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Validity of the Loadsol Pro Insole for Pedal Reaction Force Measurements During Stationary Cycling

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by

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ABSTRACT

Advancements in wearable technology have allowed clinicians, coaches, and researchers the ability to observe and quantify human movement outside the laboratory. Instrumented insoles are an example of novel technology that can be worn in the shoes and measure vertical reaction force wirelessly. The use of such insoles will prove to be beneficial for athletes as they train, patients as they progress through rehabilitation, and researchers as they experiment in their respective fields. The Loadsol Pro (Novel Inc., St Paul., MN, USA) has been shown to produce accurate and reliable measures of ground reaction forces (GRF) in various dynamic activities including walking, running, and landing. However, the insoles have yet to be validated during bouts of stationary cycling. The standard for measuring forces during cycling is through instrumented bike pedals, yet such technology is costly, difficult to obtain, and requires extensive training. The purpose of the current study was to analyze the validity of the Loadsol Pro insole for pedal reaction force (PRF) measurements during stationary cycling. A total of 18 healthy subjects (age: 20.94 ± 2.24 years, weight: 72.4 ± 23.32 kg, height: 1.67 ± 0.06 m, body mass index: 25.72 ± 7.57 kg/m^2) participated in the study. The Loadsol Pro insoles (200 Hz) and custom instrumented bike pedals (1200 Hz) were used to collect PRF data during bouts of stationary cycling at 50 W, 75 W, and 100 W. A paired samples t-test was performed to observe the agreement between both measurement systems and Cohen's *d* effect size was calculated to indicate the effect of the observed differences. The paired samples t-test resulted in no statistically significant differences in peak PRF measured by the Loadsol and the instrumented pedals. Cohen's *d* effect size resulted in small effect sizes between the Loadsol PRF and pedal PRF. Across all conditions, mean differences between the Loadsol PRF and pedal PRF were calculated to be less than 6 N with marginal errors under 4%. Thus, the Loadsol can be used to accurately measure peak PRF forces across work rates during stationary cycling. The introduction of the Loadsol to stationary cycling will provide easier access to data that is influential for health and in rehabilitative advances, and representative of athletic performance.

***Keywords*:** Loadsol, pedal reaction forces, stationary cycling, instrumented insoles, wearable technology

DEDICATION

To my late friend Christopher Bruni, thank you for providing strong mentorship and friendship through all my academic pursuits.

To my mother, for without her love and support, I would not be where I am today.

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TABLE OF CONTENTS

LIST OF TABLES

LIST OF ILLUSTRATIONS

LIST OF ABBREVIATIONS

ACSM	American College of Sports Medicine
BDC	Bottom Dead Center of the crank cycle
F_x	Mediolateral force
F_y	Anterior-posterior force
F_z	Vertical force
GRF	Ground Reaction Force
ICC	Intraclass correlation coefficient
NASA	National Aeronautics and Space Administration
PAR-Q	Physical Activity Readiness Questionnaire
PRF	Pedal reaction force
RMS	Root mean square
RPM	Revolutions Per Minute, cadence
TDC	Top Dead Center of crank cycle
TKA	Total knee arthroplasty
vGRF	Vertical Ground Reaction Force

CHAPTER I: INTRODUCTION

Wearable technology has progressed to allow scientific work outside the typical laboratory setting. Instrumented insoles are an example of advanced technology that can measure forces similar to a laboratory grade force plate. The progression of technologies with biomechanical emphases can provide insight in athletic communities, rehabilitative populations, and research fields.

Competitive cycling events consist of varying stages involving time trials, uphill cycling, and flat terrain cycling (Burke, 2003). These stages require cyclists to alter pedaling technique in order to overcome specific resistive forces like wind or rolling. To combat the resistive forces, cyclists stand versus sitting in the saddle to exert greater force on the pedals (Burke, 2003). Athletes and coaching professionals could greatly benefit from instrumented insoles that present the forces applied by the cyclist after training or competition. The recording of such data can be useful in adjusting training programs, analyzing performance, and may denote overtraining or fatigue.

Further, following a musculoskeletal injury or the diagnosis of a musculoskeletal injury or disorder, patients are prescribed rehabilitative programs with the intentions of increasing joint function, regaining strength, and reinstating mobility (Yum et al., 2021). These rehabilitative programs often include stationary cycling (Yum et al., 2021; Fang et al., 2016; Gardner et al., 2016). Because of its consecutive flexion and extension phases at the knee joint, stationary cycling resembles human gait while removing excessive load on the lower extremity (Lai et al., 2021). Removing the load on the lower extremity allows the patient to remain active and gradually reintroduces injured tissue to movement. Existing literature quantifies load reductions on the knee joint and reduced tibiofemoral and patellofemoral compressive forces as a result of stationary cycling (Bini et al., 2010; Gardner et al., 2016; Ericson & Nissel, 1986). Thus, stationary cycling provides a substantial method of rehabilitation in returning a patient to weight-bearing tasks like walking.

While patients engage in stationary cycling, professionals must remain cognizant of developing limb asymmetries and related injuries that could delay full rehabilitation. Analyzing the forces applied to the pedals by the individual can denote any abnormalities during the rehabilitation program and mitigate the risk of developing such deficits. The standard method of measuring forces during stationary cycling are instrumented bike pedals. Modern instrumented pedals consist of piezoelectric sensors which record stress changes from an applied force, subsequently converting mechanical force to change in voltage. Using a data acquisition system, electrical charge [voltage] is then scaled to Newtons for analysis. As a result, instrumented pedals are known to be costly, inaccessible to clinical populations, and require extensive training for users.

The capabilities of instrumented insoles span across disciplines. For athletic communities, instrumented insoles provide a deeper understanding of athletic performance. In biomedical spaces, these insoles can alleviate problems that may present during rehabilitation. Additionally, insoles provide a means to transfer exclusive health information to individuals themselves.

Researchers' attempts to validate instrumented insoles against accepted force measurement tools have proven to be successful. In the existing literature, the Loadsol has been investigated. Renner et al. (2019) assessed the initial version of the Loadsol in walking and running conditions with varying degrees of incline using an instrumented treadmill. High intraclass correlation coefficient (ICC) values supported the agreement between the Loadsol and the instrumented treadmill in measurements of ground reaction force. Renner et al. (2019) also analyzed the Loadsol Pro under the same conditions which furthered the established agreement between the two tools. Burns et al. (2019) analyzed the initial Loadsol in conditions of hopping, walking, and running against a force plate and an instrumented treadmill. The Loadsol measurements for ground reaction force remained consistent with the force plate and treadmill and produced ICC values comparable to Renner et al. (2019). Peebles et al. (2018) examined the initial Loadsol in conditions of a single hop and a bilateral stop jump against a force plate. The results of the study suggested the Loadsol to be a reliable and valid tool in assessing jumping kinetics. Further experimentation using the Loadsol Pro in the same conditions led the researchers to higher ICC values between the Loadsol and force plate and the recommendation of using the Loadsol Pro when analyzing landing kinetics. These findings denote the Loadsol's ability to measure forces during dynamic activities.

Although previous research is promising, there remain gaps in the literature concerning the Loadsol. As stated by Peebles et al. (2018), further research may be directed towards the use of the Loadsol in clinical settings. Studies have evaluated the measurements recorded by the Loadsol in various testing conditions (Seiberl et al., 2018; Renner et al., 2019; Burns et al., 2019; Peebles et al., 2018), but stationary cycling as a testing condition has yet to be examined. The activities in which the Loadsol has been observed are weight-bearing which increase load on the distal joints. Because stationary cycling reduces excessive distal loads, it is reasonable to believe there may be differences in force measurements and parameters that the insole must account for.

Therefore, the purpose of the present study is to determine the validity of the Loadsol Pro insole for pedal reaction force measurements during stationary cycling. It is hypothesized the Loadsol will record pedal reaction force measurements in agreement with the measurements recorded by the instrumented bike pedals.

CHAPTER II: LITERATURE REVIEW

During stationary cycling, lower extremity joints sustain less mechanical load than activities that require full weight bearing (Ericson et al., 1988). Because of this, stationary cycling is often prescribed as a means of rehabilitation or physical activity for disabled individuals (Yum et al., 2021). With the advancement of technology, ingenious and portable methods of recording and analyzing such loads have been introduced to the scientific, medical, and athletic communities. Existing literature substantiates the use and legitimacy of such devices including instrumented insoles, pedals, and shoes capable of measuring three-dimensional forces. The Loadsol Pro, an instrumented insole engineered by Novel Inc., aims to measure plantar forces during static and dynamic activities (Novel Inc., St Paul., MN, USA). The Loadsol has been validated in bouts of walking, running, and hopping (Renner et al., 2019; Burns et al., 2019; Peebles et al., 2018). To our knowledge, the Loadsol has yet to be implemented and validated in bouts of stationary cycling. Because of the prevalence of stationary cycling as an exercise prescription, the Loadsol design provides a progressive approach to measure pedal reaction forces during cycling. The introduction of the Loadsol to stationary cycling would prove to be advantageous in rehabilitative and biomedical settings because of its wireless connections, easily operated interface, and versatility. However, the use and promotion of such device in a medical setting demands precision in measurement. By comparing the forces measured by the Loadsol to forces measured by previously validated bike pedals, the validity of the Loadsol during stationary cycling can be determined.

Pedal Forces

In general, the motion of the crank during cycling can be broken into two phases: the downstroke and the upstroke or the propulsive and recovery phases, respectively (Bini et al., 2013). The crank cycle can further be simplified into halves resembling a clock. Top dead center (TDC) is defined at 0˚/360˚, or the 12 o'clock position. Bottom dead center (BDC) is defined at 180˚ or the 6 o'clock position.

During cycling, the cyclist propels the bicycle using a transfer of forces governed by the basic laws of physics and motion. Due to the configuration of the bicycle, the cyclist is mostly restricted to movement in the sagittal plane, yet movement in all three cardinal planes occurs (Bini et al., 2013). The cyclist must apply force to the bicycle pedal to alter pedaling technique or cause acceleration. During the downstroke phase of cycling, the hip, knee, and ankle extensor muscles generate the force to transfer to the pedal. During upstroke, the hip, knee, and ankle flexors are more active (Burke, 2003). There are three pedal forces that are typically investigated. These pedal forces are typically broken down into components for ease of discussion (Burke, 2003). The resultant force that generates bicycle motion is the product of vertical force (F_z), anterior-posterior force (F_y), and the mediolateral force (F_x). The resultant pedal reaction force can be resolved into effective and ineffective components. The effective component, associated with vertical force, is applied directly perpendicular to the bicycle crank and the ineffective component, associated with the anterior-posterior force, is applied parallel to the crank (Bini et al., 2013). Thus, the effective component drives the motion of the crank around its path, whereas the ineffective component does not provide motion to the crank (Burke, 2003). The mediolateral component is typically disregarded in analysis because it does not contribute to the motion of the pedal (Fonda et al., 2021). Although the mediolateral force does not provide significant contribution, Ruby et al. (1992) described varus and valgus motion as a result of the mediolateral force, which can give rise to injury. As a result, the mediolateral component should be acknowledged in conjunction with normal and tangential forces in preparing a comprehensive cycling analysis (Fonda et al., 2021).

Pedal forces can also be expressed graphically. Through graphical representation, professionals can visibly observe abnormalities that do not follow typical force profiles. Although force profiles vary during the crank cycle, vertical PRF rises and peaks around a 100˚ crank angle and declines towards the end of the crank cycle (Burke, 2003). This pattern is consistent throughout varying conditions. Burke (2003) observed peak vertical PRF around 100˚ at 350 W, 90 RPM as did Ruby et al. (1992) during a bout of steady state cycling. Vertical PRF peaking at a crank angle of ~100˚ is expected as the pedal is at the 3 o'clock position (Burke, 2003). Vertical PRF peaks when the pedal is in the 3 o'clock position because the perpendicular distance from the crank base to the pedal is the longest and consequently produces the largest torque in the crank cycle. The decline of PRF during the upstroke is expected as the cyclist changes from pushing on the pedals to pulling up on the pedals during recovery (Burke, 2003). Additionally, the tangential force produces force values much smaller than the normal because of its relation to the pedal. During the same cycling bout, the tangential force is seen to fall below zero around the same crank angle in which normal force peaks (Burke, 2003). During a bout of cycling at 300 W and a cadence of 90 RPM, the mediolateral component was observed to maximally produce lateral force during the downstroke and peak near a 100˚ crank angle (Mornieux et al., 2006).

Instrumented Insoles

With advancing technology and the declining health of general population in recent years, there is an apparent need and desire to transfer laboratory grade equipment to the public. The National Center for Health Statistics, a branch of the Centers of Disease Control and Prevention, reported approximately 42.0% of injuries occurring during sports and recreation activities presented in the lower extremity between the years of 2011 and 2014 (Sheu et al., 2016). Because the lower extremity is subject to load bearing, an understanding of forces applied to the lower extremity can potentially reduce injury and delineate points of rehabilitation (Lacirignola et al., 2017). While a laboratory grade force plate is considered the standard for measuring forces, the costliness and immovable nature limit the implementation of such device for self-monitoring (Liedtke et al., 2007). Wertsch et al. (1992) described the need for a fully portable system that can measure plantar forces and introduced the notion of sensors in a shoe-wearing subject to measure the forces encountered in daily living.

Liedtke et al. (2007) attempted to resolve the transportability issue that is presented in force plates by introducing sensors capable of measuring three-dimensional forces and moments into modified orthopedic shoes. The customized shoe was observed in ambulation over a force plate to analyze ground reaction force and gait quality. It was determined that the custom shoe computed valid measurements of total ground reaction force (GRF) and zGRF (ground reaction force in the z-direction), but inconsistencies were observed for measurements in the horizontal direction. These inconsistencies were attributed to the orientation of the sensors as the horizontal component of GRF is more sensitive to measurement error. These results were promising, yet the orientation of sensors must be further researched. This study presented innovation and proved that force plate data could be transferred to portable technology. Dyer & Bamberg (2011) furthered portability by introducing similar technology to insoles. Instrumented insoles eliminate the external wiring, power sources, and bulkiness that other measurement systems expose the wearer to (Cramer et al., 2022). Dyer & Bamberg (2011) illustrated a suitable transfer of force plates into portable, custom instrumented insoles capable of measuring the center of plantar pressure for gait analysis. The investigation consisted of a participant stepping on the custom insole, which was adhered to a force plate, while plantar pressure and force were recorded by the force plate and the insole recorded the forces on the force sensitive resistors embedded in the insole itself. The custom insole measurements resulted in good correlation of center of plantar pressure in the x-direction and very good correlation in the y-direction when compared to an Advanced Mechanical Technology Inc. force plate (AMTI, Watertown, MA, USA). However, RMS error was recorded and attributed to discrepancies in the placement and size of the force sensitive resistors. Nonetheless, Dyer & Bamberg (2011) concluded their custom, cost effective insole accurately replicated the forces measured by the force plate and showed accuracy in calculating variables indicative of abnormal gait. Both studies exhibited a preliminary means of introducing otherwise laboratory exclusive data as portable, accessible technology in the form of shoes and instrumented insoles.

Further studies advanced the portability and accessibility of instrumented insoles to include wireless Bluetooth connections. Additionally, insoles were constructed to be more time efficient, affordable, and require less technical training to operate (Cramer et al., 2022). Truong et al. (2016) demonstrated the use of a triaxial accelerometer, eight pressure sensors, and a microcontroller kit (Bluetooth capability) embedded in an insole to estimate walking distance via stride counting. The recorded pressure data was then integrated into advanced calculations to estimate walking distance. It was determined that the insoles performed accurately with an estimated walking distance error below 5%. Cramer et al. (2022) also performed a study using a Bluetooth capable insole, the Insole3 (Moticon ReGo AG, Munich, Germany). Embedded with 16 sensors, an accelerometer, and a gyroscope, the Insole3 recorded plantar pressure measurements to estimate vertical GRF (vGRF). Using a healthy population of subjects, the reliability and validity of the Insole3 in GRF measurements and impulse was investigated in randomized trials of slow-speed walking, moderate speed walking, and running. Analysis showed the insoles produced excellent agreement with GRF measurements recorded by the laboratory force plate and excellent test-retest reliability, despite consistent overestimation of impulse. Moreover, the insole was endorsed to be useful in clinical and home settings and in weight-bearing assessments (Cramer et al., 2022).

Castellarin et al. (2022) explored instrumented insoles for partial weight-bearing in patients recovering from a total knee arthroplasty (TKA). The study aimed to verify if the insole could provide load measurements of the reconstructed limb to improve rehabilitation protocols and recovery quality. Using the Blu Insole (FGP Srl, Dossobuono VR, Italy), equipped with 214 force sensitive resistors, subjects wore the insoles during the post-operative period where weight was partially re-introduced to the operated limb through various activities and altered gait patterns. During the post-operative period, knee pain was evaluated using standard scales and scoring systems (Castellarin et al., 2022). Gait and balance following the reconstruction were evaluated using the Tinetti test (Tinetti, 1986). The Tinetti test is a two-test assessment that is used to evaluate a patient's balance and gait in clinical settings using a standardized scale (Scura & Munakomi, 2022). This test is used to determine an individual's ability to partake in activities of daily living. For the balance portion of the test, the patient was observed rising from an armless chair and performing a 360° turn before sitting in the chair again. Gait was assessed by having the individual walk fifteen feet (Scura & Munakomi, 2022). The patient was graded by a healthcare professional on the quality of their movement and given a score that correlated to fall risk. Participants adhered to the rehabilitation protocols set forth by the clinic in which the study occurred. The protocol included immediate non-weight bearing mobilization using clinic technology and progressive weight-bearing starting at 50% until 90% of weight was achieved (Castellarin et al., 2022). While the participants were unable to begin at 50% weight-bearing, all participants were discharged from the clinic with the ability to withstand a 90% load. The study showed that using the insole improved patient compliance with physician recommended rehabilitation protocols in the post-operative period, and improved progress assessment and recovery satisfaction (Castellarin et al., 2022). Moreover, researchers endorsed the use of the Blu insole for the rehabilitation of TKA patients because it fortified existing rehabilitation protocols and increased patient accountability during the recovery period (Castellarin et al., 2022). This study illustrated the potential of portable measurement systems in providing real-time feedback and their practicality in rehabilitative/clinic and home settings in addition to laboratory settings. Such measurement systems allowed for continuous monitoring that provided critical information about one's health (Subramaniam et al., 2022).

Over the past 40 years, Novel Electronics (St. Paul., MN, USA) has emerged as a global leader in mobile measurement systems. Novel Electronics has vast experience in the realm of medical technology, from developing the first commercial monitoring system for the obstetrics field to pressure sensing platforms for the diabetic community. The company has developed systems to measure loads during exercise in space for NASA, analyze the interactions of horse, saddle, and rider in horseback riding, and ensure the safety of skiers. The German company, noted for their accuracy and reliability in measurements, generates families of measurement systems, capable of measuring contact forces between two surfaces. Some of these measurement systems include the *Emed*, a barefoot pressure distribution measurement, the *Pliance*, a pressure measurement system between varying surfaces, the *Buttonsens*, a mobile measurement system for finger forces, the *Texsens*, a low force, mobile system for measurements under textiles, and the *Loadsol*, for mobile in-shoe force measurements.

The Loadsol Pro (Novel Inc., St. Paul, MN, USA) is an instrumented insole that consists of three flat sensors that cover the entirety of the insole. The electronic box, which is attached to the insole and provides Bluetooth capability, can be attached anywhere on the shoe but is most often attached to the top of the shoe, interwoven in the laces (Renner et al., 2019). Through this design, the Loadsol can measure normal plantar force (force between the foot and the shoe) and partial loads in static and dynamic activities. Additionally, the design allows the insole to be completely wireless which reduces interference with its user (Renner et al., 2019). Further, the recorded data can be transmitted to a device via the Loadsol-s application for real time analysis. The application can display peak force, cadence, loading rate, contact time, and symmetry from the insole data. The insole technology is available in two options: the standard Loadsol, and the Loadsol Pro with six different models that separate the foot into distinct areas. The Pro version differs from the standard model in that the Pro has an onboard storage for later transmission. The Pro insole also reaches frequencies up to 200 Hz and is rechargeable. The Loadsol can measure forces from 2.5 to 5000 N.

Loadsol Validations

Since the release of the Loadsol, several studies have been conducted to test its potential. Burns et al. (2019) investigated the validity of the standard Novel Loadsol versus an instrumented treadmill and force plate during the dynamic tasks of single leg hopping, walking, and running. To compare the pieces of equipment, the normal force recorded by the insole was compared to the vertical GRF recorded by the instrumented treadmill and force plate. In addition, peak vertical GRF, impulse, and contact time were calculated. The study confirmed that the insoles exhibited good agreement with peak vGRF data collected via the instrumented treadmill, excellent agreement between measurements of contact time and impulse in walking, and excellent agreement with the force plate data in hopping. The calculated intraclass correlation coefficient also determined good reliability between the two-day data collection trials. Further, the insoles provided excellent consistency among peak vGRF, impulse, and contact time data in the running trial. The hopping, walking, and running trials were further analyzed using statistical tools; the study concluded good agreement between systems with minimal systemic error. It is important to note the study did uncover bias in measurements with the insole. Burns et al. (2019) concurred the bias arose from differences in the overall fit of the insole in participant shoes and concluded the insoles to be valid and reliable in measuring normal force despite the activity dependent bias.

Renner et al. (2019) investigated the validity of the Loadsol in walking and running at various speeds and inclines. The participants walked at 1.3 m/s and ran at 3.0 m/s and 3.5 m/s. Walking and running trials were performed at 0% incline, 10% incline, and 10% decline. The measurement systems included the standard 100 Hz Loadsol in the participants shoe and a 1440 Hz split fore-aft instrumented treadmill. Renner et al. (2019) calculated peak weight acceptance force (vGRF), impulse, and loading rate for both the Loadsol and instrumented treadmill. The analysis of these variables depicted high intraclass correlation coefficient values between the Loadsol and the treadmill, and Bland-Altman plots illustrated the agreement between both tools, across all conditions. Further, all recorded data met the 95% limit of agreement with little bias (Renner et al., 2019). These results led the researchers to the conclusion that the Loadsol is capable of accurately measuring loads during flat, inclined, and declined walking and running (Renner et al., 2019). Upon the completion of the initial study, the Loadsol Pro (200 Hz) was released and additionally evaluated by the same group of researchers. To analyze the 200 Hz Loadsol, researchers recruited a smaller subject pool of 10 participants and implemented the same testing and data collection protocols as in the initial study (Renner et al., 2019). Researchers performed the same statistical analyses to evaluate the Loadsol Pro. The Loadsol Pro insole data was in excellent agreement with the treadmill for all conditions and measurements. Intraclass correlation coefficients calculated for each measured variable resulted in values greater than 0.90, suggesting excellent validity of the Loadsol Pro. It was inferred the Pro insole furthered the validity of the standard insole due to the higher sampling frequency of the Pro insole (Renner et al., 2019). The study suggested the Loadsol Pro to be valid and reliable during leveled, inclined, and declined walking and running. Like Burns et al. (2019), there was significant bias in which the measurements recorded by the insole underestimated the measurements made with the force plate in peak force and impulse and overestimated loading rate. The biases were attributed to the differences in sampling frequency between the standard 100 Hz Loadsol and force plates embedded within the instrumented treadmill, a common obstacle encountered when comparing two measurement systems. Nonetheless, the Loadsol Pro mitigated some of these discrepancies.

Because impact forces are significantly greater during landing than running or walking, the Loadsol was used in bouts of single leg hops and bilateral stop jumps to further its validation (Peebles et al., 2018). Participants performed seven single leg hops (each leg) and seven stop jumps with the standard insoles in their shoe. The jumps were selected based on routine recovery protocols following reconstruction of the anterior cruciate ligament. Each jump was considered successful if the participant landed fully on the force plate and remained balanced. The study was also repeated a week later to determine between-day reliability. The force plate and insole data were used to calculate peak impact force, loading rate, and impulse. The standard insole produced excellent validity for the stop jump, but poor/good validity for the single hop based on ICC values. During the study, the Loadsol Pro was released and analyzed. The Pro insole produced excellent validity for both jump conditions. It was decided the insole produced valid and repeatable data during landing. The findings showed the Pro insole tended to consistently underestimate peak impact force measurements whereas the standard insole both overestimated and underestimated load measurements. The underestimation bias was attributed to the tendency of the standard laboratory shoe to absorb energy during impact (Peebles et al., 2018). In all, the intraclass correlation coefficients collected from the study displayed good agreement between the measurements made with the insole and measurements made with the force plate and moderate/excellent repeatability in the dominant limb. Additionally, it was stated load measurements involving dynamic activities should be collected at 200 Hz or higher because of the greater measurement accuracy seen in trials involving the Pro insole.

In comparison to the insoles produced by Wertsch et al. (1992), the Loadsol Pro exceeds previous designs. The Loadsol, and instrumented insoles in general, have advanced in accuracy of measurements, battery life, and sampling frequency in the last 30 years. The Wertsch design considered the major components that are imperative to a portable data measurement system. Wertsch et al. (1992) stated an insole must be thin and flexible to not alter natural movement, durable and capable of withstanding loads, wear-resistant, and capable of measuring loads between 0 and 1.2 MPa. Further, the device should have sufficient memory storage, a high sampling rate, and sufficient battery storage. The portable system designed by Wertsch et al. (1992) consisted of 14 sensors (seven per insole) and a two-hour recording capability, but only sampled pressure data at a frequency of 20 Hz for five seconds every minute in that two-hour recording period. Additionally, it operated eight hours without a battery charge. Yet, the insole had only been observed in limited settings. The Loadsol Pro contains three flat sensors, capable of measuring forces at the heel, the medial foot, and the lateral foot. It is less than

3.4 mm thick and weighs 16 grams, thus minimally altering natural gait. Further, it has a sampling rate up to 200 Hz, can undergo >23 hours of operation without a battery charge, consists of an on-board memory storage for up to 500 hours of measurements, and can transfer data via Bluetooth and microUSB (Novel Inc, St. Paul, MN, USA). Data is transmitted to the Loadsol-s application which provides real time feedback, and the insoles have been validated in various dynamic activities. However, the insole has yet to be investigated during stationary cycling.

Instrumented Bike Pedals

The first custom bike pedals were introduced in 1896 and included springs that deformed during pedaling. The deformed springs would then cause a marker to scribble on rotating paper thus recording pedaling forces (Burke, 2003). These initial designs were bulky and wired and potentially caused the cyclist to change pedaling technique due to their configuration. By contrast, modern instrumented pedals can include strain gauges and piezoelectric transducers and have wireless capabilities (Burke, 2003). These instrumented pedals can record normal, tangential, and mediolateral forces. In research, customized bike pedals have been connected to charge amplifiers to complement other pieces of equipment (Gardner et al., 2015). The use and validation of such pedals are described elsewhere (Gardner et al., 2015; Fang et al., 2016; Hummer et al., 2021; Shen et al., 2018).

Bike Fit

Bike fit is arguably the most important factor to consider before initiating a bout of cycling. Bike fit sets the quality and duration of cycling an individual can achieve. An improper bike setup will cause a cyclist to waste energy, affect the continuation of the activity, and incorrectly distribute the cyclist's weight, leading to overuse injuries, low force application, and reduced power (Burke, 2003). Iriberri, Muriel, & Larrazabal (2008) argued a cyclist's optimal position maximizes force application and comfort while reducing resistive forces and prioritizing injury prevention. A general rule of thumb for bike fit incorporates constant contact between the cyclist's foot and the pedals/clips of the bicycle, minimum side to side hip motion during cycling, and a slight bend in the knee when the crank is at bottom dead center (BDC). The three contact points at which the cyclist meets the bicycle are the saddle, the handlebars, and the pedals.

One of the first factors of bike fit that was explored was saddle height. Saddle height is known as the distance from the divot of the seat where one sits to the center of the pedal axle, when the pedal is at BDC, and the crank is in line with the seat tube (Burke, 2003). As saddle height can influence the knee joint and its motion through the kinetic chain, it is important to pinpoint the most appropriate position for a rider (Hummer et al., 2021). De Vey Mestdagh (1998) described optimal saddle height as the harmony of power output and energy use. In the past, cyclists implemented anthropometric formulas to determine their appropriate saddle height. Because cyclists are not restrained to a certain bicycle or cycling settings including road, mountain, stationary, and racing, these formulas present discrepancies among the cycling community. Additionally, the formulas do not account for cyclist flexibility, cycling history, or training load (Swart & Holliday, 2019). Previous formulas included multiplying 1.09 by the cyclist's inseam length to produce an upper limit value (Hamley and Thomas, 1967) and multiplying 0.883 by the cyclist's inseam measurement (LeMond and Gordis, 1987). The Holmes, Pruitt, and Whalen method (1994) is widely accepted and preferred due to the reduced joint loading conditions seen at the knee joint, straightforwardness, and inexpensiveness (Swart & Holliday, 2019). The Holmes method (1994) suggests correct saddle height allows for approximately 25˚ to 30˚ of knee flexion when the pedal is at BDC. The angle of knee flexion can be easily measured using a handheld goniometer. This method has also been seen to prevent anterior knee injuries and decrease stress by reducing the compression on the knee (Burke, 2003).

Another crucial part of bike fit is saddle position. In addition to saddle height, the saddle can be positioned forward (fore), backwards (aft), or neutral in relation to the handlebars (Burke, 2003). Cyclists aim to have the most ideal saddle position, so maximum force can be applied to the pedal and propel the bicycle. Thus, the readily accepted positioning includes the knee to be located directly over the pedal when the pedal is pointing forward and horizontal with the ground (Burke, 2003). This positioning is often referred to as the 3 o'clock position when looking at the pedal configuration. With the knee being positioned directly over the pedal, the cyclist can apply the greatest amount of downward force during the propulsive phase to the pedal due to the effective component. Additionally, a neutral position fully employs the knee flexors and extensors, decreases strain at the knee (De Vey Mestdagh, 1998), and places the center of the knee in line with the center of the pedal spindle (Burke, 2003). In sprinting events, cyclists will move to the most forward position on the saddle (Bini et al., 2013). However, the neutral position allows a cyclist to distribute weight among the bicycle and encourages appropriate pedaling technique (Burke, 2003). Swart & Holliday (2019) concluded improper saddle position promotes inadequate range of motion changes in knee. Further, Verma et al. (2016) gathered subject discomfort increased when the saddle was moved forward or backward in relation to the neutral position. It was also discovered the electromyography activity of the calf muscle was decreased in the forward position when saddle height was lowered among other biomechanical changes (Verma et al., 2016). In addition, Bini et al. (2013) investigated the effects of moving on the saddle in relation to the knee joint. They discovered moving fore and aft on the saddle solely affected the tibiofemoral shear force due to changes in the angle of knee flexion (Bini et al., 2013). As a result, the neutral saddle position is the most advantageous position for comfort, injury prevention, and power output.

Handlebar position also plays a major role in maximizing comfort and cycling efficiency. While the focus of bike fit is optimizing the performance of the lower extremity, the upper extremity can be greatly affected by improper positioning. Savelberg et al. (2003) determined trunk angle affected propulsive power and called for its consideration in cycling performance due to its effects on joint kinematics and muscle recruitment patterns. Further, it is known that a low handlebar position can cause lower back pain in cyclists due to the overcompensation of the lumbar spine (Swart & Holliday, 2019). During time-trials where speed is a deciding factor, experienced cyclists are taught to lower their upper extremity to reduce air drag (Bini et al., 2020). Because of this, De Vey Mestdagh (1998) stated optimal handlebar height is dependent on training level, abdominal strength, and flexibility. In the existing literature, there is not a set or recommended positioning for the upper body due to the vast differences among research studies, cycling performance, cycling experience, comfort, etc. Researchers have been shown to recommend 90˚ angle between the trunk and thigh when the pedal is in the 3 o'clock position (Thorsen et al., 2021; Fang et al., 2016; Shen et al., 2018). Others have been shown to adjust the handlebars to mimic participants' personal bicycle (Bini & Diefenthaeler, 2010; Fonda et al., 2014; Ferrer-Roca et al., 2012) or keep the handlebars even with the saddle (Ericson et al., 1988). Further, some experienced road cyclists opt to grip the top of the brakes for ease of steering and grip (Burke, 2003). Research settings with healthy subjects that do not regularly cycle have adopted the convention of creating a 90˚ angle between the trunk and thigh.

With the use of three-dimensional kinematics & kinetics, advanced motion capture cameras, and sensors, there has been a shift to adjust cyclists' position dynamically rather than statically (Swart & Holliday, 2019), leading to an increase in preciseness and thus approaching bike setup more scientifically.

In all, the most advantageous positioning for cycling consists of a saddle height that induces 25° to 30° of knee flexion (Holmes et al., 1994), a neutral saddle position (Burke, 2003), and a handlebar position that creates a 90° angle between the trunk and the thigh (Fang et al., 2016). Previous literature supports the evolution of load sensing technology (Wertsch, 1992; Liedtke, 2007). Instrumented insoles have facilitated the transfer of laboratory grade equipment into the hands of individuals and have been observed in research (Cramer et al., 2022; Dyer & Bamberg, 2011) and clinical settings (Castellarin et al., 2022). The Loadsol has exceeded other insoles in precision of measurement, overall design, and been recommended for use in various settings; however, the Loadsol has yet to be validated in bouts of stationary cycling. Thus, the purpose of the present study is to determine the validity of the Loadsol Pro insole for pedal reaction force measurements during stationary cycling. It is hypothesized the Loadsol will record pedal reaction force measurements in agreement with the measurements recorded by the instrumented bike pedals. Because stationary cycling is often prescribed during rehabilitation, the Loadsol would provide an accessible way to measure forces during cycling and rehabilitative exercise. It is anticipated the results of this study, if valid, will push the Loadsol towards home and healthcare settings and pave the way towards making scientific equipment more accessible. Moreover, the Loadsol will allow healthcare professionals to analyze lower extremity forces more meticulously, potentially accelerating recovery time following a lower extremity injury.

CHAPTER III: METHODS

Participants

Twenty individuals between the ages of 18 and 35 participated in this study. All participants provided signed Informed Consent approved by the Institutional Review Board of The University of Southern Mississippi. Participants were recruited through word of mouth and were included in this study if they were considered recreationally active by the guidelines set forth by the American College of Sports Medicine (i.e., at least 150 minutes of moderate to vigorous intensity exercise a week) (American College of Sports Medicine [ACSM], 2021). Participants completed the 2022 Physical Activity Readiness Questionnaire (PAR-Q) (Warburton et al., 2011) and were excluded if they answered 'yes' to any questions on the PAR-Q, had any lower extremity injury within the last 6 months, a history of major lower extremity surgery, a history of cardiovascular problems, or had a body mass index greater than 40 kg/m^2.

Materials

A Monark Ergometer was used for all testing conditions (Model 818E, Monark, Varberg, Sweden). The ergometer settings were set by the principal investigator. The cycle ergometer was fit to each participant to promote maximal comfort and effectiveness. The handlebars were adjusted to create a 90˚ angle between the trunk and thigh and measured using a handheld goniometer (Gardner et al., 2016; Fang et al., 2016). The saddle was positioned to elicit a 30˚ knee flexion angle when the crank was at bottom dead center and measured with a handheld goniometer (Holmes et al., 1994). The fore/aft position of the saddle was adjusted to a neutral position using a plumb bob, so the participant's knee was positioned vertically over the crank arm when the pedal was in the

3 o’clock position (Burke, 2003). The participants were encouraged to verbalize any discomfort in the bike positioning. Custom-made instrumented bike pedals were used to measure pedal reaction forces at a sampling frequency of 1200 Hz. Each pedal assembly contained two 3D force sensors (Type 9027C, Winterthur, Kistler, Switzerland) and each force sensor was coupled with an industrial charge amplifier (Type 5073A, Kistler, Winterthur, Switzerland). A custom jig was built to secure the bike to a floor-mounted force platform to align it to the lab global coordinate system. Prior to using the pedal assemblies, extensive calibration testing was done to ensure that the pedal reaction force and center pressure measurements were accurate. Pilot data revealed the toe cages on the instrumented bike pedals compressed the forefoot during stationary cycling, resulting in artificially inflated force measurements in the Loadsol. Because of this, toe cages were removed for subsequent testing. The instrumented insole that was used in the current study was the Loadsol Pro (Novel Inc., Loadsol Pro, St. Paul, MN, USA), with a sampling frequency of 200 Hz. The data recorded by the Loadsol was transmitted to an iPad (Apple Inc., Cupertino, CA, USA) via the Loadsol-s application.

Protocol

Upon arrival, participants were screened by the principal investigator to ensure eligibility following all criteria. Participants provided informed consent and completed the PAR-Q. Participant height was measured using a stadiometer and weight was recorded in kilograms (kg) using a force plate (AMTI, Watertown, MA, USA). Participants were provided with the appropriate size Loadsol Pro insole, and the Loadsol was placed on top of the existing insole in the shoe. The electronic unit was interwoven in the sneaker’s shoelaces. The insoles were calibrated following the instructions of loading and unloading each limb within the Loadsol-s application. Participants were encouraged to walk around the laboratory with the insole to familiarize themselves with the fit and placement of the insole.

After a three-minute warm up on the Monark, participants completed a total of three trials of cycling at varying workloads: 50 W, 75 W, and 100 W. Each trial lasted two minutes and participants were instructed to maintain a cadence of 80 ± 2 RPM. Cadence was indicated on a digital display to the participants during all conditions. The order in which workloads were performed were randomized for each participant. During the last 20 seconds of each trial, pedal reaction force was recorded from the right pedal and plantar force from the Loadsol for three consecutive crank cycles. Participants were allowed one to two minutes of rest in between each condition. After data collection was completed, participants were encouraged to cool down on the bike at a self-selected speed and stretch to deter any adverse effects of exercise.

Data Analysis

Pedal reaction forces collected during three consecutive crank cycles were analyzed using a custom MATLAB program (v. 2022A, MathWorks, Natick, MA, USA). Pedal reaction force data from both the right insole and right instrumented pedal were filtered using a zero lag and fourth-order Butterworth low-pass filter at 6 Hz. Peak vertical pedal reaction forces across all conditions were identified for statistical analysis.

Statistical Analysis

A paired samples t-test was used to test the agreement between peak vertical pedal reaction forces recorded by the Loadsol and the right bike pedal at each work rate (SPSS, v. 28.0, International Business Machines Corporation, Armonk, NY, USA).

Cohen's *d* effect size was calculated to demonstrate the effect of the observed mean differences (Cohen, 2013).

CHAPTER IV: RESULTS

A convenience sample of 18 recreationally active females (age: 20.94 ± 2.24 years, weight: 72.4 ± 23.32 kg, height: 1.67 ± 0.06 m, body mass index: 25.72 ± 7.57 kg/m^2) participated in this study. Two participants were excluded from analysis due to data inconsistencies.

The values for peak vertical PRF are presented in Table 1. The paired samples t-test between the Loadsol and instrumented bike pedals revealed no statistically significant differences for all three work rates. At a 50 W work rate, there was a mean difference of 5.96 N ($p = 0.103$, Cohen's d = 0.226). At a 75 W work rate, mean difference was 4.34 N ($p = 0.077$, Cohen's d = 0.127). At a 100 W work rate, mean difference was 2.28 N ($p = 0.294$, Cohen's d = 0.062). Using an *a priori p*-value of 0.05 and accepted Cohen's *d* effect sizes (Cohen, 2013), the results showed no statistically significant differences with small effect sizes for pedal reaction forces between the instrumented bike pedals and Loadsol (Figure 1).

Though there were no significant differences between the measurements recorded by the Loadsol and the measurements recorded by the pedals, peak vertical PRF measurements reported by the Loadsol were consistently greater than the measurements of peak vertical PRF by the pedals across all work rates. This suggests the Loadsols to be more sensitive to changes in force than the pedals. Further, mean differences between peak vertical PRF measurements of both systems decreased as work rate increased. It is assumed the larger mean differences of 5.96 N and 4.34 N at the initial work rates can be attributed to the difficulty of keeping pace with the mechanically braked stationary bicycle at low resistance (e.g., 50 W) and high cadence (e.g., 80 RPM).

Individual peak vertical PRF means recorded by the Loadsol and pedals are presented in Appendix A. At 50 W, individual peak vertical PRF recorded by the Loadsol ranged from 94.62 N to 194.35 N whereas individual peak vertical PRF recorded by the pedals ranged from 92.34 N to 193.75 N. At 50 W, the range of peak PRF, 102.01 N, were very similar among measurement systems with the Loadsol measuring a range of 99.73 N and the instrumented pedals measuring a range of 101.41 N. At 75 W, individual peak vertical PRF recorded by the Loadsol ranged from 117.4 N to 259.59 N and individual peak vertical PRF recorded by the pedals ranged from 102.84 N to 242.7 N. At 75 W, the range of peak PRF was 156.75 N with the Loadsol measuring a range of 142.19 N and the instrumented pedals measuring a range of 139.86 N. At 75 W, there was a greater difference in range between measurement systems. Additionally, the Loadsol range and the pedal range were not similar to each other whereas they were at 50 W. At 100 W, the Loadsol recorded individual peak PRF values between 122.15 N to 289.08 N and the instrumented pedals recorded individual peak PRF values between 119.77 N to 285.81 N. At 100 W, the range of peak PRF was 169.31 N with the Loadsol measuring a range of 166.93 N and the instrumented pedals measuring a range of 166.04 N.

From the reported ranges, we can infer the 75 W work rate produced greater between-subject variability in pedal force production. As previously mentioned, the 75 W work rate may have been difficult to sustain due to the low resistance and high cadence.

Table 1. Peak vertical pedal reaction forces during cycling as measured by instrumented bicycle pedals (F_z Pedal) and Loadsol instrumented insoles (F_z Loadsol) presented as mean (s.d.). Results of the paired samples t-test are presented as p-value and Cohen's *d* effect size *p (d)*.

Work rate	F_z Loadsol	F_z Pedal	*p (d)*
50 W	140.91 (25.79)	134.95 (27.12)	0.103 (0.226)
75 W	172.10 (34.88)	167.76 (33.60)	0.077 (0.127)
100 W	202.87 (36.26)	200.59 (37.01)	0.294 (0.062)

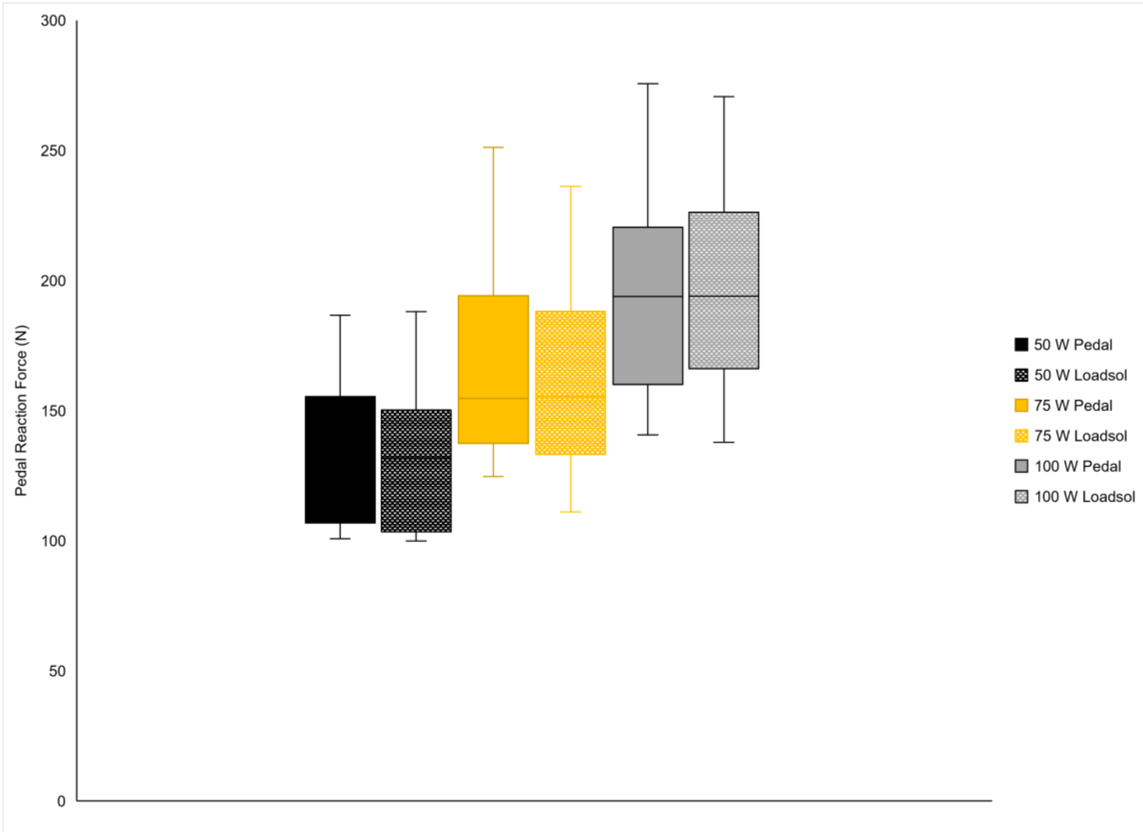

Figure 1. *Box and Whisker plot representing peak vertical pedal reaction forces during cycling across all participants as measured by instrumented bicycle pedals (solid) and Loadsol instrumented insoles (dashed) at 50 W (black), 75 W (gold), and 100 W (gray).*

CHAPTER V: DISCUSSION

The purpose of this study was to determine the validity of the Loadsol Pro insole for pedal reaction force measurements during stationary cycling. It was hypothesized the Loadsol PRF would be similar to PRF measurements from the instrumented bike pedals. Our hypothesis was supported by the results of this study. Thus, the Loadsol is an appropriate measurement system for analyzing peak PRF forces and analyzing trends in work rates during stationary cycling.

The results of this study showed no statistically significant differences and small effect sizes between the Loadsol and instrumented bike pedals with p values for all conditions > 0.05 and Cohen's $d \leq 0.02$. Mean differences for all conditions were reported to be under 6 N, denoting little difference between measurement systems. At 50 W, the Loadsols recorded an average peak PRF of 140.91 N. A mean difference of 5.96 N represents a marginal error of 4.23%. At 75 W, a peak PRF of 172.10 N and a mean difference of 4.34 N constitutes a marginal error of 2.52%. At 100 W, the Loadsols recorded peak PRF of 202.87 N. A mean difference of 2.28 N results in a marginal error of 1.12%. Thus, the slight differences in Loadsol PRF compared to the values obtained during cycling are rather insignificant. Within the 75 W condition, there was great variability observed. As seen in Figure 1, maximum and minimum PRF values varied greatly. We assume this discrepancy can be attributed to the amateur status of the recruited participants. Amateur cyclists tended to use less efficient pedaling techniques which added to the variability (Mornieux et al., 2008).

There were several limitations to the present study. Firstly, the subject pool was a convenience sample of undergraduate students which was predominantly female (n=18, f=16, m=2). It is plausible to suggest the results of this study may have differed with the inclusion of more male subjects and/or an all-male subject pool. We acknowledge that gender-related anthropometric differences exist and that different pedaling techniques between sexes may exist; however, we do not believe modifying the subject pool would have altered the peak vertical PRF since cadence and power output were regulated. Additionally, many participants were considered inexperienced cyclists, which was inferred by inefficient pedaling techniques seen in individual PRF measurements from the instrumented bike pedals. This observation was not controlled for. Another limitation of this study was the removal of the toe cages. The toe cages were observed to compress the shoe during pilot data collection and artificially inflate Loadsol force measurements. For this reason, the toe cages were removed for data collections. The removal of the toe cages may have caused participants to alter pedaling technique, yet the removal did not change measurements between the two systems. In addition, only data from the right foot and right pedal was analyzed in this study. For this reason, we cannot denote between-limb variability; however, we expect minimal variance, if any.

In previous validation studies, the Loadsol was observed in dynamic tasks like landing, walking, and running. As stated by Burns et al. (2019), a limitation exists within length differences of the existing insole and the Loadsol that was placed on top. The insoles available to us included US male shoe sizes six to eleven. While all subjects fit within the range of sizes available to us, it cannot be inferred the geometry of the participant’s foot or participant’s shoe welcomed the insole perfectly every single time. Further, previous literature compared the Loadsol to measurement systems in which the entire foot was in contact with the comparison measure, like a force plate or an instrumented treadmill. The current study is novel in that the entire foot was not in contact with the comparison measure. Rather, the foot was only in contact with the 60 cm^2 surface area of the pedal. Yet, the Loadsol produced accurate measurements of PRF. This further suggests the ability of the Loadsol to be used in stationary cycling despite limited contact area.

The results of the current study are inconsistent with previous literature involving dynamic tasks. The Loadsol was observed to underestimate peak force measurements during running and walking (Renner et al., 2019) and peak impact force measurements during landings (Peebles et al., 2018). This inconsistency may be attributed to the shoe not being fully in contact with the comparison measure, the instrumented bike pedal. Ancillary compressive forces at the heel, which may have transferred into the insole, may account for the observed mean differences and slight overestimation of PRF. The difference in sampling frequency between measurement systems may have also contributed to the overestimation. The pedals had a sampling frequency of 1200 Hz whereas the insoles sampled at 200 Hz. The reduced resolution of the Loadsol compared to the instrumented pedals may have influenced peak PRF values.

The results of this study are promising for the Loadsol for implementation in cycling research. The Loadsol can provide improved access to care that surpasses the limitations of cost and distance to a healthcare provider. The Loadsol is far more cost effective than most force measurement systems and does not require substantial additional equipment like amplifiers, signal converters, or software for use (Peebles et al., 2018). Additionally, because of its ease of use, the Loadsol is a device that can be used by a patient anytime and anywhere, regardless of how far a healthcare provider may be.

The internal memory storage and Bluetooth capabilities of the Loadsol Pro accommodate the potential of home healthcare and the transition to electronic medical records. Further, the Loadsol provides efficient treatment options following musculoskeletal injuries. Its real time analysis allows providers to monitor force output, track patient advances, and may allow coaching professionals to observe athletic performance and monitor possible limb asymmetries during their respective sport. Quality of life may also be salvaged as a patient may not require constant supervision by a physician and an athlete may be observed in their actual sport (Burns et al., 2019). The application of instrumented insoles provides endless possibilities in all realms. Lacirignola et al. (2017) even encourage instrumented insoles as an important tool for certain populations such as military personnel and prosthetics and robotics developers.

Future research may be directed towards testing between-day reliability of the Loadsol for PRF measurements. From previous literature, it is hypothesized the Loadsol would prove to be reliable, though that was not analyzed in this study.

APPENDIX A: PARTICIPANT DATA

Table A1. Peak vertical pedal reaction forces (N) for three consecutive pedal cycles of each participant during cycling at 50 W, as measured by instrumented bicycle pedals (Pedal F_z) and Loadsol instrumented insoles (Loadsol F_z).

Subject	Loadsol F_z -1	Loadsol F_z -2	Loadsol F_z -3	Loadsol Mean	Pedal F_z -1	Pedal F_z -2	Pedal F_z -3	Pedal Mean
S2	139.48	137.31	142.34	139.71	141.53	134.43	140.62	138.86
S3	189.20	187.20	182.10	186.17	155.45	150.85	155.83	154.04
S4	154.80	137.02	164.58	152.13	121.21	111.51	116.99	116.57
S5	105.07	97.23	100.11	100.80	104.58	92.34	109.71	102.21
S6	127.44	129.87	114.87	124.06	109.55	106.95	105.25	107.25
S7	94.62	112.32	104.94	103.96	105.60	114.42	101.66	107.23
S8	164.80	154.37	174.58	164.58	187.28	183.26	193.75	188.10
S9	112.28	109.43	107.24	109.65	98.96	100.75	100.26	99.99
S10	151.64	169.46	176.70	165.93	159.10	170.00	173.11	167.40
S11	137.28	122.16	129.72	129.72	134.66	125.46	130.06	130.06
S12	129.87	122.50	112.20	121.52	103.92	99.83	98.70	100.82
S13	144.58	149.55	147.07	147.07	136.16	134.76	135.46	135.46
S14	144.73	139.51	142.40	142.21	138.22	138.38	136.89	137.83
S15	145.62	132.90	137.95	138.82	136.08	131.03	129.57	132.23
S16	147.36	152.46	149.91	149.91	139.11	137.29	138.20	138.20
S17	164.56	156.78	154.63	158.66	165.82	156.05	152.89	158.25
S18	117.28	112.48	114.94	114.90	125.01	129.11	140.77	131.63
S19	194.35	187.58	178.01	186.65	189.84	186.85	172.16	182.95
Mean	142.50	139.45	140.79	140.91	136.23	133.52	135.10	134.95
S.D.	26.34	25.63	27.40	25.79	27.36	27.70	27.29	27.12

Table A2. Peak vertical pedal reaction forces (N) for three consecutive pedal cycles of each participant during cycling at 75 W, as measured by instrumented bicycle pedals (Pedal F_z) and Loadsol instrumented insoles (Loadsol F_z).

Subject	Loadsol F_z -1	Loadsol F_z -2	Loadsol F_z -3	Loadsol Mean	Pedal F_z -1	Pedal F_z -2	Pedal F_z -3	Pedal Mean
S2	144.56	137.50	141.03	141.03	146.51	137.57	142.04	142.04
S3	232.00	174.69	189.38	198.69	197.15	192.97	171.67	187.26
S4	164.69	164.64	164.50	164.61	146.39	160.75	152.96	153.37
S5	134.46	122.30	117.40	124.72	129.42	122.79	122.93	125.05
S6	134.75	124.80	142.20	133.92	107.96	102.84	122.49	111.10
S7	124.11	160.08	143.82	142.67	127.85	130.34	136.29	131.49
S8	179.74	197.21	204.60	193.85	192.04	218.83	215.55	208.81
S9	152.26	134.82	142.12	143.07	160.29	153.29	145.94	153.17
S10	189.12	205.00	189.41	194.51	179.47	188.92	197.55	188.65
S11	184.68	172.04	178.36	178.36	190.28	178.09	184.19	184.19
S12	176.80	184.68	169.74	177.07	174.04	181.67	173.96	176.56
S13	209.38	216.90	203.98	210.09	196.57	208.39	180.00	194.99
S14	147.12	134.80	140.96	140.96	139.10	137.83	138.47	138.47
S15	152.39	149.54	154.68	152.20	158.52	163.60	150.12	157.41
S16	157.17	164.64	142.38	154.73	154.75	151.93	149.92	152.20
S17	234.44	232.68	216.80	227.97	220.67	217.66	207.48	215.27
S18	160.00	162.28	182.29	168.19	160.76	162.15	167.19	163.37
S19	246.96	259.59	246.96	251.17	240.02	225.90	242.70	236.21
Mean	173.59	172.12	170.59	172.10	167.88	168.64	166.75	167.76
S.D.	36.51	38.17	33.56	34.88	34.06	35.56	33.18	33.60

Table A3. Peak vertical pedal reaction forces (N) for three consecutive pedal cycles of each participant during cycling at 100 W, as measured by instrumented bicycle pedals (Pedal F_z) and Loadsol instrumented insoles (Loadsol F_z).

Subject	Loadsol F_z -1	Loadsol F_z -2	Loadsol F_z -3	Loadsol Mean	Pedal F_z -1	Pedal F_z -2	Pedal F_z -3	Pedal Mean
S2	174.72	164.58	169.65	169.65	163.96	165.61	164.79	164.79
S3	214.62	192.00	239.19	215.27	194.38	183.10	213.74	197.07
S4	177.50	181.56	161.68	173.58	165.83	169.52	174.81	170.05
S5	207.20	199.60	207.06	204.62	184.44	171.84	189.58	181.95
S6	262.20	289.08	275.64	275.64	255.79	285.81	270.80	270.80
S7	144.30	122.15	155.80	140.75	140.38	119.77	153.25	137.80
S8	184.40	179.64	189.44	184.49	198.89	193.74	202.77	198.47
S9	142.27	149.60	159.36	150.41	147.90	149.18	154.41	150.50
S10	210.00	181.92	189.64	193.85	194.47	170.22	179.03	181.24
S11	214.32	198.94	201.60	204.95	207.70	200.33	201.83	203.29
S12	199.50	202.40	200.95	200.95	207.01	199.08	203.05	203.05
S13	256.50	244.18	241.45	247.38	260.41	240.62	242.30	247.78
S14	211.48	184.44	202.53	199.48	209.14	192.74	190.14	197.34
S15	184.39	187.12	182.18	184.56	186.95	185.43	175.74	182.71
S16	234.39	217.19	225.79	225.79	233.78	234.22	234.00	234.00
S17	223.84	231.91	252.10	235.95	220.88	238.75	246.31	235.31
S18	186.96	179.17	179.60	181.91	192.21	195.61	185.02	190.95
S19	267.75	261.66	257.09	262.17	271.92	267.75	250.97	263.55
Mean	205.35	198.17	205.04	202.86	202.00	197.96	201.81	200.59
S.D.	35.83	39.70	36.11	36.26	36.71	41.74	34.68	37.01

APPENDIX B: IRB APPROVAL LETTER

Office *of* Research Integrity

THE UNIVERSITY OF SOUTHERN MISSISSIPPI

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NOTICE OF INSTITUTIONAL REVIEW BOARD ACTION

The project below has been reviewed by The University of Southern Mississippi Institutional Review Board in accordance with Federal Drug Administration regulations (21 CFR 26, 111), Department of Health and Human Services regulations (45 CFR Part 46), and University Policy to ensure:

- The risks to subjects are minimized and reasonable in relation to the anticipated benefits.
- The selection of subjects is equitable.
- Informed consent is adequate and appropriately documented.
- Where appropriate, the research plan makes adequate provisions for monitoring the data collected to ensure the safety of the subjects.
- Where appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of all data.
- Appropriate additional safeguards have been included to protect vulnerable subjects.
- Any unanticipated, serious, or continuing problems encountered involving risks to subjects must be reported immediately. Problems should be reported to ORI via the Incident submission on InfoEd IRB.
- The period of approval is twelve months. An application for renewal must be submitted for projects exceeding twelve months.

PROTOCOL NUMBER:	22-1063
PROJECT TITLE:	Validity and Reliability of the Loadsol Pro Insole for Pedal Reaction Force Measurements during Stationary Cycling
SCHOOL/PROGRAM	Kinesiology
RESEARCHERS:	PI: Anabelle Vallecillo Bustos Investigators: Vallecillo Bustos, Anabelle~Thorsen, Tanner~
IRB COMMITTEE ACTION:	Approved
CATEGORY:	Expedited Category
PERIOD OF APPROVAL:	31-Aug-2022 to 30-Aug-2023

Donald Sacco Jr.

Donald Sacco, Ph.D.
Institutional Review Board Chairperson

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