Medical 3D printing and Standard requirement issues

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No conflict of interest

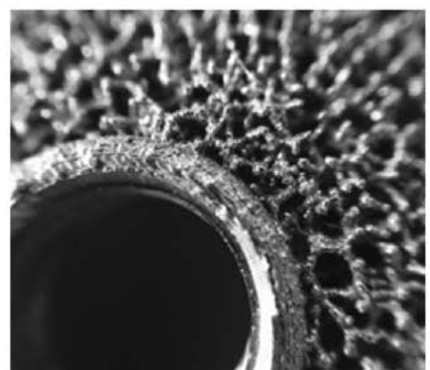
The application of 3D printing

The pros and cons of 3D printing

- **Pros**
  - High versatility of design
  - Custom made manufacturing which has been impossible to be mass manufacturing.
  - High efficient manufacturing which has no way to be possible so far.
  - Simplified and regional manufacturing
- **Cons**
  - Limitation of size and speed of manufacturing
  - No to possible to be mass production
  - Not east to reach higher level of designing and quality control
  - Limitation of materials

Medical Additive Manufacturing/ 3D Printing

Annual Report 2018



General (non-personalized instruments or prototypes).

Examples: Speci

use (e.g., plate b

process

Photo courtesy EOS

Prototy

StainlessSteel

set. O

Anatomical Modeling (patient-matched anatomical models from medical imaging studies like CT/MRI).

Examples: Cranial

simulation; scolio

stent deployment

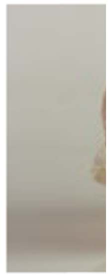
Photo courtesy Stratasys

Surgical Planning (templates, guides and models after preparing a patient-specific surgical plan in a software environmen

Examples: S

radiation shi

Photo courtesy 3D Systems Healthcare

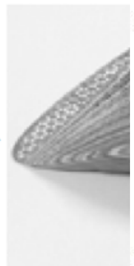


Anato

with

Precision Prosthetics (patient-matched implants, prosthetics, or orthotics). Examples: Small quantity cases (e.g., oncology case); knee

Photo courtesy Arkema Inc.

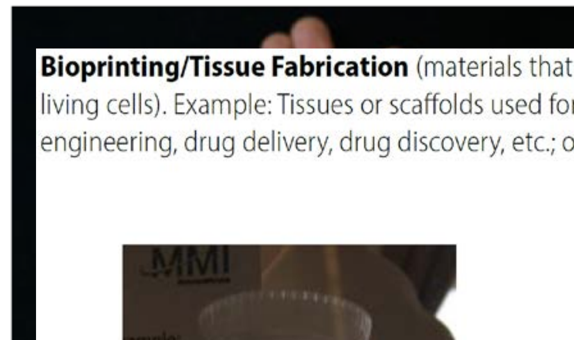


Permanent Implants ("off-the-shelf" implants). Examples: Metallic implants (e.g., titanium, cobalt chrome alloy); tracheal splint; cranial im

Photo courtesy GE Additive/Arcam

Active & Wearable Devices (devices that include electronics or other active elements). Examples: Wearable sensors; lab on a chip; microfluidics.

Photo courtesy Alex Valentine, Lori K. Sanders, and Jennifer Lewis/ Harvard University



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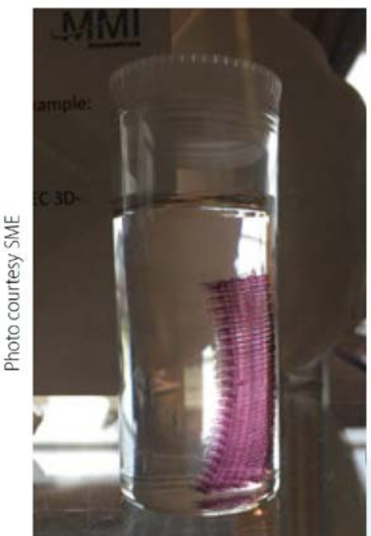
Bioprinting/Tissue Fabrication (materials that incorporate living cells). Example: Tissues or scaffolds used for regenerative engineering, drug delivery, drug discovery, etc.; organ on a chip.

Photo courtesy SME



Bioprinted gelatin for tissue repair and regeneration including bioprosthetic ovary developed at Northwestern University.

Skull Defects

Cancer which destructing skull and adjacent structures

Trauma

Infection

Common situation in Neurosurgery

Cosmetic appearance?

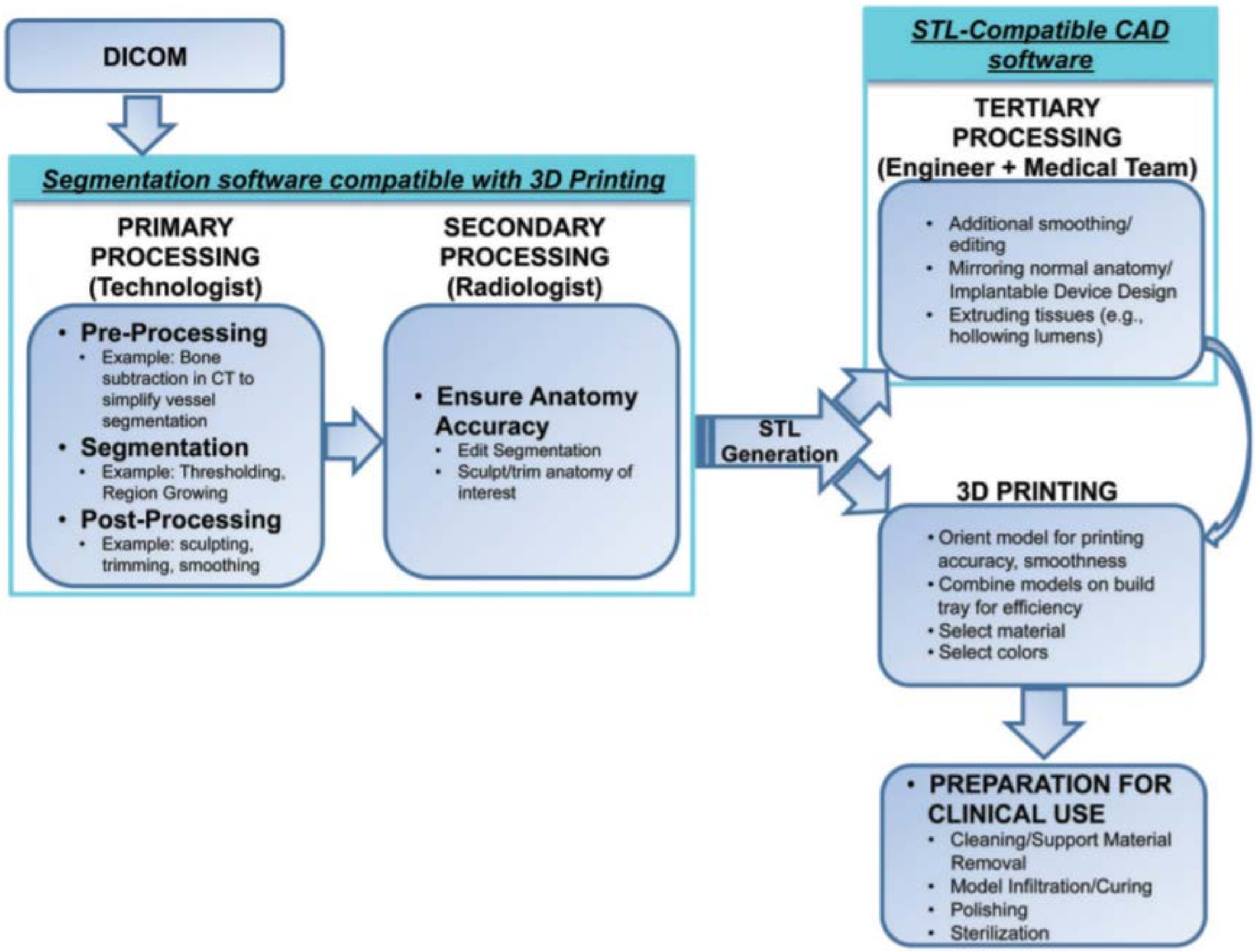
Skull

-> Protection

-> Normal CSF circulation

-> Prevention of Syndrome of Trephined.

Workflow for Medical 3D Printing



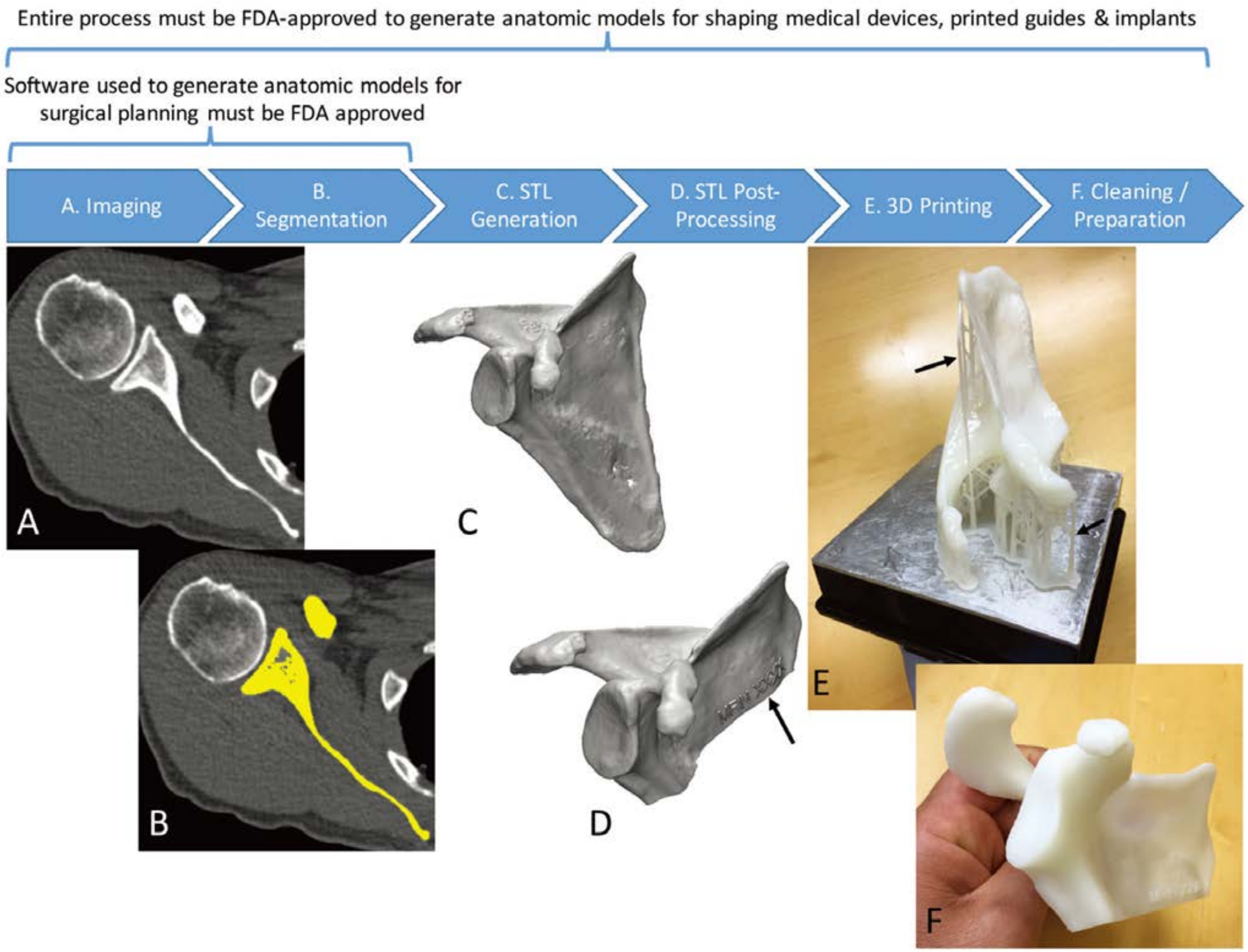


Figure 4. Process of 3D printing of tissue models. *A,* A scapula is imaged with non–contrast material–enhanced CT. *B,* The scapula (yellow) is then segmented from the CT image. *C,* A surface enclosing the segmented voxels—that is, the Standard Tessellation Language *(STL)* model—is created. *D,* The STL model is typically postprocessed—for example, to trim unnecessary portions and add identifiers (arrow). *E,* The designed model is then printed by using a 3D printer. *F,* The printed model is cleaned to remove support structures, such as the scaffold (arrows in *E*) generated by the stereolithography printer in this example.

George E, Liacouras P, Rybicki FJ, Mitsouras D. Measuring and Establishing the Accuracy and Reproducibility of 3D Printed Medical Models. Radiographics. 2017 Sep-Oct;37(5):1424-1450

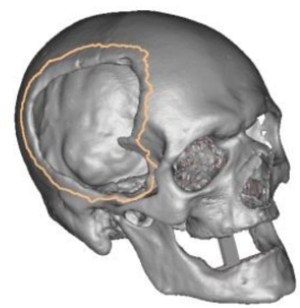
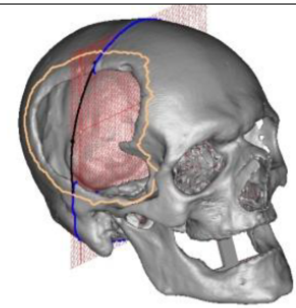
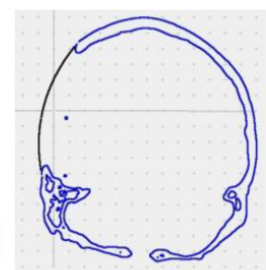
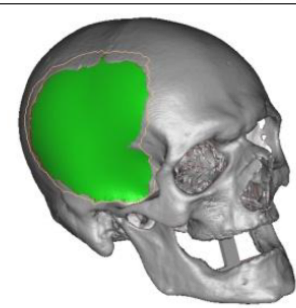
Mimics SE Materialise driving your innovations

- Materialise's Interactive Medical Image Control System
- Mimics is the medical image based processing tool for creating 3D models, and linking the models to rapid prototyping (RP), computer aided engineering (CAE), computer aided design (CAD), and surgery planning.
- SurgiCase CMF is Materialise's CT based craniomaxillofacial surgical planning software.

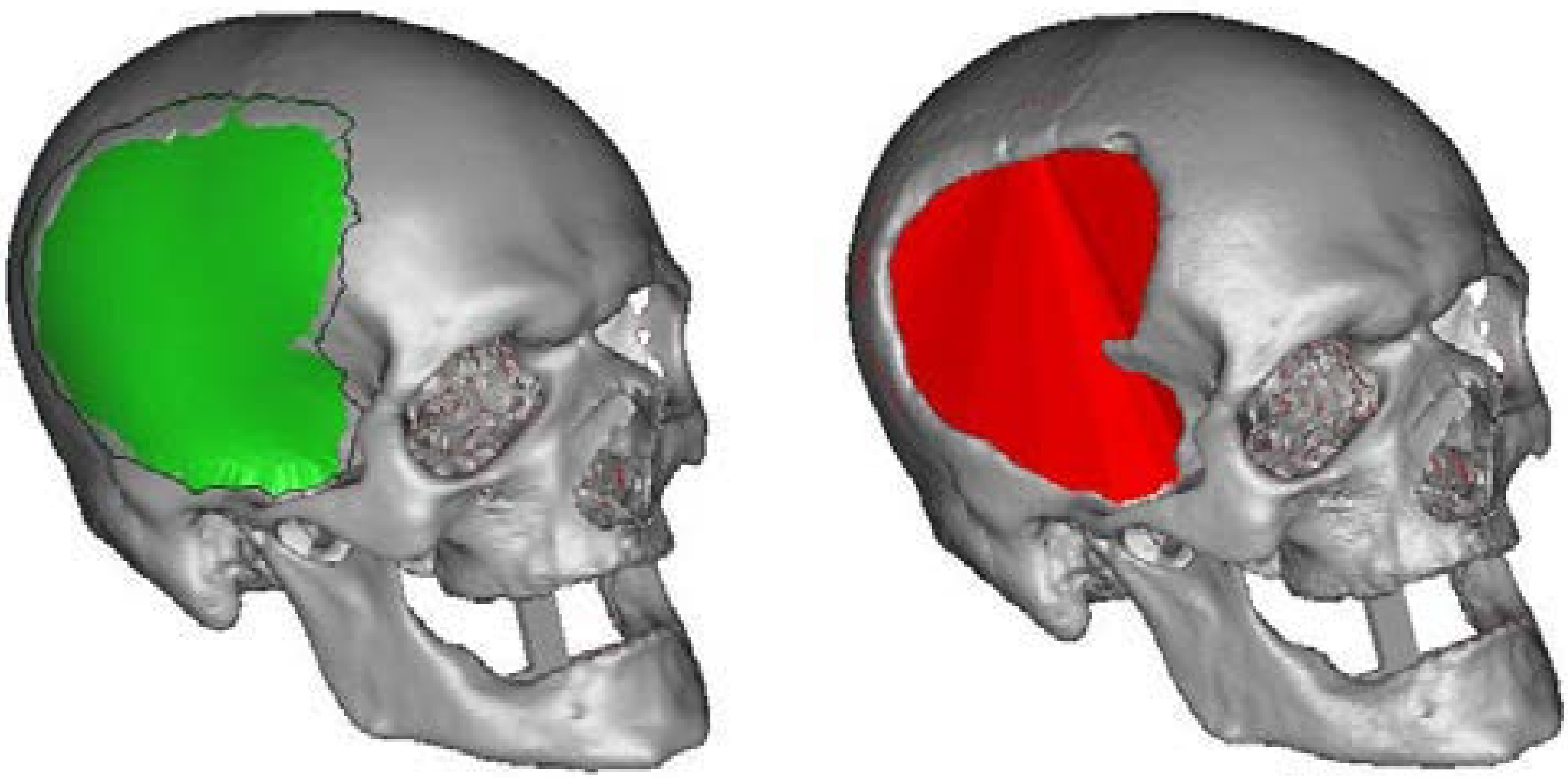
Segmentation; thresholding

- create models based on the grayvalues (Hounsfield units in CT images)
- A grayvalue is a number associated with an image pixel defining the shade (white, gray, or black) of the pixel.
- By grouping together similar grayvalues, the image data can be segmented, and models created.
-

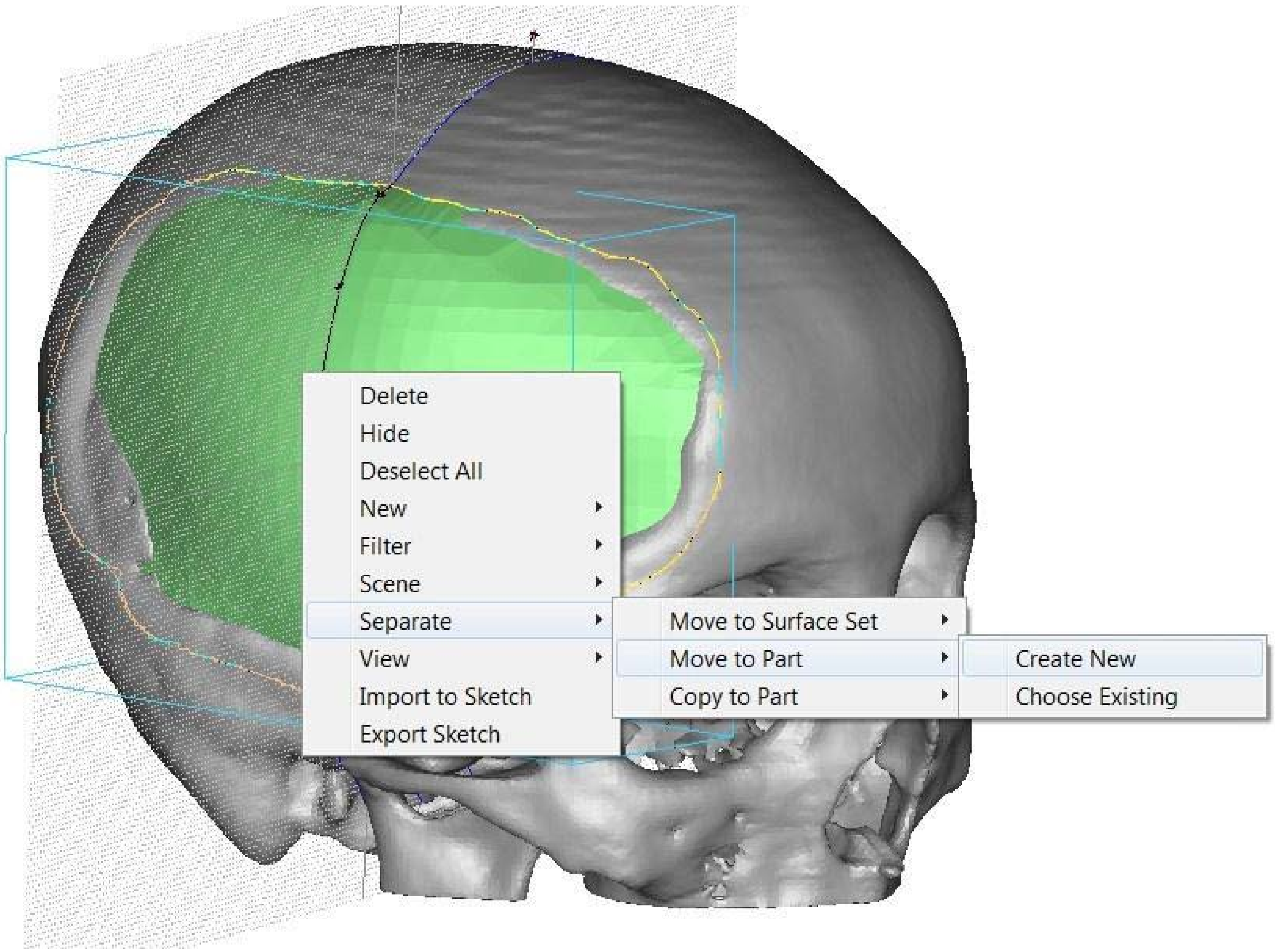
Create cranioplasty prosthesis

1	Indicate the outline of the gap.	
2	Create a guiding curve for the cranioplasty prosthesis.	 
3	Apply the "create cranioplasty prosthesis function" or manually create the prosthesis using different CAD operations	

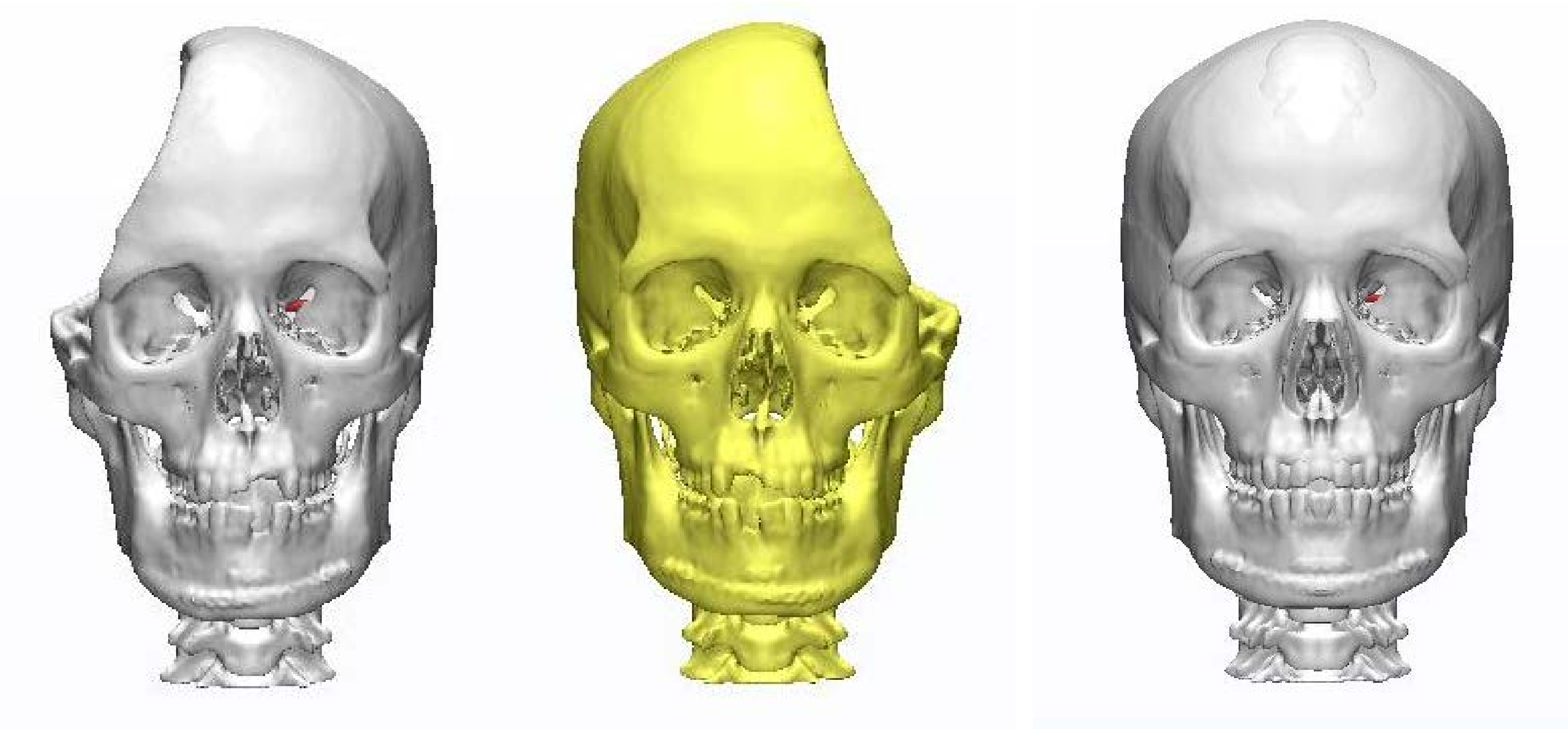
Creation of the cranioplasty prosthesis ; sequence of CAD operations



Creation of the cranioplasty prosthesis ; sequence of CAD operations

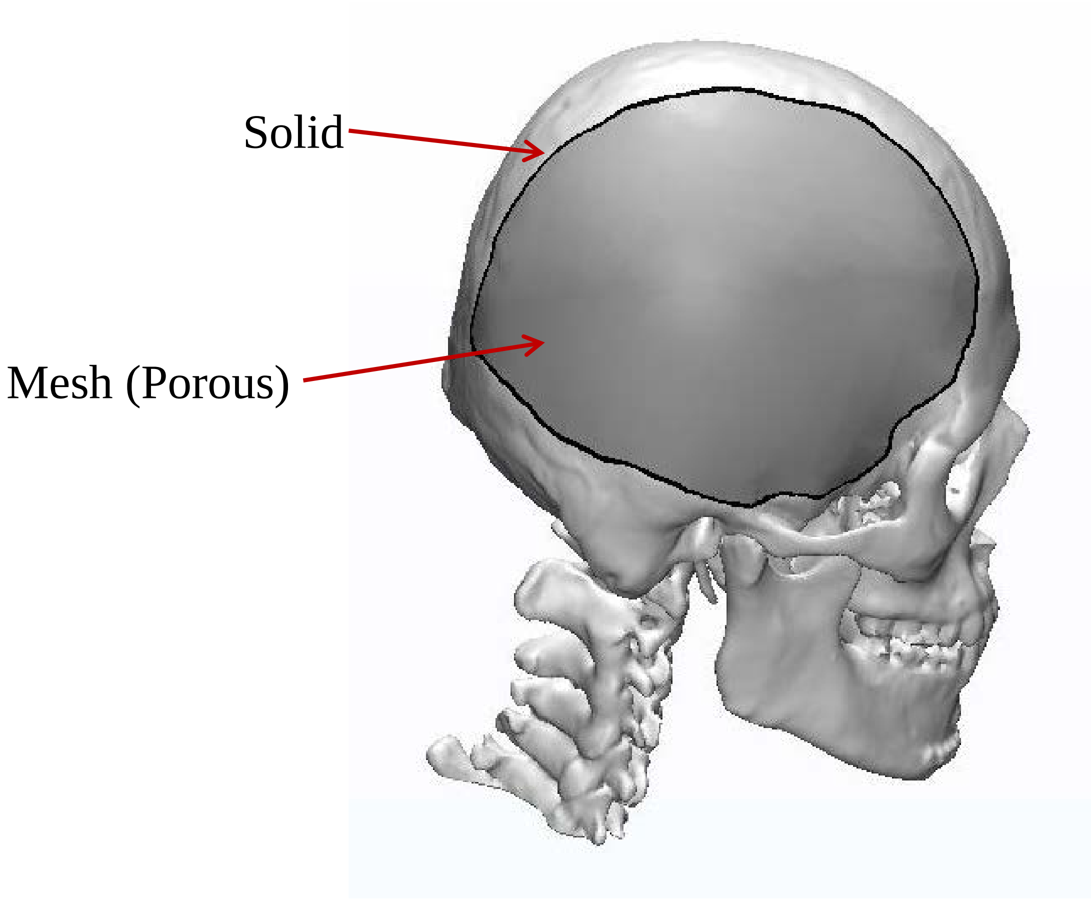


Workflow for Implant



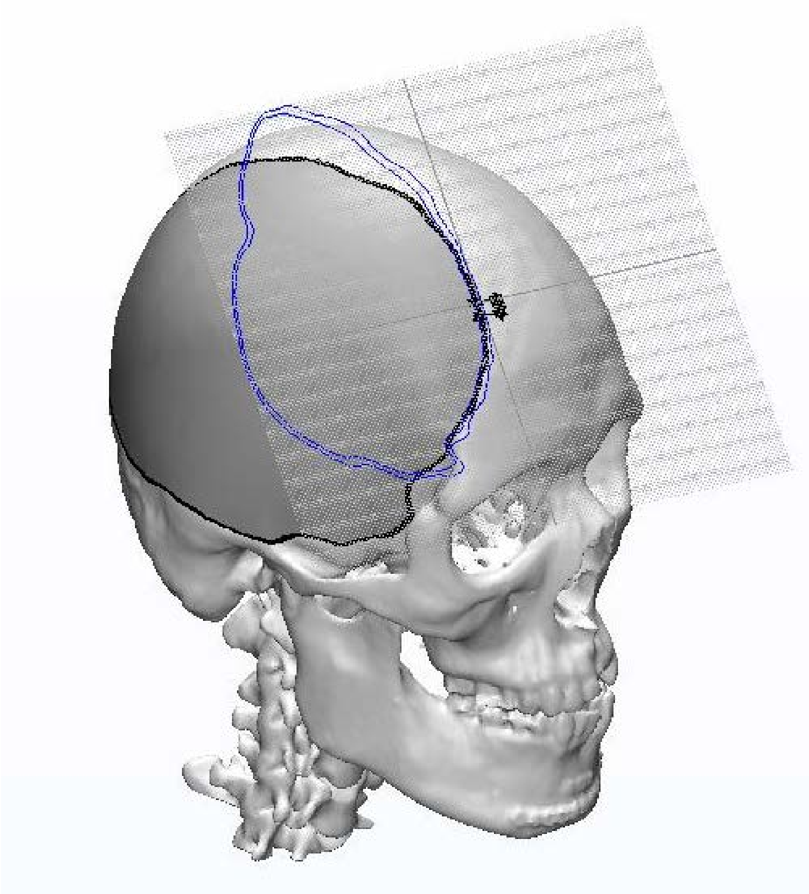
- 3D Mirroring of Defect
- Restoration of Defect

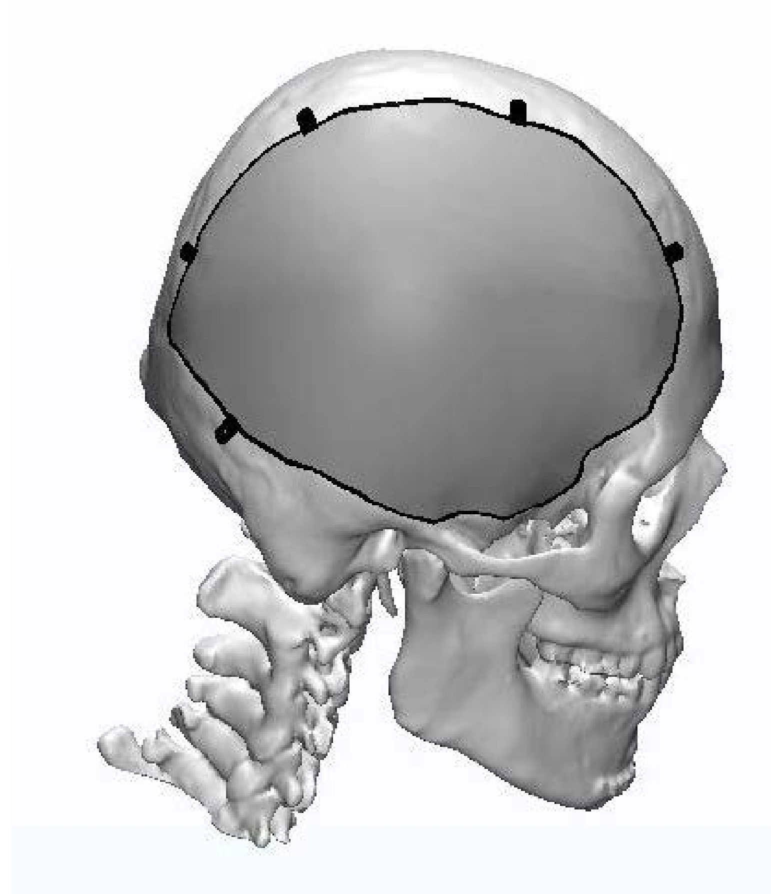
Workflow for Implant



- Restoration of Defect
- Design of basic Prosthesis
- Design of Mesh (Porous) Part and Solid Part Implant
- Maximal approximation to original 3D

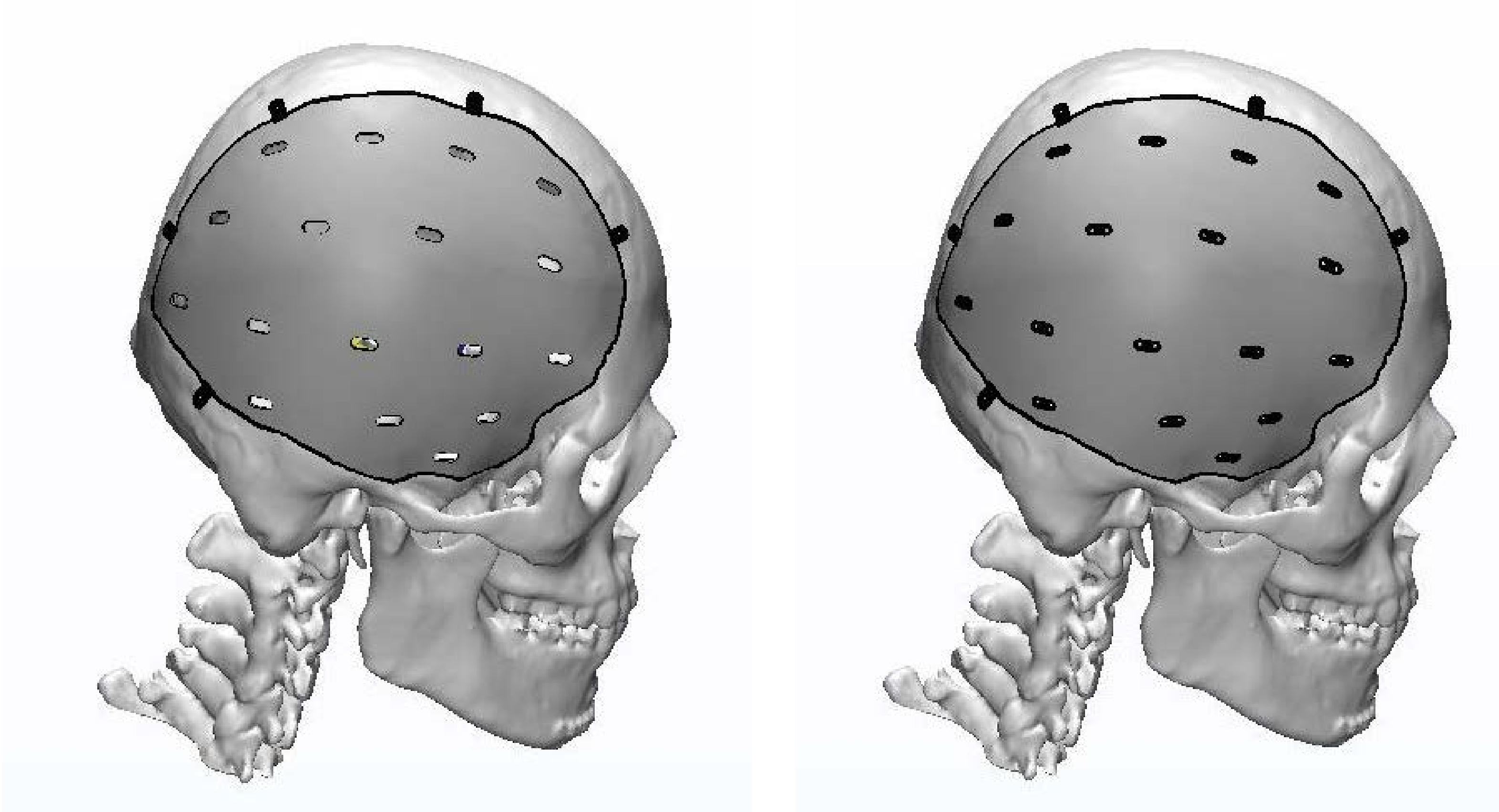
Workflow for Implant





On demand design of Flange for Screw and plate

Workflow for Implant



Creation of the cranioplasty prosthesis

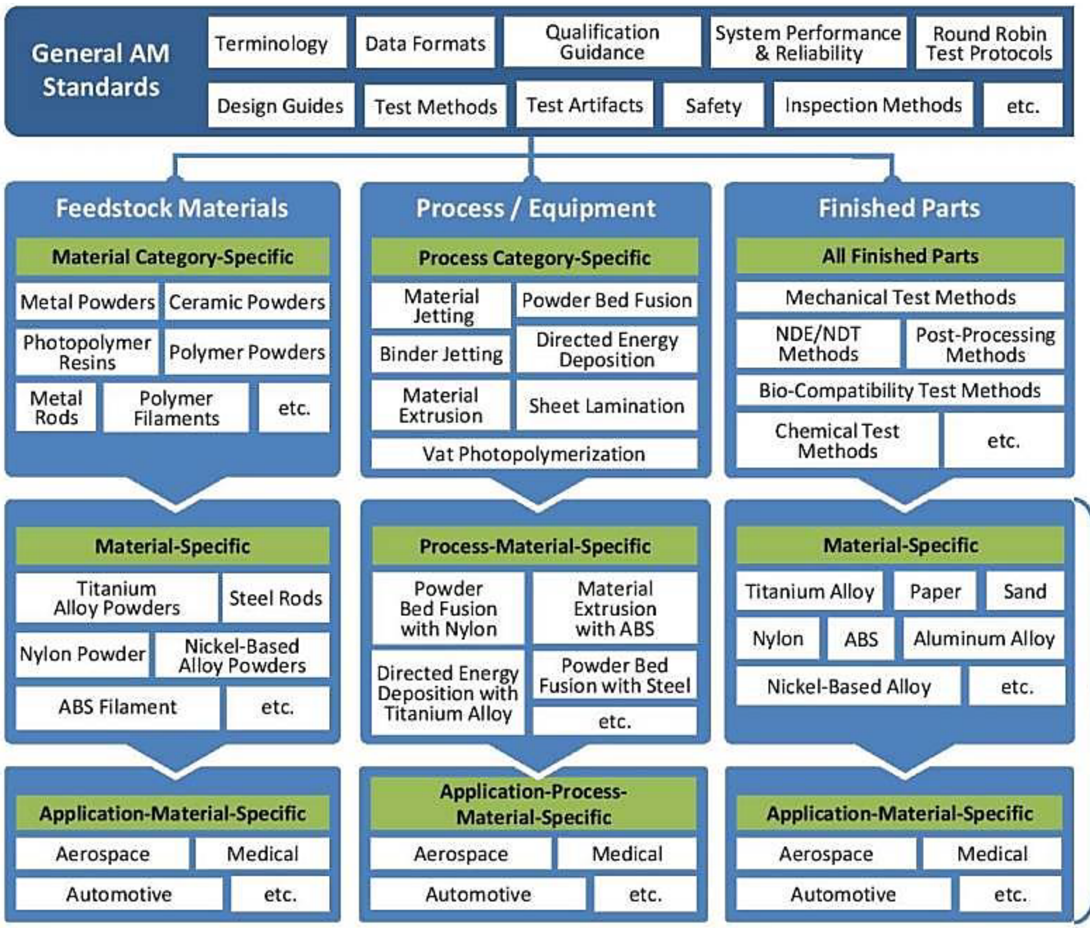
- This prosthesis has some specific characteristics:
  - A certain shape, depending on the used guiding curves.
  - A certain thickness, depending on the used offset parameter.
  - A certain clearance from the bone, depending on the used hollowing distance.

Patient-specific Implant(PSI)

Medical Requirements of PSI

1. Fully covering of defect and patients specific function
2. Low infection and inflammatory reaction
3. Physically inert
4. Biocompatible and tissue friendly
5. Easy to handle and form as we wish
6. Easy to use and be accessible

Additive Manufacturing Standards Structure



General Top-Level AM Standards

- General concepts
- Common requirements
- Generally applicable

Category AM Standards

Specific to material category or process category

Specialized AM Standards

Specific to material, process, or application

ISO/TC 261 **N 274**

ISO/TC 261
Additive manufacturing
E-mail of Secretary: lutz.wrede@din.de
Secretariat: DIN

Information on activity starting on (medical) AM part cleanliness in ASTM F04-15

Date of document 2016-07-20

Expected action Info

Background

Von: Peter Woolliams [mailto:peter.woolliams@npl.co.uk]
Gesendet: Freitag, 24. Juni 2016 13:57
An: Wrede, Lutz; 'shawn.moylan@nist.gov'
Betreff: AM part cleanliness

Not sure if you are aware of this, but I have come across activity starting on (medical) AM part cleanliness in ASTM F04-15, though it is at an early stage. From my work in the UK it would appear that agreed methods for assessing part cleanliness (vital for Aero/medical etc) would seem a sensible work item to pursue. Stephen.Spiegelberg@campoly.com is the person leading the ASTM F04 activity.

This may also be potentially going to be covered in the “medical” ISO activity [...].

I have also previously mentioned the existence of an ESA standard on cleanliness for space more generally (attached). I am sure that the space industry would also be interested and have useful input to this activity (I can provide a contact at ESA if this would be useful). As always it would be useful for everyone to work together to get best use of the different experts out there.

Technical Considerations for Additive Manufactured Medical Devices

Guidance for Industry and Food and Drug Administration Staff

Document issued on December 5, 2017.

The draft of this document was issued on May 10, 2016.

For questions about this document regarding CDRH-regulated devices, contact the Division of Applied Mechanics at (301) 796-2501, the Division of Orthopedic Devices at (301) 796-5650, or Matthew Di Prima, Ph.D. at (301) 796-2507 or by email matthew.diprima@fda.hhs.gov. For questions about this document regarding CBER-regulated devices, contact the Office of Communication, Outreach, and Development (OCOD) at 1-800-835-4709 or 240-402-8010.

DIN CS 10.5 | Server 2

Enterprise | Personal | Tools

Enterprise › ISO › ISO/TC 261 "Additive manu... ›

ISO/TC 261/JG 71 "Joint ISO/TC 261-ASTM F 42 Group, Powder"

Navigation Menu

- Committee Home
- Child Committees
- User Guides
- My Committees
- My Tasks

Structure

Type	Name
TC	ISO/TC 261 "Additive manufacturing"
WG	ISO/TC 261/AG 1 "Coordination group"
WG	ISO/TC 261/AHG 3 "Monitoring of data representation standards"
WG	ISO/TC 261/AHG 5 "Content for ISO/TC 261 homepage"
WG	ISO/TC 261/CAG "Chairman's advisory group"
WG	ISO/TC 261/JAG "ISO/TC 261 - ASTM F42 Steering group on JG activities"
WG	ISO/TC 261/JG 51 "Joint ISO/TC 261-ASTM F 42 Group, Terminology"
WG	ISO/TC 261/JG 52 "Joint ISO/TC 261-ASTM F 42 Group, Standard test artifacts"
WG	ISO/TC 261/JG 55 "Joint ISO/TC 261-ASTM F 42 Group, Standard Specification for Extrusion Based Additive Manufacturing of Plastic Materials"
WG	ISO/TC 261/JG 56 "Joint ISO/TC 261-ASTM F 42 Group, Standard Practice for Metal Powder Bed Fusion to Meet Rigid Quality Requirements"
WG	ISO/TC 261/JG 58 "Joint ISO/TC 261-ASTM F 42 Group, Qualification, quality assurance and post processing of powder bed fusion metallic parts"
WG	ISO/TC 261/JG 59 "Joint ISO/TC 261-ASTM F 42 Group, NDT for AM parts"
WG	ISO/TC 261/JG 60 "Joint ISO/TC 261-ASTM F 42 Group, Guide for intentionally seeding flaws in additively manufactured (AM) parts"
WG	ISO/TC 261/JG 61 "Joint ISO/TC 261-ASTM F 42 Group, Guide for anisotropy effects in mechanical properties of AM part"
WG	ISO/TC 261/JG 62 "Joint ISO/TC 261-ASTM F 42 Group, Guide for conducting round robin studies for additive manufacturing"
WG	ISO/TC 261/JG 63 "Joint ISO/TC 261-ASTM F 42 Group, Test methods for characterization of powder flow properties for AM applications"
WG	ISO/TC 261/JG 64 "Joint ISO/TC 261-ASTM F 42 Group, Solid modelling support"
WG	ISO/TC 261/JG 66 "Joint ISO/TC 261-ASTM F 42 Group, Technical specification on metal powders"
WG	ISO/TC 261/JG 67 "Technical report for the design of functionally graded additive manufactured parts"
WG	ISO/TC 261/JG 68 "Joint ISO/TC 261-ASTM F 42 Group, EH&S for 3D printers"
WG	ISO/TC 261/JG 69 "Joint ISO/TC 261-ASTM F 42 Group, EH&S for use of metallic materials"
WG	ISO/TC 261/JG 70 "Joint ISO/TC 261-ASTM F 42 Group, Optimized medical image data"
WG	**ISO/TC 261/JG 71 "Joint ISO/TC 261-ASTM F 42 Group, Powder"**
WG	ISO/TC 261/JG 72 "Joint ISO/TC 261-ASTM F 42 Group, Machine"
WG	ISO/TC 261/JG 73 "Joint ISO/TC 261-ASTM F 42 Group, Digital product definition and data management"
WG	ISO/TC 261/JG 74 "Joint ISO/TC 261-ASTM F 42 Group, Personnel training"
WG	ISO/TC 261/JWG 5 "Joint ISO/TC 261 - ISO/TC 44/SC 14 WG, Additive manufacturing in aerospace applications"
WG	ISO/TC 261/WG 01 "Terminology"
WG	ISO/TC 261/WG 02 "Processes, systems and materials"
WG	ISO/TC 261/WG 03 "Test methods and quality specifications"
WG	ISO/TC 261/WG 04 "Data and Design"
WG	ISO/TC 261/WG 06 "Environment, health and safety"

ISO International Organization for Standardization

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Taking part › Who develops standards › Technical Committees › ISO/TC 261

Standards catalogue

ISO/TC 261

Additive manufacturing

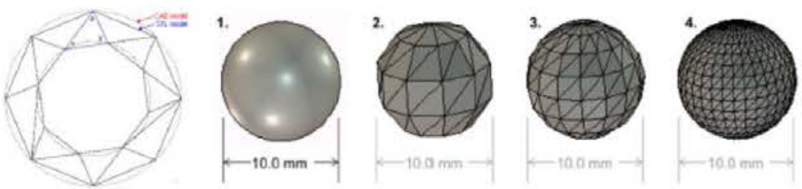
Filter: Published standards | Standards under development | Withdrawn standards | Projects deleted | Filter the li

Standard and/or project under the direct responsibility of ISO/TC 261 Secretariat (7)	Stage	ICS
ISO 17296-2:2015 Additive manufacturing -- General principles -- Part 2: Overview of process categories and feedstock	60.60	25.030
ISO 17296-3:2014 Additive manufacturing -- General principles -- Part 3: Main characteristics and corresponding test methods	60.60	25.030
ISO 17296-4:2014 Additive manufacturing -- General principles -- Part 4: Overview of data processing	60.60	25.030
ISO/ASTM 52900:2015 Additive manufacturing -- General principles -- Terminology	90.92	01.040.25 25.030
ISO/ASTM 52901:2017 Additive manufacturing -- General principles -- Requirements for purchased AM parts	60.60	25.030
ISO/ASTM 52915:2016 Specification for additive manufacturing file format (AMF) Version 1.2	90.92	35.240.50 25.030
ISO/ASTM 52921:2013 Standard terminology for additive manufacturing -- Coordinate systems and test methodologies	90.60	25.030

Taking part › Who develops standards › Technical Committees › ISO/TC 261

Standard and/or project under the direct responsibility of ISO/TC 261 Secretariat (16)	Stage	ICS
ISO/ASTM DIS 52900 [Under development] Additive manufacturing -- General principles -- Terminology	40.00	01.040.25 25.030
ISO/ASTM DIS 52902 [Under development] Additive manufacturing -- Test artefacts -- Standard guideline for geometric capability assessment of additive manufacturing systems	40.00	25.030
ISO/ASTM DIS 52903-1 [Under development] Additive manufacturing -- Standard specification for material extrusion based additive manufacturing of plastic materials -- Part 1: Feedstock materials	40.99	25.030
ISO/ASTM CD 52903-2 [Under development] Additive manufacturing -- Standard specification for material extrusion based additive manufacturing of plastic materials -- Part 2: Process -- Equipment	30.99	25.030
ISO/ASTM NP 52903-3 [Under development] Additive Manufacturing -- Standard Specification for Material Extrusion Based Additive Manufacturing of Plastic Materials -- Part 3: Final parts	10.99	
ISO/ASTM NP 52905 [Under development] Additive manufacturing -- General principles -- Non-destructive testing of additive manufactured products	10.99	
ISO/ASTM DIS 52907 [Under development] Additive manufacturing -- Technical specifications on metal powders	40.00	25.030
ISO/ASTM FDIS 52910 [Under development] Additive manufacturing -- Design -- Requirements, guidelines and recommendations	50.00	25.030
ISO/ASTM DIS 52911-1 [Under development] Additive manufacturing -- Technical design guideline for powder bed fusion -- Part 1: Laser-based powder bed fusion of metals	40.60	25.030
ISO/ASTM DIS 52911-2 [Under development] Additive manufacturing -- Technical design guideline for powder bed fusion -- Part 2: Laser-based powder bed fusion of polymers	40.60	25.030
ISO/ASTM NP TR 52912 [Under development] Design of functionally graded additive manufactured parts	10.99	
ISO/ASTM DIS 52915 [Under development] Specification for additive manufacturing file format (AMF) Version 1.2	40.99	35.240.50 25.030
ISO/ASTM NP 52916 [Under development] Additive manufacturing -- Data formats -- Standard specification for optimized medical image data	10.99	
ISO/ASTM NP 52932 [Under development] Additive manufacturing -- Environmental health and safety -- Standard test method for determination of particle emission rates from desktop 3D printers using material extrusion	10.99	
ISO/ASTM WD 52941 [Under development] Additive manufacturing -- System performance and reliability -- Standard test method for acceptance of powder-bed fusion machines for metallic materials for aerospace application	20.20	
ISO/ASTM WD 52942 [Under development] Additive manufacturing -- Qualification principles -- Standard guideline for qualifying machine operators of powder bed based laser beam machines in aerospace applications	20.20	

What is the Problem? Person or Software or File Format?



Comparison of STL & AMF - 10cm Sphere (Solid Edge)

	STL Format (Binary)	AMF Format (Curved Triangles)
PRECISION	10 micron	10 micron
NO. OF MESH TRIANGLES	49,500	320
FILE SIZE	2400k	10k

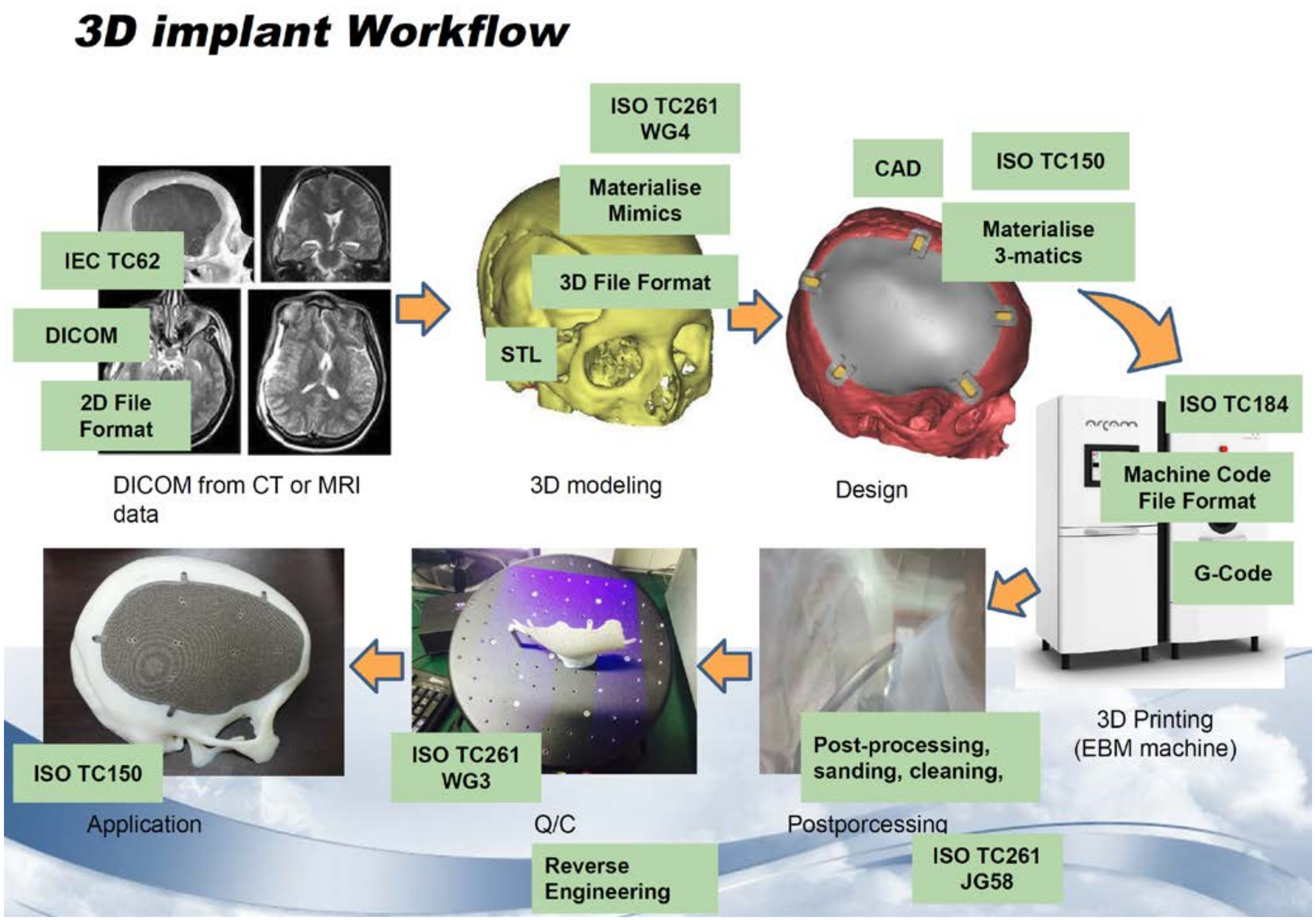
- All of them are possible error makers.
- Interpersonal error
- File formats are not suitable for human data
- Inter-software error; human data are being transferred between software to be processed as 3D images or to be 3D printed
- And also Data are being transformed to the file format as the software requires.
- Human is 3D and amorphous object.
- Additive Manufacturing is Stacking of 2D Printing.

HOW

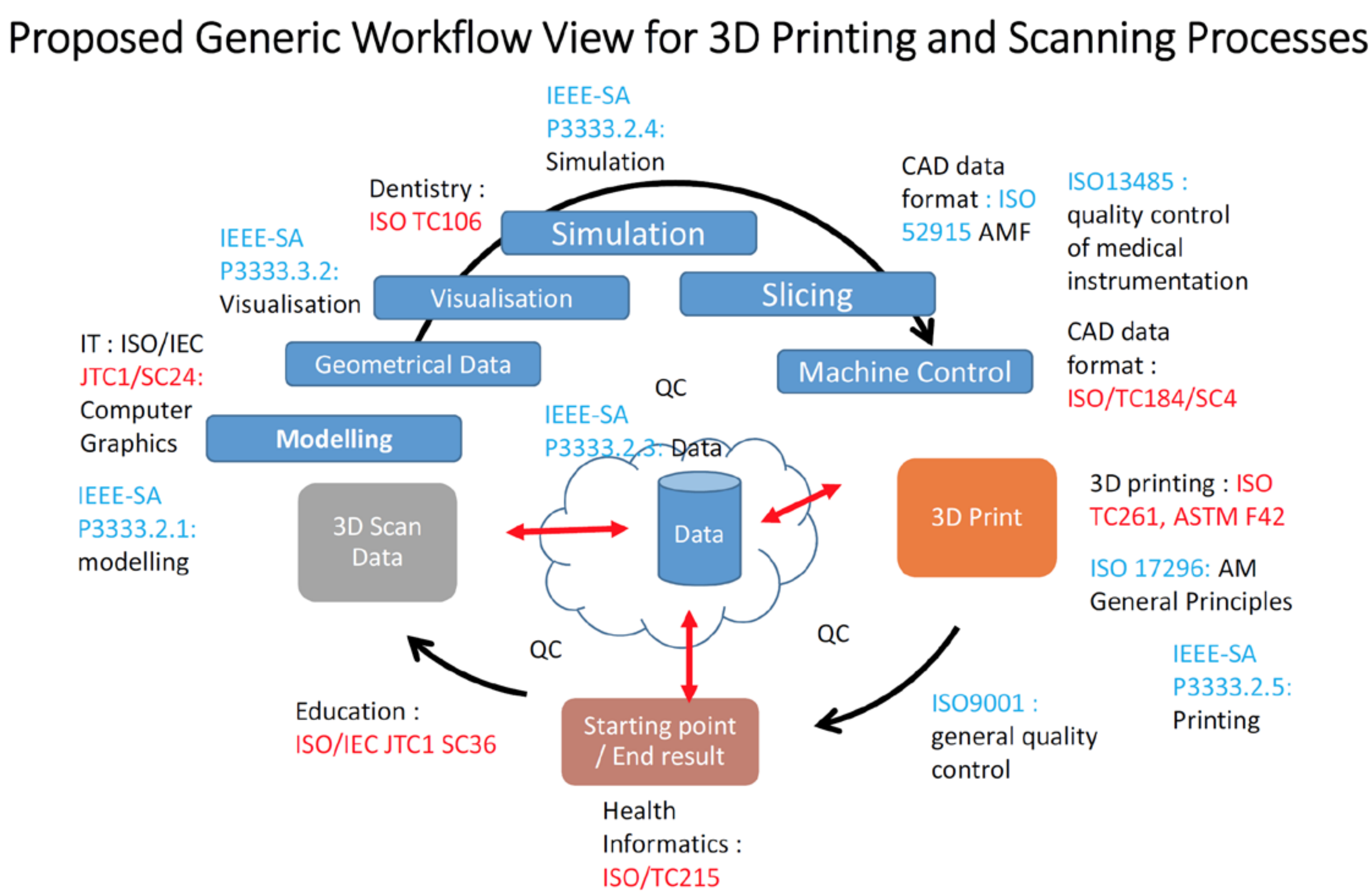
- Calibrate **Medical 3d modelling;** Minimize bias
- Volumetric File format **for Personalized Medical Products;** Optimize modelling
- Standardization of The Process **for Data Management.;** Improve convenience

Areas of expertise		Existing ISO Standards to Reference or Extend
Medical practices (Medical requirements)	⇔	ISO/TC 150
CAD Design Content *Implants Design Models, etc…*	⇔	ISO/TC 261 WG4 - ISO/ASTM DIS 52910 - GENERAL DESIGN GUIDELINES
AM Digital Content *Implants Design Models, etc…*	⇔	ISO/TC 261 JG64 – STANDARD GUIDELINES FOR AMF SOLID MODELING SUPPORT
AM Equipments, AM Materials and Processes	⇔	ISO/TC 261 WG2?
Medical Acquisition (Modality requirement) *CT Scans, MRI, US …*	⇔	ISO/TC 150 (/SC4?) ISO/TC 261 JG64 & JG59 – NON DESTRUCTIVE TESTING

ISO/IEC JTC 1 /WG 12 - 3D Printing and Scanning



ISO/IEC JTC 1/WG 12 - 3D Printing and Scanning



Segmentation: thresholding

- Create models based on the grayvalues (Hounsfield units in CT images)
- A grayvalue is a number associated with an image pixel defining the shade (white, gray, or black) of the pixel
- By grouping together similar grayvalues, the image data can be segmented, and models created

Segmentation of Medical Images

Generation	Based on	Approach	Description	Advantages	Disadvantages
1st Generation	Intensity thresholds and region growing.	Threshold Based Approach [7, 11]	Based on separating pixels in different desired classes depending on their gray level or intensity value called (*threshold*). The segmentation is achieved by grouping all pixels with intensity greater than the threshold into one class, and all other pixels into another class.	1. It works well for the object and background that have uniform brightness of distinct gray level values, respectively. 2. Simple but powerful approach for segmenting images having light objects on dark background.	1. It does not work well for images with multiple objects each having distinct gray level value. 2. Difficult to detect the correct threshold value. 3. Does not take into account the spatial characteristics of an image. This makes it to be sensitive to noise and intensity in homogeneities.
		Region Based Approach [5, 11]	Based on the principle of homogeneity - pixels with similar properties are clustered together to form a homogenous region. Region based segmentation is further divided into region growing, region splitting, region merging or their combination.	Work well when the region homogeneity criterion is easy to define. They are also more noise immune than edge detection approach.	1. By nature this approach is sequential and quite expensive in computational time and memory. 2. There are chances of under segmentation and over segmentation of regions in the image and region may contain holes.

Segmentation of Medical Images

2^{nd} Generation	Algorithms using image tools, optimization tools, and uncertainty models.	Statistical Approach [12]	In this approach, image texture is used to sub-divide the image into regions having different texture properties. Texture is defined by a set of statistically extracted features represented as vector in multidimensional feature space.	Statistical methods are particularly useful for random patterns/textures and also for complex patterns.	Difficulty associated with this approach is proper selection of the parameters which may otherwise lead excessively smooth segmentation and a loss of important structural details.
		Clustering Approach [5, 7, 11]	Cluster analysis or clustering is the assignment of a set of observations into subsets (called clusters) so that observations in the same cluster are similar in some sense. The commonly used clustering algorithms are K-means, fuzzy C-means etc.	Straightforward for classification and easy for implementation.	1. How to determine the number of clusters is difficult. 2. Features are often image dependent and how to select features to obtain satisfactory result, till remains unclear. 3. Does not utilize spatial information.
		Deformable Models Approach [5, 13]	Model-based technique which is used for delineating region boundaries using closed parametric curves or surfaces. Active contour and Active surface are included in this category.	Able to generate closed parametric curves or surfaces from images and the scheme is robust to noise and spurious edges.	1. This approach requires manual interaction to place an initial model. 2. Appropriate parameter choosing is difficult.

Segmentation of Medical Images

3rd Generation	Artificial knowledge incorporation into the segmentation process.	Atlas Guided Approach [5, 12]	This is the most powerful approach in the field of medical image segmentation. In this technique, information of anatomy, shape, size, and features of different organs, soft tissues are compiled in the form of atlas or look up table (LUT). The atlas is used as a reference frame for segmenting new images. Atlas-guided approach is implemented in the spatial domain of the image.	The approach is very powerful for medical image segmentation when a standard atlas or template is available. It also performs segmentation and classifications in one go.	1. The approach faces limitations in segmenting complex structure with variable shape, size, and properties. 2. Expert knowledge is required in building the database.
		Artificial Neural Network (ANN) (Supervised Approach) [12, 14]	Large number of interconnected processing elements work on training data (referenced imaged) to solve specific problems. Classifier algorithm falls in this category.	Ability to learn adaptively, using training data to solve complex problems within real time. Another advantage of this method is that operator can detect errors.	1. Training process is time consuming, costly and prone to human error. 2. Analysis of different image type & format, training and training data set is required to be repeatedly.

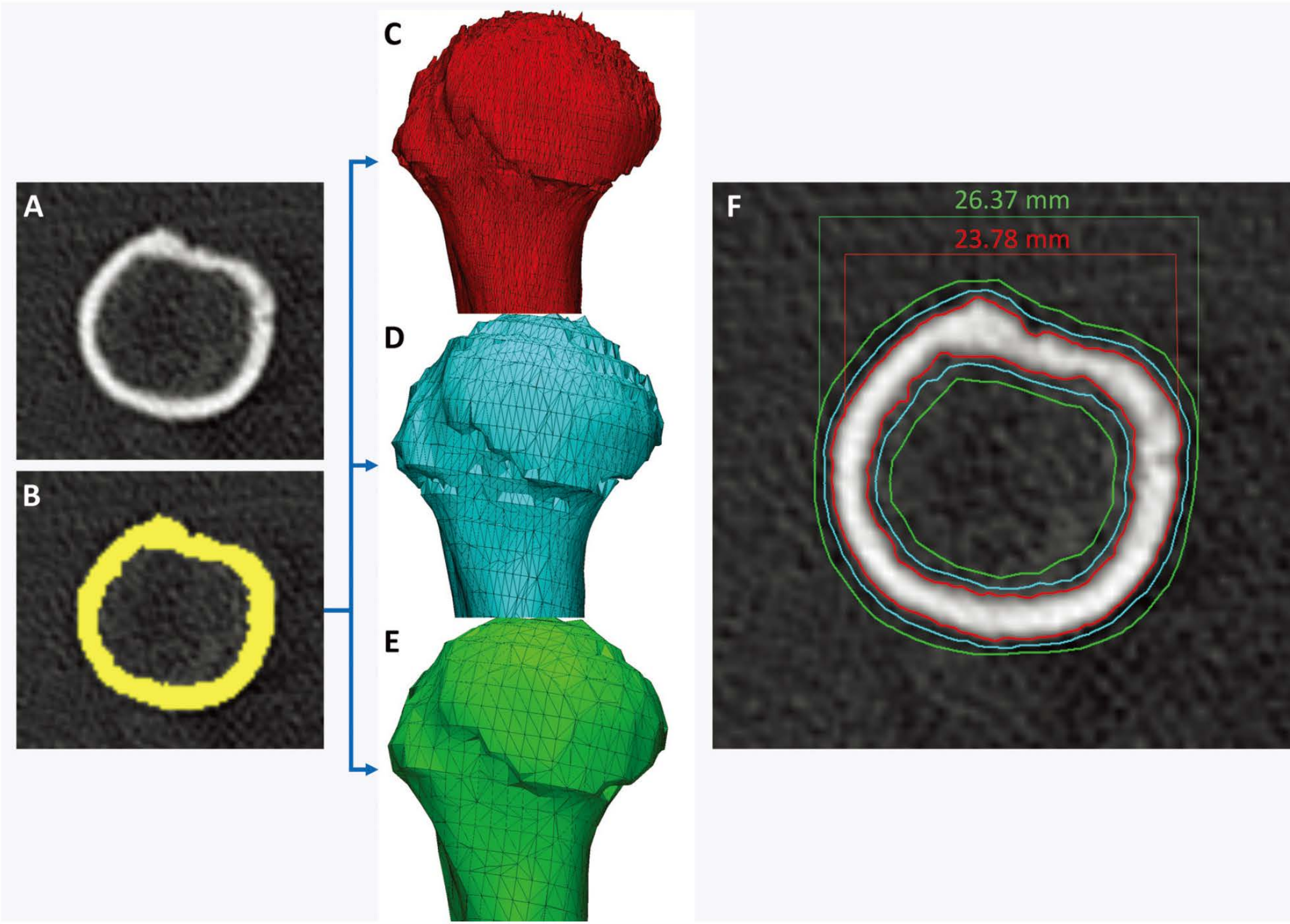


Figure 17. Differences in models based on different parameters used to generate the STL model from a segmentation. *A, B,* Axial CT image of a humerus, *A,* segmented with a 400-HU attenuation threshold, *B,* yields three STL models created by using different setting options (optimal, *C;* medium, *D;* and low, *E*) with use of one software (Mimics 18.0; Materialise NV). *C–F,* Differences among the models are seen in terms of triangle counts, *C–E,* and are nearly 3 mm in size, *F.*

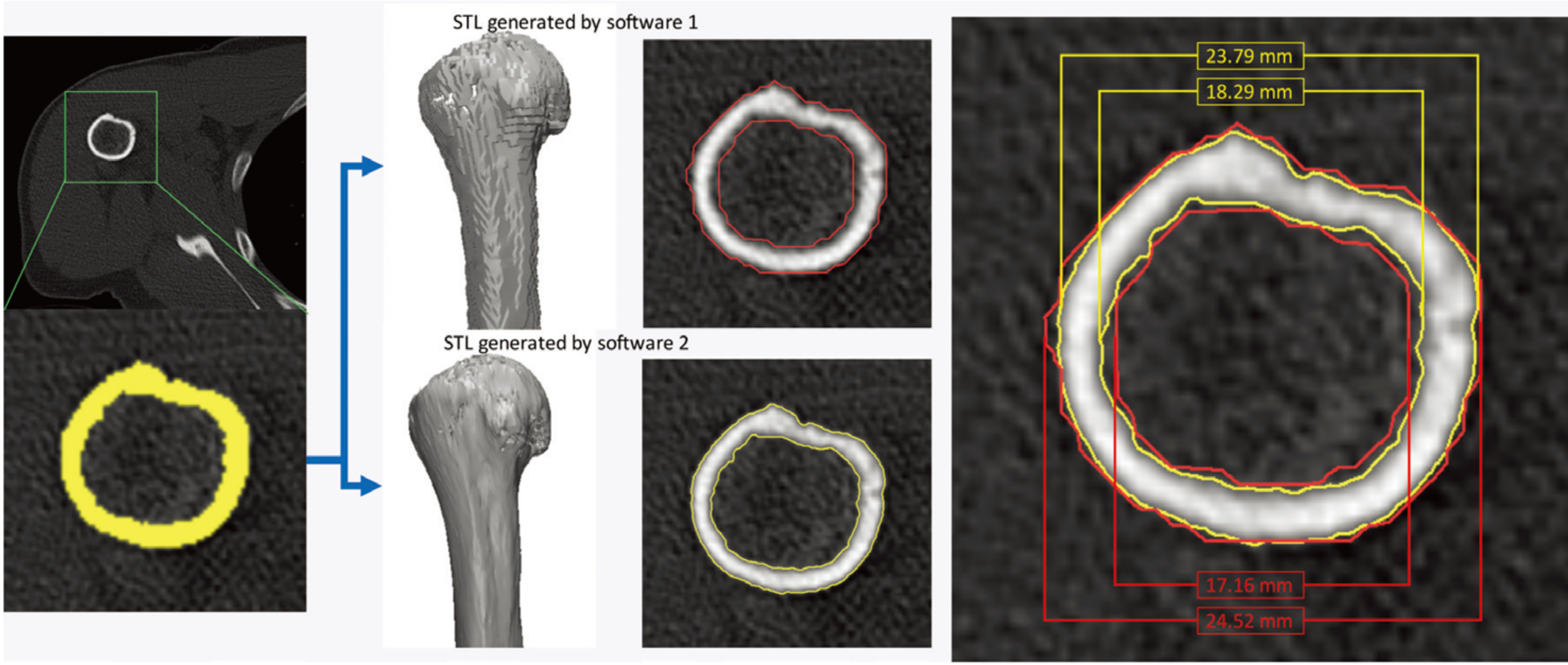


Figure 18. STL model generation algorithms provided in two software products (Mimics 18.0 and OsiriX [Pixmeo SARL, Bernex, Switzerland]). With both software products, axial CT images were loaded and identically segmented (yellow, lower left image) by using an attenuation threshold of 226 HU. The resulting STL models generated by using the default settings for each software differed by 0.73 mm for the external bone surface measurement and by 1.13 mm for the internal surface measurement.

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Measuring and Establishing the Accuracy and Reproducibility of 3D Printed Medical Models[1]

Figure 2. Photographs of a cadaveric skull (left) and the corresponding 3D printed model (right) show a loss of detail in the orbital floors (arrows) and along the margins of a maxillary defect, where the bone is thin, on the 3D model.

George E, Liacouras P, Rybicki FJ, Mitsouras D. Measuring and Establishing the Accuracy and Reproducibility of 3D Printed Medical Models. Radiographics. 2017 Sep-Oct;37(5):1424-1450

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Application orientated standardization