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SICOT AWARD PAPERS

Development of a functional prototype of a SMART (Sensor-integrated for Monitoring And Remote Tracking) foot abduction brace for clubfoot treatment: a pre-clinical evaluation

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Abstract

Purpose Recurrences following clubfoot correction by the Ponseti method can be prevented by regular use of a foot abduction brace (FAB) until the child is four to five years old. However, there is a lack of an objective method to measure actual hours of brace usage. The aim was to develop a functional prototype of a SMART (Sensor-integrated for Monitoring And Remote Tracking) clubfoot brace to record accurate brace usage and transmit the data remotely to healthcare providers treating clubfoot.

Methods A collaborative team of engineers and doctors was formed to investigate various types of sensors and wireless technologies to develop a functional prototype of a SMART brace.

Results Infrared sensors were used to detect if the feet were placed inside the shoes and magnetic Hall effect sensors to detect that the shoes were latched on to the bar of the existing FAB. Brace usage data were captured by the sensors every 15 minutes and stored locally on a data card. A Bluetooth low energy (BLE)-based wireless transmission system was used to send the data daily from the brace to the remote cloud server via a smartphone application. Accurate brace usage data could be recorded by the sensors and visualized in real time on a web-based application in a pre-clinical setting, demonstrating feasibility in clinical practice.

Conclusion The low-cost SMART brace prototype that we have developed can accurately measure and remotely transmit brace usage data and has the potential to transform caregivers' behaviour towards brace adherence, which could result in a tangible reduction in recurrence rates.

Keywords Clubfoot · Foot abduction brace · Sensors · Brace adherence · Ponseti method · Recurrences

Introduction

Clubfoot is one of the commonest musculoskeletal birth defects, with an incidence of 1.2/1000 live births [1]. Since over 90% of children born with clubfoot live in low- and middle-income countries (LMICs) where there is limited or no access to treatment, untreated clubfoot is one of the largest causes of physical disability in the world [2]. The Ponseti method has caused a paradigm shift in the way clubfoot is treated since the past two decades—from extensive surgical procedures to conservative methods of serial manipulation and casting [3]. It is now the preferred method of clubfoot treatment, with high success rates and good long-term outcomes [3–5].

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However, during early childhood when children experience frequent growth spurts, there is a tendency for the feet to relapse. Recurrences can be prevented by the use of a foot abduction brace (FAB) worn during naps and at night until the child is four to five years of age [4, 6]. The bracing phase of treatment is the biggest challenge with the Ponseti method and poor adherence to prescribed bracing is one of the most decisive factors for increased recurrence, with rates ranging from 15 to 40% [7–11]. Non-adherence to post-correction bracing has been associated with a five times greater risk of recurrence [11], with odds ratios of 120–183 [8, 9]. However, for a variety of reasons, parents often fail to adhere to this challenging phase of clubfoot treatment, and non-adherence rates of 30–60% [7–13] have been reported in literature. The reasons for non-adherence to bracing are complex and vary, from perceived discomfort to the child, to lack of understanding of the importance of bracing, lack of a family support system, language barriers and other psychosocial and cultural factors [8, 9, 11, 12]. Adherence to the bracing protocol is particularly difficult in low-income countries where there are systemic inequities and additional challenges due to long distances to reach clinics, low literacy levels, lack of accessibility and high cost of braces, and high rates of poverty among families [14].

While several authors have recommended strategies to encourage caregivers to adhere to the bracing protocol [8, 9, 11–13], there needs to be an objective method of reporting adherence to bracing. The current method of recording adherence to brace wear is using parent-reported data, which are not always reliable [7–13]. If it were possible to integrate sensor technology into clubfoot braces to record accurate brace usage and then transmit that information remotely to clinic staff using wireless technology, caregivers would be incentivized to use the braces as per the recommended protocol. The aim of this study was to develop and test a functional prototype of a low-cost SMART (Sensor-integrated for Monitoring And Remote Tracking) foot abduction brace, which would determine whether it is feasible to deploy sensors and wireless technology to accurately record and transmit remotely the hours of brace wear, in an attempt to improve brace adherence and reduce recurrences following clubfoot treatment.

Materials and methods

The study was funded by a two year grant from the SICOT Research Academy in 2018.

The process

A collaborative initiative was formed between four partners: Biomedical Engineering and Technology (incubation) Center (BETiC)—a research centre based at the Indian Institute of Technology (IIT) Bombay, India's leading engineering university; Department of Paediatric Orthopaedics at the Bai Jerbai Wadia Children's Hospital in Mumbai; MiracleFeet, an international non-governmental organization (NGO) that works to deliver clubfoot treatment in LMICs; and MetWiz, an Indian manufacturing partner. We used a collaborative innovation model comprising of four stages: defining an unmet clinical need where doctors play a critical role, developing a novel solution by researchers, delivering a well-tested product by entrepreneurs and deploying it in clinical practice supported by investors, with a goal of taking new ideas through invention and innovation to impact. This process is referred to as 'bedside to bench to business to bedside', enabling creation of affordable, effective, reliable and suitable products for healthcare.

Team building, clinical immersion and conceptualization

For developing a medical device, doctors and engineers needed to collaborate. The team consisted of a paediatric orthopaedic surgeon with > 25 years of experience in treating clubfoot, engineers from BETiC with skills in electronics, mechanical and software domains, a manufacturing partner and a project manager. The first step of the project was to understand the clinical problem and define the functional requirements of the device. The engineering team regularly visited the Bai Jerbai Wadia Children's Hospital, which treats > 200 children with clubfoot annually, to observe the clubfoot casting and bracing procedure in the dedicated clubfoot clinic. The team interacted with patients and parents in the hospital, to understand the different brace designs and the bracing protocol. The team discussed extensively on the various user requirements and functional requirements of the project, including the following:

- Should a new brace be designed or would it be possible to work with the existing foot abduction brace, without violating intellectual property and patent rights?
- What would be the appropriate sensor technology that could be incorporated into the brace?
- Which wireless technology would be ideal, considering technical requirements, availability and cost?

Brace design

Rather than design a new brace, we decided to work with the existing foot abduction brace provided by our NGO partner, MiracleFeet. The MiracleFeet brace (MFAB) is an FDA-registered, patented, assistive device conceived by MiracleFeet and designed by the Stanford d.School's Design for Extreme Affordability. Costing less than US$20 to produce, the MFAB incorporates several design elements featured in commonly used but more expensive foot abduction braces and utilizes innovative manufacturing solutions to create a low-cost, lightweight device for global use. In addition to the standard features of any foot abduction brace, the MFAB features a detachable shoe and bar combination with a clip-on system to assist in donning and doffing, and three sizes of bars which can accommodate the seven available shoe sizes. The upper portion of the shoes is made of washable canvas fabric while the shoe plates and the bar are made of ortholite/T90 and manufactured using an injection-moulded plastic process to facilitate mass production. The bar is designed with a wedge shape to keep the feet at 10° of dorsiflexion and employs a variable shoe hub that can be adjusted to 35 and 65° to accommodate unilateral and bilateral clubfeet.

In order to avoid violating the design patent, a modular attachment was developed which could be fitted on to the existing MiracleFeet brace (Fig. 1a). A virtual prototype of the modular attachment was designed using CAD-CAM technology and then a rapid prototype was manufactured using fused deposition modelling (FDM)—a type of 3D printer technology, to confirm that it could be easily inserted on to the existing snap-fit arrangements of the MFAB. For the final functional prototype, 3D printing of the assembly and the components was carried out using selective laser sintering (SLS) which has excellent mechanical properties resembling injection-moulded parts. The modular attachment, which would house the sensors and electronic components, would snap on to the bar of the MFAB and the shoes would then be latched on the top of the modular attachment, thus keeping the functionality of the original brace intact (Fig. 1b).

Results

Sensor technology

The sensor system needed to be compact, unobtrusive, reliable and utilize low-cost materials and technology that could be easily adopted in low-resource settings. We experimented with different technology and developed various types of sensors using an iterative process. For the first iteration, we developed force-sensitive resistor (FSR) sensors to get quantified pressure values (Fig. 2). In this design, the shoes and the bar were connected by magnetically coupled ports, which enabled data transmission electrically from the shoes to the bar. The disadvantage with this system was that since it was wired, the shoes had to be locked at one particular rotation of 65° and could not be changed to 35° if required. The sensors used to also wear off after continuous use and would show an erroneous fixed value. In the second iteration, touch sensors were developed (Fig. 3). These are based on capacitive coupling, which can detect and measure anything that is conductive or has a dielectric different from air. In the final iteration, it was recognized that two types of data needed to be captured by the sensors: (a) to detect the presence of the feet in the shoes and (b) to detect that the shoes were latched on to the bar of the brace. Accordingly, we developed two types of sensors to generate these data. The modular attachment incorporated an infrared (IR) sensor assembly which detects the presence of the foot in the shoe through a small aperture. The transmitter continuously transmits an infrared signal which bounces off from

Fig. 1 **a** SMART brace modular attachments fitted on to the bar of the MiracleFeet foot abduction brace (MFAB). **b** Final prototype of the SMART brace showing modular attachments and shoes attached to the bar of the MFAB

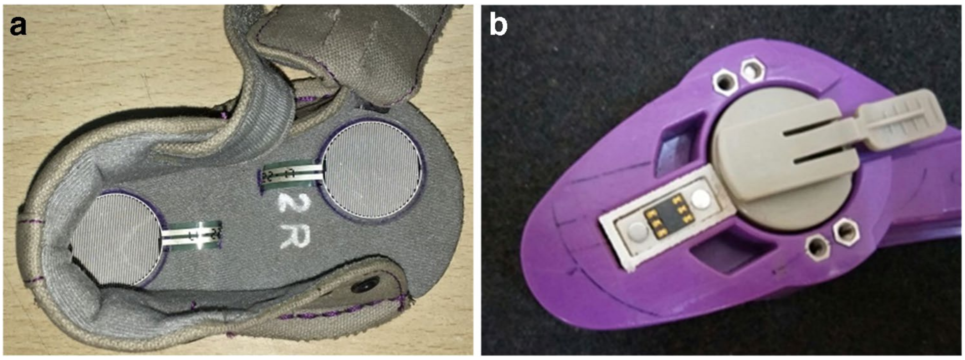


Fig. 2 First iteration of sensor design showing **a** force-sensitive resistor (FSR) sensors in the sole of the shoe and **b** magnetic port for data transmission

the surface of an object and the signals are received at the infrared receiver end (Fig. 4a). A magnetic Hall effect sensor was used to detect whether the shoe is attached to the bar or not. The Hall effect sensor was placed underneath the bar and the shoe contained a magnet which was detected by the Hall effect sensor placed inside the bar (Fig. 4b).

Wireless technology

The team deliberated on various wireless technologies including Wi-Fi, cellular GPRS, long-range radio (LORA), near-field communication (NFC) and satellite transmission. After doing a detailed cost-effectiveness analysis, we decided to use a Bluetooth low energy (BLE)-based wireless transmission system to send the data from the brace to the remote cloud server via a smartphone application. The user would have a mobile application in which data would be pushed from the local storage via Bluetooth low energy (BLE) technology, once in 24 hours, to the cloud server. The healthcare provider/clinic administrator would be able to view the records through the web interface on a laptop or desktop computer (Fig. 5).

Electronics and PCB details

The printed circuit board (PCB) was made to fit inside the modular attachment, which snaps on to the bar of the MFAB. The under surface of the PCB comprises of the two sensors—a magnetic Hall effect sensor to detect the shoe via the magnetic field and an infrared (IR) sensor which detects the presence of the foot in the shoe (Fig. 6a). The top side of the PCB comprises of electronic components to process and relay the data from the sensors to the smartphone application (Fig. 6b). For storing the data locally, a micro secure digital (microSD) memory card was used to store the data every 15 minutes, along with the time stamp.

The main controller of the device is the Nordic semiconductor which is a Bluetooth low energy (BLE) system-on-chip (SoC) having ARM® Cortex® M-4 processors (ARM Holdings, Cambridge, UK). This microcontroller collects data captured by the sensors from both right and left shoes/feet. To avoid wires going down between the modules, a radiofrequency (RF) transceiver was used to make the system completely wireless. In order to reduce the duplication of the Bluetooth chip in both modules, RF transceivers were used in both the modules to communicate the information. The RF transceiver sends the data from the left module (slave module) to the right module (master module) every 15 minutes. The right module has a Bluetooth chip for transferring the data to the smartphone. This can be seen in the electronic block diagram (Fig. 7). The device is powered by a lithium polymer (Li-Po) rechargeable battery, which has sufficient power to drive the device for one week without recharging. The device has a light emitting diode (LED) which turns on if the battery power is low and the unit needs to be charged using a micro universal serial bus (microUSB) charger. For storing the current time, a real time clock (RTC) is used. A secondary coin cell battery is provided in the unit for powering the RTC, in case the primary source is not available. Since the device logs the data every 15 minutes, if the primary battery were to fail, the microcontroller would not know the timing in the absence of a secondary battery.

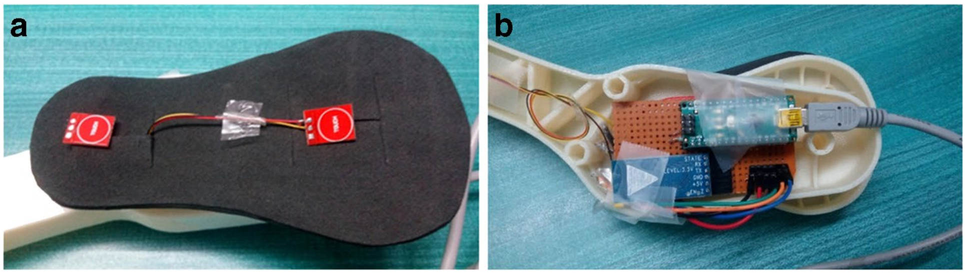


Fig. 3 Second iteration of sensor design showing **a** touch sensors on the sole of the shoe and **b** data recorder and transmitter in the shoe base

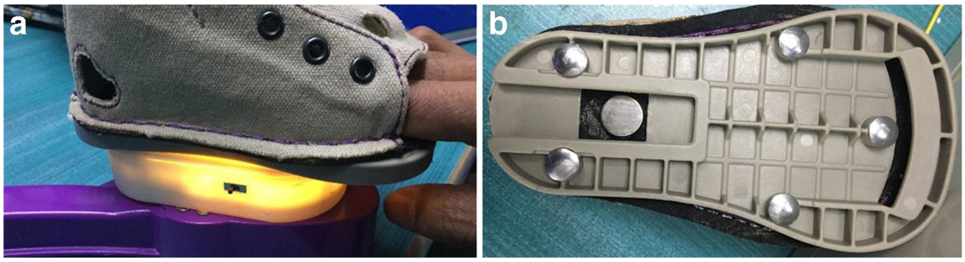


Fig. 4 Final iteration of sensor design showing **a** infrared sensor in the modular attachment and **b** Hall sensor magnet embedded in the base of the shoe

Data capture and remote transmission

Data from the sensors are captured every 15 minutes and stored in the microSD card, which has the capacity to store the brace usage data locally for about three months. Local data storage serves as a backup and can be accessed anytime the patient attends the clinic for a follow-up visit, by removing the microSD card and downloading the data on the laptop. For remote transmission, the device starts advertising at 23:00 hours every day, at which time the smartphone should be within the advertising range of the device. When the smartphone is within the range of the Bluetooth, the device automatically gets connected to the mobile application and the BLE hardware sends stored data, device information and battery percentage from the microSD card to the mobile application.

Software development—mobile and web applications

Two software applications were developed for the SMART clubfoot brace—an Android mobile application and a web application. The Android mobile application (SMART ClubFoot) would be installed manually on the user's smartphone by the clubfoot clinic administrator and would be used to store day-wise brace usage data, which can be accessed by the parents, and to transfer the data from the SMART brace to the cloud server. The web-based application would be used by the healthcare providers/clinic administrators who are supervising the clubfoot programme to monitor the daily data and see the progress of all the children under treatment. When the child is given the SMART clubfoot brace for the first time, the clinic administrator/healthcare provider first inputs the child's details and SMART brace details in the database on the web application. The mobile application is then opened and the user inputs their mobile number and date of birth of the child in order to log in. The SMART brace should be placed in close proximity with the mobile phone (within 8 feet distance) to initiate the pairing and data syncing process. Once pairing is successful, the Android mobile application receives continuous data from the BLE hardware. The data are stored in the mobile application and are pushed to the cloud simultaneously. To access the patient records, the clinic administrator/healthcare provider needs to visit the web dashboard and log in using password-secured credentials. The records of all patients associated with that particular clinic or healthcare provider are now accessible. New patients can be added and data of existing patients can be visualized by clicking on the patient's name. Weekly data are visualized as graphs per page, but one can click on a particular day to visualize more granular details of hours of brace use on that day.

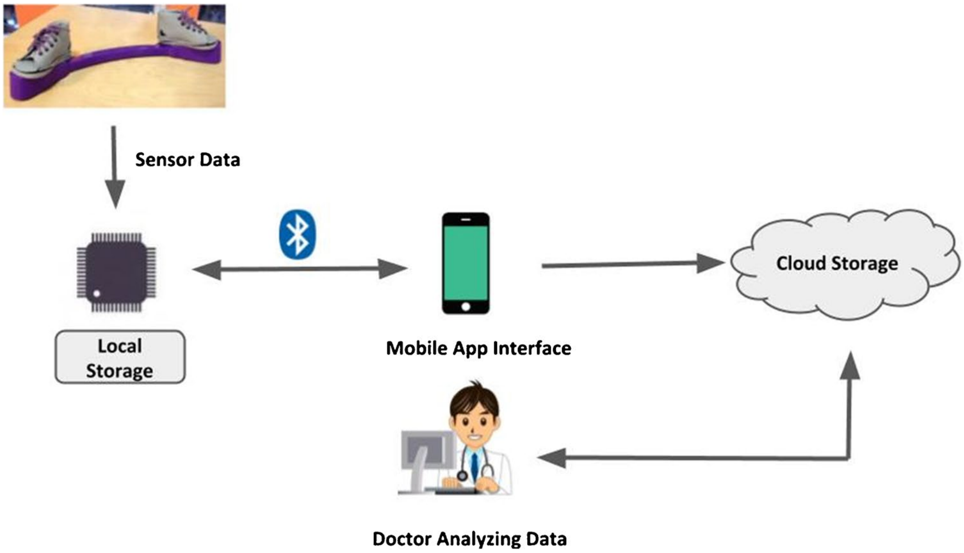


Fig. 5 Block diagram showing data flow

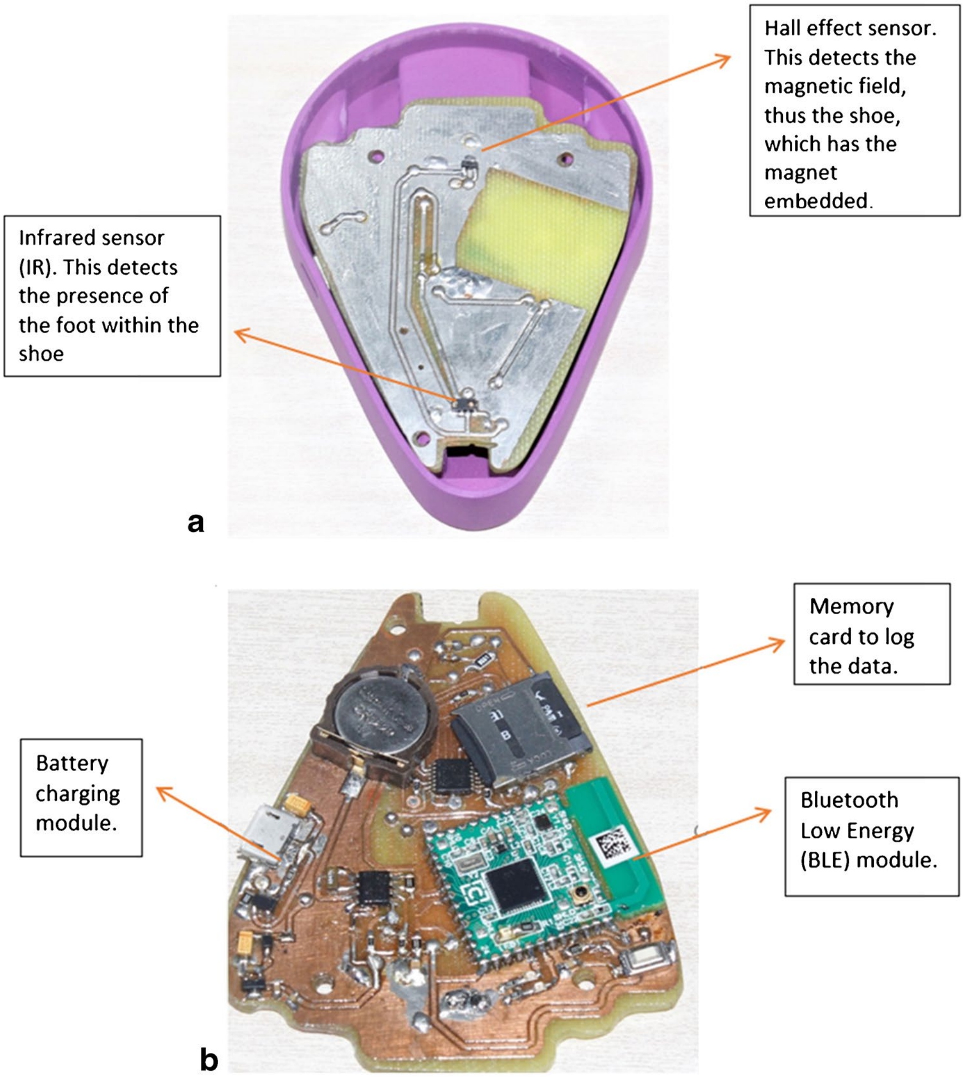


Fig. 6 **a** The under surface of the printed circuit board (PCB) showing both the Hall effect and the infrared (IR) sensors. **b** The top layer of the PCB showing electronics components

Pre-clinical testing

To carry out bench testing of the functionality of the device, a generic foot was 3D printed and used as a dummy model. The 3D printed foot was kept inside the shoe of the SMART brace for 24 hours, so as to detect the foot and the shoe independently. As seen in Table 1, we were successfully able to detect the foot and the shoe over 24 hours. The mobile and web applications were also tested extensively to confirm that accurate data were recorded by the SMART brace and that the data could be transmitted remotely using the BLE technology, by creating a dummy account and device login.

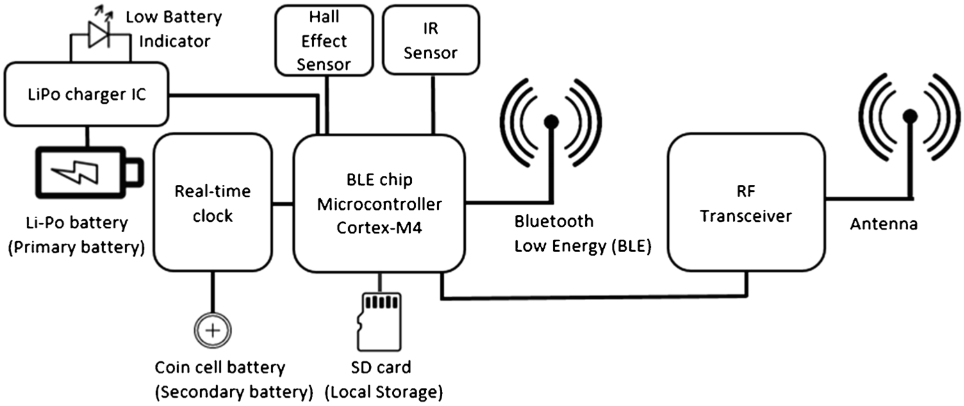
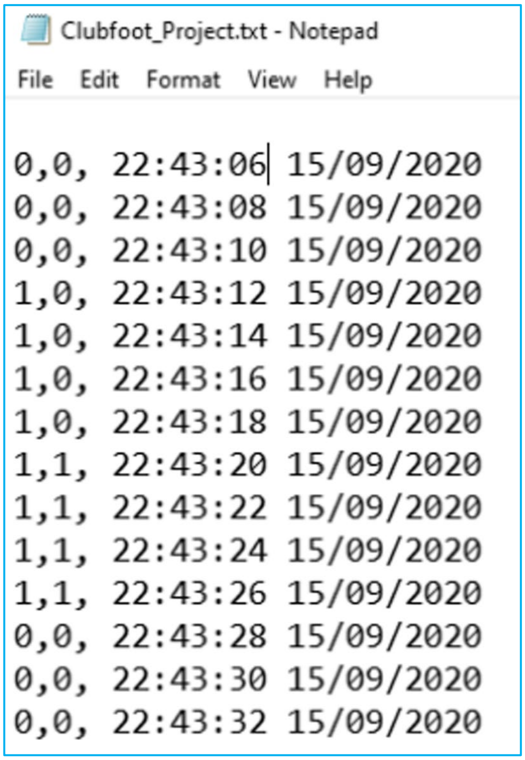


Fig. 7 Block diagram of the electronic components for the master module

Table 1 Pre-clinical testing of the SMART brace prototype using a 3D printed foot model



```
0,0, 22:43:06 15/09/2020
0,0, 22:43:08 15/09/2020
0,0, 22:43:10 15/09/2020
1,0, 22:43:12 15/09/2020
1,0, 22:43:14 15/09/2020
1,0, 22:43:16 15/09/2020
1,0, 22:43:18 15/09/2020
1,1, 22:43:20 15/09/2020
1,1, 22:43:22 15/09/2020
1,1, 22:43:24 15/09/2020
1,1, 22:43:26 15/09/2020
0,0, 22:43:28 15/09/2020
0,0, 22:43:30 15/09/2020
0,0, 22:43:32 15/09/2020
```

The first column detects if the shoe is latched on to the brace and the second column shows if the foot is inside the shoe. The third column is the time stamp and the fourth column is the date. First, both the rows show a 0 value, which means that the shoe is not attached to the module. As soon as the shoe is attached, the first digit changes to 1, at time 22:43:12. Then, when the plastic foot is kept inside the shoe, both the digits change to 1 at 22:43:20; thus, both the shoe and the foot are in in the right place. Then, when the shoe is removed at time 22:43:28, both the digits change to 0

Four possible clinical scenarios were tested to determine the accuracy of the data captured by the device (Fig. 8). On day one (2020–12-01), the 3D printed foot was placed inside each shoe and the shoes were latched on to the bar of the brace for 23 hours, to mimic the clinical recommendation of full-time brace wear for the first three months following clubfoot correction. As one can see from the graphs on the data visualization page of the web application, the presence of the foot inside the shoe was accurately detected by the IR sensor while the Hall effect sensor detected that the shoes were correctly latched on to the bar for the prescribed amount of time. On day two (2020–12-02), the dummy feet were placed into the shoes but the shoes were not latched on the bar of the brace, to mimic a similar scenario in the clinical setting where the parents only apply the shoes but neglect to use the bar. Since data are logged only when the shoes are latched on to the bar, no graphs were recorded on the web application. Hence, wearing the shoes without the bar is equivalent to not using the brace at all. On day 3 (2020–12-03), the shoes were latched on to the bar for 24 hours but the dummy feet were not inserted into the shoes. Since only the Hall effect sensors were activated but the IR sensors were not, the graphs on the data visualization page of the web application accurately depicted the same. This mimics the clinical scenario of the brace being kept aside with the shoes latched on to the bar but the child not using the brace. On day 4 (2020–12-04), the 3D printed feet were placed inside the shoes and the shoes were latched on to the bar of the SMART brace for 12 hours, to mimic the clinical recommendation of night-time brace wear. Thus, we could confirm that accurate data could be captured in all possible clinical scenarios and transmitted remotely via BLE technology to the mobile and web application.

Fig. 8 Screenshot of data visualization page of the web application showing cumulative number of hours the child has worn the brace, day-wise

Discussion

The functional prototype that we have developed has demonstrated that it is feasible to incorporate low-cost sensor technology into existing clubfoot braces and use wireless technology to transmit real-time brace wear data remotely to clinic administrators and healthcare providers who treat children with clubfoot. The use of sensors to accurately record orthotic usage is not a new concept. Previous researchers have utilized temperature or pressure sensors embedded in spinal braces to monitor brace wear in children with adolescent idiopathic scoliosis [15–18]. Valuable information gleaned from objectively measured brace adherence data demonstrated a 'dose–response curve', which correlated the risk of curve progression with hours of brace wear [17]. Such information has been shown to be eminently useful in counselling patients on the importance of brace wear, leading to improved adherence and better treatment outcomes for children with adolescent idiopathic scoliosis [18].

Over the past five years, there have been a few studies which have reported the results of measuring the wear rates of clubfoot braces using novel temperature or pressure sensors. Morgenstein et al. [19] conducted a randomized clinical trial on 67 children with clubfoot to monitor initial full-time brace use, by incorporating pressure sensors into Denis-Browne splints of 21 children with clubfoot and compared them with two other groups of children whose braces either had no sensors or non-functioning sensors. The authors reported a rapid decline in measured brace use, from ~ 91% of recommended brace use during the first month to 77% of recommended brace use at the end of three months. Furthermore, there was a significant discrepancy between parent-reported wear rates and actual wear rates (94.9% versus 91.7%, 95.6% versus 86.8% and 94.8% versus 77.1% in months 1, 2 and 3 respectively), thus confirming the lack of accuracy of parent-reported adherence to the recommended bracing protocol. Sangiorgio and colleagues [20] used wireless temperature sensors in Mitchell-Ponseti braces to record brace-use adherence in 48 children with idiopathic clubfoot grouped according to age from six to 48 months. Here again, the authors reported that the measured brace wear was a median of 62% of the recommended brace wear and the accuracy of the estimated hours of brace use reported by the parents was a median of 77% of the actual brace use. The authors further found that patients who wore the brace more than eight hours per day were less likely to experience a relapse than those who wore it for less than five hours per day, thus supporting previous observations of a close association between poor adherence to brace use and relapse. This finding was corroborated by a third study which looked at objectively documenting the daily brace wear time in 124 children with clubfeet who maintained correction up to two years of age, by incorporating temperature data loggers into the shoes of the foot abduction brace [21]. While adherence to recommended bracing was reliable during the first three months of full-time brace wear (90% of the recommended time), it gradually diminished over the ensuing months, such that at the 16–18-month bracing interval, 46% of the patients wore the braces for < eight hours per day. The authors thus concluded that eight hours of brace wear at night-time in the second year of bracing may be sufficient to maintain correction in many patients.

In all three studies, the sensor-acquired brace wear data were stored locally in a data logger for periods ranging from one to three months, and were retrieved in the clinic at the time of follow-up visits [19–21]. This necessitates the availability of a data technician or orthotist on a regular basis in the clubfoot clinic to download the data and also increases the time the patient and caregivers have to spend in the clinic at each follow-up visit. If a patient misses or delays a follow-up visit, the data are liable to be lost if the capacity of the local storage is exceeded. Furthermore, if the sensors, data logger or other electronic equipment malfunction between follow-up visits, the entire data collected in the interim period risk being lost. The functional prototype that we have developed not only stores the brace usage data locally on a microSD card, but also transmits the data remotely once a day to the cloud server where the data may be accessed on the web application by the clinic administrator or healthcare provider. This not only mitigates against the risk of data loss, but also ensures that the healthcare provider can assess the daily brace usage data on a real-time basis. The advantages of accessing brace usage data on a real-time basis are profound. Parents may be more inclined to adhere to the recommended bracing protocol since healthcare providers and clinic staff would be aware of how often they put the brace on their child. Healthcare providers would also know which children need additional surveillance and more frequent follow-up, prior to a relapse occurring. This would likely increase compliance and improve treatment outcomes for the 15–40% of children affected by relapses.

The sensors we developed needed to be lightweight, of low-cost to be affordable in LMICs and be able to collect reliable brace wear data. In the study by Morgenstein et al. [19], 39% of the patients (26/67 participants) dropped out of the study, with more than 50% dropping out within the first month of their treatment. The most common reasons (11/26) given by the parents were because of the weight of the bulky data logger affixed on to the bar, possible electrical interference with cell phones and the extra effort involved in taking the brace on and off. Accordingly, we designed our sensors to be as lightweight and unobtrusive as possible. The combined weight of both sensor modules with all electronic components was ~ 150 g, adding just one-third more weight to the existing foot abduction brace which weighs 450 g. To fulfil the final requirement of affordability and easy accessibility in LMICs, we utilized low-cost sensors and wireless technology to record and transmit brace usage data. We decided on using two types of easily available sensors—an infrared sensor assembly which detects the presence of the foot in the shoe through a small aperture and a magnetic Hall effect sensor to detect whether the shoe is attached to the bar. The entire assembly was kept wireless by using radiofrequency transceivers to transmit data to the mobile application using BLE technology. Hence, the prototype we have developed uses components and technology that adds only US$20 to the cost of the existing brace, if mass produced.

The SMART brace uses a mobile application and smartphone-based wireless technology to transmit real-time brace wear data remotely to clinic administrators and healthcare providers. Smartphones have become ubiquitous and are being used increasingly in clinical practice, education and research across the world. A multicentre survey on the ownership and clinical use of smartphones by doctors in the UK reported that 98.9% of doctors owned a smartphone, with 89.6% of them using medical apps as part of their clinical practice [22]. Recent estimates have shown that between 18 and 45% of the population in sub-Saharan Africa, South Asia and Latin America have access to smartphones, with the number of smartphone users worldwide forecasted to exceed 3.8 billion users in 2021 [23]. As global smartphone penetration increases and internet data rates become cheaper, the remote technology we have utilized in this prototype has the potential to transform the way brace usage data are collected not only in developed countries but also in countries with limited resources. The recent COVID-19 pandemic has highlighted the importance of creative uses of remote technology, such as teleconsultations. Remote clinical care has been shown earlier to provide increased access to care, lower overall costs and result in high patient-satisfaction rates [24]. Remote transmission of brace usage data will go a long way in limiting the need for physical follow-up during the bracing phase of clubfoot treatment and is uniquely poised to serve the needs of clubfoot children during such unprecedented times.

The functional prototype of the SMART brace we have developed opens exciting new vistas for future research with important clinical implications. Non-adherence to brace wear has been reported to be the strongest predictor for clubfoot relapse [7–13]; however, all of these studies are based on parent-reported data which are known to be inaccurate and proven to be unreliable [19–21]. Most recommendations in literature on the duration of brace wear are empirical and there is no good evidence on the number of hours the FAB needs to be worn per day or the optimal length of bracing required to prevent a relapse. Short-term results using sensors have shown that even eight hours of use may be sufficient to prevent a relapse [20, 21]. A prospective randomized-controlled clubfoot foot abduction brace length of treatment trial (FAB24) is ongoing, and seeks to determine the effectiveness of two year versus four year foot abduction bracing [25]. Longitudinal analysis of accurate brace wear data recorded and transmitted remotely by a SMART clubfoot brace may help answer the three existential questions regarding bracing—what is the exact correlation between brace usage and relapse, what is the minimum number of hours the brace needs to be worn daily and what is the optimal length of bracing required to prevent a relapse? We believe that objectively measured brace adherence data using sensors will help establish a 'dose–response curve' that will make brace usage recommendations more scientific and improve adherence in the long term.

Conclusions

We have developed and tested a functional prototype of a SMART clubfoot brace that can reliably and accurately record brace usage data and transmit it remotely to the healthcare provider on a daily basis. The additional cost of incorporating sensor and wireless technology into existing braces is expected to be low, based on our innovative design that includes low-cost sensor technology and remote wireless tracking. Once clinically tested, this device has the potential to revolutionize the outcomes of clubfoot treatment, by modifying caregivers' behaviour towards bracing adherence, during this challenging phase of treatment. The expected impact is a tangible reduction in relapse rates, resulting in better outcomes for children and lower costs for the healthcare system.

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Author contribution The study was conceptualized and designed by Alaric Aroojis, Tapas Pandey and Rupesh Ghyar. Material preparation, data collection and analysis were performed by Tapas Pandey, Ajay Dusa, Arun Krishnan and Rupesh Ghyar. Alaric Aroojis and Prof. B. Ravi were responsible for overall guidance of the project. The first draft of the manuscript was written by Alaric Aroojis and final edits were made by Rupesh Ghyar and Tapas Pandey. All authors commented on previous versions of the manuscript and all authors read and approved the final manuscript.

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Declarations

Ethics approval No procedures involving human participants were performed during the course of this project; hence, no ethics approval was required.

Consent to participate Not applicable.

Conflict of interest The authors have declared the following relationships: Dr. Alaric Aroojis received consultancy fees from MiracleFeet as principal investigator for this project. The other authors received part-time fees and reimbursement of incurred expenses from the funds received from the SICOT grant. BETiC has collaborations with the medical device industry on other products.

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