

PediaPack Devices

Enabling Pediatric Brain Surgery through Head Stabilization

Knowledge and Skills Gained

- Design Process (Divergent/Convergent Thinking, Quick-kill)
- Clinical Immersion incl. witnessing surgery
- Networking and Stakeholder Feedback
- Communication/Presentation Skills
- Design Documentation incl. Design History File
- Market Research and Analysis
- Rapid Prototyping
- Application of Engineering and Technical Skills
- Proof of Concept Testing

Need

Provide complete head immobilization for pediatric patients during neurosurgery to ensure a stable surgical field compliant with stereotactic systems.

Project Description

Pediatric patients offer a unique set of challenges to the field of medicine. Although they suffer from a wide variety of neurological ailments, including epilepsy, brain tumors, and hydrocephalus, treatment of these conditions through surgical intervention is complicated. Adult patients requiring neurosurgery are stabilized using a 3-pin skull clamp. This immobilization allows neurosurgeons to use neuronavigation. Neuronavigation is a highly advanced technology that combines pre-operative CT or MR images with real time feedback to assist neurosurgeons in locating targeted regions of the brain. This technology increases surgeon confidence and leads to better patient outcomes. **Due to the fragility of their skulls, pediatric patients, especially those under the age of 3 years, cannot be pinned with the traditional skull clamp;** making them ineligible for use of neuronavigation. As a team, we are committed to creating a device that addresses these shortcomings. PediaPack's innovative infant skull stabilization solution provides pediatric patients access to the often life-defining surgeries they require by providing surgeons the confidence they need to perform these critical intracranial procedures.

Health, Safety, and Welfare

Our solution first and foremost emphasizes the safety and welfare of pediatric patients in need of neurosurgical intervention. Over 7,000 children undergo surgery each year for neurological disorders. 16-20% of these patients experience. **A major cause of pediatric postoperative complications is the inability to safely immobilize their heads.** 45 depressed skull fractures are reported each year in children undergoing craniotomies with pin fixation. Our device will significantly improve the standard of care for pediatric patients by safely and securely immobilizing infants' heads; permitting critical surgeries and reducing rates of postoperative complications.

Multidiscipline Collaboration

After narrowing to a field of focus of pediatric neurosurgery, our team of engineering students expanded our outreach to include **collaboration with medical professionals in the specific field of interest, rapid prototyping resources, and relevant engineering disciplines.** Medical professionals in the field of pediatric surgery highlighted a need in pediatric neurosurgery for pediatric skull stabilization and provided Quick-kill feedback. Concurrently, **prototyping, engineering professionals, and members of the Engineering Faculty** provided insight into specific engineering and manufacturing principles that needed to be considered when developing our design.

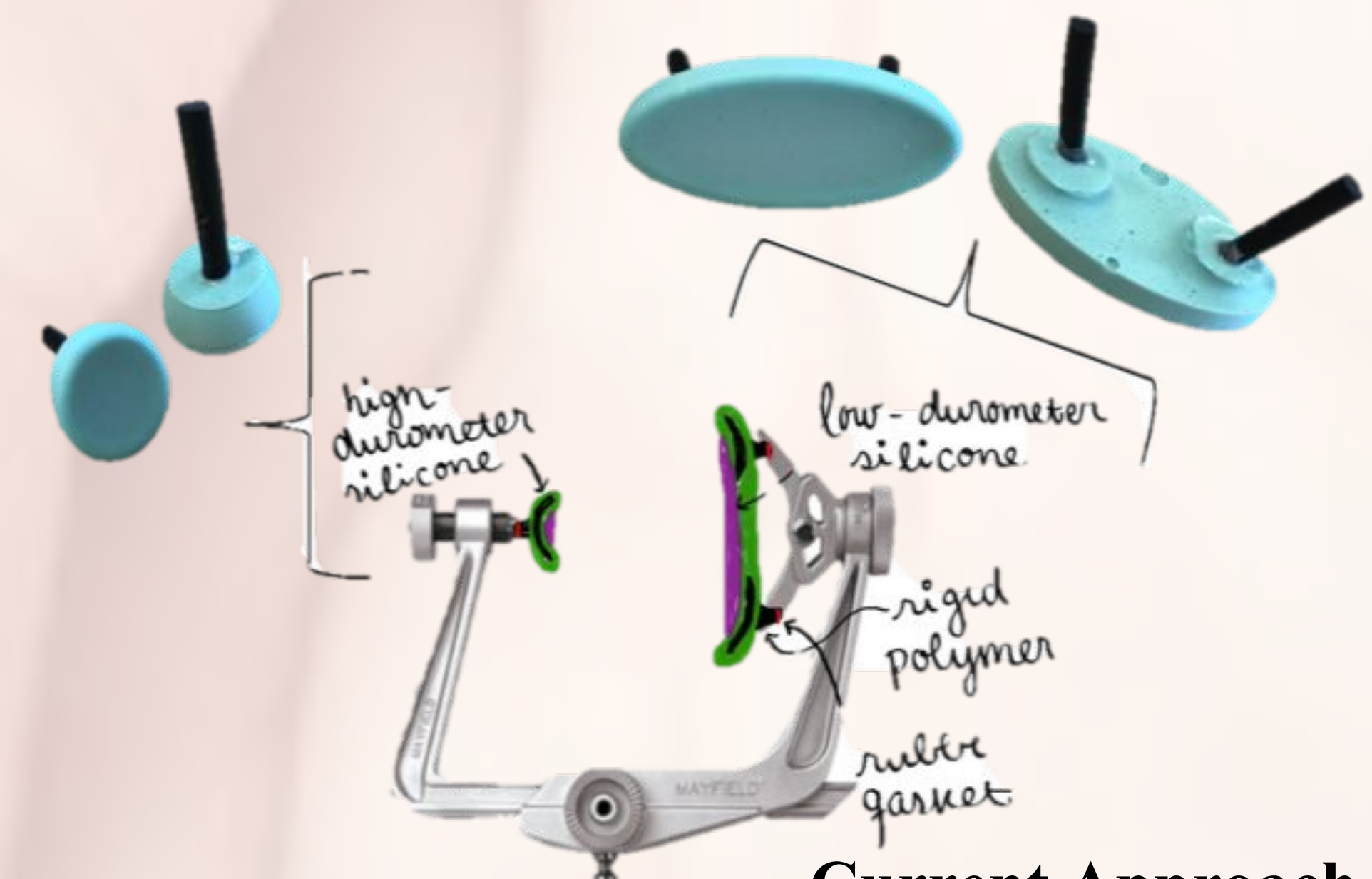
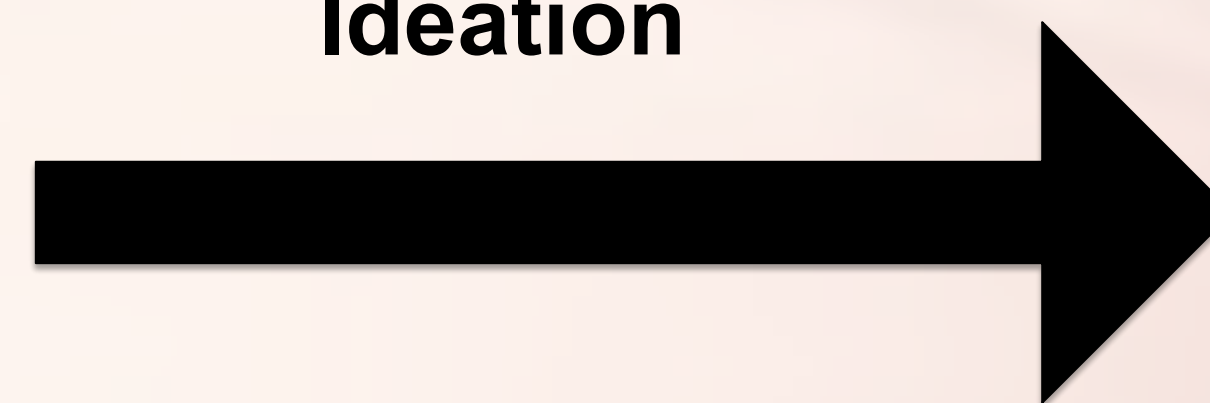
Design Progression

After **the need was identified**, the PediaPack biomedical engineering students took part in divergent thinking exercises to develop a **list of concept ideas**. These concepts were then **narrowed based on design criteria** established with the help of clinical mentors. Design criteria included stability, access to the surgical field, cost, setup time, and pressure distribution. **The first iteration** led to the development of The Octopus, disposable adaptors made with a set of pads (pictured left). Through Quick-kill ideation, this design ultimately morphed into the **current solution, the Cradle** (pictured right). Through the mentorship of professional engineers it was determined that this design would provide more stability and would decrease manufacturing burdens.



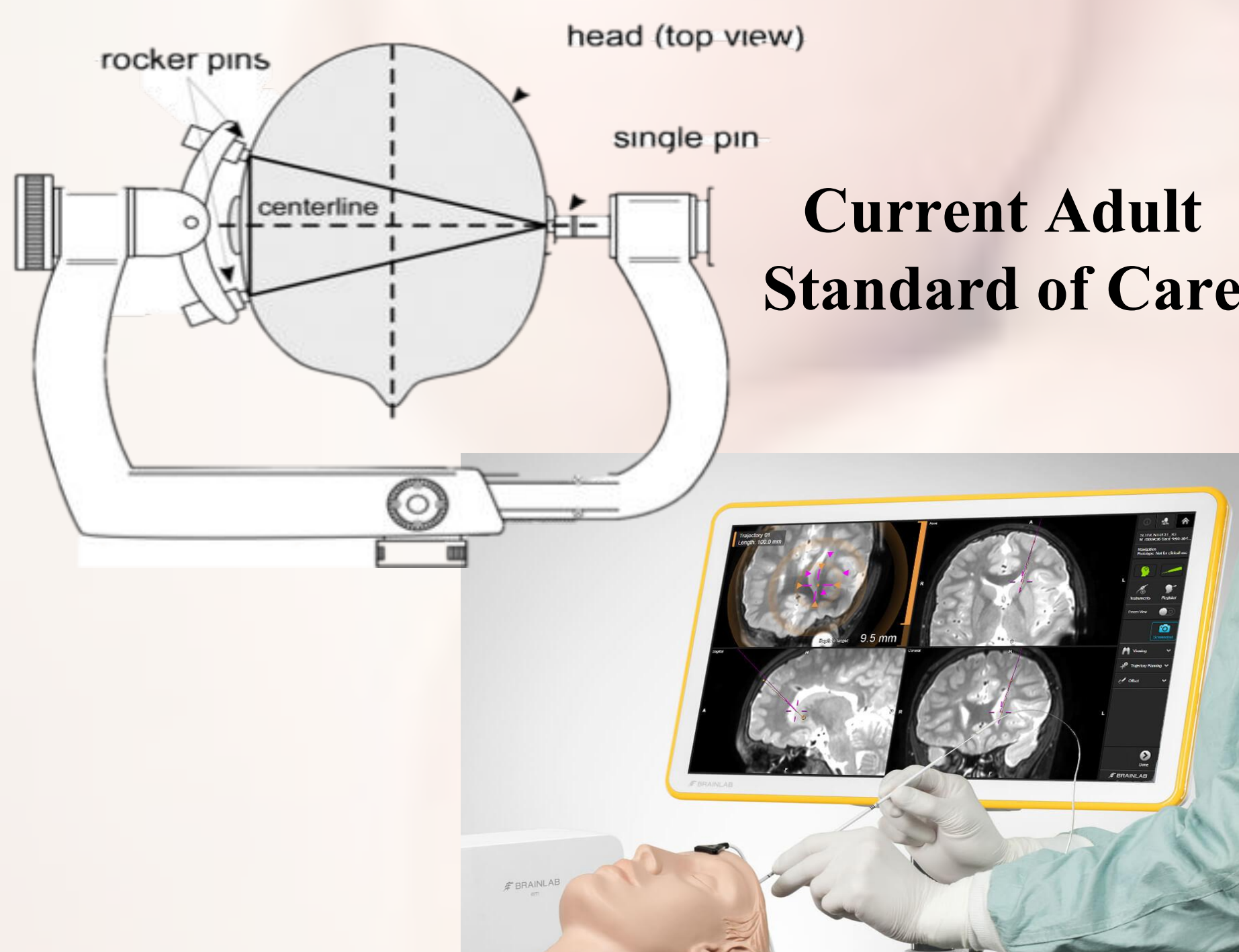
Initial Iteration

Ideation



Current Approach

Mending the Minds of Tomorrow

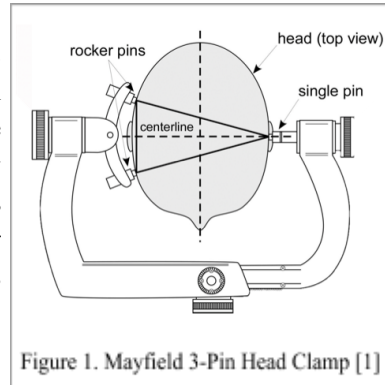


Current Adult Standard of Care

Enabling Pediatric Brain Surgery through Head Stabilization

Abstract

Neurosurgery is a field marked by precision of execution. The difference between successful outcomes can come down to millimeter margins. The gold standard of stabilization for many adult, cranial-based procedures is the Mayfield 3-Pin Skull Clamp, Figure 1. This device allows for complete immobilization of the skull and is thus compatible with neuronavigation. Neuronavigation, also known as stereotactic systems, is technology that works with preoperative MR and CT images to allow neurosurgeons performing minimally invasive surgeries to know their exact position in the brain. This technology increases surgeon confidence and leads to better outcomes. This past year a team of biomedical engineering students teamed up with clinicians and engineering professionals to combat **inadequacies in care for pediatric neurosurgery patients.**



The pediatric population offers a variety of unique challenges in the field of neurosurgery. The fragility of their skull, due to fontanelles and lack of ossification of the bone, makes them especially vulnerable to skull damage. This makes pediatric patients, especially those under the age of 3, ineligible for use of the skull clamp and thus neuronavigation technology. **Despite this, almost 7,000 pediatric patients require surgery annually [7].** Our device attempts to improve the head stability of pediatric patients. By enabling neurosurgeons to use neuronavigation technology, like BrainLab, on their pediatric patients we are opening a new frontier of possibilities for treatment of pediatric neurosurgery.

Our device, affectionately called **the Cradle**, is a set of disposable adaptors to the current Mayfield device. Polymer attachment pieces slide seamlessly into the Mayfield setup. Replacing the metal pins with silicone pads increases the surface area contacting the head, **decreasing localized pressure felt.** The device is made of two different durometers (i.e.: hardnesses) of silicone. The rigid exterior shell provides support and minimizes movement to less than 1 mm, the threshold for use with stereotactic systems. The pliable interior pad provides traction with the skin and decreases the risk of necrosis. Necrosis can occur when a device is in prolonged contact with the skin (>3 hours).

The immediate impact of this device is the possibility of treating and curing a child of an ailment that would otherwise go untreated. Treatment would improve cognitive function leading to a better quality of life for the child and the ability to live and work independently. However, through market research and stakeholder interviews, our team has determined that the implications go much further than that. Reduction of the burden of disease would impact parents and caregivers who no longer are bound to a dependent child, insurance companies including the government (Medicare) through decreased medication costs (antiepileptic drugs, chemotherapy, etc.) and reduced hospital visits, and medical staff that save time during setup and the heartache of failed procedures. Although this device was made with the pediatric population in mind, it is also applicable for use with adult patients too, as they suffer from complications due to slippage and skull fracture.

By opening a new frontier of possibilities for treatment of pediatric neurological disorders, including epilepsy, brain tumors, and hydrocephalus, our group is hoping to **mend the minds of tomorrow.**

Enabling Pediatric Brain Surgery through Head Stabilization

I. Project Description

Pediatric patients offer a unique set of challenges to the field of medicine. Although pediatric patients suffer from a wide variety of neurological ailments, including epilepsy, brain tumors, and hydrocephalus, treatment through surgical intervention is constrained due to inadequacies in head fixation. Adult patients requiring neurosurgery are stabilized using the Mayfield three-pin skull clamp, which provides complete immobilization, allowing neurosurgeons to use neuronavigation. Neuronavigation is a highly advanced technology that combines pre-operative computed tomography (CT) or magnetic resonance (MR) images with real-time feedback to assist neurosurgeons in locating specific regions of the brain during their neurosurgical procedures. By providing precise information about the three-dimensional space, this technology leads to better patient outcomes by increasing surgeon confidence, reducing length of surgery, and lowering risks of infection and neurological morbidity [2]. Due to the fragile nature of their developing skulls, young pediatric patients cannot be pinned with the skull clamp, making them ineligible for use of neuronavigation and thus denying them the same standard of care afforded to adults.

PediaPack Devices was created with this issue in mind. For our year-long senior design project, we were tasked with finding a problem for which we could develop a solution and proof of concept within a limited time period. Through the clinical immersion aspect of our process with partnering hospitals, we gained contacts in the pediatric neurosurgery department. Through conversations with clinicians and observations in the operating room, we observed first-hand the struggles that pediatric surgeons face when they are trying to operate on a small child's head. Since no device currently exists that can adequately and completely immobilize the head, surgeons must resort to using a combination of gel pads and other makeshift set-ups in attempts to partially stabilize the head. Devices like the DORO headrest system try to mimic the Mayfield skull clamp by using multiple gel pads instead of pins, but are cumbersome to set up, limit access to the surgical field, and have a very low success rates. While shadowing one particular procedure, we observed a surgeon attempt to use of one of these devices. After approximately two hours of setup time, the surgeons were still unable to adequately stabilize the child's head. This extended setup time exposes the child to anesthesia for much longer than necessary, which can lead to other health problems such as neurocognitive developmental delays. After observing the problems facing both pediatric patients and neurosurgeons, we decided to undertake the task of creating a viable solution for adequately and efficiently stabilizing a young child's head during neurosurgery.

We started working on possible solutions and, through our own research, decided that there were three main objectives we wanted to accomplish through our design. We wanted to create a device that provided a stable surgical field which would be 1) compatible with neuronavigation technology, 2) prevent skull damage, and 3) reduce surgical set-up time to in turn reduce the duration that the child would be under anesthesia. To facilitate ease of use for neurosurgeons, we decided to make a device that would be able to attach to the Mayfield device and simply replace the metal pins currently used on adult patients. Additionally, we wanted our device to be disposable like the standard Mayfield pins and comparable in price. Our initial idea was to increase the amount of surface area contacting the head in order to distribute the applied force and decrease the localized pressure imparted on the skull.

As we began to develop more ideas, a surgical resident we contacted was extremely helpful in devoting his time and effort to assisting our team throughout several meetings and conversations. He gave us valuable feedback about certain design concepts and helped us gain a better understanding of what exactly the surgeons would potentially need from our design. Additionally, our faculty advisor introduced us to a professional engineering mentor who helped us look into the specific parameters and requirements that our design would need to encompass.

During one meeting with our resident advisor, we were provided access to an unoccupied operating room where we examined and measured the dimensions of an actual Mayfield skull clamp. This was highly beneficial to us because we realized the initial design that we were ready to move forward with would not be a viable option, as it was too fragile to withstand the load applied via the Mayfield skull clamp. From there, we went back to the drawing board to brainstorm other possible solutions. At first, we had wanted our design to be a set of three pads that could be attached but, as we moved forward, we started discussing combining the two pads that would be on the rocker mechanism of the Mayfield into one larger pad, as seen in Figure 1. After consulting with our surgical resident and professional engineering mentor, we all agreed that this design would be the most plausible of our design concepts. We then consulted our professional engineering mentor to learn more about different materials that we could potentially use for our design. After many discussions and extensive research, we decided that using a combination of two different types of silicone would be the best for our proposed device. With this design, we could use a rigid silicone to adequately withstand and distribute the force applied, in addition to a softer silicone to increase contact with the patient's head, all the while avoiding necrosis, or death, of the skin and other damage that could be caused due to extended exposure during long surgical procedures.

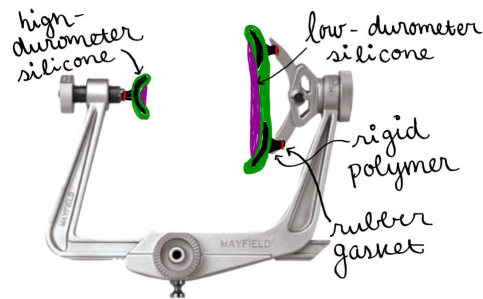


Figure 1: Mayfield skull clamp with our device

After our advisor introduced us to the founder and CEO of a local prototyping company, we met to discuss our design and get advice on how we should proceed with developing a prototype. He showed us some various examples of silicone with different material properties and helped us decide the two specific types of silicone that we wanted to use for our device. When we discussed making molds for our different pad designs, he advised that we could easily produce them in SolidWorks or a similar 3D modeling software and then print them using an ABS plastic filament. From there, the silicone could be mixed and poured into the printed molds for curing.

We started working diligently on printing the molds and, after several iterations and failed attempts, we were finally able to develop molds like we had envisioned and filled them with the silicone. We were extremely pleased with the final result, especially after seeing how well the two silicones cured together. The rigidity of the base was perfect for the amount support we wanted, and the softness on the outside was ideal for providing comfort and traction. However, we wanted to make sure that these materials would be effective in application, so we met with a faculty member from our university who helped us

envision methods for testing our design and materials. He advised us to focus on performing shear stress tests because the majority of the force during surgery would be coming from gravity and the downward pressure of the instruments as the surgeons operate. We borrowed a force transducer from his lab that allowed us to measure the force that we could apply to a simulated skull. We attached it to our molded pads, which we laid flat on a table with the soft silicone in contact with a stationary surface, and pulled until the material began to slip. From the high friction readings, we were confident that we could move forward with these materials and further testing.



Figure 2: Final prototype of our two pads using the two types of silicone

For our initial testing, we used honeydew melons and cantaloupes weighing 3-4.5 lbs to model the head of a small child. We then used multiple c-clamps in order to mimic the setup of the Mayfield device and suspended the melon over the edge of a table using our attachments, as shown in Figure 3. We placed a small force sensor we made and calibrated between the melon and one of the pads to track how much force we were applying via the clamp in order to hold the “head” in place. At different levels of clamping force, we pulled the melon in a downward fashion with the force sensor used during our material testing. This allowed use to measure how much downward force could be applied before the frictional resistance of the pads was overcome and the “head” slipped from its position. After performing these tests, our results showed that even with applying just 5lbs to the head via the clamp, our pads were able to withstand a considerable amount of downward force before slippage occurred. This showed that our design has the potential to stabilize an infant's head while applying minimal force in efforts to eliminate the risk of skull damage.

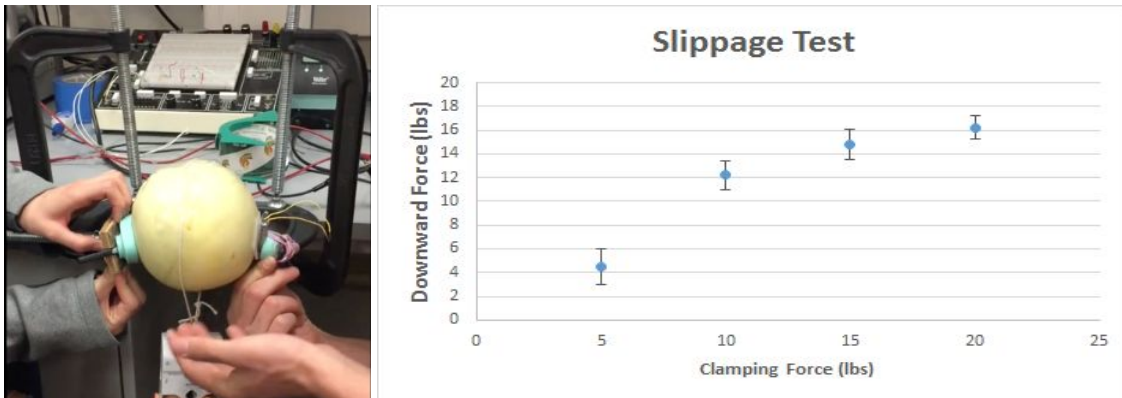


Figure 3: Setup that was used in testing our device (left), Graph of the failure forces versus each force applied by our clamp (right).

Our next steps are to continue testing by tracking the deformation caused by the force of clamping along with the displacement of the head with respects to the clamp resulting from any other reasonable force

that may be experienced during a typical neurosurgical procedure. We plan to implement motion capture technology in order to quantify deformation at different clamping forces and the displacement of the head relative to the device during mock surgical procedures on our head model. We hope this will give us a better idea as to how much force needs to be applied by the clamp in order to stabilize the head such that no more than 1 mm of movement will occur when surgical instruments are applied.

II. Collaboration of Faculty, Students, and Licensed Professional Engineers

Our team was introduced to our faculty mentor through the Department of Biomedical Engineering at a well-respected four-year university. He provided us with expertise on the design process which he gained through his many years of industry experience. Over the course of this year-long project, our faculty mentor introduced us to FDA Quality Design Controls and expected us to maintain our design history files in accordance with this process. His invaluable teachings allowed us to gain experience in the design processes that occur at prominent medical companies. Through our faculty mentor's connections in the medical field, we were allowed the opportunity to observe and work under neurosurgeons at a prestigious research hospital. During our clinical immersion at this hospital, our team gained valuable skills, and we were able to identify needs in the pediatric neurosurgery market. Our team met with multiple neurosurgeons to gain valuable feedback on our design over the duration of our project. Our connections at the university also allowed us to discuss our design ideas with other professors on campus. These experiences granted us with the opportunity to look at our need and solution through many different lenses.

Our faculty advisor also introduced us to our professional engineering mentor (PE) when we began to come up with potential solutions for our identified need. Over the course of our weekly meetings, our professional engineering mentor gave us beneficial feedback and asked questions about our design concept which we had not previously considered. He used his expertise to help our team account for variables of which we had not previously thought but which would impact the practicality of our solution. He also introduced our team to the founder and CEO of a prototyping company. Both our professional engineering mentor and our prototyping specialist helped us discover the appropriate materials to use for our project and the best way to go about molding these materials. Overall, we could not have successfully completed this project in such an expedited time frame without the connections and insight of both our faculty and professional engineering mentors.

III. Protection of Health, Safety, and/or Welfare of the Public

Our solution first and foremost emphasizes the safety and welfare of pediatric patients in need of neurosurgical intervention. The most common neurological disorders affecting children are epilepsy, hydrocephalus, and brain tumors. In the United States, 470,000 children live with epilepsy, 2 out of every 1000 are born with hydrocephalus, and brain tumors are the leading cause of cancer deaths among pediatric patients [3, 4, 5]. For each of these patients, total hospital costs range from \$3,500 to \$5,000 per day, and most require surgery [6]. Over 115,000 children undergo surgery each year, and 5-6% of those cases are for neurological disorders [7]. Out of these patients, 16-20% experience postoperative complications, 17.9% are readmitted within 90 days, and the mortality rate is 2.89% [7, 8, 9]. A major

cause for complications during these procedures is the inability to safely immobilize the heads of patients below the age of 8. While the Mayfield three-pin skull clamp is the most commonly-used fixation device for adult patients, 42 depressed skull fractures are reported each year in children undergoing craniotomies with pin fixation [10]. To ensure peace of mind for these patients and their families, neurosurgeons would be encouraged to use other methods of head fixation that would safely and securely immobilize children's heads during their operations.

Our device will significantly improve the standard of care for pediatric patients across the United States and nations with similar established healthcare systems. In developing countries, with an even greater prevalence of conditions like hydrocephalus and treatments limited by the technology available, the low cost and adaptability of our solution will expand its scope even further. Due to its lower total area of contact than current solutions on the market, neurosurgeons will have greater access to the surgical field and potential sites of incision; however, the total contact area will remain large enough to distribute pressure and guarantee no damage to the patient's skull. For the neurosurgeon, our device will ensure less than 1mm of movement between the skull and its points of contact. Such precision establishes compatibility with neuronavigation, or computer-assisted technologies incorporating brain imaging, to provide the surgeon more confidence in locating specific targets and accurately positioning instruments during operations. For the patient, our solution's ease of use will reduce set-up time in the OR, thereby decreasing the amount of time the child is kept under anesthesia. Studies have shown that the longer a patient is kept under anesthesia, the higher the risk of neurocognitive developmental delays.

During the design phase of our solution, we considered many features that would impact its feasibility, quality, and efficacy. To limit costs, we made it adaptable to three-pin skull clamps, easy to assemble with molds, and readily scalable to large-scale manufacturing. From a regulatory perspective, we worked to comply with FDA standards to market it as a Class I device. In terms of materials, the more rigid base ensures less movement closer to the skull clamp and maintains enough compressive force, while still being flexible enough to cradle the patient's head. The softer coating material provides better conforming to the shape of the patient's skull and limits the risk of slippage due to shear forces. Furthermore, we cooperated with the interests of clinicians, as the device does not significantly change the way they currently operate in the OR. We continue to address challenges by using our diverse skill set from mechanics to materials, while working with industry experts to continuously improve the quality of our product. In the future, we eagerly anticipate further collaboration and progressing our product to market.

IV. Multidiscipline and/or Allied Professional Participation

Throughout the completion of our design, it was necessary to consult with stakeholders and other professionals from various disciplines. Our team set our focus on pediatric neurosurgery and, once our focus was established, it was necessary to expand from our small group of engineers and consult with medical professionals to truly understand the needs within the field of pediatric neurosurgery. We consulted with both pediatric and non-specialized neurosurgeons, ranging from chief residents to attending physicians with over 30 years of experience in the field. These physicians gave us unique insight into the needs of this area of healthcare practice. After shadowing, observing cranial surgeries, and interviewing several physicians, we concluded that head stabilization in pediatric patients was an area of

focus requiring vast amounts of improvement. Additionally, our team collaborated with the founder and CEO of a well-respected industrial design firm to gain insight on how to manufacture a prototype of our device once we had established its primary design.

Interdisciplinary efforts between engineering fields were also required due to wide-ranging design criteria that needed to be understood in developing the head stabilization device. Materials science engineers were vital to ascertaining which materials were best suited for our purposes. After we established that we wanted to use both a rigid and softer material to create the pads, we were able to determine that silicones of different durometers, or hardness, would be best for our design. Mechanical engineers were also essential to our design process as they provided information on the applied forces and pressures that would be necessary for correct function of the device and the most effective ways in which we could test our device to obtain a proof of concept. Ultimately, biomedical engineers were necessary to understand the interaction of the head stabilization device with the pediatric patient during various neurosurgical procedures. Biomedical engineers were able to apply the engineering principles previously established within the realms of the cranial anatomy and various surgical procedures that would require head stabilization due to their understanding of anatomy and medical practices.

Furthermore, within biomedical engineering, several branches contributed to the success of our design, including biomechanics, bioinstrumentation, and biomaterials. Our team was comprised of members that have concentrated their undergraduate studies in each of these three disciplines.

V. Knowledge or Skills Gained

Over the course of our project, we have gained invaluable insight into the engineering design process, growing both individually and as a team along this iterative journey. Guided by many of the same foundational principles found in Stanford Biodesign [11], we set out to identify a pertinent need in the healthcare field. While our faculty mentor provided us with a great deal of guidance in the process of design, it was our team's responsibility to tailor this process to our specific interests and develop a project on our own from start to finish through the research and identification of a problem we observed in the healthcare setting. This fostered a great deal of independent learning and self-reliance as we took it upon ourselves to explore the many unmet needs of various different areas.

While provided an abundance of potential connections and mentors, we were faced with the task of forming our own network and reaching out to clinicians and other professionals to help facilitate our project. As a result, we developed communication and networking skills that proved to be vital in our project from start to finish. Through clinical immersion and the observation of multiple surgeries, we quickly learned how to navigate the medical environment and conduct ethnographic research. By establishing meaningful relationships with healthcare providers, we were able to gain a better understanding of how patients are currently treated, along with the inadequacies of care that are in need of innovative solutions. Throughout this project, we have constantly sought input and feedback from the many people involved in every aspect of the cycle of care. From patients and caregivers to surgeons and other clinicians, we learned the value associated with analyzing the problem at hand from the perspective

of all stakeholders involved.

Through each phase of the design process, we became proficient at documenting our progress and thus learned the importance of maintaining proper design history files. Using a program known as Greenlight Guru, we were able to manage our deliverables and focus on our design controls. In maintaining well-documented engineering design notebooks, we were able to keep record of our progress and conveniently access our previous work in order to help facilitate reiteration throughout our design process. In the medical device industry, these skills are extremely important since companies must maintain comprehensive design history files in order to make intellectual property claims and thus being the product to market.

Since our project was limited to a year, we were forced to devise and analyze many different approaches to our problem in a short period of time. Through sessions of divergent and convergent thinking, we were able to envision a multitude of potential solutions and filter those potential solution based on their practicality. Embracing the “quick kill” concept, we learned to analyze all the ways a particular solution may fail and how to avoid such failures by either altering the approach to certain solution or adopting a new solution all together. Additionally, gaining experience in the process of rapid prototyping allowed us to go through many iterations of possible solutions and evaluate the parameters that were important to the task at hand so that they may be optimized in future designs. Through prototyping and testing, we were able to develop numerous skills important to the design process such as 3D modeling, static/mechanical analysis, experimental design, and data collection. All of these skills are extremely important to providing proof of concept and design validation so that a particular device may be approved for its prospective use.

Through actively engaging ourselves in the design process and developing a project from start to finish, we have gained knowledge and skills that will prove to be indispensable in our future endeavors. Over the course of this project we have developed both professionally and personally while striving to develop a viable solution for an unmet medical need. By pursuing innovation through enlightened empathy, we hope to make an positive impact on those affected by these disparities. Once again we are PediaPack Devices, and by providing pediatric patients the opportunity for neurological surgery through proper head stabilization, we hope to help mend the minds of tomorrow.

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