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# An advanced compliance monitor for patients undergoing brace treatment for idiopathic scoliosis

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ABSTRACT

Adolescent idiopathic scoliosis is a spinal deformity affecting 2–3% of adolescents. Brace treatment, the most common non-surgical treatment, uses a hard plastic orthotic shell to prevent progression of the deformity. Previous studies have found association between treatment outcome and patients' compliance with the prescribed brace-wear regimen. However, the exact relationship between compliance and treatment outcome has yet to be elucidated. Current compliance monitoring techniques may not be providing enough information about patients' brace-wear habits. Building on previous work, we present a new compliance monitor which records both temperature and force applied to the patient's body. The combination of temperature and force readings shows both how often and how tightly the brace is worn. The new monitor is designed for minimal size and power consumption, measuring 5.2 cm × 2.5 cm × 0.8 cm, with a battery life of approximately one year. Seven patients wore the monitor in this pilot study. The temperature-based compliance estimate differed significantly from the force-based estimate in four out of seven cases. This suggests that some patients may wear their braces very loosely, and that existing temperature-only or force-only compliance monitors may not be giving a complete picture of brace-wear habits.



## 1. Introduction

Adolescent idiopathic scoliosis (AIS) is a spinal deformity involving abnormal curvature of the spine and vertebral rotation [1]. It affects 2–3% of adolescents [2]. Adolescents with AIS can have higher pain prevalence, lower social function, and lower self-image than healthy individuals [3]. AIS tends to progress (worsen) over time [3], and the risk of progression is particularly high during the growth spurt [4]. Though scoliosis can be life-threatening in rare cases [5], in general the deformity would be surgically corrected before becoming physiologically dangerous. Surgical correction involves permanent fusion of part of the spine, an extended recovery period, and severe post-operative pain [6].

The most common non-surgical treatment for AIS is brace treatment, which aims to prevent progression of the deformity. Brace treatment uses a hard plastic orthotic (Fig. 1) which applies targeted corrective forces to the patient's torso. These forces counteract the spinal curve while the brace is worn. Brace treatment generally continues until the patient reaches skeletal maturity, and is considered successful if it prevents a clinically significant progression [7] by that time.

Patients' compliance, or faithfulness in wearing the brace as long as prescribed, affects treatment outcome. This already intuitive fact was demonstrated in recent studies by Katz et al. [8] and Weinstein et al. [9], and several earlier, smaller studies [10–12]. These studies have found significant correlations between treatment success and the number of hours of brace wear per day. Unfortunately, many patients have poor compliance. Various studies have reported average compliances ranging from 33% to 75% of the prescribed amount [13–19]. Compliance is also usually over-estimated by patients, parents, and physicians [17], with the patient-reported compliance being between 113% and 267% of the actual compliance [13–17].

Though patient compliance plays a major role in the success of brace treatment, it is not the only factor: there are some failures among highly compliant patients, and successes among those with poor compliance. For example, Weinstein et al. found about a 10% failure rate among the most compliant group of patients, and roughly 40% success among those with the worst compliance [9]. Katz et al. found similar results: 18% failure among the most compliant patients and 31% success among the least compliant [8].

In practice treatment outcome depends on many factors in addition to compliance, such as patient demographics and the nature of the deformity. The relationships between all these factors and

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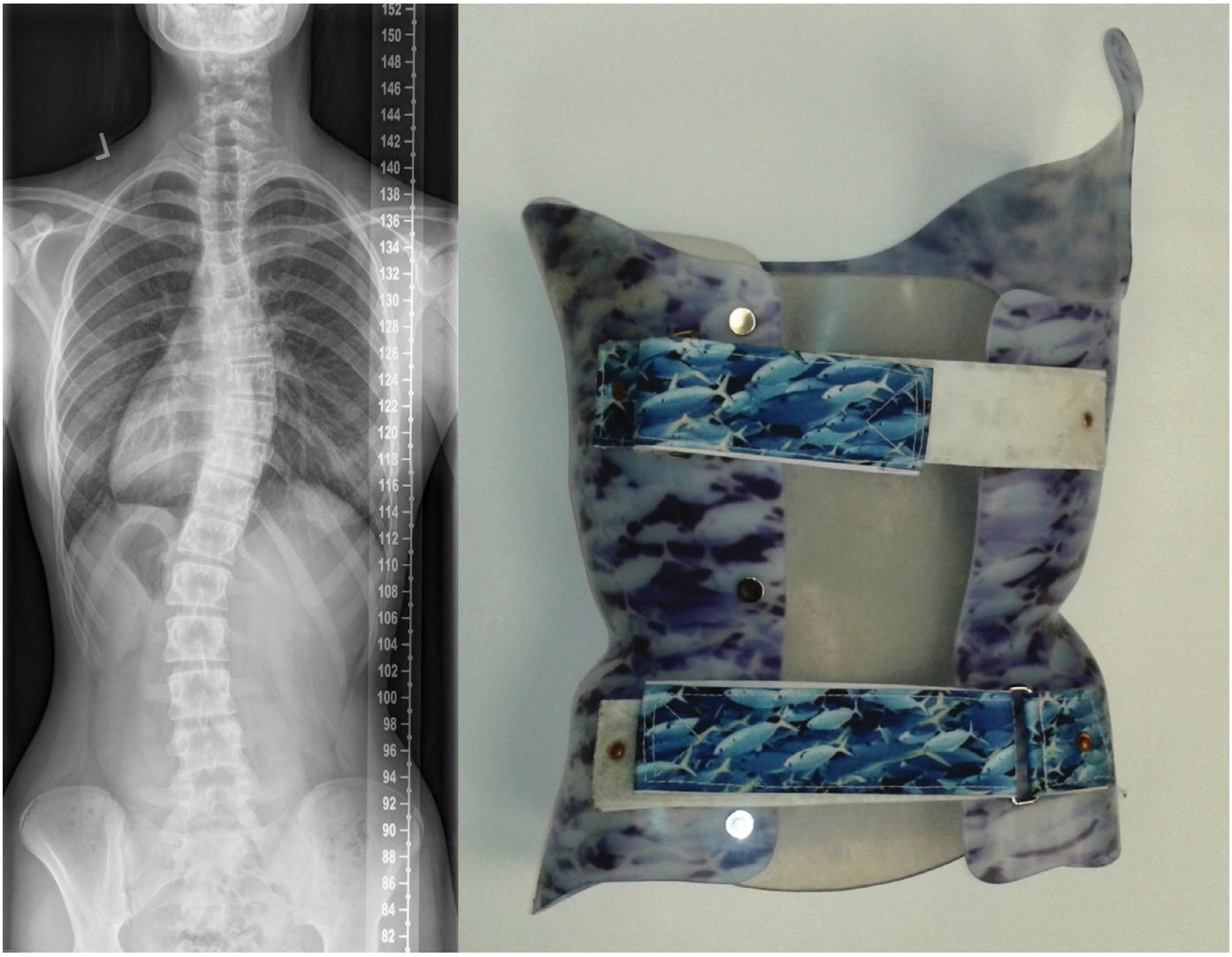

**Fig. 1.** Radiograph of an AIS patient (left), and a scoliosis brace (right) intended to stop progression of the deformity.

treatment outcome are complex and do not seem to be well understood. At least, a proven method for predicting treatment outcome as a function of these variables has not yet appeared in the literature.

It is possible that a better method of measuring compliance may be prerequisite to better understanding of the role of compliance in treatment success. Historically, compliance was measured subjectively or by simply asking the patient—leading to inaccurate compliance estimates and sometimes mistaken conclusions about brace treatment effectiveness [20]. In 2003 Landauer et al. combined patient-reported compliance, faithfulness in keeping appointments, physical evidence of brace-wear, and patient interviews to create a more robust but somewhat subjective measure of compliance [12]. Most other studies of brace-wear compliance have used electronic compliance monitors.

Electronic compliance monitors generally consist of a sensor, clock, and a battery-powered data logger to record sensor readings. They generally fall into two categories: temperature sensing and force/pressure sensing. Vandal et al. used a device which measured tension in the brace straps. A threshold of 7.8 N was used to identify when the brace was worn [13]. Havey et al. placed four pressure switches inside the brace, and considered the brace to be worn when at least two switches were activated [21]. Lou et al. designed a compliance monitor which recorded force applied to the patient's body [11,19]. Lou discretized the raw force readings to show time spent above, below, and within a reference force range. He found that patients typically wear their brace at 50–70% of the force level recommended by the orthotist—possibly decreasing the brace's effectiveness [19]. Chalmers et al. developed an active pressure control system which used inflatable air bladders to both monitor and maintain pressure inside the brace within a target range [22]. A breathing-detection algorithm was used to detect when the brace was worn.

Temperature sensing is the most popular method of compliance monitoring. These compliance monitors set a threshold on temperature in the brace (between 28 and 32 °C [8–10,14–16,18]), to differentiate ambient temperature from the skin temperature of the patient. Studies using temperature-based compliance monitors have found that younger patients are more compliant than older ones [15,18], patients are generally more compliant at night [14], and the knowledge of being monitored itself improves compliance [23].

In our experience, there are limitations to both force-based and temperature-based compliance monitoring. Temperature sensing detects *when* the brace is worn, but not *how well* it is worn: the temperature readings cannot differentiate between a patient who is wearing their brace properly, and one who is wearing their brace too loosely. Conversely, force sensing can detect how well the brace is worn, but cannot differentiate between a patient who wears their brace too loosely and one who does not wear it at all: in both cases the sensor records zero force. The distinction is clinically relevant—if the brace is too loose the patient may simply need instruction on proper