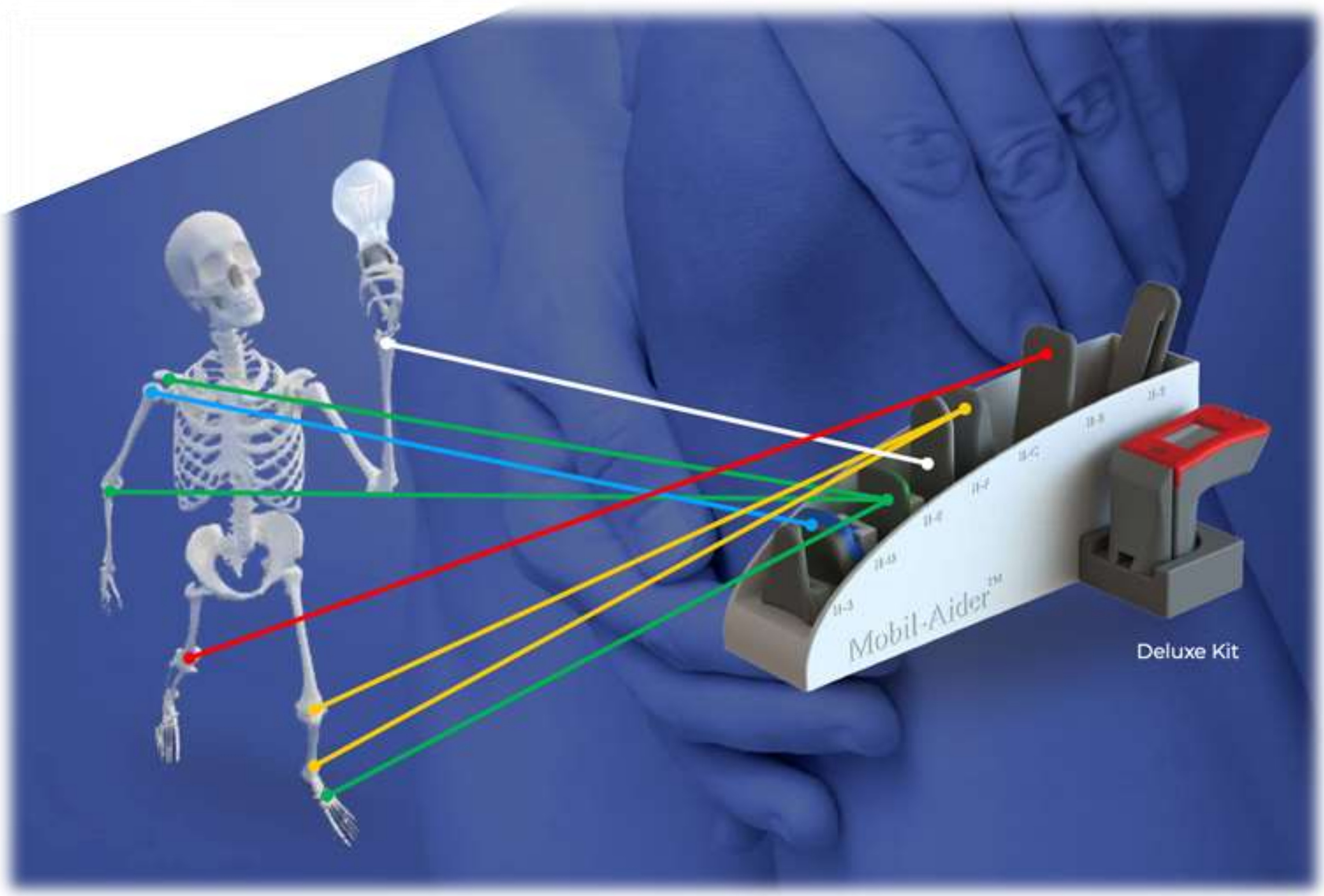
Mobil-Aider™



THE MODERN WAY TO MEASURE JOINT MOBILITY

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Clinical review

The purpose of this paper is to provide an overview of the current state of joint mobility assessment methodologies, the complexities and challenges of using existing methods and demonstrating clinical need for accurate joint laxity assessment.

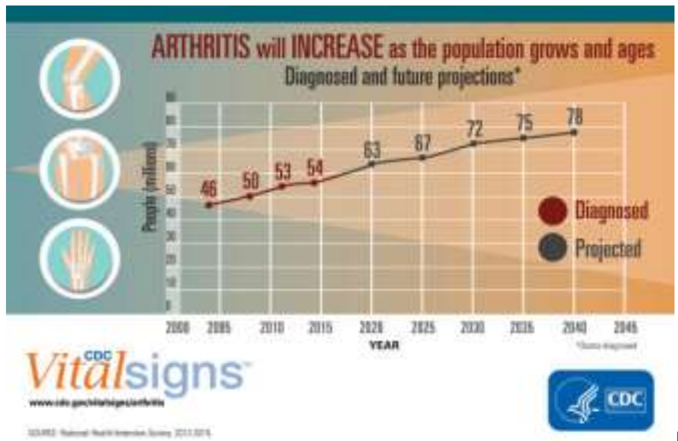
Prevalence

A 2019 analysis of Global Burden of Disease (GBD) data showed that approximately 1.71 billion people live with musculoskeletal conditions worldwide [1]. This data was reported by the World Health Organization (WHO). They described the impact of musculoskeletal conditions in significantly limiting mobility and dexterity, and leading to early retirement from work, low levels of well-being, and reduced ability to participate in society [2]. Other reports state that musculoskeletal conditions are the primary reason patients visit a physician, accounting for 131 million health care visits per year [3]. The United States Bones and Joint Initiative (USBJI) reports that musculoskeletal injuries are the leading cause of health care visits, at a rate of 77% (65.8 million), and an overall annual cost of $176.1 billion to treating musculoskeletal injuries. Research data is reported on different underlying causes of musculoskeletal injuries including occupational, sports, and joint laxity or hypermobility-related injuries. Additionally, 1 in 3 injuries are shown to be the result of falling, whereas 54% of the remaining injuries are due to a traumatic event (vehicle accidents, machinery, moving objects, and other types of traumatic injuries) [4]. Injury facts of the National Safety Council (NSC) reported 247,620 musculoskeletal disorder (MSD) injuries or illnesses in the private sector in 2020, resulting in a median of 14 days away from work [5]. On the other hand, physical activity, while an important component of health and well-being, has been directly linked to high incidence of injuries occurring at different levels of sports participation, leading to psychological, emotional, physical, social, and economic tolls [30]. Other studies reported the prevalence of generalized joint hypermobility (GJH) in the young adult population, concluding 12.5% of the overall population with GJH being prone to sustain more musculoskeletal injuries [31].

[6]

According to WHO, musculoskeletal conditions include those that affect joints, bones, muscles, or multiple body areas and systems, and are the highest contributor to the global need for rehabilitation [2]. Of the primary conditions mentioned above, joint pain is a leading symptom of arthritis, for which an estimated 78 million (26%) of US adults aged 18 years or older are projected to have by 2040 [6].

Overall, 1 in 4 people over the age of 18 report chronic joint pain, with multiple joints as the potential source of the pain. However, among 63.1 million people reporting chronic joint pain in 2012, knee pain is the most frequently cited, with 40 million accounts. Shoulder pain came second, reported by 18.7 million [7]. Pain management for conditions involving joint pain includes operative and non-operative approaches depending on type of injury, patient age, among other factors. Osteoarthritis (OA) is the most common form of arthritis resulting in joint pain. Research has reported an increasing need for non-operative treatments, requiring a multi-faceted understanding for the diagnosis, pathogenesis, history of the injury, and potential known effects of the treatment approach. Prior joint trauma, such as anterior cruciate ligament rupture and ankle fracture, increases risk, accounting for 12% of OA cases [40].



[5]

Patients with joint dysfunction are often referred to non-invasive therapy approaches aimed at maintaining joint mobility, improving muscle strength, and reducing physical pain. Those approaches include physical therapy, joint stabilization, and pain and inflammation reducing drugs [8, 9]. Physical therapy is a widely adopted nonoperative treatment approach for joint injuries or dysfunction such as the knee, ankle, shoulder, elbow, and wrist joints. In the case of knee injuries, research has shown that combining multiple approaches of manual examination and patient-specific intervention leads to symptom reduction and functional improvement [10]. Similar data is reported on shoulder joint injuries, with the combination of physical therapy and exercise leading to increased strength, decreased pain, and better function. A systemic review found that manual therapy was more effective than placebo alone in reducing pain and increasing range of motion in shoulder impingement syndrome [11, 12].

Manual therapy and physical examination

Current practice

Joint mobilizations (Arthrokinematics) are defined by the APTA Guide to Physical Therapist Practice as "a manual therapy technique comprised of a continuum of skilled passive movements that are applied at varying speeds and amplitudes." Those techniques have been established as an essential part of the orthopedic manual therapy approach and are required skills for entry level physical therapists. Joint mobilizations have been shown to be useful alongside exercise in joint treatment and involve manual application of skilled passive movements to the joint to improve physiologic joint motion, enhance motor function, and reduce pain and muscle spasms. In other words, joint mobilization techniques aim to restore accessory movement (arthrokinematics) between joint surfaces, which include roll, spin, and slide and accompany physiological movements of a joint [12, 13, 14, 15].

Existing challenges

Identifying joint dysfunction requires accurate assessment of linear translation; the relative motion that occurs between joint surfaces. Loss of linear translation due to injury or dysfunction can lead to joint hypomobility and subsequent loss of function. When assessing accessory motion to direct patient care and develop psychomotor performance of joint mobilization procedures, quantifying joint linear translation is an essential step required by clinicians [15]. This process, however, has been a challenge due to lack of consensus around the appropriate amount of force and joint movement delivered during manual therapy. Although manual techniques are standardized, lack of objective data has influenced effectiveness and reliability [12, 18]

Likewise, specific joints have a variety of manual examination techniques to assess damage. In the case of knee injuries, the anterior cruciate ligament (ACL) is one of the most commonly injured knee ligaments, accounting for over a quarter million injuries per year in the USA. Different clinical tests of the ACL have been reported to have a wide range of diagnostic accuracy, with the Lachman test being the gold standard and the most widely accepted. Research has reported that individual modifications of the test and examiner experience influence test accuracy. The Lachman test is a passive accessory movement performed on the knee to assess the integrity of the ACL. In this test, clinicians perform linear translation of the tibia on the femur and use the end feel as a quantitative parameter to assessing ACL damage [17, 19, 20, 21]. There are several issues related to the performance of the Lachman test, despite being widely adopted in the orthopedic community: [21]

1) Mismatch in the ratio between the size of the patient's leg and the clinician's hand can result in difficulty in stabilizing the knee to obtain maximal linear translation
2) Positioning of the patient's knee in too much flexion or if the hamstring musculature is not relaxed may block translation of the knee
3) Inability to quantify millimeters of translation can be a significant concern when comparing laxity between the involved and uninvolved knee, especially when relying on the "endfeel" as a key metric

These challenges can lead to potential false negatives, leading to a significant 74% of acute ACL injuries being misdiagnosed in the emergency department [16, 17].

Within the shoulder joint complex, the glenohumeral joint (GHJ) has the most mobility and susceptibility to impairment. Approximately 1-2% of the general population will experience glenohumeral dislocation in their lifetime [22]. Research reported that clinicians broadly agree on the use of translational motion in making clinical decisions regarding care. Clinicians use passive translatory glides in all planes and assess the relationship between tissue resistance and an individual's report of pain, as well as the quality of tissue at end range, or end feel, in each direction. Given accessory motion involves millimeters of movement, this poses difficulty in quantification among clinicians. Therefore, there have been a lack of evidence supporting reliability of accessory motion testing among clinicians, due to their limited ability to quantify motion and assess change in response to intervention [15].

Regardless of the dysfunctional joint at hand, there is a need for consistency with joint mobilization techniques. Major challenges remain with the variability reported among clinicians of different experience levels, the amount of force exerted, and the effect of the force on different types of joint injuries. Inter-rater reliability is defined as the extent to which two or more investigators or clinicians reach agreement in a defined parameter. However, the development of skilled performance of these procedures may be challenging when linear translation of a task is unable to be quantified. Intra-rater reliability, on the other hand, is the degree of agreement among administered tests performed by the same investigator. Studies have reported poor-moderate reliability between different clinicians, and relatively good intra-clinician reliability, specifically among well-trained and skilled clinicians. Novice practitioners and students seeking to develop proficiency in performing joint mobilization techniques are often challenged in accurate assessment of joint translation and replicating the forces applied during mobilization procedures. With young practitioners, the process of skill acquisitions requires cognitive processes to be transitioned into psychomotor skills of joint mobilization techniques within a clinical setting. To develop and master these psychomotor skills, novice clinicians require purposeful practice with visual feedback, associated with concurrent feedback given while learning a task. Both feedback and practice time have been identified as the most important variables in skill acquisition. Current process for teaching manual skills includes instructor demonstration followed by learner practice with qualitative feedback from the instructor. While critical, this feedback is provided at a distance and in a delayed manner which negatively impacts skills acquisition. Even within skilled clinicians, studies have reported a poor correlation between force and displacement, as varying degrees of joint injuries add another layer of complexity, and clinicians can use the same amount of force on two different people and achieve different quantities of linear translation of the joint [15, 18, 23].

Market landscape

Imaging methods

Diagnostic accuracy remains a question with manual assessment and treatment approaches, leading to potential false-positive or false negative results. For that reason, there are several devices and techniques that have become available to assess injury and quantify joint translation, however, most are cumbersome to use and expensive [15, 24].

Magnetic Resonance Imaging (MRI) is considered the gold standard for imaging musculoskeletal diagnostics. For ACL evaluation, MRI is an established imaging methodology often employed. However, there are many challenges associated with the use of MRI technology for ACL injury assessment [17, 19, 21]

1) MRI is a static image when the patient in is one position, not synonymous with assessing functional knee instability. Therefore, it has limited ability to identify partial tears or dynamic laxity of the ACL. Furthermore, the static image of the MRI does not provide any information on the biomechanical behavior of the ligament or the joint.
2) MRI is a relatively expensive diagnostic technique of limited availability, associated with the need to be referred by a specialist. These are often long waiting lists of patients needing specialist treatment and diagnostic imaging.
3) The machinery may be contraindicated in patients with claustrophobia or metal implants.

Ultrasonography is another commonly used method in orthopedic diagnostics and has been used for many years in the diagnosis of ACL injuries and measuring accessory joint movement. General issues have also been identified with the use of ultrasound and other radiographic methods [12, 24]

1) The method has been characterized as having low specificity and high rate of false positives, and research has failed to identify a gold standard measure for validating results of dysfunctional joint assessment when comparing painful versus nonpainful joints.
2) Difficulty in positioning the ultrasound equipment and the practitioner's hand while performing manual techniques, resulting in inability to measure joint distances in real time during passive accessory motion

Arthrometers

In addition to manual and imaging techniques, a broad variety of knee arthrometers have been available over the past three decades. Arthrometers provide linear measurement of joint translation and assist in the quantification of joint laxity or post-operative assessment of treatment effectiveness. They can be used by both orthopedic surgeons and rehabilitation specialists at different points of the patient journey [29].

Until recently, KT1000 and KT2000 were the only clinical devices used for that purpose. The device has been identified as an "objective instrument to measure anterior tibial motion relative to the femur for anterior cruciate ligament (ACL) reconstruction". Performing the test involves strapping the device to the leg, pulling the tibia in the anterior direction, and quantifying movement in millimeters (mm) [25]. Issues with device use and function include the following [15, 17, 20, 21, 23]

1) The function and placement of the device interferes with the standard Lachman techniques of stabilizing the femur. The use of the patella as a point of proximal stabilization can be both uncomfortable and inconsistent. The device is pulled away from the tibia creating an interface error.
2) Several studies have reported substantial variability in the measure using the KT1000/2000, with some suggesting a high rate of false negative results.
3) Limited scope of use, designed primarily for testing of the knee, with one study validating its use in the shoulder joint.
4) Device size was large and cumbersome, requiring additional stabilizing components for proper positioning.
5) Despite fulfilling an unmet medical need, KT devices have been off the market since 2012.

Table 1 below shows additional available technologies that have existed on the market, along with parameters that resulted in challenges in adoption [32, 33, 34, 35, 36, 37, 38]

Product	Form of Measurement	Ease of Use	Type of Use	Portable	Price
HEST	Linear strain	Poor – must be surgically implanted	Lab only	No	Very high due to the need for a surgical procedure

Rottometer	Rotational	Cumbersome	Lab only	No	Unknown
Vermont Knee Laxity Device	Linear	Moderate – requires an Aircast Foam Walker	Lab Only	No	Expensive software interface
LARS Rotational Laxiometer	Rotational	Unknown	Lab only	No	Moderate
Kinematic Rapid Assessment (KiRA)	Acceleration	Good – requires iPad	Clinical & Lab	No	Unknown
Telos	Static positioning	Easy but requires a radiograph	Lab only	No	Expensive due to the need for a radiograph
GNRB	Linear	Modest	Clinical & Lab	Yes	Very expensive ($13.5K)
KT1000/2000**	Linear	Modest	Clinical & Lab	Yes	Reasonable ($2K)
DYNEELAX	Rotational	Complex set up with multiple components	Clinical & Lab	No	Unknown
Aircast 50A Rolimeter	Linear	Modest	Clinical & Lab	Yes	~$800
LACHMETER	Linear	Modest	Clinical & Lab	Yes	Unknown

Note: All devices have published various forms of reliability testing
** No longer on the market but available via secondary sales

Overall, studies have reported issues with most existing devices, the Hall Effect Strain Transducer (HEST) was an implantable device that consisted of sensors implanted surgically onto tendons [26]. The Rottometer was a computer-assisted goniometer used to measure rotation of the tibial axis [27]. The Vermont Knee Laxity Device (VKLD) was developed to evaluate displacement of the tibia relative to the femur during weightbearing and non-weightbearing conditions. The device was bulky and required a significant amount of time to utilize [28]. In repeated measures, KiRA has not displayed consistent results in terms of inter and intra-reliability. Rolimeter has also been reported to have generally poor inter-rater reliability [29]. Intrarater, interrater, and test-retest relative reliability have been reported to be moderate for the GNRB but sources of error are thought to include incongruency between the flat surface of the displacement sensor and the non-flat tibial tuberosity, the alignment of the device relative to the knee joint itself, and the consistency of patellar pad force [39].

Mobil-Aider

Method of use

To help fill the existing need and standardize joint mobilization techniques across practitioners, the Mobil-Aider is an FDA-cleared Class I device which was developed in 2019 (US Patent # 11-123-007). It is a convenient and easy way to produce objective data used to identify joint deficits and changes in mobility in response to joint mobilization. The device sought to address the pain points of quantifying ACL laxity via simple positioning, stabilizing the femur with contoured attachments, and the use of a light-weight tool that pulls the tibia into the device in the same format as the Lachman test. The objective quantification of linear translation is essential for directing patient care and developing psychomotor performance of manual procedures.

When it comes to method of use, the Mobil-Aider axis is placed on the joint line where the device can be stabilized on the proximal side of the joint while the screen-side can mobilize the distal side of the joint. The measurement is revealed via a Light Emitting Diode (LED) display. The device also has two settings: Mode A and Mode B. In the A mode, the maximal linear translation can be assessed and the digital display is held for 3 seconds to allow adequate time for reading. The B mode is a real-time assessment that allows one to quantify the specific location in the continuum of any given mobilization. The stationary and mobile sides of the Mobil-Aider enable precise measurement of linear translation in millimeters. Furthermore, the Mobil-Aider can support the clinician when performing a technique incorrectly, as it will not translate, and a reading will not appear. The device only shows a reading when the joint line is properly aligned [12, 15, 17, 18, 19, 20, 21, 23]. The Mobil-Aider is lightweight (<370g; <13 oz) which allows for portability and was designed with 7 custom interchangeable attachments to allow measurement of passive accessory motion of the knee, ankle, shoulder, elbow, and wrist. Since objective data can yield valuable information about the laxity/stability of these joints, this can begin to develop a body of knowledge on which to base decisions regarding evidence-based practice [12, 19].

Validity and reliability across joints

The Mobil-Aider has been rigorously tested to show reliability, validity, and use among different types of joints. For ACL assessment, proof of concept study showed a strong correlation during performance of a Lachman's test when comparing translation measurements of the knee obtained using the device to radiographic images [19]. Reliability and concurrent validity were also demonstrated through several bench studies that compared the device measurements to the Zeiss Smartzoom readout as the gold standard [17]. The ability to measure the tibial translation of the knee with a portable, hand-held device could be very valuable in determining the presence and/or the magnitude of an injury to the ACL [17, 20]. The Mobil-Aider has also demonstrated the ability to accurately identify small degrees of joint translation, and its measurements were compared to those obtained through Ascension electromagnetic motion analysis when replicating clinical settings. The device was shown to have excellent intra-rater reliability among clinicians when assessing accessory motion in the glenohumeral and radiocarpal joints [12, 15, 18]

Based on the design testing of the Mobil-Aider [18, 23]

1) The device has a minimal learning curve, where students or novice therapists can replicate joint translation.
2) The quantitative feedback can assist the user in identifying faulty technique. In the case that the user does not align the device with the joint axis, an LED display will indicate a lack of movement, and the user can re-position the device for an efficacious intervention.
3) The device assists in the process of acquiring motor skills providing feedback to help users perform techniques correctly.
4) The availability of an arthrokinematics measurement tool to provide objective data can be a valuable research tool to populate the literature regarding efficacious manual techniques. The results also lead to better interventions consistency and inter and intra-rater reliability.
5) Confirmed validity by comparing data readout to MRI and other radiographic results to assess ACL laxity within millimeters of tolerance.
6) Validated reimbursement that provides extra revenue averaging $35 per use without any extra work, and providing a return on investment within a few weeks of using the device.

Market fit

Initially there were thought to be three potential commercial sectors for the Mobil-Aider in the USA: veterinary, educational, clinical. The thought of entering the veterinary market first was based on the idea that it was an easy route to revenue generation while navigating the human regulatory pathways. However, during the National Science Foundation Bootcamp and Launchpad exercises, a lot was learned about the market. In spite of over one million cruciate ligament tears in dogs each year and the ease of fabricating components for various sized dogs, the company learned veterinarians' function on a very small profit margin. Thus, the sale of a $1k device in this market does not appear to be attractive at this time. However, it may be a supplementary market to consider in the future.

Furthermore, the FDA was very accommodating. The company started the process in January 2018 with the anticipation of it being a daunting task with numerous hurdles. However, conference calls with the FDA included comments such as, "we would like to help you get to market in the most expeditious way possible." The FDA recommended the preparation of pre-submission documents using the KT1000/2000 as a predicate device. Numerous videos were used to explain the intended use of the Mobil-Aider and the company achieved the goal of obtaining a class 1 exempt status for not only the knee, but for all joints. The class 1 exempt status allows the Mobil-Aider to claim to be a "measurement tool."

With that hurdle cleared, the mobilization market appeared to be best targeted with more than 820 USA educational institutions in medicine (MD, DO), chiropractic (DC), physical therapy (PT), occupational therapy (OT), and athletic training (AT). Typically, programs have at least 50 students per class in 3 to 4-year post-bachelorette programs. If the market paralleled other testing devices (e.g., hand-held dynamometers and pulse oximeters), sales could range from 5,000 to 7,000 units in the first two years. This is a desirable market because student professionals who are exposed to the Mobil-Aider during their training would be more likely to integrate the device into their future clinical practice. Although clinicians "should" be competent in joint mobilization techniques, they could still benefit from being able to quantify the measurements for documentation purposes and achieve consistency in serial assessments. There are currently more than 125,000 physical therapists and 115,000 occupational therapists in the USA. That is a total of 240,000 professionals, all with projected growth of 14 – 34% in the next decade [33]. Likewise, there are over 235,000 orthopedic physicians in the USA. Capturing even a small percentage of these markets would provide a substantial revenue stream for the company.

Conclusion

Due to increasing number of joint injuries for different types of joints and patient populations, there is a growing need in orthopedic practice for a method that can assess joint instability in a simple, reliable, and accurate manner. Joint dysfunction assessment should include multiple factors such as mechanism of injury, swelling, range of motion, feeling of instability with weightbearing, and clinical testing. Upon assessment, performance of accurate and consistent joint mobilizations is a critical component of efficacious treatment. To demonstrate the effectiveness of manual therapy techniques, clinicians must first improve the consistency with which joint mobilizations are delivered. Once a standardized method is determined, and consistent delivery methods are documented, then the efficacy of that standardized treatment method can be determined. Additionally, imaging technologies such as MRI are static images failing to yield information about biomechanical behavior. Existing arthrometers have been called into question, with different challenges ranging from lack of consistent delivery and reliability among clinicians, to cumbersome and expensive use. It is clear from the existing evidence that new strategies for assessment of accessory motion and application of joint mobilization procedures are needed. The main challenges are to identify a means to quantify joint translation and develop joint contours to minimize potential interface errors. There is therefore a need for a device to enhance assessment reliability and enhance skill development among students and novice practitioners. The Mobil-Aider is a state-of-the-art arthrometer that is lightweight, portable, and a cost-effective device providing real-time visual feedback in the performance of joint mobility. The device aims to enhance the user's professional skills while objectively measuring joint mobility with up to 95% accuracy confidence. The Mobil-Aider is ergonomically designed with 7 custom-contoured attachments allowing for more than 14 techniques across 5 joints: knee, ankle, shoulder, elbow, and wrist. The real time visual feedback allows accurate assessment and communication of the results to the patient. The device is reimbursable via existing CPT codes and allows for return on investment within a few weeks of use, allowing to improve patient assessment and increasing revenue for the clinicians. Orthopedics is about precision. Patients demand it. The Mobil-Aider provides it.

Contacts

Website: https://mobil-aider.com/

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