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

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**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  $\mu$ 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  $0.045 \pm 0.424$  mm for soft and  $-0.093 \pm 0.240$  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

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## 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).

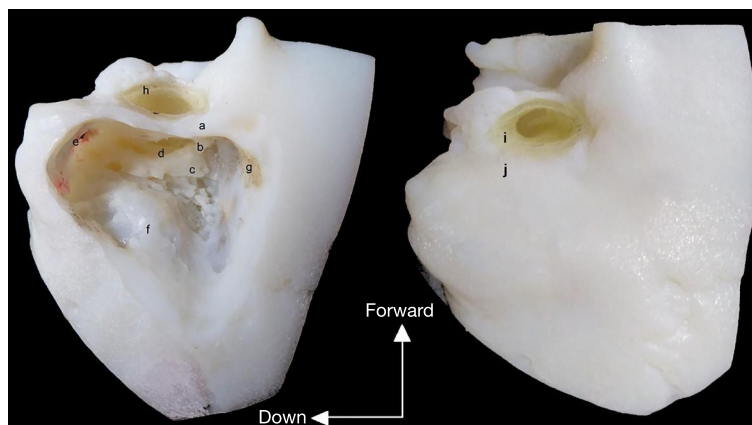
31 Alternatively, simulation of surgical procedures using  
32 virtual reality-based simulators (14-17). or artificial realistic  
33 three-dimensional (3D) models (18-20) are of great  
34 interest. Such simulators are now available for middle  
35 ear surgery education thanks to recent advances in 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.

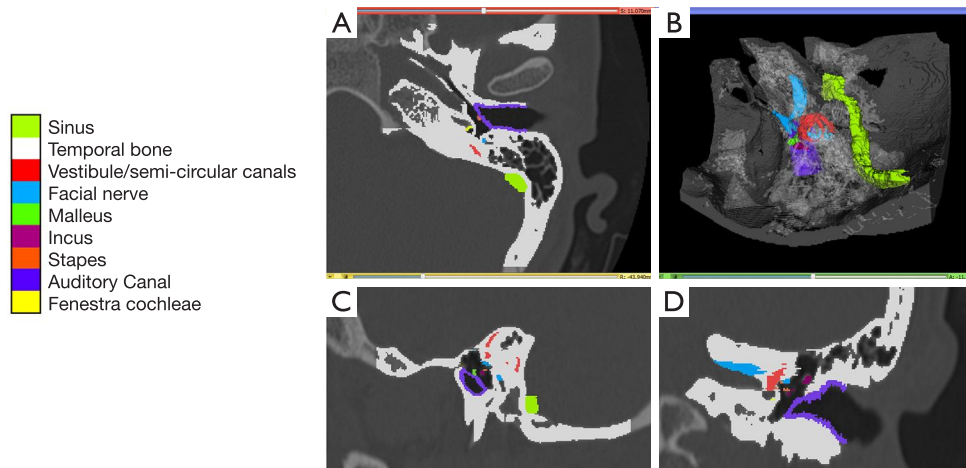
125 The DICOM files of the TB CT-scan model were  
 126 segmented manually and individually by two different

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.

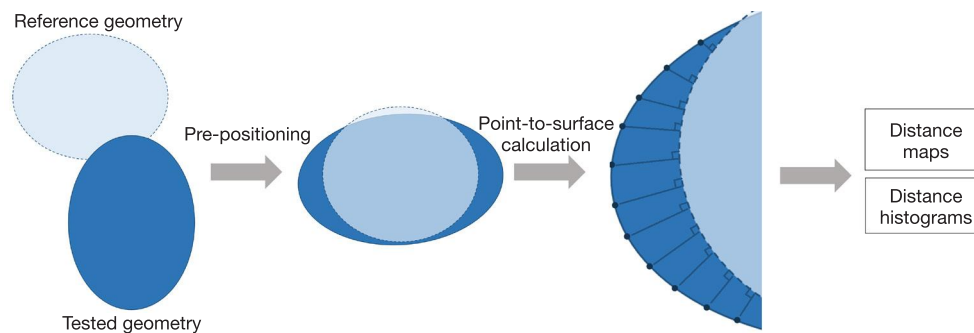
Point-to-surface distances (shortest node distances  
 between two frames, *Figure 3*) were then calculated using  
 algorithms based on the vtk visualization toolkit (32). The  
 comparison between both geometries of the STL files used  
 for 3D printing, yet smoothed, and the new ones, devoid  
 of 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 ( $\mu$ 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  $\mu$ 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  $\text{mm}^3$ . The materials constituting soft and hard tissues were  
 163 then segmented manually from the  $\mu$ 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).

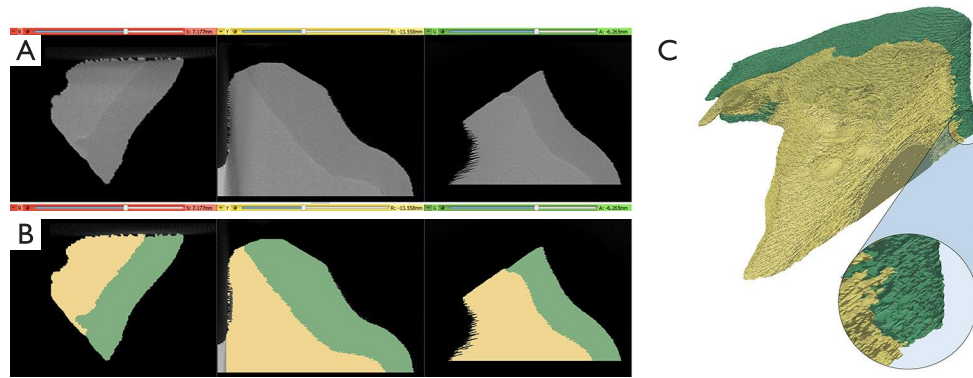
167 This geometry was compared to the initial STL files  
 168 used for 3D-printing, as described previously (point-  
 169 to-surface distances calculation and distance maps). To  
 170 achieve this, the fragment imaged in  $\mu$ CT was extracted  
 171 from the STL files and positioned in the same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

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

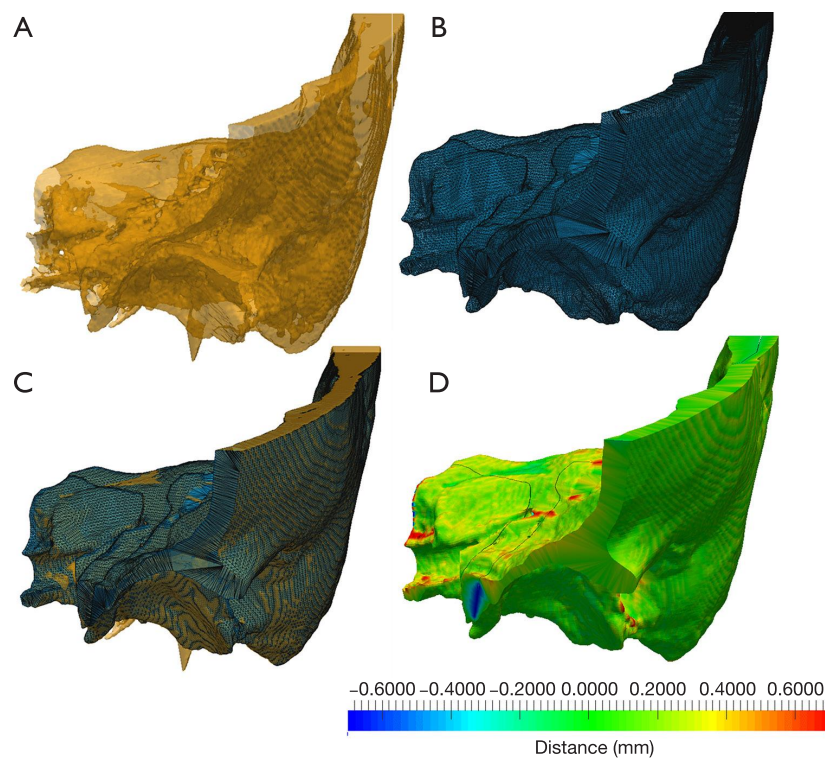
## Results

### *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



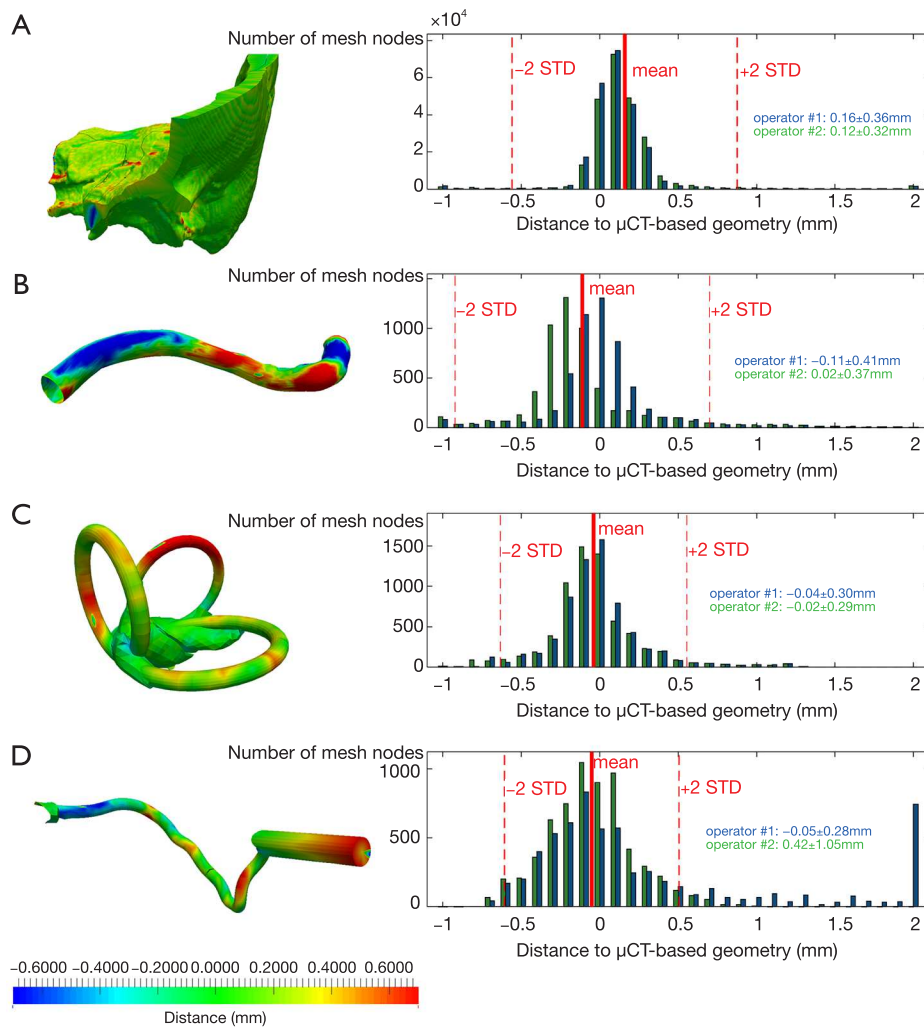
**Figure 4**  $\mu$ CT acquisition (A) and manual segmentation (B) of a fragment of the printed TB model.  $\mu$ CT data are used to generate a 3D model (C) to be compared with the initial STL files sent to the 3D printer.



**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*,  $0.02 \pm 0.37$  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).

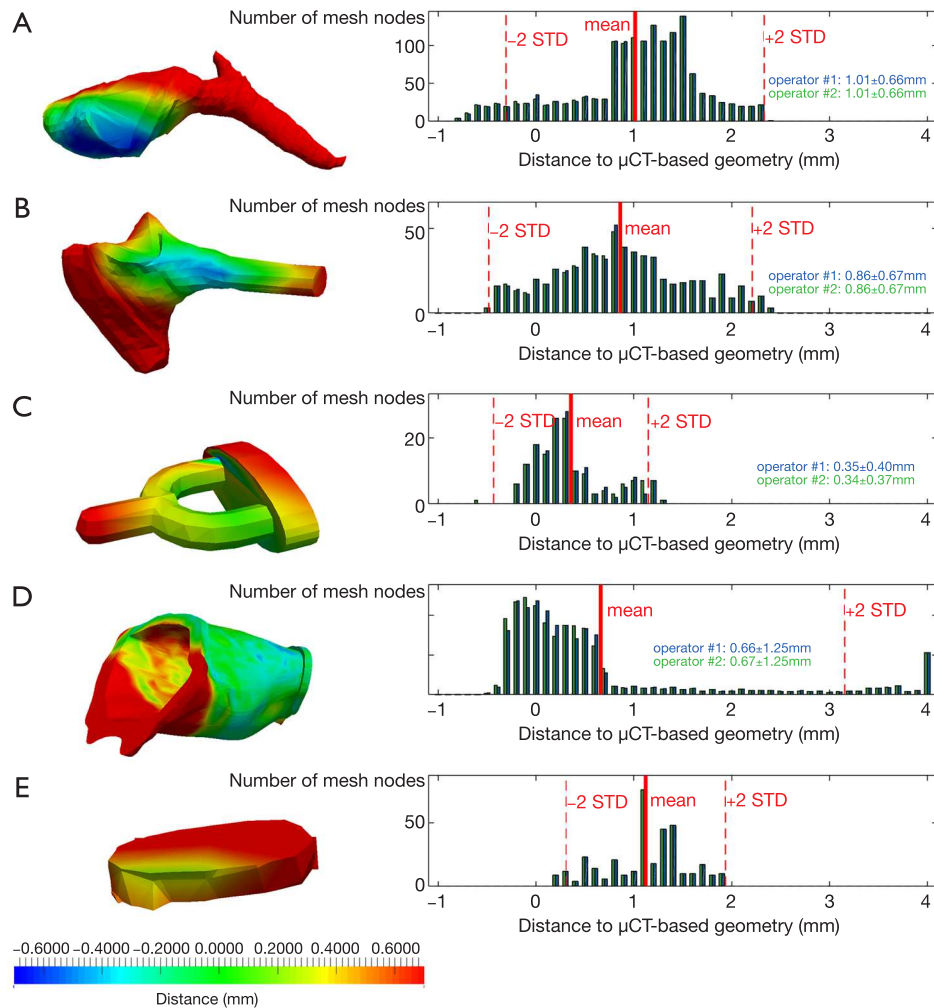
200 semicircular canals" (Figure 6C,  $-0.02 \pm 0.29$  mm for operator  
 201 #2 and  $-0.04 \pm 0.30$  mm for operator #1) and "facial nerve"  
 202 (Figure 6D,  $-0.05 \pm 0.28$  mm for operator #1). As observed  
 203 in Figure 7, maximal point-to-surface distances were found  
 204 for the middle ear with errors around 1 mm for malleus  
 205 (Figure 7A,  $1.01 \pm 0.66$  mm for both operators) and fenestra  
 206 cochleae (Figure 7E,  $1.12 \pm 0.40$  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 ( $0.66 \pm 1.25$  mm for operator  
 210 #1 and  $0.67 \pm 1.25$  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

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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  $\mu$ 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  $\mu$ 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  $0.045 \pm 0.424$  mm and  
 227  $-0.093 \pm 0.240$  mm for soft and hard tissues.

228

## 229 Discussion

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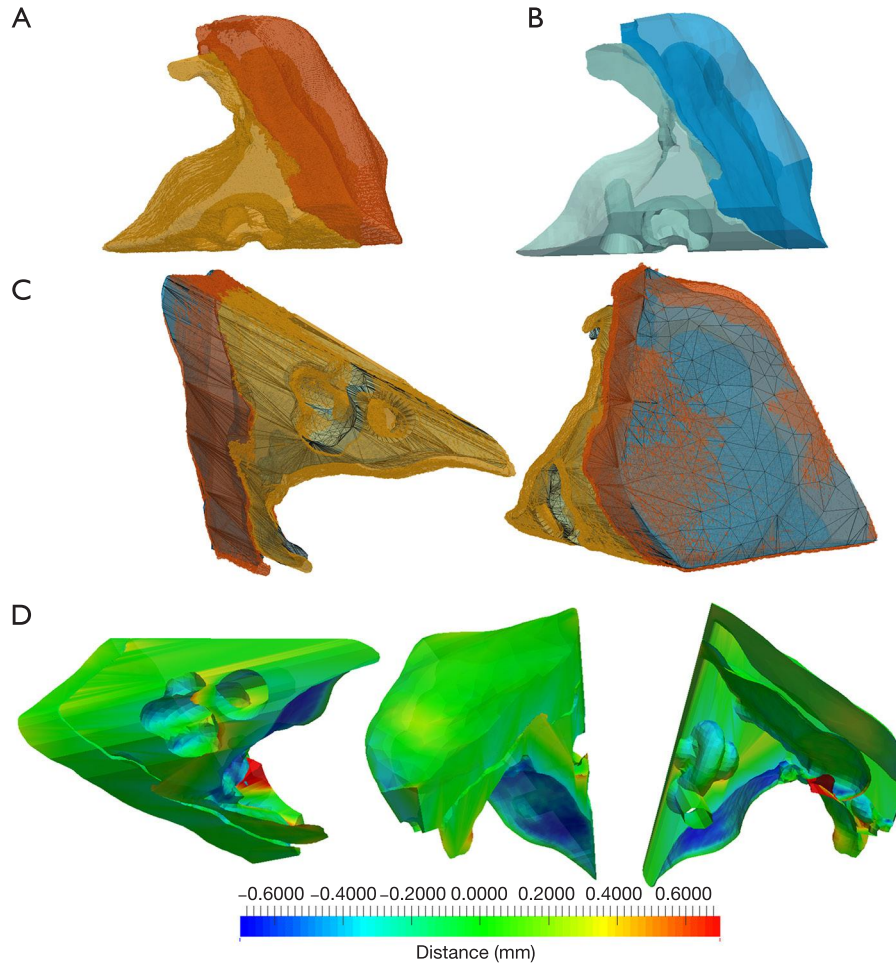
231 In the current contribution, we characterized the anatomical  
 232 reliability of an innovative bi-material model of TB, created  
 233 by 3D-printing technique, by comparing morphology of  
 234 the final object to the pre-processed files and the initial CT-  
 235 scan. Sources of errors have 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

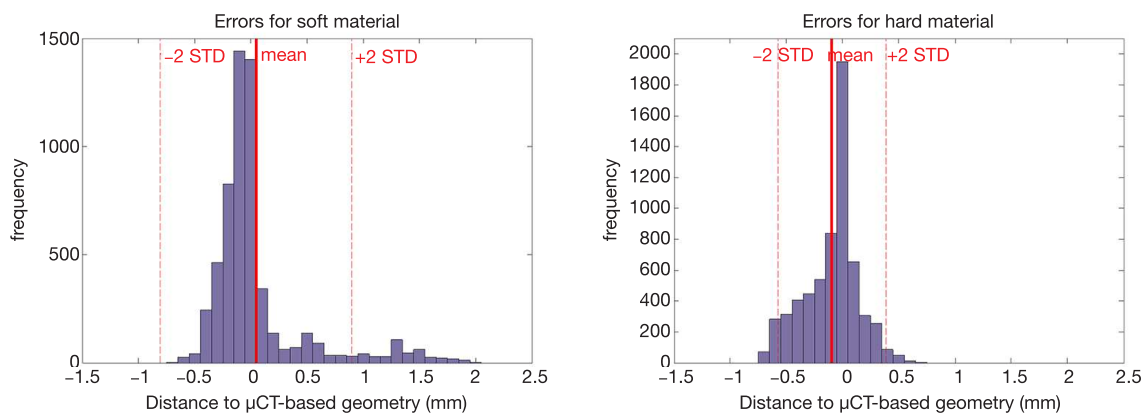
240 on duty hours for instance, supposed to reduce medical  
 241 errors on one hand, may have, on the other hand, a negative  
 242 impact on the surgical confidence and competence of  
 243 residents (33-35). This could be offset by improved surgical  
 244 simulators, moreover encouraged by institutions (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  $\mu$ CT. (A)  $\mu$ 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  $\mu$ 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 302  
 realism of 3D models. However, the question of the the 303  
 realism of such available 3D models is still to be addressed 304  
 to conclude to their suitability as educational tools. 305

Many artificial simulators are daily used in surgery 306  
 schools, even if their reliability regarding surgical anatomy 307  
 is neither evaluated nor confirmed. However, realism of 308  
 surgical artificial simulator geometry appears to be a main 309  
 parameter for the transferability of technical skills acquired 310  
 by learners during training, in the real surgical practices 311  
 (45,46). Only a few studies in literature assess the realism 312  
 of artificial TB, and rely on subjective evaluations, with 313  
 questionnaires (18). To our knowledge, our study is the first 314  
 in literature to attempt to develop an objective methodology 315  
 of geometry validation of 3D-printing surgical simulators. 316  
 For this purpose, we identified and quantified the different 317  
 sources of possible errors in the manufacturing process, as 318  
 usually practiced in the field of engineering sciences (47,48). 319

First, prior to 3D-printing, segmented regions from the 320  
 DICOM files of TB CT-scan require mesh corrections in 321  
 order to smooth geometries and delete the artifacts that 322  
 may result from the segmentation step. These mandatory 323  
 corrections consist in minor adjustments but could become 324  
 significant when concerning very small regions such as 325  
 middle ear. They should then be taken into consideration 326  
 and even evaluated, like in the present study. Moreover, 327  
 errors due to misinterpretation of the anatomical regions 328  
 are inevitable. The comparison between both geometries 329  
 displays only very slight mismatches, inferior to 1 mm, for 330  
 the components of middle ear. While these results cannot 331  
 be compared with those of other studies since this is the 332  
 first study of its kind, they may still be discussed. The 333  
 higher mismatch (up to 4 mm) was observed for skin of 334  
 the lateral side of the auditory canal which corresponds 335  
 to the cartilaginous duct and therefore does not have any 336  
 consequence since only the bony duct is considered in our 337  
 TB model. We can then consider it as an artifact. This may 338  
 be corrected in future versions of the proposed model but 339  
 has been voluntarily retained in the current study in order to 340  
 emphasize such inherent risks due to manual segmentation. 341  
 Either way, we have to notice that this only structure, not of 342  
 primary importance, is below our expectations in relation to 343  
 the whole object which displays a mean mismatch globally 344  
 inferior to 1 mm and most of the time inferior to 0.43 mm: 345  
 “temporal bone” (*Figure 6A*,  $0.15 \pm 0.35$  mm for operator 346  
 #1 and  $0.12 \pm 0.32$  mm for operator #2), “sinus” (*Figure 6B*, 347  
 $-0.11 \pm 0.40$  mm for operator #1 and  $0.02 \pm 0.37$  mm for 348  
 operator #2), “vestibule/semicircular canals” (*Figure 6C*, 349

350  $-0.04 \pm 0.30$  mm for operator #1 and  $-0.02 \pm 0.29$  mm for  
351 operator #2), “facial nerve” (Figure 6D,  $-0.05 \pm 0.28$  mm  
352 for operator #1 and  $0.42 \pm 1.05$  mm for operator #2) and  
353 “stapes” (Figure 7C,  $0.35 \pm 0.39$  mm for operator #1 and  
354  $0.34 \pm 0.37$  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  $\mu$ 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 [ $5.07 \pm 0.37$  (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  $11.9 \pm 3.3$  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  
of otology, Iyaniwura *et al.* (51) observed an absolute inter-  
observer variability average difference of  $0.90 \pm 0.31$  mm and  
an absolute intra-observer variability average difference of  
 $0.38 \pm 0.17$  mm for cochlear length measurements, on CT-  
scans. Moreover, it is also worthy to notice the resolution of  
CT-images with a voxel size of  $0.625 \times 0.39 \times 0.39$  mm<sup>3</sup>: errors  
inferior to such a resolution may thus not be preventable. All  
this considered together, our mismatches seem to be even  
inferior to the interindividual anatomical variation itself and  
may therefore be considered acceptable.

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

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

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

## Conclusions

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

446 of cross-disciplinary collaborations concerning new  
447 technologies.

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### Footnote

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