COMPARATIVE STUDY OF THE RELATIONSHIP BETWEEN MANUAL AND SCANNING METHODS FOR SPINAL BRACES

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ABSTRACT

Scoliosis is a structural 3- dimensional deformity of the spine that occurs more often during the growth of an individual just before reaching the age of puberty. Variant options are available to treat this spine deformity. The three major options could either be observation, surgery or orthotics(bracing) depending on the angle of the curvature a proper treatment may take place. Cobb angle is a term used for the measuring of the curvature severity. Orthotics are mostly used when the Cobb angle 20-45°. However, there are also variant types of orthotics(bracing) and fabrication techniques may as well differ. This research aims to conduct a comparison between two methods of fabricating the orthotic devices (Spinal braces). Manual(conventional) versus scanning technique (BioSculptor). Using each method, three subjects were recruited and we were able to fabricate two spinal braces for each of the three subjects. Few variations in circumference measurements were observed, and the average percentage difference between the two braces fabricated was 5.9% in circumference parameter. However, it was found that the manual method was more flexible than the scanning in a few aspects compared with CAD/CAM system, even though the scanning method proved to be more efficient and less messy. This result made us concludes that there are many factors effecting the fabrication process depending on the experience in making orthoses either manually or by using scanning technique.

ABSTRAK

Scoliosis adalah kelengkungan tiga dimensi struktur tulang belakang yang berlaku dengan lebih kerap semasa pertumbuhan seseorang sebelum mencapai usia akil baligh. Terdapat pelbagai pilihan variasi disediakan untuk merawat kecacatan tulang belakang ini. Tiga pilihan utama untuk merawat masalah ini adalah sama ada pemerhatian, pembedahan atau ortotik (pendakap) bergantung pada sudut kelengkungan rawatan yang wajar mungkin berlaku. 'Cobb Angle' adalah istilah yang digunakan untuk mengukur tahap keseriusan kelengkungan. Penggunaan ortotik kebanyakannya digunakan apabila sudut Cobb di antara 20-45 °. Walau bagaimanapun, terdapat juga variasi jenis ortotik (pendakap) dan teknik fabrikasi yang mungkin juga berbeza. Penyelidikan ini bertujuan untuk membuat perbandingan di antara dua kaedah untuk membuat alatan ortotik (pendakap tulang belakang). Manual (konvensional) vs teknik pengimbasan (bioSculptor). Dengan menggunakan setiap kaedah, tiga subjek telah direkrut dan kami telah menghasilkan dua pendakap tulang belakang untuk setiap subjek. Beberapa variasi dalam pengukuran lingkaran dikenal pasti, dan perbezaan peratusan purata antara kedua-dua pendakap tulang belakang yang dibuat adalah 5.9% pada parameter lilitan. Walau bagaimanapun, didapati kaedah manual adalah lebih fleksibel daripada kaedah pengimbasan kerana kekurangan pengalaman berkenaan dengan sistem CAD / CAM, walaupun kaedah imbasan terbukti lebih cekap dan lebih kemas. Dengan keputusan ini, kami menyimpulkan bahawa terdapat banyak faktor yang mempengaruhi proses fabrikasi dan ianya bergantung pada pengalaman membuat orthoses secara manual atau menggunakan teknik pengimbasan.

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LIST OF ABBREVIATIONS AND SYMBOLS

3D	Three Dimensional
2D	Two Dimensional
cm	Centimeter
FDA	Food And Drug Administration
CAD	Computer-Aided Design
CAM	Computer-Aided Manufacture
UM	University Of Malaya
UMMC	University Of Malaya Medical Centre
US	United States
FEM	Finite Element Modeling
ASIS	Anterior Superior Iliac Spine
GT	Great Trochanter
AP	Anterior-Posterior
ML	Medial-Lateral
C	Circumference
CTLSO	Cervical Thoracic Lumbar Sacral Orthosis

TLSO	Thoracic Lumbar Sacral Orthosis
°	Degrees
P&O	Prosthetist and Orthotist
VBT	Vertebral Body Tethering
VBS	Vertebral Body Stapling

CHAPTER 1: INTRODUCTION

1.1. Overview

A medical condition called Scoliosis which effects the spine is indicated by a curve to the side. This condition effects the posture and the gait of a human body making it an abnormality to have such condition. A body brace or spinal orthoses are used to provide support for someone with a severe back injury or a condition such as scoliosis. Its job is to keep the spine's movement limited to within a certain range. A body brace can be constructed from a variety of materials, both hard and soft, depending on the patient's needs. A body brace also can serve a purpose in many scenarios. Following spinal surgery, such as a spinal fusion, the brace prevents the patient from moving to the extent that the fusion could be damaged or destroyed (Weinstein & Ponseti, 1983).

For treating such condition spinal braces are used and there are many types of spinal braces available. These braces can be made from either cloth (used as belts) or Polypropylene or a mix of both. The conventional manual method of making a spinal brace orthotics is that a negative body impression in a form of cast is taken from the patient with plaster (POP). A positive cast is then prepared by filling the negative cast with POP mix. Refinement of the positive cast is done by removing and adding plaster to certain areas of the cast.

A spinal orthosis is formed by molding a plastic sheet (Polypropylene) onto the rectified positive cast. The required trim line will then be cut and straps will be secured to the orthosis. Adjustments to the orthosis would be done during the final fitting on the patient according to the flexibility and comfort to the patient. Computer-aided design and computer-aided manufacturing systems have been widely used in the industry since the 1970s. In 1979, the first CAD/CAM system for P&O was developed by James Foot and his colleagues at the Medical Engineering Resource Unit of the University of British

Columbia. The system was for below-knee socket design. Afterwards, other researchers began to develop different parts of the CAD/CAM system with James Foot. Currently a new invention has raised and it is known as Biosculptor. CAD/CAM based system does the job of positive cast without the need of POP or skillful makers. Then the sheet of plastic is molten onto the positive cast which was made using the Biosculptor machine. Manual fabricating and Scanning produce the same result of a spinal orthosis with slight alterations to it (Wong, Cheng, & Lo, 2005).

1.2. Problem statement

The process of fabrication of manual(conventional) spinal brace varies between two days up to two weeks, where on the other hand the scanning (Biosculptor) method takes between two-four hours of time. The resultant spinal brace is almost similar with minor circumferential variations. Hence Time consumption and quality of the final product are two crucial factors that affect the spinal brace fabrication process.

1.3. Report organization

This report comprises of five chapters, namely: introduction, literature review, methodology, result and discussion and conclusion. Introduction explains scoliosis briefly and the different ways spinal braces can be fabricated through. The problem statement and objective of the project are also discussed in the same section. Literature review consists of detailed background of spine deformities and scoliosis as well as bracing and its significance as an option in the treatment of scoliosis cases. Methodology comprises of the fabrication methods that takes place in the research in order to collect the relevant data. Result and discussion provides a comprehensive analysis of the data collected and discusses the significance and outflows. Conclusion summarizes the overall work that has been done in this research study.

1.4. Scope of the research

This research is conducted under the field of Rehabilitation Engineering and is conducted under CPOE, Department of Biomedical Engineering, UM authorization for the purpose of comparing different method of spinal braces fabrication.

1.5. Objective

The aim of the study is to determine the circumferential profiles analysis between a manual (conventional) made spinal brace and a brace fabricated using scanning (BioSculptor) method technology.

CHAPTER 2: LITERATURE REVIEW

2.1. Deformities of the spine

The human's normal spine is made up of 33 vertebral bones stacked together one above the other in a vertical pattern. Each vertebra is separated from the other by the presence of intervertebral discs that cushions the bones from rubbing on each other, preventing friction and providing flexibility for the spine movements. Spinal vertebrae are divided into 5 regions, namely: cervical (neck), thoracic (mid-back), lumbar (lower back), sacrum and coccyx. It has gentle curves that help in absorbing stress due to body movements and gravity, providing balance to the body and allowing a wide range of motion.

A normal spine appears as a gentle 'S' when viewed laterally; the cervical (neck) and lumbar (lower back) regions show a concave curve while the thoracic and sacral regions provide a convex curve. The human's normal spine appears straight when viewed posteriorly. However, with the occurrence of any spinal deformity the natural curvature of the spine is modified and that indicates the abnormality of a human's spine. There are three main types of spine curvature deformity; namely Lordosis, Kyphosis and Scoliosis. As shown in Figure 2.1, Lordosis (swayback) is a situation where the lower part of the spine (Lumbosacral) curves inwardly; protruding the buttocks outward. Patients suffering from lordosis have difficulties in moving in certain directions and experience back pain.

The second type of spine curvature deformity, known as Kyphosis, is a condition where the upper spine (Thoracic) curves by at least 50º, forming a rounded upper back. Kyphosis patients have a prominent hump on the upper back and the head is bent forwards. They generally experience weakness in the back and legs. The third and most common type of spinal curvature is known as Scoliosis. Patients suffering of Scoliosis have their spine curved sideways, often resembling the shape 'C' or 'S'. If the curvature of the back develops one curve, it is C-shaped curve and if the spine develops two curves it is S-shaped curve. Scoliosis occurs mostly among adolescents before the final stage of fully grown bones (Kehr, 2010).

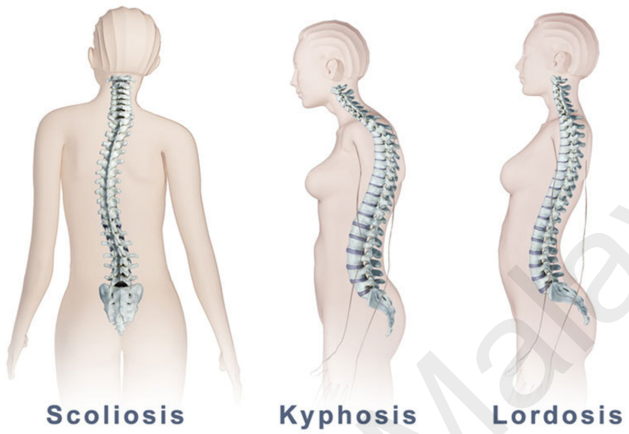


Figure 2.1: Spine deformities ("WebMD," 2014)

2.2. Scoliosis

A 3D (three-dimensional) deformity is Scoliosis that creates a curvature in the spine of the patient. The initial changes that occur to the skeletal structure of the spine are usually observed on the back shape of the patient. The unpleasant shape is of more concern to the patient rather than the deformity of the spine itself. If this disease left untreated, it may result in restructured spinal mechanics and worsening changes that may in later stages lead to loss of mobility of the spine, different levels of back pain, and in the worst case scenarios possible disability to the whole body to its effect on the spinal cord. Respiratory and cardiac dysfunction may as well occur along with the other symptoms that has been due to the deformity, depending on the period for since the deformity has been introduced to the patient (Bettany-Saltikov, Weiss, Chockalingam, Kandasamy, & Arnell, 2016).

Scoliosis may be caused by congenital, developmental or degenerative complications. The most common type of scoliosis is known as idiopathic scoliosis. Scoliosis is usually diagnosed when the spine is moderately or severely curved. It is indicated by the unevenness of the shoulder height, shoulder blades, rib cages and hips. As mentioned in Nelson Essential of Pediatrics E-Book (Marcadante, J.Nelson, & E., 2011) scoliosis can be broadly classified as: Idiopathic, Congenital, and Neuromuscular Scoliosis.

Adolescent Idiopathic Scoliosis is currently known as the most common kind of scoliosis occurring in healthy, neurologically normal children having a family history of scoliosis in 20% of the cases. The occurrence of this deformity is slightly higher in girls than boys; mostly it progresses in females and requires treatment. Idiopathic scoliosis is classified into three categories on its occurrence on patients: infantile (age: 0-3 years), Juvenile (age: 4-10 years) and adolescent (age >11years). 70% of the times it is a painless disorder, its treatment depending on the maturity of the curve and whether the curve is progressive or non-progressive.

Scoliosis progression is originally observed and monitored through radiographic scans when needed (X-ray). The chances of curve progression depend on certain factors like gender, age, curve magnitude and curve progression rate. In females it is five times more likely to progress when compared to males; also, older patients have higher chances in the curves progression compared to younger patients. Usually curves under 25º are occasionally observed (Lonstein, 1994). Progressive curves in the range of 20º and 50º in a skeletally immature patient are treated and controlled with bracing which is by using the orthosis custom-designed for the need of the patient (Katz, Herring, Browne, Kelly, & Birch, 2010). Curves that are above 50º usually require surgical treatments (Weinstein & Ponseti, 1983).There are currently two common used surgeries which are Vertebral Body stapling (VBS) and Vertebral Body Tethering. Even though these two approaches for surgical correction of the scoliosis are not yet approved by the FDA (The American

Food and Drug Administration) until the time this research is being done(Cuddihy et al., 2015). Congenital Scoliosis is due to abnormal vertebral formation during the first trimester of the pregnancy. It can be classified as Partial or complete failure of spine's vertebral formation (wedge vertebra or hemivertebra), Partial or complete failure of segmentation (unsegmented bars) and Mixed. 75% of patient suffering with congenital scoliosis will show progression till complete skeletal growth; out of which 50% will require some form of treatment. Congenital scoliosis treatment depends on the early diagnosis and identification of curve progression. Orthotic treatment is not helpful in case of congenital scoliosis; spinal surgery is performed once the curve progression is identified. Neuromuscular Scoliosis is a progressive type of scoliosis, which occurs with many neuromuscular diseases. It is mostly occurring as a result of weakness or imbalance of trunk 8 musculature. The curves produced as such continues to grow through adulthood. Neuromuscular scoliosis treatment is dependable on either the age of the patient and/or the magnitude of the deformity, with progressive curve despite the usage of bracing then bracing is not an effective approach to take in the prospective of treating scoliosis.

2.3. Degree of angle of curvature in Scoliosis

Cobb angle is the term used to describe the degree of scoliosis. According to South Florida Scoliosis Centre, curves between 10º- 25º are considered mild scoliosis; observation is the initial approach to such condition at regular intervals (approximately 2 radiographs to be recorded annually) to monitor the progression of the curve. A curve that is between 26º- 40º is considered moderate scoliosis, in this case patients are recommended to be braced and observed for curve progression (Negrini, Negrini, Fusco, & Zaina, 2011) Curves greater than 40º are considered severe scoliosis and mostly undergo corrective surgery(Weinstein & Ponseti, 1983). Figure 2.2, shows the different degrees of scoliosis curves.

The risk of progression of the scoliosis curve increases with the degree of scoliosis; for mild scoliosis the risk of progression is 22%, where for moderate scoliosis it is 68% and for severe scoliosis the risk of curve progression is up to 90%(Kehr, 2010). A person suffering from mild scoliosis experiences uneven shoulders or hips, uneven leg length, tilted head, head appears forward of shoulder when viewed from the side, few of mild scoliosis cases experience different degree of pain. Mild scoliosis is treatable if detected at the early stages of scoliosis especially when the curve is still small, but in most cases goes undetected until the curve progresses further and becomes larger. Mild scoliosis is mostly diagnosed in young girls. However, it can also be found in boys and adults. Moderate scoliosis affects the physical appearance more severely when compared to mild scoliosis where the unbalanced figure of the skeletal structure of the patients is easily noticeable. Along with uneven shoulders or hips, the patients have a shoulder higher than the other creating a rib hump. Patients may suffer from frequent headaches, fatigue after physical activities and there are also chances of experiencing pain between scapulae and at the base of rib cage. Moderate stage scoliosis patients are recommended for orthotic bracing as it is necessary to reduce or halt the progression of the curve, it is mostly curable in cases of less severe curve. In severe stage scoliosis the shape of spine (‘C’ or ‘S’) is visible outwardly, the bellybutton is not in the center, have prominent rib hump, may experience pain in the spine and frequent headaches. In this stage a surgery is typically suggested. Prominent symptoms are shown in Figure 2.3.

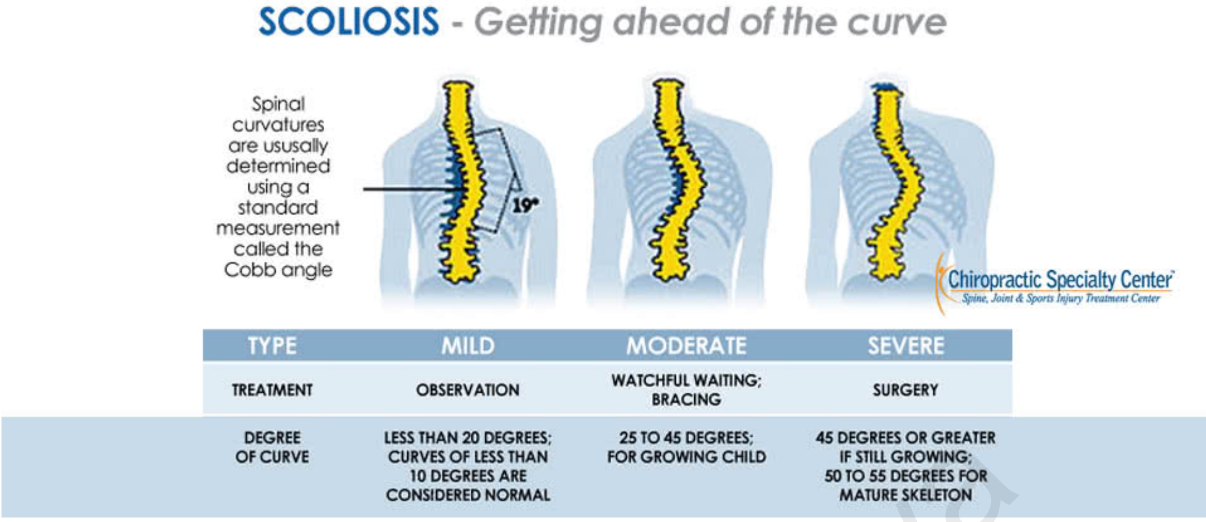


Figure 2.2: Different degrees of scoliosis ("Scoliosis Meaning and Classifications," 2015)

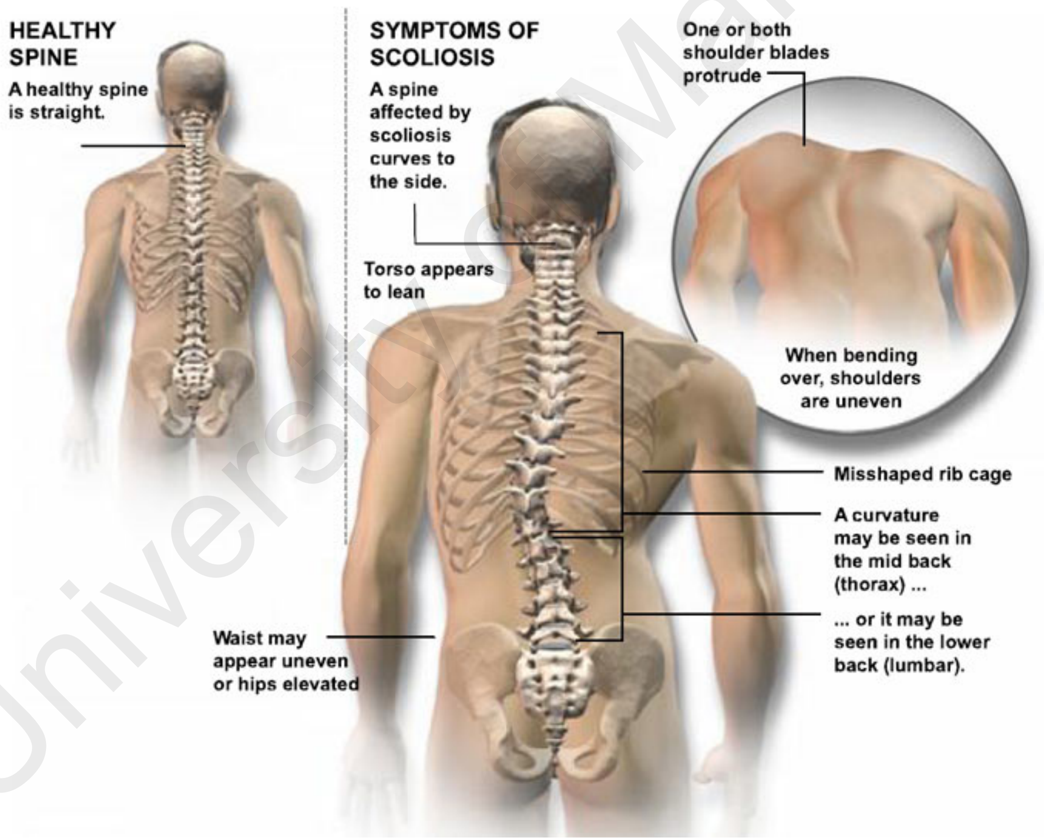


Figure 2.3: Scoliosis Symptoms (Image adopted from Bernadette west dc ("Scoliosis," 2014)

2.4. Methods for the treatment of scoliosis

Scoliosis Treatment depends on the severity of the curve and how deteriorated it can get. As certain types of scoliosis are more likely to get worse, the kind of needed treatment is indicated by the type of scoliosis. Although the three main categories of treatment include observation, bracing and surgery, some cases impose surgery as the best option. Functional scoliosis, for instance, is caused due to abnormality in another part of the same body, like leg difference length. This type of scoliosis is to be treated by placing a small wedge to align the leg length and avoid spinal curve occurrence since those people have normal spines.

As neuromuscular scoliosis is created by bone spinal abnormality development, the chances of having guaranteed treatment is weightless. However, these types of scoliosis have great credibility of drastic deterioration. Having surgery becomes the only option for many people as both of observation and bracing do not usually work well for them (Phillips, Gutheil, & Knapp, 2007).

Furthermore, Age of idiopathic scoliosis patients plays an important role on its treatment. Infantile idiopathic scoliosis, for example, can be cured without the need of any type of treatment. On one hand, bracing would not be as effective as obtaining X-rays and measurements associated to advanced visits to determine the case severity (Shi et al., 2015). On the other hand, for juvenile idiopathic scoliosis which is most likely to get deteriorated of the types, bracing attempts can be done had the curve not been quite severe. Preventing the curve from getting deteriorated is the main goal until the person's growing process rests. The need of having surgery arises badly as the curve begins on early stages of life in such cases. Moreover, the case of adolescent idiopathic scoliosis considered as the most common one. When a minor curve is first diagnosed, it is observed and followed through X-rays and measurements routinely - (twice annually). Therefore, no further treatment is considered if the curve or the Cobb's angle remains below about

20°-25°. Periodic check-up and annual X-rays are invited to detect curve deteriorating or progression. A brace is likely recommended if a growing patient curve is between 25°-40°, whereas surgery is highly recommended in case the curve of fully grown-up people is greater than 40°.

2.5. Bracing treatment for scoliosis

Over the years there has been many attempts to cure scoliosis in non-invasive ways which bracing is one of those techniques. Up until now there are multiple types of braces, e.g. Boston brace(Thoraco-Lumbo-Sacral-Orthosis), Charleston Bending Brace, Milwaukee brace, SpineCor flexible brace. These available braces proved to be useful and gave positive results to the curing of scoliosis.

2.5.1. History

Hippocrates was the first to describe the treatment of scoliosis where the treatment techniques of traction on a bench or a scamnum were on long bones and spinal fractures and then those techniques were adapted for the treatment of spinal deformities (Fayssoux, Cho, & Herman, 2010). Galen of Pergamum was a Hippocratic school of thought student. He modified the first technique that has been initially done by Hippocrates, what he done was adding pressure in combination with traction (Bademci, Batay, & Sabuncuoglu, 2005). Ambrose Pare (1510-1590) was a surgeon in the French army. Pare was considered one of modern surgery fathers. He who was the first to invent supportive braces that were used to treat spinal deformities. Pare’s first approach to treat spinal deformities were relocating the spine using extension and directed pressure on certain points of the spine to oppose the curve of the scoliosis. he was the first to note that bracing is not an effective approach for treating scoliosis after the adulthood or the maturity period of a one's life. It took about two centuries to develop what Pare has initially done by Lewis Albert Sayre in the late 1800's (Fayssoux et al., 2010). The first person to hold the title of Professor of Orthopedic Surgery was in America was called Sayre. The use of traction adding to plaster cast was first done by Sayer, and that step was done in order to hold and correct spinal deformities (J. M. Zampini & H. H. Sherk, 2008). By that technique he invented Sayre created the basis for the next generation approaches used for treating scoliosis, even though satisfactory correction in the deformity were not clearly observed after discontinuation of the jacket he created was not seen (Jay M. Zampini & Henry H. Sherk, 2008).

The discovery of X-rays which was introduced by Wilhelm Conrad Roentgen in 1895 revolutionized the study of scoliosis where physicians did not have to dissect the body in order to investigate the problem. long exposure time to x-rays resulted in poor quality radiographs plus physicians have not yet discovered the harm behind the elongated exposure to x-rays. In 1930 faster radiographic films were developed, which made obtaining clear quality of radiographs possible (Riesz, 1995), which lead to better diagnostic.

2.5.2. Types of spinal braces

There are different types of spinal braces available nowadays such as Boston Brace, Wilmington Brace, Milwaukee Brace, Cheneau Brace. The most commonly prescribed brace for scoliosis is the Boston brace. It is considered to be thoracic-lumbar-sacral orthosis (TLSO). The concept of the Boston brace efficacy is targeting the convex side of the spinal curve by applying pressure on that point and relief the corresponding area on the concave side, hence that spine migrates to the corrective side of the trunk. The Boston brace has a posterior opening so the patient may need help in wearing the brace. According to a research (Emil Lange, Steen, Gunderson, & Brox, 2011), long term results were satisfactory in most patients treated with the Boston brace with higher compliance to weaning of brace reduced or halted curve progression of the curve are observed.

Another type of TLSO is the Wilmington brace. It is a custom-fit made brace, where the cast of the patient is taken while in supine position. Modifications to the brace take place before the final stage of fabrication is done by specifying certain corrective forces to certain areas on the curve of the spine. Wilmington brace is known as full contact TLSO due to its look like a wearable tight jacket, it also lacks the gaps and spots seen on other types of braces.

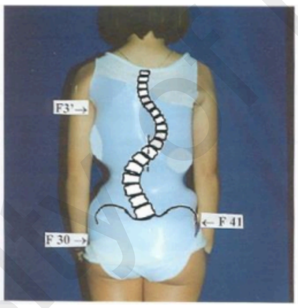
Adding to that, a cervico-thoracic-lumbar-sacral brace is known as Milwaukee brace. This CTLSO was created in the 1940's. Recently it is rarely used due to its bulkiness, efficacy and convenience compared to modern day braces. However, it is still sometimes used for curves higher in the thoracic or cervical spine.

Moreover, Another type of spinal braces is Cheneau brace which is known for its effectiveness on treating patients with thoracic hypokyphosis and scoliosis (Minsk, Venuti, Daumit, & Sponseller, 2017). Cheneau brace is entirely fabricated using plastic (Polypropylene). The fitting mechanism of this brace is the exact opposite of the Boston brace due to its anterior opening unlike the Boston brace which has a posterior one. The Velcro straps are then used to secure the brace on the patient. This brace is modelled on a hyper corrected cast of the patient. The correction principle of the brace is that of distortion and sagittal plane stabilisation, which in place will correct the coronal and transversal planes that will lead in minor elongation of the spine without any major distraction forces. The most effective brace according to different articles published is said to be The Boston style brace.

Other than using the conventional plaster-based brace construction, the baseline standard for new individual computer aided design/computer aided manufacturing (CAD-CAM) braces is the Boston brace as regarded. Individual braces can be created through CAD to reform the curvature when low-dose stereo X-rays are available for calculation as several outcomes indicated. Since it addresses the curve patterns very precisely and not by classification, such method gains very promising outcomes.

Development of CAD/CAM Based Brace models can be divided into two methods which are Classification Based Approach (CBA) versus Finite Element Modelling Approach FEMA (Weiss & Kleban, 2015). The CBA proved to be superior to FEMA with respect to in-brace correction. The CBA had been reported to have the best in-brace correction exceeding 50% of the initial value of 66%. Submitting anthropometric measurements and data of the patient to the system along with a picture (including X-ray), CBA is available readily. No stereo X-rays are necessary for acquiring CBA.

Figure 2.4-2.7 represents some types of the spinal braces.

2.4 2.5 2.6 2.7

Figure 2.4-2.7: Four different types of braces Boston brace, Cheneau brace, Wilmington brace and Milwaukee brace respectively.

2.5.3. Methods of fabricating spinal braces.

At the beginning the basic methods were used in the fabrication of spinal braces using different materials like metal and wood since those materials were the only available option back then. Gradually the methodologies varied and had more impact on others to improve and develop better techniques and better products.

Using Plaster was and still till the day the most commonly approach used to fabricate orthosis, with the flexibility and ability to modify the plaster, this made is the best option to achieve the optimal orthosis manufacturing. Usually a spinal orthosis is done manually through using the patient's negative body cast with Plaster bandages (Wong, Cheng, Wong, & So, 2005). Whereas the positive cast is made and gets prepared using the negative cast that is initially taken from the patient's body impression with POP mix. The refinement process is done completely based on the experience and skill of the orthotist; the plaster is detached and added to the needed areas on the cast to customize or correct certain spots on the positive cast in order to get the maximum correction pattern to the spinal curve.(Cottalorda et al., 2005). Once all the points of pressure and relief are marked on the positive cast, a plastic sheet (polypropylene) is molded onto the refined version of the cast. Then, needed trim line gets cut and straps are attached to the orthosis. Throughout the final fitting additional needed adjustments to the orthosis would be done.(Wong, Cheng, Wong, et al., 2005).

With the new era the clinical field is progressing in the current period of time and making correlation with the engineering field new techniques started to rise and see the light. Computer -aided design and Computer-aided manufacture CAD/CAM is one of the techniques adopted nowadays to fabricate orthosis and braces in a very accurate and precise manner.

Since the 1970s CAD/CAM systems have been widely used industrywide(Zeid, 1991). James Foort and his colleagues have developed the first CAD/CAM system for prosthetics and orthotics (Prosthetics &Orthotics) at the Medical Engineering Resource Unit of the University of British Columbia in 1979. The system was initially used for the fabrication of trans-tibial socket.

However, other researchers start to develop different parts of the CAD/CAM system along with him later. At the International Society for Prosthetics and Orthotics World Congress in London in 1983 the system was demonstrated for the first time where it had extremely constructive feedback that led to a wild competition on the development of commercial CAD/CAM systems level.(Wong, Cheng, & Lo, 2005).

Currently there are multiple CAD/CAM systems on the market such as:

1- BioSculptor(Wong, Cheng, Wong, et al., 2005), (which is the system being used in this research to fabricating the scanning method spinal brace),
2- CAPOD system (Janols 1997),
3- Clynch Technologies Inc. (Reed 1997),
4- IPOS (Kaphingst 1997),
5- Orten (Genevois 1997),
6- Seattle Limb Systems (Dowell and Poggi 1997),
7- TracerCAD system (Pratt 1997),
8- CANFIT-PLUSTM (Mason 1997) and
9- Prosthetics Design Inc. (Wong, 2011).

As observed by the dates provided for each system, almost all the systems were developed in the same period which shows how fierce the market was during that time for inventing and developing new systems.

The studies found for CAD/CAM fabrication technique are mostly related to lower limb prosthetics with minor studies that investigate on the clinical applications of spinal braces. Seemingly the approach to using CAD/CAM systems in spina orthosis manufacturing would help in standardizing the fabrication process and saving time compared to the manual process of fabrication, as well as allowing specialists to take advantage of saved time and using it on patient's interface for the purpose of training, education and counselling. While the conventional method does not have the fast and efficient feature of delivering the final product like a computerized system.

2.5.4. Comparing manual versus scanning fabricated brace

A study done by(Cobetto et al., 2017), showed that CAD/CAM with FEM proved to be a better approach in designing a brace where a simulation of the brace effectiveness in the treatment is done before the printing of the final product, that efficacy is as well made on a 3D simulation of the torso of the patient which as well leads in performing more precise measurements compared to taking measurements from a 2D radiograph of the spine. Whereas in CAD/CAM only method the effectiveness of the brace can only be observed and analyzed after the production and patient trial of suing the brace which leads to certain complication of re-modification and maybe re-fabrication of the brace.

Comparison between the two techniques used in the fabrication of the body brace taking the criteria as improvement of the curve and the patients impression of comfort, a study made by(Cottalorda et al., 2005), showed that a majority of patients felts better comfort with the CAD/CAM fabricated brace versus the manual fabricated brace. On the other hand, the clinical effectiveness of both the spinal braces showed not significant changes and both the braces were equally effective. Another study done by(A. Roberts et al., 2016) comparing manual and scanning techniques for the fabrication of foot orthosis, it was found that rectification and molding time took 50% less for the CAD/CAM based technique over the conventional manual technique, it also showed that being scanned is preferable by the patient rather than being cast. Cost effectiveness did not show any significant changes between the two techniques.

The incapability of the orthotist to position the subject correctly during the scanning process makes the correction entirely dependent on the rectification stage of the process, on the other hand casting manually the foot can be done in a precise position through making the rectification stage of the process less critical and complex compared to the scanning technique. Which on the other hand provides a better more accurate orthosis at the end of the whole fabrication process.

The process of manual casting showed that it is time consuming process, high plaster consumption, low accuracy and no data for future references(Wong, Cheng, & Lo, 2005). However, comparing the two techniques clinically both the methods provided major early control over Cobb's angle. 12.8° change was found in Cobb's angle with the BioSculptor fabricated brace, and 9.8° decrease in the manually fabricated brace patients.

The following table shows some of the studies that has been done in the comparison of manual and scanning technique.

Table 2.1 Related studies to the research

	Research title	Aim of the study	Methodology	Results	Pros	Cons	Contributors
1	3D correction of AIS in braces designed using CAD/CAM and FEM: a randomized controlled trial(Cobetto et al., 2017)	Improving the design of the spinal brace	CAD/CAM with FEM technique combined. 3D construction of patient's trunk and simulation of brace effectiveness.	FEM simulation allowed the analysis of contact area between patients and braces in order to adjust opening and relief zones in brace to obtain less coverage surface and thinner, lighter brace	The effectiveness of the brace is tested before the fabrication of the brace.		Nikita Cobetto, Carl-Éric Aubin, Stefan Parent, Soraya Barchi, Isabelle Turgeon and Hubert Labelle
2	Results of ultrasound-assisted brace casting for adolescent idiopathic scoliosis(Lou et al., 2017)	Producing better brace with minimal re-modification after the final stage of producing the brace	Two groups of patients prescribed full time TLSO fabricated using two different methods Control and Ultrasound.	Ultrasound provided radiation-free method to determine the optimum level pressure level and location	Ultrasound is effective and non-ionizing approach for scanning	No long term usage results are yet obtained	Edmond H. Lou, Doug L. Hill, Andreas Donauer, Melissa Tilburn, Douglas Hedden and Marc Moreau

3	Effectiveness of the Rigo Chêneau versus Boston-style orthoses for adolescent idiopathic scoliosis: a retrospective study(Minsk et al., 2017)	Comparing the efficacy of two types of braces, e.g. Rigo Chêneau versus Boston-style brace	Cases were studied between (1999-2014). And outcomes of their treatment approach were clinically evaluated	Patients with RCO's were less likely to spinal surgery. Smaller mean changes and smaller changes in major curves compared to Boston style brace	Investigating large amount of subjects and for a very long time (15 years)	Bias towards RCO's over Boston style orthoses	Miriam K. Minsk, Kristen D. Venuti, Gail L. Daumit and Paul D. Sponseller
4	The application of generic CAD/CAM systems for the design and manufacture of foot orthoses (Gatt, Formosa, & Chockalingam, 2016)	Integrating various readily-available technologies into foot orthosis design with a cost most attainable by the majority	Fabrication of foot orthosis using CAD/CAM techniques with the help of modifying the design with the available software in the market currently	CAD/CAM has increased accuracy, producibility of the printed/milled devices, better quality and less messy process. Reduction of inhaled dust, easier design and manufacturing process and faster time	Precise modeling techniques that provided almost perfect final product	Too many softwares were used and from different hosts. No actual source proving successful process among 300 patients	Alfred Gatt, Cynthia Formosa & Nachiappan Chockalingam
5	A Comparison of Patient-Reported Outcome Measures Following Different Treatment Approaches for Adolescents with Severe Idiopathic Scoliosis: A Systematic	Comparing different treatment approaches for Adolescent with severe idiopathic scoliosis	Reviewing past articles concerning the treatment of scoliosis	Surgical approach to treating scoliosis is avoided due to long term complications and lack of evidence of complication within scientific literature	Thorough and detailed information provided		Josette Bettany-Saltikov, Hans-Rudolf Weiss, Nachiappan Chockalingam, Gokulakannan Kandasamy & Tracey Arnell

	Review (Bettany-Saltikov et al., 2016)						
6	Anterior Scoliosis Correction in Immature Patients with Idiopathic Scoliosis (Ames, Samdani, & Betz, 2016)	Comparing different treatment approaches for scoliosis, Bracing, VBT and VBS	Studying different clinical conditions with scoliosis that were involved with different treatment approaches	Surgeries like VBS and VBT are not yet approved by FDA. VBT is done for >35° curves while VBS is done for younger patients with moderate curvature	Detailed study regarding VBT and VBS	Bias towards surgery approach for treatment of scoliosis	Robert J. Ames, Amer F.Samdani, and Randal R. Betz
7	Development of CAD/CAM Based Brace Models for the Treatment of Patients with Scoliosis-Classification Based Approach versus Finite Element Modelling (Weiss & Kleban, 2015)	In-brace correction feasibility in the fabrication of CAD/CAM	In-brace corrections achieved in a sample of patients fulfilling the inclusion criteria for studies on bracing using the classification based approach (CBA) were compared to the recent individual CAD/CAM bracing based on finite element modelling approach (FEMA).	Boston style brace gives good results for halting the progression of the curve compared to other braces CBA is preferred over FEMA.	Investigating different types of braces, e.g. Boston brace and Cheneau brace. And introducing the CBA model based on Givsengen brace series		Hans-Rudolf Weiss, Alexander Kleban

8	Vertebral Body Stapling versus Bracing for Patients with High-Risk Moderate Idiopathic Scoliosis (Cuddihy et al., 2015)	Comparing efficacy of two different treatment approaches for scoliosis	Prescribing bracing treatment for one group and VBS treatment for another group and investigating the results of booth approaches	Results of bracing is dependent of patient's age at discovery and at initiation of the treatment Thoracic and lumbar curves respond differently to treatments	Pointing out the issue with poor compliance of bracing especially among boys	Not mentioning surgery's long-term complications	Laury Cuddihy, Aina J. Danielsson, Patrick J. Cahil, Amer F. Samdani, Harsh Grewal, John M. Richmond
9	Non-Surgical Interventions for Adolescents with Idiopathic Scoliosis: An Overview of Systematic Reviews (Płaszewski & Bettany-Saltikov, 2014)	Analysis and comparison of the content, methodology, and evidence-base from systematic reviews regarding non-surgical interventions for adolescents with idiopathic scoliosis	Setting up standard criteria for evaluating reviews	Low quality evidence supporting the effectiveness of bracing in reducing the curve progression and low quality evidence favoring hard braces as compared to soft braces	Thorough and detailed information regarding different non-surgical treatment approaches to scoliosis		Maciej Płaszewski, Josette Bettany-Saltikov

10	A randomized controlled trial of laser scanning and casting for the construction of ankle–foot orthoses (Andrew Roberts et al., 2016)	Assessment of the effectiveness and efficiency of using laser scanning to produce ankle–foot orthoses	comparing fabrication of ankle–foot orthoses from casts or laser scans	Rectification and modelling time is 50% less in CAD/CAM method. However, quality of the final brace did not change. Being scanned is preferable than being cast for the AFO	Providing detailed information regarding cost and time for both the fabrication techniques	Depending of the orthotist ability to position the subject	Andrew Roberts, Johanna Wales, Heather Smith, Christopher James Sampson, Peter Jones and Marilyn James
11	New brace design combining CAD/CAM and biomechanical simulation for the treatment of adolescent idiopathic scoliosis (Desbiens-Blais, Clin, Parent, Labelle, & Aubin, 2012)	Fabrication of optimal brace to maximize efficacy of treatment	3D construction of the spine, rib cage and pelvis for all subjects. CAD-FEM-CAM approach to visualise the brace before final fabricating process	Immediate correction to the curve were achieved before the stage of brace fabrication due to the help of FEM that simulated the trunk and pressure and relief points needed to be indicated.	Using a simulation to optimize the quality of the brace fabricated		Frederique Desbiens-Blais , Julien Clin, Stefan Parent, Hubert Labelle, Carl-Eric Aubin

12	Patient specific ankle-foot orthoses using rapid prototyping (Mavroidis et al., 2011)	Custom-made orthoses using rapid prototyping	3D laser scanning is combined with rapid prototyping to create patient-specific orthoses.	No data storage for manual fabrication where the patient may need a new orthosis every other year which makes the while process start all over again from the beginning	Correlation between 3D scanning and rapid prototyping technique to produce better quality of orthoses	Claiming the reduction of cost and time without providing evidence	Constantinos Mavroidis, Richard G Ranky, Mark L Sivak, Benjamin L Patritti, Joseph DiPisa, Alyssa Caddle, Kara Gilhooly, Lauren Govoni, Seth Sivak, Michael Lancia.
13	Computer-aided optimal design of custom scoliosis braces considering clinical and patient evaluations (Visser, Xue, Ronsky, Harder, & Zernicke, 2012)	Develop a new approach to automatically identify the optimal design of custom-built brace, based on clinical and patient evaluations	Generating 3-D torso model for and then using CAD/CAM system producing spinal brace	The success of modifications done to the brace depends entirely on the technicians skill and previous knowledge of the patient's treatment history.	Development of standard medical and fabrication procedures	Minimal number of subjects were recruited	Daniel Visser, Deyi Xue, Janet L. Ronsky, James Harder, Ronald F. Zernicke

14	The Effect of Rigid Versus Flexible Spinal Orthosis on the Clinical Efficacy and Acceptance of the Patients with Adolescent Idiopathic Scoliosis (Wong et al., 2008)	To compare the treatment effectiveness and patients' acceptance of the flexible spinal orthosis, SpineCor with that of the rigid spinal orthosis for the patients with moderate adolescent idiopathic scoliosis.	Two groups of patients were randomly assigned to use the two different braces. S group = flexible brace R group= Rigid brace	S: R, 7:1 had curve progression >5° S group had problems with toileting while R group had problems with donning and doffing The rate of curve progression is S grave was significantly higher than R group Survival rate S 68%, R 95%	Providing clear evidence showing that rigid brace is more effective than the flexible one upon investigation		Man Sang Wong, Jack C. Y. Cheng, Tsz Ping Lam, Bobby K. W. Ng, Sai Wing Sin, Sandra L. F. Lee-Shum, Daniel H. K. Chow, and Sandra Y. P. Tam
15	A work study of the CAD/CAM method and conventional manual method in the fabrication of spinal orthoses for patients with adolescent idiopathic scoliosis (Wong, Cheng, Wong, et al., 2005)	Compare the CAD/CAM method with the conventional manual method in fabrication of spinal orthoses for patients with adolescent idiopathic scoliosis	Efficiency analyses of the two methods from cast filling/ digitization process to completion of cast rectification. Investigating the dimensional changes of the cast	CAD/CAM depends on the resolution of the system monitor and how clear the object can be seen Positive cast of BioSculptor was later rectified manually by adding plaster. No significant changes in dimensions.	Detailed and clear resulted obtained. Time parameter as well was considered	10 subjects were only recruited	M. S. WONG, J. C. Y. CHENG, M. W. WONG3, & S. F. SO

16	A comparison of treatment effectiveness between the CAD/CAM method and the manual method for managing adolescent idiopathic scoliosis (Wong, Cheng, & Lo, 2005)	Comparing treatment effectiveness between CAD/CAM brace VS manual brace	Fabrication of two braces and testing the effectiveness in long-term treatment period	Both the methods provided significant initial control in Cobb's angel BioSculptor could have a lightly better initial control in-brace control over the manual brace. No change shown in apical vertebral rotation.	Results obtained are positive for both the braces	Most of cited articles are of the same author	M. S. WONG, J. C. Y. CHENG, & K. H. LO
17	Orthoses for Mild Scoliosis: A Prospective Study Comparing Traditional Plaster Mold Manufacturing With Fast, Noncontact, 3-Dimensional Acquisition (Cottalorda et al., 2005)	To evaluate the therapeutic efficiency of spinal orthoses made by a CAD design procedure	Studying the cases of 30 adolescents with mild scoliosis, who were provided with two braces each fabricated using the two different methods	In traditional casting method, training of the orthotist is fundamental. However, 3D scanning method is equally as effective as the manual method fabrication of the brace.	Finding that 3D scanning method is equally effective as plaster mold fabrication method		Jerome Cottalorda, Remi Kohler, Christophe Garin, Pascal Genevois, Cyril Lecante and Benoit Berge

CHAPTER 3: METHODOLOGY

3.1. Introduction

This chapter discusses the fundamentals of anthropometry, the tools and materials needed for the fabrication and the steps involved in fabricating the spinal braces in both methods manual and scanning, and provides the needed data for the analysis. The data has been collected from three different subjects, hence the compromising discussion is reached upon three subjects who are involved in the research process. The fabrication process is done in CPOE University of Malaya with the help of experienced orthotist.

3.2. Anthropometry

Anthropometry is a science that deals with the measurements of the dimensions and certain other physical characteristics of the human body such as volumes, center of gravity, inertial properties and masses of body segments. Body segments' measurement of the subjects are compared to the anthropometry calculation. The anthropometry calculation is done by referring to Figure 2.a below where H in the diagram indicates the actual height of the subjects.

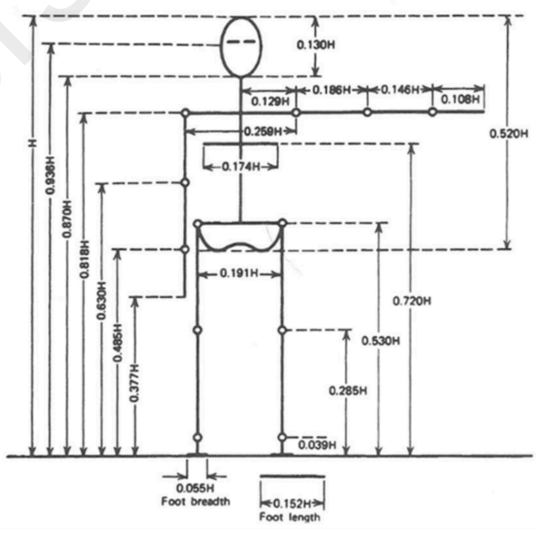


Figure 3.1: Drillis and Contini (1966). (Adapted from Biomechanics and Motor Movement, 4th Ed. by David A. Winter, pg. 83.)

3.3. Tools and equipment

Table 3.1: Tools and equipment used in the fabrication process

Assessment	Tools and equipment		Fnction
Casting	Tools	Measuring tape	To measure the length and circumferences of body segment
		Marker pen	To mark the important landmarks
		Medical scissors	To cut the POP bandages
		Basin	To contain clean for soaking POP bandages
		Cutter	To cut the negative cast when removing it off the subject
		Body calliper	To measure AP and ML measurements
		Transparent narrow tube	To avoid harming the subject when cutting the negative cast
		Indelible pen	To refresh the markings on the negative cast
	Equipment	Bioscanner	To 3D scan the subject
Modification	Tools	Surform (half-round and round)	To shape and smoothen the positive cast
		Spatula	To stir and take the slurry out of bowl
		Bowl	To put the slurry in
		Bench vice	To hold and fix the positive cast in place
		Indelible pencil	To refresh the markings and draw trim line on the positive cast
		Wire mesh	To smoothen the positive cast
	Equipment	Milling machine	To print the positive cast

Molding	Tools	Cutter	To cut the plastic when removed from the vacuum pump
		Gloves	To protect the hand when holding the heated plastic sheet
		Scissors	To cut the plastic
	Equipment	Oven	To heat the plastic sheet
		Suction machine	To remove the air between the positive cast and plastic
		Jigsaw	To cut the plastic sheet
Finishing	Tools	Measuring tape	To take the final measurements
		Hammer	To attach the rivet and straps on the mould
		Awl	To make holes on straps by heating it using heat gun
	Equipment	Grinding machine	To grind and smoothen the mould
		Hand drill	To drill holes for attaching the straps
		Heat gun	To burn the ends of each strap

Figure 3.2: Bioscanner (wand)

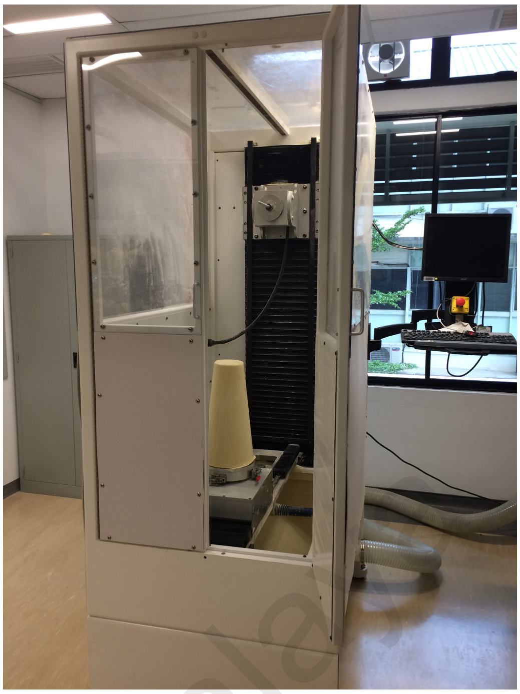


Figure 3.3: Milling Machine

Figure 3.4: Oven

Figure 3.5: Vacuum suction pump

3.4. Demographic data

3.4.1. Ethical Approval

This study was approved by the UMMC ethics committee (37912). The research has been done under the supervision of certified P&O CAT1.

3.4.2. Subjective Assessment

Subject 1

22 years old, male and a civil engineering student at the University Malaya. He is an active person as he is involved in many campus activities. He does not have any complaint about any spinal or back pain.

Subject 2

23 years old, male a third year civil engineering student at the University of Malaya. He stays in residential college within university campus and usually commutes on bus. He is a healthy adult without any medical issue.

Subject 3

23 years old, male. Lives in Seremban with his parent and a younger sister and he does not face any financial problems. He is a student and he has serious allergy. Other than the allergy he does not have any health problems. He likes jogging and travelling during his free time.

3.4.3. Objective Assessment

All required measurements of the subjects (table) were measured and recorded using a measuring tape and body calipers. These measurements were used as guide in fabricating the device to get the best-fit outcome.

Table 3.2: Subject's height and weight measurements

Type of Data	Subject 1	Subject 2	Subject 3
Height (cm)	165	172.5	167
Weight (kg)	52	53	55

Subject 1

His standing posture shows slight lordosis when observed on sagittal plane. Previously, the subject never owned any orthosis and has no history of spine injury. In this case, the subject is prescribed with a thoracic Boston brace. Generally, the design has and axillary extension as its highest component. This design is for use with double curves, and thoracic curves with an apex up to T6. Usually, it requires a trochanter extension/pad, lumbar pad and low thoracic pad.

Three types of examinations – physical, radiographic and neurological, are commonly done for cases involving fabrication body brace, especially scoliosis. For physical examination, Adam's forward bending test and lateral flexion test are the usual test done on scoliosis patients. The two tests are to determine any rib and lumbar prominence(s) and to check the flexibility of a curve respectively. In this case, only physical assessment is done as the x-ray film of the subject's spine cannot be obtained.

From the physical examination:

- The subject has an even waistline and shoulder level when assessed from anterior part.
- The arm gaps are equal.
- The scapulae are on level position.
- Neither scapula nor lumbar prominence is observed on the body posterior.
- The back's skin is in normal condition; no hair patches, skin dimples and hyperpigmentation observed.

Subject 2

His standing posture is normal. Previously, the subject never owned any orthosis and has no history of spine injury. In this case,

Three types of examinations – physical, radiographic and neurological, are commonly done for cases involving fabrication body brace, especially scoliosis. For physical examination, Adam's forward bending test and lateral flexion test are the usual test done on scoliosis patient. The two tests are to determine any rib and lumbar prominence(s) and to check the flexibility of a curve respectively. In this case, only physical assessment is done as the x-ray film of the subject's spine cannot be obtained.

From the physical examination:

- The subject has an even waistline and shoulder level when assessed from anterior part.
- The arm gaps are equal.
- The scapulae are on level position.
- Neither scapula nor lumbar prominence is observed on the body posterior.
- The back's skin is in normal condition; no hair patches, skin dimples and hyperpigmentation observed.

Subject 3

His both upper limbs have good sensation and good proprioception. He has all muscle strengths on both lower limbs with grade 5 and full range of motion. To check whether the subject is having any spinal curves, Adam's forward bending test is done. The subject is asked to put palms together with arms out straight. Next, he needs to put chin or chest and roll down until hands touch feet. He is asked to continue to roll down as far as possible until his back is parallel to the floor. Since he has no signs of scoliosis, flexibility test of the spinal curve is not done. When the subject is standing straight, it is observed whether the subject is having any spinal curve, yet nothing unusual to be noticed.

Shoulders level of the subject are observed and there is not inequality in their heights. Besides, the gap between lateral body and the hand is observed and the gaps of left and right are equal. The length of both hands is equal. The body trunk of the subject when observed from posterior plane is straight. From all the observation it is concluded that the subject is not having scoliosis.

From the physical examination:

- The subject has an even waistline and shoulder level when assessed from anterior part.
- The arm gaps are equal.
- The scapulae are on level position.
- Neither scapula nor lumbar prominence is observed on the body posterior.
- The back's skin is in normal condition; no hair patches, skin dimples and hyperpigmentation observed.

Table 3.3: Subject's body measurements

Level of body segment	Measurement (cm)								
	Subject 1			Subject 2			Subject 3		
	C	ML	AP	C	ML	AP	C	ML	AP
Axilla	83.2	27.2	18.5	77.5	27.2	18	82.0	28.7	17.5
Nipple Line	80.0	27.0	19.4	75.3	25.2	17.4	78.0	27.6	17.4
Xyphoid	75.0	27.0	18.2	69.5	24.2	16.0	72.5	26.8	16.0
Lower rib	73.2	25.1	17.8	59.2	21.8	14.8	65.5	25.6	15.2
Umbilical	74.0	24.5	17.0	59	20.1	17.5	63.2	21.6	14.3
Waist	66.5	19.5	15.3	60.9	22.8	15.8	68.3	23.5	15.5
ASIS	82.1	24.3	20.3	76.0	26.8	17.4	85.0	29.7	20.0
GT	84.1	29.5	20.0	79.3	30.2	18.0	85.0	29.7	20.0
Sacro-coccygeal	83.0	25.2	20.5	79.0	28.1	19.0	84.2	27.3	20.9

	Length (cm)		
Axilla – Nipple Line	8.0	10.0	7.0
Nipple Line – Xyphoid	5.0	8.0	5.0
Xyphoid – Umbilicus	17.0	20.0	17.0
Umbilical – Pubic Symphysis	15.0	18.0	17.0
Axilla – GT	46.5	48.3	44.5
End of Scapula – PSIS	30.0	32.0	31.0
PSIS – Apex of Buttock	6.3	7.8	6.5

*Note: C= Circumference, ML= Medial-Lateral, AP= Anterior-Posterior

3.5. Flowchart of the Fabrication Process

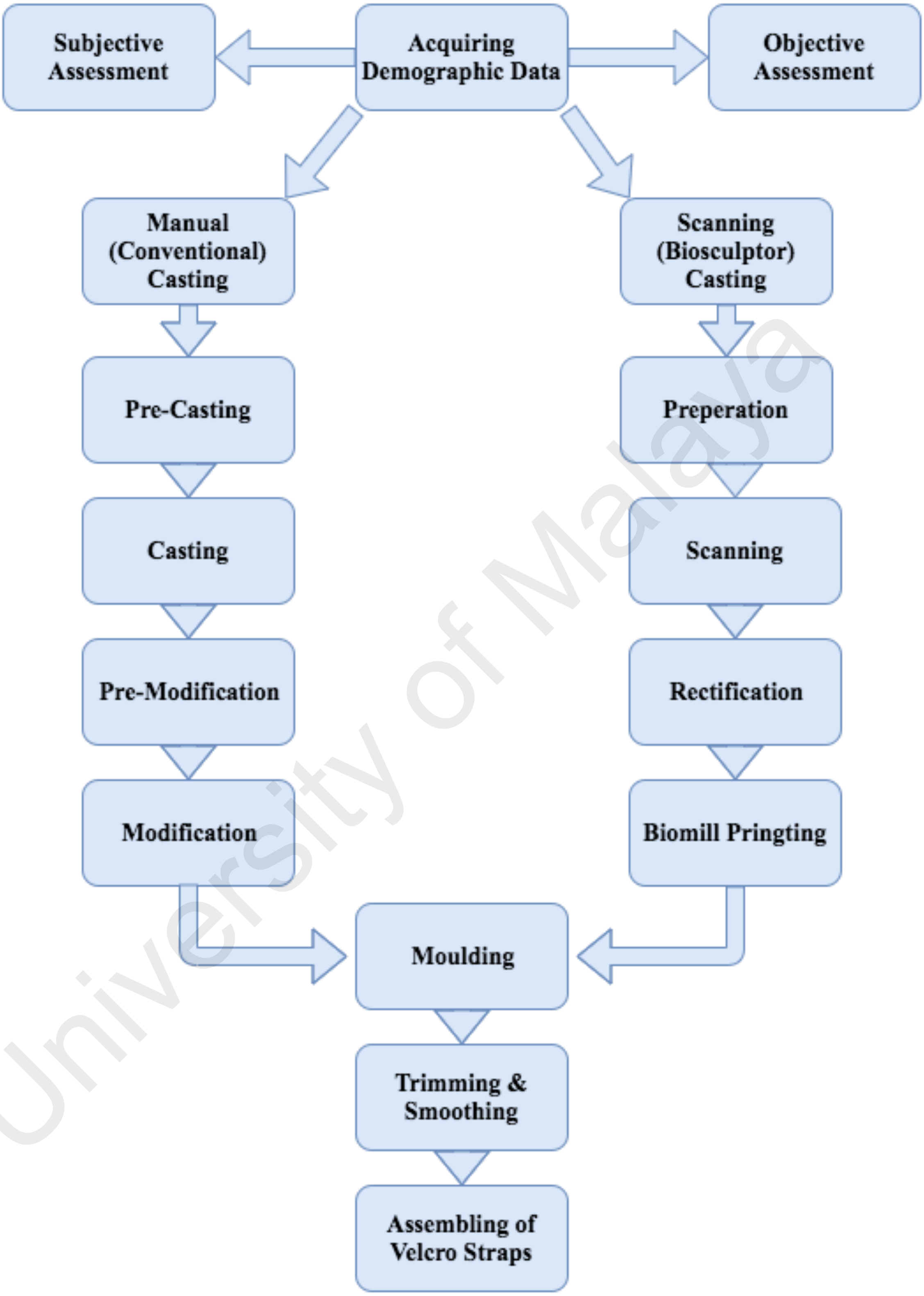


Figure 3.6: Flowchart of the fabrication process

3.6. Manual (Conventional) Method

3.6.1. Pre-casting

a. Before starting the casting procedure, an X-ray of the subject is recorded and observed. From the x-ray, the type, direction, shoulder level, pelvic level and Cobb's angle by measuring from the angle between the superior most tilted vertebrae and the inferior most tilted vertebrae. Then, the forces that are going to be applied on the patient's body have to be imagined to achieve the maximum correction of the spine.

b. A layer of plastic is wrapped on the subject's body as protection and for hygiene purpose.

c. The bony prominences and anatomical landmarks are marked.

   - Anterior markings: iliac crests, anterior-superior iliac spine (ASIS), pubic symphysis, umbilicus, xiphoid process, distal margins of 10th ribs and axillary level.
   - Lateral marking: Greater trochanters.
   - Posterior markings: sacrococcygeal junction, posterior-superior iliac spine (PSIS), inferior edge of scapulae.
   - Any sensitive areas or prominences.

d. Important measurements are measured and recorded accurately in the measurement form and it is to be used as reference during modifications of the positive cast.

e. After that the force is applied by multiple persons on the body to simulate the force patterns and one has to make sure that the patient's standing posture is correct and managed to be in the right position.

3.6.2. Casting

a. Plaster bandages are wrapped starting from pelvis making sure it is low enough to cover the greater trochanter. Plaster bandages are wrapped up to the estimated proximal trim line. Before the plaster bandages harden, the waist and iliac crest were shaped by placing the plastic tube and it is pulled anteriorly and downward.

   Constant massage over the bony areas is done to get the shape of the iliac crest and ASIS.

b. Then, the corrective forces were applied with the application of counter force and stabilization of the pelvis as same manner as practiced.

c. An anteriorly directed de-rotating force in the lumbar spine is counter balanced by a posteriorly directed force in the anterior abdomen.

d. The position of the trunk during force application is controlled.

e. Lastly, the mid-body lines in the posterior and lateral view are drawn and the cast is removed by cutting along the protective tube.

f. The landmarks are redrawn on the negative cast.

Figure3.7 Manual casting on one of the subjects.

3.6.3. Pre-Modification

a. The negative cast is filled with the mixture of Plaster of Paris (POP) powder and water in 1:1 ratio.

3.6.4. Modification

a. The circumferences, medial-lateral diameter and anterior-posterior diameter of the positive cast are measured and recorded before any modification on the cast.
b. The positive cast is modified according to the subject's measurement.
c. The area below 2cm of the Xiphoid process is reduced to give abdominal pressure. There should be no any reduction on the ribs and other bony prominence areas to avoid pinching of the brace on the patient's bone.
d. The ASIS areas are added with POP slurry to give pressure relief.
e. The midway between the iliac crest and the lower margin of the ribs are made inward protruding (reduction of POP) as a function of preventing distal or proximal migration of the brace and to aid in positioning the pelvis in a posterior directed tilt.
f. After all the modification is done, the positive cast is smoothed and ready for plastic(Polypropylene) moulding.

3.6.5. Moulding

a. Before moulding process starts, a middle line is drawn at the posterior part of the positive cast with 4cm width. This is the trim line for the posterior opening of the spinal brace.
b. The positive cast is wrapped with a layer of stockinet.

c. The polypropylene sheet is heated in the oven at 170°C for 15 to 20 minutes until it is ready to be molded on the positive cast.

d. Two of the persons are responsible for the molding of the superior and inferior part and one is in charge of the suction control and making sure all the seams are well sealed to ensure proper suction.

e. The seams are well sealed along the middle posterior of the positive cast (which is the posterior opening).

3.6.6. Trim lines

a. An area of relief is provided opposite the area of pressure so that the spine or body can shift into the area of relief. In this case, a window is made opposite to the area of pressure.

b. The anterior inferior trim line is kept as distal as the subject can tolerate.

c. The anterior superior trim line is located at the base of the sternum to prevent upon the xiphoid process.

d. The posterior inferior trim line is extended as low as possible but no more than 1-2 cm from the seat of a hard chair when the patient is sitting with hip flexed at 90°.

e. The width of the posterior opening is estimated by measuring the width of the largest lumbar vertebra.

f. The posterior superior trim line is originated at the level of the eighth thoracic vertebra.

g. The lateral inferior trim line covered one of the greater trochanter. A trochanters extension is used to stabilize the brace. The trochanter extension is placed on the concave side of a lumbosacral curve. The opposite inferior line is trimmed proximally 1cm above the greater trochanter.

3.6.7. Trimming and smoothing

a. After all the trim lines are drawn, the cast is trimmed according to the trim lines and smoothed before the first trial on the subject.

3.6.8. Assembling of Velcro straps

a. Three Velcro straps are attached at the posterior opening of the brace to allow patient tighten and loosen the brace when donning and doffing.

3.7. Scanning (Biosculptor) Technology

3.7.1. Preparation

a. Bioscanner device is turned on and the FastScan software in the Desktop is launched.
b. When all settings are set, the scanner is let to warm up for about 10 minutes.
c. The scanner status is observed; a transmitter is secured as close as possible to subject's pelvic area.
d. The room is made dark for better scanning outcome.
e. The trigger on the wand (scanning tool) is pulled once and released to connect the wand and the software.
f. The trigger is pulled again, half way, and held while aiming the laser at the transmitter. The trigger is then pulled fully and released, showing the tool is ready for scanning.

3.7.2. Scanning

a. The wand is held 3-8" from the body and the trigger is pulled fully and full sweep (scanning) of one side of the body is made vertically. A trial is made first before starting a full scan for practice.

b. The image is observed on the desktop to check on the orientation.
c. The process is repeated until all parts are scanned. Each sweep must not or minimally overlap to the previous sweep to ensure more precise scanning and data recording.
d. Once scan is completed, a shield is flipped over the laser section of the wand.
e. On the FastScan toolbar, 'Stylus mode' is selected.
f. The trigger on a stylus tool is pulled and held at the transmitter.
g. When the tool is connected to the software, the trigger is released. The stylus tool is located at landmarks required on the model and the trigger is pulled at each location to save each point. Landmarks: sternal notch, xyphoid, ASIS, end of scapulae, PSIS.
h. Then, the file is saved for modification in Bioshape.

3.7.3. Rectification

Modification of the model is done using a BioShape software in the desktop. The process is as follows:

a. After importing the scanned model into the software, the model type is set as 'Spinal' and the required landmarks are identified and labelled. Landmarks: anterior waist, xyphoid, sternal notch, ASIS (left & right), iliac crest (left & right), trochanter (left & right).
b. Then, the process is proceeded by clicking on 'continue' button and pre-alignment tool is displayed.
c. After setting the alignment, 'Export to Bio File' button is selected on the toolbar at the top of the screen to create a 'bio file' for the next step.
d. In 'Bio file' form, model display type is chosen on toolbar at the bottom of the screen.

e. The second tool on the left toolbar is selected.

f. A reference mark is set by clicking the 'Set reference' button on the top toolbar. The xyphoid is set as reference mark.

g. The 'Add Dimensional' is selected on the top toolbar to set the dimension between each reference marks from the olecranon. The dimension is set to 50 mm.

h. The green 'correct sign' button is selected for each tools on the toolbar after editing to save and exit the tool or, the red 'cross sign' is selected to discard the edits and exit the tool.

i. The 'Region tool' button on the left toolbar is selected, to modify the waist area on the model. The area is drawn just above the iliac crest on left and right waist to make and elongated groove. The upper crest along the groove is reduced about 3 mm while lower part is reduced about 5mm for both sides.

j. The lumbar area at the posterior part is increased 2 mm to reduce the slight lordosis curve.

k. Then, the model is smoothed using the 'smoothing tool' on the left toolbar by setting the 'Mode' to smooth.

l. The 'alignment' tool on the left toolbar is selected to set the alignment of the model based on transverse, frontal and sagittal planes.

m. The 'Segmental Correction Tool' is selected to correct any segment of the model. In this case, no changes is made.

n. Then, 'Orthotic Reflection Tool' is used to create and ensure the model is in symmetry.

o. The 'initial dimension' tool is selected to set the circumference dimension on each reference of the model. No changes are made.

p. ‘Cross Section Pattern Tool’ is selected to set the anterior cross section of the model.

q. The ‘tension tool’ on the left toolbar is used to apply tensions amount on the model (if necessary). For this model, no changes are made.

r. Trim lines are drawn on the model by using ‘Trim tool’ on the left toolbar to set the proximal trim line of the model. The trim line is kept just above the axilla level to get the best area for moulding process.

s. Then, the next ‘Percent tool’ is used to change the length or circumference of the model based on percentage. No changes are made for this model.

t. The final measurement of the model is checked to edit any changes by using the ‘Final Measurement tool’. No changes of measurements are made.

u. Smoothing of the model is re-done by using the ‘Final Preparation tool’ to ensure smooth surface of model for printing.

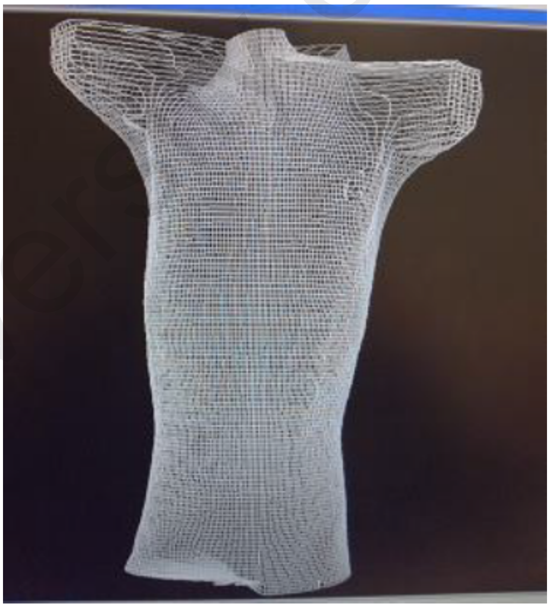


Figure 3.8 Rectification of the scanned trunk of the subject

3.7.4. Printing Positive cast

a. The model is positioned in plug suitable for milling by using the ‘Mill Preparation tool’.

b. A suitable plug type (foam size) is chosen by clicking the 'option' button on the top toolbar. A T2 plug type is chosen for this model.

c. The modified model is saved and transferred to Biomill printer for printing. The chosen plug type is fixed inside the Biomill printer and the printing is let done.

After the milling process, the surface of the foam is found to be quite rough. A sandpaper was used to smoothen the foam surface. After that, the measurement of the final model is measured and recorded by using measuring tape and body callipers.

When the model is ready, the next fabrication steps; moulding, finishing, and assembling the component (Velcro straps), are the same as the conventional method.

3.7.5. Measurements of the braces

The measurements have been taken 3 times for each section and using a body caliper and measuring tape.

CHAPTER 4: RESULT AND DISCUSSION

This chapter provides the relevant data that has been acquired from the fabrication process and analyze it.

4.1 Subject 1

Figure 4.1 shows the completed manual (conventional-fabricated) brace from anterior (a), posterior (b), sagittal (left) (c) and sagittal (right) (d) view respectively.

Figure 4.1 (a)

Figure 4.1 (b)

Figure 4.1 (c)

Figure 4.1 (d)

Figure 4.2 shows the completed (Biosculptor-fabricated) brace from anterior (a), posterior (b), sagittal (left) (c) and sagittal (right) (d) view respectively.

Figure 4.2 (a)

Figure 4.2 (b)

Figure 4.2 (c)

Figure 4.2 (d)

Table 4.1 Comparison between Positive Cast Measurements for Manual (Conventional) and Scanning (BioSculptor)

Level Starting 1.5cm below Xyphoid (cm)	Measurement (cm)					
	Positive Cast					
	Conventional			BioSculptor		
	C	ML	AP	C	ML	AP
+5	79.4	25.3	18.2	86.3	27.5	20.1
+10	74.4	23.7	16.3	80.7	25.7	18.2
+15	70.9	22.6	15.2	74.1	23.6	16.1
+20	85.4	27.2	17.6	76.3	24.3	17.3
+25	89.2	28.4	18.3	82.3	26.2	17.5
+30	92.3	29.4	19.5	86.0	27.4	16.9

Table 4.2 Comparison Between Internal and External Brace Measurements

Level Starting 1.5cm Below Xyphoid (cm)	ML Diameter Of Conventional Brace Measurements (cm)		Percentage Difference (%)	ML Diameter Of BioSculptor Brace Measurements(cm)		Percentage Difference (%)
	Internal	External		Internal	External	
+5	24.5	24.4	0.2	22.8	23.4	1.3
+10	23.0	21.7	2.9	22.0	24.3	5.0
+15	22.8	24.6	3.8	22.5	24.0	3.2
+20	26.7	28.5	3.3	21.8	23.0	2.7
+25	28.0	30.0	3.4	24.3	25.0	1.4
+30	28.8	30.4	2.7	25.2	26.4	2.3

Table 4.3 Circumference Comparison between Conventional and BioSculptor brace

Level Starting 1.5cm Below Xyphoid (cm)	Circumference Of Conventional Brace Measurements (cm)	Circumference Of BioSculptor Brace Measurements(cm)	Percentage Difference (%)
+5	75.6	73.5	2.1
+10	68.1	76.3	5.7
+15	77.2	75.3	1.2
+20	89.5	72.2	10.7
+25	94.2	78.5	9.1
+30	95.5	82.9	7.0

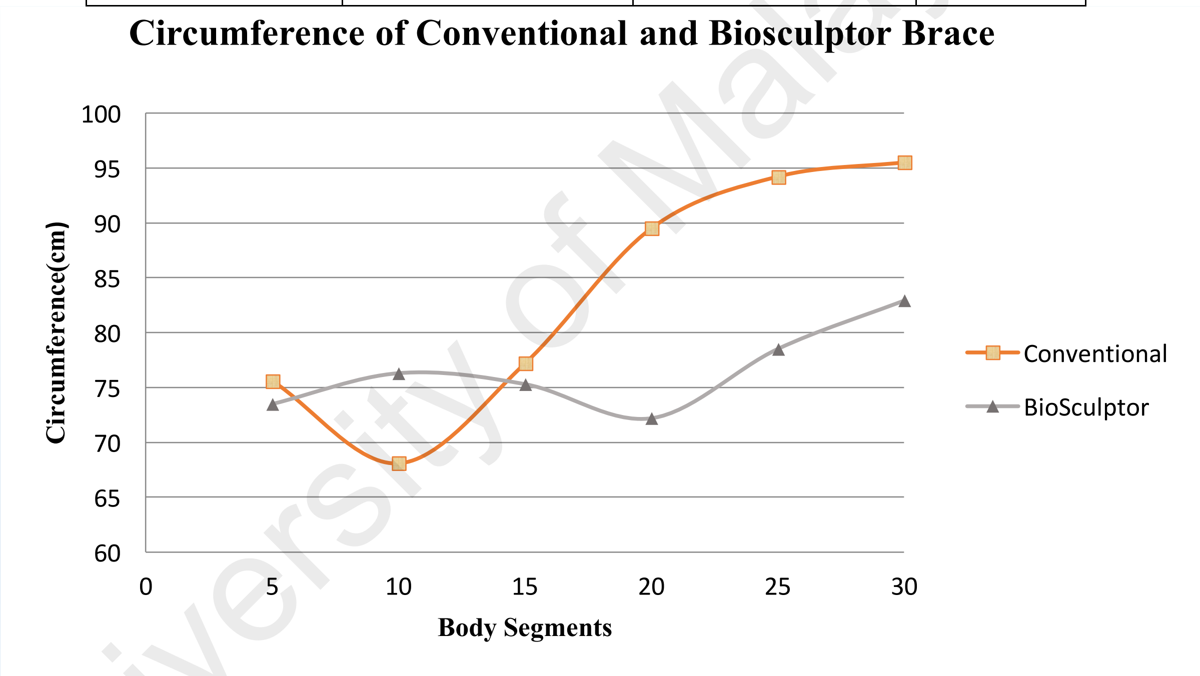


Figure 4.3: Circumference comparison between Conventional and BioSculptor brace

In Table 4.1 the measurement of the positive cast for both the methods are compared. When comparing the measurement of the positive cast of the conventional brace and the positive cast of the Biosculptor brace, the difference for every 5 cm from the reference point of 1.5 cm below the Xyphoid, is not too high. Which proves that the rectification process for both the methods might slightly change and it is dependable on the experience on how to use the software for the scanning method.

Table 4.2 portrays the results of the internal and external measurements of the completed device, both via the conventional method as well as the Biosculptor method. The percentage difference in the internal and external measurement is rather small, however, the difference is inconsistent for every 5 cm. This proves that the thickness of the polypropylene plastic is not even throughout and thus will cause an inconsistent distribution of forces, which might affect the function of the brace mildly.

Table 4.3 shows the different measurements in the two final product and how in initial points below the Xyphoid they show similar measurements. However, in later points there shows a large difference which explains the hardship of dealing with the Scanner and the software to grant optimum result for the cast. The scanning method is supposedly to produce a more accurate and precise measurement compared to the conventional method, as the scanning method practiced with the use of the Biosculptor mimics the concept of "total surface bearing". However, due to the absence of the appropriate material for patient to don while using the Biosculptor software as well as the lack of training with the software, the Biosculptor could not be used to its maximum capacity. This in turn also contributed to the inaccurate data collected. The evident advantage of the Biosculptor that can be seen based on the results is the difference between the measurements at each 5 cm interval of the Biosculptor indicates consistency as we can observe the difference being in the range of 1-2 cm. In the case of the conventional method, the difference is rather consistent except for the difference between 15-20 cm interval, which has a deviation of a 5.4 cm difference.

4.4 Subject 2

Figure 4.4 shows the completed manual (conventional-fabricated) and scanning (BiosSculptor) brace from anterior (a), (b) and posterior (c), (d) view respectively.

Figure 4.4 (a)

Figure 4.4 (b)

Figure 4.4 (c)

Figure 4.4 (d)

Table 4.4 Comparison between body measurements and positive cast measurements for manual (conventional) and scanning (BioSculptor)

Body Segment	Measurement (cm)								
	Body Measurement			Positive Cast					
				Conventional			BioSculptor		
	C	ML	AP	C	ML	AP	C	ML	AP
Axilla	77.5	27.2	18.0	77.0	27.8	18.0	76.3	26.3	17.5
Nipple line	75.3	26.3	17.1	74.2	25	16.9	74.9	24.6	17.3
Xyphoid	69.5	24.2	16.0	72.0	25.2	17.8	73.3	26.0	19.2
Lower rib	59.2	21.8	14.8	63.2	20.8	18.1	62.4	21.8	17.2
Waist	60.9	22.8	15.8	64.0	21.4	18.5	65.1	22.6	17.0
ASIS	76.0	26.8	17.4	75.0	28.1	17.5	69.2	25.2	18.1
Greater Trochanter	82.2	30.2	18.0	81.3	30.2	16.5	80.6	29.6	21.0

Table 4.5 Comparison Between Internal and External Brace Measurements

Body Segment	Circumference Of Conventional Brace Measurements (cm)		Difference (cm)	Circumference Diameter Of BioSculptor Brace Measurements(cm)		Difference (cm)
	Internal	External		Internal	External	
Axilla	78.0	78.8	0.8	71.3	74.3	3.0
Nipple line	70.3	72.1	1.8	69.5	66.5	3.5
Xyphoid	67.0	67.9	0.9	60.0	63.5	3.5
Lower rib	63.5	65.8	2.3	56.5	59.5	3.0
Waist	62.4	66.0	3.6	52.0	55.5	3.5
ASIS	72.0	75.3	2.8	56.7	60.2	3.5
GT	79.3	80.3	1.6	77.1	80.1	3.0

Table 4.5 Comparison Between Internal and External Brace Measurements

Table 4.6 Circumference Comparison between Subject's measurements with Conventional and BioSculptor brace

Body Segment	Circumference of Subject (cm)	Circumference Of Conventional Brace Measurements (cm)	Percentage Difference (%)	Circumference Of BioSculptor Brace Measurements(cm)	Percentage Difference (%)
Axilla	77.5	80.3	3.6	75.3	-2.8
Xyphoid	69.5	72.1	3.7	65.1	-6.3
Lower rib	59.2	66.0	11.4	55.5	-5.5
Waist	60.9	66.5	9.1	58.9	-3.2
ASIS	67.0	76.5	14.1	63.2	-5.6

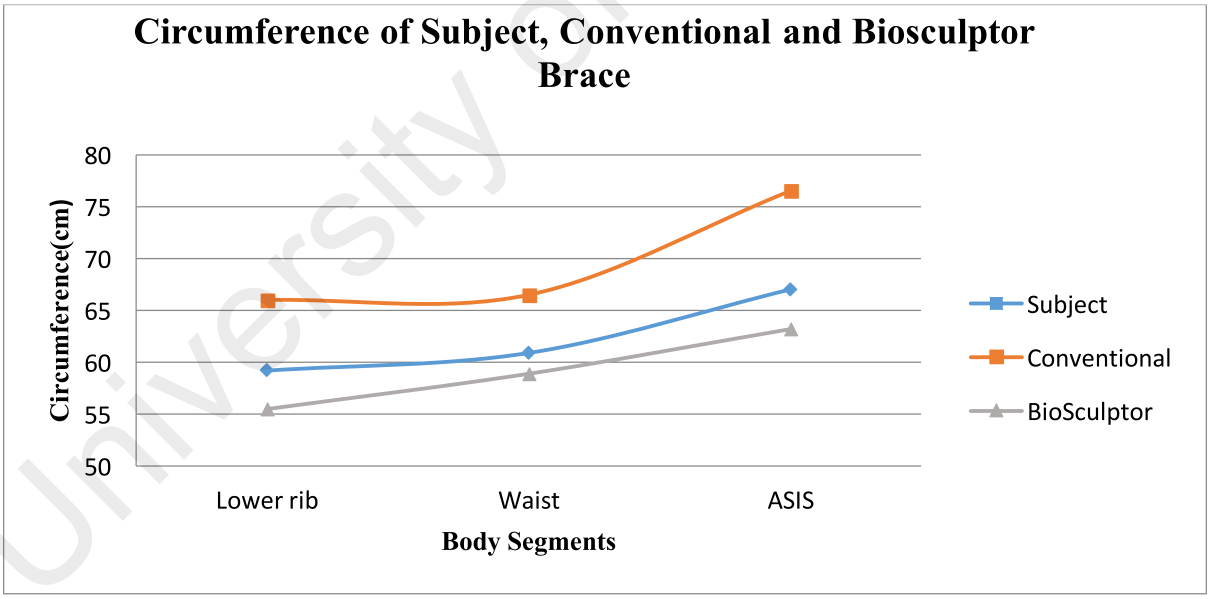


Figure 4.5 Circumference Comparison Between Subject, Conventional and BioSculptor brace

Referring to Table 4.5, the average difference in conventional when comparing internal and external circumference is 2.4cm which is higher as compared to the difference between the positive cast (Table 4.4) with external circumference is 1.65cm.

For BioSculptor method, the differences in diameter between positive cast and external braces is turned out to be negative. Based on this result, the reason could be either the plastic was shrinking during cooling process or the BioSculptor foam was shrinking during the plastic draping process. This error might be due to the vacuum system which was faulty during the draping process. When comparing the differences between internal and external, the values turn to be quite large. It is impossible for the thickness of the plastic to be almost 4cm. Once again, this might be due to the lack of measurement tools.

Based on Table 4.5, the thickness of the plastic of the braces can be obtained when comparing the internal diameter and external diameter of the positive cast and the thickness is said to be not uniform throughout the brace. Supposedly, the positive cast measurement is the same as the internal circumference of final brace. Once again, due to the lack of suitable measuring tool to measure the inner circumference, some faulty and error when measuring the circumference might occur.

As shown in Figure 4.14, it can be seen that the circumferences of lower ribs and waist on the brace fabricated using Biosculptor system are more accurate to subject's measurement than that of brace done by conventional method. Based on this result, Biosculptor system is said to be a better choice in making custom made brace as it gives more pressure to correct and prevent the deformity which fulfils the objectives of providing the brace to patients. At the ASIS region, the differences between the Biosculptor brace and subject's measurement is larger as compared to conventional brace with subject's measurement. This may be caused by the exact location of ASIS was placed wrongly when using Bisculptor system and stylus point of scanning system was not used in determining the landmarks during scanning. Even though the circumferences at the lower ribs and waist are larger, adjustment can be made on that particular areas by adding pads or tightening the straps. Moreover, a larger circumference at ASIS is preferable as it is a bony region and it will cause pain on that particular area if unnecessary pressure is applied on it due to the smaller measurement.

A study done by(Cottalorda et al., 2005) showed that for both the techniques training and experience are fundamental essential for the orthotist to have in order to achieve best results in making the orthosis.

4.3 Subject 3

Figure 4.6 shows the completed manual (conventional-fabricated) brace from anterior (a), posterior (b), sagittal (left) (c) and sagittal (right) (d) view respectively.

Figure 4.6 (a)

Figure 4.6 (b)

Figure 4.6 (c)

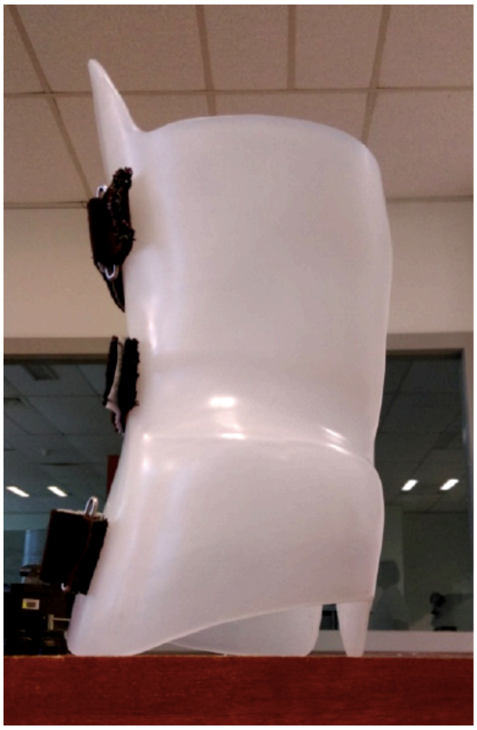


Figure 4.6 (d)

Figure 4.7 shows the completed (Biosculptor-fabricated) brace from anterior (a), posterior (b), sagittal (left) (c) and sagittal (right) (d) view respectively.

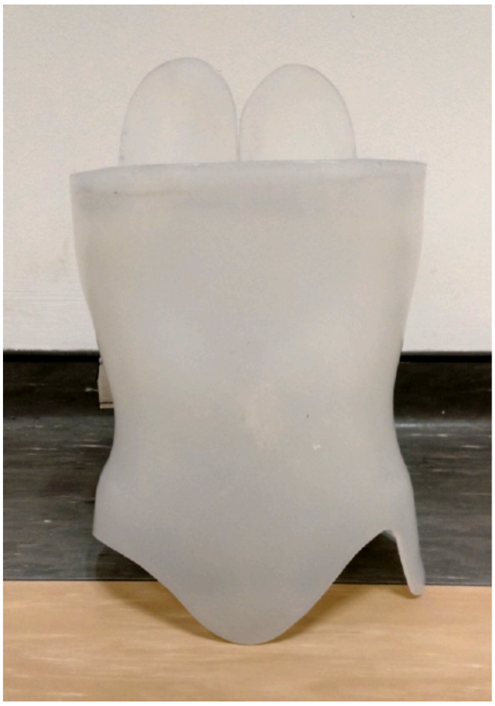


Figure4.7 (a)

Figure 4.7 (b)

Figure 4.7 (c)

Figure 4.7 (d)

Table 4.7 Comparison between body measurements and positive cast measurements for manual (conventional) and scanning (BioSculptor)

Body Segment	Measurement (cm)								
	Body Measurement			Positive Cast					
				Conventional			BioSculptor		
	C	ML	AP	C	ML	AP	C	ML	AP
Axilla	82.0	28.7	17.5	82.1	26.6	18.2	77.3	26.3	16.5
Nipple line	78.0	27.6	17.4	78.0	25.5	18.0	73.1	25.4	15.5
Xyphoid	27.5	26.8	16.0	73.0	24.6	17.0	70.3	24.9	14.5
Lower rib	65.5	25.6	15.2	69.0	24.0	15.5	64.3	23.2	14.8
Waist	68.3	23.5	15.5	65.5	23.0	15.8	65.5	21.9	15.7
ASIS	77.8	28.5	19.2	79.0	29.0	16.5	74.5	25.3	17.6
Greater Trochanter	85.0	29.7	20.0	80.0	29.0	17.3	81.0	28.1	22.0

Table 4.8 Comparison Between Internal and External Brace Measurements

Body Segment	Circumference Of Conventional Brace Measurements (cm)		Difference (cm)	Circumference Of BioSculptor Brace Measurements(cm)		Difference (cm)
	Internal	External		Internal	External	
Axilla	79.0	79.5	0.5	75.2	77.1	2.1
Nipple line	78.0	78.7	0.7	73.1	75.5	2.4
Xyphoid	73.0	74.0	1.0	70.3	73.0	2.7
Lower rib	69.0	70.0	1.0	64.3	67.0	2.5
Waist	65.5	68.5	3.0	65.5	68.5	3.0
ASIS	79.0	79.3	0.3	74.5	76.0	1.5
GT	80.2	83.3	3.3	81.0	83.0	2.0

Table 4.9 Circumference Comparison between Subject's measurements with Conventional and BioSculptor brace

Body Segment	Circumference of Subject (cm)	Circumference of Conventional Brace Measurements (cm)	Percentage Difference (%)	Circumference Of BioSculptor Brace Measurements(cm)	Percentage Difference (%)
Axilla	82.0	82.3	0.3	78.1	-4.9
Nipple line	78.0	78.0	0.0	73.1	-6.4
Xyphoid	72.5	73.0	0.69	70.3	-3.08
Lower rib	65.5	69.0	5.2	64.3	-1.8
Waist	68.3	65.5	-4.1	65.5	-4.1
ASIS	77.8	79.0	1.5	74.5	-4.3
GT	85.0	80.2	-5.8	81.0	-4.8

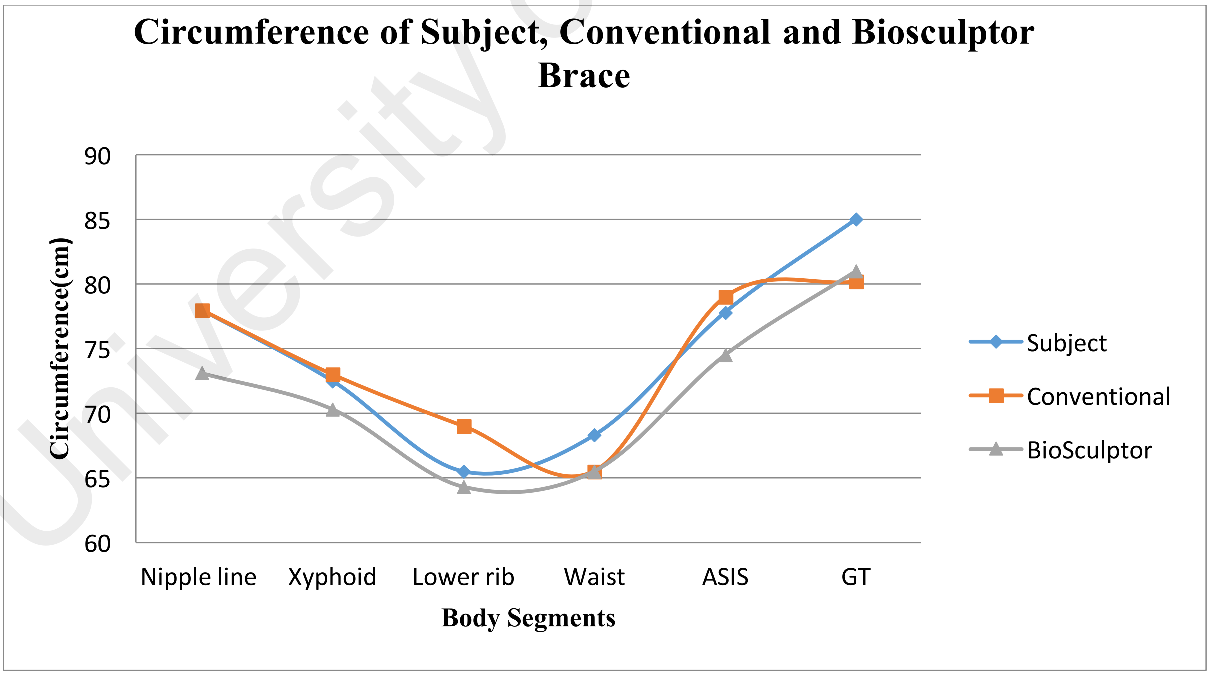


Figure 4.8 Circumference Comparison between Subject, Conventional and BioSculptor brace

Basically, the differences between the external and the internal part define the thickness of the plastic. Thus, the external measurement must be larger than the internal measurement. Based on Table 4.8, it shows that all the external measurements of both Conventional and Biosculptor brace are larger than the internal measurements which follow the above statement. Overall, it can be said that the thickness of the plastic is not evenly same throughout all parts. This may be due to the incorrect or different marking point place on the internal and external part. Also, it can occur during the draping process where stretching occurs on the hot plastic which resulted in unevenly thickness. In addition, the Waist circumference for both braces have the greatest difference which is 3.0cm. This maybe happened during draping process, where the plastic wasn't properly sucked onto the positive cast/foam which left some gap between the waist line and the plastic. This also means that the total difference of 3cm is including the gap size. Besides, it can be said that the Biosculptor brace has thicker plastic compared to the Conventional brace. This might happen because the time taken for the plastic to get heated were different for both braces where for the Conventional brace, the plastic being heated longer which lowers the thickness of the plastic compared to the Biosculptor brace. Also, it might be due to the over-stretching on the plastic during draping process.

Based on the Table 4.9, the percentage differences show that the measurements of conventional brace have smaller percentage difference compared to the Biosculptor brace. This shows that the measurement of the conventional brace is the closest to the Subject's measurement which conclude that conventional brace is more preferable compared to scanning type brace. (Gatt et al., 2016) proved that CAD/CAM fabricated brace has higher accuracy over manually fabricated design. However, based on Figure 4.23, it shown that the Biosculptor brace has the closest shape to the subject's rather than the conventional brace. This is because in the Bioshape software, the modification of the model tends to follow the subject's shape rather than change the shape. While for the conventional brace, the positive cast was being modified by applying pressure and build up at certain area until it achieved a desired shape. Apart from that, all of the Biosculptor brace measurements are smaller than the subject's measurements while for the conventional brace, there are some parts where the measurements are higher than the subject's measurement. Based on Figure 4.23 again, both the brace's pattern of the graph is not obviously equivalent to the as the subject's measurements. All of error occurred probably due to the human error, as well as it might occur due to the removing and building up process during modification either manually or in bioshape software which changes the subject's measurement, thus resulted in higher or lower graph line than the reference line.

CHAPTER 5: CONCLUSION

The manual method that has been practiced for generations shows a positive outcome in this study as compared to the scanning method. The advantages of the manual method are that the landmarks can be palpated and accurately transferred onto the positive cast with 1% human error. This ensures modification can be done precisely. Furthermore, the trim line of the conventional method covers a larger surface as compared to the Biosculptor method. This enables necessary modifications to be done onto the conventional brace once the cast as been open compared with the Biosculptor brace, which has a limited surface area. Besides, modification such as removal of the waist on the Biosculptor software is very meticulous and is time consuming if done without proper training. Furthermore, removal of the waist region with the Biosculptor software was incorrect as visually in the software the removal looked sufficient but after printing the foam the removal was insufficient to ensure proper amount of pressure to be applied from the brace onto the human body and that is entirely dependable on the experience of the orthotist with the software.

The good thing about the scanning method's software it is far more efficient and cleaner method compared to the manual method at the modification and rectification phases since of the absence of Plaster. However, cleanliness was not a factor to consider in this study. It took around 5 hours to scan, modify and print the positive cast using the Biosculptor and took 4 days to cast, fill, modify and mould the conventional brace. Therefore, the scanning method is most definitely an efficient method compared to the manual method. However, the results in terms of measurements were far off. To conclude, due to the pros and cons of both the methods stated above, the results show that the manual method gave better results compared to the scanning method whereas in other studies it was found that there are not significant changes in terms of circumferences measurements for both the techniques (Mavroidis et al., 2011) which explains the fact that the whole process is entirely dependable on skill and experience of the orthotist either manually or scanning fabrication may take place.

5.1 Future work

In the future it is aimed to apply the comparison for more than three subjects as well as with real patients of scoliosis. Comparison may as well include the efficacy of the spinal term over a long-term treatment session.

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