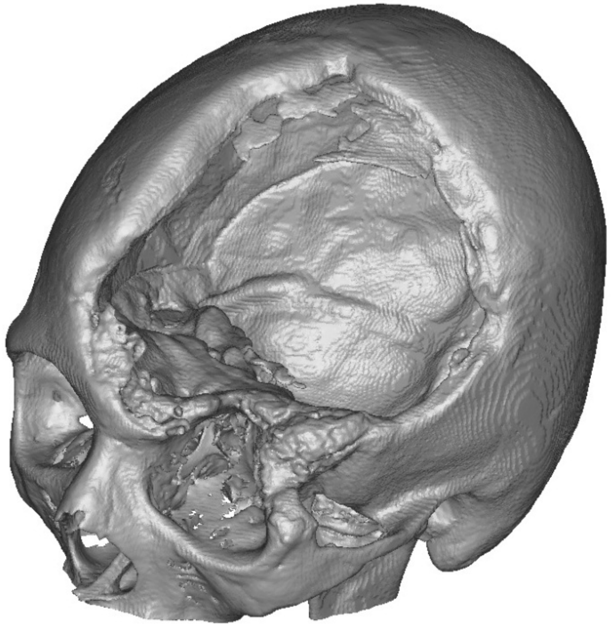
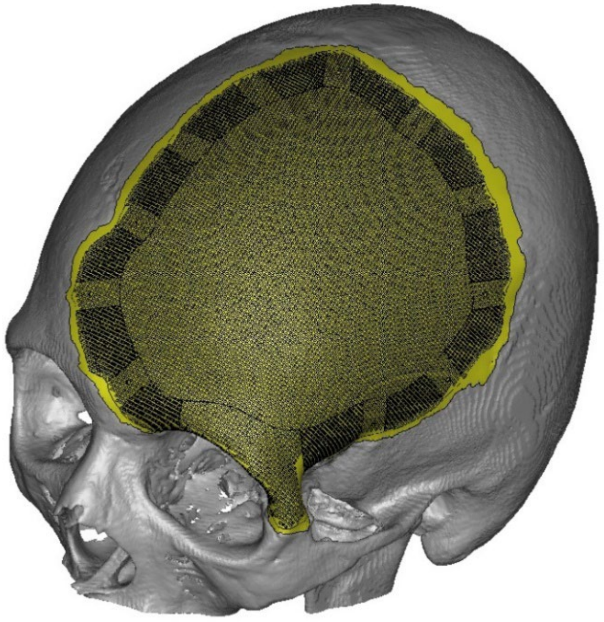
Biomedical study case : skull implants

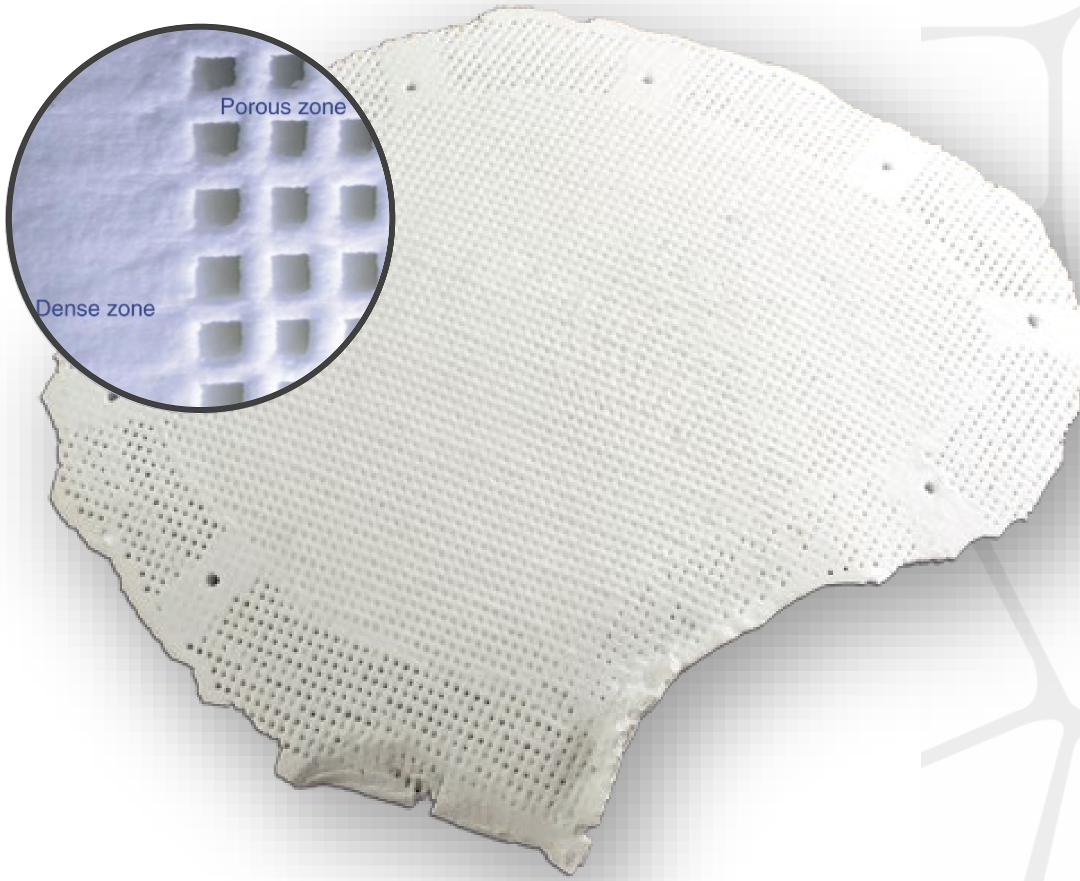
With over 15 years in the biomedical market, 3DCeram stands by our customers through every step of the 3D printing process.

Study case: biomedical implants

In 2005, a study conducted in partnership with CHU Limoges







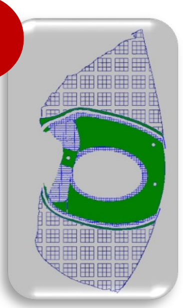
Porous and dense areas combined on the same implant

Study case: biomedical implants

1 
Scanner from hospital

2 
3D reconstructed

3 
CAD design

4 
3D printer pre process

Ceramic formulation

5 

SLA printing

6 

10 
Packaging and sterilisation

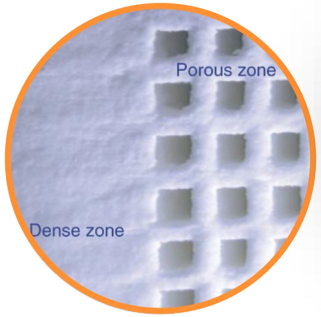
9 
Geometry Checking on the skull model

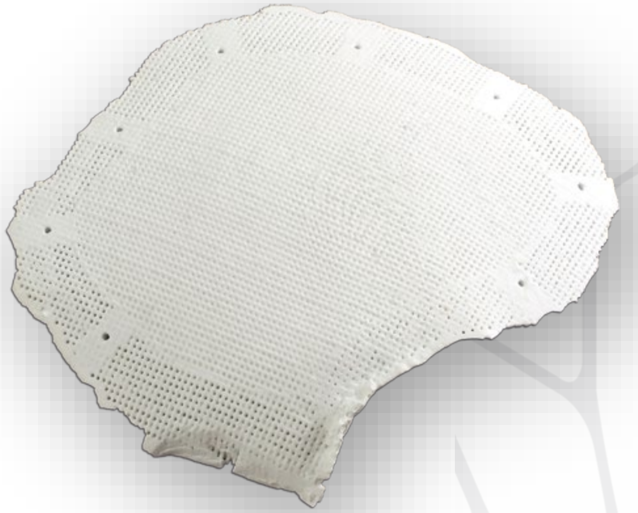
8 
Debinding - Sintering

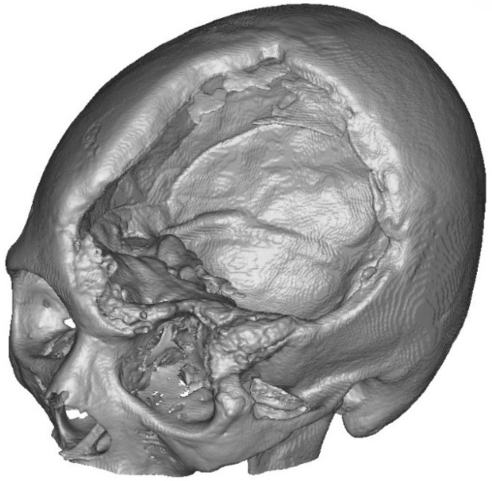
7 
Cleaning

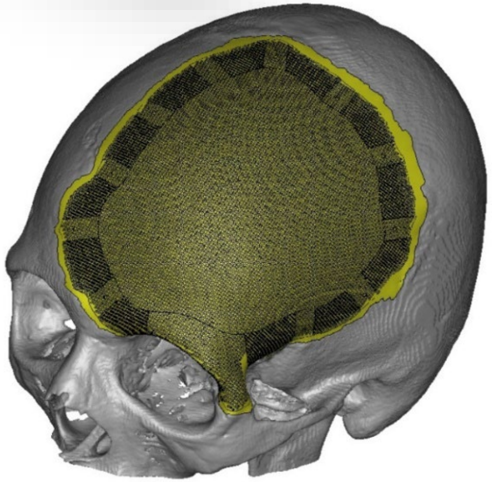
Study case: biomedical implants

- Customised implant
- No fragile structure but a 3D one
- Porous and dense areas combined on the same implant
  - Perfect Ostheo integration
  - Sturdiness wherever it is needed
- Holes in the design for temporary fixation
  - Surgeon goes faster,
  - Less down time,
- Rugosity on the outside to “fix the skin”





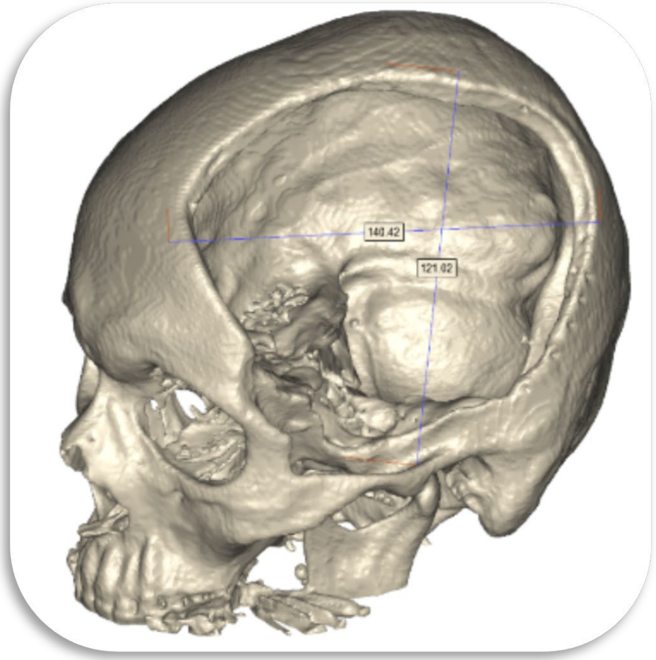




CAD WORKS – STEP 1

~0h30

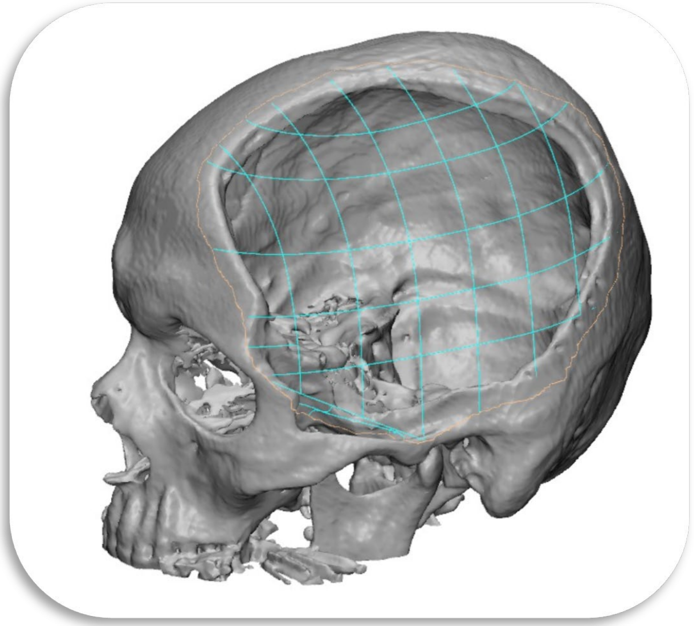
- Import DICOM.
- Export STL file of the skull.



CAD WORKS – STEP 2

~2h30

- Creation of guidelines.
- Generation of the surface and of the volume.



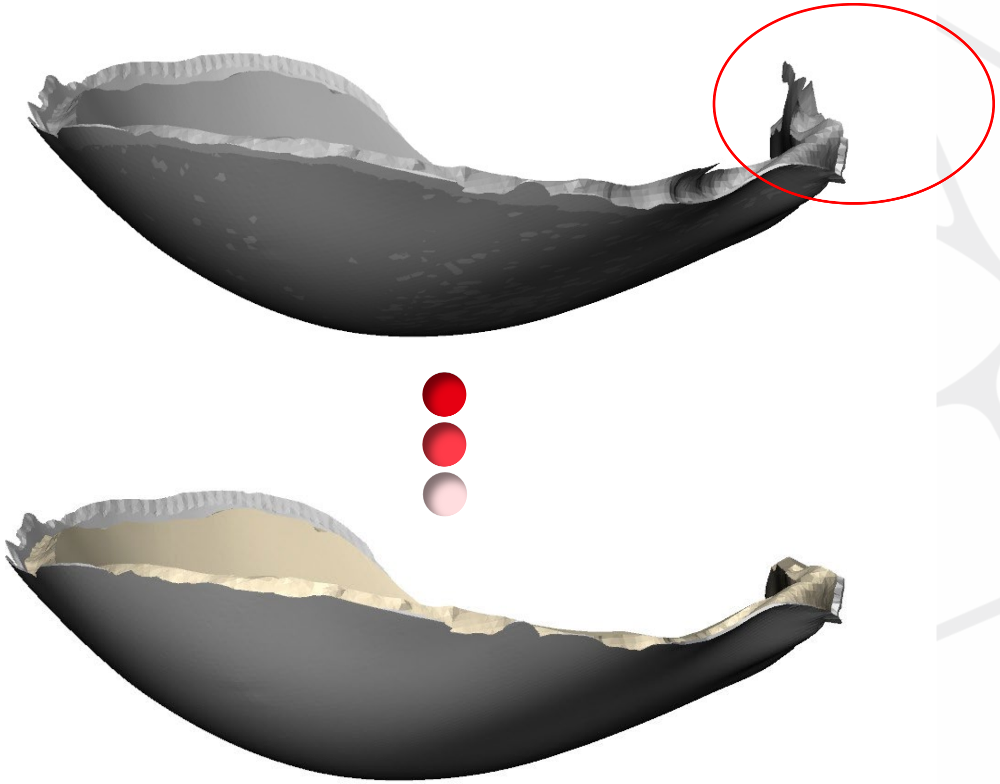
Defined with specifications of surgeron.

Study case: biomedical implants

CAD WORKS – STEP 3

~0h15

- Creation of guidelines.
- Generation of the surface and of the volume.

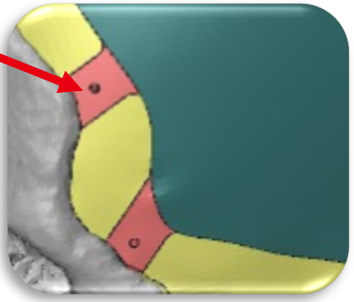


STUDY CASE | Skull implants

CAD WORKS – STEP 4

~2h45

- Selection of porous (yellow) and dense (blue and pink) volumes.
- Creation of fixing holes (diameter 1,4 mm - spaced of ~25mm)



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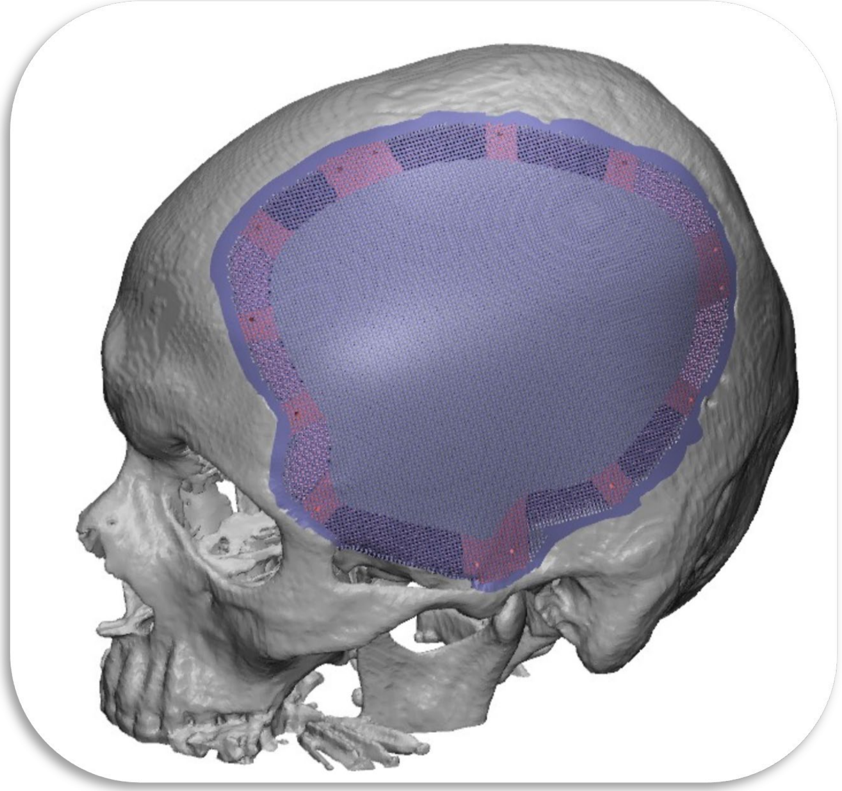
CAD WORKS – STEP 5

~4h30

- Creation of surface porosity.
- Creation of 3D porous volume.



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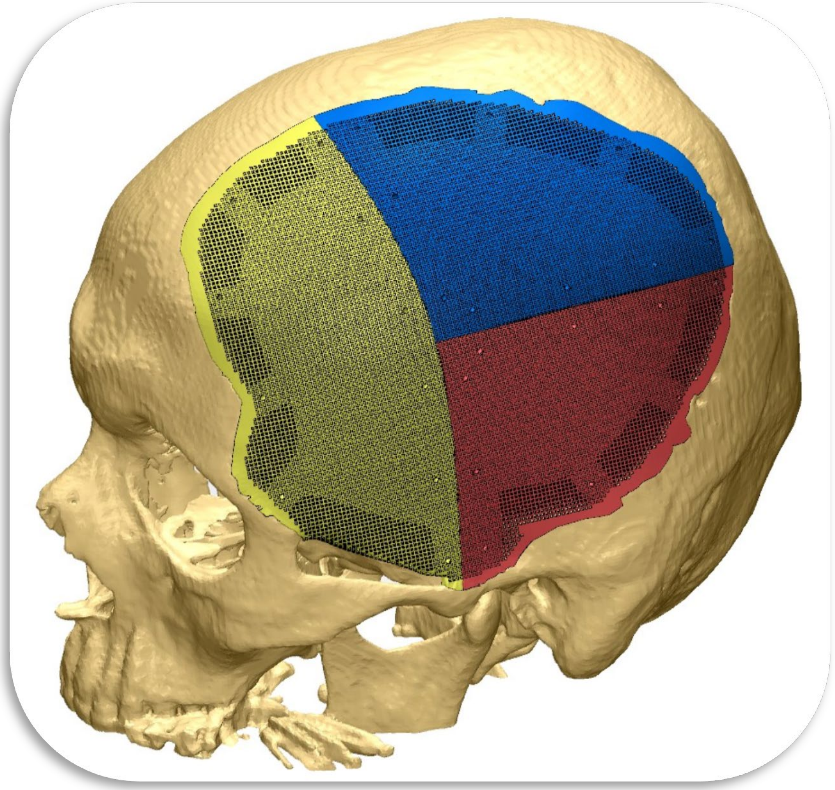
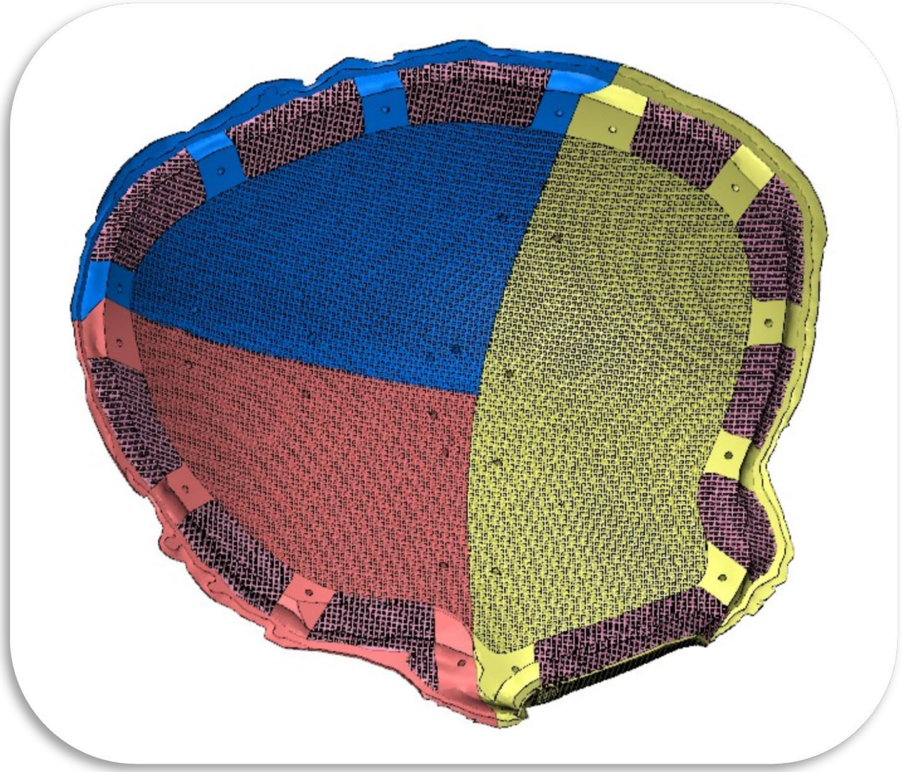
CAD WORKS – STEP 6

~2h00

- For big size implant, cutting the implant.





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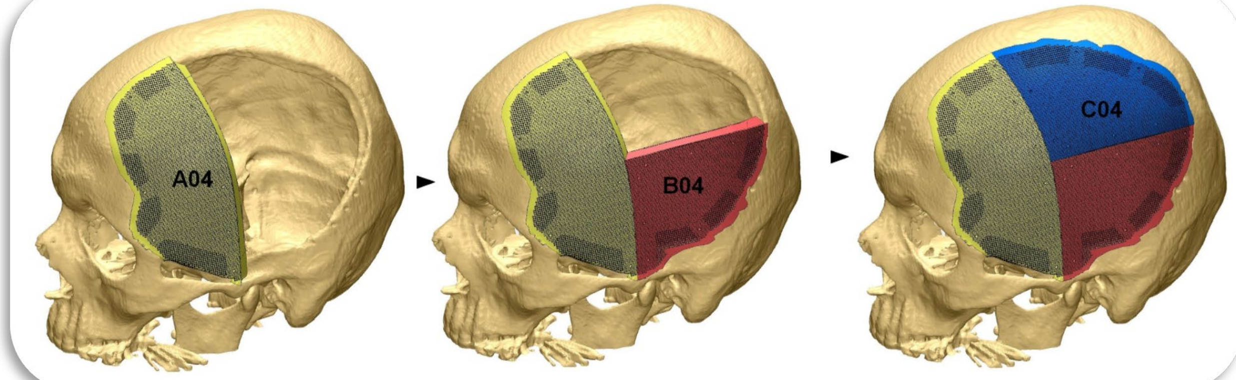
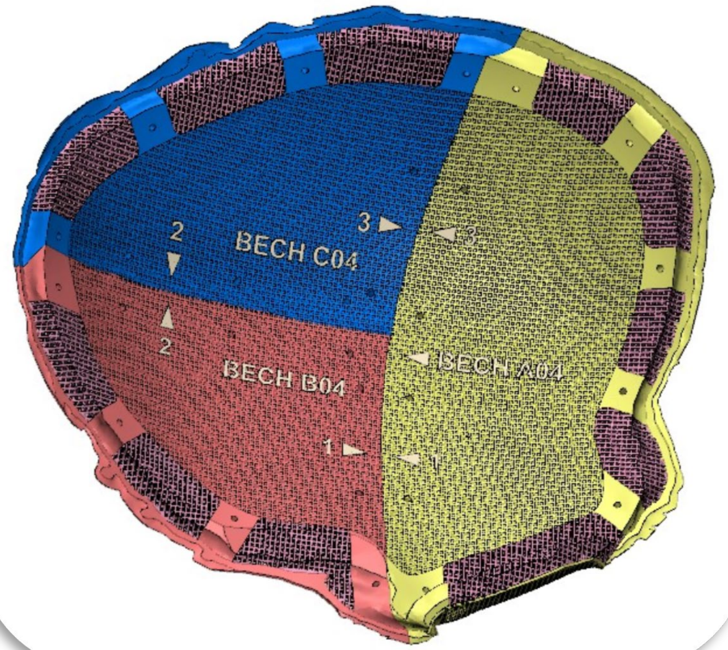
CAD WORKS – STEP 7

~2h00

- Reference on each part.
- Redaction of the assembly notice





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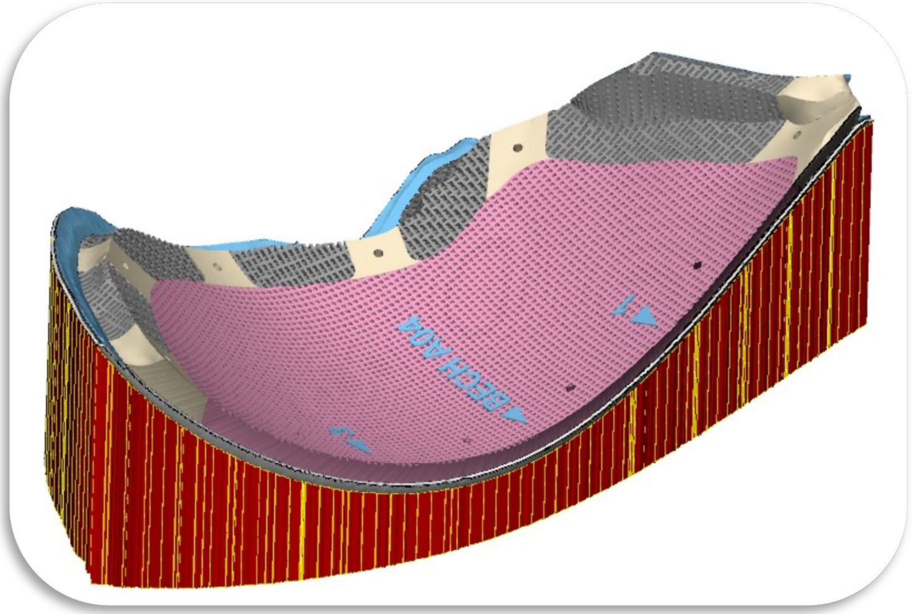
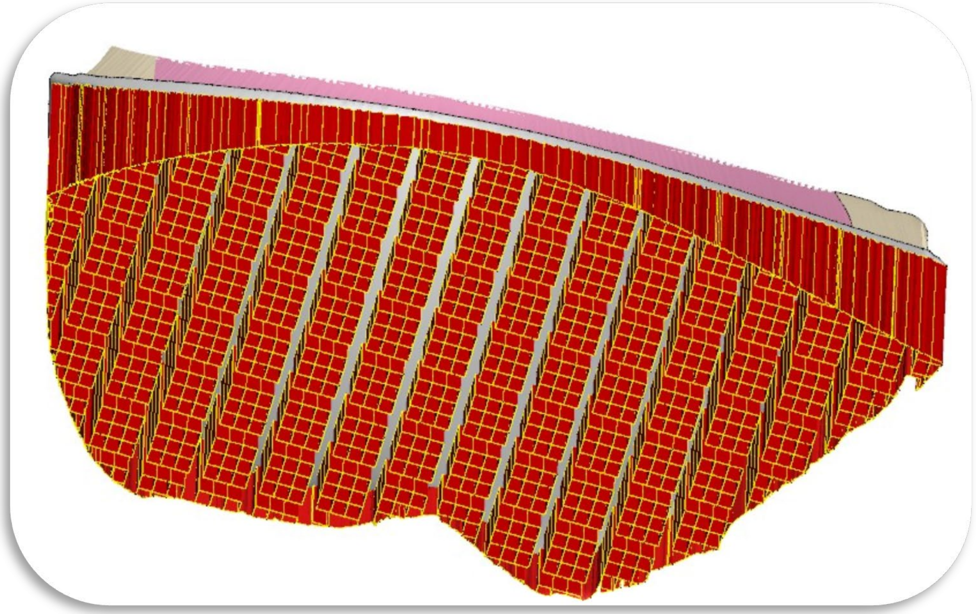
CAD WORKS – STEP 8

~2h15

- Creation of printing supports for each part.





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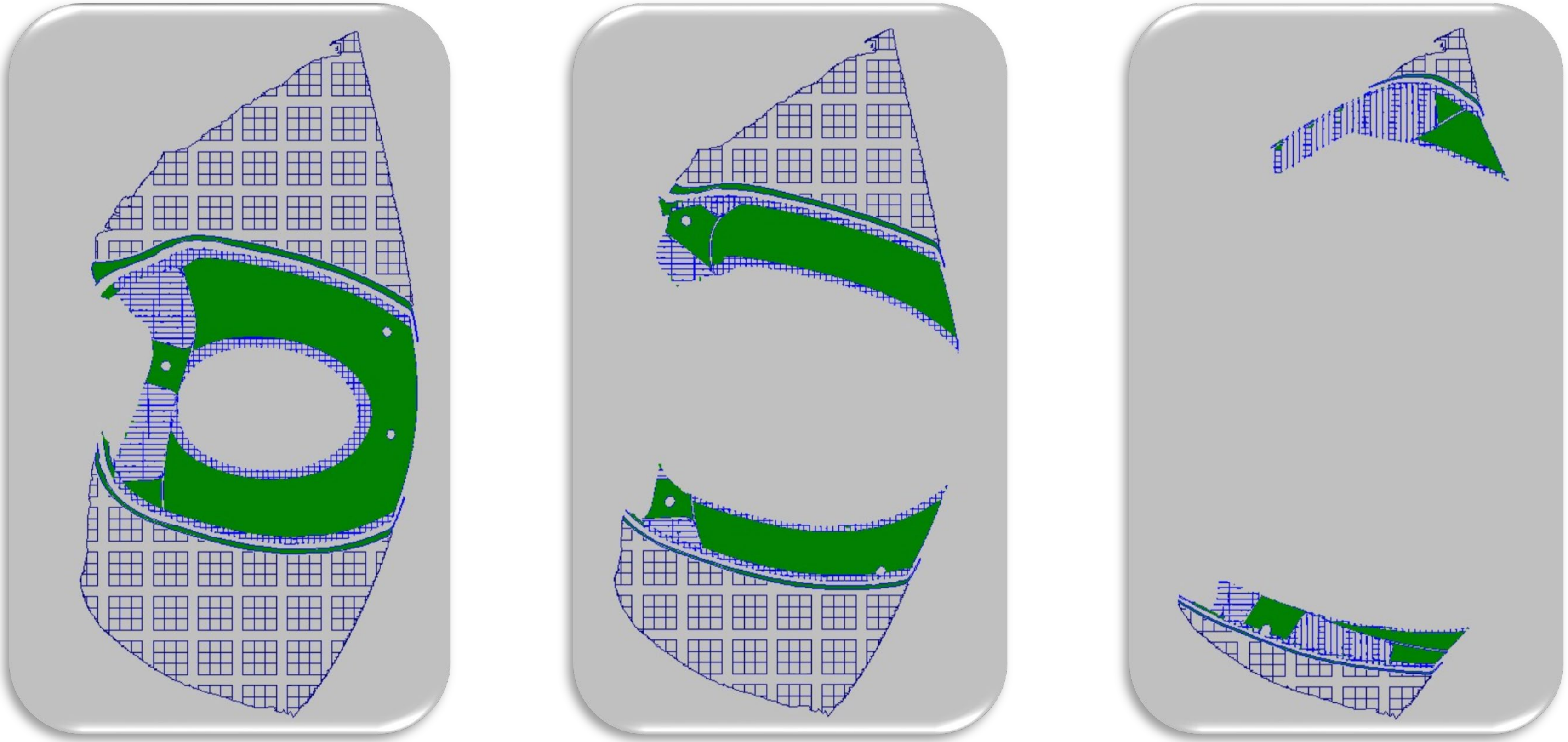
CAD WORKS – STEP 9

~1h00

- Check the slicing file (laser path)



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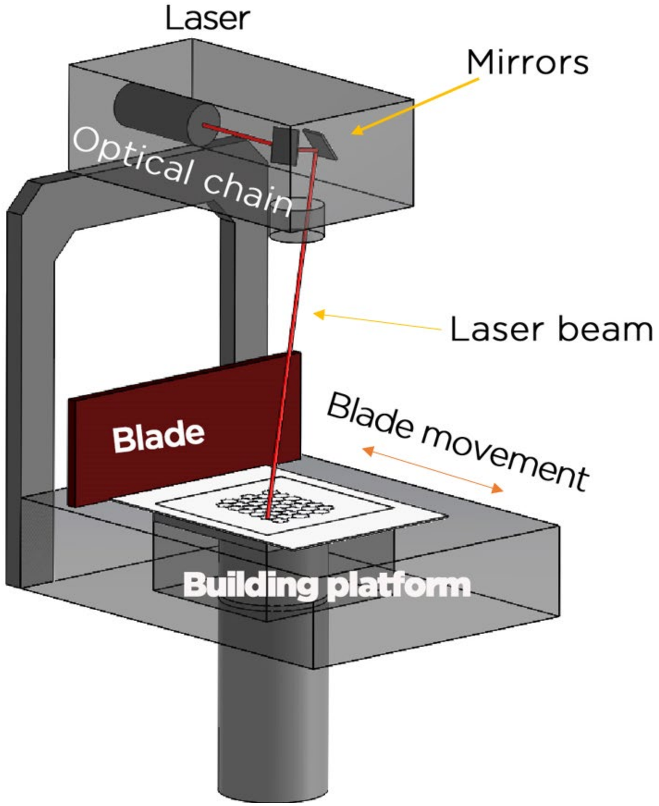
Stereolithography printing

~7h00

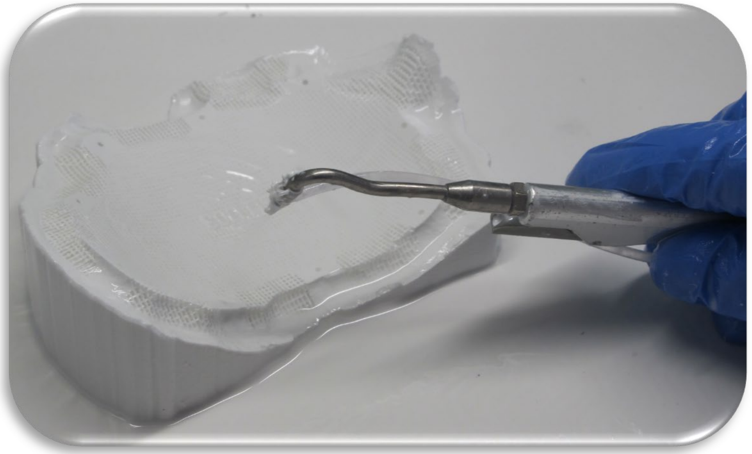
- Production in successive layers
- The UV laser polymerises the slurry

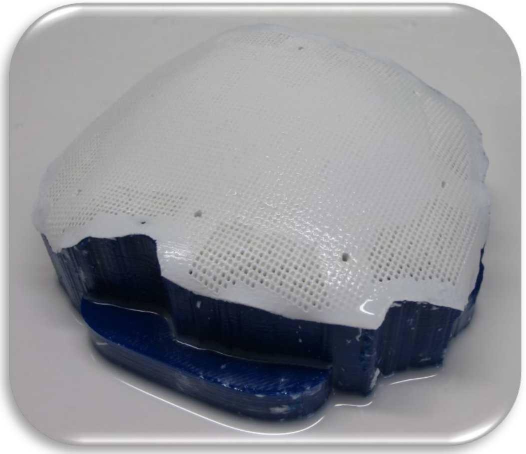


Cleaning of the implant

~3h00

- Removal of the unpolymerized paste
- Removal of printing supports
- Cleaning with specific solvents
- Using of cleaning supports





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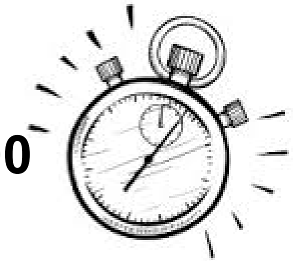
Debinding - Sintering

~73h00



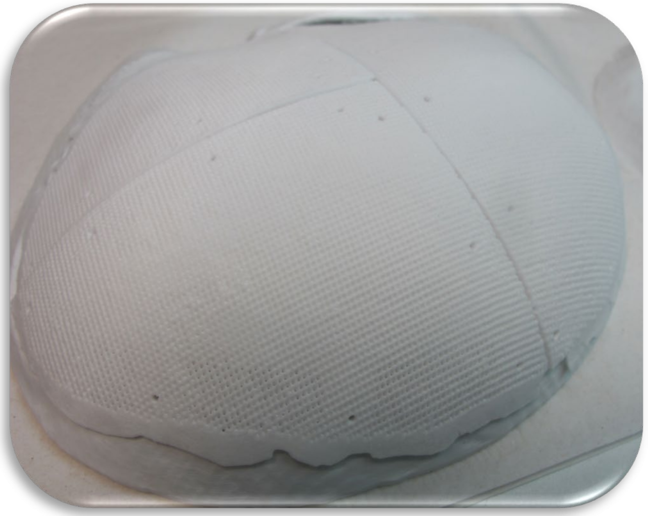
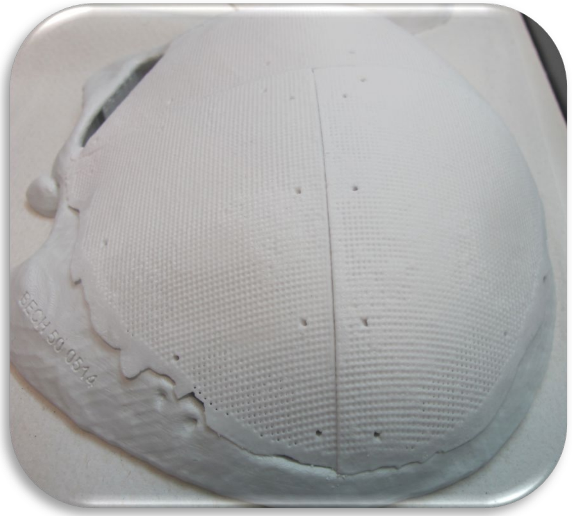
- Debinding : Heat treatment to eliminate the resin.
- Sintering : Ceramic powder densification to 98-99 %.
- Shrinkage : ~20%

Green part

Sintered part

Checking of the implant

- Under clean atmosphere
- Measure dimensions and shape on skull model
- In case of several parts, check the assembly
- Checking chemical composition and strength according standards

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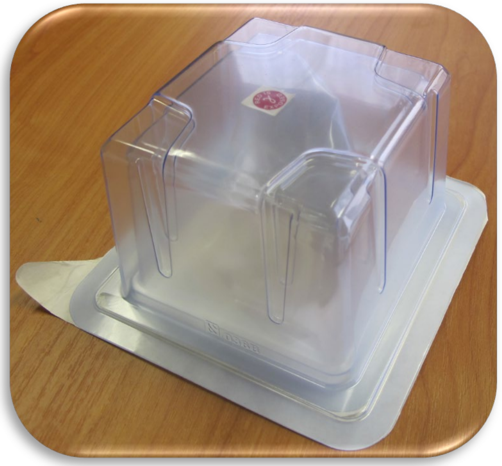
Packaging and sterelisation

- Under double blister
- Gamma sterilization (25 kGy)
- Delivered with assembly notice, declaration of conformity according standards



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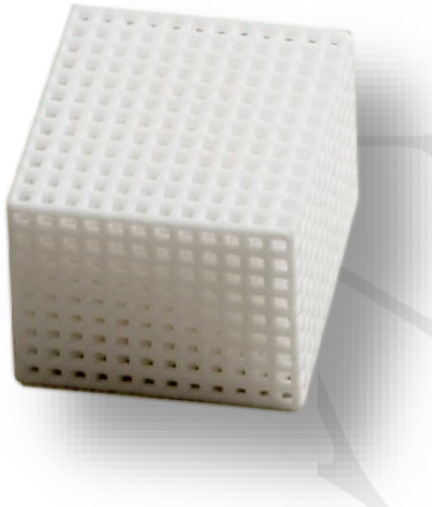

- No limitation in design of the implant
- Strictly adhere to the tolerances
  set out in customer's specifications
- The surgeon or the specialist keeps full control of the operations
- Eliminate residue or contaminant linked to production process

Unique 3D porosity control

- 3DCERAM enables to control the location and geometry of porous areas of substitutes.
- Porosity structured in 3 dimensions.
- Define a consistent diameter of pores.
- Ensure a complete interconnection of pores

Porous and dense areas combined on the same implant

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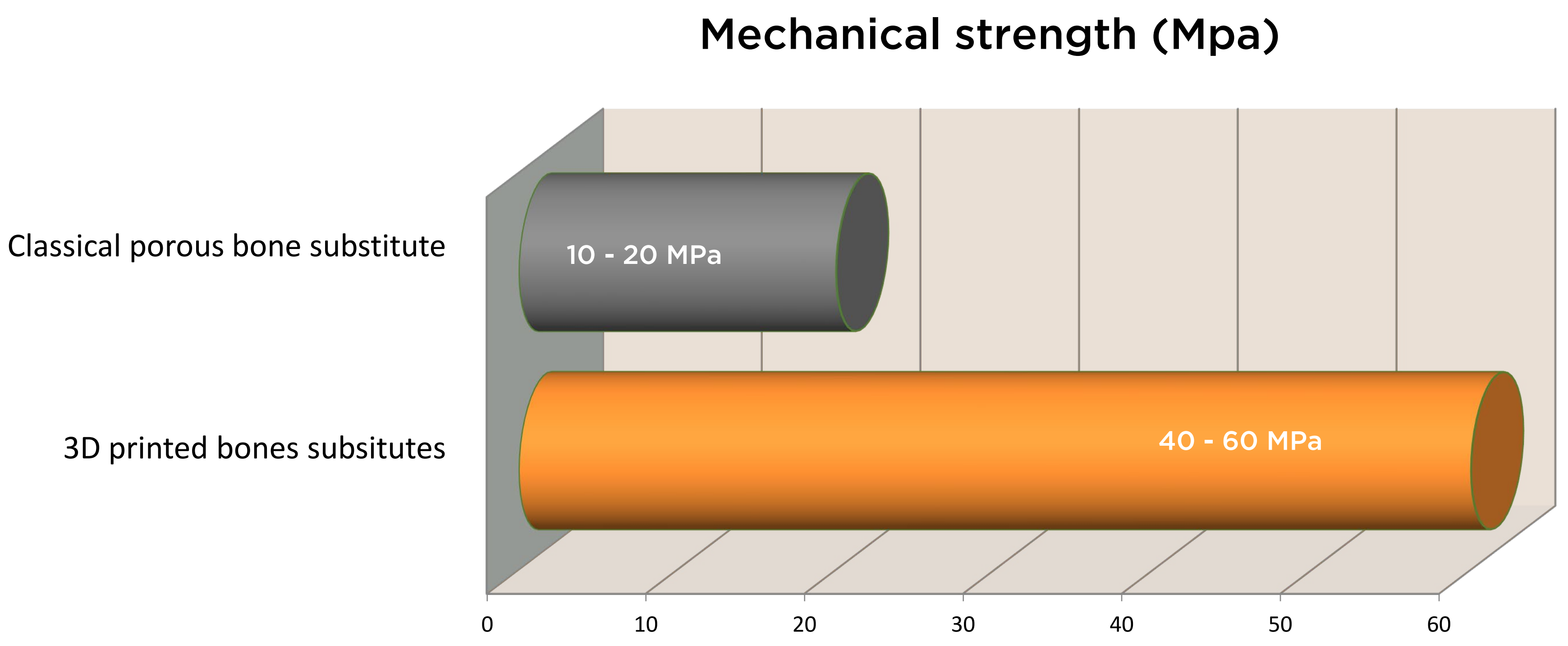
Compressive mechanical strength 3 to 5 times higher

For the same value of porosity : 60%



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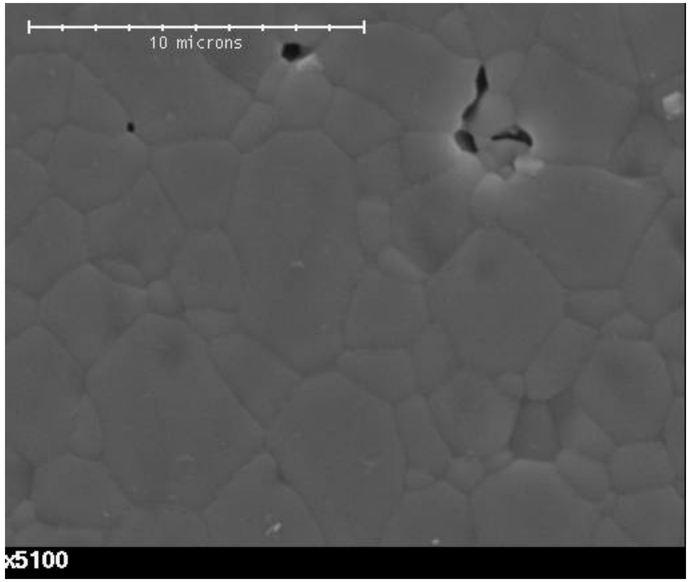
Caracteristics of HYDROXYAPATITE

- Densification rate = 98-99%/dth

- Density = 3,2
- Microstructure : grain size 1-5 µm.
- Flexural strength : 80-100 MPa.

- Chemical properties :



	Controls	STANDARD	3DCERAM HYDROXYAPATITE
HAP material according standards ISO 13 779-1 : 2008	Hydroxyapatite cristallinity	≥ 95 %	96 %
	Total of other phases	≤ 5 %	4 %
	Ca/P ratio	1,65 à 1,82	1,705

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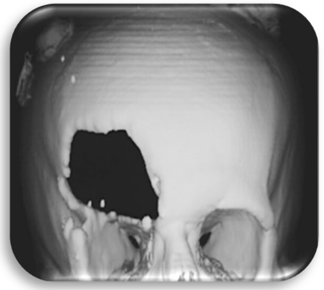
Clinical case

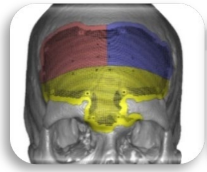


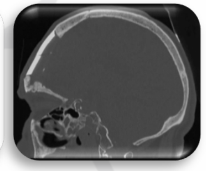
Age : 27 years
Sex : Male
Surgery date : **07/01/2005**
Surgery duration : 180 min
Implant surface : 7 x 5 cm
Implant thickness : 5 mm
Fixation holes : 4
Topography : Orbitofrontal

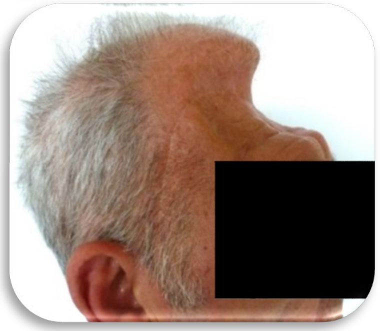
M1

M12

Age : 76 years
Sex : Male
Surgery date : 15/03/2013
Implant surface : 106cm
Implant thickness : 5mm
Fixation holes : 12
Topography : Frontal







RESULTS AND CLINICAL REPORT

Evaluation criteria

Primary :

➔Implants osteointegration evaluation : scanner data et post-operative radiography

➔Implants tolerance evaluation : clinical local exam

Secondary :

➔Implants tolerance evaluation : patients interview and clinical exam (pains, heaviness, itching and burning)

➔Functionnal consequences : patient interview (Folstein Mini Mental State)

➔Aesthetical consequences: pictures.

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Osseointegration

- Examinations of the patients' skull showed **a perfect integration** of implants in the skeletons. The implants showed **no sign of deterioration. No encapsulating membrane** was observed.

➔ Example case #6 :

1 month after surgery

12 months after surgery

Implants tolerance

- **No signs of inflammation** (warmth or redness), and **no flow** have been observed in various examinations of surgical wounds.
- **No patient had any fever episode** during the postoperative period
- **Pain, burning, heaviness and itching low to moderate** disappeared during the postoperative period

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Functional consequence

- MMSE test results showed that the implantation of the device **does not affect the higher functions** of the patient and may even improve them.

Aesthetic results

- **All the patients were satisfied with the esthetic result.** The different cases show an improvement in the result quality.