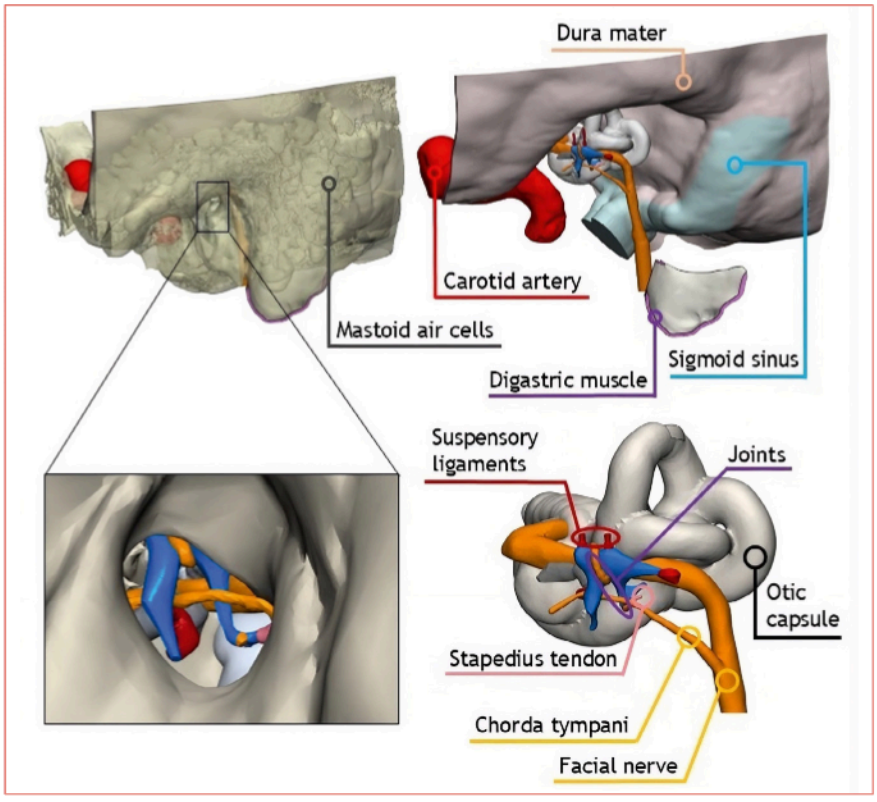
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Are 3D-printed temporal bone models the future of otologic surgical training? A national multicentre validation study



Cover figure. Novel Italian 3D-printed temporal bone model: structural design and anatomical details.

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Summary

Objective. To validate a novel 3D-printed temporal bone model as an acceptable substitute for cadaveric human temporal bones in otosurgical training.
Methods. A 3D-printed healthy temporal bone model was evaluated by 54 otosurgeons (27 experienced and 27 trainees) from Italian universities. Participants performed dissections on the model and completed a 27-question survey comparing the synthetic model with the cadaveric one. The primary outcome was the percentage of average total scores exceeding 3, with acceptability set at > 70%.
Results. Overall, 80.9% ($p < 0.001$) of participants rated the model as comparable to the cadaveric temporal bone (average total score exceeding 3). High scores were observed for "usefulness as a training tool", "task-based usefulness" and "overall reactions" domains with an average total score exceeding 3 in 95.8% ($p < 0.001$), 83.2% ($p < 0.001$), and 79% ($p = 0.004$) of questionnaires respectively. No significant differences were found between experienced and trainee surgeons' evaluations.

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Conclusions. 3D-printed temporal bone models are a viable, cost-effective, and customisable training tool comparable to cadavers. The realism of the soft tissues still needs to be refined in order to better mimic cadaveric specimens.

Keywords: 3D printing, additive manufacturing, temporal bone, training, otology

Introduction

Otosurgery is a one-surgeon discipline that necessitates extensive training and dedication. The complex anatomy of the temporal bone significantly contributes to the steep learning curve of this surgery. Continuous practice and meticulous attention to detail are crucial for maintaining the high level of manual dexterity required for successful otosurgical outcomes [1].

Surgical training has always relied on human cadavers to develop initial skills prior to actual surgical experience [2,3]. However, while human temporal bones have traditionally served as the gold standard for surgical training models, they present several limitations, including decreasing availability, increasing costs, and the potential risk of infectious disease transmission [4-6].

Animal models offer a primary alternative to human cadaveric bone. However, while these models are anatomically similar to humans, they have inherent differences that may not perfectly replicate the intricate structures of the human temporal bone. The ovine model, for instance, is suitable for middle ear surgery but has important limitations for temporal bone dissection due to the absence of a mastoid antrum and the presence of adipose tissue filling the mastoid cells [7,8].

In recent years, synthetic and virtual models have emerged as promising tools for the development and refinement of surgical skills [9,10]. Among these, 3D-printed temporal bone models have gained increasing worldwide recognition as safe and effective teaching tools in otology [11,12]. This rise is largely due to advancements in additive manufacturing technology and decreasing production costs, which have led to a significant increase in their availability. These models help trainees improve their anatomical knowledge and surgical skills before operating on actual patients [13,14]. While a synthetic model capable of perfectly replacing the cadaveric temporal bone does not yet exist, 3D-printed models are undoubtedly improving by leaps and bounds, becoming increasingly detailed and offering more realistic tactile and drilling feedback [15,16].

This study aimed to validate a novel Italian 3D-printed temporal bone model as an acceptable substitute for cadaveric human temporal bones in otologic surgical training through a national multicentre study.

Materials and methods

A novel 3D-printed temporal bone model was developed through a collaborative effort between the ENT department of IRCCS San Matteo Hospital and the 3D4Med clinical 3D printing laboratory (www.3d4med.eu). As the device is patent pending (Italian patent application no. 102025000002868, filed on 14/02/2025), specific details regarding the materials and manufacturing technologies cannot be disclosed.

The model was generated from a high-resolution cone beam computed tomography (CBCT) scan of the left ear of a healthy, anonymised subject, selected for the absence of anatomical variations, previous surgeries, or existing ear pathologies. The selection of the left ear for reproduction was arbitrary; however, utilising the right ear is equally feasible and may be advantageous for training surgical approaches bilaterally. The CBCT data were acquired as uncompressed Digital Imaging and COmmunications in Medicine (DICOM) files and processed using the open-source software ITK-Snap (https://www.itksnap.org).

A semi-automatic segmentation workflow was employed to delineate the following structures: facial nerve (from its intralabyrinthine tract to the stylomastoid foramen), chorda tympani, internal carotid artery, cochlea, semicircular canals, mastoid air cells, auditory canal, and ossicles of the middle ear. Manual refinement was then performed in collaboration with an expert otosurgeon to correct and validate the segmentation results.

Due to limited radiological visibility, certain structures - namely the cochlear process, stapedial and tensor tympani tendons, and the suspensory ligaments of the ossicular chain - were reconstructed exclusively through manual segmentation.

Subsequent anatomical modelling was carried out using 3-matic 18.0 (Materialise). The otic capsule was generated by offsetting the cochlear wall and semicircular canals. The incudomalleolar and incudostapedial joints were manually designed using anatomical landmarks. Additional features, including the insertion of the posterior belly of the digastric muscle and the dura mater of the middle and posterior cranial fossae, were reconstructed via surface offset operations. This involved applying a predefined thickness to the retrieved temporal bone surface to digitally generate these anatomical features, missing from the image dataset. The sigmoid sinus (from the lateral sinus to the jugular bulb within the posterior foramen lacerum) was isolated by projecting its course onto the bone.

Finally, surface refinement and smoothing were performed in 3-matic to optimise the model's anatomical fidelity and printability (Cover figure, Figs. 1-2).

Each component of the final 3D temporal bone model was exported in Standard Triangulation Language (.stl) format and processed using proprietary slicing software for fabrication with a photopolymer-based 3D printer. Distinct photopolymer mixtures were assigned to each anatomical structure to fine-tune both colour and mechanical properties.

The model was printed at a 1:1 scale and in an already assembled configuration, eliminating the need for post-processing beyond support material removal.

Specifically, no additional assembly, gluing, or mounting operations were required. Post-processing was limited to the removal of the support structures, deposited during fabrication to sustain overhanging geometries, using a pressurised water-jet system and manual cleaning. However, the gel-like support material within internal cavities, such as the cochlea and mastoid air cells, could not be entirely extracted due to the restricted accessibility of these anatomical regions.

As we aimed to create a training tool for trainee otosurgeons, the model intentionally employs colour enhancements to improve the visibility of crucial structures in otosurgery. The ossicular chain exhibits mobility at the incudomalleolar and incudostapedial joints, while the stapes remains fixed to ensure its stability. The cochlea is patent, though it is filled with the gel-like support material.

The final prototype was tested by ENT specialists using a temporal bone holder – similar to the patented design by Benazzo et al. [17] – to replicate surgical movements and assess procedural realism. Iterative refinements were implemented based on user feedback until the optimal configuration was achieved.

Design of the study and evaluation survey

This national multicentre study involved experienced otologic surgeons with at least 10 years of surgical experience in this field, and surgical trainees enrolled in Otorhinolaryngology or Audiology Residency Programs from all Italian universities. Trainees must have completed at least 3 cadaveric temporal bone surgery courses.

Each 3D-printed temporal bone model underwent independent laboratory dissection performed by both the expe-

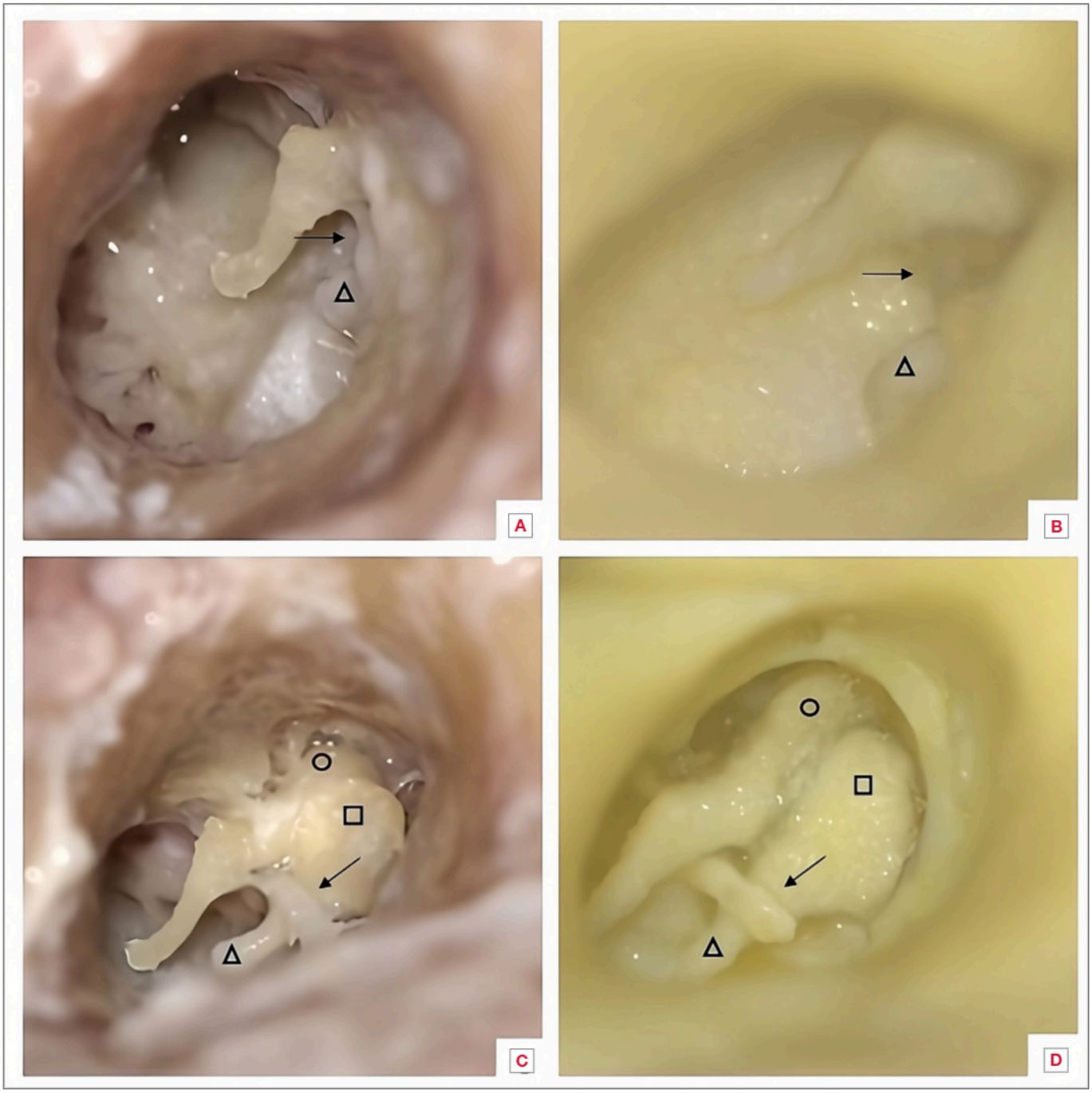


Figure 1. Comparative endoscopic view between cadaveric and 3D-printed temporal bone middle ear. **A)** Endoscopic transcanal cadaveric middle ear view; **B)** Endoscopic transcanal 3D-printed middle ear view; **C)** Endoscopic transcanal cadaveric middle ear view after atticotomy; **D)** Endoscopic transcanal 3D-printed middle ear view after atticotomy. Black arrow, chorda tympani; triangle, incus long process; square, incus body; circle, malleus head.

rienced surgeon and the trainee surgeon at each participating Italian university.

The dissection exercise included simple mastoidectomy, antro-aditus-atticotomy, opening of the facial recess/posterior tympanotomy with the possibility to perform a subfacial tympanotomy, round window surgery/cochleostomy with the option of inserting a cochlear implant array, canaloplasty, mastoidectomy with removal of the posterior

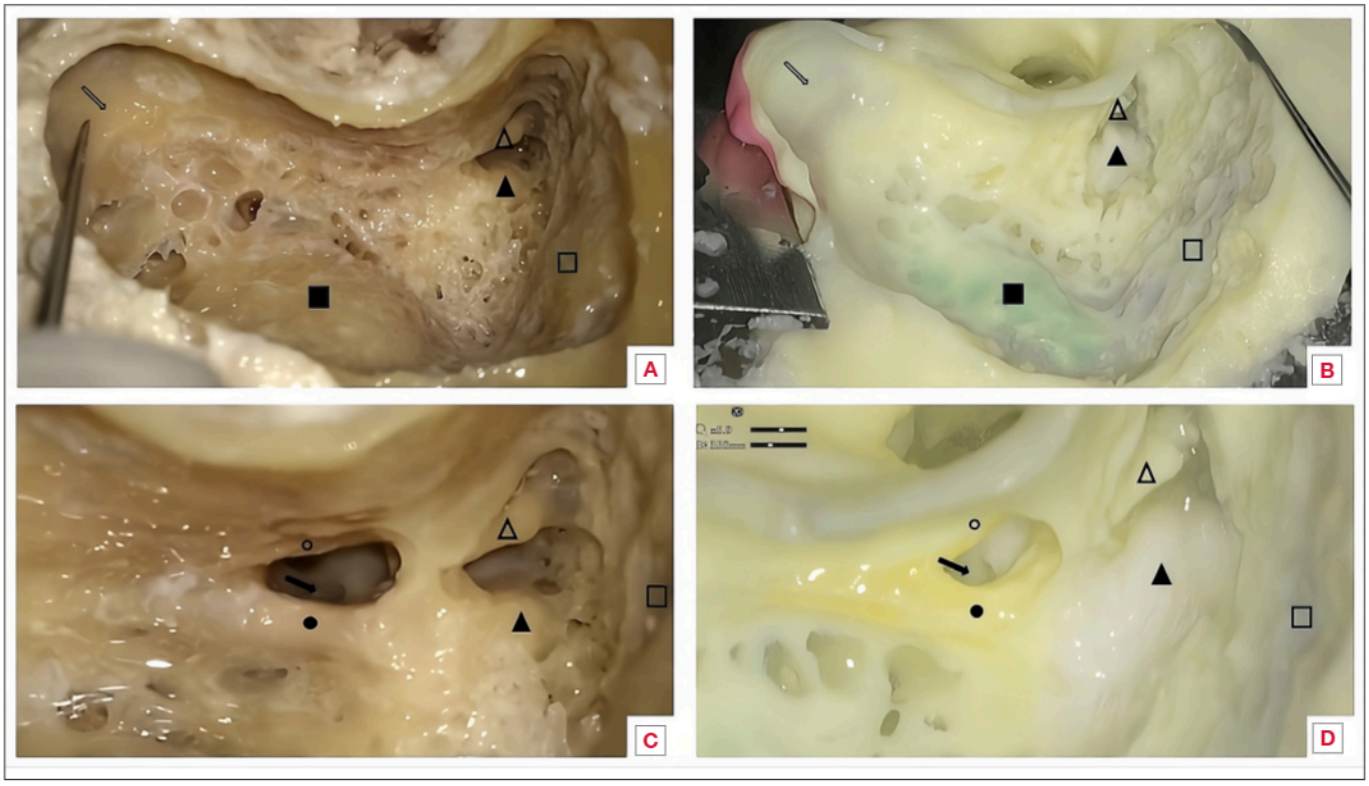


Figure 2. Comparative microscopic view between cadaveric and 3D-printed temporal bone dissection. **A)** Microscopic cadaveric mastoidectomy; **B)** Microscopic 3D-printed mastoidectomy; **C)** Microscopic cadaveric posterior tympanotomy; **D)** Microscopic 3D-printed posterior tympanotomy. Black square, sigmoid sinus; hollow square, middle cranial fossa dura mater; black triangle, lateral semicircular canal; hollow triangle, incus short process; hollow arrow, digastric ridge; black arrow, round window niche; black circle, facial nerve; hollow circle, chorda tympani.

wall of the external auditory canal, labyrinthectomy and visualisation of the internal auditory canal.

Following the dissection of the model, both the experienced surgeon and the trainee surgeon completed a survey consisting of 27 questions grouped into 5 domains (physical characteristics, anatomical realism, usefulness as a training tool, task-based usefulness and overall results) using a 5-point Likert scale ranging from strongly agree (5) to strongly disagree (1) (Fig. 3).

A score of 3 indicates that the synthetic temporal bone model was considered acceptable, though not comparable to human temporal bone. Scores below 3 suggest that the synthetic bone was not comparable and unacceptable. Conversely, scores exceeding 3 indicate that the synthetic model was deemed at least comparable to human cadaveric temporal bones.

Centre enrolment, data collection, and analysis required 2 years, from 2022 to 2024.

Statistical analysis

The primary outcome of this study is to determine the percentage of average total score exceeding 3 on the survey questionnaire. This 3D-printed temporal bone model will be considered acceptable if the percentage exceeds 70%. This threshold for model acceptability was defined a priori to reflect a robust level of consensus among users rather than a simple majority.

Secondary outcomes include evaluating the percentage of scores exceeding 3 for each domain and subdomain, comparing these data between experienced otosurgeons and trainee surgeons and calculating the mean of the average scores for the questionnaire and each domain.

Statistical analysis was performed with Stata 19 (StataCorp. 2025. Stata Statistical Software: Release 19. College Station. TX: StataCorp LLC). Two-sided type I error was set at 0.05.

The internal consistency of the survey questionnaire was evaluated using Cronbach's alpha to assess the reliability of the instrument. Alpha was calculated for the entire questionnaire as well as for each domain, separately for experienced otosurgeons and trainee surgeons.

Select between: □ **Experienced surgeon (over 10 years of experience in otosurgery)**

□ **Surgeon in training (at least 3 otologic dissection courses on cadaver)**

Surgeon's experience assessment		
Domain	**Subdomain**	**n**
Trainees' prior temporal bone operative experience	How many previous temporal bone courses have you attended?	
	How many cadaver bone exercises have you successfully completed to date?	
	How many middle-ear surgical procedures and mastoidectomies have you performed?	
	Years of experience in otosurgery	

3D-printed assessment questionnaire						
Domain	**Subdomain**	**Response**				
		(1) Strongly disagree	(2) Disagree	(3) Neither agree nor disagree	(4) Agree	(5) Strongly agree
Physical characteristics (Similarities to cadaver temporal bone – CTB)	Cortical bone hardness	1	2	3	4	5
	Trabecular bone hardness	1	2	3	4	5
	Vibrational properties	1	2	3	4	5
	Acoustic properties	1	2	3	4	5
	Drill skip	1	2	3	4	5
	Thinning of middle fossa dural plate	1	2	3	4	5
	Overall similarity to CTB	1	2	3	4	5
Anatomical realism	Depth perception is realistic	1	2	3	4	5
	Anatomical structures are realistic	1	2	3	4	5
	Tissue feel is realistic	1	2	3	4	5
Usefulness as a training tool	Useful for teaching anatomy	1	2	3	4	5
	Useful for teaching surgical planning	1	2	3	4	5
	Useful for improving hand-eye coordination	1	2	3	4	5
	Useful for improving operative technique	1	2	3	4	5
	Useful as an overall training tool	1	2	3	4	5
Task-based usefulness	Useful for teaching cortical mastoidectomy	1	2	3	4	5
	Useful for teaching atticotomy	1	2	3	4	5
	Useful for teaching facial recess dissection	1	2	3	4	5
	Useful for teaching round window surgery	1	2	3	4	5
	Useful for teaching canalplasty	1	2	3	4	5
	Useful for teaching wall down mastoidectomy	1	2	3	4	5
	Useful for teaching labyrinthectomy	1	2	3	4	5
Overall reactions	I would recommend this model to other trainees	1	2	3	4	5
	Working with synthetic 3D bones will help me feel more confident performing procedures in operating theatre	1	2	3	4	5
	This 3D printed synthetic temporal bone model should be incorporated into training curriculum	1	2	3	4	5
	Skills learned on this model are transferable to operating theatre	1	2	3	4	5
	Working with synthetic 3D bone was as useful as working with traditional frozen or formalinised cadaveric bones	1	2	3	4	5

Figure 3. Survey questionnaire on the usefulness of the novel 3D-printed temporal bone model for surgical skills development in otosurgery, using a 5-point Likert scale (1 = strongly disagree, 5 = strongly agree).

Table I. Internal consistency of survey. Cronbach's alpha for the entire questionnaire and for each domain, separately for experienced otosurgeons and trainee surgeons, are reported.

Domain	Experienced surgeons	Trainee surgeons
Physical characteristics	0.75	0.87
Anatomical realism	0.84	0.82
Usefulness as a training tool	0.65	0.80
Task-based usefulness	0.74	0.77
Overall reactions	0.43	0.34
Overall survey	0.89	0.90

Quantitative variables were summarised as median with interquartile range (IQR, 25th-75th percentiles) and range (minimum-maximum).

The percentage of average total score exceeding 3 on the survey questionnaire was reported with a 95% confidence interval (95% CI). The Wald test was used to compare this percentage to the reference value of 70%.

The percentage of scores exceeding 3 was also analysed for each domain of the questionnaire and reported with 95% CI. Finally, the average total score and the average score for each domain was compared between experienced otosurgeons and trainee surgeons.

Results

Twenty-seven Italian universities completed the study for a total of 54 otosurgeons (27 experienced and 27 trainee surgeons enrolled in Otorhinolaryngology or Audiology Residency Programmes). The questionnaire demonstrated high overall internal consistency, with a total Cronbach's alpha of 0.89 for experienced surgeons and 0.90 for trainee surgeons. Domain-specific alpha values ranged from 0.43 to 0.87 for experienced surgeons and from 0.34 to 0.87 for trainees. All domains showed acceptable to excellent reliability, except for the fifth domain, which exhibited lower internal consistency, likely reflecting the heterogeneous nature of its items (Tab. I).

Table II. Percentage of responses scoring ≤ 3 and > 3 on questionnaires regarding 3D-printed temporal bone model dissection, separated by trainee surgeons, experienced surgeons and all surgeons.

		Trainee surgeons (n = 27)		Experienced surgeons (n = 27)		All surgeons (n = 54)	
Domain	Subdomain	Score		Score		Score	
		≤ 3	> 3	≤ 3	> 3	≤ 3	> 3
Physical characteristics	Cortical bone hardness	13.6%	86.4%	13%	87%	13.3%	86.7%
	Trabecular bone hardness	13.6%	86.4%	26.1%	73.9%	20%	80%
	Vibrational properties	38.1%	61.9%	34.8%	65.2%	36.4%	63.6%
	Acoustic properties	42.9%	57.1%	39.1%	60.9%	40.9%	59.1%
	Drill skip	28.6%	71.4%	13.6%	86.4%	20.9%	79.1%
	Thinning of middle fossa dural plate	35%	65%	45.5%	54.5%	40.5%	59.5%
	Overall similarity to CTB	31.8%	68.2%	19%	81%	25.6%	74.4%
Anatomical realism	Depth perception is realistic	4.5%	95.5%	0%	100%	2.2%	97.8%
	Anatomical structures are realistic	22.7%	77.3%	21.7%	78.3%	22.2%	77.8%
	Tissue feel is realistic	45.5%	54.5%	52.2%	47.8%	48.9%	51.1%
Usefulness as a training tool	Useful for teaching anatomy	4.8%	95.2%	0%	100%	2.3%	97.7%
	Useful for teaching surgical planning	19%	81%	4.5%	95.5%	11.6%	88.4%
	Useful for improving hand-eye coordination	0%	100%	0%	100%	0%	100%
	Useful for improving operative technique	0%	100%	13.6%	86.4%	7%	93%
	Useful as an overall training tool	0%	100%	0%	100%	0%	100%
Task-based usefulness	Useful for teaching cortical mastoidectomy	4.8%	95.2%	4.5%	95.5%	4.7%	95.3%
	Useful for teaching atticotomy	9.5%	90.5%	4.5%	95.5%	7%	93%
	Useful for teaching facial recess dissection	14.3%	85.7%	31.8%	68.2%	23.3%	76.7%
	Useful for teaching round window surgery	25%	75%	36.4%	63.6%	31%	69%
	Useful for teaching canaloplasty	30%	70%	18.2%	81.8%	23.8%	76.2%
	Useful for teaching wall down mastoidectomy	4.8%	95.2%	0%	100%	2.3%	97.7%
	Useful for teaching labyrinthectomy	25%	75%	27.3%	72.7%	26.2%	73.8%
Overall reactions	I would recommend this model to other trainees	4.8%	95.2%	0%	100%	2.3%	97.7%
	Working with synthetic 3D bones will help me feel more confident performing procedures in operating theatre	9.5%	90.5%	40.9%	59.1%	25.6%	74.4%
	This 3D printed synthetic temporal bone model should be incorporated into training curriculum	14.3%	85.7%	4.5%	95.5%	9.3%	90.7%
	Skills learned on this model are transferable to operating theatre	25%	75%	13.6%	86.4%	19%	81%
	Working with synthetic 3D bone was as useful as working with traditional frozen or formalinised cadaveric bones	61.9%	38.1%	36.4%	63.6%	48.8%	51.2%

CTB: cadaveric temporal bone.

Table II presents the overall results of survey questionnaires, categorised by the percentage of scores ≤ 3 and > 3. The median of the average scores for questionnaire completed by both experienced and trainee surgeons was 4.2 (IQR: 3.9-4.5; range: 3.4-5). Regarding the primary study objective, 80.9% of questionnaires achieved a total average score exceeding 3 (95% CI: 78.5%-83.1%; p value < 0.001). These findings strongly suggest that the 3D-printed temporal bone model is an acceptable training tool for developing surgical skills in otologic microsurgery, comparable to cadaveric training.

These results are illustrated in Figure 4.

The average scores for each domain, as assessed by both experienced and trainee surgeons, produced the following mean results:

- "Physical characteristics": 3.9 (IQR: 3.6-4.3; range: 2-5);
- "Anatomical realism": 4.0 (IQR: 3.7-4.3; range: 2-5);
- "Usefulness as a training tool": 4.8 (IQR: 4.4-5; range: 3.8-5);
- "Task-based usefulness": 4.4 (IQR: 3.9-4.6; range: 3.4-5);
- "Overall reactions": 4.2 (IQR: 3.8-4.4; range: 3.2-5) (Fig. 4).

The percentage of mean scores exceeding 3 for each domain, considering all surgeons, was statistically significant for the "Usefulness as a training tool", "Task-based usefulness" and "Overall reactions" domains. In details:

- "Physical characteristics": 71.9% (95% CI: 66.5%-76.9%; p value = 0.47);
- "Anatomical realism": 75.6% (95% CI: 67.4%-82.5%; p value = 0.16);
- "Usefulness as a training tool": 95.8% (95% CI: 92.2%-98.1%; p value < 0.001);
- "Task-based usefulness": 83.2% (95% CI: 78.5%-87.3%; p value < 0.001);
- "Overall reactions": 79% (95% CI: 72.9%-84.2%; p value = 0.004) (Fig. 4).

Finally, when comparing the results of the questionnaires between experienced and trainee surgeons, no statistically significant differences were found.

A more detailed analysis was then conducted on each domain, assessing the percentage of responses with a score exceeding 3 for each subdomain. These results are schematically reported in Figure 5 and in Table III.

Regarding physical characteristics, all surgeons generally considered the 3D-printed temporal bone model a valid substitute for cadaveric bone in terms of cortical bone hardness (86.7% of scores > 3; 95% CI: 73.2%-94.9%). However, for trabecular bone hardness, training surgeons perceived the model more favourably than experienced surgeons (86.4% of scores > 3, 95% CI: 65.1%-97.1%; *versus* 73.9% of scores > 3, 95% CI: 51.6%-89.8%). Conversely, trainee surgeons were more critical regarding drill skip (71.4% of scores > 3; 95% CI: 47.8%-88.7%), while experienced surgeons showed higher agreement (86.4% of scores > 3; 95% CI: 65.1%-97.1%).

For vibrational and acoustic properties and for thinning of middle fossa dural plate, the percentage of scores exceeding 3 was lower: 63.6% (95% CI: 47.8%-77.6%), 59.1% (95% CI: 43.2%-73.7%), and 59.5% (95% CI: 43.3%-74.4%), respectively, thus suggesting potential areas for improvement. Finally, experienced surgeons perceived the overall similarity to cadaveric bone more favourably than training surgeons (81% of scores > 3, 95% CI: 58.1%-94.6%; *versus* 68.2% of scores > 3, 95% CI: 45.1%-86.1%).

Regarding anatomical realism, all surgeons perceived depth perception as highly realistic (97.8% of scores > 3; 95% CI: 88.2%-99.9%). Similarly, the realism of anatomical structures was generally well-regarded (77.8% of scores > 3; 95% CI: 62.9%-88.8%). However, all surgeons agreed that the model's soft tissue representation was less realistic compared to cadaveric specimens, with only 51.1% of scores exceeding 3 (95% CI: 35.8%-66.3%).

Regarding its usefulness as a training tool, all surgeons strongly agreed that the temporal bone model serves as a valid training model compared to cadavers, with 100% of respondents rating it as "useful as an overall training tool" with a score exceeding 3 (95% CI: 91.8%-100%).

Specifically, all surgeons highly valued the model's utility in teaching anatomy (97.7% of scores > 3; 95% CI: 87.7%-99.9%), surgical planning (88.4% of scores > 3; 95% CI: 74.9%-96.1%), improving hand-eye coordination (100.0% of scores > 3; 95% CI: 91.8%-100%), and enhancing surgical technique (93% of scores > 3; 95% CI: 80.9%-98.5%).

Within the "task-based usefulness" domain, where surgeons were instructed to utilise the 3D-printed temporal bone model for specific otological surgical procedures, high levels of agreement were observed for procedures involving the lateral part of the temporal bone. Specifically, 95.3% (95% CI: 84.2%-99.4%) of surgeons rated the model as highly useful, giving scores exceeding 3 for cortical mastoidectomy, 93% (95% CI: 80.9%-98.5%) for atticotomy, and 97.7% (95% CI: 87.7%-99.9%) for canal wall down mastoidectomy.

However, for teaching facial recess dissection, labyrinthectomy, and round window surgery, the percentage of surgeons rating the model as highly useful (scores > 3) was slightly lower, ranging from 69% (95% CI: 52.9%-82.4%) for round window surgery to 76.7% (95% CI: 61.4%-88.2%) for facial recess dissection.

Notably, opinions diverged regarding canaloplasty, with experienced surgeons demonstrating higher acceptance (81.8% of scores > 3; 95% CI: 59.7%-94.8%) compared to surgeons in training (50% of scores > 3; 95% CI: 45.7%-81.8%).

Overall, surgeons reported positive experiences using the 3D-printed temporal bone model. While not all surgeons considered the synthetic bone model as equally useful as cadavers (51.8% of scores > 3; 95% CI: 35.5%-66.7%), a significant majority (81%; 95% CI: 65.9%-91.4%) believed

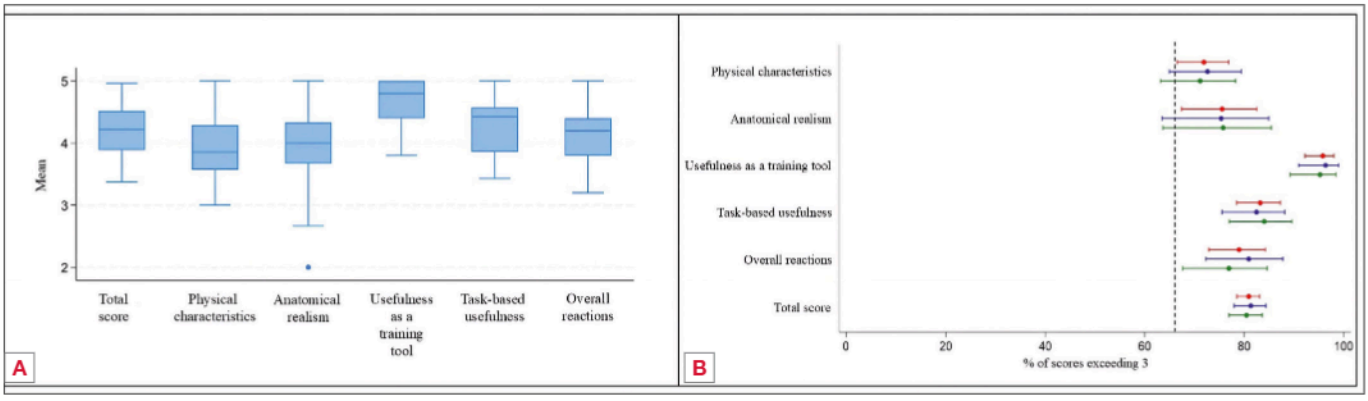


Figure 4. Overall survey results. **A)** Boxplot of the total average scores' mean for questionnaire completed by both experienced and trainee surgeons and for each domain; **B)** Percentage of average scores exceeding 3 for all questionnaires and for each domain. Red, trainees and experienced surgeons; blue, experienced surgeons; green, trainees; dashed vertical line, cut-off of 70% for statistical acceptability of the 3D-printed temporal bone model.

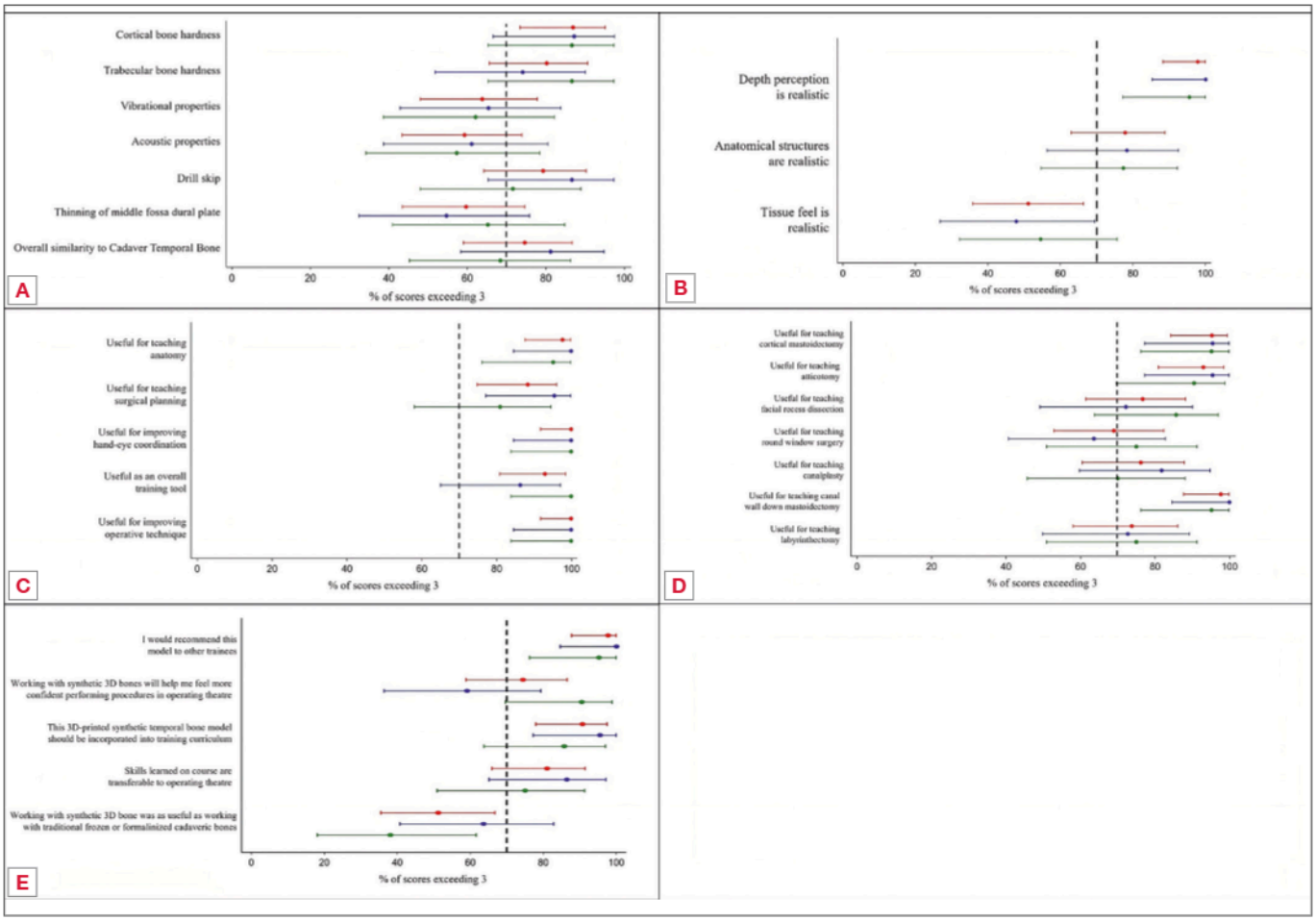


Figure 5. Percentage of scores exceeding 3 for each subdomain of the questionnaire's domains. **A)** "Physical characteristics" domain; **B)** "Anatomical realism" domain; **C)** "Usefulness as a training tool" domain; **D)** "Task-based usefulness" domain; **E)** "Overall reaction" domain. Red, trainees and experienced surgeons; blue, experienced surgeons; green, trainees; dashed vertical line, cut-off of 70% for statistical acceptability of the 3D-printed temporal bone model.

Table III. Average scores for questionnaires, according to experience of surgeons. For each domain, the median average with interquartile range (IQR) and the percentage of average score > 3 are reported.

	Experienced surgeons		Trainee surgeons	
Domain	Median (IQR)	Proportion > 3	Median (IQR)	Proportion > 3
Physical characteristics	4 (3-4)	114/157 (72.6%)	4 (3-5)	106/149 (71.1%)
Anatomical realism	4 (4-5)	52/69 (75.4%)	4 (4-4)	50/66 (75.8%)
Usefulness as a training tool	5 (5-5)	106/110 (96.4%)	5 (4-5)	100/105 (95.2%)
Task-based usefulness	5 (4-5)	127/154 (82.5%)	4 (4-5)	121/144 (84%)
Overall reactions	4 (4-5)	89/110 (80.9%)	4 (4-5)	80/104 (76.9%)

that surgical skills developed using the model are directly applicable in the operating room.

Furthermore, a high proportion of surgeons strongly recommend using the temporal bone model for surgical training (97.7%; 95% CI: 87.7%-99.9%) and advocated for its inclusion in surgical training curricula (90.7%; 95% CI: 77.9%-97.4%).

Regarding the impact of training with the 3D-printed temporal bone model on surgeon confidence, a significant difference was obviously observed between experienced surgeons (59.1%; 95% CI: 36.4%-79.3%) and trainees (90.5%; 95% CI: 69.6%-98.8%), with a boost in trainees' confidence levels.

Discussion

Otosurgery is a technically demanding surgical discipline characterised by a steep learning curve and the need for continuous practice, often involving temporal bone dissection [1,18-20]. While cadaveric dissection has long been the gold standard for surgical training, the inherent limitations of cadaveric specimens present a challenge for achieving surgical proficiency [2-5,9,10]. Although 10 to 15 procedures are sufficient to develop basic competency in mastoidectomy, up to 100 are required to reach proficiency [1,18-20]. This has prompted the exploration of alternative training modalities, with 3D-printed synthetic models offering a viable alternative [21,22].

A variety of synthetic temporal bone models are currently available; however, they are limited by a number of anatomical and economic drawbacks. Anatomically, these prototypes often fail to accurately reproduce key structures, including the mastoid trabecular bone's consistency, the intricate routes of the facial nerve and chorda tympani, and other pivotal landmarks such as dura mater, sigmoid sinus, carotid artery, otic capsule and digastric ridge. Additionally, the motility of the ossicular chain is frequently not well-simulated [21]. From an economic perspective, most commercially available synthetic models cannot be classified as strictly "ready-to-use" 3D-printed products; instead, they are typically supplied as assembled kits requiring significant post-production processing or manual modification. PHACON models (PHACON GmbH, Leipzig, Germany - https://phacon.de/en/), widely regarded as a commercial benchmark, offer high-fidelity temporal bone replicas for surgical training and educational purposes. These models are derived from patient CT data and utilise precision additive manufacturing to replicate both cortical and trabecular bones. However, publicly available documentation suggests that their production involves a multi-step manufacturing process, such as the secondary integration of soft tissue components onto a rigid base or the insertion of deformable elements. As the proprietary manufacturing technologies and specific workflows of these commercial models are not fully disclosed, it should be noted that this evaluation is based on the authors' assessment of available technical specifications and marketing materials. The most accurate multi-material solutions currently available on the market, which permit a direct comparison with the proposed approach, have a reported unit cost of approximately €385 (excluding VAT).

The 3D-printed temporal bone model developed in this study was designed to balance high anatomical fidelity with cost-effectiveness, with an estimated cost between €190 and €240 (excluding VAT). A key advantage of the proposed methodology is its applicability to patient-specific cases, enabling personalised preoperative simulation.

Producing the final model as a single, fully integrated component eliminates the need for assembly or major post-processing. Consequently, the production timeline is significantly reduced, enabling integration into clinical surgical workflows with an approximate lead time of one week.

Additionally, the initial digital nature of the model allows for rapid distribution, enabling decentralised manufacturing at any facility equipped with compatible 3D printing tech-

nology and thus redefining the provision and distribution paradigm.

This national multicentre validation study demonstrates that our novel 3D-printed temporal bone model is a viable training tool for otosurgery, comparable to cadaver specimens with a total average score exceeding 3 in 82.2% of questionnaires completed by both experienced and trainee surgeons (95% CI: 80%-84.4%; $p < 0.001$). From a microsurgical perspective, the model provides a highly realistic perception of depth, fostering the development of fine motor skills such as hand-eye coordination. This aspect led to a significant increase in confidence among trainee surgeons when performing *in vivo* surgical procedures (90.5% of scores > 3; 95% CI: 69.6%-98.8%).

Beyond allowing young otosurgeons to familiarise themselves with the anatomical relationships of the temporal bone, this model also offers advantages for teaching this complex anatomy to students and for explaining surgical procedures to patients.

A key limitation of the current model is the soft tissue consistency, which, despite advancements, did not achieve sufficient real-like feeling. This is shown by the fact that only 51.1% of all surgeons gave scores exceeding 3 for this question. This limitation may hinder the yield of acoustic properties during drilling and certain surgical procedures, such as the thinning of middle fossa dural plate.

Other limitations of 3D-printed temporal bone models arise from additive manufacturing techniques, which preclude the creation of internal voids with several implications. For instance, experienced surgeons perceived the quality of the mastoid trabecular bone as inferior to the cortical bone (73.9% of scores > 3, 95% CI: 51.6%-89.8%; *versus* 87% of scores > 3, 95% CI: 66.4%-97.2%). This may be attributed to the gelatinous material filling the mastoid cells, even though this could emulate the inflammatory tissue often present in mastoid cells in various ear diseases.

A limitation of this study is the reliance on self-reported Likert scales. While the overall survey demonstrated excellent internal consistency ($\alpha = 0.89$ for experienced surgeons and 0.90 for trainee surgeons), self-report measures are inherently susceptible to subjective biases. To address this, a future research goal is to develop objective metrics for quantitatively assessing the performance of the 3D-printed model in comparison to cadaveric specimens.

Our future perspectives include improving the model's realism by addressing the identified limitations, enhancing the model by incorporating skin and soft tissue components and expanding surgical simulations to encompass lateral skull-base approaches and craniofacial malformations.

Conclusions

The development of additive manufacturing has enabled the creation of increasingly realistic 3D-printed temporal bone models. While significant progress has been made since the introduction of the first commercially available synthetic model, the replication of soft tissue still requires further refinement to accurately mimic *in vivo* tissue. Nonetheless, 3D-printed temporal bone models have the potential to significantly impact the future of otosurgical training. They offer a cost-effective and readily available alternative to cadavers, facilitating repeated practice and refinement of surgical techniques. In the future, their applications are expected to extend beyond surgical training to include personalised preoperative planning in clinical practice [23-25].

Acknowledgements

The device can be requested at the following email address: info@3d4med.eu

Conflict of interest statement

The following authors are also listed as inventors in the patent (Italian patent application no. 102025000002868, filed on 14/02/2025): P. Canzi, S. Marconi, M. Benazzo, F. Auricchio. The patent is owned by the respective working institutions of the authors. Potential financial interest may derive by the selling of the patent or from its commercial exploitation for the device production.

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Author contributions

PC, IO, SM, MB: conception and design of the study, acquisition and interpretation of data, drafting of the article, literature revision, critical revision for important intellectual content and final approval of the version to be published; FA, EC, VVF, SM: conception and design of the study, acquisition of data, statistical analysis and final approval of the version to be published; MAC, PAV, MBo, LB, AC, FC, GC, EC, AC, SDG, FD, SF, IJF, ARF, LMG, CG, AG, AL, EL, AP, NQ, GR, FYR, BS, DS, MT, EZ: acquisition of data and final approval of the version to be published.

Ethical consideration

This study was approved by the Institutional Ethics Committee of the University of Pavia (protocol number: 48921/2022). The research was conducted ethically, with

all study procedures being performed in accordance with the requirements of the World Medical Association's Declaration of Helsinki.
Written informed consent was obtained from each participant for study participation and data publication.

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