THE RESEARCH AND DESIGN OF SPINAL ORTHOSIS TO CREATE A PATIENT COMPLIANT BACK BRACE FOR POST OPERATIVE PATIENTS

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THE RESEARCH AND DESIGN OF SPINAL ORTHOSIS TO CREATE A PATIENT COMPLIANT BACK BRACE FOR POST OPERATIVE PATIENTS

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Michael Ryan Hicks was born on October 12, 1983 in Birmingham, AL. The author has lived in Birmingham his entire life and was raised by his mother Jeanette Hicks. In 1997, the author attended the Alabama School of Fine Arts his 7^{th} thru 12^{th} grade year. Upon graduation in 2002, the author enrolled in Auburn University and entered the Department of Industrial Design. In the spring semester of 2006, the author received his Bachelor of Industrial Design from Auburn University. Michael shortly after entered the graduate program at Auburn in the summer of 2006, while receiving a minority scholarship from the department. Michael finished his academic career by receiving his Master of Industrial Design in May 2009. While at Auburn, Michael has been a member and later on president of Ministries in Action, a non-denominational Christian organization at Auburn. Michael has also served as a graduate teaching assistant for 4 semesters and a teaching assistant for a high school design camp for 3 summers. In fall 2007, Michael received the award for Outstanding Graduate student.

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There are 11,000 new injuries that affect the back each year. The injuries sustained are often serious and require surgical treatment. The treatment, along with the rehabilitation process, can often be physically and psychologically painful. Patients must often wear back braces which can cause a patient's life to become very uncomfortable, making everyday tasks difficult. While medical devices have the responsibility to correct injury, they also have the responsibility of keeping the patient's lifestyle in mind. The purpose of this thesis is to create a back brace for post operative patients and to focus on issues of patient compliance. The patient's discomfort is not just an annoyance, but it is a factor that can effect if the device is used properly. Then the issue becomes a problem for the patient and the physician. If the device is not worn properly, the patient will not fully recover. This study focuses on post surgical spinal injuries. This study includes input from physicians and research that pinpoints the areas where improvements needed to be made to improve the design of this type of orthopedic device. The result of this research is a design that improves the overall construction of this type of orthopedic device and makes the life of a recovering patient physically and mentally easier.

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1. INTRODUCTION TO PROBLEM

1.1 Problem Statement

Injuries to the back are one of the most common injuries in the United States. According to the National Spinal Cord Statistical Center (2006) there are approximately 11,000 new cases of spinal cord injuries each year (Spinal Cord Injury Facts and Figures at a Glance, 2006). In the year 2003, there were 56 million physician visits for musculoskeletal injuries, with 31 million due to back problems (Orthopaedic Fast Facts, 2003). The national scope of these injuries includes back pain, soreness, fractures, scoliosis, and tumors.

The severity of certain back injuries may require an individual to undergo spinal surgery. Advances in technology in the field of orthopedics have made spinal surgery a fairly successful option. Any type of surgery is accompanied by a healing process. In terms of spine surgery, that healing process usually includes a strong rehabilitation process. While healing from back surgery, the patient may be required to wear spinal orthosis, or a back brace to help protect, stabilize, or prevent further injury for a period of time that could last 3-6 months. The “back brace” usually associated with post surgical rehabilitation is a two piece device that can be applied while the patient is in bed. Back braces are generally effective in meeting these functional tasks. The physical aspects of back braces can make life for the recovering patient extremely uncomfortable.

Gene Bernardoni, of *Ballert Orthotics and Prosthetics,* lists the following three reasons patients avoid wearing their brace:

1. The brace is uncomfortable to wear
2. It causes embarrassment
3. The patient does not know how to wear the brace properly (Bernardoni).

Back braces are often obtrusive, and hot. Back braces are also prone to move out of position during everyday tasks such as sitting in a chair. When the brace moves out of position, the patient may readjust the brace numerous times. Constant readjustments may lead the patient to configure the device in a manner in which it will not perform its intended purpose. Sometimes a patient may experience pressure sores that may form from contact, and the application of the brace can be difficult while lying in bed. The combination of all these issues can seriously aggravate an already sensitive patient to the point where they don't wear the brace correctly or they don't wear it at all.

Orthopedic patients are in need of a post surgical brace that addresses issues that seem small to physicians, but are large in the lives of the patient. The implementation of design into the process of fabricating a post surgical back brace can lead to a device that meets all of a patients physical, cosmetic, and social needs as well as meeting the physician's functional goals. The exploration of fabrication, materials, and overall functionality will expose issues that can be corrected to create comfortable solutions for patients and physicians.

1.2 Need for Study

The need for study is to create a product for people that have had back surgery and are required to wear spinal orthosis as a part of their rehabilitation process. This area of physical rehabilitation has made progress over the years but still has many flaws that need correction especially in terms of meeting all of the patient's needs. Injuries to the spine can be treated due to advances in technology but the treatment is sometimes an extremely uncomfortable experience because of orthoses that don't address all of the patient's needs. Orthopedic nurse Mary Powell states that the treatment of a patient is incomplete unless it includes consideration of him as a whole person and as a member of society (Powell, Orthopedic Nursing and Rehabilitation, 1986). This can include physical as well as social needs. They often have problems with fit, adjustability, and bulkiness that interfere with the patients' overall quality of life. There are some factors that cannot be changed because they are necessary, but some of these issues lead to people not wearing their braces correctly and ultimately prolonging recovery. A patient that has been through back surgery should have requirements suited to their weakened and sensitive state. The efficient use of industrial design could easily improve current bracing technology for patients in this scenario. Designers can bridge together the importance of the function of the device while still considering the effects on the patient. A study in this area that can correct current problems with these devices would be beneficial for patients as well as the doctor. The physician will no longer have to worry about the patient wearing the device correctly and the patients will be much more comfortable despite their situation. A study in physical rehabilitation devices can help make the recovery process for patients a lot less uncomfortable as well as provide physicians with a process that satisfies functional necessities.

1.3 Objectives of Study

- Study the injuries that require the use of orthopedic devices
- Study the current products available for back injuries and their functions
- Define the problems in the product as well as all the processes leading up to the use of the product
- Summarize the problems into a checklist for designing the product, that eliminates problems and introduces new solutions
- Build a product from the information validated by findings research

1.4 Definition of Terms

Allograft Bone – Sterile bone derived from another human which is used for grafting procedures.

Anterior – The front portion of the body. It is often used to indicate the position of one structure relative to another.

Autogenous Bone – Bone originating from the same individual; i.e. an individual's own bone.

Autograft Bone – Bone transplanted from one part to another part of the body in the same individual.

Bone – The hard tissue that provides structural support to the body. It is primarily composed of hydroxyapatite crystals and collagen. Individual bones may be classed as long, short, or flat.

Bone Graft – Bone which is harvested from one location in an individual and placed in another individual (allograft bone) or in a different location in the same individual (autogenous bone).

Bone Marrow – The tissue contained within the internal cavities of the bones. A major function of this tissue is to produce red blood cells.

Bone Plate – Usually a relatively thin metal device which is affixed to bone via screws. Bone plates are used to immobilize bones or bone fragments such that healing can occur.

Bone Screw – A threaded metal device which is inserted into bone. The functions of bone screws are to immobilize bones or bone fragments or to affix other medical devices, such as metal bone plates, to bones.

Brace – A splint, a device which is used to assist weight bearing. Are also called calipers and leg irons. Some spinal supports come under this heading.

Cartilage – The hard, thin layer of white glossy tissue that covers the end of bone at a joint. This tissue allows motion to take place with a minimum amount of friction.

Centrum – The body of a vertebra.

Cervical – The neck region of the spine containing the first seven vertebrae.

Coccyx – The region of the spine below the sacrum. It is also known as the tailbone.

Compression – The act of pressing together – refers to the loss of vertebral body height either anteriorly, posteriorly or both.

Coronal – Refers to a section that divides the body into anterior and posterior portions.

Disc (Intervertebral) – The tough, elastic structure that is between the bodies of spinal vertebrae. The disc consists of an outer annulus fibrosus enclosing an inner nucleus pulposus.

Disc Degeneration – The loss of the structural and functional integrity of the disc.

Discectomy – Surgical removal of part or all of an intervertebral disc.

End Vertebra – i. The most cephalad (i.e. toward the head) vertebra of a curve, whose superior surface tilts maximally toward the concavity of the curve. ii. The most caudad (i.e. toward the coccyx) vertebra whose inferior surface tilts maximally toward the concavity of the curve.

Epidural – Situated outside the thin, tough dural membrane that surrounds the brain and spinal cord.

Excision – Removal by cutting away material.

Facet – A posterior structure of a vertebra which articulates with a facet of an adjacent vertebra to form a facet joint that allows motion in the spinal column. Each vertebra has two superior and two inferior facets.

Fibrosis – The replacement of normal tissue with scar tissue.

Foramen – A natural opening or passage in bone.

Fracture – A disruption of the normal continuity of bone.

Fusion – Union or healing of bone.

Herniated Disc – Extrusion of part of the nucleus pulposus material through a defect in the annulus fibrosus.

Hook – For spinal applications, a metallic medical device used to connect spinal structures to a rod.

Iliac Bone – A part of the pelvic bone that is above the hip joint and from which autogenous bone grafts are frequently obtained.

Iliac Crest – The large, prominent portion of the pelvic bone at the belt line of the body.

Immobilization – Limitation of motion or fixation of a body part usually to promote healing.

Intervertebral Disc – See Disc.

Inferior – Situated below or directed downward.

Joint – The junction or articulation of two or more bones that permits varying degrees of motion between the bones.

Kyphosis – An abnormal increase in the normal kyphotic curvature of the thoracic spine.

Lamina – An anatomical portion of a vertebra. For each vertebra, two lamina connect the pedicles to the spinous process as part of the neural arch.

Lateral – Situated away from the midline of the body.

Ligament – A band of flexible, fibrous connective tissue that is attached at the end of a bone near a joint. The main function of a ligament is to attach bones to one another, to provide stability of a joint, and to prevent or limit some joint motion.

Lordosis – An abnormal increase in the normal lordotic curvature of the lumbar spine.

Lumbar – The lower part of the spine between the thoracic region and the sacrum. The lumbar spine consists of five vertebrae.

Medial – Situated closer to the midline of the body.

Minimally Invasive Surgery – Surgery requiring small incision(s), usually performed with endoscopic visualization.

Nucleus Pulposus – The semi–gelatinous tissue in the center of an intervertebral disc. It is surrounded and contained by the annulus fibrosus which prevents this material from protruding outside the disc space.

Orthopaedics (also Orthopedics) – The medical specialty involved in the preservation and restoration of function of the musculoskeletal system that includes treatment of spinal disorders and peripheral nerve lesions.

Orthotics- Orthotics is the science of fabrication and fitting of a splint to an existing part of the body.

Orthotist- An orthotist is one who is qualified to measure fit and supply all types of orthoses.

Ossification – The process of forming bone in the body.

Osteoporosis – A disorder in which bone is abnormally brittle, less dense, and is the result of a number of different diseases and abnormalities.

Pedicle – The part of each side of the neural arch of a vertebra. It connects the lamina with the vertebral body.

Pelvic Obliquity – Deviation of the pelvis from the horizontal in the frontal plane. Fixed pelvic obliquities can be attributed to contractures either above or below the pelvis.

Physical Therapy – The treatment consisting of exercising specific parts of the body such as the legs, arms, hands or neck, in an effort to strengthen, regain range of motion, relearn movement and/or rehabilitate the musculoskeletal system to improve function.

Physiology – The science of the functioning of living organisms, and of their component systems or parts.

Posterior – Located behind a structure, such as relating to the back side of the human body.

Rod – In spinal applications, a slender, metal implant which is used to immobilize and align the spine.

Rotation – The movement of one vertebra to another about its normal or abnormal coronal axis.

Sacrum – A part of the spine that is also part of the pelvis. It articulates with the ilia at the sacroiliac joints and articulates with the lumbar spine at the lumbosacral joint. The sacrum consists of five fused vertebrae that have no intervertebral discs.

Sagittal – Refers to a lengthwise cut that divides the body into right and left portions.

Scoliosis – Lateral (sideways) curvature of the spine..

Skeleton – The rigid framework of bones that gives form to the body, protects and supports the soft organs and tissues, and provides attachments for muscles.

Spinal Disc – See Disc (Intervertebral).

Spinal Column – See Spine.

Spinal Fusion – A surgical procedure to permanently join bone by interconnecting two or more vertebrae in order to prevent motion (see Arthrodesis).

Spinal Canal – The bony channel that is formed by the intravertebral foramen of the vertebrae and in which contains the spinal cord and nerve roots.

Spinal Cord – The longitudinal cord of nerve tissue that is enclosed in the spinal canal. It serves not only as a pathway for nervous impulses to and from the brain, but as a center for carrying out and coordinating many reflex actions independently of the brain.

Spine – The flexible bone column extending from the base of the skull to the tailbone. It is made up of 33 bones, known as vertebrae. The first 24 vertebrae are separated by discs known as intervertebral discs, and bound together by ligaments and muscles. Five vertebrae are fused together to form the sacrum and 4 vertebrae are fused together to form the coccyx. The spine is also referred to as the vertebral column, spinal column, or backbone.

Splint- a device which is applied to protect and/or immobilize a part and to restrict movement.

Spondylitis – Inflammation of vertebrae.

Spondylolisthesis – A defect in the construct of bone between the superior and inferior facets with varying degrees of displacement so the vertebra with the defect and the spine above that vertebra are displaced forward in relationship to the vertebrae below. It is usually due to a developmental defect or the result of a fracture.

Spondylolysis – Displacement of one vertebra over another with fracture of a posterior portion of the vertebra. A defect in the neural arch between the superior and inferior facets of vertebrae without separation at the defect and therefore no displacement of the vertebrae. It may be unilateral or bilateral and is usually due to a developmental defect but may be secondary to a fracture.

Stainless Steel – Iron–based metal containing chromium that is highly resistant to stain, rust, and corrosion. Certain grades of stainless steel are commonly used to make surgical implants and instruments.

Tendon – The fibrous band of tissue that connects muscle to bone. It is mainly composed of collagen.

Thoracic – The chest level region of the spine that is located between the cervical and lumbar vertebrae. It consists of 12 vertebrae which serve as attachment points for ribs.

Titanium – A metallic element used to make surgical implants.

Transplant – The implantation of bone tissue, as in grafting, from one part of the body to another, or from one individual to another. Transplant also refers to the transfer of an organ such as a kidney or heart from one individual to another.

Transverse – Refers to a cut that divides the body into superior and inferior portions.

Vertebra – One of the 33 bones of the spinal column. A cervical, thoracic, or lumbar vertebra has a cylindrically–shaped body anteriorly and a neural arch posteriorly (composed primarily of the laminae and pedicles as well as the other structures in the posterior aspect of the vertebra) that protects the spinal cord. The plural of vertebra is vertebrae.

Vertebral End–Plates – The superior and inferior plates of cortical bone of the vertebral body adjacent to the intervertebral disc.

Wire – Metal thread available in various diameters and various degrees of stiffness and is generally used in surgery to transfix fractured bone.

1.5 Literature Review

The field of Medicine is a continuously evolving area. Great advances in medicine continue to help people overcome and recover from serious injury. Technology continues to grow and medical devices are starting to become more efficient in their function. While the usability and effectiveness of devices have increased, certain needs of the patient are ignored. This can be seen most notably in orthotic devices for back injuries. Braces and splints, which are used to immobilize, protect, or correct injured limbs, are still uncomfortable and awkward for patients to use and wear (Powell, Orthopedic Nursing and Rehabilitation, 1986, p. 248). The discomfort and awkwardness of these devices are troublesome in general, but they can be even more problematic for patients that require surgery with the used of an orthotic device. This type of medical device is the responsibility of the physician and orthotist. While the devices do their job, the design aspect of the devices does not take into consideration the full spectrum of patients using the device. The process of design for a medical device includes medical requirements, federal regulations, and material constraints. The process is so focused on the technical side of the equation that some psychological aspects of the design are not properly explored. By identifying the current process one will find that "design" skills can be used to improve the current system, especially concerning the area of spinal orthotics. The complete integration of design in a new process in the production of medical devices for spinal orthotic devices can correct current flaws in the devices and better incorporate the needs of all types of patients.

1.5.1 Injury

The need to improve spinal orthoses is justified by the high risk of back injury in the U.S. According to the *American Academy of Orthopedic Surgeons* injuries to the back or spine are the most common muscoskeletal injuries (Orthopaedic Fast Facts, 2003). There are an approximately 11,000 newly reported injuries to the spine each year in the U.S. (Spinal Cord Injury Facts & Statistics, 2002)This figure only accounts for the number of reported injuries and does not account for injuries that have not been reported (Spinal Cord Injury Facts & Statistics, 2002). The cause of injury ranges from a variety of different circumstances. They can take place during normal activities or during extreme physical tasks. Motor vehicle accidents, which is the number one cause of back injury, accounts for 44% of all back injuries (Figure1). Acts of violence, falls, and

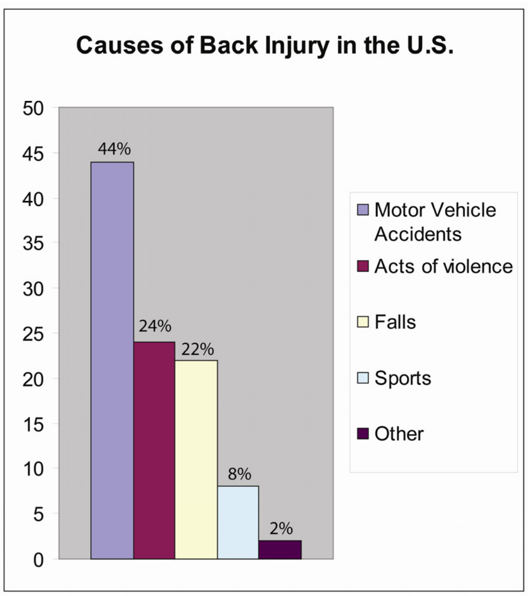


Figure 1. Causes of Back Injury

sports round out the most common cause of injuries to the back (Figure 1). The age group that is most affected by back injuries is people between the ages of 16 and 30 (Spinal Cord Injury Facts & Statistics, 2002). The cause of injury starts to change as the age of the individual changes. After an individual reaches the age of 45, "falls" becomes the second most common cause of injury (Spinal Cord Injury Facts & Statistics, 2002). Injuries caused by acts of violence and sports also decreases as age increases (www.sci-info.com). Another interesting fact about back injuries is the large disparity of injury among males and females. Men account for 82% (Figure 2) of back injuries while women only account for 18% of injury (Figure 2). The severity of the injury can leave the victim with a variety of different options to help them recover. Sometimes the best treatment is surgery.

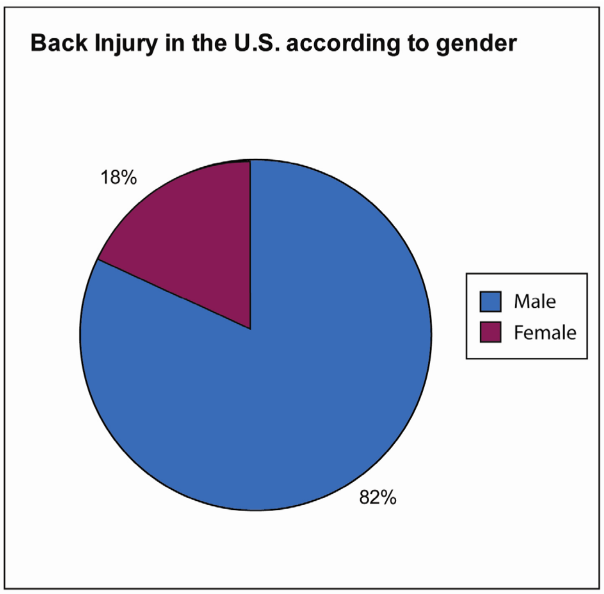


Figure 2. Back Injuries in the U.S according to gender

1.5.2 Types of Injury

The need for spinal orthoses usually depends on the type of injury it is being used to treat and most importantly the doctor's recommendations. It is important to research the different types of back injuries to know where spinal orthoses may fit into the process of fully rehabilitating the patient.

A herniated nucleus pulposus, or slipped disk, is a common back injury to the back that can be treated with spinal orthoses. A "herniated disk" is a condition when all or part of the soft center of a spinal disk is forced through a weakened part of the disk (www.nlm.nih.gov). This type of injury usually occurs when a spinal disk moves out of place or ruptures due to trauma or strain (www.nlm.nih.gov). Herniated disks are most common among middle age men who are involved in strenuous activity (www.nlm.gov). The general remedy for this injury is rest. Some cases of herniated disks may require surgery (www.nlm.nih.gov). The purpose of spinal orthoses in this type of injury is to help stabilize the spine (www.nlm.nih.gov).

Spinal fractures are another type of injury that often leads to the use of spinal orthoses. A spinal fracture occurs when the spinal vertebrae, spinal cord, or any of its attachments is damaged (www.spineuniverse.com). There are generally two types of fractures to the spine: compression fractures and burst fractures. Compression fractures are the most common types of spinal fractures (www.spineuniverse.com). A compression fracture occurs when the normal vertebral body of the spine is compressed from its normal height (www.orthopedics.about.com). A compression fracture (Figure 3) involves failure of the anterior column of a vertebra with the middle and posterior columns remaining intact (Dutton, 2005). The main causes of spinal fractures are

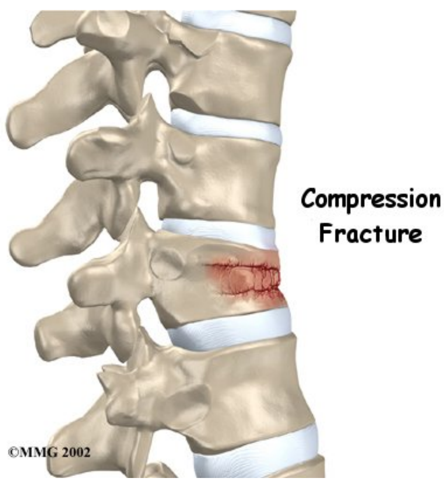


Figure 3. Compression Fracture

patients involved in traumatic accidents and patients that may suffer from osteoporosis (www.orthopedics.about.com). Compression factors may also be caused by tumors along the spine (www.orthopedics.about.com).

A burst fracture (Figure 4) involves the failure of both the anterior and middle columns (Dutton, 2005). A burst fracture is a type of compression fracture where the damage done is much more severe. Compression fractures and burst fractures both employ the use of spinal orthoses. Orthoses are used pre-operatively to stabilize the spine and its segments (Dutton, 2005). Orthoses are used post operatively to stabilize the spine as well as protect the surgically repaired areas (Dutton, 2005). The stabilization provided by the prescribed orthosis ensures that the spine maintains the correct posture and ensures the injury heals in a natural alignment.

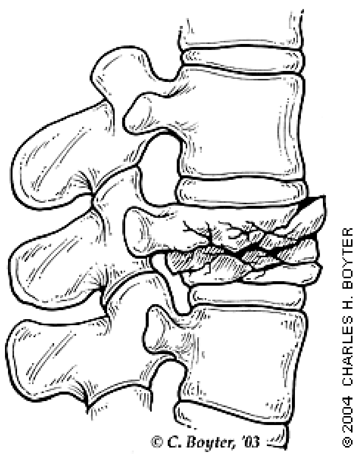


Figure 4. Burst Fracture

1.5.3 Surgical Intervention

The need for surgical intervention in back injury is reserved for situations where the severity of the injury demands immediate intervention, or non surgical methods have been tried and proven ineffective (www.spineuniverse.com). There are many different types of surgical procedures that can be performed to correct a spinal injury. This study focuses on the surgeries associated with the injuries that are listed in the previous section.

The most common surgical procedure that is used to treat these types of injuries is called spinal fusion.

Spinal fusion is a surgical procedure that corrects problems in the vertrabrae. The surgery stabilizes the back by fusing certain bones together (Medline Plus Medical Encyclopedia, 2007). The term “fuse” means to permanently place two bones together so the movement between them can no longer occur (Medline Plus Medical Encyclopedia, 2007). The procedure uses bone grafts, which are pieces of bone that are taken from a

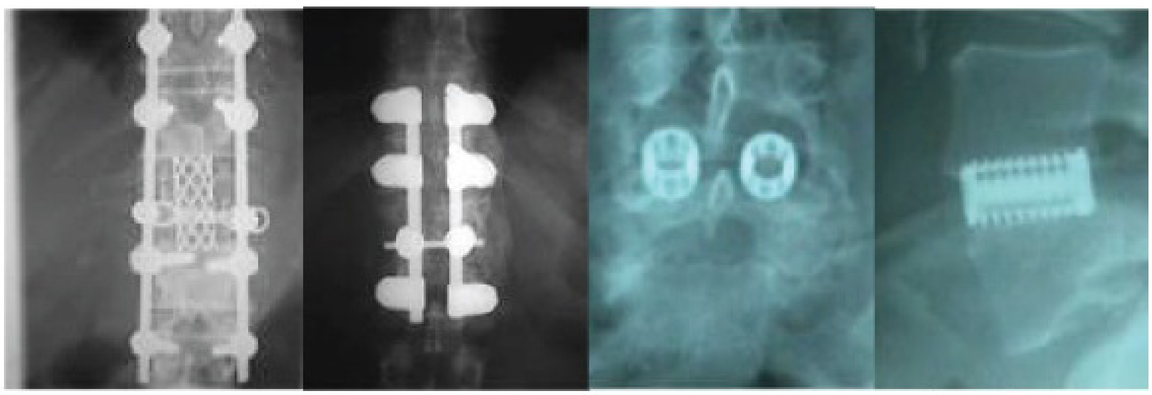


Figure 5. Examples of surgical spinal implants (www.spineuniverse.com).

different location on the patient’s body or bone harvested from another individual, to fuse bone together. Bone grafts are sometimes, but not always, accompanied by screws, plates, cages, or other types of surgical instruments. Figure 5 shows some of the different types of surgical instruments used during the fusion process. The bone graft is placed around the problem area during the surgery and joins the bones together as the body heals itself. Spinal fusions are used to treat various injuries that affect the vertebrae. The procedure consists of an incision made over the area of the spine that is being treated as well as additional cuts depending on the location of the injury. Spinal fusions are used to treat fractures, herniated disks, a weakened spine caused by infections or tumors, and it is often recommended to treat abnormal curves seen with scoliosis and kyphosis. Spinal fusions are “Usually very successful” (www.nlm.nih.gov).

1.5.4 Recovery and Rehabilitation

The role of spinal orthosis plays a vital part in the recovery and rehabilitation of the injured patient. After surgery it is very important that the surgically repaired area heals properly and is exposed to very little stress. Patients usually experience immediate discomfort and pain after spinal surgery. The *North American Spine Society* states that this period is greater for those patients who have had fusion surgery (North American Spine Society, 2005). Patients generally stay in the hospital for a 3-4 day, but a more extensive injury could require a longer stay (www.spine.org). After a patient leaves the hospital, he or she may require orthosis. After surgery, it usually takes 6 weeks for bone healing to take place after fusion (North American Spine Society, 2005), and 3- 6 months for the bone to completely fuse together (www.spine-health.com). A patient may require spinal orthosis to restrict movement and protect the repaired area. It is important that the patient wears the orthosis according to the physician’s instruction in order for proper healing to occur. Some are very restrictive and are designed to limit motion, while others are intended to provide support (North American Spine Society, 2005).

In addition to orthoses, a patient’s recovery may include a rehabilitation program. This depends on many factors such as the type and extent of the surgery that is performed. Rehabilitation is not a requirement and is suggested on a case by case basis.

1.5.5 Medical Device Design

Orthotic devices fall into the category of medical devices. The *Reliable Design of Medical Devices*, by Richard C. Fries defines a medical device as "Any instrument, appliance, apparatus, material, or other article [intended] to be used for the purpose of diagnosis, monitoring, alleviation of, or compensation for an injury or handicap" (Fries, 2006, p. 197). Equipment for physical rehabilitation such as spinal orthosis protect, assist, or repair injured segments of the spine. Medical devices are a unique set of products because of all of the requirements the device must meet. Medical devices must satisfy medical requirements, and provide an effective solution. The list of requirements are set by the tasks they are set to perform or the basic needs. The early stages of design also start with the assessment of a need. Richard C. Fries states "The first inputs to the process are the needs of the customer and the needs of the company" (Fries, 2006, p. 197). This is a common notion in the design process in general, but in the medical field this statement warrants a couple of questions. One question is whether or not the customer is the patient or is the customer the physician? The next question is which set of needs are important and which ones are ignored? The physician must assess a list of requirements and necessities. The physicians are inclined to consider the requirements as the highest priority. Fries also notes, " That the requirements and design are interdependent" (Fries,2006, p.221). He also believes that "…design can itself be considered a requirement" (Fries,2006, p.225). The orthotist, who is qualified to measure and supply all types of orthoses, is the key member in making sure the physicians requirements are met as well as considering the patients needs (Powell,1986, p. 148). The orthotists can be considered the designer in the process, but they are not allowed to go outside the physicians' requirements. They are responsible for carrying out exactly what has to be done. The orthotist and the physician need to collaborate to effectively create the medical device. The parties involved should also have more consideration for the patient. A concentrated effort on maximizing the patient's experience in terms of function vs. comfort is a job both health professionals must assess together.

1.5.6 Problems

The effective use of design should be integrated into the creation of orthotic devices to create a product that deals with all the patient's needs. Industrial Design is a profession in which people are always in consideration. Mary Powell states that "...treatment of a patient is incomplete unless it includes consideration of him as a whole person" (Powell,1986, p.76). Design has a strong foundation rooted in the area of people and how products relate to them and how that affects their everyday lives. Surgery demands the lifestyle of the patient to change while they recover. Patients are able to live a normal life but after surgery, such as fusion, it takes longer for a patient to return to a normal lifestyle. The issue is complicated when spinal orthosis is added to a patient that may have an already difficult adjustment period. Spinal orthoses present a range of problems that the patient is forced to endure while wearing the device. Spinal orthoses are often heavy, hot, and relatively uncomfortable (www.spine-health.com). Some discomfort is normal, but if the brace is not reasonably comfortable the patient will not wear it (Powell, 1986, p.26). An uncomfortable brace can be the result of a brace that does have a precise fit, or that the patient has adjusted the brace incorrectly. Pressure Sores may also form from a brace that applies too much pressure and interferes with circulation (Powell, 1986, p.26). Pressure sores (Figure 6) are localized areas of dead tissue that result from the disruption and/or occlusion of the blood supply due to excessive pressure or other mechanical forces (Davis, 1994).

Figure 6. Pressure Sore

Another issue is that some braces can have multiple straps and patients may adjust the brace in a way that it does not perform its function. These problems are increased when the patient has undergone back surgery. The brace may apply pressure to the incision and cause the patient pain. The patient's weakened body and post surgical sensitivity magnifies the problems to a level that could compromise the effectiveness of the orthoses.

The further integration of design can address these matters and create a set of guidelines that creates a product that keeps the patient in mind. The identification of the current design process provides the opportunity to find flaws and provide solutions for them. Once the problems are identified, the solution can begin by studying the different situations where bracing is necessary. The skill of a designer can help improve orthotic devices for the physician, orthotist, and most importantly the patient on all levels.

1.6 Assumptions of Study

In this study information from secondary sources such as books, journals, and internet sources will be used. The study will also feature some input from primary sources such as orthopedic surgeons and certified orthotists. It is assumed that all the information from these sources is factual and based on accurate research and material. The authors of these sources are credited with being professionals in each of their respective fields.

The information provided by the authors has been reviewed by the researcher and scaled down to fit injuries that usually require surgery. The function of the orthoses will be focused in the post surgical setting.

1.7 Scope and Limits

This thesis study will focus on spinal orthotics used in the post surgical setting. The spine encompasses a large area, and different types of injuries require different orthotic solutions. Therefore, the limits of this study will revolve around back injuries that require fusion surgery and post surgical orthoses. This study is also limited by the area of the spine that is affected by the injury. Injuries that affect the thoracic and lumbar spine will be the main focus. The type of brace generally prescribed following fusion surgery is called a Thorolumbosacral orthosis (TLSO), or clamshell brace. The revisions of this study will be made in the methodology and design criteria that assists the orthoses rehabilitating the patient.

1.8 Procedures and Methods

The procedures and methods of this study are separated into five categories:

- Research: Talk to Physicians and Orthotists on the current process that leads to bracing.Discuss the overall process from when a patient comes into the office to the point bracing or splinting is required. Discuss how long the patient might need a brace. Examine the current process of fitting a patient and pinpoint areas that can be improved.
- Orthotics: Examine the different types and uses of spinal orthotics. Explore the mechanics of orthoses and how they are effective. How does it work? How does it prevent injury? Examine what materials are used and what possible alternatives exist.
- Development: Concept sketches, renderings, and models
- Production: Documentation of the process of the product using the design criterion compiled from previous research.
- Review: Examine if the current process is useful and accurate. Outline the benefits of the new product.

1.9 Anticipated Outcome

The anticipated outcome for this study is the development of an orthopedic product that improves spinal bracing in regards to patient compliance. The changes made to the device will be effective in treating injury and will provide a solution that is much easier for the patient to deal with in a post surgical setting. The product should also make the job of physicians and orthotist easier by ensuring the patient will wear the orthosis. The product will properly fit to the patient's body and the patient will have a full understanding of how the product works. The changes implemented in the new device will be a standard of design and will have the possibility of being incorporated into similar devices.

2. INTRODUCTION TO RESEARCH

2.1 Overview

Chapter 2 will serve as an introduction to the intended area of study. The research found in this chapter introduces the back as a whole, and covers the physiology of the structures that will influence the final outcome of this study. According to Mary Powell (1986) "The study of orthopedics cannot therefore be separated from the study of the anatomy applied to the part of the body which is involved and related to the condition under discussion" (p.9). The anatomy of the back is crucial to understanding the necessities of the project. This chapter will also cover the injuries that affect the back, the medical procedures that follow in injury, as well as the rehabilitation process that follows.

2.2 Anatomy

This section introduces the area that this study targets. The "back" will be split into two parts in order to focus the information on areas that will be affected by the rehabilitation process. The primary area of study will focus on the spine, or backbone, which is the core area for this study. The bones and muscles that support the spine will also be discussed. The secondary structures will focus on the other parts of the back such as the shoulder blades, which surround the spine and will need to be considered when developing an effective solution. The secondary structures will also examine all body parts that are directly or indirectly involved with the function of spinal orthoses.

2.2.1 Primary Structures: The Spine

The spine is a series of vertebra stacked upon one another which support and protect the spinal cord. "The spinal cord is the major bundle of nerves that carry nerve impulses to and from the brain and body" (Apparelyzed, 2007). The spinal cord is 18 inches in length and is responsible for carrying signals to the human body. The spinal cord is surrounded by a set of 24 vertebrae called the spinal column. The spinal column is separated into four regions, as shown in Figure 7, which each serve a specific function (North American,2005). The four regions of the spinal column are: the cervical, thoracic, lumbar, and the sacral regions (North American, 2005,). The cervical spine is made up of seven vertebrae. The main function of the cervical spine is to support the head. Stephen Rogers Peck (1951) notes that the cervical vertebrae is the "most flexible of all the vertebrae (p. 22). The cervical spine can move backwards and forwards. The cervical vertebrae are unique because they consist of two specialized vertebrae, which are also depicted in Figure 8, that move with the skull (North American, 2005). The first cervical vertebra is called the atlas (Figure 8). It has a ring-like shape with two protrusions on the side which support the head. The second vertebra is called the axis. The axis is also unique because it consists of a bony peg-like protrusion called the dens (Figure 8), which connects to the ring of the atlas (North American, 2005,). The cervical spine portrays a curve which looks like a reversed "C" called the lordosis.

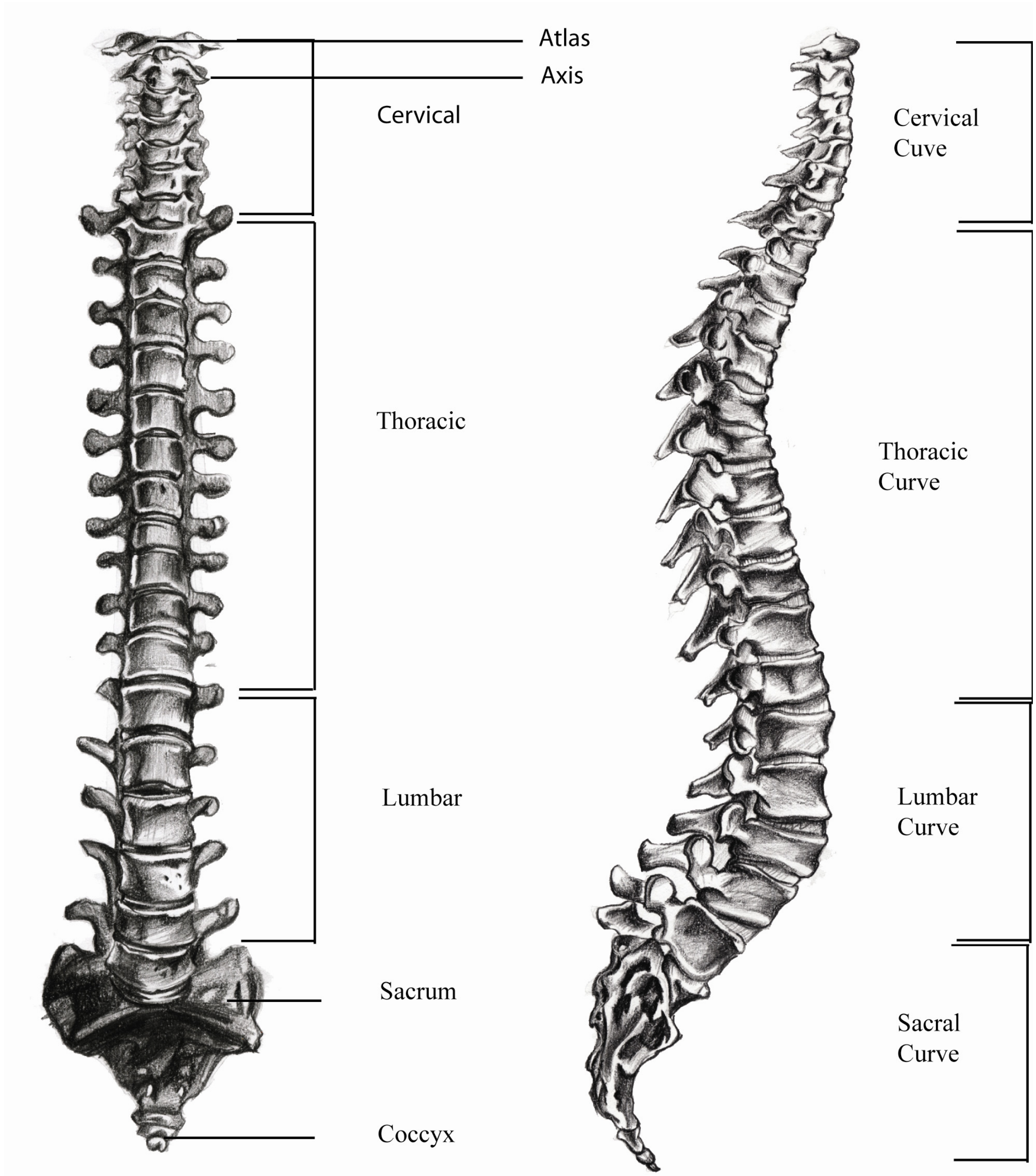


Figure 7. Front and side view of spinal vertebrae(Illustrated by Michael Hicks).

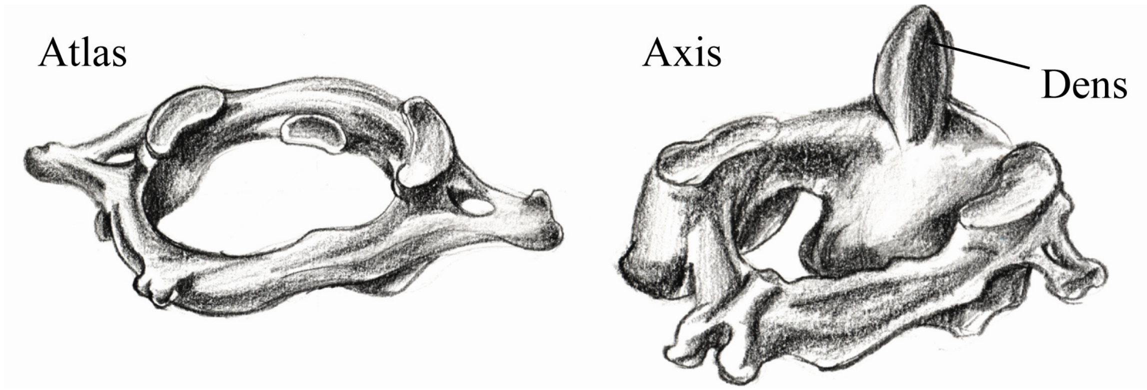


Figure 8. View of the Atlas and the Axis (Illustrated by Michael Hicks).

The thoracic spine is the next set of 12 vertebrae which make up the spinal column. The function of the thoracic spine is to protect the organs of the chest. The 12 thoracic vertebrae have one rib attached to both sides, which create a thoracic cage to protect vital organs (North American, 2005). The thoracic spine has a normal kyphosis, which is also known as a “C” curve. This region of the spine is not as mobile as the cervical vertebrae because of the thoracic cage.

The lumbar region is the next 5 vertebrae of the spinal column. The lumbar vertebrae are the largest of all the vertebrae because they bear the most weight. The lumbar, much like the cervical vertebrae also form a reverse “C” curve, or lumbar lordosis. The lumbar vertebrae are closely followed by the sacral vertebrae. The sacral vertebrae are the last 5 vertebrae which are fused together to the sacrum to form a solid unit. The coccyx, or tailbone, forms the very end of the spinal column.

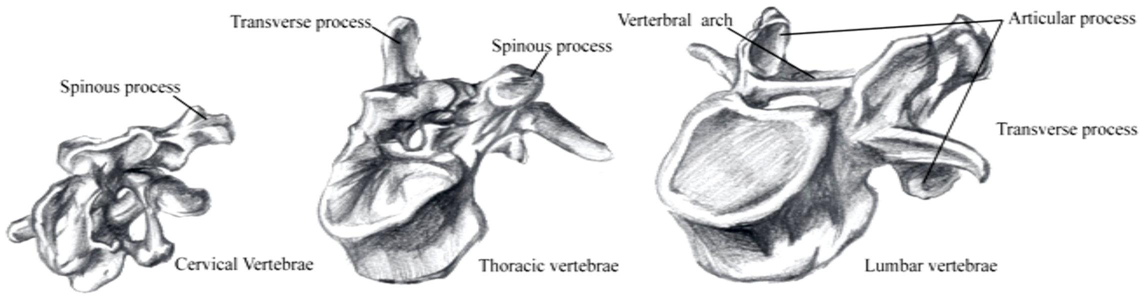


Figure 9. Cervical, thoracic, and lumbar spine segments. (Illustrated by Michael Hicks)

2.2.1.1 Primary Structures: Spine Muscles

The purpose of the spinal column is to protect the spinal cord. The spine, which is a part of the muscoskeletal system, is also supported by a series of muscles and ligaments (Figure 10) which provide spinal balance, stability, and mobility (Eidelson,2005). Assistant Professor Mary Rodts (2006) says the spinal ligaments and muscles are “Extremely important for connecting the vertebrae and for keeping the spine stable” (Rodts, 2006). The ligaments with the most important job are the anterior longitudinal ligament and the posterior longitudinal ligament , which runs from the skull all the way down to the base of the spine (Rodts, 2006). The rest of the muscles that are attached to the spine are connected to the muscles that are featured in the posterior back which adds more stabilization to the spine and torso.

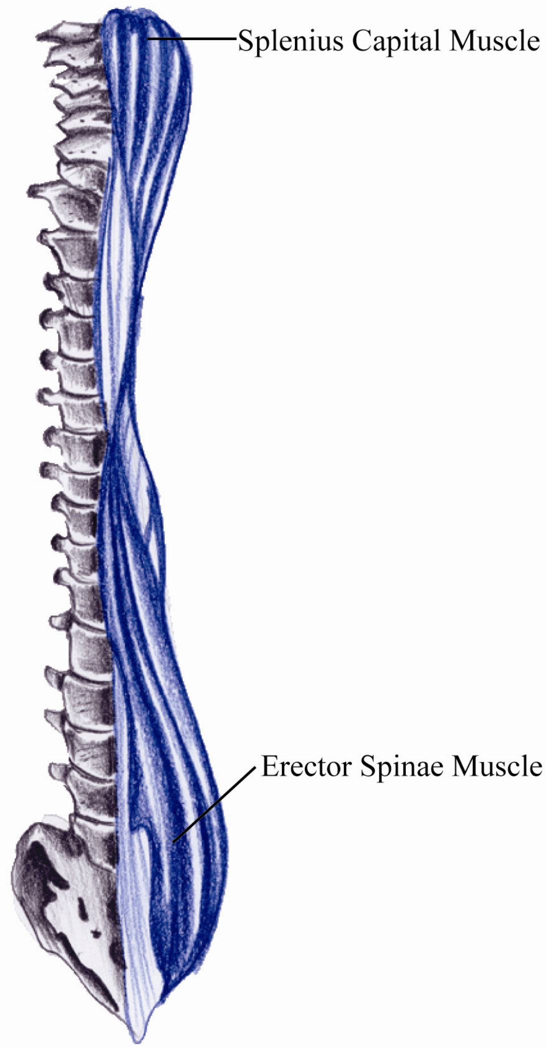


Figure 10.View of spine and primary muscles (Illustrated by Michael Hicks).

2.2.2 Secondary Structures: Scapula, Thorax, Back Muscles, and the Pelvis

The scope of this project is focused on rehabilitative devices for patients with injuries to the spine. In order to create an effective solution there must be a study of not only the spine, but also the surrounding structures. The structures for this section of the study include the Scapula (shoulder blade), back muscles, the thorax, and the pubis.

2.2.2.1 Scapula/Shoulder Blade

The scapula, or shoulder blade, is the trowel-like bony plate located on both sides of the upper back (Peck, 1951). The scapula is located between the seventh and eight ribs (Peck, 1951). The scapula provides a socket for the bone of the upper arm. It is attached to the collarbone and forms the shoulder girdle. The scapula is structurally separated into a body, a spine, and a process (Figure 11). The body is thin, triangular, and bent forward to fit the thorax. The sides of the scapula are called margins. The body also houses the *glenoida fossa*, which is the section that receives bone of the upper arm (Peck, 1951).

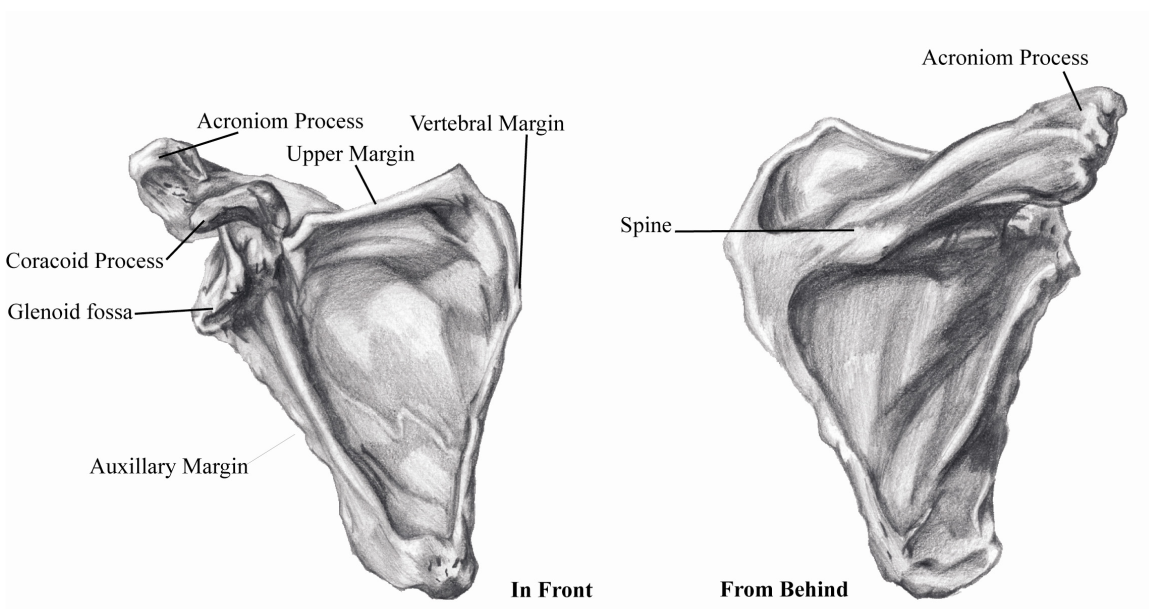


Figure 11. Anterior and Posterior view of Scapula (Illustrated by Michael Hicks).

The spine is a high crest on the back of the scapular body, positioned on a line with the glenoid fossa. It rises from the vertebral margin and it expands and projects outward creating a partial roof over the socket of the arm and is called the acroniom process. Finally, the coracoid process rises above the lateral angle (Figure 11), and protrudes forward and laterally (Peck, 1951). The shoulder blade plays an important part in the development of this type of orthopedic device for the back because it will be one of the main parts of the body the device touches. Therefore, the inclusion of this structure is important to the research.

2.2.2.2 Thorax, or rib cage

The thorax, or rib cage, is another structure that must also be considered in the study. The thorax is directly related to the spine because the ribs spring forward from the twelve thoracic vertebrae of the spine (Peck, 1951). As stated earlier, the job of the thoracic spine and the thorax is to protect the organs of the chest (North American, 2005). The thorax cannot move as individual units, but collectively the thorax may rise forward and drop backward during respiration, and is subject to slight expansion and compression. The thorax is composed of the sternum and the ribs (Figure 12). The

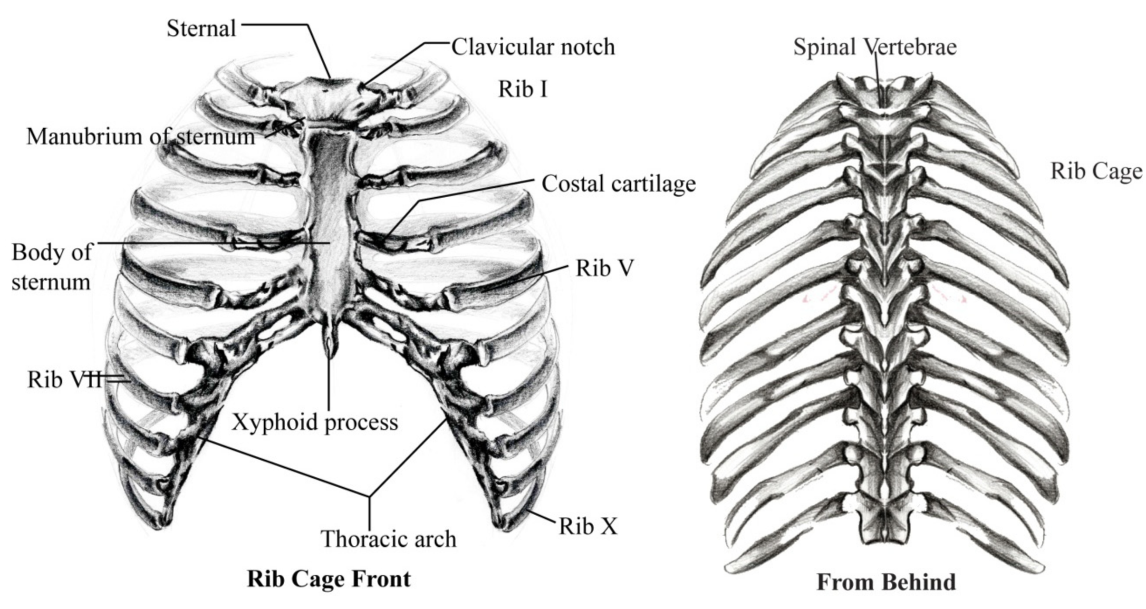


Figure 12. Anterior and Posterior view of the thorax(Illustrated by Michael Hicks).

sternum gathers the ribs in the midline of the chest. The ribs are the twelve pairs of flat, twisted blades which curve from the thoracic vertebrae from behind and swing obliquely to the front to connect with the sternum (Peck, 1951). The thorax maintains direct contact with the spine. The scope of space the thorax encompasses must be included in the design of an orthopedic device that is applied to the back. The thorax is also an important structure because the sternum plays in important role in the function of the orthosis.

2.2.2.3 Back Muscles

Knowledge of muscles that encompass the torso, in particular the back, are necessary for this study. Muscles are the responsible for stabilizing and providing motion for the body. Peck (1951) describes muscles as the agents of driving force for bodily action which are woven around the skeleton. The spine, scapula, and thorax are surrounded by masses of various muscles that each provide specific functions for its skeletal counterpart. The effects of the orthosis must also take the muscle groups into consideration. The device must not interfere with the movement of any muscle group it unless it is prescribed. Figure 13 examines the different muscle groups throughout the back. The muscles that are in the back are affected by the spinal structures. The back muscles strengthen and support the torso. After surgery the muscles must be cut to get to the spine. The post surgical process will affect the spine and the muscles that support it. Spinal orthoses must also take into consideration the weakening of muscles due to surgery. This fact may require the orthosis to help support the muscles until they regain their strength.

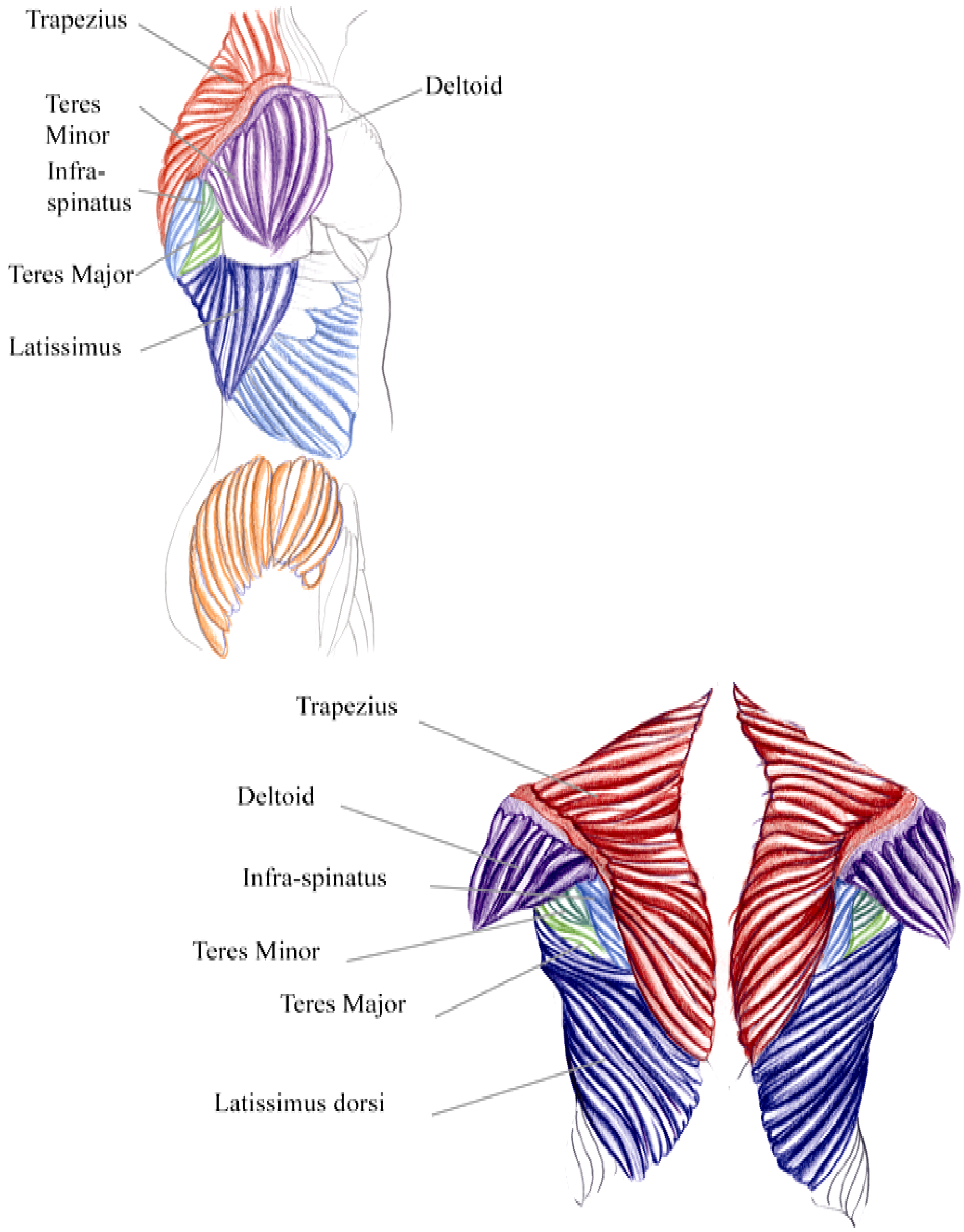
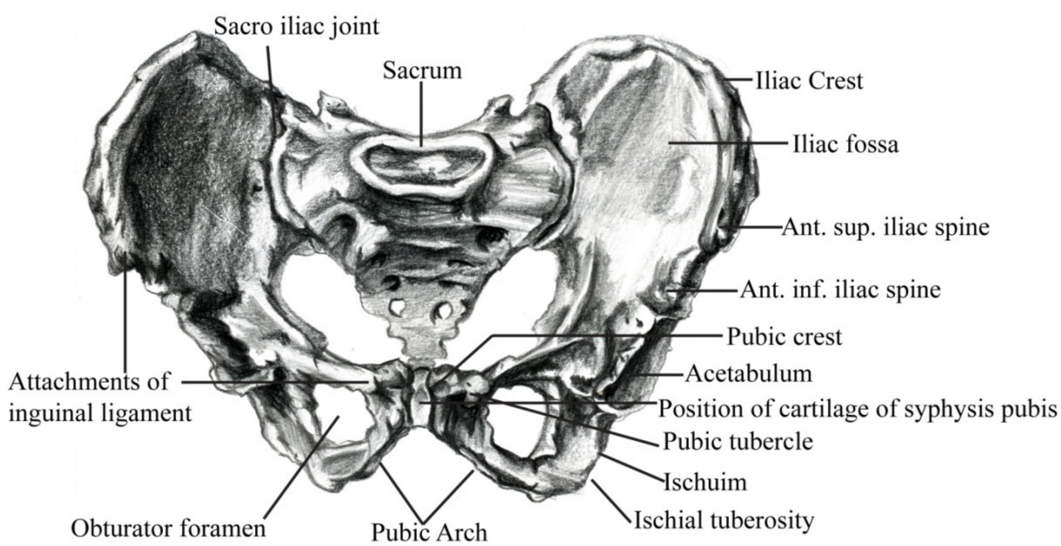


Figure 13. Back muscles (Illustrated by Michael Hicks).

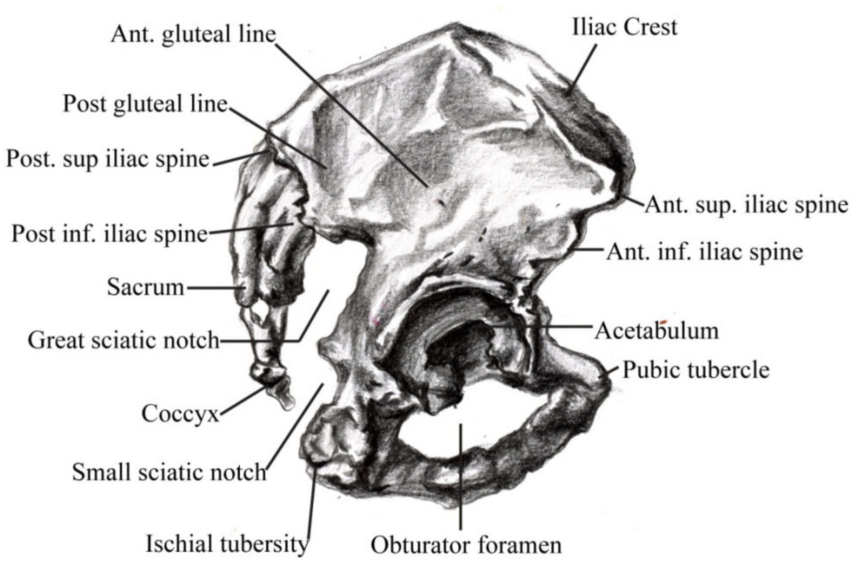
2.2.2.4 Pelvis

The anatomy of the pelvis must also be studied to gain a complete understanding of the structures affected by spinal orthosis. The pelvis, like the sternum, also plays a role in the function of the orthotic. The pelvis is the great bony ring formed by two hipbones, the sacrum, and the coccyx (Peck, 1951). The two coxal bones (Figure 14), or pelvic bones, are firmly braced through posterior articulations with the sacrum (forming the sacroiliac joint) and an anterior articulation with each other forming the symphysis pubis (Spence, 1986). Each coxal bone is a single bone formed by the fusion of three separated embryonic bones: the ilium ischium, and pubis (Spence, 1986). The ischium (Figure 14) is a broad, expanded portion of the coxal bone that extends upward from the acetabulum (Spence, 1986). The ischium (Figure 14) forms the posterior inferior portion of the coxal bone and part of the acetabulum (Spence, 1986). The pubis (Figure 14) is the anterior part of the coxal bone (Spence, 1986). Below the symphysis, the under borders of the pubic bones describe the angle of the pubic arch (Peck, 1951).

The pelvis is a structure that has several differences among males and females. Most of the differences between the male and female pelvis are due to child bearing attributes. Figure 15 lists the main differences between the male and female pelvis.
The male pelvis is characterized by height, uprightness, angularity, weight, thickness of parts, and a small cavity (Peck, 1951). The female cavity is characterized by breadth, forward tilt, generous angles, lightness, thinness of parts, and a spacious cavity (Peck, 1951).



Front view



Side view

Figure 14. Front and side view of the pelvis (Illustrated by Michael Hicks).

Characteristic	Female Pelvis	Male Pelvis
General structure	More delicate	More massive
Anterior iliac spine	More widely seperated	Less widely seperated
Pelvic inlet	Larger; circular	Heart shaped
Pelvic outlet	Wider,ischial tuberosities further apart	Narrower
Pubic arch	Obtuse(greater than 90°)	Acute(less than 90°)
Obturator foramen	Triangular	Oval
Acetabulum	Faces more anteriorly	Faces laterally

(Spence, 1986)

Figure 15. Structural differences between male and female pelvis (Spence, 1986).

2.3 Summary of Chapter

Chapter 2 illustrates the physical anatomy of the back. The information presented in this chapter presents the structures that will be affected by an orthotic device designed for the spine. The information will help in the design process by presenting all the bone and muscle structures the orthosis must accommodate. The location of certain structures such as the sternum and pubis is vital for the functional purpose of the spinal orthosis. The information from this chapter will allow the design to accurately fit the patient by allowing necessary clearance and support for the body.

3. ORTHOTICS AND THE DIAGNOSIS PROCESS

3.1 Overview

Chapter 3 introduces the profession of Orthotics. Orthotics is the science of fabricating and fitting a splint or brace to the body (Powell, 1986). The study of this profession will provide important information of the how a patient is measured for a brace as well as the requirements that the orthotist must consider while customizing the brace. This chapter will also introduce different types of spinal orthoses, and the problems that are often associated with them. The information gathered from this chapter will be used to create a list a of performance criteria.

3.2 Orthotist

An orthotist is defined as an individual who is qualified to measure, fit, and supply all types of orthoses (Powell, 1986). Orthotists provide care to patients with neuromuscular and muscoskeletal impairments that contribute to functional limitation and disability (Lusardi & Nielson, 2007). Orthopedic patients are usually referred to an orthotist after they have been diagnosed by an orthopedist. Orthotists may work alone or they may supervise several staff members. Like most medical professions, orthotists must meet certain requirements to guarantee that they are qualified to handle their job. The American Board of Cerfication in Orthotics, Prosthetics, and Pedorthics(ABC) is the national certifying and accrediting body for the orthotic and prosthetic professions (About ABC:American Board for Certification in Orthotics, Prosthetics, and Pedorthics). An orthotist may work alone or may have help. In some work environments, there is an orthotic assistant that assists the orthotist and may fabricate, repair, and maintain braces (Swain, 2002). Some work environments may also involve an orthotics technician, who takes direction from the orthotist (Swain, 2002). The technician, like the orthotics technician, repairs and maintains braces. The orthotist is the professional that usually maintains contact with the patient while the assistant has little to no interaction with the patient.

The orthotist is the health professional that is responsible for the design of the orthosis. The orthotist does not make all the decisions in terms of the patient's limitations and the overall goal of their rehabilitation program. It is important to understand the placement of the orthotist's role in the entire diagnoses process to understand where changes in design can be implemented.

3.3 Diagnoses Process

This section will examine the process that a patient experiences from the time they visit the orthopedist up until the brace is applied. This information will provide the steps in the process where important decisions influencing the design of the brace are made. The information acquired from this study will provide the basis for the performance criteria of the back brace.

3.3.1 Professions

The process for treating a patient for a spinal injury requires more than one health professional. A patient will visit an orthopedist, and orthotist as stated in section 3.2. There are some occasions where various health professions must be involved in the rehabilitation process. Michelle Lusardi, editor of *Orthotics and Prosthetics in Rehabilitation*, states ".an interdisciplinary healthcare team has become an essential in the rehabilitation of patients whose function would be enhanced by prosthesis, or orthosis (Lusardi & Nielson, 2007). Figure 16 is a chart that illustrates the professionals that are involved in the process of treating a patient for a spinal injury. The chart lists the health professionals that may be involved in the typical rehabilitation process. Each profession

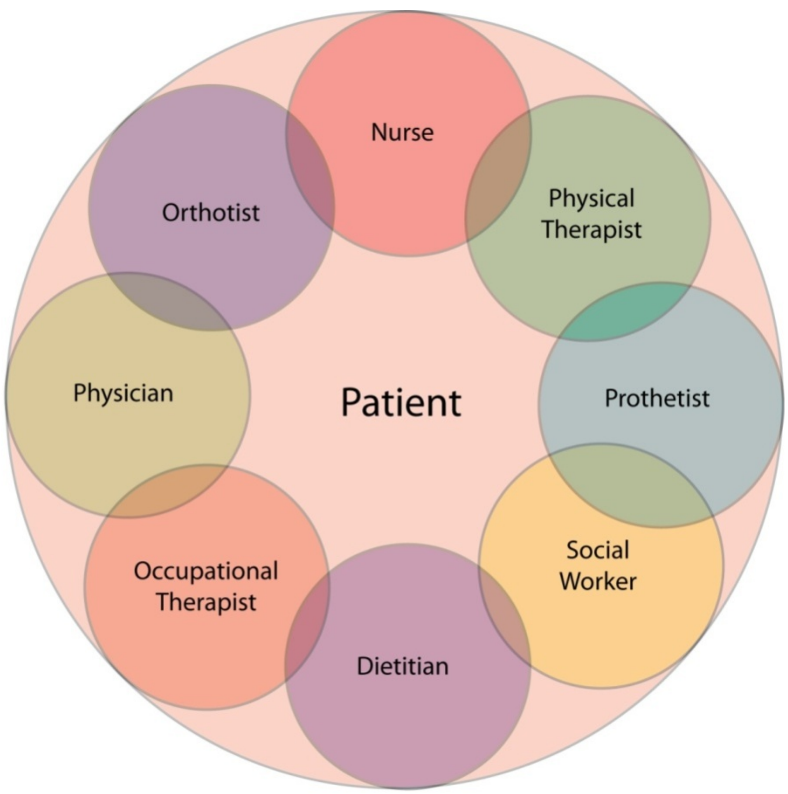


Figure 16. Chart of rehabilitation team professionals. (Lusardi & Nielson, 2007)

has an important role to play in the rehabilitaion of the patient (Lusardi & Nielson, 2007). Figure 16 shows that there can be many different disciplines involved in the successful rehabilitation of a patient. There are times when the complexity of the rehabilitation process and the multidimensional needs of patients may require the expertise of many different professional disciplines (Lusardi & Nielson, 2007). The size of the rehabilitation team may not need to involve all of these professions. The rehabilitation team is often shaped by the typical needs and characteristics of the patient population that it is designed to serve (Lusardi & Nielson, 2007). The scope of professions necessary to successfully complete this study needs to be narrowed down to the parties that have an impact on the design. Figure 17 is a hierarchy tree that indentifies the fundamental professions that will influence this study.

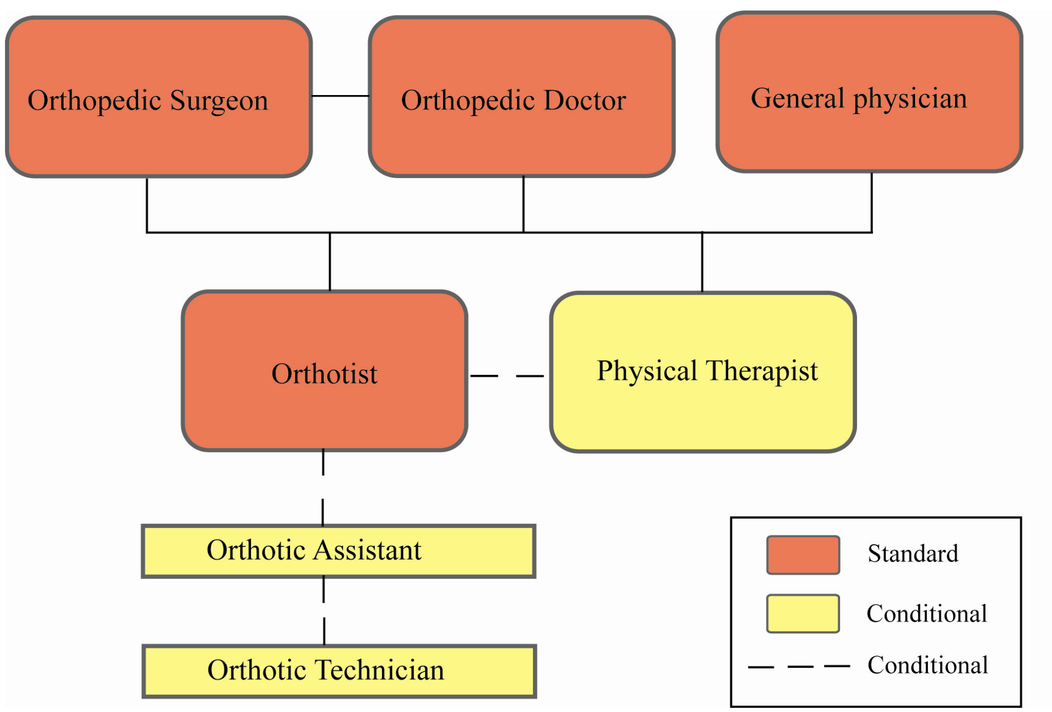


Figure 17.Hierarchy tree of health professions

The professions listed above will directly influence any changes made to the design of spinal orthoses. This chart also shows the chain of command when it comes to important decisions in the rehabilitative program. The orthopedic surgeon, doctor, and/or physician will make all of the important decisions in terms of the patient's medical requirements. They set the patients limitations, and they decide when the patient is fully rehabilitated. The orthopedic doctor and surgeon are here as being separate. It is also very common that an orthopedic doctor and surgeon is the same person. The general physician mainly diagnoses ailment and refers the patient to an orthopedist when they have reached their medical limitations. Once the patient's need has been assessed and orthosis is necessary the doctor(s) refer the patient to an orthotist. The orthotist simply follows the instructions given by the doctor. The orthotist may, or may not have an assistant or technician to help them fabricate the orthosis. A patient may also need physical therapy after surgery. This is not always necessary and the physical therapist in many cases is not necessary.

3.3.2 Sequence of Events

A patient that requires spinal orthosis may go through several steps before they actually receive the orthosis itself. It is important to understand and analyze this process to pinpoint where important design considerations in terms of fit and function are established. Figure 18, illustrates the entire process which extends into surgical repair. The areas highlighted in red showcase the areas that can possibly affect the design process. The steps outlined in sections A, B, C, and D will be considered in the process that I will use to redesign the orthosis. Section A examines the physician's role in the process. Section B observes the process of measuring and fitting the patient. Section B is also the first step in the fabrication of the device. Section C focuses on the actual orthotic device, and which kind of orthoses offers the best solution. Section D centers on the patient's understanding of the orthoses in terms of proper application and proper fit. After examining each step, a list of problems and solutions will be formed to influence the design.

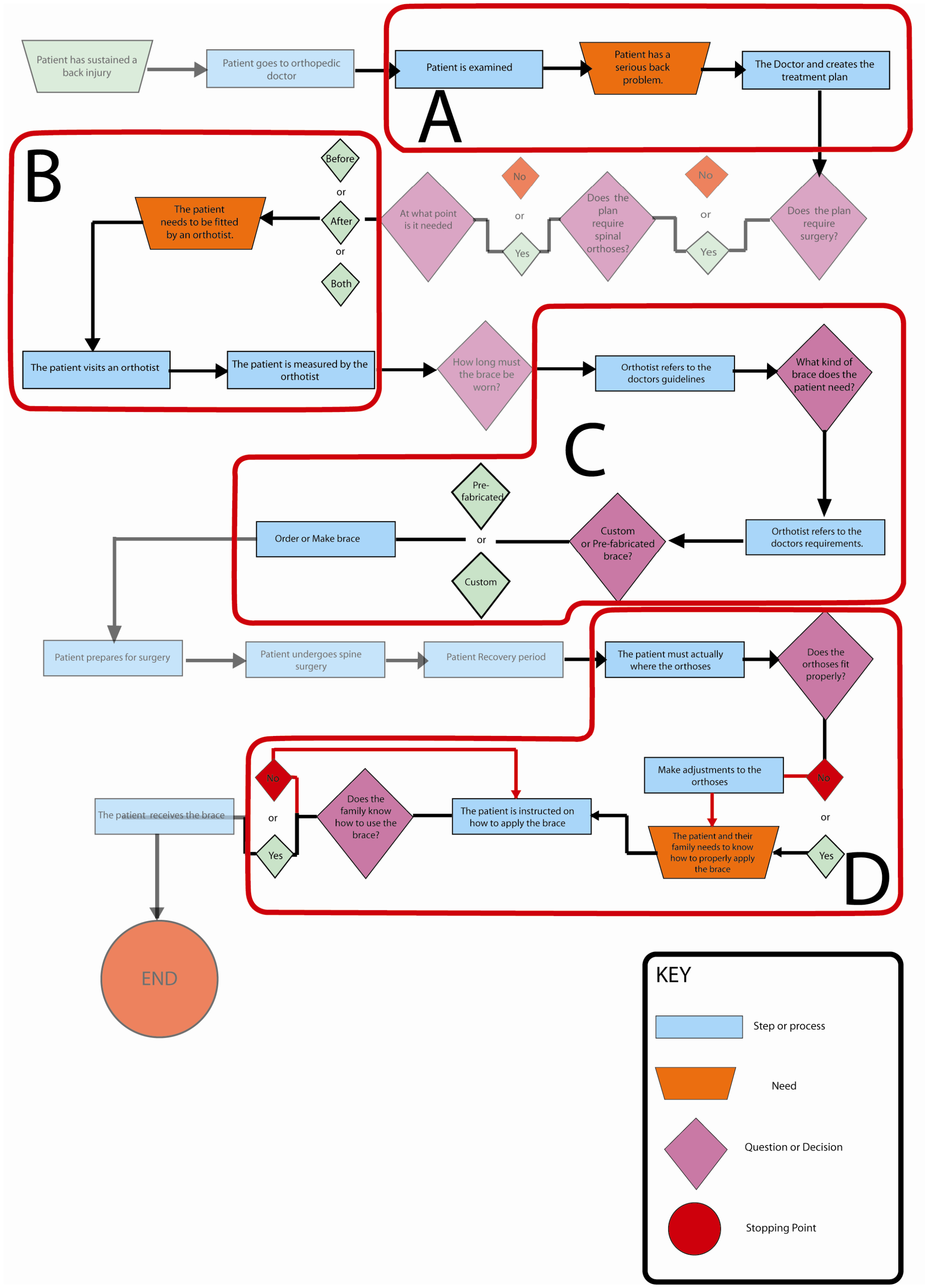
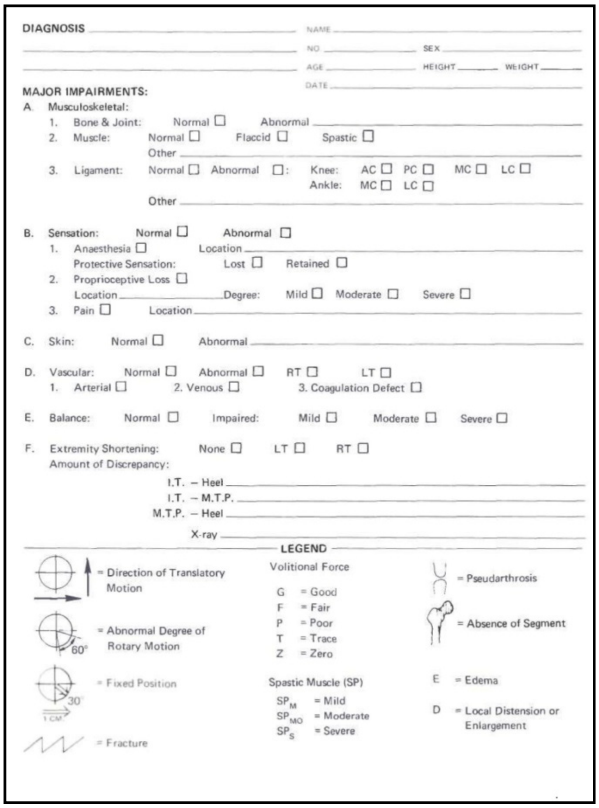


Figure 18. Flow Chart for a patient that requires surgery and orthosis.

3.3.2.1 A: Physician Evaluation

The beginning of the process starts with the patient visiting a physician after noticing or suffering from back problems. The physician evaluates the patient and advises the patient that he or she has a serious injury that requires surgery and the use of spinal orthosis. The injuries that can require surgery can be found in Chapter 1. The physician provides the orthotist with an orthotic prescription. An orthotic prescription (Figure 19) consists of a technical analysis form that defines the anatomical segments the orthosis will encompass and the biomechanical controls that are needed (Lusardi & Nielson, 2007). The form is usually four pages long and provides an overview of the patient's clinical presentation (Lusardi & Nielson, 2007). The first page lists the patient's general information and the patient's physical limitations. The second and third contains diagrams that illustrate the injured segment, in this case the spine. The fourth page lists a summary of the functional disability, treatment objectives, orthotic recommendations, and a key for the biomechanical controls of the function (Lusardi & Nielson, 2007). It also specifies the forces that need to be present in order for the



DIAGNOSIS ____ NAME ____
NO ____ SEX ____
AGE ____ HEIGHT ____ WEIGHT ____
DATE ____

MAJOR IMPAIRMENTS:

A. Musculoskeletal:
1. Bone & Joint: Normal ☐ Abnormal ____
2. Muscle: Normal ☐ Flaccid ☐ Spastic ☐
Other ____
3. Ligament: Normal ☐ Abnormal ☐: Knee: AC ☐ PC ☐ MC ☐ LC ☐
Ankle: MC ☐ LC ☐
Other ____

B. Sensation: Normal ☐ Abnormal ☐
1. Anaesthesia ☐ Location ____
Protective Sensation: Lost ☐ Retained ☐
2. Proprioceptive Loss ☐
Location ____ Degree: Mild ☐ Moderate ☐ Severe ☐
3. Pain ☐ Location ____

C. Skin: Normal ☐ Abnormal ____

D. Vascular: Normal ☐ Abnormal ☐ RT ☐ LT ☐
1. Arterial ☐ 2. Venous ☐ 3. Coagulation Defect ☐

E. Balance: Normal ☐ Impaired: Mild ☐ Moderate ☐ Severe ☐

F. Extremity Shortening: None ☐ LT ☐ RT ☐
Amount of Discrepancy:
I.T. – Heel ____
I.T. – M.T.P. ____
M.T.P. – Heel ____
X-ray ____

LEGEND

= Direction of Translatory Motion
= Abnormal Degree of Rotary Motion
= Fixed Position
= Fracture

Volitional Force
G = Good
F = Fair
P = Poor
T = Trace
Z = Zero

Spastic Muscle (SP)
SP_M = Mild
SP_{MO} = Moderate
SP_S = Severe

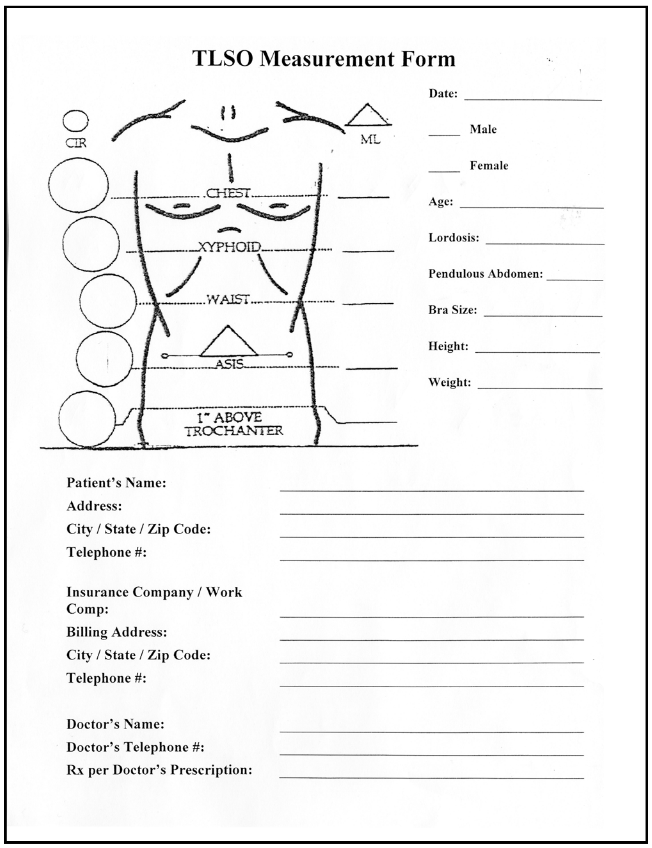
= Pseudarthrosis
= Absence of Segment
E = Edema
D = Local Distension or Enlargement

Figure 19. Orthotic prescription (McCollough III, Fryer, & Glancy, 1970)

orthosis to operate effectively. The orthotic prescription is the blueprint from which the design of the orthosis is based upon (Lusardi & Nielson, 2007).

3.3.2.2 B: Measurement and the fabrication process

Once an orthotic prescription has been filled the physician refers the patient to an orthotist to be measured for their orthosis. The patient's measurement is the first step in fabricating the orthotic device. It is important that correct measurements are taken by the orthotist. The device must fit perfectly otherwise it will be uncomfortable, ineffective, or both (Powell, 1986). The orthotist must carefully measure the patient's torso. The measurements taken by the orthotist include length, circumference, and mediolateral and anteroposterior dimensions of the body segment (Lusardi & Nielson, 2007). The measurements are recorded on another technical analysis form (Figure 20) similar to the orthotic prescription. The measurements taken by the orthotist will be used to create a positive model of the patient's torso. The positive model is used as a template to form the



TLSO Measurement Form

Date: ____
____ Male
____ Female
Age: ____
Lordosis: ____
Pendulous Abdomen: ____
Bra Size: ____
Height: ____
Weight: ____

Patient's Name: ____
Address: ____
City / State / Zip Code: ____
Telephone #: ____

Insurance Company / Work Comp: ____
Billing Address: ____
City / State / Zip Code: ____
Telephone #: ____

Doctor's Name: ____
Doctor's Telephone #: ____
Rx per Doctor's Prescription: ____

Figure 20. Measurement form

orthotic device. The method for measuring and creating a positive model can take two different paths: The traditional method, and the CAD/CAM method.

3.3.2.2.1 Traditional Method

The traditional method includes the use of common measuring tools and techniques as stated before. Once the measurements have been taken the orthotist must create a negative mold of the patient's torso. The orthotist wraps the patient's torso in tubular stocking to protect the patient's skin. Then, bony prominences or important landmarks are marked with on the segment with indelible ink which transfers onto the negative mold and positive mold. Once the patient's torso is prepared, thin layers of plaster of paris bandages (Figure 21) are place upon the patient's body. After the plaster has hardened, the mold is carefully removed from the patient and the negative is complete (Lusardi & Nielson, 2007). The negative is used to create a positive model by pouring plaster into mold. The orthotist sands down or adds material to the positive model to correct any problems with the patient's posture or to make additions for the orthosis. The orthosis can then be heat formed (vacuum formed) around the patient's torso.

Figure 21. Plaster bandages

3.3.2.2.2 CAD/CAM Method

The second method for measuring the patient is by using CAD/CAM technology. This method uses computers to scan in images of the patient's body. This technology was made readily available in the 1980s. Advances in computer hardware and software have made CAD/CAM an economic alternative for fabrication of devices for many orthotic practices (Lusardi & Nielson, 2007). The primary components of a CAD/CAM system (Figure 22) consist of a digitizing device, a computer, and a milling machine. The digitizing device scans the patient's torso and creates a 3D image that contains all of the patient's measurements. CAD/CAM technology is very precise with accuracy within 1mm (Garin, Orten l'orthomesure-Presentation, 1997). Once the image is in place, corrections to the the patient's posture can be made digitally. The 3D scan is then sent to a milling machine. Once the digital model is finished, the milling machine can create the actual orthotic device (Lusardi & Nielson, 2007). The milling machine can also be used to carve a positve model of the torso out of foam.

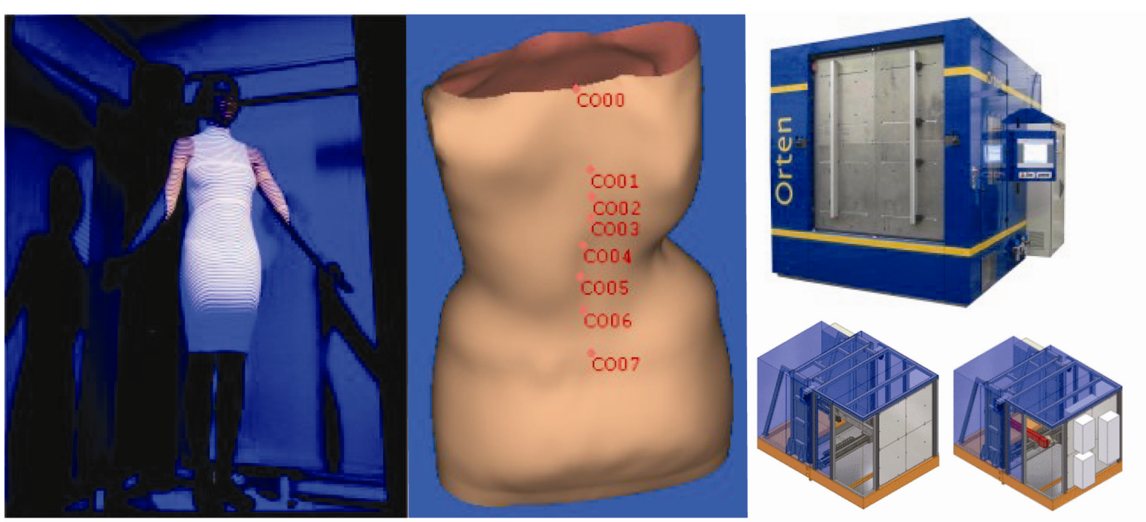


Figure 22. Orten CAD/CAM system

3.3.2.2.3 Comparison

The two methods for measuring a patient for orthoses both have their pros and cons. The traditonal method uses simple measuring techniques and tools that are readily availiable. The process can easily be done in the confines of an orthotist work space . The drawback to this method is that there are a lot of steps involved with producing the positive model. It takes a skilled and experienced professional to create a negative impression (Lusardi & Nielson, 2007). The orthotist must also make adjustments to the positive impression by hand to account for any necessary changes that need ot be made for the orthosis. This process is also subject to human error. Problems with measurement will directly affect the orthosis. This may cause changes to be made later on in the process.

The CAD/CAM system has definite benefits. CAD/CAM systems such as Orten, seen in Figure 22, virtually eliminate the casting process because it carves the torso from digital measurements (Garin, Orten l'orthomesure-Presentation, 1997). CAD/CAM systems that carve out the actual orthosis eliminates the casting process and need to heat form over a positive mold. The CAD/CAM system allows the orthotist to make adjustments digitally and it is extremely accurate. The negative to the CAD/CAM system is the potentially high cost and training. Small orthotic practices may not be able to afford or have the necessary space to implement a full CAD/CAM system. An article by Andria Segedy, in February issue of Biomechanics, states ,“A facility doesn’t need a $40,000 carver on site” (Segedy, 2007). If they have the software and capability to take a digital scan, they can send it offsite for fabrication (Segedy, 2007). This factor has led to the establishment of laboratory production companies that mill positive models (Lusardi & Nielson, 2007, p. 31). These types of facilities often reduce fabrication time and decrease production times making the use of CAD/CAM economically feasible for small orthotic facilities (Lusardi & Nielson, 2007, p. 31). A CAD/CAM system would also require training. A study conducted by Andrew Steele from the America Academy of Orthotists and Prosthesists examines the implementation of CAD/CAM into a clinicians practice. The study mentions that many facilities that are considering CAD/CAM are concerned that their staff will not have enough computer experience (Steele, 1994). A practice would have to have someone undergo training to operate the system. The survey suggests slowly implementing CAD/CAM by becoming familiar with the scanner and digitizer and letting a central fabrication center do the carving (Steele, 1994).

The postive and negative aspects of both methods need to judged by the results they yield. The measuring method needs to offer the best fitting option. A statement made by John W. Michael, Certified Prosthesits and Orthotist, states " It is our professional obligation to keep up to date on all technological developments that may give our patients an added advantage." (qtd. in Steele, 1994)

3.3.2.3 C: Spinal Orthoses

After acquiring the proper measurements, it is time to decide which type of spinal orthosis, or back brace, will be best suited for the patient. The back brace is described by Cynthia Cook (Cook, 2002) as a mechanical appliance for orthopedic use attached to the back. The actual use of a back brace can range from an array of different purposes. According to Dr. Stewart G. Eidelson, “A spine specialists prescribes braces to treat a number of conditions such as fractures, osteoporosis, scoliosis, spondyloisthesis, and whiplash” (Eidelson, 2005). The use of a back brace is not limited to one region of the spine. A back brace can be tailored to address the cervical, thoracic, or lumbar regions of the spinal column. Figure 23 shows examples of different types of back braces for each region of the spine.

Figure 23. Examples of cervical, thoracic, and lumbar back brace

Spinal bracing can also be applied during different stages of the treatment process. Eidelson also mentions the fact that spinal bracing can be used to assist in a patient’s non-surgical and post surgical treatment (Eidelson, 2005). This study emphasizes the use of spinal bracing for post surgical treatment, but there are some objectives for pre-surgical braces that will be able to be carried over into the post-surgical brace.

3.3.2.3.1 Function of Spinal Orthoses

The functional goal for spinal othosis depends on the type of injury a patient has sustained. David Falk, of Falk Prosthetics and Orthotics Inc, identifies three possible functional objectives for back bracing. The first objective of spinal bracing is to control back pain by limiting motion and unloading discs, vertebrae, and other spinal structures by compressing the abdomen (Falk, www.spineuniverse.com, 2005). This function of back bracing can be used to treat patients that have severe back pain caused by herniated discs. The second objective for using back bracing is for stabilizing weak or injured structures by immobilizing the spine (Falk, www.spineuniverse.com, 2005). This function is useful in the early post operative period for fusion surgery (North American Spine Society, 2005). Surgical implants such as Harrington rods and screws are not able to withstand certain movements immediately following surgery. The back brace prevents the implants from popping out of place. The third objective for spinal orthoses is providing three-point force systems to provide correction or prevent progression of a deformity (Falk, www.spineuniverse.com, 2005). This function is used for treating patients with scoliosis as well protecting and stabilizing post surgical correction.

The three point force system is an important aspect of orthoses. This system prevents movement of the spine by exerting opposing forces on the body to immobilize the spine. Figure 24 illustrates the theory behind this system. The top image prevents extension, or backward movement of the torso, by placing pressure on the upper back, the lower back, and the abdomen. The second image prevents flexion, or forward movement, by placing pressure on the sternum, pubis, and the middle of the back. The functional purpose of the brace sets the standard for the design considerations that must be taken into account when designing the product. A brace for one type of injury may look different from a brace for another type of injury because different forces may be needed to correct the problem.

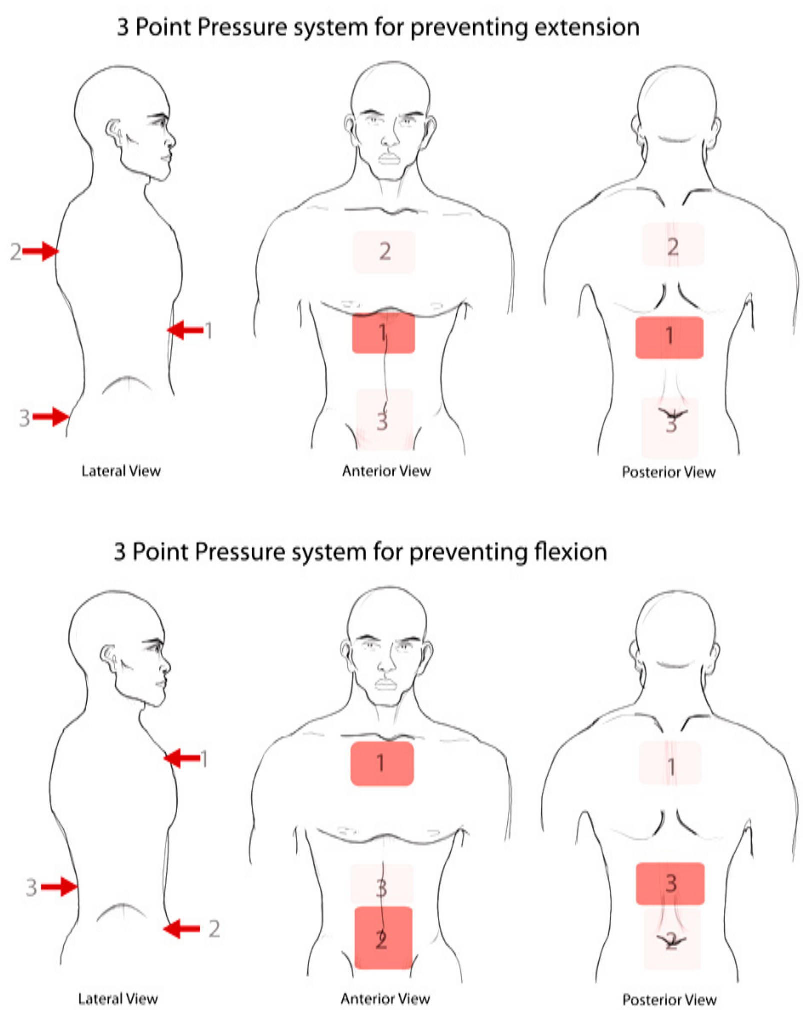


Figure 24. Three point pressure system for extension and flexion

3.3.2.3.2 Design Recommendations for Spinal Orthosis

The function of a back brace must be established early on in the rehabilitation process. The process of assigning a back brace should also measure the overall effectiveness of the device. It is important to understand the guidelines that drive the design for spinal orthoses. Michelle Lusardi's book *Orthotics and Prosthetics in Rehabiliation* (2007) states, "The groundwork of an effective and well designed orthosis starts with the ability to enhance mobility and other functions through various mechanisms and improve quality of life" (Lusardi & Nielson, 2007)

Measuring the effectiveness of a back brace and creating the "ideal" orthosis can come from two different perspectives (Lusardi & Nielson, 2007)

1. The patient
2. The healthcare professional, or orthotist

Lusardi also adds that from the perspective of the patient with orthosis, two important determinants of success are whether the orthosis is comfortable and the extent to which the device meets his or her needs and goals" (Lusardi & Nielson, 2007).

The main concern of a patient that has to wear a back brace is how it will affect their lives. Comfort is an important factor for patients. Thomas C. Gavin (2001) states the patient compliance is essential for the success of [orthotic] treatment. Patients are much more accepting of a back brace that makes the patient as comfortable as possible. The orthosis should have a minimal effect on a patient's everyday lifestyle. This includes their physical and emotional needs. An orthotic design that looks awkward can cause the patient embarrassment. If the patient has a problem with the device they may misuse or neglect it. Lusarid identifies the most important concepts the health care professional should consider when defining an "ideal" orthosis for a patient as the four C's: control, comfort, cosmesis, and cost (Lusardi & Nielson, 2007).

Control deals with how the orthosis will control function while being worn (Lusardi & Nielson, 2007). The orthotist must ask a couple of questions while assessing the control.

- How well the orthosis enables the user to accomplish tasks and be involved in activities that are important to him or her without undue skin irritation, fatigue, or other orthosis induced concerns (Lusardi & Nielson, 2007, p. 135)
- Which body segments are being controlled by the orthosis? An ideal orthosis controls only undesirable motions and permits motion where normal function can occur. The basis of the orthosis should be an accurate analysis of the person who will use the device followed by the selection of appropriate component and design features (Lusardi & Nielson, 2007, p. 135)

Comfort is another issue the orthotist must be address. The orthotist must also assess whether the device causes discomfort or pain. The orthosis should accomplish its intended goals without causing problems such as skin breakdown, excessive discomfort, or unnecessary stress to other joints (Lusardi & Nielson, 2007). It is important to remember that the most technically advanced orthosis will remain in the user's closet or under the bed if it is too hot to wear or causes notable tissue breakdown (Lusardi & Nielson, 2007). The comfort factor is important to both the patient and orthotist. It is in the best interest of both parties if the device is comfortable. An orthosis is more likely to be used if it is minimally cumbersome, easy to apply , and simple to clean and maintain (Lusardi & Nielson, 2007).

Cosmesis refers to the appearance of the orthosis. People that have to wear a back brace often want them to be worn with usual clothing and not too noticeable (Lusardi & Nielson, 2007). A person that wears orthosis does not want to wear a device that takes away from their normal life in any aspect. It is best stated that "[I]f an orthosis allows the wearer to accomplish a meaningful task or take part in an important activity that he or she otherwise would not be able to do, then cosmesis might not be a paramount issue" (Lusardi & Nielson, 2007, p. 136).

The issue of cosmesis is a concern of the orthotist, but it is not given priority and is often conveniently ignored.

The cost refers to two different aspects of the orthosis. Cost refers to the wearer's energy expenditure while wearing the device and the actual economic cost.

"In terms of *energy cost,* whether an orthosis will allow the wearer to function with reasonable (and sustainable) energy expenditure should be determined" (Lusardi & Nielson, 2007, p. 136).

The orthosis should not require an excessive amount of energy to use or to wear. Heavy, hot, and obtrusive designs can sometimes cause stress. Patients that have just recovered from surgery should not have to endure any added energy cost during recovery and rehabilitation. Their bodies should be healing and any unnecessary expenditure can be harmful. Also, Individuals with physiological, cardiovascular, and cardio respiratory problems are especially limited in the amount of energy they can spend (Lusardi &

Nielson, 2007). Lusardi notes that the characteristics of an orthosis that minimizes energy consumption or constriction of breathing include simple and lightweight design and the ability to don and doff without difficulty" (Lusardi & Nielson, 2007, p. 136).

The *monetary cost* of an orthosis is determined by the materials used and the time and skill requirements for measurement, fabrication, and fitting. Orthoses that have to use expensive materials and measuring technology can often lead to an increase in cost. Other factors that affect monetary cost include:

- Will the orthosis require expensive maintenance?
- How durable are the materials and components?
- Can the device consistently function and perform in the current treatment plan? (Lusardi & Nielson, 2007, p. 136).

Other factors that influence the design include adjustability and the ease of fabrication. It is important to design the orthosis a way that minimal adjustments need to made after the patient has received the orthosis. It is also imperative that the orthosis is easy for the orthotist fabricate. A process that is easy for the orthotists to replicate makes it easy for them to create the orthosis in a timely manner.

The effective design of an ideal orthosis cannot just focus on one perspective. The design considerations should take an overall approach to providing the best solution for the patient and orthotist in terms of function and fabrication. The information from this chapter is condensed into a checklist (see Figure 25) that will be used to help develop the final solution to this study.

Control	• Should control prescribed movements • Should not affect any other movements accept those prescribed by the physician • Should not affect prevent the patient from engaging in everyday activities
Comfort	• Should not cause extreme discomfort or pain • Should not cause skin breakdown • Should not cuase unnecessary stress on other joints
Cosmesis	• Should be able to be worn underneath clothing • Should be fairly unnoticeable
Cost (energy and monetary)	• Should be minimally cumbersome • Should be easy to don and doff • Should be Simple to clean and maintain • Should be easy to adjust and apply • Should not require expensive maintenance • Should use durable materials

Figure 25. Recommendations for designing spinal orthosis

3.3.2.3.3 Materials

The selection of the correct materials is an important aspect in the design of spinal orthoses. The selection of materials will influence the cost, performance, and appearance of the orthosis. When selecting the appropriate materials for a patient, the orthotist must consider five important characteristics of the materials: Strength, stiffness, durability, density, and corrosion resistance (Lusardi & Nielson, 2007, p. 17).

1. Strength refers to the maximum external load that the material can support or sustain.
2. Stiffness is the amount of bending or compression that occurs when a material is loaded. The material's stiffness is important when it comes to limiting or allowing motion.
3. The durability of a material is determined by the material's ability to hold up to repeated cycles of loading and unloading. Basically, how much used the material can withstand before failing.
4. The density is the material's weight per unit volume. Density is important when measuring the energy cost. The material's density must be compared to the strength and durability to ensure the material is sufficient for the patient.
5. Corrosion resistance is the degree to which the material susceptible to chemical degradation. Orthosis often generate heat and causes people to sweat. The material shouldn't absorb moisture and should be easy to clean.

Ease of fabrication is another important factor when it comes to choosing the correct materials. Some materials can be easily formed while some may take special equipment and techniques. The most commonly used materials in orthotics are leather, plastics, and foamed plastics (Lusardi & Nielson, 2007, p. 17).

Leather has been used as an interface material between the patient and orthosis. Today it is mostly used as a strapping material. Useful properties of leather include its dimensional stability, porosity, and water vapor permeability (Lusardi & Nielson, 2007, p. 17). Leather requires skills such as sewing, cutting, and molding. It may also require a technique called *skiving*, which means to thin out the edge of the flesh side of the hide.

Metals are also used in orthosis. There are generally two types of metals used for orthoses: steel, and aluminum. Steel is strong, rigid, durable and ductile, but it can be heavy susceptible to corrosion. Aluminum is a high strength to weight ratio and is resistant to some corrosion. Aluminum is not resistant to bodily fluids and has to have a hard coating before being used in orthoses. Metals are typical used to provide structure for orthoses in areas that need to be limited or supported.

Plastics are also widely used materials for orthotics. The ability to be formed over a positive model makes plastic a very popular material in orthotics. Plastics are separated into two categories: thermoplastic and thermosets. Thermoplastics are formable when they are heated and become rigid when they have cooled. One advantage of thermoplastics is they can be reheated and shaped multiple times, making it possible to make minor adjustments to orthosis after fitting (Lusardi & Nielson, 2007, p. 19). Thermoplastics are the material of choice for “shell” orthosis where structural strength is required (Lusardi & Nielson, 2007, p. 19). Polypropylene, polyethylene, acrylic, and copolymer are the most popular. Polypropylene, which is one of the most widely used, is a rigid plastic that is inexpensive, lightweight and easy to thermoform.

Thermosets are plastics that are applied over a positive model in liquid form and then chemically "cure" to solidify and maintain a desire shape. Thermosets cannot be changed by reheating. Common thermoset resins used in orthotics are acrylic, polyester, and epoxy (Lusardi & Nielson, 2007, p. 20). Thermosets are used to create components of orthoses rather than the actual "shell" itself.

Foamed plastics are used as an interface between the orthosis and the human skin. They are used to provide comfort by covering bony prominences. Foamed plastics are grouped into two classes: Open cell and closed cell. Closed cell foams are more commonly used than open cell foams because they are impervious to liquids, and are less likely to absorb bodily fluids (Lusardi & Nielson, 2007, p. 20) Closed cell foams also act as insulators and they have a tendency to trap heat.

The materials used to create a back brace need to be able to last the prescribed amount of time as well as perform its function. It is also important to remember the interaction these materials will have on the patient's body.

3.3.2.3.4 Types of Orthosis

The type of orthosis that will be used to treat an injury first depends on the area of the spine that needs to be treated. In the past, orthoses have been named by the orthosist or city where it was developed. Currently spinal orthoses are named after the initials of the regions of the spine that are encompassed by the orthosis (Lusardi & Nielson, 2007, p. 397). Figure 26 illustrates the acronyms and names for different types of spinal orthosis. The name of the site of injury will guide the health professionals in deciding which design will best fit the medical requirements. A TLSO will have to be a design that differs from a CO because it has a larger area to address.

Nomenclature for Spinal Orthoses

Acronym	Name
SIO	Sacroiliac orthoses
LSO	Lumbosacral orthosis
TLSO	Thoracolumbosacral orthosis
CTLSO	Cervico-thoracolumbosacral orthosis
CTO	Cervicothoracic orthosis
CO	Cervical orthosis

Figure 26. Nomenclature for Spinal Orthoses (Lusardi & Nielson, 2007, p. 398).

The next step is to identify the cause for the orthosis. Spinal orthoses are generally used to treat deformities such as scoliosis and spondylolisthesis, or to treat injuries such as compression fractures caused by accidents or falls. It is important to establish these factors because they will help determine variables such as the amount of time the orthosis must be worn. An orthosis for scoliosis is used to correct the deformity over a period of time, while an orthosis used for a patient who has had surgery may only require orthosis while they are healing. Some patients may require an orthosis that can be used in many occasions. It is the job of the physician and orthotist to assign the correct orthotic option that suits the assignment. Back braces are available in three main categories: rigid, semi-rigid, and flexible. Figure 27 shows examples of the different

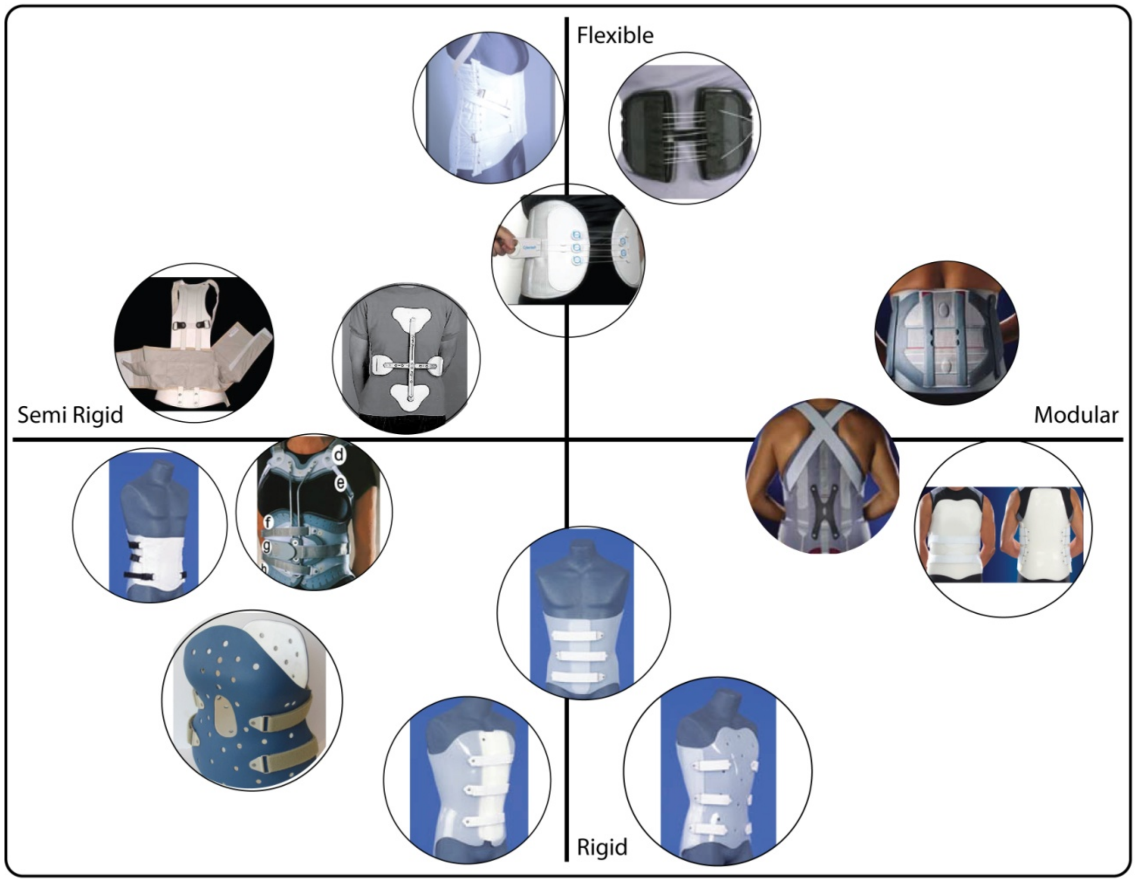


Figure 27. Comparison chart of the different categories of spinal orthosis

types of orthoses. Rigid orthoses usually provide the most support to the area being treated (Falk, www.spineuniverse.com, 2005). A TLSO, as shown in Figure 27, is an example of a common rigid orthosis. They are generally used during the post operative period. A TLSO is a two piece body jacket that limits motion in the prescribed planes. Flexible braces are used for treating back pain and for lifting. Semi-rigid orthoses provide the strength of rigid orthoses and the flexibility of cloth orthoses. This type of brace is also often used in the post surgical setting. Figure 27 also displays modular orthoses. Modular back braces can be rigid or flexible in nature. Modular orthoses feature components that can be mixed with different types of orthoses to perform its medical function. Since the level of rigidity varies, the level of comfort will also vary. Rigid orthoses provide the most support and protection. Medically it is a great solution, but they may be more uncomfortable for the patient to wear because of the amount of body area it encompasses. There is an increased chance of the device irritating the skin of bony protrusions, and an increase in heat. When you explore softer options, they lose the strength of the rigid orthoses. The orthotist is required to choose the option that best suits the patient's functional needs.

3.3.2.3.4.1 Post Operative Orthoses

Back braces can be used for different purposes, but they can also be used at different times during the rehabilitation process. Since this project focuses on the post surgical period we will focus on Post operative orthosis. The goal of post operative orthosis is to protect surgical constructs from large loads that are created from torso motion until solid biologic fusion occurs (Gavin T. H., 2001). The post operative orthosis should protect the surgical construct form the planes of motion in which the construct is vulnerable to failure (Gavin T. H., 2001). Most surgical constructs are subject to failure when movements such as flexion or rotation occur. Figure 28 shows a bivalve TLSO and a clamshell TLSO, which are two of the most used post operative back braces.

The bi-valve and clamshell TLSOs are composed of two shells that are put together to form the orthosis. The rigidity of the TLSO along with the ability to protect the surgically repaired area from outside damage, makes them ideal for post surgical settings.

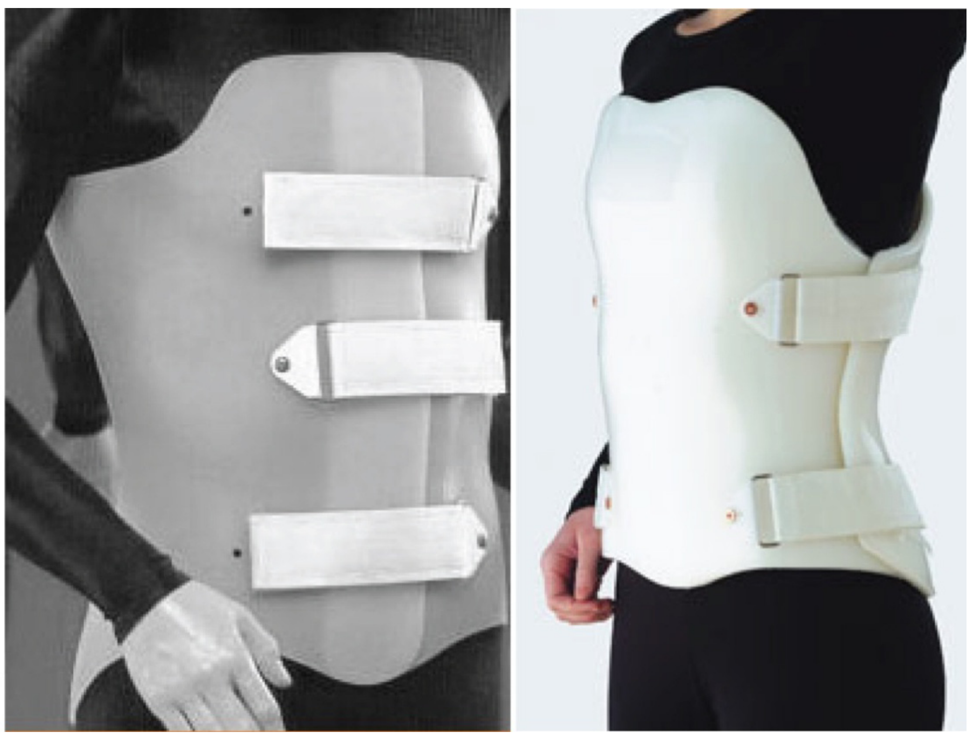


Figure 28. Bi-valve and Clamshell TLSO

3.3.2.3.4.2 Custom vs. Pre-fabricated Orthosis

The final criteria for selecting the proper back brace for a patient is to decide which method of fabrication will provide the best solution. Orthotists are faced with two options: Custom molded orthosis and Pre-fabricated orthosis. A custom molded back brace is a brace that is made from the measurements of a specific person. A pre-fabricated brace, or “Off the shelf brace,” is a brace that is made from a template and available in a variety of sizes without a specific person in mind. Custom molded braces and pre-fabricated braces both have their pros and cons. A major plus of pre-fabricated orthosis is that they are readily available and come in a variety of sizes. A question among physicians is do they work as well as custom molded brace. Does a pre-fabricated TLSO work as well as a custom molded TLSO? Gene Bernardoni, of Ballert Orthopedics and Prosthestics, has written an article contrasting the pros and cons of custom molded TLSOs versus pre-prefabricated TLSOs. After evaluating a number of pre-fabricated TLSOs with a staff of orthotists and orthopedic surgeons, Bernardoni comes to the conclusion that with regards to biomechanical control of motion, patience compliance, and overall cost, the custom-molded TLSO is superior to its OTS versions, and should remain in most cases the preferred option for post surgical and trauma patients (Bernardoni).

The first point that Bernardoni addresses is the inability of prefabricated braces to control motion. Bernardoni identifies the fact that most pre-fabricated orthoses have anterior shells with flat panels and lateral panels made of thin polyethylene tongues. Figure 29 illustrates a prefabricated TLSO with the previous features. The problem with this orthosis is that it does not do a good job in limiting triplanar motion. It will not limit lateral movement b the tongue is too thin and it is flat. Since the front of this brace is flat it will not firmly grasp the pelvis to help stop rotation.

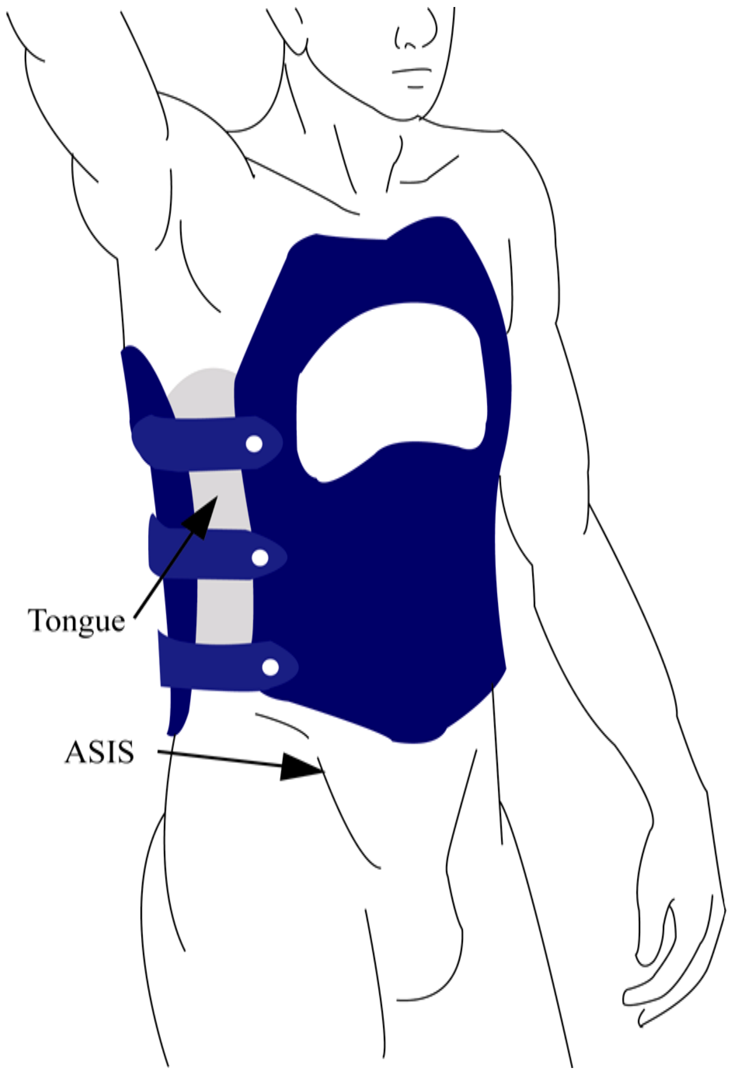


Figure 29. VertAlign Prefabricated orthosis. (Bernardoni)**.**

The second issue with controlling motion is that the flat anterior panel does not accommodate the difference in patient body types. The flat panel does not conform to the abdomen and will not fit a larger patient or a woman. Figure 30 shows the difference in body types. The flat panel may work for some patients but it definitely will now work for others. The brace will not align itself to the correct contact points. A custom brace conforms to the body and keeps the patient in a hyper extended or hyper flexed position. This is important when dealing with post surgical implants. Bernardoni states the importance of this factor as follows:

> The vulnerability of any implant is that the implants are always significantly stiffer than the bone that they are attached to. It is safe to say that a post-operative orthosis that does not perfectly match the post operative geometry of the spine may be creating artifact forces that may influence loosening of an implant (Bernardoni).

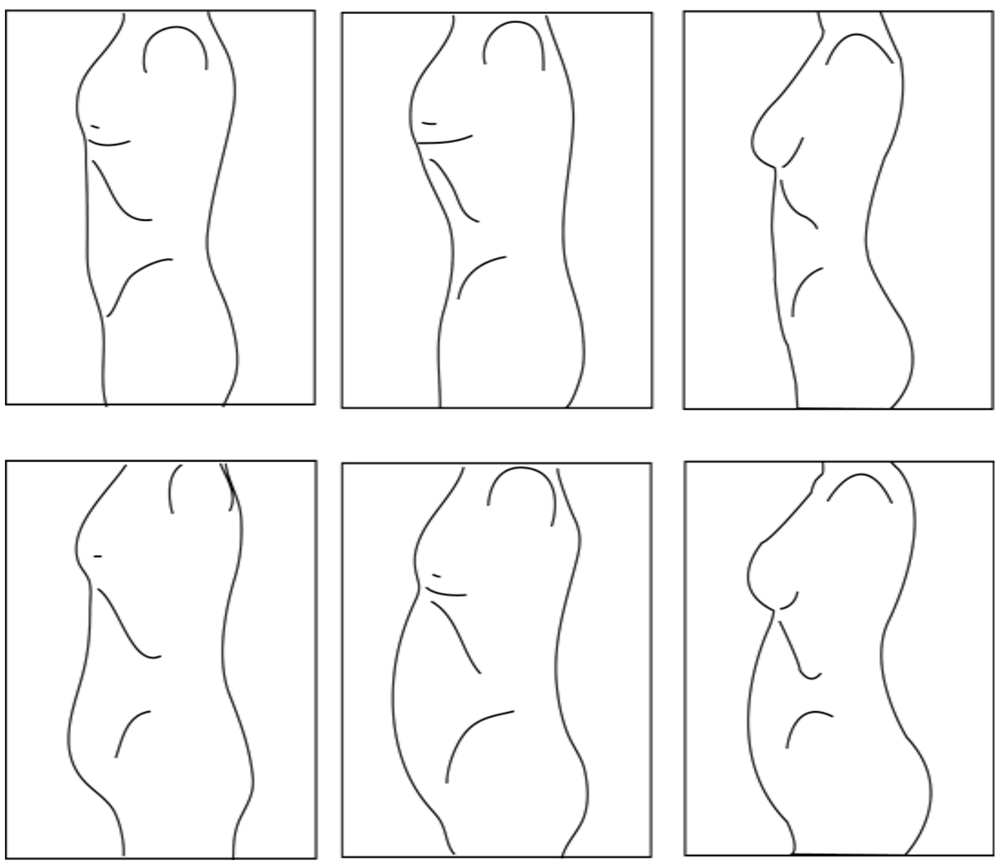


Figure 30. Potential body types for a patient

Bernardoni goes on to say that, "In summary, most OTS orthoses are made in fixed geometries that are not hyper extended or hyper flexed, and are not able to reliably match a post-operative construct alignment" (Bernardoni).

The flat anterior panel of pre-fabricated orthosis causes a variety of problems that affects the overall biomechanical functions of the orthosis. If the brace cannot perform its mechanical function it is useless.

The second factor when comparing pre-fabricated orthoses to custom molded orthoses is patient compliance. Custom molded orthoses are usually more comfortable because they are formed to the patient's body. Patients also complain about the heat of the custom TLSO because it covers a large area. Although patients sometimes complain that the plastic is hot, Bernardoni notes the custom TLSO is not as hot as the pre-fabricated TLSOs that use thick foam linings to compensate for thin plastic. In order to reduce heat both custom and pre-fabricated TLSOs drill holes in the device to allow heat to escape. In terms of comfort they are both uncomfortable in the early stages of their rehabilitation.

The last factor the author reviews is cost. In general, pre-fabricated TLSOs are viewed as cheaper than custom molded TLSOs. Bernardoni states that the cost to the hospital or patient of a pre-fabricated appliance is frequently higher than a custom orthosis (Bernardoni). He offers the following example of how a prefabricated TLSO can cost more than a custom TLSO. He states that in the case of the Aspen TLSOs, the cost to the hospital is $300 to $400 more than the custom TLSO, including the cost of follow up visits. When an Aspen is used in place of an LS corset or a Warn 'N' Form, the former can cost $500 to $600 more. And when the hospital cannot pass along the cost of the item to the patient's insurance, the cost falls directly to the hospital's bottom line (Bernardoni).

This statement concludes that the cost of a pre-fabricated TLSO is not necessarily cheaper than a custom molded TLSO. He also states that cost is not a deterrent from providing the best clinical outcome. It would be foolish to pay more for a product that produces a poor or unknown clinical outcome (Bernardoni).

The conclusion of his study shows that while pre-fabricated orthoses may seem more convenient, they are not as effective as custom molded orthoses. Custom molded TLSO's are superior to pre-fabricated TLSOs in controlling motion, providing superior fit, and patient compliance.

3.3.2.3 D: Patient Application and Understanding

The final phase in the processs is to make sure the patient understands how to apply the brace and the importance of wearing the brace properly. The job of the orthosis is to limit movement and keep the patient immobilized. For this reason, the patient is often instructed to apply the back brace in two positions:

1) sitting on the side of the bed,

2) while laying in bed.

The purpose is to keep the spine in its fixed postion. The first method of application simply requires the patient sitting upright on the bed and attaching the orthosis. The second method is to apply the brace while laying in bed. This common is often preferred among doctors. Applying the brace while lying in bed involves using a process called the “log roll method.” The log roll (see Figure 31) is used to keep the patient’s spine in alignment to apply the brace. The log roll method employs the following steps:

1. While lying on your back, bend your knees.
2. Roll onto your side. Keep your shoulders and hips together as a unit as you roll (University of Pittsburgh Medical Center Information for Patients, 2003)

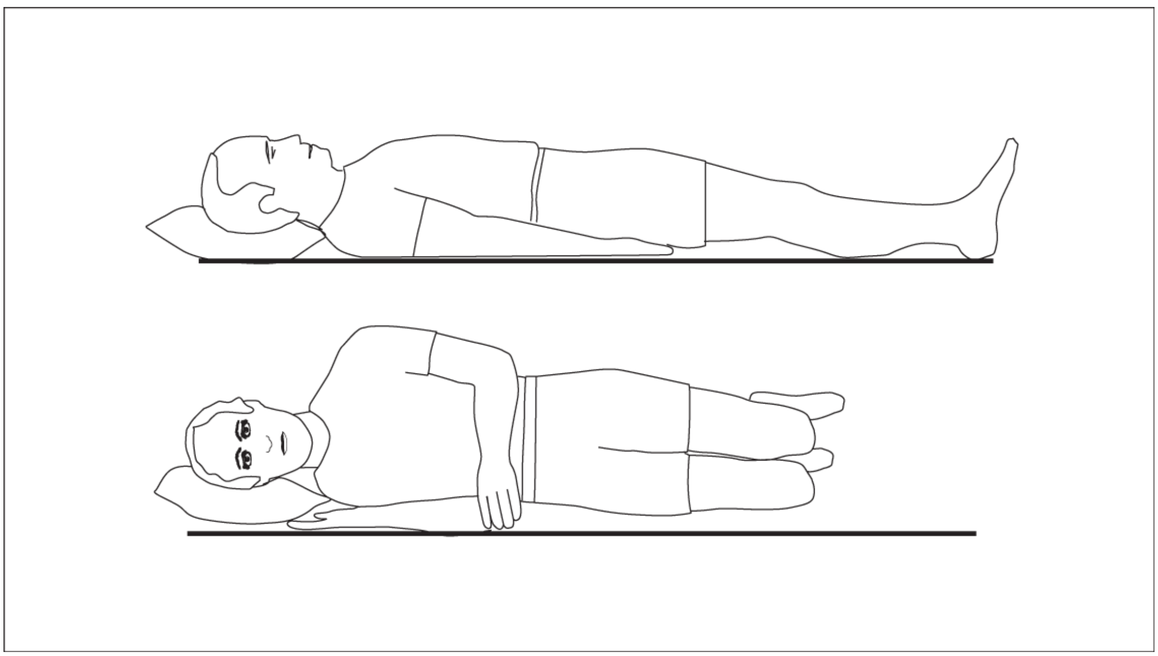


Figure 31. Log roll method (University of Pittsburgh Medical Center Information for Patients, 2003)

This method is important for the patient keep the surgically repaired constructs in place without twisting or bending. The orthosis is incorparated into the log roll method to apply the device without causing any complications. Applying the orthosis using the log roll method can be seen in Figure 32. The following steps describes how the brace is applied using the log roll method. The patient is safely transported into the brace by following steps:

1. Begin by flying flat on the bed.
2. Separate the two pieces of the brace.
3. Log roll onto your side, keeping your shoulders, hips, and knees in a line.
4. Apply the back half of the brace in the proper position on your back.
5. Carefully log roll onto your back and into the brace.
6. Apply the front half of the brace.
7. Fasten the Velcro straps tightly starting at the bottom and working up.

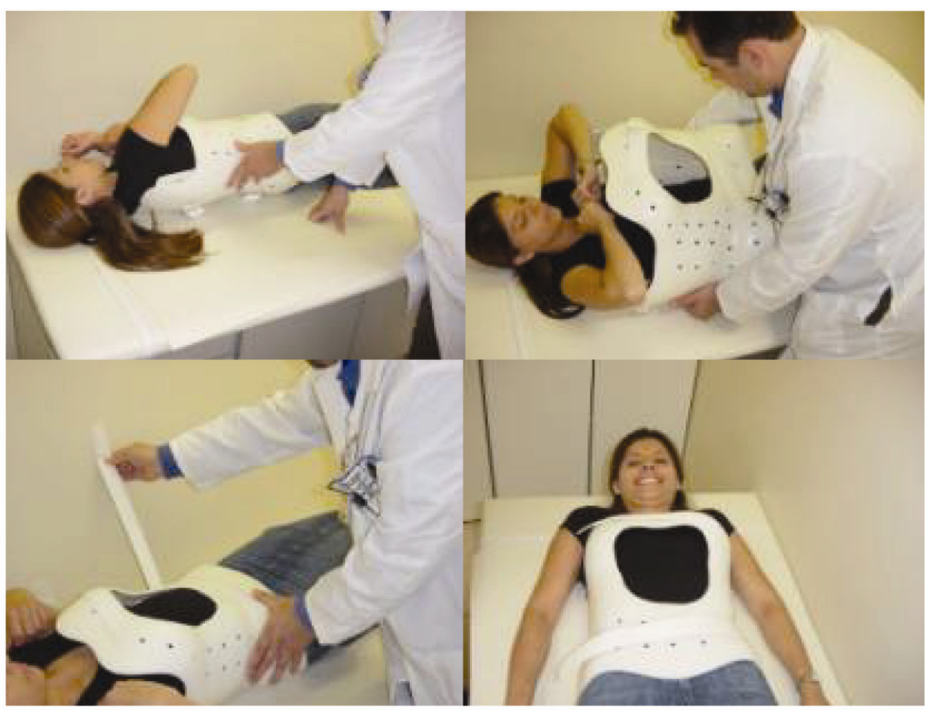


Figure 32. Applying orthosis using the log roll method (Scoliosis TLSO Brace, 2005).

The log roll method is effective, but it can be difficult to apply the brace onto the patient. The brace must slide under the patient. Sliding a brace under a patient can be difficult when the back half is curved to fit the body. It may take a couple of rolls to apply the brace correctly. It is impotant that the patient understands how and wear to apply the brace correctly. Applying the brace in the wrong position can damage the surgically repaired area. The patient also needs to make sure all straps are firmly attached. If the straps are not attached firmly the device is prone to move out of place and lose the pressure points that make the brace effective. It is important that the orthotist carefully explain how the patient should apply the brace to prevent improper usage that can result in further injury.

3.4 Performance Criteria

The examination of the evaluation process for a patient reveals several choices that must be made in the design. Information obtained in this chapter leads to the creation of a set of parameters that can be used in the design of the back brace. A performance criteria chart will set up a foundation for the objectives the orthosis needs to achieve.

3.5 Summary of Chapter

Chapter 3 introduces the field of orthotics and the process a patient might go through before they receive their orthosis. The examination of the healthcare professionals involved in the process and their responsibilities dictates what parameters can or cannot be changed. A study of the evaluation of a patient identifies key points in design. This chapter also breaks down the field of orthotics into the necessary components for this thesis. It is important to know the different types of back braces so the final outcome of this study fits its intended function without overstepping its boundaries. The TLSO is identified as the type of brace that will be used to modify in this study. A list of performance criteria were developed to define the characteristics that need to be evident in the design of the orthosis.

Performance Criteria			
Human Function	Social Economic	Price	$375 or less
		Product Life	5-10 years or length of injury(at least 3months)
		Injury	Thoracic Spine(Compression fractures w fusioin)
		Availability	Prescription
	Culteral Aesthetic	Style	Clamshell
		Color of Plastic	Generally white(color upon availability)
		Color of Foam Lining	White
		Color of Straps	Black
	Practical Physical	Weight	5lbs or less
		Size	Varies(custom molded)
		Width of straps	1",2", or 3"
		Application	Lying in bed
Technical Function	Direct Technical	Material for Plastic Shell	Copolymer(polyethylene or polypropelene
		Material for Liner	AliPlast 4E polyurethan foam
		Material for Straps	Nylon; velcro
	Indirect Tech.	Environmental resistance	Bodily fluids
Production Function	Manufacturing	Custom or Pre-Fabricated	Custom
		Method of Manufacture	Vacuum form

Figure 33. Performance Criteria

4. DESIGN DEVELOPMENT

4.1 Overview

This chapter will focus on the design and development of the orthosis. The decisions made in each step will result in the best outcome to produce an effective orthosis. The design of the device will focus on solving problems concerned with patient compliance. Sketches, renderings, and prototypes will be used to come up with a final solution. The sketches will be reviewed by orthotists and orthopedic surgeons to validate the medical function of the orthosis.

4.2 Preliminary sketching

Since the goals of the orthosis have been outlined, the development of the device can begin. The development begins with 9 preliminary sketches (See Figure 35-43). The sketches explore the different options in terms of form and function. Reducing heat is one of the goals of this study. Many of the sketches explore how much material can be taken away without affecting the function (See Figure 43). Another purpose for removing more material is to make the brace lighter. A brace that is lighter will be easier for the patient to wear. The device needs to keep contact on the sternum, pubis, and the mid back to prevent flexion. The concepts also explore different options in terms of straps and the placement of straps (See Figure 37). The brace should be able to be adjusted without the patients removing their clothing. Another option that is explored in the sketching is the difference in depth between the anterior and posterior halves of the orthosis. Figure 42 displays a brace with a back half with less depth when compared to the front. This feature would be used to help apply the brace while the patient is lying in bed.

In order to make sure the designs are medically accurate, input was provided by an orthotist and orthopedic surgeon. The concepts were reviewed by Certified Orthotist Chad Duncan and Orthopedic Surgeon Chad Duncan. The comments and suggestions offered by the two health professionals helped to validate certain concepts as well as provide any problems the concepts might present. Their observations also provided new opportunities to be explored in further development. The observations they made are the following:

- Always treat a specific injury
- Don’t discount the effects of aesthetics
- Strengthen the center piece(Corrugate the plastic) for concepts with thin sternal pieces
- Cut outs around the abdomen are good
- Make things easier for the orthotist when possible
- Using the brace itself as loop for the straps is a good idea. It helps get rid of screws and makes assembly easier for the orthotist.
- Create templates to the make loop holes.
- Having the adjustments in one centralized area is good for the patient
- Watch the clearance for the shoulder blades
- Make sure there is leg clearance for the patient while they are sitting.

- Create a 3mm relief for the spine

The concepts that received the most approval were concept 3, concept 7, and concept 8 (Refer to Figures 37, 41, and 42).

Figure 34. Preliminary sketches

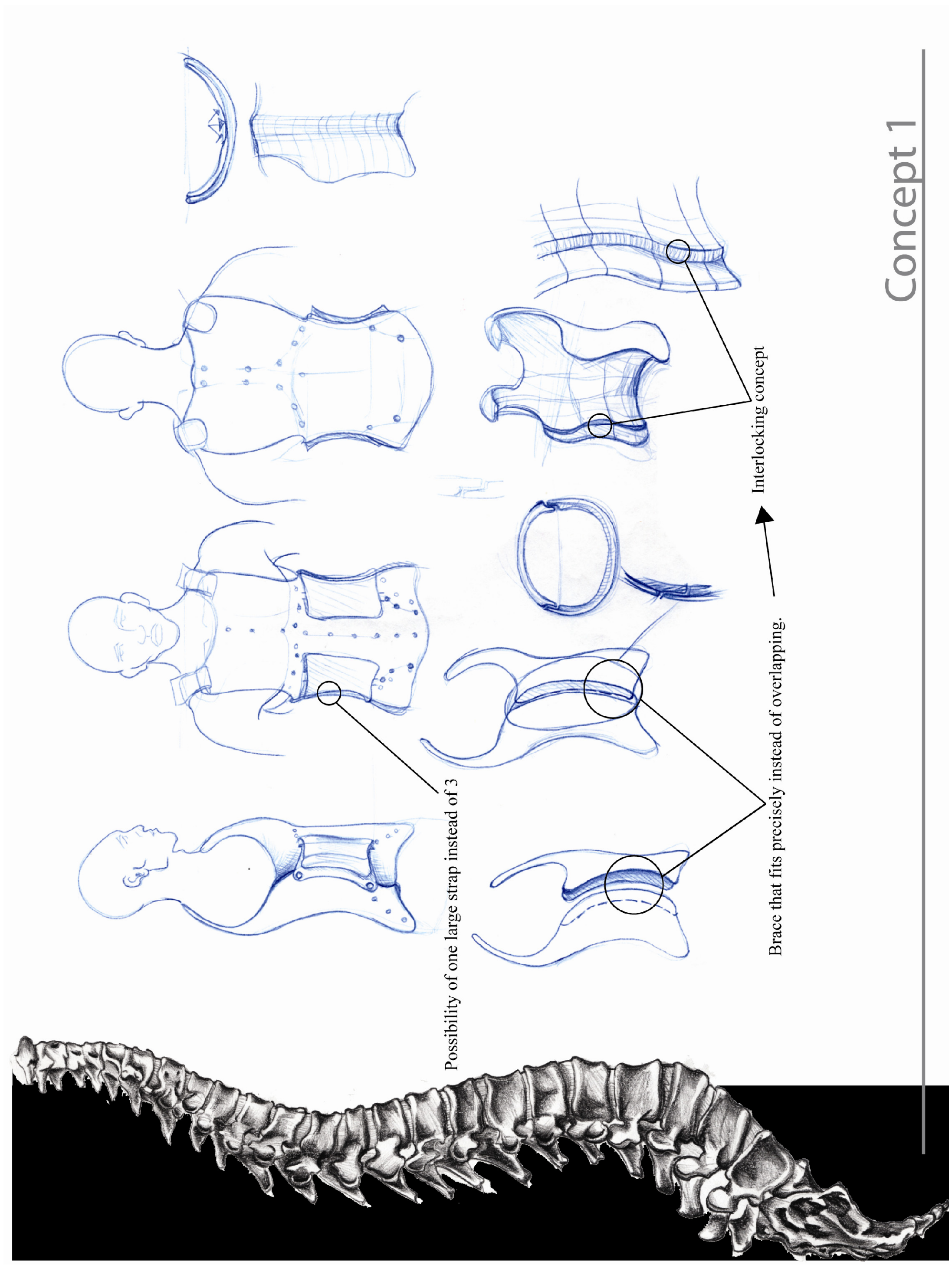


Figure 35. Preliminary Sketch 1

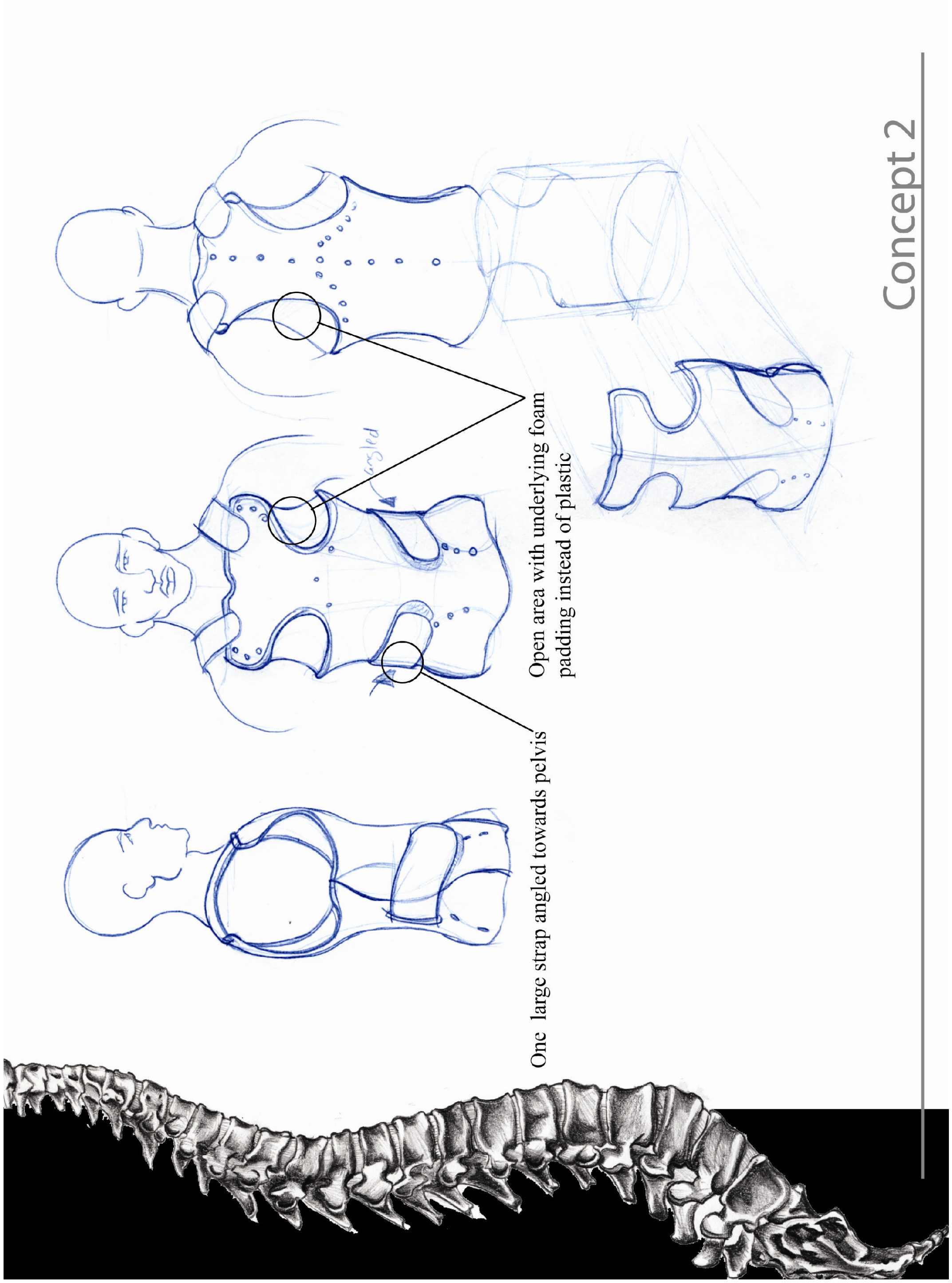


Figure 36. Preliminary Sketch 2

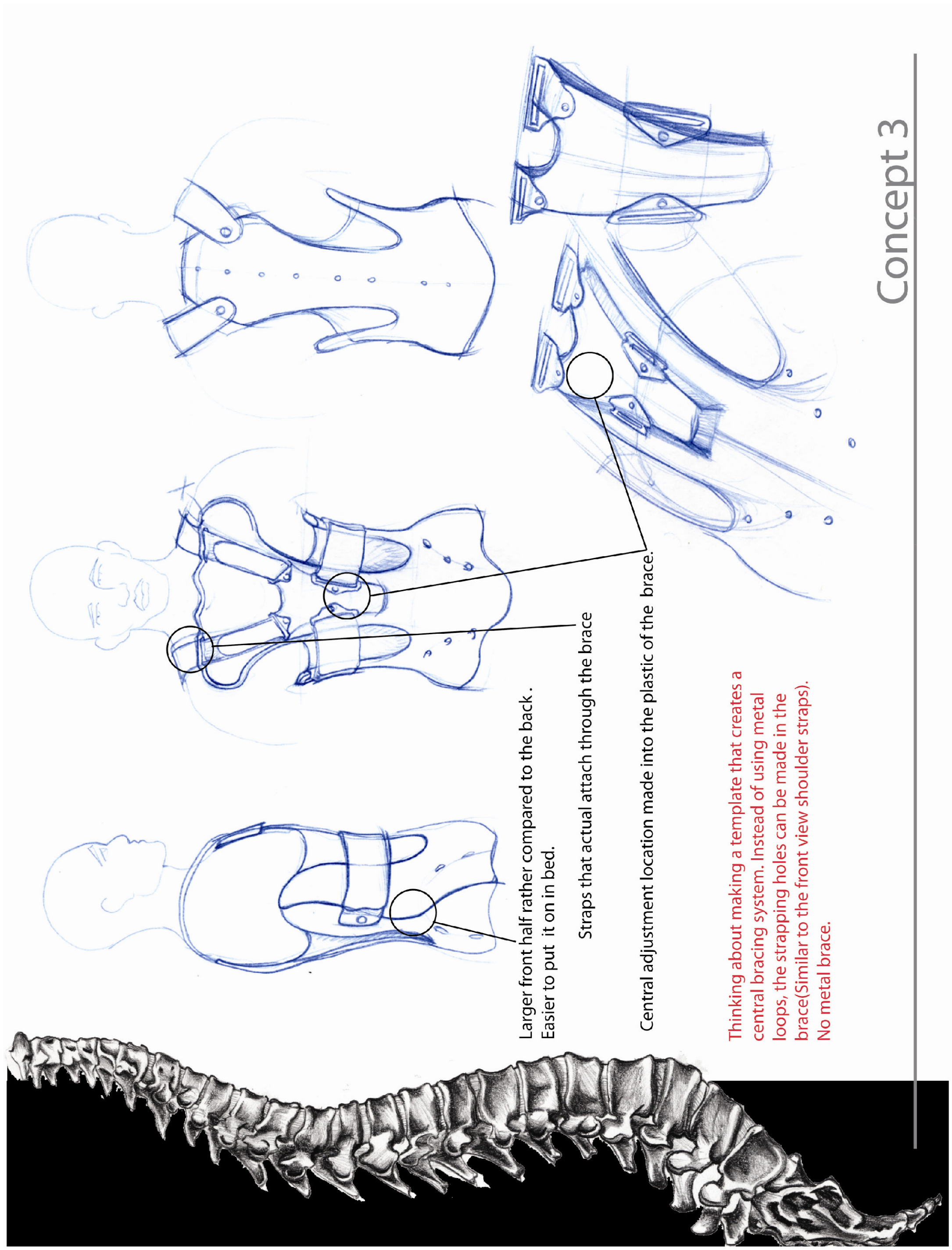


Figure 37. Preliminary Sketch 3

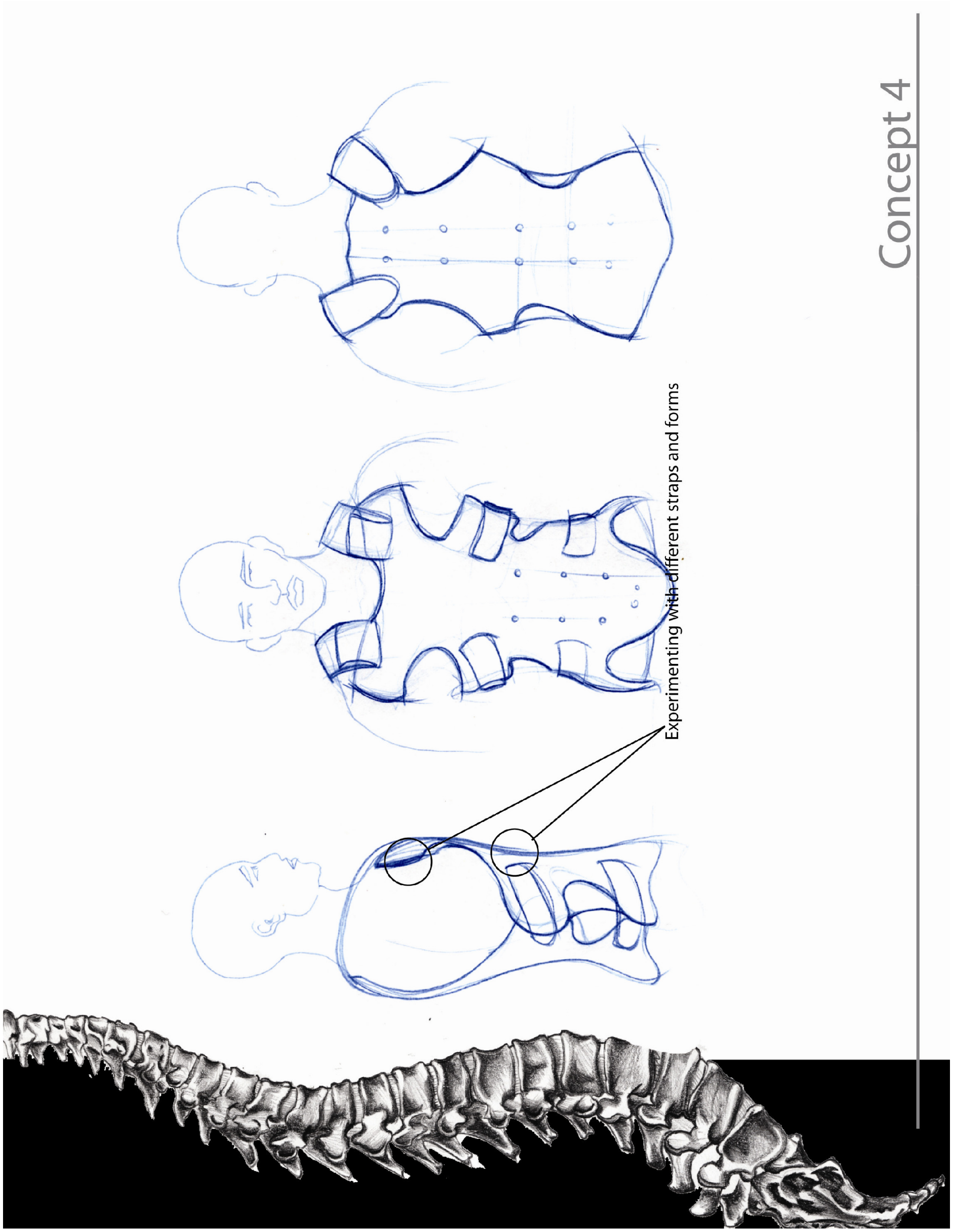


Figure 38. Preliminary Sketch 4

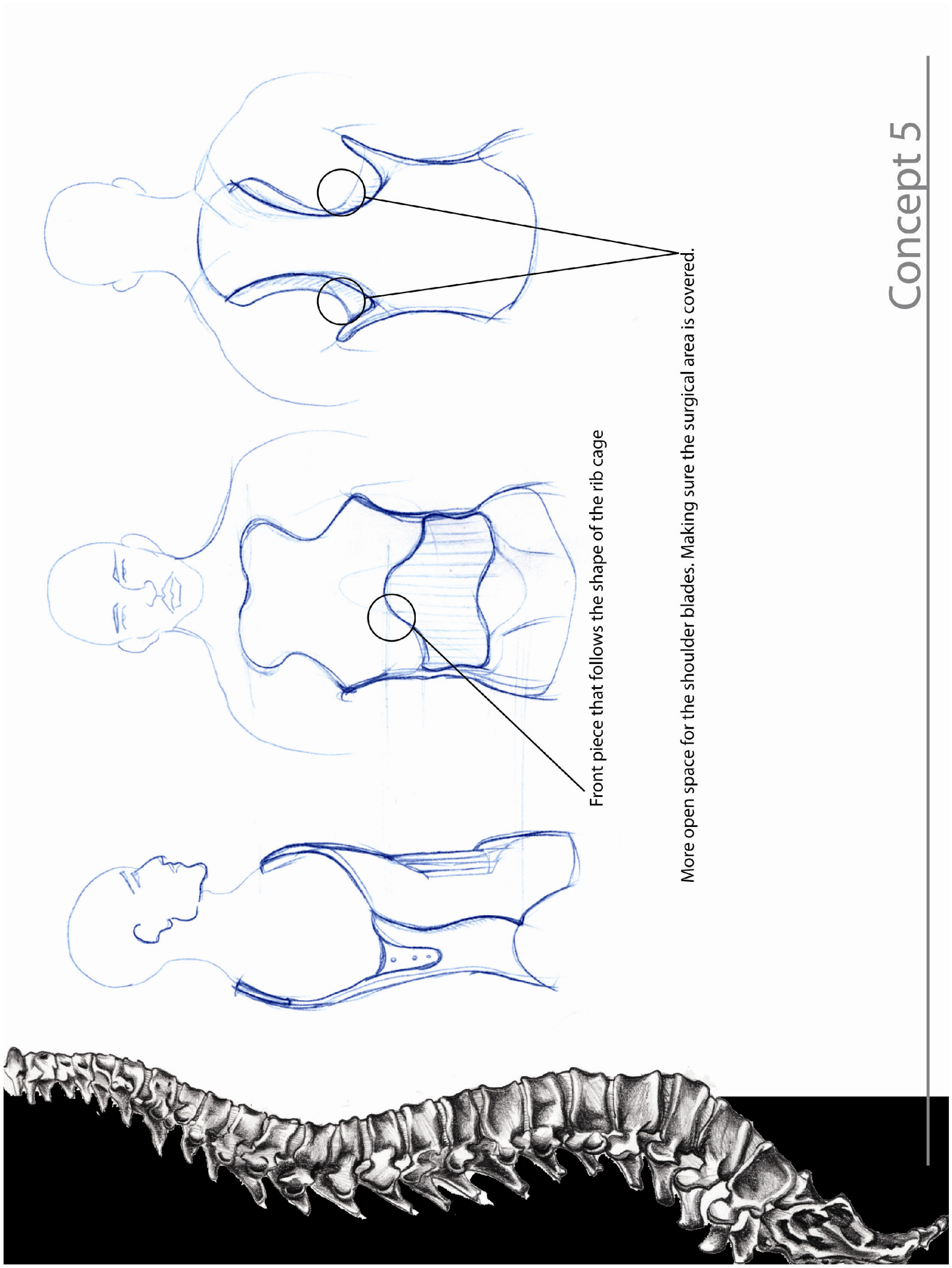


Figure 39. Preliminary Sketch 5

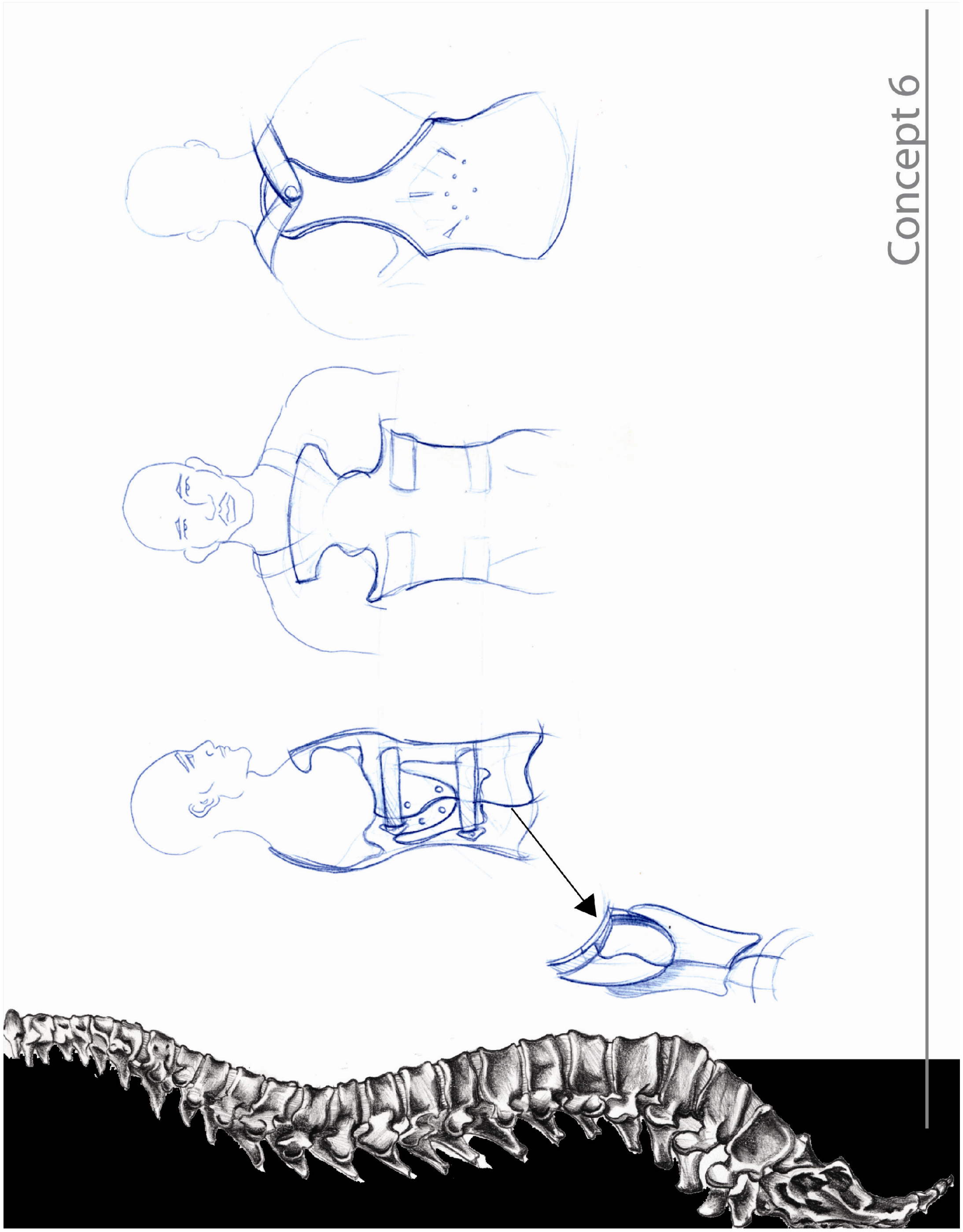


Figure 40. Preliminary Sketch 6

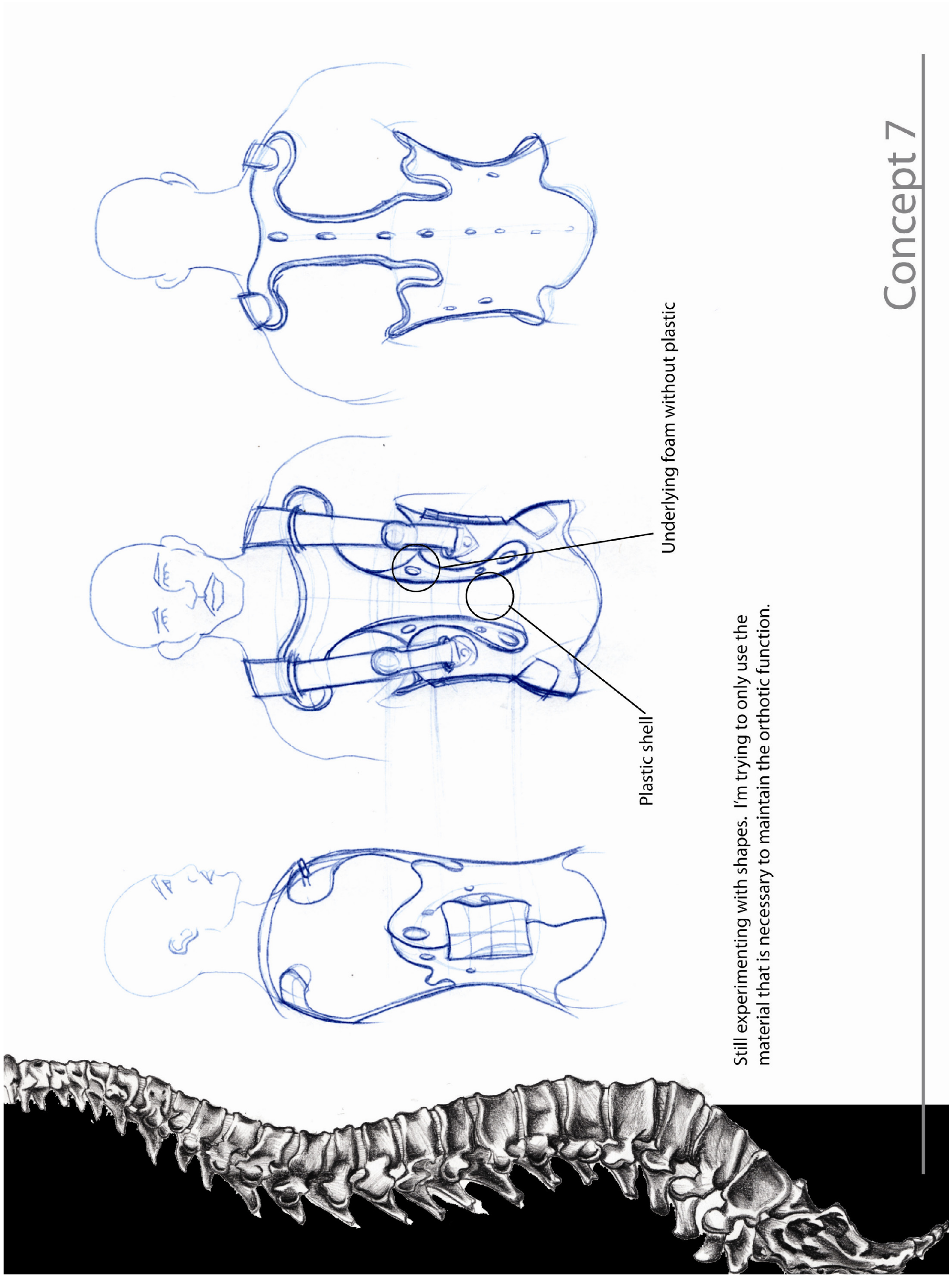


Figure 41. Preliminary Sketch 7

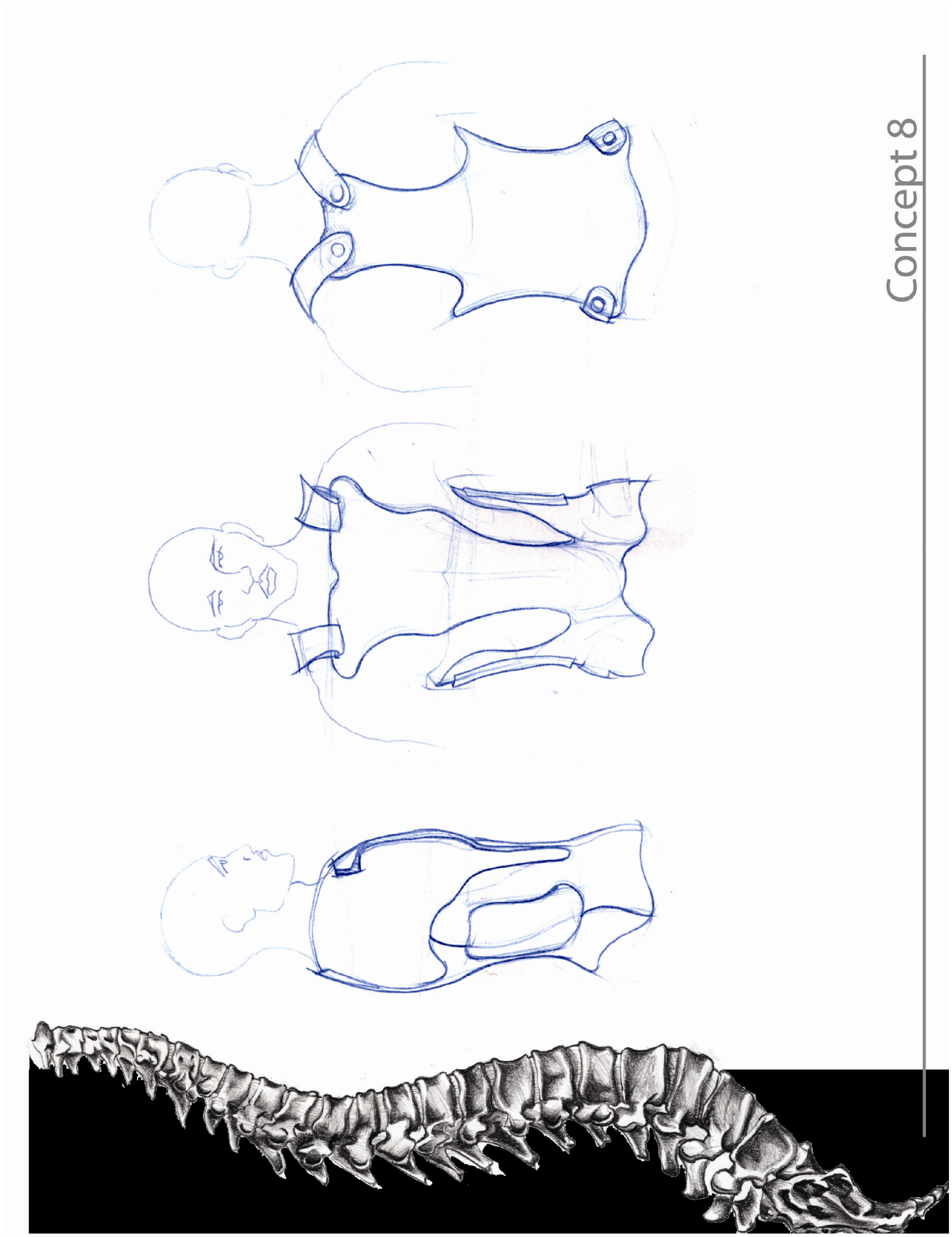


Figure 42. Preliminary Sketch 8

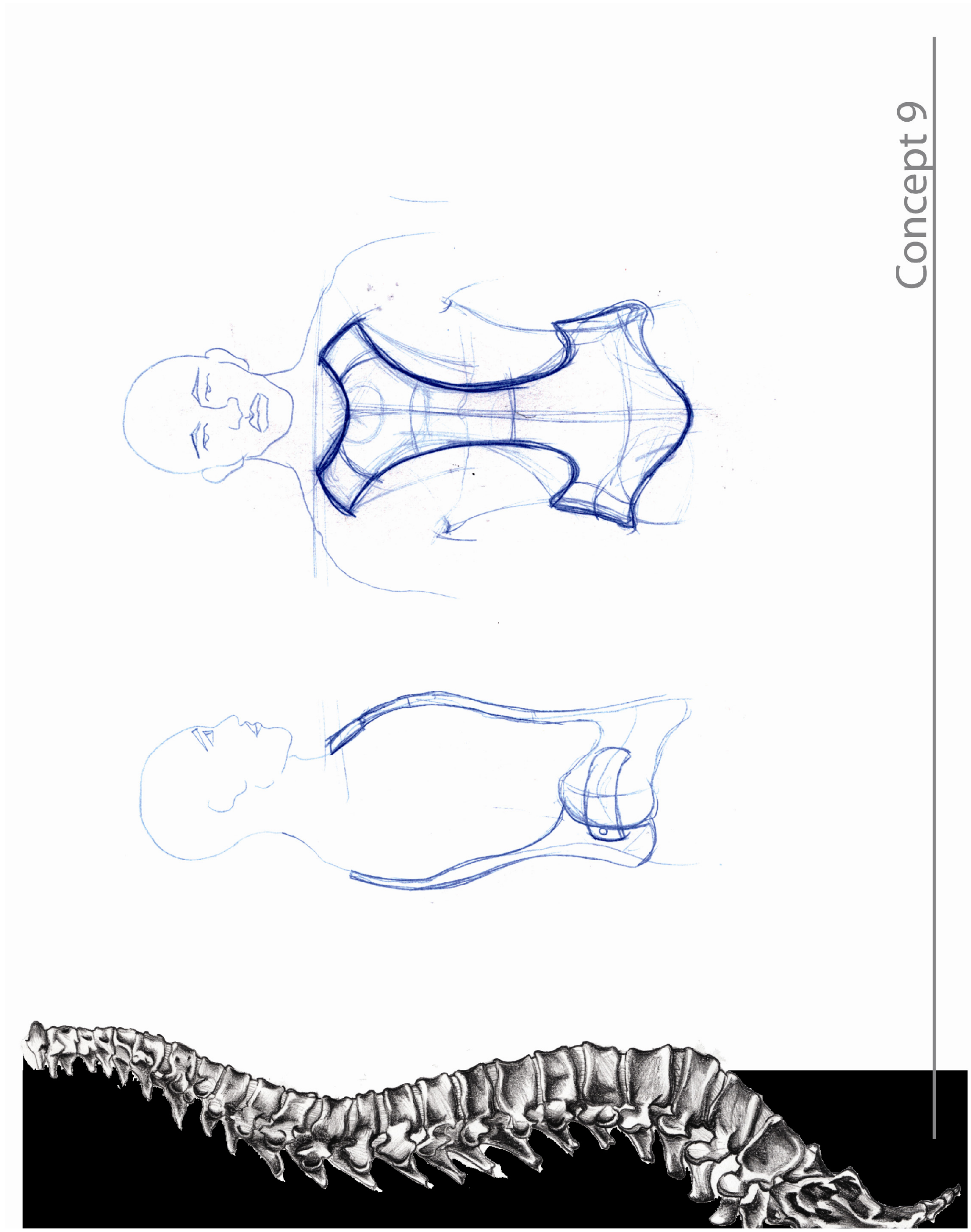


Figure 43. Preliminary Sketch 9

4.3 Concept Refinements

Once the preliminary sketches were narrowed down, refinements were made to improve the function of the brace. Five concept refinements were created to implement the suggested changes. The refinements featured the implementation of the best qualities of the preliminary sketches. The characteristics exemplified by the refinements are:

- Straps that loop through the brace itself
- Cutouts around the chest and abdomen
- Clearance for the shoulder blades
- Alternate methods for extra cooling such as ice packs

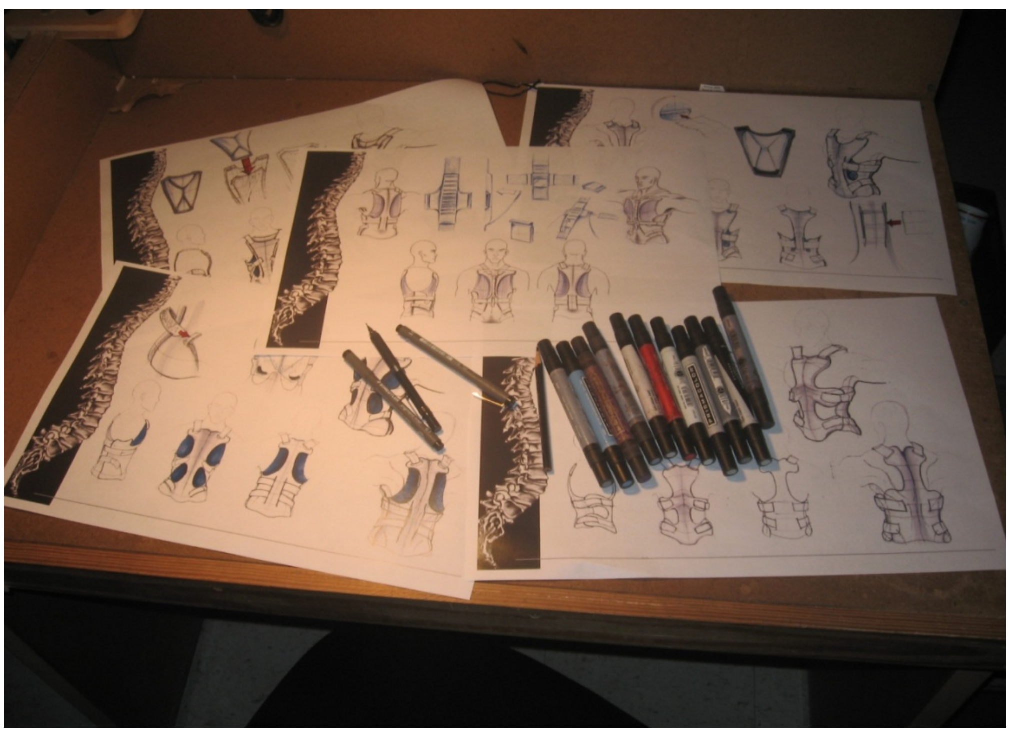


Figure 44. Refinements Sketches

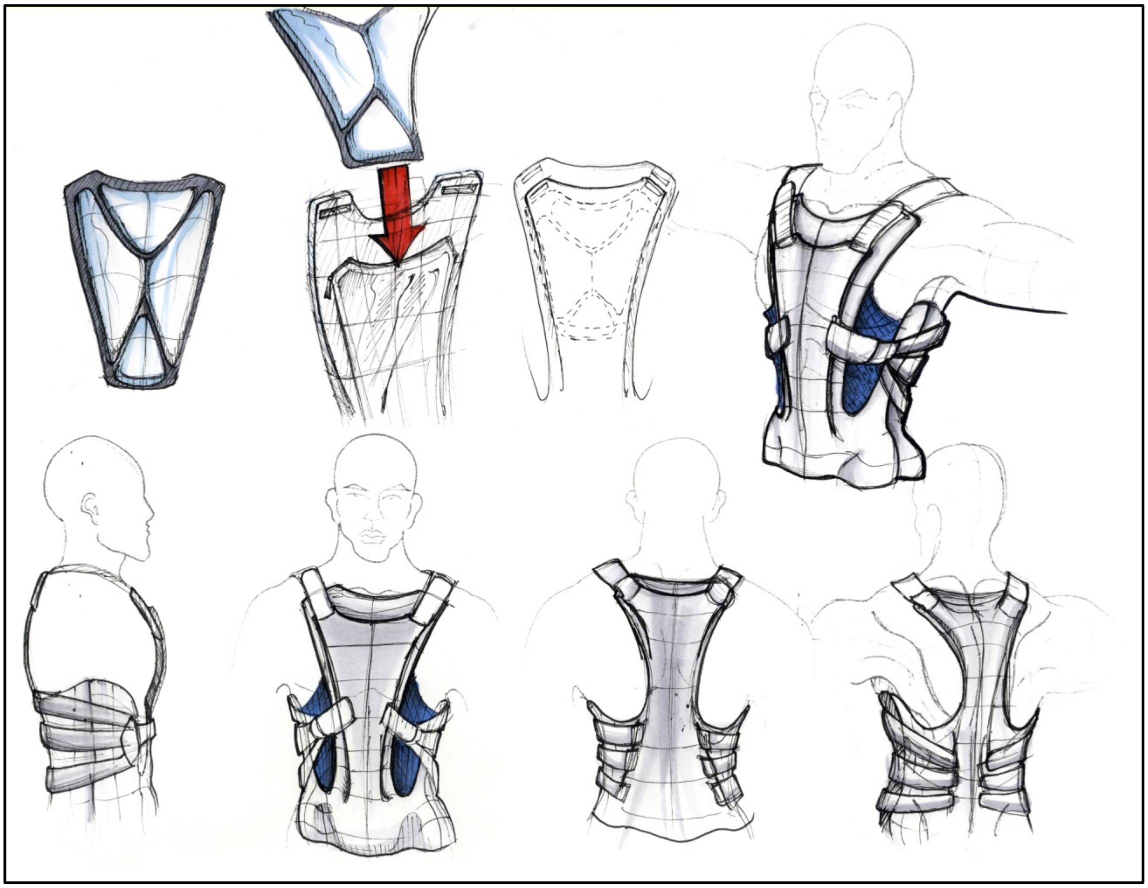


Figure 45. Refinement 1

Refinement 1 introduces the use of cool packs to help cool the patient. The anterior shell is corrugated so the straps can loop through them. This concept features a strapping system on the side where one strap is anchored to three straps on the posterior shell. This is done in attempts to further secure the posterior shell without multiple strapping points.

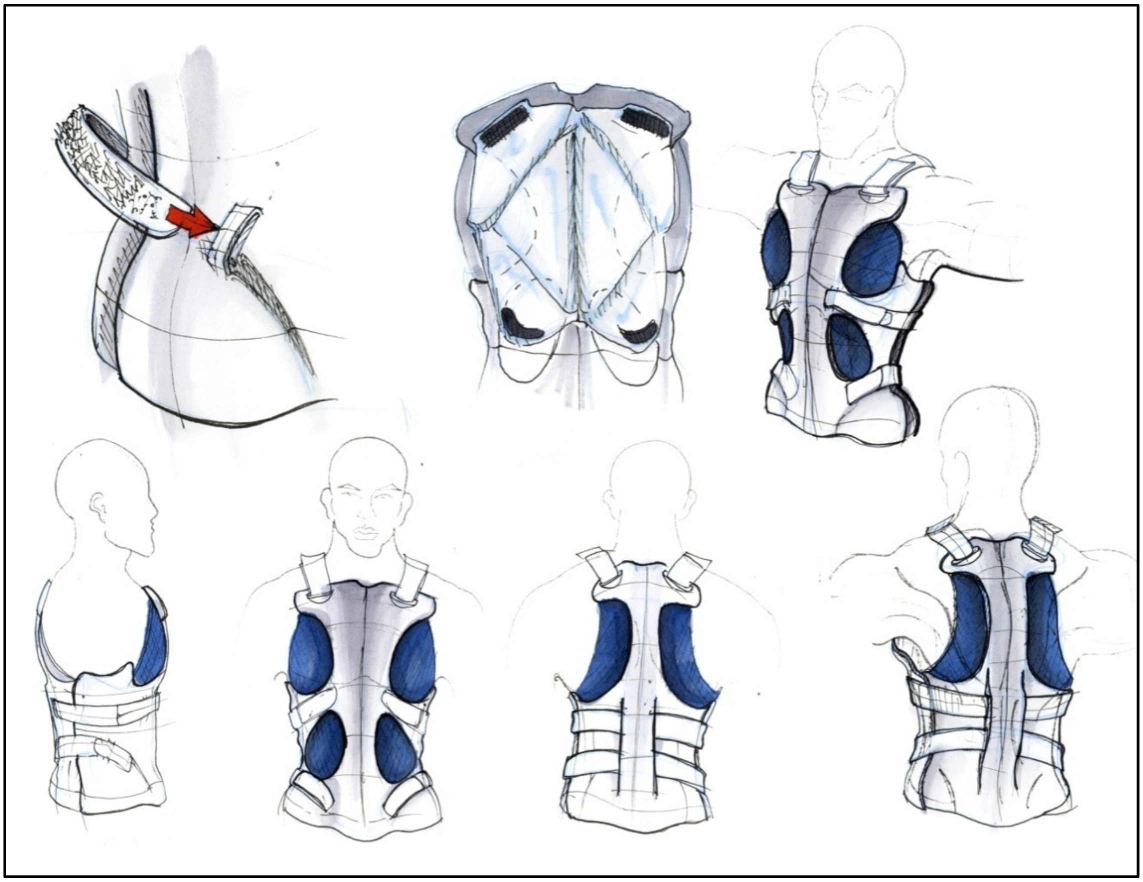


Figure 46. Refinement 2

Refinement 2 features cutouts at the abdomen and the chest with support across the rib cage. The straps in this concept are angled toward the pubis and the sternum to direct the pressure specifically to the pressure points. The posterior shell is also thinner than the anterior shell for ease of application.

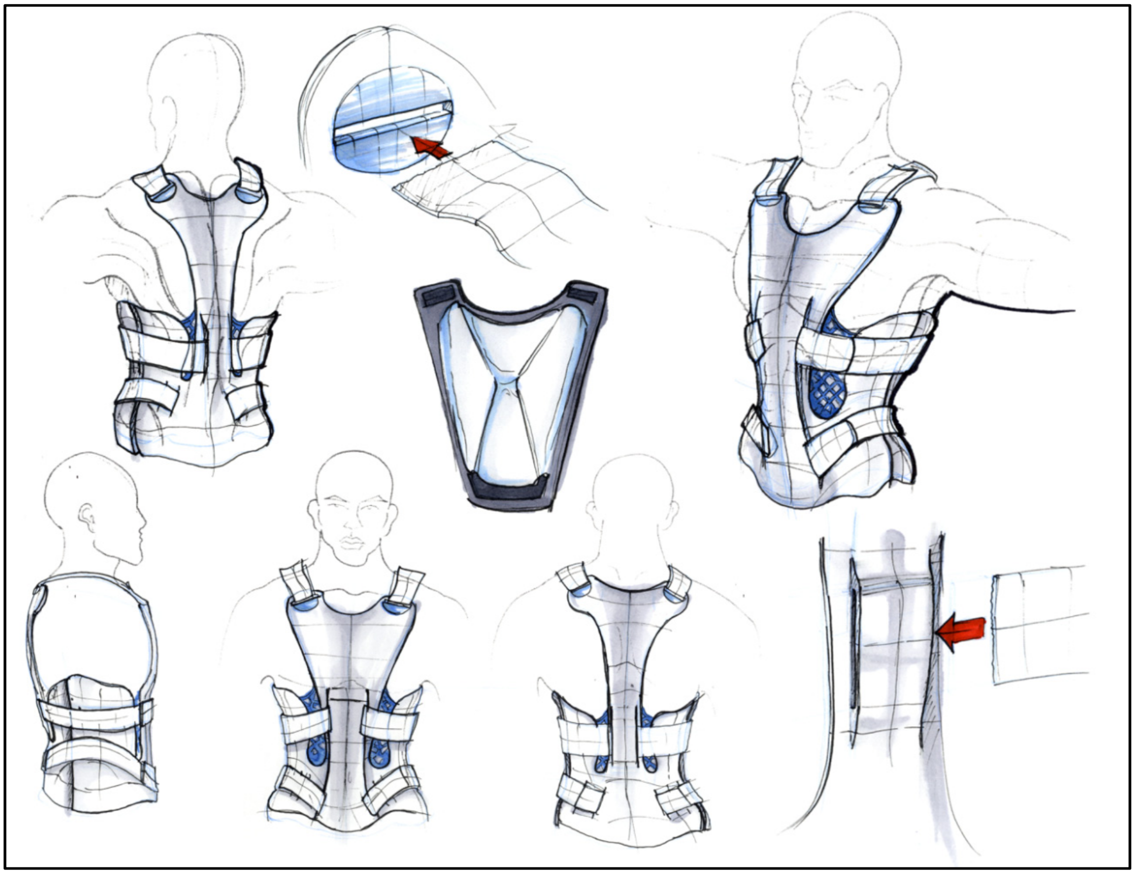


Figure 47. Refinement 3

Refinement 3 features straps that loop through the brace. This concept consists of one strap that loops from the middle of spine to the raised sternal piece, two straps that loop from the back to the pubis, and one two shoulder straps.

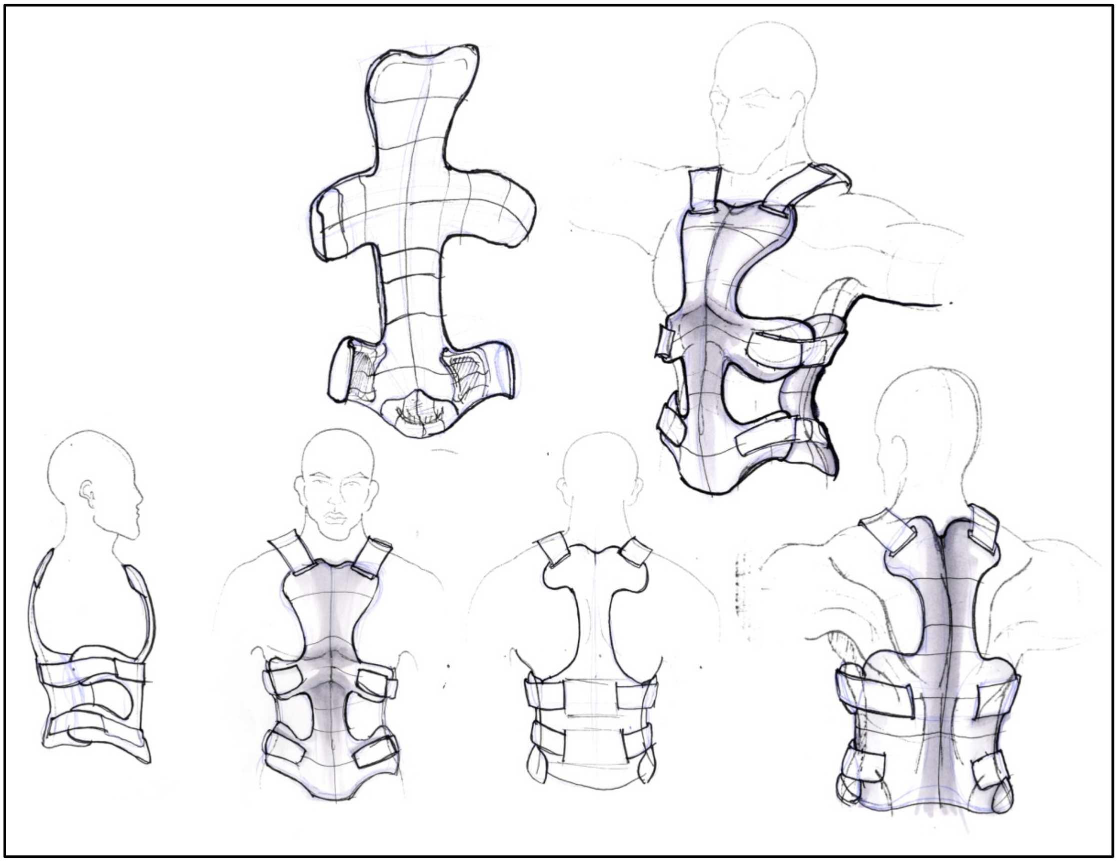


Figure 48. Refinement 4

Refinement 4 is a concept that features the least amount of material for the anterior shell. The shell conforms to the rib cage and pelvis in attempts to direct the pressure points.

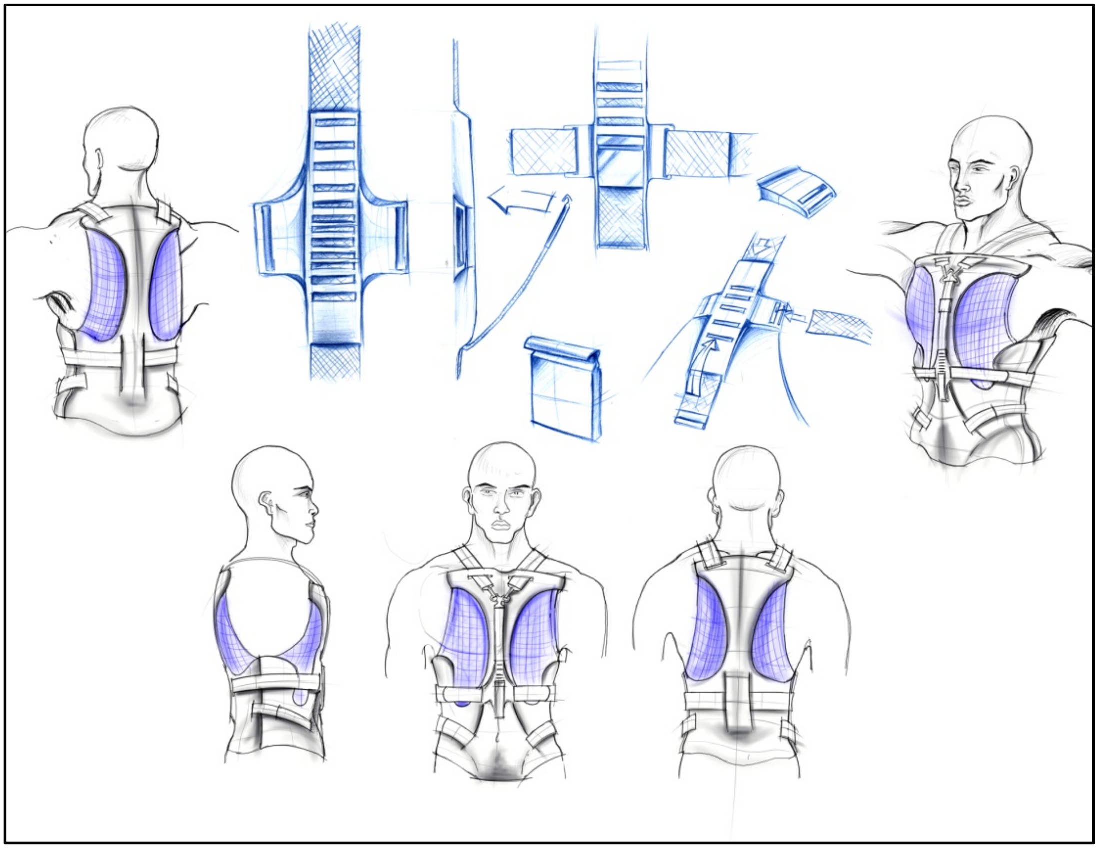


Figure 49. Refinement 5

Refinement 5 features straps that are secured in a central location. This concept uses the same strapping system as concept 3. The one addition is that the shoulder straps are attached by a buckle to a sternal strap which secures around the abdomen. This design allows the patients to adjust their shoulder straps without taking off their shirt.

After evaluating the refinements, design decisions could be made about the features that are best suited for the job. The features that work are:

- Attaching the straps through the orthosis to eliminate screws
- the shallow posterior shell for ease of application
- the central attachment area for convenient adjustments

The feature that will not work is the cooling packs. Most cooling packs only last for a few hours. Chemical cooling packs such as *Coolzone* lasts for 4 hours but are too expensive. The best method of reducing heat is to remove materials without sacrificing the rigidity of the brace.

4.4 Final solution

The final solution (see Figure 50) implements the positive aspects of the refinements and combines them into one orthotic device. The following features are benefits that this brace offers the patient:

- Once the brace is applied, all adjustments are made below the chest
- Less material is used so the brace is lighter and does not trap as much heat
- Freedom of the scapula to move freely
- A shallow posterior shell which allows the brace to be applied easier while lying in bed.
- A brace that is not as bulky and embarrassing as most TLSOs

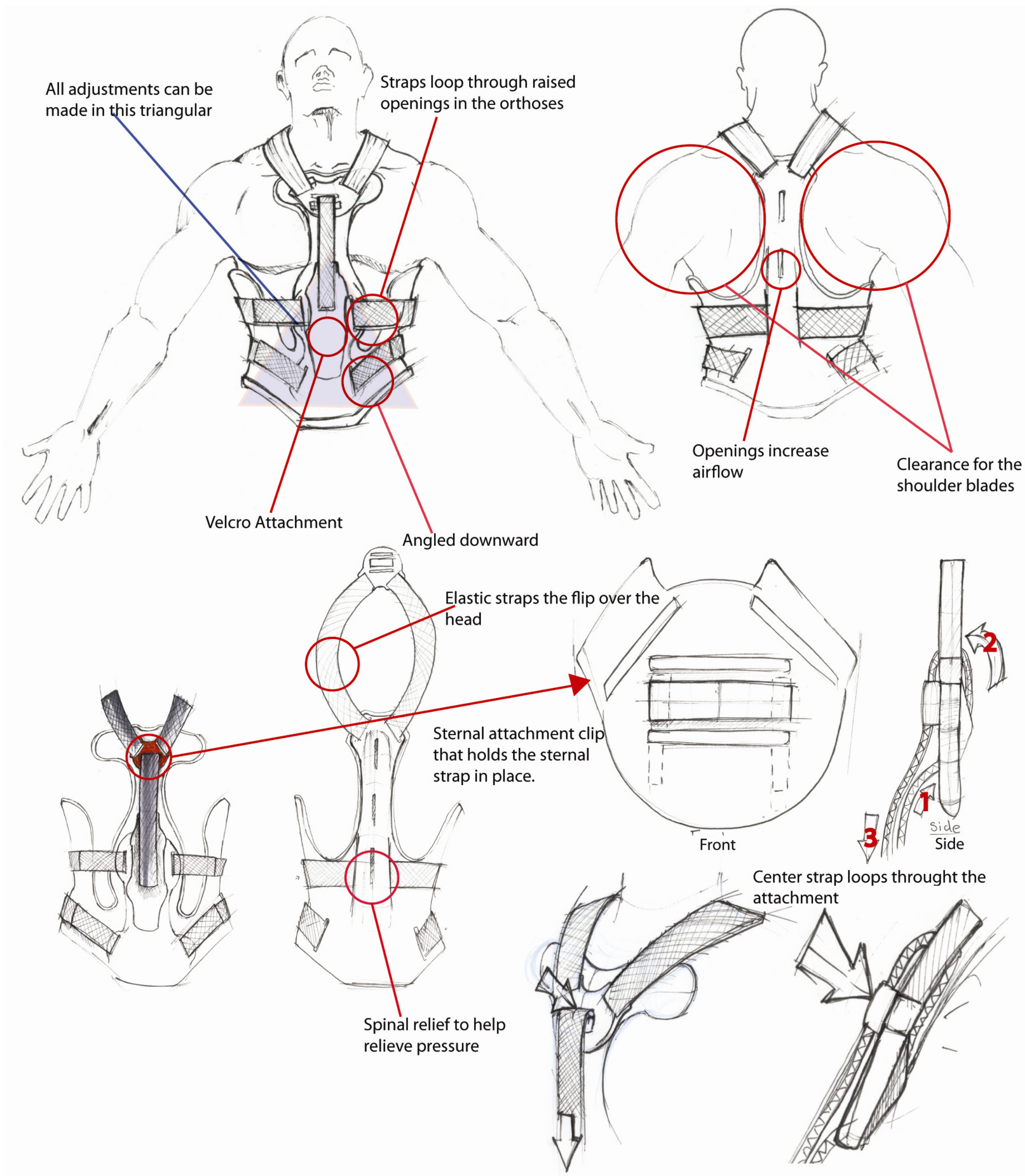


Figure 50. Final solution with callouts

4.4.1 Aesthetics

The design considerations for this study are not only medical but they are also aesthetic because of the psychological effect of the brace on the patient. As stated earlier in this study, embarassment is one of the main reasons patients don't wear their brace. It is important to make the brace look good as well as fit properly. The aesthetic qualities of this brace are styled after objects that have similar properties to the materials used in the orthosis (see Figure 51). Ski boots, cars, and body armor are the inspiration for the aesthetic appeal of the brace. This brace should make the patient feel comfortable and strong.

Figure 51. Aesthetic board for the design of the brace

4.4.2 Color

In terms of color, most back braces are white. There are some back braces that come in color and even some that have screen printed images. For this study, the color marigold was chosen. This color is a shade of yellow that almost seems orange. According to Leatrice Eiseman, from the *Pantone Guide to Communicating with Color*, yellow is a color that is often seen as cheerful and optimistic (Eiseman, 2000). Orange is a color that is known to strengthen the immune system and eliminate feelings of low-self worth (Eiseman, 2000). This color (see Figure 52) is ideal for the purposes of this study. Patients should have the option to choose what color best suites their personality (see Figure 54). They will have to wear the brace for at least 3 months so they should be able to choose the colors they like. The addition of color gives the patient a sense of style while wearing their brace. Back braces are generally worn under the clothing. The implementation of color to the orthosis may cause the patient to be less emarassed if they have to wear their orthosis in front of others.

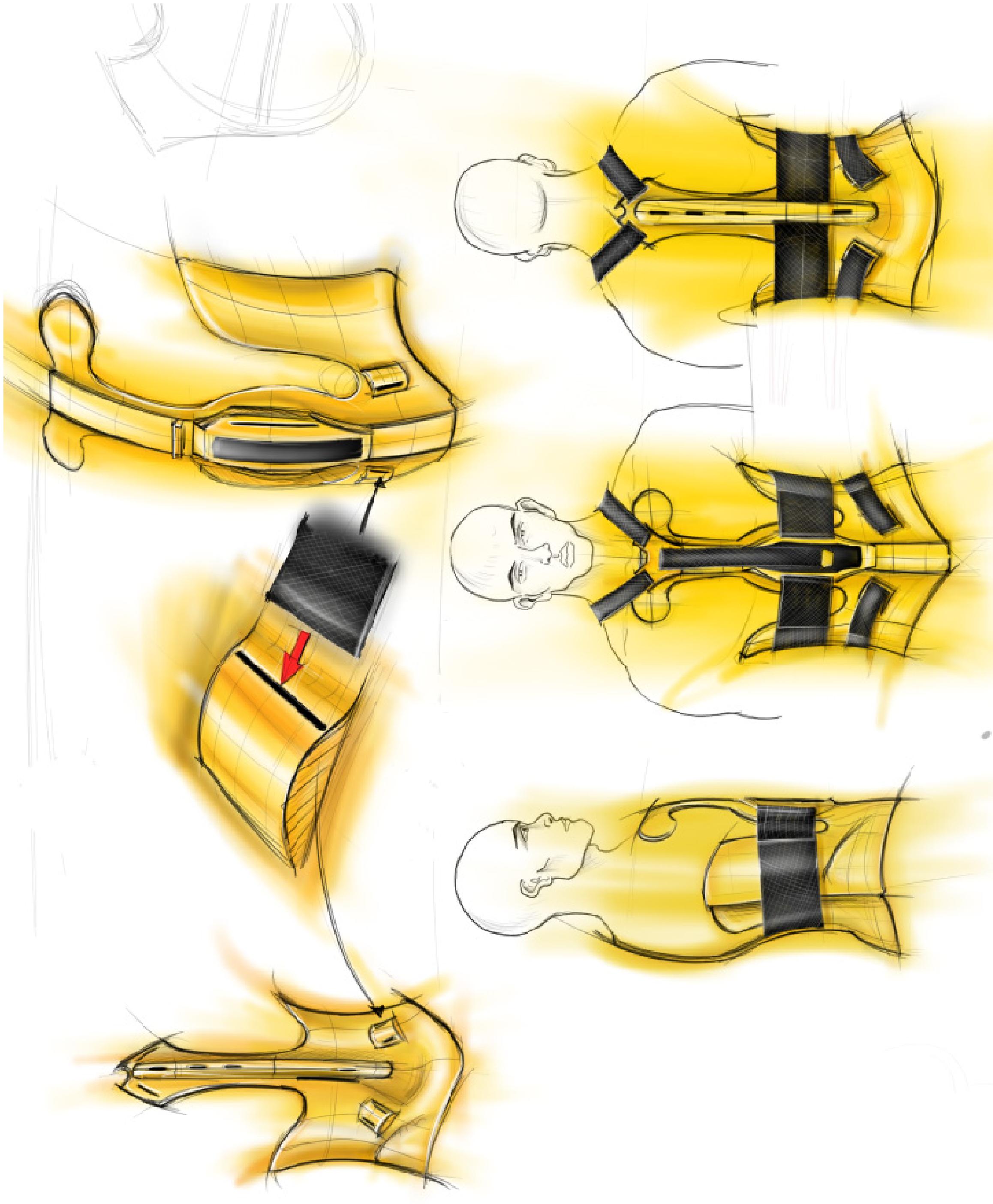


Figure 52. 2D rendering of the orthosis

Figure 53.Computer rendering of the back brace

The final solution is a back brace that considers the patient's medical as well as psychological needs. The device is designed to prevent flexion. The brace is also stylized to cause less embarrassment through the use of form and color.

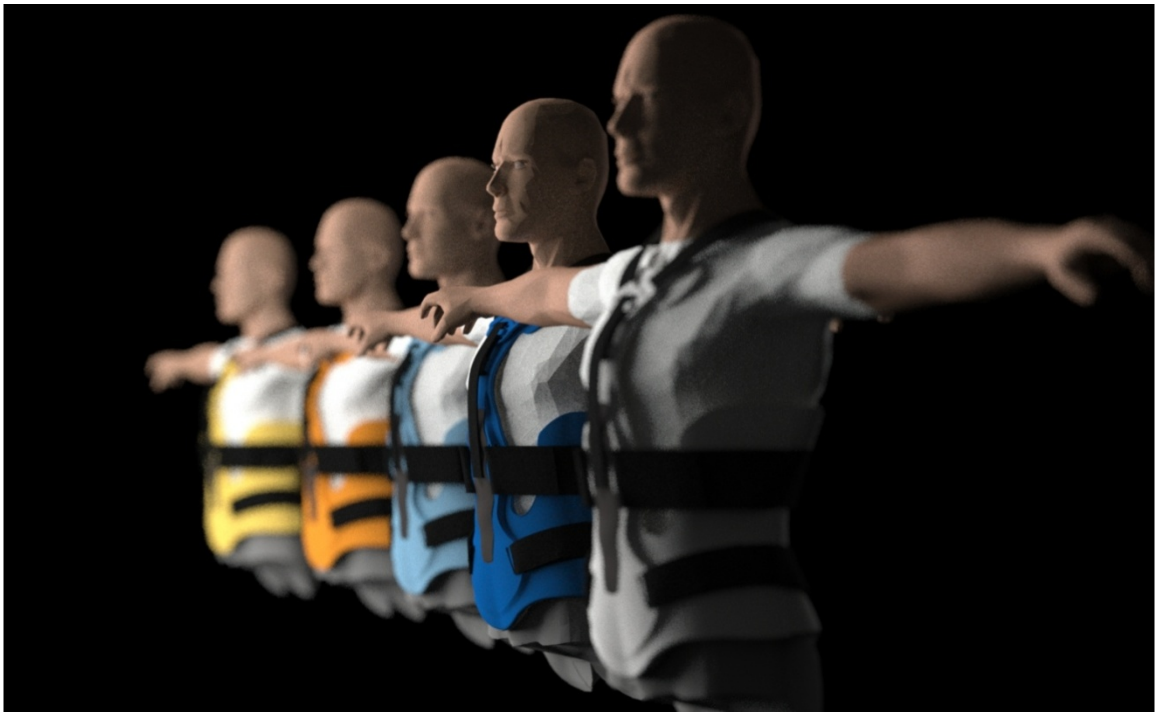


Figure 54. Computer rendering with color options

4.5 Summary of Chapter

Chapter 4 summarizes the design process for creating the orthosis. Sketches are used as a tool to explore the physical limitations of the device. The concepts were reworked and refined in order to fit the necessary medical functions of the device until a satisfactory solution was reached. The final solution included the use of less material to reduce weight and height. This also relieved discomfort from problem areas such as the scapula. The design also features a strapping system that the patient can adjust without removing their shirt. Another key feature is a shallow posterior shell is added to make applying the orthosis in bed easier. The end result is a design that meets its functional goals and the goals for this study.

5. FABRICATING THE FINAL MODEL

5.1 Overview

Chapter 5 illustrates the process of building the orthosis. The fabrication of the orthosis will be conducted in the same manner as the physical evaluation chart in chapter 3 (refer to Figure 18). The fabrication of the orthosis will differ due to certain variables such as lack of resources. The final outcome will be a final model of the design solution proposed in chapter 4.

5.2 Establish the injury

The first step is to establish the injury. Figure 46 illustrates a fictional injury that will be used to conduct this study. The injury and treatment for the patient is as follows:

- The patient suffers from a compression fracture to the Thoracic spine
- The patient requires spinal fusion surgery to repair the injury
- The patient is required to wear a TLSO to prevent forward flexion for a period of 3 months

As stated above, the patient must be restricted from any forward flexion, or forward bending in order to allow the bone fully heal. The design of the current brace must use the 3 point pressure system illustrated in Figure 55 to prevent the patient from performing movements that will cause the implant to fail. Now that the injury has been established, the patient needs to be measured for the orthosis.

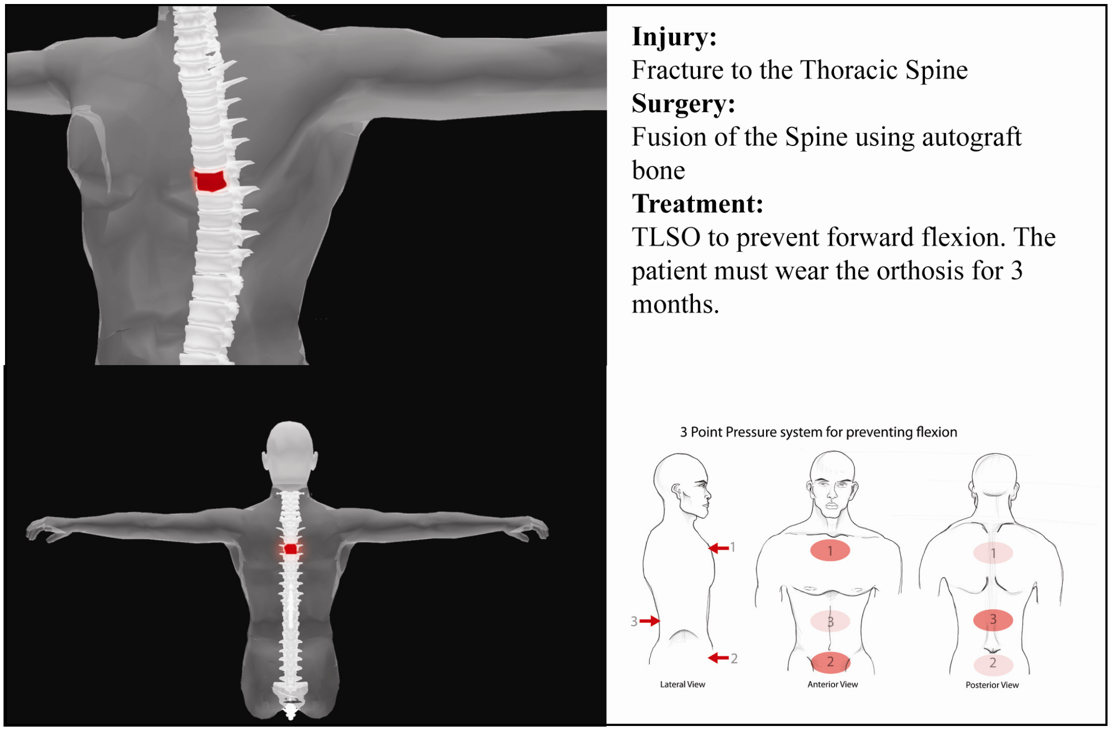


Figure 55. Patient profile with injury and treatment

5.3 Measurement

The next step in the process is to measure the patient and produce the mold for the orthosis. This study will use CAD/CAM method. The CAD/CAM method is accurate within 1mm (Garin, Orten l'orthomesure-Presentation, 1997). Figure 56 illustrates the full process of using the [TC]² body scanner. The scanner works by placing the patient in a small room. The room can be as small as 4'x5'. The room is closed off so no light can enter. The device bounces white light off of the patient's body to produce a 3d scan of the patient that can be used to create a 3d computer model of the patient. The 3d model (Figure 57) gives accurate measurements of the patient's body and is used to create a physical 3d model made of foam or plaster.

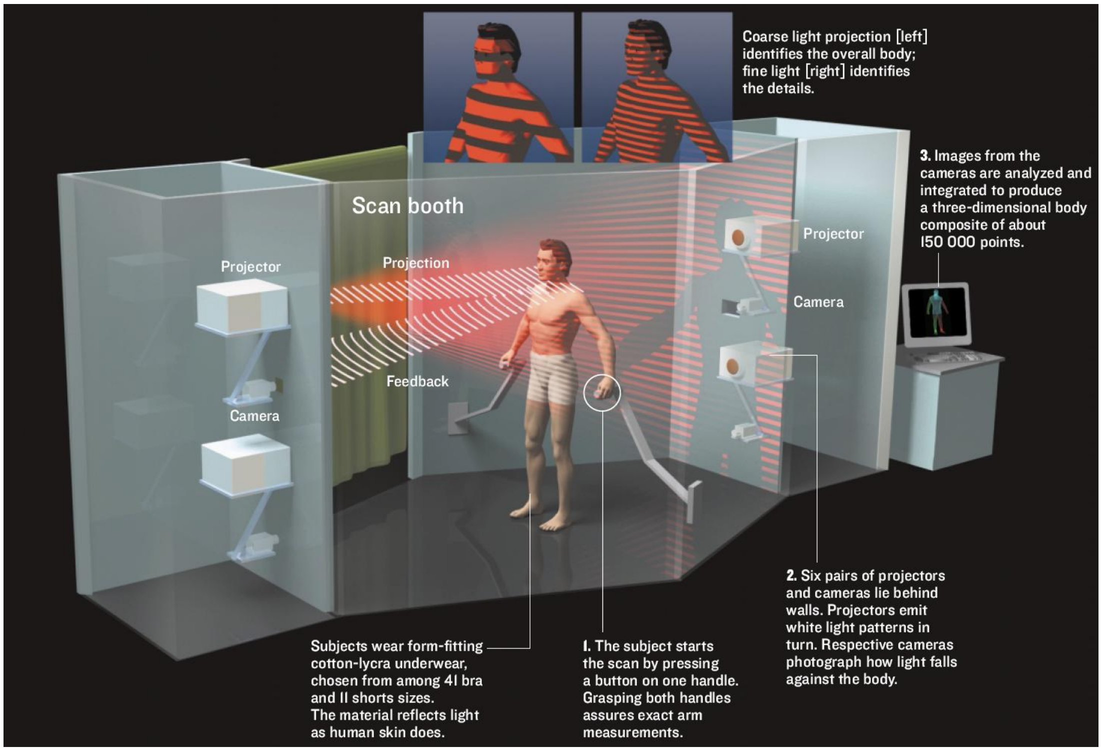


Figure 56. [TC]² 3d body scanner

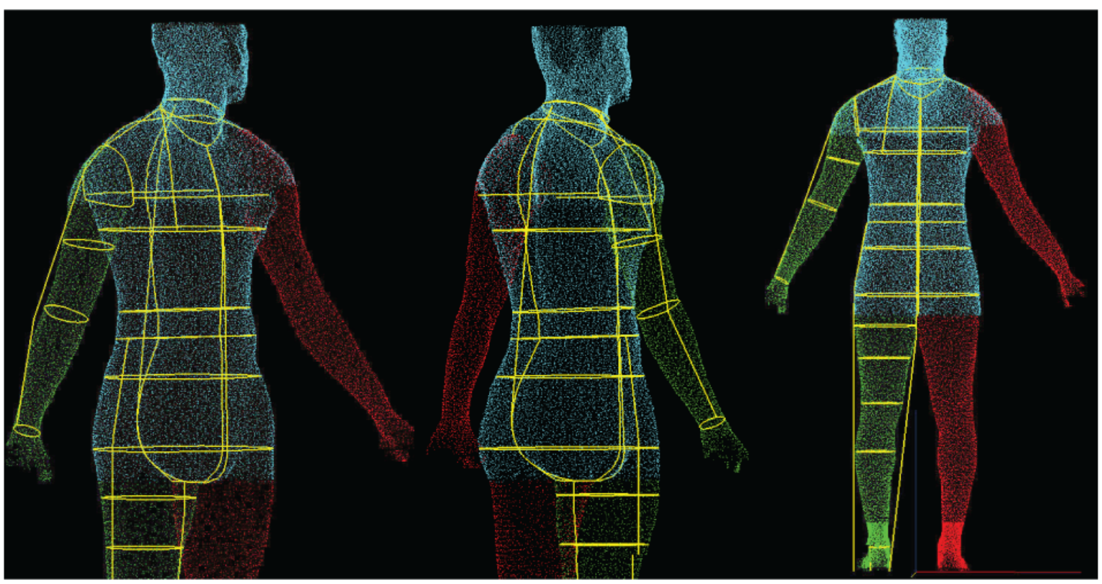


Figure 57. 3D scans from the [TC]²

5.4 Fabricating the torso

The next step is to fabricate the torso. In a normal setting the torso would be sent off to a milling station to be carved. This study is limited by the available resources so an improvised method has to be used.

The 3D scan is taken into a 3D program to be modified for fabrication. The model is cut down to display only the torso. The model is then cut into 1 inch sections (Figure 58). The sections produce 21 profile shapes that are printed off full scale. The shapes are glued onto panels of polyurethane foam. The foam is then cut on the ban saw

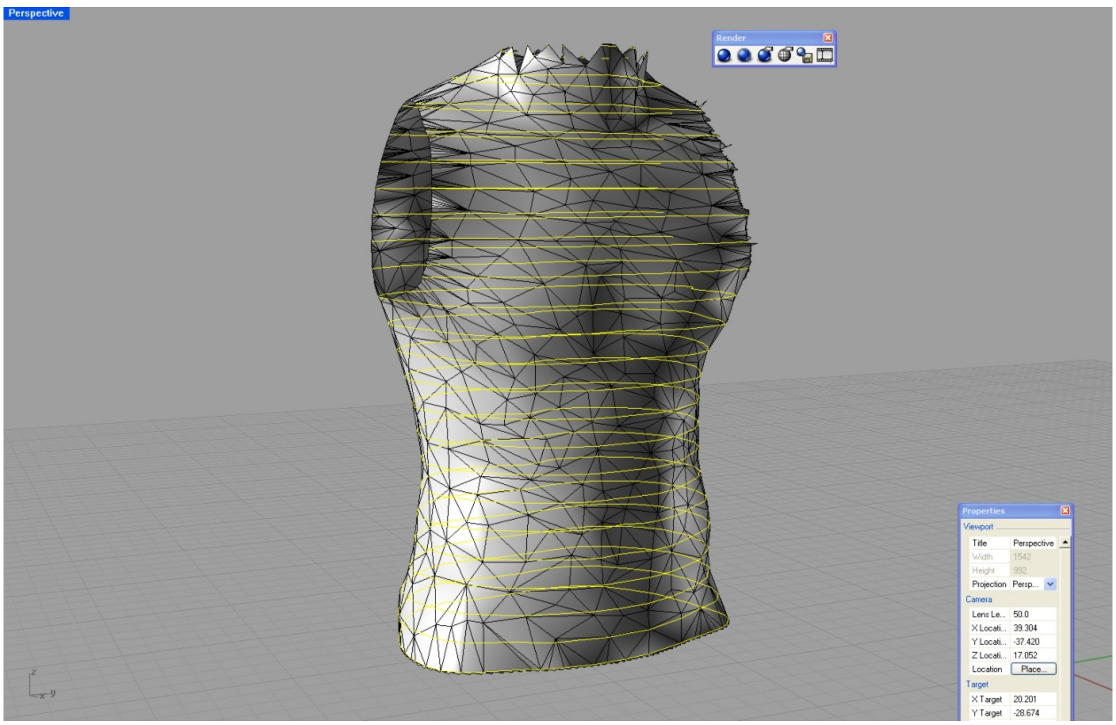


Figure 58. 3D scan of torso cut into sections.

into individual shapes the shapes are then stacked according to number to form the rough shape of the torso. The torso is finally shaved down using a hand sander to form the shape of the positive mold. Figure 59 is a visual representation of the aforementioned process. The positive mold will be the template for creating the brace. The brace will be vacuum formed over the foam model.

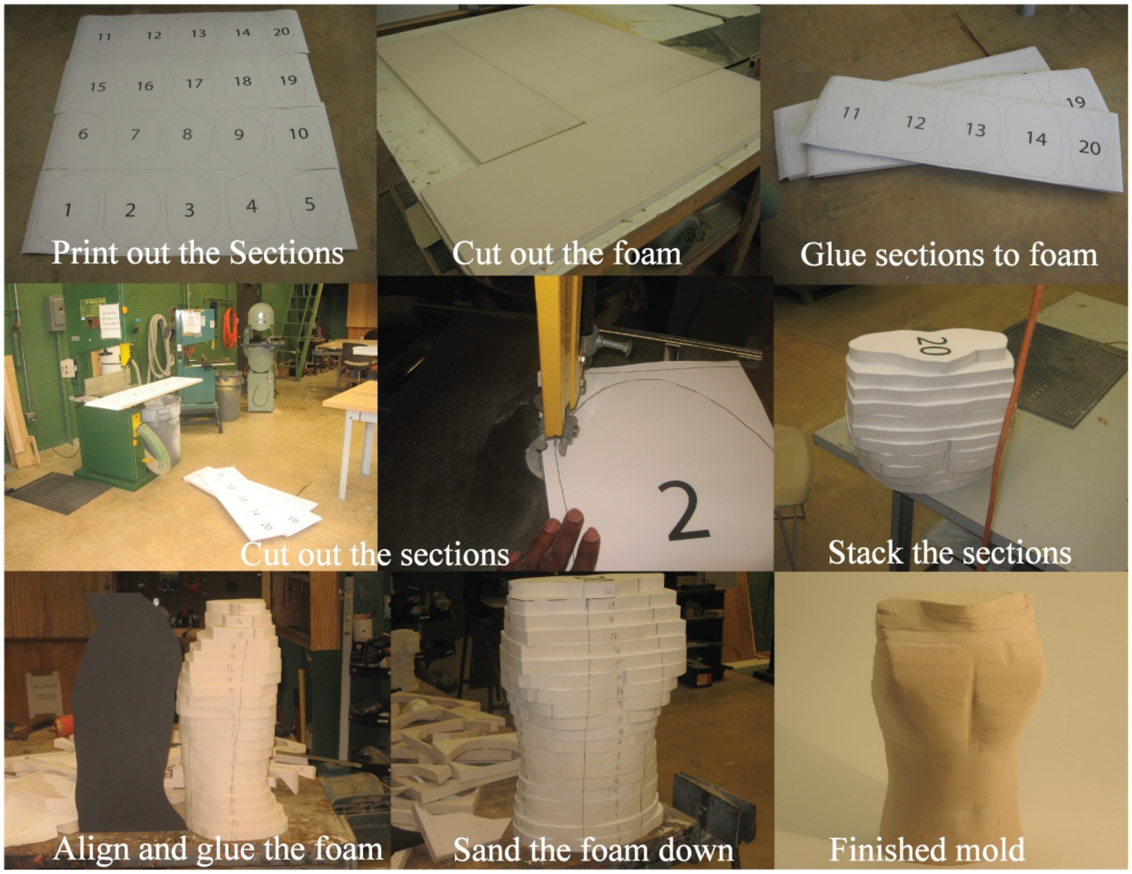


Figure 59. The process of creating the positive model for fabrication

5.5 Fabricating the templates for the orthosis

The design of the orthosis for this study uses the plastic of the brace as the securing components for the straps. The straps will loop through slots in raised areas of the orthosis. In order to create a raised surface on the foam model, templates must be attached to the model while it is vacuum formed. The templates need to be made of a material that can withstand heat, is slightly flexible, and can be used more than once. The material chosen to create the templates is liquid rubber compound. It is a two part mixture that forms rubber when poured into a mold. Figure 60 illustrates the process of creating the templates. The templates are first shaped out of wood to create the desired shapes

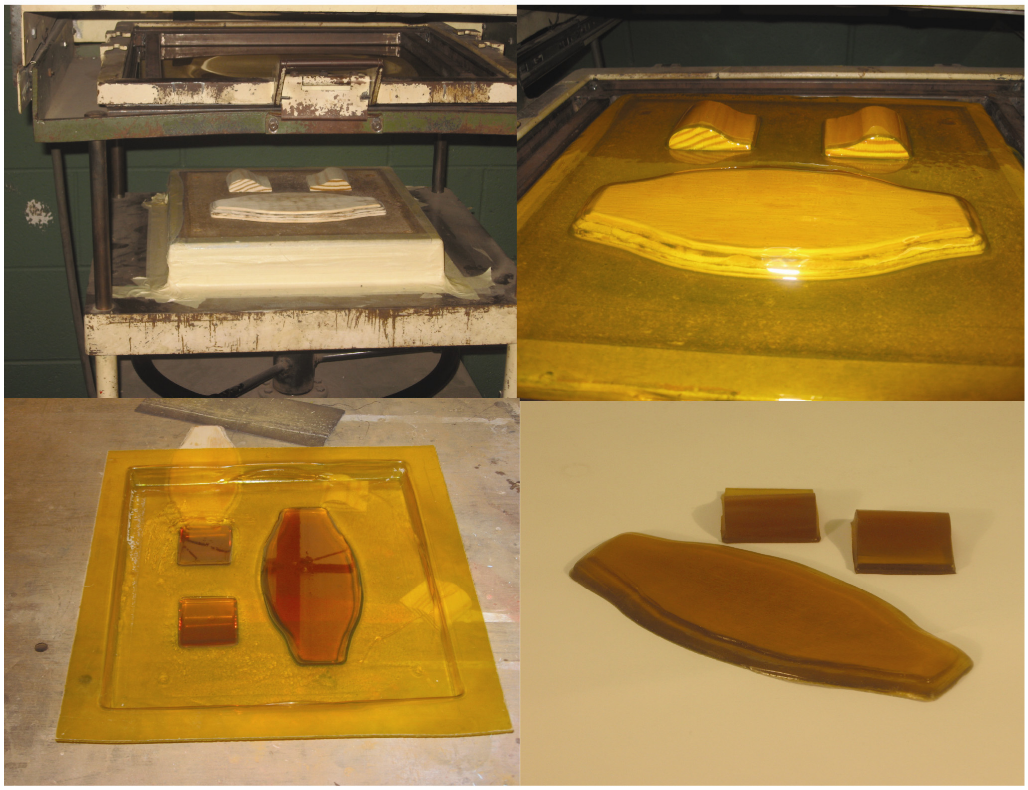


Figure 60. Creating templates for the orthosis

that fit the design. The mold is formed using a process called "vacuum forming." Vacuum forming is a heat forming process used to mold products made of plastic. It involves heating a sheet of plastic under a large oven. Once the plastic is heated, it is draped over a positive mold and a vacuum underneath the table forms the plastic to the shape of the mold. Next, a sheet of plastic is used to vacuum form over the wood to form a negative mold. Then, the liquid rubber is poured into the negative mold and left alone to cure. Once the rubber has cured it is ready to be used. The templates consist of three pieces. One piece for the center strap and two pieces for the bottom straps. The liquid rubber compound is durable and it is able to withstand heat. The templates can be used multiple times. While they don't last forever they do last long enough to use on other braces.

5.6 Vacuum Forming the Model

Once the templates have been completed it is time to create the orthosis. The orthosis is created by vacuum forming over the foam model. The foam model must be prepared with the templates in the correct position to form the design. The templates are secured to the mold using t-pins. The first step of preparation is cutting the foam mold in half. This will create two molds for the anterior and posterior shell. The same steps are repeated for each half. It is important to remember that the design calls for the posterior shell to be thinner than the anterior shell. Once that is done the templates are placed on the foam model (Figure 61). The anterior shell also needs a template on the sternum to corrugate the plastic for extra strength. Once the model is prepared it is ready to be formed.

Figure 61.Preparation of the positive mold

5.6.1 Pre-Prototype 1

This section displays the results of the first model using the templates. The model is already prepared with the templates place in the correct positions. This model is used to test the performance of the templates. The mold is vacuum formed using a large sheet of plastic. Back braces are generally made using polyethylene or polypropylene. Figure 62 shows the fabrication of the front half of the orthosis. After the piece is formed the marker and profile of the design is used to outline the trim lines on the brace. The brace is later cut out using a small pneumatic saw. This model is made of very thin plastic and is not expected to function mechanically. The next model will focus on strength and clearance.

Figure 62. Fabrication of the first prototype

5.6.2 Pre-Prototype 2

The second prototype is focused on the strength of the brace. The focal point will be the strength of the corrugated anterior sternal panel that prevents flexion. This model will also test the clearance of body segments and the strapping system. The orthosis is prepared in the same manner as the first prototype except a thicker plastic is used.

The strength of the sternum is one of the focal points of this section. Corrugating the center of the plastic did increase the strength of the plastic, but it still wasn't strong enough to prevent flexion. The model is a success in terms of clearance. The shoulder blades are free to fully rotate. The device is also a success in terms of seating clearance. The patient's thigh does not push the device upward while sitting. The straps are able to pass through the slots that are perforated into the orthosis. The straps are also effective in applying pressure. The model works fairly well in most tasks but it is useless if the front half cannot prevent flexion.

Figure 63. Second prototype

5.6.2.1 Improving strength

The issue of strength is a problem that must be solving before moving on to the final model. Corrugating the plastic does increase the strength of the plastic, but the corrugation itself was not enough. The sternal panel needs to be reinforced by another material to make it strong enough to deter forward movement. The first material that comes to mind is a metal such as steel. A steel bar can be placed inside the brace to increase its rigidity. The problem with steel is that it might significantly increase the weight of the product. Instead of metal, a strip of plastic laminated with a resin such as carbon fiber or fiberglass will provide the strength necessary to prevent flexion. This study will use fiberglass since it is cheaper and more readily available. A study conducted by Kyoung-Ja Cho recommends laminating fiberglass with plastic for orthotics. He states that if great strength is needed a laminated plastic, with resin embedded fiberglass is essential. The use of lamination can provide strength, on a small or very large sized appliance over most body segments (Cho, 1988, p. 354). Figure 64 illustrates the process of bending the plastic strip over the foam mold. Once the brace is vacuum formed with the plastic inside the plastic is removed a laminated with fiberglass resin for extra strength. The fiberglass reinforced plastic offers enough strength to prevent flexion. The fiberglass adds a little weight, but not enough to drastically change the product.

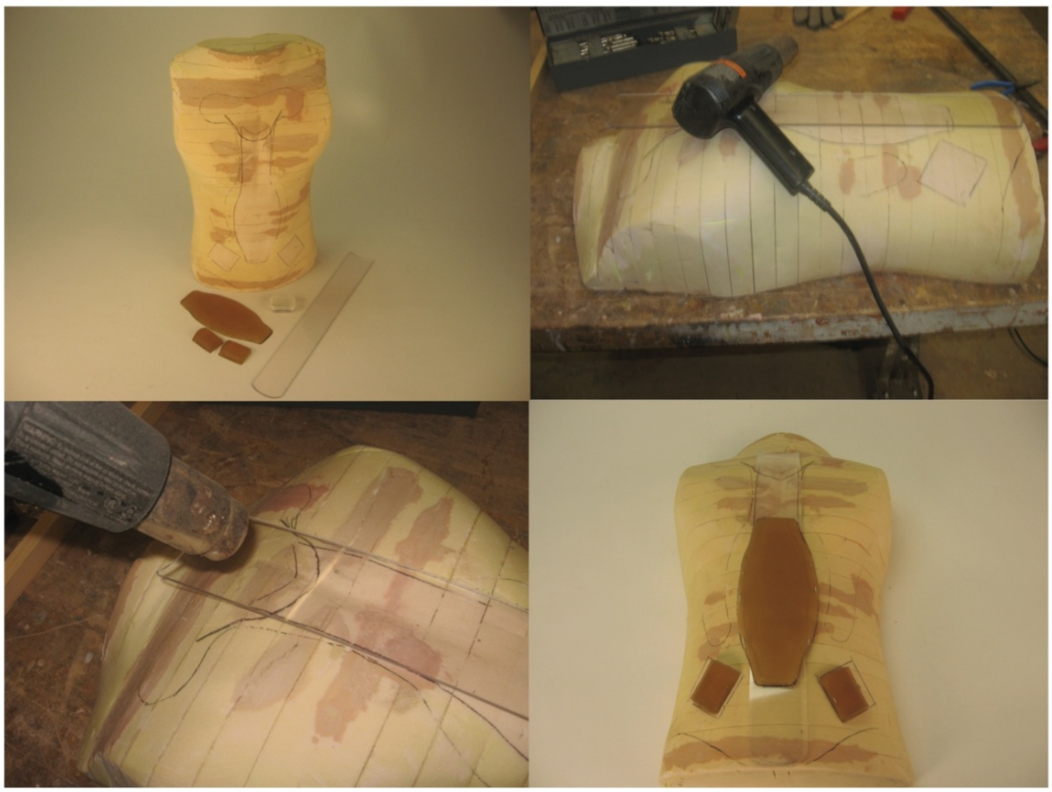


Figure64. Strengthening the anterior shell

5.7 Final model

The strengthening of the sternum allows the all the three point pressure systems to function correctly. The final model is now a functioning back brace tailored for post operative patients. Issues that involve discomfort, heat, and embarrassment are minimized without sacrificing comfort for function.

Figure 65. Final model with strap call outs

The model is made of 1/8” thick plastic, 1/4” Aliplast polyurethane foam, and 1” to 3” Nylon straps. The brace is a custom molded TLSO and weighs in at 4 pounds.

Figure 66. Posterior view of the brace

The posterior shell includes a 3mm relief for the surgically repaired area. This prevents the brace from brushing against the incision. Air holes are also included to increase air flow to the incision.

Figure 67. View of the sternal piece with the buckle

Figure 68. Detail of posterior view

6. CONCLUSIONS

6.1 SUMMARY OF THE STUDY

This thesis study began with the identification of a problem which was the lack of compliance amongst patients that require the use of spinal orthosis after a surgical procedure. The goal of this thesis was to develop a back brace that would not discourage patients from wearing it during their rehabilitation period.

The initial research established the cause and occurrence of injury. It was discovered that injuries to the spine are one of the most common causes for hospital visits. Many of these injuries require surgery and the use of orthosis. It was discovered that discomfort, embarrassment, and misunderstanding of the orthosis were the main reasons patients do not wear their braces.

Once the cause was identified, the study shifted focus onto the anatomy of the spine. It was important to study the different bones and muscles that interact with the orthosis. The study of the anatomy identified that bony protrusions such as the scapula may interact with the brace and cause significant discomfort. It was important to discover the body segments that need consideration while designing a solution.

The study of the patient's diagnosis process was a necessary component to the study. This study identified the points in the process where important decisions are made. The physician sets all of the patient's medical requirements and the orthotist is responsible for selecting the appropriate orthosis. There are various types of orthosis for variable injuries. The orthotist must make a number of decisions while deciding which orthosis meets the medical requirements. Materials, measurements, methods of application, and fabrication are all part of the process of designing and selecting the orthosis. The orthotist's criteria can be separated into 4 categories: Control, comfort, cost, and cosmesis. Priority is given to the factors that influence control and cost. These factors are the main concern of the orthotist while comfort and cosmesis, which are patient driven, are considered less important. The information gathered from this section lead to a list of criteria to be followed for the redesign of the orthosis. The criteria provided a list of requirements that the orthosis needed to have to meet its orthotic function and fulfill the goal of this thesis.

The study began by taking the orthotic functions of the brace and redesigning the device in the form of sketches to become patient friendly. The sketches provided a platform to experiment with different forms for the device. The designs focused on removing material for comfort and reduction of heat. The concepts also focused on the placement of straps and aesthetic appeal. The sketches were reviewed by orthotists and orthopedic surgeons to check the validity of the designs. The concepts were refined and redone to fit the orthotic function and the input obtained from previous research and professional opinions. The final result is a brace that reduces heat, unnecessary pressure points, and weight by removing material without compromising the medical goals of the device. Attention is also given to the aesthetic appeal of the brace through form, and the patient's ability to customize with color options.

After the design was complete, it was time to fabricate the orthosis. The orthosis was fabricated using the methods that would create the best fit, and help the orthotist in fabrication. CAD/CAM software was used to create a positive mold because of its speed and accuracy. Templates were also designed to improve strength and make the process of attaching the straps easier. In efforts to further increase strength, certain sections of the brace were reinforced with fiberglass resin. This ensured that the reduction in material did not affect the rigid properties of the brace. Once the technical aspects of the brace were complete, it was constructed ready for the patient to wear.

6.2 RECOMMENDATIONS FOR FURTHER STUDY

In the future, it might be worthwhile to experiment with different materials and processes. This study uses traditional methods and materials to improve the brace. There are new plastics that are being developed that might be useful in the orthotic setting. These materials may have different properties in terms of strength that could make them useful for creating unique designs.

This study focuses on a solution for a specific type of injury. There are several types of orthosis used for different purposes that can be redesigned to accommodate patient compliance. Diseases like scoliosis require a different type of orthotic treatment for a different amount of time. Aspects from this study concerning strengthening and focusing pressure points by using straps could be applied to injuries that have a longer lasting effect.

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