

ASSESSMENT OF THE PRESSURE DEVELOPED BETWEEN SCOLIOSIS BRACE AND PATIENT'S BODY AND EVALUATION OF THE EFFECTIVE TIME OF TREATMENT

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Abstract. *The aim of the present work is to confirm the effective time of use of the brace, for an accurate assessment of treatment from the therapist. Experiments were performed on a Dynamic Derotation Brace (DDB). Two devices have been designed, a data holder and a reader which give to the therapist the opportunity to certify the achievement of the brace's effective time. The accuracy of the recorded time is immunized by a system of switches, which are placed at appropriate points without giving direct access to the patient. The DDB together with the embedded data holder applied in 50 patients. After six months from the first application of the DDB, the therapist using the data reader is able to read and verify the exact time of use of the brace. Forty four patients had fully followed the treatment for the time period set by the therapist (23 hours every day), three followed the treatment to a satisfactory degree (18-20 hours every day) and the rest applied the treatment for a shorter period of time than prescribed by the therapist (less than 18 hours every day). Both devices offer great potential in the way of making more effective the treatment of scoliosis and may be to achieve control of pressure in the desired points of the body.*

1 INTRODUCTION

Scoliosis is a three-dimensional lateral curvature of the spine associated with vertebral rotation ^[1]. In its most common form, idiopathic scoliosis (70%–80% of cases), the causes are unknown ^[2]. Nowadays, young children and teenagers are facing an increasing level of idiopathic scoliosis deformity. The rate of Adolescent Idiopathic Scoliosis (AIS) estimated to be approximately 4 - 5% of the population aged 10 – 15 years old. The overall proportion of contested girls over boys is 3.5 to 1, however the effect is the same for girls and boys with small curves, below 10° (Table 1). Nevertheless, with the increase of curve magnitude, the ratio changes and it is observed that for curvature greater than 30° there is an overwhelming preponderance of girls compared with boys, in a ratio of 10 to 1 (Table 1). To address this problem, many technical approaches have been developed for diagnosis and treatment. These include radiography in order to measure the Cobb angle and therapy with scoliosis brace ^[3-5]. Brace treatment of AIS aims to prevent progression of the curve until the patient reaches skeletal maturity, at which time the risk of curve progression greatly diminishes. A significant number of applied therapy treatments do not have the desired results. This is due to a few factors. Two of them are the brace wear compliance and the patient's refusal to wear the brace for the time period set by the therapist.

The in-brace correction depends on curve flexibility which correlates highly with treatment outcomes and the amount of pressure that the brace exerts. The optimal amount of pressure may be different in each patient. Most researchers have only recorded how much time the brace has been worn and do not record or are unable to record whether the brace has been worn correctly, especially in terms of the amount of pressure being applied ^[6].

In many studies, compliance with brace wear is measured by asking patients if they used their brace and how many hours of wear they had each day^[7]. Some researchers added to this by looking for signs of wear on the brace to determine whether this matched with the patients' report^[8]. Some studies have reported that the amount of strap tension was highly correlated with the in-brace correction and the treatment outcomes^[9]. Such variability in the way that compliance is measured has prompted the International Research Society on Spinal Deformities (IRSSD) to develop new tools to measure compliance more objectively. Recent improvement in electronics technology have given us new ways to accurately measure brace wear, and this is making research much more reliable. Some devices use temperature or humidity sensors for measuring purposes while others use force switches and pressure sensors^[6].

| Cobb angle (°) | Frequency Girls to Boys |
|----------------|-------------------------|
| >10° | 1.4 to 2.1 |
| >20° | 5.4 to 1 |
| >30° | 10 to 1 |
| >40° | 10 to 1 |

Table 1: Adolescent idiopathic scoliosis, girls to boys ratio.

A key element for the best possible effective treatment offered by the brace, is its successful implementation on the patient's trunk. This is the result of correct measures taken during the construction of the mold under the action of which the brace is made. The brace should exert appropriate pressure at the points where the problem of scoliosis is focused. Therefore, the goal is the construction of a compact device which will warn optically and acoustically, if the pressure is outside the limits set for each case.

Furthermore, the failure of the patient, to follow the medical treatment recommended by an orthopedic doctor constitutes a serious issue. In particular many children refuse to wear the brace for the time their therapist prescribes them. This time is 23 hours during a day. The reasons for non-compliance with treatment is mainly cosmetic, (many times children with scoliosis braces accept criticism from their peers), or that simply they are tired and not willing to follow the treatment. Unfortunately, parents contribute to this direction when at the time of the reappraisal, conceal from the doctor the fact that their child did not follow the treatment, claiming the opposite. For this reason it is necessary the certification that the patient actually apply the treatment while wearing the brace on the required hours set by the therapist. This is accomplished by installing a compact device permanently at the patient's brace which will record and store the total time that the brace is worn. In order to fulfill the above objective, two simple devices have been designed. A data holder (D.H.D.) and a reader (D.H.D.R.) which give to the therapist the opportunity to certify the achievement of the brace's effective time. The reality and the accuracy of the recorded time are immunized by a system of switches (buttons), which are placed at appropriate points on the inner face of the brace without giving direct access to ones who wear the brace. Prerequisite to begin the time recording is that all the buttons must be activated simultaneously.

2 MATERIALS AND METHODS

2.1 Dynamic Derotation Brace (DDB)

Experiments were performed on a DDB. The DDB is a custom-made, underarm spinal orthosis extending from underneath the axilla to the pelvis, featuring aluminium pressure blades, set to produce derotating and anti-rotating effects on the thorax and trunk of scoliosis patients. The main body of the brace is made of one 3-mm thick piece of polyvinylchloride (PVC). It opens at the back and is fastened with four straps. The DDB was designed to correct scoliotic curve types commonly classified as thoracic, thoracolumbar, lumbar and double major (thoracic and lumbar). The function of the DDB follows concepts of passive and active deformity correction. The brace provides mechanical support to

the patient body (passive correction) and the patients pull their body away from the pressure sites (active correction). The DDB corrects the scoliotic curve through the application of forces which are transmitted to the spinal column mainly through the inner main pad, and the rest of the pads (Figure 1).

When the brace is applied, the derotating pressure blades exert anteriorly-directed forces at their fixation points and posteriorly-directed forces under the opposite half of the brace. The magnitude of the forces applied by the derotating pressure blades is added to the correcting forces already exerted by the brace at the area of the main pad, and can be controlled by changing the angle of the pressure blades backwards and the strap tension^[10].



Figure 1. Dynamic Derotation Brace (DDB).

2.2 Study subject group

The study was performed on 50 patients (83% girls, 17% boys), who attended the Department of Scoliosis & Spine, KAT Hospital, Athens, Greece, Ideal Scoliosis Centre, Athens, Greece and Ortho-Foot Centre, Nicosia, Cyprus, for a regular check-up and braces correction, or an appointment to wear the brace for the first time (Figure 2). All were asked to participate and they were selected according to the following criteria: a) patients presenting confirmed idiopathic scoliosis; b) aged 10 years and over, with a Cobb angle ranging from 20° to 40° in the absence of the brace, c) wearing a DDB brace, made by the same manufacturer and d) there were available recent posteroanterior and lateral standing thoracolumbar spine radiographs with and without the brace after six months of brace use, for a recommended wearing time of 23 hours per day.

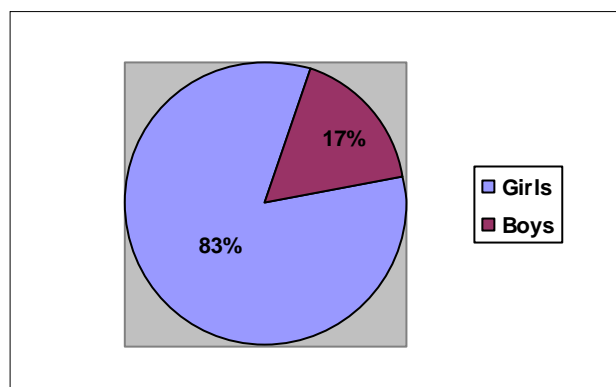


Figure 2. Study subject group proportion.

The patients' mean age was 13.7±1.9 years (10–17.2 years); height 1.6±0.1 m (1.4–1.8 m) and weight 52±10.0 kg (36–80 kg) with Risser sign of 0–4 (Table 2) The 51% of patients had right thoracic curves, 27% had right or left thoracolumbar curves and 22% had double thoracic (right) and lumbar (left) curves (Figure 3). Wearing the brace the mean Cobb angle for patients with right thoracic curves was 28 ± 6°, with right thoracolumbar curves was 30 ± 5°, with left thoracolumbar curves was 28 ± 7° and finally with double thoracolumbar, 31 ± 6° for right thoracic curves and 31± 8° for left lumbar curves.

| Parameter | Patients (n=50) |
|-------------|------------------------------------|
| Age (years) | 13.7 ± 1.9 years (10 – 17.2 years) |
| Height (m) | 1.6 ± 0.1 m (1.4 – 1.8 m) |
| Weight (kg) | 52 ± 10.0 kg (36 – 80 kg) |
| Risser sign | 0 – 4 |

Table 2: Anthropometric variables.

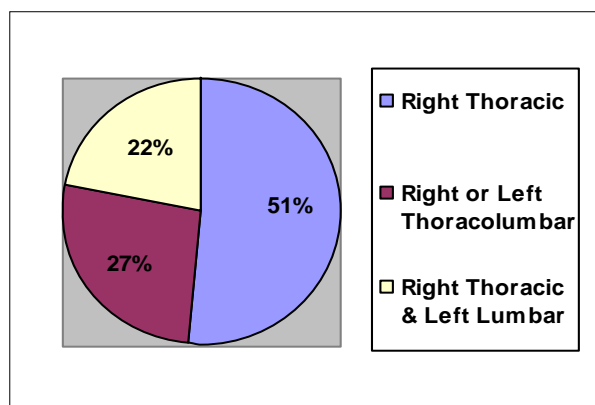


Figure 3. Type of curves.

2.3 Pressure sensor alarm device

The construction of pressure sensor alarm device seeks to ensure a way to achieve the desired maximum and minimum pressure on specific points of the patient’s body by the scoliosis brace. Also, it contributes to the construction of a brace which will apply fully to the patient’s body as well as identifying contact areas between brace and patient’s body where the applied pressure exceeds the desired limits set by the therapist. In our study, the expected mean force ranged between 70–150N^[11-14]. The force was converted pressure and then to a voltage value and compare this value with a reference voltage which corresponded to the expected pressure value.

The acquisition of the pressure generated by the brace was performed using a Flexiforce A201 pressure sensor (TekScan, Boston MA, USA) connected with Pressure Sensor Alarm device (Figure 4). The sensing area of the sensor was 9.53mm². Its thickness, length and width were 0.208mm, 197mm and 14mm respectively. The maximum pressure that the transducer could measure was 440N (100lb) which was suitable to this application. This sensor provided a linear output result with reliable and repeatable response ($r = 0.95$). Its linearity and hysteresis were less than ±5% FSS (Full Scale Span) and ±4.5% FSS, respectively. The full scale span was the algebraic difference between the output voltage at full scale load and the output at no load. The transducer was only able to measure the normal forces but not the shear forces. The shear force component would not affect the normal force magnitude. The sensor gave an accurate and stable output over the temperature range from -9 °C to 60°C. The pressure sensor was placed between the patient’s back and the inner surface of the brace, exactly at the area where the main pad was positioned, without compromising the corrective mechanism of the brace and without harming and annoying the patient.

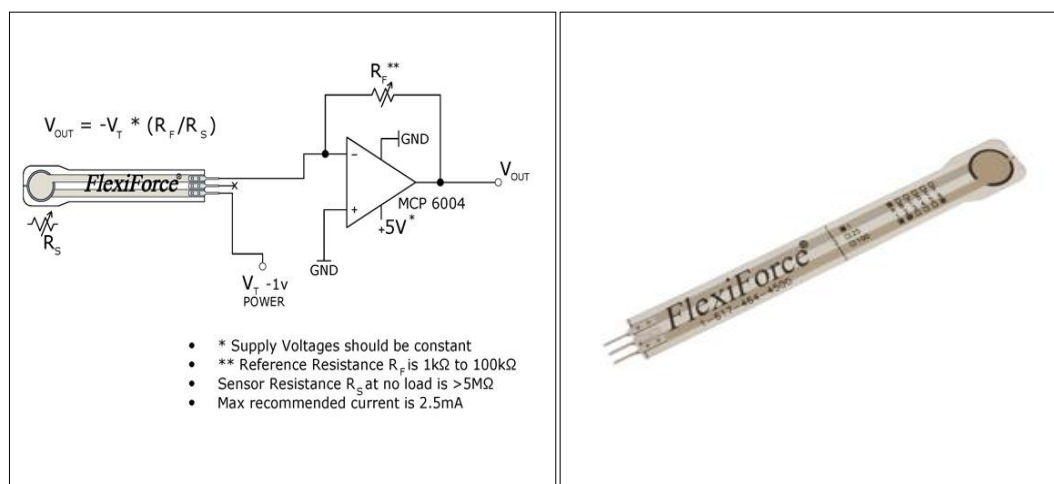


Figure 4. Flexiforce A201 pressure sensor (TekScan, Boston MA, USA).

2.4 Treatment time record

With the construction of the Data Holder Device (DHD), it was sought the record and the storage of the total time of the brace usage. This was achieved by mounting the device, the dimensions of which were small enough to allow its permanent placement into the brace and which recorded and stored the total time that the brace was worn. The reality and the accuracy of the recorded time were immunized by a system of switches (buttons), which were placed at appropriate points on the inner face of the brace and did not give direct access to ones who wore the brace. Prerequisite to begin the time recording was that all the buttons must be activated simultaneously.

The acquisition unit consisted of an 8-bit microcontroller, a flash memory and a battery management circuit. This specific microcontroller (ATTINY2313-20PI, Atmel, USA) was selected because of its small size, low power consumption and minimum external components requirement. It had a built-in 10-bit analog-to-digital converter.

The DHD, however, was only the means of recording and storing time. The reading of the recorded time and therefore its study by the doctor was fulfilled by means of a second device. The second device was the Data Holder Device Reader (DHDR), which was connected with the DHD. The main component of DHDR was also an 8-bit microcontroller similar to DHD. This allowed the accurate and precise data transfer between these two devices. More precisely the Receive serial gate of DHD microcontroller directly communicates with the Transmit serial gate of DHDR microcontroller.



Figure 5: DHD and DHDR devices in full assembly.

3 RESULTS AND DISCUSSION

The DDB scoliosis brace together with the embedded data holder applied in 50 patients. During the reappraisal, after six months from the first application of the brace, the therapist, with the use of the data holder reader, is able initially to read and then to verify the exact time of use of the brace.

It is worth noting that in addition to the successful functioning of data holder and reader, the results were very encouraging. 44 patients have fully followed the proposed treatment as they wore the brace for the time period (23 hours every day) set by the therapist. Other 3 followed the treatment to a satisfactory degree (18-20 hours every day) and finally only 3 patients applied the treatment for a shorter period of time than prescribed by the therapist (less than 18 hours every day) with the result that the treatment did not have the desired results.

Out of the patients who followed exactly the treatment, the 37.5% got better, the 52.5% were stable and the rest got worse. Wearing the DDB the 86% got better, the 7% were stable and the rest got worse. It was not possible to know the exact percentage of the curve correction for the rest of the patients who did not follow fully the treatment, because each one of them was wearing the DDB for different time period from less than 18 to 20 hours every day.

Even though bracing for treatment of scoliosis has been used for many years, there are still many unknowns on how a brace affects the spine. Brace treatment effectiveness is limited and outcomes need to be improved. The amount of time that a brace is worn is generally based on intuition. The most commonly recommended wear time is 23 hours per day; this number is not based on any objective data. Effectiveness of brace treatment for scoliosis depends on how much time (“quantity”) and how well (“quality”) the brace is worn. The measure of both quantity and quality of brace usage gives a good indication of whether a patient is properly following their treatment regimen. Measuring daily brace usage over a long period of time can provide information that how the brace has been used. When poor compliance is found, the surgeon, orthotist or a nurse practitioner can have a discussion with the patients to understand the reasons.

This research focused on scoliosis braces and in particular how could improve possible problems which are developed during the period of their application. Specifically it is sought the fulfillment of two targets: a) Providing a way to achieve the desired maximum and minimum pressure on desired body parts of the patient by the scoliosis brace.

b) The confirmation of the brace total time usage, in order the physician to make a detailed assessment of treatment.

As technology becomes more advanced, the electronic devices we used, are getting more accurate in order to measure brace compliance and effectiveness. The Pressure Sensor Alarm device is in phase of finalization. It was applied in a number of patients who took part in this research. The results were encouraging leading to the conclusion that it will be able to achieve control of pressure in the desired points of the patient’s body.

It is necessary to have measurements from much more patients in order to be able to achieve fully statistically correct results for all the patients’ categories.

4 CONCLUSIONS

The D.H.D. and the D.H.D.R. offer great potential in the long run to make more effective the treatment regardless of both the curve angle and the type of brace chosen by the therapist. Also, these devices in combination with the Pressure Sensor Alarm device that is in a stage of development will be able to achieve control of pressure in the desired points of the patient’s body whenever the brace is used.

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