DYNAFLEX: OPTIMIZING FIXED-FRAME LEG DYNAMOMETRY

Rachel McLoughlin, Damilola Ayoola, Elizabeth Mountz, Francis Talty
University of Pittsburgh

Motivation and Description of the Problem/Need: Dynamometry, by definition, is the measurement of force generated by a muscle group; it is used by physical therapists (PTs) for baseline and follow-up strength measurements or for data collection in research. On the present market, PTs can select designs ranging from large, expensive stationary units to small, cheap handheld devices. Both large and small devices can be time-consuming to set up, require participants to change positions often, and/or require PTs to physically stabilize the device causing undue ergonomic risks and positioning inconsistencies.

Two tests PTs conduct with dynamometers are the hamstring and quadriceps force tests, where the participant's hamstring and quadriceps muscle forces are measured to diagnose the extent of damage, weakness, or pain inhibition. The quadriceps and hamstrings are vital because of their use in activities of daily living such as getting up from a chair, getting out of bed, and being able to balance and walk. During the measurement process, patients typically sit and push or pull against a handheld dynamometer strapped to their ankle. However, for a current low back pain study at the University of Pittsburgh, sitting is not a comfortable position for participants. Therefore, the researchers selected the prone position with the knee flexed to 70 degrees to keep the participant's back neutral during testing (Figure 1).

When performing this test, it is important that the participant remains completely still and maintains the 70-degree angle of flexion to receive an accurate reading, but with a handheld dynamometer, this is nearly impossible to ensure. Oftentimes, two PTs are required to assist in keeping the participant in the "standardized position" while holding the dynamometer stable against the force of the participant's leg. Additionally, the protocol for the test varies between PTs due to their own body mechanics (i.e. how much taller they are from the participant, their wingspan, etc.). Finally, reading the results of the handheld dynamometer is inconvenient. The handheld dynamometer's display is placed on the same face as the loading arm, causing the PT to remove the dynamometer entirely to read it. These myriad issues with previous leg dynamometer designs are widespread due to the extensive medical usage of the hamstring and quadriceps force test. One study performed on accuracy, reproducibility, and variability of handheld dynamometers in motor neuron disease concluded that force readings recorded between just three clinicians had 53% greater variability than those obtained by a single clinician [1]. One can only imagine the variability that exists between the estimated 233,350 PTs practicing currently in the United States [2]. The same study even reported that increased experience using handheld dynamometers does not improve reproducibility or variability [1]. Consequently, our team set out to solve the need for a leg dynamometer that accommodates for prone position and yields more consistent lower extremity strength test results with ease.

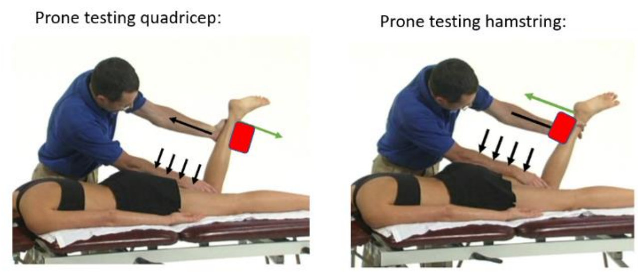

Figure 1. The handheld dynamometer (represented as a red block) can be used to measure both the quadriceps and hamstring strength of the prone-lying patient, but requires significant effort from the PT, and is susceptible to high variability between therapists.

Design Goals: Our team was tasked with developing an adjustable frame to house a newly designed leg dynamometer for testing a person in the prone position without taxing the PT. The following guidelines were requested by the PT:

1. The frame must be able to accommodate for the standard test position— knee bend of 70 degrees in prone position— with the ability to adjust the angle in case of cramping.
2. The frame must be able to accommodate for both the quadriceps and hamstring strength tests.
3. The frame must be adjustable to the participant's height and tibia length.
4. The frame must be lightweight (under 10 pounds), easily transportable, and fit on a regular-sized treatment table.
5. The frame and display must be easy to clean.
6. The device must be quick and simple for a solo PT to operate.
7. The force sensor and frame must be comfortable for the participant.
8. The force sensor must yield consistent and accurate force measurements.

Competition and Differentiation: There are two main leg dynamometers available on today's market: the handheld dynamometer and the BioDex - System 4. The handheld dynamometer is most used for its portability and low-cost. Many PTs provide at-home healthcare and need a small device to use in their patient's home. However, the handheld dynamometer is not efficient for a single PT to use in the prone configuration for an accurate reading without straining themself due to the demand of counteracting the patient's force. The BioDex - System 4 is a newly designed dynamometer that can accommodate many positions and exercises. This machine costs around $10,000 for the simpler models, which is excessively expensive for many PT clinics. Also, the machine is very large and occupies a great amount of space, considering it also comes with a monitor system to analyze the test results. Our Dynaflex device takes these shortcomings into consideration and meshes low cost with portability, accuracy, efficiency, and adjustability to meet consumer needs.

Design Process: The primary stakeholders for our product include PTs, orthopedic surgeons, clinical researchers, and patients. To develop a product best fit to solve the problem, feedback from these parties was imperative. Consequently, the iterative design process began with a design specifications meeting attended by practicing and researching professionals in the physical therapy and orthopedic surgery departments at the University of Pittsburgh. Through this meeting, our team gained valuable insight including the expected maximum load on the frame and the specifications of the treatment table, such as the cushion overhang and the configuration of the support bars. After gaining this insight and performing research into current dynamometer designs, we brainstormed sketches and drew comparisons to common “household” items to facilitate communication between engineers and medical professionals. These preliminary sketches considered a stationary, upright frame; a dynamic, adjustable-incline frame; a curved track to account for valgus/varus knee joint deformity; spring-loaded pins to adjust for tibia length and desired test; and Velcro patches to allow load cell movement for abductor and adductor strength tests. We settled on our ultimate design direction after presenting these initial ideas to our physical therapy and orthopedic surgery clients. Next, our team researched standard patient measurements and constructed low resolution prototypes out of foam core and laser cut wood to gain a better concept of size. We then tested various aspects of these prototypes on a regular-sized physical therapy treatment table at the University of Pittsburgh’s physical therapy research clinic. When moving to construct the final frame, we first explored commonly found parts such as bike-seat clamps and weightlifting clips. With advice from mentors at the University of Pittsburgh Makerspace, we learned standardizing materials is key in new product development to ensure repeatability, compatibility, and modularity. With that advice, we ordered generic aluminum t-slotted framing and connections. Several iterations of the physical dynamometer and its frame connection were also made through CAD modeling and 3D printing to secure the electronic components, ensure patient comfort, allow for code updates, and enhance force display during strength testing (Figure 2). Further clinic testing was performed with PTs present, and many methods of attaching the frame to the treatment table, including c-clamps, brackets jutting out from the sides of the table, and custom bed bars, were fleshed out. During the design process, we confirmed high stability while ensuring that the product would not damage the treatment table. Before our first completed product was handed off to our clients to be tested as part of the clinical trial, modifications such as handles, end caps, non-slip rubber cushions, and directional stickers were also added.

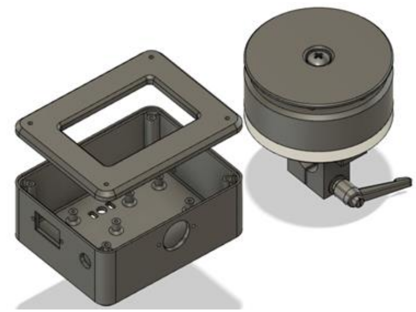

Figure 2. CAD model of dynamometer electronics enclosure, including Arduino circuit (left) and load cell (right).

Prototype of the Design: Our solution product, Dynaflex, allows for accurate individualized lower extremity strength tests that are comfortable for patients and simple for PTs (Figure 3). A typical use case involves 1) sliding the lightweight frame underneath the cushioning of the treatment table using the custom table connection brackets as guides, 2) sliding the angle adjustment bearings until they line up with the etched angle labels on the rails, 3) rotating the load cell adjustment clamp to adjust for the proper leg and strength test, 4) sliding the tibia length adjustment bearings to adjust for the patient’s tibia length, 5) pivoting the dynamometer screen to adjust for optimal viewing by the PT, and 6) instructing the patient to push their shin against the soft-cushioned load cell until the maximum force output is displayed.

Figure 3. Complete Dynaflex product with easy adjustments for patient accommodation.

Each adjustment bearing utilizes the same quick-release handbrake to make dimensional customizations quick and simple for PTs. Vinyl labels guide the user by indicating direction of clamp rotation for adjustment. Additionally, the frame is constructed from hollow anodized aluminum to make transportation painless. Finally, the electronics enclosed in the dynamometer housing center around a programmed Arduino, which can have its code updated at any time through the easy access port.

Testing and Results: The testing process for Dynaflex involved both data accuracy and usability testing. To test the accuracy of our dynamometer force readings, we ensured that force readings on our dynamometer were consistent with readings from a store-bought dynamometer for both quadriceps and hamstring tests. When measuring a known weight, the load cell performs with an accuracy of ± 0.2 kg. Our dynamometer proved to be accurate and reliable, consistently displaying precise force readings. For usability, we had multiple subjects, including several team members and University of Pittsburgh PTs, set up and adjust the dynamometer frame, testing all adjustment features in the process, to resemble how it would be used in a real test or research setting. This included attaching the frame to the therapy table at the correct position for the patient's height, adjusting the knee angle with an angle adjustment bearing, adjusting the dynamometer height with two parallel adjustment bearings, and transitioning between quadriceps and hamstring tests. All necessary adjustments were able to be made in about two minutes, and even faster with practice. Our basic design goals included being lightweight, easy to clean, and removable from the therapy table with no permanent attachments or damage. Our design meets all of these conditions, with the final product weighing just under 10 lbs, made of mostly 1" aluminum t-slotted framing, and attaching to the table as a single unit. This standardized, modular design allows Dynaflex to be sized to any treatment table. Our more functional goal included accurate force readings for testing leg muscle strength and a quick set up for all necessary components of the test. Both critical goals were met, with our testing results proving its success.

Value Proposition and Potential Impact: Leg dynamometers allow for accurate and easy quantification of muscle strength, which has important implications in healthcare and research settings. They are valuable in physical therapy to assess patient progress and response to treatment, and to motivate patients through objective evaluation, both of which help reduce cost and time spent on ineffective treatments. Leg dynamometers also help prevent injury in at-risk individuals, such as athletes, through regular observation of muscle strength. A fixed frame dynamometry system was found to be especially reliable and effective at profiling and monitoring an elite male Australian Football League [3]. Specifically, a lower hamstring to quadriceps strength ratio, as measured with an isokinetic leg dynamometer, is a precursor to lower extremity injuries [4]. Injury prevention cuts costs on injury diagnosis and treatment. Leg dynamometers also help researchers quantify normative data for different population strengths and to assess factors that alter muscle strength. A study that measured quadriceps strength in 25 women in their 20's and 25 women in their 50's enhanced understanding of the effects of age on muscle strength and helped provide normative data for observing muscle weakness in future patients [5].

Our product is actively being used in a research study for understanding causes of chronic low back pain, an extremely debilitating and costly ailment that affects 80% of the world's population [6]. The use of Dynaflex helps the researchers consider the relationship between leg strength and low back pain. The results of the study will ultimately help to improve preventative measures and treatment options for those who suffer from chronic low back pain.

The path to market is clear. Due to a rising prevalence of sports injuries, the medical dynamometer market is predicted to grow at a CAGR of 7.7% from 2020-2026 [7]. Under the FDA, our 'AC-powered dynamometer' is a Class II device, which due to the Cures Act, is exempt from premarket notification procedures such as those established in section 510(k) of the FDA Cosmetic Act. Our device infringes on none of the limitations for exemption, so we are not required to submit a premarket notification to the FDA, which streamlines our path to market. We envision our affordable product being sold directly to orthopedic clinics and research institutions.

References:

1. Goonetilleke A. et al, J Neurol Neurosurg Psychiatry. 1994; 57(3): 326–332.
2. "29-1123 Physical Therapists." *U.S. Bureau of Labor Statistics*, U.S. Bureau of Labor Statistics, 2020.
3. Ransom M. et al, J Sci Med Sport. 2020; 23(9); 826-830.
4. "A Balanced Approach to Leg Strength." *Peak Performance*, Peak Performance, 17 June 2018.
5. Young A. et al, Eur J Clin Invest. 1984; 14; 282-287.
6. Freburger J. et al, Arch Intern Med. 2009 Feb 9; 169(3): 251–258.
7. "Medical Dynamometer Market Forecast, Trend Analysis & Competition Tracking - Global Market Insights 2020 to 2026." *Fact.MR*, Fact.MR, 2020.

Acknowledgements: We thank Dr. Marit Johnson and Dr. Kevin Bell of the University of Pittsburgh Ferguson Laboratory for Orthopedic and Spine Research and Dr. Sara Piva of the University of Pittsburgh Department of Physical Therapy for trusting our team with their product development needs and providing us with constant feedback and access to the treatment table. Additionally, we thank Dr. William Clark, Brandon Barber, and Dan Yates of the Pitt XProjects program and the Pitt Makerspace for providing us with not only the initial opportunity to develop Dynaflex, but also the unwavering guidance throughout our design process.