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ISOMETRIC QUADRICEPS STRENGTH TEST DEVICE TO IMPROVE THE RELIABILITY OF HANDHELD DYNAMOMETRY IN PATIENT WITH ANTERIOR CRUCIATE LIGAMENT INJURY

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1 Background

Anterior cruciate ligaments (ACL) injuries account for a significant proportion of all sports-related injuries. Despite successful completion of a rehabilitation program, about 35% of ACL patients experience re-injury after return to sport, and studies have identified persistent quadriceps strength deficits as a potential cause [1-3]. Deficits in quadriceps strength can be monitored throughout rehabilitation using muscle strength testing. The most common test protocol involves isometric testing of quadriceps strength whereby the knee is extended against a static resistance. In this method, the clinician uses their strength to resist the patient's motion and subsequently assigns a qualitative value of strength. The highly subjective nature of this test has motivated clinicians to use devices that can more accurately assess quadriceps strength.

There are two main types of muscle strength test devices used currently in clinics: 1) isometric/isokinetic test systems (ITSs), such as the Biodex (Biodex Medical Systems, Inc., NY, USA), and 2) handheld dynamometers (HHDs) such as the microFET2 (Hoggan Scientific LLC., UT, USA) (Fig. 1A). Although ITSs offer highly reliable strength measurements of muscles across many different joints, they are expensive, complex systems that take a long time to set up for each patient and are not widely adopted in mainstream clinical practice. Conversely, HHDs incorporate a load cell that is held by the clinician and placed against any body part to obtain force measurements as the patient pushes against the device (Fig. 1B). Although HHDs are inexpensive and versatile, they suffer from low test reliability, with studies reporting up to 20-30% error in strength measurements compared to those obtained with ITSs [4,5]. Thus, given the large gap between the functionality of ITSs and HHDs, there is a clinical need for low cost, reliable measurement devices for testing quadriceps strength in this patient population.

2 Methods

A. Functional Requirements

Since HHDs are widely utilized by rehabilitation clinics, we first sought to understand the sources of variability in quadriceps strength measurements using HHDs with existing techniques. We identified three key sources of variation in typical HHD test protocols. Firstly, unreliable positioning of the patient's leg which is performed by the clinician using a goniometer. Secondly, inconsistent placement of the HHD on the patient's shin. Thirdly, there is clinician-dependent variability in the resistance that can be provided to stabilize the HHD as the patient kicks out (Fig. 1C) [6].

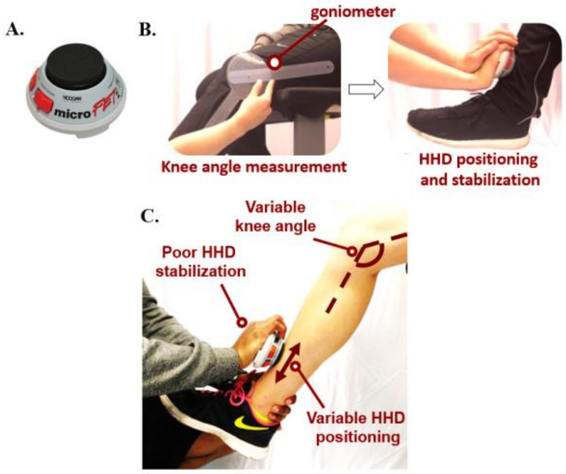

Figure 1. A) Handheld dynamometer (HHD) (MicroFET2, Hoggan Scientific LLC). B) Steps involved in quadriceps strength testing with the HHD. C) Sources of variability in quadriceps strength testing using the HHD.

TABLE I
FUNCTIONAL REQUIREMENTS

	Functional Requirement	Technical Standard
Accurate measurement of quadriceps strength	Knee angle measurement	60º and 45º ± 5º
	HHD placement	Consistent placement and stabilization
	Leg length adjustability	Accommodate most limb lengths
	Body stabilization	Restrict hip movement
Smooth integration into practice	Setup time	< 5 minutes
	Foldability	Improve storage and/or portability
	Cost	< $2000 (not including HHD)

We developed a set of core criteria for improving the use of current HHDs to obtain accurate measurement of quadriceps strength whilst retaining the high level of utility and ease of use of HHDs for clinicians at a relatively low cost (summarized in Table 1). One key requirement identified was the need for clinicians to obtain strength measurements at specific knee angles according to current clinical practice. Peak force generated by the quadriceps occurs at a knee angle of 60°, while a 45° angle is sometimes used as an alternative after certain surgical reconstructions. In addition to stabilizing the HHD against the patient's limb during testing, it is also important to minimize accessory motion of the patient's body as they extend their knee against resistance. Finally, to ensure that we retain the utility of the HHD, the proposed device must not require more than five minutes to set up and would ideally be portable or compactable for easy storage.

B. Device Design

We developed an adjustable restraining device to enable reliable quadriceps strength testing in conjunction with a commercially-available HHD (Fig. 2). The leg support can be positioned to either 60° or 45° to account for different quadriceps strength test protocols. The entire device can be slid back and folded under the table to which it is mounted when not in use. The device is modular in that can be mounted under any table or seated platform. The weight of the device does not impact the test performance of the system as long as the materials are rigid enough to withstand moment applied during knee extension.

The intent of this device is to replace the need for the clinician to set up, stabilize, and resist the patient's leg motion during testing with the HHD. The device consists of a proximal plate that is mounted to the underside of the table on a retractable slider, and a distal plate that supports the patient's lower leg. The HHD is placed in a rigid housing that is mounted at the end of the distal plate, which secures it during isometric strength testing (Fig 2C). Although the exact placement of the HHD along the distal shin is not critical, it is important to achieve repeatable placement. A pin locking mechanism on the distal plate allows the clinician to move the HHD up and down the patient's shin and repeatedly position the HHD for each test session. Pin locking mechanisms on the retractable portion and on the HHD housing, as well as a spring loaded strapping mechanism on the closure of the HHD housing allow for accommodation of different leg lengths and calf sizes. Whilst this device was designed to be used with microFET2 HHD, the 3D printed HHD housing unit can be modified to adapt the device for compatibility with other HHD models. The 3D printed housing for the HHD can also be easily adapted to the geometry of different limbs in order to test muscle function across different joints.

Figure 2. A) View of the device. B) Image of patient seated in the device. C) HHD housing unit.

The process for conducting a quadriceps strength test using the HHD with the developed device is outlined in Figure 3. Once the patient is seated on the table and secured with the body stabilization straps, the device is retracted from the table (Fig. 3A) and set to the desired angle (Fig. 3B). The patient's leg is position on the distal plate within the base of the HHD housing unit (Fig. 3C) and the HHD is inserted into the top part of the housing unit, secured onto the housing base, and aligned over the patient's shin (Fig. 3D,E).

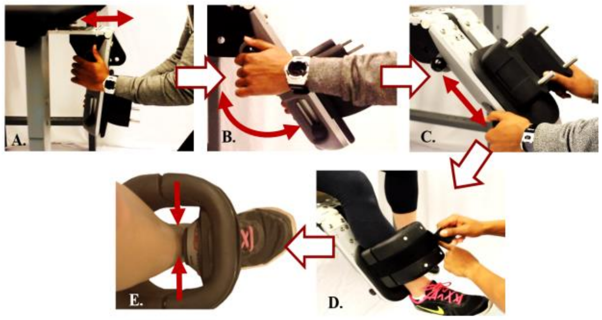

Figure 3. Test preparation workflow using the device. A) Retract the device, B) set knee angle, C) set HHD housing position, D) strap HHD housing top over patient leg, E) align the patient's shin directly under the HHD.

3 Results

Two studies were performed to demonstrate reduced variability using the device compared to manual HHD protocols in quadriceps strength testing. We can quantify the test-retest reliability, which is the accuracy of measurements from one test to the next. Reliable test-retest measurements are essential for monitoring of patient recovery. The first study investigated the reliability of repeat tests conducted by a single HHD user. The second study investigated the reliability of measurements made by three different HHD users. In each study, use of the HHD with the device was compared to use of the HHD alone. For all tests, measurements were conducted at a 45° knee angle on the right leg only. Testing was performed with the HHD positioned approximately 1-2 inches superior to the lateral and medial malleoli. Tests with the HHD alone involved measuring the subject's knee angle with a goniometer, stabilizing the leg and positioning the HHD, and resisting the subject kicking against the device for five seconds. Force values were recorded over time and the peak force measurement was logged for each test.

A. *Quadriceps strength tests conducted by a single HHD user*

Quadriceps strength testing conducted by one HHD user on three different subjects showed less measurement variability with the device compared to the HHD alone, observed as lower variation in force readings over the test duration (Fig. 4A,B). To quantify this variability, the standard deviation in force measurements was calculated over three seconds of maximal effort for all trials. Variability for a given trial was expressed as the percent of maximum force for that trial. Mean variability in force measurements recorded across all subjects was 8.6% for the HHD alone and 3.6% for the device, corresponding to a 56% reduction in measurement variability (Fig. 4C). Tests performed by one HHD user on three different subjects also showed significantly higher maximum force readings across all trials for the three subjects tested; tests conducted with the HHD alone resulted in an average maximum force of 241.6 N ± 37.9 N compared to 306.1 N ± 32.0 N with the device (paired t-test, $p<0.001$).

B. *Quadriceps strength tests conducted by different HHD users*

As shown in Fig. 4D, quadriceps strength testing conducted by different HHD users on a single subject showed significantly less measurement variability when tests were conducted using the device compared to the HHD alone; maximum force exerted by the subject across nine trials resulted in 286.5 N ± 15.8 N for the HHD alone and 340.7 N ± 6.8 N for HHD with the device (mean ± s.e.m.). This corresponds to 48% lower variability for use of the HHD with the device compared to the HHD alone, when assessing the measurement variability across HHD users as the range in force measurements recorded by the three clinicians across nine measurement trials conducted on the same subject.

C. *Setup Time*

Evaluation of the time required to conduct a quadriceps strength test showed that using the HHD with the device required the same amount of time (45 sec ± 15 sec) to complete a test as the time it took an HHD user to complete a test with the HHD alone. The setup time for the HHD alone was highly dependent on a user's prior experience using the HHD, while setup time for a test using this device was not.

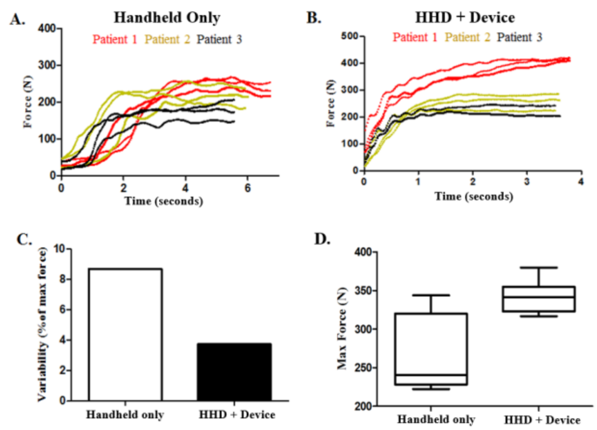

Figure 4. A) Variability in measurements taken by a single HHD user with the HHD alone and B) with the device. C) Quantification of this intra-user variability. D) Variability in measurements taken by three different HHD users with the HHD alone and with the device.

4 Interpretation

Although HHDs are portable, versatile, and inexpensive, their use requires significant clinician involvement leading to high measurement variability and low test reliability. Here we present a device that eliminates clinician-dependent factors contributing to the low test-retest reliability of HHDs.

In evaluating measurement variability in repeat tests conducted by the same HHD user on a test subject, we observed that high variability associated with the HHD alone was lowered when using the developed device, suggesting that variation in measurement may be caused by differences in user performance. The high variability in HHD testing was observed even for users with prior experience using HHDs. All subjects tested in this study also exhibited significantly higher maximum force values when tested using the device compared to the HHD alone. These values are likely more reflective of the subject's true strength since the device replaces the need for a user to resist the subject's motion.

In evaluating the measurement variability associated with tests conducted by three different HHD users on the same subject, we observed a wide range of forces recorded by the users when using the HHD alone. This suggests that assessment of subject strength with the HHD is highly dependent on the HHD user. Since the HHD users involved in this study were of the same level of experience but spanned a range of strength capabilities, the variability observed with the HHD was likely due, in part, to differences in a user's ability to resist the subject's force during testing.

In addition, since setting up a strength measurement test using the HHD alone requires user experience to measure and stabilize the knee angle, and ensure positioning of the HHD, there is a strong dependence of setup time for the HHD alone on user experience. However, this dependence was not observed with the developed device. Successful use of the device did not rely on user ability or prior experience.

The device presented here improved HHD reliability by eliminating clinician-dependent factors, such as subject positioning, HHD stabilization, as well as user experience and strength. This improved reliability of the HHD was provided at a cost of about $2000 more than the HHD alone. Compared to ITSs (~$50,000), our device offered a low cost solution to improve the performance of an already highly utilized muscle strength test device. Although our device improved the measurement reliability of HHDs, it did not retain the same degree of versatility as the HHD. A major advantage of the HHD over this device is its ability to test any muscle in the body in any direction of motion (extension, flexion, abduction, adduction, etc.) Despite this limitation, the low cost and ease of manufacturing of the subject interface components of the presented device would make it possible to expand its capabilities to more than just quadriceps testing.

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