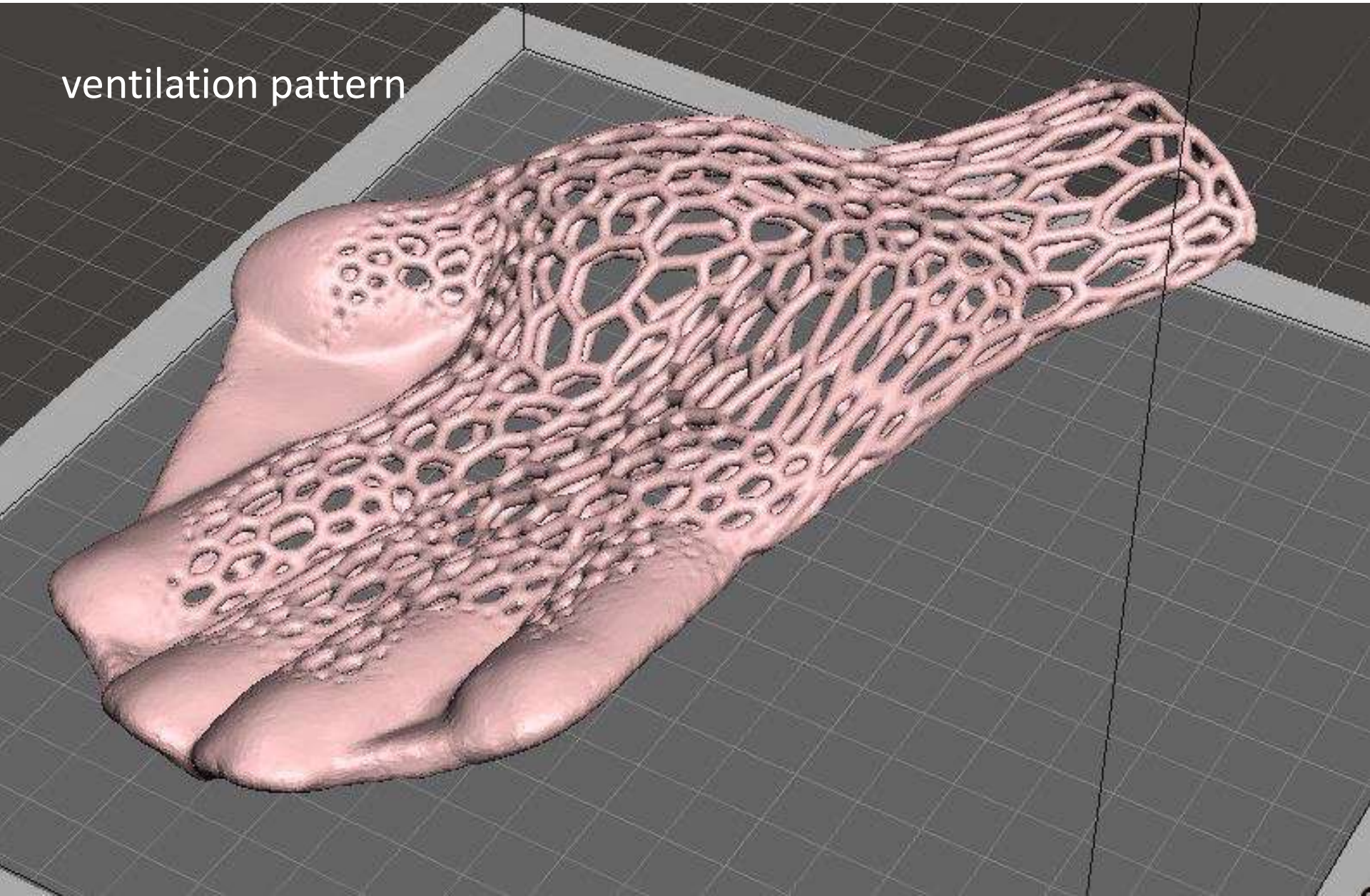
Personalized orthosis directly from the anatomy



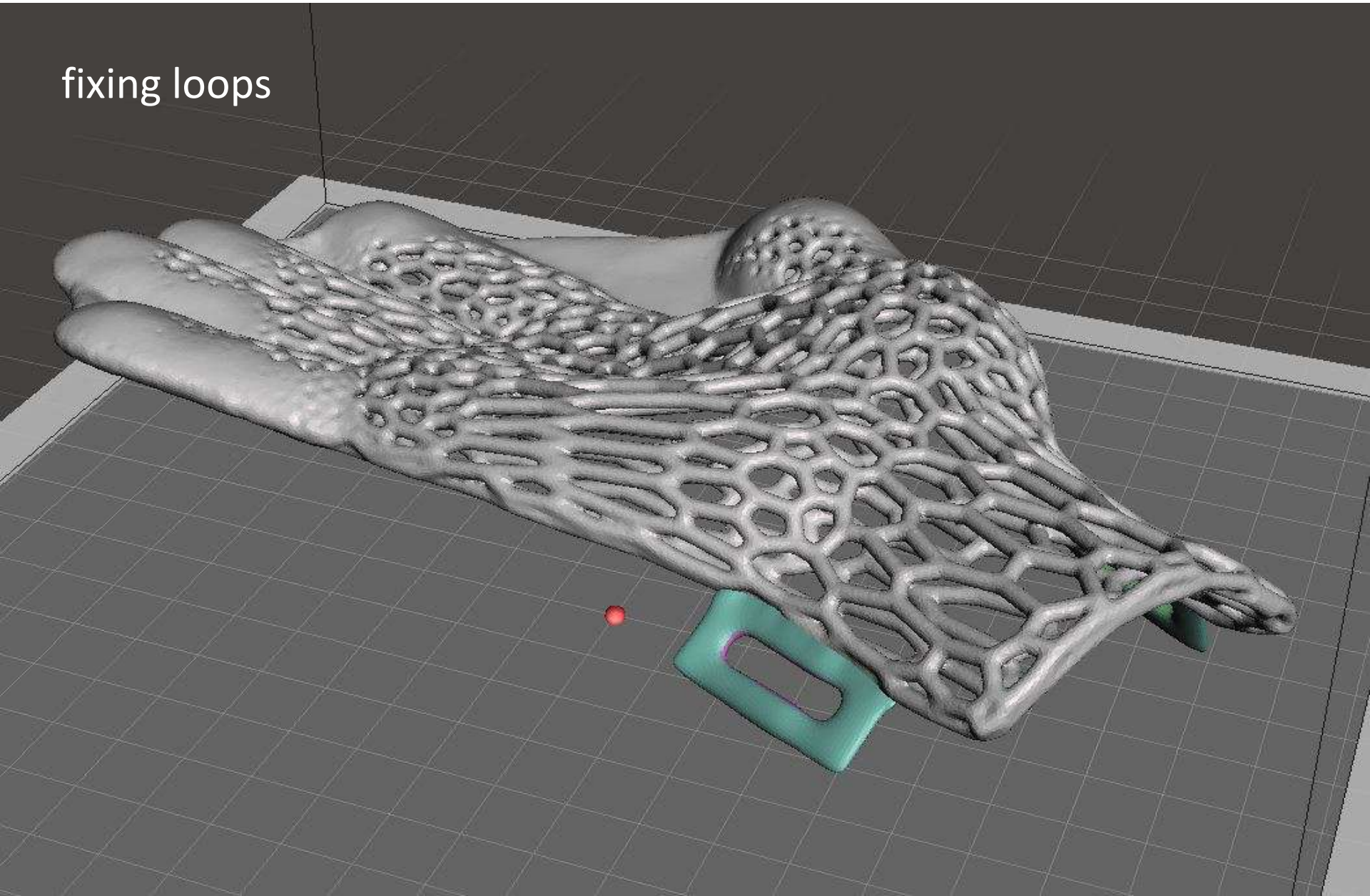
Personalized orthosis directly from the anatomy



Personalized orthosis directly from the anatomy

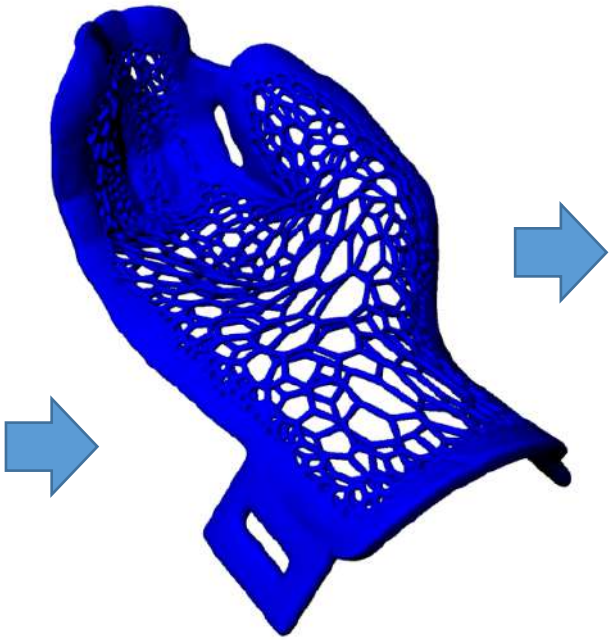


Personalized orthosis directly from the anatomy

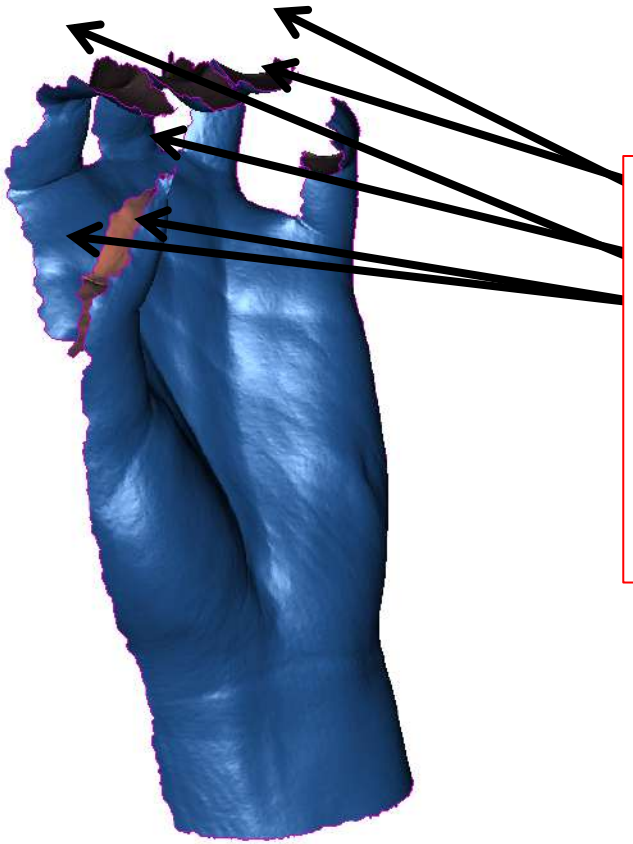


Personalized orthosis directly from the anatomy

Processo **Reverse Engineeering**/**Rapid Prototyping** complessivo



FOCUS2 hand deformation and progressive 4D design



need to “move” fingers to correct the initial posture and/or design a set of orthoses that evolves with time for a progressive therapy

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Deformation - Motivations

Why deformation?

1. Patient difficulties to keep the hand in a good position

2. Need to plan a progressive therapy

MESH Deforma[illegible] Graph

INPUT

OUTPUT

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MESH Deformation – Performance

		ARAP	SR-ARAP	OUR METHOD
Hulk (1.4M)	PRE-PROCESSING	50s	60s	13s
	100 ITERATIONS	~670s	~600s	2.2s

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MESH Deformation – Performance

		ARAP	SR-ARAP	OUR METHOD
David (507k)	PRE-PROCESSING	FAIL	FAIL	3.6s
	100 ITERATIONS	---	---	1.7s

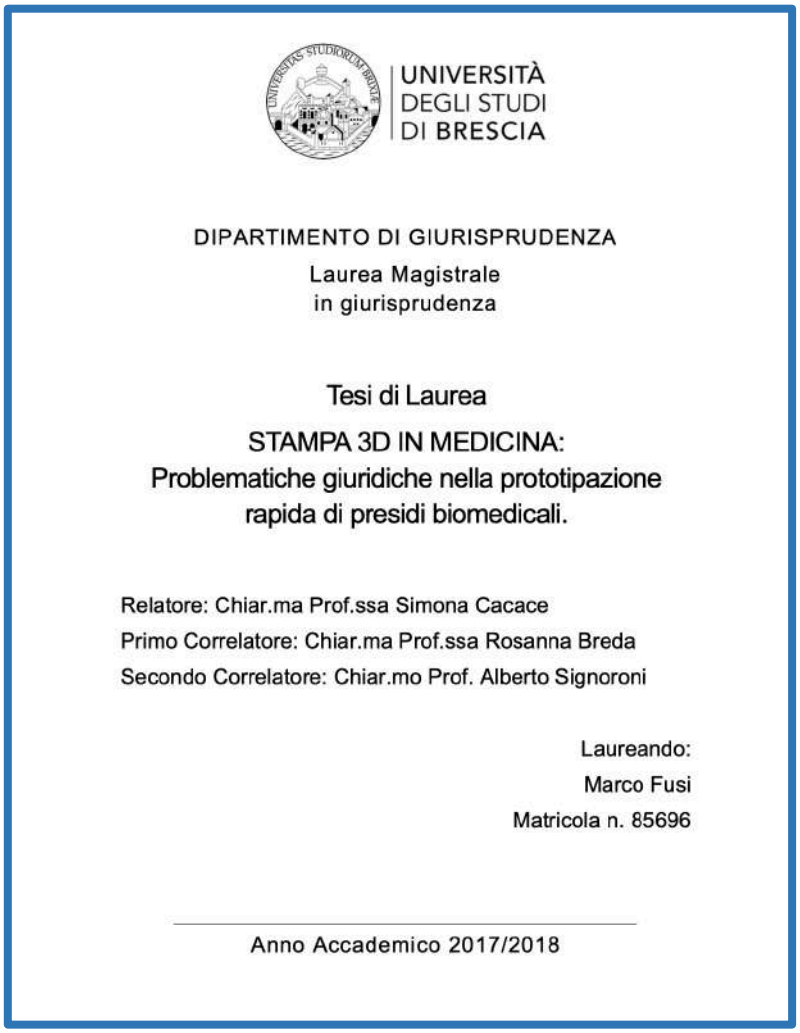
MESH Deformation – Performance

		ARAP	SR-ARAP	OUR METHOD
Dragon (3.6M)	PRE-PROCESSING	128s	120s	36s
	100 ITERATIONS	~98000s	~8000s	5s

MESH Deformation – Clinical example

1. From resting pose to the target pose
2. From target pose to the resting pose

Regulatory/certification framework and issues



UNIVERSITÀ DEGLI STUDI DI BRESCIA

DIPARTIMENTO DI GIURISPRUDENZA

Laurea Magistrale
in giurisprudenza

Tesi di Laurea

STAMPA 3D IN MEDICINA:
Problematiche giuridiche nella prototipazione rapida di presidi biomedicali.

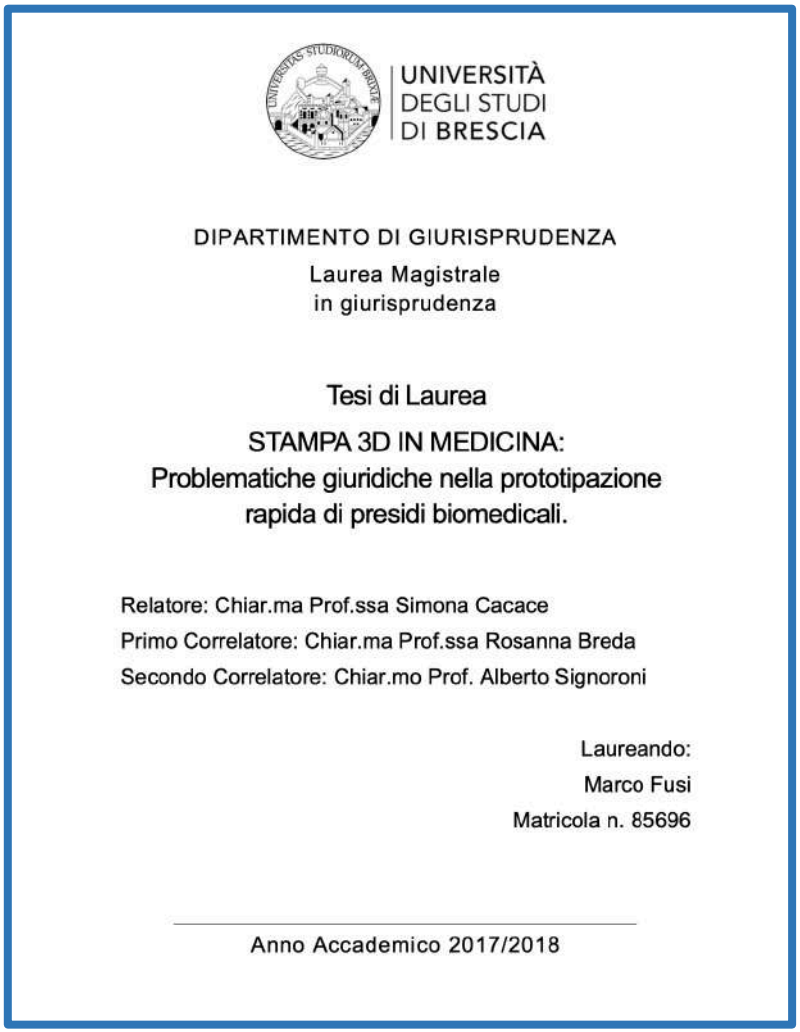
Relatore: Chiar.ma Prof.ssa Simona Cacace
Primo Correlatore: Chiar.ma Prof.ssa Rosanna Breda
Secondo Correlatore: Chiar.mo Prof. Alberto Signoroni

Laureando:
Marco Fusi
Matricola n. 85696

Anno Accademico 2017/2018

- **Assenza di regolamentazione specifica**: norma strutturata per il DM di produzione tradizionale;
- Direttiva 93/42 CEE: "**I *DM stampati in 3D rientrano nella categoria Custom Made***: *il fabbricante deve attenersi alla procedura prevista all'allegato VII e redigere, prima dell'immissione in commercio di ciascun dispositivo, la dichiarazione prevista in tale allegato"* ;
- 2015: parere d'iniziativa 2015/C 332/05*: "il quadro normativo europeo e nazionale non è stato in grado di tenere il passo con la rapida evoluzione della produzione additiva. Per questo motivo* ***serve una normativa specifica, soprattutto in materia di standard e certificazioni, di proprietà intellettuale, protezione dei consumatori, salute e sicurezza sul luogo di lavoro e ambiente****"*;
- **Nuovo regolamento europeo in materia di DM ma nessuna specifica disciplina per i DM stampati in 3D**. 2015, iniziativa NET: la CE ha creato un gruppo d'interesse europeo in materia di 3D *printing* in campo biomedicale, il cui obiettivo è la predisposizione di un *white paper* per rappresentare ai legislatori europei i principali problemi connessi alla stampa 3D dei dispositivi medici, di supporto ai legislatori nazionali in sede di applicazione del nuovo regolamento sui DM.

Regulatory/certification framework and issues



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Anno Accademico 2017/2018

Normativa: non esiste normativa ad hoc per l'utilizzo/certificazione della stampa 3D come dispositivo medico e neppure sul bioprinting.

Responsabilità sul prodotto stampato 3D: quali errori e quali conseguenze?

- errori nella progettazione o modellazione; nel formato dati; nel software; nel processo di produzione.

Brevetti: Appare necessaria una precisa regolamentazione relativa all'inclusione e all'esclusione dalla tutela brevettuale delle parti del corpo stampate in 3D.

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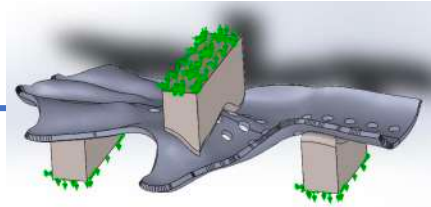
(some) Conclusion about 3D scanning and geometry processing

- Both scanner allow the acquisition of hand anatomy for orthotic application
- Patient's movement influence is limited
  - Can be compensated in the case of static scanners
  - Design of supports to facilitate position maintenance
- Hand mesh deformation enable new 4D orthotic reabilitation paradigms (still to test on patients)

In the **future**... translation to the clinic

- Hand geometry **user interface** using **mesh editing** tools to design the final **personalized orthosis**
- **FEM analysis** of 3D printed hand orthoses
- Digitization in the **prosthetics** field



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Publications

- **Journal papers**
  - Baronio G, Harran S, Signoroni A *A critical analysis of a hand orthosis reverse engineering and 3D printing process*. Applied bionics and biomechanics 2016
  - Baronio G, Volonghi P, and Signoroni A, *Concept and design of a 3D printed support to assist hand scanning for the realization of customized orthosis*, Applied Bionics and Biomechanics, 2017
  - Volonghi P, Baronio G, Signoroni A, *3D scanning and geometry processing techniques for customised hand orthotics: an experimental assessment*, Virtual and Physical Prototyping, 2018
  - Centin M, Signoroni A, *Advancing mesh completion for digital modeling and manufacturing*, Computer Aided Geometric Design 2018

- **Conference papers**
  - Baronio G, Cacace S, Centin M, Marco F, Morsucci A, Signoroni A, Volonghi P, "*Ortesi personalizzate: digitalizzazione e processing del dato anatomico come prima fase del progetto RESHAPER*", Congresso IDBN, 25-26 Maggio 2017, Bologna.
  - Volonghi P, Signoroni A, Baronio G, *3D scanning for hand orthotic applications: a comparative assessment between static and real time solutions*, 7th international conference and exhibition on 3D body scanning technologies, Lugano, 30 Nov – 1 Dec 2016. Doi:10.15221/16.061.
  - A Morsucci, M Centin, A Signoroni, *Fast Centroidal Deformation for Large Mesh Models*. Smart Tools and Applications for Graphics STAG 2018, 97-106

Thank you ☺

UNIVERSITÀ DEGLI STUDI DI BRESCIA

RESHAPER: Reverse Engineering of Self-care and Healthcare Aids for Personalized Empowerment and Rehabilitation

open technologies
Optical 3D Scanner

Fondazione Teresa Camplani
Casa di Cura DOMUS SALUTIS

brixia accessibility lab
Accessibility to Cultural Heritage & Wellbeing

IDBN
Italian Digital Biomanufacturing Network

INAIL Centro Protesi

PARTEC

Cooperativa Sociale NIKOLAJEWKA - ONLUS

Alberto SIGNORONI[1], Marco CENTIN[1], Andrea MORSUCCI[1], Paola VOLONGHI[1],

Gabriele BARONIO[2],

Simona CACACE[3], Marco FUSI[3]

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[2] ***Dipartimento di Ingegneria Meccanica e Industriale***,

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