

Horizon Scanning

TechScan

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UNPOWERED ANKLE EXOSKELETON

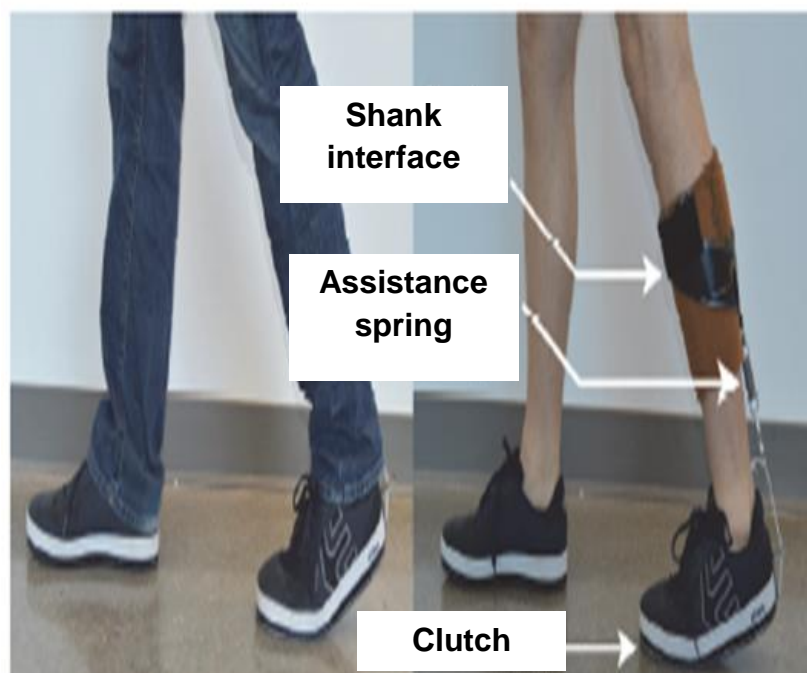
Keywords: unpowered exoskeleton, lower extremity exoskeleton, lower limbs, ankle rehabilitation

SUMMARY OF TECHNOLOGY

Unpowered ankle exoskeleton is a novel, light-weight, quiet, intrinsically adapts to different walking speeds, and does not restrict non-sagittal joint motion. This device was developed by research team from Mechanical Engineering Department, Biomedical Engineering, and Physical Medicine and Rehabilitation Department of Vanderbilt University.

This is the first ankle plantarflexion assistance exoskeleton that feasibly worn under typical daily clothing, without restricting ankle motion, and without components protruding substantially from the shoe, leg, waist and back. The design integrates under-the-foot clutch and a soft conformal shank interface, coupled by an ankle assistance spring that operates in parallel with the user's calf muscles as shown in Figure 1.

This device provides assistive ankle torque that can reduce demands on the calf musculature.



The shank interface is positioned just below the knee and attached to the assistance spring, which essentially serves as an artificial Achilles tendon.

The assistance spring connects to a fibrous rope, which runs posteriorly along the shank down to a lever arm at the heel.

From the heel, the rope is routed through a rope guide and attaches to the low profile clutch mechanism located under the foot.

Mass per leg: 459g (total mass 2 leg : 918g)

Figure 1: Unpowered ankle exoskeleton

How the device function:

- During stance, the clutch is engaged and the stiff assistance spring stretches. A portion of the ankle movement is borne through this spring, and thus reduces force on the calf muscles.
- During swing, the clutch disengage to allow the user to dorsiflex their ankle normally, encountering only small resistance due to a weak reset spring and slight friction within the clutch mechanism. This spring engagement/disengagement behavior is achieved passively, and thus the device function is qualitatively similar to unpowered exoskeleton developed by Collins et al. (2015) at North Carolina State University.

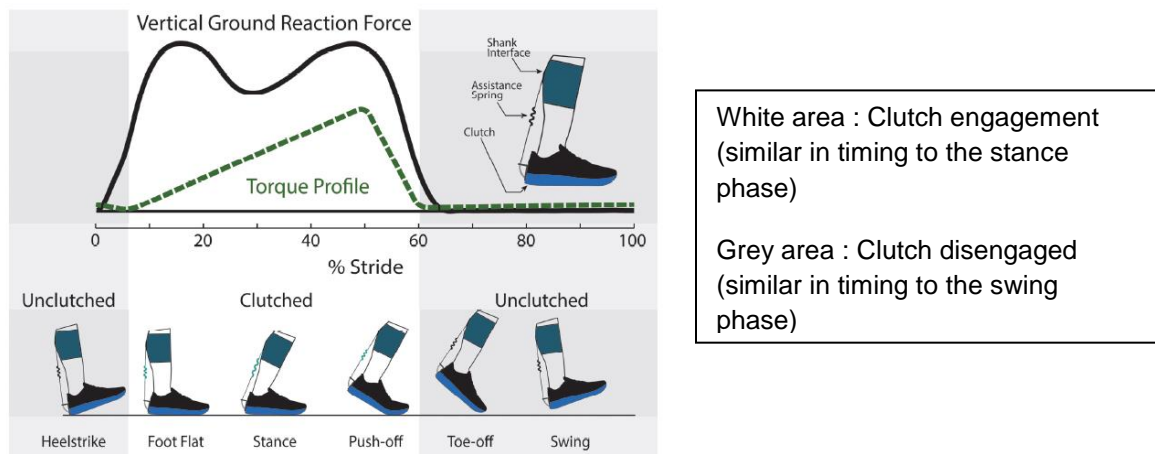


Figure 2: Exoskeleton function

- At foot contact the ankle is slightly dorsiflexed beyond neutral (foot perpendicular to shank), and the weak reset spring is in a stretched position.
- After foot contact, the ankle begins to plantarflex until the foot becomes flat on the ground. This motion allows the reset spring to recoil. Recoil of the reset spring then pulls the unstretched assistance spring to its default position.
- As the person progresses over their foot throughout stance, the center-of-pressure under the foot (i.e., location of net ground reaction force) also progresses forward.
- The ground reaction force increases the friction force (between the slider and gripper), preventing further motion of the slider.
- Because the slider is now fixed, dorsiflexion of the ankle stretches the stiff assistance spring and offloads the calf muscles and tendons.

- During late stance, the ankle begin to plantarflex. At this time, the assistance spring recoils, assisting plantarflexion. As the ground reaction forces underneath the foot rapidly decrease towards zero (toe-off), frictional forces between the slider and gripper also decrease, unclutching the mechanism.
- The slider can then move freely, with minimal resistance due to stretching of the weak reset spring. This allows normal dorsiflexion during leg swing to provide toe clearance.²

INNOVATIVENESS

Novel, completely new	√
Incremental improvement of the existing technology	
New indication of an existing technology	

DISEASE BURDEN

Gait disorder is common in stroke patients, other neurodegenerative disorder, musculoskeletal disorder (degenerative changes of ankle) and musculoskeletal injuries (ankle sprains). Ankle sprain is a common injury with a high rate of recurrence usually as a result of landing on a plantar flexed and inverted foot. Ankle sprains accounted for 85% of ligament sprain outside of foot and 25% of all sports-related injuries.³

The gait patterns are characterized by a slow gait cycle and speed, difference in stride length between the paretic side and non-paretic side, and a long swing phase and short stance phase. In particular, the ankle joints not only absorb impact and advance the body, which are their primary functions, but also function as crucial joints for the ankle strategy in maintaining balance. Movement disorder in the ankle joint is an important cause of gait disorder.⁴

CURRENT OPTIONS FOR PATIENTS

There are powered (active motor-controlled) exoskeleton with different specifications and configurations in the market.




	Type of exoskeleton	Total mass
	Powered exoskeleton from TU Delft uses an electric motor and leaf spring design. The device requires a backpack-mounted controller and battery pack. ^{5,6}	Mass per leg : 1500g Mass at waist/back : 5200g Total mass (two legs, waist and back) : 8200g
	Powered exoskeleton from MIT also uses an electric motor plus leaf spring design, but in a different configuration. A battery pack and controller unit are worn at the waist (not depicted). ⁷	Mass per leg : 1060g Mass at waist (motor controller)/back (batteries) : 2540g Total mass (two legs, waist and back) : 4660g
	Powered soft exoskeleton (exosuit) from Harvard uses motorized Bowden cables to assist ankle plantarflexion (and also dorsiflexion). A battery pack, and actuator unit are worn at the waist (not depicted). ⁸	Mass per leg (calf wrap with integrated sensors, insole and foot inertial measurement unit sensor): 502g Mass at waist (waist belt, battery pack, pulley cartridge) : 3302g Total mass (unilateral leg, waist and back): 3804g

Table 1 : Existing technologies-portable exoskeletons that assist ankle plantarflexion

For recent unpowered exoskeleton, Collins et al. (2015) from Carnegie Mellon University (CMU) and North Carolina State University (NC State) have developed a lightweight device that used a spring and clutch system working in tandem with calf muscles and the Achilles' tendon during walking phase.⁹ However this unpowered exoskeleton has protruding component that limited its usage.



Figure 3: Unpowered exoskeleton by Collins et al. (2015)

The available powered ankle exoskeletons are heavier and bigger than the unpowered ones. Powered ankle exoskeletons are generally composed of power sources, actuators, controllers and sensors and most designs have protruding compartment either out from the leg, foot, back or waist. The posterior protrusion may limit the range of motion.

POTENTIAL IMPACT OF TECHNOLOGY

A systematic search using Pubmed and Embase was conducted using these keywords either singly or combination (lower limb exoskeleton, ankle exoskeleton, unpowered exoskeleton and powered exoskeleton). All searches were conducted between 15th April 2019 to 20th September 2019.

a. Clinical Impact

This exoskeleton seemed to be beneficial. However, no clinical study was retrieved.

Only two case studies were conducted to assess various stiffness level of the exoskeleton and its effects on electromyography (EMG). A case study by Yandell MB et al. (2018) reported the benefit to soleus muscle when the subject walked with exoskeleton using split-belt force instrumented treadmill at 1.25m/s for one hour. Over the stride, reductions of 5-17% in average soleus activity was achieved for the exoskeleton conditions relative to the Shod condition (casual shoes). In a room with 57 dB ambient noise, the exoskeleton is less noisy. This is similar to walking in normal shoes (62 dB peak with the exoskeleton versus 60 dB peak in normal shoes).²

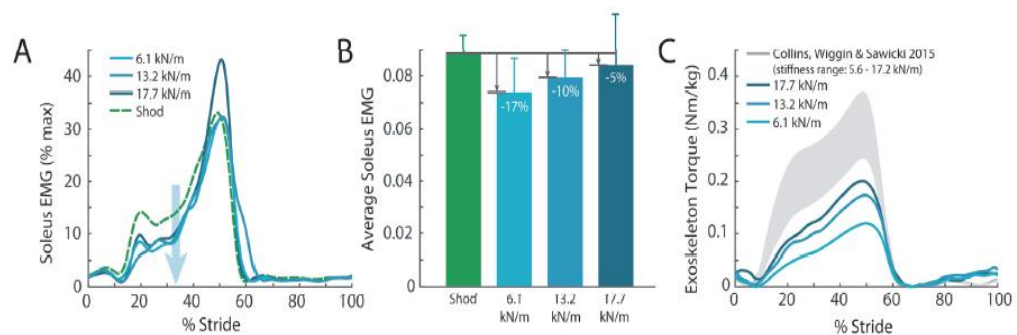


Figure 4: Case study results for assessment of different stiffness and the effect to electromyography (EMG).²

- A- Soleus EMG was reduced, specifically in mid-stance, when wearing the exoskeleton with various assistance springs versus not wearing the exoskeleton (normal shoes only, Shod). EMG was normalized to maximum muscle activation and averaged across strides.
- B- Average soleus EMG over stride (dimensionless) was reduced by five to 17% when wearing the exoskeleton. EMG mean and standard as depicted.
- C- Exoskeleton torque increased as spring stiffness increased. Spring stiffness were selected to match range of springs used in the prior study by Collins, Wiggin and Sawicki. Due to larger lever arm the prior exoskeleton provided more ankle torque (shaded grey) for same spring stiffness range.

Another case study aimed to explore the effects of stiffer assistance springs on exoskeleton ankle torque. It assessed different speed with doubled stiffness using exoskeleton prototype for over an hour, at walking speed ranging from 0.5-1.75 m/s on a level, split-belt force instrumented treadmill. From this study, the exoskeleton improved dorsiflexion angle up to 19 degrees during maximum torque tests (maximum 0.62 Nm/kg) at the same speed variations when spring stiffness doubled. If the speed is varied, peak exoskeleton torque was 0.12 Nm/kg at slow speed, increasing to a maximum of 0.14 Nm/kg at moderate speed, then decreased to 0.11 Nm/kg at the fastest speed.

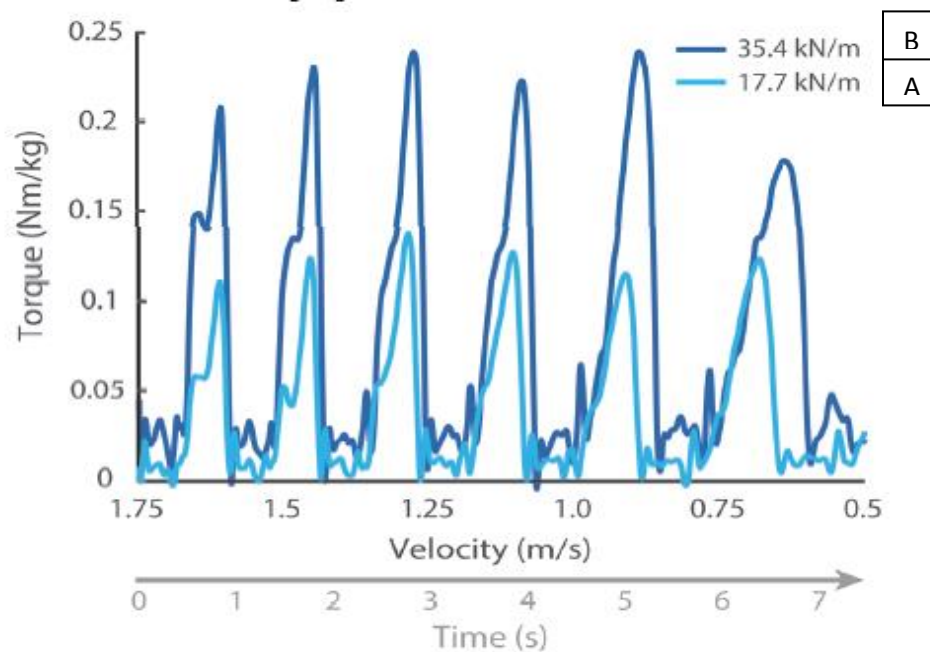


Figure 5 : Ankle exoskeleton functioning across a range of speeds. When assistance spring stiffness was doubled from 17.7 kN/m (A) to 35.4 kN/m (B), the peak exoskeleton torque approximately doubled at each speed

The effectiveness of this exoskeleton for specific indication need to be evaluated in clinical trials.

b. Cost

The price is approximately USD 100 (RM 420) in materials of which USD 67 (RM 280) is for the prosthetic liner material.

c. Organisational

The innovative designs reduces physical bulk and range-of-motion restrictions. There are no components that protrude substantially from the foot, shank, waist or back, and there is no artificial joint restricting ankle motion. It is expected to be more acceptable to the potential user than the current option.

It is easy to apply by wearing underneath typical clothing and in or under shoes, without interfering with other movement degrees-of-freedom (e.g., ankle inversion or eversion) or common daily task (e.g., driving a car). Nevertheless, a minimal training is required for user to adapt with spring stiffness that affect range of motion during walking phase. A shank interface, mechanical clutch or spring should be closely observed for maintenance purpose and repair if needed.

In addition, the users are able to engage or disengage assistance on demand without on and off the exoskeleton. This fully-passive design enable easy adaption to wide range of gaits speeds without relying on electrical sensors or specially-tuned mechanisms.

d. Societal/ethical

The device is expected to be more acceptable to the society compared to other available exoskeleton in the market which are bulky and cannot be concealed under cloth. The societal application which include, (1) assisting the elderly or individuals with impaired plantarflexor muscle strength (due to neurological or musculoskeletal injuries to augment their physical capabilities and help keep them active),(2) assisting recreational users in order to reduce musculoskeletal loading and effort during walking, running or hiking, or (3) assisting users who walk or run for substantial lengths of time to reduce musculoskeletal loading and effort during walking, running or hiking fatigue and help keep them energized and productive (e.g., postal or warehouse workers, soldiers).

However, the effects on the thermoregulation and sweat for certain population such as elderly with frail skin when using the exoskeleton is uncertain. These areas require further investigation.

e. Safety

There was no safety standards retrieved from Occupational and Safety and Health related agencies for exoskeleton. However, the safety of this device is determined based on guidelines from International Organization for Standardization (ISO) 13482:2014 and American Society for Testing and Materials F48 (ASTM F48) on Exoskeletons.

The user may experience adverse events such as leg discomfort and leg pain due to pressure over shank interface. This may lead to limited range of motion (ROM) of the leg. During repetitive movement in certain period of time, the possibility of misalignment of spring may develop. However, the usage of the device in any specific duration and distance is unretrievable.

EVIDENCE

1. Yandell MB, Tacca JR, Zelik KE. Design of a Low Profile, Unpowered Ankle Exoskeleton That Fits Under Clothes: Overcoming Practical Barriers to Widespread Societal Adoption. IEEE Transactions on Neural Systems and Rehabilitation Engineering. 2019.

REFERENCES

1. New Low-Profile Ankle Exoskeleton Fits Under Clothes for Potential Broad Adoption, Available at: <https://techxplore.com/news/2019-03-low-profile-ankle-exoskeleton-potential-broad.html>, Accessed on 29th April 2019
2. Yandell MB, Tacca JR, Zelik KE. Design of a Low Profile, Unpowered Ankle Exoskeleton That Fits Under Clothes: Overcoming Practical Barriers to Widespread Societal Adoption. IEEE Transactions on Neural Systems and Rehabilitation Engineering. 2019.
3. Physiotherapy Management For Sprain Ankle, Available at: <http://www.myhealth.gov.my/en/physiotherapy-management-sprain-ankle/>, Accessed on 17th July 2019.
4. Jang GU, Kweon MG, Park S, et al. A Study Of Structural Foot Deformity In Stroke Patients. Journal Of Physical Therapy Science. 2015;27(1):191-194.
5. Meijneke C, Van Dijk W, Van Der Kooij H, et al. Achilles: An Autonomous Lightweight Ankle Exoskeleton to Provide Push-Off Power. 5th IEEE RAS/EMBS International Conference on Biomedical Robotics and Biomechatronics; 2014: IEEE

6. Van Dijk W, Meijneke C, Van Der Kooij H. Evaluation of the Achilles Ankle Exoskeleton. *IEEE Transactions On Neural Systems And Rehabilitation Engineering*. 2016 Feb 11;25(2):151-160.
7. Mooney LM, Rouse EJ, Herr HM. Autonomous Exoskeleton Reduces Metabolic Cost Of Human Walking During Load Carriage. *Journal Of Neuroengineering And Rehabilitation*. 2014 Dec;11(1):80.
8. L. N. Awad et al., "A Soft Robotic Exosuit Improves Walking In Patients After Stroke," *Sci. Transl. Med.*, Vol. 9, No. 400, Jul. 2017.
9. Collins SH, Wiggin MB, Sawicki GS. Reducing the energy cost of human walking using an unpowered exoskeleton. *Nature*. 2015 Jun;522(7555):2

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Disclaimer: TechScan report is prepared based on information available at the time of research and a limited literature. It is not a definitive statement on the safety, effectiveness or cost effectiveness of the health technology covered. Additionally, other relevant scientific findings may have been reported since completion of this report.

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