

A Compliance Real-time monitoring System for the Management of the Brace Usage in Adolescent Idiopathic Scoliosis Patients: A Pilot Study

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INTRODUCTION

- ◆ Brace treatment has emerged as the only proven method of non-operative treatment for AIS patients with curves range from 25° to 45° ~ 50° . Compliance is a significant one for patients to achieve a satisfactory outcome of brace treatment.
- ◆ Patient compliance can be measured subjectively by conducting questionnaires, reviewing a patient diary, or simply asking patients and their parents. These subjective measurements were arguably inaccurate and could result in mistaken conclusions about brace treatment effectiveness.
- ◆ Therefore, electronic devices (temperature- and/or force-based systems) were developed to measure medication compliance objectively. The monitored data was firstly stored in the electronic device and then downloaded at the patients' routine clinical visits (range 3~6 months). In this way, the data only revealed the quantity and/or quality of brace usage during the past period before the patients returned to the clinic, so that patients were not able to make improvements in time.
- ◆ The objective of this study is to describe and evaluate a compliance real-time monitoring system of the brace usage in AIS patients. We want to find a way to measure patient compliance in real time, so as to improve AIS patients' compliance with orthoses.

METHODS

1. Compliance real-time monitoring system (Fig. 1)

◆ Compliance monitor

The compliance monitor consists of a battery-powered data logger (Fig.2a) with a force sensor (Fig. 2b).

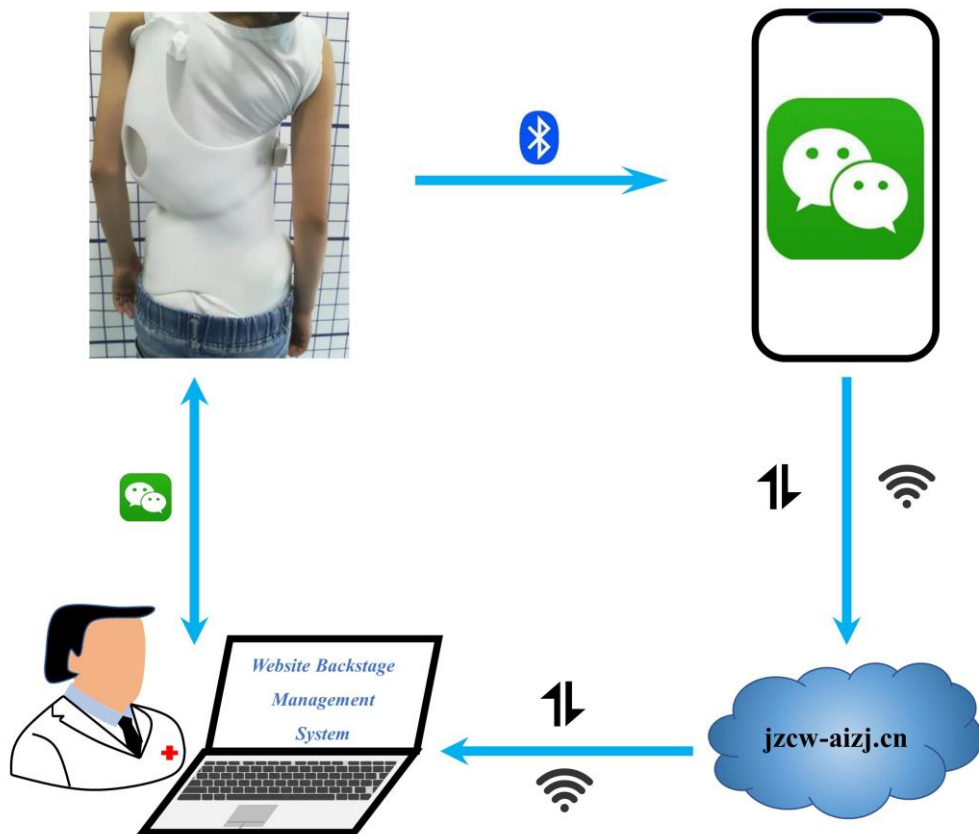


Fig. 1

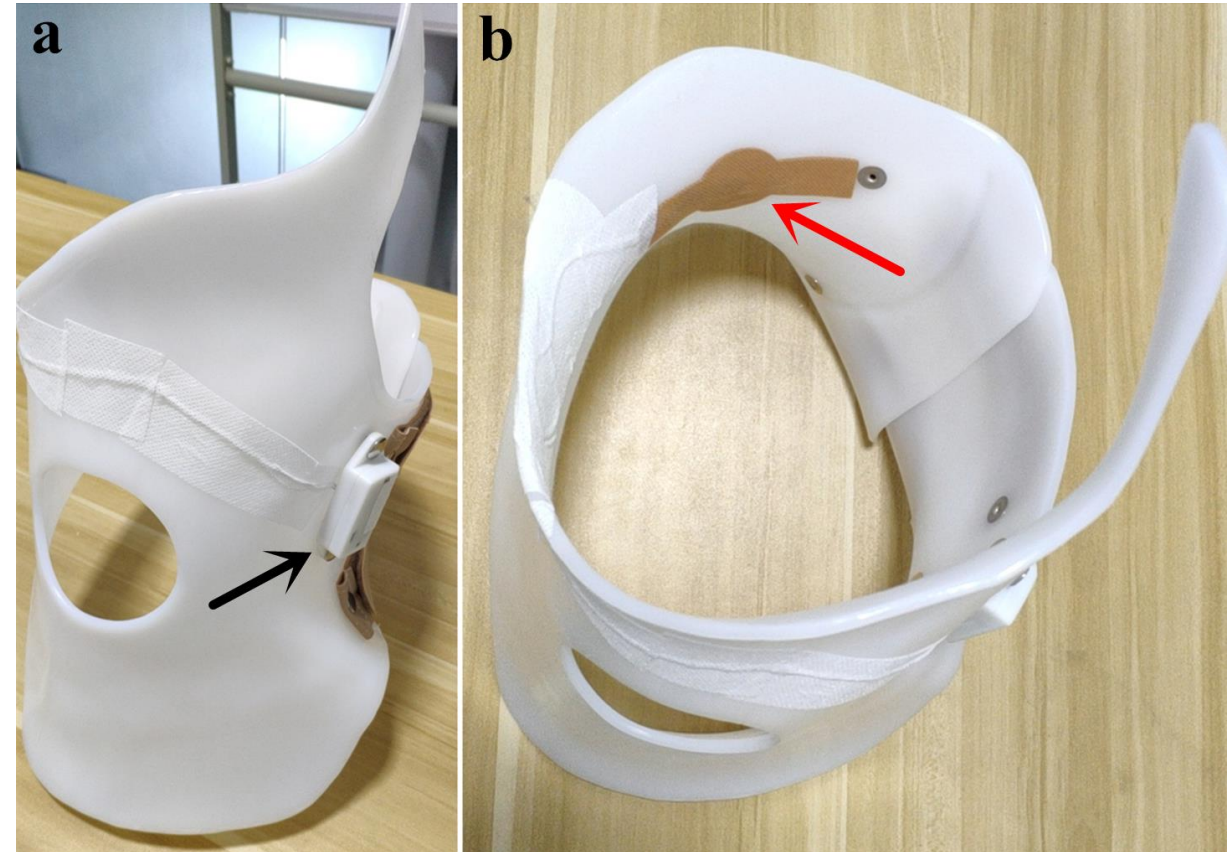


Fig. 2

METHODS

◆ WeChat Mini Program

WeChat Mini Program is an application of WeChat (Tencent, China) that can be used without downloading and installation. WeChat users can easily open the customized Mini Program by scanning its Quick response (QR) code or searching its name (支具精灵, *Zhi Ju Jing Ling*). Patients or their parents can access the WeChat app through their smartphones (Android or iOS) and bind their WeChat account with the compliance monitor. Subsequently, patients or their parents can check, review and/or upload the compliance data whenever they want. They can also communicate with the clinicians directly through the program.

◆ Cloud-based storage system

Patients or their patients can upload the compliance data from the customized Mini Program on the smartphone to the cloud-based storage system at jzcw-aizj.cn by simply pressing a button within the Mini Program.

◆ Website backstage management system

Clinicians can review or download the compliance data through the website backstage manage system and provide patients with necessary recommendations and counselling.

METHODS

2. System validation

- ◆ Inclusion criteria were: (1) age ≥ 10 years or older at the time of brace treatment, (2) Risser 0~2, (3) curves $25^\circ \sim 40^\circ$, and (4) no prior treatment.
- ◆ At initiation, patients and their parents were instructed in using the compliance real-time monitoring system. Then, clinicians measured patients' baseline brace force and told them that the prescribed brace wearing time was 23 h per day. The present study used the same method to evaluate the quantity and quality of the brace usage as was adopted in the previous study by Lou et al. The quantity of brace usage was defined as measured time (force value > 0) / prescribed time (23 h). The quality of brace usage was defined as measured force / baseline force.
- ◆ Each patient used the system for six months. At the clinic visit in 6 months, patients were also asked to rate their satisfaction as being very satisfied, somewhat satisfied, somewhat dissatisfied, or very dissatisfied.

RESULTS

- ◆ A total of 30 AIS patients were enrolled in this study. Among them, there was one patient who found her data logger detached from the brace and broken, the other patient could not upload the data from her data logger to the smartphone. Therefore, 28 patients (5 males and 23 females) were included in the final analysis. The mean patient age was 12.4 ± 1.5 years (range: 10~15 years). The follow-up period of all patients was 6 months. The mean baseline brace force was 1.23 ± 0.28 N (range: 0.82~1.95N). The mean measured force was 0.79 ± 0.29 N (range: 0.25~1.60N). The mean quality compliance was $64.8 \pm 22.2\%$ (range: 29.2~127.7%). The prescribed time of all patients was 23h. The mean measured time was 14.1 ± 2.9 h (range: 6.8~18.7h). The mean quantity compliance was $61.3 \pm 12.6\%$ (range: 29.8~81.6%).

RESULTS

- ◆ Details of measured force, quality compliance, measured time, and quantity compliance for each patient were listed in Table 1. The quality compliance during the first three months of treatment was significantly lower than the latter 3 months of treatment (49.1% vs. 80.5%, $P < 0.05$). Similarly, the quantity compliance of the first 3 months was significantly less than that of the latter 3 months (52.3% vs. 70.3%, $P < 0.05$).

Table 1

Parameters	3 months	6 months	P
Baseline Force (N)	1.23±0.28		/
Mesured Force (N)*	0.61±0.20	0.98±0.26	0.000
Quality Compliance (%)*	49.1±10.4	80.5±19.6	0.000
Prescribed Time (h)	23.0		/
Mesured Time (h)*	12.0±2.4	16.1±1.4	0.000
Quantity Compliance (%)*	52.3±10.8	70.3±6.4	0.000

- ◆ In this study, 96.4% (27/28) patients are satisfied with the use of the monitoring system, among whom 21.4% (6/28) are very satisfied and 75.0% (21/28) are somewhat satisfied. There was only one patient who was somewhat dissatisfied with the system.

DISCUSSION

- ◆ The measuring method of compliance is a key element in the accuracy of reported compliance. With advances in technology, electronic devices were utilized to measure compliance. The most common of such devices were temperature and pressure/force sensors. The temperature sensors were proved to be effective to monitor wearing time, but they could not measure the level of wearing tightness. Another limitation of the temperature sensors is that their accuracy may be affected when the ambient temperature reaches 30~40°C level.
- ◆ In this study, the thin film force sensor was chosen to monitor the patient compliance. The primary advantage of this sensor is its ability to monitor wearing quantity and quality simultaneously. In addition, this small force sensor can be installed at any position of the brace surface and is easy to mount/dismount without destructing the corrective mechanism of the brace.

DISCUSSION

- ◆ The influence of compliance is related to many factors such as age, orthosis appearance and construction, psychological feature ,daytime and nighttime wearing patterns and etc. If these influential factors with brace treatment were considered, the patient compliance would be improved.
- ◆ In this study, all patients and their parents were told at the beginning of the treatment that sensors embedded into patients' brace would monitor their wearing time and wearing tightness of the brace. In addition, clinicians provided suggestions for patients/parents according to the actual downloaded compliance data at least once every three months since the time when the brace was prescribed. The mean measured time ($14.1 \pm 2.9\text{h}$) and the mean quality compliance ($64.8 \pm 22.2\%$) were greater than that in previous studies .
- ◆ The increased compliance seen in this study can be largely attributed to the timely and frequent communication between clinicians and patients/parents. Additionally, both the quality and quantity compliance during the first 3 months of treatment was significantly lower than the latter 3 months. For one thing, the first 3 months might be a transition period as the patients were getting accustomed to their new braces. For another, the feedback provided by clinicians based on the data of the first 3 months might amplify the Hawthorne effect on these enrolled patients.

DISCUSSION

- ◆ Patients and their parents' attitudes towards electronic monitors are significant to the application and popularization of these monitors. In the present study, the percentage of patients who were very satisfied or somewhat satisfied reaches 96.4%.
- ◆ Such a high satisfaction would be attributed to the following reasons more specifically: (1) patients and their parents could review the historical compliance data and real-time wearing tightness whenever they want, (2) patients and their patients could receive regular professional and individualized advice from clinicians according to the patients' data, (3) patients or their parents could consult clinicians about the questions they met during the patient's brace treatment without restrictions of time and place, and (4) minimize the need for in-person visits to the clinic, thus maximize the reduction of patients' financial and time expense, especially for patients from remote areas.

CONCLUSION

The compliance real-time monitoring system, without evaluating the clinical and radiographic outcomes for now, has already shown some feasibility and effectiveness for the management of the brace usage in AIS patients. This system, as a useful tool for online patient management and patient-clinician communication, would be potentially employed on a large scale in future for clinicians to improve the compliance and satisfaction of AIS patients who have received the brace treatment.

CONFLICT OF INTEREST DISCLOSURE FORM

- I have no potential conflict of interest to report
- I have the following potential conflict(s) of Interest to report

Type	Name of commercial company
Receipt of grants/research supports	Not Applicable
Receipt of honoraria or consultation fees	Not Applicable
Participation in a company sponsored speaker's bureau	Not Applicable
Stock shareholder	Not Applicable
Spouse/partner	Not Applicable
Other support (please specify)	Not Applicable