Clinical evaluation of a novel assistive device for safe stair negotiation

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INTRODUCTION

No walker currently on the market is safe and effective at negotiating stairs, ramps, and steps of varying heights. Conventional walkers are affordable, but are static and do not adapt to non-level surfaces, and thus can only be used on level ground. Bilateral handrails are the gold standard during physical therapy sessions, but are rarely available in most homes or community settings. Other home adaptations, such as motorized stair glides, are stationary, costly, and do not promote physical activity or independence in the community. A safe, portable, and stable assistive device for negotiating stairs and ramps would allow users to access the non-adapted homes of their families and friends, along with the community at large. In a hospital or rehabilitation setting, it could save healthcare costs and reduce lengths of stay in expensive skilled rehabilitation facilities by accelerating training and mastery of stair negotiation. Our technology, called the Self Leveling Walker (SLW), will enable users to navigate a variety of environments utilizing a single assistive device, remain in their homes, engage in community activities, and avoid the inconvenience and economic burden of expensive architectural modifications.

Prior work with 5 subjects using the SLW suggests that it is comparable to bilateral handrails when negotiating stairs in terms of effort [1]. The purpose of this evaluation was to further pilot the SLW in a clinical rehabilitation setting with a larger patient population by incorporating it into routine physical therapy sessions and determining the rating of perceived exertion, ease of use, perception of safety, and level of assistance compared to conventional assistive devices for stair climbing.

METHODS

Design

The team at the Cleveland VA Medical Center in Cleveland, OH completed pilot testing of the SLW in a physical rehabilitation setting at two different VA Medical Centers: The Cincinnati VA Medical Center in Cincinnati, OH and The Puget Sound VA Medical Center in Seattle, WA. The design of the evaluation included the collection of four different data sets.

Perceived Exertion Rating	Description of Exertion
6	No exertion. Sitting & resting
7	Extremely light
8	
9	Very light
10	
11	Light
12	
13	Somewhat hard
14	
15	Hard
16	
17	Very hard
18	
19	Extremely hard
20	Maximal exertion

Figure 1. Borg Rating of Perceived Exertion Scale

The first data set involved applying the Borg Rating of Perceived Exertion Scale (RPE) to measure the effort and physical strain experienced by the user in completing the task. It is commonly used in exercise testing and medical rehabilitation settings. A person's overall perceived exertion rating is an important characteristic since it considers many different physiological factors, including signals from the peripheral working muscles and joints [2]. The scale, which correlates with heart rate, ranges from 6 (no exertion) to 20 (maximal exertion) [3].

The second data set collected was the overall ease of use of the device perceived by the patient. Ease of use was rated via the Usability Rating Scale (URS) [4]; it is a 7-point Likert scale ranging from very difficult (-3) to very easy (+3). Administering the scale was done in a top-down questioning approach where the patient was first asked if they felt the task was difficult, moderate, or easy. The question then proceeded to a more granular level where the patient was asked *to what degree* they felt the task was difficult, moderate, or easy. The degrees of ease were presented as very, moderately, or barely difficult/easy.

The third data set collected was the overall safety the patient felt when using the device. Safety was measured analogously to ease of use. A modified URS was created, and a similar top-down questioning approach was used to determine perceived safety when completing the task.

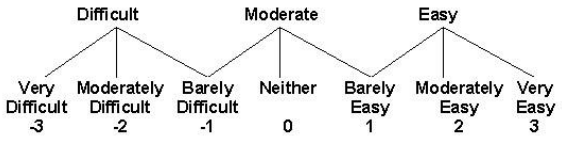

Figure 2. Usability Rating Scale – Ease of Use

In addition, the level of assistance that the physical therapist provided each patient during the evaluation was collected as the fourth data set. Assistance levels were

categorized using standard physical therapy nomenclature: independent, stand-by assistance, contact guard assistance, minimal assistance, moderate assistance, and maximum assistance.

The median was selected to describe all sets of data because the measures are ordinal, rather than interval in nature, and are therefore inappropriate for Gaussian statistics. Statistical texts advise using median or mode as the "measure of central tendency" for ordinal data when responses can be close to the ceiling of potential values and have undue influence on the mean [5,6].

Participants

The target patient populations for this device include the acute orthopedic segment, as well as patients with limb loss or partial paralysis who need a bilateral assistive device during rehabilitation. Under the supervision of physical therapists and a biomedical engineer at the Cincinnati and Seattle VA Medical Centers, 37 unique patients in our target populations were evaluated using the SLW and other conventional assistive devices, such as bilateral handrails or a single handrail accompanied by a crutch or cane. The average patient age was 67.3 ± 7.86 years and 36 were male. 34 of the 37 patients consistently used a wheeled walker during ambulation in their everyday lives. In all, 74 trials were performed as part of this evaluation study.

Emerging Technology

The SLW used for all evaluations was a full-functioning hydraulic prototype produced in collaboration with the Advanced Platform Technology (APT) Center at the Cleveland VA Medical Center and Nottingham-Spirk, a consumer product development firm. Fluid columns couple front and rear leveling pistons embedded in the legs of the walker such that applying weight to the front legs causes them to shorten and the rear legs to lengthen by the same amount when a simple control lever is held down. When the button is released, the legs are locked in the new configuration for continued stair or ramp ascent/descent until re-adjusted at the end of the staircase or incline. In the default state where the legs are level and locked, the device performs exactly like a standard walker on level surfaces.

Additionally, the SLW has overall height adjustability that allows patients ranging from approximately 5'4" – 6'2" to use the device. The SLW can accommodate patients weighing up to 300 lbs, and can be used on stairs up to 8 inches in height.

Figure 3. Self-Leveling Walker

Procedure

The intent of this clinical evaluation was to incorporate the SLW prototype into existing methods of physical therapy and compare it to standard methods of care. Thus, patients receiving physical therapy including stair negotiation training were recruited. The team from the Cleveland VA Medical Center traveled to both Cincinnati and Seattle VA Medical Centers to train their physical therapists on how to use the device and incorporate it into stair negotiation therapy for the evaluation. Before beginning any evaluations, the physical therapists at each site demonstrated the proper operation of the walker to each patient.

A flight of four stairs with each stair having a height of six inches was selected for the evaluation. Stair heights of six-inches are the most commonly encountered stair height and are typically used during stair negotiation training. At the beginning of the evaluation, the patient was positioned at the base of the stairs while standing inside the walker as one would a conventional walker. The patient then lifted the walker and placed the front legs on the first stair. While depressing the control lever, the patient gently pushed down on the walker hand rails to retract the front legs and extend the back legs to the point where they were fully resting on the floor thus creating four points of contact. The patient then released the control lever which locked the legs in the new configuration. A visual level indicator on the top of the walker allowed the patient to make minor adjustments as needed to ensure the device was in a level state. The patient then walked up the stairs using the SLW in the same way one would use a conventional walker. Once the patient had both feet on the top landing, the walker was then lifted onto the landing and front and rear legs were readjusted to be of equal length. While depressing the control lever, the patient gently pushed down on the walker hand rails to shunt fluid from the rear legs to the front legs until the device was reconfigured for level ground. Again, the visual level indicator enabled the patient to confirm the walker was back in a level state.

Evaluations involving the bilateral handrail and single handrail with a cane or crutch followed conventional methods as instructed by the physical therapist. At the completion of the evaluations, the therapist recorded the

required assistance level they needed to provide the patient to complete the task. The physical therapists then asked the patients questions using RPE and URS to collect the data for further analysis.

RESULTS

Of the 74 trials completed, 43 were performed with the SLW, 27 with the bilateral handrails, and four with a single handrail and cane or crutch. The median RPE was 9 ("very light") for trials using the SLW, 10 for trials using the bilateral handrails, and 11 ("light") for trials using the single handrail with a cane or crutch. The median safety ratings with the URS were +2 ("moderately safe") for trials using the SLW, +3 ("very safe") for trials using the bilateral handrails, and +1.5 ("barely-moderately safe") for trials using the single handrail with a cane or crutch. The median ease of use ratings with the modified URS were +2 ("moderately easy") for trials using the SLW, +2 ("moderately easy") for trials using the bilateral handrails, and 0 ("neither" difficult or easy) for trials using the single handrail with a cane or crutch.

Of the 43 trials conducted with the SLW, 81% required stand-by assistance, 14% required contact guard assistance, and 5% required minimal assistance. Of the 27 trials conducted with the bilateral handrails, 89% required stand-by assistance, 7% required contact guard assistance, and 4% completed the task independently. Finally, all four of the trials using the single handrail with a cane or crutch required stand-by assistance. There were no patient falls during the evaluation.

DISCUSSION

The results showed that the SLW performed better than the bilateral handrails and single handrail with a cane or crutch for perceived exertion. and comparably to the alternatives in terms of perceptions of safety and ease of use. We would expect this to continue and perhaps improve over the course of additional therapy sessions with the SLW and other conventional methods of therapy. Additionally, similar levels of physical therapist assistance were required for the SLW and bilateral handrails. Given the nature of the patient population, we expect that some level of stand-by assistance is warranted during stair negotiation training, regardless of the method or device used. The SLW was uniformly well received by the patients who used it. Many commented on its convenience and the versatility it could provide them in their home and community.

Limitations of the evaluation included few repeat sessions with the same patients using the SLW. Having repeat sessions would enable us to further trend the data to determine if the SLW can reduce rehabilitation times and length of stays by accelerating mastery of stair negotiation and increasing the efficiency of rehabilitation and training. Because these clinical evaluations were incorporated into existing physical therapy sessions, time and scheduling constraints did not allow for an equal number of trials conducted with the SLW and the other conventional assistive devices, as well as the inability to get repeat users.

Future work for the SLW includes the optimization of the current design. The team at the Cleveland VA Medical Center is pursuing a non-hydraulic design to reduce weight and improve the long-term maintenance of the walker. Additionally, the team will also be exploring opportunities to conduct repeat sessions with the same user to better understand the progression of the patient's rehabilitation with the SLW.

CONCLUSION

The clinical evaluation of the SLW showed that it is perceived to be less demanding than conventional assistive technology, and comparable to conventional alternatives in terms of safety, ease of use, and level of assistance required. The data suggest that the SLW may be a better long-term solution for patients in this segment of the population as it may reduce rehabilitation times and length of stays, but further evaluation should be done with repeat users over the entire course of therapy to verify this assumption.

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