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MyPectus: First-in-human pilot study of remote compliance monitoring of teens using dynamic compression bracing to correct pectus carinatum

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ABSTRACT

Background: Patient compliance is a crucial determinant of outcomes in treatments involving medical braces, such as dynamic compression therapy for pectus carinatum (PC). We performed a pilot study to assess a novel, wireless, real-time monitoring system (MyPectus) to address noncompliance.
Methods: Eight patients (10–16 years old) with moderately severe PC deformities underwent bracing. Each patient received a data logger device inserted in the compression brace to sense temperature and pressure. The data were transmitted via Bluetooth 4.0 to an iOS smartphone app, then synced to cloud-based storage, and presented to the clinician on a web-based dashboard. Patients received points for brace usage on the app throughout the 4-week study, and completed a survey to capture patient-reported usage patterns.
Results: In all 8 patients, the data logger sensed and recorded data, which connected through all MyPectus system components. There were occasional lapses in data collection because of technical difficulties, such as limited storage capacity. Patients reported positive feedback regarding points.
Conclusions: The components of the MyPectus system recorded, stored, and provided data to patients and clinicians. The MyPectus system will inform clinicians about issues related to noncompliance: discrepancy between patient-reported and sensor-reported data regarding brace usage; real-time, actionable information; and patient motivation.

Patient compliance is essential for satisfactory outcome in therapy involving medical braces. The clinical scenario for pectus carinatum (PC) is no exception. In PC treatment, surgical procedures are being replaced by noninvasive orthotic bracing that gradually corrects the condition by applying dynamic compression force. These braces have been largely successful in terms of correcting PC [1], however treatment efficacy and efficiency depend on the amount and duration of applied pressure, which in turn hinges on patient compliance. The more the patient wears the brace, the faster the brace will correct PC. Patients are recommended to only remove the brace during sports and showering. However, issues arise that negatively impact compliance. Too much pressure can cause pain and pressure ulcers for the patient, but inadequate pressure will prolong treatment time. Other reasons for reduced compliance include inconvenience and concerns related to appearance. Yet, studies of other orthotic devices, such as scoliosis bracing, have shown a positive relationship between brace wear compliance and patients' quality of life [2]. The question remains of how best to monitor and incentivize patient compliance. Consumer trends demonstrate a predilection toward personal electronic tracking devices for behavioral interventions, such as pedometers and metabolic devices. Furthermore, there are efforts to validate these devices in clinical settings. For example, Miller et al. [3] conducted a study indicating that electronic monitoring may improve compliance with brace-wearing protocols for patients with spinal deformities, and thus lead to positive behavioral modifications.

We developed the novel MyPectus system to monitor brace wear, and incentivize and optimize compliance. This paper reports the results of a pilot study in patients with PC undergoing noninvasive dynamic compression. The study took place at the Chest Wall Deformities Clinic in Buenos Aires, Argentina, where researchers have developed an effective bracing system (the FMF Dynamic Compressor System®) [4].

The objectives of this study were as follows: 1. Could our newly developed MyPectus data logger sense and record continuous pressure and temperature data? 2. Could the on board data logger connect wirelessly to a handheld device, and then to the cloud for storage? 3. Could all components of the MyPectus system connect and present data to the clinician and patient that is clinically meaningful, and trigger intervention as needed? 4. Would patients engage with the MyPectus system and act upon it?

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1. Materials and methods

The components of the MyPectus system include: data logger, smartphone app, web-based platform, and cloud-based storage system.

1.1. Data logger

The data logger inserts in the patient's current FMF® brace, sitting over the sternum (Fig. 1).

1.1.1. Specifications

Height: 10.16 cm. Width: 7.0 cm. Thickness: 1.27 cm. Weight: 130 g. It is sweat-resistant and custom machined with aluminum. Battery was a function of data log rate, which, at the time of the pilot study, was estimated to be approximately 8 months.

1.1.2. Temperature and pressure sensors

The mechanical system inside the data logger read force from the four corners and transmitted it to the single sensor point. A threshold temperature for each device was deemed indicative of skin contact, and therefore, device use, based on relative differences in recorded temperature from the threshold.

1.1.3. Data storage and distribution

The data logger recorded pressure and temperature approximately every 20 min via wireless Bluetooth 4.0 connection, then synced with the iOS app periodically throughout the day. The data logger contained an 8051 microprocessor located on the BLE113 Bluetooth Smart Module that also handled the Bluetooth communication. The data logger could store up to 2 days' worth of data on board without syncing before the data were overwritten.

1.2. iOS app

Patients used iPod Touch devices to access the iOS 7 app. Each patient had a unique username and password. Based on data logger information, patients received points for increased time spent wearing the brace. Data were not accessible to the patient for manipulation.

1.3. Cloud-based storage system

Pressing a button within the app, patients were instructed to initiate a sync to upload data from the iOS app on the iPod Touch to the cloud-based storage system on Parse.com at least every 24 h to avoid exceeding the app's storage capacity.

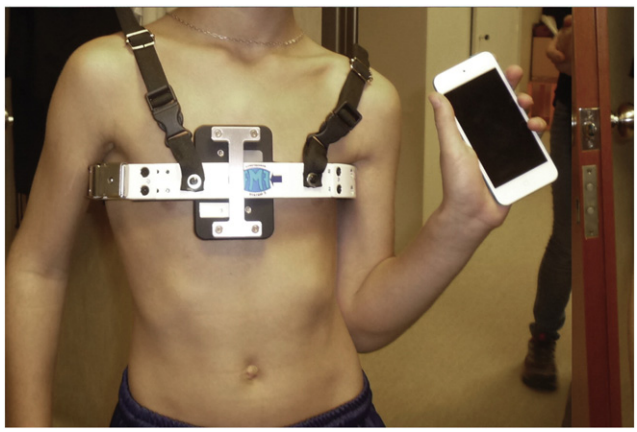

Fig. 1. Patient with MyPectus system. Patient is wearing the dynamic compression brace with the data logger inserted within the black device on his anterior chest. He is also holding an iPod Touch with the MyPectus app.

1.4. Online dashboard

The website for clinicians was hosted on Parse.com. The data were downloadable and not accessible for manipulation. Data were plotted as time versus temperature and pressure to indicate overall usage patterns.

With IRB approval and informed consent, we studied 8 patients ages 10–16 years with moderately severe PC deformities who underwent bracing with FMF Dynamic Compression System® at Fundación Hospitalaria Children's Hospital in Buenos Aires, Argentina. At initiation, the MyPectus device was attached to each patient's brace, and we measured patients' baseline brace pressure and took photos to document the deformities. Over 4 weeks, patients wirelessly synced the MyPectus iOS app on iPod Touch devices (that we lent to them for the study period) with the cloud-based storage system. With each sync, a point total appeared on the iPod Touch. Patients received points for increased brace compliance as measured by the temperature and pressure sensors. At the 4 week clinic visit, we remeasured applied brace pressure and took photos to document clinical progression of deformity. Patients completed an online survey to subjectively report compliance and their impressions regarding the device. At study completion, we compared the subjective online survey data to the objective sensor-reported data from MyPectus.

2. Results

Here, we present the results regarding the objectives of the study.

2.1. Sensing and recording pressure and temperature

In all 8 patients, the MyPectus data logger recorded a range of temperatures and pressures among patients.

2.2. Wireless connectivity between the MyPectus components

The data logger connected via Bluetooth 4.0 to deliver data to the iOS app for all 8 patients. When patients synced the app with the storage cloud within the suggested time period, the data were then pushed from the app to the cloud. However, when the app was not synced in a timely manner, the data exceeded storage capacity in the data logger and was not saved. Reasons why patients did not always sync as instructed included forgetfulness and inadequate internet connection.

2.3. Complete ecosystem and presentation of data to patient and clinician

Aside from the occasional lapses in data connection mentioned above in Section 2.2, there was a complete system of communication from the data logger, to the iOS app, to the cloud, then to the patient and clinician. The patient and clinician saw different interpretations of the data in ways that were meaningful to them. In other words, the patient received points from the app and feedback from the clinician, while the clinician saw graphs of data points and cumulative hours of usage (Figs. 2 and 3). Study coordinators were in contact with all patient parties by phone or email, depending on what was most convenient for the patient and/or their adult guardian. Two patients emailed the coordinators upon noticing that they were not winning additional points as expected despite continued brace usage. One mother contacted the coordinators to inform of the family's inconsistent wireless internet connection. When the temperature and pressure curves dropped off for extended periods of time, coordinators contacted patients to investigate if this represented a technical glitch or if the patient was noncompliant with brace usage. Thus, the MyPectus system had a complete feedback loop that empowered timely communication regarding treatment progress between patients and providers.