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SCHOOL OF DESIGN

MSc in Design and Engineering

Spinal Brace Design and Treatment

**A research on different design approaches to increase
patients' compliance**

Master of Science Thesis

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ABSTRACT

Spinal deformity is the most common problem in children and adolescents with the share of 48%. (HCUP-AHRQ 2011) Only in United states, estimated number of patient who are suffer from spinal deformity is more than 4 million. Treatment requires from patient to wear the spinal brace for 10 to 23h a day for years which could be from 2 to 6 years. A patient needs to join everyday life and socialize with people while wearing the spinal brace. Since patient needs to spend such a long time in brace, they do not want to be seen wearing 'medical device'. The appearance of the spinal brace is the most important factor for the user. Theoretically look of the brace does not have an effect on function but for the patient, it is a decision maker. Medical devices only work with the cooperation of the patient. Besides that, this long process has a potential to affect the patient not only physically but also psychologically. It has been proven that spinal brace treatment has a negative impact on quality of life. While medical devices aim to improve patient's health it should not cause new problems in the processes.

This thesis paper investigates the reasons for failure in spinal brace treatment from the design point of view and try to understand the user experience also relationship between brace and the user. Besides, exploring the possibilities to improve the effectiveness of spinal brace. In this study, people who are taken part in the treatment process (patient, family, doctors) are included to research paper. The focus of the research is directed to understanding patient's design linked reasons to not follow the treatment. The discomfort that patient is experiencing, both physically and emotionally while he/she is wearing the brace creates a compliance problem. Patient compliance issue is the reason of ineffectiveness of the spinal brace. Based on multiple case studies, experimental works and literature surveys, the research is proposing possible ways of increasing patient compliance through design and highlighting possible features/developments to make the spinal brace more efficient.

After detailed research, I came to the conclusion that product needs to be in balance between what patient medically needs and what patient willing to wear. This can be achieved by customizing the product aesthetically to improve the appearance and help the user to engage with the brace. However, improving appearance is not enough by itself. Patient requires emotional and social support which can be provided by sharing the experience with other patients. As last there must be constant communication between medical staff about patient's process so they can be more aware of patient's progress.

ABSTRACT (ITALIAN)

La deformazione della spina dorsale è la patologia più comune tra bambini e adolescenti, con una diffusione di circa il 48% (HCUP-AHRQ 2011). Solo negli Stati Uniti si stima che il numero di persone affette da questo disturbo sia oltre 4 milioni. La cura prevede che il paziente indossi un tutore dalle 10 alle 23 ore al giorno per un periodo che può variare dai 2 ai 6 anni. I pazienti sono costretti ad affrontare la vita di tutti i giorni ed interagire con altre persone indossando il tutore, e poiché è necessario che lo portino per un tempo molto prolungato, non vogliono mostrarsi in pubblico con addosso un "dispositivo medico". L'estetica del tutore è uno degli elementi più importanti per l'utente. Benché l'aspetto del tutore non ne influenzi teoricamente la funzione, è comunque un fattore di scelta: i dispositivi medici funzionano anche grazie alla cooperazione del paziente. Oltre a questo, la lunga durata del processo di cura può potenzialmente affliggere il paziente non solo fisicamente ma anche psicologicamente. È stato provato che il trattamento delle patologie legate alla deformazione della colonna vertebrale può avere un impatto negativo sulla qualità della vita del paziente, e lo scopo dei dispositivi medici è quello di migliorare la sua salute, e non causargli ulteriori problemi.

Questa tesi indaga sulle ragioni della mancata riuscita del trattamento di correzione della deformazione della spina dorsale dal punto di vista del design, e cerca di cogliere la user experience e la relazione tra utente e tutore, esplorando, inoltre, le possibilità di ottimizzare l'efficienza di quest'ultimo. In questo studio giocheranno un ruolo fondamentale le persone coinvolte nel processo del trattamento (paziente, famiglia, dottori). Il punto nevralgico della ricerca è incentrato sulla comprensione delle ragioni - legate al design - per cui il paziente decide di non proseguire la cura. Il disagio che il paziente prova sia fisicamente sia emotivamente nel momento in cui indossa il tutore crea problemi relativi all'acquiescenza, che sono la causa dell'inefficacia dello stesso. Sulla base di molteplici casi studio, lavori sperimentali e sondaggi, la ricerca propone alcuni modi possibili per incrementare l'acquiescenza del paziente attraverso il design, ed evidenzia alcuni potenziali sviluppi e caratteristiche per rendere il tutore più efficiente.

Dopo una ricerca dettagliata, si è giunti alla conclusione che il prodotto necessita di un equilibrio tra quello di cui il paziente ha bisogno da un punto di vista medico e quello che vorrebbe indossare. Ciò può essere ottenuto da una personalizzazione estetica del prodotto per migliorarne l'aspetto e aiutare l'utente ad accettare il tutore. Ad ogni modo, migliorare l'estetica non è abbastanza. Al paziente serve un supporto emotivo e sociale che può essere dato dalla condivisione dell'esperienza con altri pazienti, ed è infine opportuno un implemento dello scambio di informazioni all'interno dello staff medico, in modo da avere una maggiore consapevolezza dei progressi del paziente.

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1.INTRODUCTION

1.1PROBLEM DEFINITION

Treatment of the patient with spinal deformities has a long past. Through history varies of treatment has applied to prevent further deformation or completely reverse the deformation. One of the first and most important treatment technique was immobilization of the spine with cast or brace.

The first supportive brace has developed by Ambrose Pare in 1500's and it has evolved since then. Technology has revamped the field of spinal orthotics, with new stronger and lighter materials. Although materials which available for spinal orthotic construction have changed, basic theory for treatment has remained same for years. Especially development in braces were lack of aesthetic till recent years. Some of the braces which are designed in this period still in use only with a bit of a change.

Currently, there are lots of case studies and researches on spinal orthoses and today we are seeing new solutions are coming to light by designers and doctors. However, most of the development and researchers are focusing on purely result of the treatment. When we think about designing orthotics there many aspects that need to be considered. Besides the conclusion, there is a whole treatment process we should not ignore, and patients view on this subject. For many patients, the motivation they are looking for is an improvement in their appearance or how they are seen during treatment rather than solving the underlying problem. Therefore, cosmetic concerns and understanding psychological impacts of the deformity is a big part of the solution. Being healthy is not something only physical. World Health Organization's (WHO) definition of health "the state of complete physical, mental and social well-being and not merely the absence of disease or infirmity." As we can understand from this definition, solution needs to serve more than one aspect.

Successful treatment does not only require most effective brace but also requires an understanding relation between user and product. Factors which affect patients mostly is the length of treatment and type of brace they are wearing. As a result, patients suffer self-esteem and emotional disturbances. (Scoloveno, Yarcheski , Mahon, 1990) These reasons affect compliance directly and when patient stop following treatment, he or she is not getting result does not matter how effective the brace is.

Brace treatment does not only patient's concern. Physical treatment is only for patient but since these deformities appears in early ages, parents are also part of the process. It has been approved that bracing has measurable impacts on family as well as patient itself. (MacLean, Green, Pierre, Ray, 1989) In order to achieve successful treatment, doctors need to engage with both parent and patient in psychological level. (Bridwell, Shufflebarger, Lenke, 2004)

As a designer, we need to analyze patient needs and doctors request clearly. Rather than focusing on creating a product which will work, we need to create a product which patient compliance will not be a problem.

1.2 RESEARCH OBJECTIVES

Since the first attempt for treating spinal deformity, various of braces have been invented. Development of brace treatment was strictly limited by brace itself till recent past. The aim of this thesis work examines the existing design solutions and highlights the best ones but not only a product but also as a treatment approach. The directions of research topic are;

- Organization of data which obtained so far and interpreting them from design view;
- Analyzing current brace solutions with advantages and disadvantages;
- Exploring possible design solutions to increase compliance;
- Investigating conceptual solutions;
- Creating a guideline to develop spinal brace and spinal treatment processes which improves patient compliance to the treatment;

There is more than one reason why the bracing process does not work so, what needs to be done is highlighting the reasons of failures in treatment by observing both patient and doctor in the process. When a patient is prescribed for use of a brace, it is essential to understand why the treatment has failed or there can be any development on a matter of comfort. Existing design solutions need to be examined to determine the current issues. Few attempts have been made to increase the success rate of treatment and these can be beginning of new perspective for a solution.

Investigate not only applicable design solutions but also conceptual design solutions might give us a new approach to solve the problem. With help of current technology, new design solutions are promising a great deal such as integrating extra features to increase the compliance could be one of them.

The main purpose is analyzing both patients and doctors view on bracing processes as well as the treatment itself and exploring potential opportunities for bracing treatment. Understanding the reasons and environmental factors for brace compliance of patient is very important for further developments and proposal of effective design.

My proposal in this work is identifying best design solutions, service designs and highlighting extra possible features to support the process and make the brace more efficient and wearable.

1.3 METHODOLOGY

In this research, I will explore the reasons for non-compliance to the spinal brace treatment from a design perspective - understanding the primary user, patient and any involvement from their environment which affects their response to the treatment. Starting from analyzing the current spinal braces which are in the market. Their production and design details will be presented and issues in the terms of use. Also, users' relationship with each of these products and their reasons for non-compliance or compliance. In the section of recent developments, it will be examined the possible solutions and technologies based on case studies clinical trials and few experimental design studies. These experimental studies will be used as a base to attempt for

improving better compliance through design perspective.

In this paper, I did not only analyze patients as a primary user but also included the doctors and parents in the research. I focused on understanding each subjects' perspective and expectations from the spinal brace and how these different expectations effect on compliance outcome. Therefore, besides case studies, I get in contact with few doctors as well as the patients to understand their point of view. Also, personal blogs, online support groups and videos and essays published by former patients are used as a source in this research. Starting from these, I pointed out possible ways to encourage subjects to participate in the treatment and suggested additional inputs to increase compliance.

In the final section, based on the findings established from research, there will be inferences and suggestions for possible improvements. Also, there will be a proposal of service system design which is integrated with the product in order to improve compliance to the product



2. MEDICAL ISSUES

2.1 DEFINITION OF SPINAL ORTHOSIS/BRACE

A spinal orthosis is a brace that is placed on the outside of the body to hold the spine in a certain position. It may be used to correct a deformity or to improve the overall function of the spine. Normally human spine has natural curvatures. When you look at the spine from behind, the healthy spine should be straight and placed the center of the body. However, when you look at the spine from the side, it has three small curves which keep the body in balance.

In some cases, spine grows unnaturally and creates curves on front view or/and exaggerates existing curves on the side view. Spinal orthotic devices, which also called back braces, are used to cure this deformation.

Back brace is an external structural support. It is used to limit the motion of body, correct deformity, reduce axial loading or to improve the function of a particular spinal segment of the body.

They are mostly used to treat low back pain, trauma, infections, muscular weakness, and special conditions which are scoliosis and kyphosis. They immobilize and support the spine when there is a condition that needs to be treated.



Figure 1 Spinal orthosis samples

2.2 ANATOMICAL PLANES AND ANATOMY OF SPINE

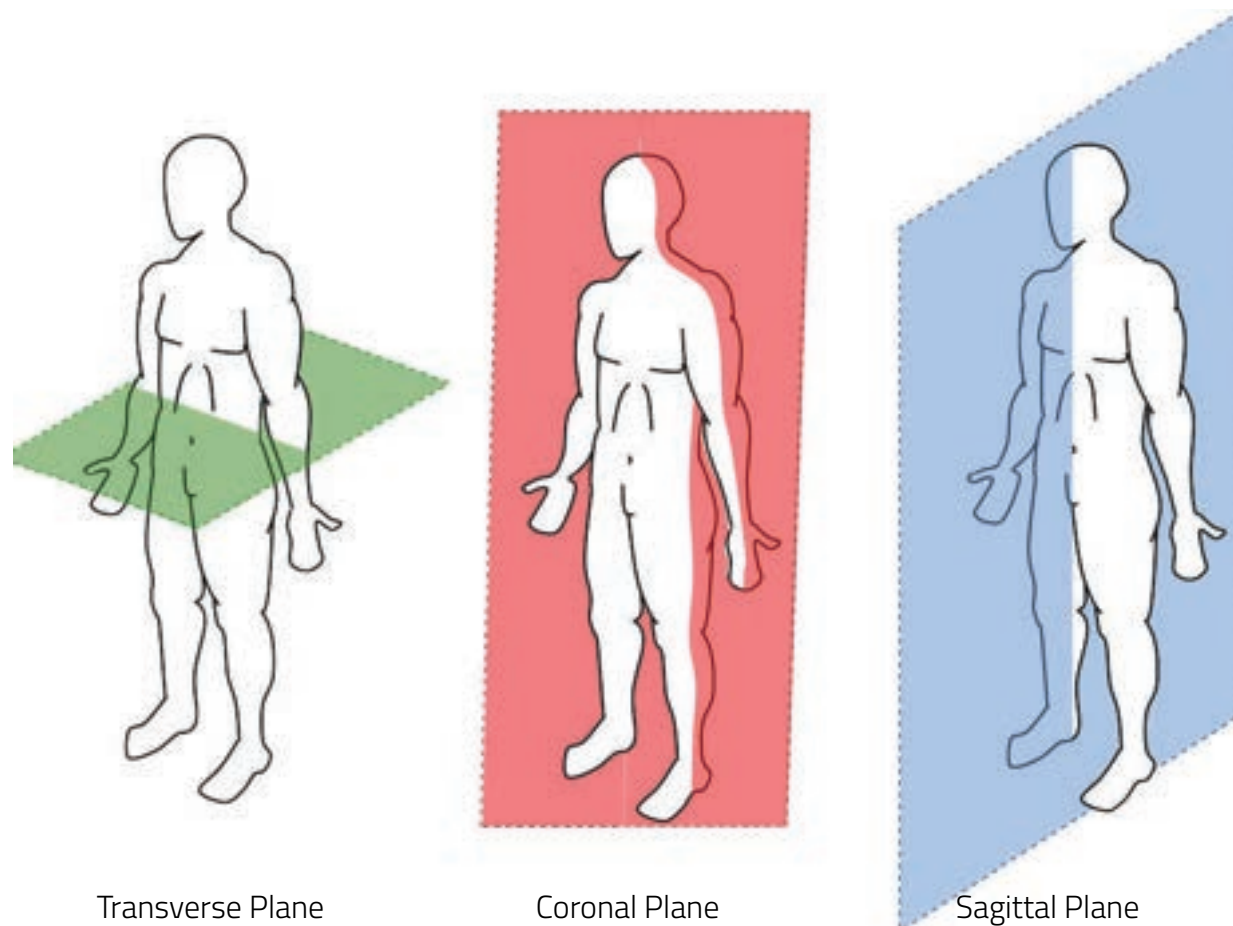


Figure 2 The definitions of the anatomical planes

The sagittal plane divides the body into left and right sides, coronal into front or anterior and back or posterior sections. The transverse plane divides the body into top and bottom parts.

The spine or vertebral column comprises of 33 stacked bones which call vertebrae. The spinal column is divided into four major sections, as shown in Figure 3, 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.

The cervical spine consists of seven vertebrae. The vertebrae in this section named between C1 and C7, according to their place on spine. The main function of the cervical spine is to support the head. Stephen Rogers Peck (1951) notes that the cervical vertebrae are the "most flexible of all the vertebrae. The first cervical vertebra is called the atlas. The second vertebra is called the axis. The convex on the spine which appears like a reversed "C" called the cervical lordosis.

The thoracic spine is starting right after cervical spine and it has twelve vertebrae. The vertebrae in this region designated T1 to T12, depending on their place. The function of the thoracic area is to protect the organs. The thoracic area has also curve on it which called thoracic kyphosis. Spine in this region is not flexible as cervical lordosis. This is the part where most of the spinal deformations appear. Either kyphosis or scoliosis.

After thoracic spine, the lumbar region comes which is consist of five vertebrae. The vertebrae in this section named between L1 and L5, according to their place on spine. Lumbar vertebrae are the largest vertebrae as a size because they are the one carries the weight of the body. As others, lumbar lordosis has a small curve on it. Much like the one cervical spine has and it is called lumbar lordosis. After thoracic area, the lumbar region has most spinal deformities.

The lumbar region follows by the sacral vertebrae. Sacral vertebrae are the last 5 vertebrae on spine

When we need to point out certain vertebra on the spine, it can be called as T-7. This represents 7th vertebra in the Thoracic area. The first letter of the vertebrae section and later ranking of the vertebra in that section

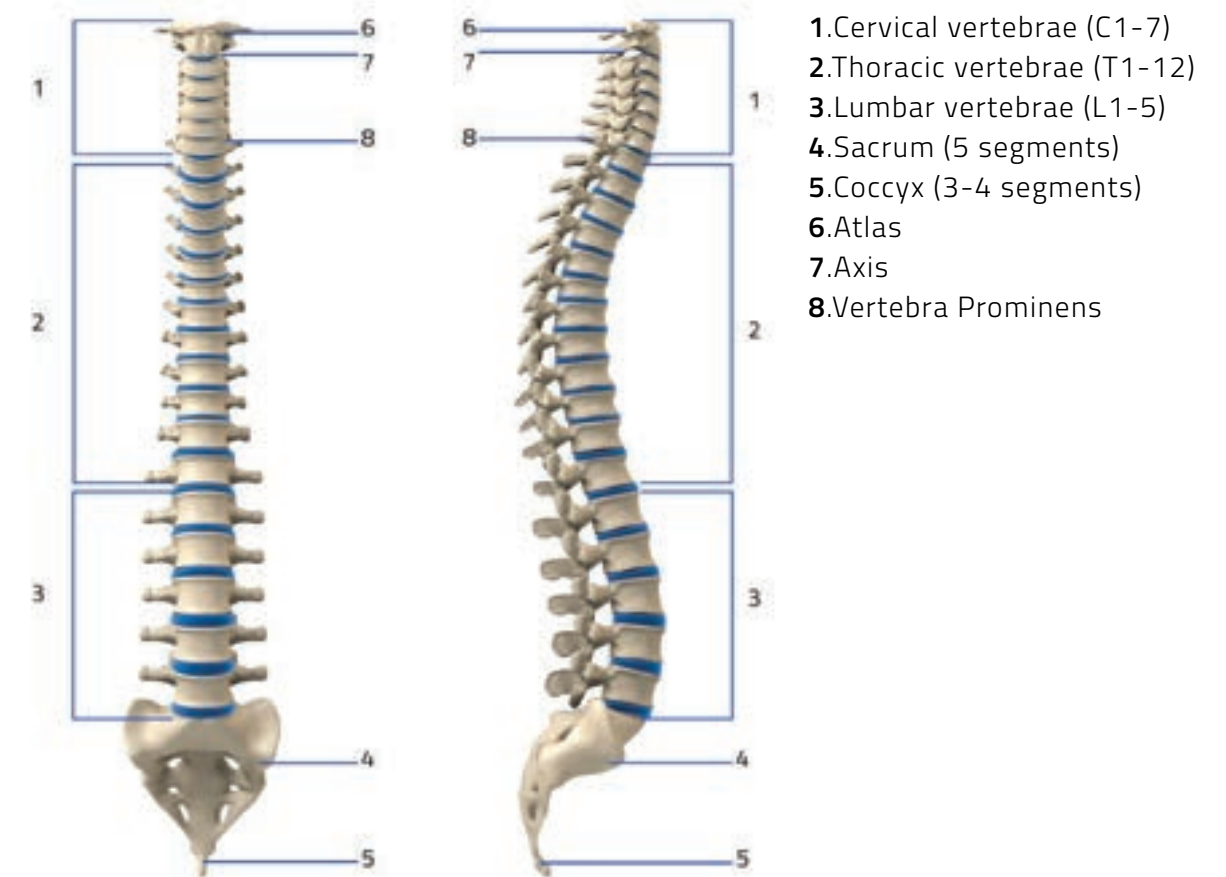


Figure 3 Structure of spine

The vertebral column is straight when viewed in the coronal plane. Four curves which mentioned before can be observed on the sagittal view. Appearance of curves creates mild S shape. Two curves (thoracic and sacral) have a posterior facing convexity termed kyphosis and two with anterior convexity, lordosis (cervical and lumbar).

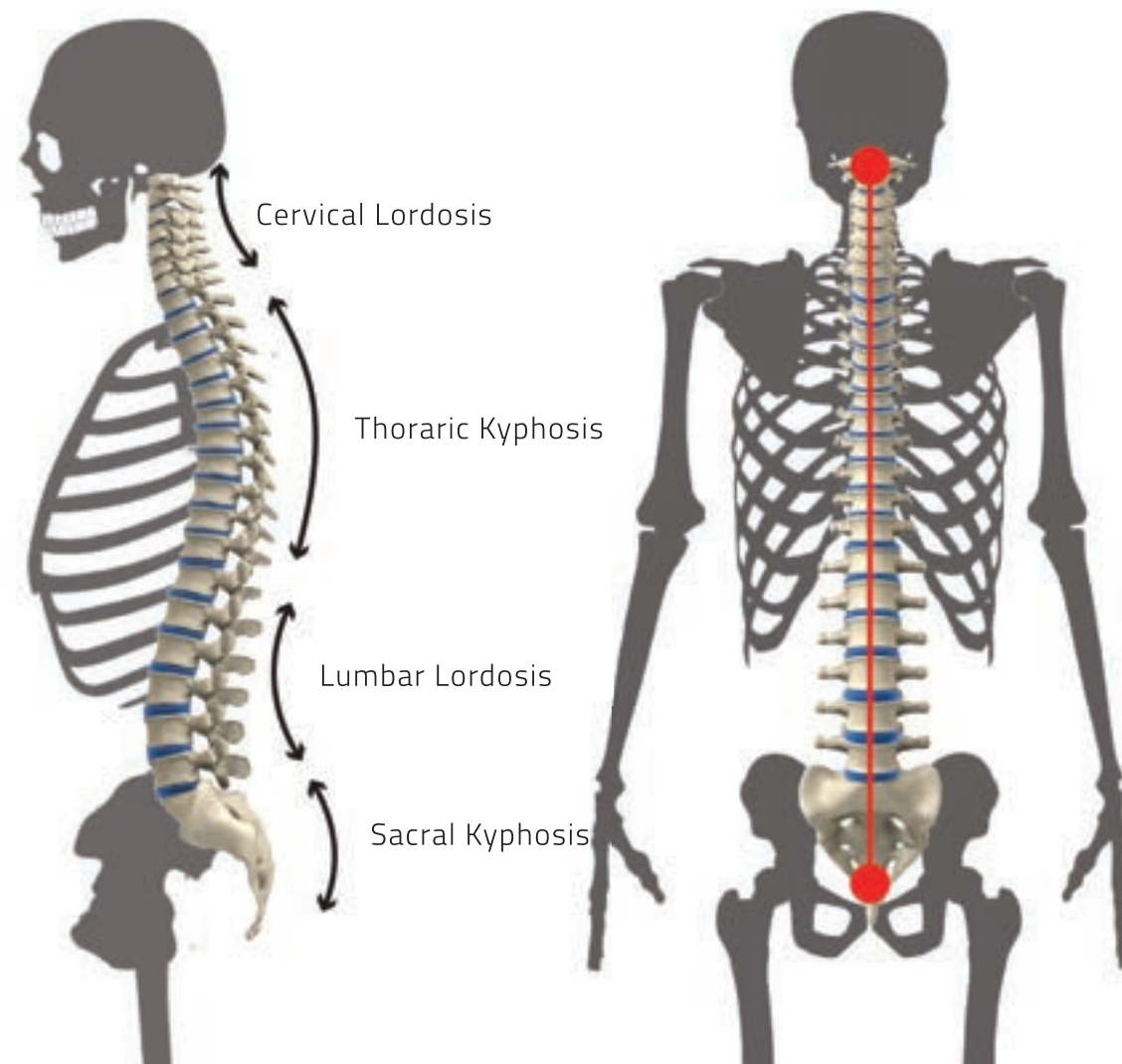


Figure 4 Section of human spine

Lordosis is a term used to describe the inward curves in the spine and it can be found in the lumbar and cervical part of the spine. On the other hand, word of kyphosis represents the curve of the spine which it outward and it exists in the thoracic and sacral area. Degrees of these curves considered natural in a certain range which are;

Cervical Lordosis 20°-40°
 Thoracic Kyphosis 20°-40°
 Lumbar Lordosis 30°-50°
 Sacral Kyphosis 30°-50°

When curves exceed these range, it is considered either hyperlordosis or hyperkyphosis. Figure 4 represents how healthy spine should look. On sagittal view, there are four curves which are described before. On the coronal, plane center of Atlas and Coccyx should be on the same axis which creates one straight line through the spine.

2.3 SPINAL DEFORMITIES

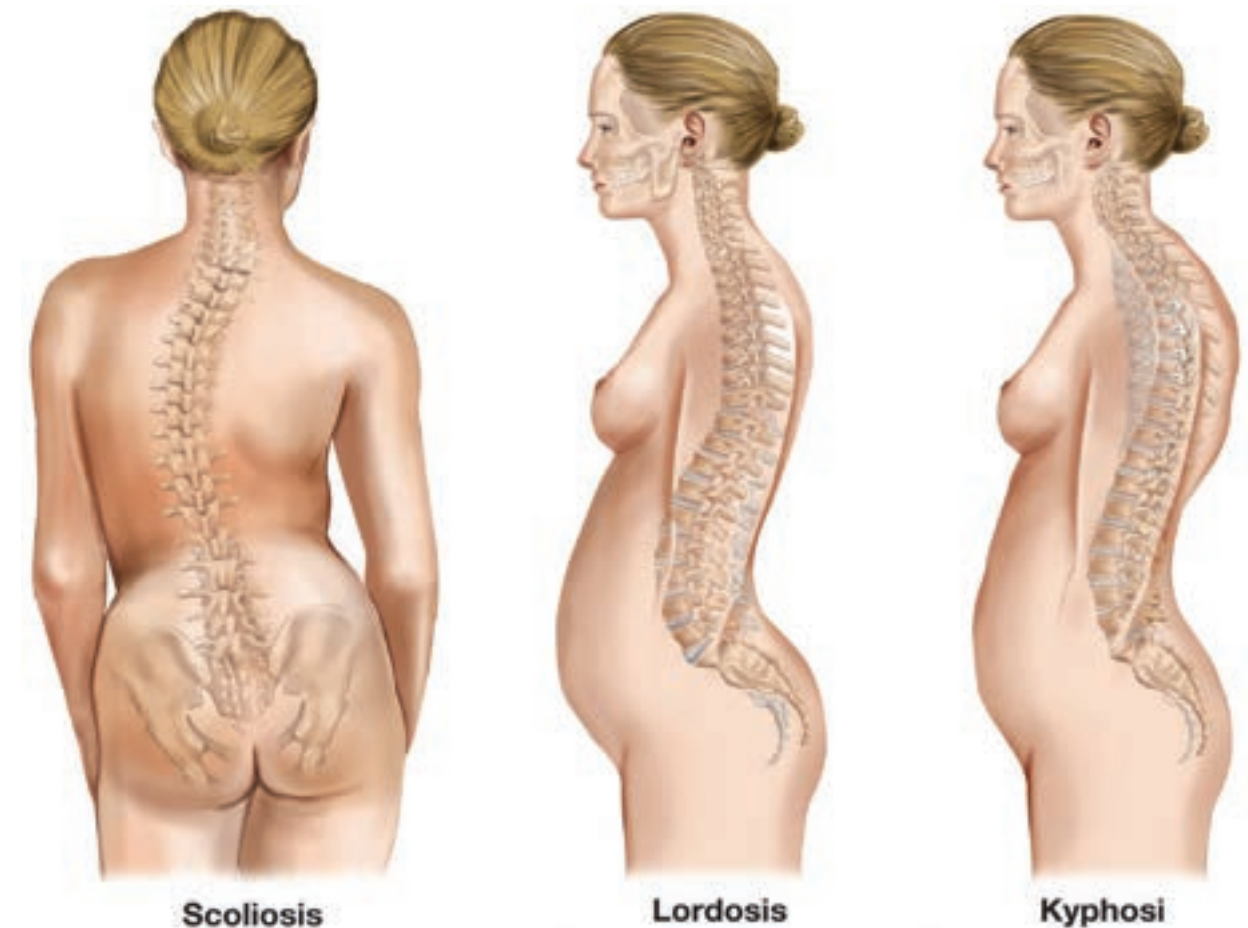


Figure 5 Types of spinal deformities

2.3.1 DEFINITION OF SCOLIOSIS

Scoliosis is a most common deformation of the spine and it affects 2-3% of the population worldwide. Every year scoliosis patients make 600,000 visits to private physician offices and approximately 30,000 kids are put into braces. (National scoliosis foundation, 2014)

Scoliosis is an abnormal lateral curvature of the spine which sometimes combined with rotational deformation of some vertebrae. The simplest explanation for the condition is, the spine can take the shape of a letter S or a letter C on coronal plane. The severity of scoliosis can be assessed by X-ray. Angles, to express the degree of curvature can be calculated with Cobb method. (figure 7) In order to diagnose the patient with scoliosis, curvature angle must be greater than 10. (James, 1954)

There are two types of categorization for scoliosis. One is taking its name after the section that deformation occurred, and the other categorization takes the name after the cause of the scoliosis

There are four types of scoliosis according to their cause:

Idiopathic Scoliosis

The most common type of spinal deformity according to orthopedic surgeons. (Lonstein, 1995) According to national scoliosis foundation, 85% of the cases are classified as idiopathic.

The word of 'idiopathic' means, unknown origin. As we can understand from the name causes of this particular type of scoliosis is unclear. There are significant efforts has been made to identify the reason, but nothing had proven so far. There is, however, a known relationship with gender. Scoliosis occurs 5-10 times more often in girls than in boys. (Cailliet, 1975) Genetic research showed there is higher chance to have scoliosis if one of your first-degree family member already has it but as we referred before this research has not proven yet and it is still going on. (Miller, 2007) (Grauers, 2016)

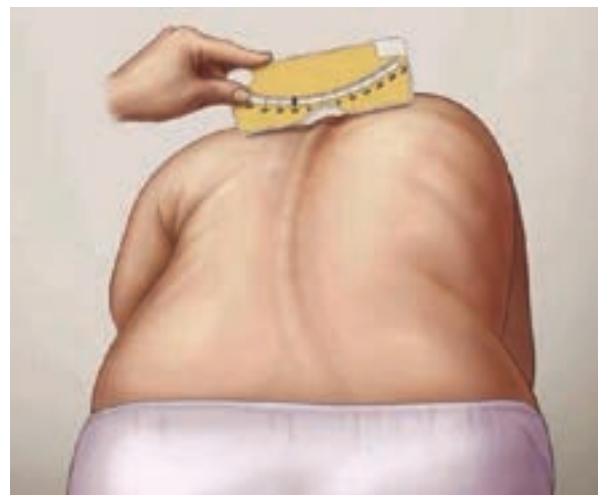


Figure 6 Adams bending test

Adolescent idiopathic scoliosis is a structural, lateral, rotated curvature of the spine that occurs in puberty (Weinstein, 2008). First findings for idiopathic scoliosis, mostly provided by application of Adams forward bend test (figure6)

The patient needs to bend forward dangling the arms, as if they are diving, feet together and knees straight. If there is a deformity on spine, it is more visible in this position. Examiner stands behind of the patient and looks along the horizontal plane of the spine. If there is imbalance on ribcage or one side is higher than other, this is the first clue of spinal deformity. A definite diagnosis cannot be made without determine the Cobb angle, so doctors need x-ray result of patients after Adams test. (figure 7)

Depending on the age idiopathic scoliosis can be divided into four categories;

- Infantile idiopathic scoliosis is found in children ages 0 to 3.
- Juvenile idiopathic scoliosis is found in children ages 4 to 10.
- Adolescent idiopathic scoliosis is found in adolescents ages 11 to 18.
- Adult idiopathic scoliosis is found in patients older than 18.

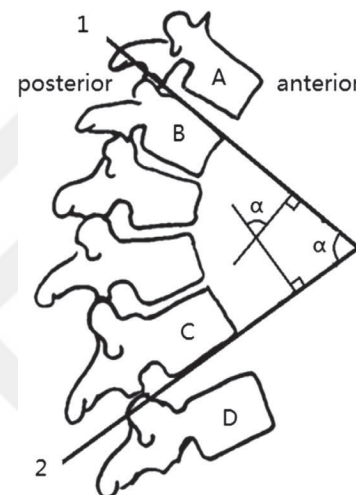


Figure 7 Cobb angle calculation

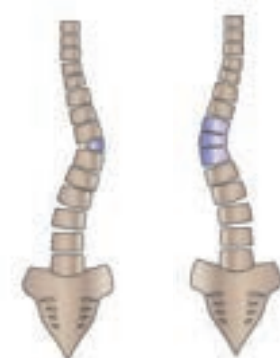


Figure 8 Congenital scoliosis

Congenital scoliosis

Congenital scoliosis can be diagnosed much earlier than other forms of scoliosis because it occurs during fetal development. It is rare, and it is affecting 1 in 10,000 newborns. Malformation of the vertebrae is the most common reason for congenital scoliosis which later leads to spinal deformity. It can also be the result of a tumor, injury, or infection.

Neuromuscular or myopathic scoliosis

Neuromuscular scoliosis is caused by disorders of the brain, spinal cord, and muscular system. Nerves and muscles are not able to create natural curves on spine and trunk which mostly leads unevenly tilted pelvis on the patient.

Degenerative scoliosis

Adult scoliosis; a degenerative condition that typically occurs after age 50-65. Overtime facet joints and discs can degenerate and this degeneration pressure on the spine which can cause curvature.

There are four kinds of deformation type according to view of a Coronal plane;

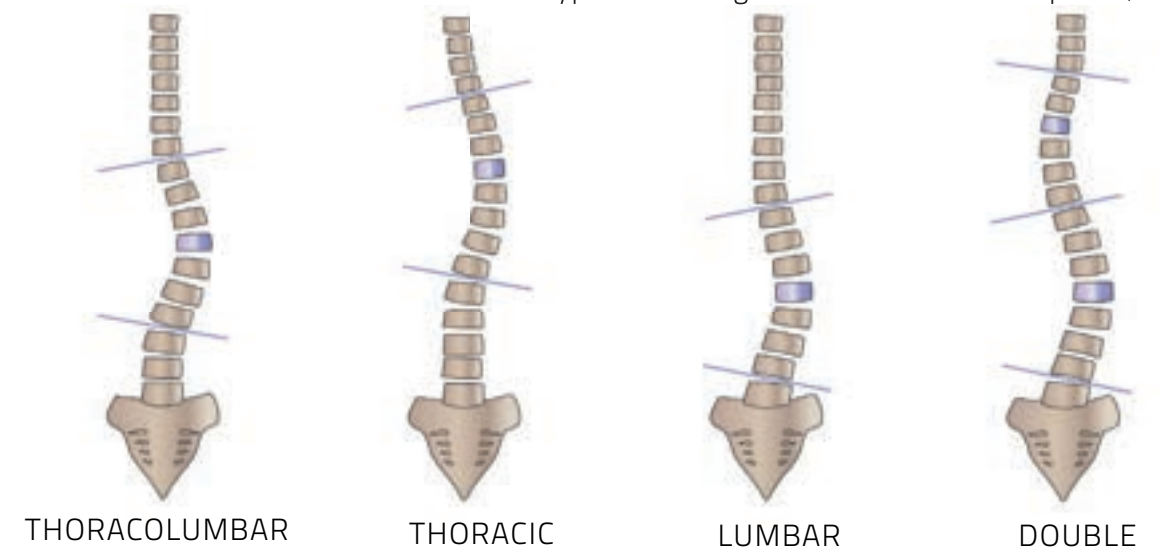


Figure 9 Types of scoliosis

2.3.1 DEFINITION OF KYPHOSIS AND LORDOSIS

The spine has three types of curves: lordotic (inward), kyphotic (outward), and scoliotic (curves on the coronal plane).

Unlike scoliosis, where any curve on the coronal plane is a deformity, sagittal side of spine has natural curves. When natural curve ranges exceeded, it is considered either Kyphosis or Lordosis. Kyphosis can show more than one symptoms depends on how large the abnormal curve is. Larger the curve, more serious is the problem like heart and lung problems.

Kyphosis appears as hunch on the back. Until some range it is normal, but the term "kyphosis" refers to an exaggerated rounding on the back. There are three main types of kyphosis: postural, Scheunemann's, and congenital.

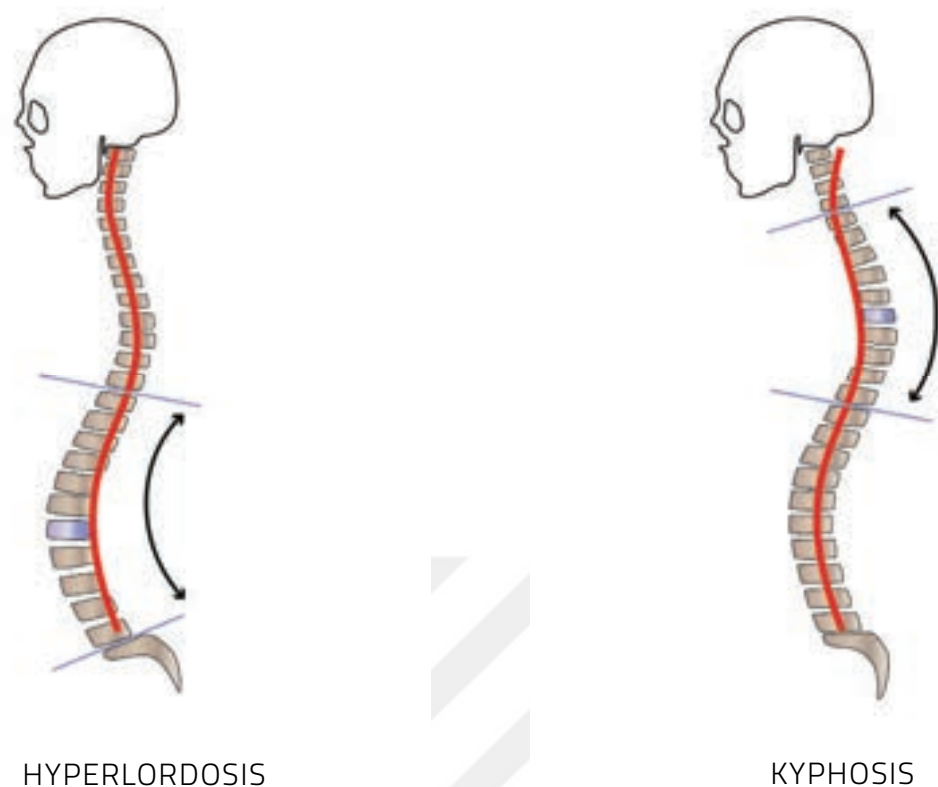


Figure 10 Types of kyphosis

Postural Kyphosis-Round back

Postural kyphosis is the most common type of kyphosis and it can be called as “round back” either. It is usually detected in puberty and it is more common in girls than in boys (Jason C, 2016) In standing or sitting position kids usually slouch which causes postural kyphosis. That posture weakens the muscles and ligaments in that area. There is no shape deformation on the vertebrae for postural kyphosis.

Distinction between upper normal kyphosis and adolescent round back deform is unclear due to lack of studies. (Weiss, 2009)

Scheuermann’s kyphosis- Calvé disease

Scheuermann’s kyphosis also first appears during adolescence. It is an abnormal growth of the thoracic vertebrae (upper back), but in some cases, it can also be found in the lumbar vertebrae (lower back). The cause of this kyphosis is uneven growth on vertebrae. Normally vertebrae are a rectangular shape and stacked on top one another but in some cases, vertebrae appear more like a triangle. The back side of vertebrae grows faster than the front side of vertebrae which creates an unusual curve.

There are two major forms of Scheuermann’s kyphosis which are thoracic kyphosis and thoracolumbar kyphosis. A thoracic form has an apex between T7-T9. A thoracolumbar form has an apex between T10-T12 and is more likely to continue into adulthood. (Lowe, 2007a)

According to documented methods there two type of braces which are common to treat Scheuermann’s kyphosis which is Boston and Milwaukee brace. (Gomez, 2002)

Congenital kyphosis

Congenital kyphosis is not common as others. It means the person born with a deformation of the spine. In rare situations, vertebra evolves in abnormally even more than one vertebra grows together. This can lead to a severe abnormal kyphosis. With this type of kyphosis, brace treatment doesn’t work or any other non-operative treatments.

Another kind of abnormally for the spine on a sagittal plane is Lordosis. Lordosis is an increased inward curving of the lumbar area of the spine. When the lordotic curve is greater than natural, it is called “hyperlordosis” These conditions are usually a result of poor posture and can often be reversed by using back brace and proper exercises.



3. SPINAL ORTHOSIS

3.1 BRACE TREATMENT

Brace treatment is the oldest treatment for correction of spinal deformities. When we consider the age of the patients, it is the first treatment to apply in order to fix deformities. Surgical treatment is the second option but before maturity, it is not preferred by doctors to treat patients with surgery. Besides patient mostly willing non-operative treatment first rather than get into surgery. Also, sometimes spinal deformities are placed in risky parts of the vertebra which makes surgery scary for a patient. However, a timing of brace application is very important. Treatment for spinal deformities requires least 2 years of growth remaining period in order to be efficient. (Newton, 2006) After this period if the patient did not achieve the desired correction surgical applications can be suggested.

Treatment consists wearing a rigid or flexible brace around the upper body for a prescript amount of time per day. This time can change depending on deformity of the patient has. Most braces are used between 4-23 hour per day. Working principle of a brace is that external forces which applied by a brace, forces spine to grow in its natural curve before skeletal maturity reached. Vertebrae, the one experiencing force or compression will grow less, and vertebrae feel less force or distraction will grow more which presumably this will even the curve. Bracing tries to slow down the curve's growth on the side that needs to be slow, and speed up growth on the side that needs to speed up. At the end of the treatment, there is a high chance that patient will not surgery later.

Brace treatment seems reproducible and promises permanent correction of vertebral deformity if treatment has started during adolescence. (Pizzutillo, 2004) According to The New England Journal of Medicine 75%of brace treatment is completed successfully.

In order to achieve this result, patient compliance is essential. As curve progression and suggestion of surgery are significantly higher in patients with low compliance. However, patient compliance is lower than desired, reported average wearing time is 65% (DiRaimondo, 1988) and 75% (Brox, 2012) One of the most common reasons of low compliance in girls is low self-esteem, poor body image and low expectations of treatment. Sleeping problems experienced during brace treatment were also an indicator of low compliance (Lindeman, 1999)

Even tho there are few new application about braces doctors are most willing to prescribe the known ones. There are 7 major brace types which are most popular in spinal deformities. These braces are shown on the figure 11.

Brace Treatment	Type	Daily wear	Comments
Milwaukee Brace	- TLSO - Rigid	Full time	- Rarely used today - Sometimes used for curves in the higher thoracic or cervical region
Boston Brace	- TLSO - Rigid	Full time	- Most commonly prescribed brace - Choice of a selection of prefabricated molds
Wilmington Brace	- TLSO - Rigid	12 hours to full time	- Designed as a more light-weight alternative for the Milwaukee brace
Charleston Brace	- TLSO - Rigid	Night time	- Patient specific brace by using a cast - Overcorrects in-brace curvature during nighttime
Providence Brace	- TLSO - Rigid	Night time	- Patient specific brace by using a cast - Often with the help of computer assisted design and manufacturing
SpineCor Brace	- Non-rigid	20 hours	- Software records data and specifies brace fitting details - Increases in-brace movement
Cheneau brace	- TLSO - Rigid	Full time	- Patient specific brace by using a overcorrected cast

Figure 11 A summary of the most widely used brace treatments. Adapted from Schiller et al.

3.2 TREATMENT PROCESS

There is a certain path that patient needs to follow before he or she receives the spinal orthosis and start treatment. The understanding sequence of process is important to understand the patient situation.

There are two possible scenarios about brace treatment;

In the first scenario, the patient goes to the orthopedic doctor about his back pain. After the examinations, the doctor creates a treatment plan for the patient. This treatment plan can be either bracing or surgery. If the treatment plan is bracing doctor tells patient that he needs to go to orthotist for a spinal brace. Some cases custom brace is advised but in this point is up to the patient. He can either choose custom mold brace or standardized size brace depending on deformation he has. After the patient receives the prescription from the doctor he goes to orthotist to have his brace. After braced confirmed by the doctor, patient start to use it for the prescribed amount of time and he needs to go to doctor every three or four months.

The second scenario is the same until to the point where patient prescribed brace by the doctor. The difference is in brace making processes doctor is also involved as much as orthotist. Either patient assigns to see the orthotist which suggested by the doctor or hospital provides the service the service inside the institute.

In the first scenario, a patient goes to orthotist with diagnose and rest of the processes evolves without doctors' observation. Second scenario doctor is well aware that which brace patient going to use, more integrated with the brace making processes.

3.3 MEASUREMENT AND FABRICATION PROCESS

3.3.1 TRADITIONAL METHOD OF MEASUREMENT

In order to make the brace first, orthotist needs to assign how spine needs to stay in a brace. If deformation is not extreme patient stays in stand-up position but if the curves are severe he needs to lay down in Cotrel frame.(figure12) In this frame, orthotist bend the spine in necessary direction with help of bandages and keep the patient in a certain position until he is done with casting. Orthotist wraps patients body with wet plaster body bandage. When the plaster hardens, the cast is cut on one side and take it off from the patient. Now orthotist has a shell of patient's torso to create negative and later positive mold.

The first orthotist cover the bottom part of the shell with same plaster bandages and fill inside with pourable plaster. It takes approximately 20 minutes for the plaster to set. Once plaster hard enough to touch it is removed from the shell and clamped into a standing vise. Surfaces smoothen and adjusted according to the clinical requirement by sanding and in some cases adding material. After the surface of casting ready for molding, a piece of plastic sheet cut to the size which is enough to cover plaster cast. First, this plastic sheet placed in an oven and heated between 160-180 degree. In this phase, if the patient wanted to have a special pattern on his brace transfer sheet apply on the heated plastic sheet and peel it off. Before it gets cold plastic quickly removed from the oven and wrapped over the cast. With the help of clamps, plastic sheet stabilized on the plaster cast. When it gets cold it is removed from the cast by cutting and later trimmed to achieve the desired look. Edges smoothen by sanding and later straps attached to the brace.

Once brace is ready patient comes to orthotist to check the fitting. If there is a problem with fitting, soft pads are placed into the brace to accomplish the work.

Storyboard of processes presented in the next page in order to clarify the application.



Figure 12 Plaster bandage



Figure 13 Cotrel frame

Story Board of making spinal brace (Traditional method)



Figure 14 Traditional method of brace making process

3.3.2 CAD/CAM METHOD OF MEASUREMENT

The second method for measuring patient for brace is CAD/CAM technology. One of the reason for changing the method is eliminating close physical contact. Some case studies recorded that how the casting process can be uncomfortable on a patient side because of this physical closeness. (Jeffrey, 2007) CAD technology provides more accurate control on brace design. Primary required tools are a computer, scan and milling machine.

First patient's torso scanned by the special device and later data is transferred to specific software that orthotist will work on. The created 3D image contains patient's measurements almost complete accuracy. Once the image is in software, it is merged with X-rays of the patients so orthotist will have the complete body and bone structure of the patient. On this 3D model, postural corrections can be made digitally. After corrections are made, digital data send to the milling machine to make the positive mold of the torso. Rest of the processes is same as the traditional method. A heated plastic sheet wrapped around the torso and after cool down it can be cut and shaped to achieve the desired result.



Figure 15 CAD/CAM method of brace making process

3.3.3 COMPRASION OF TWO METHODS

The two methods have pros and cons from different perspectives. The traditional method is already widely used so tools that are needed in the processes is easy to get it. Workplace equipments are not advance as CAD modeling method. On the other hand, there are way more production steps which increase the possibility of mistake and since these steps performed by a human there is not constant accuracy like the one in CAM. Another problem in traditional method is when orthotist make patient's torso he presumes pressure points on the brace but with CAD modeling X-ray and scan can be merged so orthotist can actually see precisely where he needs to apply force.

The CAD/CAM system has certain benefits. First of all, it eliminates whole plaster casting processes which also eliminates potential human mistakes. Corrections are more accurate and to the point. It is much faster than the traditional method. On the other hand, CAD/CAM modeling requires more advanced and expensive tools. Small facilities don't have the income to circulate the business for CAD method. (Segedy, 2007) Also, staff needs to be trained professionally to be able to use a milling machine and CAD software.

As we can see both methods have its own advantages but it is clear that for the effectiveness of brace cad modeling gives more accurate results. To see the effect of different measurement methods on the outcome of treatment, Chinese University of Hong Kong produced two different braces for 40 patient and randomly divide them to two group. The first group treated with the brace made by traditional measurement method and the second group treated with the brace made by CAD/CAM measurement method. End of the study their initial Cobb angle compared with the result. As you can see in figure 16 brace which made by CAD technology was more effective than traditional one. The reason for this CAD technology provides more accurate information to assign the force to the right vertebrae and with the right amount.(Wong, 2005a)

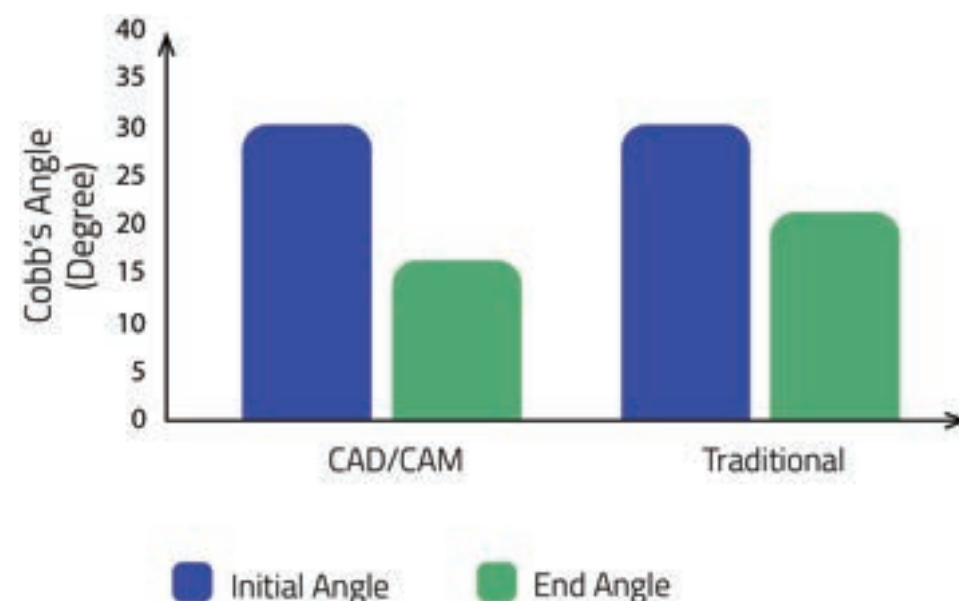


Figure 16 CAD/CAM method vs Traditional method

3.4 CATEGORIZATION OF BRACES

Prevalence of naming braces without solid ground (name doesn't represent any valuable information) makes scientific classification major issue. This random naming makes comparison of braces challenging. We need precise categorization to analyze each brace. Today braces are mostly called by names derived from cities they are invented or the people who developed the spinal brace. Names are totally isolated from function of braces they are not referring anything important. The International Society for Scoliosis Orthopedic and Rehabilitation Treatment SOSORT recently released new classification of braces called BRACE MAP. (Negrini, 2009b) In this proposal there are six different type of classification for spinal braces and each one has different ground. These categories are;

- Rigidity
- Anatomical
- Construction of the envelope
- Mechanism of action
- Plane of action
- Building type

In this study braces will be investigated in two categories; Anatomical and Rigidity. Anatomical brace takes its name from the area that brace aiming to treat. Figure 17 illustrates how to name the brace. Brace takes the initials of the regions of the spine where brace covers it. CTLSO, TLSO and LSO each letter stands for certain range on spine. Name of the brace is also guideline for orthotist to know which areas he needs to apply force to treat.

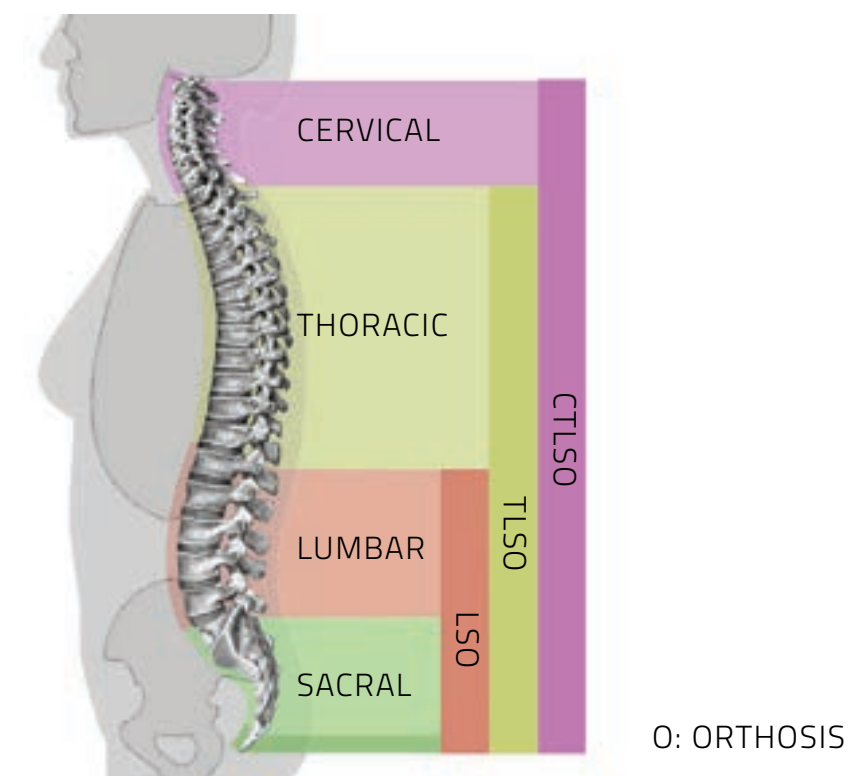


Figure 17 Anatomical categorization of brace



Figure 18 Rigidity categorization of brace

Another categorization that will be examined in this paper is the rigidity of the brace. In this category consist of three types of braces; rigid, semi-rigid, flexible. Rigid braces do not allow any movement. It provides a strong force on the region that needs to be treated. It covers most of the upper body, unlike flexible or semi-rigid braces. Semi-rigid braces partly provide strength like the one in a rigid brace and partly provides flexibility. This flexibility can be delivered by either cloth-like textures or mechanisms that allow people to bend when they are active. As it can be understood from the name flexible braces made by flexible cloth-like materials which allow a user to move and bend during the day. Flexible and Semi-flexible braces are mostly not covering the upper body completely as rigid one. Some brace samples of these three categories can be seen in figure 18.

3.5 CORRECTION PRINCIPLES AND LOADS

In order to understand correction forces on brace first we need to understand existing loads and forces on spine. The major load on healthy spine is axial loading. It creates compression force on each vertebra, but this force distributes from center equally, so it does not cause any deformation. Soft tissue deforms slightly under compression force as well as bony structure. Any deformation composed in spine, it is because axial loading is not distributed equally on each vertebra which creates constant loading on side of vertebra. Therefore, in time vertebra adjust itself to the new loading which causing back pain, spinal deformity, and spine injury.

As it is mentioned before bracing is the most common non-surgical treatment for spinal deformities. Brace treatment has shown great success to reduce the number of surgical treatments. Generally speaking, mechanism of spinal orthosis should unload pressure in concave and load force on convex. Deformity created by stress can be corrected if the load on vertebrae reversed. (Stokes, 2000) With this logic, if the subject hasn't reached to skeletal maturity, he can be treated with the help of accurate forces.

Spinal braces serve three purposes. Immobilization, correction, and support. Immobilization; Stops the forces which created the deformity and immobile the area. Correction; Actively apply force to correct the disorder in the area. Support; Externally helps weakened parts to function properly. These three functions sometimes can be combined in one brace.

There is two type of correction in the spinal orthosis. Column correction and Active/passive correction.

3.5.1 COLUMN CORRECTION

There are three types of correction for deformed spinal and it is defined by column mechanics. Figure19 illustrates these three forces. Axial loading, transverse loading, and hyperextension.

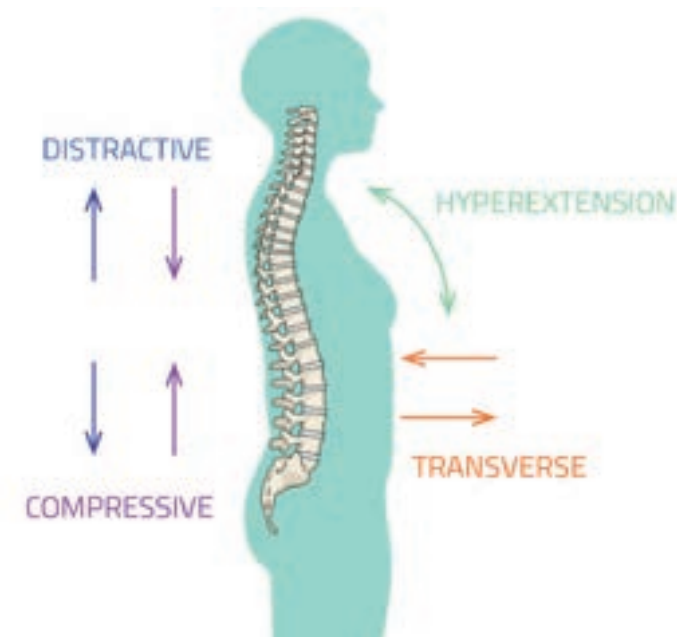


Figure 19 Applied force on spine by brace

Axial loading divides into two type of loading which is a distractive corrective force and compressive corrective force. Distractive forces can stretch the spine with the help of external axial supporting. In this force, vertebrae don't expose any force or loading individually. The effectiveness of distractive force directly related with the material capability of transferring the force but since distractive force is applied on chin area so rigidity of material needs to be chosen carefully. Mostly soft collar or halo system is in use for distractive force. On the other hand, a compressive

force is on the same axis with distractive but opposite direction. It can be used for shortened the segment.

Transverse loading is a horizontal force. Preferably apply to perpendicular to the curve. Unlike axial loading, it will not have any effect on length of the spine. Corrections do not have to be only coronal or sagittal plane. Sometimes transverse force can be applied as a rotational correction on the transverse plane. Treatment of some scoliosis made by rotational corrective force.

Hyperextension force is the combination of axial and transverse loading. Three-point pressure system works based on hyperextension force. This system most acceptable treatment application in the spinal orthosis.

THREE POINT PRESSURE SYSTEM

The logic behind the three-point system is assigning three points on the spine to apply force and these forces correct the spine by balancing each other out. Two of these points needs to be on one, side third point needs to be located in the middle of two points on the opposite side. (figure20) The single force needs to be equal to the other two. ($F_1 + F_2 = F_3$) Three-point system is used for immobilization of spine.

It is also important to understand not every section of spine reacts the same way to forces. Cervical region is the most flexible part of the spine. It has a considerably greater motion capacity, so it is more delicate than rest of the spine. After cervical region lumbar region has the great motion capacity. However, it does not have an axial rotation like cervical, but it has flexion and extension. Thoracic region is least mobile part other than bending ability on the sagittal plane so any force which is going to apply there needs to be carefully calculated. (figure 21)

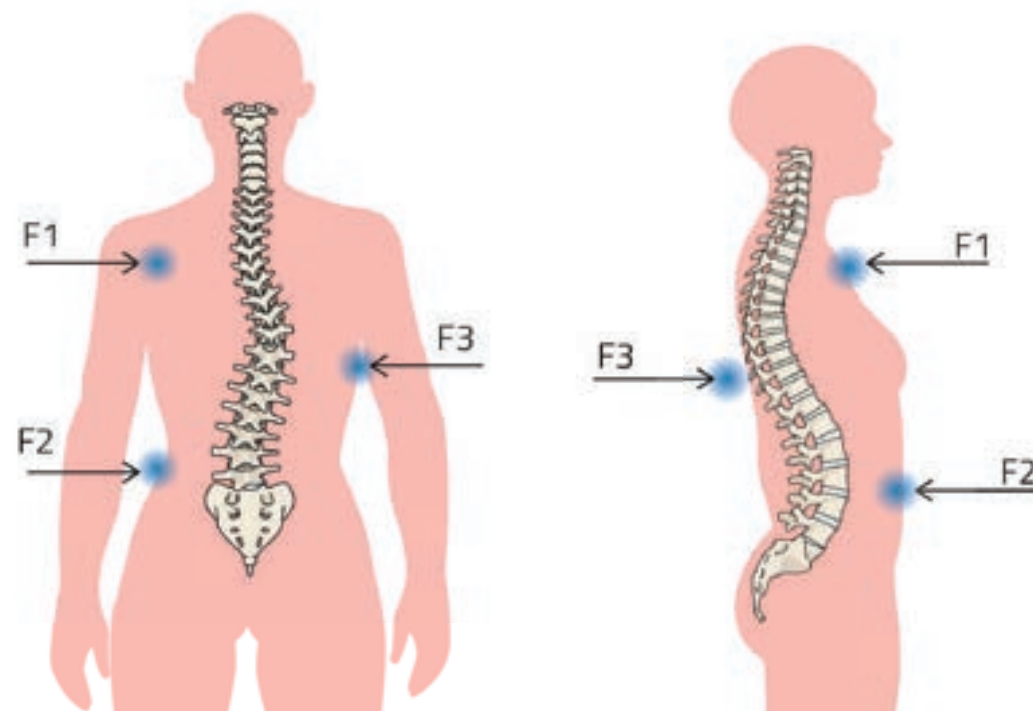


Figure 20 three-point pressure system

3.5.2 ACTIVE/PASSIVE CORRECTION

Column correction divides forces by direction, in this category forces are divided by way that are applied. Like in night time brace passive correction only provides support. Most of the rigid braces are in this category. Movement on body simple stabilized by the brace to prevent further deformation. On the other hand, active brace does not stabilize the whole trunk. There are points where there is more force and where is less. Active correction as it can be understood from the name actively pull or push the spine. This correction is established with material selection. The flexibility of brace is able to provide active correction. This two principles threat spine in a different way. Passive correction focus on not damaging the spine more but active correction tries to teach the body how spine must be. It uses muscle memory so instead of constantly use external force to keep the spine in a correct way, it helps the muscle to gain enough strength to pull the spine in a correct way. It is not applicable for every spinal deformity.

At the end aim is fixing the deformed spine but what it needs to be remembered that, this is not construction side. Therefore, before using most effective force and principles there is two main point needs the be considered.

1. Pain tolerance of the patient. Necessary force can change for each individual so patient's tolerance to the pain is essential.
2. Choosing pressure points carefully. Our body consists of soft and rigid tissue. Instead of directing the force to the bony rigid area, soft tissue areas can be used. This is one of the mechanical advantages our body provides.

In addition to that, there is one last type of force. It is not like the other forces that we represent before but still, it is part of the system. The kinesthetic reminder is created with the help of material. Most generally pads are in use for this purpose. The duty of these pads without applying any active force reminding a patient to not move in a harmful way. These materials also partly prevent skin possible skin damage by eliminating friction.

3.6 MATERIALS

Selection of material is an important part of brace treatment. Choice of material could affect more than one aspect like cost, design, and performance of brace. According to research made by Lusardi and Nielson, there are five important criteria for material selection which are; Strength, stiffness, durability, density and corrosion resistance. (Lusardi, 2006)

Strength stands for the maximum load that material can support. Especially strength is really important in the thoracic area because that is the part where the material will feel the highest pressure on the brace.

Stiffness is the amount of bending or compression that occurs when the material is loaded. Stiffness is used to limit the motion. Most of the braces are using stiff material which means it is either not flexible or there is only little room for motion. What it needs to be considered that different section vertebrae have a different range of flexibility so in the place where motion does not obstacle material needs to less stiff depends on the section. (Figure 21)

Durability is the materials ability to stand repeated cycles of loading and unloading during use. It determines how long brace can withstand before material fail.

Density is the material's weight per unit volume. Density is significant when calculating the cost but more than that it has a direct relationship with the user. A patient needs to be comfortable with the weight. There are already forces that are applied to user's torso, so any extra force will be uncomfortable. The aim is finding possible lightest material that can also ensure necessary strength and stiffness.

Corrosion resistance is the susceptible to chemical degradation. Spinal orthosis covers most part of the torso which cause patient to sweat so material needs to porous to prevent it. However, it is hard to completely avoid sweat so in that situation material should not absorb moisture, easy to clean and not keep the smell on it. (Lusardi, 2006)

Production method is also consideration for material. Some materials are easier to mold, and custom fitted, and some others might need more processes which reflected as cost to the customer. The most commonly used materials in orthotics can be listed as leather, plastics, and foamed plastic. (Lusardi, 2006)

In the past leather mostly used to prevent friction between patient skin and spinal orthosis in order to keep the skin from irritation. Reason for leather to be chosen is its dimensional stability, porosity (breathability) and water vapor permeability. (Lusardi, 2006) These features are the reason leather is still use in some spinal braces. Unlike in the past today leather is mostly used as a strapping material because even though in the past leather was perfect to create the shape of torso, today there are more practical materials exit. However certain qualities of leather still needed in some situation.

Metals have wide use in the spinal orthosis. It might be popular in the past but currently, there are still different kind of braces which are using either metal structure or metal support system. Metals can be divided into two as steel and aluminum. Steel is strong, rigid, ductile, and durable but their biggest disadvantage is its weight. Especially if it is used as the structural material weight of brace is hardly tolerable. Besides corrosion is another disadvantage of steel. Aluminum is a better choice when weight is a consideration and it is competitive with steel when strength to weight ratio although it is not resistant to sweat so before use aluminum, it needs to be coated. In general, because of their strength metals are used on the part where motion needs to be limited.

Plastics are the most popular material for the spinal orthosis. Reason for it popularity is its ability to be formed over a positive model and it has lots of different types of plastics that can choose from. Generally, plastics group into two groups which are thermoplastics and thermosetting. Thermoplastics are formable when they are heated and once it cools down it becomes rigid again. It can be reheated and formed multiple times which created a great advantage in orthosis because first models almost always need the second touch in the fitting process. Since they are used mostly for shell design it is a very compatible choice for a brace. Polypropylene, polyethylene, acrylic, and copolymer are the most popular. Polypropylene is a rigid material which relatively cheaper than others, lightweight and easy to thermoform. Therefore, it is widely used in braces.

Thermosets are plastics that are applied over a positive model in liquid form and then chemically "cure" to solidify and maintain the desired shape. (Lusardi, 2006) Thermosets, unlike thermoplastics, cannot reform by heating. The only way to reshape the model is grinding. Most common thermosets resin for orthosis are acrylic, polyester, and epoxy.

Disability to reshape the thermosets, make them better option to create components of orthosis rather than creating torso with it.

Foamed plastics are used as an interface material between shell and skin. Their soft texture creates a comfortable surface for bony areas. Foamed plastics are grouped into two classes; Open cell and closed cell. Open cell foamed plastic is less likely to use in a spinal brace because of liquid absorbing potential. On the other hand, closed-cell foamed plastic common in the orthosis. It is less likely to absorb liquid, but it acts as an insulator, so it can cause heat which eventually causes a patient to sweat. (Lusardi, 2006)

In addition to these materials with help of evolving technology now there is a new type of casting bandages. Traditional ones are Paris plaster bandages and they are only in use to model patient's torso. Fiberglass bandages apply in the same way but the difference it is a long-term treatment. Fiberglass bandages are fiberglass cloth impregnated with polyurethane resin. It has a good air permeability. Also, it is considerably faster to mold. It provides good quality of strength with minimum weight.

The materials need to be used in a spinal brace to be able to last the prescribed amount of time. Material selection is not purely related to correction. There are other factors needs to remember such as these materials will have constant interaction with human skin. Also, treatment area needs to take into the consideration cause not each region of spine creates the same amount of force and shear can be changed for each situation such as the prescribed amount of time.

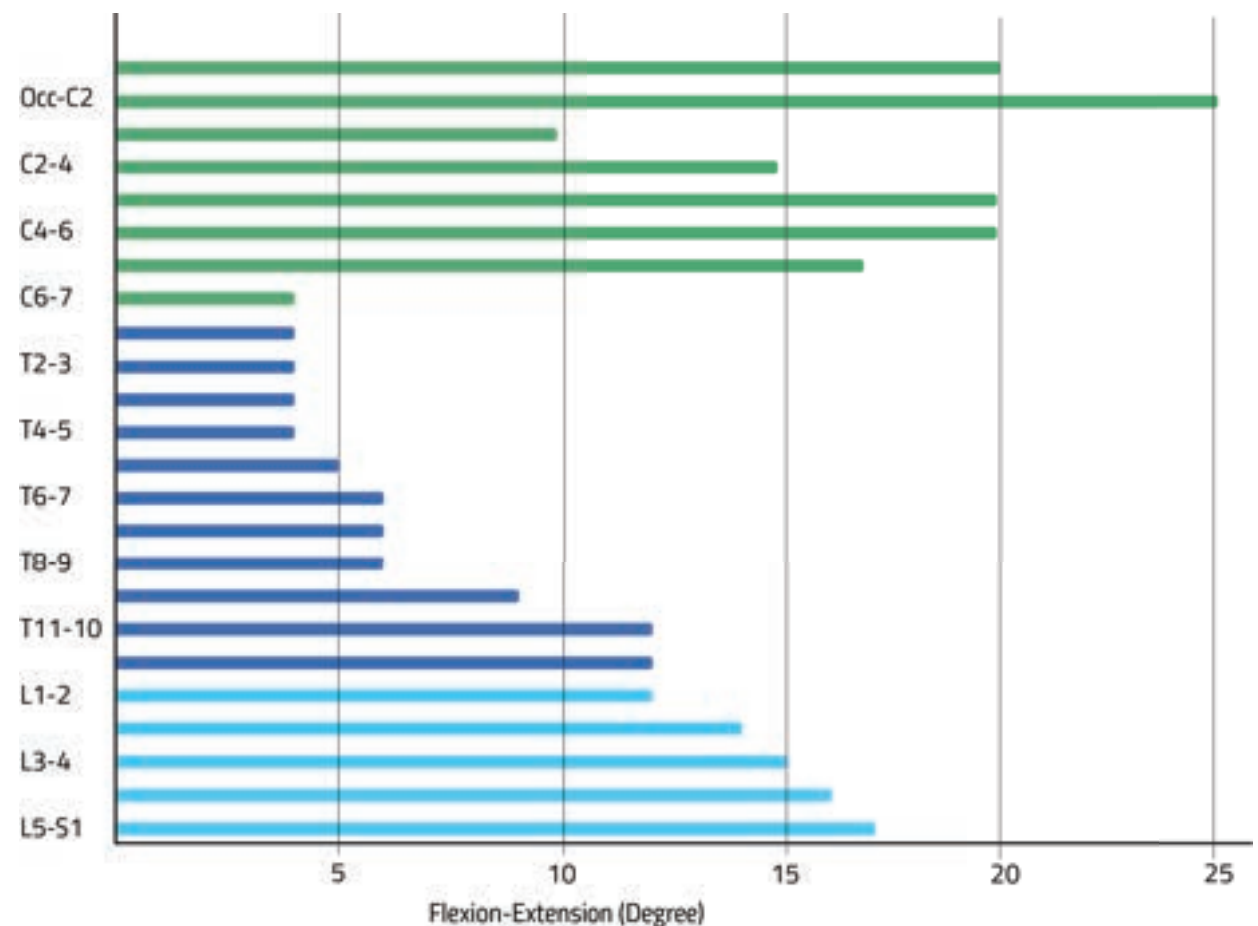


Figure 21 Flexion and Extention ability of vertebrae based on their region



Figure 22 Pre-fabricated TLSO

3.7 CUSTOM BRACES VS PRE-FABRICATED BRACES

In some type of deformities, a patient has two options with brace selection; pre-fabricated brace and custom molded brace. Custom molded brace is specifically made for one person from his measurements and it is targeting exact points on the spine that needs to be focused. A pre-fabricated brace, which also called 'off the shelf brace'. These braces made according to ready templates orthotist has which these templates designed based on most common spinal deformities. Pre-fabricated braces offer different sizes from big to small and long to short. Each brace has its own advantages. The biggest advantage of pre-fabricated could be the cost of the brace for the

patient but there are many aspects that we need to consider before deciding which one is the better option.

First of these aspects is clearly general fitting. Unsurprisingly custom-made braces are fit better to the user. Although pre-fabricated braces contain certain functional accessories to give the user opportunity to adjust the brace in his body. Gene Bernordini and Thomas Gavin from Ballert Orthopedics and Prosthetics have discussed this topic in detail. In Berdoni's research, they identified that for TLSO braces pre-fabricated ones their anterior shells composed of flat panels which are attached to each other with a help of polyethylene straps. (figure22)

These types of orthosis are not well able to control triplanar motion. They are only able to provide flexion and extension (Bernardoni, 2012) However, because of elastic straps, these two function can compromise. When pre-fabricated braces are compared to custom made, they are not able to control lateral motion and rotation as well as custom ones.

SAGGITAL PLANE MOTION

Motion on this plane controlled by anterior and posterior parts of brace. Longer the panel is limited motion on that side such as if brace has longer rigid anterior panel, user will not be able to lean forward. Even though naturally spine doesn't have wide range to bend backward, longer posterior panel prevents the same motion. Most of the pre-fabricated braces keep their anterior panel shorter than posterior because in this way it is easier to adjust brace to different users. However most of the times motion that needs to be prevent is frontal bending. Most orthosis agrees that longer lateral panel would serve better to purpose. (Bernardoni, 2012)

CORONAL PLANE MOTION

Coronal plane motion is limited by lateral panels of the brace. In some cases, these panels consist of straps. Especially in pre-fabricated ones. Same logic as it is mentioned on sagittal plane, is can apply on coronal plane. Longer the plane limited the motion but since in pre-fabricated brace use this side of the bust for adjustment with straps, mostly they are not capable of preventing the motion. Using non-rigid material on the sides where the motion needs to be limited even though if it is long panel it will not work.

TRANSVERSE PLANE MOTION

Motion on this plane is rotation so in order to prevent the rotation we need to control lateral, posterior and anterior panels all together. Best way to prevent to any rotational motion is using long panel enough to cover pelvis area and reach to collarbones. (figure23) As we mentioned before most TLSOs does not cover that much amount of torso. (Bernardoni, 2012) In tests that has been made by Bernardoni showed greater difference between custom made and pre-fabricated TLSO for angular motion. Same patient wore custom made and pre-fabricated TLSO and differences on spinal rotation

was in custom TLSO 0 degree, pre-fabricated 30-50 degree. (Bernardoni, 2012)

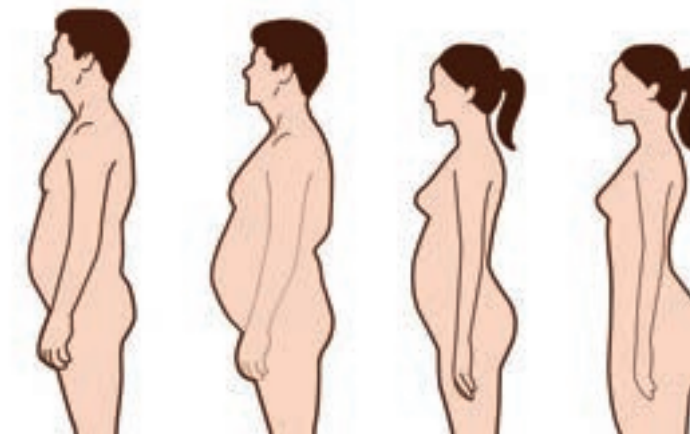


Figure 23 Different body types

Besides these motion limitations, the main problem with these orthoses is they are not adjustable enough to fit a different type of body. Most of them only provides tightness and looseness as an adjustment but there are many different types of bodies that can face problem with use of pre-fabricated TLSO. (figure23)

Especially flat anterior panels limits the variety of body range because abdomen part makes really hard for pre-fabricated TLSO to fit larger size user. Fitting is very important on abdominal area on brace because whole system gets its support from trunk part. If brace doesn't fit on trunk it will not be able to align itself to contact points. Custom braces work perfectly on trunk support due to the fact that it is formed from patient's torso.

On the other hand, if deformation on spine does not require any trunk support like in the example of hyperkyphosis some pre-fabricated braces are more economical and it can meet with patient needs. Adjustable anterior panels may not be able to limit spinal rotation, but it can work quite well to prevent thoracic bending.

The other factor when comparing pre-fabricated braces to custom ones is compliance. It is understandable that custom molded orthosis is more comfortable than pre-fabricated orthosis because they are molded based on user's body. However, at the end by nature spinal orthosis are not generally comfortable because of the function they carry which is limit the motion. Other than motion limitation some other factors also can affect comfort like heat. According to Bernordini pre-fabricated orthosis are hotter

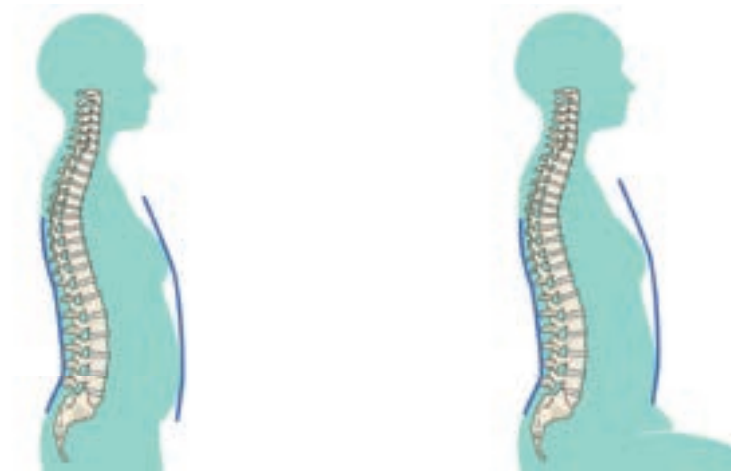


Figure 24 Flat anterior shell does not fit abdomen
flat anterior shell causes excess abdominal tissue to escape
under shell (Bernardoni, 2012)

than custom molded ones because pre-fabricated orthosis uses thick foam and contains more texture than custom molded. (Bernardoni, 2012) In order to create adjustability most of the braces have large thick straps around the waist. Also because of adjustability, it takes more effort to wear it and take it off when it is compared to custom one. Custom braces have only one opening point and there is no adjustment which makes the wearing process quite faster.

Cost is another important factor for the patient. The pre-fabricated orthosis is cheaper than custom molded but only as a product. Interestingly Bernardoni examines whole treatment process for both brace and the conclusion he came was custom molded orthosis are cheaper because pre-fabricated one requires more visit to the doctor's office. On the other hand, custom molded only requires one visit for every three or four months. Cost difference created by doctor visit is approximately \$300 to \$400 more. (Bernardoni, 2012) Thus, pre-fabricated brace doesn't necessarily cheaper than a custom molded brace. This research proves in most cases custom molded is a better option. (Bernardoni, 2012) Pre-fabricated orthoses may seem more convenient but when we analyze it in deeper level it is not the case in every scenario. It is not able to limit the motion as a custom brace. If patients have all the knowledge of pre-fabricated orthosis his choice would quite clear when the clinically approved brace is also the cheaper one.

3.8 COMPLIANCE

Importance of compliance did not comprehend in 1900's because once doctors prescribed the amount of time needs be worn for braces, they had no other source than a patient to confirm the use of a brace, so doctors needed to rely on subjective surveying of patients about their brace wear. For a period, compliance has been measured through questionnaires and verbal reports. Therefore, studies were also not accurate with detecting the used amount of time, so in theory, compliance was not issue because they had no data about non-compliance. The biggest reason for this was patients either on purpose or unconsciously were not aware of the time of brace treatment so when doctors asked them, most of the time patients were telling that they are following the orders. Last studies showed more accurate results about compliance with help of technology, so these technologies proofed the inconcinnity between actual brace wear time and questionnaires that answered by the patient.(Donzelli, 2015) (figure 25)

In order to detect the brace wearing time special kind of sensors integrated into braces, such as a heat sensor (help with body temperature) and force sensor (help with the daily body movement). (Harvey, 2002, Helfenstein, 2006) With these technologies,

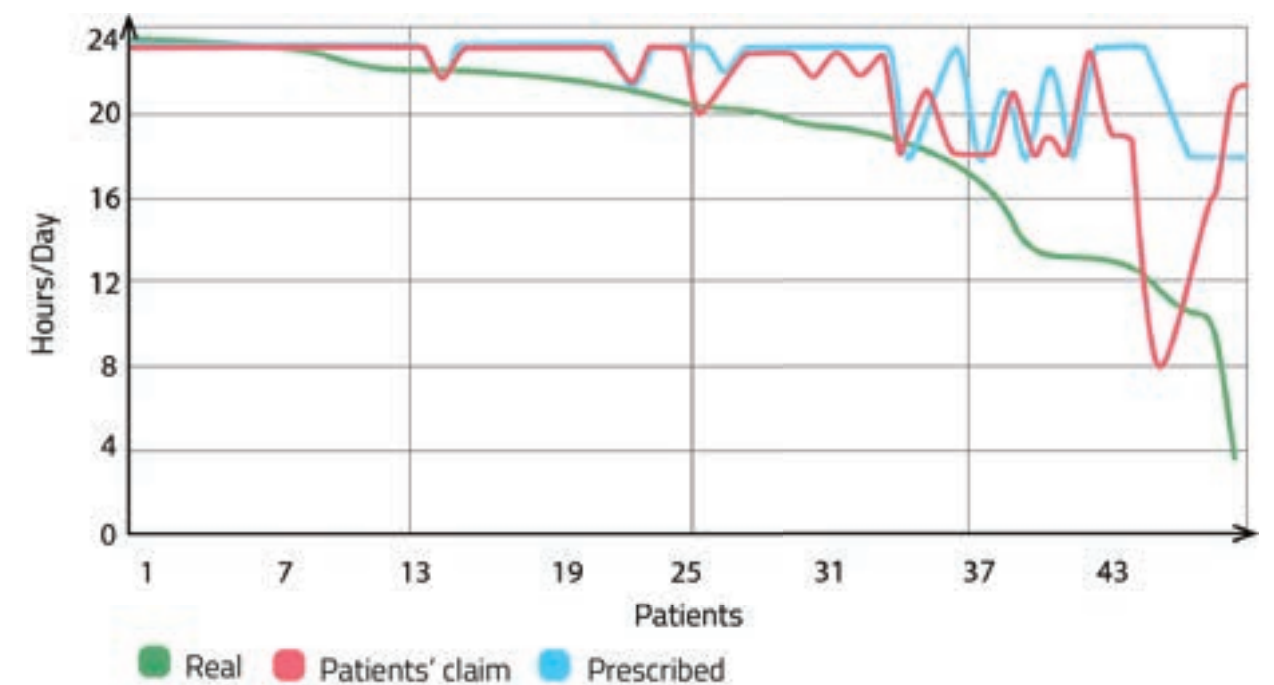


Figure 25 The real compliance VS Prescribed time (Donzelli, 2012)

researches are able to see the exact amount of brace wear time. (figure 26)These objective measurements proved that actual brace compliance is much lower than patients' statement. Most of the studies that are made to see the effectiveness of braces, did not include non-complaint patients in studies because at the time they had no opportunity to confirm the brace wear time. After use of tracking device, another question appeared. Should studies include non-compliant patients to do result? Some researchers assume if patients are not following the prescribed time they cannot be a part of study anymore. Later, Scoliosis Research Society (SRS) released inclusion criteria for studies which is 'All patients to be included in bracing studies should belong to the



Figure 26 Monitoring system

intent-to-treat statistical concept which does not exclude non-compliant patients from the study.' With this statement, the importance of compliance recognized by studies.

It has been proven that high correction results from braces come with high compliance. (Weiss, 2003) However, bracing is a traumatic experience in some cases and it can affect rest of the patient's life in an emotional way. (Dickson, 1999) Since bracing treatment is a long process which can take years it has a big potential to impact patient's lifestyle and behavior.

In order to increase the compliance different kind of braces are introduced to the market such as flexible braces and night time braces because most common excuse for a patient was an appearance with a brace. Therefore, either by hiding the brace or limiting the treatment hour with night time, experts tried to increase the compliance. Research made by LouAnn showed that limiting the treatment time actually has a positive effect on compliance. (LouAnn, 2009) Another variable effect compliance is age. Younger the patient is higher the compliance. Highest compliance age range in patients is 11-14. After 14 to 18 convincing the patient to a treatment is more challenging because till adolescent patients are more willing to listen to their doctor or parent (Panagiotis, 2007) It is a known fact that adolescent is a difficult period in its own. In this period, they are more open to affect by treatment psychosocially. (Ryszard, 2012)

Proven psychological effects of treatment are (Vasiliadis, 2006);

- Self-esteem
- Negative body image
- Interaction problem with other

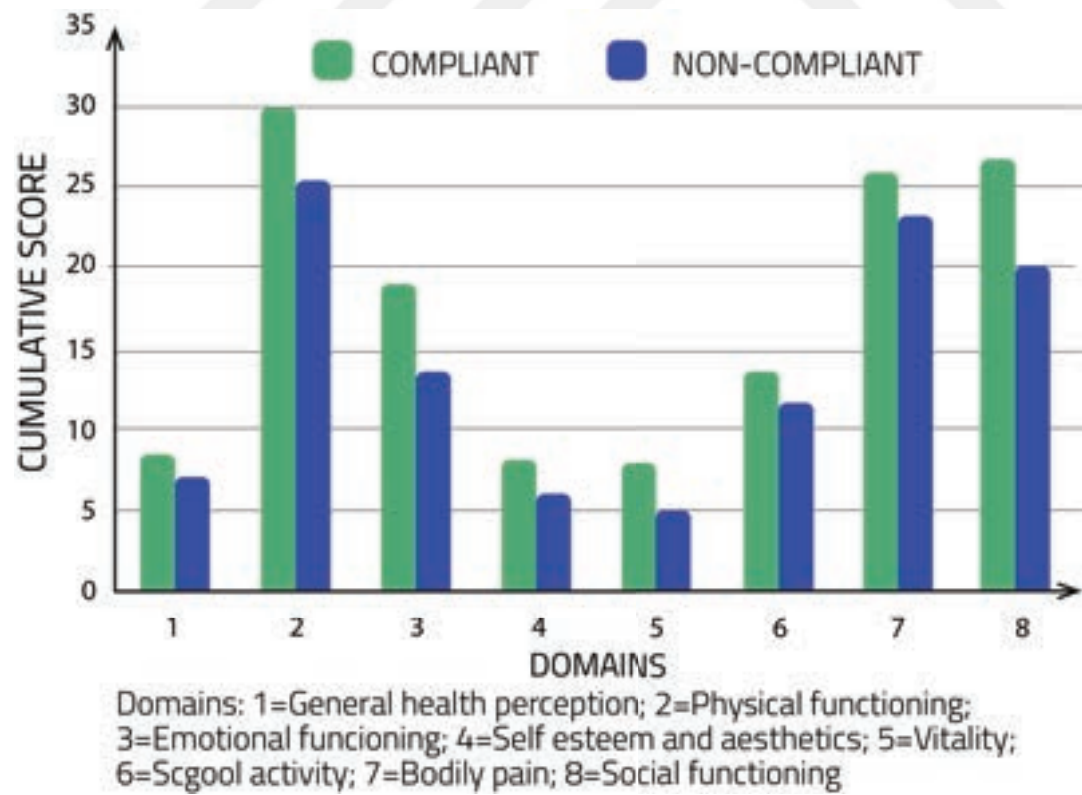


Figure 27 Distribution of scores between compliant and non-compliant group

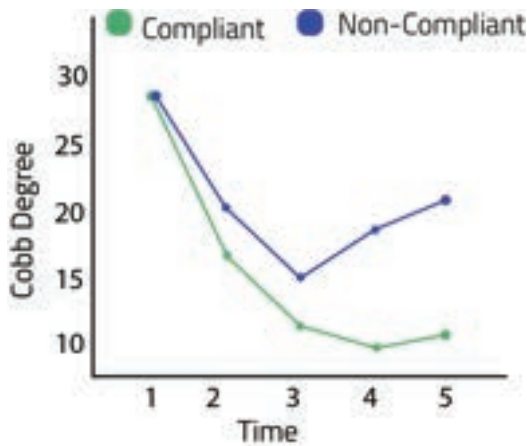


Figure 28 Cobb Degree change between compliant and non-compliant patients during time

Self-esteem is the most common found side effect on girls because of their appearance in adolescent especially important. Since girls are creating most patients for spinal deformities, the majority of patients suffer from self-esteem.

Psychological issues alone have been the cause for a lack of compliance with a brace protocol (Hawes, 2002) Therefore people who are involved in the processes need to understand social and psychological effects of treatment. (Mirtz, 2005) However, it is still not possible to see considerable effort for the emotional side of treatment but at very least in recent years importance of

compliance has acknowledged more. Some studies and research centers are trying to set standardization to detect emotional stage of the patient by questionnaires or a different approach in treatment. Recently a group of researchers developed the first self-report questionnaire to detect patients emotional stage and their perception of body image. (Auerbach, 2014) Another important standardization about bracing is health-related quality of life (HRQoL). The SOSORT 2005 consensus paper, reported that only 1,48 percent of scoliosis studies take HRQoL to consideration in their paper. (Negrini, 2006) Thus the brace questionnaire (BrQ) is designed to test Health-Related Quality of Life. (Vasiliadis, 2006) The questionnaire covers the issues of function/activity, pain, self-image/appearance and mental health. There are different standards for determine the quality of brace. Society on Scoliosis Orthopedic and Rehabilitation Treatment (SOSORT) believes management of brace in daily use either by patient or by the people who are involved in the processes is also determines quality of bracing. (Negrini, 2009) It is promising to see experts are working on these kinds of surveys to increase efficiency in treatment.

In one of the research who applied BrQ questionnaire to a patient, find an interesting correlation between health-related quality of life and brace treatment. (LouAnn, 2009) Non-compliant group in this study prefer to wear their braces in a time when they are not interacting with other so mainly either in their sleep or at home. However even though they were not wearing their brace during activity with friends, they showed lower self-esteem and body perception about themselves. (figure 27) Patients who have higher compliance, despite the fact they were interacting with people while they are in a brace, they had a higher opinion about their appearance.

It is important to see these kinds of questionnaires are included in researches to a more accurate outcome. At this moment there are lots of cases and some of them took place nearly for seven years but in the processes, patient psychological stage completely ignored even more non-compliance patients are not considered as drop-out at all. They completely excluded from the final conclusion. Hence these researchers' conclusions are not quite accurate and not able to make a fair judgment for bracing treatment. Since non-compliant patients twice as more likely to have curve progression, treatment cannot fairly judge without considering compliance factor. (Jens, 2012)

3.9 PRODUCT RESEARCH AND ANALYSIS

3.9.1 MILWAUKEE BRACE



Figure 29 Milwaukee Brace

Milwaukee brace is the first brace that has been used for spinal treatment and most common one. It has introduced to the market first 1946. It is actually designed for post-surgery to stabilize the spine until recovery period is over. Later it is started to use as a non-operative treatment for correction and became part of conservative treatment. Milwaukee is the first spinal brace for used correction and fixation purpose. It is considered TLSO type of brace which means it covers all the regions on the spine. Mostly prescribed for idiopathic scoliosis and Scheuermann disease and it is very effective with the apexes above T7. (Frenkel, 2011) The brace is intended to keep the body straight. It prevents almost every possible movement on the torso.

The Milwaukee brace commonly prescribed for 23 hours of a day. In that one free hour patient needs to exercise. Problem with the long-time braces is while it stops the progression, it takes the function of muscles in the torso. After long period treatment patients are having a hard time to live without brace because weakened muscles are no longer to keep the body in a straight position. For this patient needs to exercise while he is treated by brace otherwise he will have back pains too.

WORKING PRINCIPLE

It takes its support from trunk area, so it needs to fit the body perfectly. Therefore, Milwaukee brace is always customized. It covers whole pelvic area and reaches to the neck region. Between pelvic girdle and neck ring connected with metal bars which they can be adjustable during patient's growth. These metal bars create a distractive force on the spine while neck ring keeps the head in the center of the body. On these metal bars few pressure pads placed depending on curvature patient has and they are attached to the bars with straps. These pads create a transverse force on the torso. Neck ring is a passive reminder, so it does not apply actual force to the mandible. As the patients grow brace can be adjusted as long as the pelvic area still fits but if the pelvic area does not fit anymore, the patient requires a new brace.

APPEARANCE

The appearance of brace did not evolve since 1940's. Materials have changed thanks to technology but because of the function, it needs to serve Milwaukee brace still keeps its bulkiness which is why it is one of the braces which has a negative effect

on patient's self-image (Clayson, 1987) and that results with patients' unwillingness. The neck extension on Milwaukee makes brace almost impossible to hide. When you think about effectiveness actually Milwaukee brace most effective brace with patient compliance, but patients are not willing to wear Milwaukee at all. Researches have shown that Milwaukee brace is considered the most stressful for its impact on the psychosocial area and back flexibility. Milwaukee-treated patients have a worse body image and worse experience with the hospital staff in comparison with the group of operated patients (Climent & Sánchez, 1999) Consisted structure from pelvic to neck prevent daily activities or any social activity in that matter. Quality of life is significantly more affected by Milwaukee brace than others.

The most common negative feedbacks from patients was; (Maruyama, 2011)

Hard to find a proper outfit to cover brace.

Because it is too visible there is constant staring by others

In order to reduce a bit psychological effect of Milwaukee brace Maruyama et al. reduced wearing time so the patient will have time where he does not need to think about hiding brace.

One of the hypotheses about Milwaukee brace was there is an important emotional difference between stress caused by Milwaukee braces and stress caused by body image. When researches checked their form patient emotional stress level they noticed big part of the stress caused by brace itself. (Misterka, 2018)



Figure 30 Milwaukee Brace in use

3.9.2 BOSTON BRACE



Figure 31 Boston Brace

kind of deformities and angles seen in patients. In order to select the correct size, there are few measurements need to know by orthotist. Main measurements to assign the brace to the patient is waist, hips, and length of the torso. Custom molded brace is made from the patient plaster cast.

It is most commonly used for slow down the progression. If the patient does not have a critical level of apex they do not need a surgery for after but if the curve is critical, then Boston brace is used to stop progression until surgery. Prescribed time depends on the severity of curve but most of the cases Boston brace is prescribed for 18h to 23h. Therefore, Boston brace also needs exercise with bracing treatment. After not using muscle for so long the body needs to adjust the weight of the torso otherwise the patient will suffer from back pain.

WORKING PRINCIPLE

Like Milwaukee brace, Boston brace has a certain amount of pads placed inside the brace depending on the direction of the apex. These pads create a transverse force on the spine as well and apply corrective force to the convex. On the opposite side where the concave is, the brace does not apply any force and, in some design, to assure the relief there is a small window opening on the concave side. It covers from the pelvic to the chest. It keeps the lumbar region of the spine in a flexed position with the help of force applied to the stomach. It takes its support from the pelvic area, so Boston brace needs to fit to the pelvic area

perfectly.

APPEARANCE

As we mentioned before it is produced by aesthetic concern against Milwaukee brace. Hence, patients are more willing to wear Boston brace than Milwaukee. Since it does not reach to the cervical area and does not have a metal structure, it can be hidden under the cloth. Boston braces have a lower effect on the quality of life, which is why the compliance rate is relatively higher than when it is compared to Milwaukee brace. (Panagiotis, 2007) Since patients are able to hide the brace under their clothes, the compliance rate of Boston brace is relatively higher, so it can really be effective to stop curve progression. (Katz, 2010) In one of the researches, the compliance rate of Boston brace was 76% (it is measured by pressure pad) (Lou, 2002).

The most common complaint comes from the patient is how hot they get while they are wearing braces. It has one or two windows opening but most of the time Boston brace covers the whole stomach and back area. Another complaint is that the straps of the brace are located on the back side of the brace so most of the patients are not able to reach that way and they require additional help from a family member. In the situations when they take off the brace in school activity, they do not want to ask for help from their peers.



Figure 32 Boston Brace in use



Figure 33 Different pattern of Boston Brace

3.9.3 WILMINGTON BRACE



Figure 34 Wilmington Brace

The Wilmington it is also known DuPont brace is another type of TLSO type of brace. It is designed by G. Dean MacEwen in order to make the less bulky and less heavy. Studies have shown that treatment with Wilmington brace was able to give same results with the ones treated Milwaukee brace. (Allington, 1996) It is custom made plastic underarm brace and used for conservative treatment. Wilmington brace does not have the option of pre-fabricated so it is always custom molded. There few types of plastic used in production but most common one is Orthoplast. It presents itself as body jacket so unlike Boston brace Velcro straps reach front side of the brace. The difference from Boston brace is Wilmington brace almost cover whole torso and reaches to collarbone, but Boston braces mainly apply forces from

sides, so it ends middle of the chest.

Like Boston brace, Wilmington brace is also long time use from 18h to 23h and it requires exercise with it.

WORKING PRINCIPLE

The fabrication method is the same with Boston brace. Mold is created from patient's torso and used for the end product. Corrective forces applied by pads places inside the brace. Wilmington brace applies transverse correcting along with passive correction.

APPEARANCE

Wilmington brace does not have any opening or window which it is why is also known as full contact TLSO. However, it is still can be cover with clothes which is the reason why it is designed in the first place. In DuPont institute when the patient refuses to wear Milwaukee brace doctor MacEwen designed Wilmington and he was satisfied with compliance of the patient to the brace.

Wilmington brace can be wear like a jacket, so patient does not need any supervisor. Velcro straps placed in front of the brace and it provides tightness option besides opening access. However, straps are more visible even under clothes.

In some cases, Wilmington brace can cause few problems like skin irritation and another is mild chest wall and inferior rib deformation. The second problem comes with the fact there is no window opening on the brace and front Velcro might create the possibility tight brace more than necessary which cause deformation in ribs in long-term use.

Wilmington brace has been used in few studies to increase compliance. One of them was changing the amount of time for brace treatment so rather than 23/24h per day, patients prescribed 12/16h with Wilmington brace. (Emans, 1986) Only night time use of brace has a less negative effect on body image and psychology. (Climent, 1999)

However, according to Allington and Bowen study, there is no compliance difference when it comes to full time or part time treatment with Wilmington brace.

3.9.4 CHARLESTON BRACE

It is designed by Frederic Reed and Ralph Hooper in 1990 and they referred the brace 'side-bending'. Charleston spinal brace is a different type of braces than Milwaukee and Boston. While the braces presented before work for a long amount of time, Charleston brace developed to be worn night time. It is actually designed based Boston brace, but it is adapted to night time only. This change in the time aims to increase the compliance. In overall shape, it covers the same amount of body as Boston brace, but it is a bit bulkier. It is produced from rigid plastic by molding.

Charleston brace use greater force than traditional braces which is why the prescribed amount of time for this brace between 8h to 10h. However, even with the reduced time schedule, there is a compliance issue with Charleston brace. Patients stated that it is uncomfortable because of overcorrection force stretches body too much.

On the curves greater than 36° Charleston brace showed 83% success. In the meantime, Boston brace was 43%. (Katz, 1997) Up to 36° patient may prefer to wear Boston if he please but larger than that it is better to use Charleston.

WORKING PRINCIPLE

Unlike daily braces, Charleston brace applies stronger force. It bends the body to the opposite side of the curve and it is called 'over-correction'. While patient wears the brace, he is actively pushed to opposite side of the curve he has. This is another reason why brace is only night use because forces applied to the body, make impossible to move so there is no way patient would be able to do daily activities while in Charleston brace.



Figure 36 Charleston Brace in use



Figure 35 Charleston Brace

Differences between the applied forces in day brace and night brace is; night brace is covering missing time by applying lager amount of force to a patient which of course not more than spine can handle. Theoretically, Charleston brace stretches the soft tissue and unload the vertebra where the concave occurs. (Price, 1990)

Trunk support is not essential as in traditional TLSO braces. Therefore, there

is a possible use brace made without formed by patient's torso. In some websites (Charleston Bending Brace Solutions) gives form in order to know exactly where the convex is. (On which vertebra such as T5)

APPEARANCE

Since Charleston brace does not fit to body as Boston or Wilmington it is not possible to hide under clothes, but it is because only nightwear in aesthetic appearance it is not a problem for the user. However, it is recorded that some patients are not able to sleep in the position Charleston created. (Panagiotis, 2007) Control of Charleston braces relatively easier because once patient wears it, he does not need to deal with a brace until morning. Also, openings of brace placed in front of the brace so the patient can take it of brace without help.

On the overall quality of life, Charleston has a lower impact on patients' life because the patient doesn't need to perform a daily activity with the brace. (Panagiotis, 2007)

3.9.5 PROVIDENCE BRACE

Providence brace is another kind of nighttime brace. It is designed by Charles d'Amato Barry in 1992. Providence is effective on one or double curve on the spine. It is able to minimize the curve without the discomfort that Charleston brace create. (D'Amato, 2003) Instead of using over corrective force like Charleston brace it uses lateral and rotational forces to stabilize the spine in the middle. Since it is a combination of two type force it is really challenging for a patient to continue to do her daily activities. In this matter, it is same with Charleston braces. It is using forces which would be a problem in daily life, but it would be okay during the night time.

It is produced by polypropylene plastic. Two types of production system exist for Providence brace, first is traditional casted plaster on the patient body. Another one is a plastic board which helps orthotist to create a proper measurement for the patient. Holes on the board assign the forces needs to be applied and later made proper modification on virtual software. (figure 38)

The effectiveness of brace is comparable with full-time TLSO brace. It has accomplished 74% success rate when it is compared to full-time TLSO brace. (D'Amato, 2001) Patients have a more willing approach to Providence brace. In one study researchers



Figure 37 Providence Brace

mentioned that in their previous work they needed to change their brace type because patients were unwilling to wear TLSO 22 hour per day. Therefore, a study has changed and instead of TLSO, they prescribed Providence orthosis for night time. In their further study, they worked with both custom TLSO and Providence orthosis and their hypothesize was the compliance with the Providence brace is greater and leads to improved results. (Joseph, 2007)

WORKING PRINCIPLE

Working principle, a bit different from Charleston brace. It uses lateral and rotational forces on the trunk at the same time. It tries to push the spine to midline while Charleston tries to bend the spine on the opposite direction. Correction principle of the brace is a good example of three-point pressure. It applies two forces on the one side which is the wider side of the brace. Another for on the opposite side equal to other two force.

Rotational force is created by two different ways. First, pressure pads located just up to the hip and twelfth rib. These pads apply forces on opposite direction and that creates controlled rotation on the spine. Another way is created by cad modeling. On transverse plane angle created between the thoracic section and lumbar section. Amount of the rotation force can be simulated on CAD model.

APPEARANCE

As in Charleston brace appearance does not matter for use since it is only night wear. It is less bulky than Charleston, so it gives more comfortable sleep position. The opening of the brace is in front of the brace, so the patient can control the brace without help.

3.9.6 SPINECOR BRACE

SpineCor is completely different from the usual traditional brace. Unlike others, it dynamic brace not rigid. It is developed in Sainte-Justine Hospital by the Spine Corporation in 1992. It is full-time brace like traditional TLSO, so it recommended to wear the brace for 20 hours. Users have two free hours in the morning and two free hours in evening.



Figure 38 Measurement board



Figure 39 SpineCor Brace

SpineCor designed with the intention of treating all kinds of scoliosis. The designer took three factors into consideration for development of scoliosis when they design the SpineCor; postural disorganization, muscular dysfunction, and possible miss growth in the spine. (Coillard, 2003) They believe if they can control these factors they can prevent the spinal deformity.

SpineCor is an effective brace to treat scoliosis; in fact, a study performed by Colliard came to result that it is very effective to treat juvenile idiopathic scoliosis. Also, he claimed it might be the most encouraging way of treatment and results can be kept for the long term. (Coillard, 2010) As a 2010 SOSORT winner this result SpineCor proves this claim. SpineCor can be used also in the treatment of small curves. This is one of the major differences between traditional TLSO and SpineCor. Traditional TLSO only prescribed for the curves are critical but SpineCor can be used for the curves as small as 15. This feature brings SpineCor forward among the others because with this possibility patient can intervene his spinal deformity in a really early stage.

SpineCor system actively used in hospitals and clinic centers. So far there are 752 patients recorded and 57% of the patients showed improvement while 32% of them stabilized (Coillard, 2003)

WORKING PRINCIPLE

SpineCor brace consists of a thermoplastic pelvic base, thigh and crotch bands, a cotton bolero, and four corrective elastic bands. Thermoplastic pelvic base and cotton bolero is two anchor point of the spine. Corrective bands between them get support from these two points. Corrective bands are the parts actually apply correction force to spine. Tension on bands will prevent spine to bend in a specific direction. (Coillard, 2010)

Tension on the bands is arranged by length of bands. Orthotist creates the needed tension on the needed points depending on patient deformation. Once it is settled only thing the user needs to do attach and detaching the brace.



Figure 40 SpineCor Brace motion freedom

APPEARANCE

Since it consists with the elastic material it is easier to hide when we compared with a rigid brace. Also, users do not move like a robot while in a brace, unlike rigid braces. Physical activities are way easier to perform in SpineCor. Therefore, quality of life is quite high in SpineCor when it is compared with other braces. Because it is less visible, it is more easily accepted by patients.

Results of the case study that has been done in Cincinnati Children's Hospital Medical Center for the effectiveness between braces shows the compliance difference between the Dynamic SpineCor brace and traditional TLSO brace. Patients who were wearing SpineCor brace followed the treatment three times longer than the patients who were wearing the traditional TLSO brace.

Patients are most likely to wear flexible or semi-flexible braces when it is compared to rigid braces. Both types of braces have a different complaint. Rigid braces mostly founded uncomfortable because of heat problem. Patients are sweating in braces and there is no way to clean is without interrupting the treatment process. On the other hand, like every other brace, SpineCor also has its own negative aspects. The most common problem in SpineCor is once it is worn adjustment needs practice it takes time also it is inconvenient for the patient to make the arrangement every time he goes to the bathroom. problems in everyday use (eg. clothes change, toilet use).

3.9.7 CHENEAU BRACE

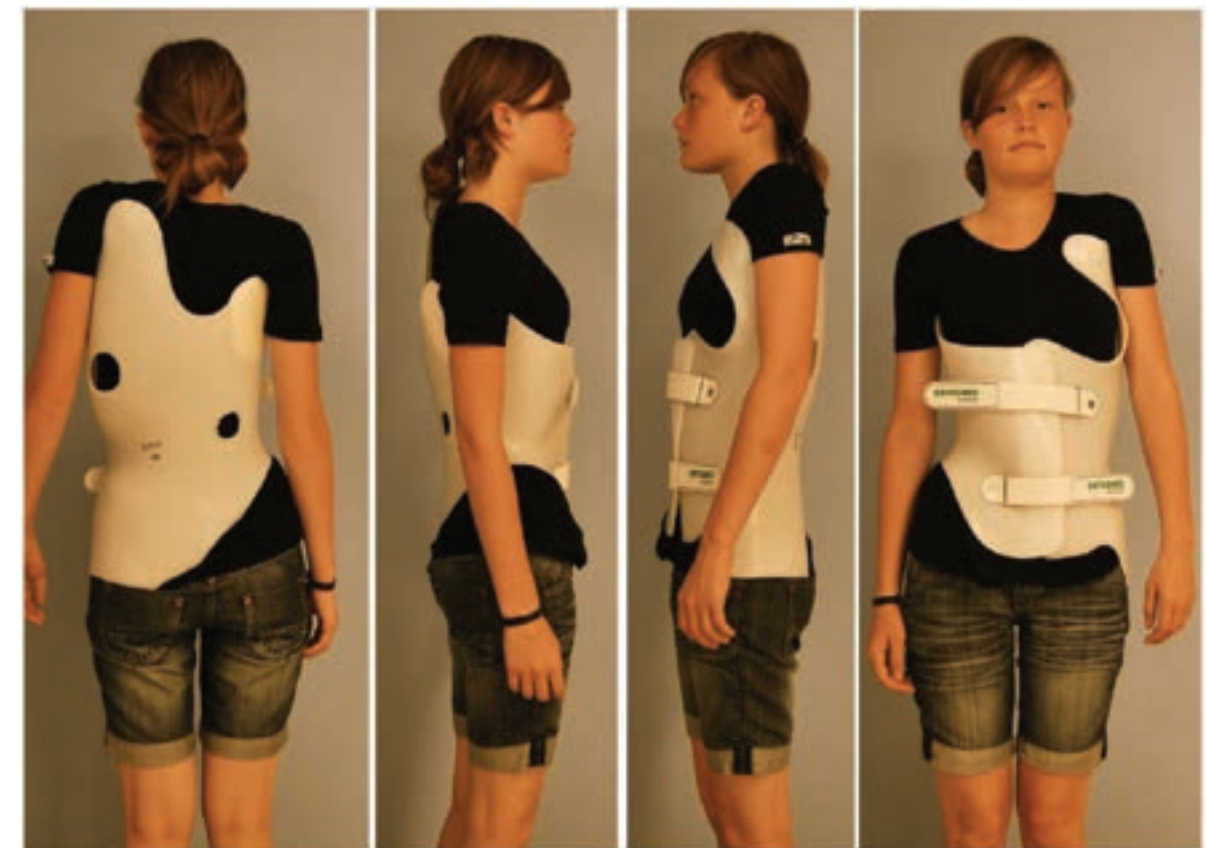


Figure 41 Cheneau Brace

Cheneau brace developed by Dr. Jacques Cheneau in 1960's but it is started to use actively after 1979 now it is one of the worldwide accepted conservative treatment

tools. Cheneau mostly used in the treatment of scoliosis and hyperkyphosis. It is not common in United state as much as in Europe. It is one of the most common TLSO type braces and it is most widely used in Poland (Kotwicki, 2008)

It has more than one point which applies forces to the spine to correct three-dimensional deformation. (Kotwicki, 2008) It is able to correct thoracic, lumbar and double cases with the rate 41% percent. (Périé, 2001) In a recent report showed that Cheneau brace has succeeded 23% correction on Cobb angle after 5-year treatment. (Cinnella, 2009) This is the proof of Cheneau brace does not only stops progression but also able to reverse it partly.

The brace is made of polypropylene plastic and used Velcro straps for the opening. The production method is thermoplastic like any other rigid brace. The mold used for thermoplastic is created from patient's torso.

WORKING PRINCIPLE

Cheneau brace is TLSO rigid brace providing three-dimensional correction. Forces that Cheneau brace apply is a passive correction and active correction at the same time. It applies detorsion and tries to normalize the spine on the sagittal plane. This detorsion causes correction also on the coronal and transversal place without applying any distraction force.

The general correction principle is that of detorsion and sagittal plane normalization, which would correct the coronal and transversal planes, resulting in some elongation of the spine, without any significant distraction force, (Rigo, 1999a).

APPEARANCE

The opening of the Cheneau is provided with Velcro straps and placed in front of the brace. It does not have a smooth surface like other TLSO braces (Boston, Wilmington). That makes it harder to hide under the cloth so mostly it is visible. Therefore, in some cases, Cheneau brace was accepted unwillingly due to aesthetic concern by adolescent girls. (Katarzyna, 2011)

Another issue quality of life. Since Cheneau brace applies a three-dimensional force it makes hard to proceed daily life as it so patients considering that brace is an obstacle for daily life movements and activities. (Katarzyna, 2011)

The number of studies has shown compliance rate in Cheneau brace is relatively higher than usual. (Goldberg, 2014, Rahman, 2005, Weinstein, 2013, Landauer, 2003) One of the possible reason for that might be Cheneau's light weight feature. When it is compared with other TLSO uses plastic is thinner so that makes brace lighter and it does not bend body as Charleston (other three-dimensional correction) Another reason could be that Cheneau brace doesn't contact the body too much because it applies three-dimensional force, so it does not cause patient to get hot.

3.9.8 LYON BRACE

The Lyon Brace is invented by Pierre Stagnara in 1947. It is also known as Stagnara brace. It is most commonly used in Europe. It was the first adjustable brace after plaster cast. It is made by Poly(methyl methacrylate) which also known as acrylic or acrylic glass and aluminum bars. It is an adjustable brace without requiring any additional padding.

It is full-time brace like many other TLSO. The biggest advantage of Lyon brace is while the treatment progress in the desired way, adjustments can be done. Metal bars

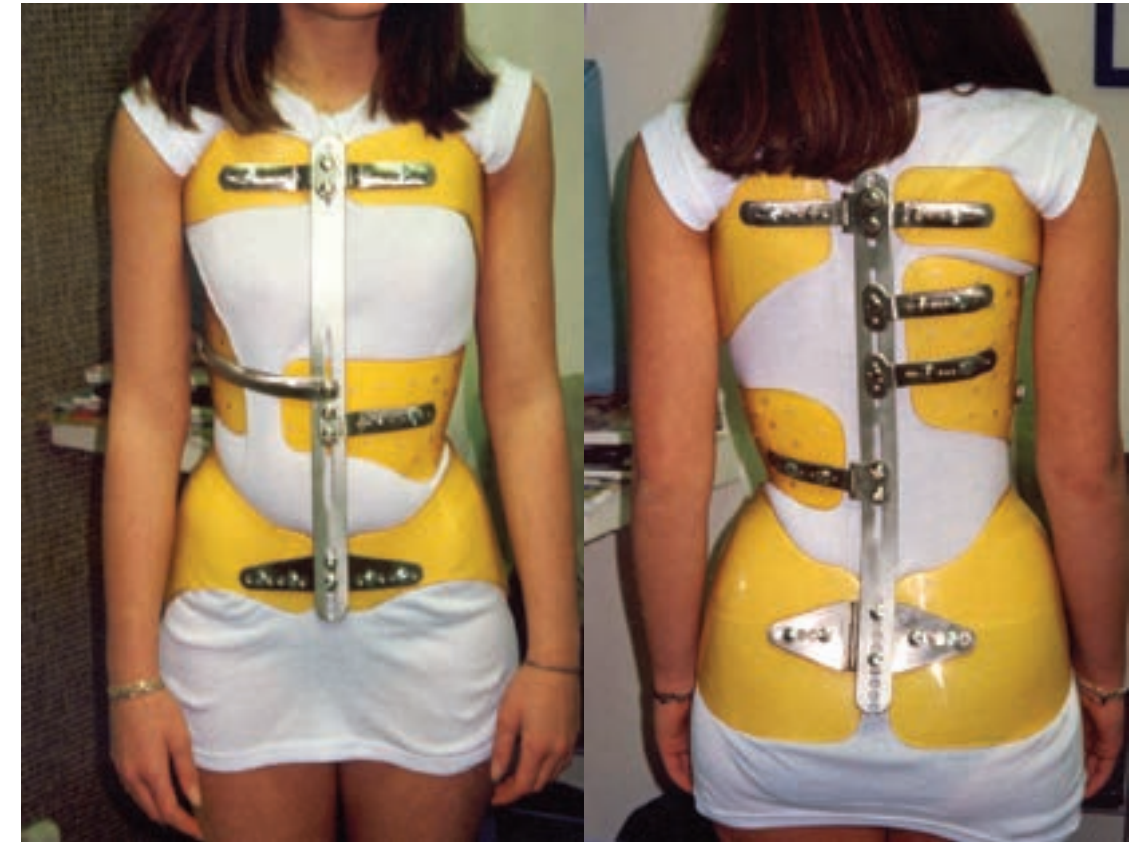


Figure 42 Lyon Brace

provides fixation point for plastic shells but also with the gap in the middle it gives an opportunity to move shells on axial position. The same principle exists for plastic shells. Holes on the shells adjust the magnitude of the force. Wider the brace smaller the force applied to the spine. Because it is adjustable there are 14 different blueprints designed by Lenke's scoliosis classification. (Grivas, 2010)

Lyon brace is effective to fix the deformation on the brace when the patient follows the prescribed time but in the case studies have been done there is no clear data about compliance because drop-outs are excluded from the result. (De Mauroym 2011)

WORKING PRINCIPLE

The Lyon brace is designed to correct deformity on the coronal place. Since it consists with the individual lateral panel the brace is also able to apply a rotational force on the pelvic region. Correction principle of brace created based on three-point pressure system. Force is applied on apex fo spine while two counterforces balance it.

Aluminum bars which are placed in the middle on coronal plane stretches the spine while lateral panels apply necessary forces.

APPEARANCE

It has a strong industrial look mostly because of the time it is invented. On the other hand, since it has a full contact with torso it can be hidden with clothes.

3.9.9 SFORZESCO BRACE



Figure 43 Sforzesco Brace

The Sforzesco brace is designed by Stefano Negrini and Gianfranco Marchini in 2004. The Sforzesco brace combines some features of Risser, Lyon and Milwaukee braces. It is produced with same material Lyon which is Poly(methyl methacrylate) but Sforzesco has only two big pieces which cover the body from pelvic to armpits.

Sforzesco brace designed as a better alternative to casted braces. It contains the basic character of riser cast but in a more elegant way. The biggest advantage it has that brace design aims to keep the body image as much as possible so the appearance of brace symmetrical. Since it aims to keep the body image, brace needs to fit patient perfectly so torso of the patient's created with CAD technology in a virtual platform. It consists with two lateral shells that are attached by straps in the front and aluminum from behind.

WORKING PRINCIPLE

On sagittal plane, brace needs to be perfect because changes are almost impossible unlike on coronal plane. Forces are applied by pressure pads that are placed inside the shells, depending on patient's curvature. Sforzesco brace can also fix the spine on a transverse plane by creating an angle between the pelvic region of the brace and top part. (Atanasio, 2008)

APPEARANCE

Left lateral part and right lateral part creates normal body appearance by being symmetrical which makes brace almost invisible under clothes.

Compliance for Sforzesco gave better results than Lyon brace. The main reason for that is keeping the symmetry of body made patients more volunteer to follow the treatment. (Atanasio, 2008)

3.9.10 PROGRESSIVE ACTION SHORT BRACE (PASP)

The Progressive Action Short Brace (PASB) is started to be used in 1976. It is prescribed for the thoracolumbar and lumbar idiopathic curves. (Grivas, 2010) It is a custom molded TLSO but it does not reach till armpits, unlike most TLSO. Working mechanism is based on the force that applied abdominal part which creates a counter force for the lumbar curve. Lateral forces work with the same logic in Charleston brace, but the force applied is not as big as in Charleston.

After patient's plaster cast made, mold sanded in the places where needs pushing. PASP also applies rotational force which created asymmetric appearance on the brace. This rotational force can be observed on the transverse plane. On this plane brace's asymmetric ellipse shape can be seen.

It has a front opening which serves the user well but with the asymmetric shape, it is not easy to hide under clothes.



Figure 44 PASP Brace

3.9.11 TRIA C



Figure 45 TriaC Brace

Tria C was developed by Dr. Albert Gerrit Veldhuizen in 2002. Unlike other braces presented before Tria C is not a rigid brace, it can be called 'semi-rigid'. Tria C is a representation of three C which are Comfort, Control, and Cosmesis. It is applied to the patients who have idiopathic scoliosis with a Cobb angle of between 20 and 40 degrees. Also, the apex of the curve or curves should be between T7-T11. (Grivas, 2010) It is custom adjusted by orthotist to patient depending on deformity he has.

WORKING PRINCIPLE

It is a tension based dynamic brace. Since it does not apply forces in big magnitude and it doesn't limit patient's life like others, it requires full time wearing. Tria C follows transverse force system which is anterior for counteracted by posterior force and torque. (Grivas, 2010) The pressure created on the front balance itself with the pressure created on the back. On sagittal plane brace only able to apply pressure on thoracic region cause there is no support from the pelvic region which also the reason of flexibility Tria C provides.

APPEARANCE

The major advantage that Tria C does not restrict patient's daily life as other braces which leading to better compliance on the patient side. Feedback is taken from patients about 'Quality of Life' showed that they are quite satisfied with the appearance of brace cause it way more easy to hide under clothes when it is compared with other braces (Zeh, 2008) The Tria C got many positive comments s from patients when they compared with Boston brace. Unlike Boston, brace Triac has considerably small surface and because of that, it is lighter. This lighter construction gives patient freedom other braces cannot. Freedom in motion effects the Quality of Life in a positive way. (Fairley, 2007) Also, it is easy to take the brace off for a patient without help because openings are placed on side of the brace.

3.9.12 SCOLISMART

ScoliSmart is one of the latest inventions for curve progression. It is a dynamic brace which means brace itself allows you to move. In fact, it requires to be physically active in order to be efficient. More you move in brace more effective it is going to be. Working principle is that ScoliSmart tries to create new muscle memory so it is encouraging the body to create a counterforce to curve progression with muscle strength. New muscle memory reduces and stabilizes asymmetrical muscle memory on the concave side of the spine, so it reduces the progression. It does not force the body like rigid braces but teaches the body how it should react. Every resistance body shows while brace on is the way to assign that brace is working. (ScoliSMART)

ScoliSmart first teaches the muscle how to behave and spine adapts the muscle. It never uses direct pressure on the spine.

Since it is fabric-like material it can be easily hidden, and it does not cause tilting or any other type of unusual physical movement, it is not noticeable by others. ScoliSmart does not require assistance to wear it or to take it off which is really comfortable for the user. (ScoliSMART)

It does not have enough outcome like other braces but there are positive comments about brace and treatment on socials platform like YouTube.

ScoliSMART is the only brace brand who supports the treatment with the community. On their website they providing a platform for the user to meet with each other where they can share their stories. It is also possible to see event activities like going camping. It offers more than brace it also provides social support. Even though it is flexible brace there are still compliance issues with users so providing this kind of support helps patient to follow treatment.



Figure 46 ScoliSmart

3.9.13 SPINAL CAST (RISSEY CAST)

Body cast is the oldest method in the treatment of spinal deformities. It serves both conservative treatment and post-surgery. In the past cast was made of plaster bandages which called Paris plaster bandages. However, with advanced materials, now it is made of fiberglass bandages. Production of a casted brace is same as the cast which made to create mold. The patient lay down on Risser frame and he wears some kind of t-shirt to have something between cast and skin. Later by doctors he positioned in the desired way and put pads on places where force is applied and wrap the bandage around the patient.

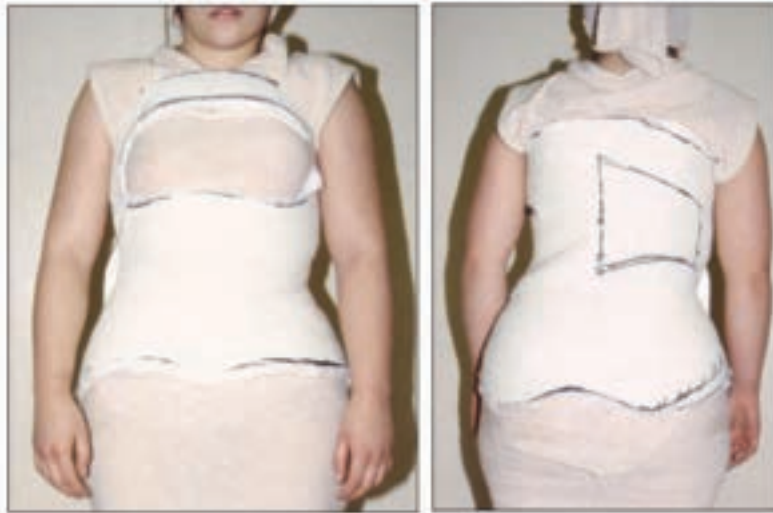


Figure 47 Spinal Cast

Once casting done patient does not have the choice to take the brace off because there are no openings. Every 3 or 4 months patient goes to the doctor and after check-ups either he would have new casted brace based on a new curve or he would change to plastic brace.

The main problem with this kind of brace is patient does not have any free time for months. Daily activities become really challenging like take a shower or just relax for a couple of minutes. Also, even though it is not bulky as Paris plaster, casting is still bulky brace than normal so no matter what patient wears it will always be seen. Another problem is how hot it becomes because of paddings and t-shirt. It is one of the most uncomfortable braces. It is not in use so much but there are still doctors who are preferring to use casting in severe conditions in order to be sure compliance will not be a problem.

APPEARANCE

It has a really bulk appearance and it is not possible to hide it under any clothes. It is almost uncomfortable as Milwaukee brace. Since the patient cannot take the brace off, it is quite effective. However, it causes a very stressful brace treatment process which is why it is not chosen by the patient willingly. If patient's situation is severe it can be suggested by the doctor but with modern day braces, there are not so many hospitals who are using casting brace anymore only for measurements.



Figure 48 Fiberglass bandage

3.10 RECENT DEVELOPMENTS

3.10.1 3D PRINTED SPINAL RACE



Figure 49 UNYQ Align 3d printed brace

3D printing or additive manufacturing one of the revolutionary manufacturing method in today's world. Production technique allows producing complicated shapes without any additional application. It has the ability to print one-time customized products which fit perfect for medical applications. It has already been in use for numerous applications such as implants, Prosthetic Parts, and Cranium Replacement. Now we started to see 3D printed product in the orthosis.

Production of a Spinal brace made by a 3D printer is still evolving and it is not completely on the market as traditional ones, but it is possible to find few manufacturers. As it is mentioned in the paper before brace treatment requires 10h-23h per day for years. Therefore, it is more than a medical device for users. It is part of them which is why appearance is important as much as a function for users. 3D printing technology does not have so many constraints like traditional ones so the design of brace is not limited by manufacturing. Therefore, 3D printer gives the opportunity to create elegant braces with less material which can also efficiently serve.

UNYQ Align which specializes in orthopedic and prosthetic products, worked with Francis Bitonti (fashion designer) to produce 3D printed spinal brace. As it can be seen in figure49 design itself quite different than what is in the market. UNYQ describes the



Figure 50 ANDIAMO 3d printed brace

it makes them different from others by its bulky structure. However, 3D printed braces unlike traditional ones can offer breathable, personalized and elegant braces. In a pilot program run by UNYQ showed adolescent are more willing to wear 3D printed braces which is really important because the effectiveness of brace depends on the compliance of the user. Unlike traditional braces, 3D printed braces use less material which makes the brace quite thin. The sample UNYQ produced has a 3.5mm thickness so it can be either embrace by user and display or it can be hidden under clothes. There is also small monitor attached to design to control pressure points and see if the brace is working as the way it should. In another 3d printed spinal brace program run by the 3D system, tested 22 patients from Children's Hospital of Oakland and responses from patients proved that level of compliance was more than what they experienced in traditional braces.

UNYQ is not the only company working on 3D printed braces. There is also ANDIAMO from London and WASP from Italy are working on this technology. In near future, 3d printing technology seems promising for medical sector and spinal brace.



Figure 51 WASP 3d printed brace

ADVANTAGES OF 3D PRINTED BRACES

- While traditional spinal braces accurate to 1 to 3 mm, 3D printed ones can be accurate to 0.1mm, which means they almost do not require any further adjustment.
- The measurement method is easier/accurate than the traditional one and it is more comfortable for the patient.
- Even most complicated braces can be produced in short amount of times.
- It is easy to hide under clothes because they are relatively thinner than traditional ones.
- Patients have a more positive approach to the brace treatment because 3D print technology is able to offer aesthetical and beautiful braces.

brace as "personalized, fashionable and breathable". They managed to produce the brace %75 less material than its predecessor which is Boston brace. (Howarth, 2016) 3D printed brace is still able to apply necessary force even with less material. Bitonti stated that "The first patient to try it on was very happy that she could actually bend from her waist when wearing it, something she had never been able to do before."

It is a known fact that adolescent does not like to wear a brace because

The Brace designed by Bitonti has presented in White house (figure 49) and now its part of the permanent collection in New York City's Cooper Hewitt Smithsonian Design Museum. It is also presented in New York fashion show which is a big sample of showing how spinal braces can be fashionable and can display rather than hiding under clothes.

3.10.2 DYNAMIC MECHANISM SPINAL BRACE



Figure 52 Dynamic spine brace prototype

One of the recent development in spinal brace orthosis is Dynamic Mechanism. The dynamic mechanism is a complex system for spine because unlike ankle or elbow there are multiple joints in the spine. This mechanism provides a constant corrective force on the spine which can adjust the change on the torso while the patient is moving. Technically it allows you certain flexibility while it still able to apply the necessary force to correct the spine. Rigid

braces keep the torso as it is, and it does not allow any movement while in it. However necessary force to correct spine is changing during treatment. Dynamic braces give the opportunity to change the external force acting during treatment.

Major breakdown first made by Columbia University. Columbia Engineering researchers developed first dynamic brace and name it Robotic Spine Exoskeleton (RoSE). Professor Sunil Agrawal from Columbia Engineering stated that RoSE is the first design for scoliosis and kyphosis which able to create forces in all six degrees-of-freedom on spine. (Phys.org, 2018) RoSE consists of three rings which assigned for the different region on the spine. Each ring connected to each other with special modules which allows torso lateral bending, flexion-extension, axial rotation and also it can create 3- point pressure system. This mechanism also has the ability to the characterized stiffness of human torso. In a pilot study run by Columbia Engineering proofed that RoSE is able to determine the stiffness of the torso this by using certain movements. (Phys.org, 2018) The aim in their research was to provide possible movements to the patients without interrupting treatment process because traditional braces are not allowing any movement on the torso. In this project with the help of dynamic mechanism brace can adjust external force during the day.

The work they have done is promising which is why they received \$1 million grant from the National Science Foundation's National Robotics Initiative. At



Figure 53 Dynamic spine brace

the moment structure of brace is quite bulky and it is not suitable for patients, but it is the inspiration for us to develop treatment tools by using today's technological advantages.

Another example of the dynamic brace is proposed by Jamie Haggard (co-founder and CEO of Green Sun Medical) in the National Capital Consortium for Pediatric Device Innovation competition (2017). Their design offers constant check-up by orthotist so with this connection orthotist can know brace is working properly and he can make any necessary adjustment in the distance. The team tested the brace by pressure sensors to be sure mechanism is able to provide enough external force on the spine. As the last step they covered their prototype with soft fabric, so the user would be more comfortable. The aim in the mechanism that not only slowing down the progress but also be able to reverse it. Haggard stated that constant external force on required places actually gives a better chance for correction when it is compared to the rigid braces. The result they achieved was quite satisfying but as the team said they still need to work on both technology and the system. (Metzler, 2017)

3.10.3 DIFFERENT APPROACH IN TREATMENT

In order to increase the effectiveness of treatment and quality of life different kind of approach tested in treatment. 2011 SOSORT Award winner case study showed how different outcome could be if treatment approach change. (Tavernaro, 2011) In this study, researchers created two different teams for patients and two different team patients as well. Each team assigned only one team. The main idea was in one of the treatment team all the professions (physiotherapists orthotist and physician) will have strong collaboration and following the exact same treatment and same regulations. This group called 'TEAM'. In the other team, professions will only have weekly connections

Questionnaire	TEAM NOT	
All professionals as a team (Medical Doctors/Orthotist/Physiotherapists)		
1. Do you work in a multiprofessional team (physician, orthotist and eventually physiotherapist), through continuous exchange of information, team meetings, and verification of braces in front of single patients?	Yes	No
2. Do you give thorough advice and counselling to each single patient and family each time it is needed?	Yes	No
4. Do you check each single brace in team (physician, orthotist, and possibly physiotherapist)?	Yes	No
8. Do you check the brace and patient compliance regularly and reinforce the usefulness of brace treatment to the patient and his/her family?	Yes	No
Physiotherapists		
43. If you are a member of the treating team, have you been trained to face the problems of compliance, and the needs of explanation by the patient or his/her family?	Yes	No
44. If you are not a member of the treating team, do you avoid acting autonomously?	Yes	No

Figure 54 Answers to the SOSORT questionnaire of two different team. (Negrini, 2009a)

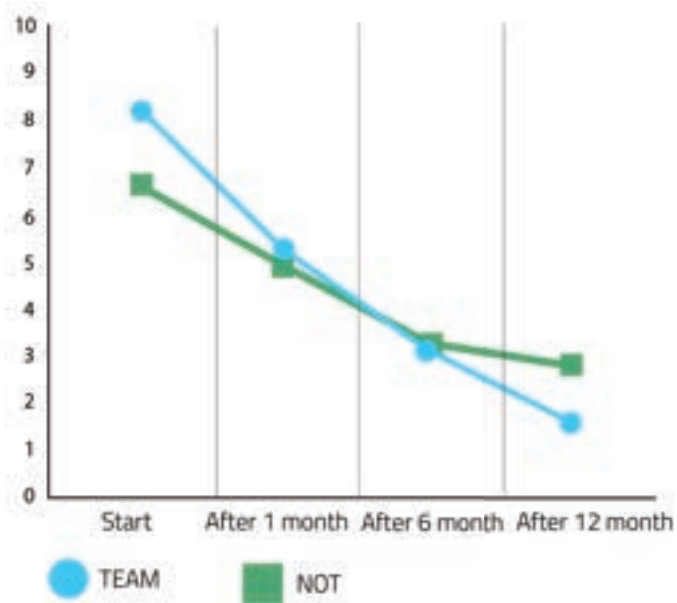


Figure 55 Difficulties with the brace

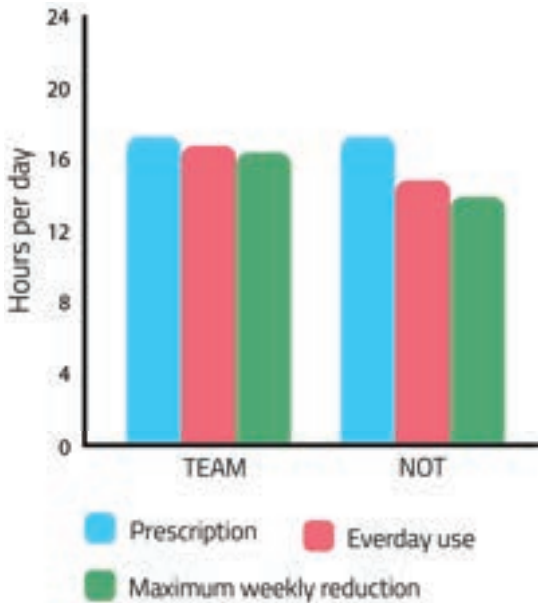


Figure 56 Use of the brace

Wand this group called 'NOT'. In order to understand how both team work, SOSORT few questions from the questionnaire replied by teams presented in figure 55.

Member of 'TEAM' updated each other about treatment process constantly and they assigned the treatment as a group so there was unity in the process. Member of 'NOT' worked as more like traditional way. They worked individually in their specific fields and unless there is something critical in the process they contact with each other on a regular basis. The outcome of this study evaluated by two criteria which are; Quality of life and brace compliance. Quality of life was better in TEAM than NOT with the score of 92% versus 48% and compliance was also better in TEAM with the score of 69% versus 40% according to the SRS-22 questionnaire. During time TEAM managed to control their braces in time but NOT could not adapt their braces like TEAM so at the end TEAM members had a better experience with their brace. (figure 55) Also, in the treatment pain received by patients view showed a significant difference. Pain scored by 55% for NOT, 7% for TEAM which means patients controlled by TEAM had better Quality of Life. This is another reason in differences between compliance. TEAM members almost follow the exact prescript amount while NOT did not. (figure56) In addition to that in absence of well-organized team patient increase, 5.5 times the risk reduced compliance. (Tavernaro, 2011)

In the end, this case study shows how important to maintain the data circulation between patient orthotist and doctor. If the medical team updates each other about the patient treatment process, intervention to the treatment is faster than monthly controls.

3.10.4 THERMOBRACE TREATMENT

As it pointed out in the research, the biggest problem in traditional brace treatment is patient compliance. In order to increase the compliance different developments has

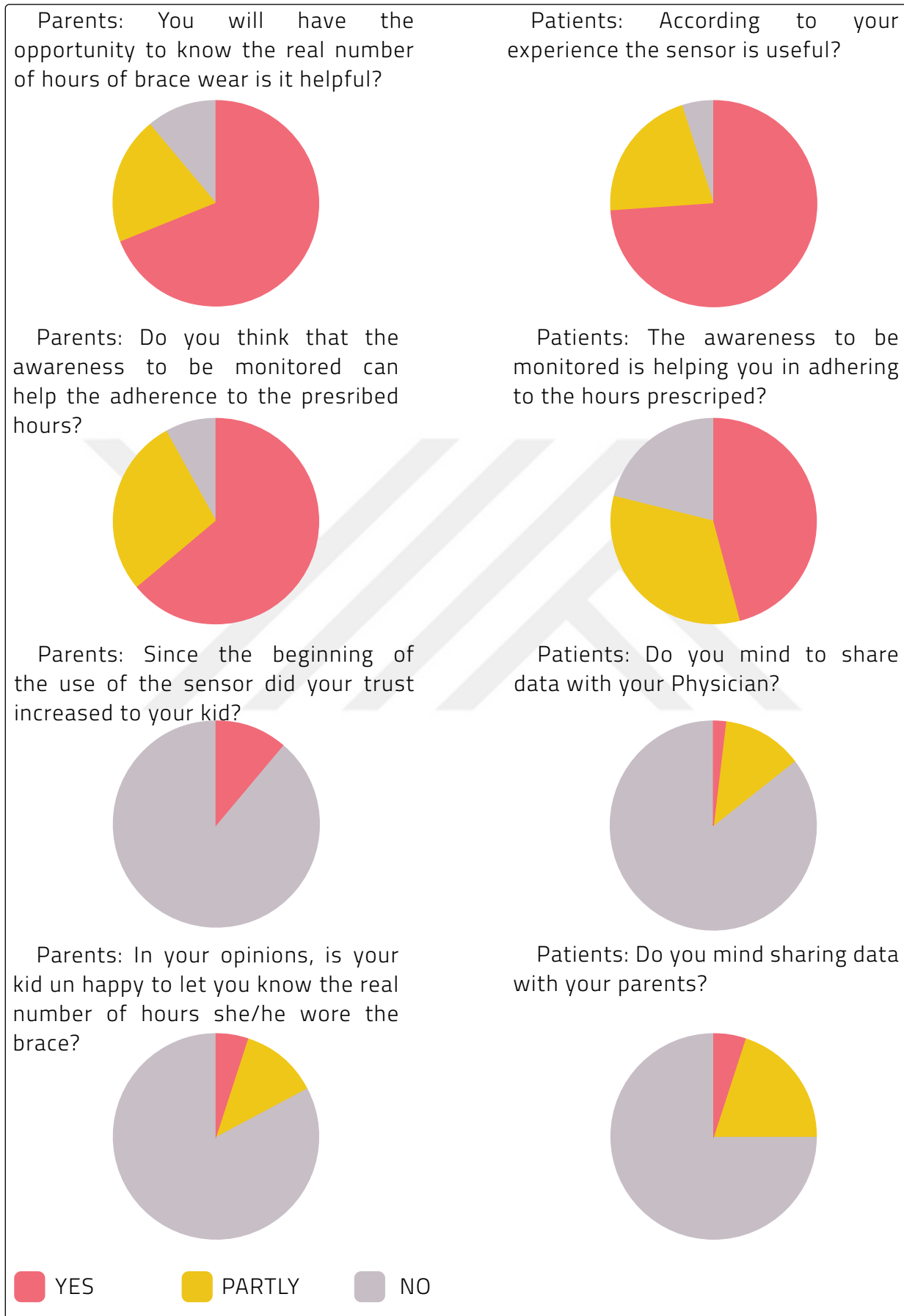


Figure 57 Questions answered by parent and patient about thermobrace (Donzelli, 2017)

been tried. Improving the product itself is one type of solution. Especially since today's technology is involved in our life like never happened before, combining brace with technology is one of the smart solutions to solve the adherence problem.

One of these improvements is using a heat sensor to monitor compliance on the patients. This technology first introduced market by researchers to be able to assess the objective time of compliance, so they can determine whether conservative treatment is effective or not. After using thermobrace, researchers noticed that patients who are aware of monitoring system were more compliant to the treatment than usual. In the research made in 2017 stated that there are 2579 patients who are currently using thermobrace in their treatment. (Donzelli, 2017) Some doctors are strongly advising the device but some of them have a concern about what would patient's psychosocial response to the monitoring. Therefore, in the study, they had the consent of the families and children. Thermobrace collects the data of wear time and sends to doctors, physiotherapist so they will have a chance to evaluate the compliance and keep the treatment in control. (Regular clinic control times are once in every 3 months for physiotherapy, once in every 6months for a doctor) These evaluations are not only leading effectiveness of treatment, but it is also playing an important part for the medical team to detect patient's emotional situation about treatment. When a patient is not following the treatment, as it is referred in this research, there is always another underlying problem behind it so it not just simply non-compliant patient.

Research made by Donzelli and her team proofed when the reasons are explained to both patient and parents, they are willing to use thermobrace in brace treatment and after study, their feedback was quite positive. Figure 57 shows both parents and the patient's response to the process.

Compliance is really important in order to succeed in treatment but even with high compliance, there is a still possibility of surgery. There is only a 70% chance that treatment will work so other 30% still needs a surgery. If the doctor has objective data about patient compliance he can determine early whether treatment is working, or patient needs a surgery because it has been proven that the emotional effects of brace treatment are deeper than surgery. (Danielsson, 2001) This is the most important reason why the doctor needs to know the compliance because if it is unnecessary patient can avoid whole brace treatment process and goes to surgery without spending years in a brace. When the importance of compliance explained to parents and patients they accept the idea of using the thermobrace in a study run by Donzelli and her team. (Donzelli, 2017) Further, they were happy with the results and they stated that they would advise other parents and patients to use thermobrace. Parents claimed that objective measure about wear time helped them to track the treatment because sometimes without noticing patient can spend more time without brace than the permitted amount. Physicians were also satisfied with the study because when they have real data about compliance they are more effective.

This study made with parent permission and during the study, only 6.7% of the patients did not want to be monitored. (Donzelli, 2017) Therefore, we can assume the monitoring system does not pose a problem for users when the efficiency of monitoring explained. Some doctors are suggesting their patient to use a heat sensor so they can follow their patient. It is an individual attempt not part of the treatment process but in near future, it can be part of standard treatment

3.10.5 MOBILE APPLICATION

One of the biggest issues in spinal deformity treatment is late diagnosing. Until certain angle sometimes deformity on the spine is not visible so patients only know that there is a problem when he or she is having back pains. Early diagnose is really important for treatment because as it is mentioned in research brace treatment only works if skeletal maturity is not completed. Therefore, today is it possible to see some applications for smartphones to detect spinal deformities. They are mostly designed for scoliosis because it is the most common type of deformity on the spine, but it is a start. Importance is here raising awareness to the situation because it is a common health problem, 3% of the children suffer spinal deformity.

The deformity is not completely invisible if you know where to look. There are certain techniques you can apply to see if there is anything wrong on your spine. Created applications are trying to give you a direction about what to do in order to see if there is something wrong. In some hospitals, doctors are encouraging the patient's parents to use these tools. (Shiners Hospitals, 2017) Regular screening made by parents can detect deformation in early stage so brace treatment would have more possibility to succeed to stop progression.

One of the application creates the simulation of measurement tool from Adam's bending test and gives you directions on how to use it. Another application asks a certain question and also want you to upload a photo of you from backward and with advanced technology it tries to find deformation through the photo. There are variable of the sample for applications and few of them is already in the app store and it can be download. (SpineScreen and ScolioTrack and Scoliometer)



Figure 58 Screening application for Scoliosis

3.10.6 TECHNOLOGY SUPPORTED STRAP

In traditional braces like Charleston and Boston connection in the brace provided by straps. Straps are carrying important role because if they are not tight enough brace is not able to apply necessary external force. On the other hand, if it is tighter than it should be it creates an uncomfortable position for the patient. Therefore, doctors need to mark the right closure on straps, so the patient can use the brace in the most efficient way, but it is not always easy. Some braces have their straps on the back and

the patient requires someone else's help and if they are alone they are not able to assess the correct tightness.

One of the new development about brace is creating smart strap which can give you feedback about tightness. Wellinks foundation invented smart strap Cinch in 2015. It works exactly same with a regular strap but as an addition, it also provides a monitoring system. In regular straps, doctors need to test the brace and mark the right point on the strap for the user, so the user can close the strap from the same point when he is alone. In Cinch, the doctor saves the data about how tight strap should be so when patients come to the exact point that straps need to be close, the strap starts vibrating. This feedback tells patients that the exact point to fix the strap. Once the strap is close technology inside the strap also provides a monitoring system. Technology in the strap is connected to the application via Bluetooth which both patient and doctor can access. The application shows how tight the straps are and do they need to be pulled more and also wearing time. Doctors can access this data through the web page, so they can be updated about patient compliance and closure of the straps, so the doctor can see the usage of the brace is efficient or patients miss using the brace. Patients are able to follow their compliance through the application and they can share this information with their parents as well.

This idea awarded \$100,000 in YEI Innovation Fund and they launched the first working application in 2017 October but it is still in development phase so the efficiency of straps are not proven yet but it certainly gives more control and data overtreatment for patients when it is compared what it is used to be.



Figure 59 Cinch Smart Strap



4. USERS' POINT OF VIEW

4.1 PATIENTS

Most of the time reaction gave by patients is not believing the treatment. Especially girls are thinking about the possibility of failure and they do not expect that treatment would work so this causes a lack of compliance. (Panagiotis, 2007) In a word, they accept the defeat before even trying. When they accept the treatment, there is a fact that bracing treatment might be a just one phase of the whole treatment. In some cases, brace treatment does not give the result that is desired, so the next step comes after bracing is surgery. Fear of surgery makes patient really nervous and most of the times it is the only persuasion to start brace treatment. In theory best results to avoid surgery comes with the most effective brace but for patient aesthetic concerns is play a big role in patient's decision. As a matter of fact, aesthetic concerns are usually the only criteria for the patient. In most of the cases, patients tend to choose less visible braces under the cloth. Especially in girl patients, it is reported that they are ashamed to undress in front of their friends. Body image has a deeper meaning to adolescent girls than boys which is why the appearance of the brace is a huge effect for them to take a decision about treatment. (Ryszard, 2012) Most of the patients having trouble to deal with the situations when they are in a position that their brace can be seen. Such as changing clothes in front of their friends. They are not comfortable with being in public with their brace, but they are twice much uncomfortable where they need to change clothes in front of others because in that scenario their deformity can be seen clearly. Boys are dealing with this problem better but that does not mean they do not have a problem. One factor for that is their culture of dressing is more suitable to hide brace than girls. Loose t-shirts are what generally prefer to wear with or without a spinal brace. There are only a few situations they are having trouble as in one of the cases studies patient did not want to wear Milwaukee brace because it was preventing his social life. Also, CLTSO braces are nearly impossible to hide when we compare them to TLSO. Therefore the doctor offered him to use TLSO instead. (Miguel, 2007)

Unfortunately, this is not the solution for all cases. Adolescence is a difficult period in a psychological matter already and it comes even harder when teenage feels like he/she is different from his friends. 56% of patients struggle with their social relationships. (ScoliSmart, 2016) During bracing, they are excluding themselves from social events and for later this creates social isolation for the kid. Hereat 43% of children's ending up spending times indoor. (ScoliSmart, 2016) Research that has been made in 2001 observed subjects emotional and psychological reaction. The result of this research shows patients who are following brace treatment are not happy to see themselves in a bathing suit especially in front of their peer. (Danielson, 2001) Also almost half of the patients stated that because of their treatment they limited their contact with the opposite sex. This reaction they gave to the opposite sex has the potential to affect their emotional relationship in the future.

In one of the study, subjects had the freedom to choose the time range to wear the brace and most of the patients preferred to wear the braces either night time or when



Figure 60 Scoliosis T-shirt

they are not in public. They specifically avoid wearing braces in when they are socially active, and fashion is matter. (Siu Ling, 2014) This time preference proofs, they do not want to be seen in public with braces which shows the psychological effect of the brace on the patient. Especially during school hours patients are not happy to wear braces only in few cases subjects did not have a problem with a brace in school but their explanation for was their uniform is able to hide brace well. (Nicholson, 2003) As we can understand from this statement the primary concern for the patient is his appearance. As long as they are able to hide the brace their more open the idea of wearing a brace and obedient with their wearing schedule.

Concern about appearance creates two types of the outcome on patients. Most common one is trying to cover of the brace, so no one would notice it. These kinds of information are not something that patient can receive from her doctor or orthotist, so internet comes to help. Former or current patients are giving tips about brace such as best skin products that can be used. One of the web pages I found is designed to give fashion advice for teenagers, like what are the best clothes to hide your brace. (Kathryn, 2016) Furthermore, there are specially designed t-shirts for people with scoliosis. (Strut for Scoliosis, 2018) Personal bloggers sharing their experience of treatment and gives advice to parents or the patients. One of the examples; scoliosis patient Sophie was suffering from brace treatment and her mom was expressing how stressful she was because she was not able to hide the brace under clothes. However, after she attends one of the events prepared for people with spinal braces she had more knowledge about fashion for a spinal brace which make her more confident get in public in her daily life. (Radsken, 2015)

National Scoliosis Foundation is one of the biggest platforms where patients and their parents meet. It is a Boston USA based non-profit organization which helps both children and their parents about spinal deformities by providing a platform where members can share their experience and knowledge. This is very important because the primary emotional support they need is knowledge of they are not alone. In this blog, you can reach personal opinions about specific treatment, advice to patients or the parents and get any kind of information from people who already experienced the situation.

Another approach to bracing treatment by the patient is, trying to embrace the brace. Like what they do with their daily clothes they are decorating their braces with colors and stickers. Sometimes patients can assign a pattern on the brace that can be placed by orthotist. Most of the patients are preferring to customize their brace on their own. Many examples can be found on the internet like scoliosis patient Blakely shows how she colors and customize her braces during her treatment on YouTube. (Blakely, 2017) There are many stories on Youtube shared by former patients and patients they are still under treatment. Patients using these kinds of platforms to give advice to others who

are experiencing the same problems. The benefit of these platforms is you can actually learn so much about treatment processes than a doctor cannot provide you because even though the doctor knows every technical detail he does not information which comes from experience.

Another way to make the brace prettier is 3d printed braces. The only difference is these modifications are more effective and done by professionals. As it is mentioned before 3d printing promises a huge deal in the aesthetic matter. Due to their aesthetical appearance, patients are actually willing to use without concerning about hiding it. (Dara, 2014) According to Stanford medical doctor James Policy, once the children in hospital saw the 3d printed braces, they all wanted to have one. He said that he never seen children respond brace so positively. UK based company Andiamo is another institution who work on 3d printed braces. Even though it is a small startup, they are still receiving



Figure 61 Gathering organized by Curvy Girls

lots of preorder about their 3d brace design. Since 3d printed braces are not completely on the market there are not so many first-hand experiences we can benefit from but even in this stage it still attracts attention from patients which at very least it more than we can say about traditional spinal braces. Patients have more positive approaches to the brace treatment when the 3d print brace is offered for treatment rather than traditional ones.

Besides using an aesthetically better spinal brace, patients react better to treatment when they see their peers also getting through the same problem. Therefore, their only concern is not only making the brace prettier or how to hide but they are also eager to meet with others who are suffering from the same problem, so they can understand each other. As it is referred before social media gives great opportunity not just for

sharing information but also creating a community with the people like themselves. CurvyGirlsScoliosis web page founded in 2006 with this purpose. There are hundreds of girls are currently a member of the page from all over the world. On their website, you have the opportunity to reach other members and they are constantly organizing events, so you can join one of the gatherings and meet with others. One of the events they had was fashion show in Philadelphia to encourage other people to embrace their braces and not to be ashamed to go in public.

Founder of Curvy Girls Leah was a former scoliosis patient and she explains her purpose to create Curvy girls' platform was that she simply wanted to meet with other people who are also suffering from the same condition. She was feeling alone and different which is a common problem among patients. (Curvy Girls, 2006) These kinds of support groups mentally help patients who are in the brace treatment process. Another example of support groups could be the pages on facebook. Scoliosis Warriors is one of the popular pages which has over 33,000 members currently. They are sharing their individual story to inspire other or you can see people who are looking for emotional support such as just stating how upset they are and sharing their emotions with others.

4.2 DOCTORS

Influence of the doctor is essential. The patient is the one who needs to be cured but there are lots of other factors surrenders him/her which effect his judgment about the process. Adolescents are usually stressed because of bracing and most of the times their first instinct is to ask the question 'What if it does not work?'. Even though there is a possibility that they might need surgery afterward, they need to be convinced that this is the best treatment she or he can receive at the moment because once patients having doubts about the effectiveness of brace, this influence compliance negatively. As we refer before compliance is one of the key points for treatment to work.

In some cases, doctor's approach to the patient only reason bracing treatment is working. Conservative treatment creates social isolation, depression, and effect of these emotions can lead to psychological issues for the patient. Therefore, brace treatment is considered as an important risk factor, discomfort and huge impact of quality of life. (Ryszard, 2012) While the doctor tries to heal the spine they need to be aware they are not causing new problems. As it is mentioned before in one of the case studies made by Miguel Gomez, the doctor felt the necessity to change the type of brace because of his patient socially active life. Therefore, he made a fair judgment and instead of forcing the patient to wear the most efficient brace, he chose to suggest something less effective brace but not impact patients' quality of life. (Miguel, 2007) In this case, the doctor prescribed TLSO brace instead of Milwaukee as a result patient agreed to follow treatment because not only being socially active was the problem but how he appears was a factor for the patient.

Another approach is using a track system. Tracking system invented for the need to measure the compliance with objective data. This system first used in clinical trials and case studies but later doctors who attend these trials noticed how effective monitoring is. It is not only because they have data they can rely on but also patients are more careful with compliance when they know that they are being monitored. (Scoliosis &

Spine, 2016) Therefore, some doctors are started to use this tracing system. First, they are explaining its benefit to the treatment and once the patient and his parent gave consent they are starting to use this monitoring device. These devices are really effective because as we refer before not all brace treatments are a success. Even though there is a better chance if the patient follows bracing he will not need a surgery, sometimes some deformities are not capable to reverse. If the doctor can see bracing is not working even with compliance he can intervene the processes sooner so the patient would not need to spend years on treatment that it will not work. These devices are cheap, really small and easy to attach. Some doctors are individually advising to use a heat sensor to their patient such as Sabrina Donzelli (Specialist in Physical and Rehabilitation Medicine) stated in researchgate that she is using temperature sensor since 2010 and she thinks it is really useful. (Donzelli, 2014)



Figure 62 Daily life in Risser cast brace

In some of the treatment process patients and their parents were aware of the monitoring from the beginning and no complaint recorded about monitoring by research. In fact, end of the study short questionnaire presented to patients and their family and they said they would recommend monitoring system to others. (Donzelli, 2017)

On the contrary not in all cases outcome from patients' side is promising. Unfortunately, most of the time while doctors treating spinal deformities they are causing psychological one. Brace treatment has a considerably more psychological effect than other treatments. Several researchers made by experts prove compliance is directly related with the psychological reaction of the patient. (Panagiotis, 2007) However most doctors are focusing on the result, so they are not aware of the psychological situation that develops during treatment. In one of the observations I made in Fondazione Don Gnocchi Milano, the doctor was aware of the problem compliance and his solution to this problem was making Risser cast braces for the patient but instead of plaster bandage, they were using fiberglass bandage. Therefore, the patient was not able to take the brace of three to four months even in the shower. After three months patient comes to the hospital, checked her spine and they build a new brace on her body. This method can be repeated up to four times. From doctor perception, he guaranteed the compliance because the patient does not have any way to take the brace off. However, it is a clear fact this creates a huge obstacle in daily life. The patient loses the opportunity of few hour freedom to take shower, sleep or just relax. This method lowers the life quality drastically.

Doctors role for the effectiveness of brace is essential. Questionnaire made by S.Skevington and Z. Juczynski showed that patients who have attached with the doctor also on an emotional level, not a just patient-doctor relationship, are more willing to follow doctors order. (Juczyński, 2001) The trust doctor builds, gives the patient the idea they can impact on their lives and this gives patient will to go on with treatment. Which is why the doctor needs to be able to create healthy communication with the patient. In case of Dr. Jaren Riley who works in Denver/Colorado as orthopedic surgeon wore full-time Boston brace for a week in order to understand his patients. After this trial, Riley stated that now he understands the tears of the patients. (CBS, 2017) This experiment provides some insight about treatment to the doctor which most of the doctors does not have one. After the bracing experience, Riley noticed how uncomfortable the treatment is so now he is aiming to create a better brace which will not affect the patient's Quality of Life as traditional ones.

4.3 PARENTS

Coming to terms with wearing a brace is challenging not only for the patient part but also for patients' parent too. In order to proceed productive treatment period, treatment method needs to be accepted also by parents and the patient. It is important that both the patient and parents have an idea about a treatment plan which will give them little control over the process. Since these deformities mostly occur in young ages such as 8 or 10 years old, the patient will more likely to listen to his or her parents.

In most of the cases, parents are being too emotional when they heard about the treatment process. Their first reaction is mostly denial and trying to find an explanation for why it happens. (Ryszard, 2012) After initial shock parents are starting to worry about their children and like doctors they choose the most efficient brace to prevent surgery. Their over-protective reaction is part of being a parent but in the outcome, children feel a bit pressure on them. Especially in the beginning of the treatment parents are making decisions for their kids. (Donnelly, 2004) In one case study parents stated that they did not even ask their daughter what she thinks about the brace because it was a necessity. (Donnelly, 2004) Also in the same research parents expressed how frustrating the whole treatment process. Even though kid knows brace is the right thing to do at the moment, she still does not want to wear it and at that point parents being aggressive. According to survey parents said that in many times there were tears in their argument. (Donnelly, 2004) Parents situation is especially hard in the treatment process because like doctors they know what is necessary for their kid to be better but because of their emotional connection, they are overreacting and sometimes being pushy.

Parents are the one who gets the all the information about treatment and decides what is going to be done so when there is inconsistency in information given they are frustrating. Especially opinion differences between orthotist and doctor. One parent stated that doctor was not hopeful that brace will work, doctor's idea was there is a big chance that it will end up with surgery but when you go to the orthotist they are saying 98% success rate which is too optimistic. (Donnelly, 2004) When parents receive such a different perspective from both professions they feel insecure about treatment.

It has been proven that brace treatment has an emotional effect on the patient, but

it is logical to assume that it also has emotional effects on parents as well since they are experiencing every step with their kid. Parents also feel the need of support and community during treatment. Therefore, it is suggested that along with the patients' families also need to get psychological support through the whole treatment process. (Bridwell,2000) In most of the times, parents are the ones who are forcing or convincing their child to wear a brace, but they also feel for them which puts them in a really difficult position. Knowing that your child is suffering at the moment because of the treatment only because of the possibility of preventing suffers more in the future and end up with surgery. This dilemma prompt parents look for a help. Purpose of supporting each other there are many websites on the internet. They are mostly founded as a support group but as it is referred before since parents are the decision maker they are the one more actively look for a help on social media.

National Scoliosis Foundation forum even has a section of Parents&Family Members. In this section, parents are asking a question about treatment, brace or just emotional support. Parents are actively following recent developments and sharing their experience with each other. The forum is full of topics opened by parents and some users in their profile sharing the information of their kid's condition. Such as user named Jillw shares the info of her daughter; Diagnosed at age of 12 and started to brace treatment with Spinecor which lasted for four years. In the process curve slightly decreased Later they switched Providence brace which it kept the curve as it is and currently her daughter in Boston brace. (NationalScoliosisForum) On the website, most of the users registered as someone's mom or dad. Parents are more involved in the process than their kids because these deformities appear in really young ages and since the diagnosed person is their kids they are being over-protective.

Scientifically proved that psychological support during treatment has a positive impact to process. (Ryszard, 2012) Parents definitely require some kind of emotional support which is why they are trying to create their own community. Sometimes they are willingly applying for psychological support because they are sensing that putting the brace on the kid is not enough. However, these are all individual attempts of parents, not provided service by the hospital.



5. RESULTS

5.1 OUTCOME OF RESULTS AND RESEARCH

The results from the research showed the success of conservative spine treatment is not only affected by design of brace but also affected by treatment approach itself. The biggest reason for failure in conservative treatment, it is not the design of the brace but how the treatment managed by professions. Management issue creates a compliance problem which means does not matter how well designed the brace is it will not give the desired outcome.

Importance of compliance in conservative treatment did not understand for a while. This attitude explains the fact until 2005 most trials in case studies did not include drop-outs or non-compliant patients. Therefore, while research focuses on the effectiveness of brace they missed the point no matter how effective the brace is it will not work if the patient is not wearing it. The international Scientific Society on Scoliosis Orthopedic and Rehabilitation Treatment (SOSORT) released the criteria of 'Intention-to-treat concept' in 2005. Now all patients who are started clinical trial whether they are drop-out or non-compliant had to be included in results. Researches have shown the importance of compliance after they started applying SOSORT new criteria because in some trials a considerable number of subjects were dropping the brace treatment but since they were excluded from result they never really draw attention.

Research showed that there are different types of approaches for treatment. It should be highlighted that brace treatment is a teamwork which means there are different professions are involved in the process. Subjects generally do not seek help. This needs to detect by experts which this can be done if the professions are synchronized well.

- Physician/Doctor
- Orthotist
- Physiotherapist

Professions above are the ones who are included to process. There is no protocol standardization between professions yet, depending on the doctor and the hospital approach to the patient is changing. The issue is data circulation between professions. When it comes to assigning the most efficient brace to the patient, communication between orthotist and doctor is essential. In most cases after a doctor diagnosed the patient, he refers the patient to orthotist. After orthotist taken care of his part, physiotherapist starts to meet with the patient once in every two weeks. The problem in this order that lack of communication between professions prevents them to follow the progress of the patient. The doctor only meets with the patient once every three months to see the progression. In most cases after brace is done orthotist is not part of process and physiotherapist only help the patient with the exercises. Even if the physiotherapist would have some kind of feedback he does not have a connection with the doctor to share opinions or the orthotist. As a result, these individual professions tell their concern about treatment to the patient such as 'I believe another type of brace

would be more effective for you' or 'It seems like bracing is not giving result'. If a patient sees disagreements about treatment between professions he will lose his faith in the treatment which affects the compliance and he might even stop wearing the brace. As it is pointed out before in research made in 2009 by SOSORT showed how much data circulation can affect the outcome. (Negrini, 2009a) Professions who are updated about patient progress and each other's process, are more in control of treatment. This data circulation gives better results at the end.

According to patient's perception about treatment, these professions might not be enough. Clinical researches proofed that brace treatment has a more serious psychological effect than physical. (Danielsson, 2001) In some researches, the importance of psychological support has been taken into consideration so as addition to the treatment they include psychological sessions. (Katarzyna, 2011) As conclusion researchers believe when they are able to motivate the patient and the family, treatment is more effective. The reason for that, when patient psychologically motivated to follow treatment, compliance is increasing. The help of this information and with patients review, it would be a good approach to have a psychiatrist in treatment. In some cases, and it can be seen how emotionally loaded the treatment is for the patient and his parents. Parents are feeling desperate because they cannot help their children, or they do not know how to help their children. Beginning of treatment is especially challenging. In this period both the patient's and parents' stress level are higher. This emotional load is too much to endure by patient and family itself only. Participation from their support networks, such as friends and psychiatrist can provide the psychological support patient need.

Another outcome obtained from research is that patients have a more positive approach to conservative treatment when they know other patients like them. Brace treatment causes isolation from social life because the patient is not able to participate in daily activities as used to be. Therefore, when he meets with his peers who are also following conservative treatment, he knows that he is not alone. Feeling of isolation is also another reason for non-compliance. This isolation feeling inspiring patient to create community through social media. Facebook, YouTube, and some personal blogs are the most common type. Through these platform patients helping each other about the treatment process. There are daily life details that no one can understand other people who are following the brace treatment. This is the point where no professions can help so patients are trying to create their own community in order to give advice and learn some tricks such as what kind of clothes would hide brace better.

When all the data is gathered in this research, it shows patient preferences for brace treatment is mostly night braces or half time. In figure 63 shows when patients have the freedom to the time period for brace wearing time, they are more willing to wear brace night rather than day. (Panagiotis, 2007). Another fact that studies showed, longer the prescribed time for brace treatment less obedient the patient becomes. After one-year observation, LouAnn Rivett and her team discovered patients who were obligated to wear brace 10h showed higher compliance than the ones who were obligated to wear a brace for 17h. (LouAnn, 2009) Majority of patients are preferring to wear braces either night time but not with friends or in school. (Panagiotis, 2007) A common complaint about treatment is their appearance during bracing which is the reason why patients are preferring night time or half-time braces. Appearance is the biggest issue which affects

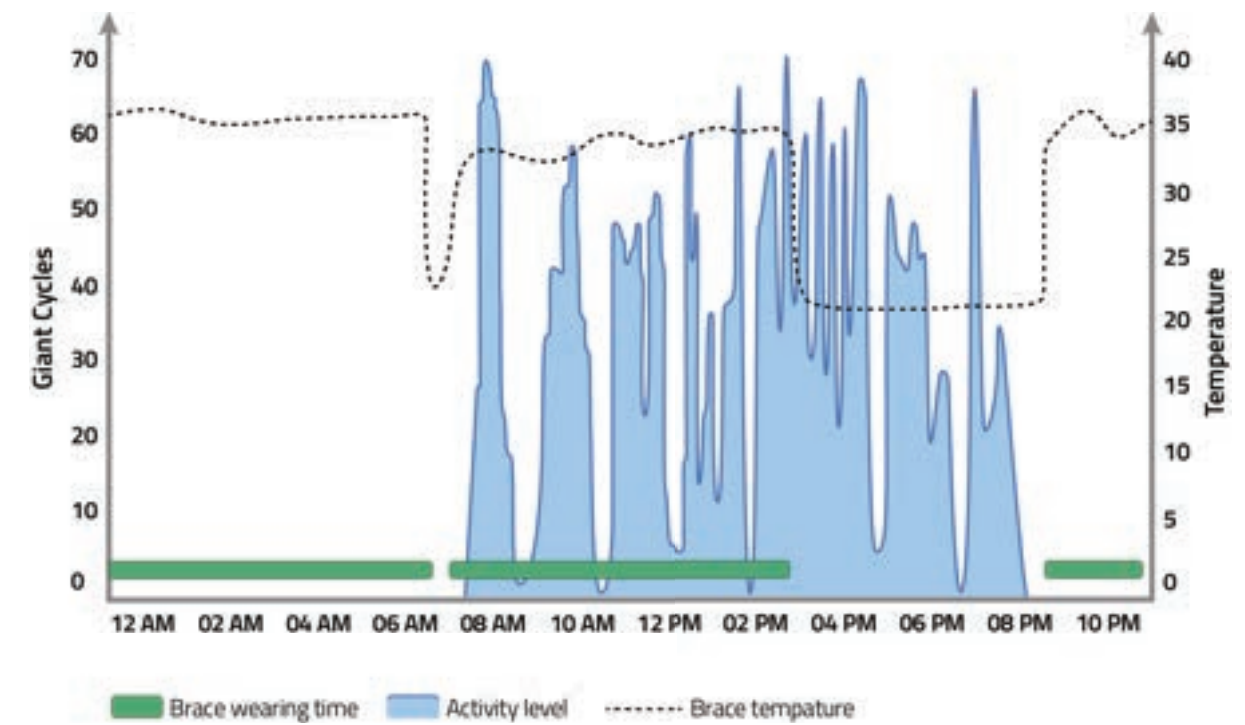


Figure 63 Brace wear time during day

many other emotional situations in the patient and it is more important when it comes to the female patients. In the results that have been provided by many kinds of research showed that most of the patients who wear braces are girls. (Ryszard, 2012) Therefore, their spinal deformity is creating deeper emotional damage besides the physical one. The patient needs to treat by brace but in the meantime, it needs to appear in a certain aesthetic also emotionally needs to be supported so patient compliant will not be an issue. Among the girl patients, most common reaction to the brace was complaining about how brace looks even without trying it. Therefore, patient's compliance is changing depending on brace type she needs to wear. Patients are most likely to wear flexible or semi-flexible braces when it is compared to rigid braces. Both types of braces have different complaints. Rigid braces mostly founded uncomfortable because of the heat problem. Patients are sweating in braces and there is no way to clean it without interrupting the treatment process. On the other hand, for flexible braces, the most complained problem was a toilet. When patients were in the bathroom, releasing them self from brace was taking too much effort. (Negrini, 2015) However, the difference in compliance comes from brace's potential to be seen underdress. Flexible braces are given better results in appearance because the material has been used is not thick as in rigid brace. In case of the rigid brace, there are two different type of construction. First one fits the body perfectly so in appearance it does not create tilting. On the other hand, some rigid braces are creating visible tilting such as Cheneau brace because it is using over-correction force, so they cannot be hidden even with loose clothes.

Compliance rate has been shown in figure 64 based on users' feedbacks and clinical trials. Compliance is directly proportional with Quality of life. If the patient able to maintain his or her daily life as normal as possible, he/she is more willing to follow treatment. SpineCor gives the highest compliance because of its flexibility but it is not as effective as rigid ones in doctors' criteria. Therefore, even with high compliance doctors

	Compliance of patient	Quality of Life	Cost
	● ● ● ● ●	● ● ● ● ●	\$5.800-6.800
	● ● ● ● ●	● ● ● ● ●	\$2.500
	● ● ● ● ●	● ● ● ● ●	\$5.000
	● ● ● ● ●	● ● ● ● ●	\$6.000
	● ● ● ● ●	● ● ● ● ●	\$4.000-5.000
	● ● ● ● ●	● ● ● ● ●	\$4.000-5.000
	● ● ● ● ●	● ● ● ● ●	\$4.000

● ● ● ● ● Good ● ● ● ● ● Bad

Figure 64 Compliance, QoL and Cost comparison between braces

are not prefer to prescript SpineCor as a brace. (figure 65) On the other hand, Boston brace also has high compliance because tubular shape the brace has made easier to hide under clothes. It is not flexible, so it has more impact on Quality of life than SpineCor but every rigid brace has a certain impact on QoL because of their working mechanism. Patients first preference about brace depending on how long he needs to wear and how the brace itself appear (less medical). Patients are more willing to wear braces which appears less medical. Lyon and Boston brace both are fit body perfect, so they are not visible under clothes but the appearance of Lyon brace with metal structure and screws seems less friendly for the user. Therefore, patient preference is higher for the Boston brace. (figure 65) As it can be seen on the chart patients are more willing to wear Boston and SpineCor or they are preferring to wear night braces like Providence and Charleston. Differences between preferences of patients and doctors come from their priority. Doctors are usually working result-oriented. Their aim to assign most effective treatment and the brace while patients' priority is more emotionally loaded. The gap in this process when the emotional situation of the patient is ignored by the doctor, drop-outs, and non-compliant cases are showing up. The patient's first concern is how will they look in the brace and how this will affect their social life. Since adolescents are the ones follow conservative treatment, taking responsibility is not their strong suit so their perception of treatment might completely different from their parents and their doctors. In the figure 65 Preference differences between patient and doctors can be

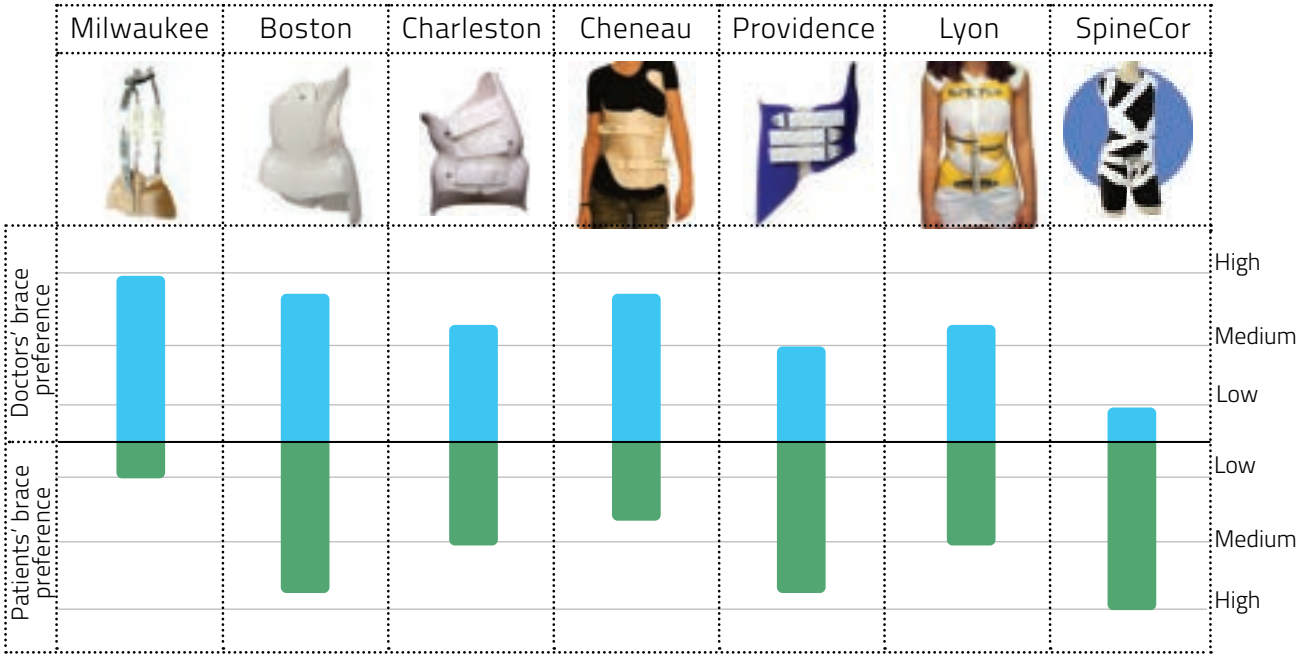


Figure 65 Preference differences between doctors and patients

seen. Doctors are more willing to assess the full time bracing because the success rate is higher but in most cases patients the first question is how long he needs to wear the brace. While doctors are choosing the most effective one, patients are choosing they are more comfortable. The same reason applies in flexible brace too because applied force is not as strong in rigid brace doctors are not preferring to use even though flexible braces have higher compliance than usual.

Patients feedbacks collected during research and few criteria which are important for

the patient is listed in figure 66. In the chart, it can be seen how these criteria match with the braces. Lighter component and less visibility are the common requirements as it is mentioned before but there are some other details which are important as much as weight and visibility. 'Window Opening' present the small windows on the brace to make the brace more light and breathable. In patients' case, these windows give access to their torso because even though patient wear t-shirt under brace because of sweating brace makes the patient itchy and if there is no access to body patient either has to suffer a whole day or he\she needs to take it off every time. 'Less hip Coverage' means less trunk support in another word. If brace covers hip that means when the patient leans, there will be a bump on the back. This coverage also prevents patient to sit but erect sitting.

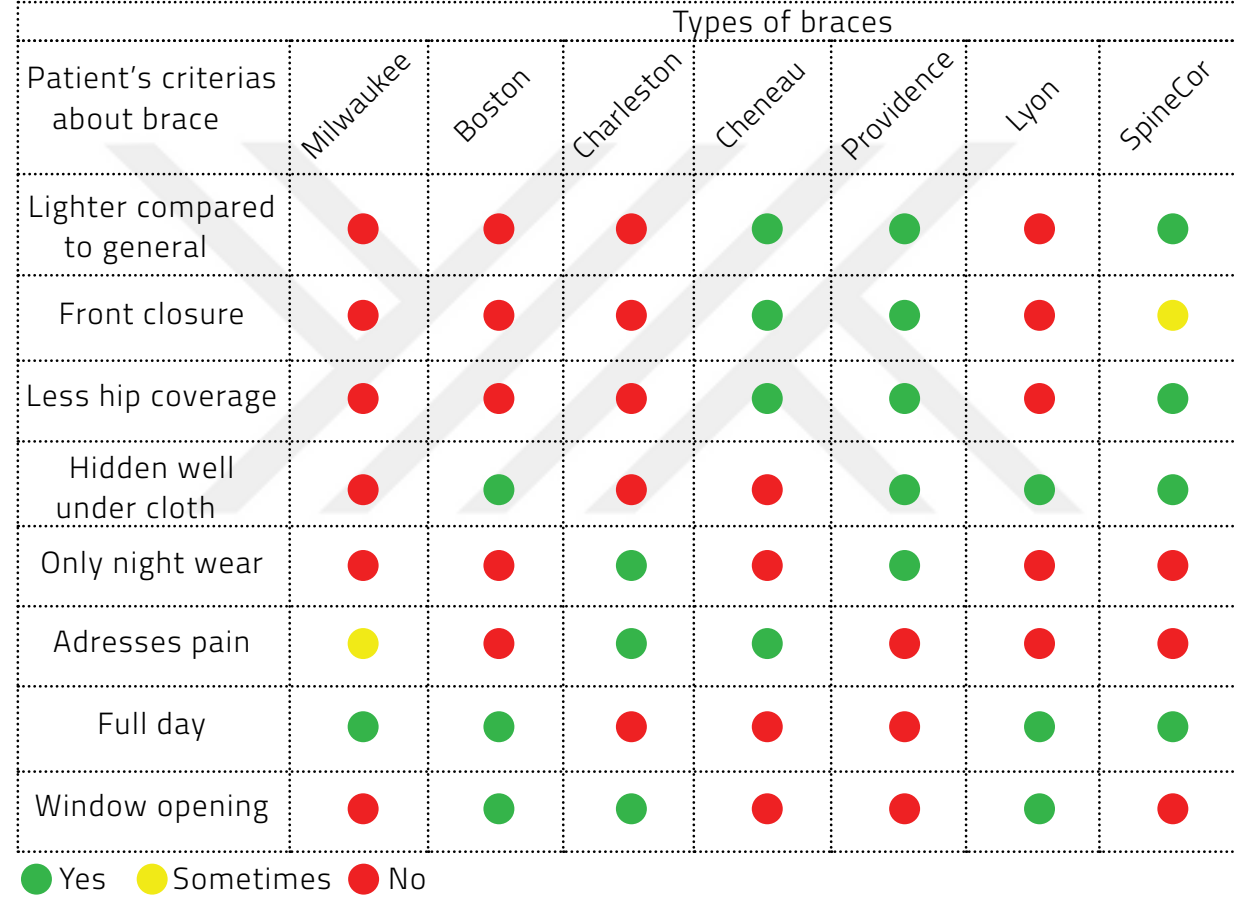


Figure 66 Patients' criterias to choose brace

On the appearance criteria of the brace with new technologies new solutions coming to the light. One of the new approaches 3D printed brace is quite game changer in compliance issue. There is not enough clinical trial data, but the beginning is promising. Even though it is a rigid brace, it is lighter than traditional rigid braces because of the advantage of production method makes possible to produce the brace with less material. Also, since there is very little production obstacle in a 3D printer, variety in brace design has potential to increase. First reactions of the patients to the 3D-printed brace is quite different than usual. It seems patients are more willing to persuade the treatment with a brace. It is not because advantages of technical features but it because aesthetically 3D-printed braces sweep the bulky appearance and make the product more elegant.

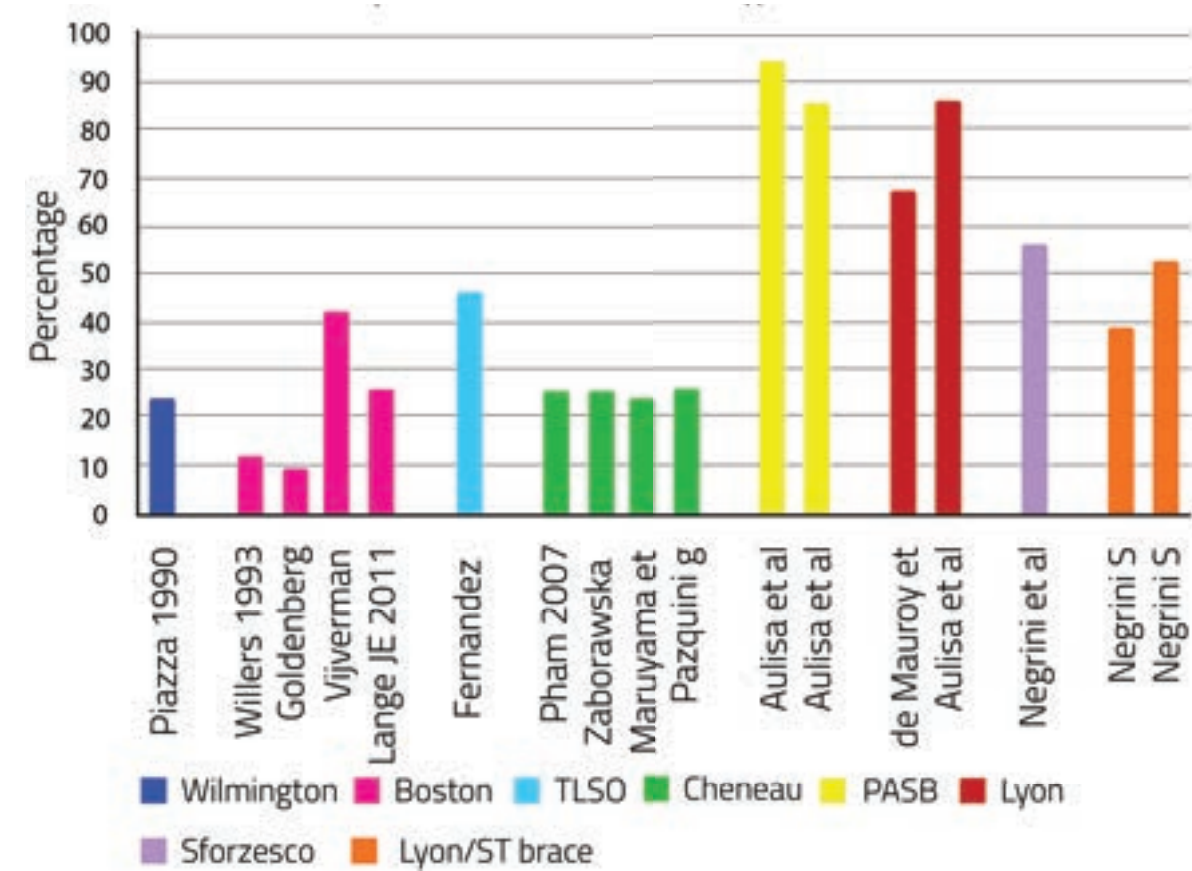


Figure 67 The improvement rates between different types of braces (from 1990 to 2016).

Making product elegant is really important to convince patient to start to treatment with a 3D printed brace, it will be easier to suggest conservative treatment to the patient. On the other hand, the elegance of brace seems only working for the acceptance stage of treatment so patient still wants to have the option to hide the brace under clothes.

Another result provided from research that technology can be used to increase the compliance. A monitoring system which is invented to assess the objective time of brace wearing can be used to encourage patients to follow treatment. Some doctors have discovered this positive effect of monitoring and they are persuading their patients to use. However, these are individual attempts made by doctors so there is no protocol for it.

As last standardization for the concept of 'success' for brace treatment defined by SRS in 2005 which is less than 5° progression is considered a success. Lack of standardization in protocol prevents researchers to create detailed comparison chart between braces. Between 1990-2016 chart has been created to see just the overall differences in effectiveness in a brace. (figure 67) Some of the presented works have been done before SRS criteria so results are not completely compatible. One of the main reason for the difference in outcome is the purpose of use. Boston brace in best scenario aims to stop the progression but surgery is still an option for later if it is required. However European braces (Lyon, Pasp, and Sforzesco) are aiming to stop and possibly reverse the progression so at the end treatment outcome might be better because they are aiming to stop surgery completely. This chart also shows which brace is widely used in clinical trials and case studies. Boston brace and Cheneau brace are one of the most common ones which took place in lots of clinical trials, unlike Sforzesco.

5.2 GUIDELINE FOR NEW PRODUCT/SYSTEM

From the research works, it is clear that effective and well-designed spinal brace does not only require a device which meets with all the technical aspects to treat the spine, it also requires well-designed service to provide emotional support to the patient. The biggest problem is compliance; the user is not willing to wear the brace. In order to create an effective product, we need to understand every person who is involved in the process. Patient as a primary user, parents, doctors, and orthotist.

Presented research showed that users' primary concern is how he/she will appear during treatment. Patients do not want to be different from their peers which are the main reason for them to not wearing the brace. Another concern they have is how brace will affect their daily life. Comfort is an important factor. If the patient comfortable with the brace both emotionally and physically, he/she is more willing to follow treatment. In order to provide this comfort, improvements cannot be done only on a brace itself. The patient needs an emotional support during treatment, the knowledge of 'I am not alone'. Research has shown patients are more compliant with the treatment when they know other patients like them to share their experience. It is important for the patient to get in touch with the people who already have experience and asking them questions about treatment. This is an important point because doctors and orthotists are not able to answer these types of questions since they do not have practical use experience.

Another important detail is understanding patient's engagement with the brace. It is more than a medical device for the patient, there is an emotional investment. Therefore, customization is important for the user not just because make it prettier but creating a sense of belonging.

Parents are also part of the process because in most cases patients' age to start treatment is between 7 to 14. Since patients are quite young, parents are playing important role in treatment as a decision maker. Therefore, as in the patient, parents are requiring emotional support. In the research, we analyze the social groups, communities for spinal deformities and the majority of the members consist of parents who are looking for advice or some kind of help for their children.

Another issue, as it is pointed out before is the appearance of the brace. Patients' only concern about appearance is not being seen. Since they need to wear the spinal brace from 10 to 23h every day they do not want to wear something medical. Customization of the brace helps the patient to connect with the treatment. In recent years 3D printed technology seems the best manufacturing technique to make personal braces. Spinal braces need to be personal to be able to work but the 3d printer has the potential to offer more than just imitating torso. It can offer special patterns and colors. Making brace more fashionable makes easier to convince patient to start brace treatment. Afterward, with social support, continuity of treatment can be achieved.

On the other side of the treatment is the professional team which is doctor, orthotist, and physiotherapist. These individual professions focus on their field and most of the time they do not have an active communication between them about the patient. In order to increase the efficiency of treatment, these professions need to be updated regularly so they would have up-to-date information. Also, the medical staff is mostly working result-oriented. They need to understand patients' emotional situation and

choose the treatment accordingly. If the patient is not willing to wear the brace doctor needs to find a balance between what the patient wants and what the patient needs. Therefore, rather than assigning a full-time brace that the patient is not going to wear, assigning the brace for a shorter amount of time could be one approach.

The suggested design solution to increase compliance is;

As a first step patient should be willing to wear the brace and best way to do this **providing 3d printed customized brace**. 3D printed braces have less 'medical device' appearance which makes the patient more positive about brace treatment. However, this positive attitude does not keep long. After patient starts to treatment he/she needs to be emotionally supported and persuaded to continue treatment.

The second step is providing emotional support. To do that brace will also have integrated heat sensor to monitor the wearing time. This sensor will daily upload the compliance data to the server. This server will be divided into two platforms; Application for patients and their parents which will provide **Social support**, the Professional platform for medical staff which will provide **Medical support**.

SOCIAL SUPPORT;

Tracking personal progression; Progression on the curve is not visible in first six months so if patient can see the progress in virtual platform he can be motivated to proceed the treatment

Platform where patient can share his experience or learn from others; There are lots of things need to know about wearing brace – not only technical use but which kind of clothes patient can choose to hide the brace or what kind of skin product can be use while they are wearing the brace. These kinds of information come with the experience which is something doctors cannot provide so creating platform where patients can get in contact and share their knowledge with each other would help them in the progress.

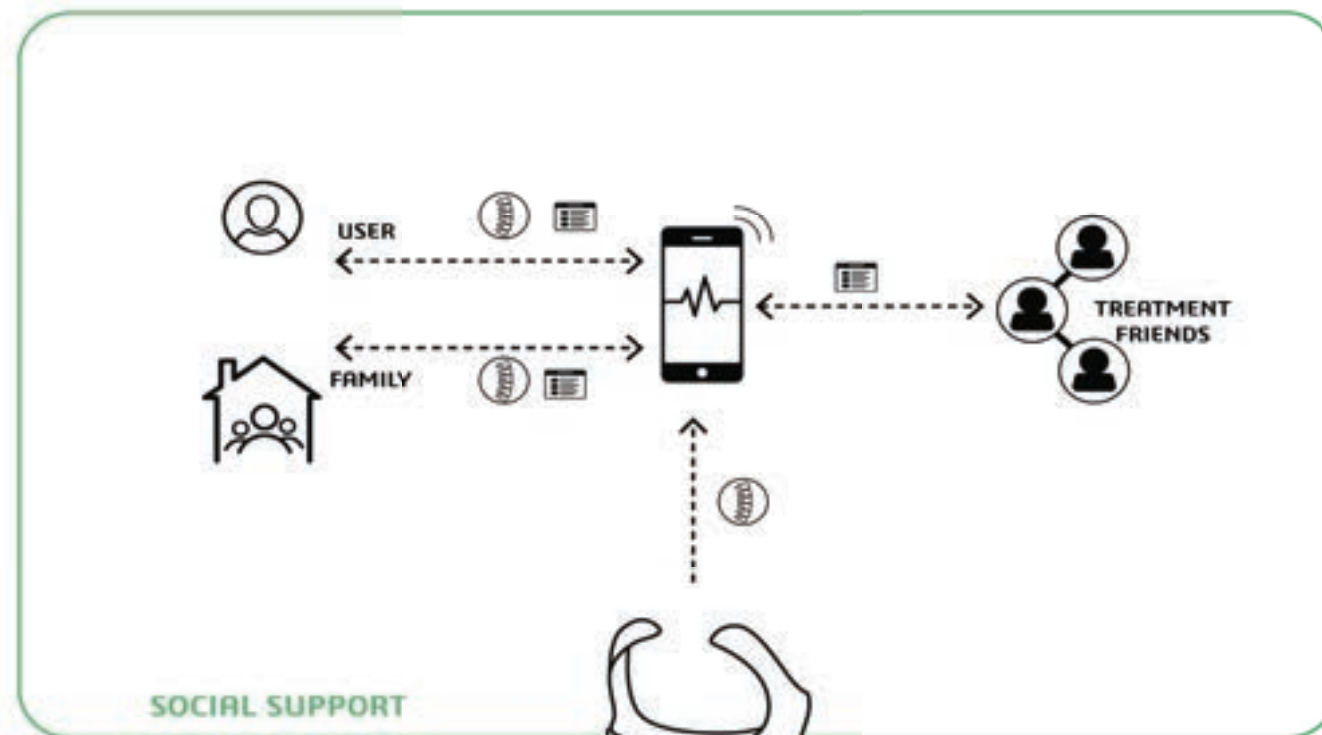
Platform where patient can meet with his or her peers; Patients are already trying to create community through social media (Facebook, Youtube, etc.) More solid platform can be introduced to them through monitoring device so whole treatment process can be integrated to each other

Sharing/updating the family; If families are able to see their children progression or compliance to the treatment they can be more supportive but more than that families are also part of progress and they also need a support. Meeting with more experienced parents and take advice from them could help them and it would wake more awareness about their children.

MEDICAL SUPPORT;

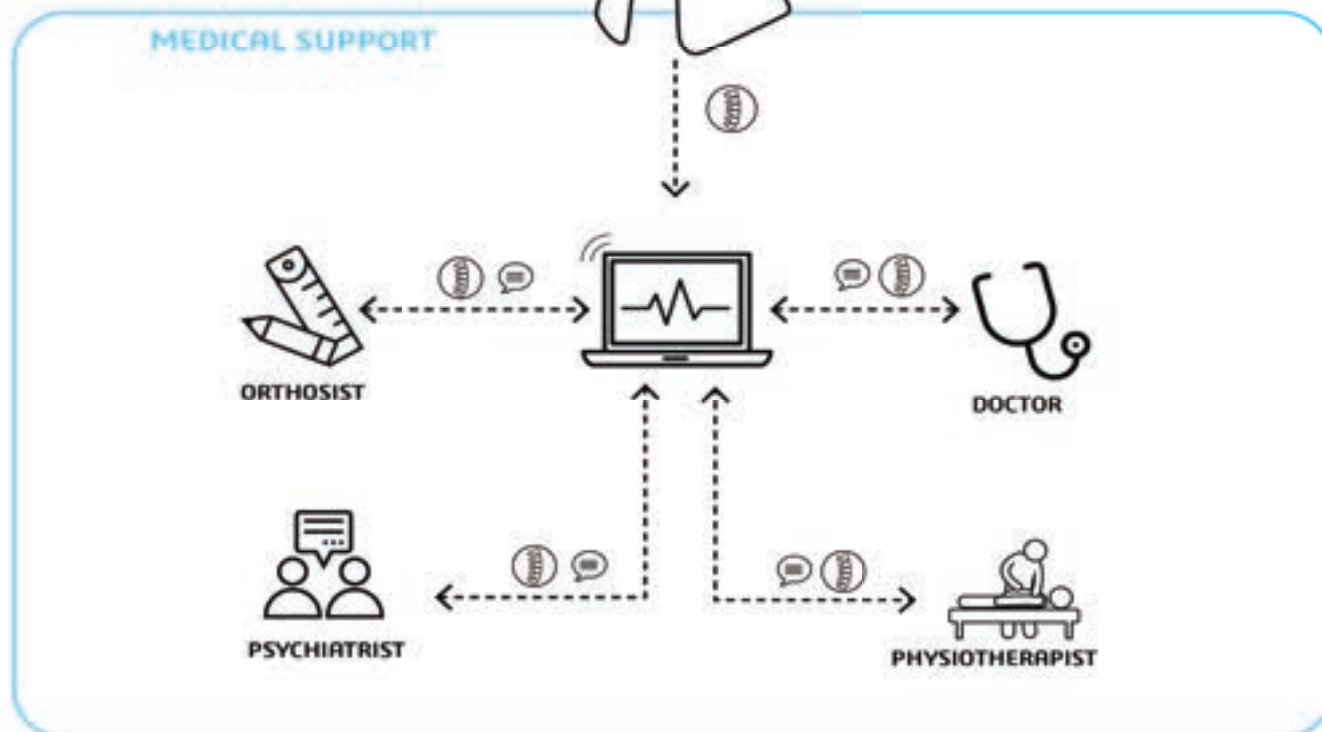
Updating medical staff about compliance of the patient; If professional team have more updated information about patient they will be more effective in the treatment and if anything is not working they will know sooner.

Exchanging information between professions; If professions have more information about their progress about treatment they can be more efficient. Every profession needs other professions' help and once they have the info they need they all can agree on best treatment program for patient not most efficient.



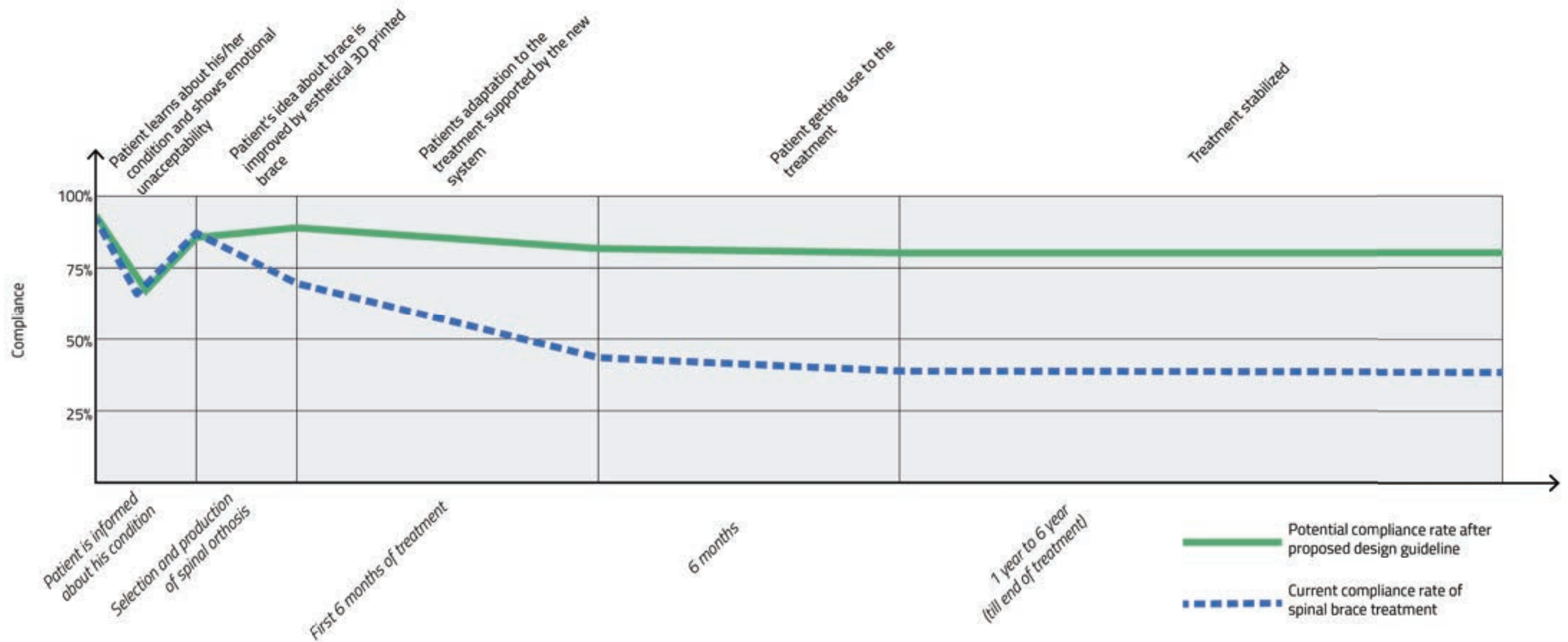
SOCIAL SUPPORT

- Personal tracking for patient about their progress and compliance
- Sharing experience / Learning from others
- Opportunity meet with other patients
- Update the family



MEDICAL SUPPORT

- Update the professions about compliance of the patient.
- Create platform for professions to update each others about patient's progression.
- Opportunity to early diagnose whether is treatment working or not.



After the patient learns about his/her condition, they react very emotionally and does not want to accept the treatment. After convinced by the doctor, the patient needs to go to orthotist for the measurement. This is the first time that patient sees the spinal brace that he/she will use. In this part, some patients do not want to persuade treatment because they are intimidated by the appearance of the brace. In my proposed design I am aiming to decrease the number of dropouts by using the 3D printed brace because of the aesthetical appearance of brace is more appealing traditional ones. Second major dropout occurs in the first 6 months of the treatment. In the traditional treatment process, patient starts to feel isolated and alone which causes emotional distress. Therefore the largest amount of the dropouts are seen in first 6 months.

In the proposed design system I am aiming to create a social support system which will help to improve the patient emotionally because he/she will be engaging with other patients so he/she will not be isolated. Also, with the help of medical support patient will convince to persuade the treatment because more the professional team get in contact with the patient, more the patient will feel that treatment is working. In the traditional process, it is still possible to see dropouts because of lack of support and discomfort. On the other hand in the proposed design patient will get used to the treatment and start to become more comfortable with the brace sooner. After one-year treatment in both scenarios, treatment stabilized and at the end proposed system will present better outcome.

5.3 SUGGESTIONS FOR FURTHER DESIGN SOLUTIONS

This research has highlighted the importance of compliance in designing a spinal brace. New technology and new production techniques are in use to address this issue. It seems until recent years, the focus was on improving the spinal brace itself to increase compliance but with evolving technology alternative solutions has presented to the market.

There is no doubt 3D printed production is a perfect fit for the customized spinal orthosis. Production technique offers a wide variety of personalization possibilities. When it is supported with the right equipment it is promising for the future. Some technologies reviewed in the research is a good alternative to support spinal braces such as integrated heat sensors or pressure sensors. There are already current studies working on technology supported 3D printed braces which presented research shows this is the future of spinal braces.

In order to increase compliance patient needs to connect with the product like how today's people connect with their smart-phone. The relationship between product-user should be emotionally loaded. To create this bond it would be wise to use smartphone and applications. If patients' interaction with the brace can be used as a base for other sorts of activities which will encourage patient to go on with the treatment, compliance rate to the brace could increase. Recent development made by Clinch (smart strap) is a good example of how brace can be integrated with the application and create a platform for doctors to check compliance.

Research has shown that patient and parents want to have more control over the process so including parents and patients in the data circulation would give them an assurance about the treatment is working.

There is a two-design direction here that we need to improve. First is the spinal brace design as a product; aesthetical concerns. Second is a technology supported service design; application etc. In order to create effective well-designed spinal brace, these two aspects need to exist together. It is still necessary to have further research and analytical outcome to prove this but with the documents has been presented in this research, shows this is the path we need to take action as a designer.

5.4 LIMITS OF THE RESEARCH

Presented research conducted on two continents which are Europe and the United States because clinical trials and case studies mostly were done in these two parts of the world. To keep the relationship among results, researches from other continent is not included in the paper because spinal braces show differences depending on where they are produced. The United States and Europe share the same product culture for the spinal orthosis. Some researches from Asia excluded due to the compatibility of the data because spinal braces were not the same as the rest of the research.

The study was mostly limited with accessible data on the internet and in books. The only professional contribution was an interview made with two doctors from Italy and Turkey. Information presented in the research is provided from articles and case studies. In addition to that numerous personal blog and videos has been used to deduce users'

perception about the spinal brace.

Lack of standardization for clinical trials was another limitation. Recently authorities trying to set some regulations for studies in order to create comparable works such as before the 'success' definition made by SRS in 2005 which is less than 5° progression is considered success, every research had their own criteria which makes it hard to compare works have been done.

Even though in presented work I tried to examine all the available data, extended investigations with the contribution of the professions (doctor, orthotist, hospital staff) may give a more accurate results on topic.

6. CONCLUSION

From the research work, it is presented it is clear that design improvement for spinal braces cannot be done by developing just product's design itself, it needs well-designed service system to support the product and ensure the compliance. In spinal brace, compliance is the key word because does not matter how efficient and well designed the brace is if the patient is not willing to wear the brace it is meaningless.

After a detailed analysis of traditional products research showed that creating aesthetically acceptable and still able to apply necessary force is challenging. After all spinal braces have to apply certain external force on torso so the patient can improve his condition. On the other hand, when a spinal brace meets all technical needs, it is becoming quite bulky and the patient is not wearing the brace. Research showed that with today's advanced technology there is a better chance to design and manufacture the brace with desired technical details and aesthetic. 3d printer technology is a perfect fit for this need but no matter how well designed the brace is, it still needs to prevent certain moves on the torso. Therefore, even with most advanced technology spinal braces will always be certain amount uncomfortable. Therefore, spinal brace design needs to improve by offering more advanced treatment process which can be provided by effective service design with help of technology. To ensure the compliance, brace needs to be supported with technology such as application and needs to provide service system which actively includes the patient into the process. The research has shown parents and patient want to be more active and regularly informed about treatment so by actively including them in the process chance of compliance can be increased.

Another improvement to increase patient compliance is creating better data circulation between professions (doctor, orthotist, physiotherapist, psychiatrist) Research has shown that when professions work as a team, they have a better influence on process thereby on compliance. This data circulation can also provide by the help of technology and service design.

The result of this study shows a combination of different design aspects have a better chance to ensure patient compliance which is the only way a provide an effective product and an effective process.

7. LIST OF FIGURES

Figure 1: <https://www.orthopedicappliancenco.com/products/orthotics>
Figure 2: <https://dacpersonaltraining.com/2018/04/01/why-its-important-to-understand-planes-of-motion-no-matter-your-level-of-fitness/>
Figure 3: <https://primalbowspring.com/2017/11/15/radiant-heart/>
Figure 5: <http://body-disease.com/wp-content/uploads/2012/03/Scoliosis-Lordosis-Kyphosi.jpg>
Figure 6: <https://it.pinterest.com/pin/390687336396943005/?lp=true>
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Figure 11: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2816747/>
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Figure 15: https://www.youtube.com/watch?v=2k_73wsqIHl
Figure 16: redrawn <http://journals.sagepub.com/doi/pdf/10.1080/17461550500069547>
Figure 17: modified https://commons.wikimedia.org/wiki/File:Spinal_column_curvature-en.svg
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Figure 19: Illustrated by author
Figure 20: Illustrated by author
Figure 21: redrawn <https://musculoskeletalkey.com/orthoses-for-spinal-dysfunction/>
Figure 22: https://www.ortoped.ca/en/spinal-trauma-orthotic-positioning-s-t-o-p-brace-i.html?__from_store=fr
Figure 23: modified from <http://thehealthy-food.com/wp-content/uploads/2017/05/6-types-of-body-fat-how-to-get-rid-of-it.jpg>
Figure 24: redrawn from <http://ballert.com/index.php/articles/are-off-the-shelf-tlsos-helpful-or-harmful>
Figure 25: redrawn from <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3475113/pdf/1748-7161-7-12.pdf>
Figure 26: redrawn from <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3475113/pdf/1748-7161-7-12.pdf>
Figure 27: redrawn from <https://bmcmusculoskeletdisord.biomedcentral.com/track/pdf/10.1186/1471-2474-10-5>
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Figure 29: <https://www.kisspng.com/png-milwaukee-brace-back-brace-scoliosis-orthotics-sch-998288/>
Figure 30: <https://www.youtube.com/watch?v=PEPHA9k1vCc>
Figure 31: <https://feedyeti.com/hashtag.php?q=bostonbrace>

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Figure 65: Illustrated by author
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