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Pediatric Neurosurgical Head Fixation Device

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Pediatric Neurosurgical Head Fixation Device

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Abstract

Head fixation is required for most neurosurgical procedures. In neurosurgery, the current gold standard devices are the three-pin skull clamp and horseshoe headrest. However, these devices can cause pressure-related complications when used on young pediatric patients. The purpose of this project was to design a novel head fixation device that is safe for children under 5 years old and reduces potential complications such as skin necrosis and pressure sores. A combined two-pin skull clamp and actuated headrest was developed. The pins feature polyurethane foam cushion on the base to prevent depressed skull fracture. The headrest features three contoured polyurethane foam pads arranged in a horseshoe-like shape with the forehead pad actuated by a cam-follower mechanism to redistribute pressure and allow capillaries in the forehead to open and restore the blood flow. Testing with force sensors showed a baby mannequin head on actuated polyurethane foam pad could experience lower and more dynamic pressure (between 52.9±14.5 and 98.2±18.5 mmHg) compared to on static headrest (77.1±11.8 mmHg). Stability testing showed minimal movement of head (1.48 mm) while actuation was in action; therefore, head fixation was stable enough for most procedures. Based on preliminary results, this device has the potential to be the first neurosurgical head fixation device that can safely be used on young children.

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Authorship

Both team members equally participated in the writing of this paper.

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1. Introduction

The central nervous system dictates major functions inside the human body including homeostasis, emotion, movement, speech and thought. A major organ in the central nervous system is the brain. In the first phase of life, the brain plays a major role in the growth of the infant. However, this organ may be subjected to diseases and injuries such as hydrocephalus, tumors, and birth or trauma injuries. Most neurosurgery procedures performed to fix these problems require rigid fixation of the head. Head fixation device becomes one the most important medical device in neurosurgery. Stable head fixation allows the neurosurgeon to operate properly on the patient.

For general head fixation, there are two commonly used methods; pin fixation and horseshoe headrests. The gold standard for head fixation in neurosurgery is the Mayfield® three-pin skull clamp where 96% of surgeons use this device [1]. This device utilizes three pins to fixate the head; these pins are arranged in a triangular arrangement where one pin is on one side and two more pins on the opposite side. These pins penetrate the skin and then partially into the skull to stabilize the head. The other method used for head fixation is the horseshoe headrest which is a U-shaped frame with gel pads for the patient's head to rest on during surgery.

In pediatric neurosurgery, several complications occur by using the pin fixation and the horseshoe headrest. For children under five years old, the skull is not yet fully calcified and therefore it is softer and more fragile compared to the adult skull [2]. For this reason, pin fixation induces a high risk of skull fracture, skull depression, hematoma and other complications. The horseshoe headrest is the more recommended head fixation method for children especially those under two years old. However, in long surgical procedures, prolonged contact and pressure with the headrest may cause skin necrosis and pressure sores [3]. This occurs because pressure on areas, especially the forehead, for long periods of time prevents proper blood circulation and oxygen supply to the area. Also compared to the pin

fixation method, the horseshoe headrest does not provide adequate stability for certain surgical procedures. Although these methods are both used today, surgeons desire a more secure and stable head fixation device. Especially a device of which the surface could reduce the interface pressure below 32 mmHg is desired [4].

The goal of our project was to review current technology and design a novel head fixation device for pediatric neurosurgery specifically for children between birth and 5 years old. The device needs to provide adequate stability for use in complicated surgical procedures therefore pins need to be incorporated because they provide the best stability. It also needs to be safe for the patient and prevent complications which means that the materials used need to be biocompatible and the device must require less pressure to stabilize the head. It must be non-intrusive and provide adequate space for the surgeon to perform surgical procedures. Lastly it needs to be intuitive and easy to use to be widely adopted.

A modified device combining the pin and headrest fixation methods was developed. Pin fixation component are comprised of two pediatric pins on the lateral axis of the skull. The pediatric pins feature two layers of cushioning on the metal surface to prevent skull depression. The headrest component is comprised of three contoured polyurethane foam organized in a horseshoe-like shape. The forehead is actuated by cam-follower mechanism to redistribute the pressure and allow the capillaries on the forehead to open and restore the blood flow.

Interface pressure on the forehead was tested with Tekscan® force sensors to evaluate risks of skin necrosis and pressure sores. The tests were also performed, together with stress relaxation tests, to determine the optimal material, between viscoelastic gel and polyurethane foam, for the paddings in this device. With polyurethane foam pads, pressure on the forehead was effectively redistributed over time while actuation was in action and reduced below a safe pressure threshold at which capillaries can

open to restore the blood flow. Stability testing was also conducted with a video-based motion tracking system to determine the amount of movement of the head on the pad during actuation. The maximum displacement of the head was found to be minimal and therefore head stability is good for most neurosurgical procedures.

2. Literature Review

2.1 Clinical Significance

Modern neurosurgical procedures in children has been performed since 1930s [5]. Since then, different biomedical devices and surgical instruments have been developed to better serve the practice of pediatric neurosurgery. In 2008, this market was valued at more than $400 million, with expected annual growth rate of 6.0% [6]. Head fixation device is an important piece of equipment in this category, which is required at all medical centers that perform pediatric neurosurgery. The current technology, however, are not considered entirely safe and optimal by neurosurgeons. A better device that meets safety and functionality criteria is still demanded.

Without an optimal head fixation device for infants, neurosurgeons are still using the adult gold standard devices, such as the Mayfield® three-pin skull clamp, in many cases. According to a survey conducted at the Keck School of Medicine at the University of Southern California, 158 participating neurosurgeons (96%) reported using cranial pin fixation in their pediatric patients. Eighty-nine (54%) of them were aware of complications due to using this device in the past [1]. There have been efforts of modifying the adult devices for infants to fix their disadvantages; however, none of the new designs are widely accepted by neurosurgeons. This opens up opportunity and market space for a better innovation in pediatric neurosurgical head fixation.

2.2 Diseases of the Brain and Neurosurgical Treatments

Neurosurgical procedures are done in newborns and young children to treat brain diseases and injuries. A pediatric head holder device is necessary to support these surgeries. According to Dr. Cataltepe, UMMC neurosurgeon, the most common pathological conditions that require neurosurgical intervention are hydrocephalus, brain tumors and head injuries. Head fixation is essential in all neurosurgeries; however, the required levels of stability differ among surgical procedures.

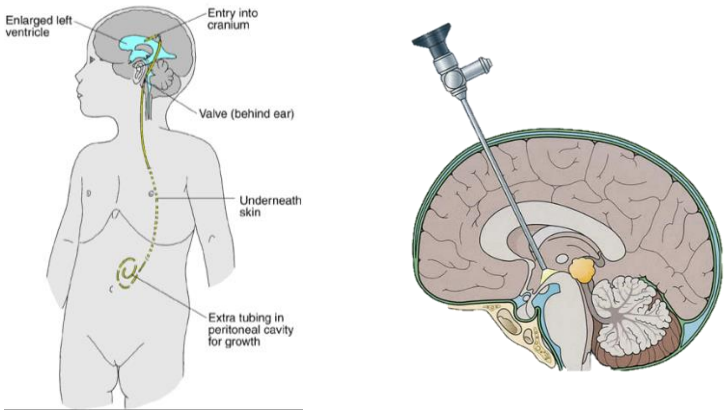
2.2.1 Hydrocephalus

Hydrocephalus is the accumulation of cerebrospinal fluid (CSF) in the brain. It is one of the most common congenital anomalies that affect the nervous system, occurring with an incidence of 3 to 4 per 1,000 live births [7]. It also develops in a variety of other brain diseases and brain injuries where the CSF pathways are obstructed. Every year, around 70,000 neurosurgery cases are performed to treat hydrocephalus in infants in the United States [8].

Cerebrospinal fluid, also known as "the water of the brain", is produced by the choroid plexus, a collection of specialized ependymal cells, inside the ventricles. Flowing through the ventricles, subarachnoid space and the central canal of the spinal cord, CSF serves as a liquid cushion and a shock absorber to protect the brain from trauma. CSF is produced by the ventricles and drained into the veins at a constant rate [9]. The mean circulating volume of CSF in the neonate is 50 mL, compared with 150 mL in the adult [10]. The pressure of CSF determines an important neurological health sign called the intracranial pressure (ICP). The normal ICP values range between 3 and 4 mmHg between birth and one year of age, and 5 and 10 mmHg in young children [11]. If something (such as a congenital malformation or a tumor) obstructs the circulation or drainage, CSF build ups and exerts pressure on the brain. Sustained increased ICP can cause severe neurological damage to infants.

Hydrocephalus cannot be treated by medications and therefore, the most practical treatment is by surgery. Surgery is recommended as soon as the baby is medically stable, including newborns. There are two neurosurgical options: shunt placement and third ventriculostomy. In the most common shunt placement procedure called ventriculoperitoneal (VP) shunt placement, the neurosurgeon makes a small incision on the frontal or occipital areas of the head and another in the belly. A shunt is inserted into the ventricle to drain the excess CSF from the brain into the peritoneal cavity. In third ventriculostomy, the neurosurgeon makes a small incision on the lateral frontal area of the head and use an endoscope to create a bypass for CSF drainage between the third ventricle and the interpeduncular cistern (the cavity

between the two temporal lobes) [7]. Both procedures are usually performed in less than 2 hours under general anesthesia. Because they are not very complicated, only moderate stability of the infant head is needed.



A B

Figure 1. Neurosurgical treatments of hydrocephalus: A) shunt placement and B) third ventriculostomy [12] [13]

2.2.2 Brain Tumors

Brain tumors are the second most common cancer occurring in infants after leukemia. The incidence of brain tumors is nearly 2.1 per 100,000 children. About 60% of brain tumors in children are located in the infratentorial compartment, as compared with adult brain tumors, which are primarily located in the supratentorial compartment.

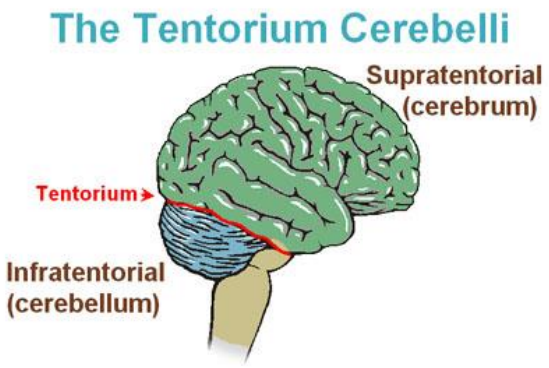


Figure 2. 60% of brain tumors in children are located infratentorially and 40% are located supratentorially [14]

Treatment options for brain tumors include radiation therapy, chemotherapy, surgery or a combination of therapies and surgery. Surgery is very frequently first step of the treatment for brain tumors. Radiation therapy and chemotherapy are other options which might be considered depending on the pathology, extent of the disease and patient's age. For a lot of young infants, surgery is the most practical option. There are two neurosurgical approaches: resection and lobectomy. Resection is performed to remove tumors and lesions when they are accessible for surgery. Surgeries are performed with microscope and patients are under general anesthesia. Because they are the most complicated surgeries and can take up to 8 hours, stability of the infant head is very important.

2.2.3 Head Injuries

Infant brain is especially prone to injury in the first five years of life as the protecting skull is not fully calcified and fragile. In fact, head trauma is the third leading cause of death in infants less than 1 year old, and the leading cause of death in infants over 1 year old. The incidence of head injury in infants between birth and 4 years of age is 150 per 100,000 population [7]. Causes of head injuries include birth injuries, falls, accidents and child abuse.

The most common operative head injuries are skull fracture, hematoma and intracerebral hemorrhage. For minor skull fractures, the skull is able to heal and close the fractures over time. However, operative intervention for skull fractures is necessary for the following cases: the fracture is depressed more than 1 cm, it is located near the sutures, bone is broken into multiple pieces, or the fracture overlies vascular channels [7]. Operations are also performed to fix hematoma and intracerebral hemorrhage especially if there are substantial clots and development of hydrocephalus. For these neurosurgeries, the required stability of infant head varies from moderate to high importance depending on the severity of trauma and surgical procedure.

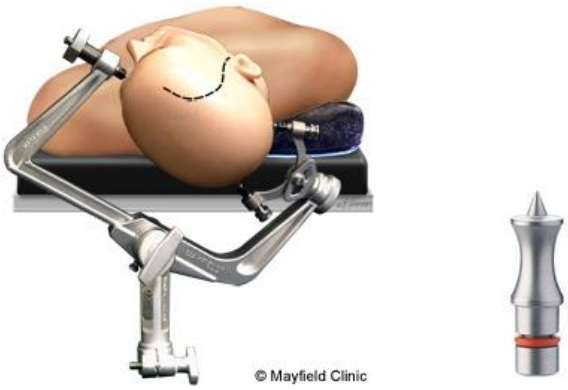
2.3 Current Technology and Their Limitations

2.3.1 Pin Skull Clamps

The current gold standard for head fixation in neurosurgery is the Mayfield® skull clamp. It is comprised of a mounting device, an arm, a clamp and three skull pins. The mounting device which is typically made of stainless steel attaches to the table and connects with the arm. The arm has a few joints to give the device a high degree of freedom. It is typically made of a glass-infused PEEK composite which is light (low density) and strong, and its joints are typically made from powder-coated anodized aluminum. The clamp is attached to the arm and is also typically made of glass-infused PEEK composite. It can be rotated at the base to allow the head to be positioned and holds three skull pins in place. The skull pins which are made of titanium or stainless steel hold the head in place and are fixed to the clamp. These pins pierce partway into the skull to make sure they are held in place. The amounts of pressure pins exert on the skull are measured by spring loaded pressure gauges which are located at the pin insertion points.

The major problem with this device is the fact that it is not suitable for young children which have much more fragile skulls. Skull penetration and depression are common when this device is used

in younger children. There are specialized pins with a flat surface made of rigid plastic or metal at the base of pin to prevent skull penetration. However, these pins can cause skull depression when the hard base is pressed against the skull [3].



A B

Figure 3. A) Pin fixation [15] and B) DORO® pediatric skull pin [16]

2.3.2 Horseshoe Head Holders

Another commonly used technology for head fixation is the horseshoe head holder. This device has the patient's head rested in between the legs of a padded horseshoe shaped device. Also the forehead can either contact the base of the "U" or be exposed to the open surface depending on the need. The pads are typically made of gels such as viscoelastic polymer Akton® [17].

The major problems with this device is its stability. It does not provide nearly as much stability as the pin head holder and therefore is not appropriate for surgeries which require absolute stability such as those which use microscopes. It is more commonly used for the surgeries where the stability is not extremely critical such as hydrocephalus treatment [6]. However, during long surgeries, prolonged contact with the device, lack of oxygen to the skin, and constant pressure can cause skin necrosis or pressure sores which are discussed later.

Figure 4. DORO® horseshoe head holder [16]

2.3.3 Combined Head Holder Devices

There are other devices that aim to solve the problems of the previous two devices. One of them is the "multi-purpose" head holder which holds the head using several gel pads as shown in figure 5. It also has interchangeable parts; the pads can be exchanged for different shaped ones or pins can be put in place of the side gel pads [18]. According to our client, Dr. Cataltepe, this device is too intrusive to be used and gets in the way of surgical procedures. In addition, these devices can cause skin necrosis and pressure sores on its multiple contact areas.

Figure 5. DORO® multi-purpose head holder [18]

2.4 Patient Head Positioning and Fixation

Positioning of the patient is a critical step in neurosurgical care, and it begins with fixation of the head. Appropriate head positioning helps the neurosurgeon perform an effective operation and prevents serious complications. As infant head is delicate and prone to prolonged pressures, the ideal positioning involves balancing surgical comfort against the risks related to the desired intraoperative position, particularly during long procedures [19]. There are 3 fundamental positions in neurosurgery: supine, lateral and prone.

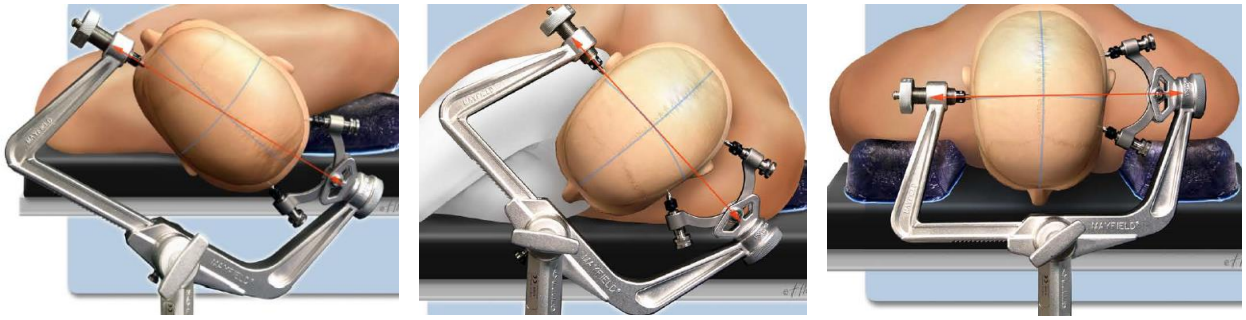


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Figure 6. Three standard patient positioning: A) supine, B) lateral, and C) prone [20]

- Supine position: this position is the most frequently utilized position in neurosurgery. The head can be neutral straight or slightly turned. This position allows access to the frontal, parietal and temporal lobes.
- Lateral oblique position: this position is used for surgical approach in the temporal lobe, skull base and posterior fossa (near the brainstem and cerebellum).
- Prone position: the head is placed neutral downward. This position is commonly utilized for approaches to the occipital and suboccipital regions.

Among the three standard head positions, supine position is the simplest positioning and easily achievable with any current head fixation devices. On the other hand, prone position is the most

difficult positioning and compatible with fewer devices. It is also associated with more challenges in securing lines and maintaining adequate ventilation, as well as increased risk of complications due to prolonged pressure on the face and eye area [19]. No position is ideally safe for pin fixation as fontanelles and sutures are located around the skull.

Once the fixation position is determined, antiseptic solution is applied on the surgical site as well as pin fixation site, if pin head holder is used, to prevent surgical site infection. The pins are recommended to be placed within the sweatband area, as seen in Figure 7.

Figure 7. "Sweatband" area for pin positioning [21]

The pins should also avoid to be placed on muscle areas to prevent slippage and on fontanelles and sutures to prevent penetration. The two pins in the dual pin rocker should be equidistant from the centerline to achieve optimal stability. When the pins are aligned to the desired position, the arms are squeezed together by sliding the ratchet gear until the pins contact with the skull. The pins are screwed into the skull by tightening the knobs, starting with the single pin and then the dual pins. In most of current pin fixation devices, the knobs are equipped with spring loaded force gauges to indicate the amount of applied forces. The total amount of applied forces on three pins should comply with the following suggested guidelines [1]:

- Children under 2 years old: use pin fixation with extreme caution and consider non-pin fixation methods
- Children between 2 and 3 years old: apply 10 to 20 lbs of force
- Children between 3 and 4 years old: apply 21 to 30 lbs of force
- Children between 4 and 5 years old: apply 21 to 40 lbs of force

2.5 Anatomy of the Infant Brain

One of the most vital organs in the body, the brain, is housed inside a bone structure called the skull or cranium. Knowing the anatomy of the skull is critical in designing the device where skull structures need to be taken into consideration for the design. The skull is not uniform throughout and thus have there are several weak spots across that skull which are common sites of injury such as penetration and depression. This structure is formed from several bones (22-30 depending on the source) joined together by ossified joints called sutures [22]. The skull is divided into two areas; the neurocranium or the area that protects the brain and the viscerocranium or the skeletal face [23]. The major bones in the neurocranium are the parietal, occipital, and temporal, sphenoid and ethmoid bones, and the major bones in the viscerocranium are the frontal, zygomatic, maxilla, and mandible bones. Other smaller bones that are on the viscerocranium are the greater wing of the sphenoid bone, and the mastoid. The frontal bone is at the anterior of the skull where the forehead is located. The parietal bones are at the anterolateral sides of the head and form the top of the skull. The occipital bone is located at the posterior of the skull and forms the back of the skull. The temporal bones are located at the lateral sides of the skull along the midline. The zygomatic, maxilla, and mandible bones form the lower face of the skull along with the nasal palatine and lacrimal bones [3]. The major sutures that divide the skull are the coronal suture, sagittal suture, and the lambdoidal suture. The coronal suture is located in the superior anterior region of the head and divides the frontal bone plate with the

two parietal plates (sides). The sagittal suture divides the two parietal bone plates and the lambdoidal suture separates the occipital bone and the two parietal bones [22].

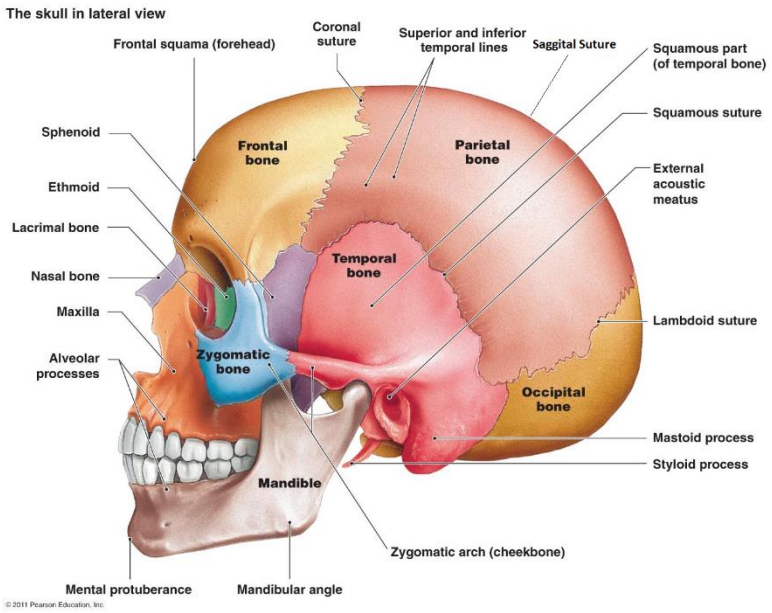

Figure 8. Anatomy of the infant skull [24]

Bone is comprised of three layers: 2 outer layers of cortical bone and an inner layer of cancellous or spongy bone [25]. Cortical bone is harder bone substance that makes up the outer layers of most bones. Cancellous bone has a porous or spongy structure to allow bones have a certain amount of give when experiencing compressive forces.

Bones are comprised primarily of collagen fibers, bone mineral and water. Bone in the living body contains between 10% and 20% water, 60% to 70% minerals, and the remainder is collagen. The majority of the mineral substance is hydroxyapatite ($Ca_{10}(PO_4)_6(OH)_2$) in small crystal structures. These minerals provide the bone with its stiffness to allow it to sustain compressive stress. Collagen is a triple helix protein which is the nucleation site for the mineral crystals. Collagen provides the bone with elastic properties making it not completely brittle and reduces the risk of failure [26].

2.6 Development of the Infant Skull

Many of the issues involving the skull pin head fixation are due to the membranous areas of the skull which are not yet calcified. The plates on the skull are formed through ossification of a membranous tissue that surrounds the developing brain. The neurocranium is primarily formed from intramembranous ossification, while the viscerocranium is formed primarily from endochondral ossification [23].

Intramembranous ossification primarily involves the formation of spicules or thin needle-like structures. These spicules radiate from a primary ossification center in the membranous tissue towards the surface. Eventually the spicules fuse with one another to form a network, cells trapped in the network differentiate into osteoblasts and secrete bone to form the bone network or trabeculae. Finally the spicules near the surface become surrounded by compact mesenchymal cells and form the periosteum [27].

Endochondral ossification begins when the mesenchymal cells in the membranous tissue surrounding the skull differentiate into chondrocytes and form a cartilage model of the bone. The chondrocytes in the center of the bone die and forms a hollow region for vascularization by blood vessels. These blood vessels recruit osteoblasts which deposit the bone matrix [27].

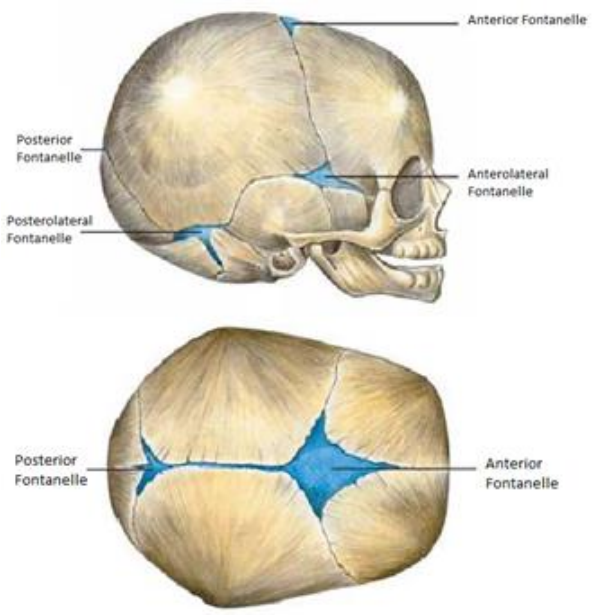

Figure 9. Fontonelles in a newborn skull [28]

When the infant is born, the skull is not yet fully calcified. There are large uncalcified areas called fontonelles, and the joints or sutures between each bone plate have also not been fully calcified. This allows the developing infant brain to grow in size, and it also facilitates birth. The sutures do not fully close until adulthood but the fontonelles close during the early stages of life. There are six major fontonelles in a newborn child. The first to close is the posterior fontonelle located between the occipital bone and the two parietal bones, this fontonelle closes between 2-3 months after birth. There are two anterolateral fontonelles located at an interface between the occipital, parietal and temporal bones. This fontonelle closes by 6 months after birth. The next set of fontonelles to close are the posterolateral fontonelles located at the interface between the frontal, parietal, temporal and sphenoid bones. These two fontonelles close between 6-18 months after birth. The last fontanelle to close is the anterior fontanelle located at the interface between the two parietal bones and the frontal bone, this fontonelle closes between typically between 1-3 years after birth [29].

Generally, after the first year of birth, 38% of fontonelles are closed and by age 2, 96% of the fontonelles are closed. At the latest the fontonelles close completely by age 5 [29]. When a child is born their head diameter is generally around 34 cm in females and 36 cm in males. This increases to 46 cm in females and 47 cm in males by age 1. By age five females generally have a head diameter of 51 cm and males have a head diameter of 52 cm. Their head continues to grow through puberty but the growth per year slows [3].

2.7 Mechanical Properties of the Infant Skull

The mechanical properties of the skull are important in describing the areas that are weak in the skull such as fontanelles and sutures. A recent study at the University of Pennsylvania tested the mechanical properties of cranial bone plates of children of various ages using three-point bending at 2.54 mm/min and 2540 mm/min strain rates. The main bones that were tested in this experiment were the left and right parietal bones of children 1 week after birth and 6 months after birth. The main properties that were tested were the rupture modulus which is the stress on the bone before it yields and the elastic modulus which is a measure of the stiffness of the bone [30].

The study found that the rupture modulus of a left parietal bone is 10.6 MPa and at 6 months is 42.1MPa. Compared to an adult skull which has a rupture modulus of about 85.1 MPa, the infant skull fractures much more easily and thus is more susceptible to injury. The elastic modulus of an infant skull 1 week after birth is about 821 MPa and 2111 MPa 6 months after birth. Compared to the adult skull which has an elastic modulus of 7460 MPa, an infant's skull is much less stiff and more malleable. The study also found that the elastic modulus of a suture in young children is about 200 MPa which is much more elastic than other areas on the skull [30].

The skull is covered by an outer layer of skin which is a viscoelastic and anisotropic material. Viscoelasticity means that the material has a time dependent change where the mechanical properties change over time as the material relaxes. For example, memory foam will relax slowly after an application of an initial force and it recovers. Anisotropy means that the material has differing mechanical properties throughout, for example it can be stiffer at one end and softer at another. The properties are mainly dependent on type I and III collagen which provides much of the mechanical properties of the skin and elastin which gives the skin some elastic properties [31]. Generally, the Young's Modulus of skin is between 4.5-8 kPa making it an extremely elastic material. Also the skin thickness is about 1.5 mm in children, compared with 2 mm in adults [32].

2.8 Complications Related to Head Fixation

The use of current head fixation devices in pediatric neurosurgery such as pin skull clamp and horseshoe headrest have been reported with several complications. The most common complications are pressure-related, including skull penetration and skull depression caused by pin fixation and skin necrosis and pressure sores by the headrest. An understanding of the causes of these complications is necessary to come up with preventive solutions for the new device.

2.8.1 Skull Depression

Depressed skull fracture occurs in 0.65-1.1% of all neurosurgical procedures that require the use of a three-pin head holder and is further increased in pediatric patients [33]. As discussed above, the following is a guideline in pressure applications to children under 5 years of age. The total amount of applied forces on three pins should comply with the following standards:

- Children under 2 years old: use pin fixation with extreme caution and consider non-pin fixation methods
- Children between 2 and 3 years old: apply 10 to 20 lbs of force

- Children between 3 and 4 years old: apply 21 to 30 lbs of force
- Children between 4 and 5 years old: apply 21 to 40 lbs of force

However, use of the three-pin head holder on pediatric patients is still not recommended and other methods are suggested to be used if allowed, such as the horseshoe head rest. The following image depicts CT scans of a 2-year-10-month-old female child after surgery with a right temporal fracture and minimal epidural hematoma. The CT scan shows a fracture on the bottom left of the skull which translates to the right middle area of the skull near the ears. Epidural hematoma is the accumulation of blood in the inner skull and the dural membrane [34].

Generally minor skull penetrations and skull depressions are not treated and the wounds can heal themselves over time. Younger children are kept in the hospital for observation. More serious skull depressions such as those that exceed 5mm below the adjacent bone require surgical operations. These depressions are elevated through craniotomy and later cranioplasty [34]. There are also some preventative measures that are suggested in the articles. Use of lower pressures depending on age is suggested and avoiding the use of pin fixation is not recommended below the age of 5. Also using a plaster of Paris which is a mold ring around the forehead area is suggested so the pins penetrate the plaster rather than the skull [33].

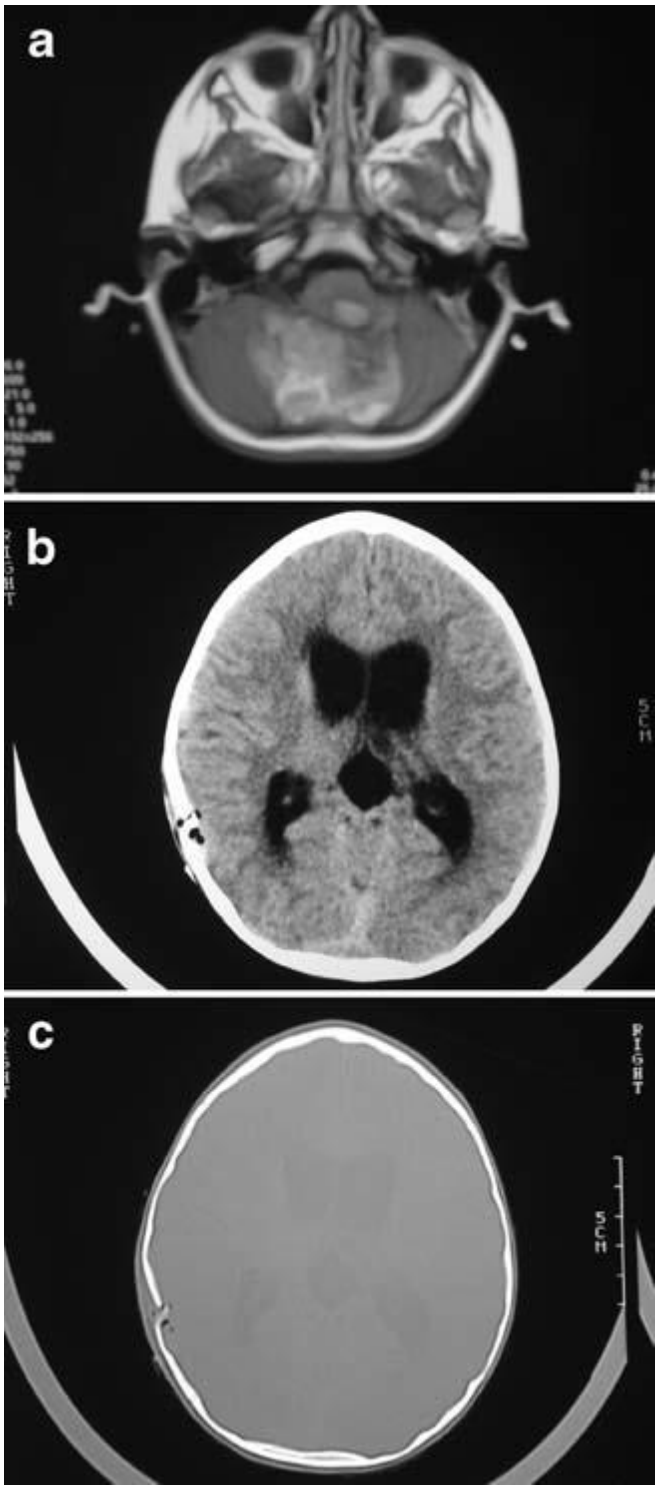

Figure 10. Post-operative CT scans of the head which shows a right temporal fracture a. Pre-operative MRI scan b. CT scan of the head c. Bone window CT scan [35]

2.8.2 Skin Necrosis and Pressure Sores

Complications that result in the death of the skin tissue is called skin necrosis, pressure sores or pressure ulcers. Extrinsic factors that can cause these complications include pressure, shear force and friction. This type of complications tend to develop on bony prominences and on areas of the body that have little body fat to support the skin surface. The fat serves as a natural cushioning to protect tissues from impact and friction. The forehead with large frontal bone and little fat is an example of site where skin necrosis and pressure sores typically develop after surgery due to prolonged contact with the headrest in the prone position.

Skin necrosis starts to develop when unrelieved pressure from the weight of the body part causes compression and distortion of tissue between the bone and the hard supporting surface [36]. The blood vessels in the capillary bed are compressed from the normal pressures, which are 32 mmHg in the arteriole ends and 11 mmHg in the venule ends. When compressed, blood cannot circulate properly causing a lack of oxygen and nutrients to the tissue cells. In addition, the lymphatic system cannot function properly to remove waste products. Researches have demonstrated that the pressure at 12.5 mm below the skin surface is 3 to 5 times greater than the interface pressure. The tissue die from the deeper layer upward to the surface, explaining signs of tissue damage are not visible until after the surgery. Pressure sores can develop within 2-6 hours. A study conducted on animal models has shown that applying interface pressure above 70 mmHg for 2 hours results in irreversible tissue damage [37]. The amount of interface pressure and the duration of pressure are both important factors to consider in order to control the complication.

Skin necrosis accelerates when additional impact such as shear and friction apply further stress on the superficial tissue that is already under pressure from the weight of the body part [36]. These impacts lead to further distortion of the tissue and cause blood vessels in the capillary bed to break. Influx of blood to the surrounding tissue, followed by the stagnation of blood finally causes the death of

tissue. Skin necrosis due to shear and friction is typically more severe compared to that caused by pressure solely.

Skin necrosis and pressure sores occur mostly to the forehead of pediatric patients, whereas those developing in the occiput (back of the head) are less visible. According to Dr. Cataltepe, these complications typically occur when surgeries last more than 5 hours with the current horseshoe headrest being used to fixate the head. The estimated cost of treatment is between $500 and $40,000 per pressure ulcer, depending on the severity [37]. There are four stages of pressure ulcer, as established by the National Pressure Ulcer Advisory Panel [38].

- Stage 1: Observable pressure-related alteration of an area of skin whose indicators, as compared with adjacent tissue, may include one or more of the following: skin temperature (warm or coolness), tissue consistency (firm or soft) and sensations (pain, itching). The ulcer appears red on lightly pigmented skin.
- Stage 2: Partial-thickness loss of epidermis or dermis, or both. The ulcer is dry shallow open with a red pink wound bed without slough or bruising.
- Stage 3: Full-thickness loss of subcutaneous tissue, which may extend down to but not through underlying fascia. The ulcer appears as a deep crater.
- Stage 4: Full-thickness skin loss with extensive necrosis to exposed bone, tendon or muscle.

Skin necrosis and pressure sores are not only aesthetic problem but also associated with pain and infection-related complications. Bacteria entering through the ulcers and broken skin can infect the bloodstream causing sepsis, infect the skin and connective tissue causing cellulitis, or infect bones and joints causing osteomyelitis and septic arthritis [39]. Treatment of pressure sores is not only expensive but also extends the hospitalization time. Stage I and II pressure sores takes from several weeks to

months with conservative care of the wound to heal. Stage III and IV pressure sores are more difficult to treat and may require surgery.

3. Project Strategy

3.1 Initial Client Statement

There is a need for a new headrest specifically designed for infants and young children to provide a safe and very stable head position during surgery. The goal of the project is to review current technology and come up with a new design idea for a pediatric head holder that will provide safer and very stable head position during neurosurgical procedures.

3.2 Design Goals

The design of the pediatric neurosurgical head holder has several goals to be achieved for the patient and the surgeon. The main goal is to create a head fixation device that can securely hold the head of a child between 0 and 5 years stable during neurosurgical procedures while limiting complications. Dr. Cataltepe would ideally like a device that can fixate the head to be as stable or nearly as stable as the pin head holders while reducing the risk of skull fracture and skull depression. Along with that, the surgeon would require adequate space for operation and thus the device must be non-intrusive to the surgeon's operating area.

3.3 Revised Client Statement

There are large uncalcified areas in an infant skull making it much more fragile than an adult skull. Due to this fragility, much of the devices for neurosurgical head fixation in adults are not suitable for pediatric patients. Therefore, there is a need for a new head fixation device designed specifically for young children between birth and 5 years old. The goal of the project is to review current technology and create a new device that is safe for the patient, easy to use and set up, stable enough for long surgeries especially those that require microscopes, and non-intrusive to the surgeons who are operating.

3.4 Objectives

There are 4 primary objectives and 4 secondary objectives that are aimed to achieve in this device. They were ranked using a pairwise comparison chart, which is included in Appendix D. The pairwise comparison chart reflects the order of importance of objectives based on the client and design team's consensus.

The following objectives are ranked starting with most important:

I. Primary objectives:

1. **Hold the head in stable positions:** The device needs to provide stable support for the infant head in different positions. During surgery, the motion of the head must be minimized, and the device must not require periodic adjustment or re-fixation. Stability is the most important objective, as the function of the head holder device is to support the head and enable the surgeon to operate safely on the patient.
2. **Safe for use in children:** The device provides safe support for the infant head without causing any serious complications especially during long surgical procedures. Serious complications that the device must avoid are skull fracture and skull depression related to using pins, and skin necrosis and pressure sores related to using pads. In addition, the device must be sterilizable and does not cause infection. Safety is considered as the second most important objective as complications will affect the outcome of the surgery or require further surgery to correct them.
3. **Non-intrusive to surgeons:** The device should not obstruct the surgical site or restrict the surgeon's maneuvers. This is important as the surgeon needs to feel comfortable with the device and is able to perform surgery normally. Restricted view or movement might result in surgical mistakes, which needs to be avoided.

4. **Easy to use:** The device can be set up easily and quickly especially for emergency cases. It should not require special training to use and can be prepared by nurses, anesthesiologists and surgeons. This is essential for the device to be used most effectively and properly and suitable for different circumstances.

II. Secondary objectives:

1. **Marketable:** The device should be innovative and contains features that are different from current technology in the market. It should be compatible with standard equipment in the operating room (OR), such as the operating table or the head holder mounting device. In addition, it should be cost effective to be widely accepted and adopted by most medical centers in the U.S. These characteristics are desired to increase the competitiveness and popularity of the device.
2. **Mostly reusable:** The device or primary components of the device can be reusable so that it is more cost-effective and does not require frequent replacement. Hospitals would be more likely to adopt a heavily used device that does not require a large inventory or constant restocking.
3. **Suitable for use in both infants and adults:** The design of the device can be modified and adopted to be used in adults. The device can be made larger or is able to apply a higher amount of pressure to fixate the adult head. Although not a required objective, upgradability will make the device available to a larger market.
4. **MRI-compatible:** A few number of neurosurgical procedures require intraoperative image-guiding systems, such as MRI in stereotactic surgery. The device needs to be made of non-ferrous materials and be radiolucent in order to be used in these procedures and avoid interfering with those systems. However, this is not a considerable need and there are already specialized devices for these types of surgery. On the other hand, if MRI-compatibility is achieved, the device can be made multi-functional for use in different surgical procedures.

3.5 Design Requirements

In order to achieve aforementioned functional requirements and objectives, the device must meet certain design requirements. These requirements are categorized into physical characteristics, performance, and user requirements. There are specifications in each requirement that need to be considered during the design process.

Table 1. Design requirements and specifications

Design requirements	**Specifications/ metrics**
Physical characteristics	
• Dimension	The dimension of the device should be optimized to give adequate space for surgery. This includes the operating space, the surgeon's seating space, the assistant and scrub nurse's spaces and the space for the microscope. The dimension of the device is also limited to the dimension of the operating table. For example, most standard operating tables are 22 inches wide, so the width of the skull clamp when fully expanded cannot exceed 22 inches. Also, the fixation screw component that locks the skull clamp into the mounting device should have similar dimension with that of the mounting device. The gel pad headrest might be made different sizes if it is a complete piece, or the headrest needs to be separated into multiple pads to be clampable. The dimension of the headrest is restricted by the diameter of the skull at different ages. However, children that suffer

	from hydrocephalus typically have enlarged heads, and children that are born prematurely have smaller heads. Therefore, the minimum and maximum size of the headrest will support both below normal average newborn and above 5-year-old established skull diameters. Based on the head circumference of children between 0 and 5 year of age, the inner diameter of the headrest is determined to be between 9.5 cm and 17.5 cm (or 3.74 in - 6.90 in) [3].
• Melting point	In order for the device to be sterilizable, especially by autoclaving, materials used to fabricate the device must have melting points above the maximum autoclaving temperature, which is 121^0C. However, as a common practice in surgery, sterile U-drape is used to cover fixtures that are in contact with the patient body. Therefore, the device might not contact directly with the patient except the pins, and this requirement is not a must for the headrest.
• Magnetic property	The device should be made of non-magnetic materials to be MRI-compatible. These materials are typically non-ferrous.
• Absorbency	Absorption of blood and body fluid by the head fixation device should be prevented so that it is more durable, reusable and the mechanical properties are not affected by the fluid contents. Polymer materials that are used for paddings on the base of the pin and the pads of the headrest should be hydrophobic.
• Bio-compatibility	As the skull pin is partially invasive and comes in contact with the skin, bone and blood, the material of the pin should be bio-compatible. It should not induce allergy and inflammation.

	The headrest supports the head and contacts with the skin in a prolonged period. Therefore, the material of the headrest should be bio-compatible and does not cause skin allergy.
Performance	
• Adjustability	In order for the device to support the head in different position, the skull clamp must be adjustable and can be aligned to different angles. This can be done by the incorporation of joints and segments in the design or separating it into multiple pads.
• Accuracy	Applying a safe and adequate amount of pressure with the pins or maintaining a low interface pressure with the headrest is important to prevent pressure-related complications. The variation due to human factor can be reduced by the incorporation of a more precise pressure gauge or pressure sensor.
• Strength	The weight of human head is about 8.1% of the total body weight [40]. Thus, the average weight that the combination of pin head holder and the headrest must support is between 0.5 lbs and 3.5 lbs [41].
User requirements	
• Ease of use	The device should be intuitive to set up, and fixation of the head with the device should require minimal training. One approach is to reduce the number of parts so that the device can be set up quickly and easily.

• Ease of cleaning	In order for the device to be reusable, it should be cleanable and sterilizable. The materials of the pin fixation device and the headrest should have good corrosion resistance to standard disinfectant liquids.

3.6 Constraints

Pressure constraints: Pin fixation cannot exceed a total of 40 lbs of pressure on the skull [3]. This value is the suggested maximum threshold for children between 4 and 5 years old. Headrest cannot continuously exert more than 70 mmHg (1.35 psi) of interface pressure for more than 2 hours [4]. Depending on the patient's conditions, this recommended threshold might be lower.

Positional constraints: The device must be able to hold the patient in at least the supine, lateral and prone positions. These are the fundamental positioning in neurosurgery. However, in this project, the client would like the design team to focus on the prone position where skin necrosis and pressure sores mostly develop to children with current head holder devices.

Stability constraints: The device must stabilize the head and minimize its motion less than ½ inch (~ 12.7 mm). Based on a previous study, a shift in surgical view above this threshold can result in severe inaccuracy to the procedure [42].

Duration constraints: The device must be able to hold the head stable without failing for at least 8 hours during long surgeries.

Biocompatibility: The device must not cause reactions with the skull or the skin when in use for up to 8 hours.

3.7 Standards

There are several standards that detail the requirements of aspects of our device. Below are some of the standards that we will be addressing throughout the project:

ISO 9001 titled “Quality Management Systems” is a system which ensures that products meet the requirements of customers and improve customer satisfaction while also consistently improving the product as well. This standard mainly handles the process by which the products are made and outlines the things that organizations must do in regards to the aspects of the process that affects quality. This standard can serve as a guideline to control the quality of our device. Complying with this standard will make it more likely for FDA approval [43].

ISO 13485:2016 is a standard that outlines the quality management for medical devices and regulatory purposes. The standard outlines the all stages of medical devices including production, research and development, production, storage, distribution, installation if required and servicing. This standard effects all medical devices including this one and would increase the chances of FDA approval if followed [43].

ISO 14001:2015 is titled “Environmental Management Systems” deals with the environmental impact of the processes in creating the device. This standard affects our device in the fabrication of parts and how those processes can affect the environment. Complying with this standard will limit the impact of the device on the environment in terms of fabrication [43].

ISO 11137 is a family of standards that specifies the standards for the minimum amount of sterilization required for health care products. This family of standards outlines the requirements of several sterilization procedures such as ethylene oxide and radiation. This standard affects our device because of the invasive skull pins that penetrate the skin and skull. These pins must be sterilized and

this standard outlines the requirements of sterilization. Complying with this standard will limit the complications that can arise from improper sterilizing of the pins in the device [43].

ISO 10993-1 is a standard that outlines the evaluation and testing of medical devices which takes into account the biocompatibility of materials and how long the materials are in contact with the body. This standard tests biocompatibility aspects such as cytotoxicity, irritation and other aspects that may affect the body. This standard affects our device because the skull pins must be biocompatible with human tissue. Complying with this standard will limit complications that can arise due to biocompatibility [43].

4. Design Process

4.1 Clinical Need

Pediatric neurosurgery procedures have been performed in the U.S. since early 20th century. Since then, thousands of procedures are performed every year to treat different brain diseases, trauma and injuries in children. With the advancement of modern medicine, the age of a child that can safely undergo surgical treatment has decreased, with smallest patients being a few days after birth. These advancements include the introduction of minimally invasive surgical techniques and inventions of new diagnostic devices and highly precise surgical equipment. However, with increasing complexity of the surgery, stabilization of the head, the first and foremost condition for success of an operation, remains an obstacle for pediatric neurosurgeons. Even today, surgeons are left with very few options for a head fixation device that can safely be used on children. The gold standard device, the Mayfield three-pin skull clamp, is still used in children many cases especially those that require high head stability such as microscopic surgeries. The device uses pin fixation and provides superior head stability but imposes significant risk of skull penetration and depression. Less penetrative devices such as the horseshoe headrest, on the other hand, do not provide as much stability and also cause skin necrosis and pressure sores during prolonged procedures. None of the current head fixation devices in the market are considered optimal by the majority of surgeons.

The design of the new pediatric head holder was aimed to address this clinical need to provide neurosurgeons with a safer and more reliable device for use in children from 0 to 5 years old. The device is based on a combination of pin fixation and headrest with modified safe features for each. The advantage of the combination device is strategically designing the two components to supplement each other's strengths while limiting and compensating for each other's weaknesses. The development of the device adhered to the design requirements established by the team and client as explained in section 3.5 to ensure the device would meet the following primary objectives:

- Hold the head in stable positions, with focused application on the supine and prone positions
- Safe for use in infants and does not cause serious complications such as skull penetration and skin necrosis
- Occupy minimum space and be non-intrusive to surgeons
- Easy to set up and use

4.2 Generation of Design Alternatives

Design of a novel device requires background information on all aspects of the need and this device was no different. The initial problem stated that a new pediatric neurosurgical head holder was needed to prevent issues such as skull penetration, pressure sores, and skin necrosis. After extensive research on the variables that cause these problems, several design ideas were created and presented to Dr. Cataltepe for consideration. Most of the initial ideas were deemed not appropriate and more ideas were generated. After more brainstorming, several major ideas were presented to the doctor.

The first major idea to consider was altering the pins in a skull clamp style headrest to have padding to reduce chances of penetration and reduce the pressures on the head overall. The padding would be made of a polyurethane foam to reduce pressures on the head from the base of the pins. These pins would be a modified version of pediatric pins and fit into skull clamp devices currently being used. However, this idea would not solve the issues of skull fracture.

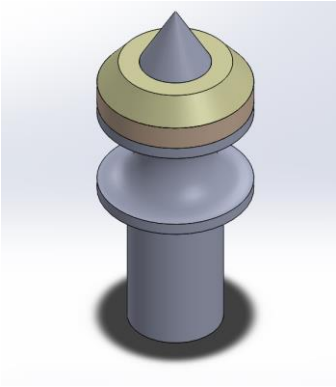

Figure 11. Modified pediatric pin with padding at the base

Another major idea presented was to create a band that wrapped around the head in the sweatband area of the head mentioned earlier. The band would have an area that is connected by two wires meant to cover the surgical site and give the surgeon more room to operate. Pins would then interact with the belt rather than the head itself greatly reducing the risks of skull depressions and skull fracture. However, the surgeon did not like having his surgical site obstructed and thus this idea was not appropriate.

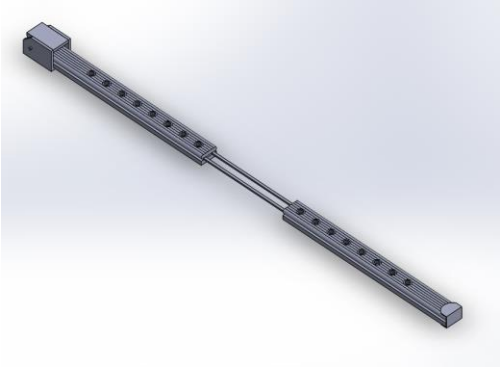

Figure 12. Forehead Belt

A third major idea presented was modifying the horseshoe headrest by adding contours to the padding to avoid the delicate areas in the face such as the eyes and the mouth. The pad was also contoured more closely to a person's face rather than having it in the common horseshoe shape making it more comfortable for the patient. However this idea did not solve the problems of pressure sores or

skin necrosis. The pressures on the face have also increased due to the decreased interface pressure of the face. Lastly the holes create pressure concentration areas which may increase the risks of pressure sores and skin necrosis.

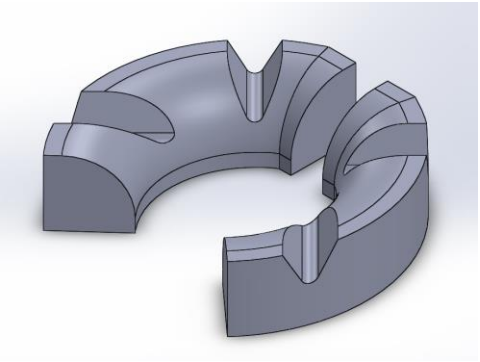

Figure 13. Contoured Headrest

Other ideas were also presented including neck support, increased degree of freedom for the horseshoe head rest, and using padding instead of pins. After discussing these ideas with the doctor and Professor Billiar, it was decided that none of the ideas fully solved any of the issues provided. It was then suggested that the focus should be narrowed down to a common problem. Dr. Cataltepe decided that the most common problem that he ran into was skin necrosis on the forehead when the patient is in the prone position. The project was then refocused to attempt to solve this problem. An actuated headrest was decided to be a proper solution to the problem where the pressure would be shifted from one place to another. Designs of this type of headrest was then constructed. This device also incorporated some components of the previous ideas to improve the device.

The preliminary designs of the headrest looked much like others on the market; however, the main source of innovation involved trying to solve the issues of skin necrosis and pressure sores on the forehead. From reading an influential paper on operating table pressure sores, it was determined that the most important causation factors included pressure from the body weight, in this case it would be the weight of the head, shear forces from deeper tissue rubbing against one another, and friction when

the body is moved on the bed [36]. The areas where bed sores were common were areas where the skin was in direct contact with bony protrusions such as the sacrum. The most important factor in causing pressure sores was determined to be pressure on the head because the head is fixated enough so that shear forces and friction would be negligible and focusing on one problem would lead to greater results. With this information in mind, the focus of the design shifted to being a head holder that could relieve stresses in the forehead.

4.3 Design Alternatives

The design is based on the horseshoe headrest which is a standard in neurosurgical head fixation. It involves three separate pads and optional pins for increased stability. There are two pads on the sides which contact the cheek area and an actuated pad which contacts the forehead. The actuated pad moves up and down to shift the centers of pressure to prevent skin necrosis and pressure sores.

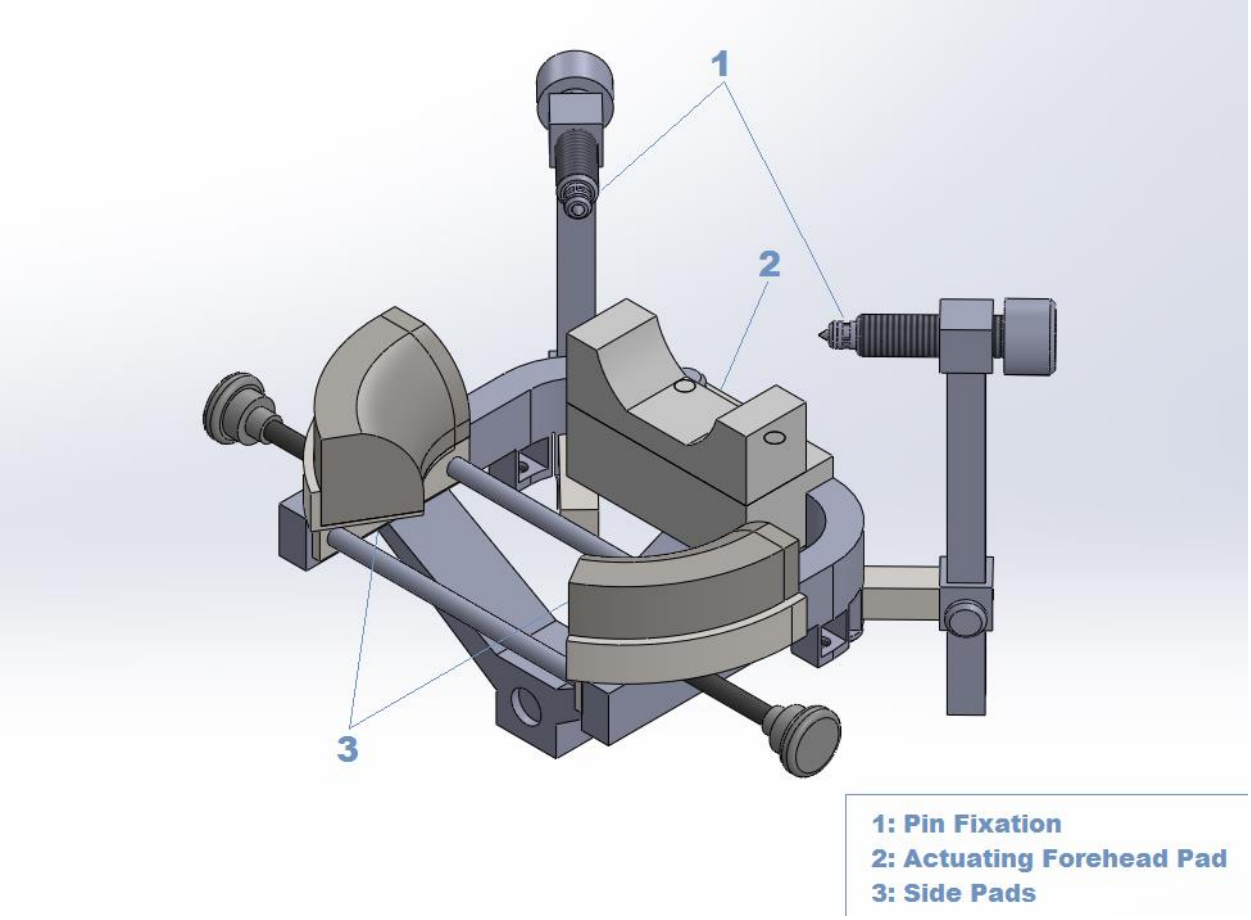

Figure 14. Head fixation full design

4.3.1 Skull Clamp

Detachable skull clamps are provided between each side pad and the center forehead pad with three different locations of attachment. These skull clamps have adjustable heights, can move further or closer to the patient. Skull pins rest at the top of these clamps and are inserted into large screw mechanisms that allow the doctor to tighten the pins onto the skull as needed. The main reasoning to include these skull clamps into the design is to offer surgeons a way to stabilize the head for the surgical procedures that require maximal stability. It also allows the surgeon to reduce the amount of force needed to be exerted by the side pads of the device.

Several mechanisms for the skull clamp was considered before this particular one was decided. The first configuration comprised of three pin to hold the head similar to the Mayfield skull clamp in conjunction with the resting pad. Two pins were decided upon because a third pin was deemed unnecessary as rotation of the head around the pins would not be possible due to the padding.

Figure 15. Three pin configuration [20]

The pin design was also considered, including the size, shape and materials used. An initial idea was to use small pads rather than pins, but was decided that it would not provide enough stability and may be intrusive similar to the “multi-purpose” head holder. Common pediatric pins were used as a model to create the final design of the pins.

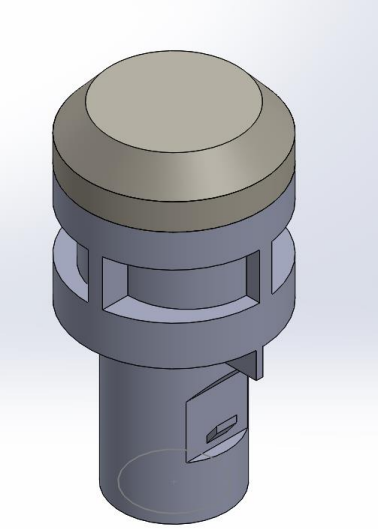

Figure 16. Small padding alternative (in place of pins)

The pins at the ends of the skull clamps are small disposable pediatric sized pins with padding at the base to prevent skull penetration. These pads are also in place to relieve forces that the pins exert on the skull and prevent skull depression. Pins are fixed into the screw mechanism of the clamp by clipping into them. The screw mechanism allows the surgeon to apply more force to the pins as needed. The vertical and horizontal rods are attached and fixated using a screw tightening mechanism where a screw provides a shear load to hold the rods in place.

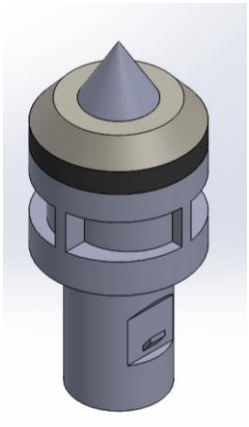

Figure 17. Design on padding fitted on a pediatric skull pin

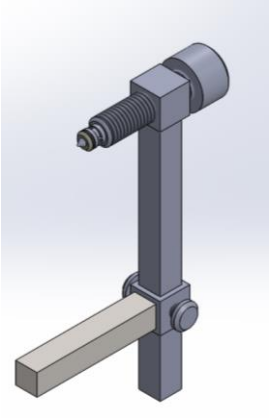

Figure 18. Side skull clamp assembly

4.3.2 Headrest

The design of the head rest is influenced largely by the popular horseshoe shaped headrest which is one of the gold standards in neurosurgical head rest technology. Other current designs were also taken into account such as the donut head rest.

An initial headrest design involved the horseshoe shaped head rest with increased degrees of freedom, where the arms are allowed to move to relieve stresses on the forehead. The arms would have joint in the middle to allow lateral movement and another joint at the base of the "U" to allow the arms to tilt inward. This design, however, was deemed hard to use and lowered the stability of the patient and was thus reconsidered.

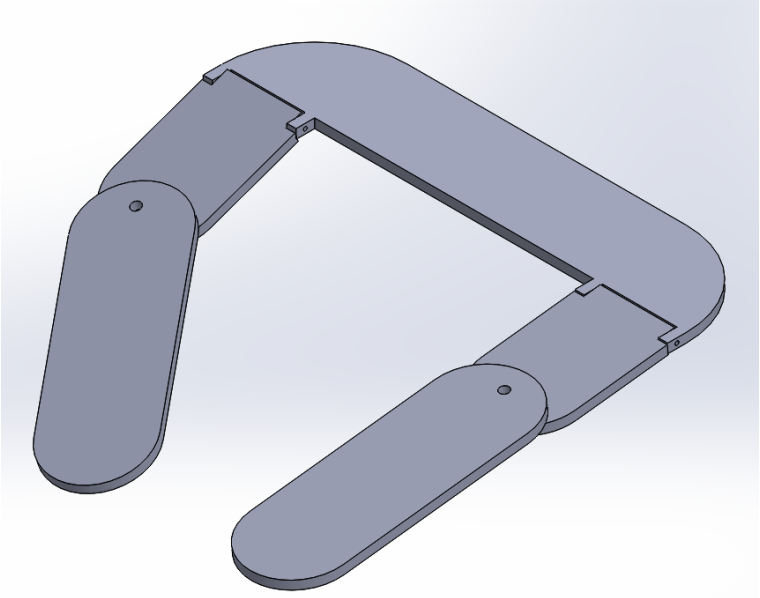

Figure 19. Increased degree of freedom horseshoe headrest base

The final design comprises a horseshoe shaped head rest sectioned into three parts, two side parts and one center part. The two side pads would contact both cheeks on the patient which are areas where pressure sores are less common. These pads would press laterally against the patient's cheeks as well as providing vertical support. A third pad is located in the top middle region or the base of an inverted "U" and contacts the forehead. The center is contoured in a way to give a larger area of contact to the forehead to distribute the stresses as much as possible. Under the center pad will be actuated rods which will move up and down to shift the centers of pressure to give relief to forehead and also massage it to prevent pressure sores.

4.3.3 Actuation Mechanism

The center pad in the headrest needs to be actuated to provide the vertical motion needed to shift the centers of pressure and relieve areas of the forehead momentarily to prevent pressure sores and skin necrosis. Several actuation mechanisms were researched and considered for the design.

The first consideration was to use hydraulics or pneumatics to control the motion where pockets will be filled with fluid or air. However these methods were thought to be harder to control and may

cause sudden shifts in the patient's head which may cause surgical mistakes the surgeon may lose his place. Also these methods would be loud which may disturb the surgeon during their operation.

A second consideration was to use linear actuators to move several sets of rods vertically. Rods would be attached to a bracket and many of them would move at once. However this option was extremely expensive and linear actuators were generally quite large, thus this option was reconsidered.

The third consideration was to use a CAM follower mechanism to actuate 50 rods where rods would move along the face of a spinning object and change heights depending on the varying radii of the CAM. However this required the use of many CAM followers making it quite heavy. Also having many moving parts creates more room for error.

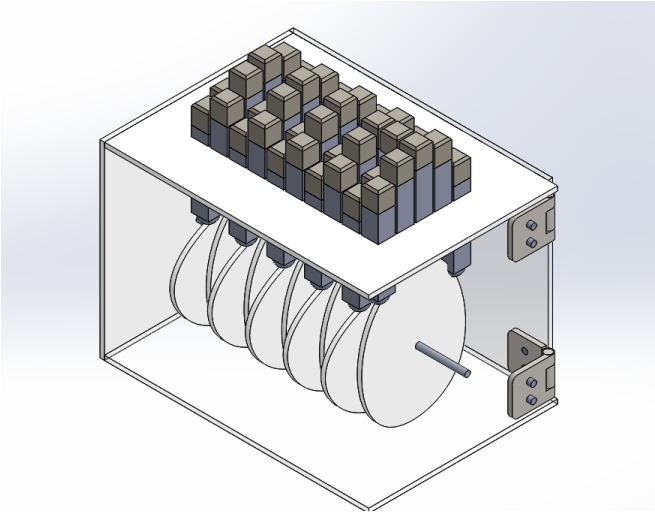

Figure 20. Multiple rods and CAM followers

The fourth actuation mechanism was a modified CAM follower mechanism where the rods would follow a horizontal spinning disk with a contoured surface that changed heights. However the spinning disk had to be quite large to move all of the 40 rods correctly.

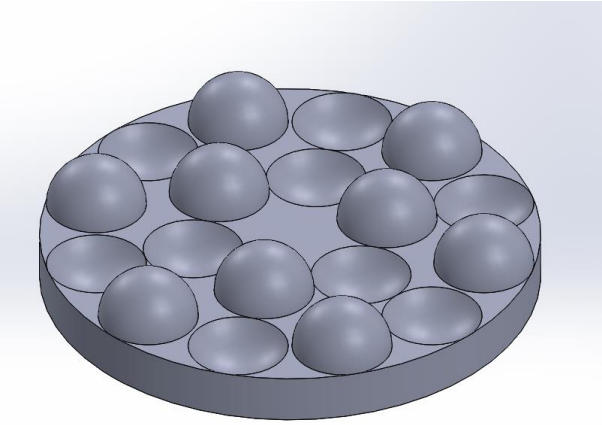

Figure 21. Rotating base

The final design was a modification of the fourth design where three CAM followers were present to move three rods which would then push against the padding. Less amounts of rods are required when pushing against the padding because each rod created a localized area of increased stress and thus didn't need more actuation.

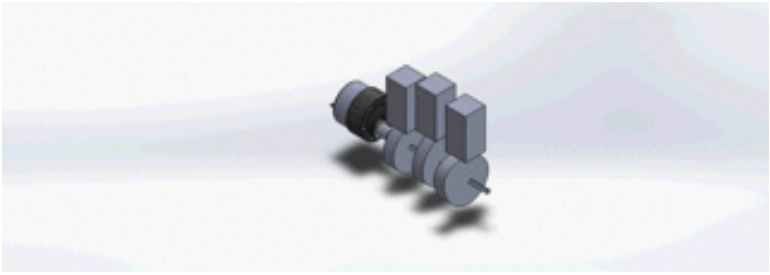

Figure 22. Three CAM followers and rods

4.3.4 Pressure Sensor

The American Guidelines for Pressure Ulcer Prevention established by the U.S. Department of Health and Human Services recommended that at-risk patients be repositioned every 2 or 3 hours during surgery. The widely-accepted safe threshold for interface pressure between the support surface and the patient skin is 70 mmHg (approximately 1.35 psi) [4]. When the interface pressure occurs above 70 mmHg, repositioning should be considered to relieve the pressure and recover obstructed blood flow underneath the skin. However, this threshold pressure does not ensure tissue viability for every

individual. The variability of individual conditions makes it impossible to define a single universal threshold.

In neurosurgery, repositioning is typically not advisable especially in procedures that are performed with microscopes and require high head stability and immobility. Repositioning should not be done unless definitely necessary, for example when an evidence of hyper-pressure on the head is present. For this reason, a pressuring sensing system was developed and embedded in the forehead pad of the headrest where skin necrosis and pressure sores mostly develop to constantly inform the surgeons of interface pressure.

The pressure sensing system is comprised of a Tekscan's FlexiForce A401 force sensor controlled by an Arduino UNO microcontroller board powered by a 9V replaceable battery and connected with an LCD display module powered by a 12V rechargeable battery. FlexiForce A401 is a paper-thin force sensor made of flexible polyester film with sensing area of 25.4 mm (1 inch) and force range of 0-25 lb. It is slipped into the top layer of the forehead pad to measure the interface pressure. The sensor is automatically controlled and processed by an Arduino UNO, and the pressure readings are constantly displayed on the LCD screen. The microcontroller is pre-programmed so that when the pressure reading exceeds a threshold, a warning will be displayed. This threshold is set at 1.06 lb, which is equivalent to 70 mmHg (1.35 psi) of pressure applied on the surface of the sensor and is the recommended pressure threshold. Beyond this limit, a "hyper-pressure" warning will show up. This warning alerts the surgery team and serves as a suggestion for repositioning to prevent the complications.

The circuit of the pressure sensing system is demonstrated in the following diagrams. This circuit was created with the electronic prototyping software Fritzing®. In order to be more compact, the circuit can be fabricated into printed circuit board (PCB).

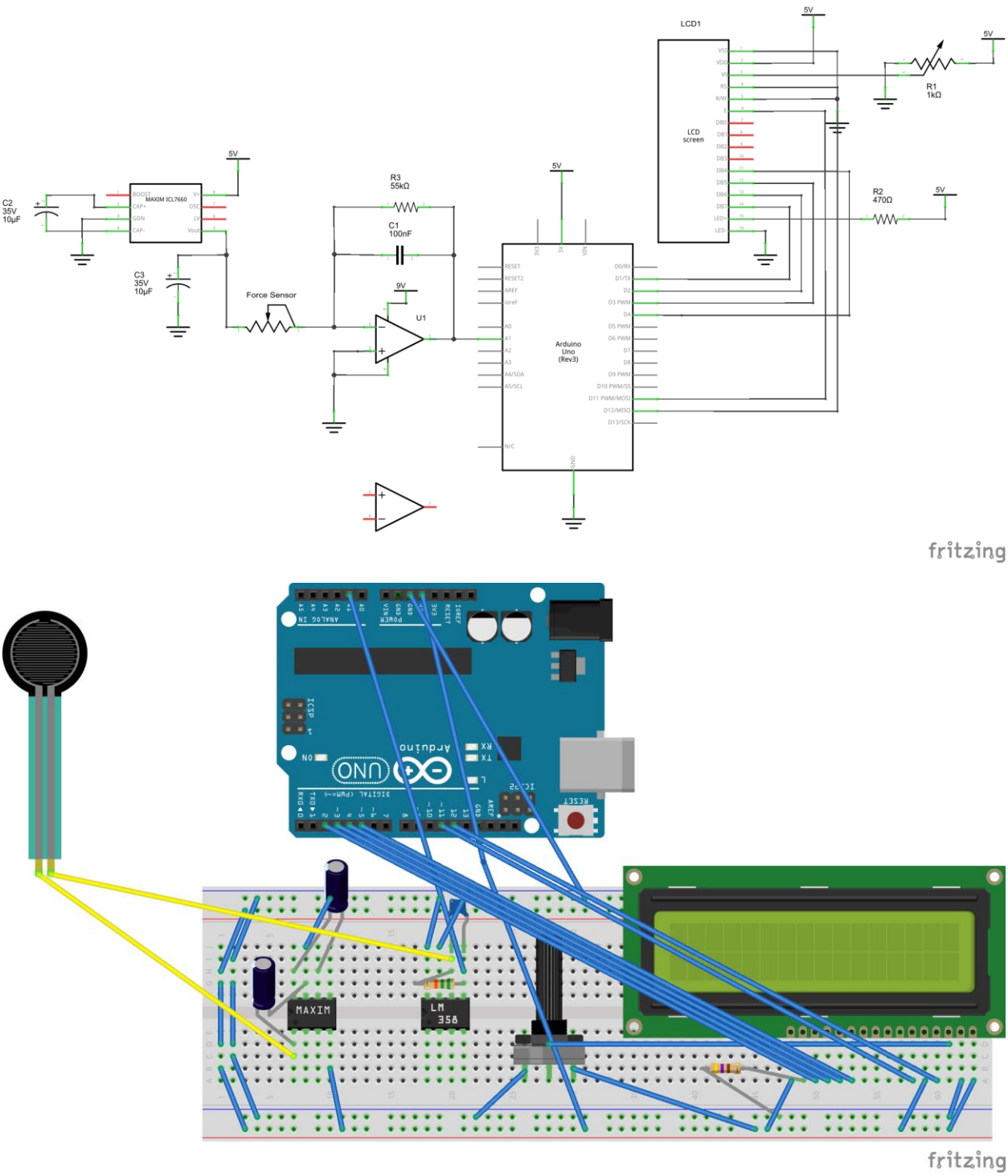

Figure 23. Pressure sensor circuit layout

4.4 Material Selection

The efficacy of this device in reducing complications such as skull depression and skin necrosis depends not only on the design but also on material selection for components that are in contact with

the corresponding body parts. The components of which the materials require special consideration are the paddings on the base of the pin and the pads of the headrest. These two components perform some similar functions such as providing cushioning support, redistributing the pressure and absorbing external stress on the skull and skin. In order to fulfil these functional requirements, the chosen materials need to have suitable surface properties and bulk properties. The most important properties were determined to be density, stiffness and viscoelastic behavior. The ideal materials would have low density, low stiffness, and good stress relaxation response. Selecting a low-density material would reduce the weight of the component and therefore reduce the amount of normal stress that is applied onto the skin and skull. A compliant material would allow the pad to deform, take the shape of the body part and distribute pressure more evenly on its surface. A viscoelastic solid material is preferred as this class of material is recognized as good materials for absorbing shock. Viscoelastic solid material dissipates the energy it absorbs as heat and return to its original shape when the stress is removed [44].

Research was done to determine potential materials for the pin and headrest paddings. Materials that are being used for current head fixation devices, as well as operating table mattress were looked at. Based on literature, product research and examination of material samples, the team came up with two options: viscoelastic gel and polyurethane foam.

Viscoelastic gel is the most common material used in current horseshoe headrests and do-nut headrests. The specific type of gel is kept as a business secret in most companies, including at Integra, the leading manufacturer of head fixation devices. The gel pads were presumed to be made of polyurethane gel, silicone gel or a gel composite based on limited information provided by retail sellers. The gel used in the Integra's MAYFIELD® horseshoe headrest is light but has low compliance and a rough surface by feel. According to the CES EduPack 2015 material database, polyurethane gel has a higher and broader range of glass transition temperature than silicone gel (polydimethylsiloxane), suggesting that silicone gel can be softer than polyurethane gel at room temperature. Polyurethane gel also has a

higher density and elastic modulus, and thus it is slightly heavier and much stiffer than silicone gel. Their properties obtained from the Database are listed in Table 2.

Another commonly used material for both operating table cushioning and horseshoe headrests is polyurethane foam. According to the Database, open-cellular polyurethane foam has a similar range of glass transition temperature to polyurethane gel. However, polyurethane foam has a much lower density, and thus is lighter than the gels at the same size. It also has a lower elastic modulus and is more compliant than the gels.

Table 2. Possible padding materials and their properties [45]

	Glass transition temperature (^{0}C)	Density (kg/m^3)	Elastic modulus (MPa)
Silicone gel	-70 – -60	1.05e3-1.07e3	0.205-0.215
Polyurethane gel	-73 – -23	1.19e3-1.21e3	2.5-30
Polyurethane foam	-73 – -23	60-70	0.02-0.05

Material selection was also based on previous scientific research on materials that prevent can pressure ulcers. In one commonly cited study, cushions made of viscoelastic gel, polyether foam and polyurethane foam were compared for the efficiency in reducing interface pressure in the ischial tuberosities [4]. The study utilized an Ergocheck measurement system, which is a pressure measuring pad with hundreds of small embedded pressure sensors distributed across the testing surface, to determine the interface pressure. The pressures on all parts of the body, including the head, were recorded in different intraoperative positions for at least two hours for each material. The results of this study demonstrated that gel had little or no pressure-reducing effect, while polyether foam and polyurethane foam reduced interface pressure more significantly.

Air and fluid flotation which are utilized in some pressure-relieving mattresses in the market were also considered as more complex options for cushioning materials. However, studies in the past

have shown that they are better than gel but not as effective as foam [46]. Difficulty in designing and maintaining air and fluid flotation systems is also a minus to these options. The mean interface pressures under the ischial tuberosities (IT) reported for the four cushion types are shown below:

Table 3. Mean pressures under the ischial tuberosities (IT) for the four cushion types

Cushion Type	IT pressure from Cochran and Palmieri (1981) study	IT pressures from Souther study (1974)	IT pressures from Mooney et al (1971) study
Foam	67 mmHg	58 mmHg	68 mmHg
Gel	93 mmHg	67 mmHg	80 mmHg
Fluid flotation	71 mmHg	41 mmHg	70 mmHg
Air	79 mmHg	53 mmHg	73 mmHg

Research of material properties and literature both support polyurethane foam possesses the most ideal combination of properties such as low density, high compliance, viscoelastic behaviors and the best pressure-reducing effect. The viscoelastic gel and polyurethane foam were tested in practice to confirm this hypothesis, and the results are reported in Chapter 6.

4.5 Prototype Construction

4.5.1 Aesthetic model

An aesthetic model was created to give users an object to visualize and touch and consider how the final product would act. It also gives them an idea on how the device would be used in their clinical setting. This model was created using high-density fiberboard which was cut using a band-saw into the individual parts that made up the model. Holes were then drilled onto the sides to provide room for the rods that the pads slide on to be placed. These rods were created by cutting large wooden dowels into the correct length. These pieces were assembled together using hot glue and wood screws as necessary. The pieces were then sanded to the correct shape using a Dremel. The platforms that the side pads rest on were created using a laser cutter and then glued together using gorilla glue. Brackets were then made using metal from a robotics kit to attach to the sliding bars. These brackets were then attached to a strip of wood using screws and the platform was then glued to the strip. Padding was then glued to the platforms and the forehead area and sanded to the contoured shape using a Dremel.

Figure 24. Aesthetic model

4.5.1 Working model

A working model was constructed to prototype the design concept and perform testing to validate the proposed design. Specifically, this working model was made for the forehead pad, the area where skin necrosis and pressure sores mostly occur and requires closer examination. The model is made of linkage bars for the frame, and its circuit is comprised of a DC motor, a voltage regulator, an on/off switch and a 12V rechargeable battery (Figure 25). The motor drives the motion of three cam follower linkages. The cams were laser cut from acrylic, and the rod followers were machined from PVC square bars. The cams were aligned differently on the shaft, so that the rod followers would be moved up and down alternately. The voltage regulator controls the speed of the motor by adjusting the output

voltage going through the motor and releasing unused energy as heat. Padding for the forehead headrest would be chosen between viscoelastic gel and polyurethane foam through testing.

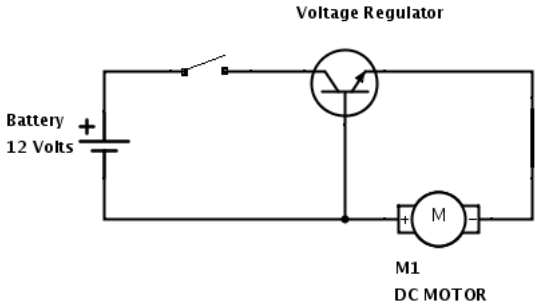

Figure 25. Circuit of the actuation mechanism on the forehead pad prototype

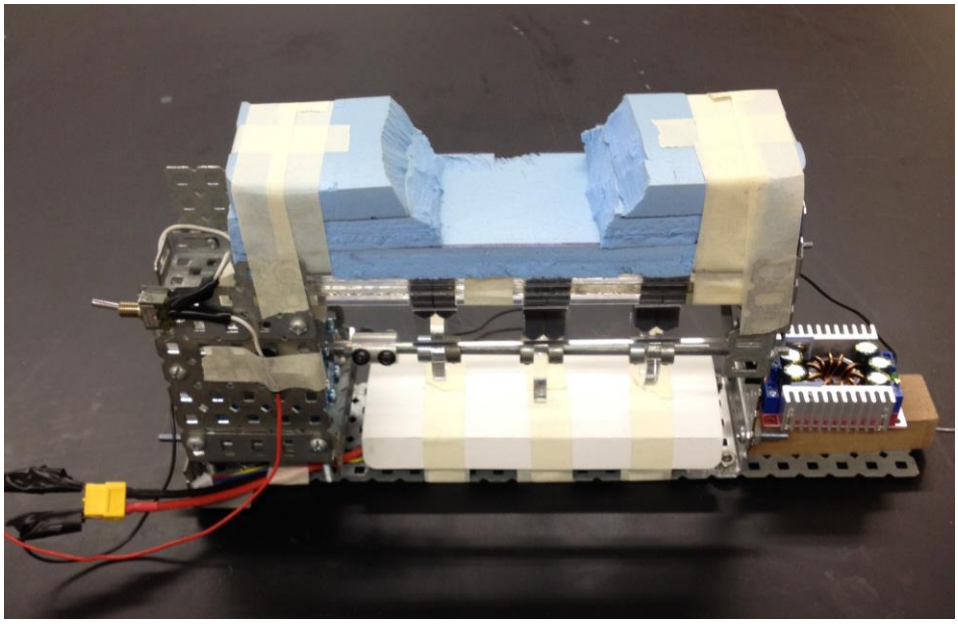

Figure 26. Forehead pad prototype

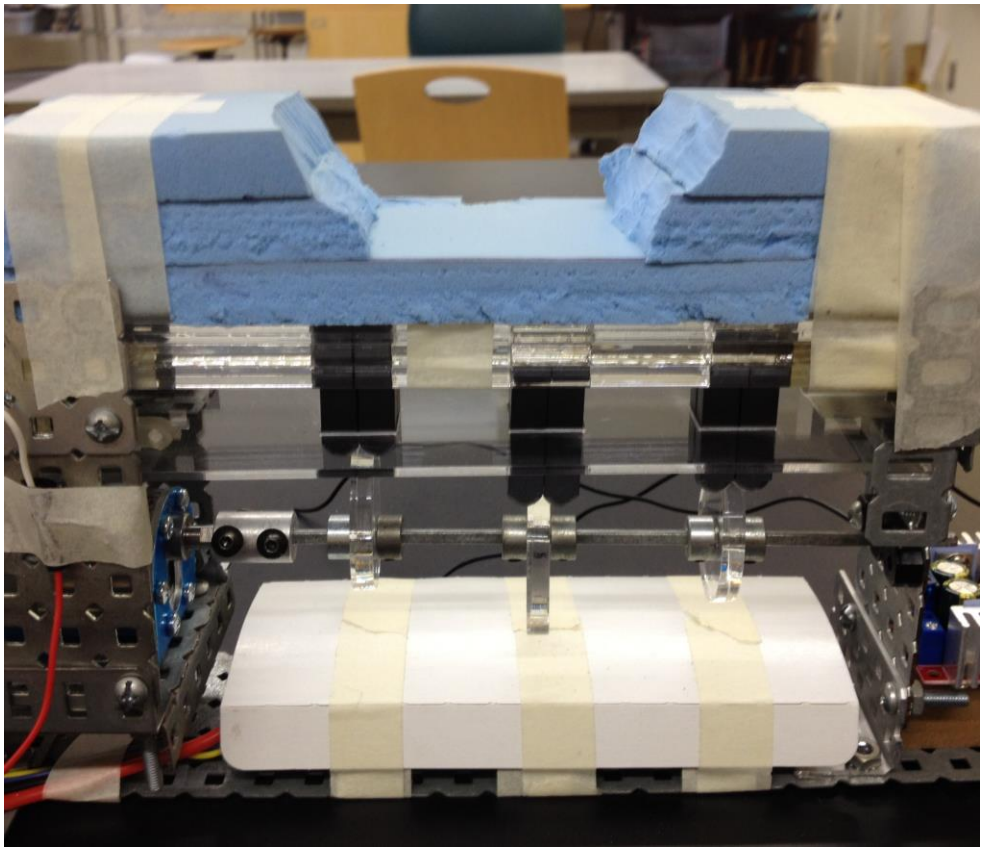

Figure 27. Cam follower linkage

5. Design Verification Methodology

5.1 Interface Pressure Testing

The interface pressure or the pressure on the forehead was tested to determine if the actuation was effective at reducing pressure below the pressure threshold and restoring blood flow in the forehead. The test was also conducted to evaluate and compare the interface pressure on two different padding materials, viscoelastic gel and polyurethane foam, in order to select the better material at redistributing pressure. This test was done using a baby mannequin with weights in the head totaling to 1.5 lbs to mimic the weight of a male child's head around one year of age. The weight estimate was obtained by taking the average weight [41] of the child at that age and using an anthropometric table to obtain the weight of the head.

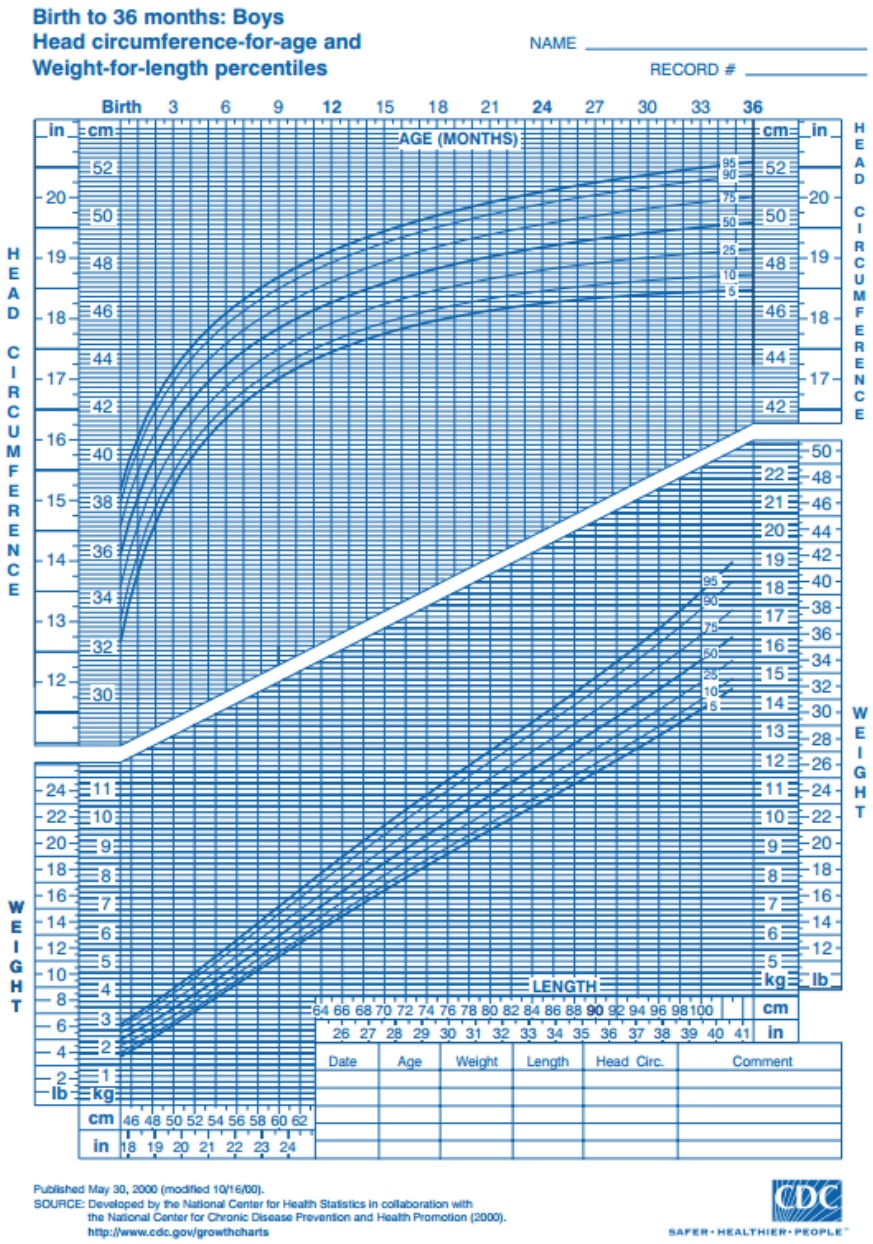

Figure 28. Body weight percentiles for boys from birth to 36 months [41]

TABLE 4.1 Anthropometric Data

Segment	Definition	Segment Weight/Total Body Weight	Center of Mass/ Segment Length Proximal	Distal	Radius of Gyration/ Segment Length C of G Proximal	Distal	Density
Hand	Wrist axis/knuckle II middle finger	0.006 M	0.506	0.494 P	0.297	0.587	0.577 M	1.16
Forearm	Elbow axis/ulnar styloid	0.016 M	0.430	0.570 P	0.303	0.526	0.647 M	1.13
Upper arm	Glenohumeral axis/elbow axis	0.028 M	0.436	0.564 P	0.322	0.542	0.645 M	1.07
Forearm and hand	Elbow axis/ulnar styloid	0.022 M	0.682	0.318 P	0.468	0.827	0.565 P	1.14
Total arm	Glenohumeral joint/ulnar styloid	0.050 M	0.530	0.470 P	0.368	0.645	0.596 P	1.11
Foot	Lateral malleolus/head metatarsal II	0.0145 M	0.50	0.50 P	0.475	0.690	0.690 P	1.10
Leg	Femoral condyles/medial malleolus	0.0465 M	0.433	0.567 P	0.302	0.528	0.643 M	1.09
Thigh	Greater trochanter/femoral condyles	0.100 M	0.433	0.567 P	0.323	0.540	0.653 M	1.05
Foot and leg	Femoral condyles/medial malleolus	0.061 M	0.606	0.394 P	0.416	0.735	0.572 P	1.09
Total leg	Greater trochanter/medial malleolus	0.161 M	0.447	0.553 P	0.326	0.560	0.650 P	1.06
Head and neck	C7–T1 and 1st rib/ear canal	0.081 M	1.000	— PC	0.495	0.116	— PC	1.11
Shoulder mass	Sternoclavicular joint/glenohumeral axis	—	0.712	0.288	—	—	—	1.04
Thorax	C7–T1/T12–L1 and diaphragm*	0.216 PC	0.82	0.18	—	—	—	0.92
Abdomen	T12–L1/L4–L5*	0.139 LC	0.44	0.56	—	—	—	—
Pelvis	L4–L5/greater trochanter*	0.142 LC	0.105	0.895	—	—	—	—
Thorax and abdomen	C7–T1/L4–L5*	0.355 LC	0.63	0.37	—	—	—	—
Abdomen and pelvis	T12–L1/greater trochanter*	0.281 PC	0.27	0.73	—	—	—	1.01
Trunk	Greater trochanter/glenohumeral joint*	0.497 M	0.50	0.50	—	—	—	1.03
Trunk head neck	Greater trochanter/glenohumeral joint*	0.578 MC	0.66	0.34 P	0.503	0.830	0.607 M	—
Head, arms, and trunk (HAT)	Greater trochanter/glenohumeral joint*	0.678 MC	0.626	0.374 PC	0.496	0.798	0.621 PC	—
HAT	Greater trochanter/mid rib	0.678	1.142	—	0.903	1.456	—	—

Figure 29. Anthropometric table [40]

Weight of child at 12 months of age (75 percentile) is about 20 lbs. Head and neck weight is 0.081 times of body weight. Therefore, the head weight at 12 months of age is: 20 lbs x 0.081 = 1.62 lb.

The mannequin was placed in prone position onto the forehead head-holder as shown below. The experiments were run with pads made of viscoelastic gel and polyurethane foam respectively.

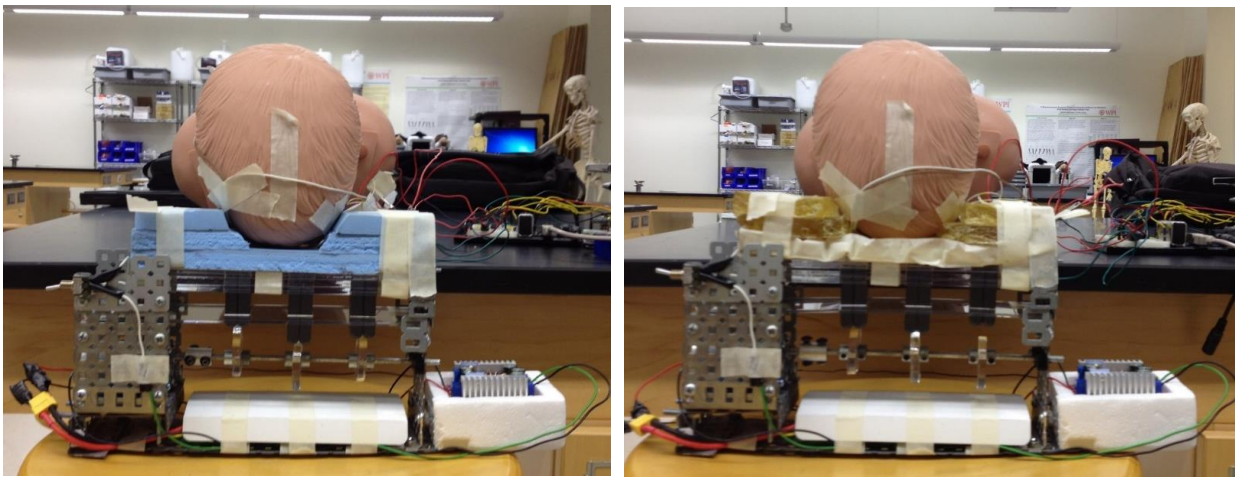

Figure 30. Interface pressure testing with two materials in prone position

There were two sensors on the head measuring the interface pressure, one directly in the middle of the forehead and one an inch to the right. The pressure an inch to the left was assumed to be similar to that of the right which had been confirmed through some brief tests.

Tests were run where the actuation mechanism was turned off in the first five minutes to use as a control for the experiment. These tests then continued for another twenty minutes with the actuation mechanism on. They were run for a total of twenty-five minute intervals. The tests were conducted using two different padding materials, polyurethane foam obtained through Rogers Corporation [47] and viscoelastic gel from Akton [17]. Testing was repeated five times for each material.

5.2 Material Testing

A stress-relaxation test of the two available materials, viscoelastic gel and polyurethane foam, was performed to find the effectiveness of both materials in responding to actuation and redistributing pressure. This test determines the damping coefficient (η) which is a measure of how the material lessens or dampens changes in stress. A larger damping coefficient is desired in this device to respond accordingly to the actuation and not dampen its effects.

The test was performed using an Instron 5544 Material Testing System. The material was placed into the clamps as seen in Figure 31, stretch to 20% strain and was let relaxed for ten minutes. Three tests was performed on each material and an average value was taken. The, moduli, damping coefficient, and time constant were calculated using the Standard Linear Solid model for viscoelastic materials.

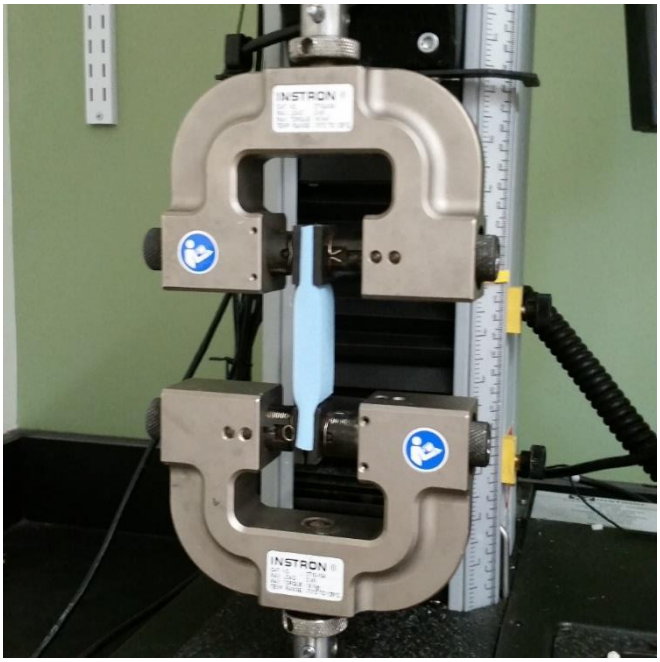

Figure 31. Stress relaxation test of two materials for padding

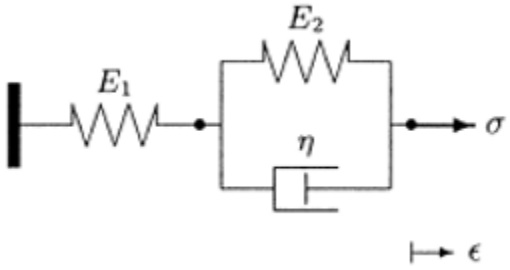

Figure 32. Standard Linear Solid Model [48]

Equation 1. Equation for Standard Linear Solid Model [48]

$$\sigma(t) = \varepsilon_0 \frac{E_1 E_2}{E_1 + E_2}\left[1 + \frac{E_1}{E_2} e^{\left(\frac{-\eta}{E_1+E_2}\right)t}\right]$$

where E_1 and E_2 are modulus values, η is viscosity, ε_0 is the initial strain, and τ is the time constant.

Stress values at time 0 and at infinity were used to determine to E1 and E2. Then stress at time constant was calculated when $\left(\frac{-\eta}{E_1+E_2}\right) t$ was set to equal -1. With this calculated stress, the time constant was determined from its stress relaxation graph. Finally, the damping coefficient (viscosity) was determined from the relationship $\eta = \tau(E_1+E_2)$.

5.3 Stability Testing

This test was performed to measure the amount of movement a patient head would experience in the device. Adequate stability is required for the surgeon to have a stable environment to operate on. Testing was done on the same mannequin as mentioned in section 5.1 and with the forehead prototype using the polyurethane foam padding. This testing was done by placing high-contrast fiducial markers at the top and one side of the head. Using a video-based motion tracking system, the head's displacement can be determined by measuring the movement of the markers over time. The camera that was used had a sampling rate of 29 frames per second. The actuation operated at 6 cycles per minute. The test was run in one minute for each position. Frames were extracted from the videos every second, and coordinates of the markers in video (image) coordinate system (x, y) was determined with MS Paint. The displacement of markers was calculated using the following formula:

Equation 2. Equation to determine the length of displacement vector

$$d = \sqrt{(x_2 - x_1)^2 + (y_2 - y_1)^2}$$

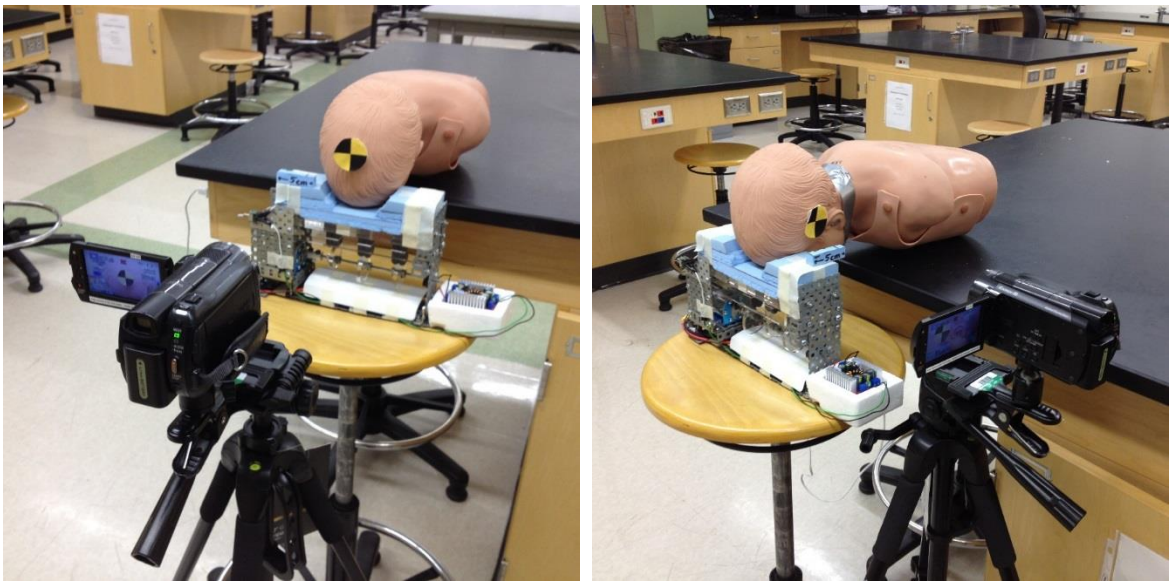

Figure 33. Stability test using video-based motion tracking system

6. Design Verification Results

6.1 Interface Pressure

The efficacy of actuation mechanism in redistributing interface pressure was evaluated with the interface pressure testing. The two most common padding materials, viscoelastic gel and polyurethane foam, were also tested to determine the better material in pressure reduction. Tekscan force sensors were used to measure interface pressure on the forehead of a one-year-old infant mannequin in the headrest prototype. The sensors imported values in the unit of force (pound-force or lb.f). In order to compare with the recommended pressure threshold, the force values were converted to pressure. The circular active sensing area of each sensor is 1 inch in diameter. Therefore, 1 pound-force exerts 66 mmHg of pressure onto the sensor. This conversion was determined as follows:

$$F = 1\ lb.f$$

$$P = \frac{F}{A} = \frac{1\ lb.f}{\pi(\frac{1}{2}in)^2} = \frac{4}{\pi}\ psi \approx 1.27\ psi \approx 66\ mmHg$$

The recommended pressure threshold is determined to be 70 mmHg. According to literature, applying interface pressure above 70 mmHg constantly for 2 hours could result in irreversible tissue damage [49]. If external pressure exceeds this threshold, blood perfusion is likely to be reduced, and for a long period of time can lead to skin necrosis and pressure sores.

Viscoelastic gel:

Viscoelastic gel has been widely used as padding material for different positioners and headrests. Akton®, a common viscoelastic gel product designed for medical applications, was tested for our application [17]. Interface pressure testing with force sensors were conducted five times with the

gel pad. Change in pressure distribution on the center and side of forehead during 25 minutes of testing was recorded and plotted below:

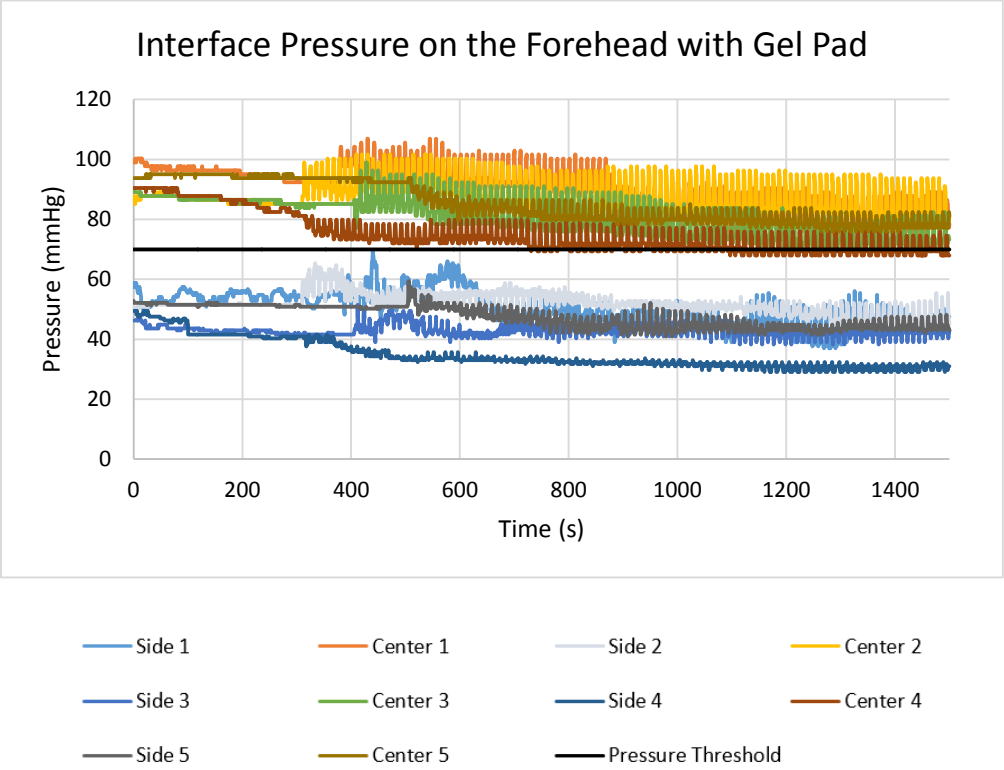

Figure 34. Interface pressure on the forehead with viscoelastic gel pad

Pressure was not distributed equally between areas in the forehead. Specifically, the force sensors showed considerably higher interface pressure on the center than on the side of the forehead, indicating pressure was more concentrated on the center of the pad. The mean pressure on the center was 90.1±4.72 mmHg in the first five minutes, and alternately shifted between 72.7±4.03 mmHg and 96.8±9.28 mmHg in the next twenty minutes when actuation was in action. These pressures, however, were above the pressure threshold during most of the time in five tests. The pressures were not redistributed effectively enough with gel pad to reduce the pressure below the threshold to restore the blood flow. This result is consistent with complication cases reported with the use of gel pad headrests where skin necrosis and pressure sores mostly develop at the center of the forehead in prone position.

The wounds in the forehead are also more noticeable than in the other areas and therefore are considered more unpleasant and serious. Pressures on one inch to either side of the forehead were lower, observed at 48.7±5.15 mmHg without actuation and between 37.5±5.16 mmHg and 57.4±11.1 mmHg with actuation. They were below the pressure threshold during the entire test periods, indicating no obstruction to blood flow at the sides of the head.

Polyurethane foam:

Polyurethane foam has been suggested as a good padding material to prevent pressure ulcers according to literature [4]. A sample of PORON Medical® polyurethane foam was provided by Rogers Corporation and tested for our application [47]. Interface pressure testing with force sensors were conducted five times with the foam pad. Change in pressure distribution on the center and side of forehead during 25 minutes of testing was recorded and plotted below:

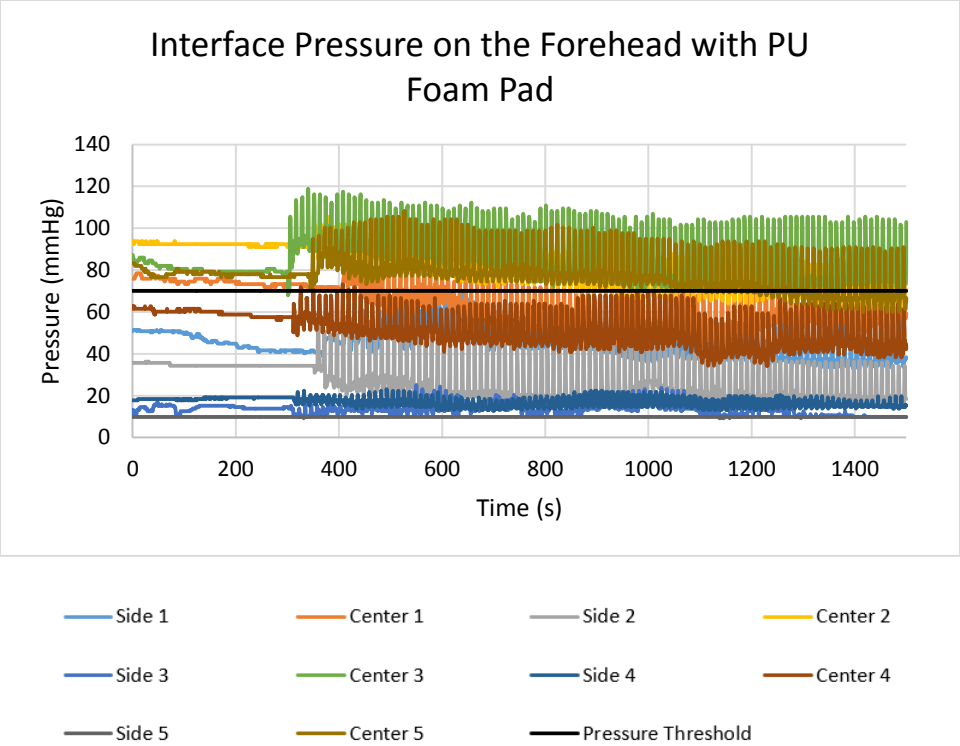

Figure 35. Interface pressure on the forehead with polyurethane foam pad

Similar to viscoelastic gel testing, pressure was not evenly distributed between areas in the forehead on polyurethane foam. The center experienced higher interface pressure than the side of the forehead, indicating a concentration of pressure at the center of the pad despite the contour shape of the foam. Pressure on the center remained relatively static in the first five minute without actuation, with a mean value of 77.1±11.8 mmHg among five tests. When actuation mechanism was activated, the pressure shifted alternately between 52.9±14.5 mmHg at maximum and 98.2±18.5 mmHg at minimum. Therefore, there were points of time when the pressure was reduced below the pressure threshold so that the capillaries on the forehead could open to restore the blood flow. Pressures experienced on the side of the head were always lower than on the center and also below the pressure threshold. They were observed at a mean value of 24.8±15.3 mmHg without actuation and between 16.5±9.74 mmHg and 36.6±24.8 mmHg with actuation.

Viscoelastic gel vs Polyurethane foam:

Viscoelastic gel and polyurethane foam were examined as two material options for the padding in the forehead headrest. Interface pressure testing with force sensors showed similar unequal distribution of pressure with higher pressure at the center of the pads although they were cut into contour shape to increase contact surface with the head. The interface pressure on the side was lower than on the center and below the recommended pressure threshold, and therefore is not considered an evident risk for pressure ulcers with both materials. Pressures on the center of the forehead were more significant and need to be taken a closer look. The mean interface pressure in five tests for each material is reported in Table 4.

Table 4.Interface pressure on the center of the forehead with viscoelastic gel pad vs polyurethane foam pad (mmHg)

	Viscoelastic gel		Polyurethane foam	
	First 5 minutes (without actuation)	Next 20 minutes (with actuation)	First 5 minutes (without actuation)	Next 20 minutes (with actuation)
Mean Pressure	90.1 ± 4.72	81.5 ± 6.16	77.1 ± 11.8	70.4 ± 14.8
Mean Minimum Pressure		72.7 ± 4.03		52.9 ± 14.5
Mean Maximum Pressure		96.8 ± 9.28		98.2 ± 18.5

By comparison, viscoelastic gel pad exhibited higher mean pressures than polyurethane foam pad in both static and actuation phases of testing. In both phases, the pressure on viscoelastic gel pad was constantly above 70 mmHg, the pressure threshold, and therefore the capillaries were not likely to

open and blood flow was still obstructed. With polyurethane foam, the pressure started higher than the threshold; however, its mean value was reduced to a value that was close the desired threshold when actuation was introduced to the pad. Specifically, with actuation, the pressure was relieved and lower than the pressure threshold whenever the rods at the center of the pad were moved down. At these moments, the capillaries were allowed to open and the blood flow was restored. To illustrate this, the median pressure distribution in five tests for the two padding materials were plotted in Figure 36 for comparison.

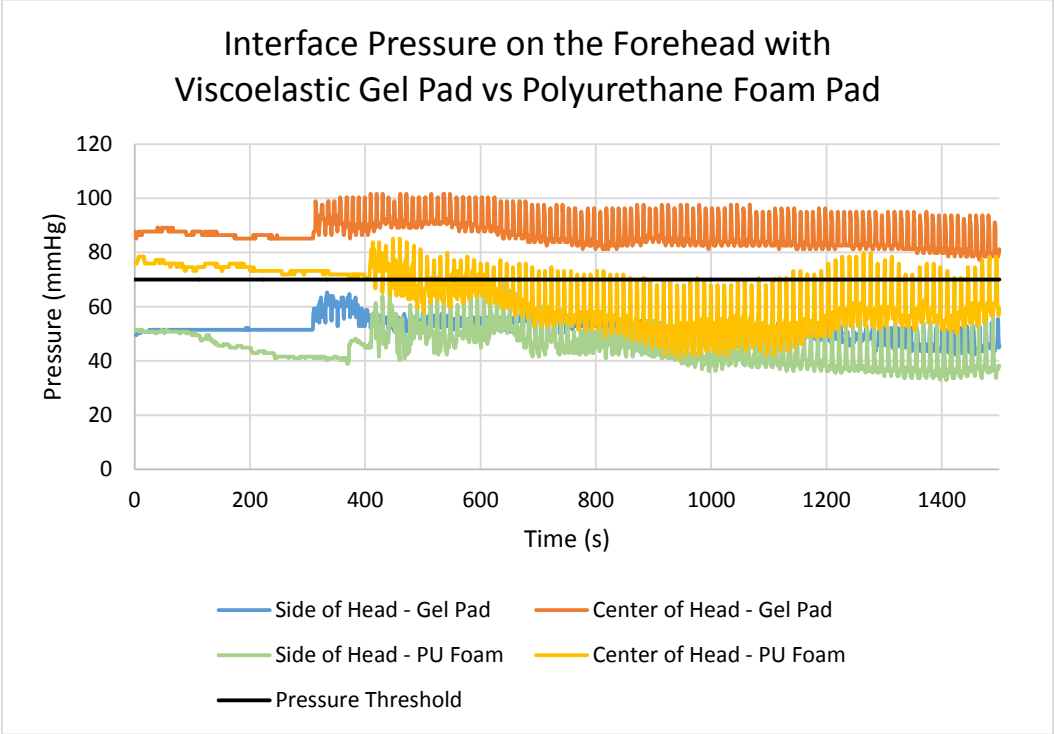

Figure 36. Median interface pressure on the forehead with viscoelastic gel pad vs polyurethane foam pad

Results of the interface pressure testing confirm two hypotheses. First, the actuation mechanism helps redistribute interface pressure applied on the forehead and thereby reduce pressure at the center of the pad. Secondly, polyurethane foam is more effective than viscoelastic gel in pressure relief, which is consistent with previous studies found in literature. Polyurethane foam, therefore, is the more suitable material for this application.

6.2 Padding Material Properties

Two commonly used padding material for medical purposes are polyurethane foam and silicone gel which both have their own benefits and are commonly used for different applications. In this design, a material that can respond to actuation, reduce pressure for the patient and has low damping for the actuation is desired. The two materials used were polyurethane foam from Roger's Corporation [47] and Akton® viscoelastic gel [17]. The following are the averaged results of three tests of each material:

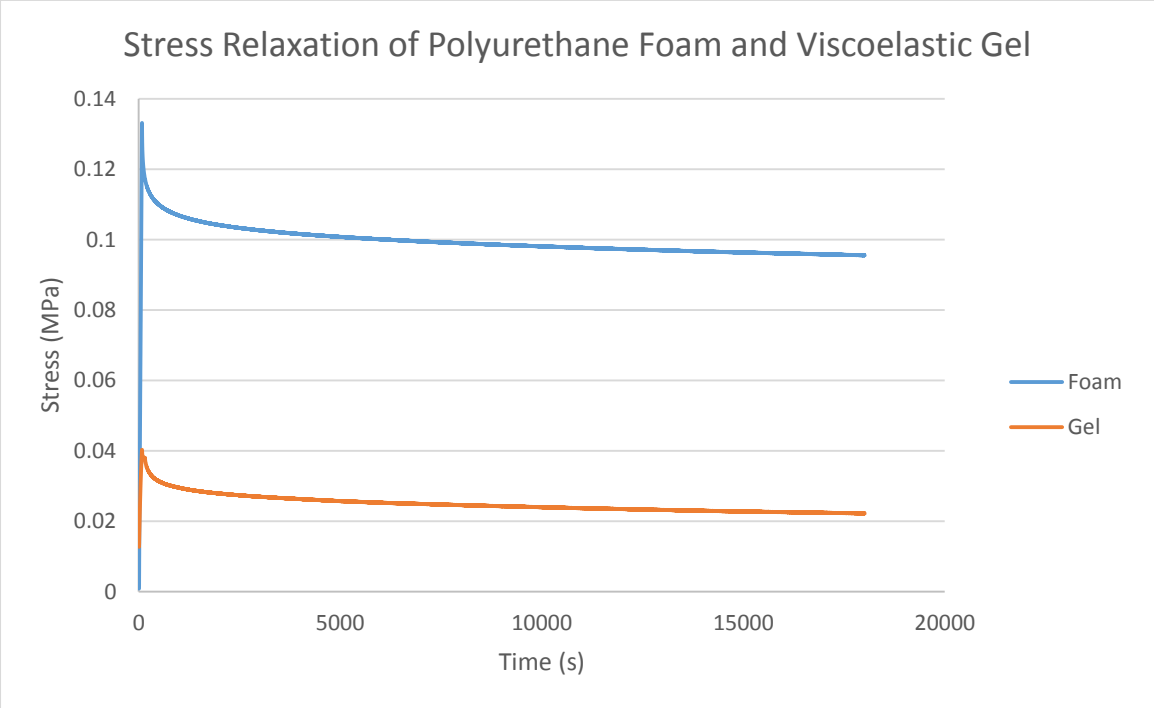

Figure 37. Stress relaxation tests of polyurethane foam and viscoelastic gel

Using the Standard Linear Solid model mentioned in section 5.3, the following parameters of each material was determined:

Table 5. Properties determined from stress relaxation test of polyurethane foam and viscoelastic gel

Material	E_1 (MPa)	E_2 (MPa)	η (MPa*s)	τ (s)
Polyurethane foam	0.664	1.71	0.079	30.1
Viscoelastic gel	0.245	0.179	0.016	27.0

The two modulus values (E1 and E2) suggest that the polyurethane is a stiffer material than the gel. However, the foam has a higher viscosity (η) meaning that it responds more quickly to stress and dampens the effects of the actuation less, which is more desirable for this design. They both also have similar time constants or τ values which indicates that both materials relax after initial stress at about the same rate.

An important note is that since the tests were only done three times on each material, the statistical significance of the data is quite low. However, due to the magnitude of the differences in modulus and viscosity, one can tell that there are major differences in the two materials.

6.3 Stability

Stability of the head is one of the most important design objectives in our new device. Without adequate stability, the procedures can be dangerous, deeming the device useless. With microscopic surgery, stability becomes a matter of the utmost importance. The movement of the head needs to be minimized, or its movement needs to be well-controlled. The surgical view through a microscope is more limited but focused and magnified. According to literature, a shift of even half an inch (~1.27 cm) to the surgical view can alter the precision of the procedure, particularly at high magnifications [50]. In order for the device to be usable in complicated surgeries, movement of the head must be reduced below this threshold.

Stability was tested with a video-based motion tracking system. Using high-contrast fiducial markers, the movement of the head rested on the actuated polyurethane foam pad forehead prototype in prone position was tracked. Actuation was operated at a frequency of 6 cycles per minute. The test was run to inspect the movement in the middle and side of the head in one minute each. The movement of the head was determined from the displacement of the markers. The coordinates of the markers in the video coordinate system was determined in MS Paint. Based on a known dimension of a

piece of foam included in the capture frame, pixel coordinates were converted into SI length unit (figure 38). The conversion ratios were determined as follows: in the capture frame of the middle of the head, the foam piece had a length of 5 cm, and it was found to be 313 pixels long. Thus in this frame, 1 pixel is equivalent to 5/313 cm (16e-3 cm). In the capture frame of the side of the head, the same foam piece was found to be 346 pixels long. Hence in this frame, 1 pixel is equivalent to 5/346 cm (14.5e-3 cm).

Figure 38. Displacement in the middle and side of the head determined from the fiducial markers' coordinates

Assuming the displacement of the head is relative the same from cycle to cycle, the lowest and highest coordinates of the markers, corresponding to their positions when the rods were moved down and moved up, were recorded to determine the maximum possible displacements. The origin of the video (image) coordinate system is located in the top left corner.

Table 6. Change in coordinates (x, y) of the markers placed in the middle and side of the head (pixel, pixel)

	Middle of the head	Side of the head
Lowest position	403, 231	249, 177
Highest position	401, 222	249, 171

Using the conversion ratios and formula specified in Section 5.3, the maximum displacements of the markers and thus the head were calculated. The middle of the head experienced a maximum displacement of 1.48 mm, while the side of the head had a maximum displacement of 0.87 mm. Both

displacements were minimal and well below the stability threshold. Therefore, the stability testing shows that device is able to support and fixate the head very stably in the prone position.

Stability was tested with only the forehead prototype. However, it is predicted extra stability can be achieved with the use of side clamps and optional pin fixation. In case movement of the head is absolutely not allowed at some periods of time during the procedure, the circuit is designed so that the actuation mechanism can be manually turned off and then turned on again as needed. The frequency of actuation can also be adjusted to achieve the desired degree of stability.

7. Discussion

7.1 Cost Comparison

Compared to the current gold standard head fixation devices such as the three-pin skull clamp and the horseshoe headrest, this device utilizes more advanced material and technology. With the addition of padding on the base of the pins, polyurethane foam on the headrest and actuation by cam follower mechanism on the forehead pad, the device aims to prevent pressure-related complications and has the potential to be the first device to be safely used in young children. However, technology comes with the price of increasing cost. Specifically, some special components and manufacturing techniques will account for the additional cost, including molding of polyurethane foam padding into standard contour shapes, a cam and rod follower system, a motor, a circuit powered by a rechargeable battery to drive the actuation mechanism, an embedded force sensor, LCD screen and a small circuit controlled by an Arduino to display the pressure distribution to the surgeon. This extra cost is estimated to be as high as $200. The other materials in this device are similar to those used in the gold standard devices such as the frames made of stainless steel. Manufacturing will need to be outsourced especially for padding, while R&D and branding costs will be lower than the current devices in the market. Overall, the device cost should be comparable or not much higher than that of the currently available devices.

Despite its potential higher cost, the device is designed to last. Except the disposable pediatric pins, the other components do not have to be replaced and have a long lifespan. Stainless steel is a common, strong, durable and easy to manufacture material, and therefore is chosen to be the primary material to fabricate this device.

The cost to prototype this device is much lower than the cost estimated to manufacture it. This prototyping cost is less than $150. The frame is primarily made of wood, the less expensive material, instead of stainless steel for the looking-like model. The components for which costs are significant are

electrical components, including sensors, Arduino board, rechargeable batteries and regulators for the working-like model.

7.2 Economics

The United States is known to have the highest per-capita health costs in the world [51]. Health care spending contributes to 20% of gross domestic product (GDP), or one-fifth of the U.S. economy by 2021 [52]. Of total spending, half (51 percent) is paying for the cost of medical services provided by hospitals and physicians [53]. Hospital cost is significant due to different factors, including costs of procedures, medical devices and hospitalization. This new head fixation device is developed to reduce the cost in neurosurgery. While the cost of the device is not much higher than the current devices in the market, it is built to last, and most importantly designed to be safely used in pediatric patients. By preventing common complications such as depressed skull fracture, skin necrosis and pressure sores, the device helps reduce the cost of follow-up procedures to correct them, accelerate recovery time and shorten hospitalization period. For example, this device by eliminating the risk of pressure sores saves $500 to $40,000 -the estimated cost of treatment per pressure ulcer [37]. When the procedures are safer and patient outcomes are more positive, cost of healthcare also decreases.

7.3 Environmental Impact

In order to reduce the negative impact on the environment, the device is designed so that it can be fabricated from common materials such as stainless steel and polymers. Stainless steel is known as one of the most environmentally friendly materials. It is easy to manufacture, theoretically 100% recyclable, has long term life and can be used in different environments [54]. Polyurethane polymer is also a highly recyclable material. At the end of its service life, it can be sent for reuse, rebonding or chemical recycling. It is also not known to cause adverse impact on waste handling process, landfills or incineration [55]. The device is also designed to save energy and reduce battery waste. The circuits for the cam follower actuation mechanism and the force sensors are powered by small-voltage

rechargeable batteries. Finally, the looking-like model is made of wood to reduce prototyping cost; however, wood will not be used in the actual design.

7.4 Social Influence

Pressure management is a problem not only in neurosurgical head fixation but also in a lot of other healthcare and rehabilitation areas. Different materials and technology have been researched and developed for this application. However, some of them are too complicated to be used in every area, and high cost also makes them inaccessible to developing countries. The principle of redistributing the pressure by mechanical actuation behind our design is simple, efficient and can be adapted to many areas. From a social perspective, the community of engineers, clinicians, and researchers can base on this principle to further develop it into more useful pressure management devices.

7.5 Ethical Concern

The main ethical concern during development of this device was designing so that while utilizing mechanical actuation on the pads to redistribute the pressure, stability and thus safety of the device was not ignored. This was achieved by balancing between actuation and head stability. Preliminary results indicate the prototype meets with both requirements. However, more tests can be done to determine an optimal set-up that further reduces the pressure on the forehead but provides adequate stability.

No animal or human subjects were involved with the development and testing of the device up to this stage. Instead a baby mannequin was used for brainstorming and testing. Pressure and stability thresholds were based on previous researches in literature and were not results of experimental tests. If this project is to continue, testing must progress to more sensitive subjects, for example through in vitro studies, anesthetized animal to cadaver models.

7.6 Health and Safety

The device is developed to prevent or reduce common complications occurring to young children when using head fixation devices in neurosurgery. The device shows potentials to improve safety and outcome of procedures. However, the device has not been approved by the U.S. Food and Drug Administration (FDA) and is therefore not safe for use in humans. The device must go through an extensive process to gain approval for clinical trial and then commercial use, as well as similar separate processes in other parts of the world.

7.7 Manufacturability

There are three fundamental manufacturing techniques that are required to fabricate this device. First, the frame assembly is primarily made of stainless steel, which is an easy to manufacture material with computer-controlled (CNC) machining. Three-dimensional CAD designs of the frame need to be translated into computer-aided manufacturing (CAM) files so that they can be processed by the CNC machines. Although WPI has facility to support CNC machining, it is limited to prototyping and small-scale manufacturing. Therefore, mass production needs to be outsourced considering the expenses of the machines to acquire. Second, polyurethane foam pads can be fabricated with molding to achieve the contour shapes. Molds need to be designed and manufactured to be used to make customized foam pads. However, the manufacturing process of foam is comprised of different complicated steps beside molding. These include formulation to determine ingredients of foam, material preparation, dispensing and mixing [56]. Thus manufacturing of foam also needs to be outsourced. Finally, the circuits used to run the sensor and motor for actuation can be made more compact and durable by fabricating printed circuit boards (PCB). Since the circuits are relatively simple, WPI facility has the ability to support this manufacturing step.

7.8 Sustainability

The device can be manufactured using established methods as described in Section 7.7. All chosen materials are highly recyclable and commonly used in industrial and medical device applications. The device has competitive advantage with the potential to be the first head fixation device in the market to be safely used in pediatric patients. Overall, the device is considered highly sustainable and can be further developed.

8. Conclusions and Recommendations

The final design utilizes a combination of pin fixation and gel headrest to stabilize the head and reduce the amount of pressure needed on each component. The forehead pad features cam follower actuation mechanism to redistribute the pressure and allow the capillaries to be relieved from constant pressure and open to restore the blood flow.

Through the many tests done on aspects of the proposed designs, several conclusions have been determined. Interface pressure tests have determined that actuation has a profound effect on the amount of pressure the forehead experiences. The reduction in pressures is below capillary opening pressure allowing blood to flow in the forehead and thus drastically reducing the risks of pressure sores and skin necrosis in the forehead during long surgeries. Tests were also done using both the viscoelastic gel Akton® and polyurethane foam from Roger's Corporation. Interface pressure tests have determined that the polyurethane foam performed better in reducing pressure as well as transmitting the changes from actuation. A stress relaxation test of both materials confirmed that the polyurethane foam had a higher damping coefficient (0.079 MPa.s) compared to the viscoelastic gel (0.0157 MPa.s) meaning that the gel reduces changes or dampens changes in stress. This also means that the polyurethane foam responds faster to stresses which is more ideal for this design to responds to the changes in actuation. Stability tests have confirmed that the actuation creates maximum movements around 1.48 mm which is less than the 12.7 mm maximum amount of movement that surgeons can experience while performing high stability surgeries that use microscopes.

Future work can be done to determine an optimal ratio of actuation amplitude to stability to create a more idealized device or even a device which can adapt to different surgical procedures. More work can also be done on material testing to generate higher statistical significant data. Also more types of material can be tested to find the best padding material. Skull fracture and depression tests can

be done using an Instron and applying simultaneous torsion and normal forces to a porcine skull using pediatric pins with padding at the base.

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Appendix A: Three Pin Skull Clamp

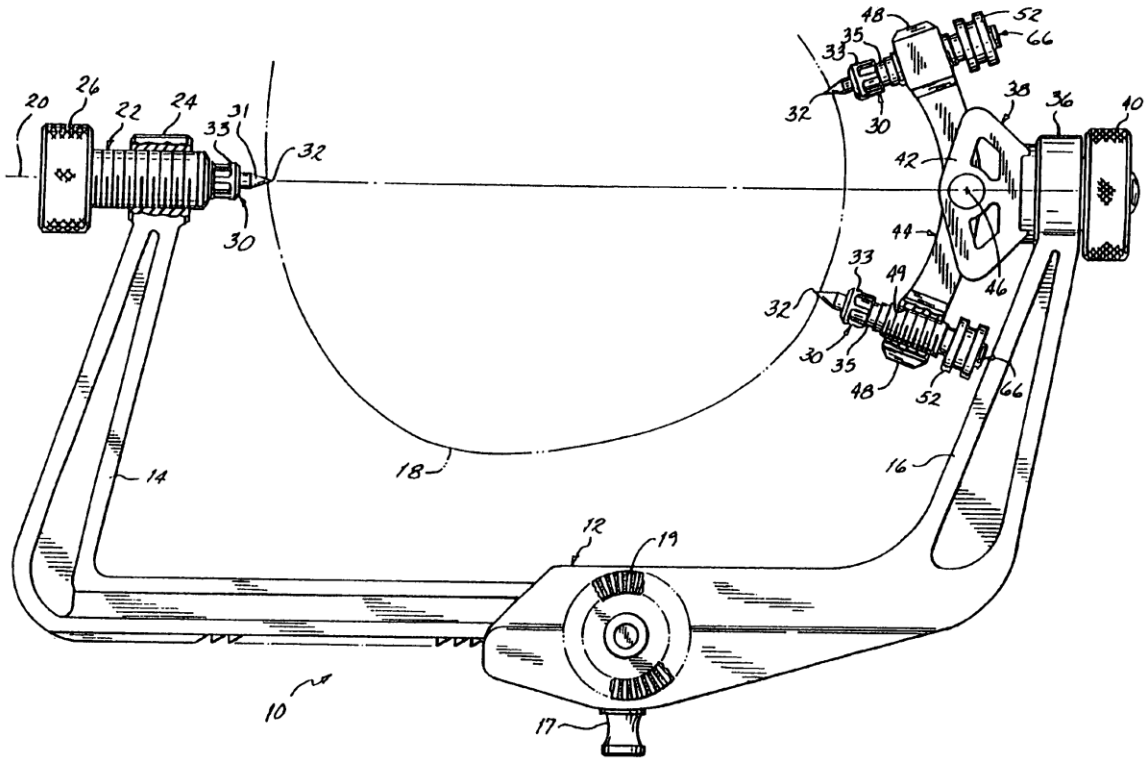


Figure 39. Mayfield® Three-Pin Skull Clamp using three pediatric pins to penetrate partially into the skull to stabilize the head. The pins are clamped against the head around an area called the "headband area". [57]

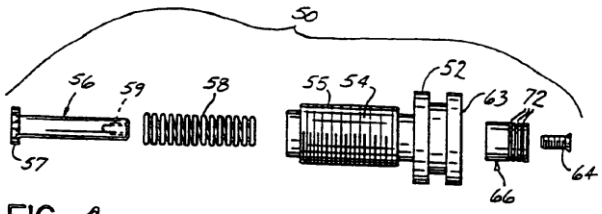


FIG. 4

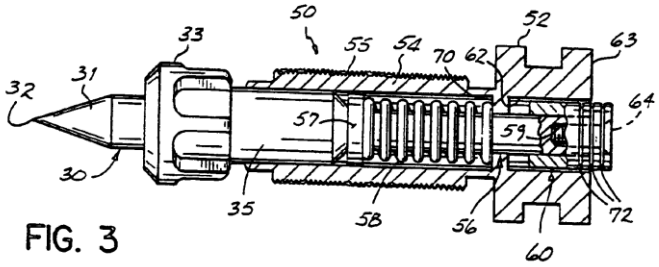


FIG. 3

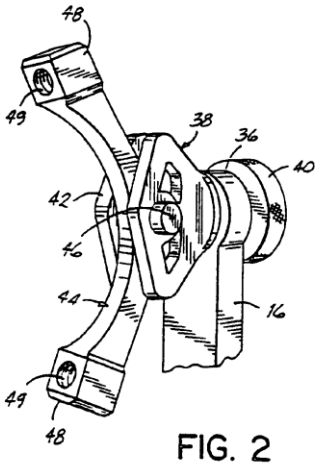


FIG. 2

Figure 40. The Pin Pressure Gauge System allows the surgeon to see how much pressure has been applied to prevent applying hyper-pressure causing skull penetration. It does not, however, prevent skull depression. Skull depression is caused by the hard surface at the base of the pins pressing against the skull. [57]

Figure 41. Device on the Market [20]

Appendix B: Horseshoe Headrest

Figure 42. Mayfield Adult Swivel Horseshoe Headrest utilizes either polyurethane foam or viscoelastic gel padding to stabilize the head non-invasively. This device, however, does not provide as much stability and flexibility as the three-pin skull clamp. [21]

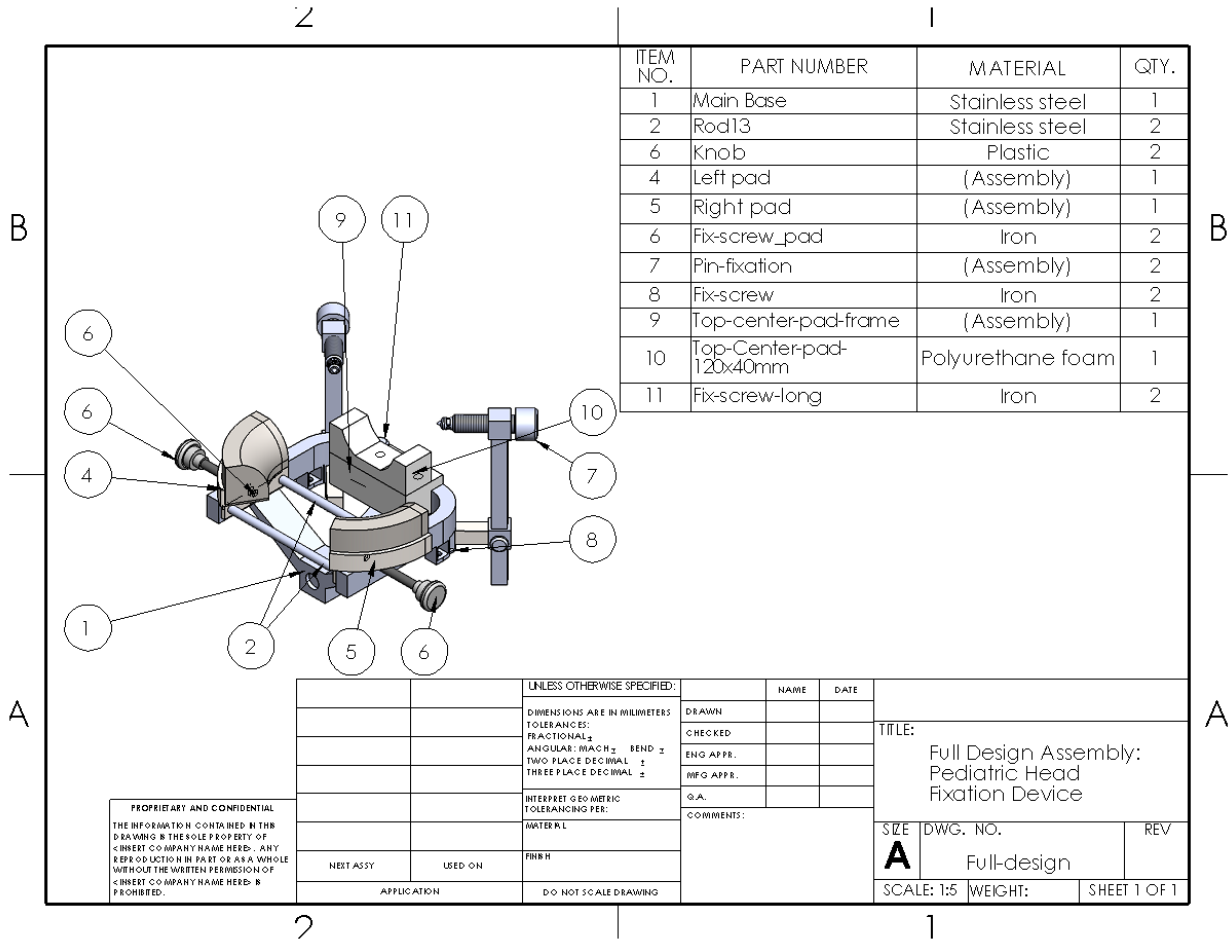
Appendix C: Multi-purpose Head Holder

Figure 43. DORO® Multi-Purpose Skull Clamp is provided with removable paddings with different shapes. It does not utilize pin fixation and therefore is not invasive but more stable than the horseshoe headrest. However, with more paddings, the device is more intrusive and can cause more skin necrosis and pressure sores. [18]

Appendix D: Pairwise Comparison Chart

Objectives	Hold the head in stable positions	Safe for use in infants	Non-intrusive to surgeons	Easy to use	Marketable	Reusable	Suitable for adults	MRI Compatible	Score
Hold the head in stable positions	x	1	1	1	1	1	1	1	7
Safe for use in infants	0	x	0.5	1	1	1	1	1	5.5
Non-intrusive to surgeons	0	0.5	x	1	1	1	1	1	5.5
Easy to use	0	0	0	x	1	1	1	1	4
Marketable	0	0	0	0	x	1	0.5	1	2.5
Reusable	0	0	0	0	0	x	1	1	2
Suitable for adults	0	0	0	0	0.5	0	x	0.5	1
MRI Compatible	0	0	0	0	0	0	0.5	x	0.5

Appendix E: Final Design CAD Drawings



ITEM NO.	PART NUMBER	MATERIAL	QTY.
1	Main Base	Stainless steel	1
2	Rod13	Stainless steel	2
6	Knob	Plastic	2
4	Left pad	(Assembly)	1
5	Right pad	(Assembly)	1
6	Fix-screw_pad	Iron	2
7	Pin-fixation	(Assembly)	2
8	Fix-screw	Iron	2
9	Top-center-pad-frame	(Assembly)	1
10	Top-Center-pad-120x40mm	Polyurethane foam	1
11	Fix-screw-long	Iron	2

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NEXT ASSY | USED ON
APPLICATION

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	NAME	DATE
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MFG APPR.		
Q.A.		

COMMENTS:

TITLE:
Full Design Assembly:
Pediatric Head
Fixation Device

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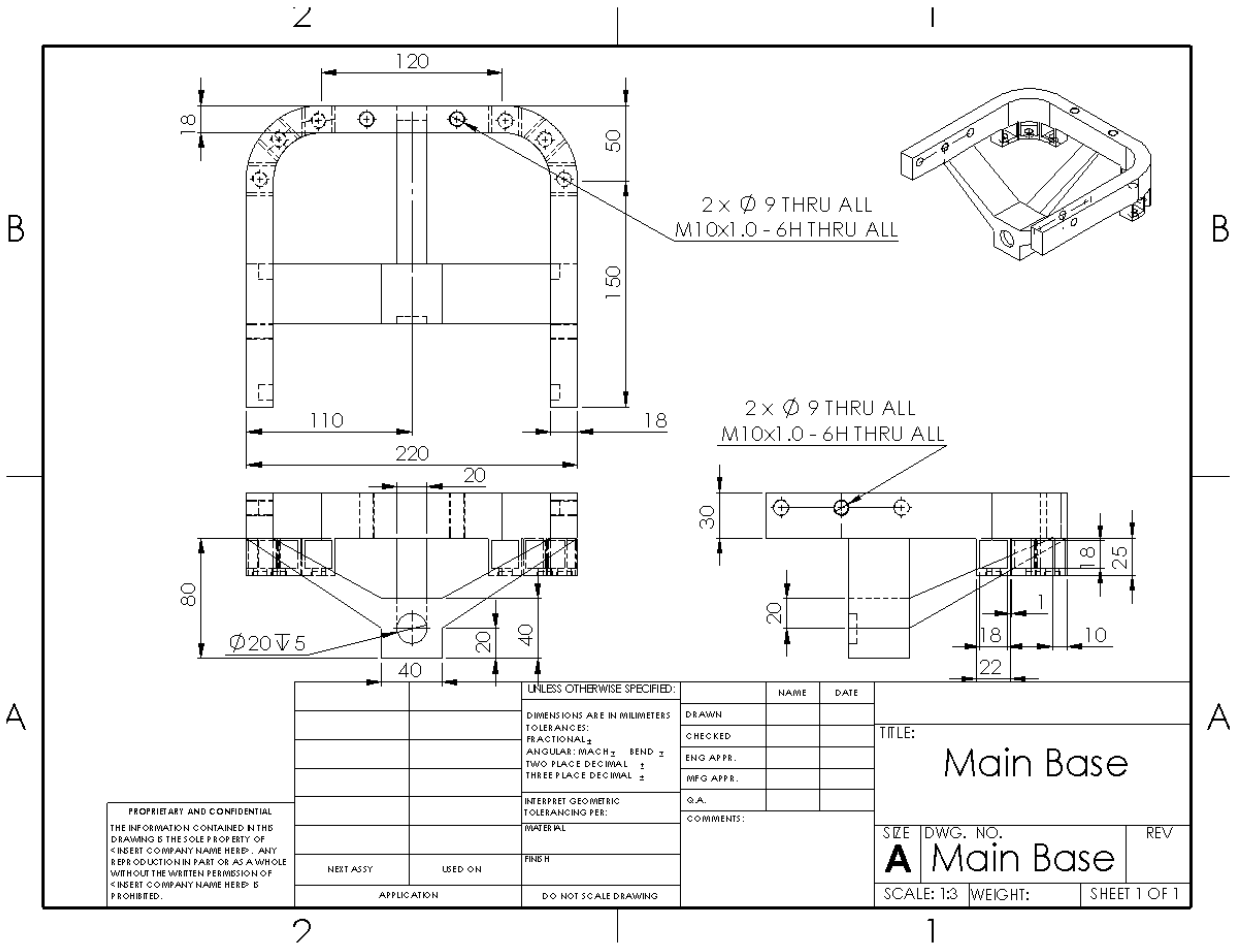
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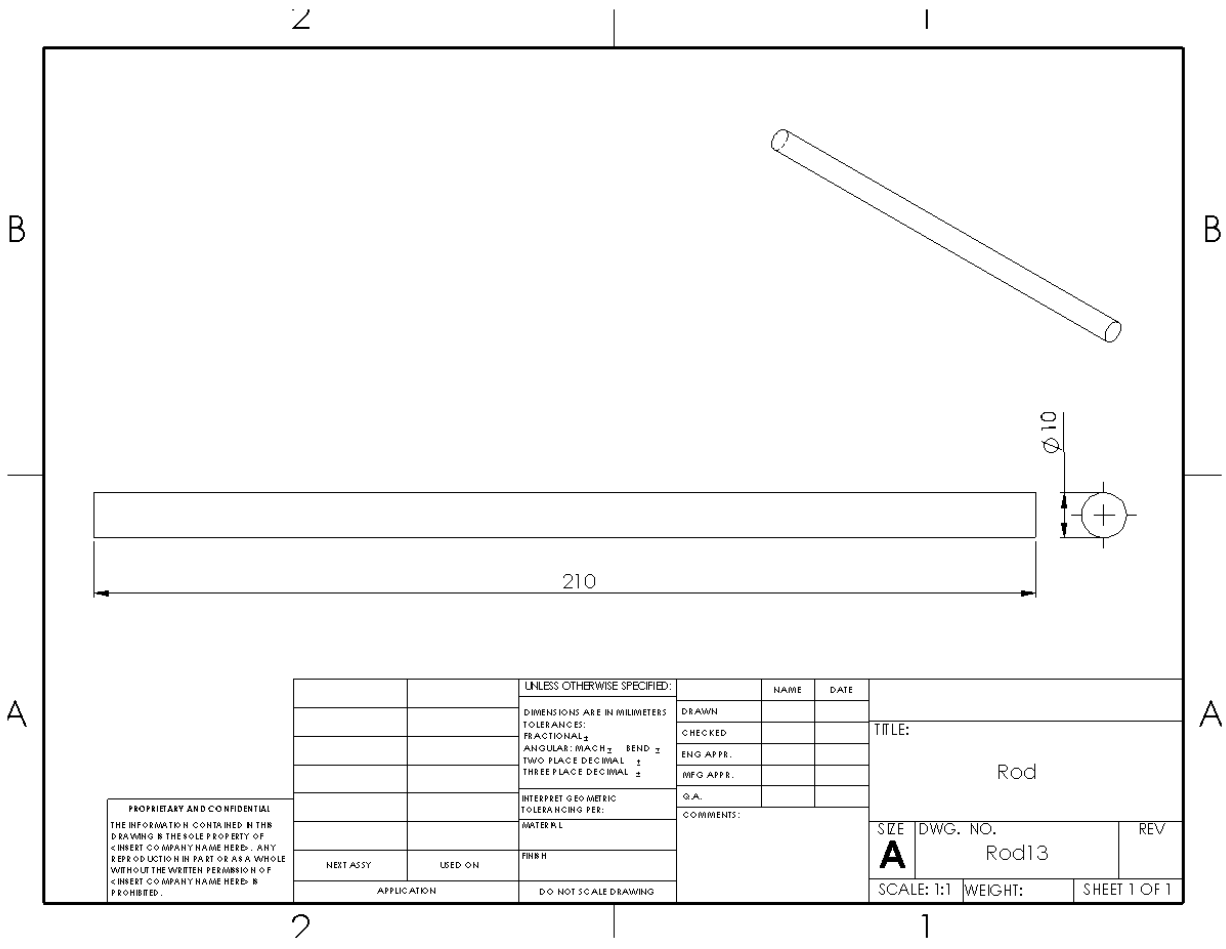
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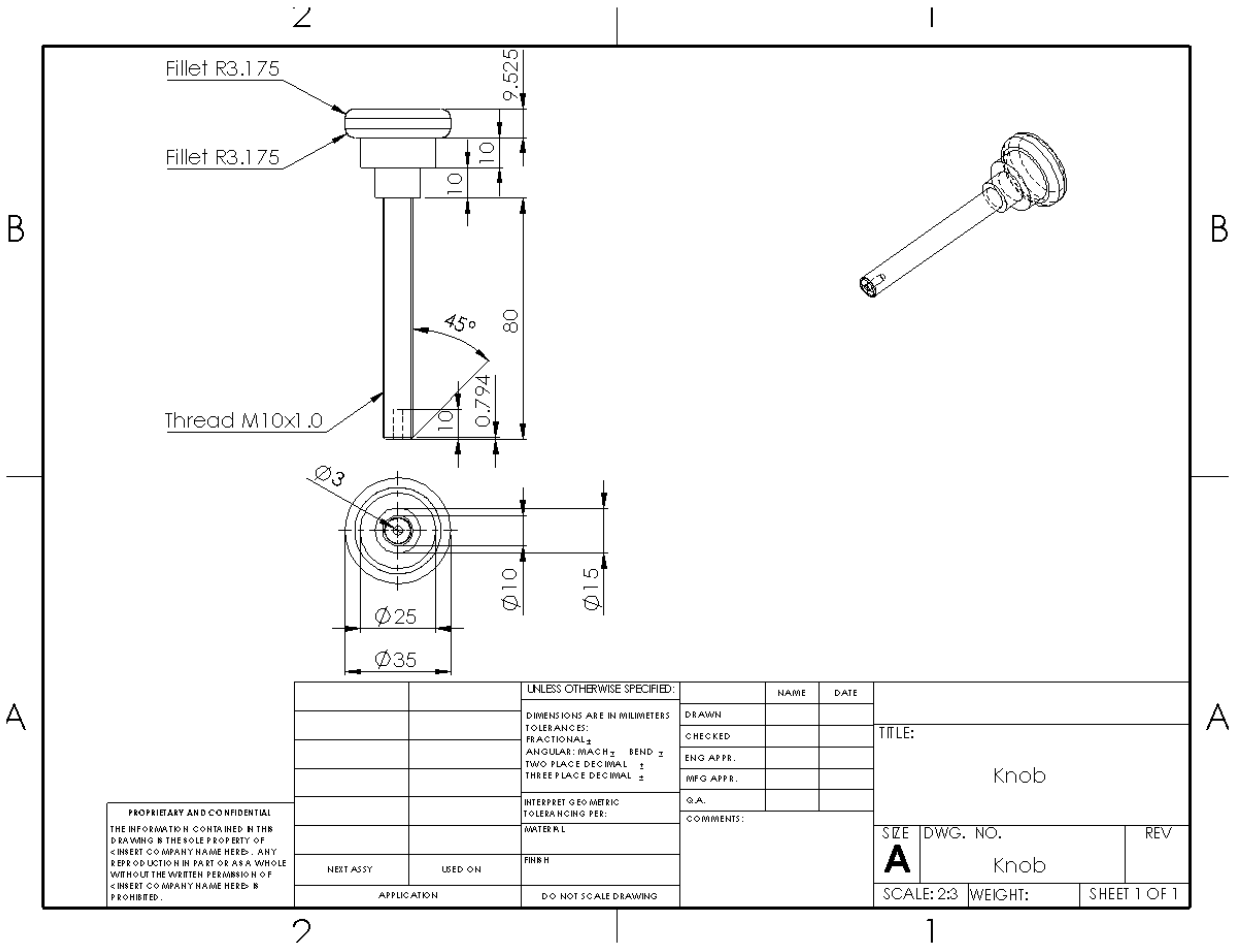
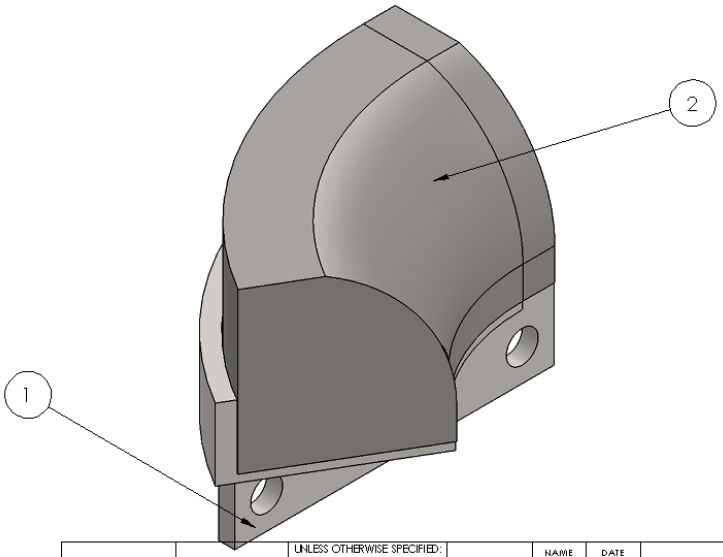
WEIGHT:
SHEET 1 OF 1


Fillet R3.175
Fillet R3.175
Thread M10x1.0
9.525
10
10
80
45°
10
0.794
Ø3
Ø10
Ø15
Ø25
Ø35
B
A
2
1
UNLESS OTHERWISE SPECIFIED:
DIMENSIONS ARE IN MILIMETERS
TOLERANCES:
FRACTIONAL ±
ANGULAR: MACH ± BEND ±
TWO PLACE DECIMAL ±
THREE PLACE DECIMAL ±
INTERPRET GEOMETRIC TOLERANCING PER:
MATERIAL
FINISH
DO NOT SCALE DRAWING
NAME
DATE
DRAWN
CHECKED
ENG APPR.
MFG APPR.
Q.A.
COMMENTS:
NEXT ASSY
USED ON
APPLICATION
PROPRIETARY AND CONFIDENTIAL
THE INFORMATION CONTAINED IN THIS DRAWING IS THE SOLE PROPERTY OF <INSERT COMPANY NAME HERE>. ANY REPRODUCTION IN PART OR AS A WHOLE WITHOUT THE WRITTEN PERMISSION OF <INSERT COMPANY NAME HERE> IS PROHIBITED.
TITLE:
Knob
SIZE
A
DWG. NO.
Knob
REV
SCALE: 2:3
WEIGHT:
SHEET 1 OF 1

ITEM NO.	PART NUMBER	MATERIAL	QTY.
1	Left-pad-base	Stainless steel	1
2	Left-pad-L110mm	Polyurethane foam	1



		UNLESS OTHERWISE SPECIFIED:		NAME	DATE
		DIMENSIONS ARE IN MILIMETERS TOLERANCES: FRACTIONAL ± ANGULAR: MACH ± BEND ± TWO PLACE DECIMAL ± THREE PLACE DECIMAL ±	DRAWN		
			CHECKED		
			ENG APPR.		
			MFG APPR.		
		INTERPRET GEOMETRIC TOLERANCING PER:	Q.A.		
		MATERIAL	COMMENTS:		
NEXT ASSY	USED ON	FINISH			
APPLICATION		DO NOT SCALE DRAWING			

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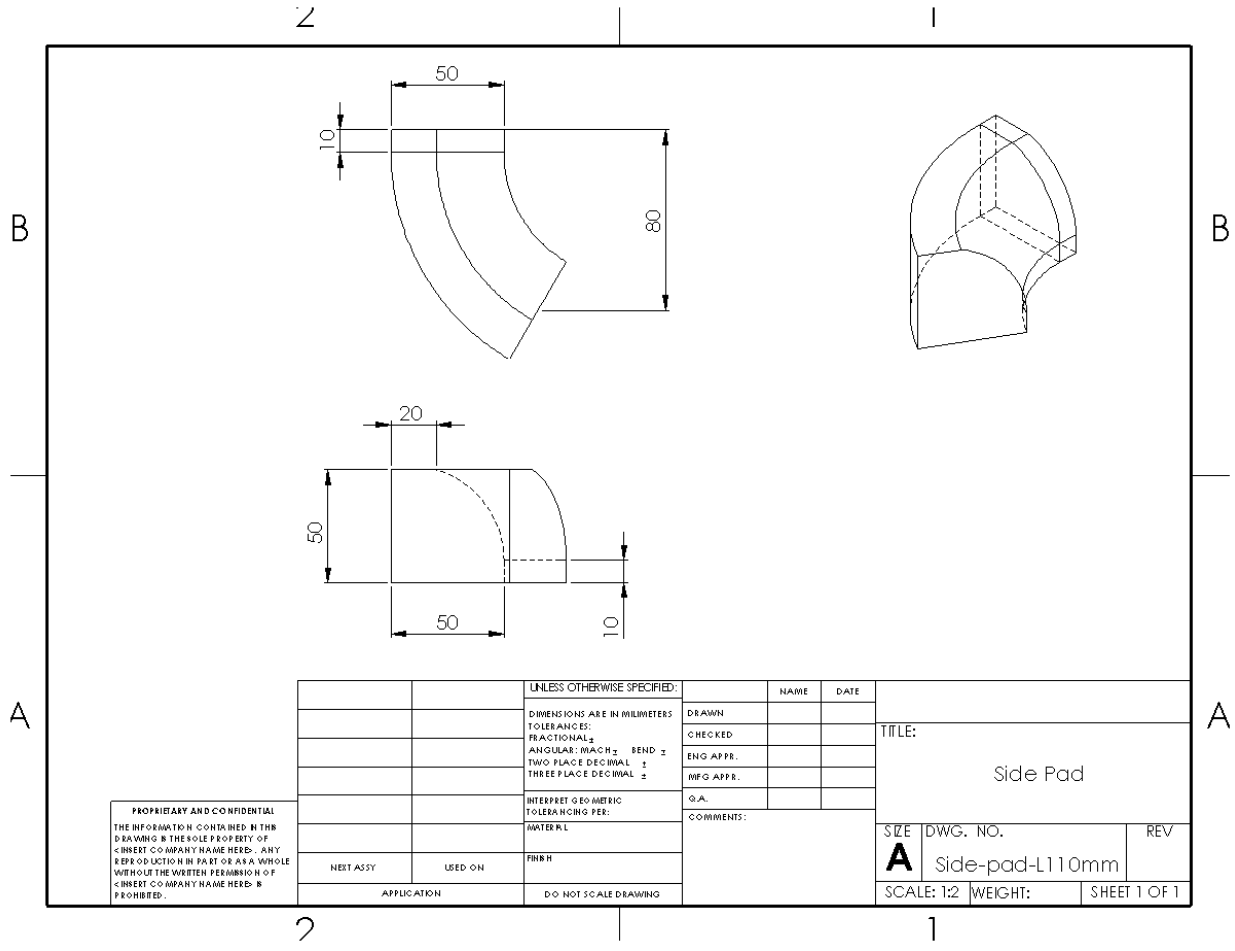
TITLE:

Side Pad Assembly

SIZE	DWG. NO.	REV
A	Side-pad	
SCALE: 1:1	WEIGHT:	SHEET 1 OF 1


2
1
B
A
50
10
80
20
50
50
10
UNLESS OTHERWISE SPECIFIED:
DIMENSIONS ARE IN MILLIMETERS
TOLERANCES:
FRACTIONAL ±
ANGULAR: MACH ± BEND ±
TWO PLACE DECIMAL ±
THREE PLACE DECIMAL ±
INTERPRET GEOMETRIC TOLERANCING PER:
MATERIAL
FINISH
DO NOT SCALE DRAWING
NAME
DATE
DRAWN
CHECKED
ENG APPR.
MFG APPR.
Q.A.
COMMENTS:
NEXT ASSY
USED ON
APPLICATION
PROPRIETARY AND CONFIDENTIAL
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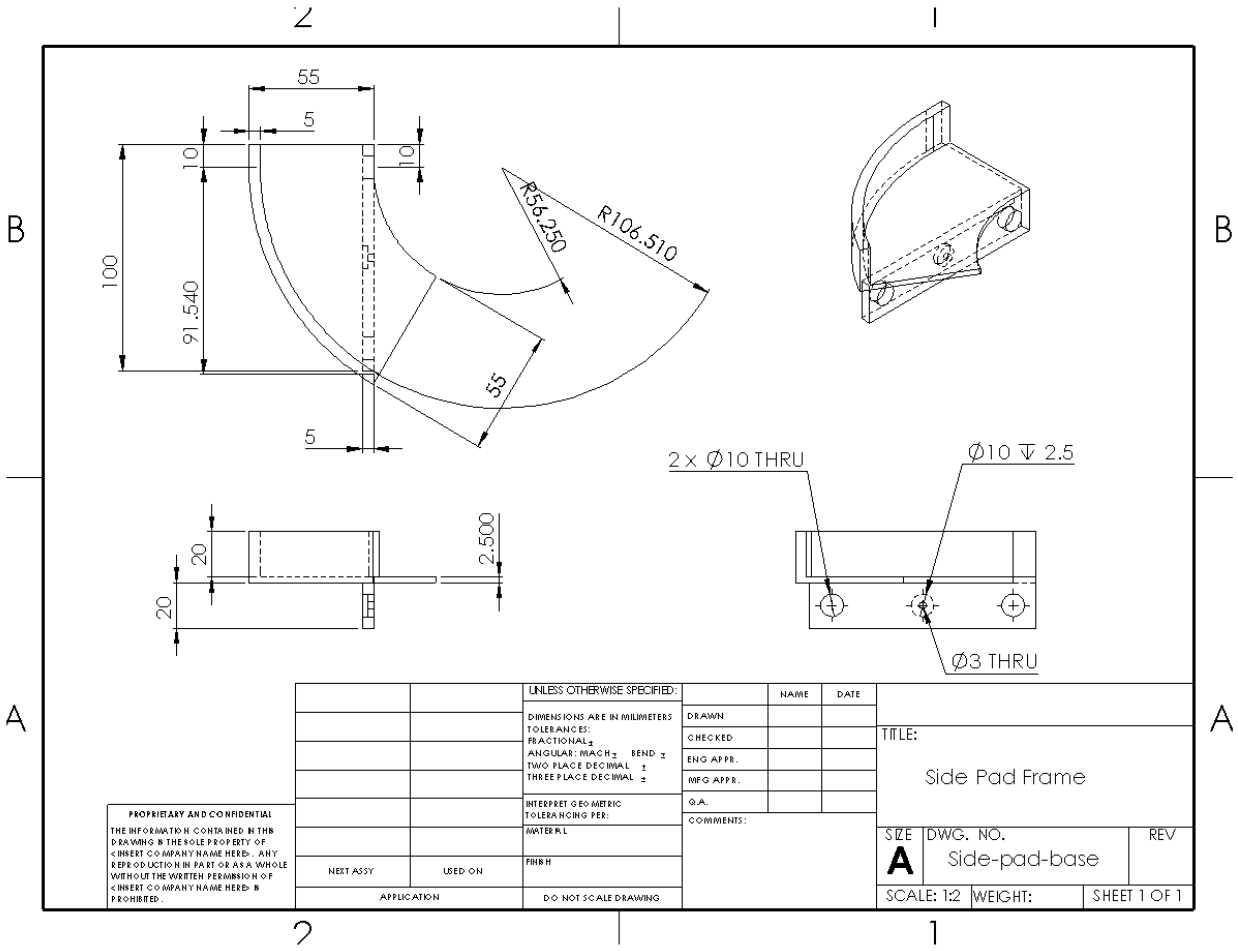
TITLE:
Side Pad
SIZE
A
DWG. NO.
Side-pad-L110mm
REV
SCALE: 1:2
WEIGHT:
SHEET 1 OF 1


55
5
10
10
100
91.540
55
R56.250
R106.510
55
5
20
20
2.500
2 × Ø10 THRU
Ø10 ↧ 2.5
Ø3 THRU
UNLESS OTHERWISE SPECIFIED:
DIMENSIONS ARE IN MILIMETERS
TOLERANCES:
FRACTIONAL ±
ANGULAR: MACH ± BEND ±
TWO PLACE DECIMAL ±
THREE PLACE DECIMAL ±
INTERPRET GEOMETRIC TOLERANCING PER:
MATERIAL
FINISH
DO NOT SCALE DRAWING
NAME
DATE
DRAWN
CHECKED
ENG APPR.
MFG APPR.
Q.A.
COMMENTS:
TITLE:
Side Pad Frame
SIZE
A
DWG. NO.
Side-pad-base
REV
SCALE: 1:2
WEIGHT:
SHEET 1 OF 1
NEXT ASSY
USED ON
APPLICATION
PROPRIETARY AND CONFIDENTIAL
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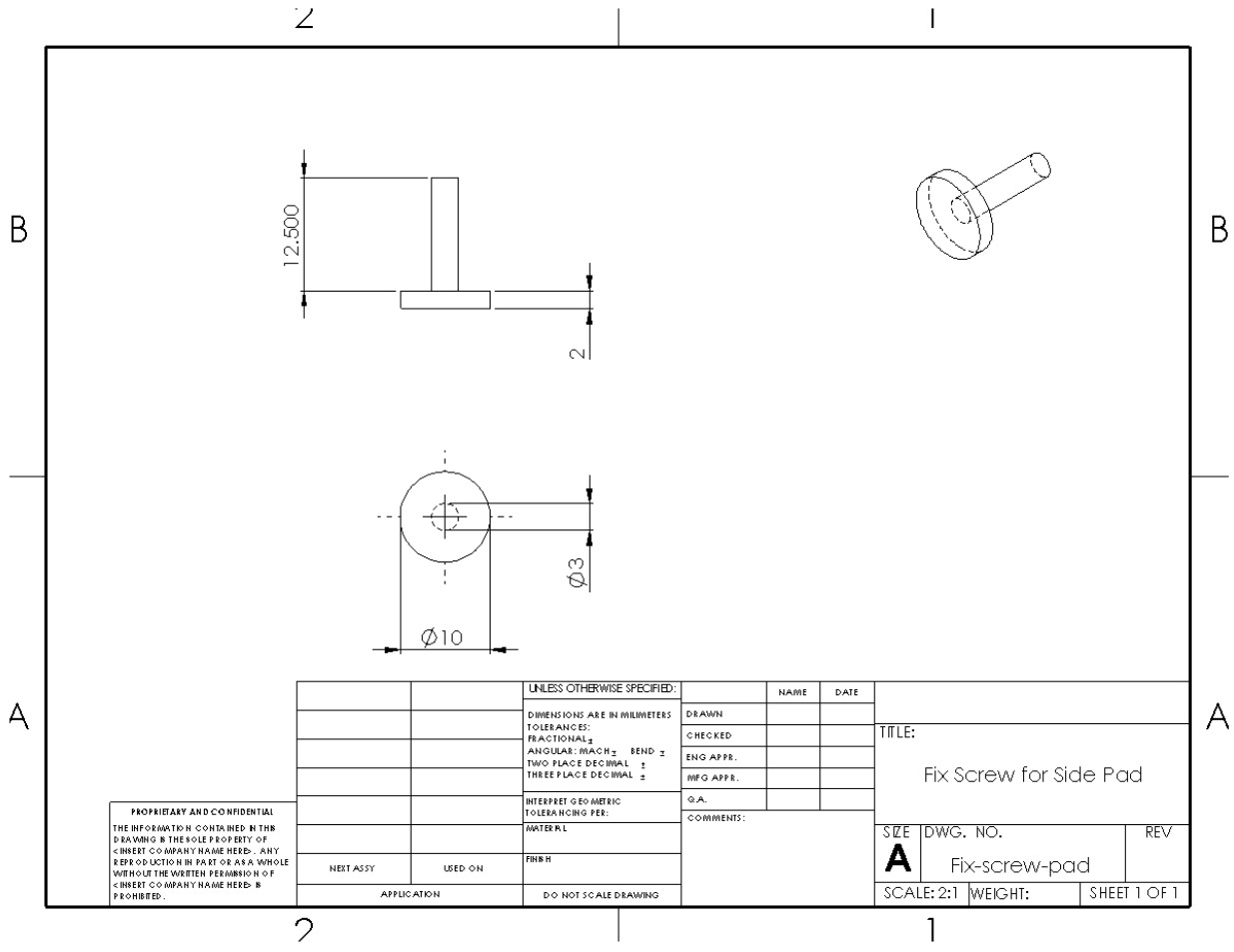

		UNLESS OTHERWISE SPECIFIED:		NAME	DATE
		DIMENSIONS ARE IN MILIMETERS TOLERANCES: FRACTIONAL ± ANGULAR: MACH ± BEND ± TWO PLACE DECIMAL ± THREE PLACE DECIMAL ±	DRAWN		
			CHECKED		
			ENG APPR.		
			MFG APPR.		
		INTERPRET GEOMETRIC TOLERANCING PER:	Q.A.		
		MATERIAL	COMMENTS:		
NEXT ASSY	USED ON	FINISH			
APPLICATION		DO NOT SCALE DRAWING			

PROPRIETARY AND CONFIDENTIAL

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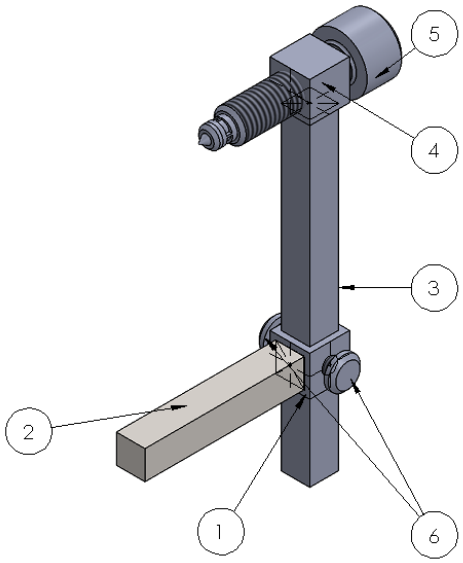
TITLE: Fix Screw for Side Pad

SIZE	DWG. NO.	REV
A	Fix-screw-pad	
SCALE: 2:1	WEIGHT:	SHEET 1 OF 1

ITEM NO.	PART NUMBER	MATERIAL	QTY.
1	Bottom-connector	Stainless steel	1
2	Short-tube	Stainless steel	1
3	Long-tube	Stainless steel	1
4	Top-connector-M14	Stainless steel	1
5	Screw-and-pin	(Assembly)	1
6	Fix-screw	Iron/Plastic	2



UNLESS OTHERWISE SPECIFIED:
DIMENSIONS ARE IN MILIMETERS
TOLERANCES:
FRACTIONAL ±
ANGULAR: MACH ± BEND ±
TWO PLACE DECIMAL ±
THREE PLACE DECIMAL ±
INTERPRET GEOMETRIC TOLERANCING PER:
MATERIAL
FINISH
DO NOT SCALE DRAWING

	NAME	DATE
DRAWN		
CHECKED		
ENG APPR.		
MFG APPR.		
Q.A.		

COMMENTS:

NEXT ASSY | USED ON
APPLICATION

PROPRIETARY AND CONFIDENTIAL
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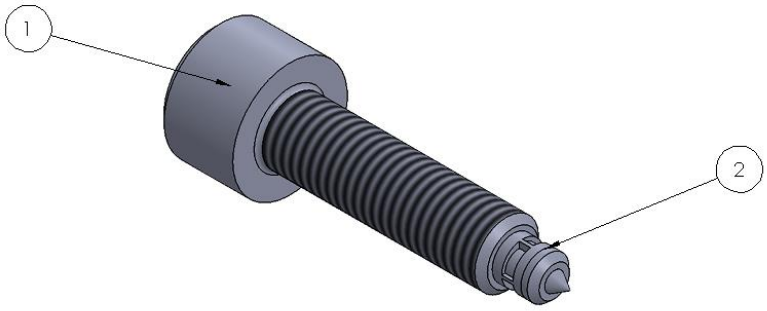
TITLE:
Pin Fixation Assembly

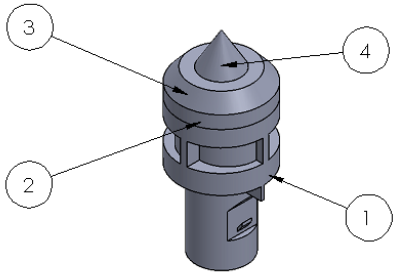
SIZE	DWG. NO.	REV
A	Pin-fixation	
SCALE: 1:2	WEIGHT:	SHEET 1 OF 1

ITEM NO.	PART NUMBER	MATERIAL	QTY.
1	Pin-insert-screw	Stainless steel	1
2	Assem-Pin	(Assembly)	1

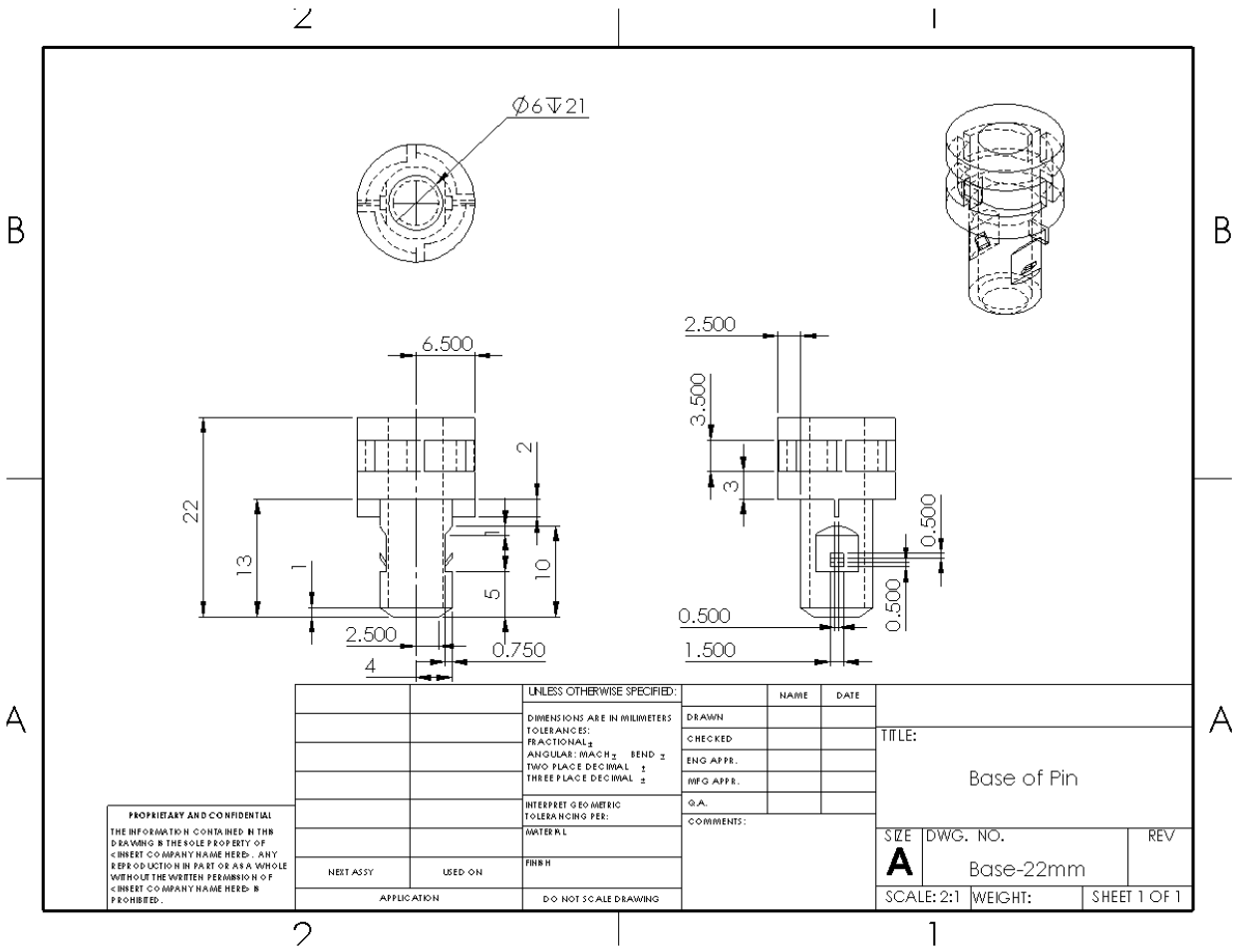


		UNLESS OTHERWISE SPECIFIED:		NAME	DATE	
		DIMENSIONS ARE IN MILIMETERS TOLERANCES: FRACTIONAL ± ANGULAR: MACH ± BEND ± TWO PLACE DECIMAL ± THREE PLACE DECIMAL ±	DRAWN			TITLE: Pin and Screw Assembly
			CHECKED			
			ENG APPR.			
			MFG APPR.			
		INTERPRET GEOMETRIC TOLERANCING PER:	Q.A.			
		MATERIAL	COMMENTS:			SIZE A / DWG. NO. Screw-and-pin / REV
NEXT ASSY	USED ON	FINISH				
APPLICATION		DO NOT SCALE DRAWING				SCALE: 1:1 / WEIGHT: / SHEET 1 OF 1

ITEM NO.	PART NUMBER	MATERIAL	QTY.
1	Base-22mm	Plastic	1
2	Bottom-ring-2mm	Polyurethane foam	1
3	Top-ring-2mm	Polyurethane foam	1
4	Pin-5mm	Stainless steel	1



		UNLESS OTHERWISE SPECIFIED:		NAME	DATE	
		DIMENSIONS ARE IN MILLIMETERS TOLERANCES: FRACTIONAL ± ANGULAR: MACH ± BEND ± TWO PLACE DECIMAL ± THREE PLACE DECIMAL ±	DRAWN			TITLE: Pin Assembly
			CHECKED			
			ENG APPR.			
			MFG APPR.			
		INTERPRET GEOMETRIC TOLERANCING PER:	Q.A.			
		MATERIAL	COMMENTS:			SIZE A / DWG. NO. Assem-pin / REV
NEXT ASSY	USED ON	FINISH				
APPLICATION		DO NOT SCALE DRAWING				SCALE: 2:1 / WEIGHT: / SHEET 1 OF 1


Ø6↧21
6.500
22
13
1
2
5
10
2.500
4
0.750
2.500
3.500
3
0.500
0.500
0.500
1.500
UNLESS OTHERWISE SPECIFIED:
DIMENSIONS ARE IN MILLIMETERS
TOLERANCES:
FRACTIONAL ±
ANGULAR: MACH ± BEND ±
TWO PLACE DECIMAL ±
THREE PLACE DECIMAL ±
INTERPRET GEOMETRIC TOLERANCING PER:
MATERIAL
FINISH
DO NOT SCALE DRAWING
NAME
DATE
DRAWN
CHECKED
ENG APPR.
MFG APPR.
Q.A.
COMMENTS:
NEXT ASSY
USED ON
APPLICATION
PROPRIETARY AND CONFIDENTIAL
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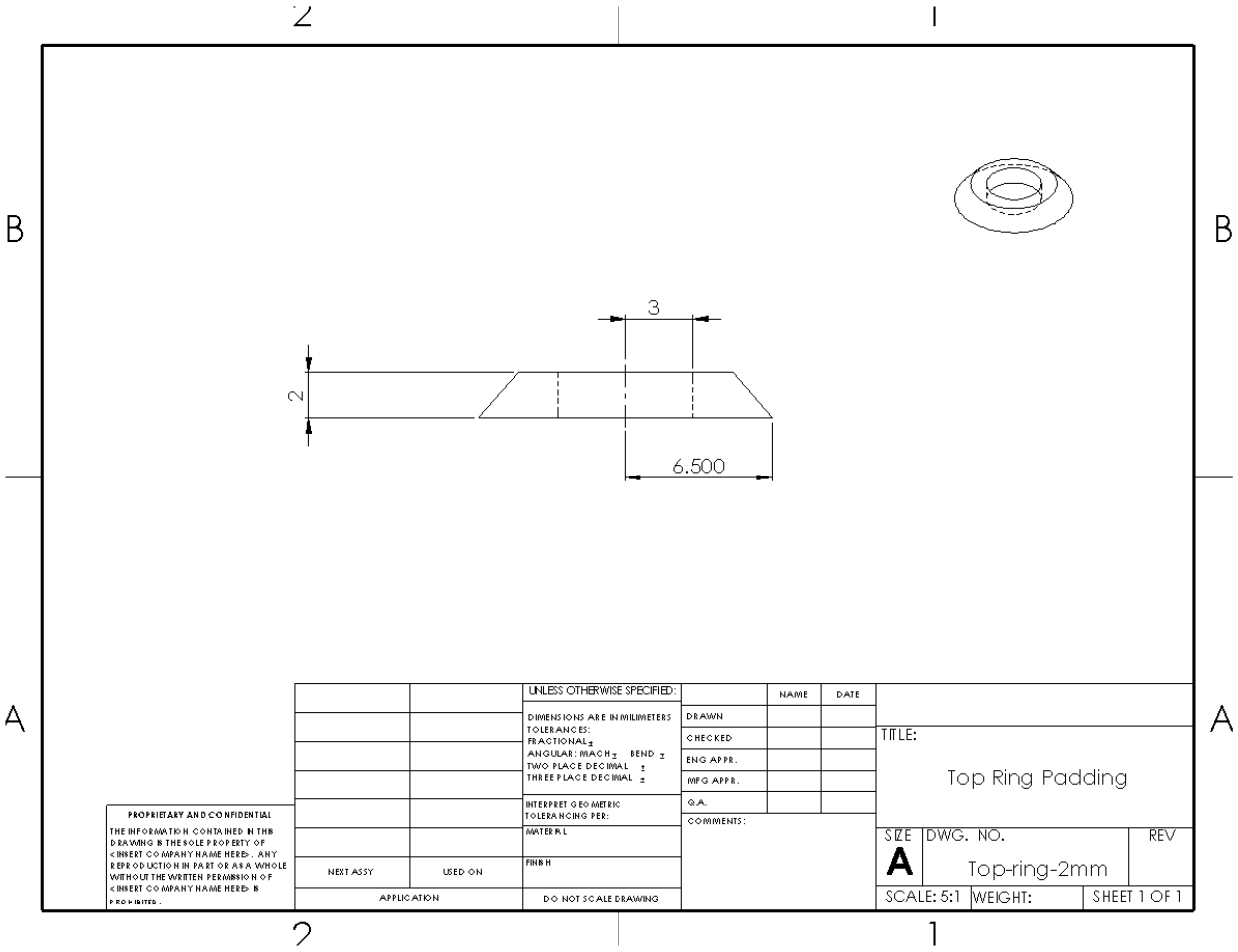
TITLE:
Base of Pin
SIZE
A
DWG. NO.
Base-22mm
REV
SCALE: 2:1
WEIGHT:
SHEET 1 OF 1


2
1
B
B
3
2
6.500
A
A
UNLESS OTHERWISE SPECIFIED:
DIMENSIONS ARE IN MILIMETERS
TOLERANCES:
FRACTIONAL ±
ANGULAR: MACH ± BEND ±
TWO PLACE DECIMAL ±
THREE PLACE DECIMAL ±
INTERPRET GEOMETRIC TOLERANCING PER:
MATERIAL
FINISH
DO NOT SCALE DRAWING
NAME
DATE
DRAWN
CHECKED
ENG APPR.
MFG APPR.
Q.A.
COMMENTS:
TITLE:
Top Ring Padding
SIZE
A
DWG. NO.
Top-ring-2mm
REV
SCALE: 5:1
WEIGHT:
SHEET 1 OF 1
NEXT ASSY
USED ON
APPLICATION
PROPRIETARY AND CONFIDENTIAL
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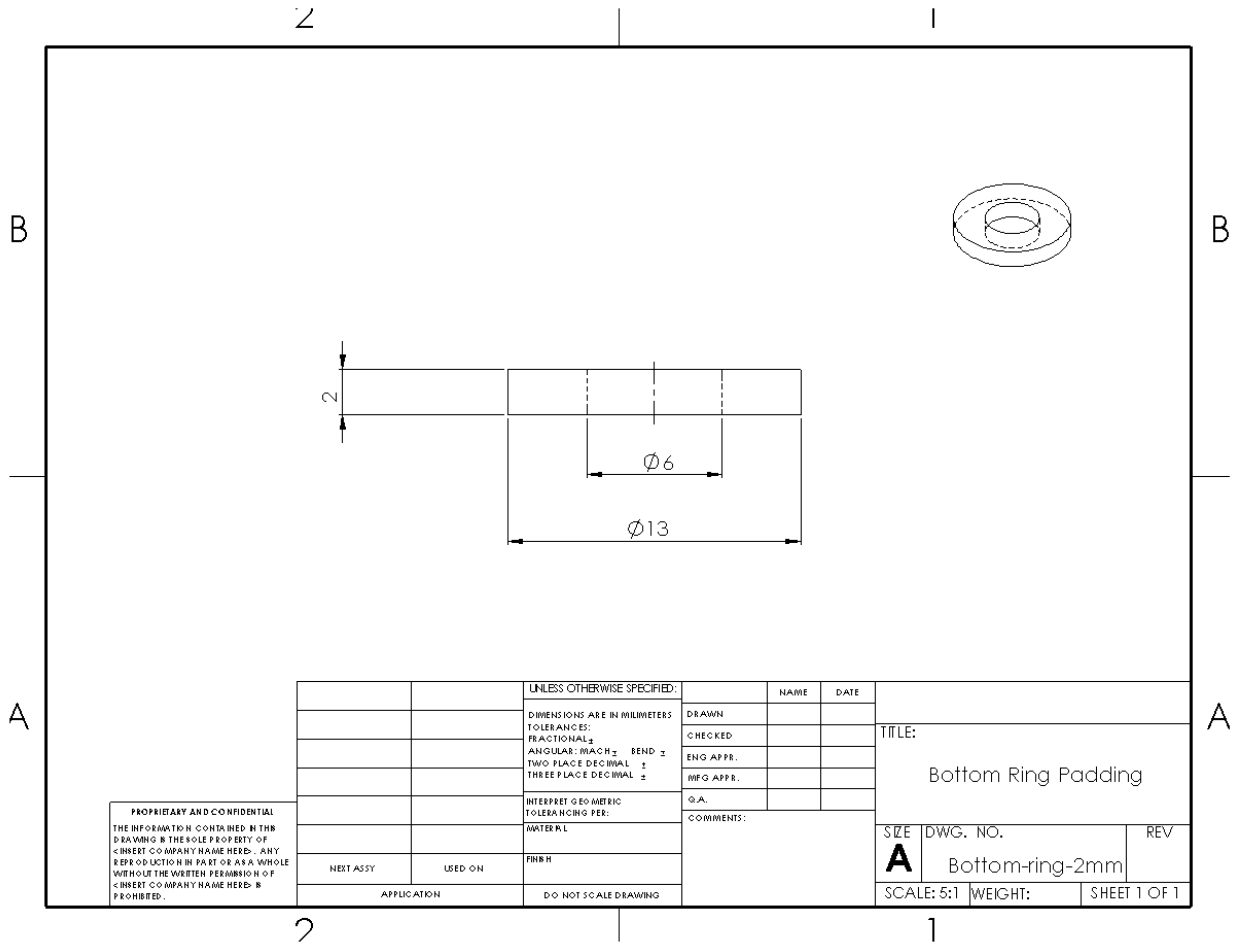
2
1



		UNLESS OTHERWISE SPECIFIED:		NAME	DATE
		DIMENSIONS ARE IN MILIMETERS TOLERANCES: FRACTIONAL ± ANGULAR: MACH ± BEND ± TWO PLACE DECIMAL ± THREE PLACE DECIMAL ±	DRAWN		
			CHECKED		
			ENG APPR.		
			MFG APPR.		
		INTERPRET GEOMETRIC TOLERANCING PER:	Q.A.		
		MATERIAL	COMMENTS:		
NEXT ASSY	USED ON	FINISH			
APPLICATION		DO NOT SCALE DRAWING			

PROPRIETARY AND CONFIDENTIAL
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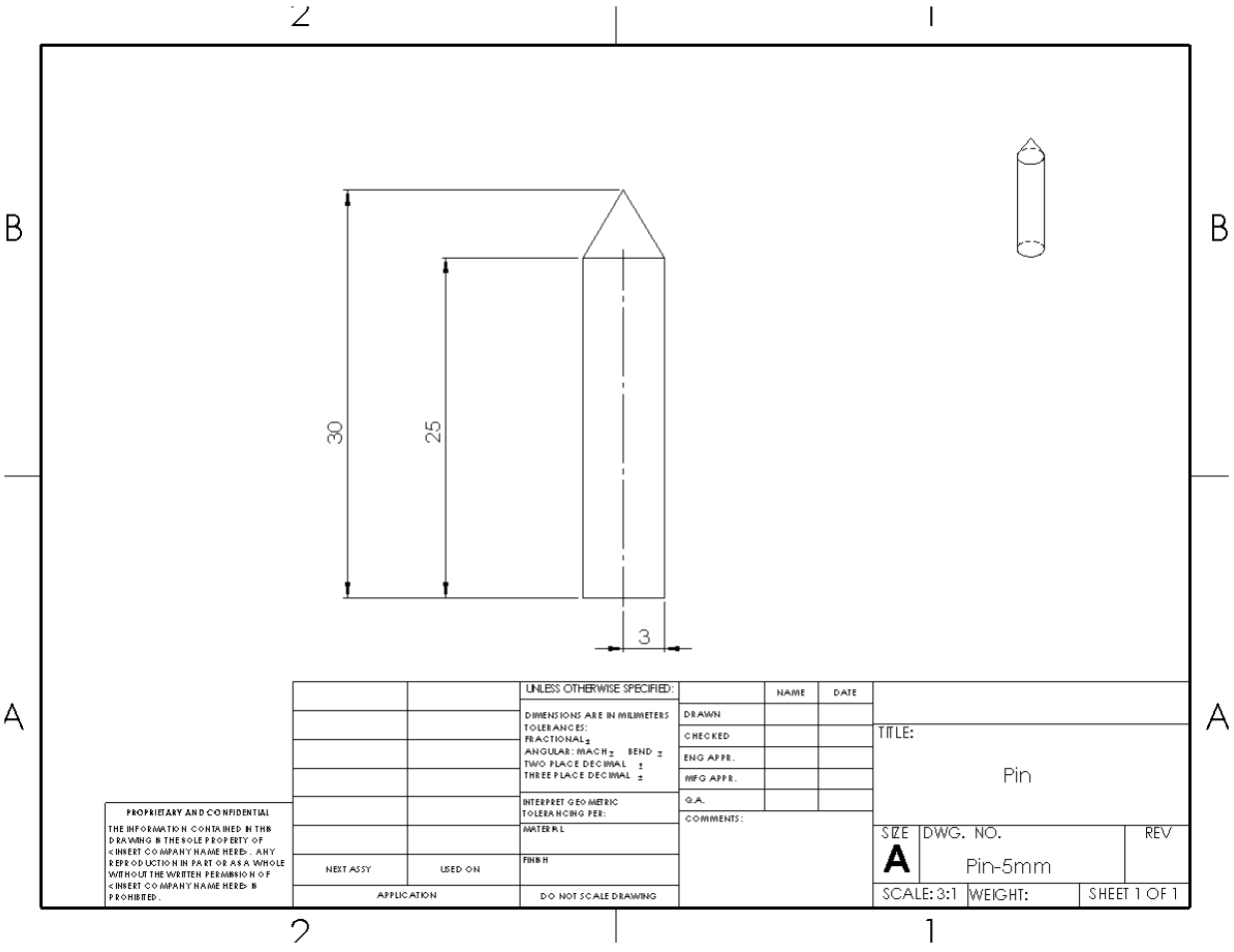
TITLE:
Bottom Ring Padding

SIZE	DWG. NO.	REV
A	Bottom-ring-2mm	
SCALE: 5:1	WEIGHT:	SHEET 1 OF 1


2
1
B
A
30
25
3
UNLESS OTHERWISE SPECIFIED:
DIMENSIONS ARE IN MILLIMETERS
TOLERANCES:
FRACTIONAL ±
ANGULAR: MACH ± BEND ±
TWO PLACE DECIMAL ±
THREE PLACE DECIMAL ±
INTERPRET GEOMETRIC TOLERANCING PER:
MATERIAL
FINISH
DO NOT SCALE DRAWING
NAME
DATE
DRAWN
CHECKED
ENG APPR.
MFG APPR.
Q.A.
COMMENTS:
NEXT ASSY
USED ON
APPLICATION
PROPRIETARY AND CONFIDENTIAL
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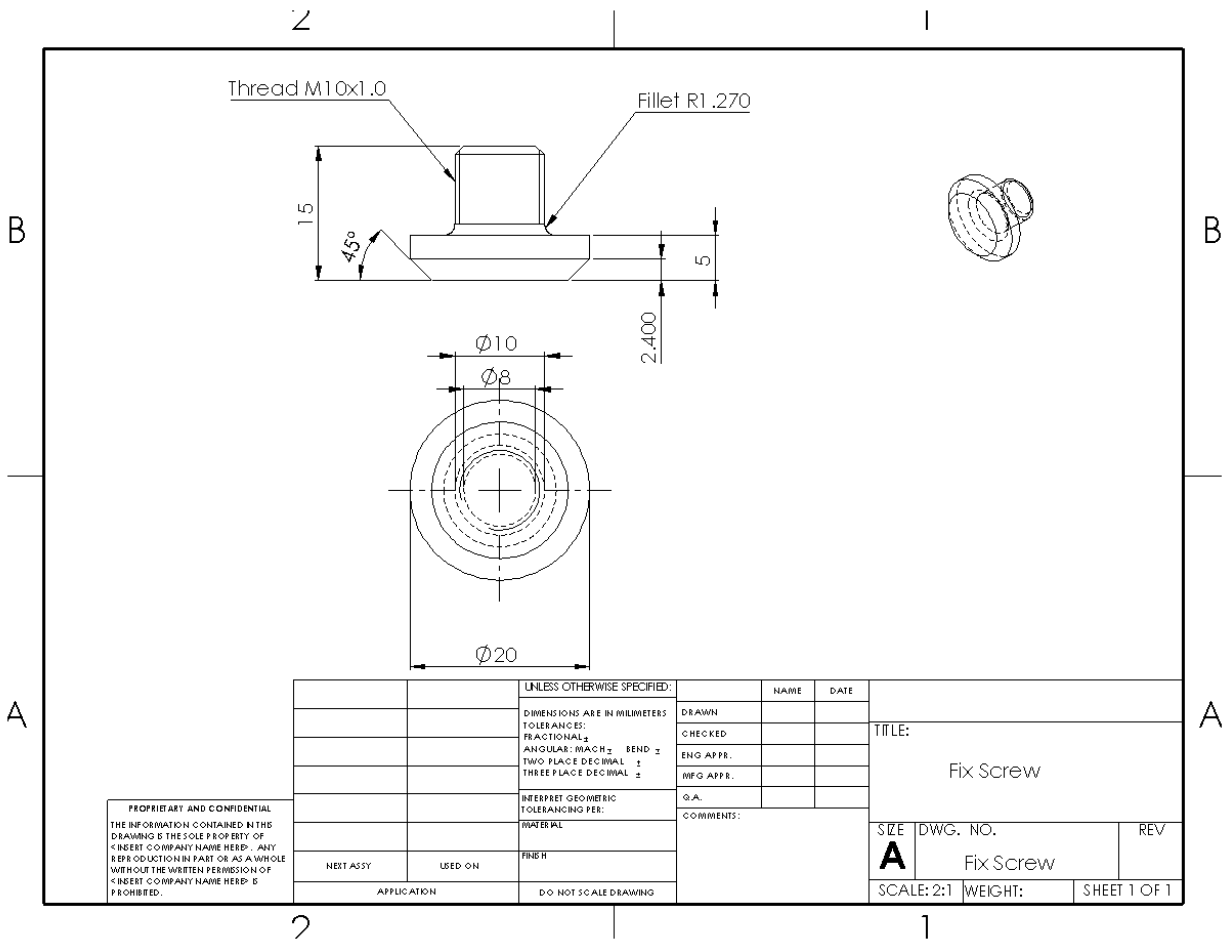
TITLE:
Pin
SIZE
A
DWG. NO.
Pin-5mm
REV
SCALE: 3:1
WEIGHT:
SHEET 1 OF 1


Thread M10x1.0
Fillet R1.270
15
45°
5
2.400
Ø10
Ø8
Ø20
UNLESS OTHERWISE SPECIFIED:
DIMENSIONS ARE IN MILIMETERS
TOLERANCES:
FRACTIONAL ±
ANGULAR: MACH ± BEND ±
TWO PLACE DECIMAL ±
THREE PLACE DECIMAL ±
INTERPRET GEOMETRIC TOLERANCING PER:
MATERIAL
FINISH
NEXT ASSY
USED ON
APPLICATION
DO NOT SCALE DRAWING
NAME
DATE
DRAWN
CHECKED
ENG APPR.
MFG APPR.
Q.A.
COMMENTS:
TITLE:
Fix Screw
SIZE
A
DWG. NO.
Fix Screw
REV
SCALE: 2:1
WEIGHT:
SHEET 1 OF 1
PROPRIETARY AND CONFIDENTIAL
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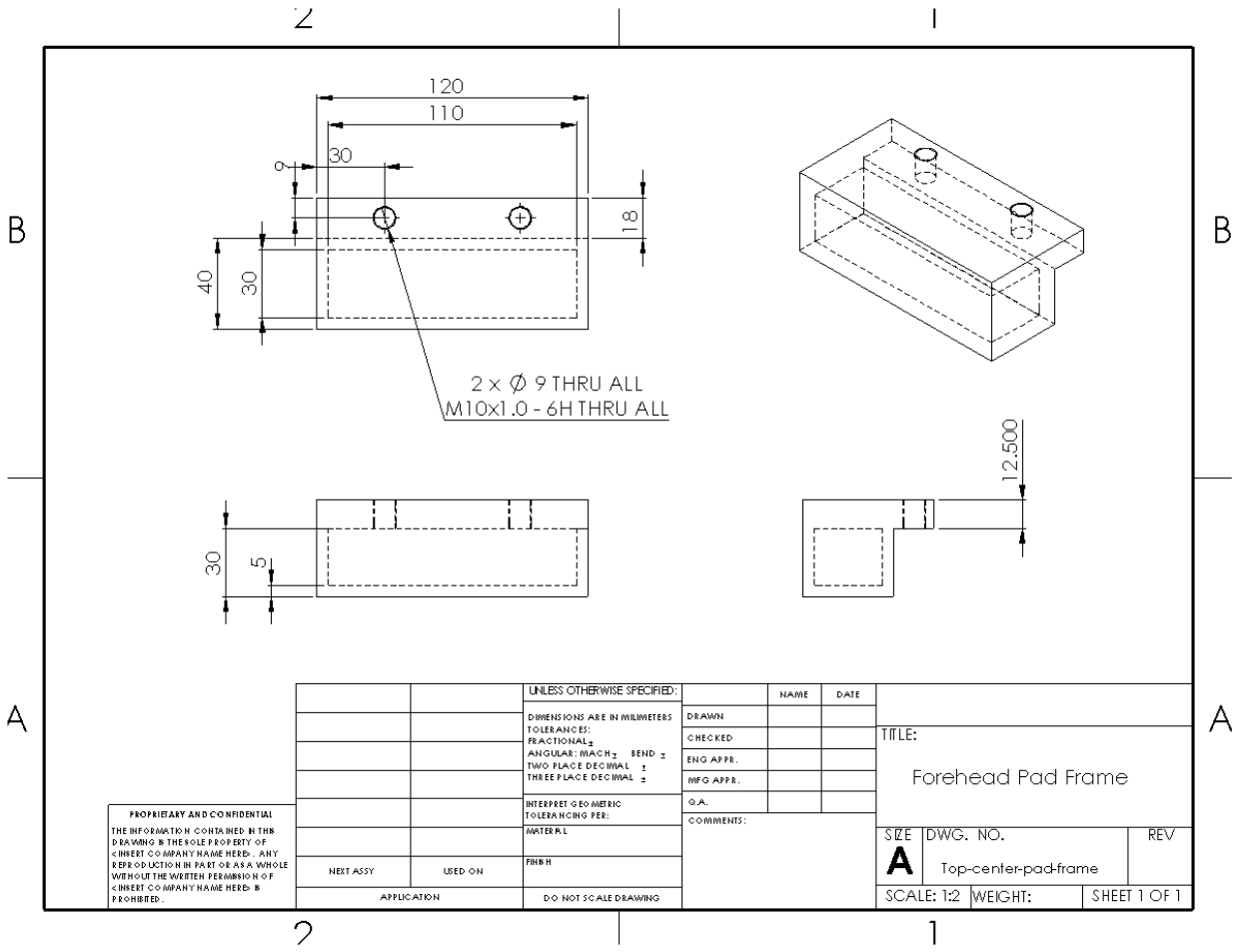
2
1
B
A
120
110
30
9
18
40
30
2 x Ø 9 THRU ALL
M10x1.0 - 6H THRU ALL
30
5
12.500
UNLESS OTHERWISE SPECIFIED:
DIMENSIONS ARE IN MILLIMETERS
TOLERANCES:
FRACTIONAL ±
ANGULAR: MACH ± BEND ±
TWO PLACE DECIMAL ±
THREE PLACE DECIMAL ±
INTERPRET GEOMETRIC TOLERANCING PER:
MATERIAL
FINISH
DO NOT SCALE DRAWING
NAME
DATE
DRAWN
CHECKED
ENG APPR.
MFG APPR.
Q.A.
COMMENTS:
TITLE:
Forehead Pad Frame
SIZE
A
DWG. NO.
Top-center-pad-frame
REV
SCALE: 1:2
WEIGHT:
SHEET 1 OF 1
NEXT ASSY
USED ON
APPLICATION
PROPRIETARY AND CONFIDENTIAL
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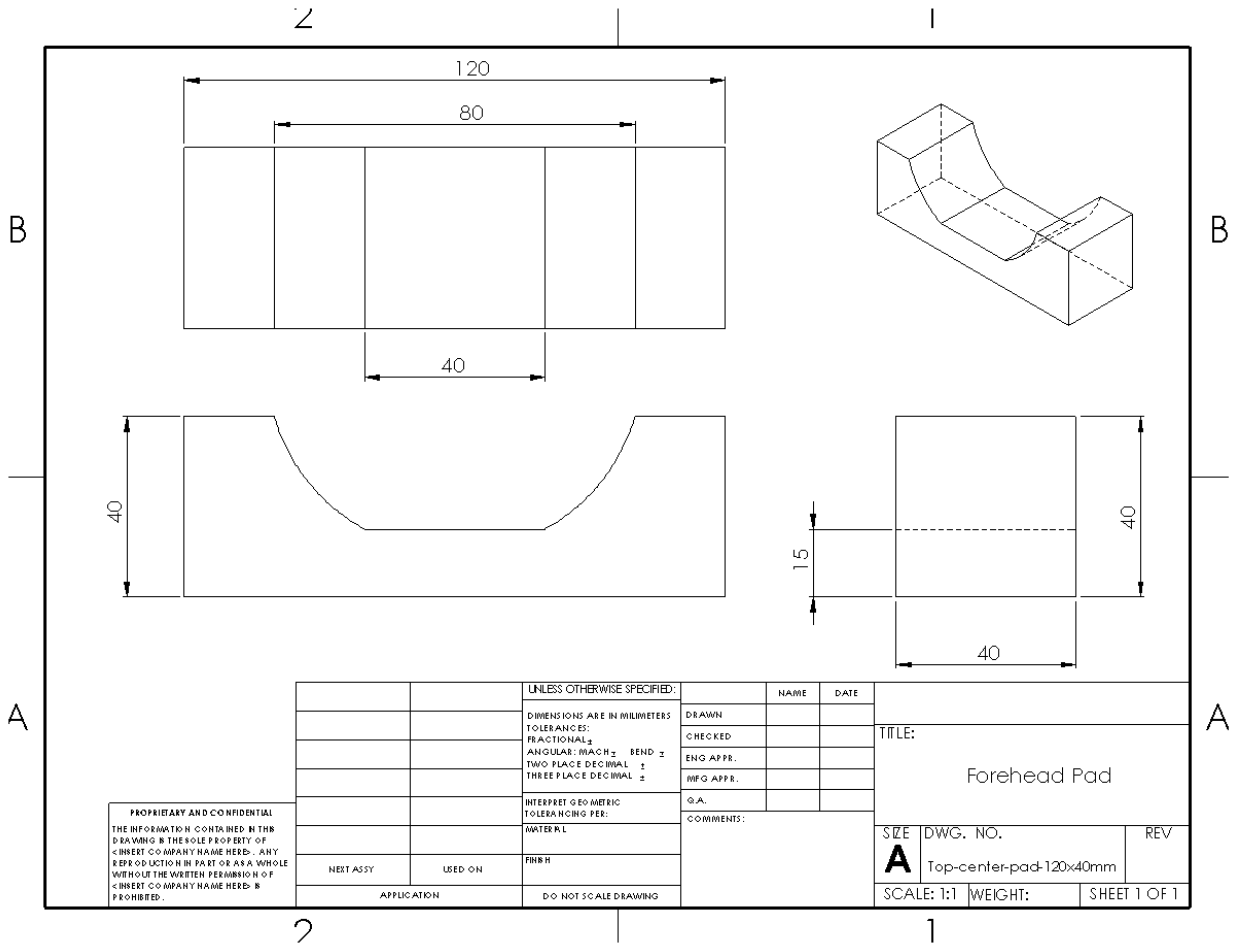
2
1
B
A
120
80
40
40
40
15
40
UNLESS OTHERWISE SPECIFIED:
DIMENSIONS ARE IN MILIMETERS
TOLERANCES:
FRACTIONAL ±
ANGULAR: MACH ± BEND ±
TWO PLACE DECIMAL ±
THREE PLACE DECIMAL ±
INTERPRET GEOMETRIC TOLERANCING PER:
MATERIAL
FINISH
DO NOT SCALE DRAWING
NAME
DATE
DRAWN
CHECKED
ENG APPR.
MFG APPR.
Q.A.
COMMENTS:
NEXT ASSY
USED ON
APPLICATION
PROPRIETARY AND CONFIDENTIAL
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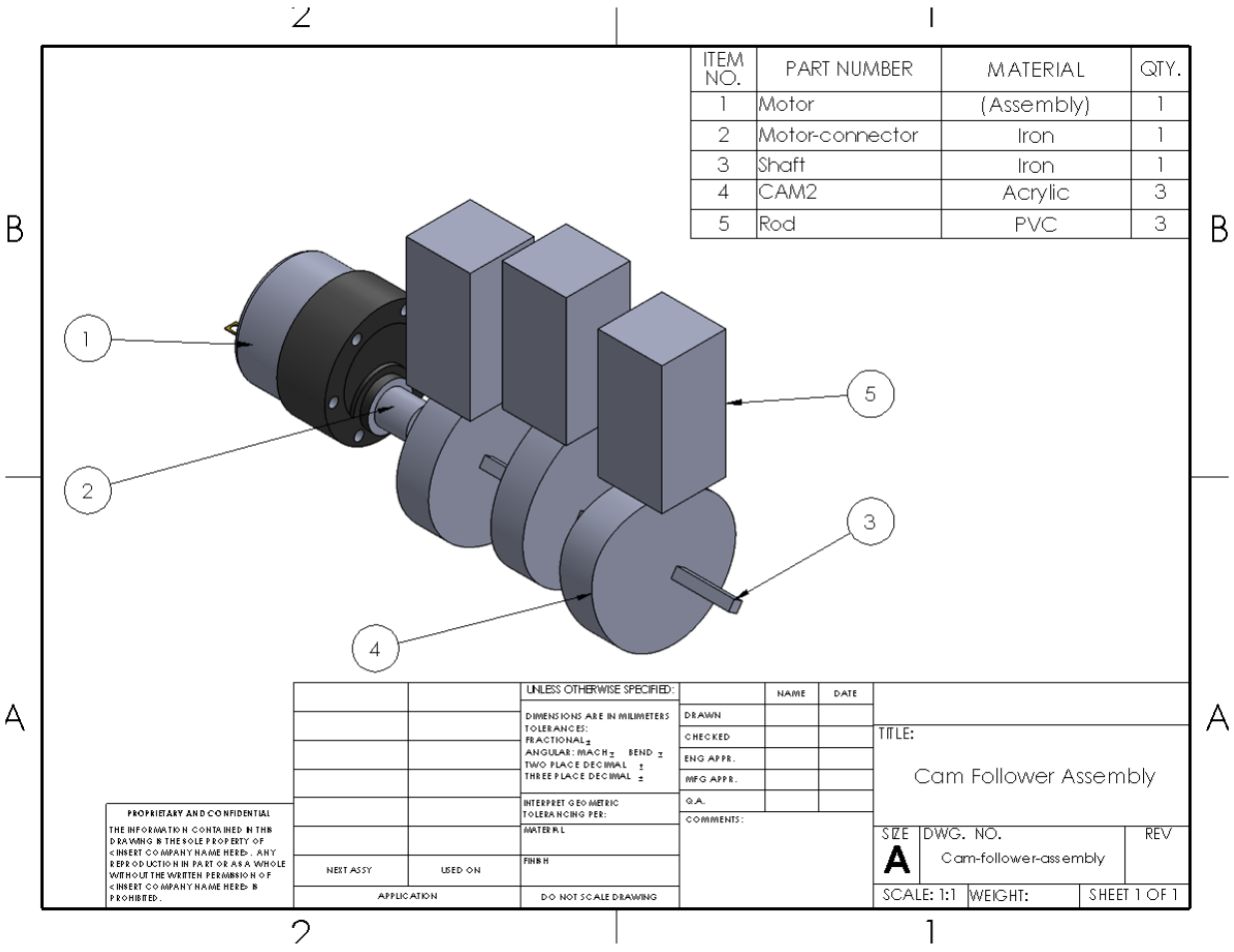
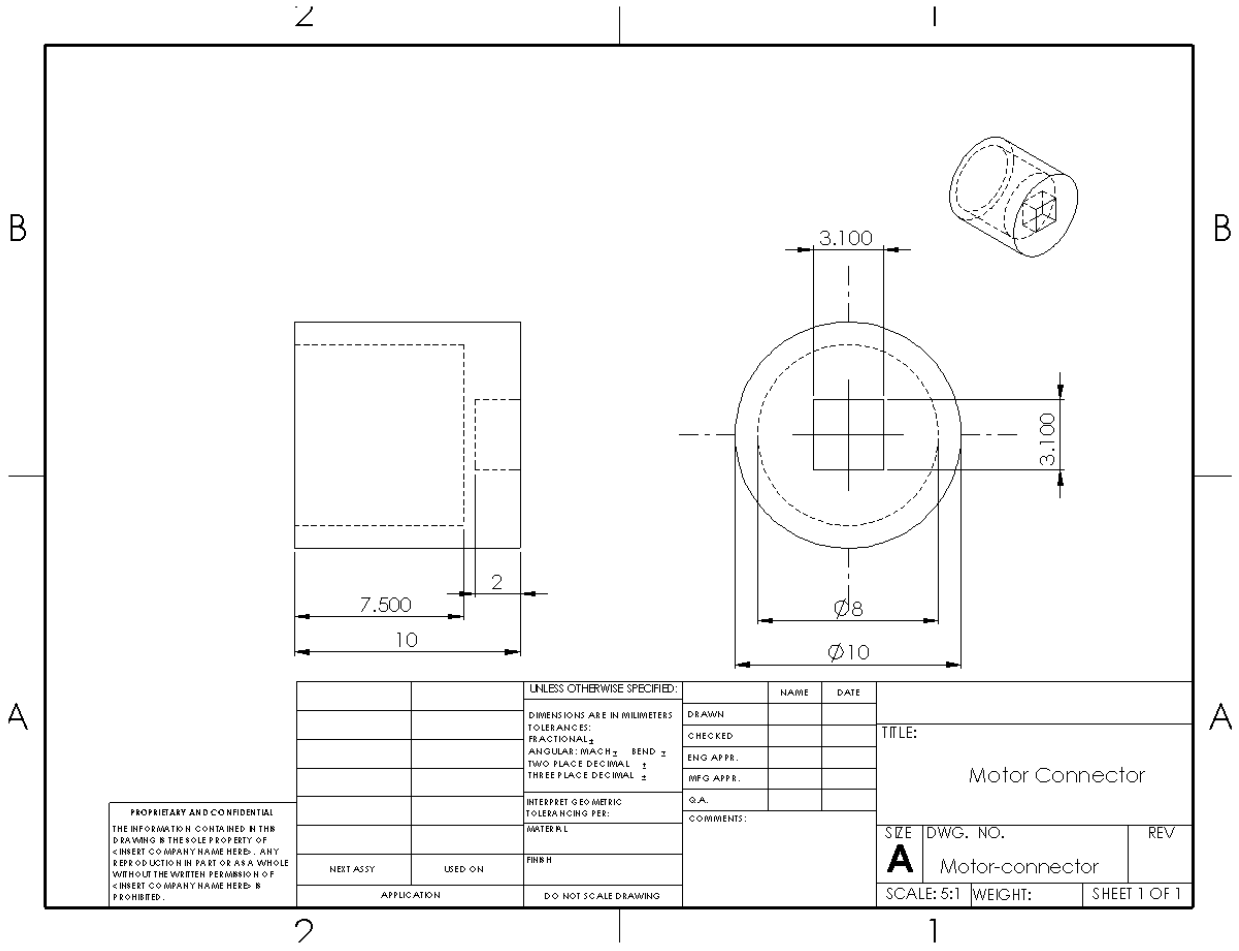
TITLE:
Forehead Pad
SIZE
A
DWG. NO.
Top-center-pad-120x40mm
REV
SCALE: 1:1
WEIGHT:
SHEET 1 OF 1



* The motor assembly was not created by the team. The motor design was obtained from free CAD sharing platform GrabCAD [58].


2
1
B
A
3.100
3.100
7.500
2
10
Ø8
Ø10
UNLESS OTHERWISE SPECIFIED:
DIMENSIONS ARE IN MILLIMETERS
TOLERANCES:
FRACTIONAL ±
ANGULAR: MACH ± BEND ±
TWO PLACE DECIMAL ±
THREE PLACE DECIMAL ±
INTERPRET GEOMETRIC TOLERANCING PER:
MATERIAL
FINISH
DO NOT SCALE DRAWING
NAME
DATE
DRAWN
CHECKED
ENG APPR.
MFG APPR.
Q.A.
COMMENTS:
NEXT ASSY
USED ON
APPLICATION
PROPRIETARY AND CONFIDENTIAL
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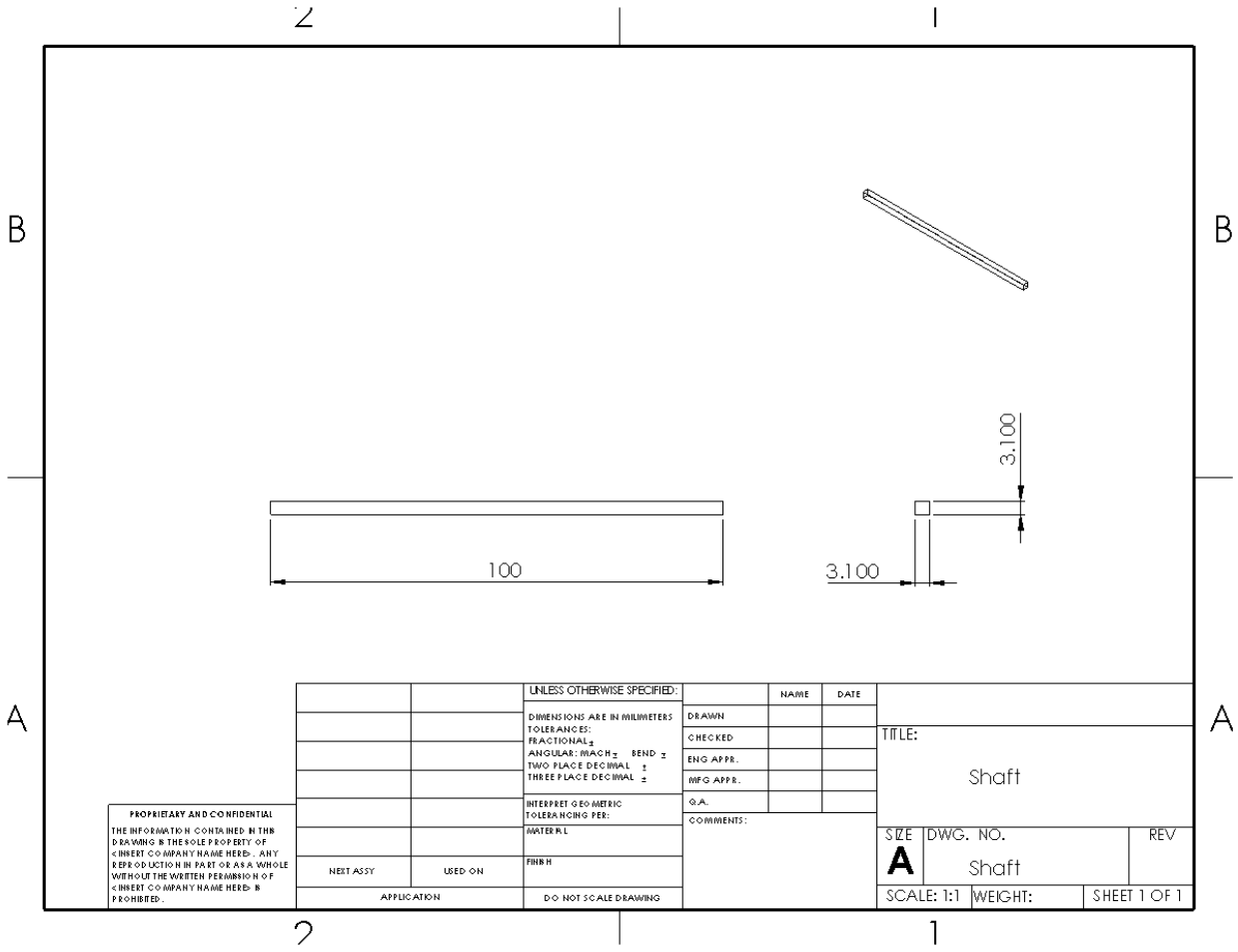
TITLE:
Motor Connector
SIZE
A
DWG. NO.
Motor-connector
REV
SCALE: 5:1
WEIGHT:
SHEET 1 OF 1


2
1
B
B
A
A
3.100
100
3.100
UNLESS OTHERWISE SPECIFIED:
DIMENSIONS ARE IN MILLIMETERS
TOLERANCES:
FRACTIONAL ±
ANGULAR: MACH ± BEND ±
TWO PLACE DECIMAL ±
THREE PLACE DECIMAL ±
INTERPRET GEOMETRIC TOLERANCING PER:
MATERIAL
FINISH
DO NOT SCALE DRAWING
NAME
DATE
DRAWN
CHECKED
ENG APPR.
MFG APPR.
Q.A.
COMMENTS:
NEXT ASSY
USED ON
APPLICATION
PROPRIETARY AND CONFIDENTIAL
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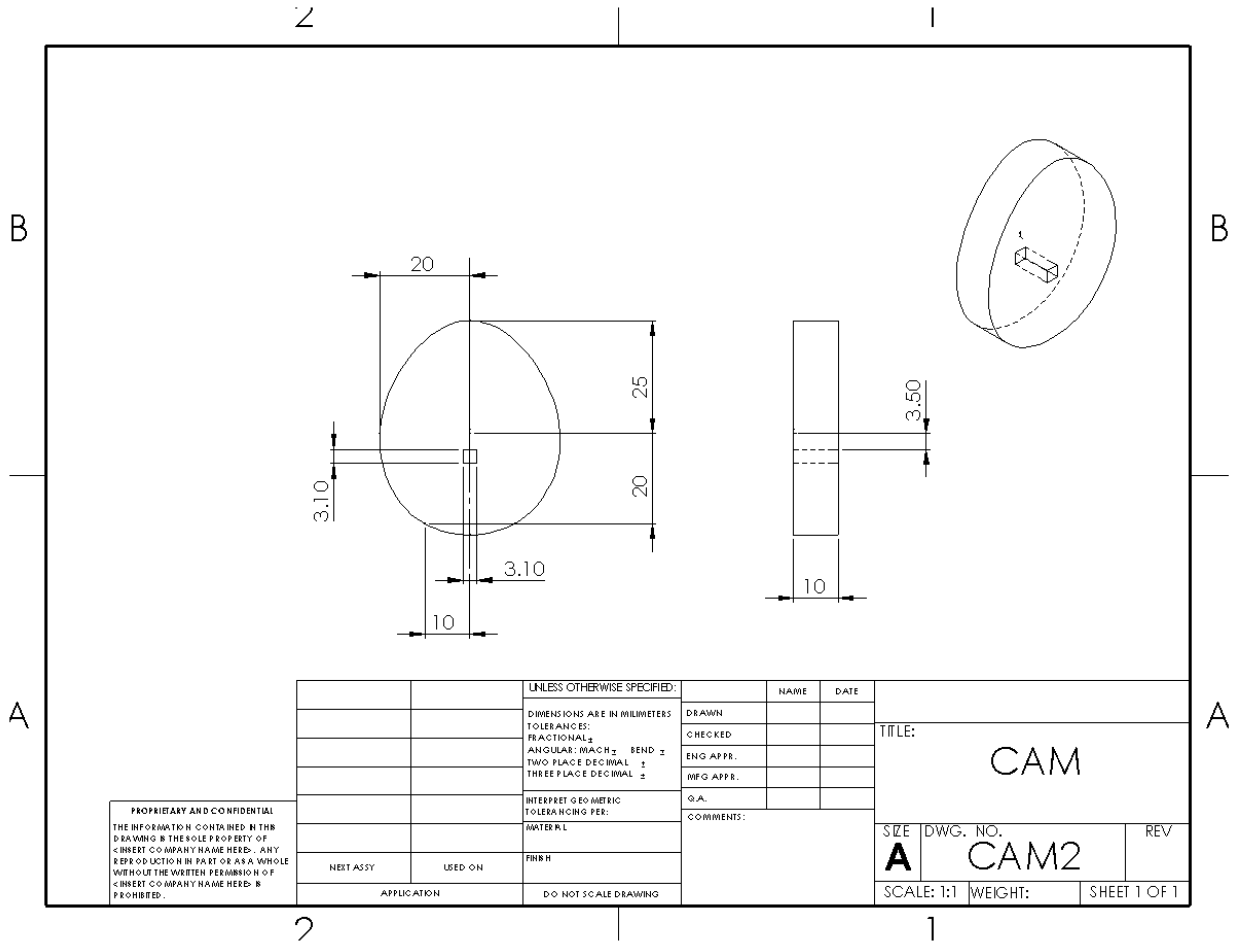
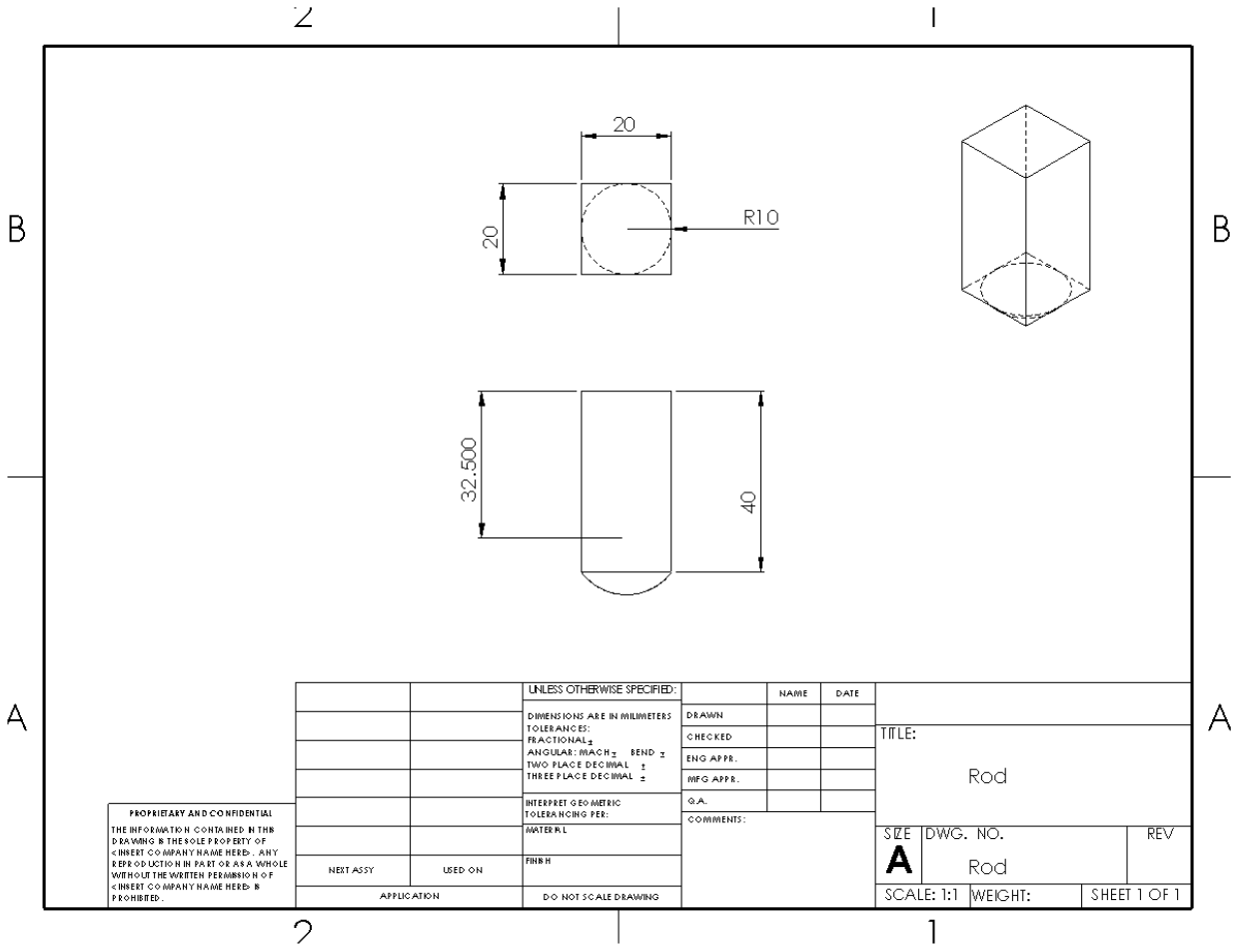
TITLE:
Shaft
SIZE
A
DWG. NO.
Shaft
REV
SCALE: 1:1
WEIGHT:
SHEET 1 OF 1


20
25
20
3.10
3.10
10
3.50
10
UNLESS OTHERWISE SPECIFIED:
DIMENSIONS ARE IN MILLIMETERS
TOLERANCES:
FRACTIONAL ±
ANGULAR: MACH ± BEND ±
TWO PLACE DECIMAL ±
THREE PLACE DECIMAL ±
INTERPRET GEOMETRIC TOLERANCING PER:
MATERIAL
FINISH
DO NOT SCALE DRAWING
NAME
DATE
DRAWN
CHECKED
ENG APPR.
MFG APPR.
Q.A.
COMMENTS:
NEXT ASSY
USED ON
APPLICATION
PROPRIETARY AND CONFIDENTIAL
THE INFORMATION CONTAINED IN THIS DRAWING IS THE SOLE PROPERTY OF <INSERT COMPANY NAME HERE>. ANY REPRODUCTION IN PART OR AS A WHOLE WITHOUT THE WRITTEN PERMISSION OF <INSERT COMPANY NAME HERE> IS PROHIBITED.
TITLE:
CAM
SIZE
A
DWG. NO.
CAM2
REV
SCALE: 1:1
WEIGHT:
SHEET 1 OF 1



		UNLESS OTHERWISE SPECIFIED:		NAME	DATE	
		DIMENSIONS ARE IN MILIMETERS TOLERANCES: FRACTIONAL ± ANGULAR: MACH ± BEND ± TWO PLACE DECIMAL ± THREE PLACE DECIMAL ±	DRAWN			
			CHECKED			TITLE: Rod
			ENG APPR.			
			MFG APPR.			
		INTERPRET GEOMETRIC TOLERANCING PER:	Q.A.			
		MATERIAL	COMMENTS:			SIZE A / DWG. NO. Rod / REV
NEXT ASSY	USED ON	FINISH				
APPLICATION		DO NOT SCALE DRAWING				SCALE: 1:1 / WEIGHT: / SHEET 1 OF 1