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The Validity of Compliance Monitors to Assess Wearing Time of Thoracic-Lumbar-Sacral Orthoses in Children With Spinal Cord Injury

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Study Design. Prospective multicenter observation.

Objective. To determine the validity of 3 commercially available at recording thoracic-lumbar-sacral orthosis (TLSO) wearing time of children with spinal cord injury (SCI) and to assess each monitor's function during daily activities.

Summary of Background Data. A major limitation to studies assessing the effectiveness of spinal prophylactic bracing is the patient's compliance with the prescribed wearing time. Although some studies have begun to use objective compliance monitors, there is little documentation of the validity of the monitors during activities of daily life and no comparisons of available monitors.

Methods. Fifteen children with SCI who wore a TLSO for paralytic scoliosis were observed for 4 days during their rehabilitation stay. Three compliance monitors (2 temperature and 1 pressure sensitive) were mounted onto each TLSO. Time of brace wear from the monitors was compared with the wear time per day recorded in diaries.

Results. Observed *versus* monitored duration of brace wear found the HOBO (temperature sensitive) to be the most valid compliance monitor. The HOBO had the lowest average of difference and variance of difference scores. The correlation between the recorded daily entries and monitored brace wear time was also highest for the HOBO in analysis of dependent and independent scores. Bland-Altman plots showed that the pressure sensitive monitor underestimated wear time whereas the temperature monitors overestimated wear time.

Conclusion. Compliance to prescribed wearing schedule has been a barrier to studying TLSO efficacy. All 3 monitors were found to measure TLSO compliance, but the 2 temperature monitors were more in agreement with the daily diaries. Based on its functional advantages compared with the HOBO, the StowAway TidbiT will be used to further investigate the long-term compliance of TLSO bracing in children with SCI.

Key words: paralytic scoliosis, pediatric, spinal cord injury, compliance monitor, spinal orthosis. **Spine 2008; 33:1554–1561**

Although it has been reported that up to 96% of children who sustain a spinal cord injury (SCI) before skeletal maturity will develop scoliosis,[1] the literature available on the treatment of paralytic spine deformity with bracing in children with SCI is limited. Two retrospective reviews have reported that prophylactic bracing may prevent severe progression of scoliosis in children with SCI.[2,3]

There is extensive literature available on the efficacy of bracing for idiopathic scoliosis.[4–14] Recently, the Scoliosis Research Society Committee on Bracing and Nonoperative Management completed a literature review of 32 brace treatment studies to standardize the testing parameters for adolescent idiopathic scoliosis.[15] Recommendations for optimal inclusion criteria and the assessment of brace effectiveness were made. Although they recommended that "all patients, regardless of subjective reports on compliance," be included in the analysis of results, there were no recommendations on how to assess brace compliance.

Regardless of the patient population, a limitation to studies assessing the effectiveness of prophylactic bracing is the lack of objective data on how long a brace is worn (actual wearing time) by a patient. The majority of available literature regarding brace compliance is based on the assumption that subjective reports of brace compliance are accurate. Diaries, logs, and self-reporting have all been used as means of recording compliance with bracing. DiRaimondio and Green[16] reported less than 15% of their patients were highly compliant with the prescribed wearing schedule based on patient interview. Compliance rates as high as 64% and 88% have been reported with subject self reporting.[17,18] Subjective reports should not be considered the most accurate measurement of brace compliance. According to a recent study, Helfenstein *et al*[19] found that subjective reporting

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does not appear as accurate as using an objective measure of brace compliance. The investigators in this study used a temperature data logger to monitor the brace wear of 9 women with idiopathic adolescent scoliosis up to 3 months. A questionnaire to measure self-reported compliance was used. The average objective compliance was 68% (subjects were recommended to wear the brace 23 hours per day), and the subjective self-reported compliance average was 94%. The results of this study indicate that more objective data collection is needed to determine brace compliance, since there may be discrepancies between subjective and objective data collection.

Over the last several years, sensors that can be attached to braces have been designed to measure wearing time objectively. Takemitsu *et al*[20] used a temperature sensor imbedded in the thoracic-lumbar-sacral orthosis (TLSO) of children with idiopathic scoliosis. The reliability of this monitor was assessed through a comparison of self-tabulated on or off times of 5 volunteers to that of the on or off times determined by the temperature sensor. Havey *et al*[21] developed a force sensitive resistor that was placed in TLSOs to assess wear time in normal volunteers and found it to be accurate and reliable when compared with a diary. With the use of a data logger that recorded temperature, Nicholson *et al*[22] reported that 10 women patients with idiopathic scoliosis overestimated their compliance by 150%. Although these studies have begun to use objective compliance monitors for the recording of brace wear, there is little documentation of direct observation of the monitor during activities of daily life and no comparisons of available monitors.

This prospective study was designed, primarily, to compare the validity of 3 monitors that are currently commercially available and easily implanted into a TLSO for recording brace compliance. The second purpose was to document each monitor's ease of use and ability to record valid measurements while the child performs daily activities, such as dressing, wheelchair propulsion, and play. The identification of a valid compliance monitor to record wearing times in children with scoliosis secondary to SCI will allow for future prospective studies on bracing efficacy.

Materials and Methods

Subjects

A convenience sample comprised of 15 subjects (9 men and 6 women) between 5 and 14 years of age with cervical or thoracic level of SCI were recruited from outpatient SCI clinics of Shriners Hospitals for Children, Philadelphia, Sacramento, and Chicago. Twelve children had thoracic paraplegia and 3 had midcervical tetraplegia. Based on the International Standards of Neurologic Classification of Spinal Cord Injury,[23] there were 12 subjects with clinically complete injuries and the remaining 3 had incomplete injuries (Table 1). Inclusion criteria included: (1) children with SCI and scoliosis of any degree who could tolerate sitting in their wheelchairs with a TLSO for 5 or more hours a day, and (2) no cognitive or behavioral disabilities that could inhibit informed consent. Full institutional review board approval was obtained and voluntary informed consent and assent were received from all children ages 12 years and older, and all parents or guardians.

Table 1. Subject Demographics

Patient Study No.	Gender	Age at Time of Testing	Injury Level	ASIA Level*
N001	F	8 yr + 2 mo	T5	A
N002	M	6 yr + 10 mo	T7	A
N003	M	8 yr + 6 mo	T6	A
N004	M	14 yr + 5 mo	C6	D
N005	F	12 yr + 7 mo	T3	A
P001	M	5 yr + 6 mo	T9–T10	A
P002	M	7 yr + 6 mo	T3	A
P003	M	13 yr + 7 mo	T4	A
P004	F	6 yr + 3 mo	C5–C6	A
P005	M	8 yr + 7 mo	T3–T4	A
P006	F	11 yr + 0 mo	T4–T5	A
C001	M	12 yr + 5 mo	T4	A
C002	M	6 yr + 0 mo	C4 (R) C8 (L)	C
C003	F	7 yr + 10 mo	C5 (R) C6 (L)	C
C004	F	12 yr + 11 mo	T6	A

*Based on international standards for neurologic classification of spinal cord injury.

ASIA Impairment Scale	Definition
ASIA A	Complete spinal cord injury. No sensory or motor function in the lowest sacral segments (S4–S5).
ASIA B	Incomplete spinal cord injury. Sensory but no motor function is preserved below the neurologic level and includes the sacral segments (S4–S5).
ASIA C	Incomplete spinal cord injury. Motor function is preserved below the neurologic level and more than half of the key muscles below the neurologic level have a muscle grade less than 3 (0–2).
ASIA D	Incomplete spinal cord injury. Motor function is preserved below the neurologic level and at least half of the muscles below the neurologic level have a muscle grade greater than or equal to 3.
ASIA E	Normal. Sensory and motor functions are normal.

Compliance Monitors

The HOBO H8 4-Channel External device consists of a data logger and a temperature sensor (Figure 1) and is manufactured

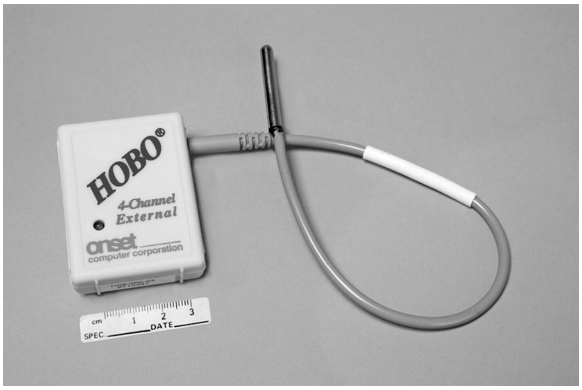

Figure 1. HOBO H8 4-channel external.

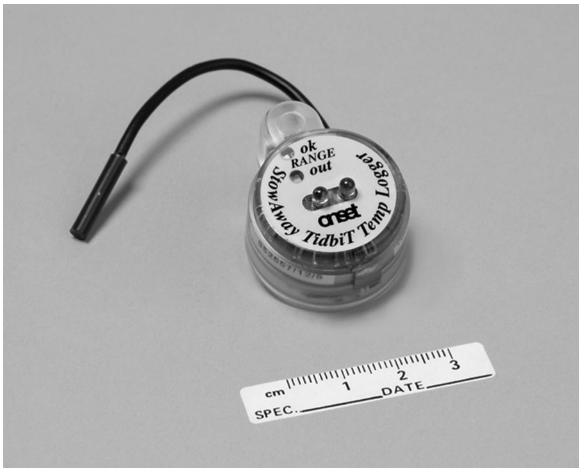

Figure 2. StowAway TidbiT.

by Onset Computer Corporation (Bourne, MA). This compliance monitor measures 2.4 × 1.9 × 0.8 inches and weighs approximately 1 oz. For the present investigation, Velcro or vacuum-formed cases were used to mount the HOBO onto the TLSOs. Data obtained by the HOBO were uploaded by using Onset Computer Corporation's BoxCar Pro software and personal computer (PC) interface cable.

The commercially available StowAway TidbiT consists of a data logger and an internal temperature sensor (Figure 2). This device was adapted for this study by Onset Computer Corp., the manufacturer, with a permanently attached external temperature sensor. The TidBiT measures 1.2 × 1.6 × 0.65 inches, and weighs 0.8 oz. For the present investigation, the StowAway TidbiT was mounted onto TLSOs with Velcro. To upload data obtained by the StowAway TidbiT to a PC also required use of Onset Computer Corporation's BoxCar Pro software. For launching and readout purposes, the StowAway TidbiT uses an Optic Base Station connected to the PC.

The IntelliBRACE System consists of a data logger and force sensor that detects pressure (Figure 3). This compliance monitor is manufactured by X3 Technologies (Edmonton, Canada).

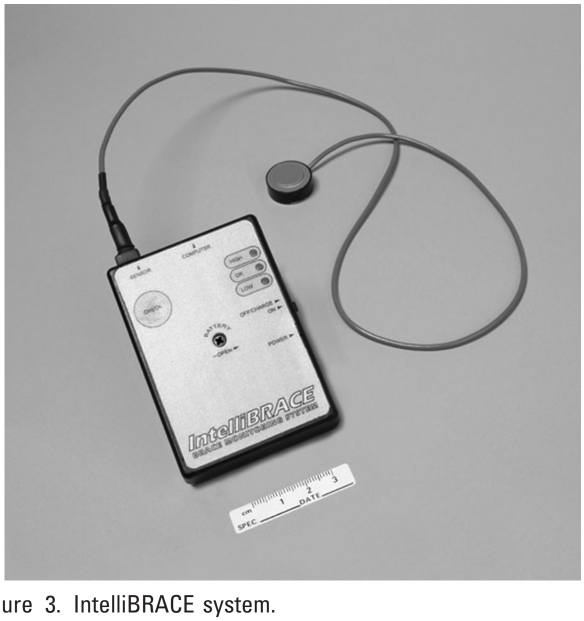

Figure 3. IntelliBRACE system.

The IntelliBrace measures 3.3 × 2.4 × 0.8 inches. The IntelliBRACE was mounted via Velcro or vacuum-formed cases to the TLSOs. Data obtained from this compliance monitor were read using IntelliBRACE Clinical Analysis Software and a PC interface cable.

Type of TLSOs

The majority of the TLSOs used in this study consisted of a copolymer shell with an AliPlast liner. Of the 15 TLSOs, 4 were bivalved, 8 had posterior openings, and 3 had anterior openings.

Experimental Procedures

All subjects had the 3 compliance monitors installed into preexisting or prescribed TLSOs by certified orthotists. Under the advisement of the orthotists, the 2 temperature sensors were embedded in the anterior portion of the TLSO and the pressure sensor was embedded in the posterior portion of the TLSO under the foam pad where there would be direct pressure from the child's ribcage or adipose tissue. All 3 monitors were set to collect data every minute during the six-hour data collection period for each of the 4 test days.

Patients were either inpatients on a SCI rehabilitation service or participants in an intensive outpatient day program, and so testing mainly occurred in a relatively climate controlled hospital setting. Parent(s)/legal guardian(s) or study personnel documented times that the TLSO was donned or doffed on a daily diary and the activities that occurred during the testing period. Any problems that occurred with the monitors were also recorded on the diary. Each day consisted of 6 hours of alternating 1 hour and 30 minute periods of brace wearing or not wearing. Data were uploaded from the compliance monitors to a PC after each day of data collection. Those responsible for data collection had practiced using the monitors on several occasions before patient use and were all given standardized set-up and uploading instructions.

Determination of Temperature and Pressure Cut-off Values

Data collected from the HOBO and StowAway TidbiT were analyzed using a Braced Minutes Sum Spreadsheet that calculated cut-off temperature points to indicate when the TLSO was worn by the patient. To calculate the proper temperature cut-off point for each subject, trends in the data were analyzed by systematically inputting different cut off temperatures. When the Braced Minutes Sum Value remained constant over a range of temperatures, the time recorded at temperatures lower than the set range was considered "brace off" time. The time recorded at temperatures at or above the set range was considered "brace on" time (Figure 4).

Data collected by the IntelliBRACE System were analyzed based on the offset value generated when the sensor was embedded but unloaded. The amount of time the recorded force was above the offset was considered "brace on" time (Braced Minutes Sum). The amount of time when the recorded force was at or below the offset was considered "brace off" time.

Statistical Analyses

The observed duration of brace wear time served as the benchmark for assessing the validity of the measurements of the 3 compliance monitors examined in this study. Averages for duration of time of brace wear from the Hobo, Tidbit, and Pressure monitors were first compared with the average for the observed scores. Next, Pearson correlations coefficients were calculated between

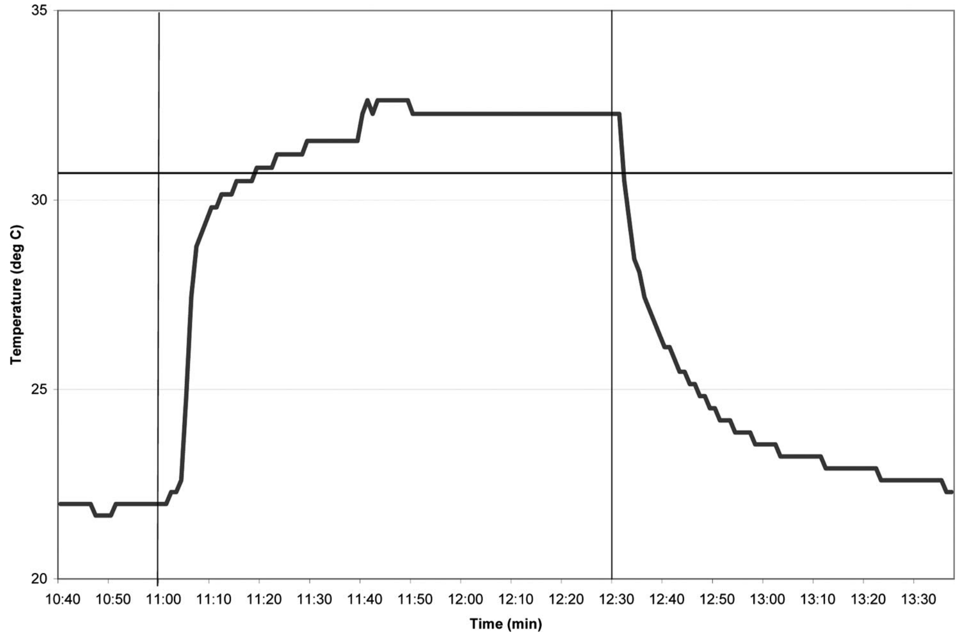

Figure 4. Example of exported data from the StowAway TidbiT with determined cut-off temperature (30.6°C) represented by the horizontal line.

the measurements of each monitor and the observed brace wear time. Scores for each of the compliance monitors were then subtracted from the observed scores. The average and the variance of the difference scores were then computed. The initial set of analyses were conducted using the complete dataset, which included up to 4 observations per patient. A second set of analyses were conducted based on independent scores, which were derived by taking the average of duration of time scores for each patient (Table 2).

Results

HOBO H8 4-Channel External

The HOBO had the highest correlation (0.65) between the reported daily entries of minutes the brace was worn by the patient to the Braced Sum calculation of minutes (Table 2). The HOBO data also had the lowest variance (1261 min^2). The Bland-Altman plot showed the HOBO overestimated wear time by an average of 3.5 minutes (Figure 5). When comparing the TLSO observed time to the HOBO Braced Sum minutes, the average difference was 8.9%.

Table 2. Statistical Analysis Results

	Hobo	TidbiT	IntelliBRACE
Average score (observed = 176.42)*	179.38	185.45	136.18
Pearson correlation			
Dependent observations*	0.652	0.558	0.339
Independent observations†	0.685	0.505	0.386
Average of difference			
Dependent observations*	−3.53	−9.09	37.98
Independent observations†	−4.16	−10.19	38.40
Variance of difference			
Dependent observations*	1261.47	1416.98	2960.97
Independent observations†	619.14	1164.87	1461.64

*Includes up to 4 scores per patient; Hobo, n = 53; TidbiT, n = 56; Pressure, n = 45.

†Independent observations derived from mean of up to 4 scores per patient; Hobo, n = 15; TidbiT, n = 15; Pressure, n = 12.

Ninety-three percent of the data obtained by the HOBO was analyzed (53 of 57 data sets). The remaining 7% (4 data sets) were corrupt or not recorded. There were 2 out of 53 trials with discrepancies of over 50% between the monitor data and the daily entries (Table 2). In these instances, daily entries noted problems encountered with this monitor.

StowAway TidbiT

The Bland-Altman plot showed TidbiT overestimated wear time by an average of 9.1 minute (Figure 6). When comparing the daily entries of minutes to the calculated TidbiT Braced Sum minutes, the average difference was 9.0%.

Ninety-eight percent of the data obtained by the StowAway TidbiT was analyzed (56 of 57 data sets). There were 4 trials of Braced Sum data that were more than 50% different from the daily minutes worn (Table 2). Graphically, these data sets did not have a consistent on/off pattern. No apparent problems were noted on diary entries with this specific monitor or the sensor itself.

IntelliBRACE System

The Bland-Altman plot showed that the IntelliBRACE underestimated total wear time by an average of 53 minutes. Between the daily entries of minutes and the calculated IntelliBRACE Braced Sum minutes, the average difference was 25.2% (Figure 7).

Only 79% of the data collected by the IntelliBRACE pressure monitor was able to be analyzed (45 of 57 data sets). There were 12 sets of data that were unusable due to many mechanical problems with the device that occurred during data collection. The largest discrepancy between the Braced Sum calculation and the daily entries of minutes was 99%. In this case, only 1 minute out of 180 minutes was captured by the pressure monitor. Six of 45 trials had differences larger than 50% (Table 2).

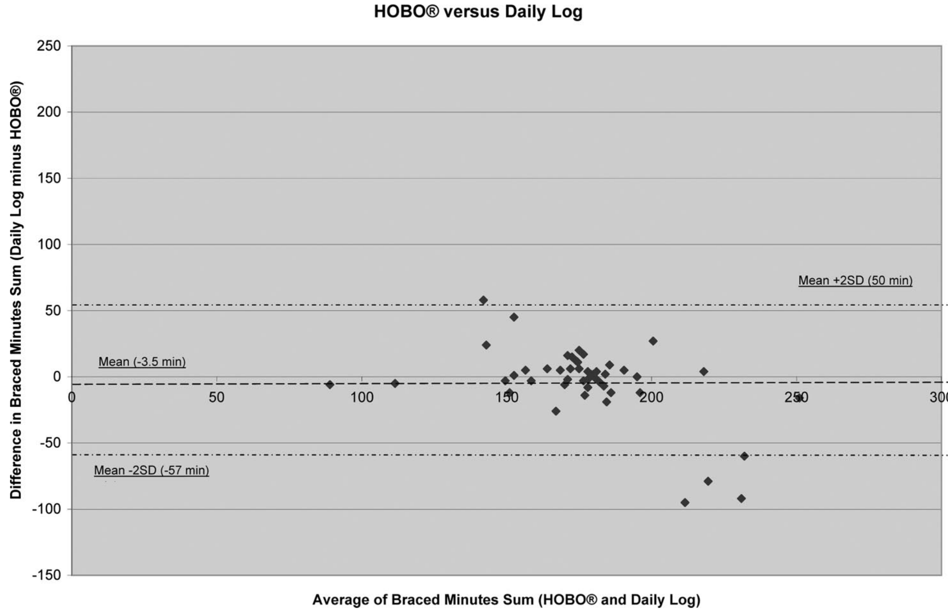

Figure 5. Bland-Altman Plot for HOBO H8 4-channel external.

Comparisons Among the Three Brace Monitors

The correlation coefficient of the StowAway TidbiT between the reported daily entries of minutes the brace was worn by the patient to the Braced Sum calculation of minutes was 0.56, which was not significantly different from the HOBO ($P > 0.05$; Table 2). The StowAway TidbiT temperature monitor had a variance of 1417 min^2. The IntelliBRACE pressure monitor had the lowest correlation value (0.34) and the highest variance (2961 min^2) of the 3 monitors. The IntelliBRACE correlation coefficient was statistically less than that of the HOBO ($P < 0.05$; Table 2).

■ Discussion

A limitation to studies involving the effectiveness of bracing has been determining patient compliance to brace wear with an objective measurement. Over the past 5 years, several studies have shown that some temperature and force-sensitive monitors are capable of quantifying brace wearing compliance.[4,19–21] The main objective of this study was to investigate the validity of 3 compliance monitors when compared to direct observation. A secondary objective was to determine each monitor's ease of use and the ability to record measurements when a child who has a SCI and scoliosis performs his/her daily activities.

This study showed that the HOBO, a temperature monitor, demonstrated the highest correlation (0.65) with the daily entries, and a pressure monitor, the IntelliBRACE, demonstrated the lowest (0.34). The HOBO and StowAway TidbiT were statistically equivalent ($P < 0.05$) in terms of correlation coefficients. According to

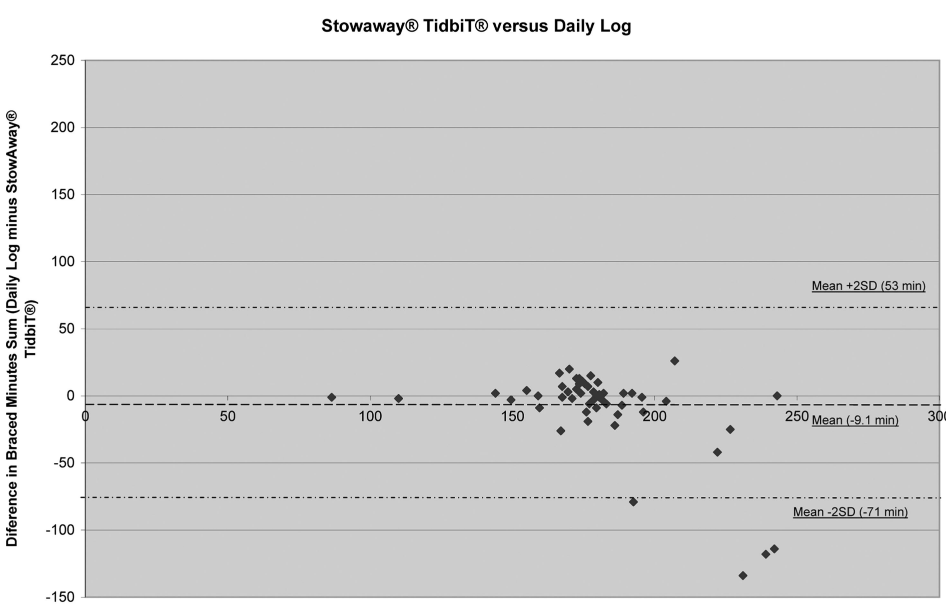

Figure 6. Bland-Altman Plot for StowAway TidbiT.

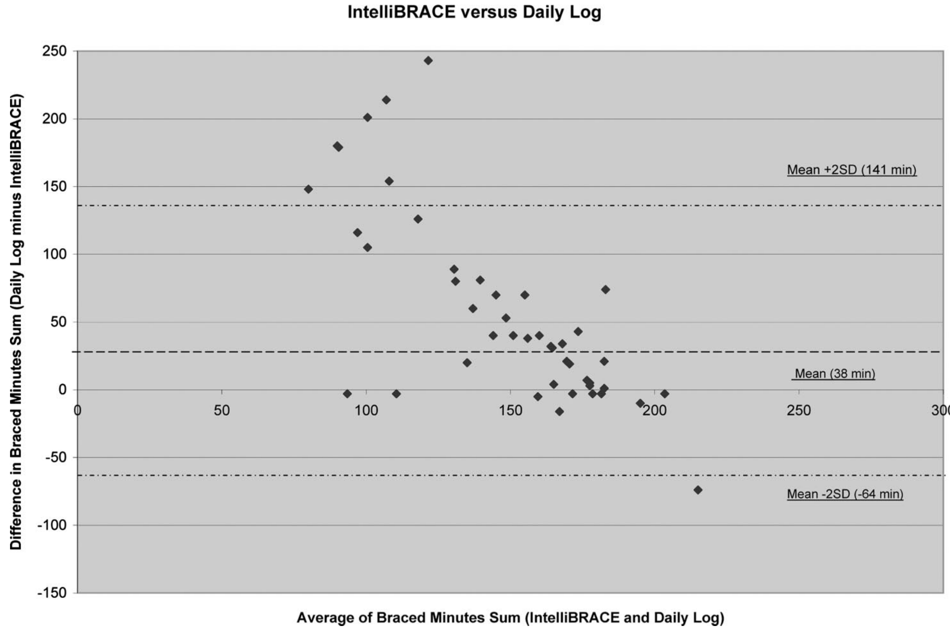

Figure 7. Bland-Altman Plot for IntelliBRACE.

Portney and Watkins,[24] the correlation coefficients for these 2 monitors were moderate to good, and the correlation coefficient for the IntelliBRACE was fair.

In terms of variance between each of the 3 monitors and the daily entries, the HOBO showed the least amount of variance (1261 min^2), and the IntelliBRACE (2960 min^2) showed the greatest. The variance values for all 3 monitors were high.

Bland-Altman plots were created to compare the agreement of the brace compliance monitors to the daily observation data in order to determine which monitor was superior in recording brace compliance. From the Bland-Altman plots, the HOBO monitor overestimated brace wear by an average of 3.5 minutes; this was the highest agreement among all 3 compliance monitors when compared to direct observation. The StowAway TidbiT overestimated brace wear by 9.1 minutes, and the IntelliBRACE had the least agreement with an underestimation of brace wear by 53 minutes. Overall, the statistical analysis and use of Bland-Altman plots showed that the HOBO temperature monitor was superior to the other 2 monitors used in this study, although the HOBO and StowAway TidbiT were not statistically different in terms of correlation and variance values.

Additionally, there were some mechanical issues that also influenced as to which of the 3 monitors were deemed the most valid and easy to use. There were recurrent problems with the IntelliBRACE pressure sensor. The pressure sensor of the IntelliBRACE is loosely connected to the monitor, so the child's normal activities of daily living often led to the sensor becoming disconnected. Concerning the research diaries, 12 out of the 15 children tested had instances where the IntelliBRACE sensor was disconnected numerous times during data collection. Two of the primary causes of the disconnection were wheelchair propulsion and donning or doffing a shirt over the brace. Other causes included reaching for objects while in the wheelchair or transferring from the wheelchair to a mat or other surface. This inadvertent disconnection of the sensor during activities of daily living limits the usefulness of this device for long-term data monitoring at home or in other environments.

Another difficulty with the IntelliBRACE involved sensor placement and obtaining consistent pressure against the sensor while the TLSO was on the patient. Due to the mechanics of chest excursion during breathing, the contact with the trunk between the brace and sensor was variable despite attempts to optimize the position of the monitor on the child.

Mechanical difficulties with the HOBO monitor included recordings of large temperature ranges and broken sensor connections. In 2 patients, the HOBO monitor recorded temperatures ranging from 37.8 to 260°C. One patient's TLSO was left outside of the hospital on a sunny day, which may have triggered the abnormally high values for the temperature monitor. The other patient was indoors during the data collection period, and so the reason for monitor failure was unknown. There were also problems with the HOBO temperature sensor becoming bent or broken at the connection site. One patient had an anterior opening TLSO, which decreased the amount of space on the anterior portion of the TLSO to mount the HOBO. In this case, the HOBO was mounted on the lateral portion of the TLSO underneath the axilla area. The size of the HOBO temperature monitor interfered with the patient's ability to propel his wheelchair causing the sensor of the HOBO to break at the connection site.

Finally, there were no mechanical difficulties with the StowAway TidbiT monitor. The StowAway TidbiT was easily mounted to the child's brace, is relatively small and waterproof, and the set-up and uploading of data requires less than 5 minutes. It also consistently recorded the most data points of all 3 monitors. It was able to function during the course of the child's day and withstand all activities, such as donning/doffing a shirt, transferring to and from a wheelchair to a bed or mat, and propelling a wheelchair.

There were limitations to the design of this study. The sample included limited numbers of patients with incomplete SCI. The performance of the monitors would not likely be affected by the presence of a complete or incomplete injury, and so all patients were included without regard to completeness of injury. Another limitation was that the calculated correlation coefficients ranged from 0.34 (IntelliBRACE) to 0.65(HOBO). The range of correlation coefficients suggests that none of the monitors are completely valid or show good to excellent correlations when compared to the direct observation standard used in this study. In hindsight, it is apparent that the study was not optimally designed to test correlation because the duration of the braced time was always 90 minutes. A range of braced time durations would have provided more evidence for correlation.

In addition, compliance was monitored for only 4 days and in a relatively climate controlled environment of a hospital setting. A longer period of data collection using compliance monitors with subjects performing activities of daily living at home and in their community under varied climates would add to the ability to validate these monitors when compared with direct observation.

Another limitation is that the methods used for direct observation were not optimally controlled. Parents(s)/legal guardian(s) or study personnel recorded the on/off times of the brace monitors. On some days, more than 1 staff member was responsible for recording on/off times. It takes time to get the brace in position or off; the time recorded could have been at the start or end of those maneuvers. A clinical setting does not provide the same rigorous control of a protocol as does a laboratory. Thus even the "gold standard" is not perfectly accurate. These factors could have limited the times that were documented on the daily diaries.

Conclusion

Based on the results of the statistical analysis, including use of Bland-Altman plots, and taking into consideration the ease of use and technical design, the StowAway TidbiT was found to be the most optimal indicator of brace compliance for children with a SCI and scoliosis. However, there were limitations with the design of this study that could have been responsible for some of the significant discrepancies that were found between all 3 monitors and the direct observation, especially with respect to the range of data used to calculate correlation coefficients. On the basis of this study, the authors of this study are further investigating the StowAway TidbiT's ability to assess long-term compliance with brace wear.

Key Points

- A major limitation to studies assessing the effectiveness of prophylactic bracing in patients with scoliosis is the patient's compliance to a prescribed wearing schedule.
- Although some studies have begun to use objective monitors to record wearing time, there is little documentation of the validity of these monitors during activities of daily life and no comparisons of available monitors.
- Of the 3 commercially available monitors used in this study, the StowAway TidbiT, a temperature sensitive compliance monitor, was determined to be the most optimal monitor for documenting TLSO compliance in children with SCI in a hospital setting based on statistical analysis of measurement validity, device size, and functional integrity during daily activities.
- Future studies that investigate the efficacy of TLSO bracing in children with SCI using valid brace monitors to document compliance in daily life in the community are needed.
- Fifteen children with a SCI with paralytic scoliosis each wore 3 brace compliance monitors to investigate their validity and functional use. A temperature monitor was determined to have equivalent agreement to the most effective monitor and has properties making it optimal for documenting brace compliance during daily activities.

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