

DESIGN AND DEVELOPMENT OF BRACES FOR ADOLESCENT IDIOPATHIC SCOLIOSIS USING 3D PRINTING TECHNOLOGY

Submitted in partial fulfillment of the requirements for the award of

Master of Technology Degree in Medical Instrumentation

By

PREETHA .V (Reg No.40440006)



DEPARTMENT OF BIOMEDICAL ENGINEERING

SCHOOL OF BIO AND CHEMICAL ENGINEERING

SATHYABAMA

**INSTITUTE OF SCIENCE AND TECHNOLOGY
(DEEMED TO BE UNIVERSITY)**

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JEPPIAAR NAGAR, RAJIV GANDHI SALAI, CHENNAI - 600 119

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This is to certify that this Project Report is the bonafide work of **PREETHA.V** (Reg No.40440006) who carried out the project entitled "**Design and Development Of Brace For Adolescent Idiopathic Scoliosis Using 3D Printing Technology**" under our supervision from **November 2021 to May 2022**.

Internal Guide
Dr. J. Bethanne Janney, ME., Ph.D.,
Associate Professor

External Guide
Dr. M. D. Sayem Alam, Ph.D.,
Principal Scientist

Head of the Department
Dr. T. SUDHAKAR, M.Sc., Ph.D.,

Submitted for Viva voce Examination held on 11-05-2022

Internal Examiner

Dr. J. PREMKUMAR

External Examiner

DECLARATION

I **PREETHA. V** (Reg No.40440006) hereby declare that the Project Report entitled “**Design And Development of Brace For Adolescent Idiopathic Scoliosis Using 3D printing Technology**” done by me under the guidance of **Dr. J. Bethanne Janney, Department of Biomedical Engineering** and **Dr. M. D. Sayem Alam** at **Central Leather Research Institute (CLRI), Adyar** is submitted in partial fulfillment of the requirements for the award of **Master of Technology** degree in **Medical Instrumentation**.

DATE: 18.04.2022

PLACE: CHENNAI



SIGNATURE OF THE CANDIDATE

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डॉ. मो. सायेम आलम Dr. Md. Sayem Alam

प्रधान वैज्ञानिक Principal Scientist
पॉलीमर साइंस और प्रौद्योगिकी प्रयोगशाला Polymer Science &
Technology Laboratory
सीएसआईआर-केन्द्रीय चमड़ा अनुसंधान संस्थान CSIR-Central
Leather Research Institute
(वैज्ञानिक और औद्योगिक अनुसंधान परिषद Council of Scientific
& Industrial Research)
अड्यार, Adyar, चेन्नई Chennai - 600 020, भारत INDIA.

☎ : + 91 44 24437106 EXT:
7106

Fax: +91 44 24911589

E-mail: sayem@clri.res.in;

sayemalam@gmail.com

CERTIFICATE

This is to certify that **Ms. Preetha.V (Reg Number: 40440006)**, has worked on ***"3D PRINTED BRACE FOR ADOLESCENT IDIOPATHIC SCOLIOSIS PATIENTS"*** under my supervision at the Polymer Science and Technology Lab of CSIR-Central Leather Research Institute, Adyar Chennai, for a period of 6 (SIX) months (during September 2021 to March 2022), for the partial fulfillment of the Degree of Master of Technology (M. Tech.), in Medical Instrumentation, from the Department of Biomedical Engineering, Sathyabama Institute of Science and Technology, Chennai, Tamil Nadu, during the academic year 2021-22.

(Dr. Md. Sayem Alam)

Chennai

Date: 17th March, 2022

ABSTRACT

Adolescent Idiopathic Scoliosis (AIS) is a three-dimensional deformity of the spine which causes a deformation of the spine with a sideways curvature; hence it is vigorously affecting the activities of daily life of such patients. To treat AIS, braces are used over the years to provide corrective forces to the spine and to sustain the spine during postoperative rehabilitation. Bracing is established as the most popular method of treatment for non-operative management of AIS. The effectiveness of brace treatment is specifically associated with the average brace-wear time per day, but patients are not able to wear for the specified hours due to the complaint of discomfort in wearing. Hence, Application of three-dimensional printing technology (3DPT) is one of the flourishing fields of orthosis is used to remedying this problem by providing suitable 3Dprinted customized scoliosis orthopaedic device to ease the discomfort of wearing. Polyethylene terephthalate glycol (PETG) filament is used to print the braces and the variables associated with the 3D printed braces such as comfort, weight, flexibility and mechanical strength, and are taken into consideration for the fabrication. The 3D Printed brace is subjected to the curvature analysis to find out the location where the pressure would be maximum. The found maximum pressure at scapula at either side of the backbone is then fitted with the pressure sensor device and connected to measured continuously by changing forces. The influence of 3D Printed braces in pressure variations and in correcting spinal curvature and its state of deformity were studied.

Keywords: AIS, Spine, 3D Printing, Braces, Idiopathic Scoliosis, FSR

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LIST OF ABBREVIATIONS

ABBREVIATIONS	FULLFORM OF ABBREVIATIONS
AIS	Adolescent Idiopathic Scoliosis
CAD/CAM	Computer aided manufacture /computer aided design
3D	Three dimensional
2D	Two dimensional
TLSO	Thoracolumbar sacral orthoses
STL	Stereolithography
FDM	Fused deposition modeling
FSR	Force sensing Resistor
PSSE	Physiotherapeutic scoliosis-specific exercise
PE	Polyethylene
PP	Polypropylene
PET	Polyethylene terephthalate
PETG	Polyethylene terephthalate glycol
3DP	Three-dimensional Printing
FFF	Fused filament fabrication
SRS	Scoliosis research society
IDE	Integrated development environment
PTF	Polymer thick film
UTM	Universal Testing Machine
PLA	Poly lactic Acid
N	Newton

CHAPTER 1

INTRODUCTION

1.1 AIS AND SPINE

Adolescent idiopathic scoliosis (AIS) is a three dimensional deformity of the spine including asymmetry of neckline, shoulder blades, waistline and abnormal rib hump. Scoliosis is characterised by increased stiffening of the major curvature, which is not overcorrected easily (Asliza Ahmad *et al.* ;2019). Although discovered in adolescence, the curve, quite likely, was present at an earlier age and only became prominent with the adolescent growth spurt. In idiopathic scoliosis, the number and segmentation of the vertebrae are the same as in the normal spine. However, the column is no longer straight in the frontal plane. Instead, there are lateral curves, typically right convex in the thoracic region and left convex in the thoracolumbar and lumbar region. The major curve, also called the primary curve, is the origin of the deformity and is always considered structural by definition according to the Lenke classification. Secondary curves arise as compensation for the imbalance caused by the primary curve. The primary curve is always more rigid than the compensatory curve(s). The most lateral point of the curve from a central line is called the curve's apex and may either be a single vertebra or the disc between two vertebrae. According to Schultz *et al.* when curve on the spine exists, powered by the body weight, the trunk creates a lateral bending moment that tends to increase over time. Approximately 80% of the scoliosis cases are AIS, in which the reason of origin is unknown. AIS manifests as lateral curvature of the spine, rotation of the vertebrae, and a flexible or rigid deformity on the frontal plane. AIS majorly affects individuals the risk of progression in adults occur with a cobb angle above 30° during the adolescent period of 10 to 14 years of which 1–3% of adolescents. Girls have about eight-times as much of a risk of curve progression compared with boys. During adolescent period, deformity may progress rapidly. Scoliosis limits activities of daily living and can cause damage to musculoskeletal, respiratory, and nervous systems (Athaar ali *et al.* ;2021). Serious health problems and quality of living are affected when the curve is above 50° and hence requires surgery. Hence several treatment of scoliosis aimed to improve

pain and quality of life, Avoid surgical treatment, Improve clinical appearance, Halt progression or even partial correction and to provide Three-dimensional treatment of the deformity(Nikos Karavidas *et al.* ;2019).

Quality of life of patients with AIS is influenced by several consequences of the condition including,

- Reduced pulmonary function
- Back related problems such as pain and stiffness
- Degenerative spine disease
- Physical ability and function
- Body image concerns
- Mental well being
- Social and psychological consequences
- Occurrence of other co-morbidities



Figure 1.1 scoliotic spine

1.2 BRACING TECHNIQUE

Conservative treatment with high corrective exercises and high corrective braces are proposed to prevent scoliotic curve's progression. Scoliosis treatment can be either conservative or surgical. Non-operative treatment consists of observation, physiotherapy and/or bracing. In the case of moderate spinal deformities such as idiopathic scoliosis, physiotherapy is carried out but brace treatment is preferred in the case of AIS.

Corrective forces are applied to the trunk externally for patients with AIS which is called the brace treatment. Treatment for AIS patients using brace is one of the most prominent non-surgical procedures. Conventional methods of bracing include a customized plaster cast method. Computer aided design/computer aided manufacturing (CAD/CAM) and 3D imaging provides a virtual geometry of the patient data (Inigo Sanz-Pena *et al.* ;2021). The technique of bracing is a conservative method for treating AIS and its main objective is to deteriorate the progression of scoliosis. The main aim of brace treatment is the prevention of progression of the deformity to an extent that needs surgery (Bhavuk Garg *et al.* ; 2020). Concept of brace design follows the „three-point system“ correction principle where force is applied at the apex, the vertebra that is the most laterally deviated from the center spinal column, followed by two counterbalancing forces: one superior and one inferior to the apex.

The design of a plaster mould TLSO is divided in two steps. First, the creation of a positive mould from the cast of the patient's torso and, second, the rectification of the positive mould . The rectification of the positive mould involves both removing and adding plaster in areas of the torso and pelvis to generate the desired mould geometry from which the brace shape is thermoformed. The rectification process is based on the orthotist's experience to achieve optimal in-brace spinal correction. (Inigo Sanz-Pena *et al.* ;2021). Despite the wide use of this technique, there are downsides of manual mould rectification, is that casting requires a significant amount of materials, tools, and time . On average, it takes 60 min to cast a patient. Furthermore, the geometry of the rectified mould is highly dependent on the orthotist expertise, and the manufacturing process involves the use of large equipment.

Hindrances in the conservative treatment of bracing include low adherence, negative psychosocial impact in the adolescent, and correction of deformity in a single plane. These factors determine the failure of treatment resulting in surgeries (Haroldo Oliveira De Freitas Júnior *et al.* ;2021). Patient compliance with brace are affected by many factors like negative cosmetic appearance, physical and functional discomfort resulting from pressure points, humidity and restriction of movement. High correction bracing is the most effective conservative treatment for

patients with scoliosis during growth (Hans-Rudolf Weiss *et al.* ;2017). Impact of brace treatment is depends on the in-brace correction, hours worn and patient compliance. Brace efficiency is related to brace wear time. The more patients complied with brace treatment, the better their chances were of obtaining a positive outcome. Results of bracing depends upon the timing with adolescent growth spurt, spine flexibility, and patient compliance to treatment (Nikita Cobett *et al.* ; 2017) .



Figure 1.2 Customized brace with straps for fastening

1.3 3D PRINTING

Computer-aided design/computer-aided manufacturing (CAD/CAM) systems that are used for brace design, established to be as effective compared to the traditional plaster-cast methods, using 2D metrics (Nikita Cobetto *et al.* ;2017). 3d printing is a booming revolution in the biomedical sector which provides customizable results, speedy design and low cost (Youyu Zhang *et al.* ; 2020). CAD/CAM technology along with 3D printing helps to manufacture a personalized prototype. Additive manufacturing, also known as three-dimensional printing (3DP), has bestowed with patient-specific solutions in the medical field . This technique enables to create complex and customized devices based on digital models.3DP is user-friendly, material usage is already known, and does not require the formation of positive mould. Less handwork is needed, reducing the

risks of human errors and improving inter-operator repeatability (Davide Felice Redaelli *et al.* ; 2019). Employing CAD/CAM method, a prototype of brace can be manufactured by capturing the body shape with a 3D scanner and sending the output stereolithography file (.STL) for printing directly. Manufacturing of brace using 3d printing is a novel approach. Besides the brace design process, fused deposition modeling (FDM) is a 3D printing method that can be applied to prosthetic and orthotic applications. FDM melts solid filament and extrudes it out of a nozzle to form a layer of an object thereby final prototype is created by adding material layer by layer. (Kenwick JL Ng *et al.* ; 2019).



Figure 1.3 trial version of mini prototype 3d printed using PLA filament

1.4 SENSOR TECHNOLOGY

The Force sensors which have been reported to be reliable for monitoring spinal orthosis compliance in the treatment of scoliosis. The challenges that refer to FSR include sensor design, evaluation, calibration, validation, costing and the final application inside the brace. Main requirements are: lightweight, thin enough, plastic, electrically connectable sensor. We do not want too precise force measurement, because in this application we wanted to create categories on display: “not touching”, “too small force”, “normal force”, “too much force”. Cobb angle is the sideward deflection angle which is used for diagnostic purposes and therapeutic decision making. Hence the integration of FSR sensor with arduino is done to conduct studies about brace and its compliance. Simulation studies were also conducted and the prototype was manufactured using 3dp technology.

CHAPTER 2

LITERATURE REVIEW

Yoyu Zhang *et al.* (2020) presented the design of a randomized controlled trial on the clinical effectiveness of 3D-printed braces versus thoraco lumbosacral orthosis (TLSO) for patients with AIS. Primary outcome measures include average brace-wear time per day, Quality of life and Cobb angle progression of the primary curve. Secondary outcome measures will include immediate in-brace correction of Cobb angle rate of conversion to surgery and incidence of any adverse events. This trial is a comparative effectiveness trial in a setting similar to the real-life clinical situation. Participants and physicians are not blinded to the intervention under evaluation. The compliance associated with 3D-printed brace was 50% higher than that with conventional TLSO.

Haroldo Oliveira De Freitas Júnior *et al.* (2021) proposed to evaluate the immediate correction capacity of the Wood-Chêneau-Rigo brace (WCR), in primary and secondary curves of AIS. The brace fabrication process involved four steps: 3Dscanning of the trunk of the patient using CAD/CAM ;planning of the scoliotic curve correction from the scanned images ; production of an individualized mold of the trunk with the proposed correction and, finally, making the WCR brace in polypropylene using the mold as a base. The brace permits correction of scoliosis in the three planes of the deformity. The WCR brace serves for the immediate correction of curves in patients who underwent conservative orthotic treatment for AIS.

Inigo Sanz-Pena *et al.* (2021) conducted a study that demonstrates steps of the manual rectification process that can be characterized. The plaster-casting method to create a scoliosis brace consists of mold generation and rectification to obtain the desired orthosis geometry. The 3D surface deviation maps were used to locate the largest rectification areas on the mold. The results showed no direct relationship between the Cobb angle and the ALP displacement in the medial/lateral direction. Characterization parameters found in this study could be implemented into 3D sculpting software for the digital design of scoliosis braces.

Sukran Cakmak *et al.* (2021) have developed a posture supporting garment (soft exosuit) design for individuals aged 10–18, with Cobb angles of 25°–40°, which is the most rapidly progressing stage of the disease. Soft exosuit prepared with experimental research method and user-centered design approach. The posture supporting effect is achieved by pattern engineering using fabric, belts, baleens and a gradual zipper system for to increase functionality, ease of use and fit. Soft exosuit has been found effective in supporting the posture of individuals who had ongoing spinal growth. Patient was satisfied with the prototype and its functionality, ease of use, fit and comfort.

A new scoliosis orthopedic device was designed and manufactured by optical scanning, CAD and 3D printing, and its correction effect was evaluated. Lu Dezhi *et al.* (2021) analyzed scoliosis before and after intervention to observe the clinical efficacy. Suitable 3D printed personalized scoliosis orthopedic device was produced. The Cobb angle and angle of trunk inclination were significantly different before and after treatment.

Davide Felice Redaelli *et al.* (2020) evaluated the feasibility of producing orthopedic scoliosis braces by 3D printing, comparing performance and costs with classical thermoforming procedures. manufacturing methods are currently based on producing a positive mold of the patient's body. The mold can be realized either using plaster of Paris or via 3D scanning and computerized milling. The captured 3D image was exported to CAD to extract the final 3D model. Patient reported the perception of improved support and no significant comfort differences compared with the thermoformed brace. 3D printed structures properly resist the fatigue produced during use by the patient.

Very low evidence exists regarding bracing over 40 degree and adult degenerative scoliosis. Nikos Karavidas *et al.* (2019) showed that CAD/ CAM braces have shown better initial correction and are more comfortable than conventional plaster cast braces. Analysis was divided into different categories: Evidence for scoliosis bracing. Predictive factors for successful treatment, Brace weaning, Brace and physiotherapeutic scoliosis-specific exercises (PSSE), Adult bracing, Comparing different brace types. CAD/CAM braces provide better IBC than traditional plaster braces, Improve clinical appearance and quality of life, Avoid surgical treatment.

Furthermore, CAD/CAM braces could save time, be lighter and more comfortable.

Athaar ali *et al.* (2021) presents a review of the conventional passive braces and highlights the advancements in spinal orthoses in terms of improved sensory designs, active actuation mechanisms, and new construction methods (CAD/CAM, three-dimensional (3D) printing). Measuring the progression of the spine and adjusting the brace accordingly will expedite the process of recovery. Use of sensors to track the brace compliance, interface pressure, force distribution, and torso parameter characterization was analyzed. 3D-printed braces solve the socio-economic barrier and seem more appealing to the patients. FDM is the least expensive method to produce scoliosis braces among these 3D printing techniques. Braces reduce surgical intervention.

Hans-Rudolf Weiss *et al.* (2017) Describes of the steps of virtual brace adjustment as available today as well as an outline of the great potential that is present for the future 3D printing technology. CAD / CAM brace production mainly relies on carving a polyurethane foam model which is the basis for vacuuming a polyethylene (PE) or polypropylene (PP) brace. Braces can be adjusted virtually by using the hand measurements of the patients' trunk, but a 3Dscan of the patient's body is preferred. Textures and structures can be added to the brace models at certain well defined locations offering the potential of more wearing comfort without losing in-brace correction.

A brace applies an external force to the trunk, which imparts corrective forces on the spine. Kenwick JL Ng *et al.* (2019) conducted a study that aims to determine the appropriate material and thickness to improve wear comfort. Using the CAD/CAM method, a brace is formed by capturing the body shape with a 3D scanner and sending the output file (.STL) for printing directly. FDM melts solid filament and extrudes it to form a layer of an object. Material properties had shown better strength and elongation. 3D printing included customized geometry, generation of printed objects with high accuracy and smooth surfaces.

Nikita Cobett *et al.* (2017) performed a study that aims to assess the 3D immediate effectiveness of braces designed using CAD/CAM and FEM compared to CAD/CAM only. AIS patients who were randomized into two groups. For both

groups, 3D reconstructions of the spine and patient's torso, were obtained and braces were designed using the CAD/CAM approach. For the test group, additionally used to generate a personalized FEM to simulate and improve the brace design. The combination of numerical simulation and CAD/CAM approach allowed designing more efficient braces in all three planes.

Jason Pui Yin Cheung *et al.* (2020) conducted a study To determine consensus among Asia-Pacific surgeons regarding non-operative management for adolescent idiopathic scoliosis (AIS). The main aim of non-operative treatment is to prevent curve progression and adulthood progression. The questionnaire was constructed based on a Delphi method panel discussion. Aspects under study included access to screening, when MRIs were obtained, quality-of-life assessments used, role of scoliosis-specific exercises, bracing criteria, type of brace used, maturity parameters used, brace wear regimen, follow-up criteria, and how braces were weaned. CAD/CAM techniques have been shown to be effective and increases productivity.

Hard-shell thoracolumbar sacral orthoses (TLSOs) are used for treating idiopathic scoliosis, a deformation of the spine with a sideways curvature. Franz Konstantin Fuss *et al.* (2021) performed a study that aimed to develop a cost-effective but accurate pressure sensor system for TLSOs. The sensor reacted to the changing pressure during breathing and different activities when tested underneath a chest belt at different tensions. The more uneven the pressure distribution, the more the conductance at peak load is expected to change. Piezoelectric pressure sensor proved to be both accurate and cost effective because it reacts to the changing pressure during breathing and different activities.

The Cheˆneau brace has proven its effectiveness in treating the adolescent idiopathic scoliosis patients. Asliza Ahmad *et al.* (2019) In this study, evaluated the interface pressure of the Cheˆneau brace action in double-curve adolescent idiopathic scoliosis patient treatment. The F Socket transducers (9811E) were used to evaluate the pressure on the right thoracic and left thoracolumbar curves. The MPP exerted on the patient body was higher after the strap adjustment for all activities, indicating that the strap tension had a greater impact on the magnitude

of the exerted force. Proves to evaluate the proper brace fabrication and can help in achieving optimum curve in-brace correction for patient with double-curve AIS.

Shahrbanoo Bidari *et al.* (2019) made a review that aimed at comparing the efficacy of braces made by the conventional method with those made by two computer-aided methods: computer-aided design and manufacturing (CAD-CAM), and computer-aided design and finite element modeling (CAD-FEM). The external torso geometry is reconstructed by using a surface topography method from which the brace model is created by using CAD software. CAD-CAM braces confirmed immediate Cobb angle improvement even in severe scoliosis. CAD-CAM methods reduces manufacturing time to one third that of the conventional method .It Employs standard manufacturing processes and promotes accuracy. Provides a higher hygiene level and consumes less raw material compared to conventional methods.

Bhavuk Garg *et al.* (2020) proposed a narrative review which focuses on the role of bracing in the management of AIS in terms of the brace history, types, indications, results, and drawbacks with relevant literature. With the increasing utilization of computer-assisted technology in scoliosis management, it is now possible to design a topographic virtual 3D model of a scoliotic trunk. This allows the physicians or orthotists to identify the areas of corrective padding along with post fabrication assessment of 3D pressure dimensions for final customization and validation of the brace design. CAD/CAM braces , they have been effective in reducing or limiting the curves in the coronal plane, highly accurate, reduces man power , light weight.

Davide Felice Redaelli *et al.* (2019) developed a virtual design process of scoliosis braces ,briefly analyzing the choice of the most convenient 3D printing technology and the selection of a proper material that can be comparable to the ones used for thermoforming. The final goal is to pass from the current thermoforming production to the use of additive manufacturing. Because of the big volume of the back brace and of the print speed, the most convenient printer is the one based on the technology Fused Filament Fabrication (FFF). The setting of the printer and the

orientation of the orthosis in the printer are critical for the final result. 3D Printing a complete back brace is feasible and low initial investment required for both machine and materials.

Hans-Rudolf Weiss *et al.* (2021) focuses to review the literature showing improvements after brace treatment and to show what can be done conservatively via bracing in curvatures exceeding 45° Cobb clinically and radiologically. A case series of three patients with curvatures exceeding 45° is demonstrated within this paper revealing radiological and clinical improvement when using the recent Chêneau standard of bracing with a reliable CAD library of braces and an experienced team. Also there is future advancement potential of baseline quality in braces produced using CAD/CAM technologies.

Bracing has widely been applied in the conservative treatment of AIS . study done by Leilei Xu *et al.* (2019) aims to investigate effectiveness of brace treatment in patients with adolescent idiopathic scoliosis with curve between 40° and 45° and to determine predictive factors associated with bracing outcome. Factors including Risser sign, age, sex, curve pattern, curve magnitude, and initial curve correction were compared .Logistic regression analysis was used to determine the independent predictors of curve progression. Bracing produces a favorable outcome in certain patients with curve between 40° and 45°.thus eliminating the surgical treatment.

Matthew Halsey *et al.* (2021) performed a survey stating that while the Scoliosis Research Society (SRS) has established criteria for brace initiation in adolescent idiopathic scoliosis (AIS), the SRS Non-Operative Management Committee decided to evaluate the consensus or discord in AIS brace management. the “bracing is more in the 20°–25° range”, and “now offer a brace for 20° curves”, when maintained. It is noted that they no longer use night time only braces and now prescribe TLSO orthoses, or that they no longer wean patients out of the brace.

CHAPTER 3

AIM AND SCOPE

3.1 AIM

The aim of this project is to fabricate a prototype of scoliotic brace. Novel design through engineering approach is proposed to develop a customized brace using the polyethylene terephthalate glycol filament is done. PETG is chosen since it is durable, temperature resistant and has high strength. The idea is to develop sensor integrated scoliotic brace using 3D printing technology.

3.2 EXISTING SYSTEM

A characteristic of scoliosis is increased stiffening of the major curvature which is not overcorrected easily. This is why scoliosis cannot be satisfyingly corrected using unspecific symmetric braces, or soft braces allowing mobility. The conventional way to treat spinal deformities, such as scoliosis, kyphosis, and spondylolisthesis, is to use spinal orthosis (braces). Braces have been used for centuries to apply corrective forces to the spine to treat spinal deformities or to stabilize the spine during postoperative rehabilitation. The plaster-casting method to create a scoliosis brace consists of mold generation and rectification to obtain the desired orthosis geometry. In traditional orthosis manufacturing technology needs a lot of time and materials. The conventional braces use a pre-existing fabricated symmetric module with modifications with respect to padding, trim lines, and areas of relief based on individual's anthropometry and physical dimensions or indirectly using plaster cast of the patient's trunk (Bhavuk Garg *et al.* ; 2020).

3.3 PROPOSED SYSTEM

The project work involves the fabrication of sensor integrated 3D printed brace for spine and its related deformities. Bracing is known to be one of the best non-surgical procedures to treat AIS. A larger study on more brace designs and more curve types are required before an algorithm can be developed for clinical use.

Literature reviews have proven that Trunk and back shape can be improved conservatively even in patients with curvatures between 20 - 45°. CAD/ CAM braces have shown better initial correction and are more comfortable than conventional plaster cast braces. Three-dimensional (3D) printing technology is a recent advancement that offers unique opportunities for biomedical applications, and customization of scoliosis braces will lead to greater patient satisfaction and improved compliance. Also, 3D printing gained considerable attention in the orthopedic sector. The fabrication involves the following steps,

- Design and Development of Scoliotic brace from patient scan data (MRI/ Back surface scan data)
- Assessment of Sensor placement in Brace to identify the wearer spine status.
- Production of Braces using Additive manufacturing technique.
- Building the circuit combining force sensors with arduino to assess the spine deformity and patient comfort.
- Integration of the 3d printed brace and the sensor circuit for the construction of the scoliotic brace.

3.3.1 Advantages of proposed system

Three-dimensional printing not only reduces manufacturing time to one third that of the conventional method and exhibits a standard manufacturing processes and promotes accuracy. force sensors employed showed better performance in terms of repeatability, linearity and time drift. Integration of sensor provide information about the wearer spine status and notifies discomfort. 3DP is environmentally friendly, produces limited waste material, and does not require molds, human error is minimized. FDM is the least expensive and the most suitable to produce scoliosis braces. (Davide Felice Redaelli *et al.* ; 2019). 3D printed structures properly resist the fatigue produced during use by the patient. 3D-printed braces solve the socio-economic barrier and seem more appealing to the patients. 3D printing would offer making braces lighter and more comfortable by using alternative materials, easy-to-use tools for quick, individual redesign of certain brace regions targeting weight reduction, local stiffening, adaptivity and aeration.

3.4 SCOPE AND APPLICATION

Customized scoliotic brace will lead to greater patient satisfaction and improved compliance. Scoliotic brace Prevents progression of spinal deformity and also helps in the alignment of skeletal structure. Technique of bracing is most importantly one of the best methods of Non-surgical procedure to correct deformity. (Nikos Karavidas *et al.* ; 2019) Using 3D Printing techniques more customized designs can be done.

CHAPTER 4

MATERIALS AND METHODS

4.1 HARDWARE COMPONENTS

4.1.1 Arduino UNO

Arduino is a single-board microcontroller which renders incorporating electronics in multidisciplinary activities fully available. The hardware is a basic open source hardware board based on an 8-bit Atmel AVR or a 32-bit Atmel ARM microcontroller. On the microcontroller, the device consists of a common programming language compiler and a boot loader. Arduino is an open-source prototype framework of simple hardware and software (Amer Nasr A. Elghaffar *et al.* ;2021). It is made up of a programmable circuit board (also known as a microcontroller) and ready-to-use software labeled as Arduino IDE (Integrated Development Environment), which is used to write and transfer programming code to the physical device.

➤ Specifications

- Microcontroller: ATmega328
- Operational Voltage: 5V
- Input Voltage: 7 - 20V
- 14 Digital I/O Pins of which 6 provide PWM output
- Input Pins (analog): 6
- DC Current: 20 mA per I/O Pin
- DC Current: 50mA for 3.3V for each Pin
- Flash Memory: 32 KB
- SRAM: 2 KB
- Clock Speed: 16 MHz
- Length: 68.6 mm
- Width: 53.4 mm
- Weight: 25 g



Figure 4.1 Arduino uno board

4.1.2 FSR Sensor

The FSR 402 model is a single-zone Force Sensing Resistor optimized for use in human touch control of electronic devices such as automotive electronics, medical systems, and in industrial and robotics applications. FSRs are two-wire devices. They are robust polymer thick film (PTF) sensors that exhibit a decrease in resistance with increase in force applied to the surface of the sensor. The standard 402 sensor is a round sensor 18.28 mm in diameter. FSR Sensors are easily customizable to a wide range of sizes, Cost effective , Simple and easy to integrate.

➤ Specifications

- Size – 18.28 mm diameter
- Active Area: 12.7mm
- Nominal thickness: 0.55 mm
- Thickness – 0.1 to 1.25mm
- Switch Travel: 0.05mm
- Actuation force as low as 0.1 N
- Force Sensitivity range – 0.1 – 10.0² N
- Highly repeatable force reading; as low as 2% of initial reading with repeatable actuation system.
- Ultra-thin; 0.45 mm
- Robust; up to 10 million actuations
- Force Resolution- Continuous (analog)
- Force Repeatability Single Part - +/- 2%

- Force Repeatability Part to Part - $\pm 6\%$ (Single Batch)
- Non-Actuated Resistance - >10 Mohms
- Hysteresis - $+10\%$ Average $(RF+ - RF-)/RF+$
- Device Rise Time - < 3 Microseconds
- Temperature operating range - -30 to $+70^{\circ}\text{C}$



Figure 4.2 Front and back view of Force sensing Resistor

4.1.3 General Purpose Board

Printed circuit Board is commonly abbreviated as PCB and is the base of electronics. The PCB provides support as well as electrically connects various Electronic Components in the circuit. For testing or for mounting your components you can either design and manufacture a custom PCB or else you can mount it on a zero PCB and accordingly make the connections. General Purpose PCB are perfect if you have not finalized the design or you are making the circuit just once. Advantages of using General Purpose PCB include its Low cost. Also Perfect for Prototyping and testing small circuits, Perfect for experiments which are starting with electronics And short design time.

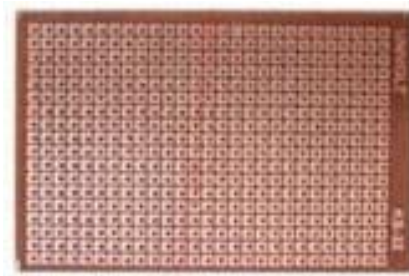


Figure 4.3 image of general purpose board used for the circuit construction

4.1.4 Resistor

A resistor is a passive two-terminal electrical component that implements electrical resistance as a circuit element. Resistors reduce current flow in electronic circuits, a property that is utilized to adjust signal levels, to divide voltages, bias active elements, and terminate transmission lines, among other uses. Resistors are common elements of electrical networks and electronic circuits and are ubiquitous in electronic equipment. Practical resistors as discrete components can be composed of various compounds and forms. Resistors are also implemented within integrated circuits.



Figure 4.4 10Kohm resistor a component for integrating FSR and arduino.

4.2 SOFTWARE DESCRIPTION

4.2.1 Arduino IDE

A cross platform framework (for Windows, macOS and Linux) written with functions C and C++ is an Arduino Integrated Development Environment (IDE). It is used for writing and uploading Arduino compatible applications, but also for other developer boards with the support of third-party core systems. The IDE source code is released under the GNU General Public License. The Arduino IDE uses special code structuring guidelines to support the languages C and C++. The Arduino IDE supplies a wiring project software library that provides a number of common input and output procedures. User-written code only needs two simple functions to start the sketch and the main program loop, which are compiled and connected into an executable cyclic executive program with the GNU tool chain, which is also included with the IDE distribution (Amer Nasr A. Elghaffar *et al.* ;2021). The Arduino IDE uses the software to translate the source codes to a text file in hexadecimal that is loaded into the Arduino board by a loader program in the

circuitry of the board.

➤ Initial Setup

If the Arduino IDE has been opened, here is what it looks like. It opens in a blank sketch where you can start programming right away. First, we need to customize the board and port settings to enable us to upload code. Connect your Arduino board to your PC with a USB cable.



Figure 4.5 Arduino IDE

4.2.2 Mimics Innvotvation Suite

Mimics is a medical 3D image-based engineering software that efficiently takes you from image to 3D model and allows you to scale from R&D to high-volume clinical operation (Guangxuan Yan *et al.* ;2022). Medical image data thus serves as a powerful basis for engineers and researchers striving for solutions that will lead to safer and more predictable patient outcomes. The Mimics Innovation Suite is designed to make using medical image data for engineering purposes.

➤ Features

- **Segments the anatomy effectively** : Combine automated tools with smart editing tools to obtain accurate 3D models
- **Characterize an anatomy**: Identify landmarks and quantify the anatomy by using an extensive set of tools to create landmarks, as well as simple and advanced measurements directly in the 3D space.

- **Plan your procedure virtually** : Visualize for different scenarios of procedures for better understanding. Position devices in the anatomy virtually to understand anatomical fit
- **Automate your workflow** : Python scripting allows you to automate repetitive steps in your workflow. If you don't feel like coding yourself or have a bigger automation project, you can leverage our custom plug-in services.



Figure 4.6 mimics innovation suite

4.2.3 Materialise 3-Matic Software

A great design for Additive Manufacturing usually starts with a CAD design, a topology optimized model, a simulation, or scanned data as input. With Materialise 3-matic, you can clean up rough data for simulation or convert your mesh back to CAD. In addition, it allows you to enhance your design by creating 3D textures, lattice structures and conformal structures, ready for Additive Manufacturing. 3-matic also includes scripting automation to make it easier to create ranges of validation samples and improve overall productivity. Materialise 3-matic offers 3D modeling, design modification, design simplification, 3D texturing, re-meshing, various analysis forward engineering all on an STL level.(Bhavuk Garg *et al.* ; 2018)

➤ Features

- Design Optimization
- Post-Topology Optimization
- Adding Textures, Patterns and Perforations
- Lattice, Conformal and Porous Structures Modules
- Conversion of mesh to CAD
- Automates the workflow



Figure 4.7 3-matic materialise

4.2.4 Siemens NX

Siemens NX software is a flexible and powerful integrated solution that helps to deliver better products faster and more efficiently. Siemens NX delivers the next generation of design, simulation, and manufacturing solutions. Supporting every aspect of product development, from concept design through engineering and manufacturing, NX gives you an integrated toolset that coordinates disciplines, preserves data integrity and design intent, and streamlines the entire process (Jana Dvorakova *et al.* ; 2021).

It is used for:

- Design (parametric and direct solid/surface modelling)
- Engineering analysis (static; dynamic; electro-magnetic; thermal, using the

finite element method; and fluid, using the finite volume method).

- Manufacturing finished design by using included machining modules.



Figure 4.8 Siemens NX

4.2.5 CURA

Cura is simple but powerful 3D slicing software produced by Ultimaker. The software supports STL, 3MF and OBJ 3D file formats and also has a function that will import and convert 2D images (.JPG .PNG .BMP and .GIF) to 3D extruded models. The software will allow you to open and place multiple models on the print bed (each with different slicing settings if required). Cura is desktop software that can be downloaded free of charge from the Ultimaker website and is available for Windows, Mac and Linux (M sljivic *et al.* ; 2019).

Technical specifications:

- Ultimaker Cura works by slicing the user's model file into layers and generating a printer-specific g-code. Once finished, the g-code can be sent to the printer for the manufacture of the physical object.
- The open source software, compatible with most desktop 3D printers, can work with files in the most common 3D formats such as STL, OBJ, X3D, 3MF as well as image file formats such as BMP, GIF, JPG, and PNG

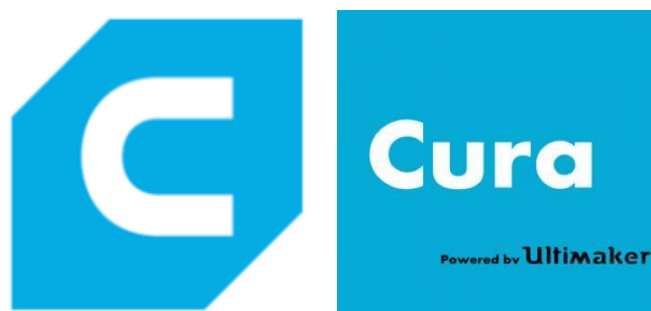


Figure 4.9 Cura software

4.3 UNIVERSAL TESTING MACHINE

The Instron Universal Testing Machine (Model 3369) used for compression tests. Universal testing machines include electromechanical and hydraulic systems to perform static testing, including tensile, compression, bend, peel, tear, shear, friction, puncture, and other mechanical tests (Henrique Ramos *et al.* ; 2022). Tensile Testing Machine is widely used in aviation, aerospace, petroleum chemical industry, machinery, metal materials and products, electric wire and cable, paper, printing and packaging, tape, bags handbags, textile fiber, pharmaceutical, food industry, etc. The universal testing machine INSTRON model 3369 perform tensile, compression and automotive parts where maximum forces are less than 50 kN (11,250 lbf).

➤ Specifications:

- Force capacity: 50 kN (11,250 lbf)
- Max speed load: 500 mm/min (20 in/min)
- Vertical Space: 1193 mm (47 in)



Figure 4.10 UTM used for sensor calibration

4.4 3D PRINTER

HyCube Works is leading in additive manufacturing or 3D printing technology and is the manufacturer of ALPI, 3D printers in India. The company's technologies are used to create prototypes, manufacturing tools, and production parts for industries, including aerospace, automotive, healthcare, consumer products, and education.

ALPI V4 series of 3D Printers are capable of printing high quality with Accurate repeatability without compromising on performance which makes it one of the most innovative and re-label in the market. ALPI V4 3D Printers come with a heated bed of 400mm x 400mm x 400mm in all X, Y, Z axis. ALPI Basic 3D Printers enable us to 3D Print with high performance and reliability with high quality swappable nozzle in a sturdy metallic chamber.

➤ Specifications of ALPI V4 Single Extruder 3D Printer

- Model Number - SB400
- Printing Technology - FDM/FFF
- Printable Volume - 400×400×400mm
- Built Speed - 10- 40mm³/s
- Nozzle Temperature - 140-260°C
- Built plate Temperature - 40-90°C
- Printable Materials - ABS, PLA, PLA+Pro's, PETG
- Layer Resolution - 10-400µm*
- Position Resolution (X,Y,Z) - 12.5x12,5x2.5 Microns
- Heated Built Plate - Aluminium Heated bed
- Built Plate Calibration - Automatic levelling with Calibration
- Number of Extruders – 1
- Nozzle Diameter - 0.2- 1mm (Swappable)
- Interface - Touch Screen
- Filament Sensor - N/A
- Connectivity - SD Card
- Filament Storage - Not Present
- Noise level - Less Than 55 dB
- File Type - STL, G-Code

- Power Input - 220V AC, 50-60Hz
- Operating ambient temperature - 5-35°C. 10-90%RH
- Storage temperature - -25°C to +55°C. 10-90%RH

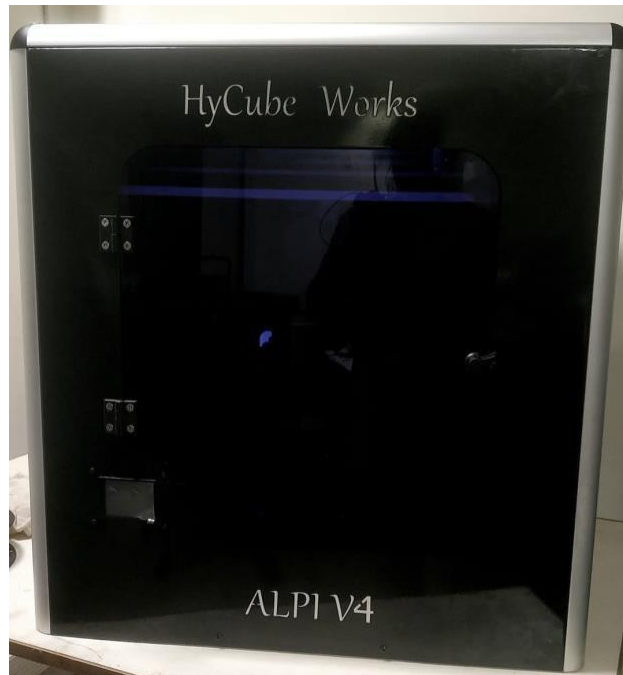


Figure 4.11 Hycube works – Alpi V4 Single extruder 3D Printer

4.5 PETG FILAMENT

PETG is a modified PET, usually adding a small amount of "Glycol", where the letter G comes from. Glycol modifies the properties of PET in two key aspects:

- It lowers the melting temperature of the material, so that it can be printed on most 3D printers, since generally the optimum printing temperature is usually around 230°C, being compatible even with extruders with teflon in the hot zone.
- It increases the flexibility of the filament, this makes it ideal for mechanical parts, since the unmodified PET would be too rigid. This additional flexibility makes it similar to ABS and can replace it in many applications.

PETG is much more flexible than PLA, even than modified PLA like 3D850, making it a better material for 3D printer printed parts. It has a softening temperature higher than the PLA, so it can be used on parts that are very close to

the hot end or motors that get very hot and it maintains its shape. The chemical resistance is also higher, The PETG resists these situations much better . It deforms before breaking. If the part is exposed to shock or excessive force PETG is first deformed elastically recovering its shape, if the force is too high you can get to deform permanently, but without breaking. It mechanizes better, since it can be sanded and drilled much more easily. The result in the printed parts for 3D printers is better in all aspects, the parts are more precise and flexible(Davide Felice Redaelli *et al.* ; 2020).



Figure 4.12 PETG Filament

4.6 CIRCUIT DIAGRAM

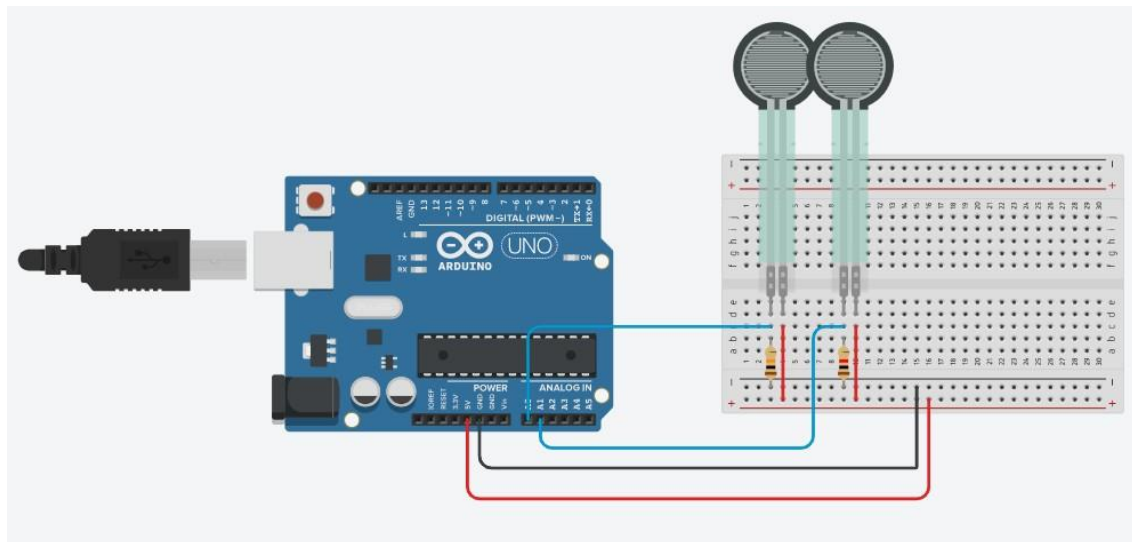


Figure 4.13 Circuit diagram proposed for FSR and Arduino integration

4.7 METHODOLOGY /WORKFLOW

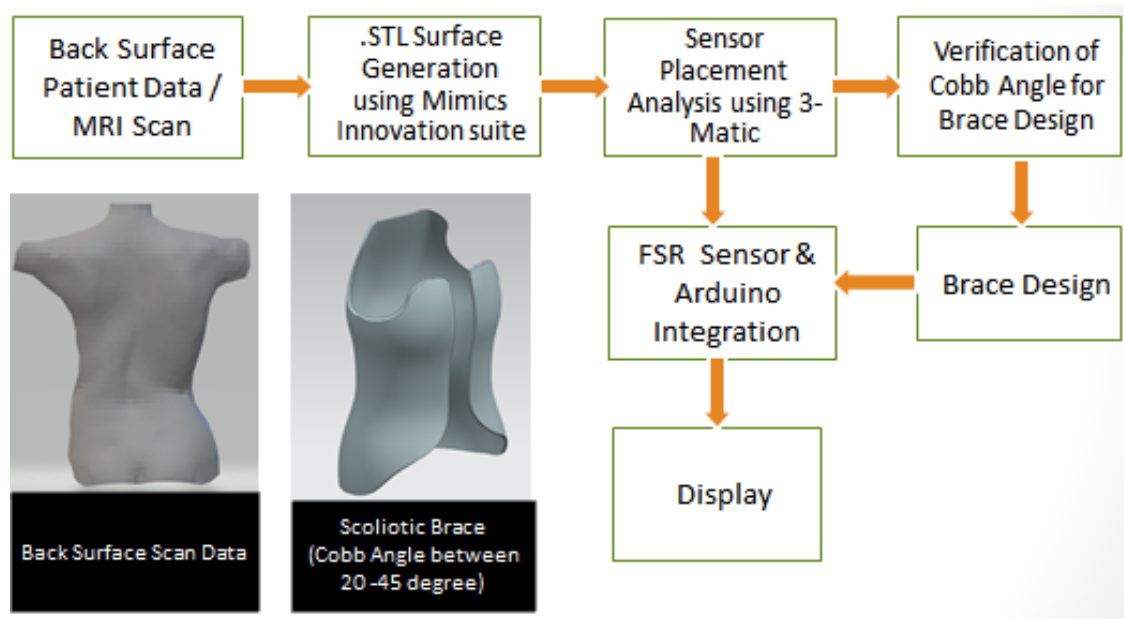


Figure 4.14 Methodology adopted for the fabrication of prototype

4.8 EXPERIMENTAL STUDY

4.8.1 Stl Surface Generation

Mimics integrates seamlessly into hospital's workflow and quickly converts medical image data (DICOM files) to 3D anatomical models. Thus it involves in converting the patient back surface scanned data into a stereolithography(.stl) file. Mimics provides you with 3D models that improve pre-surgical planning, patient consultation, support medical education and become an essential component of your multidisciplinary team.

4.8.2 Sensor Calibration

Calibration of the FSR sensor verifies the precision and reproducibility of measurement. Sensors that are calibrated are the prerequisite for precise, reliable and reproducible measurement results. Calibration is done to check the accuracy of the FSR 402 sensors(Luca Gioacchini *et al.* ;2022).

The FSR 402 sensor was inserted into that metallic hollow cylinder held with a stand. The compression force was applied on the plier handles by the load cell of

0 N and then the force kept increasing at the order of 20N, 30N , 40 N . The maximum de-bonding forces were recorded in newton (N) units by the associated software And Correspondingly the voltage or the resistance obtained was measured with a multimeter.

4.8.3 Sensor Placement

The regions for the placement of the sensors were selected with the help 3-matic materialise software. When curvature analysis was carried out to the scanned data of the patient back surface, the sensor placement points were understood.

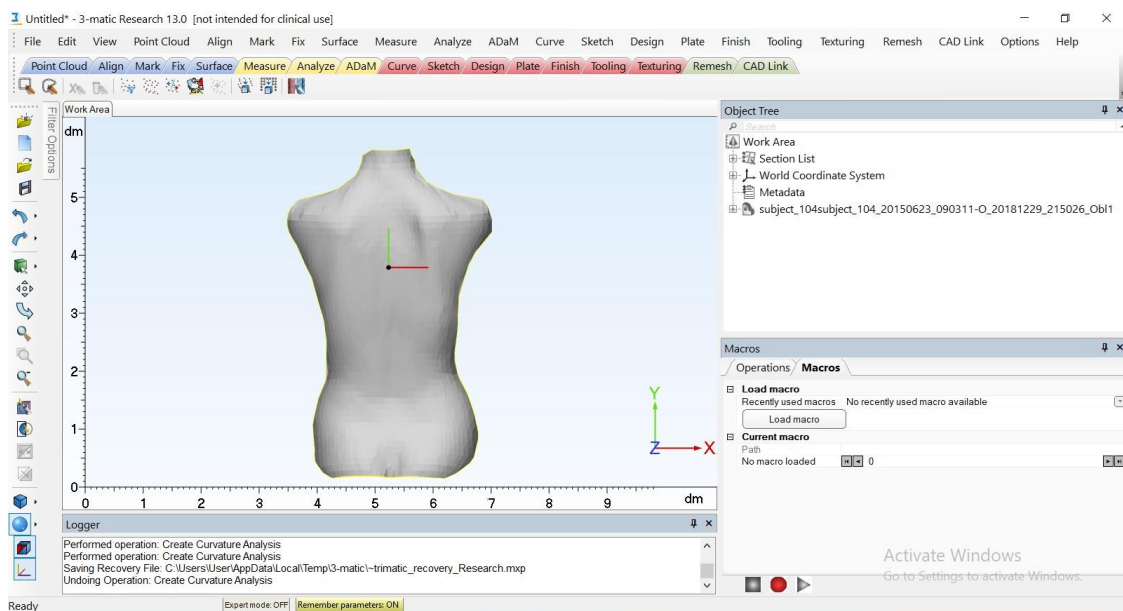


Figure 4.15 Patient back-surface data in 3-Matic software

4.8.4 Design Of Brace

Designing the brace involves a customized pattern according to the patient spine deformity. Design was developed using NX Siemens Software. The brace design information is extracted from the patient data. Using the scanned data , The cobb angle and curvature are known and hence the back portion of the brace is designed. Also knowing the anthropology of the patient. The height and size of patient is assessed and the front side of the brace is designed accordingly.

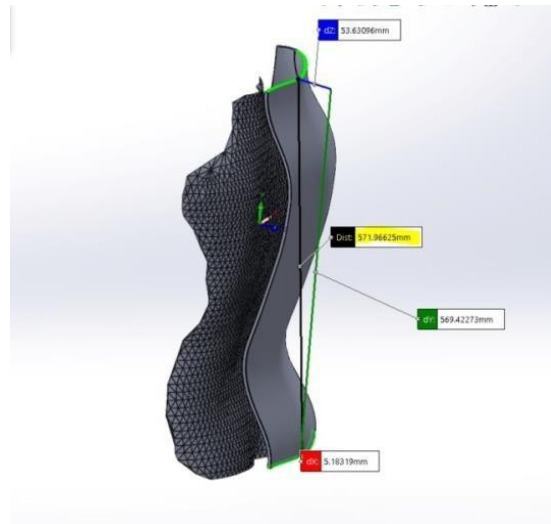


Figure 4.16 3d modeling of design using patient data

4.8.5 Circuit Design

The circuit design consists of an arduino uno ,general purpose circuit board, FSR 402 sensors , 10kohm resistors and connecting wires. The board is taken and each resistor is connected to one lead of the force sensor and other end of the resistor is grounded. Where as the other lead of the force sensor is connected to the next pin by side , the pin next to the sensor leads is chosen and given as analog inputs .Note that the one of the sensor lead and pin next to sensor lead which is connected to A0 for sensor 1 and A1 for sensor 2 are soldered.

4.8.6 3d Printing Of Brace

4.8.6.1 Fundamental Working Principles of 3d Printing

All 3D printed parts come from an initial digital 3D model model is generally in a proprietary file format, unique to the given CAD program. The designer will then export that part to an STL, OBJ or 3MF file. The STL file format is the most widely used 3D printing file format .This is a native file format for 3D modeling CAD software. STL is the abbreviation for "Standard Triangle Language" or "Standard Tessellation Language". The job of the STL file is to store data about the structure of a 3D model(Neal D. Kravitz *et al.* ; 2018). The format works by using millions of small triangles to map the surface of the 3D model that it is representing. Once the model is created, it will need to be translated into the language that the 3D printer

will execute. Only the geometric data of the model is stored using this format. Information like the color, texture or other material properties are not stored. It is important to ensure that the STL file has a high resolution. The resolution is equivalent to the level of detail that the 3D printer can replicate on the actual printed model. The 3D printer is interested in the 2D layers of 3D STL model. At this step, a 3D slicing software is used to literally slice the STL file into thin layers. This will make up the GCode file that the 3D printer understands.

➤ FILAMENT LOADING

After the file is fed into 3dp printer , The filament load is loaded into into the tube through the lever system and the filament reaches the extruder .

➤ BED AND NOZZLE HEATING

After the printing is given, the printer begins to heat the bed to 50 degree celsius from the room temperature and the nozzle temperature is set to 235 degree for petg filament and nozzle begins to heat.

➤ BED SETTING

Having a perfect heating bed when printing is important to making sure that your first layer sets accurately. Most other printer accomplish this by ensuring the bed is leveled when it is initially setup. The drawback for this approach is that any errors from wear, tear or even build quality will then be permanent. Auto setting of the bed is done at specific locations of the bed .after the bed auto levelled it is ready to the filament extrusion to begin the 3d printing .

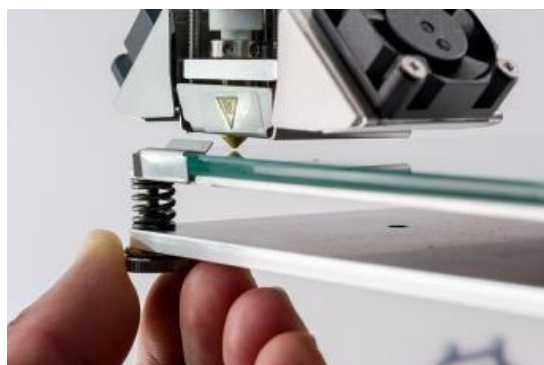


Figure 4.17 image of the 3d printer bed while Bed setting

4.8.6.2 FDM Technique

Fused deposition modeling, often known as FDM 3D Printing, is an additive manufacturing technique in which layers of materials are fused together in a pattern to form an artifact. Typically, the material is melted slightly past its glass transition temperature, then deposited in a sequence adjacent to or on top of prior extrusions, successive layers, to create an item (Kenwick JL Ng *et al.* ; 2019). Lines of filament are laid down in a predetermined 2D format. These lines form what we call the layers of the 3D models. As the layers continuously are laid onto each other, the 3D model is formed. FDM is often regarded as the easiest method for achieving 3D printing. It is also inexpensive and somewhat effective.

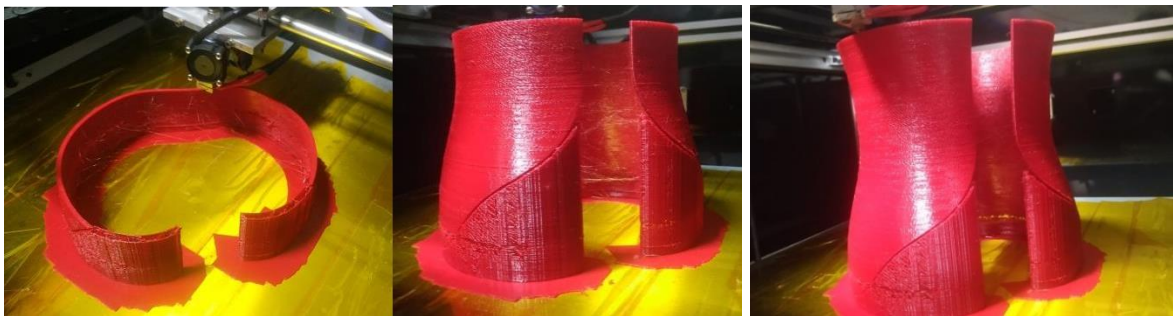


Figure 4.18 Stages of 3dp printing – FDM TECHNIQUE

CHAPTER 5

RESULTS AND DISCUSSIONS

5.1 RESULTS

5.1.1 Sensor Calibration

FSR estimation is done to find the patient comfort and also to keep on track about the overall improvement of structure. Calibration of the sensor is done by applying the force in newton to obtain the resistance of both the sensors respectively.

Table 1.1 Output Readings when both the FSR sensors are calibrated .

Table represents the readings that were obtained when force was given through UT machine and resistances were measured with the multimeter accordingly. As the force increases the resistance decreases. Thus the FSR exhibits a non-linear relationship with force .

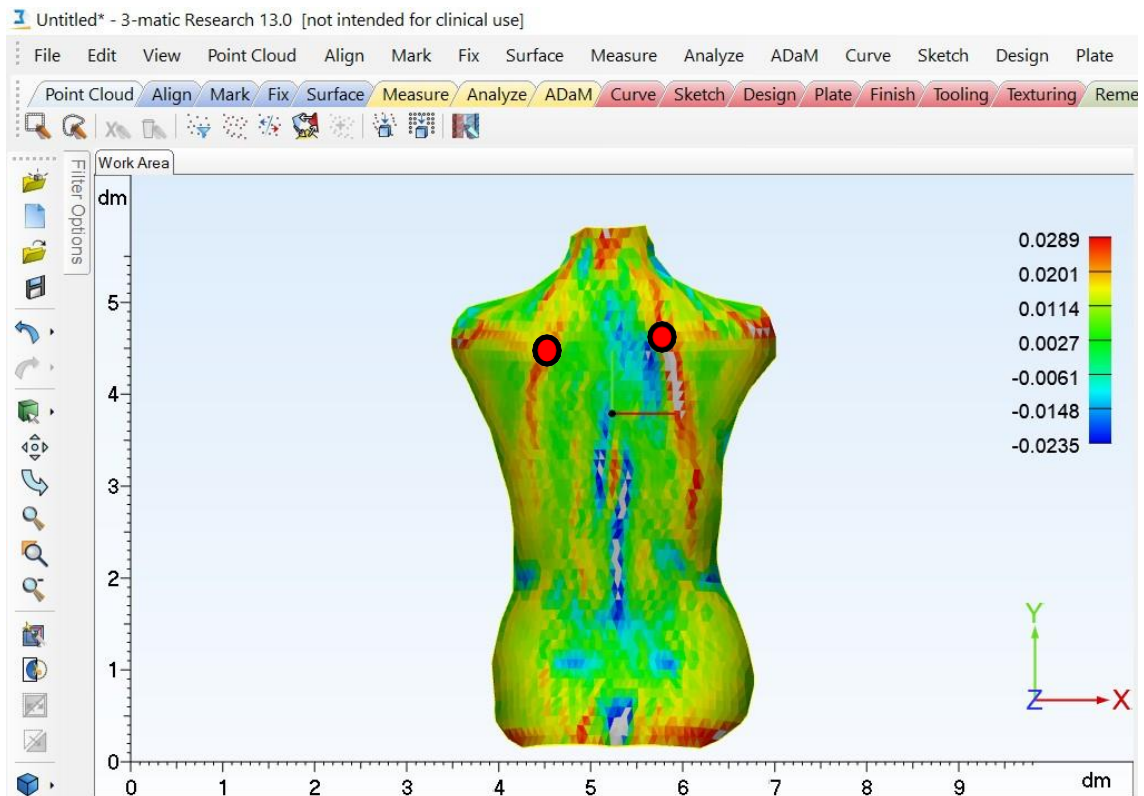
FORCE (Newton)	RESISTANCE (Kohms)	
	FSR 1	FSR 2
0	0	0
2	0	6.2
5	0	2.45
10	0	1.78
15	16.20	1.54
20	15.12	1.45
30	14.25	1.31
40	14.03	1.23
50	13.94	1.18
60	13.86	1.13
70	13.79	1.10
80	13.76	1.08
90	13.74	1.06
100	13.71	1.04
110	13.71	1.03
120	13.69	1.01
130	13.67	1.00



Figure 5.1 calibration of FSR sensors

5.1.2 Curvature Analysis For Sensor Placement

The curvature analysis is carried out for the patient back surface data using the 3-matic research13.0 software. Based on the inferences of the curvature analysis, the sensor placement has been finalised. The red regions denote the high stress concentration regions on the back surface. The force is usually acts on the scapula region of the bone with which pressure and the effectiveness of the spine correction can be understood.



● - FSR Sensor Placements

Figure 5.2 curvature analysis of the patient back surface data

5.1.3 Brace Design Model

The brace design is obtained for an adolescent patient whose cobb angle range is between 20 to 45 degree. The height and weight of the patient is also known. Using the SIEMENS NX software, the CAD model of the brace is designed.

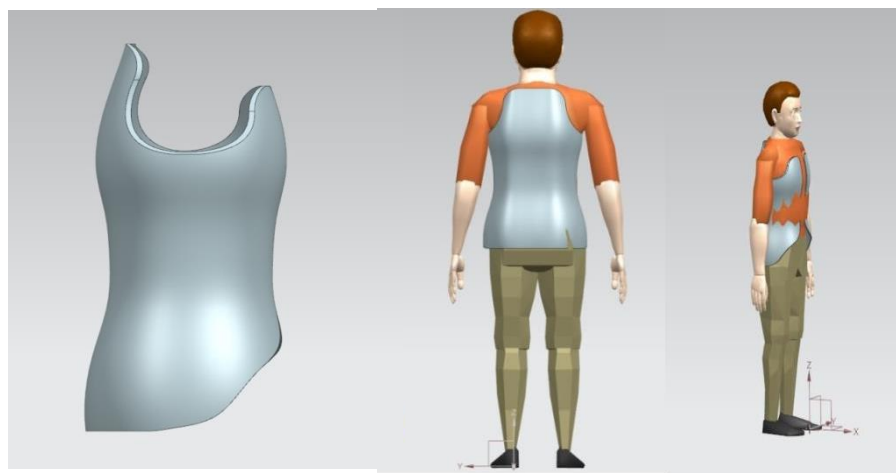


Figure 5.3 patient wearable 3d model of the brace design

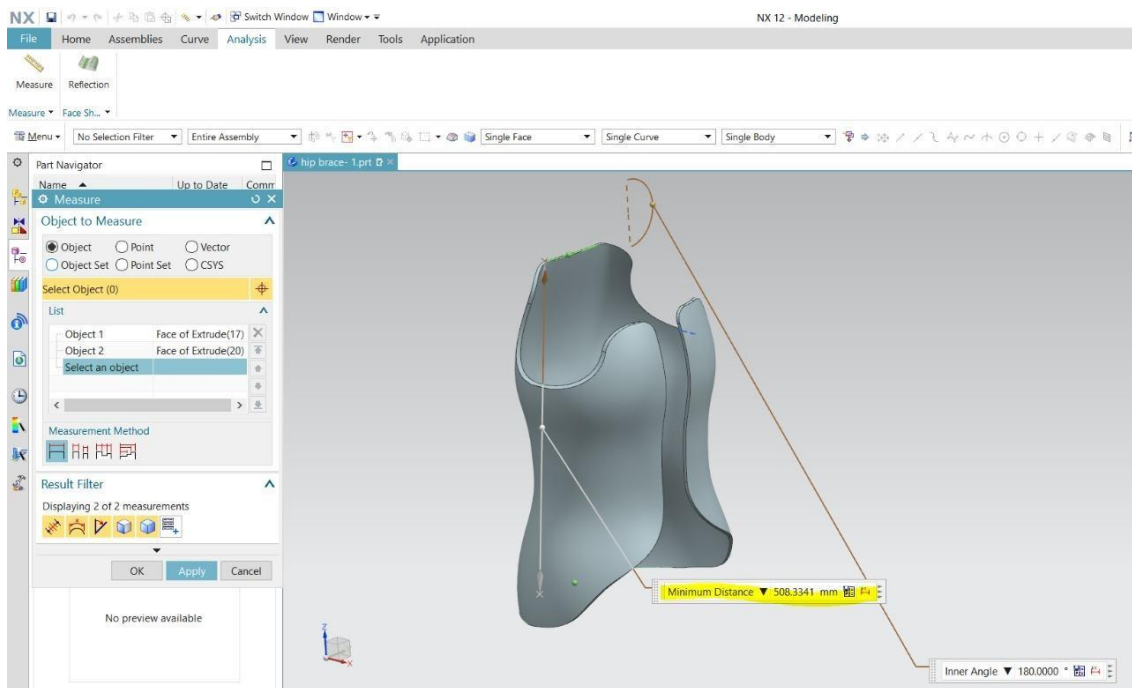


Figure 5.4 Designing of the 3d model of brace in siemens nx software

5.1.4 Curvature Analysis Of Brace

Analysis is done by Selecting the Create Curvature Analysis button and loading the design file. Choose Maximum curvature as Analysis type, Noise as Mesh type and set the Fitting radius to 6.0mm. Apply the operation. A histogram with the curvature distribution is displayed and the 3D object is represented in a range of colors. The blue color represents the regions with local convexity, absence of red color represents no area of concavity, proving that the design is uniform.

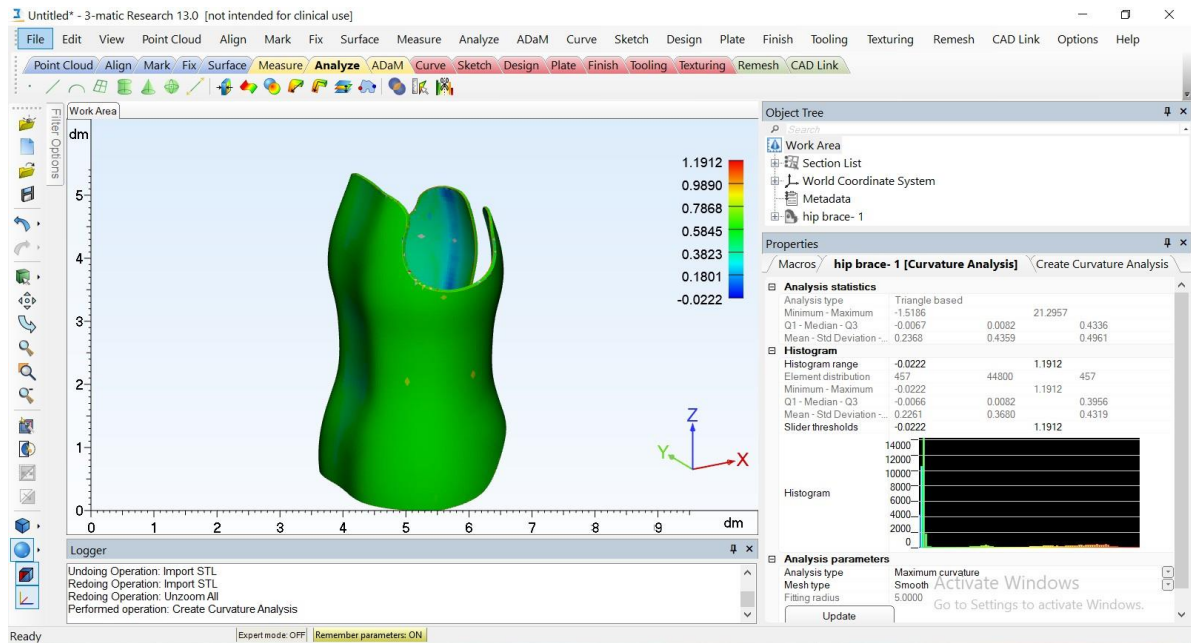


Figure 5.5 – curvature analysis of brace design

5.1.5 3d Printed Brace

The .stl file given to the 3d printer, the printer undergoes the initial adjustments such as the nozzle and bed heating and also auto leveling of the bed is done. The total duration of the print is about 35 hours. Polyethylene Terephthalate Glycol filament is used in the fabrication of the 3d printed brace. The length of the filament consumed is about 126.80 meters that weighs 378 grams.

➤ Dimensions of the scoliotic brace

- X axis - 157.7 mm
- Y axis - 198.0 mm
- Z axis – 303.7 mm

➤ Parameters fixed in 3d printer

- Fill density – 30
- Print speed – 50 m/s
- Temperature – 235 °C
- Layer height – 0.2 mm
- Shell thickness – 1.2 mm
- Support type –Everywhere

- Platform adhesion type – Raft
- Filament diameter – 1.75 mm\
- Nozzle – 0.4 mm



Figure 5.6 scoliotic brace fabricated using 3d printing technology

5.1.6 Hardware Assembly

The hardware model is assembled to study about the wearer spine status in relation to the spine deformity .different analog values were obtained with respect to the pressure detected by the sensor .

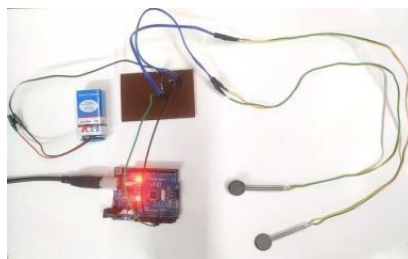


Figure 5.7 Circuit intergrating arduino and FSR

it consists of an arduino board connected to the two Force Sensing Resistors to measure the pressure, the body exerts on the 3d printed brace. Resistors are placed at the point where one of the lead of the sensor is fixed. the power supply is taken from the arduino board and analog inputs are given to a0 and a1 pins of arduino uno.

5.2 DISCUSSIONS

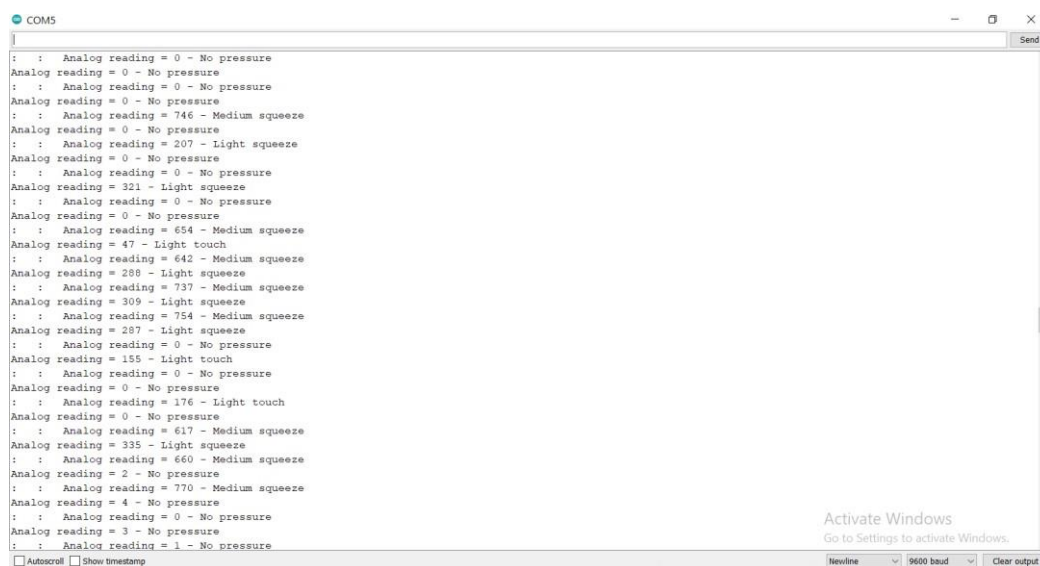
5.2.1 Sensor Output

The sensors were used to take readings based on the pressure that was experienced by the brace at different point of time. The output was obtained using the arduino IDE in two different forms which is the serial plotter and serial monitor. The serial monitor showed different analog readings based on the amount of pressure the brace experienced such as light touch, light squeeze , medium squeeze, big squeeze and no pressure when the brace was left undisturbed.

Table 1.2 shows the information about which command is executed based on the analog value of pressure indication.

ANALOG VALUES	COMMAND
Less than 10	No Pressure
Less than 200	Light Touch
Less than 500	Light Squeeze
Less than 800	Medium squeeze
Greater than 800	Big Squeeze

➤ Serial Monitor



```
COM5
: : Analog reading = 0 - No pressure
Analog reading = 0 - No pressure
: : Analog reading = 0 - No pressure
Analog reading = 0 - No pressure
: : Analog reading = 746 - Medium squeeze
Analog reading = 0 - No pressure
: : Analog reading = 207 - Light squeeze
Analog reading = 0 - No pressure
: : Analog reading = 0 - No pressure
Analog reading = 321 - Light squeeze
: : Analog reading = 0 - No pressure
Analog reading = 0 - No pressure
: : Analog reading = 654 - Medium squeeze
Analog reading = 47 - Light touch
: : Analog reading = 642 - Medium squeeze
Analog reading = 288 - Light squeeze
: : Analog reading = 737 - Medium squeeze
Analog reading = 309 - Light squeeze
: : Analog reading = 754 - Medium squeeze
Analog reading = 287 - Light squeeze
: : Analog reading = 0 - No pressure
Analog reading = 155 - Light touch
: : Analog reading = 0 - No pressure
Analog reading = 0 - No pressure
: : Analog reading = 176 - Light touch
Analog reading = 0 - No pressure
: : Analog reading = 617 - Medium squeeze
Analog reading = 335 - Light squeeze
: : Analog reading = 660 - Medium squeeze
Analog reading = 2 - No pressure
: : Analog reading = 770 - Medium squeeze
Analog reading = 4 - No pressure
: : Analog reading = 0 - No pressure
Analog reading = 3 - No pressure
: : Analog reading = 1 - No pressure
Autoscroll Show timestamp
Newline 9600 baud Clear output
```

Figure 5.8 output data obtained in Serial monitor

➤ Serial Plotter

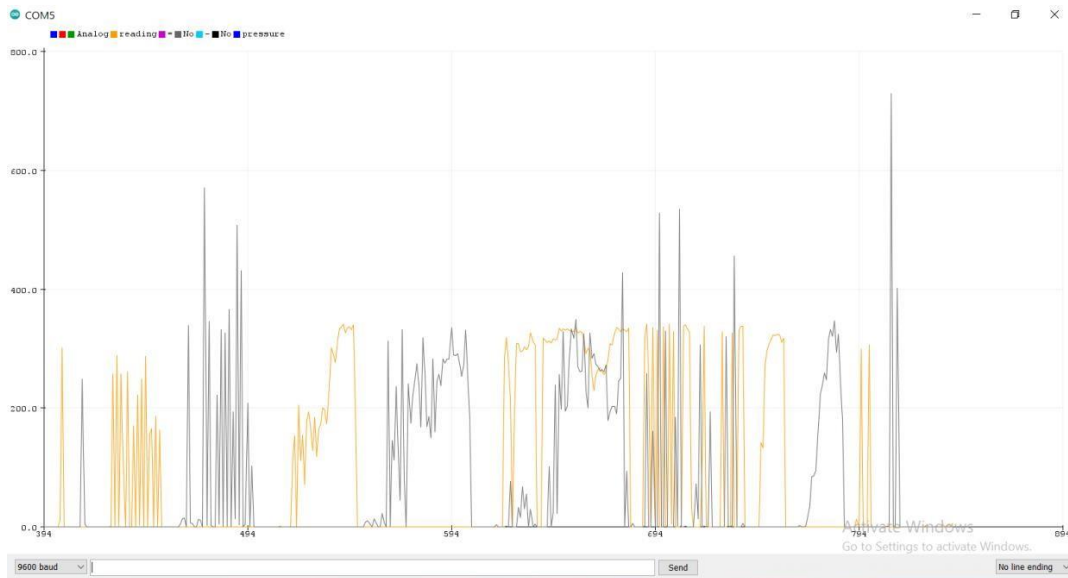


Figure 5.9 output data obtained in Serial plotter

The serial plotter shows the waveforms for pressure that is undergone by both the sensors. Here orange color indicates sensor 1 and blue color indicates sensor 2 respectively. Initially a short pulse is given to both sensors that is seen as a small spike, then back to back pulses type pressure was given to sensor 1 and sensor 2 respectively. Continuous pressure was given separately first to sensor 1 and then to sensor 2, there after same type of pressure was given simultaneously to both the sensors. Also back to back pulse type pressure was also given and the waveform was obtained.

The setup focused in building a circuit that is able to sense any discomfort and also to analyze the progression of the state of spine with the values obtained. Thus the arduino integrated FSR sensor produced successful outcomes in detecting different types of pressure both individually and simultaneously.

5.2.2 Prototype

Applying 3D printing technology may improve the accuracy of fabricating spinal orthosis according to the original design and allows more versatile designs. Thus,

this study applied 3D printing technology in the design and fabrication of orthosis for patients with AIS. Direct prototyping can avoid the accumulated error during the manual fabrication procedures, which can reduce the deviations from the biomechanical correcting design. Furthermore, the orthotic thickness and weight can be reduced during the design period to enhance the comfort level. These may improve the patient's compliance to the orthotic treatment protocol and its subsequent treatment outcome. Though utilizing 3D printing sounds to be an efficient solution, it is facing both technological and clinical challenges. Fabrication of the prototype using PETG showed **greater strength and durability** and most importantly for 3D printing it is more flexible than PET, thus preventing it from becoming brittle when printed. Petg printed brace also showed excellent layer adhesion and is flexible hence it serves the purpose of medication of the scoliotic spine.

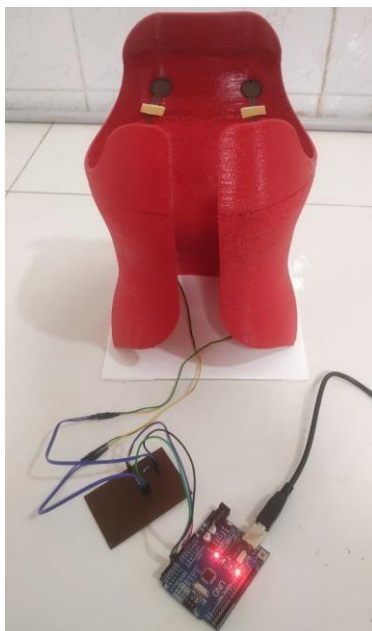


figure 5.10 shows the prototype of sensor integrated 3d printed brace.

The brace is 3d printed with PETG, a biodegradable material. Siemens nx software was used to design this model. This is less time consuming method with accuracy and more promoted finish of the model. 3d printed brace can be customized based on our requirements of AIS patients.

The conventional method to develop a scoliotic brace consists of mould generation

and rectification to obtain the desired orthosis geometry. (Inigo Sanz-Pena *et al.* ;2021). This conventional method has some drawbacks, such as a lengthy mould-rectifying process time, high volume of material consumption, low accuracy, not recording the patient's body geometry data for future use, weak mechanical properties of the brace, low brace compliance because of point contact, high friction, pressure sores, and movement limitation. Moreover, the lack of aesthetic pleasure when using conventional braces is a concern, which may affect the social life of the patient. (Shahrbanoo Bidari *et al.* ;2019)

Whereas manufacturing of the brace employing CAD/CAM technologies involves in obtaining a virtual geometry of the patient data, also 3D printing helps to manufacture a customised prototype ,which can be lighter, more aesthetic and comfortable(Youyu Zhang *et al.* ; 2020). Most importantly patient-specific braces are obtained. This technique enables to create complex and customized devices based on digital models.3DP is environmentally friendly, produces limited waste material, and does not require moulds. Each part can be customized and replicated without additional preparation cost. Comparing the conventional method human this is less laborious, reducing the risks of human errors (Davide Felice Redaelli *et al.* ; 2019). Thus Manufacturing of this brace using 3d printing is a novel approach . 3D printed brace are more breathable with addition of voids and the ability to customize different thickness at specific brace sections (Kenwick JL Ng *et al.* ; 2019).

This Study has developed and tested a low-cost, but accurate pressure sensing system for scoliosis braces by addressing the challenges related to pressure sensors for medical applications. FSR sensors are placed to assess the spinal deformity and patient comfort. Region at the scapula is chosen due to high bony landmass which can hence be used to detect wearer spine status. Hence the FSR sensor with arduino along with integration of brace is manufactured by 3dprinting technology providing better results in terms of accuracy, efficacy and convenience.

CHAPTER 6

SUMMARY AND CONCLUSION

6.1 SUMMARY AND CONCLUSION

A Novel design through engineering approach is done to develop a customized scoliotic brace. . The thesis provides information from the working of the sensors to its integration with three dimensionally printed orthosis.

The project focused on the following aspects,

- Literature review was done to study about the design types and considerations. Also the parameters was identified to study design inputs.
- Data collection about the patient scanned data was obtained .
- Possibilities of sensor interface was analyzed by carrying out studies. Thereafter function and working of force sensors was analyzed. Circuit integration with two sensors is done and the Sensors provided information about the pressure experienced by the scoliotic brace in order to assess the spine status.
- Brace design was made using the patient back-surface data through the designing software.
- An elaborate discussion about the 3d printer and the fused deposition modeling technique is made. PETG material was chosen to print the prototype.3D printing technology has its advantages such as human resources saving, environmentally friendly and more flexibilities of design.
- Fabrication of the Prototype was done.

This is project shows that it is possible to fabricate a sensor integrated scoliotic brace by additive manufacturing technique which is much easier, accurate and also reduces the time consumption to one third of conventional methods. Also it is a proven effective method for non-surgical treatment of scoliosis .

6.2 FUTURE WORK

Though the three dimensionally printed sensor integrated brace showed results, it

is important to note that a larger study on more brace designs and more curve types would be required before an algorithm can be developed for clinical use. Future studies will need to provide further evidence for long-term reliability of the technology, patient acceptance and clinical efficacy. Further clinical study with development of applications is needed to investigate long-term treatment effectiveness. Bracing in AIS may be improved in 3D by the use of simulation platforms. There may be a trend of applying 3D printing technology in the clinical service in the near future. However, technical improvements and further clinical evaluations with longer term and larger sample size are demanded to this state-of-the-art application.

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APPENDICES

- **PROGRAM FOR SENSING PRESSURE USING FSR SENSORS WITH ARDUINO UNO**

```
#define fsrpin1 A0

#define fsrpin2 A1

int fsrreading1;

int fsrreading2;

void setup() {
    Serial.begin(9600);

}

void loop() {

    fsrreading1 = analogRead(fsrpin1);
    Serial.print("Analog reading = ");
    Serial.print(fsrreading1);

    if (fsrreading1 < 10) {
        Serial.println(" - No pressure");
    } else if (fsrreading1 < 200) {
        Serial.println(" - Light touch");
    } else if (fsrreading1 < 500) {
        Serial.println(" - Light squeeze");
    } else if (fsrreading1 < 800) {
```

```

    Serial.println(" - Medium squeeze");

} else {
    Serial.println(" - Big squeeze");
}

delay(500); //Delay 500 ms.

Serial.print(": ");
Serial.print(" ");
Serial.print(": ");
Serial.print("\t");

fsrreading2 = analogRead(fsrrpin2);
Serial.print("Analog reading = ");
Serial.print(fsrreading2);

if (fsrreading2 < 10) {
    Serial.println(" - No pressure");
} else if (fsrreading2 < 200) {
    Serial.println(" - Light touch");
} else if (fsrreading2 < 500) {
    Serial.println(" - Light squeeze");
} else if (fsrreading2 < 800) {
    Serial.println(" - Medium squeeze");
} else {
    Serial.println(" - Big squeeze");
}

```

```
}  
  
delay(500); //Delay 500 ms.  
  
}
```