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MALAYSIAN HEALTH TECHNOLOGY ASSESSMENT SECTION

REWALK REBOOT SOFT EXOSKELETON DEVICE IN STROKE PARAPLEGIA PATIENTS

EXECUTIVE SUMMARY

Stroke is a primary cause of long-term impairment and may cause hemiparesis walking. Currently available alternatives to locomotion include wheelchairs, orthotics, and neuroprosthetic functional electrical stimulation systems, although each has a number of limitations. ReWalk ReBoot Soft Exo-suit is a customisable personalised soft exoskeleton device for stroke survivors that can be used at home and in the community settings. It was claimed that it is made to aid in walking and mobility and specifically designed to help those with impaired ankle functions caused by neurological injuries like strokes. This device is a sister product to ReWalk Restore device in which will be followed by ReBoot as a predicate device. However, there was a significant amount of performance variability among users of ReWalk ReStore due to the severity of the injury and other unknown factors.

Keywords: Rewalk Reboot, Rewalk Restore, Exo-suit, Stroke, Paraplegia, Rehabilitation

INTRODUCTION

Malaysia is a Southeast Asian country with a developing economy, and stroke is becoming more widely recognised as a major public health risk. According to the Institute for Health Metrics and Evaluation's 2019, stroke is Malaysia's second cause of mortality and disability.[1,2] Meanwhile in United States, the stroke mortality rates among adults 35 to 64 years of age increased from 14.7 per 100 000 in 2010 to 15.4 per 100 000 in 2016.[3] Rates decreased among adults ≥65 years of age from 299.3 per 100 000 in 2010 to 271.4 per 100 000 in 2016.[3] The empirical study on stroke trends in Malaysia revealed a worrying increase in stroke incidence among the younger population.[4] Despite a declining trend, mortality rates remained moderately high especially in women.[4]

A stroke occurs when the blood supply to part of the brain is suddenly interrupted or when a blood vessel in the brain bursts, spilling blood into the spaces surrounding brain cells.[5] The symptoms of a stroke include sudden numbness or weakness, especially on one side of the body; sudden confusion or trouble speaking or understanding speech; sudden trouble seeing in one or both eyes; sudden trouble with walking, dizziness, or loss of balance or coordination; or sudden severe headache with no known cause.[5]

Stroke is a primary cause of long-term impairment [6], with 80% of survivors experiencing trouble walking following a stroke.[7] Hemiparesis, or substantial weakness on one side of the body, can occur after a stroke.[8] Hemiparetic walking after a stroke is characterised by a sluggish, asymmetrical, and inefficient gait.[8] Impaired paretic ankle function, particularly during the push-off and swing phases of the gait cycle, is a primary contributor to poststroke walking impairments.[9] Impaired paretic ankle plantarflexion (PF) lowers the contribution of the paretic leg to forward propulsion during push-off.[9] This causes severe reduction in stamina, limited mobility, and a decrease in the overall quality of life of the patient.[7] Physical therapy is a conventional treatment whereby a patient works to regain function on the paretic side of the body.[7]

Targeted gait interventions that improve paretic ankle function after stroke are therefore warranted.[10] ReBoot device is a lightweight, battery-powered orthotic exo-suit intended to assist ambulatory functions and rehab in home and community settings for individuals with reduced ankle functions due to stroke.[11] Clinical trials on the predicate device ReWalk Restore to date have yielded promising results in improving walking performance with some variability due to level of injuries.[12]

THE TECHNOLOGY

The ReWalk ReBoot is a lightweight, battery-powered exo-suit designed to aid ambulatory functions in people who have reduced ankle function due to neurological injuries like stroke.[11] It is a customisable device that patients can use to assist with walking at home or in their community and a sister product to the ReStore device, which was approved by the Food and Drug Administration (FDA) for the use in rehabilitation settings since 2019.[13] It consists of fitted, metal braces that support each leg and part of the upper body with joints running parallel to the hip, knee, and ankle.[11] It works in conjunction with the muscles of the affected leg to assist individuals not only with maintaining safe foot positioning but also with pushing off the ground, which means it may improve their gait.[11]

The exo-suit consists of functional apparel that is worn on the paretic leg. A shoe insole and calf wrap provide textile attachment points for Bowden cables located in front of and behind

the paretic ankle. An actuator unit and battery are secured close to the body center-of-mass using a waist belt. From the actuation unit, Bowden cables connect to the attachment points on the calf wrap and insole. Retraction of the Bowden cables deliver assistive dorsiflexor and plantar flexor torques during targeted phases of the gait cycle. Shoe-mounted inertial sensors enable gait detection and the delivery of the assistive forces in synchrony with the wearer's gait.[14]

The company claimed that the ReBoot device helps patients by supporting the leg and foot for safe positioning and to assist with pushing off the ground with each step.[11] Patients who use the ReBoot may improve their gait and help their muscles re-learn how to work, especially plantar flexor function.[11] Other potential benefits of the ReBoot include less muscle atrophy from disuse, better range of joint motion, great speed, and endurance while walking, along with fewer falls.[11]

In November 2021, ReWalk Robotics, Ltd. announced its ReBoot device has been granted designation as a Breakthrough Device by the Food and Drug Administration (FDA).[11]

Figure 1: ReWalk ReBoot Soft Exo-Suit[11]

CURRENT PRACTICE

Wheelchairs, orthoses, and neuroprosthetic functional electrical stimulation systems are among the locomotion alternatives accessible to people with paraplegia but the alternatives have certain drawbacks.[15] For paraplegics, the wheelchair remains the most prevalent form of transportation. While wheelchairs provide users with mobility that allows them to perform many daily activities, they are limited by a number of architectural and environmental barriers, the risk of shoulder and arm injuries, and the height restrictions for eye-to-eye interaction with adults who do not have a spinal cord injury. Wheelchairs do not reduce the poor clinical circumstances associated with spinal cord injury since they do not allow the user to put weight on his or her legs.[16]

According to the third edition of Malaysian Clinical Practice Guidelines on the Management of Ischaemic Stroke, discharge planning and individualised assessment for post-acute rehabilitation services should also be discussed as soon as the patient has been stabilised.[17] All older persons with stroke should be offered falls and fragility fracture risk assessment and management during the rehabilitation period.[17] After receiving acute care, rehabilitation which is typically complex for older persons is offered as soon as possible.[17] Decisions about rehabilitation are made by the patients, family, and a multidisciplinary team.[17] The use of comprehensive specialised stroke care (stroke units) that incorporates rehabilitation services are able to reduce mortality and disabilities among stroke patients.[17] Transcranial Magnetic Stimulation has shown some promising results in improving the motor recovery after stroke but it may need more evidence before it can be used as a daily rehabilitation tool.[17]

Rehabilitation needs rigorous and extended sessions to evaluate individual starting points and progress in which a patient walks for predetermined amounts of time and/or set distances.[18] Stance support, propulsion, and limb advancement are the three phases of normal gait mechanics.[18]

Some people with paraplegia have employed mechanical (non-powered) orthoses to help them stand, walk and in rehab. These devices are notoriously difficult to put on and take off, and they are widely acknowledged as taking a significant amount of energy from users. Overuse of the upper limbs is also a concern with these devices. According to published reports, the rate of abandonment was high with these orthoses.[19,20] Although functional electrical stimulation has been utilised successfully, it is known to cause muscular fatigue.[19]

Additional gait-training options exist within rehabilitation facilities, such as treadmill systems, some of which incorporate powered exoskeletons.[18] However, the inability to receive or continue the therapy at home may limit the frequency and intensity of walking.

EFFICACY AND SAFETY

According to the developer, no specific clinical trials had been done on ReWalk Reboot soft exo-suit as for now. However, this exo-suit is the consumer version of current clinical gait system called the ReWalk ReStore Exosuit. This is the predicate device that will be followed by ReWalk ReBoot for the consumer to use for home and community ambulation. The ReWalk Restore contains a pair of hips and a pair of knee joint motors powered by rechargeable batteries and a control system housed in a user-worn backpack. The system is entirely self-contained and subject-directed. Users control their own walking through minor trunk movements and a wrist-pad controller. There was one systematic review, randomised controlled trial, non-randomised study, observational study, single-subject consideration-of-concept trial, and prospective self-centered feasibility study that examined the effectiveness and safety of ReWalk Restore.

A systematic review by Lajeunesse et al included seven studies that assessed five lower limb exoskeletons Rewalk™, Mina, Indego®, Ekso™ (previously known as the eLEGS™) and Rex® in functional mobility by people with spinal cord injury.[21] This review aimed to outline the characteristics of the exoskeletons' design, evaluate their usefulness as assistive mobility devices in the community and document functional mobility outcomes of using these exoskeletons.[21] All the exoskeletons were found to be effective in enhancing locomotion, as walking had been possible for people who were unable to walk before.[21] The best result was with the ReWalk which could achieve a speed of 0.51 m/s after 45 training sessions lasting 60 to 120 min.[21] The Indego achieved a speed of up to 0.22 m/s from the first session. The study on Mina did not provide any data on walking speed.[21] Thus, the mobility outcomes reported in the studies showed that exoskeletons was effective for locomotion in a laboratory (all the participants could walk while without the exoskeleton they could not).[21] However, the applicability and the effectiveness of these mobility outcomes to people with SCI in the community has not been demonstrated since all the studies were conducted in a laboratory.[21] The ability to perform tasks other than walking and the benefits of wearing the exoskeleton (standing position and exercise) could be enhanced for potential use of lower limb exoskeletons in the community.[21]

Besides that, a multi-site clinical trials were conducted on 36 study participants who completed all five training days with the ReStore soft exosuit under supervision of qualified

physical therapist.[22] The training involved treadmill and over ground walking to assess the safety and device reliability in assisting the propulsion and ground clearance subtasks of post-stroke walking by actively assisting paretic ankle plantarflexion and dorsiflexion.[22] Average satisfaction ratings for the study participants were between “quite satisfied” and “very satisfied.[22] Regardless of their reliance on ancillary assistive devices, after only 5 days of walking practice with the device, approximately 61% of study participants increased their exosuit-assisted maximum walking speed by the lower bound of 0.05 m/s, 44% increased by 0.10 m/s, and 22% surpassed the higher bound of 0.16 m/s.[22] Study participants also presented with an average 0.07 ± 0.03 m/s ($p = 0.01$) increase in their unassisted maximum walking speed.[22] No device-related falls or serious adverse events were reported.[22] Therefore, ReStore™ soft exosuit has demonstrated to be secure and reliable for use during post-stroke gait rehabilitation to provide targeted assistance of both paretic ankle plantarflexion and dorsiflexion during treadmill and overground walking in this trial.[22]

A prospective, single-intervention, open, non-randomised study was conducted to evaluate the safety and usability of the ReWalk Restore twelve adults with chronic (at least 6 months post-injury) motor-complete cervical and thoracic (C7YT12) spinal cord injury for gait training.[20] Dynamic electromyogram was collected during walking from selected lower limb proximal muscles to confirm that no lower limb muscle activity was present.[20] By completion of the trial, all subjects had walked under their own control, without human assistance while using ReWalk, for at least 50 to 100 m continuously and for a period of at least 5 to 10 mins.[20] Velocities ranged from 0.03 to 0.45 m/sec (mean, 0.25 m/sec).[20] Velocities were considerably slower for the first 2 of the 12 subjects who participated compared to other participants.[20] Some subjects reported improvements in pain, bowel and bladder function, and spasticity during the trial.[20] ReWalk was found to be effective in allowing people to walk independently at various levels of ambulatory performance.[20]

Adults with chronic (>6 months) motor complete and incomplete paraplegia due to traumatic or nontraumatic spinal cord injury at low cervical level and below were included in another study to evaluate the velocity, number of sessions, and level of assistance and the relationships among them in a hospital setting.[23] The findings reported that seven of the twelve individuals in this study were able to walk at a speed of 0.40 m/sec or faster, which they considered adequate for restricted community ambulation.[23] Velocity may ultimately be correlated to the spinal cord injury level.[23] Participants with lower-level injuries (to thoracic vertebrae T9 to T12) walked longer distances than those with higher-level injuries (to thoracic vertebrae T5 to T7) in another study by Zeilig et al.[24] In the 10-metre walk test, participants with lower-level injuries walked significantly faster than those with higher injuries.[24] Five participants walked with modified independence, three with supervision, three

with minimal assistance, and 1 with moderate assistance.[23] Significant inverse relationships were noted between level of assistance and powered exo-skeleton velocity for both six-minute walk test (MWT) (Z value = 2.63, Rho = 0.79, p = 0.0086) and ten-MWT (Z value = 2.62, Rho = 0.79, p = 0.0088).[23] Modified independence and supervision groups ambulated with 2-point alternating crutch pattern, whereas the minimal assistance and moderate assistance groups favoured 3-point crutch gait.[23] Thus, ReWalk exoskeleton may be conducive to outdoor activity-related community ambulation and considered a safe device for in-hospital ambulation.[23]

A single-subject consideration-of-concept trial with repeated baseline measurements assessed the feasibility and rehabilitative potential of Robotic Exosuit Augmented Locomotion (REAL) by using the Soft Exo-Suit was done to measure the comfortable walking speed and maximum walking speed and 6-minute walk test distance.[14] A 54-year old male with chronic left-sided hemiparesis after a right middle cerebral artery ischaemic stroke was chosen to complete the five daily sessions of REAL gait training.[14] The comfortable walking speed was stable at 0.96 m/s prior to training and increased by 0.30 m/s after training.[14] Clinically meaningful increase was seen in maximum walking speed (1: 0.30 m/s) and 6-minute walk test distance (1: 59m). Improvements in paretic peak propulsion (1: 2.80 %BW), propulsive power (1: 0.41 W/kg), and trailing limb angle (1: 6.2 degrees) were observed at comfortable walking speed (p's < 0.05).[14] Likewise, improvements in paretic peak propulsion (1: 4.63 %BW) and trailing limb angle (1: 4.30 degrees) were observed at maximum walking speed (p's < 0.05).[14] After 5 days of REAL training, rapid and meaningful improvements in walking speed were observed by way of improved paretic propulsion.[14] This consideration-of-concept trial provides initial evidence that an exosuit-augmented gait training program centered on high intensity, task-specific, progressive, and individualised training elements is feasible to implemented after stroke and capable of facilitating rapid and meaningful improvements in paretic propulsion, walking speed, and walking distance.[14] This early-stage clinical investigation provides several design considerations and insights that can inform subsequent clinical trials of the soft robotic exosuit technology and next generation robot-assisted gait rehabilitation.[14]

The ability of patients to perform a wide range of primary and secondary standing or walking was tested in a randomised controlled trial.[25] In addition to basic skills such as standing, sitting, use of the remote wristband, and walking, the study also assessed the ability to stop walking on command, manoeuvre to a wall to rest, walk on carpet, and other irregular surfaces, as well as to navigate electric doors, elevators, revolving doors, and stairs.[25] Seven persons with motor-complete paraplegia were studied over an average of 45±20 sessions.[25] Sessions consisted of one to two hours of standing and overground ambulation

for 3 sessions per week.[25] All seven participants learned to perform sit-to-stand, stand-to-sit, and to walk 50 to 166 m in 6 minutes with none (n=4) to varying levels (n=3) of assistance.[25] Four of seven participants learned to ascend and descend ≥5 stairs with assistance, and these four patients also achieved some outdoor-specific walking skills.[25] Navigating elevators and revolving doors was attempted by four and three participants respectively, and all were successful without assistance.[25] No relationship with achievement of exoskeletal-assisted mobility skills was found with duration or level of spinal cord injury; however, the participant with the highest cord lesion (thoracic level 1) did require the most assistance.[25] Thus, with the use of the ReWalk exoskeleton, individuals with motor-complete paraplegia displayed proficient indoor and some outdoor walking skills.[25]

Benson et al. measured performance at multiple points during the training period with five participants completed the training programme.[26] Training sessions lasted 120 minutes and were intended to occur twice per week over a 10-week period.[26] Participants in this study initially trained for 60 minutes, and further increased to 120 minutes as participant tolerance permitted.[26] The average number of training sessions was 55 (range 12 to 120).[26] While walking speeds were higher and walking distances were longer in all exoskeleton users when compared with non-use, the exoskeleton generally did not meet subjects' high expectations in terms of perceived benefits.[26] The conduct of a controlled trial evaluating the benefits of using exoskeletons that require a lengthy user-commitment for training especially individuals involving chronic motor complete or incomplete spinal cord injury comes with considerable feasibility challenges.[26] However, this published study offers no details regarding participant performance in the sub-categories of activity. In this trial, it was reported a high incidence of skin issues. Five grade 1 skin aberrations occurred in three participants, and 10 grade 2 aberrations occurred in five participants.[26] All of the skin aberrations resulted in interruptions to the training program, and two participants were forced to withdraw because of recurring skin issues.[26] An additional study participant was required to withdraw because of what the authors described as a near serious fracture of a bone in the ankle.[26]

In the ReWalk investigations, no significant adverse events, such as death or hospitalisation, were reported. In a case series observational study done in a national spinal cord injury center, use of system was generally well tolerated, with no falls, skin or joint injuries, cardiovascular episodes, or changes on spine radiographs.[24] Changes in blood pressure and pulse rate were typical for physical activity, without reaching abnormal levels.[24] The fatigue level after the activity was considered to be moderate and no increased in pain after use. Individuals with lower level of spinal cord injury performed walking more efficiently.[24]

Nevertheless, according to Esquenazi et al, five users had skin abrasions in areas of contact with the device, lightheadedness, or lower-limb oedema.[16] Yang et al. reported slight skin abrasions that were resolved with padding and equipment modifications.[23]

It was mentioned instances where users lost their balance and either saved themselves from falling or were stabilized by staff.[20] It was also reported instances where the device misfired and failed to step, a situation that might lead to an adverse event.[20] Benson et al. cautioned that the continuous expert supervision characteristic of clinical environments may underestimate the real risk of falls and fractures in community settings.[26]

ESTIMATED COST

The cost of ReWalk ReBoot Soft-Exosuit was not revealed yet by the developer.

However, ReWalk Restore is currently used in rehabilitation centers in the United States. It costs US$71,600 (MYR 302,101.88; 1 USD=MYR 4.22) for a personal device and US$85,500 (MYR 360,750.15; 1 USD=MYR 4.22) for an institutional device, with additional annual service fees of US$8,000 (MYR 33,754; 1 USD=MYR 4.22) per year.[12] The device comes with a two-year warranty with a servicing contract of three times per year.[12] The personal-use system costs US$71,600 (MYR 302,101.88; 1 USD=MYR 4.22) and the post-warranty service contract costs US$4,000 (MYR 16,877.20; 1 USD=MYR 4.22) per year.[12] The life expectancy of the device is five years.[12]

POTENTIAL IMPACT

According to the clinical trials done on the predicate device ReWalk ReStore with a close supervision of physical therapist, most subjects achieved a level of walking proficiency close to that needed for limited community ambulation. A high degree of performance variability was observed across individuals. Some of this variability was explained by level of injury, and other factors that have not been completely identified.

Overall, ReWalk holds considerable potential as a safe ambulatory powered orthosis for stroke patients with paraplegia. The ReBoot device, as mentioned by the developer, is designed to be customised for each individual user to be used outside of the rehab center. It is anticipated to aid in the user's increased independence, decrease the risk of falls, and offer the opportunity for regular assistance at home and in the community. In the aftermath, it will help to reduce the healthcare burden especially in the rehab center.

However, clinical trials and further evaluation of ReWalk ReBoot need to be done with full economic evaluation to determine and evaluate the effectiveness and practicability to be use in the home or community settings and to be incorporated into the current treatment strategies.

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