



HAL
open science

Morphological validation of a novel bi-material 3D-printed model of temporal bone for middle ear surgery education

Jordan Chauvelot, Cédric Laurent, Gael Le Coz, Jean-Philippe Jehl, Nguyen Tran, Marta Szczetyńska, Abdelhadi Moufki, Anne-Sophie Bonnet, Cécile Parietti-Winkler

► To cite this version:

Jordan Chauvelot, Cédric Laurent, Gael Le Coz, Jean-Philippe Jehl, Nguyen Tran, et al.. Morphological validation of a novel bi-material 3D-printed model of temporal bone for middle ear surgery education. *Annals of translational medicine*, 2020, 8 (6), pp.304. 10.21037/atm.2020.03.14 . hal-02889423

HAL Id: hal-02889423

<https://hal.univ-lorraine.fr/hal-02889423>

Submitted on 7 Dec 2020

HAL is a multi-disciplinary open access archive for the deposit and dissemination of scientific research documents, whether they are published or not. The documents may come from teaching and research institutions in France or abroad, or from public or private research centers.

L'archive ouverte pluridisciplinaire **HAL**, est destinée au dépôt et à la diffusion de documents scientifiques de niveau recherche, publiés ou non, émanant des établissements d'enseignement et de recherche français ou étrangers, des laboratoires publics ou privés.



Distributed under a Creative Commons Attribution - NonCommercial - NoDerivatives 4.0
International License

Morphological validation of a novel bi-material 3D-printed model of temporal bone for middle ear surgery education

Jordan Chauvelot¹, Cedric Laurent², Gaël Le Coz², Jean-Philippe Jehl³, Nguyen Tran⁴, Marta Szczetyńska², Abdelhadi Moufki², Anne-Sophie Bonnet², Cecile Parietti-Winkler¹

¹ENT Department, University Hospital of Nancy, Vandœuvre-lès-Nancy, France; ²CNRS, LEM3, UMR 7239, University of Lorraine, Metz, France; ³CNRS, IJL, UMR 7198, University of Lorraine, Campus Artem, Nancy, France; ⁴School of Surgery Nancy-Lorraine, Faculty of Medicine, Vandœuvre-Lès-Nancy, France

Contributions: (I) Conception and design: J Chauvelot, C Laurent, G Le Coz, A Moufki, AS Bonnet, C Parietti-Winkler; (II) Administrative support: JP Jehl, N Tran, AS Bonnet, C Parietti-Winkler; (III) Provision of study materials or patients: C Laurent, G Le Coz, N Tran, C Parietti-Winkler; (IV) Collection and assembly of data: J Chauvelot, C Laurent, G Le Coz; (V) Data analysis and interpretation: J Chauvelot, C Laurent, G Le Coz, M Szczetyńska, A Moufki, AS Bonnet, C Parietti-Winkler; (VI) Manuscript writing: All authors; (VII) Final approval of manuscript: All authors.

Correspondence to: Jordan Chauvelot. Service ORL, CHRU de Nancy, 5 rue du Morvan, 54500 Vandoeuvre-Les-Nancy, France.

Email: jordanchauvelot@yahoo.fr.

Background: A new model of 3D-printed temporal bone with an innovative distinction between soft and hard tissues is described and presented in the present study. An original method is reported to quantify the model's ability to reproduce the complex anatomy of this region.

Methods: A CT-scan of temporal bone was segmented and prepared to obtain 3D files adapted to multi-material printing technique. A final product was obtained with two different resins differentiating hard from soft tissues. The reliability of the anatomy was evaluated by comparing the original CT-scan and the pre-processed files sent to the printer in a first step, and by quantifying the printing technique in a second step. Firstly, we evaluated the segmentation and mesh correction steps by segmenting each anatomical region in the CT-scan by two different other operators without mesh corrections, and by computing distances between the obtained geometries and the pre-processed ones. Secondly, we evaluated the printing technique by comparing the printed geometry imaged using μ CT with the pre-processed one.

Results: The evaluation of the segmentation and mesh correction steps revealed that the distance between both geometries was globally less than one millimeter for each anatomical region and close to zero for regions such as temporal bone, semicircular canals or facial nerve. The evaluation of the printing technique revealed mismatches of 0.045 ± 0.424 mm for soft and -0.093 ± 0.240 mm for hard tissues between the initial prepared geometry and the actual printed model.

Conclusions: While other reported models for temporal bone are simpler and have only been validated subjectively, we objectively demonstrated in the present study that our novel artificial bi-material temporal bone is consistent with the anatomy and thus could be considered into ENT surgical education programs. The methodology used in this study is quantitative, inspired by engineer sciences, making it the first of its kind. The validity of the manufacturing process has also been verified and could, therefore, be extended to other specialties, emphasizing the importance of cross-disciplinary collaborations concerning new technologies.

Keywords: Artificial temporal bone; 3D printing; surgical training; educational tool; simulation

Submitted Jan 26, 2020. Accepted for publication Feb 04, 2020.

doi: 10.21037/atm.2020.03.14

View this article at: <http://dx.doi.org/10.21037/atm.2020.03.14>

1 Introduction

2 Surgery requires thorough anatomical knowledge and
3 acquisition of technical skills that inevitably required long
4 and repetitive hours of practice. Obviously, surgical training,
5 or evaluation of trainees, based on supervised practice of real
6 surgeries should not be acceptable (1,2) anymore, especially
7 in the first steps of surgical education. Middle ear surgery
8 concerns a very small anatomical region, volume of which
9 does not exceed 5 to 6 drops of water. Indeed, this region
10 includes the smallest bone of the whole human body: the
11 stapes (not exceeding 3 mm) (3) and many other at-risk
12 structures such as facial nerve, dura-mater, sigmoid sinus,
13 balance and auditory sensors. Consequently, the main part of
14 middle ear surgery is performed with operative microscope,
15 during which the otologic surgeon proceeds to millimetric
16 gestures with an extreme precision and tactfulness. Such
17 gestures, realized without direct vision and during several
18 hours, are tiring and represent a challenge for surgeons.
19 In such a context, millimetric errors may have dramatic
20 consequences, including facial paralysis (4,5), labyrinthine
21 effraction with hearing loss and vertigo, or dura mater
22 effraction with a cerebrospinal fluid leak (6-9). Prior to
23 real surgeries, it seems crucial that the future surgeons can
24 rehearse and be evaluated in the most realistic possible
25 context, generally consisting in cadaveric human samples.
26 However, such traditional surgical educational tools are
27 rare, costly and even hazardous because they may constitute
28 potential vectors of diseases (10,11). Besides, unlike in other
29 surgical specialties, there is no animal model that can be used
30 as educational tool in middle surgery (12,13).

31 Alternatively, simulation of surgical procedures using
32 virtual reality-based simulators (14-17). or artificial realistic
33 three-dimensional (3D) models (18-20) are of great
34 interest. Such simulators are now available for middle
35 ear surgery education thanks to recent advances in these
36 new technologies. They may represent complementary
37 educational tools to cadaveric samples, facilitating
38 anatomical knowledge and technical skills acquisition
39 in learners, without risk or stressful context neither for
40 patients nor for learners. In the present study, a 3D-printed
41 bi-material TB has been designed for surgical training,
42 using multi-material printing, which constitutes a well-
43 known technique widely applied to create high-resolution
44 polymeric biomaterials (21-24) allowing a distinction
45 between bone and soft tissues. However, before being
46 used in pedagogic programs, or even more for learners'
47 certification, simulation devices must be validated as

49 educational tools. Indeed, learning with surgical simulators
50 makes sense only if these devices both provide learning
51 context and present characteristics close enough to the real
52 clinical situation (14). Concerning artificial temporal bones
53 (TB), for example, their geometry needs to be consistent
54 with the real TB anatomy with minimal discrepancies.
55 Unfortunately, the realism of currently available artificial
56 TB models, in comparison with a real TB, is debatable.
57 Indeed, their validation as reliable educational tools is rare
58 in literature and when exists, it is most of the time based on
59 subjective qualitative comparisons (18-20,25). Subjective
60 evaluation through dissection performed by expert appears
61 limited, and there is a lack of further objective validation
62 and quantitative methodologies. Such validation would
63 allow concluding to the clinical suitability of the simulation
64 device. To fill this gap, one way of assessing the geometry
65 of such a simulation device could be to compare the
66 artificial model with the source patient's real anatomy.
67 Such an objective methodology is inspired from the field
68 of engineering sciences (26) and allows identification of 3
69 potential sources of errors, leading to mismatches between
70 the real patient's anatomy (related to the source patient's
71 TB CT-scan) and the artificial TB. The first one may
72 occur during the segmentation step performed manually by
73 clinicians from the Digital Imaging and Communications
74 in Medicine (DICOM) files that inevitably involved a
75 subjective interpretation of the different structure limits.
76 The second one may result from the smoothing and
77 simplifications of the mesh patterns after the segmentation
78 step [required to prepare the files for 3D-printing and result
79 in appropriated STereoLithography (STL) files] (27,28),
80 potentially leading to discrepancies with the initial anatomy
81 of DICOM files. The last potential source of error may
82 come from the multi-material 3D-printing process that can
83 lead to mismatches between the STL files used for printing
84 and the actual printed device.

85 As a result, the aim of the present study was to assess the
86 ability of our new 3D-printed bi-material artificial TB to
87 reproduce the complex anatomy of the source TB, proving,
88 all at once, the reliability of its manufacturing process.

90 Methods

91 An anonymous adult female, without history of middle
92 ear pathology, underwent a TB CT-scan with a standard
93 protocol for TB examination achieved by a "VCT
94 lightspeed—General Electric healthcare Chicago Illinois
95 U.S" with 0.625 mm sections. Both an otologist expert and
96

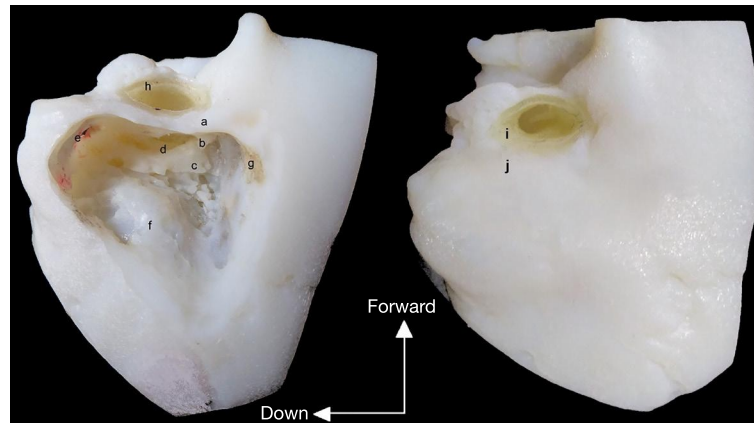


Figure 1 The bi-material 3D-printed temporal bone in operating position. Left: dissected model with identification of both hard (a: cortical bone; b: short process of the incus; c: external semi-circular canal) and soft (d: facial nerve; e: digastric crest; f: sigmoid sinus; g: dura mater; h: external auditory canal) resins. Right: full model with visualization of both soft (i: external auditory duct) and hard (j: mastoid bone) resins.

97 a neuroradiologist expert corroborated that the whole TB
 98 was normal (29), namely: a good airing of mastoid cells, a
 99 good shape and position of the ear-drum, ossicles, facial
 100 nerve and inner-ear components and finally, no protrusion
 101 of sigmoid sinus. The left side has been chosen arbitrarily.
 102 The DICOM files obtained were then segmented (by
 103 otologists and medical engineers with Blender (30) free
 104 software) in order to extract: outer ear, ear-drum, middle
 105 ear with malleus, incus and stapes, inner ear with the whole
 106 labyrinth (cochlea, vestibule with semi-circular canals,
 107 fenestra vestibuli and fenestra cochleae), dura mater,
 108 sigmoid sinus and the facial nerve (with chorda tympani).
 109 A mesh model under a standard tessellation language
 110 (STL) format was then obtained and smoothed to fit for
 111 3D-printing. We used different hardness of resins (“shores”
 112 for hard (bone) and soft (facial nerve, *chorda tympani*, *dura*
 113 *mater*, sigmoid sinus, ear drum, fenestra vestibuli, fenestra
 114 cochleae, membranous semi-circular canals and skin)
 115 tissues. The whole and dissected final printed models are
 116 shown on *Figure 1*.

117 118 *Evaluation of the CT-scan segmentation and mesh* 119 *correction steps*

121 The final device has been compared to the initial CT-scan
 122 of the source patient, considered by experts as “normal”
 123 concerning ear structures and settled as a basis for the
 124 design of this device.

125 The DICOM files of the TB CT-scan model were
 126 segmented manually and individually by two different

operators (to maximize segmentation variations), slice
 by slice (*Figure 2*), with “3D-slicer” software (31). The
 different anatomical structures were extracted without any
 further smoothing process (to emphasize the impact of
 mesh corrections) and the two sets of patterns thus obtained
 were compared to the STL files used for 3D-printing.

Point-to-surface distances (shortest node distances
 between two frames, *Figure 3*) were then calculated using
 algorithms based on the vtk visualization toolkit (32). The
 comparison between both geometries of the STL files used
 for 3D printing, yet smoothed, and the new ones, devoid
 of any smooth correction, requires the same reference
 frame. Thus, a preliminary manual repositioning was
 performed for each anatomical region [bone, vein (sigmoid
 sinus), semicircular canals, facial nerve, malleus, incus,
 stapes, fenestra cochleae and external auditory canal (with
 eardrum)], using bone structures of the new segmentation
 as a reference to compute the suited transformation. This
 procedure permitted to evaluate both the shape and the
 position of each structure in the whole model.

Evaluation of the multi-material 3D printing technique

This second characterization aimed at evaluating the
 mismatches related to the bi-material 3D printing process,
 by comparison between both geometries of the initial
 STL files and the actual 3D-printed geometry. High-
 resolution micro-Computed Tomography (μ CT) scan was
 required to distinguish both resins but generated heavy
 files. Only a fragment of the whole TB was then selected,

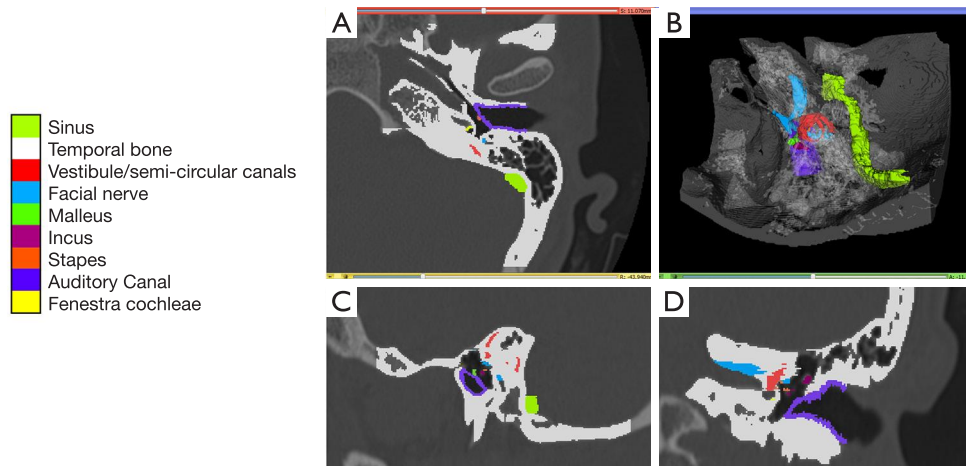


Figure 2 Manual segmentation of anatomical structures within the CT-scan. (A) axial view; (B) global 3D view; (C) sagittal view; (D) frontal view.

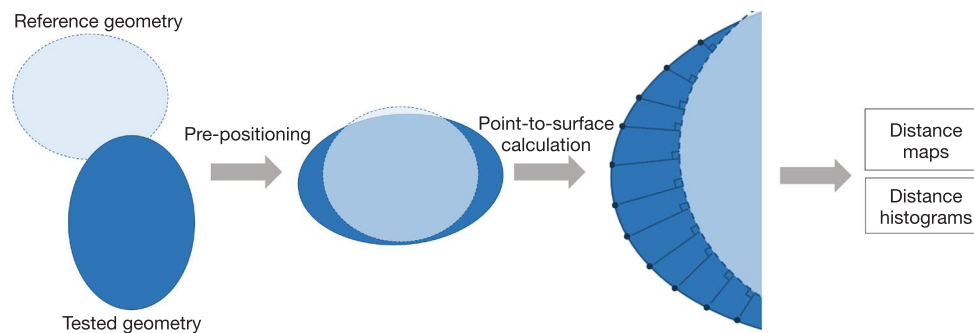


Figure 3 Explanatory diagram of the point-to-surface distances calculation. “Reference geometry” represents the segmentation of the CT-scan devoid of correction. “Tested geometry” corresponds to the geometry with mesh corrections.

157 enabling images with a sufficient resolution and contrast
 158 to perform the multi-material comparison between both
 159 geometries (Figure 4). The μ CT was performed using a
 160 Nanotom Phoenix device (General Electrics) with a voxel
 161 size of $10.4 \times 10.4 \times 10.4 \mu\text{m}^3$ and a window of $23.8 \times 23.8 \times 23.8$
 162 mm^3 . The materials constituting soft and hard tissues were
 163 then segmented manually from the μ CT images using the
 164 3D-slicer (31) and the geometries were finally extracted
 165 without any smoothing process to keep a maximum of
 166 information (Figure 4).

167 This geometry was compared to the initial STL files
 168 used for 3D-printing, as described previously (point-
 169 to-surface distances calculation and distance maps). To
 170 achieve this, the fragment imaged in μ CT was extracted
 171 from the STL files and positioned in the same frame that
 172 the reconstructed printed geometry. The point-to-surface

distance was then computed from every point of the STL
 files, using the μ CT-based geometry as a reference.

Results

Evaluation of the segmentation and mesh correction steps

The comparison between the STL files and the geometry of
 each anatomical region issued from a separate segmentation
 of the DICOM files, without any mesh correction, was
 performed. An example of such comparison is given in
 Figure 5 for bone tissue. Geometries issued from the manual
 segmentation without any mesh preparation (Figure 5A)
 and the STL mesh files corrected and prepared for 3D
 printing (Figure 5B) were compared by computing the
 point-to-surface distances map using the new rough
 segmentation files as a reference (Figure 5D). This approach

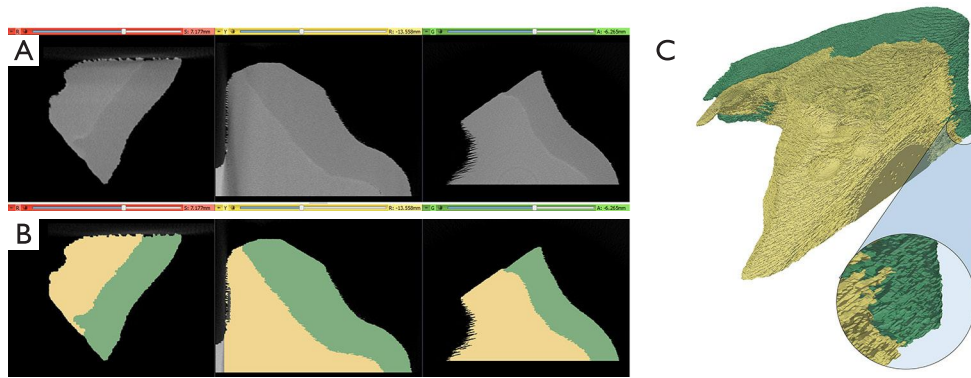


Figure 4 μ CT acquisition (A) and manual segmentation (B) of a fragment of the printed TB model. μ CT data are used to generate a 3D model (C) to be compared with the initial STL files sent to the 3D printer.

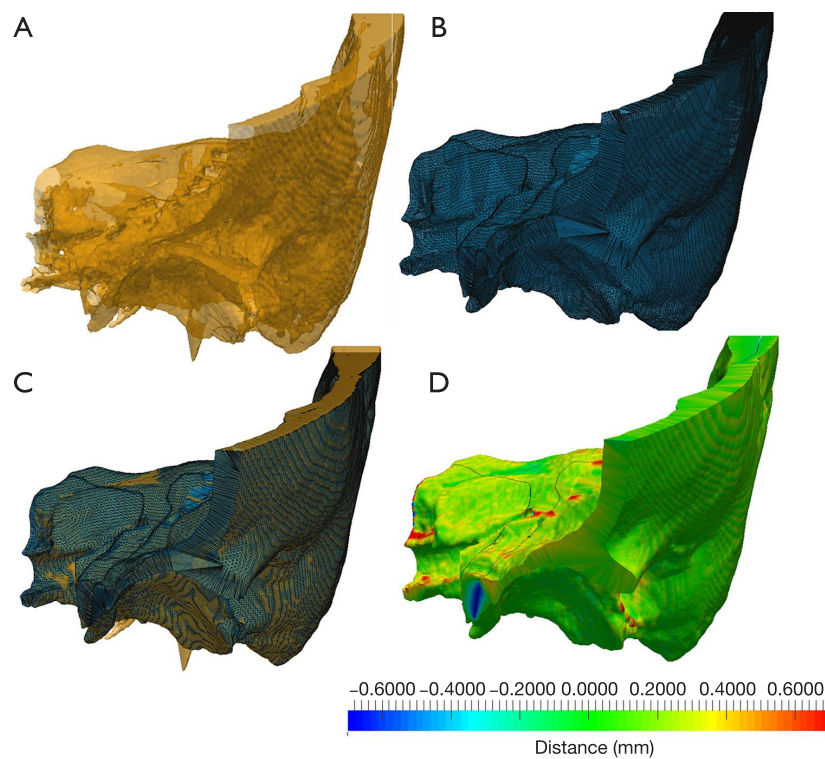


Figure 5 Example of comparison between rough reconstructed geometry issued from manual segmentation of the DICOM files (A) and the STL mesh files corrected and prepared for 3D printing (B). A superposition of both geometries is given in (C), and a distance map between these two geometries is calculated (D).

190 was applied by two different operators to each anatomical
 191 region present in the TB model, and the resulting distance
 192 maps are summarized in *Figures 5,6,7*. *Figure 5* provides a
 193 qualitative overview of the superposition of frames, with a
 194 majority of green color, equivalent to zero distance between

geometries. Blue colored (extreme negative distances) and 195
 red colored (extreme positive distances) surfaces are rare 196
 and scattered. *Figures 6,7* record quantitative results (each 197
 mesh node distance is calculated) with best results for “sinus” 198
 (*Figure 6B*, 0.02 ± 0.37 mm for operator #2), “vestibule/ 199

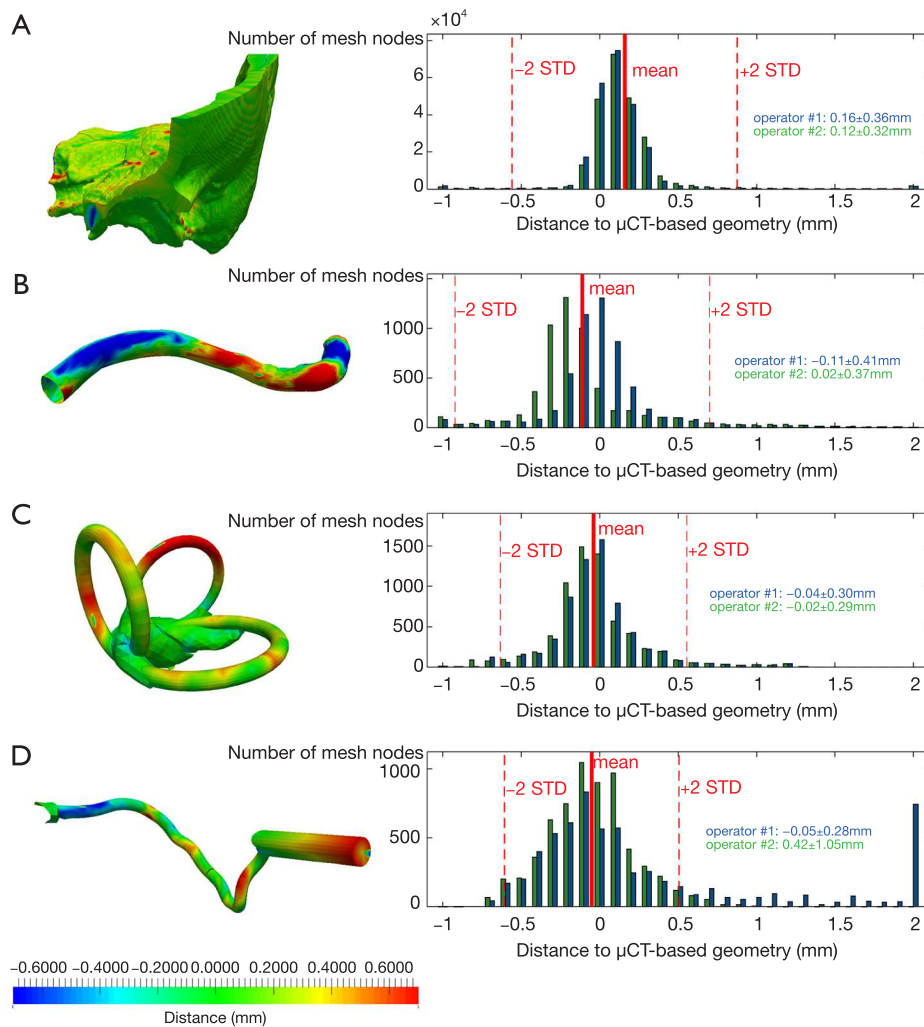


Figure 6 Distances between the rough reconstructed geometry issued from manual segmentation of the DICOM files and the STL mesh files corrected and prepared for 3D printing, for temporal bone (A), sinus (B), vestibule/semicircular canals (C) and facial nerve (D).

200 semicircular canals” (Figure 6C, -0.02 ± 0.29 mm for operator
 201 #2 and -0.04 ± 0.30 mm for operator #1) and “facial nerve”
 202 (Figure 6D, -0.05 ± 0.28 mm for operator #1). As observed
 203 in Figure 7, maximal point-to-surface distances were found
 204 for the middle ear with errors around 1 mm for malleus
 205 (Figure 7A, 1.01 ± 0.66 mm for both operators) and fenestra
 206 cochleae (Figure 7E, 1.12 ± 0.40 mm for both operators) with
 207 globally small ranges (around millimeter) except one and
 208 only: the distal extremity of the auditory canal (Figure 7D)
 209 which differs higher than 4 mm (0.66 ± 1.25 mm for operator
 210 #1 and 0.67 ± 1.25 mm for operator #2). Globally, the
 211 reconstructed geometries agree with the STL files prepared
 212 for 3D printing within a mean error of less than 1 mm.

Evaluation of the 3D printing technique

213
 214
 215
 216
 217
 218
 219
 220
 221
 222
 223
 224
 225

With the same process, qualitative (like in Figure 5) and quantitative (like in Figures 6,7) comparisons were performed between the geometry of STL files used for 3D-printing process and the actual printed TB model (reconstructions issued from μ CT). Qualitative results are represented in Figure 8. We observed that the distance between both geometries was generally below 0.5 mm except for precise regions that were not easily identified from manual segmentation.

A quantitative analysis (Figure 9) indicated that the mean distances between μ CT-reconstructed geometry and

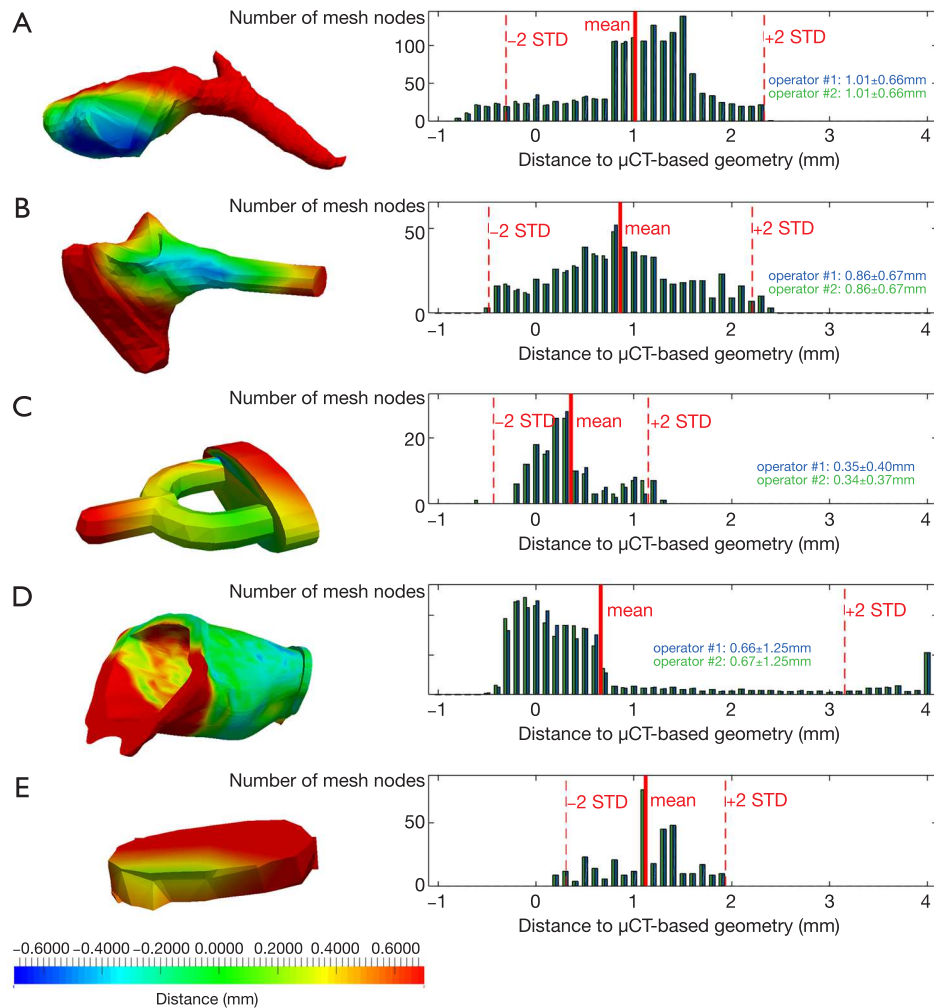


Figure 7 Distances between the rough reconstructed geometry issued from manual segmentation of the DICOM files and the STL mesh files corrected and prepared for 3D printing, for malleus (A), incus (B), stapes (C), auditory canal (D) and fenestra cochleae (E).

226 STL initial files were respectively 0.045 ± 0.424 mm and
 227 -0.093 ± 0.240 mm for soft and hard tissues.

228

229 Discussion

230

231 In the current contribution, we characterized the anatomical
 232 reliability of an innovative bi-material model of TB, created
 233 by 3D-printing technique, by comparing morphology of
 234 the final object to the pre-processed files and the initial CT-
 235 scan. Sources of errors have been identified and quantified.
 236 Thereafter, the place of this tool in surgical simulation and
 237 training is discussed.

238 Recent reforms guided by the Accreditation Council for
 239 Graduate Medical Education (ACGME), with restrictions

240 on duty hours for instance, supposed to reduce medical
 241 errors on one hand, may have, on the other hand, a negative
 242 impact on the surgical confidence and competence of
 243 residents (33-35). This could be offset by improved surgical
 244 simulators, moreover encouraged by institutions (1).

245 So far, cadaver dissection constitutes the training “gold
 246 standard”, but is associated with different limitations.
 247 Corpses may carry infectious agents such as Mycobacterium
 248 tuberculosis, Hepatitis B or C viruses, and prions associated
 249 with encephalopathies such as Creutzfeldt-Jakob disease
 250 (11,36). Exposure to formaldehyde, when used for fixation,
 251 may potentially be carcinogen (37). Moreover, cost and
 252 availability widely vary between countries, or between regions
 253 in a same country, and may be prohibitive in case of supply

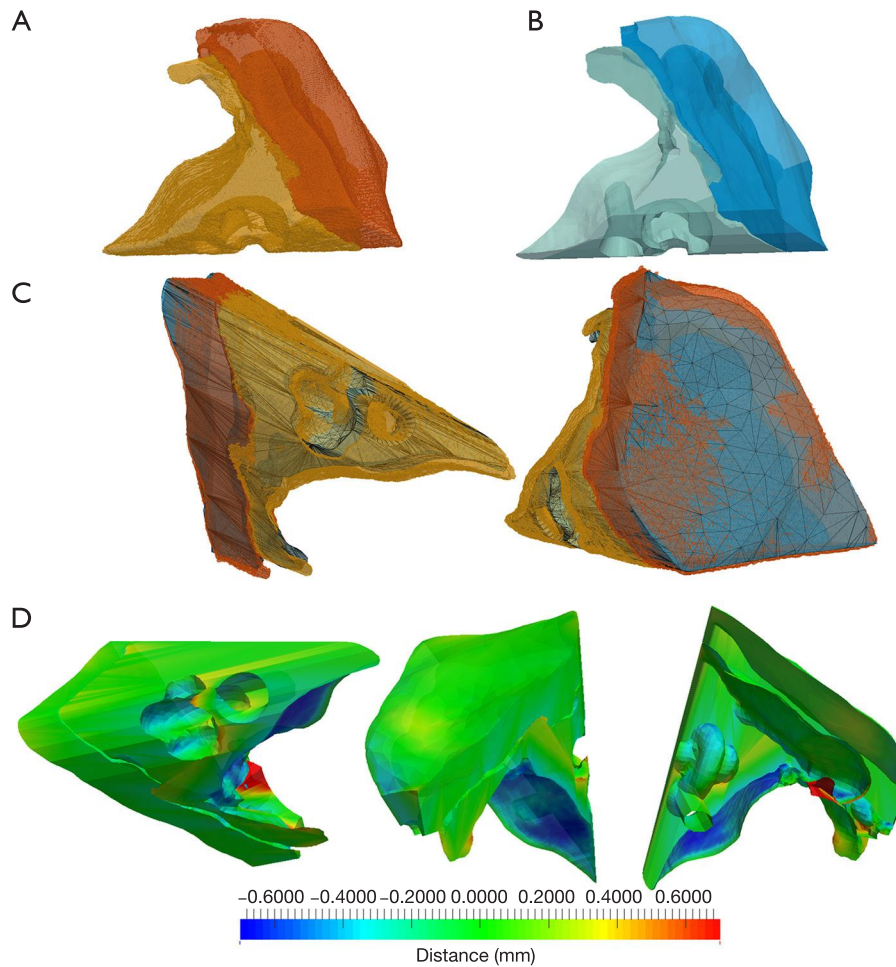


Figure 8 Qualitative comparison between STL files sent to the 3D printer and the actual geometry of the printed model issued from μ CT. (A) μ CT reconstruction of soft and hard tissues from the bi-material printed model. (B) Corrected STL files initially sent to the 3D printer, separated into soft and hard tissues. (C,D) Superposition of the geometries before and after printing.

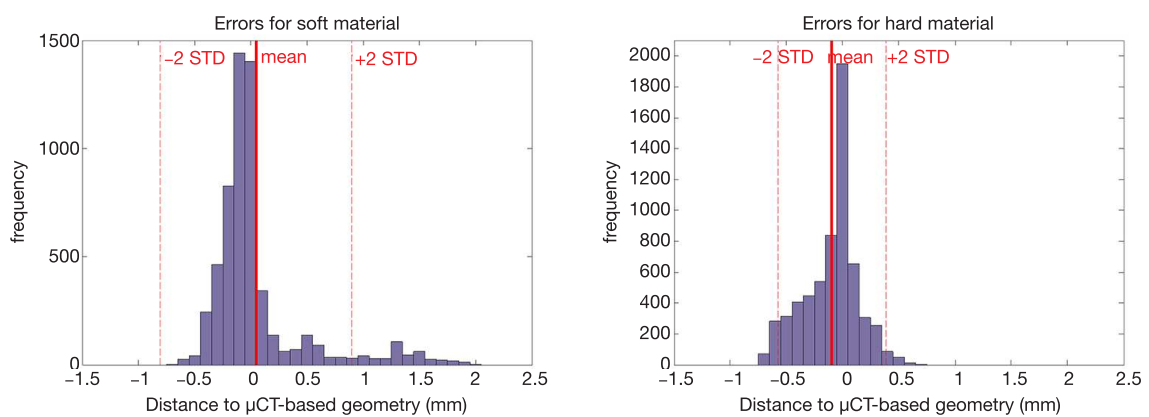


Figure 9 Quantitative comparison between STL files geometry sent to the printing machine, and the actual TB model issued from μ CT reconstructions for both soft and hard materials.

254 limitations due to financial or cultural issues. Referring to
 255 a study from Pakistan in 2011, 37% of medical students
 256 avoided cadaveric dissection due to moral or ethical grounds
 257 and another 18.6% for religious reasons (38). An additional
 258 downside in using cadaver TB for training is the inability
 259 to either standardize specimens for training and testing
 260 skills or provide customized scenarios for teaching. This is
 261 made possible somewhat with virtual reality or synthetic TB
 262 simulators (14). Trainees can learn through trial and error
 263 approach and repeat infinitely surgical tasks both to learn
 264 anatomy and relationships between 3D structures and to
 265 improve knowledge and technical skills (gesture precision,
 266 speed etc.) (39). It is worthy to emphasize that simulators do
 267 not replace traditional educational tools (such as training on
 268 cadaveric TB or supervised practice of real surgeries in the
 269 last learning steps), but they appear complementary, allowing
 270 to widen the range of educational tools, particularly for the
 271 very first steps of training. Then, these educational simulators
 272 [virtual reality like Voxelman (14), or artificial tools like our
 273 3D-printed TB], combined with traditional educational tool
 274 within an education program, allow a step by step tailored
 275 education.

276 In recent years, 3D printing technology benefited from
 277 major improvements while the generated costs dropped
 278 significantly, allowing extending its applications to the field
 279 of medical use. Multi-material printing technology used
 280 in the present study resulted in a synthetic final model
 281 reproducing both soft and hard tissues, in different colors
 282 and textures, when most of reported models settle for hard
 283 tissues only (18,20,40,41).

284 By 2007, Suzuki *et al.* (42). developed models with
 285 polyamide nylon and glass beads, primarily used for
 286 teaching anatomy, even if the authors discussed their
 287 potential as a cadaver specimen substitution in TB surgical
 288 training. In 2010, Bakhos *et al.* (18) used white resin to
 289 reproduce the bony anatomy of the TB based on CT scans
 290 of cadaveric specimens. In 2013, Mick *et al.* (43) developed
 291 TB prototypes with an improved similarity to human,
 292 with multiple colors, using plaster powder and a binding
 293 agent containing cyanoacrylate. The middle fossa plate was
 294 coated with painted latex to simulate dura mater. In 2014,
 295 Hochman *et al.* (44) used four different binding agents for
 296 infiltration of the powder material, and solved the problem
 297 of support material filling void spaces within the model
 298 during printing. In 2015, Rose *et al.* (19) managed, with
 299 an additive manufacturing technique, to create a pseudo
 300 bi-material temporal bone by varying ratios of multiple
 301 thermoset polymers, achieving unique biomechanical

properties for different structures, increasing anatomical
 realism of 3D models. However, the question of the the
 realism of such available 3D models is still to be addressed
 to conclude to their suitability as educational tools.

Many artificial simulators are daily used in surgery
 schools, even if their reliability regarding surgical anatomy
 is neither evaluated nor confirmed. However, realism of
 surgical artificial simulator geometry appears to be a main
 parameter for the transferability of technical skills acquired
 by learners during training, in the real surgical practices
 (45,46). Only a few studies in literature assess the realism
 of artificial TB, and rely on subjective evaluations, with
 questionnaires (18). To our knowledge, our study is the first
 in literature to attempt to develop an objective methodology
 of geometry validation of 3D-printing surgical simulators.
 For this purpose, we identified and quantified the different
 sources of possible errors in the manufacturing process, as
 usually practiced in the field of engineering sciences (47,48).

First, prior to 3D-printing, segmented regions from the
 DICOM files of TB CT-scan require mesh corrections in
 order to smooth geometries and delete the artifacts that
 may result from the segmentation step. These mandatory
 corrections consist in minor adjustments but could become
 significant when concerning very small regions such as
 middle ear. They should then be taken into consideration
 and even evaluated, like in the present study. Moreover,
 errors due to misinterpretation of the anatomical regions
 are inevitable. The comparison between both geometries
 displays only very slight mismatches, inferior to 1 mm, for
 the components of middle ear. While these results cannot
 be compared with those of other studies since this is the
 first study of its kind, they may still be discussed. The
 higher mismatch (up to 4 mm) was observed for skin of
 the lateral side of the auditory canal which corresponds
 to the cartilaginous duct and therefore does not have any
 consequence since only the bony duct is considered in our
 TB model. We can then consider it as an artifact. This may
 be corrected in future versions of the proposed model but
 has been voluntarily retained in the current study in order to
 emphasize such inherent risks due to manual segmentation.
 Either way, we have to notice that this only structure, not of
 primary importance, is below our expectations in relation to
 the whole object which displays a mean mismatch globally
 inferior to 1 mm and most of the time inferior to 0.43 mm:
 “temporal bone” (*Figure 6A*, 0.15 ± 0.35 mm for operator
 #1 and 0.12 ± 0.32 mm for operator #2), “sinus” (*Figure 6B*,
 -0.11 ± 0.40 mm for operator #1 and 0.02 ± 0.37 mm for
 operator #2), “vestibule/semicircular canals” (*Figure 6C*,

350 -0.04 ± 0.30 mm for operator #1 and -0.02 ± 0.29 mm for
351 operator #2), “facial nerve” (Figure 6D, -0.05 ± 0.28 mm
352 for operator #1 and 0.42 ± 1.05 mm for operator #2) and
353 “stapes” (Figure 7C, 0.35 ± 0.39 mm for operator #1 and
354 0.34 ± 0.37 mm for operator #2). It is worthy to note that separate
355 segmentations performed by two different operators did not
356 result in major differences, indicating that the segmentation
357 does not constitute the major source of reported errors.

358 Secondly, the accuracy of the printing technique was
359 assessed by comparing the geometry of the STL files (to
360 be printed) to the obtained printed geometry imaged using
361 μ CT. This was limited to a fragment of the whole TB
362 model because of the power needed to differentiate both
363 resins with X-ray signals on high-resolution geometries,
364 generating heavy files. Usable files of the whole object
365 did not allow to differentiate materials satisfactorily and
366 comparisons would have been uncertain. As a result, a
367 comparative study was performed between these two partial
368 geometries, and concluded to differences lower than $100\mu\text{m}$
369 for both soft and hard tissues. These differences may be
370 attributed to the errors inherent to manual segmentation
371 of the CT images (DICOM of the printed TB), and the
372 resolution of the 3D printing machine; this would imply
373 that the real error, generated by the printing process, is
374 nearly inexistent.

375 Overall, the morphological analysis concluded to a high
376 correspondence between the initial source patient’s TB CT
377 scan, the corrected STL files prepared for 3D printing and
378 the resulting 3D artificial TB. It may be considered that
379 such errors, globally inferior to 1mm, are not of primary
380 importance compared to the inherent TB anatomy variability
381 in normal subjects (49-51). Indeed, Quam *et al.* (52) showed,
382 in a series of cadaver dissections, that even a very small part
383 such as the short process length of the incus for instance,
384 had a range of 1.84 mm [5.07 ± 0.37 (4.02 to 5.86 mm)].
385 Kamrava *et al.* (3) showed that variations of stapes height are
386 above 2 mm and range from 2 to 5.5 mm. Singh *et al.* (50)
387 showed that the variability of chorda tympani’s position in
388 the mastoid can reach more than 10 millimeters (distance
389 of the chorda tympani from the facial nerve posterior genu
390 was 11.9 ± 3.3 mm) without any statistical difference ($P=0.08$)
391 between subjects. Beyond inter-human variability in size,
392 shape or position of structures within the TB, we could
393 consider intra-observer and inter-observer variations of
394 interpretation: Frangi *et al.* (53) showed in a 3D cardiac
395 segmentation study that intra-observer variability reach 0.556
396 mm for manual and 1.785 mm for automatic landmarking
397 while inter-observer variability reach 0.908 mm for manual

and even 2.003 mm for automatic landmarking. In matter 398
of otology, Iyaniwura *et al.* (51) observed an absolute inter- 399
observer variability average difference of 0.90 ± 0.31 mm and 400
an absolute intra-observer variability average difference of 401
 0.38 ± 0.17 mm for cochlear length measurements, on CT- 402
scans. Moreover, it is also worthy to notice the resolution of 403
CT-images with a voxel size of $0.625 \times 0.39 \times 0.39$ mm³: errors 404
inferior to such a resolution may thus not be preventable. All 405
this considered together, our mismatches seem to be even 406
inferior to the interindividual anatomical variation itself and 407
may therefore be considered acceptable. 408

Once the geometry of 3D-printed TB has been 409
validated, the model can be printed infinitely. Other models 410
could thus be considered: adult or child TB, with normal 411
or unusual anatomy and even with pathologic scenarios. 412
Furthermore, similar TB models could be manufactured 413
based on clinical CT-scans for preoperative simulation of 414
specific challenging cases, potentially reducing medical 415
errors and surgeon stress. But, to do so, the time-consuming 416
manual segmentation step should be overtaken in the future 417
by developing automatization for structure identification, 418
based on atlas (54). 419

Perspectives of this first study developing objective 420
validation methodology of artificial surgical simulator 421
are numerous. Indeed, the methodology developed here 422
and inspired from the field of engineer sciences could be 423
applied to the other surgical specialties. Moreover, while 424
the present study focused on the geometric characteristics 425
of the artificial surgical simulator, it would be of crucial 426
interest, in the future, to assess the material characteristics, 427
including its response to machining, especially in terms of 428
drilling resistance compared to human bone. 429

Finally, such simulators, once validated, should be 430
considered, like in aeronautics, for use in standardized 431
testing and compulsory certification (55) before real in- 432
vivo surgery. Some protocols now stand, like in robotic 433
surgery (56,57), or for learning curves (58-60) by comparing 434
simulator users versus non-users over time. 435

436 Conclusions 437

As a conclusion, our TB model is reliable regarding 439
anatomy and thus could be considered into ENT surgical 440
education programs. The methodology used in this study 441
is objective, drawn from engineer sciences, making it the 442
first of its kind. The validity of the manufacturing process 443
has been verified in the same time, and could therefore be 444
extended to other specialties, emphasizing the importance 445

446 of cross-disciplinary collaborations concerning new
447 technologies.

448

449

Acknowledgments

450

451

452

453

454

455

456

457

458

459

460

Footnote

461

462

463

464

465

466

467

468

469

470

References

471

472

473

474

475

476

477

478

479

480

481

482

483

484

485

486

487

488

489

490

491

492

493

1. Granry JC, Moll MC. Rapport de mission: état de l'art (national et international) en matière de pratiques de simulation dans le domaine de la santé, dans le cadre du développement professionnel continu et de la prévention des risques HAS 2012. Paris, 2012. Available online: https://www.has-sante.fr/portail/upload/docs/application/pdf/2013-01/guide_bonnes_pratiques_simulation_sante_format2clics.pdf

2. Levrant J, Fournier JP. Jamais la première fois sur le patient ! Available online: <http://link.springer.com/10.1007/s13341-012-0259-9>

3. Kamrava B, Roehm PC. Systematic review of ossicular chain anatomy: strategic planning for development of novel middle ear prostheses. *Otolaryngol Head Neck Surg* 2017;157:190-200.

4. Hohman MH, Bhama PK, Hadlock TA. Epidemiology of iatrogenic facial nerve injury: a decade of experience. *Laryngoscope* 2014;124:260-5.

5. Alzhrani F, Lenarz T, Teschner M. Facial palsy following cochlear implantation. *Eur Arch Otorhinolaryngol* 2016;273:4199-207.

6. Migirov L, Eyal A, Kronenberg J. Intracranial

complications following mastoidectomy. *Pediatr Neurosurg* 2004;40:226-9.

7. Senechaut JP, Hazan A, Henrion P, et al. Severe iatrogenic complications of surgery of the middle ear and their medicolegal aspects. *Ann Otolaryngol Chir Cervicofac* 1988;105:377-82.

8. Mancini F, Taibah AK, Falcioni M. Complications and their management in tympanomastoid surgery. *Otolaryngol Clin North Am* 1999;32:567-83.

9. McManus LJ, Stringer MD, Dawes PJD. Iatrogenic injury of the chorda tympani: a systematic review. *J Laryngol Otol* 2012;126:8-14.

10. Scott A, De R, Sadek SA, et al. Temporal bone dissection: a possible route for prion transmission? *J Laryngol Otol* 2001;115:374-5.

11. Demiryürek D, Bayramoğlu A, Ustaçelebi Ş. Infective agents in fixed human cadavers: A brief review and suggested guidelines. *Anat Rec* 2002;269:194-7.

12. Arloing S, Chauveau A, Fleming G. The comparative anatomy of the domesticated animals. New York: D. Appleton and Company, 1873. Available online: <http://www.biodiversitylibrary.org/bibliography/39284>

13. Treuting PM, Dintzis SM, Montine KS. Comparative anatomy and histology: a mouse, rat, and human Atlas. Second edition. London San Diego, Calif: Academic Press, 2018: 552.

14. Varoquier M, Hoffmann CP, Perrenot C, et al. Construct, face, and content validation on Voxel-Man® simulator for otologic surgical training. *Int J Otolaryngol* 2017;2017:2707690.

15. Kelly DC, Margules AC, Kundavaram CR, et al. Face, content, and construct validation of the da Vinci Skills simulator. *Urology* 2012;79:1068-72.

16. Lin Y, Wang X, Wu F, et al. Development and validation of a surgical training simulator with haptic feedback for learning bone-sawing skill. *J Biomed Inform* 2014;48:122-9.

17. Fang TY, Wang PC, Liu CH et al. Evaluation of a haptics-based virtual reality temporal bone simulator for anatomy and surgery training. *Comput Methods Programs Biomed* 2014;113:674-81.

18. Bakhos D, Velut S, Robier A, et al. Three-dimensional modeling of the temporal bone for surgical training. *Otol Neurotol* 2010;31:328-34.

19. Rose AS, Kimbell JS, Webster CE, et al. Multi-material 3D models for temporal bone surgical simulation. *Ann Otol Rhinol Laryngol* 2015;124:528-36.

20. Suzuki R, Taniguchi N, Uchida F, et al. Transparent model

- of temporal bone and vestibulocochlear organ made by 3D printing. *Anat Sci Int* 2018;93:154-9.
21. Jin SJ, Jeong ID, Kim JH, et al. Accuracy (trueness and precision) of dental models fabricated using additive manufacturing methods. *Int J Comput Dent* 2018;21:107-13.
22. Rebong RE, Stewart KT, Utreja A, et al. Accuracy of three-dimensional dental resin models created by fused deposition modeling, stereolithography, and polyjet prototype technologies: A comparative study. *Angle Orthod* 2018;88:363-9.
23. Tappa K, Jammalamadaka U. Novel biomaterials used in medical 3D printing techniques. *J Funct Biomater* 2018. doi: 10.3390/jfb9010017.
24. Dietrich CA, Ender A, Baumgartner S, et al. A validation study of reconstructed rapid prototyping models produced by two technologies. *Angle Orthod* 2017;87:782-7.
25. Okada DM, de Sousa AMA, Huertas R de A, et al. Surgical simulator for temporal bone dissection training. *Braz J Otorhinolaryngol* 2010;76:575-8.
26. Capello E, Semeraro Q. The harmonic fitting method for the assessment of the substitute geometry estimate error. Part I: 2D and 3D theory. *Int J Mach Tools Manuf* 2001;41:1071-102.
27. Manmadhachary A, Ravi Kumar Y, Krishnanand L. Improve the accuracy, surface smoothing and material adaption in STL file for RP medical models. *J Manuf Process* 2016;21:46-55.
28. Béchet E, Cuilliere JC, Trochu F. Generation of a finite element MESH from stereolithography (STL) files. *Comput Aided Des* 2002;34:1-17.
29. Ahuja AT, Yuen HY, Wong KT, et al. Computed tomography imaging of the temporal bone—normal anatomy. *Clinical Radiology* 2003;58:681-6.
30. Blender. Available online: <https://www.blender.org/>
31. Slicer. Available online: <https://www.slicer.org/>
32. VTK. Available online: www.vtk.org
33. Landrigan CP, Rothschild JM, Cronin JW, et al. Effect of reducing interns' work hours on serious medical errors in intensive care units. *N Engl J Med* 2004;351:1838-48.
34. Fonseca AL, Reddy V, Longo WE, et al. Operative confidence of graduating surgery residents: a training challenge in a changing environment. *Am J Surg* 2014;207:797-805.
35. Ahmed N, Devitt KS, Keshet I, et al. A systematic review of the effects of resident duty hour restrictions in surgery: impact on resident wellness, training, and patient outcomes. *Ann Surg* 2014;259:1041-53.
36. Correia JC, Steyl JL, De Villiers HC. Assessing the survival of Mycobacterium tuberculosis in unembalmed and embalmed human remains. *Clin Anat* 2014;27:304-7.
37. Whitehead MC, Savoia MC. Evaluation of methods to reduce formaldehyde levels of cadavers in the dissection laboratory. *Clin Anat* 2008;21:75-81.
38. Naz S, Nazir G, Iram S, et al. Perceptions of cadaveric dissection in anatomy teaching. *J Ayub Med Coll Abbottabad* 2011;23:145-8.
39. Arora A, Swords C, Khemani S, et al. Virtual reality case-specific rehearsal in temporal bone surgery: a preliminary evaluation. *Int J Surg* 2014;12:141-5.
40. Suzuki M, Ogawa Y, Kawano A, et al. Rapid prototyping of temporal bone for surgical training and medical education. *Acta Oto-Laryngologica* 2004;124:400-2.
41. Wang H, Northrop C, Burgess B, et al. Three-dimensional virtual model of the human temporal bone: a stand-alone, downloadable teaching tool. *Otol Neurotol* 2006;27:452-7.
42. Suzuki M, Hagiwara A, Ogawa Y, et al. Rapid-prototyped temporal bone and inner-ear models replicated by adjusting computed tomography thresholds. *J Laryngol Otol* 2007;121:1025-8.
43. Mick PT, Arnoldner C, Mainprize JG, et al. Face validity study of an artificial temporal bone for simulation surgery. *Otol Neurotol* 2013;34:1305-10.
44. Hochman JB, Kraut J, Kazmerik K, et al. Generation of a 3D printed temporal bone model with internal fidelity and validation of the mechanical construct. *Otolaryngol Head Neck Surg* 2014;150:448-54.
45. Ahmed K, Keeling AN, Fakhry M, et al. Role of virtual reality simulation in teaching and assessing technical skills in endovascular intervention. *J Vasc Interv Radiol* 2010;21:55-66.
46. Okraïnc A, Farcas M, Henao O, et al. Development of a virtual reality haptic veress needle insertion Simulator for surgical skills training. *Stud Health Technol Inform* 2009;142:233-8.
47. Oropallo W, Piegler LA. Ten challenges in 3D printing. *Eng Comput* 2016;32:135-48.
48. Yao AWL. Applications of 3D scanning and reverse engineering techniques for quality control of quick response products. *Int J Adv Manuf Technol* 2005;26:1284-8.
49. Würfel W, Lanfermann H, Lenarz T, et al. Cochlear length determination using Cone Beam Computed Tomography in a clinical setting. *Hear Res* 2014;316:65-72.
50. Singh D, Hsu CCT, Kwan GNC, et al. High resolution

- 638 CT study of the chorda tympani nerve and normal
639 anatomical variation. *Jpn J Radiol* 2015;33:279-86.
- 640 51. Iyaniwura JE, Elfarnawany M, Riyahi-Alam S, et
641 al. Intra- and Interobserver Variability of Cochlear
642 Length Measurements in Clinical CT. *Otol Neurotol*
643 2017;38:828-32.
- 644 52. Quam RM, Coleman MN, Martínez I. Evolution of the
645 auditory ossicles in extant hominids: metric variation in
646 African apes and humans. *J Anat* 2014;225:167-96.
- 647 53. Frangi AF, Rueckert D, Schnabel JA, et al. Automatic
648 construction of multiple-object three-dimensional
649 statistical shape models: application to cardiac modeling.
650 *IEEE Trans Med Imaging* 2002;21:1151-66.
- 651 54. Powell KA, Liang T, Hittle B, et al. Atlas-Based
652 Segmentation of Temporal Bone Anatomy. *Int J Comput
653 Assist Radiol Surg* 2017;12:1937-44.
- 654 55. Abou-Elhamd KEA, Al-Sultan AI, Rashad UM.
655 Simulation in ENT medical education. *J Laryngol Otol*
656 2010;124:237-41.
- 657 56. Hubert J, Perrenot C, Trand N, et al. Simulation
chirurgicale (dv-trainer®) et formation chirurgicale
robotique. *E-memoire de L'Academie Nationale de
Chirurgie* 2012;11:80-4.
57. Rapoport LM, Bezrukov EA, Tsarichenko DG, et
al. Methods for training of robot-assisted radical
prostatectomy. Available online: <http://www.mediasphera.ru/issues/khirurgiya-zhurnal-im-n-i-pirogova/2019/1/downloads/ru/1002312072019011089>
58. Gromski MA, Cohen J, Saito K, et al. Learning colorectal
endoscopic submucosal dissection: a prospective learning
curve study using a novel ex vivo simulator. *Surg Endosc*
2017;31:4231-7.
59. Colaco HB, Hughes K, Pearse E, et al. Construct validity,
assessment of the learning curve, and experience of using
a low-cost arthroscopic surgical simulator. *J Surg Educ*
2017;74:47-54.
60. Podolsky DJ, Fisher DM, Wong Riff KW, et al. Assessing
technical performance and determining the learning curve
in cleft palate surgery using a high-fidelity cleft palate
simulator. *Plast Reconstr Surg* 2018;141:1485-500.

Cite this article as: Chauvelot J, Laurent C, Le Coz G, Jehl JP, Tran N, Szczetyńska M, Moufki A, Bonnet AS, Parietti-Winkler C. Morphological validation of a novel bi-material 3D-printed model of temporal bone for middle ear surgery education. *Ann Transl Med* 2020. doi: 10.21037/atm.2020.03.14