Validation Testing of a New Crutch Tip Biofeedback Device for Prescribed Lower Extremity Weight-Bearing

Kevin E. Brueilly, Amanda M. Feller, Jonathan M. Ahearn, Jonathan S. Goodwin

ABSTRACT

Introduction: Modified weight-bearing recommendations are commonly prescribed after surgical intervention for injuries to the lower extremity to reduce the risk of nonunion and delayed healing associated with load bearing through the injured limb and to combat the deleterious effects of immobility. The physical therapist (PT) in the acute care setting is likely to instruct patients after lower extremity injury in weight-bearing-restricted ambulation. A new device is now available for use in the training of weight-bearing status. The study examines whether the ComeBack Mobility crutch tip reporting weight-bearing on the lower extremity is a reliable and valid tool in determining force when compared with the gold standard force plate measurement of lower extremity weight-bearing.

Review of Literature: Previous studies have shown that patients are often not able to adequately learn or adhere to restrictive weight-bearing modifications. This may be due to an inability to provide immediate and ongoing feedback on weight-bearing. The new ComeBack Mobility crutch tip system is now available for the acute care PT to use in instruction and for patients to receive real-time feedback throughout their rehabilitation process.

Subjects: A sample of convenience of 6 able-bodied PTs was used.

Methods: Each subject performed 30 trials of axillary crutch-assisted weight-bearing ambulation using the new device. The weight-bearing reported by the device was compared with the weight-bearing measured through force plates via correlations, ***t*** tests, and Bland-Altman plot.

Results: The new device demonstrated moderate-good reliability in the measurement of non-weight-bearing and 50% partial weight-bearing in trials completed.

Discussion and Conclusion: The ComeBack Mobility crutch tip system could be useful and should be considered for clinical use as a reliable and valid tool in providing auditory feedback for compliance to a prescribed weight-bearing protocol. The system could be useful in the training of patients in the first use of crutches such as prior to discharge from an acute care hospital. Further research is needed with clinical populations as well as with varied weight-bearing protocols.

In the United States, more than 300,000 people sustain a hip fracture annually and the majority require surgical intervention to promote optimal healing, reduce pain, and reduce the risk of complications.[1]

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Additionally, hundreds of thousands more persons are involved in an injury, condition, or repair involving the lower extremity, who require modification of lower extremity weight-bearing to allow proper healing.[2,3] Modified weight-bearing recommendations are commonly prescribed after surgical intervention[4] for injuries to the lower extremity to reduce the risk of nonunion and delayed healing associated with load bearing through the injured limb[5] and to combat the deleterious effects of immobility.[6,7] In these circumstances, the acute care physical therapist (PT) is often tasked with training patients to adhere to restricted weight-bearing gait in preparation for discharge.

One significant issue in partial and non-weight-bearing (NWB) recommendations is the concern regarding patient compliance. Dabke et al[8] discovered that after training both healthy subjects and patients, following a lower extremity fracture or surgery with a bathroom scale for feedback, neither group was able to accurately reproduce the prescribed weight-bearing, with

the majority of subjects exceeding the target.[8] Factors including patient age, weight of the patient, body mass index, type of weight-bearing education, and physical activity have also been shown to negatively affect compliance with prescribed weight-bearing.[9-11]

To instruct patients in modifying their lower extremity weight-bearing, the first clinician involved is generally the PT at the site of the orthopedic procedure, with instruction provided prior to patient discharge from the facility. To date, there have been limited means clinically available to the PT or the patient to monitor weight-bearing during instruction and any activities that follow. Current training strategies identified in the literature and summarized by Hustedt et al[5] include tactile feedback from the clinician's hand or foot beneath the foot of the patient, and others[8,9] reviewed the use of a bathroom scale to provide visual feedback. Patients trained with these methods were unable to demonstrate accurate partial weight-bearing (PWB) initially or subsequently after training, often significantly exceeding the target for weight-bearing set by the surgeon.[8,9]

Portable biofeedback devices such as pressure sensing insoles and sandals have been investigated to determine validity and effectiveness for use by the PT in instructing modified weight-bearing. These biofeedback devices can provide immediate feedback to the patient on the weight-bearing applied but have been shown to lose effectiveness after the training sessions in patients following hip arthroplasty.[12] Hustedt and colleagues[5] reviewed methods of training patients in weight-bearing restriction and concluded that biofeedback devices improved compliance to prescribed weight-bearing over traditional training techniques but that retention of the prescribed weight-bearing after biofeedback continues to be of concern.[4,13] Also adding another level of complexity to their use, biofeedback devices often require additional components such as a tablet or computer, a wearable feedback device, and internet access, potentially limiting the device user friendliness to the patient and the clinician.[14] Force plates represent the gold standard for validating other force measurement devices. Force plates able to provide feedback based on ground reaction forces are typically reserved for use in research and are not often used in the clinic due to the high cost and lack of portability.[4]

Recently, ComeBack Mobility, Inc (New York, New York) has developed a set of assistive device tips that can provide real-time feedback on the weight-bearing being accepted on the affected lower extremity. By measuring the force applied through the crutch(es) and translating that information by inference of a patient's weight, the device can provide immediate feedback to the user and clinicians involved in the patient's care if weight-bearing through the lower extremity is maintained within prescribed limits. To complement the device and increase its clinical value, ComeBack Mobility has created 2 associated smartphone applications, 1 for the health care provider and 1 for the patient, to allow the prescribing provider to set up, monitor patient compliance, and potentially modify adherence to a weight-bearing program. The ComeBack Mobility crutch tips are paired with the smartphone ComeBack Mobility patient application by Bluetooth (Bluetooth SIG, Inc, Kirkland, Washington) connectivity. The ComeBack Mobility patient smartphone application provides real-time feedback through auditory and visual mechanisms. Auditory feedback is provided via an announcement from the application instructing the patient to put more or less weight on the affected limb based on the weight-bearing compliance of the most recent step. Visual feedback is provided via a flashing light from the crutch tip as well as a graphical representation of the affected limb's weight-bearing status for multiple steps that can be viewed on the application. This unique device provides a biofeedback option that provides timely feedback through either a smartphone or the crutch tips themselves without requiring another device such as a watch or ankle cuff to be worn. The new crutch tips have been evaluated clinically but have yet to be validated in a laboratory setting. This study aimed to examine whether the ComeBack Mobility crutch tip reporting weight-bearing on the lower extremity is a valid tool in determining force when compared with the force plate measurement of lower extremity weight-bearing. If shown to be a valid reporting tool, PTs training patients in restricted weight-bearing ambulation may find easily accessible clinical usefulness of the device.

SUBJECTS

A convenience sample of 6 licensed PTs teaching in a Doctor of Physical Therapy program was recruited to participate in this study. The study was approved as exempt from review by the Institutional Review Board of Charleston Southern University. The subjects (3 female and 3 male) were absent of any musculoskeletal injuries that could hinder their participation, allowing them to manipulate bilateral axillary crutches properly. Informed consent was obtained, and each subject was fitted with standard crutches containing the ComeBack Mobility device and instructed to perform 15 trials each of 2 prescribed weight-bearing gait patterns on a lower extremity of their choice.

METHODS

The weight of each subject was recorded in newtons as displayed in static standing while situated entirely on 1 Bertec (Bertec Corporation, Columbus, Ohio) force plate. The force plate system had recently (last 12 months) been installed and calibrated by technicians from Bertec. Each subject's weight was then computed in

pounds and entered into the ComeBack Mobility mobile application recently downloaded and updated for current software on a standard Apple iPhone mobile digital device (Apple Inc).

Subjects then practiced the 2 gait patterns, a swing-through (ST) NWB (corresponding to 10% PWB setting within the app) gait pattern using bilateral axillary crutches and a 50% PWB gait pattern with 50% weight-bearing on the foot of their choice and 1 axillary crutch in the contralateral hand. The PWB corresponded with a 50% weight-bearing setting within the app. The ST pattern involved total weight-bearing through the upper extremity via the crutches with each crutch landing on 1 force plate for recording, and no weight distributed through the feet. The PWB pattern involved the crutch landing on 1 force plate and the weight-bearing foot landing on a separate force plate. Following acclimation, subjects ambulated at a self-selected velocity with the respective gait patterns over a runway of approximately 10 ft in length with 2 embedded Bertec force plates positioned to capture ground reaction forces as necessary. Vertical ground reaction forces were sampled via Qualisys (Gothenburg, Sweden) software at 1000 Hz. Subjects completed 15 trials of the ST gait pattern followed by 15 trials of the PWB gait pattern.

The preprogrammed mobile application assessed all entered weight-bearing restrictions within a ±10% error window. Therefore, during the ST gait pattern, reported weight-bearing was set to the lowest allowed value of 10% weight-bearing, which required weight-bearing to fall within 0% to 20% of body weight for a successful trial, or an announcement would be heard through the crutch tip device to either "step on the foot harder" or "step on the foot softer." Visual feedback is provided through a graphical representation on the smartphone application and through the presence or absence of a flashing light from the crutch tips. During the PWB trials, the successful weight-bearing range was 40% to 60% of body weight. If the subjects' estimated weight-bearing fell outside the 40% to 60% window, as calculated and interpreted by the crutch tip device, the crutch tip would emit visual (flashing light) and auditory feedback indicating that the subject should place more or less weight on the foot. During a successful trial, the prescribed weight-bearing through the foot was met; thus, no announcement of weight-bearing adjustment was necessary, and the crutch tip remained silent, and no lights flashed.

During all the trials, graphical representations of the percentage of weight-bearing of each step were calculated and presented within the mobile application in graph form (see Figure 1; ComeBack Mobility app graph). Each of the 180 trials' graphical output was recorded for review, along with whether auditory and visual feedback was generated from the crutch tip. No feedback from the crutch tips and app indicated a successful trial that remained within the prescribed weight-bearing limits.

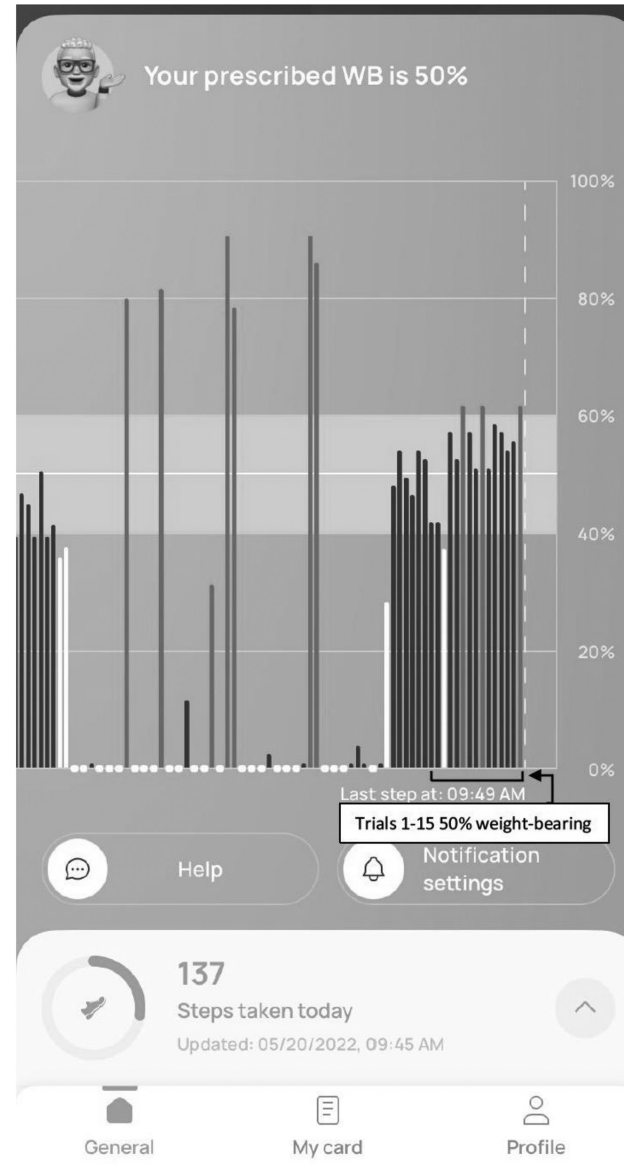

FIGURE 1. ComeBack Mobility Application Graph. The graphical presentation of weight-bearing captured and recorded by the device and delivered to the user's mobile device.

Normalization of Force Output

During normal ambulation, subjects typically exhibit peak vertical ground reaction forces greater than body weight during overground walking and are estimated to strike with approximately 20% more than body weight.[15] To compensate for this expected excess (peak) in force measurement, the percentage of body weight from the force plates during landing was calculated (peak vertical ground reaction force divided by 1.2) and recorded as normalized vertical ground reaction force.

Data Analysis

Force plate data were exported from Qualisys into a custom LabVIEW (National Instruments, San Antonio, Texas) software and the peak vertical ground reaction force was recorded for each trial from the involved

force plates. Visual representation of the percent weight-bearing in the mobile application was recorded, inspected, and rounded to the nearest 5% to estimate weight-bearing from the crutch tip. This rounding was required due to the data provided from the ComeBack Mobility app utilizing a graphing output that lacked the ability to record a discrete data point beyond a 2% to 3% body weight error of measurement. Additionally, a successful or unsuccessful trial was recorded depending on whether feedback from the device was provided to the subject.

For the ST trials, peak vertical ground reaction force from both plates was combined and assessed with the feedback provided by the device via a Spearman correlation.

For the PWB trials, the crutch tip loaded by forces placed by the upper extremity and mobile application estimated whether the subject successfully placed 50% weight-bearing on the foot. This was recorded as the "reported" variable in pounds. Additionally, peak vertical ground reaction force data were collected from the force plate, which recorded the foot strike. This was recorded as the "measured" variable in newtons and converted to pounds. Percent body weight was calculated from the respective data from the device and force plates and divided by body weight collected at the start of the data collection. An independent *t* test was calculated between the measured percent body weight from the foot on the force plate and the reported percent body weight from the mobile application. A Pearson correlation was also calculated from the measured percent body weight from the foot on the force plate and the estimated percent body weight from the mobile application. Finally, a Bland-Altman plot was created from the measured percent body weight from the foot on the force plate and the reported percent body weight from the mobile application, plotting the difference between the reported and measured variables on the x-axis to the average of the reported and measured variables on the y-axis. A 95% confidence interval (CI) was then calculated and scribed on the Bland-Altman plot

RESULTS

Swing-Through (NWB) Gait Trials

During the ST (ie, NWB gait pattern of testing), the lowest value of weight-bearing, 10%, was entered into the software application. Preprogrammed software allowed a ±10% value to programmed weight-bearing; thus, trials were evaluated for maintenance of 0% to 20% weight-bearing on the foot, extrapolated from the weight-bearing recorded by the crutch tips in relation to the programmed subject's weight (see Figures 2 and 3). In the ST trials, the force plate and the crutch demonstrated perfect agreement in all 90 trials, meaning the device agreed that less than 20% weight-bearing had been maintained in each trial, thus no announcement

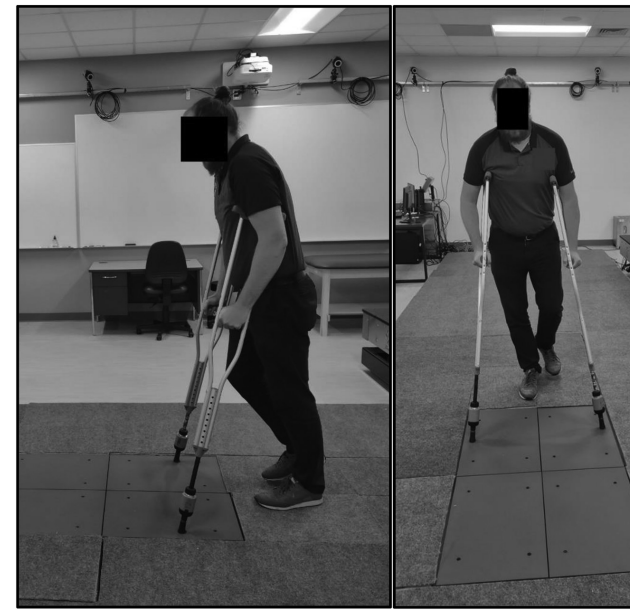

FIGURE 2. 10% Weight-Bearing Trial Configuration for Data Capture.

of noncompliance was issued. A Spearman correlation coefficient was calculated for the relationship between the ComeBack Mobility crutch tips reporting of 0% to 20% weight-bearing per trial and the measurement of lower extremity weight-bearing by the foot placed on the force plate. A very strong positive correlation was found (rho(88) = 1.00, $P = .017$), indicating a significant perfect linear relationship between the 2 variables. The auditory response of the crutch tip device was perfectly correlated with the force plate measurement indicating that the crutch tip correctly identified within the range

FIGURE 3. 50% Weight-Bearing Trial Configuration for Data Capture.

of 0% to 20% weight-bearing 100% (90 of 90) of the ST trials.

Partial-Weight-Bearing Gait Trials

Preprogrammed software provided a ±10% value to programmed 50% weight-bearing; thus, trials were evaluated for maintenance of 40% to 60% weight-bearing on the foot, extrapolated from the weight-bearing recorded by the crutch tips in relation to the programmed subject's weight. A Pearson correlation coefficient was calculated for the relationship between the ComeBack Mobility crutch tips reported weight-bearing on the foot per trial and the force plate measurement of lower extremity weight-bearing for both ST and PWB trials. A moderate positive correlation was found ($r(88) = 0.432$, $P = .000$), indicating a significant moderate linear relationship between the 2 variables.

An independent *t* test compared the means between the weight-bearing determined via the ComeBack Mobility crutch tips and the weight-bearing measurement via the force plate during the PWB trials. No significant difference ($P = .87$) was found between calculated percentage of body weight from the crutch tips (52.72% ± 7.72%) versus force plate (52.92% ± 9.22%).

Two 1-sided *t* tests were completed to determine equivalence between the force plate and crutch tips. The smallest effect size of interest was estimated at $d = 0.5$[16] providing a range of −0.5 to 0.5 for a 90% CI. The estimated 90% CI for the measures was determined via a free, online effect size calculator (https://www.psychometrica.de/effect_size.html) of −0.222 to 0.269, which falls with the bounds of the −0.5 to 0.5 90% CI interval. Given this, the measurements of the crutch tip and force plate measurement can be considered equivalent. No significant difference was found ($t_{(89)} = -0.216$, mean = −0.2077, SD = 9.11696, $P = .829$). A 95% CI of comparison between the force plate and crutch tip calculation was computed at −18.077 for the lower limit and 17.662 for the upper limit. A Bland-Altman plot compared the difference between the ComeBack Mobility crutch tip calculation and the force plate measurement to the mean between the 2 measures (see Figure 4; Bland-Altman plot). A significant number of PWB trials (n = 88/90, 97.8%) were within the 95% CI indicating an agreement between the ComeBack Mobility crutch tip reported weight-bearing and the force plate measurement of lower extremity weight-bearing.

DISCUSSION AND CONCLUSION

The purpose of this study was to determine whether the ComeBack Mobility crutch tip system is a valid representation of a patient's weight-bearing during gait when using axillary crutches. Validity studies investigating new products are best assessed compared with a known gold standard. In this case a Bertec force plate system coupled with the Qualisys motion capture system was used as the gold standard in measuring vertical ground reaction forces compared with the new product, the

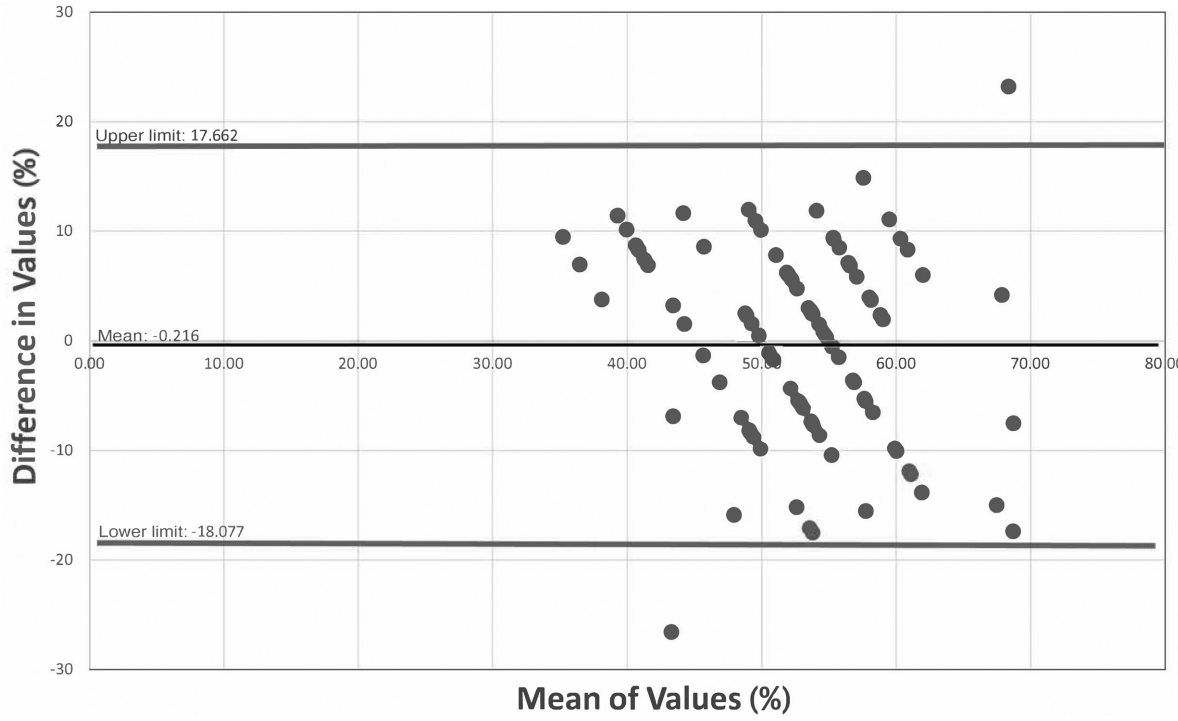

FIGURE 4. Bland-Altman Plot of the Difference Between the Reported Percent of Body Weight via the ComeBack Mobility Crutch Tip Calculation and the Force Plate Measurement (Y-Axis) to the Mean of Calculation and Measurement (X-Axis). Reported in percentage of body weight. Mean and +95% confidence interval shown.

ComeBack Mobility crutch tip system. In comparison to the known gold standard of weight-bearing using a force plate, the ComeBack Mobility crutch tips demonstrated good reliability and validity during both ST and PWB trials.

In the ST trials, the ComeBack Mobility device was in perfect agreement with the gold standard confirming validity in use during NWB trials. The PWB trials demonstrated nonsignificant differences between reported values from the crutch tip compared with the measured values via the force plates. Use of this novel device is further supported with 88 of 90 (97.8%) of the trials falling within the upper and lower limits of the 95% CI on the Bland-Altman plot.

The findings of a significant moderate correlation ($r(88) = 0.432$, $P = .000$) were not surprising, given the software application limitation for the study to estimate the nearest 5% of the reported weight-bearing on the foot due to an imprecise graphical output recorded on the ComeBack Mobility software. It should be noted that the device is not marketed to capture a finite weight-being placed on the foot, but rather is designed to provide auditory and visual feedback to the patient regarding the weight-bearing instance in each step. The graphical output is provided for the clinician and the patient to review trends and for quick scanning of compliance.

This study demonstrates that the ComeBack Mobility crutch tip system could be useful and should be considered for clinical use as a valid tool in providing auditory feedback for compliance to a prescribed weight-bearing protocol of 50% PWB and NWB. This device could be potentially useful in the training of patients by a skilled PT in the first use of crutches such as prior to discharge from an acute care hospital. Previous methods of training weight-bearing limitations in gait have been lacking in the ability for the PT to have a convenient method to evaluate weight-bearing maintenance during instruction. Health care providers have long recognized the need for prescribing and monitoring weight-bearing in patients following lower extremity injury or repair. This device is the first of its kind to provide an immediate and ongoing feedback system to optimize the healing of the lower extremity while maintaining mobility for the patient.

Limitations of the study include a small sample size, the use of subjects who are well trained in the performance of assistive device use and compliance to weight-bearing protocols, the use of a healthy population of subjects, and the use of only one type of assistive device. Additional limitations exist in the weight-bearing output graphical format of the new device not allowing discrete data point recordings (estimate required from a visual assessment of graphing output) and the programming limitation of having the lowest weight-setting at 10% versus 0% for true "non-weight-bearing." Further research is indicated to evaluate the validity and reliability of the crutch tips across a greater spectrum of weight-bearing protocols and progressions as well as devices within a clinically appropriate population in the acute care and outpatient PT settings where weight-bearing protocols are initiated, implemented, and progressed. Further research is also indicated to evaluate the use of the ComeBack Mobility crutch tips and the relationship to patient compliance with prescribed weight-bearing protocols. Finally, as additional assistive device tips are developed, those appliances will also need to be evaluated for their ability to perform the desired goal of the assistive device.

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