Smart orthosis for the treatment of adolescent idiopathic scoliosis

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Abstract—*There is considerable controversy regarding the effectiveness of orthotic treatment for patients with adolescent idiopathic scoliosis. Most researchers believe that, to be effective, the orthosis must be worn as prescribed for both compliance and tightness. Compliance is the time the brace is worn relative to the prescribed time. A battery-powered microcomputer system was developed to monitor and maintain the loads exerted by orthoses used to treat children with spinal deformities during daily living. This system not only records how well and for how much time the brace has been used, but also helps patients to ensure that the brace is being worn at the prescribed tightness. Laboratory tests were performed, and five patients used the system for four weeks. The patients reported that the system helped them to wear the orthoses correctly and comfortably. The time that the patients wore the orthoses at the prescribed tightness level increased from 53 $\pm$ 9% during the monitoring period (first 2 weeks) to 68 $\pm$ 14% during the automatic adjustment period (last 2 weeks).*

Keywords—*Smart orthosis, Scoliosis, Orthotic management, Wearable computer*

Med. Biol. Eng. Comput., 2005, **43**, 746–750

1 Introduction

IDIOPATHIC SCOLIOSIS (IS) is a three-dimensional curvature of the spine with vertebral rotation, the cause of which is not known. This curvature affects the rib cage and presents deformities of the trunk (Fig. 1*a*). Treatment modalities for scoliosis are based on the patient's physiological (not chronological) maturity, curve severity, curve location, surface deformities and the risk of progression.

Orthotic (brace) treatment is the most commonly used method to control curve progression during the high-risk growth period of early adolescence. Boston-type braces are most commonly used in North America. Localised pressure pads are usually added inside the brace to provide support to the spine.

Brace actions depend on two components. The passive component has the brace provide mechanical support to the body; the active component depends on the patient pulling away from the pressure sites. The curve should be reduced when the brace is worn properly (Fig. 1*b*). The goal of the brace treatment is to prevent further curve progression. Any permanent reduction in the curve or deformity is usually considered a 'bonus'.

To be effective, the brace must be worn as prescribed, either full-time or part-time, until the child has completed growth (EMANS *et al.*, 1986). However, some studies have questioned its effectiveness (GOLDBERG *et al.*, 2001; KAROL, 2001), whereas others have concluded that the use of an orthosis effectively attenuates the natural progression of addescent IS (AIS) (FERNANDEZ-FELIBERTI *et al.*, 1995; LONSTEIN and WINTER, 1994; ROWE *et al.*, 1997). The efficacy of orthotic treatment remains a controversial topic among pediatric orthopaedic surgeons.

The most important issue concerning the effectiveness of orthotic management is whether patients wear the orthosis as prescribed, in both quantity (compliance) and quality (tightness). To assess compliance, the most commonly accepted methods are to ask the patient or family if the orthosis is being used and to inspect visually for signs of wear. To investigate how tightly patients wear their orthoses during their normal usage, patients at scoliosis clinics are asked to demonstrate how they tighten their orthoses. A mark is usually placed on the straps to help patients to tighten their orthoses properly. However, stretching of the orthosis straps or thinning of the lining foam can occur after the orthosis has been used for a few months, causing the mark to be inaccurate.

Other methods (JIANG *et al.*, 1992; WONG *et al.*, 2000; LAVELL *et al.* 1996; 1997; NICHOLSON *et al.*, 2001; HAVEY *et al.*, 2002) have been used to study either load or compliance while patients wore their orthoses. However, most of these methods could only be used in the laboratory environment. The others used temperature sensors to activate a timer to log orthosis usage; those required a significant difference between body and ambient temperatures to avoid false positive readings. None of these studies measured the quantity and quality of orthosis usage at the same time.

To study both the quantity and quality issues, a low-powered portable load monitoring system was developed in our laboratory (LOU *et al.*, 2002). Clinical trials indicated that patients who wore their orthoses more frequently, as well as tightened to the prescribed tension, either improved or stabilised their spinal curvature (LOU *et al.*, 2004*a*). Therefore a 'smart' computerised orthosis was developed (LOU *et al.*, 2004*b*) to maintain a constant prescribed load on the pressure pad imposed on the trunk during daily living.

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Paper received 16 March 2005 and in final form 21 September 2005
MBEC online number: 20054062

Fig. 1 *(a) Radiograph of scoliotic patient. (b) Radiograph of same scoliotic patient with orthosis on*

2 Objective

This preliminary study was to determine the capability of the smart orthosis and to investigate whether the smart orthosis could increase the portion of time that patients used the orthosis to the prescribed tightness level.

3 Methods and materials

3.1 *Smart orthosis*

The smart orthosis system was a further development of the portable load monitoring system (LOU *et al.*, 2004*a*). It consisted of a force transducer*, a data logger, and an automatic force adjustment module. Custom software was also developed to simplify the laboratory training session and data analysis procedures. Remote control and monitor features were built into the system so that it could save patient travelling time. Fig. 2 shows the smart orthosis system installed in a Boston-type brace. Fig. 3 is the block diagram of the system.

The force transducer and the air bladder were installed at the main pressure pad area. When the average pad force was less than the target level over a period of 15 min, the pump and valve 2 would be turned on for 1 s to inflate the air bladder. The system entered a fast checking mode, with the sampling rate at once per 2 s. In this mode, 15 samples were taken within 30 s, and the average was compared with the acceptable range. If the average was within the acceptable range, the system went back to the normal sample mode with a sample rate of 1 min^{-1}. Otherwise, more air would pump into the bladder. These procedures were repeated until the acceptable range was attained. However, if the pressure was beyond the acceptable range, air valve 1 would be opened for 0.5 s to release air from the bladder. The system entered a fast checking mode again, with the sampling rate at once per 2 s. The procedure would be repeated until the acceptable target range was attained. Valve 2 was activated longer than valve 1, because the deflation rate was faster than the inflation rate. A detailed description of the components is given in the following Sections.

*FS01, Honeywell Inc.

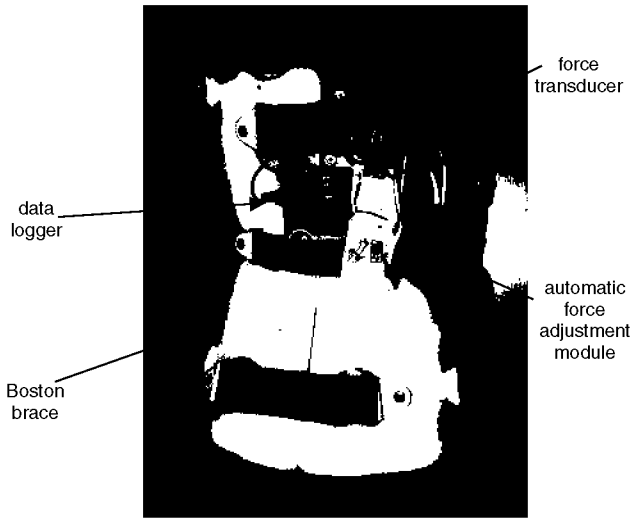

Fig. 2 *Smart orthosis, which included force transducer, data logger and automatic force adjustment module with Boston Brace*

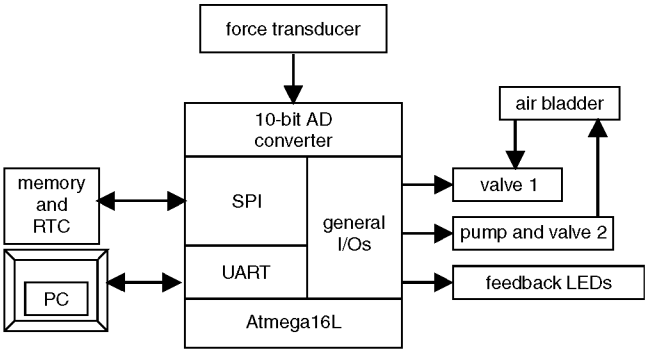

Fig. 3 *Block diagram of electronics of system*

3.1.1 *Force transducer*

The force transducer was selected based on its low profile, force range and power consumption. The thickness of the sensor was approximately 8 mm. It was sensitive to the forces normal to the orthotic surface, but not to shear forces. The operating force range of the transducer was 0–6.82 N. Its linearity and hysteresis were $\pm 1.0\%$ full scale span (FSS) and $\pm 0.5\%$ FSS, respectively. The full scale span is the algebraic difference between the output voltage at full scale load and the output at zero load. The span is dependent upon the supply voltage. The nominal FSS of this sensor 3 V. The temperature effect on span is $\pm 1.0\%$ FSS at a temperature range from 0 to 50°C. The accuracy of the sensor is $\pm 2\%$ FSS (± 0.15 N). The transducer was calibrated *in situ* with an air bladder placed inside the brace. The foam that covered the transducer distributed the applied force evenly. Fig. 4 shows the calibration graph of the force transducer with three trials. The applied force can be converted to the applied pressure using the equation

$$\text{pressure} = \text{force/sensing area of the transducer} \quad (1)$$

where the sensing area is 1.17 cm^2.

3.1.2 *Data logger*

The major components of the data logger were the microcontroller†, the real-time clock (RTC)‡ and the memory. Fig. 3 shows the block diagram of the system. The specific

†ATMEGA16L, Atmel Inc.
‡DSI305 Dallas Semiconductor

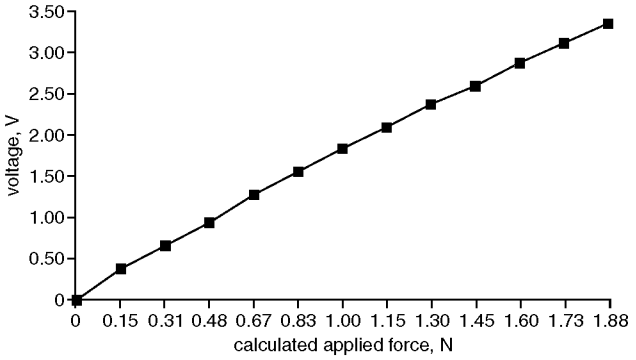

Fig. 4 *Calibration results of sensor for range of load levels applied by brace upon body ($r^2 = 0.99$). (-□-)trial 1; (-▲-) trial 2; (-■-) trial 3*

microcontroller was chosen mainly because of its low power consumption and built-in 10-bit analogue-to-digital (AD) converter. The RTC controlled the sample duration and interval and provided the necessary interrupts to the microcontroller. The 256 Kbytes memory stored the data during the study period. This logger also had a force level indicator that consisted of one green (within range) and two red (below and above range) light emitting diodes (LEDs). These LEDs provided information to patients regarding how tightly they wore their orthoses. The indicator could be used when the patient first donned the orthosis. A physician or an orthotist set the prescribed pad load (target level) after the force transducer was installed, and the subject donned his/her orthosis. The acceptable range was defined as 80–120% of the target level, which was the prescribed tightness with the patient in a standing position.

The size and weight of the system were 5.5 × 8 × 1.7 cm and 60 g, respectively. The system consumed 1 mA during the low-power sleep mode and 20 mA while taking a sample. With the valve and pump activated, the current consumption was 150 mA. Two AAA-sized (700 mAh) nickel-metal hydride rechargeable batteries were used to power the system. Nominal use of the system would require the user to charge the system once per week.

3.1.3 *Automatic force adjustment module*

The automatic force adjustment module consisted of a disposable neonatal blood pressure cuff** (size 4) that served as an air bladder, an electronic pump†† and two electronic valves‡‡. The air bladder was located at the pressure pad area and secured with a neoprene cover. The force transducer was placed underneath the bladder as well. The pump could provide pressure up to 51 kPa (380 mmHg), and the air valve could hold up to 42 kPa (320 mmHg). The selection of the pump and the valves was based on a previous study (JIANG *et al.*, 1992), where the maximum pressure applied by the orthosis at the pad site to the body was 16 kPa (120 mmHg). The function of the pump and valves was to maintain the pad load level within the acceptable range of the target load level.

3.1.4 *Custom software*

The custom software was written in Microsoft Visual Basic to run on a PC with Windows 2000 or XP operating system. Two programs were developed: one for the researcher and the other for the user. The researcher program simplified the set-up procedures. The sample rate, target level, feedback activation period (for example, from 0800 h to 2200 h) and the feedback activation date (the first 2 weeks could be set for the passive mode only, for monitoring purposes, and the last 2 weeks could be set for the active mode, which would provide feedback) could be set from this program. Data and battery level analysis could be performed as well. Real-time force level measurements were allowed.

The researcher was also able to retrieve the data remotely from the data logger or change the protocol through the Internet. This telerehabilitation feature helped save patient travel time and allowed the research team to provide feedback immediately if the patient had concerns about the system. The function of the user program was to guide the user to download data from the system. It also helped the user to send the data to the researcher through the Internet. After that, the patient could decide whether he/she will use the system continuously until the next clinic visit or not.

4 Tests

4.1 *Laboratory test*

A subject with no scoliosis volunteered to test the system in the laboratory. A custom Boston brace was made for the subject. The subject donned the brace, at the appropriate tightness, with the assistance of an orthotist. The pressure between the brace and the body at the pressure pad site was measured at 3.7 kPa (27.8 mmHg). The feedback system was enabled, and the data logger was set to a quick sample rate of 30 samples min^{-1}. The quick sample mode was run for 20 min to confirm the system worked properly and to allow the brace to seat properly to the body. After the system was proved to be working properly, the subject wore the orthosis for two equal consecutive time periods, each 1.5 h. During the first session, the feedback module was disabled. During the second session, the automatic adjustable feature was enabled. The sampling rate was set to 1 sample min^{-1}. The subject's activity was similar over the duration of the test periods.

4.2 *Clinical trials*

Five orthosis candidates, one male and four female, aged between nine and 14, average age 12.6 ± 2.2 years, who had worn their orthoses for up to 3 months, were recruited for this study. All patients signed the consent forms before participating in this study. The Cobb angles of the major scoliosis curve of the patients prior to orthosis was 31 ± 5°. After the system was installed, each patient performed in-laboratory measurements. Loads were measured when each patient adopted the following postures: normal standing, bending forward and backward, bending to the left and to the right, sitting normally, sitting with support and holding breath (sample rate: 5 samples s^{-1}, an average of 25 samples taken for each static posture). These measurements verified that the device was functioning properly, served as a training session for the subjects and showed them how various postures and activities affected the amount of pressure applied by their braces. The sample rate of the clinical trial was set to be 1 sample min^{-1}.

Each patient used the system for four weeks. During the first two weeks, the system only monitored the load; this was called the passive session. During the last two weeks, the feedback module was activated, and the air bladder was adjusted automatically; this was called the active session. The pressure pad level was defined as below, in-range and above when the level was below 80%, between 80 and 120%, and above 120% of the prescribed level, respectively.

**Critikon Inc.
††Sensidyne Inc.
‡‡Electrodyne Inc.

5 Results

5.1 *Laboratory results*

Fig. 5 shows the results from the quick sample test period (20 min) in the laboratory. The data for the first 7 min (200 samples) had a greater variation that may be due to the brace seating to the body. The target range was set to be 3–4.4 Pa (25–33 mmHg) (80–120% of the level set by the orthotist). Once the system was activated, the air pressure was adjusted to bring the tightness to the optimum level. After the adjustment period (approximately 15 min), the average pressure in the bladder was in the acceptable range. This confirmed that the system was working properly.

The acceptable range of the pressure pad was the same as for the quick test period, 22.5–33 mmHg. Fig. 6 compares the results between the first and second 1.5 h sessions. The subject was sitting and using his computer in both of the sessions. He also walked around the laboratory a few times. The sitting and standing activities varied the pressure level. The percentage of the time that the pressure level was above the range, in-range and below the range, in the first and second sessions, were (57%, 28%, 15%) and (44%, 47%, 9%), respectively. The target range was maintained 19% more often (47% against 28%) with the feedback system.

5.2 *Clinical results*

Five subjects used the device to measure the daily force patterns exerted by the orthosis upon the trunk. The average pad pressure was 7.7 $\pm$ 2.6 kPa. The results were close to other studies (JIANG *et al.*, 1992; LAVELL *et al.*, 1997; WONG *et al.*, 2000). The real-time clock logged how much time the subjects actually used their orthoses (compliance). The average time that the orthoses were used was 72 $\pm$ 15% (12.6 h per day) of the prescribed time (17.5 $\pm$ 3.8 h per day) over the study period. As this study was to investigate whether the smart

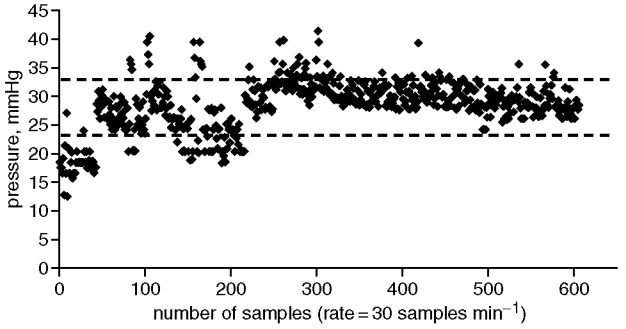

Fig. 5 *Fast sample test period (20 min). (----) Target range of prescribed tightness level*

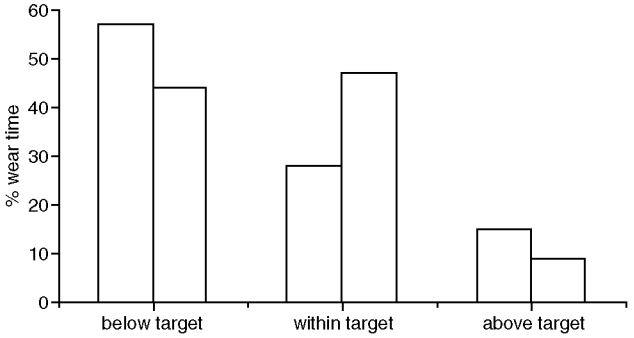

Fig. 6 *Comparison of laboratory results between feedback (■) disabled and (□) enabled*

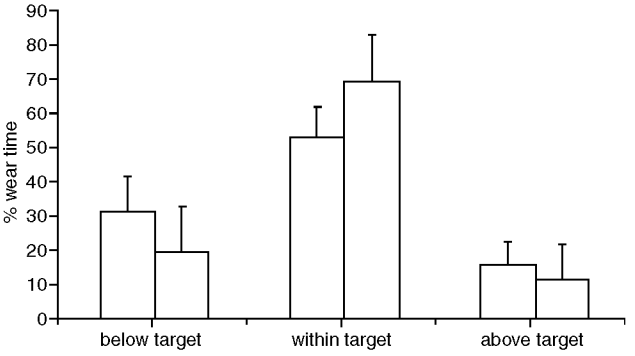

Fig. 7 *Comparison of clinical results between feedback (■) disabled and (□) enabled*

orthosis can increase the portion of time that the orthosis was at the prescribed tightness level, the period that the orthosis was not used was not counted in the analysis process. During the passive session (the first two weeks), the time that the pressure level was below, in-range and above was 30 $\pm$ 11%, 53 $\pm$ 9% and 16 $\pm$ 7%, respectively. During the active mode (the last two weeks), the time that the pressure level was below, in-range and above was 17 $\pm$ 13%, 68 $\pm$ 14% and 15 $\pm$ 11%, respectively. Fig. 7 summarises the results of the percentage of time against pressure distribution over the passive and active periods.

6 Discussion

Although orthotic treatment is currently favoured as a means to treat children with moderate scoliosis, it remains controversial. To investigate the effectiveness of orthosis, the minimum requirement is to consider how the subject wears the orthosis, in terms of both quality and quantity. The orthotic treatment is considered effective if the Cobb angles can be reduced or maintained within 5° of the pre-orthosis level. In this study, all patients knew that their compliance was being monitored; no deception took place. We felt that, being aware of the monitoring, the patients might wear their orthosis more (a good side effect). From this pilot study, patients reported that the time they wore their orthoses (compliance) was not affected by their wearing the monitor. However, the smart orthosis was able to increase the quality of wearing, which means the time that the pressure pad level maintained the prescribed level was increased. The Cobb angles of all five subjects were reviewed at their next clinic appointment, approximately 3–4 months after they used the smart orthosis. Their Cobb angles were the same (within measurement error) as at the first visit. All patients mentioned that, when they first put on their orthoses, they used the indicator lights to adjust the tightness to the prescribed level. Although the smart orthosis seems to be able to maintain the patients' Cobb angles, a conclusive statement cannot be made, because the number of patients was still small, and all patients have not reached skeletal maturity yet.

7 Conclusions

Although the pressure applied by the pad of an orthosis for the treatment of scoliosis varies greatly during daily activities, the smart orthosis was able to improve the portion of time the orthosis was worn at the prescribed tightness level (from 53% to 68%).

Acknowledgment—The authors gratefully acknowledge the financial support from the Hospital for Sick Children Foundation and the Edmonton Orthopaedic Research Society.

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