ToeTronics: a portable device measuring the toe extensor strength

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Problem Statement and Background

The ability to measure toe strength accurately and reliably is necessary for clinicians and researchers to enable them to monitor strengthening or identify weakness[1]. The number of cancer patients surviving chemotherapy is skyrocketing. Today there are over 14 million cancer survivors, up by 1 million in just two years[2]. The University of Texas MD Anderson Cancer Center expects this number to swell to 18 million by 2022[3]. Cancer survivors who undergo chemotherapy not only have to face the consequences of cancer itself, but of the therapy they endure. One of the most severe side effects of chemotherapy is peripheral neuropathy, caused by the dying of neural cells. Patients suffering from peripheral neuropathy may experience numbness, tingling, burning, and muscle weakness; the consequences can be impaired motion or even complete immobilization. Measuring the progression of neuropathy in conjunction with chemotherapy treatment is currently done with a very subjective manual strength test of a patient's toes, which are often the first place neuropathy can be detected[4]. A physical therapist or other clinician places their hand on a patient's toes and asks them to lift their toes, which demonstrates the strength in the toe extensor muscles. Oncologists have to rely on the intuition of these professionals who have no empirical data, only the resistance they feel when they push on the patient's toe, to advise chemotherapy dosing and treatment decisions for their patients. This method is imprecise and results are not comparable across clinicians.

Existing medical devices that measure strength do not solve this problem because they are inappropriately sized or lack precision for toes or are designed specifically to measure other body parts. Hand dynamometers are common apparatuses in physical therapy and occupational therapy clinics. They measure the force output by a patient's handgrip, but the design is not compatible for use on toes. All-purpose hand-held dynamometers exist but suffer from several problems. Because the clinician must apply their own force to one side of the dynamometer to obtain a reading, these technologies are still relatively subjective. In addition, because of the relatively large size of all the commercially available hand-held dynamometers, their use on toes is impractical if not impossible. There were research and development on devices being able to measure the toe flexion but not able to measure toe extension[5]. Clinics looking to detect and treat chemotherapy-induced peripheral neuropathy demand a new device that can quickly, accurately, and objectively measure a patient's toe extensor strength.

In order to remedy this problem, we designed the ToeTronics, a portable device could quantify the strength of their patient's toes. With the force reading, the clinicians can easily assess the patient's toe strength. The researchers could also better study the relationship between toe strength and chemotherapy-induced peripheral neuropathy. The device would be useful for physical therapists, medical oncologists, and neurologists to keep on hand in their clinics or hospital departments in order to better treat the cancer patients they serve. The use of the device, however, may not be limited by its applicability to cancer treatment. Therapists could use it to measure neuropathy in diabetic patients or to measure the toe strength of athletes.

Methods

One of the most important features of this device is its adjustability. The prototype itself is adjustable for and can fit the foot of any patient ranging from a woman's size 5 to a men's size 14. This prototype accomplishes that range with a rectangular tongue in slot system that allows the length between the front and back of the prototype to vary, which can been seen in Figure 1. Also visible in Figure 1 is the flat heel stop that allows lateral movement of the foot on the device. Additionally, the entire sensor assembly can be moved through a hollow channel on the prototype, which allows not only lateral movement of a foot, but also measurement of either the left or the right foot, shown in Figure 2. This can allow physicians to measure either foot in the case of an injury or strength difference. These features combine to make ToeTronics optimally adjustable.

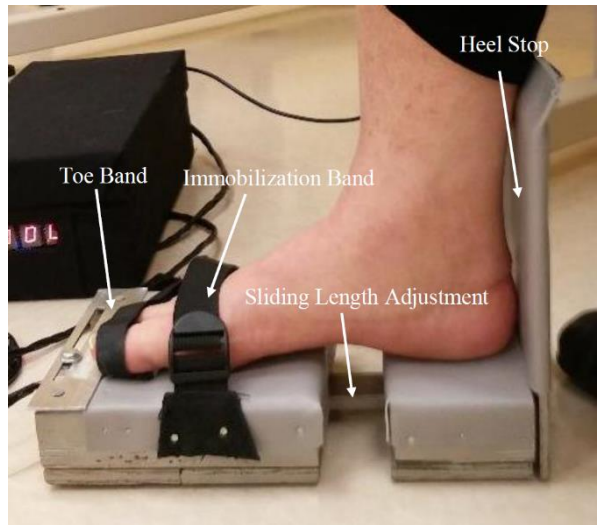

Figure 1 the prototype of ToeTronics Gen1 with an adjustable length and heel stop

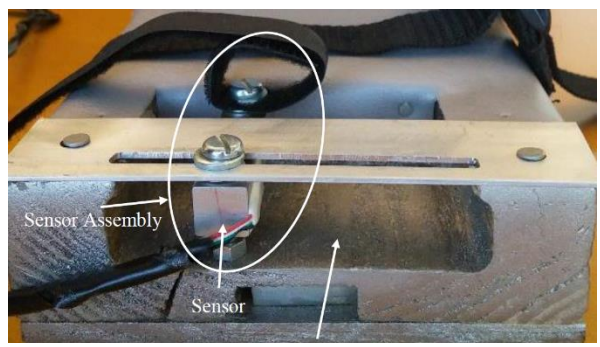

Figure 2 the load cell and sensory assemble for ToeTronics Gen1

Objectivity gives the use of this device great value over the current manual testing method. It allows any doctor to obtain the same strength reading from a given patient, and the design of the device facilitates that repeatability. A heel stop on the prototype gives clinicians more repeatability in their testing of patients, while encouraging patients to hold their ankle at the desired 90° with the ground. The latest prototype utilizes a strain gauge load sensor that measures the force applied to one end of the sensor. This sensor is attached to a toe band that wraps around the toe. This band can be adjusted to fit any size of toe, and should be placed over the great toe interphalangeal (IP) joint. The sensor chosen can read a max strength of 50 lbs, which is well above the average toe strength. This sensor also has a precision of 0.1 lbs, which has been shown to be precise enough through initial clinical testing. The device also features a band that prevents the ankle from flexing. This forces to patient to only exert a force using their toe, and allows for an accurate measurement of toe strength. These aspects combine to make each use of ToeTronics an objective reflection of the patient's toe strength.

The first prototype had been designed to be easy to use by using an intuitive digital display. The device itself houses electronics beneath the foot platform that take the force reading and output the strength in units of force onto an LCD screen. This was done by converting a voltage from the strain gauge into a force reading using a microprocessor. The attached LCD screen is angled at 45° with the ground. This angle allows the physician to easily see the toe strength reading and prevents the patients from easily seeing their force reading. Physicians have reported that patients who see their reading from a test may attempt to

change their reading, and may injure themselves straining to increase their force output. Additionally, the screen has three different electronic interfaces. The first is a button which allows the operator to change the mode from reading an average force or a maximum force. The next button clears the previous reading and launches the device into its next force reading. The last electronic interface is a simple on/off switch which toggles power to the electronics. These switches are shown in Figure 3. Some future innovation goals have been identified which would increase the ease of use of the device, including a designated application for the use of ToeTronics. This application could include the option to graph the force output over the time of the measurement for even more analysis options for the clinician. However, this current embodiment has the ease of use to motivate clinicians to actually use this device in their daily practice.

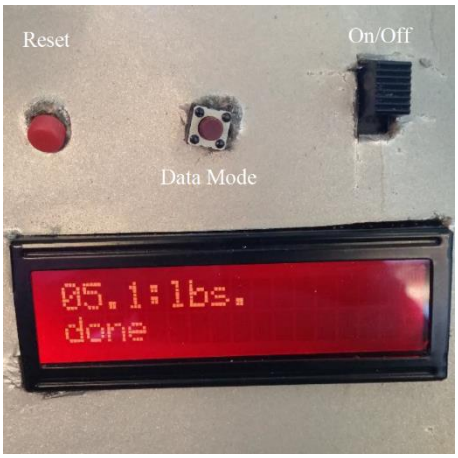

Figure 3 the control and display interface of ToeTronics Gen1.

The ToeTronics device was covered in soft vinyl-coated fleece material for comfort and ease of sterilization. After the device had been used, all polyvinyl foam surfaces could be wiped down with a disinfectant towel, which should then be discarded. The toe and immobility straps could be wiped down during this process and cleaned thoroughly each week with antifungal, antibacterial solution.

Final Design

With the prototype having been developed and fabricated, it was tested and evaluated by three physical therapists on its design and usability. The PTs recommend that we added second and more distal foot strap, positioned closer to toes than the first prototype for greater stabilization of the foot (to isolate the motion to the toe). It was also suggested that straps should be soft but wider (to spread out the force, for less chance of discomfort, or even skin damage). Move the actual great toe strap back (proximal), to target the IP joint of the great toe, or the region between MTP and IP. This should help stop the 'clawing' back out from under the strap we saw with smaller toes.


Figure 4 current design of ToeTronics Gen2 based on user feedback

Based on the user testing and feedback from the physical therapist, we had modified our design and the current prototype was shown in Figure 4. In addition, we had validated the system using an experimental set-up as shown in Figure 5. Different known loads were applied and Figure 6 showed the calibration results. We calibrated the system with both adding load and decreasing load and as shown in the Figure 6, the measurements were accurate and consistent.

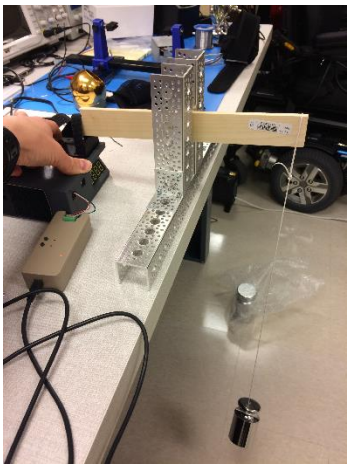

Figure 5 experimental set-up for the validation of ToeTronics Gen2

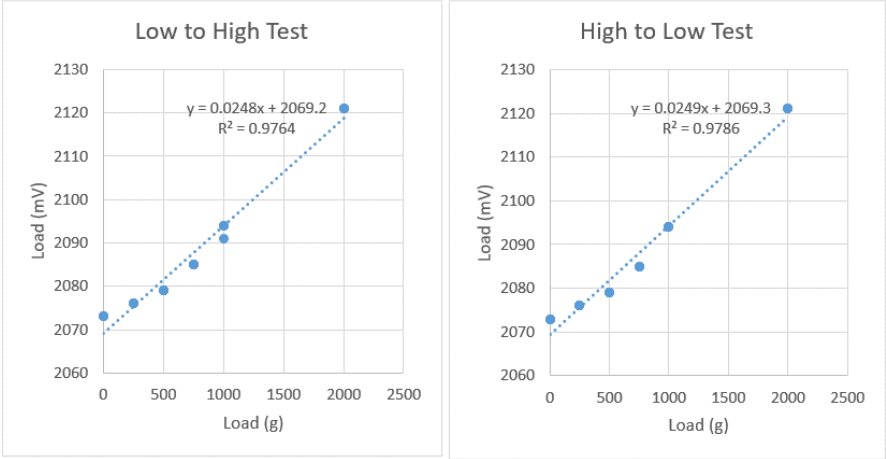

Figure 6 validation test results of ToeTronics Gen2 measurements with known load (left: increase the load from 0 to 2000g; right: decrease the load from 2000g to 0)

Outcome

We had filed an invention disclosure on the ToeTronics through the Office of Technology Development in University of Oklahoma (No.15HSC050). The current ToeTronics has been preliminary assessed by physical therapists and they all agreed on the high importance of portability, quickness of set up, ease of use, accuracy of the measurement, and ease to clean and maintain of the prototype.

In addition to the current validated prototype of ToeTronics. We also developed a user manual for the device with operation instructions including device set-up, taking a measurement, cleaning the device, and replacing the batteries. We are in the process of testing the new prototype with different therapists as well as able-body subjects. At the same time, we are working on improve the technology such as adding a Bluetooth module to enable wireless communication to decrease the hazards of wires. We are also working on development of a smartphone app for the device, which will make it easier for the therapist to use at different clinical settings without using a laptop. In addition, we are planning adding more sensory measurement of the device, such as heating, cooling and vibration.

Cost

For the current prototype, the total cost for duplicate the ToeTronics is around $200 including the electronics, the Arduino microcontroller, the display, the load cell, the straps and 3-D printed enclosures. The cost on the 3D printing was high but with increased manufacturing efficiency we expect to reduce the cost to $150 or less for the final commercial version.

Significance

This device, referred to here as ToeTronics, is the only device that can measure toe extensor strength effectively and efficiently. The device will be used to quantify the toe strength of patients' toes in order to determine the level of severity of neuropathy. Peripheral neuropathy can have both motor (muscle weakness) and sensory (numbness and tingling) components. The motor component is harder to recognize in its early stages, so is often

overlooked, yet the resultant foot and toe weakness can interfere with mobility and balance. Because it can be irreversible and lead to injurious falls and even lost independence, it is critical to catch neuropathy early, when chemotherapy schedules can still be modified to lessen progression. While sensory neuropathy starts with symptoms that can be perceived and reported by patients, the earliest clinical sign of motor neuropathy appears to be toe weakness, particularly of the toe extensors (toe lift). But too often toe weakness goes unrecognized by both patients and providers until it progresses to foot drop, a condition often requiring life-long orthotic intervention and strongly associated with falls. Further, oncologists currently rely on patients' qualitative symptom reports to make treatment decisions, but even sensory reports can be unreliable if patients fear their chemotherapy will be withdrawn. The measurement of toe strength will inform the dosing and scheduling of chemotherapy in order to avoid life-threatening complications from neuropathy.

Acknowledgements

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