Preliminary Report:
DRUJ-Instability Quantification Rig

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Background

The Distal Radioulnar Joint (DRUJ) connects the radius and ulna at the wrist, and is responsible for stabilizing articulation of the radius around the ulna during pronation and supination [2]. The Triangular Fibrocartilage Complex (TFCC) is a network of connective tissue responsible for the stability of the DRUJ. *Figure 1* depicts an overview of these structures.

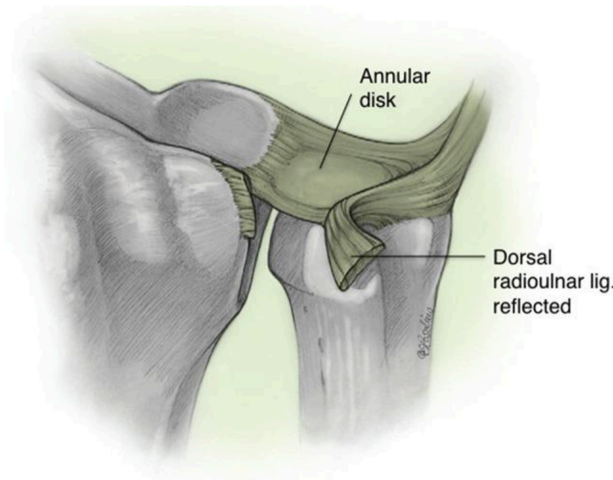

Figure 1: The Distal Radioulnar Joint. Taken from Wolfe SW et. al., 2011 [14]

TFCC injuries, a leading cause of DRUJ instability, can result in acute pain and diminished grip strength [1]. While considered rare, these injuries most commonly occur alongside distal radial or ulnar fractures. Stevens and Cadogan note that "they are missed in as many as 50% of cases in the acute period, delaying appropriate treatment" [13]. Without proper intervention, TFCC injuries can progress to lasting complications, including arthritis, persistent weakness, and gross instability, significantly impacting the patient's quality of life [1].

Although surgical interventions for DRUJ injuries are well-established, the decision-making process is complicated by a severe lack of quantitative diagnostic methods [12]. Current techniques for assessing DRUJ instability are qualitative in nature, limiting their efficacy. The gold standard of these methods, the DRUJ ballottement test (illustrated in *Figure 2*) relies solely on the physician's subjective judgment of "stable" or "unstable." While this approach can be informative in some cases, it often fails to provide the objective data required to confidently guide surgical decisions.

Figure 2. Ballottement Test shown in pronation. Taken from Physiotutors.com [10]

Our client, Dr. Charles Goldfarb, a hand and wrist surgeon at the Washington University School of Medicine, frequently sees DRUJ injuries, and, given the limitations of current diagnostic methods and the potential consequences of missed, delayed, or improper treatment, recognizes the critical need for quantitative assessment methods. A reliable, quantitative testing setup would aid clinicians in surgical decision making process, and more readily offer appropriate treatment in the acute stage of injury. Such a diagnostic tool could be widely implemented in orthopedic clinics and hospitals, enhancing the ability to determine the nature and severity of wrist injuries.

Need Statement & Project Scope

Need Statement:

When orthopedic hand surgeons attempt to understand distal radioulnar joint instability, there is a need to efficiently and practically quantify joint stability to succinctly inform surgical decision-making for more favorable outcomes.

Project Scope:

Diagnosis of instability in the distal radioulnar joint is limited to a qualitative judgment of "stable" or "unstable;" efficient, practical assessment of distal radioulnar joint stability currently remains out of reach. Presently, qualitative wrist ballottement tests are used to elicit doctor opinion and patient pain response to determine structural instability. A rig involving drilling into the arm bones of cadavers to mount electromagnetic tracking sensors and a Microscribe transducer was used as an invasive, yet accurate method of instability quantification. With a similarly capable portable, noninvasive, and comfortable device, surgeons could better judge the surgical methodology required for an individual patient and reliably determine post-operative efficacy.

We intend to develop a non-invasive system to gauge joint instability by February 2025, and deliver a final prototype to Dr. Goldfarb by April 20th, 2025 so that his surgical team can gauge the system's accuracy and reliability in a clinical setting. Alongside prototype delivery, we will provide manufacturing plans and relevant design files needed to reproduce the rig in the event of success. A Gantt Chart granularly detailing these major milestones alongside other relevant deadlines and design targets is displayed in *Figure 6*.

Key Stakeholders

An overview of the relevant stakeholders for this project, arranged by influence and interest, is shown in *Figure 3*.

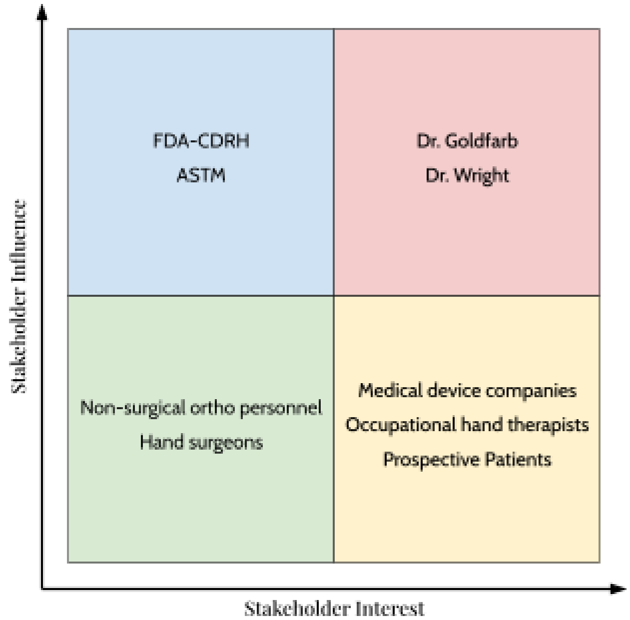

Figure 3. Stakeholder matrix for DRUJ-instability quantification rig

The most important stakeholders for this project are Dr. Charles Goldfarb, a hand and wrist surgeon at the Washington University School of Medicine, and Dr. David Wright, a hand and wrist surgeon at UC Irvine. Drs. Goldfarb and Wright have been able to successfully quantify DRUJ-instability in cadaver studies, and have spearheaded the discussion within the field for a practical, noninvasive method of DRUJ stability quantification. They can provide supplemental, context-specific biomechanical and anatomical information about the DRUJ, and would be the primary operators of the device along with other hand surgeons. Requirements set by regulatory bodies, including the FDA's Center for Devices and Radiological Health (CDRH) and the American Society for Testing and Materials (ASTM) will be frequently referenced to ensure the device adheres to established standards. Occupational hand therapists and individuals with DRUJ-instability will also be consulted to verify device comfort and ergonomics. Medical device companies will be the primary mode of distribution for the completed device, even with a limited role in design and development stages. Finally, non-surgical orthopedic professionals play a role alongside hand surgeons in the operation of the device; by moving standard-of-care from qualitative surgeon-led joint characterization tests to standardized quantitative exams made with the device, other personnel are able to assist with data collection.

Design Specifications

The preliminary design specifications for the DRUJ-instability quantification rig are detailed in *Table 1.* Design criteria may change as the device evolves.

Table 1: Preliminary Design Specifications

Category	Specification
Sensitivity	Sensitive to < 0.5 mm joint displacement
Testing Setup Comfort	Comfortable arm set-up in chassis/rig to prevent patient discomfort, Adjustable resting height for arm to account for height disparities (different furniture, wheelchair users, children, etc.), Adjustable wristlet size/diameter to account for limb sizes
Sensor Implementation	Non-invasive, epicutaneous, can be calibrated for multiple wrist diameters
Isolation	Chassis and wristlet must be vibrationally isolated to dampen any ambient noise (less than 0.1mm movement) and the chassis must be electrically isolated/grounded
Device Dimensions	< 20 cm x 20 cm x 20 cm
Data Analysis Output	Universal data output with recognizable .txt or .csv file formatting
Operation Regulations	Easily operated with low learning curve, tactile buttons and large numerical readouts alongside a clean interface

Category (continued)	Specification (continued)
Safety	Hypoallergenic, repeatable trials without patient injury, sanitizable, quick disassembly/removal in case of emergency, physical and software-triggered shut-off switches
Applicable Force Input + Range	Granular and customizable input scale ranging from 0-10 N with 0.25 N resolution, and input-to-actuation lag time of < 1 second
Mounting System	Static/acute mounting for forearm to completely prevent unwanted rotation
Software + Visual Interface Sampling Rate	Real time force and rotational displacement readings, 100 samples/sec, Large readable data display
Rig Chirality	Testing rig should be ambidextrous and capable of force application on dorsal and ventral sides of both wrists
Cost	< $1000

Existing Solutions

An extensive literature and patent search of existing solutions and relevant research methods was conducted to assess possible approaches for the development of the device. The most relevant of these are summarized below.

Invasive Cadaver Rig:

Dr. Wright has developed a preliminary testing rig capable of quantifying DRUJ instability to within ~1 mm. A cadaveric specimen is mounted in a plexiglass testing stand with forearm in neutral rotation and the radius fixed proximally and distally, with the ulna left unhindered to simulate ballottement. A 3D microscribe along with electromagnetic tracking sensors embedded in the radius and ulna were used to measure relative translation when known, alternating dorsal and volar loads were applied to the ulna. *Figure 4* depicts an overview of the testing setup.

Figure 4: Overview of invasive cadaver rig for DRUJ instability quantification

While this apparatus can successfully quantify translation in the DRUJ in response to known, applied loads, it has two glaring issues. The first issue is that it requires drilling into the arm bones to mount the tracking sensors, making it unsuitable for use on live patients. The second issue is practicality; the tracking sensors are highly sensitive to electromagnetic interference, meaning no metal or electrical components can be placed near the setup. Component cost also totals over $10,000, likely rendering this specific approach unmarketable. A different cadaver testing rig developed by Moritomo et. al. in 2017 [8] achieved similar results, but suffers from the same invasiveness and practicality issues as Dr. Wright's setup.

DRUJ Ballottement Test:

Various clinical tests for qualitative wrist assessment are employed, however the gold standard among these is the DRUJ Ballottement test [9]. Hand surgeons perform it to generally assess DRUJ instability and patient discomfort. To do so, the examiner stabilizes the patient's distal radius and hand together while the forearm is held in neutral rotation. Using their other hand, the examiner grasps the distal ulna and presses it in the dorsal and palmar direction relative to the radius. This is then repeated with the forearm in relative supination and pronation. Stability is assessed by the qualitative movement of the joint, with greater laxity compared to the uninjured wrist and recreation of painful symptoms indicating a positive test [10]. Despite this, however, the validity of the ballottement test has been contested, with Pickering & Giddins describing it as "unreliable" and further adding that "instability (in the DRUJ) is typically underrecognized" [11]. A 1995 study by LaStayo and Howell placed the sensitivity of the ballottement test at 64%, and the specificity at only 44%, with these metrics being worse for other qualitative assessment methods [7]. At best, the ballottement test is useful for indicating whether a patient requires further investigation, and at worst can lead to erroneous surgical intervention.

Ultrasound Quantification Rig:

The only other discovered instance of DRUJ stability quantification comes from a testing rig developed by Ishii et al. in 2019 with ultrasound as their sensor modality [15]. *Figure 5* depicts the testing setup from a bird's eye view with the main rig components labeled.

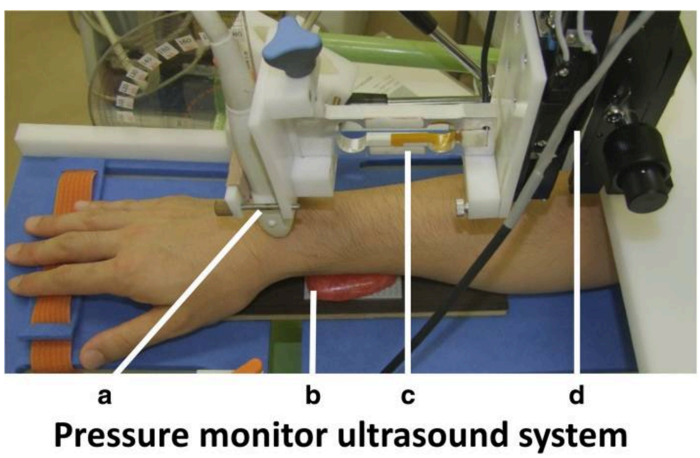

Figure 5: Non-invasive ultrasound rig for DRUJ instability quantification. Taken from Yoshii et. al., 2019. [15]

This system consists of a transducer pressing into the patient's arm (a), a block to rest the limb on (b), a pressure sensor and strain gauge sensor to determine transducer output (c), and the actuating motor (d) [15]. A linear array transducer was added to the ultrasound scanner to produce a uniform density rectangular FOV scan. The compression reducing the distance between the ulnar head and the distal radius' dorsal surface was recorded in the ultrasound scans to be used as translation metrics. Averaging 5 results for each setup produced results of a higher degree of accuracy than Dr. Wright's rig with an additional significant figure [15]. Furthermore, the system sensitivity and specificity were 82% and 86%, respectively [16]. However, an expensive ultrasound system along with further limitations in operator experience, forearm position options, and system reliability are the main disadvantages of this setup. This rig effectively provides another gold standard to use as a benchmark for a new rig's accuracy and reliability.

Patent Search:

Four patents were found relevant to DRUJ instability quantification device design: (1) A biomechanical data collection system using wireless body-mounted sensors, providing insights on integrating multiple biosensors [6]. (2) An apparatus for positioning forearms at various angles for imaging and analysis, particularly for DRUJ instability diagnosis using CT. Its methodology for consistent forearm positioning during torque application could be relevant [3]. (3) A wearable joint tracker using IMU and EMG to measure joint angles and muscle activation, with potential applications in instability quantification [5]. (4) A discreet movement measurement system using accelerometers and gyroscopes to detect instability and monitor range-of-motion. It includes a smartphone app for analysis and can incorporate various sensors [4].

Design Schedule & Team Responsibilities

Design Schedule:

An initial design schedule for the project was drafted, and is depicted in *Figure 6* as a Gantt chart.

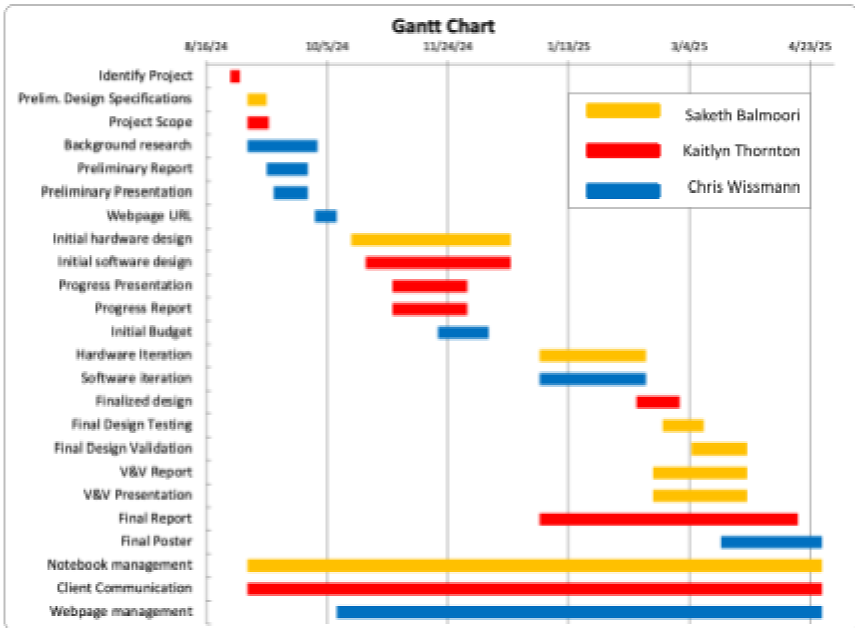

Figure 6. Project Gantt Chart. Items and their start/end times are subject to change

The color-coding of the chart items indicates the team member leading the task, as all members are expected to contribute to every task.

Team Responsibilities:

Team members were assigned aspects of the project that best aligned with their skills, which are outlined in [*Table 2*]. Despite these overarching responsibilities, all team members are expected to meet deadlines and contribute meaningfully wherever possible.

Table 2: Team Responsibilities

Member	Responsibilities
Saketh Balmoori	• Primary research lead • CAD, mechanical testing • V&V Presentation
Kaitlyn Thornton	• Primary client liaison • Sensor and device integration • Progress Presentation
Chris Wissmann	• Primary notebook manager • Software development, website manager • Preliminary Presentation

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