Evaluation of efficacy & efficiency in implementing Knee Ankle Foot Orthosis (KAFO) as a functionally assistive indoor ambulatory device for motor complete thoracic level (T10 – T12) spinal cord injury in males

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Extended Article

Abstract:

The objective of this study was to evaluate the walking velocity, walking endurance, energy expenditure & risk of fall in use of KAFOs (Knee Ankle Foot Orthosis) over the alternative Aluminum Back Slab & Toe Raising Straps (ABS & TRS) on paraplegic (T10 –T12) ambulation which has not been performed among Sri Lankan patients. This was a case cross over study where fifteen, T10 – T12 motor complete paraplegic males who were using indoor ambulation with ABS & TRS and recommended to use KAFOs were recruited. A two weeks standardized ambulatory training was provided with either device prior to test. The 10 meter walk test, 6-minute walk test, physiological cost index (PCI) & time up & go test (TUG) were used to assess walking velocity, walking endurance, energy expenditure & risk of fall respectively. Testing was done 6 weeks apart. A statistically significant difference was seen in walking velocity ($z = -3.30$, $p = 0.001$), with ABS & TRS having faster velocity. The walking endurance with 6-minute walk test was significantly less with KAFOs ($z = -3.41$, $p = 0.001$,). A statistical significant difference was seen in energy expenditure ($z = -3.41$, $p = 0.001$), with KAFOs having a higher energy expenditure. There was statistical significant difference in risk of fall ($z = -3.29$, $p = 0.001$,) where it was higher with KAFOs.The results are closely compatible with previous studies, but remarkably differed with values of healthy individuals in normal ambulation. The walking velocity & the walking endurance of participants were relatively greater with less energy expenditure during ambulation with ABS & TRS. Therefore, it is concluded that KAFOs have less efficacy & efficiency as a functional indoor ambulatory device over ABS & TRS in rehabilitation of T10 –T12 paraplegic males. Patients with paraplegia due to spinal cord injury (SCI) perform activities of daily living (ADL) while lying down or seated due to the loss of the ability to stand or walk. Such changes in living patterns induce complications by diminishing the functions of each organ, including the musculoskeletal system. Limited activities may lead to multiple problems in these patients, including reduced physical fitness, obesity, cardiovascular disease, osteoporosis, fracture, and muscle atrophy. Therefore, independent standing and walking presents numerous physiological benefits for paraplegic patients, including prevention of complications, such as osteoporosis, fracture, pressure ulcers, spasticity, joint contracture, and infection, while facilitating circulation, and easier hygiene management. Furthermore, even if functional gait is impossible, training to stand or walk using a lower extremity assistive device could produce positive effects in all aspects of physical, mental, and social life.

Various assistive devices have been developed to help paraplegic patients stand and walk, and they have been applied to various degrees depending on the patient's functional requirements. Of these, knee-ankle-foot orthoses (KAFO) are essentially the only assistive devices currently used for complete paraplegic patients in clinical practice. The KAFO is applied from the femur to the

foot. In particular, it is prescribed to promote knee stability during standing and walking for patients with SCI, and it enables independent gait up to a certain distance.

Until recently, gait for patients with complete paraplegia due to SCI mostly consisted of gait using mechanical gait-assistive devices, such as KAFO. However, because KAFO lacks an external power source, it requires substantial upper limb muscle strength and has low energy efficiency. This increases the user's fatigue from gait, and in serious cases, it may induce musculoskeletal injuries in the upper limbs . KAFO devices are frequently utilized for standing postures or gait training, as opposed to functional gait. A previous study reported that among paraplegic patients with SCI who were discharged with a KAFO, only 14.7% continued to use the KAFO at home. The result indicated that patients find it difficult to utilize KAFO as a gait-assistive device for ADL.n response to the limitations of KAFO devices, exoskeleton robots are being developed to enable over-ground walking. The exoskeleton gait-assistive robots can be worn directly owing to their light and simple structure and can assist with lower limb muscle strength by providing power through the motorized joint. This will have an advantage in energy efficiency when walking, unlike walking with KAFO, which relies entirely on upper extremity muscle strength. Gait-using exoskeleton gaitassistive robots that enable over-ground walking can be used in an actual gait environment, such as outdoors, indoors, and in an environment with obstacles, thereby motivating users to walk .Owing to these advantages, it is expected that walking with exoskeleton gaitassistive robots can make up for the limitations of using a traditional KAFO daily. However, in Korea, there have been few clinical studies on walking with exoskeleton gait-assisted robots in patients with SCIs. In particular, there was no study comparing this to walking with KAFO as a gait-assistive device to be used for ADL.

The purpose of the present study was to compare spatiotemporal variables and energy efficiency in an exoskeleton gait-assistive robot (ReWalk) device and KAFO in patients with paraplegia due to SCI and evaluate patient satisfaction througha usability evaluation questionnaire for both walking devices. As there was no suitable usability questionnaire for evaluating the usability of exoskeleton gait-assistive robots, the questionnaire was developed and applied through expert consultation.

The exclusion criteria were severe neurological disorder in addition to SCI (e.g., multiple sclerosis, cerebral palsy, amyotrophic lateral sclerosis, traumatic brain injury, or stroke), a recent history of medical disease (e.g., infection, cardiovascular disease, or pressure ulcer), spinal instability, unhealed wound in the extremities, pelvic fracture, hip and knee range of motion (ROM) $\leq 90^{o}$, severe spasticity, severe osteoporosis with a risk of fracture, mental or cognitive disturbances that hinder gait training, history of treatment using exoskeleton gait-assistive robots, and failure to provide consent for study participation.

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