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Original Article

The effect of 3D modeling on family quality of life, surgical success, and patient outcomes in congenital heart diseases: objectives and design of a randomized controlled trial

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ABSTRACT

Background. Understanding the severity of the disease from the parents' perspective can lead to better patient outcomes, improving both the child's health-related quality of life and the family's quality of life. The implementation of 3-dimensional (3D) modeling technology in care is critical from a translational science perspective.

Aim. The purpose of this study is to determine the effect of 3D modeling on family quality of life, surgical success, and patient outcomes in congenital heart diseases. Additionally, we aim to identify challenges and potential solutions related to this innovative technology.

Methods. The study is a two-group pretest-posttest randomized controlled trial protocol. The sample size is 15 in the experimental group and 15 in the control group. The experimental group's heart models will be made from their own computed tomography (CT) images and printed using a 3D printer. The experimental group will receive surgical simulation and preoperative parent education with their 3D heart model. The control group will receive the same parent education using the standard anatomical model. Both groups will complete the Sociodemographic Information Form, the Surgical Simulation Evaluation Form - Part I-II, and the Pediatric Quality of Life Inventory (PedsQL) Family Impacts Module. The primary outcome of the research is the average PedsQL Family Impacts Module score. Secondary outcome measurement includes surgical success and patient outcomes. Separate analyses will be conducted for each outcome and compared between the intervention and control groups.

Conclusions. Anomalies that can be clearly understood by parents according to the actual size and dimensions of the child's heart will affect the preoperative preparation of the surgical procedure and the recovery rate in the postoperative period.

Key words: congenital heart diseases, 3D printing, heart modeling, family quality of life, surgical simulation.

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Congenital heart disease (CHD) is a group of disorders characterized by a series of individual structural cardiac pathologies that are usually rare and involve a wide range of anatomical defects and complexity.[1] The degree to which the defect deviates from normal anatomy determines the severity of symptoms.[1-3] Globally, between 0.8% and 1.2% of all live births are affected by CHD.[4-6] Approximately 25% of children born with CHD require open-heart surgery due to defects.[7] Reliable diagnostic methods provide much better treatment options, leading to a significant reduction in mortality. According to Sachdeva et al.[8], in recent years, 3D modeling and printing technologies have been added to imaging methods such as computed tomography (CT), magnetic resonance imaging (MRI), and echocardiography (ECHO). There are differences and benefits among the different imaging methods.[9] The most recent and rapidly developing method among them is 3D printing technologies.

It is stated that beneficial results can be obtained for multiple purposes, from planning and simulation before the definitive surgical procedure to patient-specific preoperative education.[10-12] There are several techniques for modeling organs using 3D printing technology, which has developed rapidly in recent years. For the heart, two types of cardiac modeling are performed. These are filled solid models (blood pool) and hollow models. The hollow models are obtained from signals sent in a way that limits the perimeter of the area where the blood pool is located. These models are printed as a cross-section and show the intracardiac structure.[10] However, technically, the peak heart rate of children is higher than that of adults, so the images may lose clarity, require more time and effort, and may not be as useful. Solid models have filled models of the atria and ventricles. They are typically modeled and printed from contrast-enhanced CT or MR images. Extracardiac structures are very guiding in surgical simulation with easier and faster modeling than intracardiac structures.[13] Recurrent pulmonary artery stenosis and aortic coarctation can be successfully treated, and positive outcomes can be achieved with fast and patient-specific models.[10,14] The operating time of surgically simulated patients is reduced, and procedures can be completed with less cost and fewer complications.[15]

Targeted patient outcomes can be achieved by managing a multidisciplinary team that includes the patient and family and by using surgical simulation.[10,16,17] In life-threatening diseases such as CHD, diagnosis, treatment, and surgical planning are long-term processes. This process causes serious psychological distress in parents, such as post-traumatic stress disorder.[18] Parental/caregiver stress increases, and the family's quality of life deteriorates, especially when the surgical procedure and interventions are not clearly understood.[19] This situation negatively affects the postoperative recovery process of patients.[20,21] A surgical procedure performed with good technique followed by poor postoperative management renders many interventions ineffective.[10,22-24] Understanding the severity of the disease from the perspective of the parents can improve both the health-related quality of life of the child[25] and the quality of life of the family, leading to more positive patient outcomes.[26] Patient-specific modeling using 3D printing technology with images obtained through traditional methods is believed to eliminate all of these issues.

Aims

The aims of this study are to:

Aim 1: Compare the effect of education with a patient-specific 3D heart model on family quality of life with standard education/care.

Aim 2: Plan and simulate the surgical procedure with a patient-specific 3D heart model to obtain the surgeon's opinions about this method and to evaluate patient outcomes.

Hypotheses

In this study, the control group will receive only standard education/care, while the experimental

group will receive 3D model-based education in addition to standard education/care. The hypotheses are as follows:

H1: The family quality of life of the experimental group receiving preoperative education with a patient-specific 3D heart model will be higher than that of the control group.

H2: Surgical simulation using a patient-specific 3D heart model will positively affect surgical success and patient outcomes (operation time, hospital stay, intensive care unit stay, and complications) compared to standard care.

Methods

Study design

The study is a two-group pretest-posttest randomized controlled trial. The design and all phases of the randomized controlled trial (RCT) were based on the Consolidated Standards of Reporting Trials (CONSORT) 2017 recommendations and guidelines.[27] In addition, the recommendations for Standard Protocol Items Recommendations for Interventional Trials (SPIRIT 2013) checklist were followed.[28] This trial study was registered to clinicaltrials.gov in May 2023 (NCT05852106).

Study setting and population

This study will take place in two hospitals affiliated with a foundation in Istanbul, Turkey. The imaging used in this study will be reviewed by a specialist radiology doctor at another hospital belonging to the same foundation after patients have been examined and diagnosed by a pediatric cardiology specialist. The study will recruit patients whose images meet the inclusion and exclusion criteria. The study will be explained to the legal guardian/parent of the identified volunteer patients, and those who wish to participate and give written consent will be included. Recruitment will continue until the target sample size is reached.

Sample and recruitment

The study population consists of pediatric patients (0-18 years old) admitted to a foundation hospital in Istanbul within the last year. In the sample calculation of the study, the effect factor value reported by Ladak et al. was used.[29] In this study, in which they compared the health-related quality of life of children and adolescents with CHD by revealing the difference between siblings, they stated that the most significant difference was in the total quality of life score (effect size: -1.35). The sample of this study was analyzed using the G*Power (v3.1.7) statistical program with an effect size of -1.35 and 95% power (1- β), and alpha was set at 0.05. The sample size was calculated as 13 experimental, 13 control, and 26 children in total. Considering there may be a 20% loss in the study, it was decided that the total sample size should be 30 to reach the target sample size.

Randomization and blinding

For participants who agree to participate in the trial, a randomization list generated by a computerized random number generator (https://www.randomizer.org/) will be used to determine which group of patients will be enrolled. This process will be carried out by a person independent of the investigators. Due to the feasibility of this trial, it is not possible to blind the investigator and patients to group allocation. However, an independent statistician will evaluate the data. In this way, there will be no bias due to the coding of the experimental and control groups as A and B.

Eligibility criteria

The inclusion criteria are as follows: The participant has a CHD between the ages of 0-18 years, the congenital defect has extracardiac structure malformations (this is because the modeling to be done before the operation is done in a shorter time, and it is desired to be trained for preoperative education). Hollow modeling requires more detailed technique and time.[13]

In addition, the difficulty of 3D printing the hollow model made in the pilot study was also effective in this decision being a candidate for elective surgery, having a contrast-enhanced CT image taken during and before the patient's routine diagnostic procedure outside the scope of the study, having at least 15 days between the imaging and the surgical procedure plan, and having the parents/legal guardian give permission to participate in the study were the inclusion criteria of the study.

The exclusion criteria for the study are as follows: Patients who do not require CT for diagnosis or treatment (no patient will undergo CT imaging within the scope of the study unless necessary for this study only), emergency surgical procedures, heart defects involving intracardiac structures (atrial septal defect, ventricular septal defect, tetralogy of Fallot), additional anomalies/syndromes, chronic diseases (such as neurodevelopmental disorders, bleeding disorders, asthma or Down syndrome), history of cardiac arrest, contrast agent reflection in the images, image quality preventing modeling.

Data collection

This study aims to determine the eligibility of children scheduled for pediatric cardiac surgery to participate in the research. Inclusion criteria will be assessed through personal interviews, where informed consent and socio-demographic data will be collected. Following this, participants will be randomly assigned to either the experimental or control group in a 1:1 ratio using a computer-generated list created through randomization. An independent researcher, who is unaware of the group allocation, will evaluate the quality of life of the family (PedsQL) and the surgical simulation (Surgical Simulation Evaluation Form - Part I) one week before the operation. The surgical simulation and parental education will be completed on the same day. Both groups will complete the Surgical Simulation Evaluation Form - Part II on postoperative day 0. On postoperative day 15, both groups will complete the Surgical Simulation Evaluation Form - Part II and the Pediatric Quality of Life Inventory (PedsQL) Family Impacts Module (Table 1).

Table I. Participant timeline.

	Study period									
	Intervention group					Control group				
Time of evolution	Pre-op	One week before admission	Post Operative Day 0 to Discharge		Post Operative Day 15	Pre-op	One week before admission	Post Operative Day 0 to Discharge		Post Operative Day 15
Determination of patients with inclusion and exclusion criteria	x					**x**				
Written informed consent and randomization	x					**x**				
Sociodemographic Information Form		x					**x**			
Surgical simulation		x								
Surgical Simulation Evaluation Form- Part I		x								
Education with 3D heart modelling		x								
Standard education with booklet		x					**x**			
Surgical Simulation Evaluation Form- Part II				x	x				**x**	**x**
PedsQL	x				x	**x**				**x**

PedsQL: Pediatric Quality of Life Inventory, Post Op. Post Operative , Pre Op. Pre Operative

Data collection tools

Socio-demographic information form

This form was prepared in light of the literature and includes descriptive data about the child and family (child's age, height, weight, mother's age and educational status, etc.) and consists of 11 questions in total.[22-24,29]

Surgical Simulation Evaluation Form Part I and Part II

Part I includes eight questions that the surgeon should answer, such as the surgeon's age, professional experience, the effect of the 3D model on defining pathologic findings, the effect of the 3D model on surgical technique, and the strengths and weaknesses of the 3D model. Part II consists of seven questions about surgical success (the effect of the 3D model on surgical operation time and complications) and patient outcomes (operation time, hospital stay, intensive care unit stay, need for repeat operation, unusual complications) of 3D model-based interventions. The surgeon's opinions about the model will also be obtained through this form.[30-33]

Pediatric Quality of Life Inventory (PedsQL) Family Impacts Module

The Turkish validity and reliability study of this scale, first developed by Varni et al.[34], was conducted and published by Gürkan et al.[35] In this methodological study, 201 parents were included. As a result of the study, the internal consistency coefficient was 0.926. The data on the sub-dimensions and Cronbach alpha values of this scale, which has eight sub-dimensions in total, are as follows: physical (0.85), emotional (0.83), social (0.82), cognitive (0.86), communication (0.51), anxiety (0.79) activities of daily living (0.89), family relationships (0.95). A total score of 0.92 was reported. In addition, Cronbach alpha values for all subscales were also included in the original study. As a result of this study, Cronbach alpha values for all subdimensions will be reported when the measurements are completed. The scale consists of 36 questions in total and is a 5-point Likert type. Scale items are scored as never (0), rarely (1), sometimes (2), often (3), and always (4). Items are reverse scored when converted into scores (0= 100; 1 = 75; 2 = 50; 3 = 25; 4 = 0). The scale does not have a cut-off point. A high score indicates a good family quality of life functioning, while a low score indicates a negative family quality of life. Within the scope of this study, a comparison between mean scores will be made.

Data management

The researchers will ensure that all data are accurately and completely coded and consistently entered into the statistical analysis software. The researchers will keep all original documents, including medical records, questionnaires, informed consent forms, and other relevant records obtained during the study, confidential. Data will be kept for five years after the end of the study.

Preliminary study

For the study design, a preliminary study was conducted using retrospective data from the pediatric cardiologist's previously diagnosed and treated patients. Available CT images were analyzed, and images without contrast enhancement were selected and used for the pilot study. Four patient datasets were analyzed, and model testing was performed, representing approximately 10% of the total sample size of 30 patients. One intracardiac abnormality was detected in the patient data acquired for the first model. It was decided to exclude patients with intracardiac malformations from the study as the image of the heart filling with blood was perceived as a solid structure. This could not be excluded from the model until the time of the operation. In the second set of images, a coarctation of the aorta was examined and it was found that there was a stent in the vessel as a result of the completed procedure that there was a contrast reflection, and that the reflections were reflected in the modeling as a vascular heart structure, and it was not successful.

Therefore, it was decided to examine the CT scans of the patients beforehand and to include patients with appropriate CT scans in the study. Finally, the aortic coarctation of the two patients were modeled quite clearly, and the printing was completed. One of the two aortic coarctations was printed piece by piece and painted with different colors to provide more effective education. However, the compatibility and integration of the structures with each other were problematic due to the material used (Fig. 1). Therefore, the second successful model, aortic coarctation, was printed as a whole-heart model (Fig. 2).

Reconstruction of a 3D heart model

The modeling work for models to be obtained with 3D printing technology involved three steps. The first step was to model the CT images in a virtual simulation environment using computer-assisted programs.[36] Since the image resolution increases as slice thickness decreases, virtual modeling should be done on the CT images with a slice thickness of less than 1mm. In this study, the CT scans were obtained using standard techniques at 100 kVp and 256 mAs, with a slice thickness of 0.5 mm and a resolution of 512 × 512 pixels (voxels approximately 0.7 × 0.7 × 0.5 mm3).

Materialize Mimics software program was used to model the patient's heart and major mediastinal vessels. The modeling was done semi-automatically. The patient's CT images were transferred to the modeling software. The first step in the modeling process is masking. Masking with the most accurate Hounsefield unit (HU) is one of the most important factors for successful modeling. For different body tissues, different HU units are defined. For soft tissues, an average of +100 to +300 has been specified, while for harder tissues such as bone, up to +1900 HU has been reported.[37-39] For this study, the average minimum value for masking ventricles and large vessels was set between

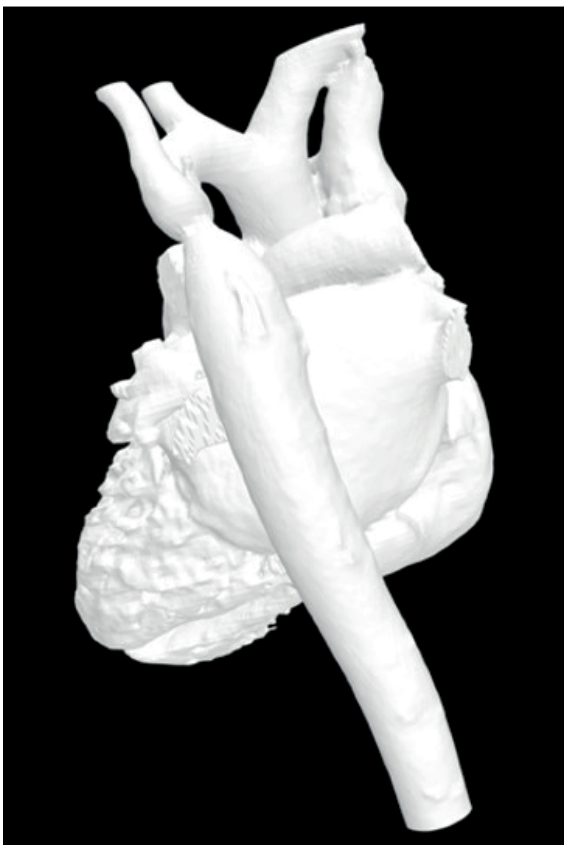

Fig. 1. A two year old female patient.

Fig. 2. A 17 year old male patient.

80 and 200 HU[40] Threshold values of min 216 HU - max 1502 HU were used. At these HU values, the blood in the heart and great vessels was masked, and the outline of the heart was revealed. As Hounsfield decreases, hollow structures (such as lungs) appear darker, while filled structures (such as bones) appear brighter and whiter.[41] Lowering the minimum HU value is necessary to make the heart walls more visible. However, this results in masking unwanted soft tissues other than the heart, such as muscle and fat. In this case, the unwanted tissues can be deleted from the mask by manual selection. The masked, unnecessary surrounding tissues other than the heart, such as muscle, bone, and fat) were removed first with the cropping mask and then manually by marking along the contours of the heart and great vessels. Thus, a model containing only the heart and the desired large vessels was created and cleaned from the surrounding tissues. With this mask, 3D reconstruction could be performed, and the model was ready for printing.

The virtual model obtained in the second step was transferred to the 3D printing machine in STL (Stereolithography or Standard Tessellation Language) format to be translated into physical conditions. Using the program's Blender, a series of surface correction operations were performed on the model. The purpose of this smoothing process was to prevent breaks and visual distortions that can occur during the printing process. However, in case where distortion occurs during this smoothing process, the validity of the model was re-checked by the radiology specialist, and the model was corrected if necessary. In the final stage, the model was checked, and the printer settings that best reflect the defect were determined (temperature 205-210 C°, layer height 0.14-0.3 mm, printing speed 50-55 mm/s). The images were printed with 1.75 mm white PLA filaments by converting the model to gcode type, the file format the printer can understand, on Ultimaker Cura, which is a free software. Although the printing time varies depending on the model size and defect type, the total printing time for a complete model was approximately 15 hours.

Re-evaluation of the model

The compatibility of the 3D heart model with the patient's radiological images were checked by a radiologist experienced in cardiac radiology and the patient's primary cardiologist surgeon. Both doctors reviewed the model and made their final decision together. If an error was detected in the model, the necessary corrections were made to the 3D model, and the printing process was repeated. This process must be repeated until a patient model that is fully compatible with the radiological images is created.

Interventions

Intervention Group:

Preoperative period: Once the surgery date is set, appointments will be made with the surgeon for surgical simulation and with the family for education one week prior to surgery. The meetings are held in separate rooms. After completion of the surgical simulation with model demonstration and radiological images, the surgeon will be asked to complete the Surgical Simulation Evaluation Form-Part I. At the same time, another researcher will complete the family sociodemographic information form and PedsQL questions in the examination room. After completion of the pre-test and the surgical simulation, the families are given a 30-minute preoperative education with the "Congenital Heart Disease Parent Education Booklet" prepared in light of the literature, together with a life-size 3D heart model obtained from their child's own heart, and drawings on paper where they are not understood. The education is followed by an average of 15 minutes of questions and answers, and the education is completed in 45 minutes. The education booklet is given to the parents after the intervention.

Postoperative Period: After surgery, the patient will be followed until discharge, and only Part II of the Surgical Simulation Evaluation Form will be completed. On the 15th postoperative day, the Surgical Simulation Evaluation Form Part II and the PedsQL will be given again as a post-test.

Control Group:

Preoperative Period: When the operation date is determined, one week before the operation, the patients included in the study's control group will be asked the Sociodemographic Information Form and Pediatric Quality of Life Inventory Family Module (PedQL) questions in the examination room. After the pre-test, standardized education will be given to the families by the same researcher. In the first half hour of this education, the disease process will be explained to the patients with the same 'Congenital Heart Diseases Parent Education Booklet' prepared in light of the literature, and the disease process will be presented with the heart model used in standard medical faculty anatomy courses, and the ununderstood parts will be detailed by drawing on paper. The remaining 15 minutes of the education will be conducted as a question and answer with the parents. In addition, a parent education booklet on CHD will be provided to the parents at the end of the education.

Postoperative Period: After the operation, the Surgical Simulation Evaluation Form Part II and PedsQL will be filled out again as post-tests for this group.

Criteria for discontinuing the recruitment

Researchers will stop the intervention if the patient has any harm during the research process. The most significant potential harm is the 3D modeling period. If the patient has emergency surgery before the intervention, prioritization will be done. One of the researchers, who is the responsible cardiologist MD, will make this decision. This patient's variables, such as the pretest, will be excluded.

To improve the patient's post-test adherence, both groups will be called and asked if they have any questions by the primary investigator after the post-op 7th day. Researchers will conduct an intention to treat test (ITT) when the research data is completed in order to protect the actual data results. In addition, two researchers will revise the data independently.

Outcomes

The primary outcome of this study is the quality of life score obtained from the Family Impacts Module of the Pediatric Quality of Life Inventory (PedsQL). In contrast, the secondary outcome is the patient outcomes of the patients who underwent surgical simulation (duration of operation, duration of hospital stay, duration of intensive care unit stay, need for repeat operation, other unusual complications other than pain, cardiopulmonary resuscitation, need for ECMO (Extracorporeal Membrane Oxygenation), seizures, rhythm changes, etc.).

Statistical analysis

Descriptive analyses will be presented as percentage and frequency values, and scale score averages will be presented as mean and standard deviation. In addition to descriptive statistical analyses, a normality test will be applied before comparative analyses. First, skewness and kurtosis values will be evaluated. If these values are between +1.5 and -1.5, parametric tests will be used.[42] In the first comparative analyses, the intergroup analysis will be performed, and no difference will be sought between the experimental and control groups. The chi-square test will be used to compare nominal variables between the two groups, and the student t-test will be applied between the nominal variables and the intragroup quality of life scale. Ordinal variables will be evaluated among themselves again with the chi-square test. At the same time, a one-way ANOVA method will be used in comparison with the average scale score within the group. In order to reveal the differences between the scale scores in the follow-ups, the evaluation will be made with the Pearson correlation test. When the study data do not fit the normal distribution, nonparametric evaluations of these tests will be performed. When necessary, expert statistician support will be obtained for further statistical analysis. The significance level of the study data will be accepted as 95%, and when $p<0.05$ in the analyses, it will be considered statistically significant.

Harms

In the trial, the researchers will record all adverse events reported by participants or unexpected and unwanted events. These possible events will be categorized as intervention-related and unrelated. The biggest risk that may be encountered within the scope of the study may be some technical problems that may occur in the model that emerges after 3D modeling, and the defect size or shape may be incorrect. In order to prevent this, a double control method will be applied. The CT report written by the specialist radiology doctor independent of the researchers in the hospital, where the patients were examined and their images were taken, will be compared with the evaluation of the specialist radiology doctor among the researchers, and the comparison process will be ensured again with the images after the model is printed.

Auditing

Auditing by the researchers will take place at every stage of the research. This means that each stage (3D modeling, data analysis, etc.) will be audited by all researchers during the process and after its completion.

Ethics approval and consent to participate

The study will adhere to the ethical principles declared by the Declaration of Helsinki. This study protocol was approved by the Acibadem University Medical Research Evaluation Board (date: 11.11.2022; approval no/number: 2022-17/50), and written institutional approval (date: 09.02.2023) was obtained for the institutions where the research will be conducted. Any protocol changes will be informed to the same ethical board and institution that gave the research permission at the beginning. The study was registered on clinicaltrials.gov in May 2023 (NCT05852106). All authors confirm that all methods will be carried out in accordance with ethical guidelines. In addition, parents of patients who meet the inclusion criteria will be informed about the study's purpose, procedure, benefits, and possible risks. Verbal consent from the children and informed written consent from their parents/legal guardians will be obtained by the researcher in a face-to-face interview. Participation will be voluntary; they will be informed that they can refuse to participate in the study or leave the study at any stage without any penalty.

Discussion

The study is expected to significantly improve the quality of life of children with CHD and their parents. Anomalies that parents can clearly understand according to the actual size and dimensions of the children's hearts will affect the preoperative preparation for surgery and the recovery rate in the postoperative period. Parents with less anxiety will be able to provide better parental care for their children during the recovery process. This will result in fewer complications.[22,23]

The recovery process after heart surgery involves a range of care needs. Many of these include care activities that involve parents, especially in the pediatric setting. Examples include painful procedures such as turning in bed, coughing and deep breathing exercises, mobilization, and wound care can be examples.[43] At this point, studies show that parents who understand the disease cooperate better.[44-46] Marella et al.[47] conducted a pilot study that showed that using 3D modeling for preoperative parental education is feasible. The study found that this method produces results that are equal to or better than the current standard of care in terms of parental understanding and knowledge. Onyekachukwu et al.[48] conducted a prospective study at a single center. The study used 3D-printed heart models to educate and counsel families. The researchers enrolled 75 participants and found that using 3D-printed heart models was highly effective in helping families understand their child's disease. The study also assessed, similar to this plnned study, caregiver satisfaction and found a significant improvement after the educational intervention

was provided Another RCT implemented by Karsenty et al.[49] with 76 patients showed that 3D heart models improve parental knowledge and reduce their anxiety level.

Good care received by patients in the postoperative period reduces complications and directly affects the recovery process. In a study conducted in 2016, 22 physicians, 38 nurses, and 10 ancillary care providers who were caring for patients with heart models created through 3D printing reported that nurses were better able to manage their patients when they received brief information about the procedure performed in the postoperative period along with the model.[50] In addition, children will be prevented from being traumatized with reduced surgical complications such as less pain and infection, and biopsychosocial healthier children will be raised.[43] Moreover, surgeons who can perform surgical simulations can perform their procedures, which will be completed in a shorter time with this method, with less risk of complications. A multicenter international study made in 2017 revealed that modeling before complex cardiac surgeries has significant effects. Surgeons stated that 19 out of 40 patients changed their surgical procedure after modeling and completed the treatment with a different surgical technique than the initial one.[15] Models obtained with 3D printers contribute significantly to preparing surgeons for complex procedures, reducing costs, and improving outcomes. According to a study by Chaudhuri et al.[51], surgical simulations with anatomical models reduced procedures by 1.5-2.5 hours. Although it is stated in the literature that cardiac surgery methods performed with 3D modeling are not very common, this study states that the cost of the procedure is significantly reduced. Similarly, Tack et al.[52] completed a research in 2021 and they mentioned that the savings varied according to the surgical procedure, ranging from 366 to 1485 euros. The most savings were achieved with the Norwood operation in atrial septal defects with 1485 euros.[52] When the operation time is reduced, more patients can be admitted, patients can be treated with fewer complications, and with the education provided, there will be fewer repeated hospitalizations and fewer outpatient visits. This also means a significant financial gain. 3D printing is a new technology and it should not be considered expensive. With proper expertise, it can potentially provide useful and low-cost 3D models.[53] In a seven-year prospective study conducted by Gomez Ciriza et al.[54] in 2021, it was discovered that affordable facilities can produce 3D-printed heart models that meet high technical and clinical standards.

Limitations

This study has some limitations. The first and most important is that patients were selected according to the quality of CT images taken during their diagnosis and treatment procedures. As a result of this practice, to protect children and avoid repeated imaging, a bias in patient selection may be identified. The second limitation is that intracardiac structures take longer to be modeled than extracardiac structures, and therefore, very common diseases such as ASD and VSD must be excluded. To conduct more feasible research, we highly recommend using imaging, modeling, and surgical procedures, which require physical proximity. One of the most significant limitations of this study is the need to obtain CT images from one hospital, carry out modeling in different laboratories, and complete printing in various locations. The most challenging and time-consuming parts were going back to the hospital, obtaining the surgeon's opinions, and revising the model. Although using this novel technology in treatment and care can be highly beneficial, future research needs to be conducted to address these limitations.

Conclusions and Recommendations

3D modeling and printing technologies are rapidly increasing today. With good technological equipment and knowledge, the use of these technologies can lead to higher family quality of life and better surgical simulation and operation preparations. The strength of

this study is that it reveals the 3D modeling and practical implementation procedures. It is important to inform the scientific world of our difficulties, challenges, and solutions for further development. To our knowledge, there has been no randomized controlled trial that uses 3D heart modeling to examine the effectiveness of family quality of life. Our study aims to fill this gap in research. In order to expand the use of these technologies and demonstrate their clinical effects, it is recommended that more studies with a larger sample size in different populations and a better technical team be included in the literature.

Declarations

Consent for publication

All authors and patients who have provided written consent for participation have agreed to the publication. As we have not yet started recruitment, we do not possess any written consent at this stage. However, the retrospective patient information provided to us for the preliminary study contained no personal identifiers. It solely consisted of medical images intended for practice and the determination of inclusion and exclusion criteria. Consequently, we did not obtain informed consent from their parents. However, in anticipation of the recruitment phase, we have prepared a written informed consent form for parents and children aged 16 years and older. Furthermore, all authors have given their final approval to the manuscript.

Availability of data and materials

All researchers will have access to the research dataset throughout the research process. The data will never be shared with any third party other than the researchers and will be kept in encrypted files for five years after the study is completed. At the end of five years, they will be destroyed.

Ethical approval

The study will adhere to the ethical principles declared by the Declaration of Helsinki. This experimental protocol was approved by the Acıbadem Mehmet Ali Aydınlar University Medical Research Evaluation Board (ATADEK) (date: 11.11.2022; approval no/number: 2022-17/50) and written institutional approval (date: 09.02.2023) obtained for the institutions where the research will be conducted. The study was registered on clinicaltrials.gov in May 2023 (NCT Number is: NCT05852106). All authors confirm that all methods will be carried out in accordance with ethical guidelines.

Author contribution

The authors confirm contribution to the paper as follows: study conception and design: AAS, AVI, PI Author; data collection: AAS, AVI, EP, AC Author; analysis and interpretation of results: AAS, AVI, PI, DN, TG, AC, DOS, GNC Author; draft manuscript preparation: AAS, DOS, AVI, PI, TG, AC, CZE, GNC, DN, EP Author. All authors reviewed the results and approved the final version of the manuscript.

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Conflict of interest

The authors declare that there is no conflict of interest.

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