

Exploring the Impact of 3D-Modeled Berlin Hearts on Patient Education and Anxiety: A Protocol Paper
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Abstract

The Berlin Heart is a state-of-the-art machine that significantly advances congenital heart disease treatment by sustaining life while patients with severe cardiac dysfunction either await a heart transplant or recover from surgery. The transplant process, though life-extending, can significantly heighten anxiety and stress, severely impacting quality of life. Due to its advanced nature, the workings of the Berlin Heart can be better explained to patients and their families through a physical model of the device. We propose that the patient groups that utilize the 3D Berlin Heart Model for educational purposes will exhibit

Utsav Sharma^{1*}; Hannah Kennedy^{1*}; Sanandan Ojha^{1*}; Ayush Jain^{1*}; Ania Kelegama¹; Marlena LaRubbio^{1*}; Sneha Suresh^{1*}; Vahini Srikakulapu^{1*}; Saketh Damera^{1*}; Arun Chandran²

¹Dream Team Engineering University of Florida Gainesville US

²Department of Pediatric Cardiology University of Florida College of Medicine Gainesville US

*these authors contributed equally

Corresponding Author:

Utsav Sharma
Dream Team Engineering
University of Florida
Gainesville, FL 32611
Gainesville
US

Abstract

Background: Review of Literature

In recent years, integrating surgical models into medical practice has gained traction due to their potential to enhance patient education and understanding of their procedures. By creating the Berlin Heart (BH) model for the pediatric population, we wanted to explore the effectiveness of this unique model in alleviating patient anxiety.

Psychological Impact

When studying anxiety in the pediatric population, it is essential to understand the parents' role. In a study conducted by Holly Clisby, eight parents of children supported by the Berlin Heart were interviewed. The study captured the anxiety-inducing effects of prolonged hospitalization. The research suggested that patient and family education about the BH model can mitigate

psychological burden, further supporting that models alleviate stress.

Additionally, Dr. Tilman Humpl studied the effectiveness of VADs, with a particular focus on the BH model in pediatric patients. The study supported that VADs, particularly the BH model, offer efficient and extended support for pediatric patients until they receive a transplant. However, the wait time can induce anxiety in patients because the device may not support them long enough as they await a transplant (Humpl et al., 2010). Furthermore, Ronald Hetzer and his team investigated the effectiveness of the device. Their study found that the Berlin Heart provided support for up to 841 days before a heart transplantation became viable for a 5-year-old boy. Another patient, a 14-month-old boy with decompensated dilated cardiomyopathy, remained stable with the BVAD for 547 days until heart transplantation. Therefore, it was reported that a pediatric mechanical circulatory support device, the Berlin Heart, can be reliable for circulation for extended periods.

Perioperative Education and Reducing Anxiety

Several studies have been conducted to understand how models have reduced perioperative anxiety and improved patient anxiety. For instance, Mark Biro and his colleagues had a compelling case for the impact of their three-dimensional printed Mohs Micrographic surgery (MMS) model with standardized education. The study used the Visual Analog Scale (VAS) and State-Trait Anxiety Inventory (STAI) to assess anxiety and understanding. One group received the MMS model and standardized education; the other received standardized education (verbal counseling). It was found that anxiety levels significantly decreased when given a combination of verbal education and the model versus just standardized education (Biro et al., 2019).

Despite this, the study had a mean age of 67.8 years; thus, it was vital to continue research to understand the implications of a model in the pediatric population. When educating patients on their procedure, specificity is a critical approach. That being so, the models used should pertain to their diagnosis and anatomy, as this will ensure optimal understanding and reduction of anxiety. In a pilot study, seven patients with a kidney tumor underwent a four-phase multidetector computerized tomography (MDCT) scanning from which renal volume data were extracted to create life-size patient-specific 3D printed models. Patient knowledge and understanding were evaluated before and after presenting the model, and there was a significant improvement in understanding their surgical procedure (44.6%, $p = 0.026$). As a result, it can be concluded that personalized 3D-printed models enhance patients' subjective satisfaction (Zhuang et al., 2019).

Objective: To properly assess the effect that education using the 3D-printed Berlin Heart Model has on patient anxiety levels and surgical outcomes, preoperative anxiety levels of the patients and their parents must be measured (qualitatively and quantitatively) and then statistically contrasted with anxiety levels of patients and their parents after education on the BH model.

Methods: Inclusion/Exclusion Criteria

The study subjects selected for the test population will be predicated on the patient and their respective nuclear family receiving a Berlin Heart LVAD surgery. This will present two subsets within the inclusion population: the actual patient being the first subset and the second subset being the patient's parents.

Patients who have already received a Berlin Heart LVAD transplant and or patients who have received similar heart transplants like the Berlin Heart will be disqualified from testing.

Study Design

Before proceeding with the study, around half of the selected subjects will be randomly assorted into a control group. This control group will only receive a standard education compared to the test control group, which will receive standard education supplemented by the 3-D-printed Berlin Heart Model. Both groups will undergo the same outlined study phases.

For the pre-education phase of this study, patients will be administered the PARS inventory for the quantitative assessment of anxiety and the Wong-Baker face scale for the qualitative evaluation of anxiety. During the pre-education phase, parents will be administered the STAI-AC inventory and a modified Likert Anxiety scale for quantitative and qualitative anxiety assessment, respectively.

The education phase of the study will be composed of regular education that families undergo before operations, supplemented by the 3D-printed Berlin Heart model. There are two separate Berlin Heart models, with the first being a handheld version that will be handed out during the presentation and showcasing how a Berlin Heart works, complete with flowing water and pumps. The second is a heavier interactive model, more aimed at pediatric patients, with a drawing surface that showcases the Berlin Heart's placement and functionality in the body of a friendly man.

During the post-education phase of the study, the PARS and the STAI-AC are administered to the patient and parents,

respectively, to assess post-education anxiety levels quantitatively. For qualitative assessment, the Wong-Baker Face scale will be distributed to the patients, and the modified Likert Anxiety Scale will be given to the parents to determine anxiety levels.

Statistical Analysis

If the data from the inventories and surveys appear to be in normal distribution, a one-way ANOVA should be used to compare the model's effectiveness on patient and parent anxiety levels. The pre-education anxiety levels and the post-education anxiety levels are linked events where one event influences the other. Therefore, a one-way ANOVA should be done on the PARS and STAI-AC inventory.

Regarding the qualitative data, the Wong-Baker face survey can be converted into numerical data, which can then be run through a one-way ANOVA to determine the effectiveness of the 3D-printed learning aid. Moreover, the Likert scores can be converted and understood as interval data, which can also be used within a one-way ANOVA. This assumes the data has been corrected for no outliers and a normal distribution. If the data has no normal distribution and outliers, a Wilcoxon-signed rank test could be used with regression tests to determine the correlation between patient education and anxiety levels.

Results: Data is yet to be collected.

Conclusions: The present study sought to assess the impact of employing a 3D-printed model of the Berlin Heart on alleviating preoperative and postoperative anxiety among pediatric patients and their families. The absence of empirical data herein highlights the challenges inherent in pioneering research fields, particularly those intersecting medical innovation with patient psychological well-being. The theoretical implications of our study, however, contribute to a broader understanding of patient education mechanisms and their potential to transform patient experiences. Moreover, the established methodological framework sets a precedent for subsequent empirical inquiries into the use of tangible educational aids in clinical settings.

Future research must empirically validate the proposed benefits of 3D-printed models in medical education and anxiety reduction. Subsequent studies should refine the approach based on the lessons learned during the preliminary phases of this research, possibly extending the investigation to include diverse patient cohorts and a broader spectrum of medical devices.

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Original Manuscript

Original Paper

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Dream Team Engineering, University of Florida
Arun Chandran, M.D., College of Medicine

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Abstract

The Berlin Heart is a state-of-the-art machine that significantly advances congenital heart disease treatment by sustaining life while patients with severe cardiac dysfunction either await a heart transplant or recover from surgery. The transplant process, though life-extending, can significantly heighten anxiety and stress, severely impacting quality of life. Due to its advanced nature, the workings of the Berlin Heart can be better explained to patients and their families through a physical model of the device. We propose that the patient groups that utilize the 3D Berlin Heart Model for educational purposes will exhibit improved outcomes and lowered perioperative anxiety. Decreased anxiety levels in pediatric patients improve prognoses and may reduce adverse reactions to potential complications while on the machine. We offer a protocol to ascertain the 3D-printed Berlin Heart Model's efficacy in alleviating patient anxiety and boosting perioperative outcomes through quantitative and qualitative analysis. This hints at the potential for expanding enhanced health education to other complex treatments, ultimately fostering a more informed pediatric patient population overall.

Keywords: Berlin Heart; patient anxiety; patient education; surgical education; 3D-printing

Introduction

Pediatric heart failure, often due to cardiomyopathy or myocarditis, is a difficult diagnosis for a family to process emotionally. Thousands of children who need heart transplants due to heart failure outpace the population of viable pediatric heart donations annually. Fortunately, using a Berlin Heart as a long-term ventricular assistive device (VAD) has proven to be a successful temporary solution awaiting the successful availability of a donor heart or spontaneous cardiac recovery (Morales et al., 2017). However, this procedure is often expensive, stressful, and foreign to patients and their families. The lack of patient education on the Berlin Heart device and related physiology and complications can result in high anxiety, unease, and mistrust associated with the procedure. Preoperative education and therapy can alleviate these negative emotions caused by a lack of patient knowledge (Tadesse, 2022).

Review of Literature

In recent years, integrating surgical models into medical practice has gained traction due to their potential to enhance patient education and understanding of their procedures. By creating the Berlin Heart (BH) model for the pediatric population, we wanted to explore the effectiveness of this unique model in alleviating patient anxiety.

Psychological Impact

When studying anxiety in the pediatric population, it is essential to understand the parents' role. In a study conducted by Holly Clisby, eight parents of children supported by the Berlin Heart were interviewed. The study captured the anxiety-inducing effects of prolonged hospitalization. The research suggested that patient and family education about the BH model can mitigate psychological burden, further supporting that models alleviate stress.

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Methods

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Results:

Data not yet to be collected.

Discussion

The STAI-AC is a general-purpose self-reported measure of anxiety that excels at distinguishing between state anxiety and trait anxiety. It also has a high validity that allows for accurately estimating anxiety in the parent cohorts. The high validity combined with the ability to distinguish between general state anxiety and trait anxiety will allow for an accurate estimation of how much the usage of the model reduces anxiety without measuring trait anxiety. Due to the nature of pediatric populations, they cannot complete the STAI-AC effectively, as it requires a higher level of reading comprehension. The PARS was explicitly created to be given to pediatric populations and doesn't rely on the knowledge and skills of the examinee. PARS is quite comprehensive, covering several aspects of anxiety, including separation anxiety, social phobia, and generalized anxiety. Since trained clinicians give and grade the PARS, the results do not depend on the kids' knowledge. It also has high interrater and test-retest reliability, meaning the results can be relied on.

The two qualitative surveys proposed are the Wong-Baker and Likert scales. The Wong-Baker scale is unique in that it's visual; respondents can simply point to a face they resonate within the moment, making it more effective for very young patients. The Likert scale is prevalent among anxiety tests, and the literature supporting it is widespread.

PARS, due to its specialized nature compared to the STAI-AC, also requires a trained clinician to administer and score, which may limit the availability of the test to be administered. Additionally, since the test is administered and graded by a clinician, it may not always reflect the child's subjective experience. However, the STAI-AC, which is much cheaper and self-administered, cannot be used in place of the PARS as it requires a minimum level of reading comprehension and self-awareness that children lack. The PARS is also better able to pick up on the effects of treatments, such as an education session, which is vital for the aim of the study. The STAI-AC is not as sensitive to changes in anxiety over time, which can hamper its ability to detect small changes in anxiety due to treatment, which, in this case, is the education session. Both inventories have good validity in measuring anxiety; however, the slight difference between them must be considered when comparing

the results from both cohorts.

Moreover, future testing or adjustments to the protocol can include investigating the relationship between reduced anxiety via the 3D printed model and patient outcomes after the surgery. This could further determine the efficacy of 3D printed models being used in conjunction with the education of procedures within surgery. For this type of study to have a more substantial sample population, the nature of the surgeries can be expanded to any 3D-printed model representing any cardiac pathology so that the amount of available data can increase. The only drawback to this approach is that the model's integrity needs to be standardized as multiple cardiothoracic procedures are being modeled.

Conclusions

The present study sought to assess the impact of employing a 3D-printed model of the Berlin Heart on alleviating preoperative and postoperative anxiety among pediatric patients and their families. The absence of empirical data herein highlights the challenges inherent in pioneering research fields, particularly those intersecting medical innovation with patient psychological well-being. The theoretical implications of our study, however, contribute to a broader understanding of patient education mechanisms and their potential to transform patient experiences. Moreover, the established methodological framework sets a precedent for subsequent empirical inquiries into the use of tangible educational aids in clinical settings.

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Acknowledgements

Abbreviations

BH: Berlin Heart

MDCT: Multidetector Computerized Tomography

LVAD: Left Ventricular Assist Device

ANOVA: Analysis of Variance

STAI-AC: Spielberger State-Trait Anxiety Inventory

PARS: Pediatric Anxiety Rating Scale

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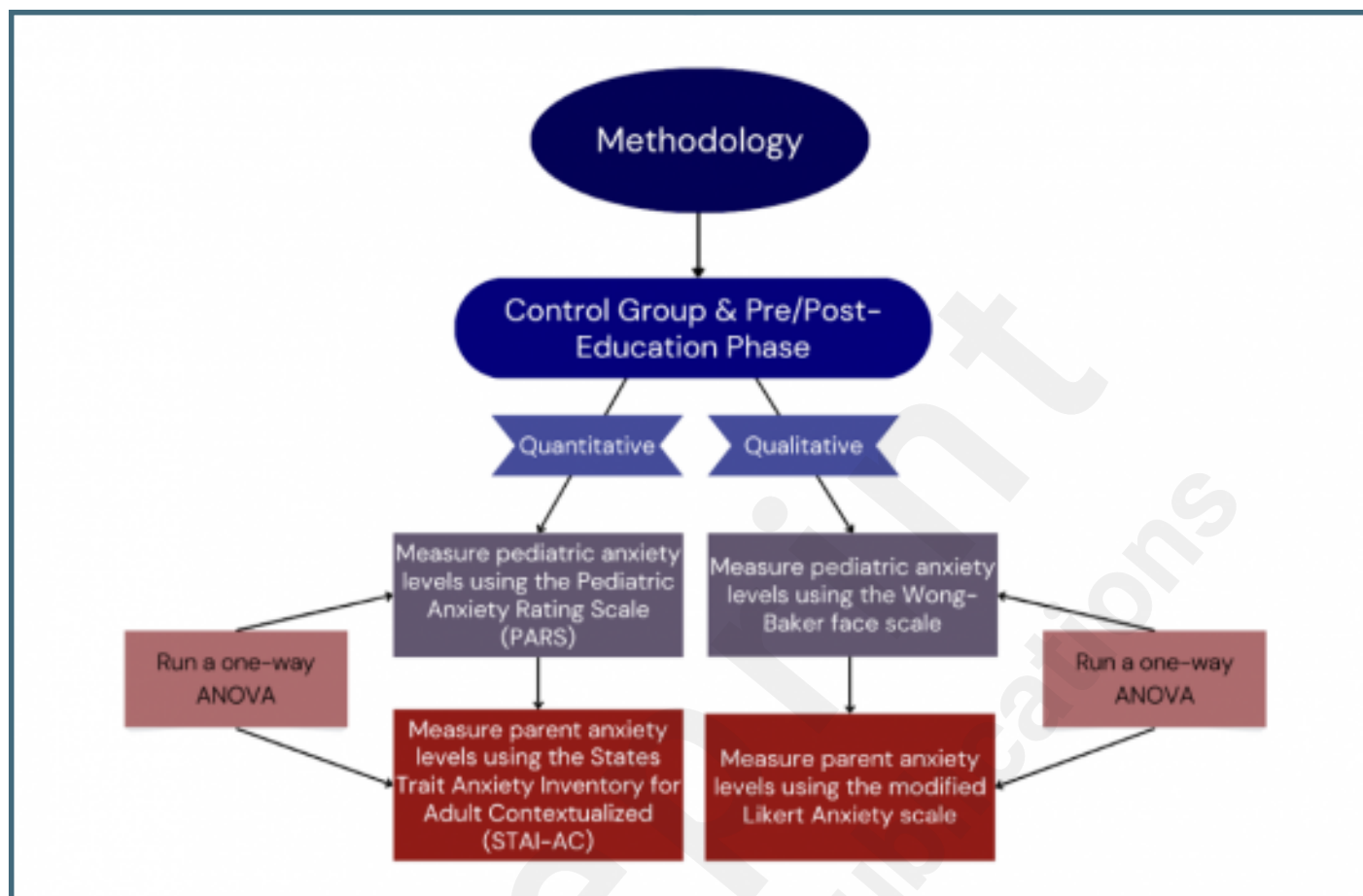
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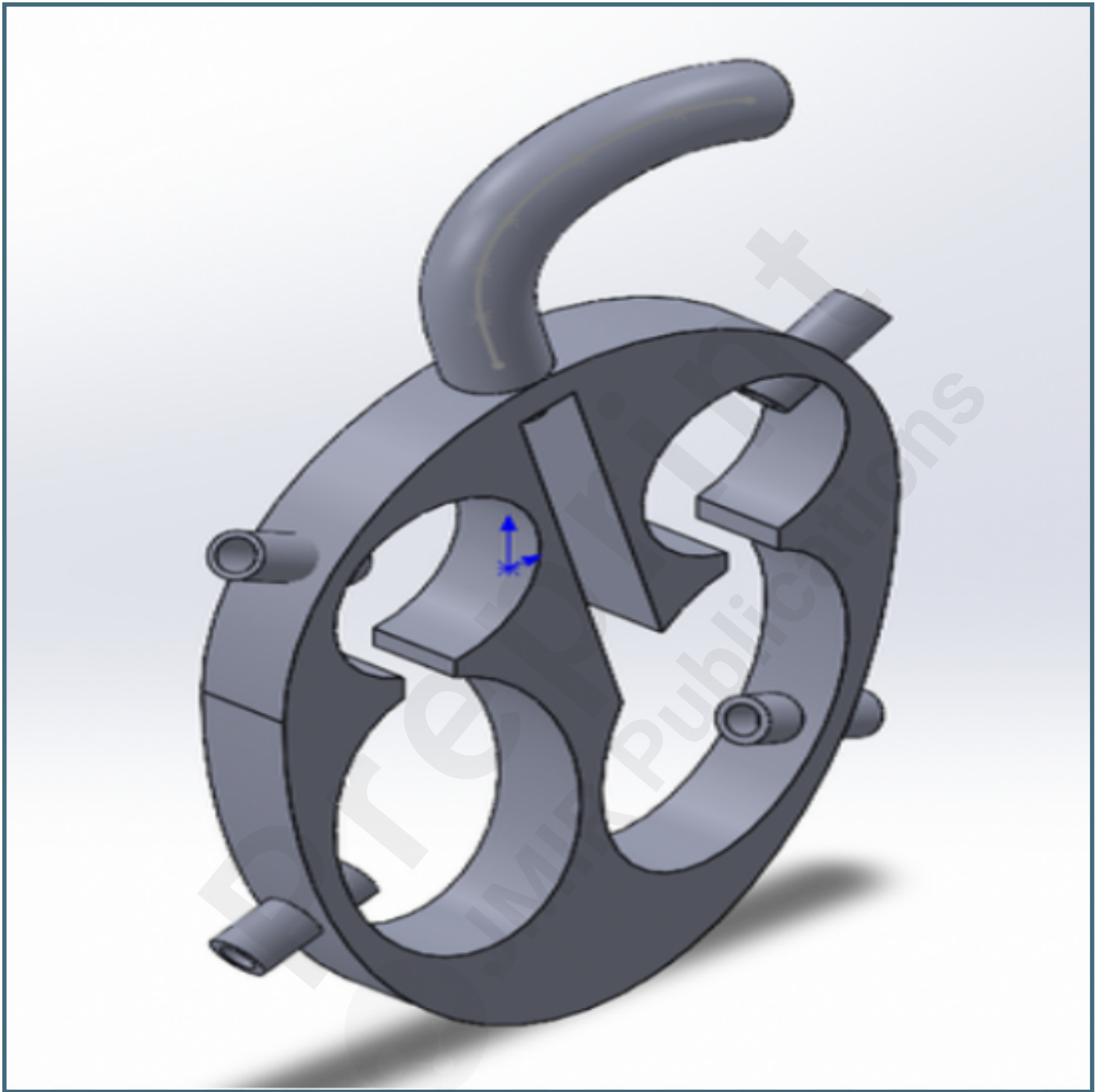
Supplementary Files

Figures

Flowchart of methodology.



SolidWorks heart sketch.



3D-Printed assembled heart.



Final small-scale berlin heart model.

