Simulated Surgical Model Design for Myringotomy and Tympanostomy Tube Insertion in Children using Medical Image Processing and 3D-Printing Technologies

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ABSTRACT

Objective: Researchers aimed to design surgical simulation models using medical image processing and 3D-printing technologies to train otolaryngologie residents with correct surgical techniques and study their skills improvement.

Materials and Methods: The models were produced for three age ranges (group A: 8-12 years old, group B: 3-7 years old, and group C: 10 months - 2 years old). Eleven residents were practiced from older to younger child models. Overall surgical time and results were evaluated to determine improvement. Both residents and specialists assessed satisfaction surveys after training.

Results: The median operational time was significantly reduced by 64.57% in model A and 50.24% in model B ($p < 0.05$). Operating time and surgical skills improved in order from models A, B, and C. Model C showed the most improvement with correct operational techniques in myringotomy incision (66.7%, $p = 0.003$) and tympanostomy tube insertion (48.5%, $p = 0.011$). Residents' and specialists' satisfaction assessments exhibited prominent satisfaction results with surgical simulation model training.

Conclusion: Surgical simulation models training enhanced residencies' confidence and improved correct surgical techniques. Residencies can gradually practice skills from fundamental to more complicated techniques in younger child model where symptom occurs.

Keywords: Myringotomy; tympanostomy tube insertion; medical image processing; 3D-print; surgical simulation

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INTRODUCTION

Otitis media with effusion (OME) is accumulation of fluid in middle ear that causes inflammation and fluid build-up behind eardrum. 90% occurred in children between six months and four years.[1,2] Build-up of fluid in middle ear affects tympanic membrane and middle ear functions, leading to conductive hearing loss and occasional pain from pressure changes while also affecting speech, cognition, behavioral problems, and language development. Ear tube insertion is a procedure whereby doctor inserts a tympanostomy tube into eardrum to ameliorate ear infections and allow drainage of excess fluid

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from middle ear. The myringotomy and tympanostomy tube insertion require precise surgical skills under a microscope.[3-5]

Medical practitioners should improve their knowledge of operational procedures and practice performing with correct surgical techniques to reduce surgical risks. The major problem is the procedures are difficult to learn and practice. Anatomical structures of children are significantly different from adults concerning anatomy and physiological differences in bone growth and development. The research study by Ungkanont et al., also found that 70% of the children with cleft palate had their first myringotomy before they were 3 years old, while 62.5% of normal children had their first ventilation tubes within their first 5 years. The mean age at first myringotomy in children with cleft palate was 1.3 years old, which required precision surgical techniques for operation.[6] The complication from myringotomy and tympanostomy tube insertion can also develop to granular myringitis in the patient with a history of other ear diseases. Having the ability to better operations can reduce the risk factors for the development of complications after surgery.[7] Many simulation models are designed for practicing myringotomy and tympanostomy tube insertion. But use easily found materials, such as boxes and syringes to simulate the ear holes,[8-10] which model appearance is unrealistic.[11-13] Also the medical models are designed as adult, and have not been designed as a child, where the symptom most occurs.[14] Hence researchers aimed to design and build more realistic simulation models of the children in various age ranges that allow unlimited practice with the operating microscope and surgical instruments used during the actual operation, which can be a beneficial teaching tool for medical practitioners. The designed simulation models were continued to be beneficially used for training the otolaryngology residents at the Department of Otorhinolaryngology, Siriraj Hospital, Mahidol University, until the present. In addition, the researchers suggested that the study subjects should be conducted with a larger population in future studies

Medical imaging data conversion to surgical simulation models

Image data were collected from CT scans of healthy children's heads and related organs. Patients' age ranges were categorized into three groups; group A: 8 to 12 years old, group B: 3 to 7 years old, and group C: 10 months to 2 years old. Two-dimensional image data from CT scans were transferred to Materialize Mimics software by uploading DICOM files and selecting the particular tissues.[15,16] Anatomical positions of tympanic membrane, ossicular ligaments, and oval window were captured to ensure that ear canal, tympanic cavity, and middle ear were accurate. 2D image data processing in Mimics software makes it possible to generate three-dimensional models in stereolithography (.stl) file format that can be designed on a computer-aided design software (Pixologic ZBrush).[15-17] Connective parts between ears and head were designed, and model head circumference was adjusted to match average data from World Health Organization (WHO). Standard ratios of model perimeters as follows; group A: 52 – 54 cm, group B: 49 – 51 cm and group C: 45 – 48 cm. (Fig 1)

The designed 3D models were imported to Ultimaker Cura 4.2.1 software to convert to G-code (gcode) that commands path and instructs 3D printing machine (Anet A8 Plus).[18,19] The selected thermoplastic material was Polylactic-acid plastic (PLA). Injector temperature was set at 220 °C, with build plate temperature at 70 °C and layer detail as 'Normal' (0.15 mm). Solid 3D printed models appeared horizontal lines of plastic filaments. Hence surfaces of the models were polished to remove lines from silicone casting molds. Yellow polyester putty was used as a primer before workpieces were polished using No. 800 and No. 1000 sandpapers. Clean water was applied to surface before spraying with a gray primer (Leyland Polypropylene Primer) to detect any rough areas on 3D printed models. Primer provided a smooth surface that was easy to separate from mold. Various types of silicone rubber are used for casting medical models, depending on underlying objectives and level of realism required by application. 1300 silicone rubber was chosen

Fig 1. Surgical simulation models designs for three age ranges (Model A, Model B and Model C)

to create ear models, with RTV-357 silicone rubber to create head models. A food-grade plastic bag with 15-18 microns thickness was selected by specialists in pediatric otolaryngology for artificial eardrum. When viewed from a microscope, the material is slightly opaque with a glossy surface, and surface tension is similar to eardrum. The artificial eardrum was attached by applying a thin layer of latex glue over cylindrical end of ear model, using an O-ring (No. 113) to tighten. After straightening plastic sheet, a skin-color marker was used to draw the line to refer to malleus bone location.

MATERIALS AND METHODS

Ethical consideration

The research was approved by the Institutional Review Board of the Faculty of Medicine Siriraj Hospital, Mahidol University (SIRB) (Si 251/2020). The study has requested permission to use CT scan image data of healthy children's heads and related organs from the Department of Radiology, Siriraj Hospital, Mahidol University. There are three groups of patients categorized by the age range: the age of 10 months to 2 years old, 3 to 7 years old, and 8 to 12 years old, with three patients in each group, for a total of 9 patients. The names are concealed, and the data only indicates their ages and genders. The subjects of the study are first-year otolaryngology residents who had not previously experienced myringotomy and tympanostomy tube insertion. The researchers announced participants who volunteered by posting an invitation poster at the Department of Otorhinolaryngology, Siriraj Hospital, Mahidol University inviting residencies to participate in the practice session. If any participants did not want to join this research project, their study and grades would not be affected. The clarification participant information sheet was distributed to the participants who voluntarily registered before joining the research project, which informed the study's objectives, methods, data collection, and expected benefits. The participants' data were kept in confidence, and the research findings will be reported in the overall results.

Recruitment and instruction

Residencies who volunteered to participate in the study were advised the myringotomy and tympanostomy tube insertion procedures before training. Instruction included lectures and a demonstration of operational techniques using surgical simulation models. The list of equipment used for training includes; 1) microscope, 2) ear speculum, 3) alligator forceps, 4) myringotomy knife, 5) straight pick, 6) tympanostomy tube or grommet; polyethylene tube no.90, 7) simulated surgical models, and 8) adjustable table

Data collection

Two videos recorded otolaryngologie residents' training using a microscope (OPMI Pico) to view tympanic membrane, DSLR camera (Canon 7D) captured hand movements and the use of equipment. (Picture 2) Participant information was encoded by a number instead of student's name and ID, with faces and voices concealed. Participants performed in order from model A, B, and C, the older to younger child model. The second training session was repeated in the same setting after one week. The videos were arranged side-by-side to show time duration of operation.

Fig 2. Myringotomy and tympanostomy tube insertion training.

Case record form and surveys

1. The residencies' operation times were recorded from the beginning to the last procedure. The three specialists in pediatric otolaryngology watched videos and assessed residencies' proficiencies in each procedure in the case record form. By the scoring criteria, 10 (completed), 5 (not completed), and 0 (not performed) in the corresponding score box.

2. The satisfaction survey was used to assess the residencies' satisfaction in surgical simulation model training. The residencies rated their level of agreement as strongly agreed, agreed, disagree, and strongly disagree regarding knowledge, understanding, and confidence in operation. The comments section is open for residencies to suggest improvement ideas for the surgical simulation model training.

3. The specialists in pediatric otolaryngology also

completed a satisfaction survey to assess the effectiveness of the training with simulated surgical models compared with their regular teaching experiences, rated by the level of satisfaction as very satisfied, satisfied, neutral, and not satisfied. The comments section is open for specialists in pediatric otolaryngology to suggest improvement ideas for the surgical simulation model training.

Statistical analysis

1) The residencies' operation time were compared, ranked, and calculated statistically by Wilcoxon's Signed Ranks Test. PASW Statistics (SPSS) version 18.0 (SPSS Inc., Chicago, IL., USA) was used for the statistical analysis. If the p-value less than 0.05, the result is concluded that the operation time was reduced with statistical significance. And would be concluded that the medical models could enhance faster operation time.

2) The analysis of the residencies' operation skill results; McNemar Bowker Test was used in each procedure to test the significance of the score comparison in Test 1 and Test 2, and calculated the testing results with the statistical SPSS Program. When the p-value less than 0.05, it is concluded that the residencies' skill was developed in the particular operative procedure with statistical significance.

3) Satisfaction survey analysis; the competencies of the medical models were rated by level of agreement as strongly agreed, agreed, disagree, and strongly disagree regarding knowledge, understanding, and confidence in operation. The researchers summarized the statistical scoring results in the table with frequency distribution and conversed them into percentages.

RESULTS

Improvements in operational time

The otolaryngologie residents spent a shorter time performing model A and B, with statistically significant results. The median operational time was 64.57% faster in model A, while model B was 50.24% faster. The Wilcoxon signed-rank test's statistical analysis showed a two-tailed significance ($p < 0.05$) in model A ($p = 0.007$) and model B ($p = 0.003$). Results in model C gave fluctuating operational time ($p = 0.147$) Overall operational time were reduced from model A, B, and C in order, indicating that residencies have gained familiarity by frequent repetition practices. (Table 1)

TABLE 1. Operational time using the simulated surgical models.

	n	Time (sec) Median	IQR	Minimum	Maximum
Model A Test 1	11	587	325	197	1195
Model A Test 2	11	208	263	125	515
Test 1 – Test 2	11	379	363		
Percentage		64.57%			
P-value[a]		0.007*			
	n	**Time (sec) Median**	**IQR**	**Minimum**	**Maximum**
Model B Test 1	11	613	205	156	759
Model B Test 2	11	305	280	157	483
Test 1 – Test 2	11	308	159		
Percentage		50.24%			
P-value[a]		0.003*			
	n	**Time (sec) Median**	**IQR**	**Minimum**	**Maximum**
Model C Test 1	11	382	263	104	1044
Model C Test 2	11	204	267	88	527
Test 1 – Test 2	11	178	270		
Percentage		46.6%			
P-value[a]		0.147			

[a]Wilcoxon signed rank test

Operational skill results

The operational skill results also indicated that residencies improved their correct surgical techniques in order from model A, B, and C. The number of proficiencies that showed statistical significance evaluated by the McNemar-Bowker test was increased from older to younger child model ($p < 0.05$). (Table 2) For instance, model A showed one proficiency improvement 54.4% in checking the tympanostomy tube position on completion ($p = 0.004$). Model B showed three proficiencies improvement as 42.4% in correction of holding the myringotomy knife in the right direction ($p = 0.039$). Correction of incision size showed 54.6% improvement ($p = 0.021$), and 47.7% improvement in checking the tympanostomy tube position on completion ($p = 0.057$). While model C showed four proficiencies improvement as 42.4% in microscope camera adjustment ($p = 0.046$). The correction of incision size showed 66.7% improvement ($p = 0.003$). The correction of tympanostomy tube insertion showed 48.5% improvement ($p = 0.011$), and 42.4% improvement in checking the tympanostomy tube position on completion ($p = 0.039$).

Additional results in model A also occurred that some residencies had difficulty making an incision in the correct position. The incision should be made on the anterosuperior quadrant or anteroinferior quadrant of tympanic membrane. Some residencies could not estimate the incision size during first performance. The incision is too wide and causes to dropped the tympanostomy tube into middle ear, which is unacceptable in actual operation. Results in model B also showed that some residencies used straight pick to push the tympanostomy tube through the myringotomy incision using the outer flange instead of inner flange. Model C results also showed that some residencies encountered difficulties pushing tympanostomy tube into the incision in narrower ear canal and often accidentally touched the malleus, which is also unacceptable in actual operation.

TABLE 2. Operational skills using the simulated surgical models.

		P-value[b] (Percentage of Improvement)		
Item	**Proficiency**	**Model A**	**Model B**	**Model C**
1	Adjust the microscope camera to clearly see the eardrum	18.2% (0.613)	6% (0.816)	42.4% (0.046*)
2	Select the correct ear speculum	66.6% (0.388)	18.1% (0.312)	12.2% (0.5)
3	Hold the myringotomy knife in the right direction	24.2% (0.065)	42.4% (0.039*)	36.4% (0.109)
4	Correct incision position	30.4% (0.168)	48.4% (0.076)	36.4% (0.2144)
5	Correct incision size	30.2% (0.5287)	54.6% (0.021*)	66.7% (0.003*)
6	Use the knife without touching the ear canal or causing the eardrum to tear apart	12% (0.5313)	12.2% (0.774)	24.2% (0.359)
7	Handle the tympanostomy tube properly using alligator forceps	48.5% (0.078)	6.1% (1)	36.4% (0.302)
8	Insert the tympanostomy tube in the correct direction at the myringotomy incision	24.2% (0.348)	-12.1% (0.847)	48.5% (0.011*)
9	Use the straight pick to push the tympanostomy tube or alligator forceps to insert the tympanostomy tube through the myringotomy incision	12.1% (1)	60.6% (0.15)	-15.2% (0.668)
10	Check the tympanostomy tube positionon completion	54.4% (0.004*)	47.7% (0.057*)	42.4% (0.039*)

[b] McNemar-Bowker test

Recidencies satisfaction with the training

The satisfaction assessment showed strongly agreed results in all competencies. (Table 3) The major influencing competencies indicated that the simulated surgical models effectively increased residencies' operational skills ($\bar{x}$ = 3.91), and the models should be expanded to encompass different medical practices. ($\bar{x}$ = 3.91). The minor influencing competencies showed that the simulated surgical models increased residencies' confidence when operating ($\bar{x}$ = 3.82). The simulated surgical models were effective and easy to understand learning techniques ($\bar{x}$ = 3.82) and had a level of difficulty in practicing skills suitable for residencies year ($\bar{x}$ = 3.82). Additional comments from residencies also noted that using the same tympanostomy tube repeatedly during training caused the outer flange to deteriorate. The residencies suggested changing the tympanostomy tube after repeating the training, while the material used for the tympanic membrane was too elastic, making it difficult to attach to the tympanostomy tube.

Satisfaction of the specialists in pediatric otolaryngology with simulated surgical models training

The simulated surgical models can simulate complicated hands-on surgical procedures to supplement observation before operating on patients. The major influence on specialists' satisfaction indicated that simulated surgical models improved residencies' understanding in operational processes ($\bar{x}$ = 3.67). The residencies gained confidence through practicing the operational techniques ($\bar{x}$ = 3.67) and were consistent with the learning objectives according to the training content ($\bar{x}$ = 3.67). The simulated surgical models were easy to use, durable, and easy to maintain for repetitive training ($\bar{x}$ = 3.67) and should be further developed to simulate other operational techniques in the future ($\bar{x}$ = 3.67). (Table 4) Additional comments from the specialists in pediatric otolaryngology also suggested that the position of the malleus was uncertain. This issue caused some residencies to accidentally touch the malleus. In some cases, the tympanic membrane was not tight and less realistic, while the O-ring should not be too tight because this caused narrowing of the ear canal and presented difficulties for some residencies.

DISCUSSION

The results showed that the residencies have gained more confidence and enhanced surgery fundamentals through repetitive training with surgical simulation models. Residencies can understand operational procedures with

TABLE 3. Training satisfaction using the simulated surgical models.

Item	Competency	Mean ($\bar{x}$)	SD	Result
1	Simulated surgical models improved knowledge and understanding of the operational processes	3.73	0.47	strongly agreed
2	Simulated surgical models increased operational skills	3.91	0.30	strongly agreed
3	Simulated surgical models increased confidence when performing the operation	3.82	0.40	strongly agreed
4	Simulated surgical models were practical and easy-to-understand learning techniques	3.82	0.40	strongly agreed
5	Simulated surgical models were easy to use, durable and simple to maintain	3.55	0.52	strongly agreed
6	Simulated surgical models were effective tools that increased their roles as practitioners	3.73	0.47	strongly agreed
7	Simulated surgical models had a level of difficulty in practicing skills suitable forresidence's year	3.82	0.40	strongly agreed
8	Simulated surgical models should be developed to practice skills in other clinical areas	3.91	0.30	strongly agreed

* Four-points scale: 1 = strongly disagree; 4 = strongly agreed

TABLE 4. Satisfaction of the specialists in pediatric otolaryngology with simulated surgical models training.

Item	Competency	Mean (x̄)	SD	Result
1	Simulated surgical models improved residencies' operational processes	3.67	0.58	very satisfied
2	Simulated surgical models increased residencies' operational skills	3.33	0.58	satisfied
3	Simulated surgical models increased residencies' operational confidence	3.67	0.58	very satisfied
4	Simulated surgical models were consistent with the learning objectives according to the training content	3.67	0.58	very satisfied
5	Simulated surgical models had a level of difficulty in practicing skills appropriate for the residencies' year	3.33	0.58	satisfied
6	Simulated surgical models increased interaction between the instructor and residencies	3.33	0.58	satisfied
7	Simulated surgical models were cost-effective and suitable for the number of trainees	3.33	0.58	satisfied
8	Simulated surgical models were easy to use, durable and easy to maintain	3.67	0.58	very satisfied
9	Simulated surgical models should be further developed for other operational simulations	3.67	0.58	very satisfied

* Four-points scale: 1 = not satisfied; 4 = very satisfied

an improvement of operation times in Model A (64.57%, $p = 0.007$) and Model B (50.24%, $p = 0.003$) and develop better skills in correct incision size in Model B (54.6%, $p = 0.021$) and Model C (66.7%, $p = 0.003$), and inserting the tympanostomy tube in the correct direction in Model C (48.5%, $p = 0.011$), which these skills are essential to reduce surgical complications. The major influence on residents' satisfaction showed that the surgical simulation models effectively increased residencies' operational skills ($\bar{x} = 3.91$). Residencies can encounter problems or unforeseen circumstances and help improve skills for practitioners who lack the experience to reduce the risks of surgery with real patients. To date, residencies can only learn by observing medical lecturers or seniors. Hence, the second major influence on residents' satisfaction showed that the models should be expanded to encompass different medical practices. ($\bar{x} = 3.91$) The specialists' satisfaction assessment also showed prominent satisfaction results with surgical simulation model training. The major influence on specialists' satisfaction showed that simulated surgical models improved residencies' understanding in operational processes ($\bar{x} = 3.67$), gained confidence through practicing the operational techniques ($\bar{x} = 3.67$), and were consistent with the learning objectives according to the training content ($\bar{x} = 3.67$). The models were easy to use, durable, and easy to maintain for repetitive training ($\bar{x} = 3.67$) and should be further developed to simulate other operational techniques in the future ($\bar{x} = 3.67$). The specialists' satisfaction was evaluated with the normal teaching experiences and found that the simulation-trained residencies were notably outperformed. Simulators can provide a safe and standardized method for surgery training without risks. They allow trainees to practice their surgical skills, contribute detailed feedback by performance assessment, and enable better patient safety and standards of care. The evidence exhibits that surgical skills are acquired through simulation training, and specialists are positively considered to transfer simulation training to the clinical teaching setting and improve operative outcomes.

From the study, the surgical simulation models can be further developed to become more realistic. The following areas of improvement were discussed. 1) The ear canal in Model C is narrower than Model A and B. Some residencies encountered difficulties during operation in model C that were more complicated than Model A and B. 2) Scanned file of the ear canal is too narrow, which may cause problems for residencies in operating procedures. CT scans were captured with the head of the patient (temporal area) lying on a pillow, which caused uncertainties in ear canal size. Future simulation models need to adjust the ear canal width to be suitable for production and training purposes. 3) The material used to imitate the tympanic membrane had a muscular and bouncing surface tension, which caused difficulties when placing the tympanostomy tube in the incision. A more appropriate material should be used. Whereas, the appearance of the studied material when looking through a microscope camera was already similar to real tympanic membrane. 4) A skin color marker pen used to imitate the malleus was uncertain. Marking the position of the malleus should have a standard setting. 5) Some residencies pressed down on the outer-ear during training, which compressed the gap inside the middle ear part and made it difficult to insert the tympanostomy tube in the incision. The gap between the tympanic membrane and the middle ear should be increased. With more realistic simulation model design, medical practitioners can practice with the microscope and surgical instruments as the actual operation. Real-time myringotomy simulations using virtual reality (VR) are beneficial, with savings on manufacturing costs.[20-22] However, the tangible surgical simulation models lack response to feedback from the practitioners as other simulations. With current technology, surgical simulation models can incorporate capacitive sensing technology to track equipment placement and quantitatively measure operator proficiency in live surgical procedures.[23] Researchers suggest combining medical models with innovative features such as sensors and intelligent tracking systems that can enhance realistic experiences for medical practitioners. Researchers believe that more research studies will need to develop and transfer the benefits of surgical simulation training to clinical teaching and aim to create surgical simulation models for other symptoms in the future.

The limitation in this study was due to a small number of sample subjects, which affected the study's statistical results. Hence, the researchers recommended that future research should be conducted with more sample subjects in the study.

CONCLUSION

The myringotomy procedure and tympanostomy tube insertion require specialized training with the microscope. Using surgical simulation models as a learning tool increased confidence and improved the expertise of the residencies to reduce surgical risks and improve their knowledge of operational procedures. Training with various model age ranges also allows residencies to frequent repetition practices from fundamental to experiment with more complicated techniques in the younger child model where the symptom most occurs.

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