Adaptive Biking for Children with Cerebral Palsy

by

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Abstract

Background: Evidence to understand the effects of adaptive biking on physical performance has only recently started to surface. There is the emerging potential for the use of an adaptive bike as a therapeutic intervention to improve the physical function of children and adolescents living with cerebral palsy.

Purpose: The purpose of this feasibility study was twofold: 1) to assess the effectiveness of physical performance measures to integrate with an adaptive bike for capturing physical performance of a rider; and 2) to establish a baseline intervention study protocol for future use of measuring performance on an adaptive bike.

Method: The feasibility study focused on exploring- power output using the NCTE_128 BB torque sensor; range of motion using the Delsys® Goniometer, Kinovea Beta, and Altius Analytics Labs; and postural data using FSA pressure mapping system. Data were collected while two riders engaged in dynamic biking on a 30-metre pathway.

Findings: The NCTE_128BB torque sensor, although feasible to integrate with an adaptive bike, captured data that were not useful for the intended purpose due to the sensor's inability to capture data at low values. The NCTE_128BB captured power data from the left leg only and the sensor's inability to track data throughout the entire biking trial made the system unviable. For evaluation of knee ROM during dynamic biking, the Altius system was identified as the best option, given that it did not require placement of sensors on the limbs, was automated, and provided accurate data. The Force Sensing Array mat exhibited consistent performance and produced robust data in each trial. Overall, both test riders were able to perform all three active

biking trials and two passive biking trials without difficulty. Based on the results of this study, a protocol for the next phase of the study was developed.

Conclusion: Through this study, select physical performance measures were analyzed and recommendations were made to effectively quantify physical performance, and potential change in performance over time, during dynamic biking on an adapted bike.

Implications: Study findings suggest the next step will be to conduct a feasibility study with children with neurological conditions to test the data collection configurations. In the next phase of this study, recommendations emerging from the current study that explored feasibility of various instruments and configurations can be implemented.

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Nomenclature

Abbreviations and acronyms

CP	Cerebral Palsy
GMFM	Gross Motor Function Measure
GMFCS	Gross Motor Function Classification System
DCP	Discovery Series
AS	Adventurer Series
ASR	Odyssey Series
ROM	Range of Motion
NCTE_128BB	NCTE_128 Suare Taper Torque Sensing Bottom Bracket
V3 CA	V3 Cycle Analyst
V3 CA-DPS	V3 Direct Plug in Cycle Analyst with Speedometer Pickup Sensor
RPM	Revolutions Per Minute
HW	Human Watts
PAS	Pedal Assist Sensor
FSA	Force Sensitive Applications/ Force Sensing Array
CoP	Centre of Pressure
2D	Two-Dimensional
3D	Three-Dimensional
Li-ion	Lithium-ion
USB->TTL	Universal Serial Bus -> Transistor Transitor Logic
EMG	Electromyogram
LED	Light Emission Diode
ANOVA	Analysis of Variance

ICC	Intraclass Correlation Coefficient
MAX	Maximum
MIN	Minimum
FLEX	Flexion
EXT	Extension
T	Trial
PT	Passive Trial

Background

Cerebral Palsy

Cerebral palsy (CP) is the most common neurodevelopmental disorder among children (Aisen et al., 2011). About 1 in 400 children have been identified with CP according to estimates from CanChild- a non-profit research and educational center (*CanChild*, n.d.).

CP can impede the body's ability to function in a coordinated and purposeful manner (Aisen et al., 2011). CP can adversely affect muscle tone that may then impact motor skills (Bermejo-Cantarero et al., 2017). Children with CP have also reported psychosocial challenges such as feeling excluded from a community, having low self-esteem, and a sense of dependence (Hayden, 2016).

Cerebral palsy is generally characterized by motor and muscle tone deficiency. The cardinal feature of children with CP is a weak muscle response associated with abnormal posture (O'Shea, 2008), resulting in uncoordinated motor movements. Secondary features of CP such as muscle spasticity/rigidity or flaccidity of a limb and unsteady balance can also cause uncoordinated movements in children with CP. Even though impaired motor and postural control are defining features of CP, many secondary conditions could co-occur (*National Institute of Neurological Disorder and Stroke*, 2020), including: poor cardiorespiratory health, difficulties in motor and fine motor movements, uncoordinated speech or speaking difficulty, limited range of motion, impaired oral motor control, attention deficits, learning disabilities.

Causes of Cerebral Palsy

Generally, there are two major causes of CP: congenital and acquired. Congenital CP can result from any injury or disease to a child's brain during or before birth. It is known to be the most common cause of CP (Case-Smith, 1985; Rosenbaum, 2014). Some prevalent causes of congenital CP are pre-mature birth, hypoxia, an insufficient supply of other nutrients, and infection during pregnancy affecting the brain. Acquired CP can result from an early childhood injury such as trauma, head injury, increased intracranial pressure, cranial hemorrhage, or brain malformation (Case-Smith, 1985; Patel et al., 2020).

Classifications of Cerebral Palsy

Symptoms/characteristics of CP differ from person to person. Some children may have challenges with speaking, swallowing, or walking whereas for some children those tasks are comparatively very easy. Based on their gross motor function, children with CP can be classified into 5 different levels using a classification method known as the gross motor function classification system (GMFCS) (Oeffinger et al., 2004). GMFCS levels are numbered from level I to level V and indicate an increasing impact of the condition on their functional ability condition. The breakdown below explains how children and adolescents are classified based on their functional ability in daily routine.

GMFCS I

- Can walk, climb stairs without support,

- Can perform running, jumping,
- Limited with speed, coordination, and balance.

GMFCS II

- Can walk but trouble walking for long, on uneven surfaces and inclines; can climb stairs with support/railings,
- Difficulty in performing gross motor skills

GMFCS III

- Able to walk or maneuver using an orthosis,
- May also be able to climb stairs with assistance,
- Can propel manual assistive devices such as wheelchair,

GMFCS IV

- Extremely difficult to navigate even with assistive devices, or non-ambulant,
- May need assistance for standing or sitting transfers,

GMFCS V

- Severely restricted movements, or non-ambulant,
- Unable to propel assistive devices, needs support to navigate using an assistive device.

Children with CP may experience limitations in their ability to participate in the community (Hayden, 2016) due to restricted motor functions. Isolation from the community

negatively affects their quality of life and may hinder children with CP's ability to develop meaningful peer relationships (Logar, 2012). In a study of adaptive bike riding for children with CP, researchers found that children and adolescents with CP tend to feel detached from their community due to their lack of involvement in the community (Pickering et al., 2013a).

Physical Activities

There is strong evidence that engagement in physical activity in children is essential for their healthy physical and psychological development (Janssen & LeBlanc, 2010; Ortega et al., 2008). According to a World Health Organization (WHO) report, obesity, weak bones, inadequate muscle strength, and mental health issues (including anxiety, behavioral changes, and depression) are increasing in prevalence among all children (*World Health Organization*, n.d.). Engagement in physical activity can provide benefits to children such as building a healthy body composition (stronger bones, muscles, and joints), increasing cardiorespiratory fitness, maintaining healthy weight range, and increasing concentration and coping abilities with stress (Bermejo-Cantarero et al., 2017).

It is important to encourage all children to participate in health-enhancing physical activities. For children and youth with CP, the health-related issues prevalent in the general population are of equal concern. Several studies have investigated improvements in children with CP's physical and psychosocial function when involved in physical activities such as swimming/aquatic exercises (Roostaei et al., 2017), treadmill walking (Visser et al., 2017; Wu et al., 2017), cycling (Siebert et al., 2010), and other strengthening exercises (Fowler, Kolobe, et al., 2007) In 2019, Clutterbuck and colleagues conducted a systematic review where they

concluded that many studies have shown a positive relationship between physical activity and improved gross motor function in children with cerebral palsy (Clutterbuck et al., 2019).

Current State of Knowledge: Effects of Biking on Children with Cerebral Palsy

Children with CP are encouraged to spend their leisure time in a fun and recreational way. Well-spent leisure time positively impacts an individual's quality of life (QoL) (Przepiorka & Blachnio, 2017). Biking has been identified as one physical activity that can improve the physical and psychological function in children with CP (Hayden, 2016; Pickering et al., 2013a). Toovey et al., (2019) further supported that biking can be a fun endurance activity which is highly valued by families of children with CP.

Stationary Biking and Children with Cerebral Palsy

Existing research regarding the effects of stationary biking on children with CP has focused on improving physical and psychosocial health. In general, studies of children with CP using stationary bikes have shown positive outcomes on lower extremity muscle strength and cardiorespiratory fitness (Bryant et al., 2013; Fowler, Knutson, et al., 2007; Siebert et al., 2010).

In a randomized control trial, biking was identified as an effective intervention for children with CP who have severely restricted functional movements (Bryant et al., 2013). The study involved children (n=35) aged 8-17 years with GMFCS level IV and V. All participants were able to walk with partial body weight support and could pedal an adapted stationary bike. Participants were randomly assigned to either an intervention [stationary biking (n=11) or

treadmill (n=12)] group or a control group (n=12). Vision Fitness E3200 upright cycles were used for the cycling intervention and a standard treadmill was used for the treadmill intervention. Participants in the intervention groups engaged in the intervention for thirty minutes, three times a week, for six weeks and participants in the control group continued with their usual therapeutic activities (floor exercises, stretching, and standing using a standing frame or swimming).

The motor function of participants was assessed using the Gross Motor Function Measure (GMFM) -66 and dimensions D (standing) and E (walking, running, and jumping) of the GMFM-88. Secondary outcomes included the speed and biking duration of the intervention group. The outcome measures were administered four times for each participant: pre-intervention at week 0 (baseline), immediately after post-intervention at week 6, at an initial follow up at week 12, and a final follow up at week 18. Secondary outcomes were collected for those in the intervention group at pre-intervention (week 0) and post-intervention (week 6).

In this study, the authors reported significant improvement post-intervention, at week six in the GMFM 88D (standing) scores in the biking and treadmill group compared to the control group (Bryant et al., 2013). Mean change in GMFM 88D scores were higher for biking group (+5.9, SD=6.8) than treadmill group (+3.7, SD=4.4). GMFM 88E (walking, running, and jumping) scores were higher for both biking and treadmill group compared to control group at post-intervention (week six) although the change was not statistically significant. Exercise capabilities increased in both the intervention groups, i.e., participants were able to exercise for a longer time duration by the end of their intervention period as compared to the beginning of the intervention. The intervention groups showed an increase in their maximal speed for both biking and treadmill. However, the post-intervention follow-up assessment showed that the participants from both biking and treadmill groups were unable to maintain their gains after the intervention.

While the results were positive in favor of the biking intervention, it is unclear how the participants with extremely restricted motor control (GMFCS IV and V) were able to actively ride a bike and participate in an active biking intervention.

Similarly, another randomized control trial was conducted with 62 ambulatory children aged 7-18 years with a GMFCS level I-III (Fowler, Knutson, et al., 2007). Fifty-eight participants completed the study; 4 participants withdrew from the study. Participants were randomly assigned to a control group (no intervention) or a stationary cycling group (n=29, in each group). The cycling intervention with increasing resistance took place three times a week for a total of 30 sessions, over a 12-week period, although, the study report does not identify the cycling duration at each session. Peak knee flexor and extensor isometric and isokinetic moments, GMFM-66 section D-E, the 600-yard Walk-Run Test, and a thirty-second walk test were examined as the primary outcomes. Peak joints moments from both left and right limbs were averaged for each speed and measured in Newton meter per kilogram (Nm/kg).

The cycling group showed improvement in locomotor endurance, gross motor function and strength while no such improvements were reported for control group. All participants, except the child with lowest level of physical function, were able to cycle with maximum load capacity during the intervention. However, identified differences between the cycling and control group for any outcomes were not statistically significant (Fowler, Knutson, et al., 2007).

Siebert and other researchers conducted a single-subject case study including two children with CP (GMFCS I-II) (Siebert et al., 2010). The focus of this research was to differentiate participant's individual responses to the intervention. Both participants were part of the intervention arm of the larger randomized control study (Fowler, Knutson, et al., 2007),

where children were involved in 30 biking sessions over 12-weeks on a stationary bike. In the case study, the Biodex Cyclocentric Semi-recumbent Cycle (Biodex Medical Systems, Inc., Shirley, NY) was used for the intervention. The intervention focused around two outcomes of interest: lower extremity strengthening and cardiorespiratory fitness training. In the analysis conducted by Siebert and colleagues, both children demonstrated increased peak knee flexor-extensor moments and improved performance on GMFM-66 after participating in the intervention (Siebert et al., 2010). Of the two participants, participant 1 (GMFCS level II) exhibited a higher training intensity than participant 2 (GMFCS level I), i.e., participant 1 improved their ability to cycle at higher Typical Exercise Heart Rate (TEHR) while participant 2 maintained a low TEHR throughout all 30 sessions. The researchers concluded that "exercise intensity is an important parameter driving the effectiveness of an intervention" (Siebert et al., 2010).

Dynamic Biking and Children with Cerebral Palsy

Little is known about the effects of dynamic biking on children with CP. Studies have used various outcome measures to report on many different outcomes in the same population. One study was conducted using a two-wheeled, non-adapted bicycle for children with movement disabilities including CP (Angeli & Foster, 2017). This study involved 30 children with movement disabilities (aged 7-21) participating in a week-long bicycling camp. All participants could walk independently without any assistance. Children participated in a 45-minute bicycling session in a gymnasium each day for all 7 days of the camp. During sessions, participants worked with a trained volunteer who assisted participants as needed. The postural stability of participants was assessed using a portable force plate on the first and final day of the camp, with

30-second trials in eyes open and eyes closed condition. Findings from the postural sway data revealed all the participants benefited from the program. The total amount of postural sway and its variability in the medial-lateral plane with eyes closed trials and in anterior-posterior plane with eyes open trial were reduced after day 5 compared to day 1 of bicycling camp. However, the authors did not provide any further clarity about the study design and statistical values for the postural sway change data reported in the paper.

A poster abstract on "Locomotion efficiency while riding an adapted tricycle compared to walking in children with cerebral palsy" presented the preliminary results of a trial and compared participants' cycling efficiency using an adaptive tricycle to walking efficiency. Seven participants with CP (GMFCS level I to III), aged 5 to 10 years, performed a six-minute cycling and walking exercises on a 55m path at self-pacing speed. The authors did not mention the number of exercise repetitions in the abstract. The primary outcome, energy expenditure, was assessed by Energy Expenditure Index (EEI), based on heart rate. The study also evaluated pain level of participants using an adapted visual analog scale. The results showed that during cycling, participants demonstrated better locomotion efficiency than when walking. The researchers concluded that the use of an adapted tricycle may "increase the autonomy of children with CP in their daily activities" (Dussault-picard et al., 2016, p 231).

In addition to these studies, a study abstract and its poster on "Pedal power pilot study: adapted dynamic cycling for children with cerebral palsy" were presented as a conference proceeding (Visser et al., 2012). This pilot study reported the effects of Adapted Dynamic Cycling (ADC) sessions on lower limb muscle strength in children with CP. Participants engaged in six cycling sessions over eight weeks, increasing time and distance cycled as they were able. Eleven children, five boys and six girls (aged 2.6-17.8 years, GMFCS level I-IV) voluntarily

participated in the study. Children who had any lower limb orthopedic intervention and/or Botulinum toxin injections within the past six months were excluded from the study. Bilateral quadriceps and hamstring strength were measured in sitting at 90° knee flexion, four times pre and four times post participation using a hand-held dynamometer. Result reports mean strength differences (right quads=11.51N; SD 3.99; left quads=17.43N; SD 14.96; right hamstrings=8.4N; SD 1.80; left hamstrings=7.4N; SD 1.6), statistically significant for quadriceps strength (right, p=0.028; left, p=0.026) and statistically not significant for hamstring strength (right, p=0.075; left, p=0.114). The findings of this study suggest adapted dynamic cycling has some potential health benefits in a young population with CP. The researchers concluded that further investigation with a larger sample and longer intervention period is required to confirm the effects of cycling intervention in children with CP.

An abstract from the same group of researchers on "Adapted cycling physical health benefits for children with cerebral palsy" was published at the annual meeting of the European Academy of Childhood Disability (EACD) (Visser et al., 2014). Researchers conducted a Randomized Control Trial (RCT) to explore the effects of ADC on lower limb muscle strength. Children aged 2-18 years, diagnosed with CP classified as per GMFCS level I-V volunteered to participate in the study. Similar inclusion-exclusion criteria and method as their previous study were used for this study as well (Visser et al., 2012). Thirty-five children participated in the RCT, with eighteen children in the control group (no intervention group) and seventeen children in an intervention group (ADC group). The cycling group was engaged in six outdoor ADC sessions throughout an intervention (authors did not indicate the total data collection period).

Quadriceps and hamstring muscle strength in supported sitting at 90 degrees was measured using a handheld dynamometer and length was measured using a goniometer placed at

the popliteal angle (PA) with the hip at 90 degrees flexion and the individual lying supine. For results, comparisons between cycling and control group were made using ANCOVA. Participants within the cycling group demonstrated a statistically significant increase in quadriceps strength (Right p=0.018; left p=0.021) and no significant difference in hamstring strength. Comparison of data between the groups exhibited no significant difference in PA or strength measures. Overall, the cycling group increased quadriceps and hamstring strength (Quadriceps increased by Right=12.14N ±6.5; Left=15.56N±13.87; Hamstrings by Right=5.19N±3.5; Left=4.23N±5.94), while the control group had a trend of decreased strength (Quadriceps decreased by Right=3.62N±4.73; Left=0.41N±1.4; Hamstrings by Right=1.03N±0.06; Left=1.05N±3.05). The hamstring length remained unchanged for both the groups.

Finally, in a pilot study of a school-based cycling intervention using a single subject case study design, three participants aged 8-14 years (GMFCS level IV) were involved in a school-based cycling intervention over 27 weeks (Daly et al., 2019). Using an A-B-A-B (A- baseline; B-Intervention) design, the first baseline phase lasted for 4 weeks, the second baseline phase was for 7 weeks and both intervention phases were for 8 weeks each. During the intervention phases, participants were asked to ride an adaptive dynamic bike (Freedom Concepts Inc., Winnipeg) five days a week for up to 30 minutes. Gross motor function (as measured by the GMFM-66), cardiorespiratory fitness (using the Energy Expenditure Index), and goal attainment (using the Goal Attainment Scale: GAS) were assessed. EEI data was analyzed using 2-SD band method.

The results of the study showed that only participant 2's cardiorespiratory fitness significantly improved as EEI data points dropped below the 2-SD band. In participant 1 EEI data points dropped below the 1-SD band at first intervention (B1), second baseline (A2) and

maintained consistency during second intervention phase (B2) indicating improvement. For participant 3, EEI data points showed lower scores and greater consistency during B2 phase where data points are at or below 1-SD band. However, EEI data points of participants 1 and 3 did not drop below 2-SD band and therefore were not statistically significant for participant 1 and 3. All participants showed an increase in their GMFM 66 scores at the end of the B2, Participant 1 (A1= 28, B1=30, B2=32.9), participant 2 (A1= 36.4, B1=42.4, B2=42.4), participant 3 (A1= 35.7, B1=41.6, B2=42.8).

For GAS goals, all participants obtained improvement in their performance. Participant 1 was able to maintain the improved performance of B1 phase to B2 phase (raw score +2, T=70). Participant 2 improved performance after B1 phase and retained at slightly lower rate at the end of the B2 phase (raw +1, T=60). Participant 3 improved performance slightly at the end of B1 phase and improved more after B2 phase (raw +2, T=70).

Thus, while there are some studies of dynamic adaptive biking for children and adolescents with CP to track children's physical performance, further research and investigations with larger samples are required to establish the strength of current findings and to establish the dependent measures that are reliable and sensitive to change due to a biking intervention.

A foundational study, fundamental to the current feasibility study, discussed the selection and testing of assessment tools to capture physical performance of neuro-typical riders (Ros, 2020). The foundational study assessed the effectiveness of the selected assessment tools by analyzing the data collected from 2 neuro-typical riders. The study provided a groundwork for the current feasibility research, where there was an interest in implementing technologies and testing measures to assess physical performance of a population with neurological disorders.

Based on the foundational study's result and engineering recommendation, assessment tools in the current feasibility study were selected and tested.

Effects of a Biking Intervention on Psychosocial Outcomes

A limited number of studies have identified positive effects of biking on children's psychosocial health, their ability to engage in meaningful activities, and on their overall quality of life (Hayden, 2016; Pickering et al., 2013b, 2013a).

Hayden (2016) reported on the effects of an adapted tricycle (referred to as "AmTrykes" in the study) on health-related quality of life (HRQoL) of children with neurodevelopmental disorders including CP, Down syndrome, Autism, and Spina Bifida. Six children aged 4 to 18 years received the AmTrykes. Twelve more participants who had previously received the AmTrykes were asked to participate in a follow-up survey. The Pediatric Outcomes Data Collection Instrument (PODCI), the Pediatric Quality of Life Inventory Parent Report (PedsQL-PR), and the AmTryke Parent Survey-Adapted (APS-A) were used as the primary outcome measures in this study. PODCI is a questionnaire used to evaluate functional outcomes such as physical activity, basic mobility, function, physical restrictions and expectation (Lerman et al., 2005). PedsQL-PR is used to measure quality of life in general, and includes items such as physical functioning, social functioning, and emotional functioning. The APS-A was a survey tailored for this study to understand the usage and the benefits of AmTrykes. A survey and questionnaire were completed by parents/guardians before and after the intervention to evaluate the effects of the adapted tricycle (AmTrykes) on the children's function, physical activity, participation, and HRQOL. The PODCI and PedsQL-PR were completed by the parents or

guardians as a pre-assessment prior to their children receiving AmTrykes. After four weeks of participants receiving their AmTrykes, the PODCI and PedsQL-PR were sent out via mail to parents or guardians. The APS-A was sent out to parents of current and previous recipients of AmTrykes.

Results from the study did not suggest improvements after the children received AmTrykes on the PODCI and PedsQL-PR. Only the Global Functioning Score of the PODCI showed a statistically significant decrease in scores after the intervention (pre=1.33, post=-8.67, p=0.04. However, parents reported positive effects on their child since they have received AmTrykes. From the APS-A data, 55.6% parents reported an increase in play time after receiving AmTrykes, 77.8% parents reported an increase in physical activity, 88.9% reported an improvement in their child's sense of independence, and 72.2% parents noted health benefits to their kids since using AmTrykes. Therefore, the researchers concluded that the AmTrykes may improve participants' psychosocial health, including daily physical activity, mood, sense of independence, and health-related quality of life.

Qualitative findings of a mixed method adapted dynamic cycling research were published by Pickering et al. (2013b). The purpose of the qualitative arm of this study was to understand the experiences and views of children and young adults with CP and their families around activity and participation after an intervention. This study included thirty-five participants, of which seventeen were in the intervention group (cycling group) and eighteen participants were in a control group. Seventeen children who participated in six sessions of adapted dynamic cycling were interviewed before and after six weeks of Adapted Dynamic Cycling (ADC) intervention. Semi-structured interviews were audio or video recorded. Participants and their families maintained a diary, recording their views and experiences regarding cycling. Out of seventeen,

nine participants completed two interviews, eight participants completed one interview, and eight participants completed the diary. Each researcher also maintained a separate reflective journal. Analysis of interview data demonstrated development in cycling skills, enhancement in social participation, refinement in exposure to the enriched environment and, improvement in the overall health of children and young adults with CP (Pickering et al., 2013b). Results suggested improvement in health, cycling skills and, social participation of participants. Many parents described their child improved in terms of controlling the bike, pedaling, and steering. One parent described how his daughter who could not sit up independently, could pedal a bike, and described how pleased he was with her progress. Based on the interview data, the researchers suggested that there were overall benefits to children and young adults with CP both in community and at school, where they participated in ADC.

The same group of researchers conducted a second study to explore participation and Quality of Life (QoL) using the ADC intervention with children with CP (Pickering et al., 2013a). This was a three-year study where two groups of children with CP (n=35; up to age 18) were recruited. One group (cycling group) of children with CP (n=17) were already registered to start cycling at the voluntary charity and another group (control group) of children with CP (n=18) were not currently engaged in cycling, were recruited. The cycling group was encouraged to keep a diary for their physical activity. Twenty-five children completed interviews and diaries after the ADC intervention. As a result, children reported positive experience riding an adapted bicycle and an improved sense of well-being. Some children from the control group also went on to try adapted bicycling.

In summary, existing research suggests biking can provide psychosocial benefits to a young population with CP. Less is known about the long-term effects of biking on activity,

participation and quality of life and further research will be required to understand the longer-term effects of cycling intervention on children with CP.

Summary on the Use of an Adaptive Bike on Children with Cerebral Palsy

There is some emerging evidence focused on understanding the effects of adaptive biking on physical performance among children with CP. There is the potential for the use of an adaptive bike as a therapeutic intervention to improve the physical function of children and adolescents with CP. Although limited, existing studies explored effects of adaptive dynamic biking on children's quantitative measures such as gross motor function, muscle strength, and cardiorespiratory health. Limited or no information is available that has examined the effects of adaptive biking on other physical performance measures of children with CP such as lower limb range of motion, postural symmetry, and power output while pedaling**.**

One of the many challenges in the collection of the above-mentioned data is the paucity of evidence on the use of sensor-based or person-instrumented technology to understand the effects of adaptive biking on physical performance. There is also limited research that has studied the effects of adaptive biking using existing technologies to measure the physical performance and activity of children with CP while engaged in dynamic biking. The current study was an attempt to address this research gap and work towards understanding the effects of an adaptive bike by examining various physical performance measures used to measure physical performance of children and adolescents with CP while engaged in dynamic biking on an adapted bike. In context with this thesis, the term "Physical performance measures" indicates assessment instruments that capture and examine physical measures of a rider i.e., power output,

postural data, and ROM. For this study, we primarily focused on analyzing various existing technologies to assess physical performance of a rider engaged in dynamic biking, and to detect potential technological issues that might impact future research in this area.

Research Methodology

The objective of this section is to define the study purpose and specific objectives of this study. The following subsections discuss the rationale for the study, research apparatus, detailed research design, data collection procedure and outcome measures.

Study Purpose and Objectives

The **purpose** of this feasibility study was twofold: 1) to assess the effectiveness of physical performance measures to integrate with an adaptive bike for capturing physical performance of a rider; and 2) to establish a baseline intervention study protocol for future use of measuring performance on an adaptive bike.

The specific **objectives** of this study were:

1. To test the feasibility of integrating various physical performance measures with an adaptive bike to assess the physical performance of a rider while biking,
2. To test the consistency of integrated physical performance measures for capturing riders' physical measures of postural symmetry, knee joint's range of motion (ROM), and power output while engaged in dynamic biking, and to gauge riders' overall biking experience,
3. To establish and test the baseline protocol for a future intervention study of adapted biking.

Rationale for the Study

The current feasibility study is the first phase of the larger study that is aligned with the goal of the Winnipeg-based Canadian company "Freedom Concepts Inc." to create Smart Adaptive Bikes. Anecdotally, the adaptive bikes produced by Freedom Concepts Inc. are reported to provide many physiological and psychosocial benefits to children and adults with neurological disorders. To advance their goal of benefitting people with disabilities, the company is seeking to provide clinicians ease of assessment and monitoring of physical performance with their "Smart Adaptive Bikes". They seek to support clinicians' ability to gauge riders' progress over time, as well as to streamline the assessment routine.

The current feasibility study was conducted to develop a set of physical performance measures that capture a rider's physical performance while engaged in dynamic biking. The present study also sought to establish and test a baseline protocol for a future intervention study to understand the physical and psychosocial impacts of adaptive biking over time on children and adolescents with CP. The future intervention study will be guided by the technological and engineering recommendation of this feasibility study.

The engineering recommendations emerging from this study will facilitate the selection of physical performance measures that can be implemented to capture a rider's physical performance in the intervention study. The study was guided by the intent to select performance

measures that can eliminate the need to attach instruments directly on a rider, while effectively quantifying physical performance, and with the potential to measure change in performance over time.

Research Apparatus

Adaptive Bikes

Freedom Concepts Inc. is a Canadian company based in Winnipeg, Manitoba, whose mission is to design, develop, and build bikes and mobility devices for children and young adults having special needs. The company works with medical and rehabilitation professionals, and families to design and develop their custom products for individuals with disabilities. Freedom Concepts Inc. offers a range of bikes, including recumbent and upright styles, to accommodate the various needs of an individual with neurological conditions. Each bike is customized to the individual's needs for mobility, therapy, recreation, and fun. Any bike can be further customized and adjusted with special seating, headrests, footplates, accessories and/or any unique requirement of the rider, ensuring the safety and comfort of the rider. For each rider, a Freedom Concepts Inc. sales representatives completes a fitting process. The fitting process ensures natural hip positioning, precise hip to toe positioning, as well as comfort and safety of a rider. Freedom Concepts Inc. suggests that these bikes provide several proposed benefits such as anti-gravity muscle strengthening, enhanced blood circulation, improved range of motion, development of balance and coordination, and overall improved mobility (*Freedom Concepts Inc.*, n.d.).

Bike Features: Freedom Concepts Inc. provides various features and accessories to further customize their bikes. Core features of the bike includes:

- Direct drive gearing with average pedal power to encourage reciprocal pattern of the legs.
- Customizable front brake and parking/transfer brake: stabilized bike with parking brake for secure transferring
- Rear steer™: allows caregiver to steer or brake from the back of the bike; Rear steer extension handle can also be installed for comfort of caregiver for effortless maneuvering and control of the bike.

Figure 1 Rear steer™

- Quick release mechanism on all adjustable parts: quick release locks help swing bike components out of the way for transferring.
- 4-Point chest harness: offers help to riders with torso weakness and spinal deformations. The 4-point butterfly configuration empowers riders to keep an upright body position permitting them to concentrate on pushing the bike. Chest harness of the bicycle gives further developed equilibrium and backing to the rider.

Figure 2 4-Point chest harness

- Ratcheting molded Acrylonitrile Butadiene Styrene (ABS) footplates provides secure positioning for children and adolescents with more spasticity; customers can submit foot tracings to ensure the certain fit around shoes or Ankle-foot orthoses (AFOs). These footplates provide several other benefits such as assists with leg alignment, reduces heel flexion, encourages riders to propel downwards, helps achieve reciprocal patterning, and promotes a neutral hip/knee position.

Figure 3 Ratcheting Molded ABS

- Adjustable Velcro Occiput Cushion: provides targeted head support that grows along with the rider. “Adjustable Velcro Occiput Headrest is an ideal accessory for therapy settings. Caregivers and therapists can easily adjust the height of the headrest to provide support in targeted areas” (*Freedom Concepts Inc.*, n.d.).

Figure 4 Adjustable Velcro occiput

The Discovery, the Adventurer, and the Odyssey series are the most popular bikes sold by the company and are available in a variety of models. Depending on the weight and inseam of a rider, an appropriately sized bike is provided, as determined by the sales representative of Freedom Concepts Inc. The Discovery series, popularly known as DCP comes in three variety of sizes: DCP MINI (inseam: 8”-16”), DCP 12 (inseam: 13”-21”), and DCP 16 (inseam: 19”-26”). DCP series can easily accommodate any child with his/her physical needs. Figure 5 shows DCP bike and design specifications.

Figure 5 Discovery series adaptive bike

The Adventurer series (AS) has two models: AS 2000 and AS 2600. For this study purpose and the population, AS 2600 was the appropriate fit based on its size and specifications. Both researchers were provided with AS 2600 with appropriate adjustment according to their comfort for a secure ride. Figure 6 shows AS 2600 bike and its configuration.

Figure 6 Adventurer series adaptive bike

The Odyssey series, also known as ASR series, comes in two sizes: ASR 2011 and ASR 16. ASR 16 is the newest addition to the Odyssey series. Along with the standard features and design of ASR 2011, ASR 16 comes with an adjustable tilt seating system (0^{o}-10^{o}), adding additional trunk support. Add-on- a Nexus 8-speed shifter gear choice aids riders to keep pace with the others while still enjoying the bike's therapeutic benefits. Figure 7 shows ASR 16 bike and its structure.

Figure 7 Odyssey series adaptive bike

Instrumentation

For this study, several instrumentation configurations were studied. Specifically, instruments that collect three areas of physical performance were studied: postural symmetry, bilateral knee ROM, and power output.

The adaptive bike, model AS 2600, was instrumented with two hard technologies: NCTE_128 square taper torque sensing bottom bracket (NCTE_128 BB) with V3 Cycle Analyst (V3 CA) (Grin Technologies Ltd.) to collect power output of a rider, and a wired Force Sensitive Applications (FSA) pressure mat (Vista Medical Ltd.) to collect interface pressure (physical interaction between buttocks, lower back, and the bike seat surface) during dynamic biking. The NCTE_128 BB and its assembly were embedded in the AS 2600 bike, while the FSA mat was placed on the bike, covering the seat and the backrest as an interface between a rider and the AS 2600.

To collect bilateral knee ROM data, first, the Delsys® Trigono™ Avanti Goniometer adapter with Biometrics twin-axis goniometer sensor assembly was attached (taped) to the rider's lateral femoral tibial joint. Subsequently, we sought an alternate method to assess ROM remotely, by eliminating the need to instrument the rider. Two remote methods were selected and their efficacy to assess the rider's knee ROM during dynamic biking trial was tested: two-dimensional (2D) video analysis platforms from Kinovea Beta and Altius Analytics Labs.

A Go Pro Hero 7 was used to capture video of the sagittal view of the rider (for analysis in Kinovea Beta and Altius Analytics Labs). The student researcher and the engineering team of Freedom Concepts Inc. combined the Go Pro jaw clamp mount with a custom metal frame

designed to mount the Go Pro to the side of the AS 2600 bike. The Go Pro was wirelessly connected to a smart phone to monitor all the biking trials. Each instrument will be further discussed in the outcome measures section below.

Study Design

This feasibility study acquired quantitative information on the effectiveness of the integrated physical performance measures with an adaptive bike. Specifically, the study sought to understand the efficacy of performance measures to capture the select physical performance measures of a rider. Prior to any intervention study, a feasibility study can provide evidence as to whether the study can be done and can support the likelihood of success in conducting a large-scale intervention study (Orsmond & Cohn, 2015). While conducting a large-scale physical intervention study is challenging and resource-intensive, feasibility studies can provide a structured and controlled method to study resource requirement and essential groundwork for the intervention studies (Eldridge et al., 2016). Before evaluating intervention efficacy, feasibility studies can be used to conduct comprehensive research that can assist with evaluating selected physical performance measures, an implementation protocol can facilitate a research team to identify uncertainties around technology, potential effects of the proposed protocol, and identifying associated risk (Pearson et al., 2020). To advance scientific inquiry, a feasibility study determines if a particular instrument choice makes sense from an economic and operational perspective. The results of the feasibility study further guide researchers to identify whether the technology and findings can be used to understand the prospective implementation and if the intervention outcome will be valid. For this study, I primarily focused on analyzing technologies to assess physical performance, and to detect potential technological issues that

might create a threat to the future study.

Feasibility studies inform researchers if the ideas and findings can be shaped to be relevant to the study population. For this feasibility study, I anticipated recruiting five children with CP to perform the biking trials. Although it was hoped that children and adolescents with CP (GMFCS level II,III, and IV) would be recruited to the feasibility bike assessment trial, data collection with neuro-typical researchers was conducted due to the research restrictions implemented by the University because of the outbreak of Corona Virus Disease- 2019 (COVID-19). Specifically, there was a limitation on recruiting and collecting data with human participants imposed by the University of Manitoba in compliance with the public health directives issued by the Government of Manitoba to the outbreak of COVID-19, pilot data were collected from two members of the research team instead.

Riders

Given the restrictions notes above, two researchers (advisor - aged 50 and student - 27 years) provided the pilot adaptive bike assessment data.

Data collection procedure

Researchers (now riders) provided their demographics including self-reported age, sex, height, and weight prior to the bike assessment trial. The developed data collection protocol was followed prior to and during the biking trial (Appendix A). Each rider was provided with an adaptive bike (Adventurer Series AS 2600-Freedom Concepts Inc.), sized according to their weight, inseam, strength, and flexibility. There was a fitting process with each rider, conducted

by a trained employee of Freedom Concepts Inc., to ensure their safety, comfort, and proper adjustment to the adaptive bike as per their physical stature (hip to toe positioning, footplate positioning, proximity of handlebars).

Once the bike was adjusted, each rider completed three, self-paced, active biking trials, and two, passive biking simulation trials of a 30-meter indoor biking track. The indoor biking track was made of a concrete floor (Figure 8). During the passive biking simulation trials, an assistant propelled the bike using the rear-steer while the rider sat idly on the bike without applying any force to the pedals. Both the riders wore a fitted bike helmet provided by Freedom Concepts Inc. during each biking trial. There were no scheduled breaks between the trials. After each trial, the student researcher obtained readings and saved all the recorded data to a password protected research laptop. The physical performance of each rider while engaged in dynamic biking was assessed by collecting applied force on the pedals (human torque-Nm), average and energy expended/produced (human watts), postural symmetry, and bilateral knee joints ROM. Details on each of these performance measures are provided in the following "Outcome Measures" section. An engineer from Freedom Concepts Inc. recorded all the biking videos captured through Go Pro Hero 7. All the video files were recorded on a micro-SD card.

The rider's response to biking enjoyment was addressed using a facial expression five-point Likert scale. At the end of the trials, both riders responded either verbally or by checking a box at any one smiley face of the Likert scale to report their responses. Responses from the Likert scale reflected the overall enjoyment of riders riding an adaptive bike with instrumentation (Appendix B). A paper copy of their responses was stored in a file and was protected in a locked cabinet along with the micro-SD card.

Figure 8 Indoor bike path

Physical Performance Measures

In this study, power output, knee range of motion (ROM), and postural symmetry were explored as output data. See Appendix C for a summary of the study's physical performance measures, and the placement of the sensors.

Power Output

Measurement of muscle strength (in torque) is not a novel concept in the field of rehabilitation sciences. Several studies have used a hand-held dynamometer to evaluate lower limb muscle strength in children with CP in other intervention studies (Crompton et al., 2007; Dodd et al., 2003; Eken, 2017; Goudriaan et al., 2018; Sahin et al., 2008). However, in these studies participants were required to be in a static position during the assessment. We were unable to locate any rehabilitation studies that reported measuring power output during dynamic biking.

Power output during biking is equal to work over time (P = Work/Time). There are two ways to increase power output while biking; one is to apply more force on the pedals and another is to increase the number of times the pedal rotates in a minute (Revolutions per Minute-RPM), known as pedal cadence. Such measures of power output during biking are valuable in understanding the improvement of rider's engagement over time. Measurement of torque performance appears to be of growing interest among cyclists to track their biking performance (Bertucci et al., 2005). For the current feasibility study, we selected the NCTE_128 square taper torque sensing bottom bracket with V3 Cycle Analyst based on the sensor's immediate availability to Freedom Concepts Inc. NCTE_128 BB was embedded in an adaptive bike to attain power output during dynamic biking.

NCTE_128 square taper torque sensing bottom bracket with V3 Cycle Analyst

An NCTE_128 square taper torque sensing bottom bracket (NCTE_128 BB) having the spindle size of 128mm was installed by removing the crankset (crank arm and chain ring) on the adaptive bike AS 2600. A square taper bearing assembly of the AS 2600 was removed and replaced with the NCTE_128 square taper bottom bracket assembly. After the installation of the NCTE_128 BB, the crankset was reinstalled to complete the bike assembly.

Figure 9 NCTE_128 BB

This NCTE_128 BB with an 8-pole cadence sensor measures the torque across the spindle and requires a supply voltage of 10-16V. The output cable of the NCTE_128 BB is a 5-pin male JST-SM connector that plugs directly to the V3 direct plug-in cycle analyst with speedometer pickup (V3 CA-DPS).

The speedometer sensor, or pickup sensor, provides speed and distance reading. This sensor was attached to the front fork of the bike with two cable ties and positioned in a way that is aligned perpendicularly with the wheel radius. The spoke magnet was fastened to one of the spokes using a screw in the spoke magnet body. The spoke magnet was aligned with the speedometer sensor in a way to keep the distance between the two as minimum as possible (as seen in Figure 10 below- maximum 6mm). Both sensors (torque and speedometer) output channels fed directly to the V3 CA-DPS.

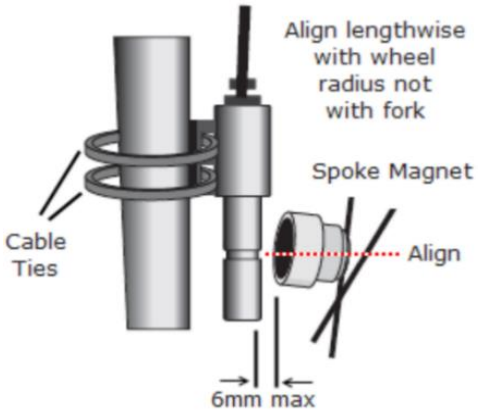


Figure 10 Speedometer sensor

The V3 CA-DPS is a passive display console, mounted on the adaptive bike handlebar, that measures and displays bike and rider's performance data. The console monitors and controls several optional inputs received from different sensor channels. The V3 CA-DPS allows inputs from a temperature sensor, pedal-assist sensor (PAS), torque sensor (NCTE_128 BB), speedometer sensor, Ebrakes, and throttle. The V3 CA has a 140cm cable terminated with a 6-pin JST-SM series connector that connects to the controller via CA molded external shunt. To provide sufficient supply voltage to the setup, a 41V Lithium-ion (Li-ion) battery was connected and was set at the back of the bike on the basket platform. Li-ion batteries have a lower self-discharge rate than that of other batteries (Deng, 2015).

Figure 11 V3 CA-DPS

The battery was connected to the V3 CA via CA molded precision 1.0 mOhm external shunt. The CA shunt acts as an interface between the battery and the system. The CA shunt regulates high voltage coming from the battery and provides the required supply voltage (10-16V) to the system. As this study setup did not use pedal assist, the controller end of the CA shunt was isolated with insulating tape.

Figure 12 CA molded precision shunt

The standard use of the V3 CA is to take combined control signals as an input from various sensor channels and deliver it to the controller via CA molded external shunt. The controller assesses the received input and provides a controlled output signal that drives the motor. The assembly is conventionally used to track a rider's performance and provide pedal-assist to the bike when needed. In this study, the V3 CA assembly was used unconventionally; the system had only two active input channels, one from the NCTE_128 BB and another was from the speedometer sensor, eliminating the use of all other input channels and motor-controller setup. This set up tracked the rider's performance during biking, devoid of pedal assist.

During biking, the output was displayed on the V3 CA, on 12 different display screens. For this study setup, five screens provided all the output data as there were only two active input channels (torque and speed) as all other sensor channels are abandoned. Therefore, the display screens were customized to display only five, corresponding to the measures required for this study.

Figure 13 is a primary display screen that shows key information such as battery voltage, battery bar, instantaneous speed, and distance.

Figure 13 Primary display

Figure 14 is the human power display. Values on this display are available only if the torque sensor is installed (in this case the NCTE_128 BB). Battery voltage, human power output (in human watts- HW), instantaneous speed, and pedal cadence are measures shown on the screen.

Figure 14 Human power summary

Figure 15 provides a summary of human power statistics for the trip, including total human watt-hours, average watts, and average pedal cadence of a rider. Average human watts are only

averaged while the rider is applying force to the pedals, i.e., the average human watts value is not affected while coasting.

Figure 15 Human power statistics summary

Figure 16 is the speed display screen, showing maximum and average speed of a rider for the trip. It also displays trip time.

Figure 16 Speed display

Figure 17 is an odometer display. This display provides trip distance (as the first screen but with increased accuracy to 3 digits). It also provides lifetime odometer for the bike.

Figure 17 Odometer display

The V3 CA gathers all the data but displays only the brief output summary. To procure detailed output for each trip, output data needs to be serially transmitted to a laptop using a Universal Serial Bus->Transistor Transistor Logic (USB->TTL) cable (Grin Technologies Ltd.). The TTL end of the TTL to USB converter cable was directly connected to V3 CA and USB end to the laptop for the data logging.

Output data was recorded into a Microsoft® Excel sheet. The Excel file was stored in a password protected research laptop. Data from the V3 CA display screens were also detailed into a paper log sheet after each trial by the student researcher. Paper log sheets were secured in a locked cabinet for data security and privacy.

In summary, the whole system assembly provided the following output:

- total and average speed,
- applied force to pedals (human torque in Nm),
- energy expended/produced (human watts in HW), and
- average pedal cadence (RPM)

Range of Motion

Range of motion (ROM) is a widely used evaluation method to test effectiveness of rehabilitation interventions necessary for functional movement (Kumar et al., 2015). However, assessing ROM is inherently quite different and difficult during dynamic biking compared with stationary biking. The study aimed to assess relative knee joint angle during dynamic biking.

Relative knee joint angle can be defined as an angle between two segments in reference to the body's anatomical position (Glassbrook et al., 2017).

The Delsys® goniometer wearable assembly is a reliable instrument to assess ROM as it has been extensively used in many interventions to obtain lower extremity joint angle, ROM, and electromyogram (EMG) (Alhammoud et al., 2020; Hannah et al., 2012; Jakobsen et al., 2019; Knoll et al., 2019; Lee et al., 2018; MacKenzie et al., 2014).

Delsys® Trigono™ Avanti Goniometer adapter with Biometrics Ltd. twin-axis goniometer sensor

The Delsys® Trigono™ Goniometer adapter (Delsys Incorporation, n.d.) is designed to provide relative joint angle measurements. The goniometer adapter is compatible with SG series twin-axis goniometers from Biometrics Ltd. These goniometers are available in different sizes to enhance performance in various scenarios. Twin-axis goniometers use strain gauge transducers that simultaneously detect angle movement in a joint in up to two orthogonal planes. Flexible, lightweight, and robust Biometrics' goniometers are simple, quick, and precise for joint angle measurement. The goniometer and adapter assembly can be comfortably worn under loose clothing, without obstructing the actual movement of joint.

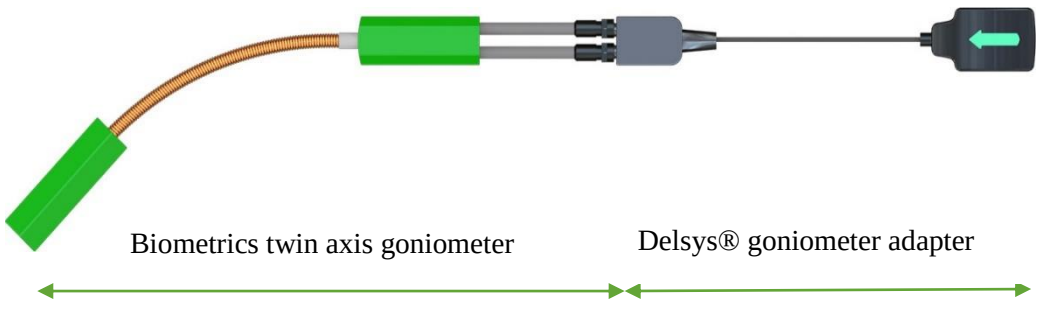


Figure 18 Goniometer sensor and goniometer adapter assembly

(Delsys® Incorporation, n.d.)

The twin-axis goniometer has two separate output connectors to measure angle movement in two planes. In this study, the twin-axis SG150 goniometer was used. As ROM of a single axis joint (knee) was to be measured, one channel of the goniometer was connected and the other remained redundant. This goniometer connects to the Delsys® Trigono™ Avanti Goniometer adapter that supports three different gain settings, from low to high, to maximize the dynamic range of the SG150 twin-axis goniometer. The adapter has multiple features such as onboard orientation calculation, Light Emission Diode (LED) user feedback, self-contained rechargeable battery, low power mode, and has a 20m wireless transmission range.

After placing the goniometer assembly on the desired joint angle and enabling the goniometer and adapter assembly, angular data transmits wirelessly to the Trigono™ base station. The base station then streams real-time synchronized angular data to the EMGWorks® software (by Delsys Incorporated) run on the laptop.

Figure 19 Delsys® base station

The goniometer assembly captures and records data wirelessly within a 20m range. Before the data collection trial, test trials were conducted to see if all instruments were on and recording. During the test trials, the original setup of the base station was set 20m away from the 30m path as shown in Figure 20. Due to the limited sensor range, the resultant output signal showed many dropped packages (i.e., lost signals during the signal transmission) when pedaling out of range.

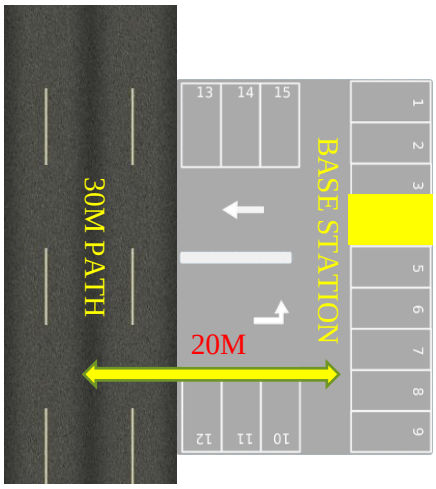


Figure 20 Delsys® base station setup

Figure 21 shows the output signal of the left knee received with the original base station setup. As the left knee was the farthest from the original setup, the graph indicates instances of the signal dropping to zero (dropped packets) due to the limited sensor range.

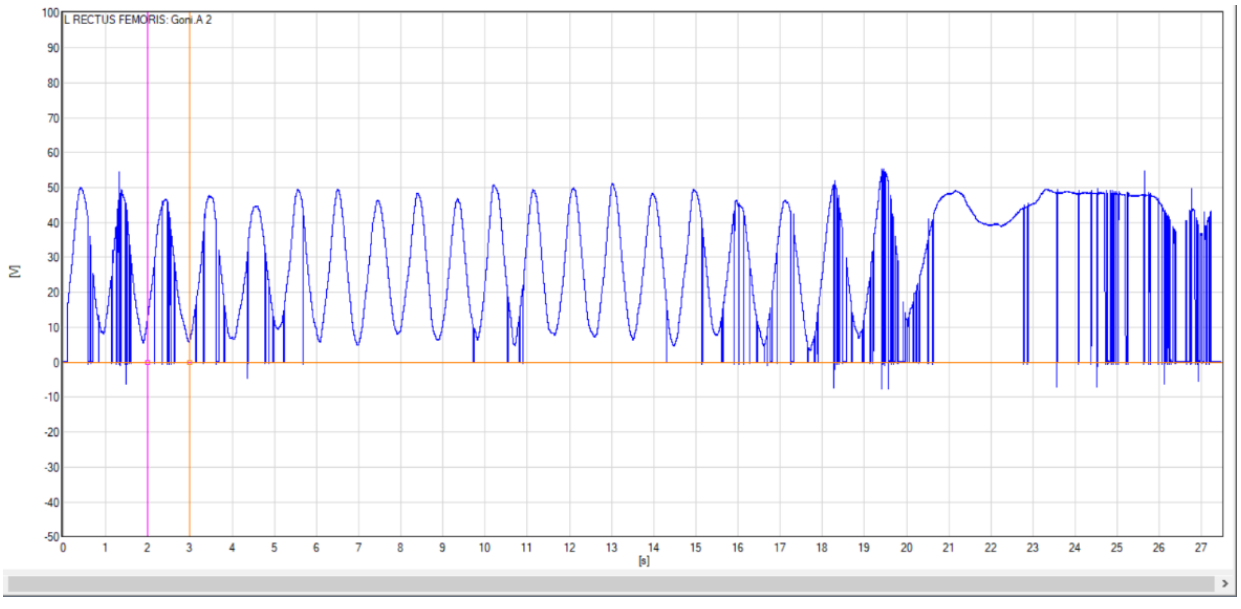


Figure 21 Output with original base station setup

The base station was then moved closer to the path and data were recorded again to test the resultant output. Test trial 2 showed a cleaner output signal than test trial 1. Signal reaching towards zero represents extension, and signal moving away from zero represents knee flexion. The peak and valley of the signal represents maximum knee flexion and/or maximum knee extension.

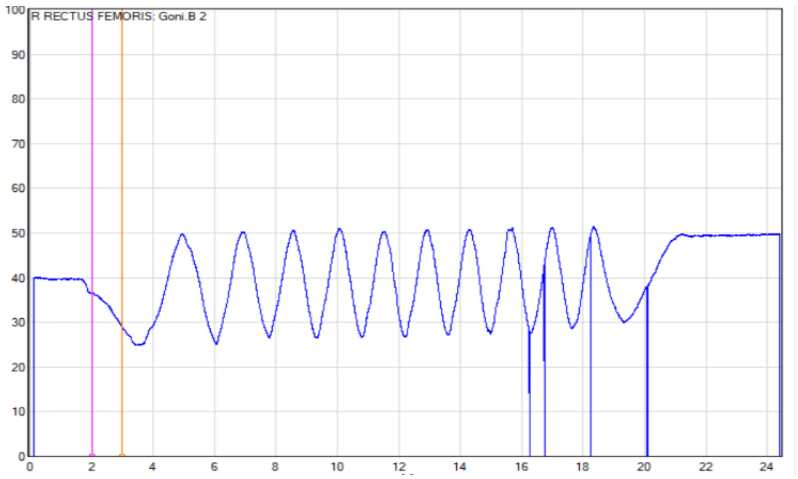


Figure 22 Output after shifting the base station

For this study purpose, the goniometer and the adapter assembly were attached to both the knee joints of the rider (as shown in Figure 23). The sensor assembly was secured into position with medical tape. The base station was set near the 30m track to avoid drop packets in the receiving signal. Real-time data were captured and streamed wirelessly using Bluetooth to EMGWorks® software via the base station. The output signal represents relative change in knee angle while the rider was engaged in biking. Further signal processing and

Figure 23 Goniometer placement

signal analysis could then be done using EMGWorks®, whereas numerical data manipulation can be done using Microsoft Excel.

The Delsys® Trigono™ goniometer adapter and Biometrics SG150 twin-axis goniometer assembly were attached to a participant's lateral side of both knees. The proximal end of the assembly was attached to the lateral femur while the distal end was attached to the lateral fibula. The rider was then fitted correctly to the AS 2600 bike model with the help of a trained staff member of Freedom Concepts Inc.

Figure 24 Rider with Delsys® assembly on the AS 2600

The rider performed three trials of 30m of self-paced active biking and two trials of passive biking. Relative knee angle measurement data were collected and streamed to a dedicated research laptop for recording and further analysis.

Published research suggests that, for movements primarily in one plane such as biking, two-dimensional (2D) video analysis correlates well with more complicated and expensive method of three-dimensional (3D) analysis (Grigg et al., 2018). In the current field of

biomechanics, there is an increased demand for 2D software to capture, observe, and to analyze subject movements; and 2D software is becoming more popular due to its cost-effectiveness and multifunctional features (Furrer et al., 2015; Redler et al., 2016). There are several 2D video analysis software platforms available for clinicians and researchers to use. Considering the future goal of this study, i.e., to measure ROM of children with CP while engaged in dynamic biking, it was deemed preferable to identify methods that did not require direct instrumentation of the child's joint. Thus, one open-source software (Kinovea), and one proprietary commercial software (Altius Analytics Labs) that enabled joint angle tracking and analysis of joint angles were considered for future use.

Kinovea Beta Video Player: 2D sport analysis software

Kinovea is a cost-effective, non-invasive, and multifunctional software that was tested for feasibility. Kinovea is a 2D video analysis software available in two versions: Kinovea stable, and Kinovea beta version. All the standard features are common in both Kinovea stable and beta version. However, Kinovea beta version has additional experimental features that allow in-depth movement analysis. The goniometer tool of the Kinovea beta version allows dynamic tracking of a multi-point object. Linear and angular kinematics (based on tracking of a multi-point object)

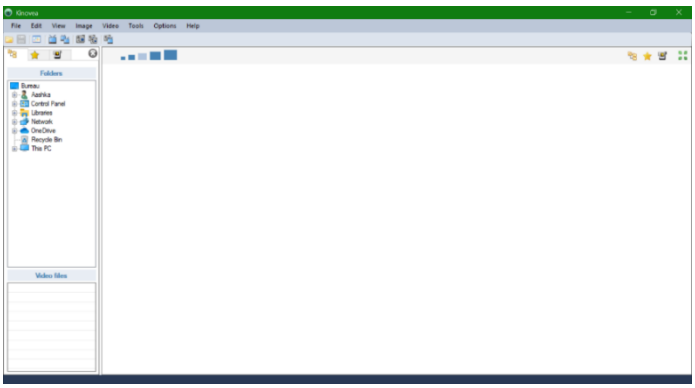


Figure 25 Kinovea beta home screen

can be obtained using Kinovea beta version. Such features of Kinovea beta led us to consider and test the suitability of the software for measuring ROM for this study population during dynamic biking.

Kinovea beta is a simple and user-friendly software reported with good validity and reliability that does not require any special training to use (Puig-Diví et al., 2019). Once the video is recorded, a user can navigate through file explorer to see, choose, and open a video to analyze. Once the video is opened, a user can access a player control pane with various features and controls.

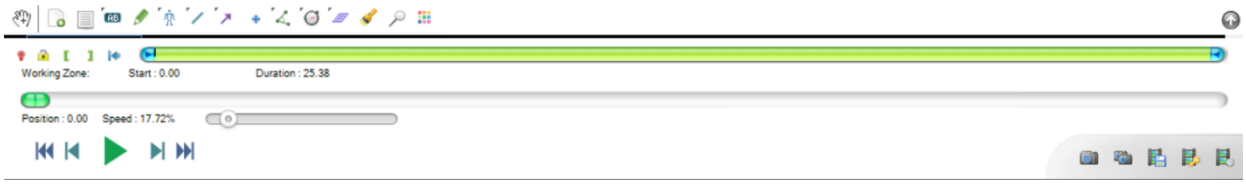


Figure 26 Kinovea control menu

Users can select and lock the segment of a video where they want to work, called as a working zone, to stay in that segment of the video. Various tools such as markers and the goniometer tool can be placed on the desired angle/s and the user can perform continuous angle

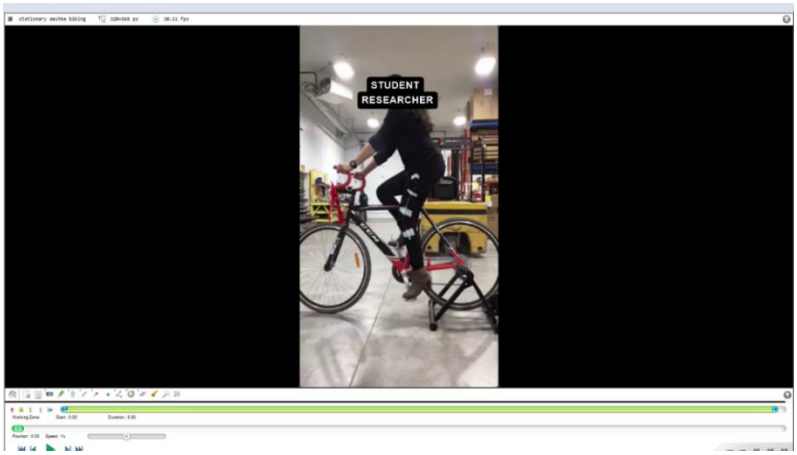


Figure 27 Kinovea assessment screen

tracking throughout the video.

Altius Analytics Labs

Assessing ROM using system that requires to mark the subject for assessment can be challenging in populations with neurological disorders due to their low tolerance to body sensors/markers (Lang et al., 2020).

Altius Analytics Labs is a video analysis software that assists with physical assessment of an individual. It assesses human performance objectively and virtually without any wearable sensors or markers. The user/operator does not require any special training or skills to operate this video analysis software. The first step to the analysis is to create a rider's profile: all videos can then be uploaded to the profile. Each video is available to be analyzed separately. Altius allows the user to evaluate the uploaded video with various available measures. Joint angle, velocity, and acceleration output graphs for the same video are produced. Altius can simultaneously assess multiple movements such as head, neck, shoulder, elbow, hip, knee, and ankle. The software is under development to assess smaller movements such as those in the digits. The output from the Altius can be acquired in .jason files and through recording the assessment screen.

In this study, the output for each trial using Altius was recorded using the screen record function of the computer. The downloadable output file (.jason) generated from the software is generalized for all body joints and is data intensive. To extract the desired numerical data of a specified joint from the software is challenging. Thus, any further data manipulation is not attainable. As Altius Analytics Labs is a new start-up and the software is under development, developers and engineers are yet to add features such as text version of the output file for

selected joints, and ROM assessment of a frontal view video to the software. The software is marker-less, i.e., it does not require any physical or virtual placement of markers on the subject. The algorithm, based on artificial intelligence, is configured in the software to detect human movement, and provide human movement data. As seen in Figure 28, output waveform of each video input is played along with the input video. The software can generate sagittal, frontal, and horizontal views of the person.

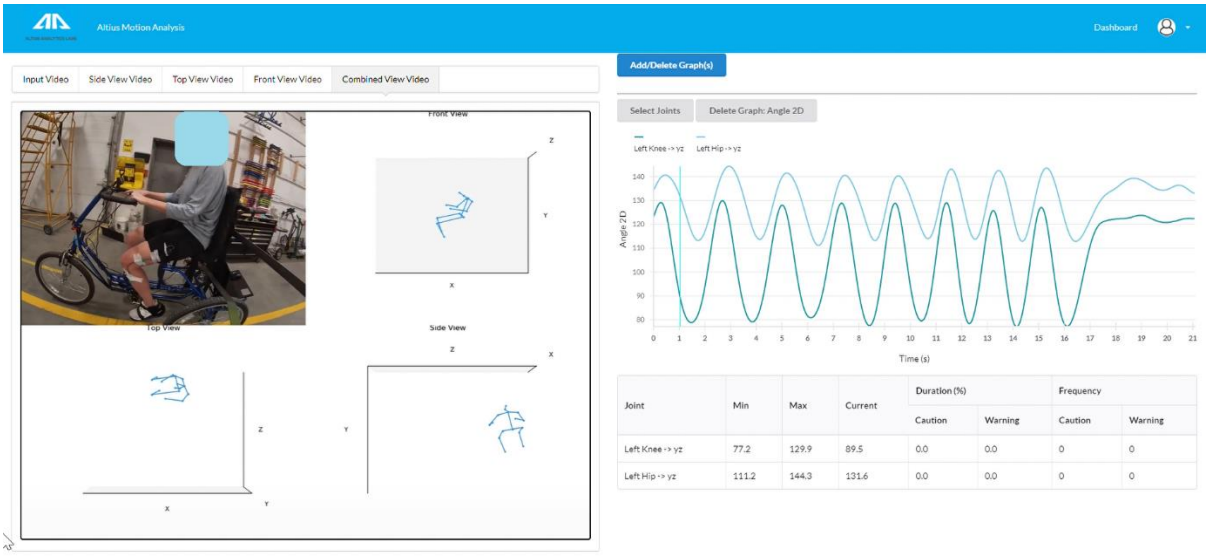


Figure 28 Altius assessment screen

Postural Symmetry

Postural control requires correct alignment of body position supported by the appropriate amount of muscle tension against gravity to attain orientation and stability whereas movements are defined by change in posture (Brogren et al., 1998; Massion, 1998; Nwaobi, 1987). Developing and maintaining postural control is one of the primary challenges affecting daily life activities in children with CP (Brogren et al., 1998). Various physical therapy interventions have

been proposed to improve postural control in children with CP (Dewar et al., 2015). Center of pressure (CoP) is a point of an integration of the created vectorial pressure field on the surface. CoP and its displacement can provide vital postural sway data of a user (Lacoste et al., 2006). In a study by Lacoste et al., (2006), the FSA pressure mapping system was identified as an effective method to assess postural asymmetries during seating position in children, with reported good validity and reliability. This study was a concurrent validity and reliability study comparing the FSA pressure mapping system with the Advanced Mechanical Technology Inc. (AMTI) force platform. Results revealed that, clinically, the FSA was as effective as the AMTI in measuring COP displacement.

FSA pressure mat and assembly

The FSA system (*BodiTrak*, n.d.) consists of a wired FSA pressure mat, an interface module, connector cables and custom FSA software. The 16x16 FSA pressure mat contains 256 thin, flexible fabric piezo-resistive pressure sensors covered with polyurethane coated rip nylon. Figure 29 shows an FSA pressure mat and an interface module.

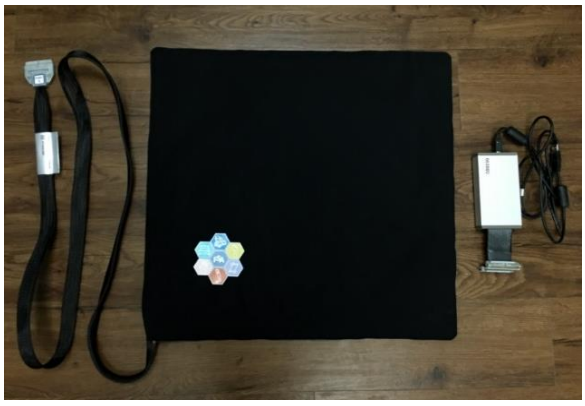


Figure 29 FSA pressure mat

An interface module provides an electronic interface between the FSA pressure mat and the computer. The FSA pressure mat can be placed on a seat, treadmill, bed and/or on any surface to collect real-time contact pressure between a surface and an individual. The sampling rate for FSA 4.0 is 5 Hz. Data gathered from the FSA pressure mat is transmitted in real-time through an interface module to the computer via USB cable. The FSA software allows clinicians and researchers to scan, record, play, select frames, and analyze pressure data gathered from the pressure mat (*Yumpu*, n.d.). The pressure values are shown in the units of millimeter of mercury (mmHg). The pressure range of the FSA pressure mat is 0-200mmHg, and differentiated by ROYGBIV colours, where red represents the maximum pressure and white represents the lowest pressure. The display screen of the FSA software provides contour plots (2D), surface plots (3D), statistical values, and the colour scale to identify the pressure range.

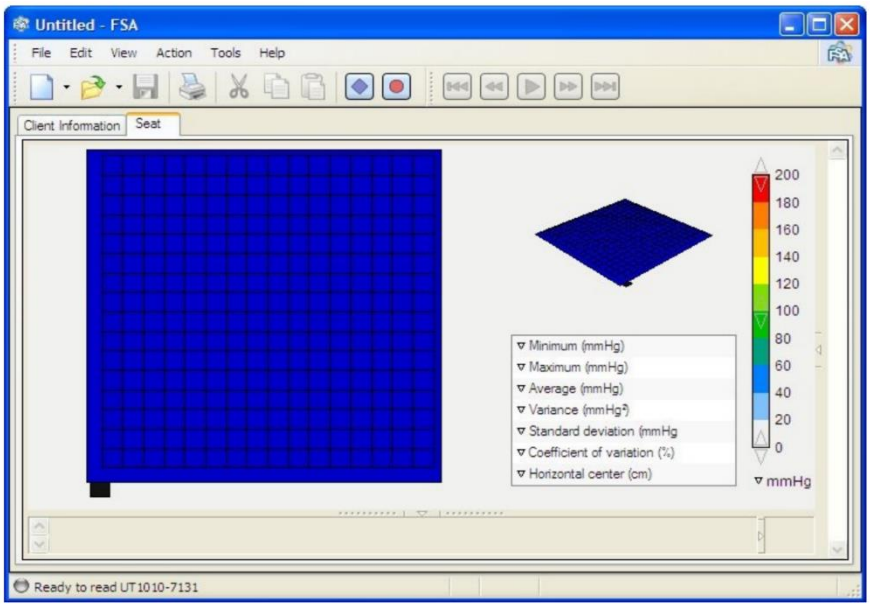


Figure 30 FSA output display screen

Besides numerical values, the FSA pressure mapping software also indicates the position of the CoP and its displacement with a visual presentation of a small black circle on the

contour plot. This small black circle leaves a trace and tracks the CoP position for up to 10 seconds of scan time. Single frames or sections of each frame can be selected from the contour plot to gather selective information from the plot. The pressure value of each cell can be obtained by exporting the data file into Microsoft® Excel sheet for further analysis.

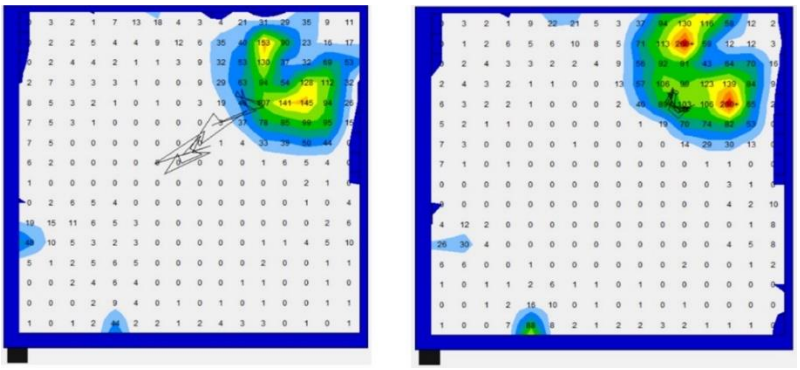


Figure 31 Visual representation of CoP

For this study purpose, the FSA mat was placed diagonally on the seat to cover the triangular seat and the back portion of the seat. The locking strap was attached to both ends of the FSA mat and then locked to the seat to keep the mat from sliding. A thin neoprene fabric cover was placed on the top of the seat and mat assembly to protect the mat. The seat-cover also helped to maintain the position of the FSA mat on the seat.

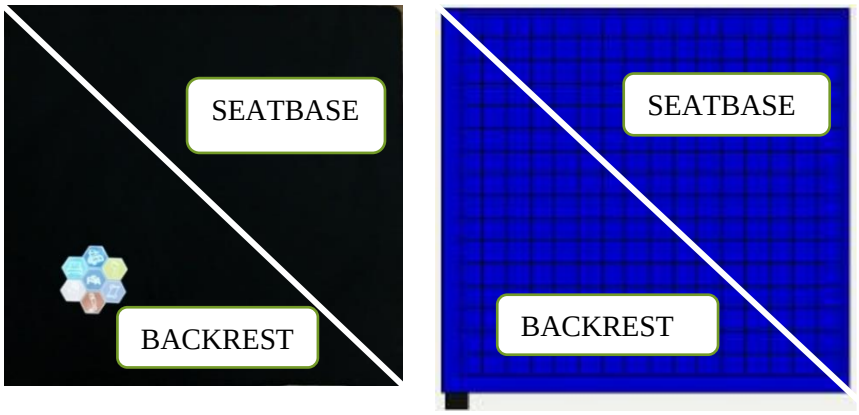


Figure 32 Placement of the mat

A research laptop was placed at the back of the bike on the basket/platform connected to the FSA pressure mat and V3 CA. Data were captured in real-time while participants rode the adaptive bike. Figure 33 represents the pressure data output in FSA software:

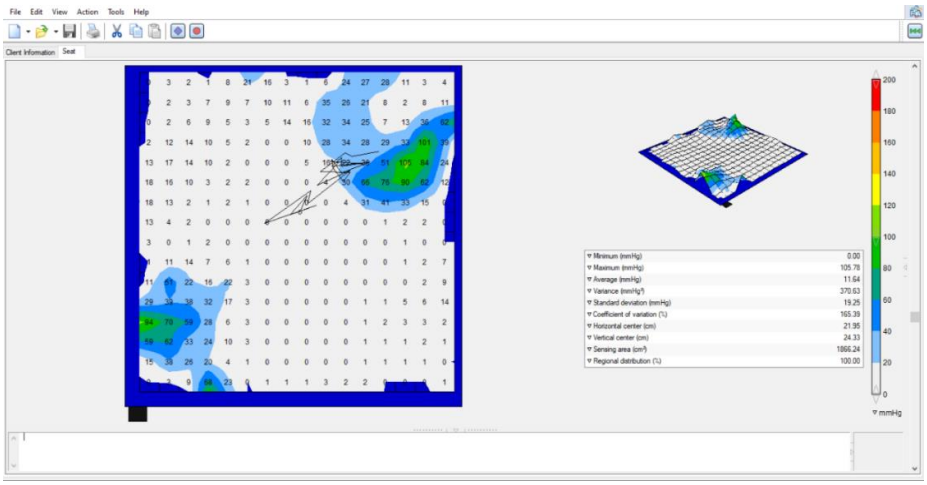


Figure 33 FSA output during biking

In Figure 34, the red square segment on the contour plot represents the rider's pressure on the seat whereas the green rectangular segment represents pressure on the backrest while biking. The red section is divided into two black triangular sub-sections. Triangular sub-sections differentiate pressure of volunteer's right hip from the left. The FSA software allows selection of

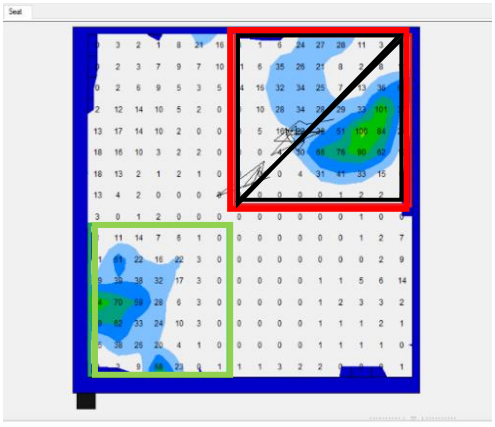


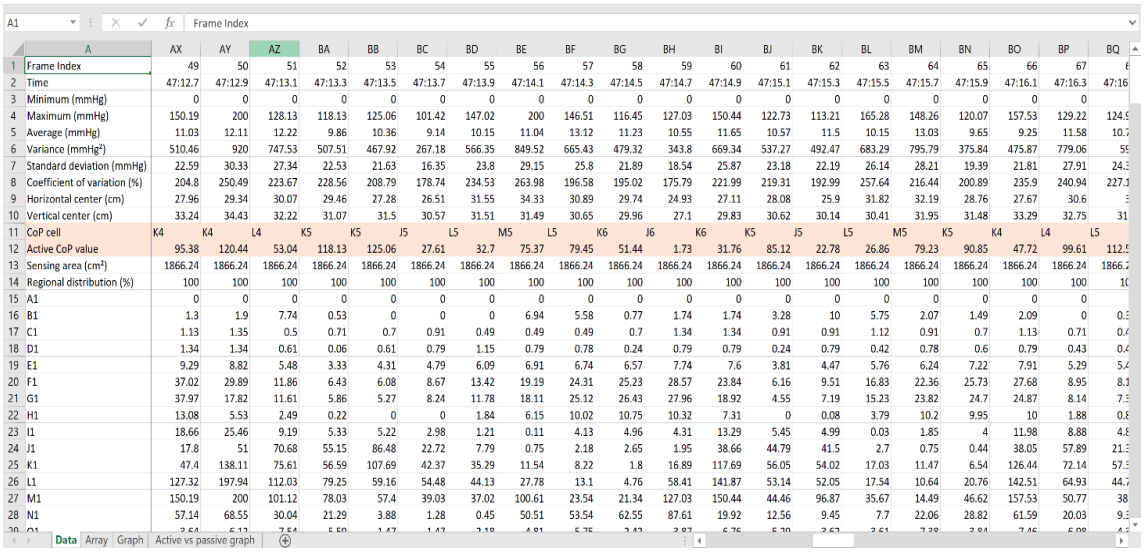
Figure 34 FSA screen segment- seat pressure (red),

back pressure (green)

different segments (in the red and green square) for each frame and displays statistics for each segment in a statistical table under the surface plot (Ros, 2020).

For this study, along with pressure data, the FSA pressure sensing mat was also used to detect the CoP to distinguish active biking from (simulated) passive biking. To obtain the value of CoP for each frame, an algorithm was formed. After importing all pressure data of a 30m biking trial in an excel sheet, an array was created in another tab sheet. The FSA software assigns each sensor with a unique alphanumerical value. The horizontal line of sensors is assigned from A to P (from left to right) while the vertical line of sensors is assigned from 1 to 16 (top to bottom). Each sensor is a combination of its alphanumeric position: e.g., the upper left sensor is assigned as A1, and the lower right sensor is assigned as P16. The approximate size of each sensor is 2.66cm. Considering the size of sensors, the position of each sensor on the mat was decoded. The array is comprised of horizontal and vertical assignment of each sensor, and position of each sensor on the mat for each frame (in cm).

Considering the horizontal and vertical center assignment of each sensor for each frame, an algorithm was created to track the CoP position on the mat by identifying the alphanumeric code of the sensors on the mat. Another algorithm was developed in Microsoft® Excel to extract the pressure value on that sensor. This algorithm was then applied to all the data to extract the CoP position and value for each frame. Algorithm generated values were visually confirmed by matching the algorithm generated values with the values available on the pressure map. It was identified that the algorithm-generated CoP values were accurate.



	A	AX	AY	AZ	BA	BB	BC	BD	BE	BF	BG	BH	BI	BJ	BK	BL	BM	BN	BO	BP	BQ
1	Frame Index	49	50	51	52	53	54	55	56	57	58	59	60	61	62	63	64	65	66	67	
2	Time	47:12.7	47:12.9	47:13.1	47:13.3	47:13.5	47:13.7	47:13.9	47:14.1	47:14.3	47:14.5	47:14.7	47:14.9	47:15.1	47:15.3	47:15.5	47:15.7	47:15.9	47:16.1	47:16.3	47:16
3	Minimum (mmHg)	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
4	Maximum (mmHg)	150.19	200	128.13	118.13	125.06	101.42	147.02	200	146.51	116.45	127.03	150.44	122.73	113.21	165.28	148.26	120.07	157.53	129.22	124.9
5	Average (mmHg)	11.03	12.11	12.22	9.86	10.36	9.14	10.15	11.04	13.12	11.23	10.55	11.65	10.57	11.5	10.15	13.03	9.65	9.25	11.58	10.7
6	Variance (mmHg²)	510.46	920	747.53	507.51	467.92	267.18	566.35	849.52	665.43	479.32	343.8	669.34	537.27	492.47	683.29	795.79	375.84	475.87	779.06	55
7	Standard deviation (mmHg)	22.59	30.33	27.34	22.53	21.63	16.35	23.8	29.15	25.8	21.89	18.54	25.87	23.18	22.19	26.14	28.21	19.39	21.81	27.91	24.3
8	Coefficient of variation (%)	204.8	250.49	223.67	228.56	208.79	178.74	234.53	263.98	196.58	195.02	175.79	221.99	219.31	192.99	257.64	216.44	200.89	235.9	240.94	227.1
9	Horizontal center (cm)	27.96	29.34	30.07	29.46	27.28	26.51	31.55	34.33	30.89	29.74	24.93	27.11	28.08	25.9	31.82	32.19	28.76	27.67	30.6	
10	Vertical center (cm)	33.24	34.43	32.22	31.07	31.5	30.57	31.51	31.49	30.65	29.96	27.1	29.83	30.62	30.14	30.41	31.95	31.48	33.29	32.75	31
11	CoP cell	K4	K4	L4	K5	K5	J5	L5	M5	L5	K6	J6	K6	K5	J5	L5	M5	K5	K4	L4	L5
12	Active CoP value	95.38	120.44	53.04	118.13	125.06	27.61	32.7	75.37	79.45	51.44	1.73	31.76	85.12	22.78	26.86	79.23	90.85	47.72	99.61	112.5
13	Sensing area (cm²)	1866.24	1866.24	1866.24	1866.24	1866.24	1866.24	1866.24	1866.24	1866.24	1866.24	1866.24	1866.24	1866.24	1866.24	1866.24	1866.24	1866.24	1866.24	1866.24	1866.2
14	Regional distribution (%)	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100	10
15	A1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
16	B1	1.3	1.9	7.74	0.53	0	0	0	6.94	5.58	0.77	1.74	1.74	3.28	10	5.75	2.07	1.49	2.09	0	0.3
17	C1	1.13	1.35	0.5	0.71	0.7	0.91	0.49	0.49	0.49	0.7	1.34	1.34	0.91	0.91	1.12	0.91	0.7	1.13	0.71	0.4
18	D1	1.34	1.34	0.61	0.06	0.61	0.79	1.15	0.79	0.78	0.24	0.79	0.79	0.24	0.79	0.42	0.78	0.6	0.79	0.43	0.4
19	E1	9.29	8.82	5.48	3.33	4.31	4.79	6.09	6.91	6.74	6.57	7.74	7.6	3.81	4.47	5.76	6.24	7.22	7.91	5.29	5.4
20	F1	37.02	29.89	11.86	6.43	6.08	8.67	13.42	19.19	24.31	25.23	28.57	23.84	6.16	9.51	16.83	22.36	25.73	27.68	8.95	8.1
21	G1	37.97	17.82	11.61	5.86	5.27	8.24	11.78	18.11	25.12	26.43	27.96	18.92	4.55	7.19	15.23	23.82	24.7	24.87	8.14	7.3
22	H1	13.08	5.53	2.49	0.22	0	0	1.84	6.15	10.02	10.75	10.32	7.31	0	0.08	3.79	10.2	9.95	10	1.88	0.8
23	I1	18.66	25.46	9.19	5.33	5.22	2.98	1.21	0.11	4.13	4.96	4.31	13.29	5.45	4.99	0.03	1.85	4	11.98	8.88	4.8
24	J1	17.8	51	70.68	55.15	86.48	22.72	7.79	0.75	2.18	2.65	1.95	38.66	44.79	41.5	2.7	0.75	0.44	38.05	57.89	21.3
25	K1	47.4	138.11	75.61	56.59	107.69	42.37	35.29	11.54	8.22	1.8	16.89	117.69	56.05	54.02	17.03	11.47	6.54	126.44	72.14	57.3
26	L1	127.32	197.94	112.03	79.25	59.16	54.48	44.13	27.78	13.1	4.76	58.41	141.87	53.14	52.05	17.54	10.64	20.76	142.51	64.93	44.7
27	M1	150.19	200	101.12	78.03	57.4	39.03	37.02	100.61	23.54	21.34	127.03	150.44	44.46	96.87	35.67	14.49	46.62	157.53	50.77	38
28	N1	57.14	68.55	30.04	21.29	3.88	1.28	0.45	50.51	53.54	62.55	87.61	19.92	12.56	9.45	7.7	22.06	28.82	61.59	20.03	9.3

Data | Array | Graph | Active vs passive graph

Figure 35 Calculated CoP position and its statistical values

The CoP values for active and passive biking for each frame were subsequently plotted on a line graph. The illustrative sham data presented below in a graph, green line on the graph displays the CoP value for active biking while the orange line displays the CoP value obtained during passive biking.

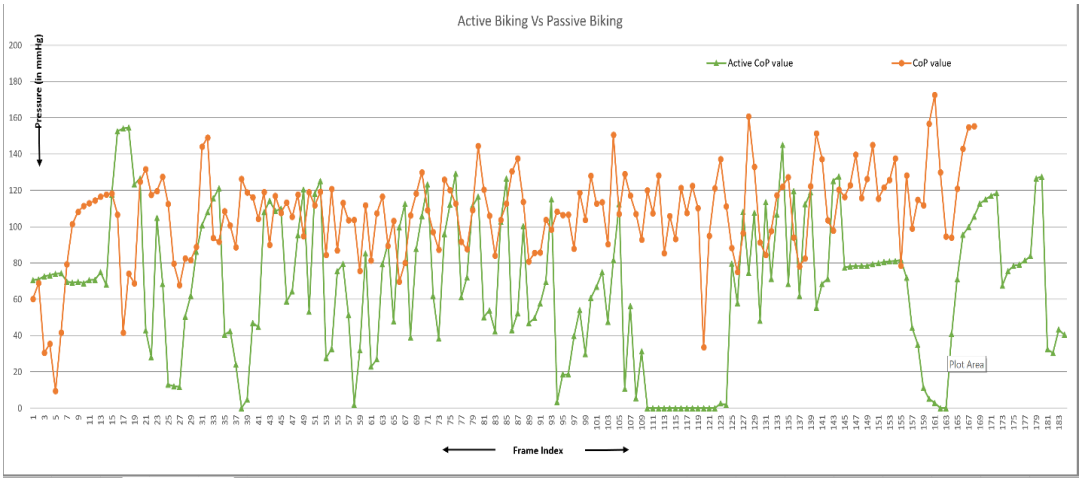


Figure 36 Active vs passive CoP

Data Analysis

Feasibility of the biking trials was considered based on the participants' ability to perform all five 30m rides indoors without any difficulty. Data collected from the NCTE_128 BB were exported to Microsoft® Excel for further analysis. Data from both the software, the FSA and the Delsys® were stored in a research laptop as software generated graphic files. These data files were also exported to Microsoft® Excel and a copy was stored in the same research laptop with the graphic files.

As this was a feasibility study to assess the capability of the various tools to measure selected physical measures, outcome data were plotted and analyzed individually for each rider. Data were visually inspected for each measure of interest to assess consistency, and to focus on differences among trials, trends, and patterns observable in data. To summarize observations and to draw inference, collected data were analyzed using descriptive statistics. Findings on the level of performance and consistency of the performance was estimated using measures of central tendency and measures of variability, respectively. In the future, additional statistical methods (i.e., one-way ANOVA and ICC- Appendix D) to supplement visual analysis are recommended if the data are collected with children and adolescents with neurological disorders. For example, a one-way Analysis of Variance (ANOVA) can be performed to assess the reliability of physical performance measures to capture select physical measures. The reliability statistic most often reported for continuous measurements is the intra class correlation coefficient (ICC). High positive values of ICC reflect good reliability (Zou, 2012). However, as only pilot data were able to be collected for the present feasibility study, findings are based on visual representation of output and not based on statistical significance.

Results

This section starts by reporting rider demographics and explaining the feasibility indicators for the study related components. The following sections evaluate the physical performance measures discussed earlier in the "Physical Performance Measures" section. Each performance measure was visually analyzed and summarized for each outcome to determine consistency and differences among trials, patterns, and trends.

Rider Demographics

Both riders' demographics were obtained prior to the bike assessment trial. For the next phase of research additional variables will be attained such as GMFCS classification.

Table 1 Rider demographics

Variables	Rider I	Rider II
Age (years)	50	27
Sex	Female	Female
Height (in ft)	5'6"	5'4"
Weight (in kg)	62.60	64.86

Feasibility Indicators

Table 2 Feasibility indicators summary

Components	Criteria	Feasibility Outcome
Integrated Tools	80% of the data will be collected for all the biking trials successfully	Achieved

Biking trial/intervention	Both the researchers will be able to perform all five 30m rides indoor	Achieved

Power Output

The power output of each rider was assessed by analyzing human watts, torque profile, speed, and pedal cadence data. Sample data from Riders 1 and 2 are presented for illustration and discussion purposes.

Human Power Statistics

Figure 37 shows human power statistics for Rider I. Human watts and torque profiles for illustrative active biking trial are plotted here. The shape of human watts (HW) and torque (Nm) throughout active trials are similar and cyclic. The graph suggests that biking was divided into two phases: defined as the power phase and the relaxation phase for this study. The rider applied more power at the beginning of the biking period (accelerating) or when the bike was slowing down (decelerating): this phase was called the power phase. Once the bike reached a certain momentum the rider did not pedal as much. This decrease in pedaling is evident on the graph where a decrease in human power was produced: this was called the relaxation phase. The combination of these phases formed a cyclic rhythm and as shown on the graph and is representative of the human biking pattern. At the end of the biking trial, the torque reading increased due to the rider's attempt to keep the bike in a steady stop position by applying brakes and maintaining high pressure on pedals to resist pedal moments.

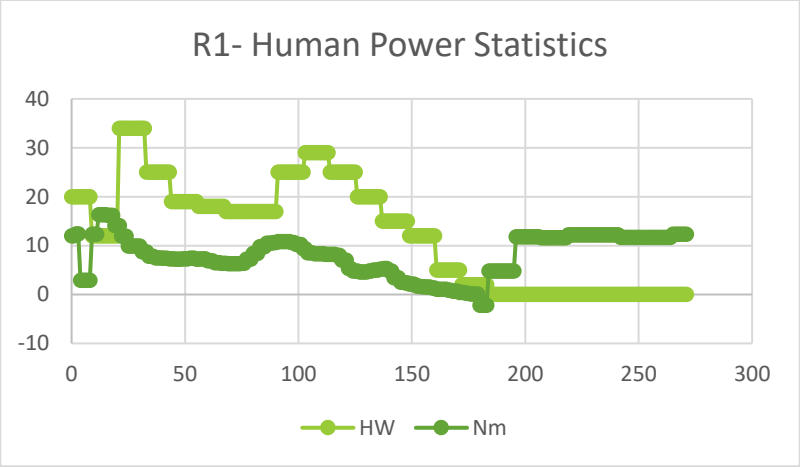


Figure 37 Illustrative human power statistics- active biking trial (Rider I)

Rider II exhibited a similar pattern as the Rider I. During the power phase, human power reached a high of 63 human watts and similarly the maximum torque recorded was 46.9Nm. For both riders, a limitation of the sensor was that human power was not measured for the first 54 frames and then later from frame 200 and onwards, due to the sensor's limitation to detect low human watts. The same pattern was found for all the active trials.

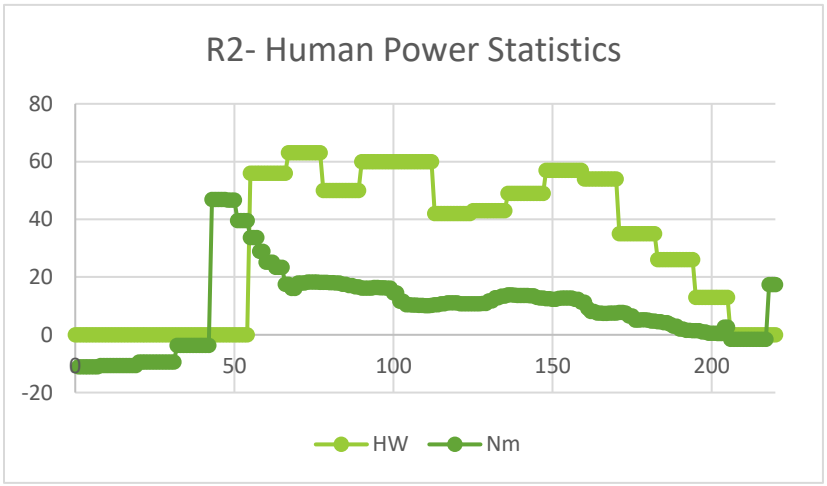


Figure 38 Illustrative human power statistics- active biking trial (Rider II)

As was identified, the sensor was found to be unable to capture lower power values. Even when the rider was exerting power on the pedal, the reading was displayed at 0 and the first power reading captured was at the reading of 76 human watts.

Figure 39 Human power output

Considering our interest in future study populations who might experience a limited ability to exert power on the pedal, capturing their first or initial power to propel the bike is important to understand in order to gauge their current physical power as well as their progress over time. Thus, the inability to capture these lower values is considered a major limitation of this power meter system.

Speed and Pedal Cadence

A similar output pattern was witnessed while analyzing the pedal cadence profile of the rider. Low pedal cadence and low-speed data were not captured and reported. For the first graph, the sensor did not capture the initial RPM until the reading reached 18.7 RPM. Similarly, at the end of the same biking trial, as the RPM was reduced, the sensor did not capture any data past 33 RPM that is higher than 18.7 RPM. The speed profile is a replica of the pedal cadence profile. Therefore, it can be concluded that the sensor failed to capture human power statistics during the first few pedal strokes: this phase is deemed to be important in determining the rider's initial power production.

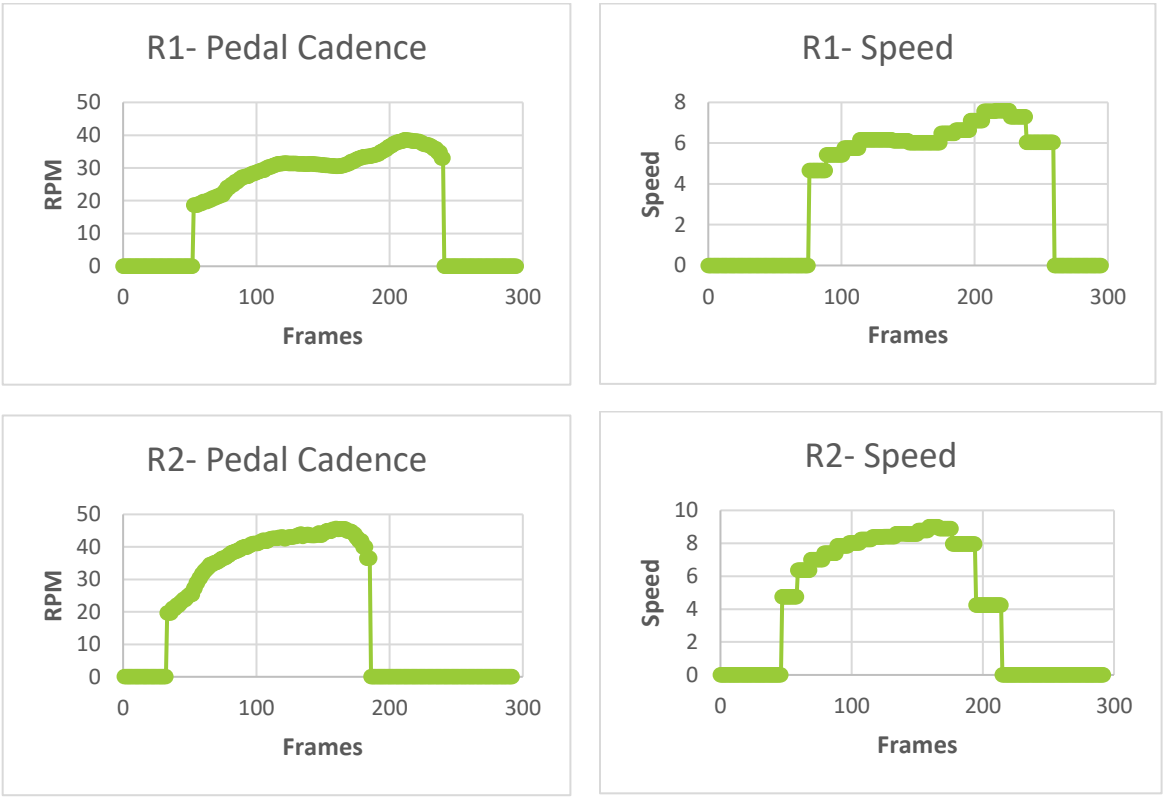


Figure 40 Output- speed and pedal cadence

Active vs Passive Biking- Human Watts

Average human power applied during active biking trials and passive biking trials are plotted in Figure 41. As the riders were actively engaged in biking and there was no external assistance provided to propel the bike, both the riders were observed to exert more power during active trials than during passive trials. The similar results pattern for Rider I and Rider II reveals the consistency of the sensor and confirms the sensor's limitation in capturing low values of human power data.

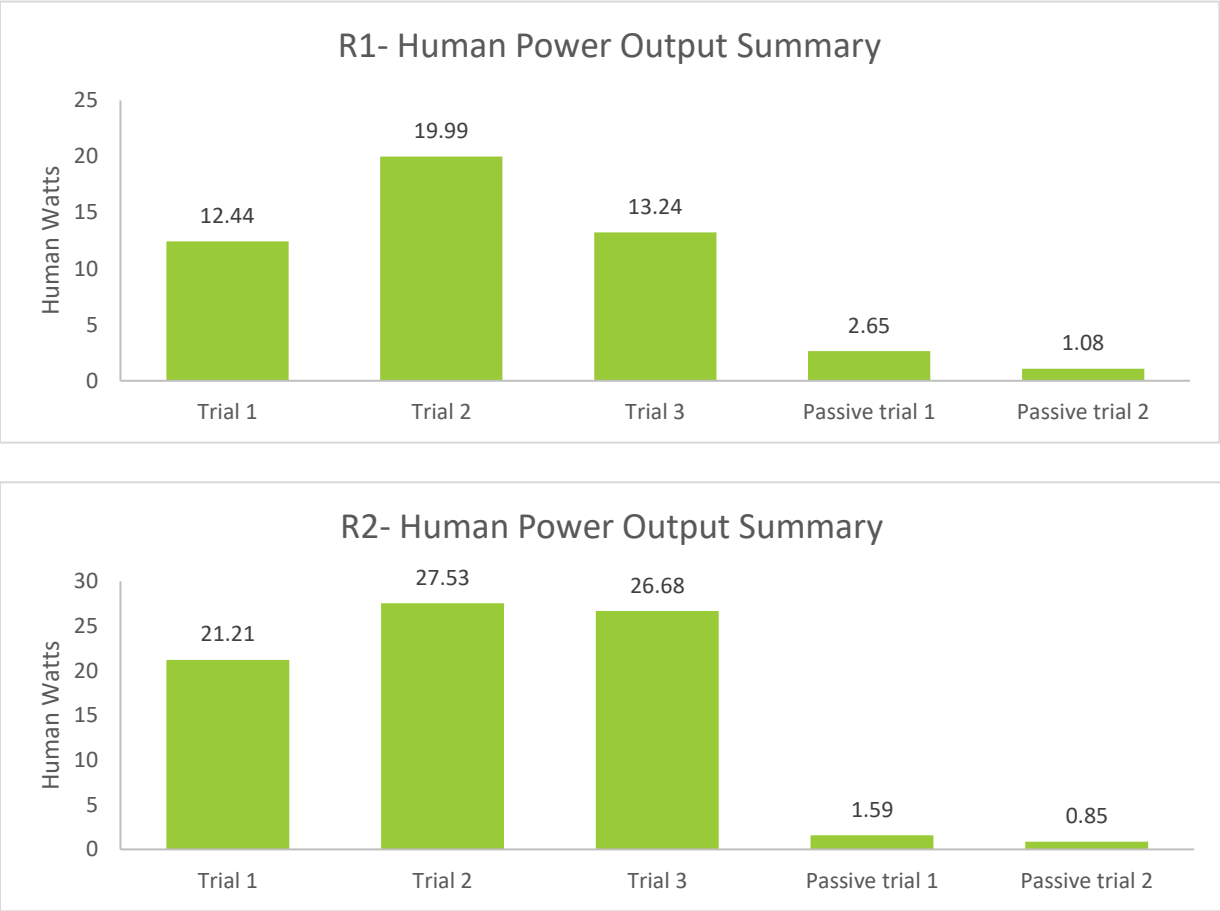
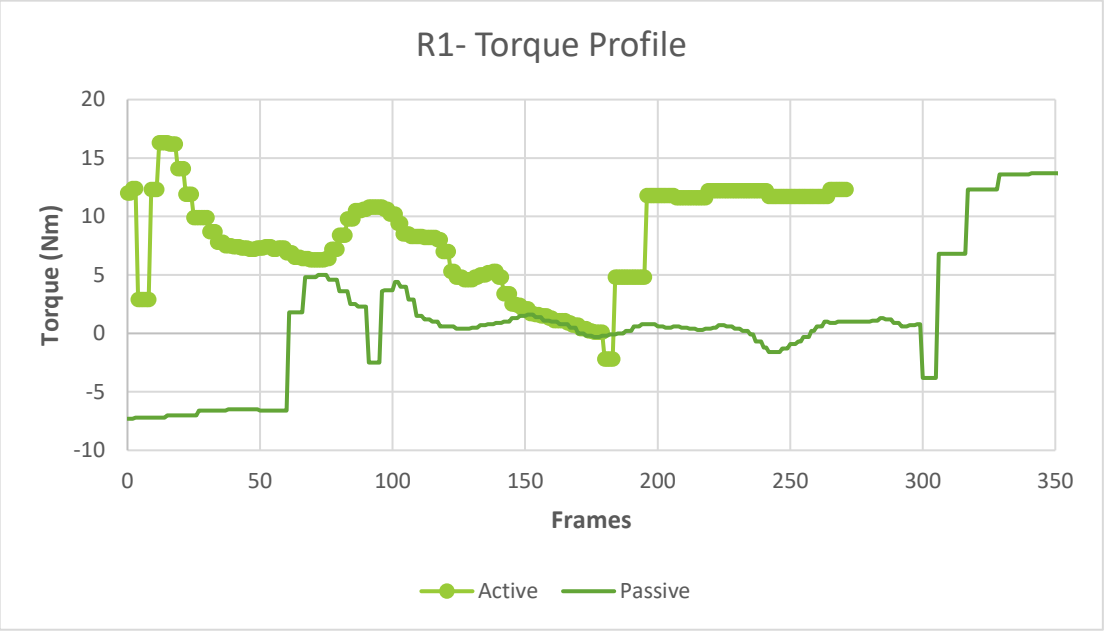


Figure 41 Active vs passive biking- human power summary

Active vs Passive Biking- Torque Profile

As the human power statistics were not captured for low values, comparing human watts for active and passive trials will provide misleading data i.e., the rider's initial power production is missing. Comparing the torque profile for Rider I, torque during active biking trial ranged from -2Nm to 16Nm whereas, torque during passive biking ranged from -7.2Nm to 13.6Nm. For Rider II, torque during active biking trial ranged from -11Nm to 46Nm whereas, during the passive biking trial torque ranged from -13.5Nm to 3.2Nm. Negative torque was observed during restricted pedal movements i.e., when resistance was applied to the pedals. Both graphs comparing active biking and passive biking trials show higher torque output during active biking trial. Consequently, it was concluded that the torque profile can provide an estimation of the rider's active versus passive engagement during biking.



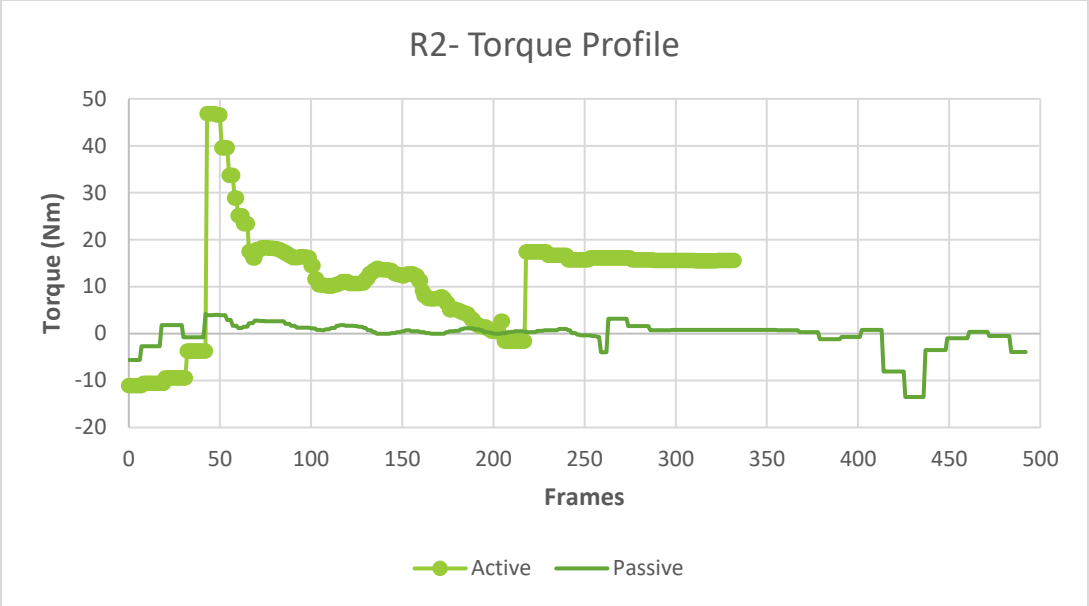


Figure 42 Active vs passive biking- torque Profile (A) Rider I (B) Rider II

Summary of Power Output Data

It was determined that the torque sensing bottom bracket provides consistent human power statistics. It should be noted that the current set-up only senses the left pedal force, thus, there can be some delay in capturing data if a rider starts from a standstill and begins by applying force to the right crank. Analyzing both rider's data, we identified that this torque sensor was unable to capture the lower range of human power values. This is identified as a limitation for the future study, given we anticipate lower power values will be produced by some of the study population (children with CP). Considering this important limitation of the NCTE_128 BB, it is recommended that other power meters be investigated to determine their ability to capture the lower range of values, such as the Garmin power meter (*Garmin Power Pedals*, n.d.), the Power2max power meter (*Power2Max*, n.d.), and the Pioneer power meter (*Pioneer Electronics*, n.d.).

Review of the technical specifications indicates that the Pioneer power meter (a complete crankset) provides both left and right leg power output independently. The Pioneer power meter has other advantages such as the ability to connect to a smartphone or a laptop wirelessly using Bluetooth. This wireless feature would eliminate the need to place the laptop and Li-ion battery on the bike platform; this would be an advantage as it would reduce the overall weight of the bike. However, the available crank set sizes of Pioneer power meters are too large to be installed in the available adaptive bikes from Freedom Concepts Inc. The Garmin Rally XC200 are dual-sensing power pedals that can easily be transferred between bikes. As well as capturing a rider's total power and cadence, the Rally XC200 can evaluate a rider's power phase (i.e., how much power a rider is producing in a pedal stroke), and the position of power application on the pedals. Threshold values of these power pedals are unknown and subject to further testing. Continued exploration of power meters, customization of existing models, and further testing will be required.

Range of Motion

Delsys® Trigono™ Avanti Goniometer with Biometrics ltd. twin-axis goniometer sensor

In this study, the Delsys® Goniometer assembly was used to assess relative knee joint angle for both left and right knees during biking. Figure 43 shows the standard representation of the graphical output received in the EMGWorks®. The software shows two separate graphs for each of the left and right knees. For each trial, a sagittal video of the rider biking was overlaid on the output file in the EMGWorks® to visually inspect and understand the graph.

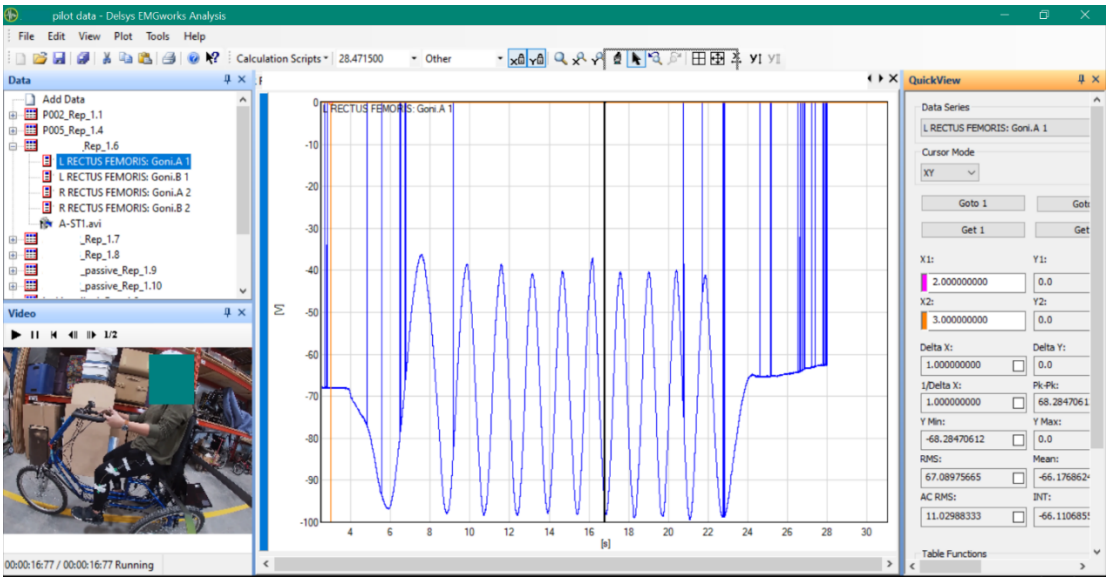


Figure 43 Delsys output in EMGWorks

Figure 44 shows bilateral knee relative angle data during the active biking trials of trial 1. Visual representation of plotted data revealed that both left and right leg produce a cyclic rhythm. The output of Delsys® is presented in the form of sinusoidal waveforms. The output signal, on the Y-axis, moving away from zero shows flexion, and the signal progressing towards zero represents knee extension. Note that 0° shows complete knee extension and the crest and trough represent the highest degree of knee flexion or knee extension the rider achieved for one complete cycle of pedaling. The ROM for each trial was calculated manually by extracting maximum knee flexion and knee extension data. Data were collected from three active trials and two passive biking simulation trials for both the riders and were analyzed in EMGWorks®. Later, analyzed data were exported to an Excel file for simple graphical representation. For the left knee angle data, each crest depicts maximum extension, and every trough illustrates maximum flexion for each pedal stroke: the opposite is true for the right knee.

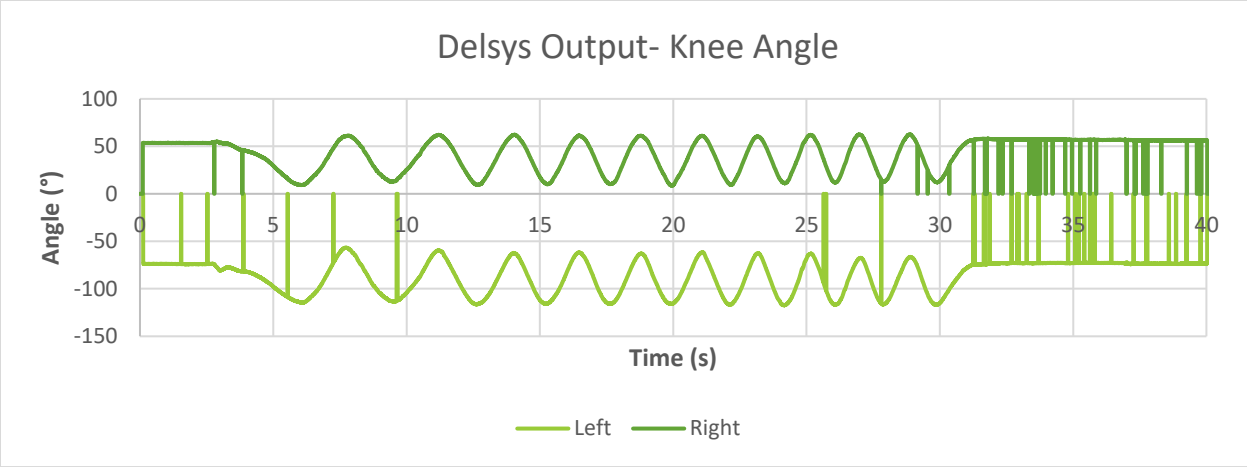


Figure 44 Knee angle output for active biking trial

Rider I took 32s to complete the first trial of 30m self-paced biking. Due to a system error, the Delsys® assembly did not track relative knee joint movement for the whole trial and hence, the output of trial 1 has a limited graph scale consisting of frame 0-16 only. Like trial 1, trial 3 also did not capture relative knee joint movement for the whole trial and therefore, trial 3 also has a limited graph scale.

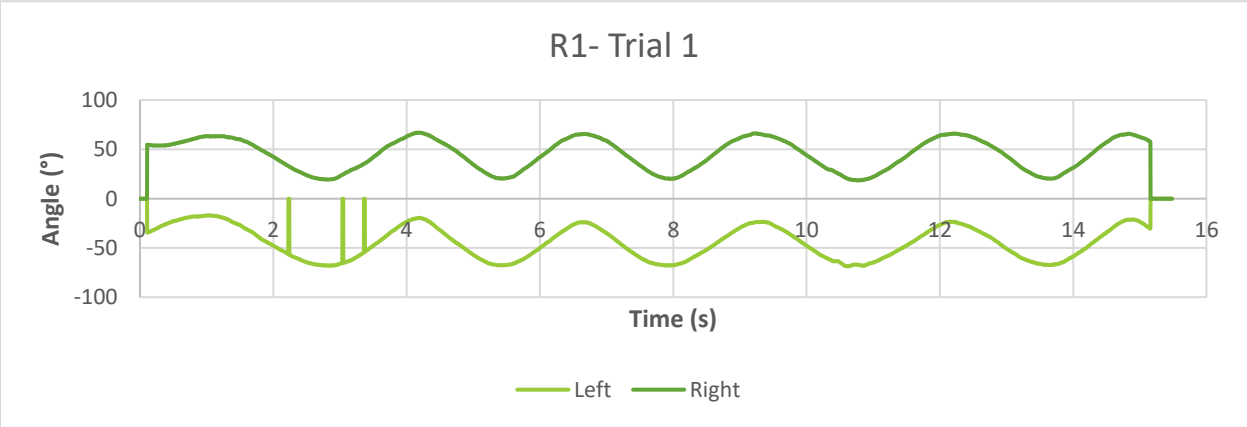


Figure 45 Active biking trial 1

The Delsys Base station set up needs to stable sensor connectivity to the base station throughout. It was determined that the initial base station setup that was 15m away from the

biking path affected sensor connectivity. As a result, we received numerous dropped packets in our trial data. After moving the base station closer to the biking path there were noted to still be a number of dropped packets in the output data; a limitation in the use of the Delsys® system for assessing ROM in clinical settings such as ours. Figure 46 below shows many dropped packets as the bike approached the end of the 30m biking path.

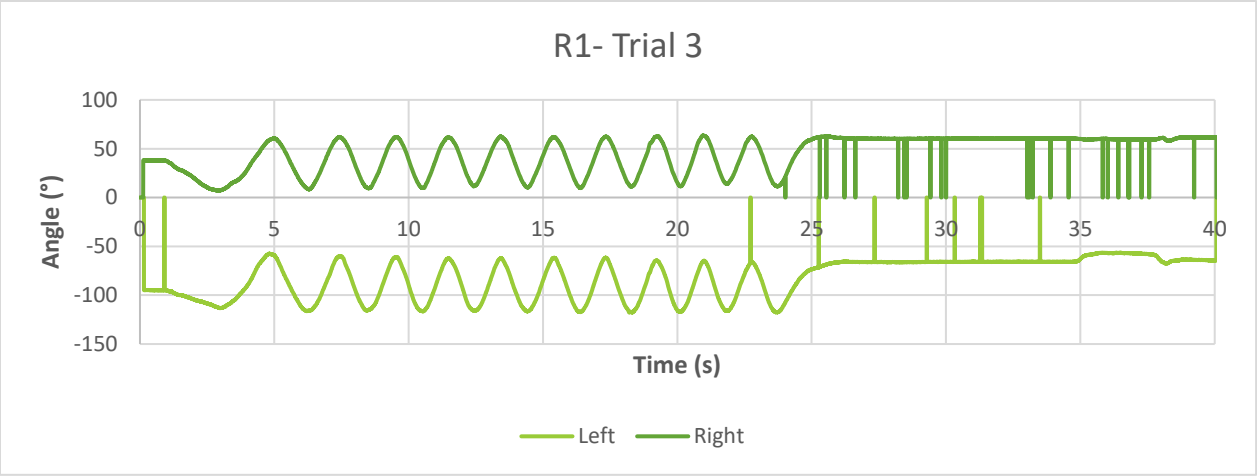


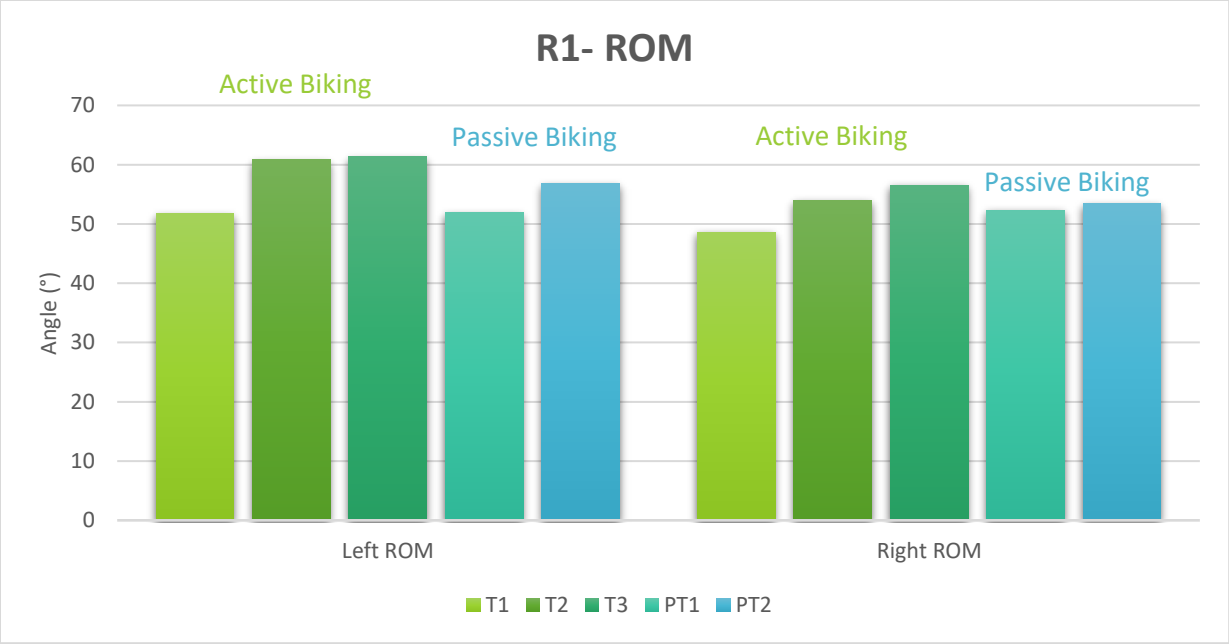
Figure 46 Active biking trial 3

As the rider's feet were strapped to the pedals, average knee ROM data during active biking and passive biking show a similar pattern and range. Subsequently, ROM is an ineffective way of understanding rider's active engagement during biking.

Figure 47 shows the summary of the rider's left knee- maximum extension (max ext) and flexion (max flex) during all trials. As the Delsys® assembly did not capture the rider's trial 1 and trial 3 accurately, the maximum flexion and extension data may not be reliable nor consistent with other active trials. Active trial 2 exhibits greater consistency. Rider II biking data were captured error-free and therefore, values plotted in a bar graph are more comprehensible for the Rider II.

Figure 47 Left knee flexion extension summary

Based on the data collected, the ROM for each trial was calculated manually for both the left and right knees. The graph below suggests slightly higher bilateral knee ROM during active biking trials than during passive biking trials.



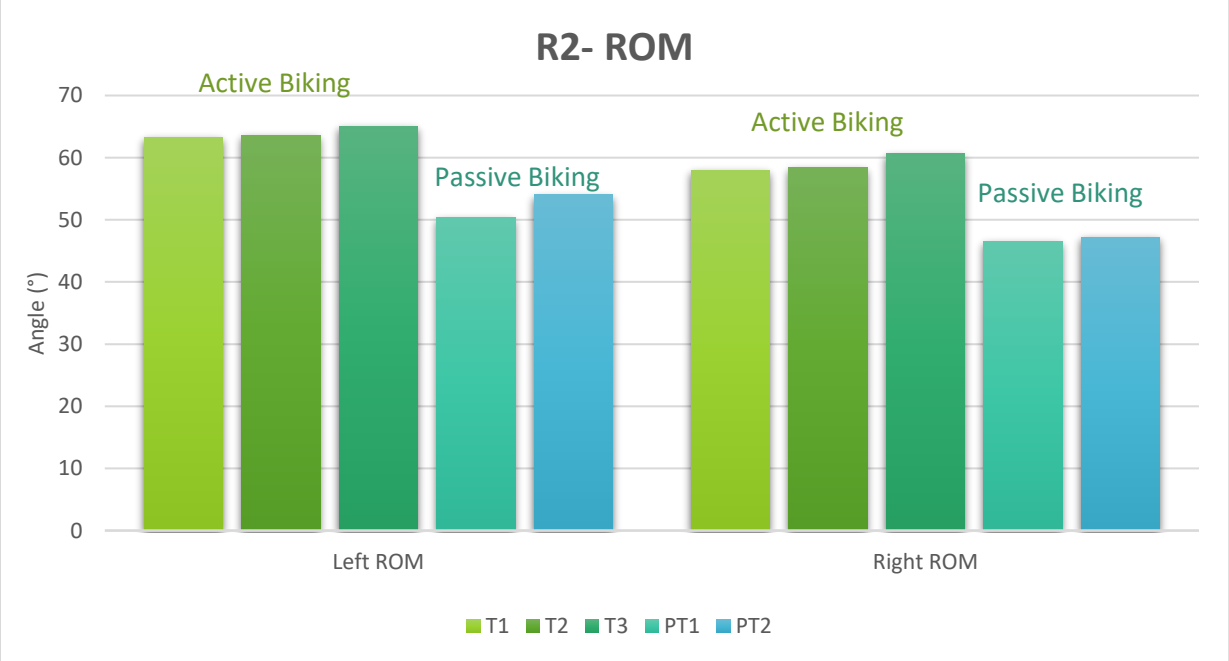


Figure 48 Left knee ROM summary

Kinovea Beta Video Player: 2D sport analysis software

We captured videos of all trials for Rider I and Rider II. Those videos were analyzed using Kinovea beta to capture knee ROM during dynamic biking and to test the feasibility of Kinovea beta for use in the future study. As mentioned in the instrumentation section, a GoPro Hero 7 was attached to the metal frame and then to the left of the bike to capture left view sagittal videos of a rider performing dynamic biking. These videos were then opened in Kinovea software- beta version for joint angle analysis for each trial. Using the Kinovea software, the video was divided into several frames captured at 0.03sec interval; the student researcher then was able to manipulate each frame as needed for analysis. As seen in figure (49), initial joint angle, prior to the first pedal stroke, was captured. For each rider, a continuous angle tracking tool was placed and set up at the knee joint separately in the software for dynamic tracking.

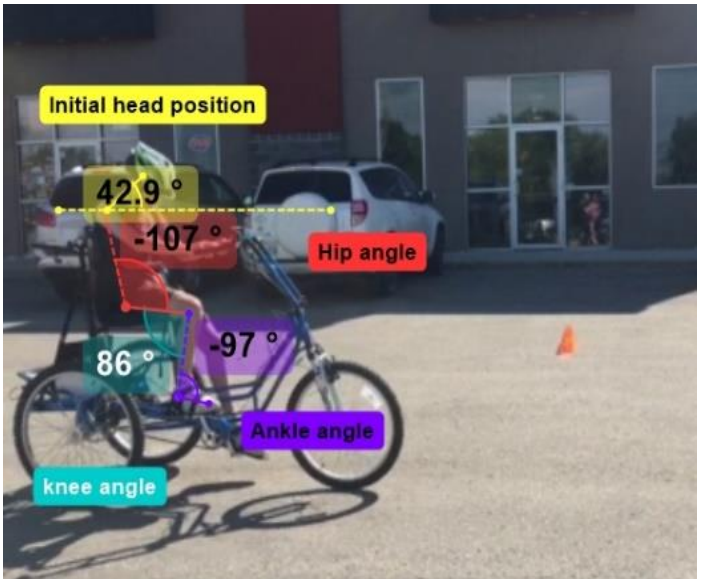


Figure 49 Initial position assessment prior to biking using Kinovea beta

Before conducting the biking trials, Kinovea beta was tested without any placement of physical markers on Rider II. During the dynamic angle tracking of the knee joint, it was identified that the three angle points of the automated angle tracking tool shifted in each frame to a different position, resulting in inaccurate angle measurements. Figure 50 shows initial virtual angle tool placement, following figure 51 illustrate shifting of the tool in various frames.

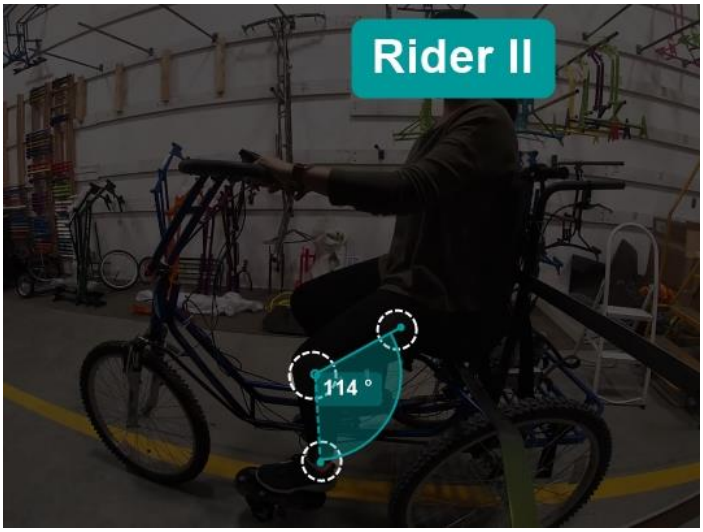


Figure 50 Initial placement of virtual angle tracking tool

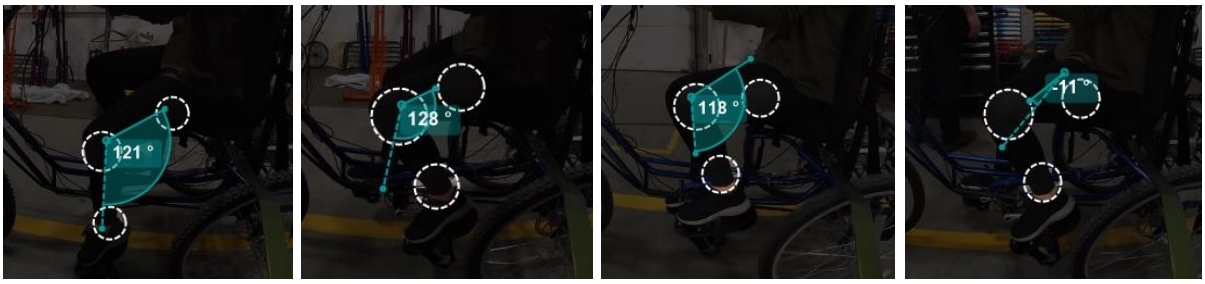


Figure 51 Illustration of angle shifts through a trial- no markers

After the automated analysis, angular kinematics were plotted on the graph. Angular kinematics were software-generated graphs based on continuous knee angle tracking. The resultant angular kinematics showed high irregularities in the knee ROM during dynamic biking.

Manual correction of each joint marker for each frame was required to ensure accuracy, defeating the advantage of automated analysis. The time taken to manually correct the markers was considered excessive (i.e., approximately 1.15 hours for a 30 second video clip or 1000frames).

To test the Kinovea system for biking trials, Delsys® markers were attached to Rider I and Rider II, while the GoPro Hero 7 camera simultaneously collected sagittal video data for use with the Kinovea software.

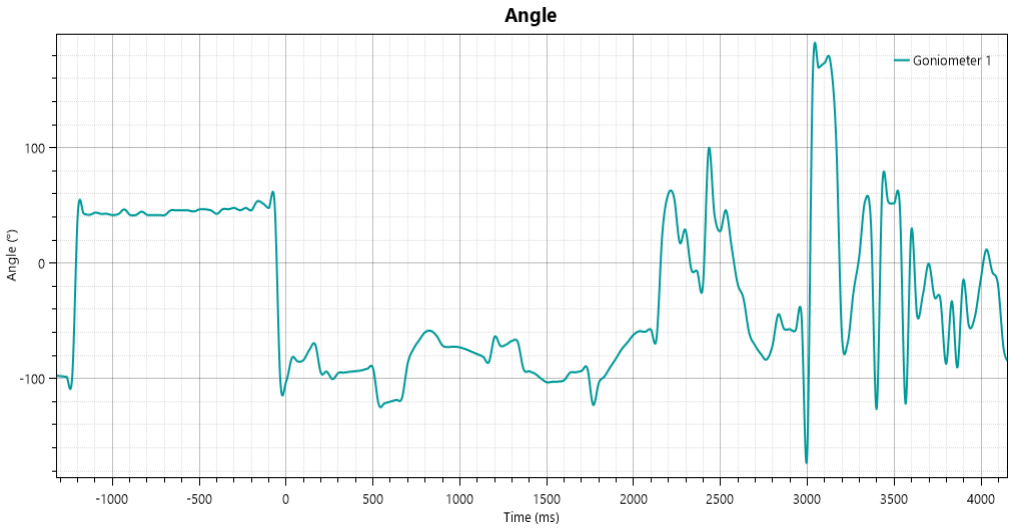
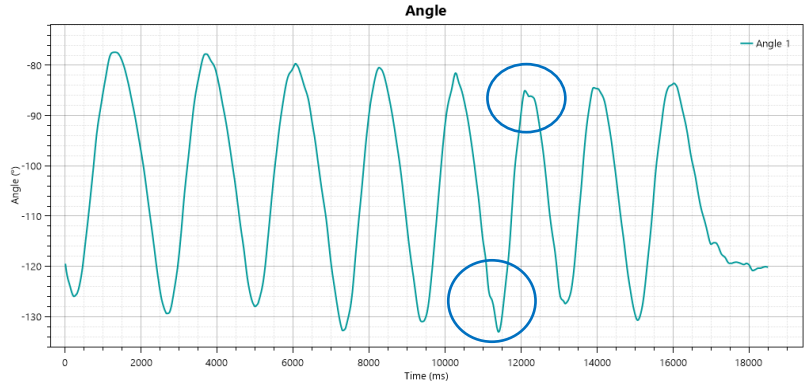
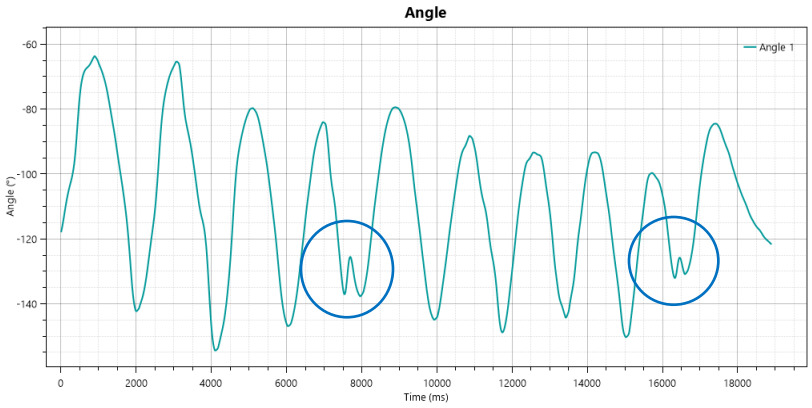


Figure 52 Resultant angle kinematics

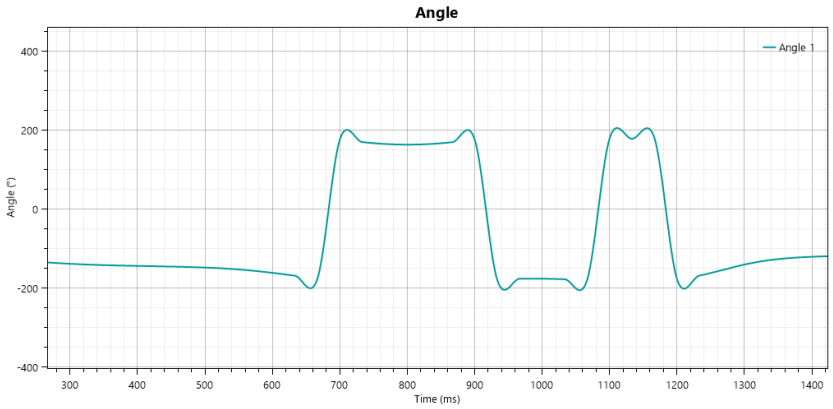
The continuous angle tracking tool traced relative knee joint angle. A few examples of the riders' output for these active trials are plotted below. The circles on Figure 53 (A) and (B) active biking angle graphs show unexpected irregularities in form of noise noticed during the analysis.



(A)



(B)



(C)

Figure 53 Resultant angle kinematics (A) trial 1, (B) trial 2, (C) trial 3

It was noted in Figure 54 that the three angle tracking tool points in Kinovea continued to shift and needed to be manually adjusted every other frame. We noted that the proximal end of the angle (flexible arm- dotted line) tracking point was more prone to shift than the other two. Figure 54 shows unexpected angle shifts throughout active biking trials.

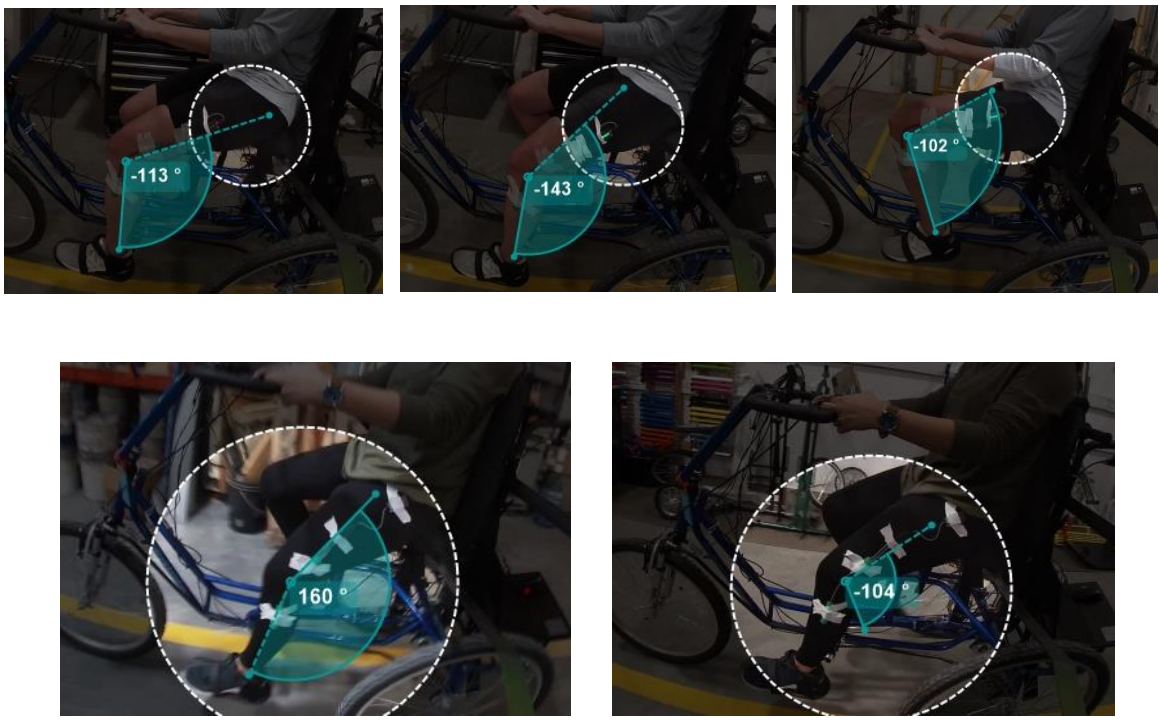
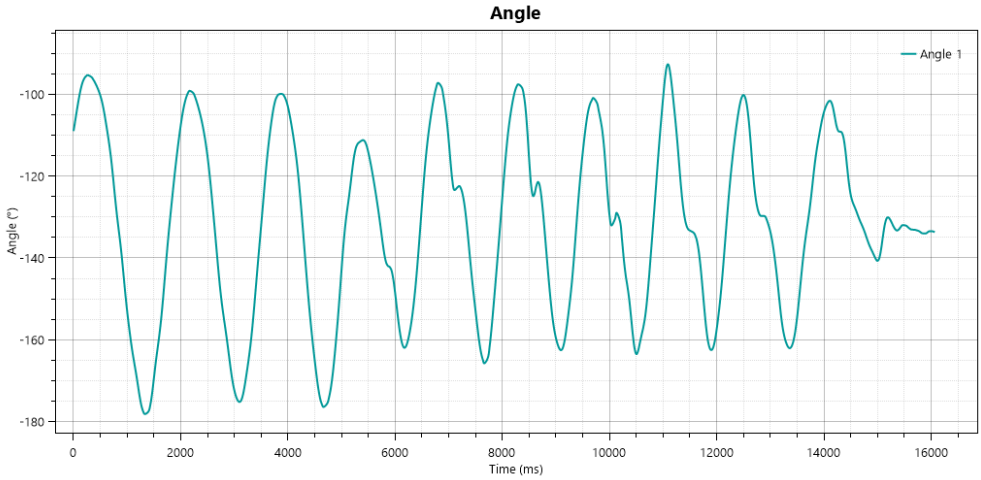


Figure 54 Random errors during ROM assessment- with physical markers

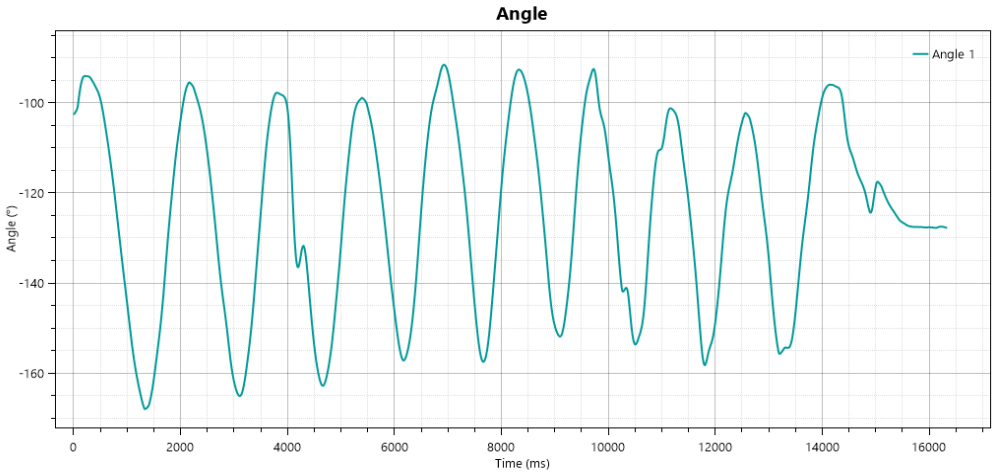
Similar errors were observed during the analysis of Rider II's data. Shifting of the angle tracking tool points was noted for Rider II's. In fact, all three points of the Kinovea angle tracking tool required manual readjustment in each frame. There appeared to be fewer errors in Rider II's data, likely due to the Kinovea system being able to use the Delsys marker system as a consistent point for tracking as Rider II was wearing black pants with the white markers attached whereas Rider I's marker system was less clearly distinguished.

Reliability Analysis:

To test the test-retest reliability of Kinovea Beta for assessing ROM during dynamic biking, each trial was assessed twice in the software to compare resultant angular kinematics. Figure 55 shows the comparison of trial 1 data with a re-assessment of trial 1.



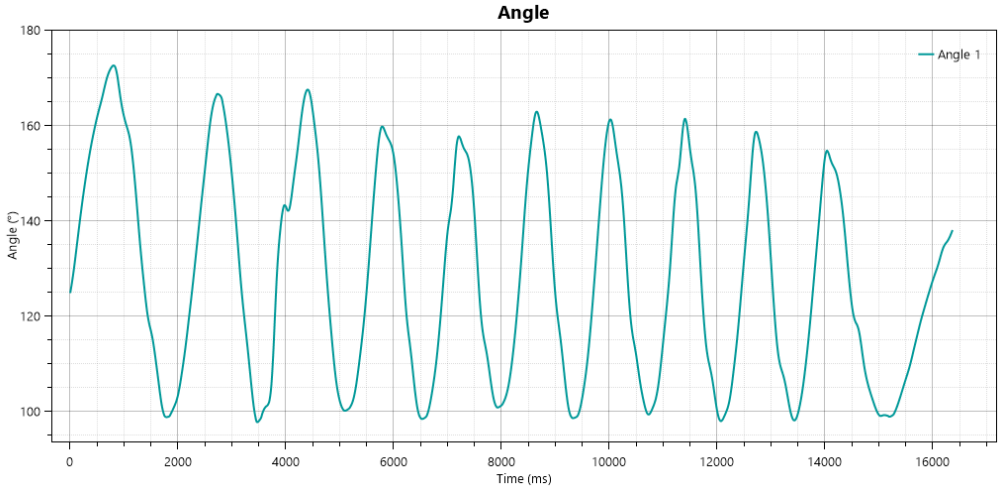
(A)



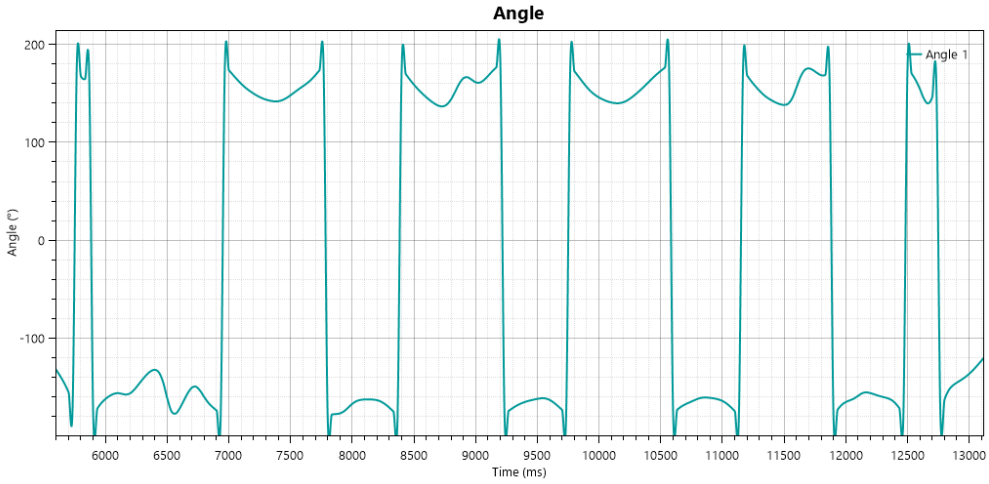
(B)

Figure 55 (A) assessment of trial 1 (B) re-assessment of trial 1

Figure 55 suggested differences between both assessment outputs even though both assessments were done for the same biking trial. Similarly, another active biking trial was also re-assessed in Kinovea beta and resultant angular kinematics are plotted in Figure 56.



(A)



(B)

Figure 56 (A) assessment of biking trial 3 (B) re-assessment of biking trial 3

Re-assessment of another active biking trial showed unexpected output. In this situation, the angle tracking tool points were required to be readjusted manually, at the points of complete knee flexion and knee extension of each cycle. At every crest and trough in the graph, an unusual curve was observed, due to the repositioning of the angle tracking tool points to its original position.

The above analysis revealed the challenges of using Kinovea beta to measure ROM during dynamic biking. To increase the accuracy of bilateral knee ROM measurement, two cameras, one mounted on each side of the bike would be required. With the setup of two separate cameras, two different sets of data, one for each knee, would need to be analyzed manually. It was concluded that the analysis process using Kinovea beta was cumbersome, time-consuming, and inaccurate in its automated process. For each frame (every 0.03s), the marker position required manual correction. After piloting use of Kinovea Beta, we concluded that all ROM measurements were subject to an additional degree of measurement inaccuracy due to potential human error in manual marking.

Altius Analytics Labs

Next, Altius Analytics Labs software was investigated. Output of all the biking trials was recorded. Using the Delsys® system data as comparison data (as it was collected via video at the same time), maximum knee flexion and maximum knee extension of each trial were manually entered in Microsoft Excel®. Like Kinovea beta, Altius Analytics Lab was used to assess the left knee joint angle only, as the left sagittal video was captured using the GoPro Hero 7.

The output of Altius is a sinusoidal waveform, and like Delsys®, a signal moving

towards zero represents extension and a signal moving away from zero signifies flexion. Maximum flexion and maximum extension for each trial were manually logged in Microsoft® Excel and plotted on a graph to estimate trial-trial variability. Visual representation of the data in Figure 57 indicates the maximum flexion and extension for each trial are similar to one another.

Figure 57 Altius output summary

The maximum knee flexion and extension data collected using the Altius system as compared to the Delsys® system are shown in Figures 58 and 59. Through visual inspection, the data from the active trials is within 1° of each other, whereas more variability in the output was observed in the passive trials (up to 9°).

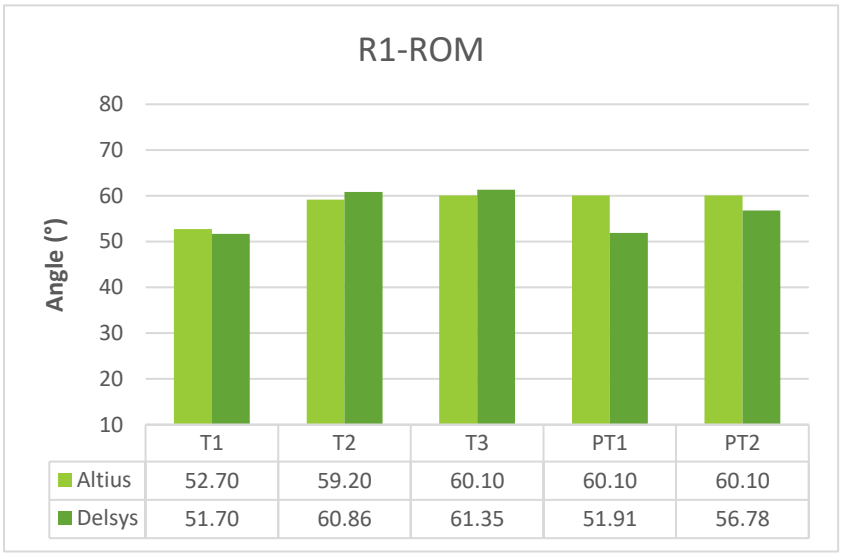


Figure 58 ROM comparison- Altius vs Delsys Rider I

For Rider II, there were more differences observed than with Rider I when comparing Altius with the Delsys® in the active biking trials. The discrepancy may be due to dropped packets during Rider I's trials 1 and 3 that may have caused data attenuation. The maximum flexion and extension data for those trials might not be reliable and therefore the resultant ROM may not correspond with other trials.

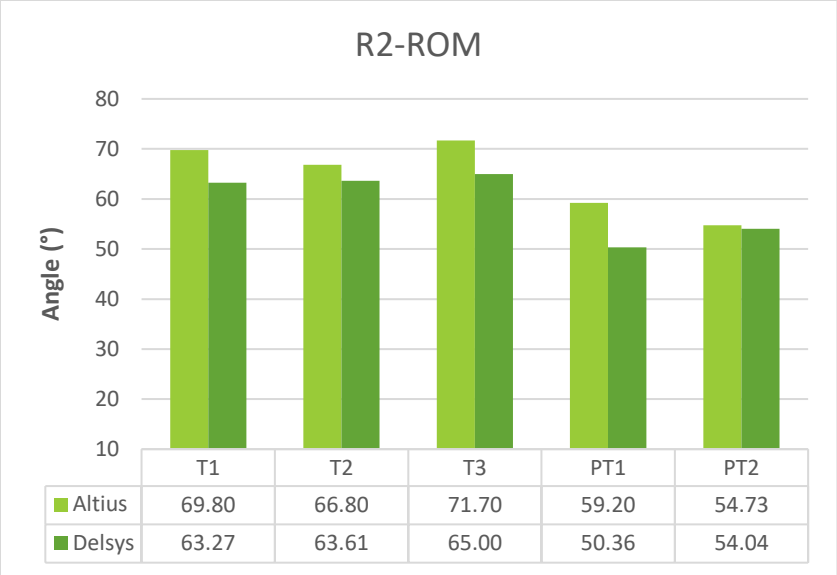


Figure 59 ROM comparison- Altius vs Delsys Rider II

Summary of Range of Motion Data

Considering the future study goals, we sought to identify a way of capturing knee ROM during active and passive biking that would be easy to use, accurate and reliable.

While Delsys® Trigno™ goniometer adapters and Biometrics SG150 twin-axis goniometer assembly demonstrated adequate output results for the study, assessment using Delsys® assembly required pre-preparation (i.e., calibration, sensor assembly placement, etc.), extensive training, and engineering knowledge to acquire and assess the output data. The Delsys® system setup did allow recording of bilateral knee ROM data, posing an advantage over Kinovea Beta and Altius Analytics Labs.

Kinovea beta, although user-friendly, provided an inaccurate assessment of knee ROM. This open-source software was found to be time and resource-demanding when a user is interested in assessing bilateral knee ROM. Having to set up two cameras, attached on either side

of the bike would increase the complexity of the adaptive bike set up and cause the bike to become cumbersome.

Figure 58 and 59 showed Altius data to be within +/- 10° error to the Delsys® but was found to provide much more flexibility in terms of assessment and, accessibility. Altius was found to be user-friendly, quick to learn, process and, does not require any expertise to conduct the data collection. Further advancement anticipated in the in software such as selected output and front view analysis will facilitate the data collection of bilateral knees in children with CP (B. Lee, personal communication, May 8, 2021). Detailed pros and cons of each system are summarized in the discussion section.

Postural Symmetry

The postural symmetry of each rider was assessed by studying pressure data, specifically pressure patterns on the pressure map, and CoP displacement. As discussed in the earlier outcome measure section, the mat was divided into two different segments (i.e., the seat base and the backrest) to analyze separately. However, prior foundational research (Ros, 2020) suggested that in the neuro-typical population, the backrest data had irrelevant and negligible values compared to the seat base and thus, we determined that the backrest data would not be subject to analysis. For the current feasibility study, pressure data was not segmented in the seat base and backrest for analysis, rather overall pressure data from the entire mat were analyzed and compared in the various trials. Considering that the future study population will be children with CP, it is likely that they may have different postures that include pressure patterns on the backrest and thus it was deemed essential to capture data from the whole mat rather than solely

the seat base.

Pressure Data

As the pressure mat was attached to the bike seat using lock straps on both sides of the mat to prevent the pressure mat from sliding, it was noted that the lock straps generated some pressure at the corners in the absence of the rider. Figure 60 shows the baseline lock strap pressure on the FSA mat.

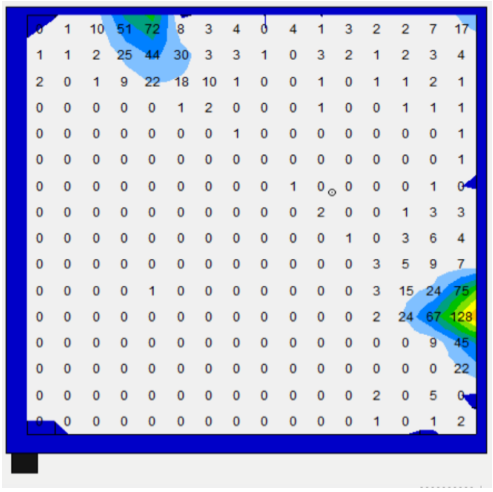


Figure 60 Locking strap pressure

To evaluate the effect of the locking strap pressure on the rider data, two separate analyses were performed (Figure 61). For the first scenario, the pressure mat was considered as a whole and the average pressure of the whole mat for each frame was plotted. For the second scenario, the seat base was manually selected excluding lock strap area, all zeros, and smaller values, and the average pressure data of only the selected seat base area was analyzed and plotted on a graph.

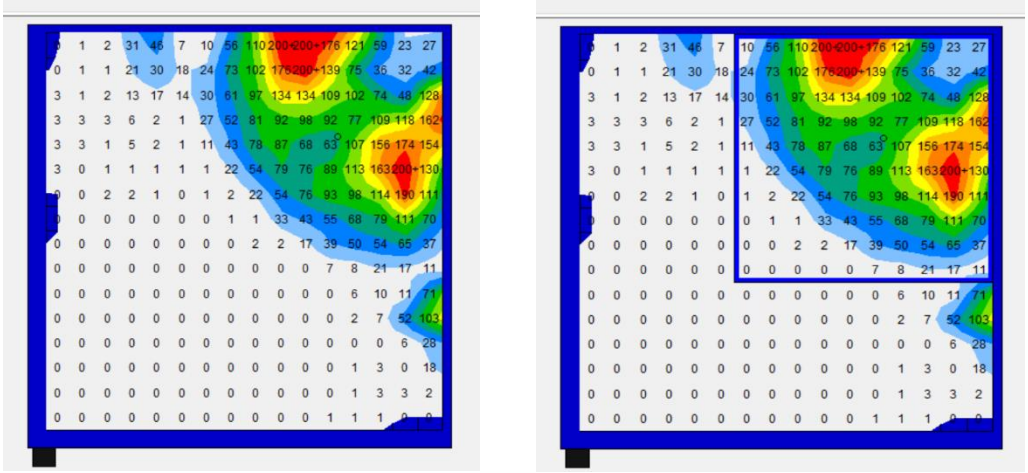


Figure 61 Whole mat vs selected seat area

Average pressure data of active biking trial was plotted in a graph (Figure 62). The x-axis represents frames. The y-axis of graph I represent average pressure across all 256 sensors on the mat, whereas the y-axis of graph II shows the average pressure of only selected sensors of the seat base. Both the graphs have similar waveform shapes for every instance of the frame and thus, it was concluded that the strap pressure did not interfere with the rider data.

In figure 62 both graphs show a similar pattern although, the average pressure values are elevated on y-axis when only the seat base area is considered. The whole mat pressure map graph suggests no data loss during analysis. Although more pressure exists in the seat base than any other area, it is important to consider the whole mat to monitor and consider pressure on any other part of the pressure map, if available, for any trial.

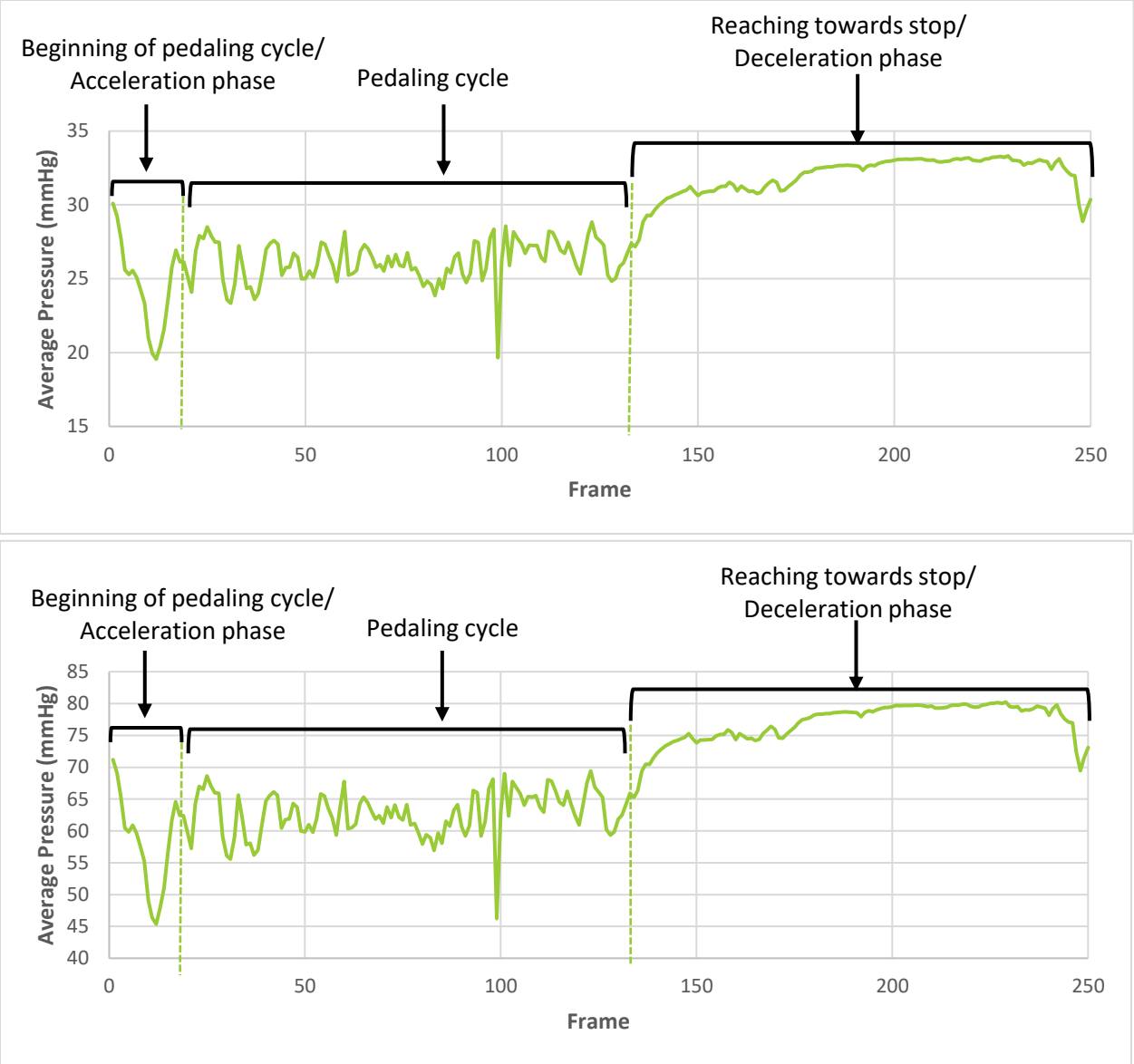


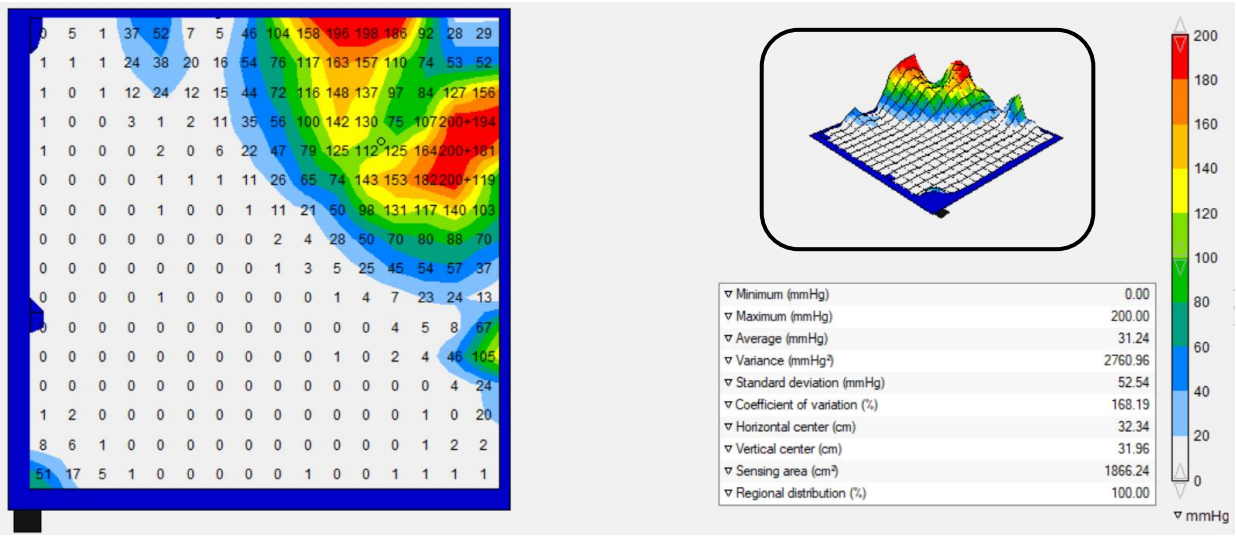
Figure 62 Pressure output comparison (A) whole mat (B) selected seat area

As can be seen, the graphs in Figure 62 are divided into three observational sections: the beginning of the pedaling cycle (acceleration phase), pedaling phase, and reaching towards stop (deceleration phase). At 0 on the x-axis, pressure on the seat was recorded while the rider was stationary. During the acceleration phase, the sharp decline in the graph suggests that the rider shifted her weight from the seat to exert pressure on the pedals to begin the acceleration phase.

As a result, there was average pressure diminution from 72mmHg to 45mmHg at the beginning of the pedaling cycle. The opposite occurred in the deceleration phase. As the rider approached the 30m finish line and stopped pedaling, the rider stopped applying force to the pedals and thus, pressure on the seat base gradually increased. The deceleration phase during the trial was noted to be the longest, containing 100 frames (from frame 150 to 250). This is because after several frames of pedaling the rider reached a certain speed and the deceleration phase consisted of coasting and braking.

Maximum Pressure

To understand the rider's engagement during biking, the lowest value from the mat's maximum pressure values was extracted. Figure (63) shows the pressure map of the rider's initial position. As can be seen, the rider's initial position contains the highest-pressure value on the mat i.e., 200mmHg. When the rider is actively engaged during biking, the pressure reduces.



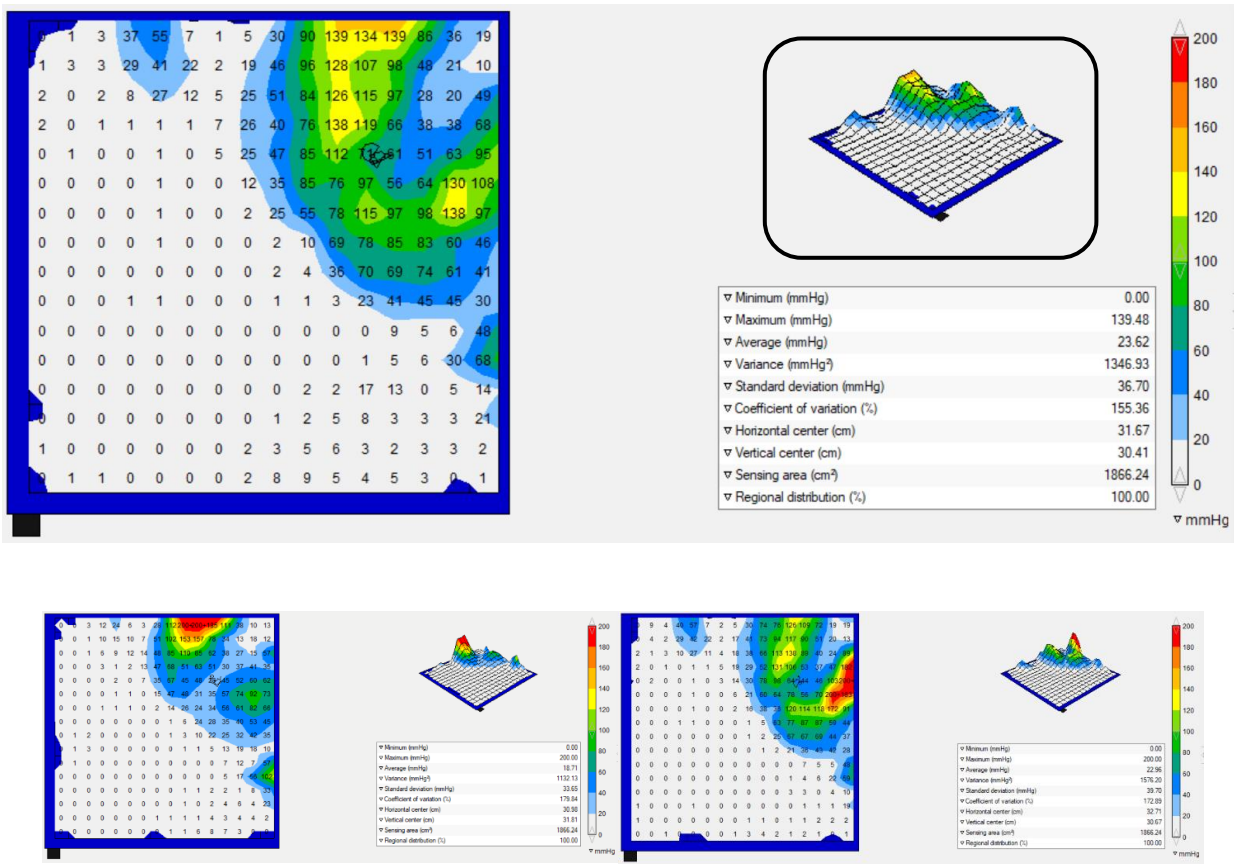
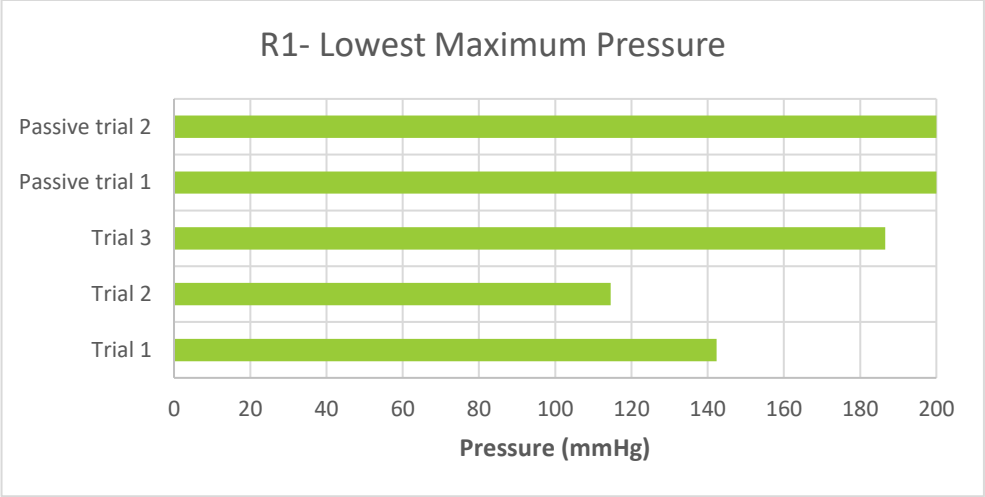


Figure 63 Pressure mapping during biking

The bar graph below depicts that, during the active biking trial, the rider was engaged in biking whereas during the passive biking trial, the rider had no active engagement. Thus, in the passive biking trials, the lowest maximum pressure from all the frame is 200 mmHg (i.e., the maximum pressure that can be recorded).



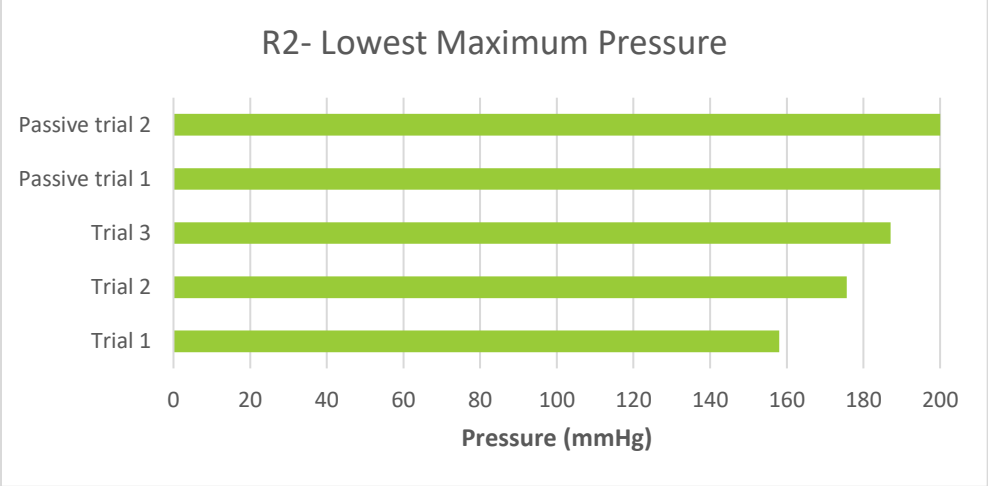


Figure 64 Lowest value of maximum pressure for each trial

Average Pressure

All three active trials and two passive trials were analyzed. The average pressure data for each trial were averaged and plotted in a bar graph for comparison. As seen in the graph, the average values during active trials were lower than the passive biking trials.

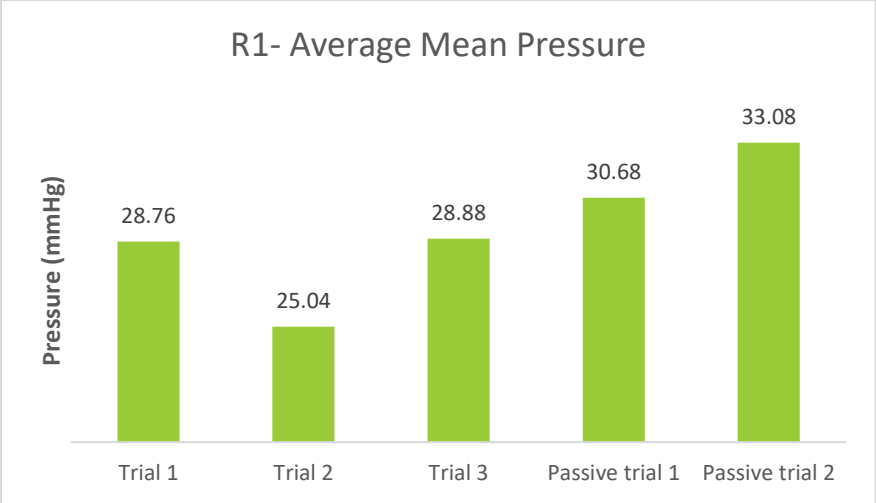


Figure 65 Average of mean pressure- Rider I

Average pressure value of the Rider II demonstrates the average values during active trials were lower than the passive biking trials. It was noted that Trial 1 and PT 1 are similar, likely due to the difficulty in simulating passive biking. This was less evident in PT 2, as perhaps the rider was more relaxed and allowed the bike to be pushed without applying any force to the pedals.

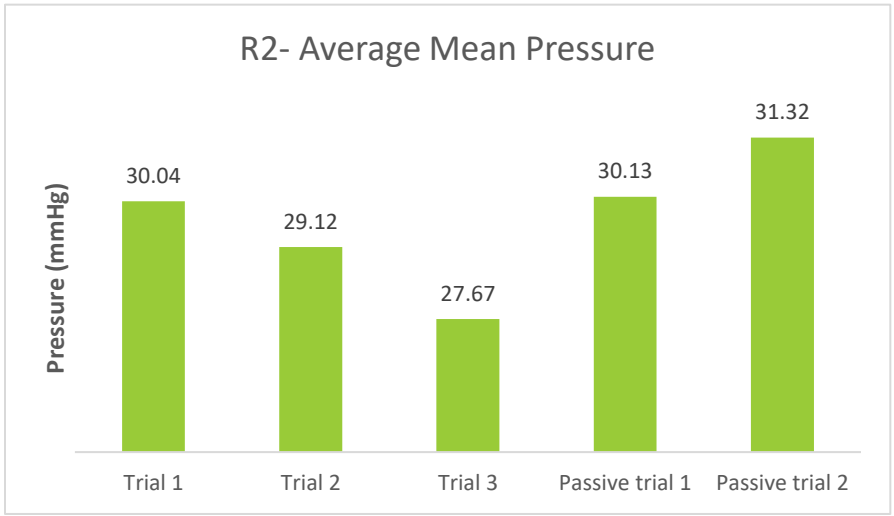


Figure 66 Average mean pressure- Rider II

Average pressure values of the active biking trial were plotted against the passive biking in Figure 67 to support the claim made in Figure 66. From the Figure 67, it can be seen that pressure values on the seat are lower during the active biking trial compared to the passive biking trial. The difference in time for biking shown by the different number of frames captured is attributed to the fact that, during passive biking, the rider was pushed by an assistant through the 30-meter biking track and thus reflects walking time.

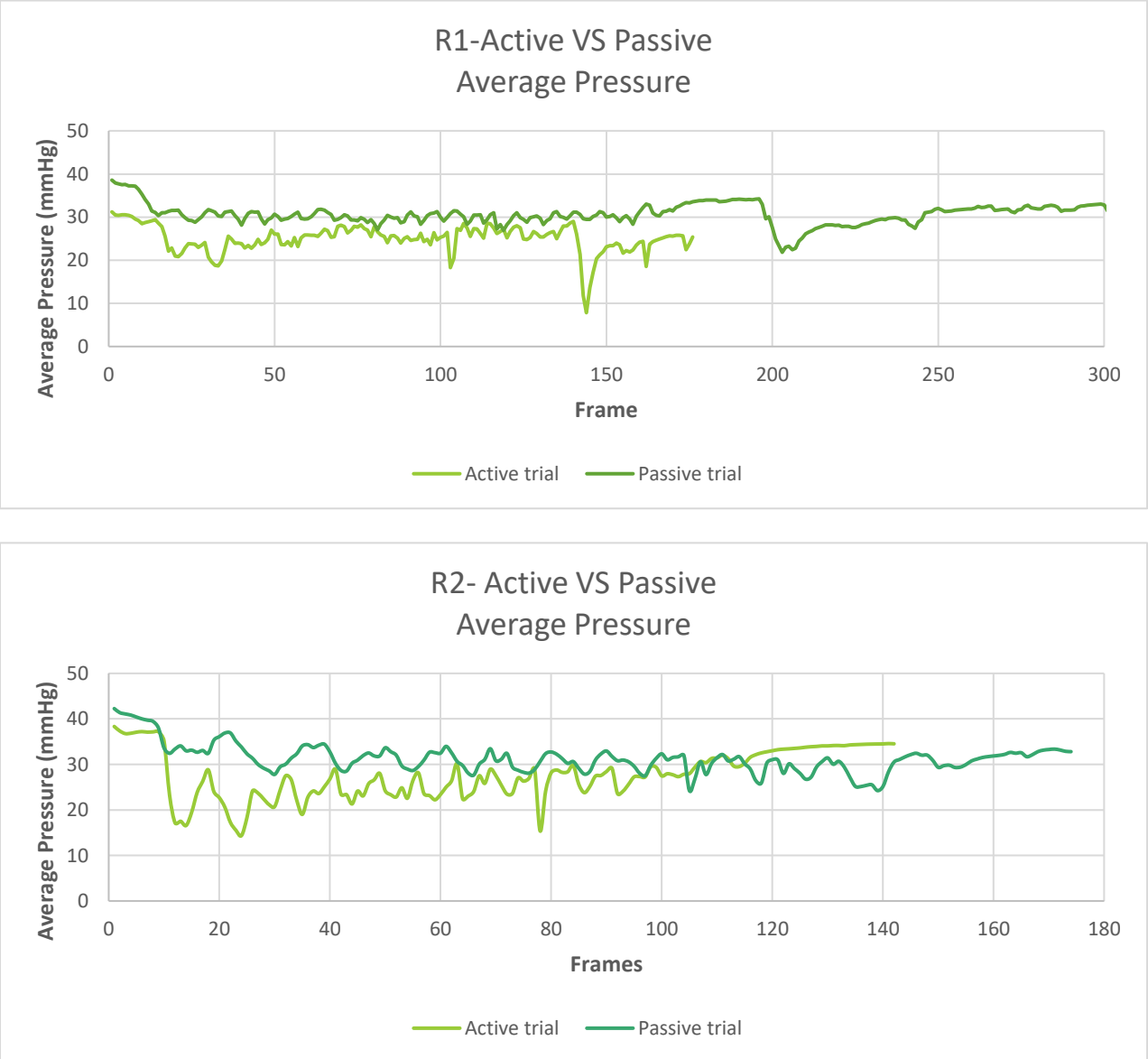


Figure 67 Active CoP vs passive CoP

Centre of Pressure (CoP)

To study the difference between active biking and passive biking trials, CoP values were obtained for all biking trials. During the passive biking trials, the rider sat comfortably on the bike holding the handlebars while an assistant pushed the bike from behind using the rear steer through the 30m of the path. The rider was asked to not apply any active pressure to the pedals and allow the pedals to rotate with no involvement of the rider. Thus, the rider did not displace pressure from the seat to the pedals. Visual inspection showed that displacement of CoP was more controlled and rhythmic in the passive biking trial, as compared to the active biking trial.

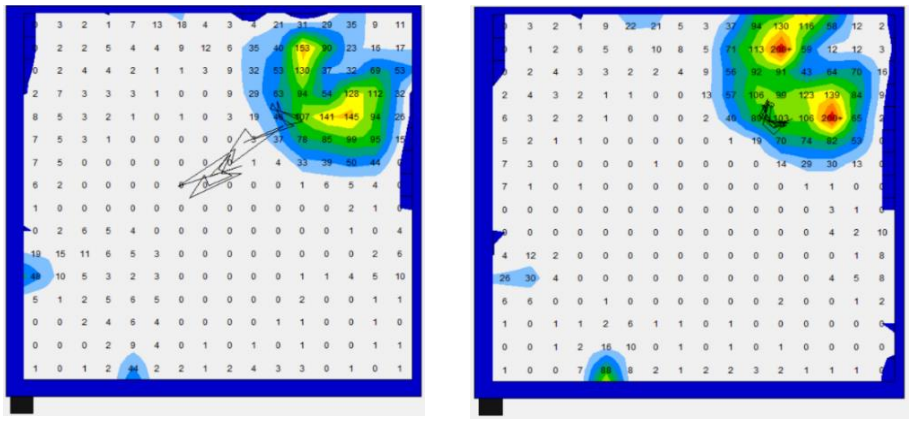


Figure 68 Active biking vs passive biking on contour plot

Figure 69 shows CoP values obtained for an active biking and a passive biking trial. As shown, the CoP values during the active biking trial ranged from 29mmHg to 120mmHg, whereas the passive biking trial CoP ranged from 115mmHg to 200mmHg.

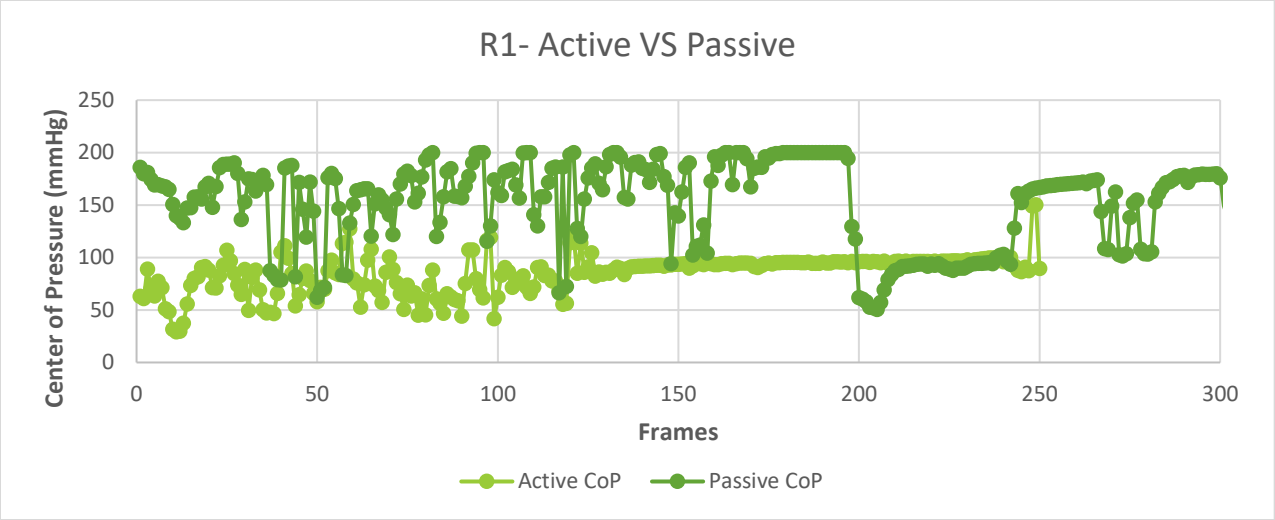


Figure 69 Active vs passive CoP plot- Rider I

Figure 70 shows CoP values obtained for active biking and passive biking trial for the Rider II. CoP values during the active biking trial range from 25mmHg to 80mmHg which is relatively low compared to the passive biking trial. CoP of the passive biking trial ranged from 70mmHg to 131mmHg.

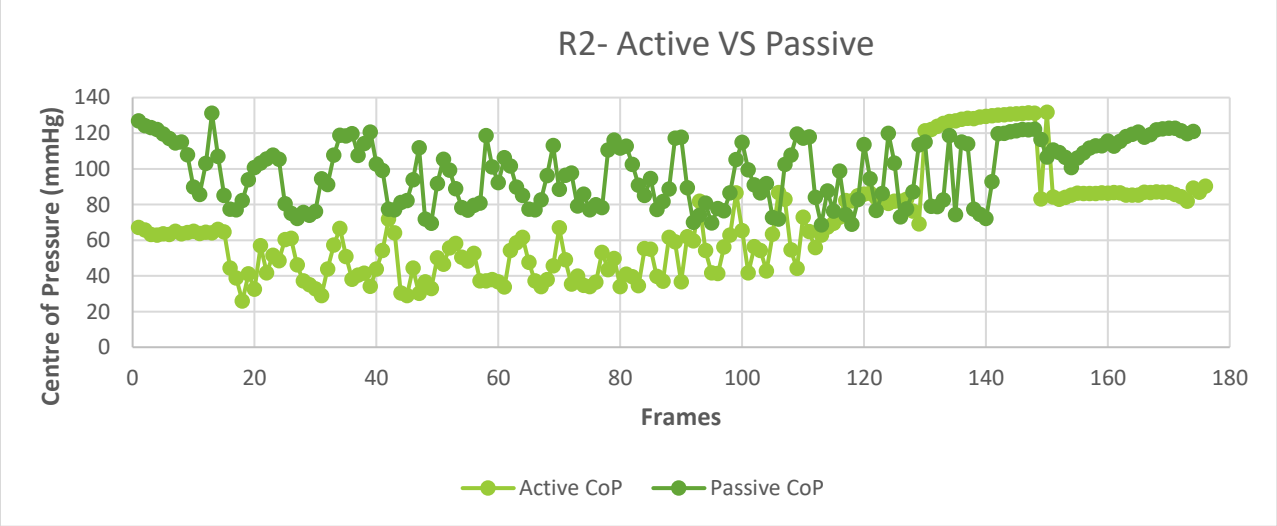


Figure 70 Active vs passive CoP plot- Rider II

Summary of Postural Symmetry Data

Visual and observational analysis was performed and completed on all the biking trials for both the riders. From the rider's initial position and pressure mapping data, it was concluded that the rider's active engagement in biking can be differentiated from passive biking. The instrumentation set-up used in the current feasibility study was selected after piloting and trialing the different methods of placement in different scenarios in the prior foundational study (Ros, 2020). After closely comparing and considering results from the pilot trials, the finalized study setup was confirmed. The mat used for this study and the previous study was wired and the research laptop was set on the bike attached to the pressure mat on the bike. BodiTrak produces a wireless version of the pressure mat. The pressure mat, specifically the wireless version, is recommended for the future study as it will provide insight into streamline assessment of pressure data as well as reduce the weight of the laptop attached to the bike and simplify remote data capture.

Enjoyment Evaluation

In the overall enjoyment of biking experience questionnaire, both the riders responded positively and gave a 4/5 score, indicating comfort and ease of riding an adaptive bike. In this case, the enjoyment evaluation questionnaire was independent and not a comparison with previous biking experience. In the next phase of this study, an additional question should be added to evaluate whether the rider enjoys biking at school or home; this will allow a comparison of the biking experience when using the assessment bike. After analyzing the results from all the performance measures, a protocol for the next phase of the study was developed (Appendix E).

Discussion

This feasibility study explored various methods of capturing a rider's physical performance while actively and passively biking on an adapted bike. While the original intent was to test the feasibility of these physical performance measures for children and adolescents with CP, due to COVID-19 restrictions, all data were collected on neuro-typical riders. Analysis and comparison of the different methods and data produced by those methods helped the researchers to understand challenges, clarify and interpret the output results, and consider the feasibility of these physical performance measures for capturing select physical performance of a rider. Through this study, the student researcher was able to establish the baseline protocol (Appendix E), and obtain ethical approval, for the next stage of this research to be conducted with children and adolescents with CP.

Physical Performance Measures

Power output assessment provided a wide range of human power variables, including torque, human watts, and pedal cadence. Torque data provided clear information regarding rider's biking performance. For example, negative torque values were reported when the rider was resisting the pedal movements to slow the bike. Overall torque output demonstrated features of the rider's biking pattern. However, assessment of power output was deemed to be difficult to interpret due to the data attenuation. The existing torque sensor unveiled many drawbacks of the system including limited threshold value, wired and bulky attachments to the bike, and difficulty with serially transmitting output to the laptop. For future research, wireless and technically advanced equipment that can evaluate low values of power output is recommended to capture all

the data throughout biking trials.

During the ROM data collection process, many challenges were encountered. Three different performance measures to assess ROM were tested. Pros and cons of each measure to evaluate ROM in a dynamic biking setting are outlined in Table 3 below.

Table 3 ROM performance measures- advantage vs disadvantage

DELSYS® Goniometer System	
Advantages	Disadvantages
Multi-axis angle tracking	Licensed system; Expensive
Widely used for dynamic angle tracking in research	20m wireless sensor range
Assess left and right knee ROM simultaneously	Engineering skill and training required to analyze the data
	Pre-calibration and preparation of goniometer adapters and sensors before data collection is required
	Might cause discomfort from the physical sensor tapped to a rider's skin

Kinovea Beta	
Advantages	Disadvantages
Open source software; No cost	Inaccurate dynamic joint angle tracking
Automated; No special skill or training was required to analyze the data	Manual manipulation of virtual joint markers during the data analysis was required
No calibration or pre-preparation required	Data analysis was time consuming and cumbersome; Data discrepancies
	Resource intensive (two cameras required to capture both left and right knee ROM)
	High risk for potential human error during assessment due to manual marking- causing inaccurate analyses

Altius Analytics Labs	
Advantages	Disadvantages
User friendly	Resource intensive (two cameras required to capture both left and right knee ROM)
No calibration or pre-preparation required	Large output file makes it difficult to extract essential data for analysis
No special skill or training required	High cost
Quick automated angle data analyses (2-3 min for 30sec video)	Potential breach of privacy as the data is analyzed elsewhere

The FSA pressure mapping system provided various outputs, including average pressure, minimum and maximum pressure, and displacement of CoP, that could be used to analyze a rider's positioning and postural displacement during biking. The FSA pressure mat required calibration before the bike assessment trial to minimize measurement inconsistency and to confirm accurate measurements. The major drawback of using the FSA wired pressure mat was the system's requirement to have a wired connection with an attached computer needed to capture data and the resultant need to attach the computer to the bike. This set up added weight

to the bike. A wireless mat is recommended for future intervention studies for improved data collection. Further suggestions are outlined in the engineering recommendation section.

Objectives- What was learned?

The study had three primary objectives.

Objective 1 stated that physical performance measures will be considered feasible if an instrument can collect 80% of the data from all the biking trials successfully. Selected physical performance measures, i.e., the FSA pressure sensing mat and the Altius analytics labs were found to be feasible to integrate with an adaptive bike. The NCTE_128BB, although was able to integrate into the adaptive bike and was accurate, did not provide low human output statistics such as human watts and pedal cadence during the initial biking phase. Altius Analytics Labs can be used to evaluate a rider's knee ROM in future intervention studies. Sensor-less and marker-less analysis of Altius assessed 30s video in 2 to 3 minutes.

Objective 2 was to test the accuracy and consistency of the tools to capture a rider's select physical performance while engaged in dynamic biking. As reviewed in the results section, accuracy, and consistency of NCTE_128BB was complicated to assess due to its limitation in collecting lower values. For both riders, the power output (human watts, pedal cadence, and torque profile) was found to replicate the cycling rhythm in all the biking trials. Hence, considering drawbacks of the system to attenuate low range output data, the NCTE_128BB is not a feasible tool to assess power output for the desired study population and intervention setting. The max flexion and max extension output from Altius were consistent through all the biking trials. Altius exhibited accuracy within approximately ± 10° when output visually compared with

the Delsys® system. The FSA system showed similar consistent output attributes for average pressure and CoP for both the riders. The average pressure output of the current feasibility study also strengthens the output of the foundational study done prior to the current study (Ros, 2020). The rider's enjoyment scale was deemed an appropriate and straightforward method of understanding a rider's comfort and experience of biking. In the next phase of this study (evaluation of biking with children with CP) it is recommended to add a question gauging their enjoyment of previous biking experiences prior to asking the question inquiring about their biking experience in the study. The differentiation may to customize features of the assessment bike for a rider's better experience.

Objective 3 was to establish and test the baseline protocol for a future intervention study of adapted biking. Both the riders were able to perform all three active biking trials and the two passive biking trials without any difficulty, and without taking any breaks. Based on the results of this study, the baseline protocol for the Phase II of the study was developed is outlined in Appendix E.

Given the findings of the case study conducted by Daly et al. (2019), that the use of an adaptive bike promotes physical health in children with CP, this study sought to explore the use of available technology and resources to better understand the effects of adapted biking on physical performance. As this study was not conducted with children with CP, direct comparison with existing literature regarding biking by children with CP could not occur. However, the present study adds to the existing literature by introducing novel techniques and assessment tools to capture various physical performance during adaptive biking that will be used in a future study of children with CP .

Engineering Recommendations

The results of this study indicated the feasibility of selected tools to effectively capture a rider's physical performance. For future research, using the most updated version of these tools will provide a better opportunity for a clinician to capture and analyze data with relative ease. For example, instead of using a wired pressure mat, a wireless FSA pressure mat will lighten the bike weight and ease data collection.

Data collected from the NCTE_128BB torque sensor were not useful for this setting due to the sensor's limitation to capture data at low values. The NCTE_128BB captured only left leg power data and the sensor's inability to track data throughout the trial makes the system not likely to be able to capture comprehensive data. Collecting data using NCTE_128BB was also difficult. Along with managing the system, a user is required to manage software for serial transmission of output. Data cannot be saved and instead must be manually entered in an excel sheet. This serial transmission allowed only limited rows to be saved and the remaining data can be mismanaged if not extracted accurately. Further research is recommended to determine the effectiveness of other power meters. Capturing power output during low human power output will be essential for future studies with this population. Ideally, the power output would be captured for each leg separately as strength in each leg for children with CP may vary. Further investigation is required to obtain and test another human power meter for its accuracy and threshold values.

Evaluation of knee ROM during dynamic biking proved to be demanding. A stable video capture set up needed to be constructed, consisting of the Go Pro on a jaw clamp with a customized metal frame to capture a sagittal full body view of the rider. Altius was identified as

the best option, given the lack of needing to place sensors on the limbs, the automation, and the data accuracy. Unlike the Delsys® goniometer assembly and Kinovea Beta, Altius also proved to be the most user-friendly for analyzing the data.

The FSA mat exhibited consistent performance and as expected by previous testing. Except for the need for frequent calibration, the FSA produced robust data in each trial. Boditrak (Vista Medicals) offers two different wireless pressure mats: Boditrak Pro and BodiTrak Lite. BodiTrak Pro is specifically designed as a tool for research. The system allows a user to export the data to Excel for further analysis. BodiTrak Lite is designed to only allow for visual inspection. Data from Boditrak Lite cannot be extracted for any further manipulation or analysis. The company can further customize the mat in different sizes and can provide a separate mat for the seat and the backrest. Thus, for the Phase II of the research BodiTrak Pro seat and back mats, 12x12 (for seat) and 16x16 (for backrest), is recommended.

Research Implications

Conducting a small pilot study with children with CP to test the data collection configurations is the recommended next step. In Phase II of this study, physical performance data will be captured using the recommendations emerging from the current study that explored feasibility of various instruments and configurations. The protocol for proposed pilot study follows in Appendix E: this study protocol was approved by the University of Manitoba Health Research Ethics Board (HS23582; H2020:024).

Conclusion

Although limited, various studies had reported that biking could improve physical and psychosocial function of children with CP (Bryant et al., 2013; Daly et al., 2017; Hayden, 2016; Shikako-Thomas et al., 2014; Visser et al., n.d., 2014). However, existing studies had used primarily clinical outcome measures that did not capture details of performance, nor the dynamic aspects of biking. In the current study, various technologies were explored for their feasibility in capturing some aspects of physical performance when using an adaptive bike. After a thorough analysis of the measures, recommendations were made to measure the physical performance of the rider. For those measures that were found to be unfeasible in the given setting, further investigation of other options is required.

The current preliminary work introduced the use of technology to assess human performance with ease, speed, accuracy, and reliability. Just as technology has made day-to-day lives better, faster, and easier, similarly, use of technology in this area of research can make data collection and analysis better, faster, and easier. Given the novelty of this area, careful validity and reliability evaluation of these tools is crucial prior to using them in future intervention study.

Finally, the current study led to specific recommendations for moving to the next phase of data collection with children and adolescents with CP and the development of a research protocol. Further pilot research is recommended to determine the effectiveness of adaptive biking on the physical performance of children with CP.

References

Aisen, M. L., Kerkovich, D., Mast, J., Mulroy, S., Wren, T. A. L., Kay, R. M., & Rethlefsen, S. A. (2011). Cerebral palsy: Clinical care and neurological rehabilitation. *The Lancet Neurology*, *10*(9), 844–852. https://doi.org/10.1016/S1474-4422(11)70176-4

Alhammoud, M., Hansen, C., Meyer, F., Hautier, C., & Morel, B. (2020). On-Field ski kinematic according to leg and discipline in elite alpine skiers. *Frontiers in Sports and Active Living*, *2*(May), 1–14. https://doi.org/10.3389/fspor.2020.00056

Angeli, J., & Foster, E. (2017). Bicycling in children with movement-disorders: postural control changes. *Developmental Medicine & Child Neurology*, *59*, 50–50. https://doi.org/10.1111/dmcn.75_13511

Bermejo-Cantarero, A., Álvarez-Bueno, C., Martinez-Vizcaino, V., García-Hermoso, A., Isabel Torres-Costoso, A., & Sánchez-López, M. (2017). Association between physical activity, sedentary behavior, and fitness with health related quality of life in healthy children and adolescents: A protocol for a systematic review and meta-analysis. *Medicine (United States)*, *96*(12), 1–10. https://doi.org/10.1097/MD.0000000000006407

Bertucci, W., Grappe, F., Girard, A., Betik, A., & Rouillon, J. D. (2005). Effects on the crank torque profile when changing pedalling cadence in level ground and uphill road cycling. *Journal of Biomechanics*, *38*(5), 1003–1010. https://doi.org/10.1016/j.jbiomech.2004.05.037

BodiTrak. (n.d.). https://www.boditrak.com/products/medical/wheelchair/pro.php#top

Brogren, E., Hadders-Algra, M., & Forssberg, H. (1998). Postural control in sitting children with

cerebral palsy. *Neuroscience and Biobehavioral Reviews*, *22*(4), 591–596. https://doi.org/10.1016/S0149-7634(97)00049-3

Bryant, E., Pountney, T., Williams, H., & Edelman, N. (2013). Can a six-week exercise intervention improve gross motor function for non-ambulant children with cerebral palsy? A pilot randomized controlled trial. *Clinical Rehabilitation*, *27*(2), 150–159. https://doi.org/10.1177/0269215512453061

CanChild. (n.d.). Retrieved June 7, 2018, from https://www.canchild.ca/en/diagnoses/cerebral-palsy

Case-Smith, J. (1985). *Occupational therapy for children* (K. Falk & M. Kuster-Deutsch (Eds.); fifth). Elsevier Mosby.

Clutterbuck, G., Auld, M., & Johnston, L. (2019). Active exercise interventions improve gross motor function of ambulant/semi-ambulant children with cerebral palsy: a systematic review. *Disability and Rehabilitation*, *41*(10), 1131–1151. https://doi.org/10.1080/09638288.2017.1422035

Crompton, J., Galea, M. P., & Phillips, B. (2007). Hand-held dynamometry for muscle strength measurement in children with cerebral palsy. *Developmental Medicine and Child Neurology*, *49*(2), 106–111. https://doi.org/10.1111/j.1469-8749.2007.00106.x

Daly, C., Haneline, C., Johannes, S., Middleton, J., & Kenyon, L. (2016). A school-based intervention to improve fitness and function in severe cerebral palsy: A pilot study. *2016 Academy of Pediatric Physical Therapy Annual Conference*. https://doi.org/10.1097/PEP.0000000000000323

Daly, C., Moore, C. L., Johannes, S., Middleton, J., & Kenyon, L. K. (2020). Pilot evaluation of a school-based programme focused on activity, fitness, and function among children with cerebral palsy at GMFCS level IV: Single-subject research design. *Physiotherapy Canada*, *72*(2), 195–204. https://doi.org/10.3138/ptc-2018-0053

Delsys Incorporation. (n.d.). *Delsys Wearable Sensors for Movement Sciences*. https://delsys.com/trigno-goniometer-adapter/

Deng, D. (2015). Li-ion batteries: Basics, progress, and challenges. *Energy Science and Engineering*, *3*(5), 385–418. https://doi.org/10.1002/ese3.95

Dewar, R., Love, S., & Johnston, L. M. (2015). Exercise interventions improve postural control in children with cerebral palsy: A systematic review. *Developmental Medicine and Child Neurology*, *57*(6), 504–520. https://doi.org/10.1111/dmcn.12660

Dodd, K. J., Taylor, N. F., & Graham, H. K. (2003). A randomized clinical trial of strength training in young people with cerebral palsy. *Developmental Medicine and Child Neurology*, *45*(10), 652–657. https://doi.org/10.1017/S0012162203001221

Dussault-picard, C., Houle, E., Parent, A., Pouliot-laforte, A., Cherriere, C., Lemay, M., & Ballaz, L. (2016). Locomotion efficiency while riding an adapted tricycle compared to walking in children with cerebral palsy: Preliminary results. *Gait & Posture*, *49S*, 231. https://doi.org/10.1016/j.gaitpost.2016.07.284

Eken, M. M. (2017). *Lower limb muscle endurance and muscle strength in children and adolescents with cerebral palsy* [VU University Medical Center]. https://revalidatiegeneeskunde.nl/sites/default/files/attachments/Wetenschap/Promoties/2017/maaike_eken_thesisindesign_eken_definitief_vkl.pdf

Eldridge, S. M., Lancaster, G. A., Campbell, M. J., Thabane, L., Hopewell, S., Coleman, C. L., & Bond, C. M. (2016). Defining feasibility and pilot studies in preparation for randomised controlled trials: Development of a conceptual framework. *PLoS ONE*, *11*(3), 1–22. https://doi.org/10.1371/journal.pone.0150205

Fowler, E., Knutson, L., DeMuth, S., Sugi, M., Siebert, K., Simms, V., Azen, S., & Winstein, C. (2007). Pediatric endurance and limb strengthening for children with cerebral palsy (PEDALS) - A randomized controlled trial protocol for a stationary cycling intervention. *BMC Pediatrics*, *7*, 1–37. https://doi.org/10.1186/1471-2431-7-14

Fowler, E., Kolobe, T., Damiano, D., Thorpe, D., Morgan, D., Brunstrom, J., Coster, W., Henderson, R., Pitetti, K., Rimmer, J., Rose, J., & Stevenson, R. (2007). Promotion of physical fitness and prevention of secondary conditions for children with cerebral palsy: Section on pediatrics research summit proceedings. *Physical Therapy*, *87*(11), 1495–1510. https://doi.org/10.2522/ptj.20060116

Freedom Concepts Inc. (n.d.). https://www.freedomconcepts.com/

Furrer, M., Bichsel, L., Niederer, M., Baur, H., & Schmid, S. (2015). Validation of a smartphone-based measurement tool for the quantification of level walking. *Gait and Posture*, *42*(3), 289–294. https://doi.org/10.1016/j.gaitpost.2015.06.003

Garmin Power Pedals. (n.d.). https://buy.garmin.com/en-CA/CA/p/658594

Glassbrook, D. J., Helms, E. R., Brown, S. R., & Storey, A. G. (2017). A Review of the biomechanical differences between the high-bar and low-bar back-squat. *Journal of Strength and Conditioning Research*, *31*(9), 2618–2634. https://doi.org/10.1519/JSC.0000000000002007

Goudriaan, M., Nieuwenhuys, A., Schless, S. H., Goemans, N., Molenaers, G., & Desloovere, K. (2018). A new strength assessment to evaluate the association between muscle weakness and gait pathology in children with cerebral palsy. *PLoS ONE*, *13*(1), 1–22. https://doi.org/10.1371/journal.pone.0191097

Grigg, J., Haakonssen, E., Rathbone, E., Orr, R., & Keogh, J. W. L. (2018). The validity and intra-tester reliability of markerless motion capture to analyse kinematics of the BMX supercross gate start. *Sports Biomechanics*, *17*(3), 383–401. https://doi.org/10.1080/14763141.2017.1353129

Hannah, R., Minshull, C., Buckthorpe, M. W., & Folland, J. P. (2012). Explosive neuromuscular performance of males versus females. *Experimental Physiology*, *97*(5), 618–629. https://doi.org/10.1113/expphysiol.2011.063420

Hayden, D. M. (2016). *Effects of adapted tricycles on quality of life, activities, and participation in children with special needs* (Issue April). East Carolina University. https://thescholarship.ecu.edu/handle/10342/5649

Jakobsen, T. L., Jakobsen, M. D., Andersen, L. L., Husted, H., Kehlet, H., & Bandholm, T. (2019). Quadriceps muscle activity during commonly used strength training exercises shortly after total knee arthroplasty: implications for home-based exercise-selection. *Journal of Experimental Orthopaedics*, *6*(1). https://doi.org/10.1186/s40634-019-0193-5

Janssen, I., & LeBlanc, A. G. (2010). Systematic review of the health benefits of physical activity and fitness in school-aged children and youth. *International Journal of Behavioral Nutrition and Physical Activity*, *7*. https://doi.org/10.1186/1479-5868-7-40

Knoll, M. G., Davidge, M., Wraspir, C., & Korak, J. A. (2019). Comparisons of single leg squat

variations on lower limb muscle activation and center of pressure alterations. *International Journal of Exercise Science*, *12*(1), 950–959. http://www.ncbi.nlm.nih.gov/pubmed/31523343%0Ahttp://www.pubmedcentral.nih.gov/articlerender.fcgi?artid=PMC6719809

Kumar, Y., Yen, S. C., Tay, A., Lee, W., Gao, F., Zhao, Z., Li, J., Hon, B., Xu, T. T. M., Cheong, A., Koh, K., Ng, Y. S., Chew, E., & Koh, G. (2015). Wireless wearable range-of-motion sensor system for upper and lower extremity joints: A validation study. *Healthcare Technology Letters*, *2*(1), 12–17. https://doi.org/10.1049/htl.2014.0100

Lacoste, M., Therrien, M., Côté, J. N., Shrier, I., Labelle, H., & Prince, F. (2006). Assessment of seated postural control in children: Comparison of a force platform versus a pressure mapping system. *Archives of Physical Medicine and Rehabilitation*, *87*(12), 1623–1629. https://doi.org/10.1016/j.apmr.2006.08.344

Lang, C. E., Barth, J., Holleran, C. L., Konrad, J. D., & Bland, M. D. (2020). Implementation of wearable sensing technology for movement: Pushing forward into the routine physical rehabilitation care field. *Sensors (Switzerland)*, *20*(20), 1–21. https://doi.org/10.3390/s20205744

Lee, S. P., Bailey, J. P., Smith, J. A., Barton, S., Brown, D., & Joyce, T. (2018). Adaptations of lumbar biomechanics after four weeks of running training with minimalist footwear and technique guidance: Implications for running-related lower back pain. *Physical Therapy in Sport*, *29*, 101–107. https://doi.org/10.1016/j.ptsp.2016.11.004

Lerman, J., Sullivan, E., Barnes, D., & Haynes, R. (2005). The Pediatric Outcomes Data Collection Instrument (PODCI) and functional assessment of patients with unilateral upper

extremity deficiencies. *Journal of Pediatric Orthopaedics*, *25*(3), 405–407. https://doi.org/10.1097/01.bpo.0000149866.80894.70

Logar, S. (2012). Psychological factors in children with cerebral palsy and their families. *Eastern Journal of Medicine*, *17*(4), 204–212.

MacKenzie, S. J., Lavers, R. J., & Wallace, B. B. (2014). A biomechanical comparison of the vertical jump, power clean, and jump squat. *Journal of Sports Sciences*, *32*(16), 1576–1585. https://doi.org/10.1080/02640414.2014.908320

Massion, J. (1998). Postural control systems in developmental perspective. *Neuroscience and Biobehavioral Reviews*, *22*(4), 465–472. https://doi.org/10.1016/S0149-7634(97)00031-6

National Institute of Neurological Disorder and Stroke. (2020). https://www.ninds.nih.gov/Disorders/Patient-Caregiver-Education/Hope-Through-Research/Cerebral-Palsy-Hope-Through-Research

Nwaobi, O. M. (1987). Seating orientations and upper extremity function in children with cerebral palsy. *Physical Therapy*, *67*(8), 1209–1212. https://doi.org/10.1093/ptj/67.8.1209

Oeffinger, D. J., Tylkowski, C. M., Rayens, M. K., Davis, R. F., Gorton, G. E., D'Astous, J., Nicholson, D. E., Damiano, D. L., Abel, M. F., Bagley, A. M., & Luan, J. (2004). Gross motor function classification system and outcome tools for assessing ambulatory cerebral palsy: A multicenter study. *Developmental Medicine and Child Neurology, 46*(5), 311–319. https://doi.org/10.1017/S0012162204000519

Orsmond, G. I., & Cohn, E. S. (2015). The distinctive features of a feasibility study: Objectives and guiding questions. *OTJR Occupation, Participation and Health*, *35*(3), 169–177.

https://doi.org/10.1177/1539449215578649

Ortega, F. B., Ruiz, J. R., Castillo, M. J., & Sjöström, M. (2008). Physical fitness in childhood and adolescence: A powerful marker of health. *International Journal of Obesity*, *32*(1), 1–11. https://doi.org/10.1038/sj.ijo.0803774

O'Shea, T. M. (2008). Diagnosis, treatment, and prevention of cerebral palsy. *Clinical Obstetrics and Gynecology*, *51*(4), 816–828. https://doi.org/10.1097/GRF.0b013e3181870ba7

Patel, D. R., Neelakantan, M., Pandher, K., & Merrick, J. (2020). Cerebral palsy in children: A clinical overview. *Translational Pediatrics*, *9*(1), S125–S135. https://doi.org/10.21037/tp.2020.01.01

Pearson, N., Naylor, P. J., Ashe, M. C., Fernandez, M., Yoong, S. L., & Wolfenden, L. (2020). Guidance for conducting feasibility and pilot studies for implementation trials. *Pilot and Feasibility Studies*, *6*(1), 1–12. https://doi.org/10.1186/s40814-020-00634-w

Pickering, D., Horrocks, L., Visser, K. S., & Todd, G. (2013a). "Every picture tells a story": Interviews and diaries with children with cerebral palsy about adapted cycling. *Journal of Paediatrics and Child Health*, *49*(12), 1040–1044. https://doi.org/10.1111/jpc.12289

Pickering, D., Horrocks, L., Visser, K., & Todd, G. (2013b). Adapted bikes - what children and young people with cerebral palsy told us about their participation in adapted dynamic cycling. *Disability and Rehabilitation: Assistive Technology*, *8*(1), 30–37. https://doi.org/10.3109/17483107.2012.680942

Pioneer Electronics. (n.d.). https://www.pioneerelectronics.ca/POCEN/Cycle+Sports/Power+Meters/SBT-

PM91+SERIES+POWER+METER

Power2Max. (n.d.). https://power2max.cc/

Przepiorka, A. M., & Blachnio, A. P. (2017). The relationships between personality traits and leisure time activities: development of the Leisure Time Activity Questionnaire (LTAQ). *Neuropsychiatry*, *07*(06), 1035–1046. https://doi.org/10.4172/neuropsychiatry.1000313

Puig-Diví, A., Escalona-Marfil, C., Padullés-Riu, J. M., Busquets, A., Padullés-Chando, X., & Marcos-Ruiz, D. (2019). Validity and reliability of the Kinovea program in obtaining angles and distances using coordinates in 4 perspectives. *PLoS ONE*, *14*(6), 1–14. https://doi.org/10.1371/journal.pone.0216448

Redler, L. H., Watling, J. P., Dennis, E. R., Swart, E., & Ahmad, C. S. (2016). Reliability of a field-based drop vertical jump screening test for ACL injury risk assessment. *Physician and Sportsmedicine*, *44*(1), 46–52. https://doi.org/10.1080/00913847.2016.1131107

Roostaei, M., Baharlouei, H., Azadi, H., & Fragala-Pinkham, M. A. (2017). Effects of aquatic intervention on gross motor skills in children with cerebral palsy: A systematic review. *Physical and Occupational Therapy in Pediatrics*, *37*(5), 496–515. https://doi.org/10.1080/01942638.2016.1247938

Ros, A. C. (2020). *Instrumentation and assessment of an adaptive bike for tracking physical performance of children with disability* (Issue July). https://upcommons.upc.edu/handle/2117/333600

Rosenbaum, P. (2014). What causes cerebral palsy? *BMJ (Online)*, *349*, 5–7. https://doi.org/10.1136/bmj.g4294

Sahin, N., Baskent, A., Ugurlu, H., & Berker, E. (2008). Isokinetic evaluation of knee extensor/flexor muscle strength in patients with hypermobility syndrome. *Rheumatology International*, *28*(7), 643–648. https://doi.org/10.1007/s00296-007-0493-4

Shikako-Thomas, K., Kolehmainen, N., Ketelaar, M., Bult, M., & Law, M. (2014). Promoting leisure participation as part of health and well-being in children and youth with cerebral palsy. *Journal of Child Neurology*, *29*(8), 1125–1133. https://doi.org/10.1177/0883073814533422

Siebert, K. L., Demuth, S. K., Knutson, L. M., & Fowler, E. G. (2010). Stationary cycling and children with cerebral palsy: Case reports for two participants. *Physical and Occupational Therapy in Pediatrics*, *30*(2), 125–138. https://doi.org/10.3109/01942630903578399

Toovey, R., Spittle, A. J., Nicolaou, A., McGinley, J. L., & Harvey, A. R. (2019). Training two-wheel bike skills in children with cerebral palsy: A practice survey of therapists in Australia. *Physical & Occupational Therapy In Pediatrics*, *39*(6), 580–597. https://doi.org/10.1080/01942638.2019.1585404

Visser, A., Westman, M., Otieno, S., & Kenyon, L. (2017). A home-based body weight-supported treadmill program for children with cerebral palsy: A pilot study. *Pediatric Physical Therapy*, *29*(3), 223–229. https://doi.org/10.1097/PEP.0000000000000406

Visser, K., Pickering, D., Todd, G., & Horrocks, L. (2014). Adapted cycling physical health benefits for children with cerebral palsy. *Developmental Medicine & Child Neurology*, *56*, 19–29. https://doi.org/10.1111/dmcn.12484

Visser, K., Todd, G., Horrocks, L., & Pickering, D. (2011). Pedal power pilot study: adapted dynamic cycling for children with cerebral palsy. *World Congress of Physiotherapy*.

https://orca.cardiff.ac.uk/31260/

Visser, K., Todd, G., Horrocks, L., & Pickering, D. (2012). Proceedings of SRR. *Clinical Rehabilitation*, *26*(3), 280–287. https://doi.org/10.1177/0269215511425764

World Health Organization. (n.d.). Retrieved March 2, 2018, from https://www.who.int/classifications/icf/en/

Wu, M., Kim, J., Gaebler-Spira, D. J., Schmit, B. D., & Arora, P. (2017). Robotic resistance treadmill training improves locomotor function in children with cerebral palsy: A randomized controlled pilot study. *Archives of Physical Medicine and Rehabilitation*, *98*(11), 2126–2133. https://doi.org/10.1016/j.apmr.2017.04.022

Yumpu. (n.d.). https://www.yumpu.com/en/document/read/15443748/fsa-40-users-manual-3rd-edition-vista-medical

Zou, G. Y. (2012). Sample size formulas for estimating intraclass correlation coefficients with precision and assurance. *Statistics in Medicine*, *31*(29), 3972–3981. https://doi.org/10.1002/sim.5466

Appendices

Appendix A: Protocol for Data Collection

Adaptive Bike Assessment Protocol

Subject #: _____ Date (DD/MM/YY): _____

☐ Start Time (00:00): _____

Course Preparation

☐ Clear course of any obstacles or obstructions
☐ Ensure you have Equipment and Forms prior to participant arrival.
☐ Equipment includes- Adaptive bike, Delsys sensors, FSA pressure mat, bike helmet, cellphone camera, power meter, li-ion battery, timer, and research laptop.

Introduction (INDOORS)

☐ Greet participants in predetermined indoor meeting location.
☐ Obtain 2 copies (each) of assent from participant before proceeding. *Have spare copies of the assent form available. Briefly review the assent form and ensure it is completed entirely (see below).*
☐ Consult with parent/guardian regarding presentation of information;
☐ Ensure participant is adequately informed of study procedures;
☐ Participant provides signature OR provides verbal consent;
☐ Researcher signs form;
☐ Place consent form in Participant file.
☐ Provide a signed copy to each participant.
☐ Review adaptive bicycle assessment procedures with participant

Safety

☐ Ensure participant is wearing helmet.
☐ Ensure course is free of distractions and obstacles.

Assessment Trials

☐ Fit participant for adaptive bicycle. Ensure seat is at an appropriate height and participant is comfortable.
☐ Place assessment instruments on participant.
☐ Test to see if all instruments are on and recording.
☐ Have participant cycle a distance of 30 meters. Repeat for 3 trials

Trial:	1	2	3
Completed (Y or N)			

Feasibility Issues

☐ Did the instrument cause the participant any distractions?
If yes, which instrument(s)_____ Description:

☐ Did the sensors experience any time of interference?
If yes, which instrument(s)_____ Description:

☐ Was the participant's performance representative of typical biking?
If no, please explain:

☐ Other Adverse Events: YES _____ NO _____
If yes, how many: _____ Description:

_____

_____

_____

_____

Conclusion

☐ Ensure all data is recorded and saved.

☐ Thank participant, provide 20$ honorarium for participation and answer any questions

Breaks from Protocol: Yes _____ No _____

Describe:

Issues:

Appendix B: Rider Evaluation Form

Appendix C: Physical Performance Measures Summary

Table 4 Physical performance measure summary

INSTRUMENTATION	MEASURES REPORTED		
	MEASURED	CALCULATED	PLACEMENT OF SENSOR
NCTE_128 BB	AVERAGE TORQUE AVERAGE HUMAN WATTS PEDAL CADENCE		IN THE BIKE CRANCKSET
DELSYS® SYSTEM	MAX KNEE FLEXION MAX KNEE EXTENSION	AVERAGE MAX KNEE FLEXION AVERAGE MAX KNEE EXTENSION KNEE ROM	ON THE RIDER
FSA PRESSURE MAPPING SYSTEM	AVERAGE PRESSURE MAX PRESSURE MIN PRESSURE	COP	ON THE BIKE SEAT AND BACKREST AS AN INTERFACE

Appendix D: Sham Data Analysis

TORQUE data

Obs	subject	TORQUE
1	1	9.79
2	1	6.09
3	1	7.22
4	2	4.64
5	2	3.83
6	2	6.02
7	3	10.09
8	3	9.46
9	3	8.53

The GLM Procedure

Class Level Information

Class	Levels	Values
subject	3	123

Number of Observations Read 9

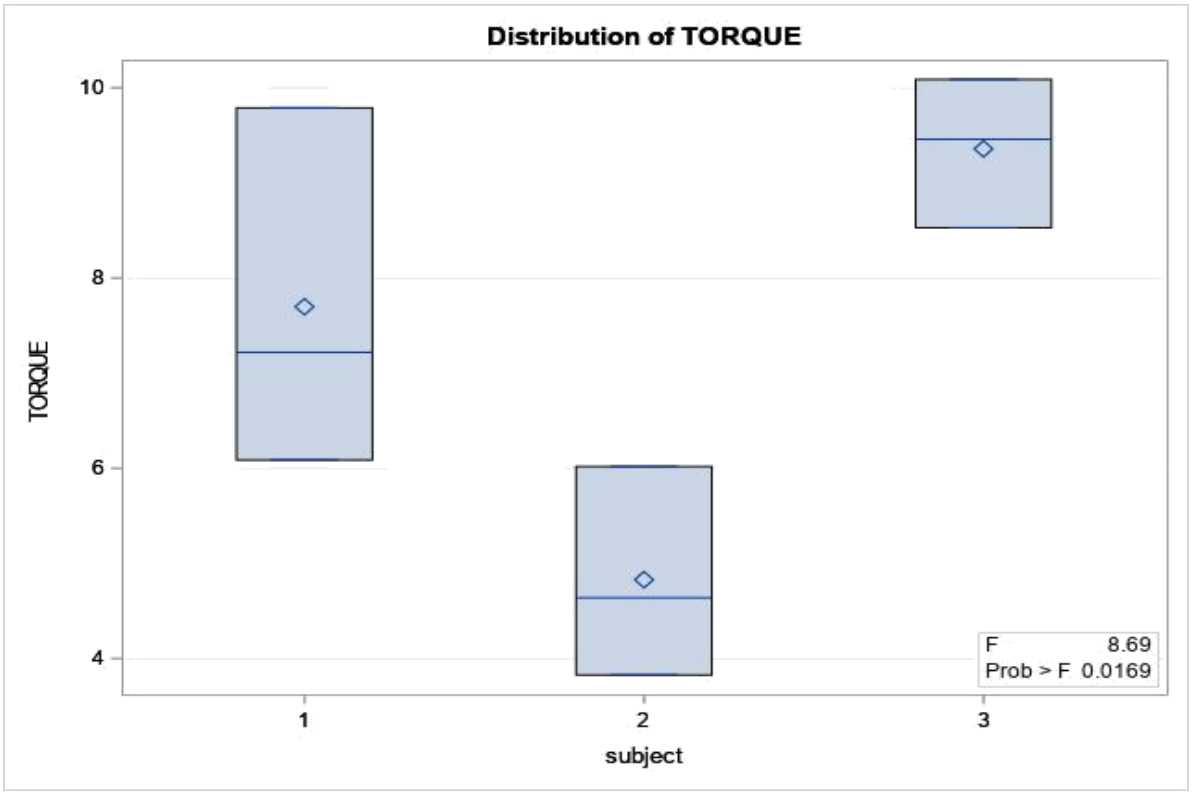
Dependent Variable:

Torque

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	2	31.51340000	15.75670000	8.69	0.0169
Error	6	10.87460000	1.81243333		
Corrected Total	8	42.38800000			

R-Square	Coeff Var	Root MSE	TORQUE Mean
0.743451	18.45043	1.346266	7.296667

Source	DF	Type III SS	Mean Square	F Value	Pr > F
subject	2	31.51340000	15.75670000	8.69	0.0169



AVGPRESS data

Obs	Subject	AVGPRESS
1	1	22.71
2	1	23.79
3	1	22.96
4	2	20.82
5	2	21.79
6	2	19.75
7	3	12.87
8	3	14.24
9	3	12.39

The GLM Procedure

Class Level Information

Class	Levels	Values
subject	3	123

Number of Observations Read 9

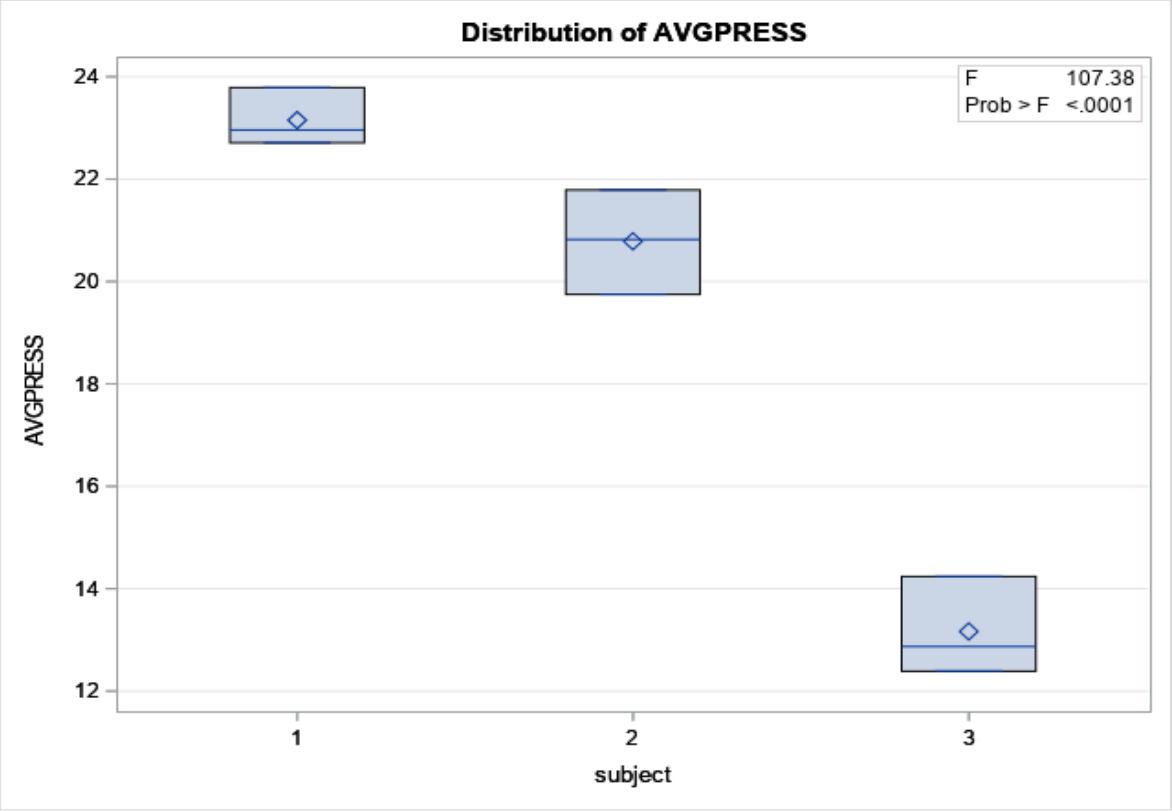
Dependent Variable:

AVGPRESS

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	2	163.3990222	81.6995111	107.38	<.0001
Error	6	4.5650000	0.7608333		
Corrected Total	8	167.9640222			

R-Square	Coeff Var	Root MSE	AVGPRESS Mean
0.972822	4.582255	0.872258	19.03556

Source	DF	Type III SS	Mean Square	F Value	Pr > F
subject	2	163.3990222	81.6995111	107.38	<.0001



avgCoP data

Obs	Subject	avgCoP
1	1	103.51
2	1	94.81
3	1	106.72
4	2	90.71
5	2	144.68
6	2	149.70
7	3	30.47
8	3	79.59
9	3	65.90

The GLM Procedure

Class Level Information

Class	Levels	Values
subject	3	123

Number of Observations Read 9

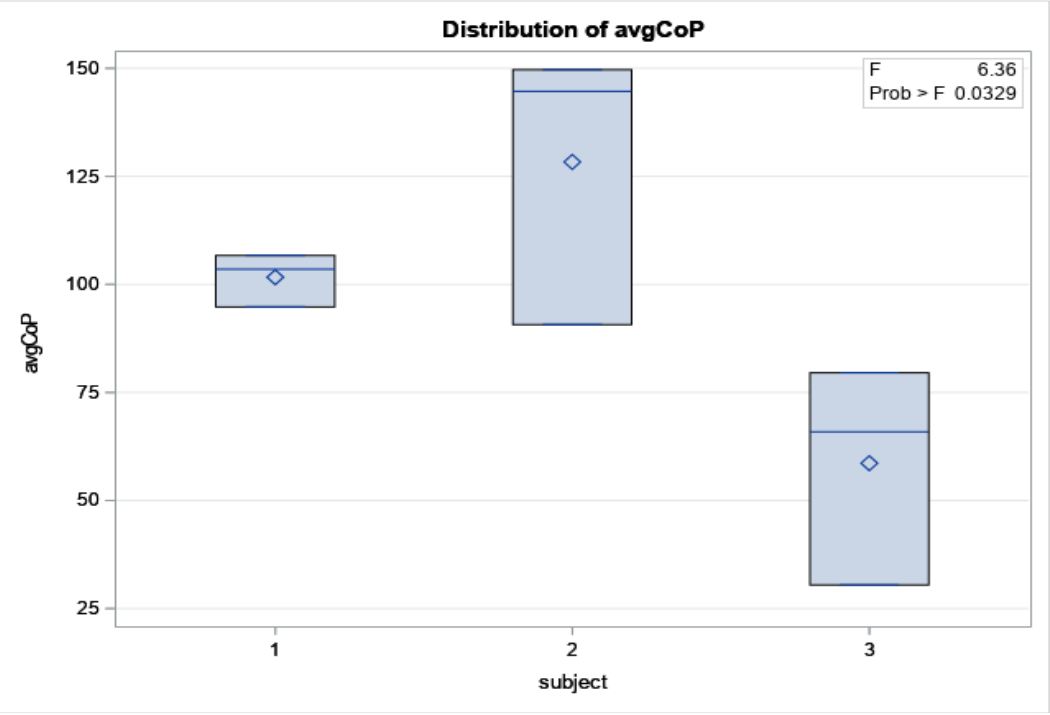
Dependent Variable:

avgCoP

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	2	7422.77842	3711.38921	6.36	0.0329
Error	6	3500.36633	583.39439		
Corrected Total	8	10923.14476			

R-Square	Coeff Var	Root MSE	AVGPRESS Mean
0.679546	25.09924	24.15356	96.23222

Source	DF	Type III SS	Mean Square	F Value	Pr > F
subject	2	7422.778422	3711.389211	6.36	0.0329



Results shows Torque ICC = 0.72, good reliability; Average Pressure ICC = 0.97, very good reliability; Average CoP ICC = 0.64, pretty good reliability. The graphs in this appendix represent reliability of each variable. When the measurements from each person are tightly grouped, and the mean value is different between people, this reflects a small within person variability, relative to the large variation between people. This will result in a high ICC in support or high reliability.

Appendix E: Protocol for Phase II

Study **Purpose**

The purpose of the feasibility study is to assess the physical performance of children and adolescents; ages 5-21 years, with CP while using instruments embedded adaptive bike in a community setting.

Study **Objectives**

1. To assess participants' physical measures of postural symmetry, knee joint's range of motion (ROM), and power output while engaged in dynamic biking, and to gauge participant's overall biking experience,
2. To ensure the feasibility of the baseline protocol for the future intervention study.

Research Method

Participants

Five participants, children ages 5-21 years, diagnosed with CP (GMFCS level II, III, and IV) with previous experience of riding an adaptive bike (of Freedom Concepts Inc.) in a school or any community setting will be included. For the bike assessment trial, participants will receive the similar adaptive bike as their school or community to ensure comfort. GMFCS level II, III and IV deliberate to be an appropriate range for this feasibility study, considering the study population will most likely possess some functional abilities to pedal and allow the instrument set to take assessment above their lower threshold limit excluding GMFCS level V children. As this study evolves around testing the feasibility of the assessment tools and the biking trial, it is

essential to test participants encountering higher challenges than of GMFCS level I children, excludes GMFCS level I children from the study. Inclusion criteria also includes that individual must be living in Winnipeg and the understand spoken English. Children who have undergone orthopedic surgery or have received Botox injections within six months prior to the study will be excluded.

Recruitment

Participants will be recruited by sending out invitation letters, and a poster advertisement through mail and social media to customers of Freedom Concepts Inc. Interested participants will contact the student researcher to receive further information about the study prior to scheduling data collection meeting. The student researcher will collect contact information to correspond with participants and their families regarding potential meeting times for the biking data collection. If individuals agree to participate, consent and assent forms (Appendix F and G) will be shared in advance and completed and signed upon their arrival to the bike assessment trial.

Data collection Protocol

Participants' parents or guardians will be asked to provide participant's demographics including self-reported age, sex, height, and weight prior to the biking assessment trial. Data collection protocol will be followed prior and during the biking trial (Appendix A). Each participant will be provided with an adaptive bike (Discovery/Adventurer Series-Freedom Concepts Inc.), sized according to their weight, inseam, ability, strength, and flexibility. There will be a fitting process by a trained employee of Freedom Concepts Inc. with each participant to ensure comfort and safety of the participant and proper adjustment of the adaptive bike as per each participant's physical stature (hip to toe positioning, footplate positioning, proximity of

handlebars).

Once the bike is adjusted to the rider, participants will be asked to complete three, self-paced, trials of a 30-meter biking track. After each trial, the student researcher will take readings and save all the recorded data to a dedicated research laptop. There will be no scheduled breaks between the trials, however, if the participant requests a break, or appears visibly fatigued or distressed a break will be implemented. The student researcher will record the number and length of breaks taken. All the participants will receive bike helmets and will be required to wear a fitted bike helmet during biking. The student researcher will supervise and will capture a sagittal view video of each participant while they bike. The research supervisor will be monitoring and helping each participant to bike as required. The physical performance of participants while engaged in dynamic biking will be assessed by collecting applied force on pedals (human torque), and power output, postural symmetry through the FSA, and knee joints range of motion while biking. The collected data will be stored in a dedicated, password protected research laptop. Participant's response on how much they enjoyed biking at their school/community setting, and how much they enjoyed biking trial on the day of the bike assessment trial will be addressed using five facial expression Likert scale. At the end of the third trial, all the participants will require to respond either verbally or by checking a box at any one smiley face of the Likert scale for each question to report their responses. If children unable to understand or respond to the questions, a student researcher request parents or caregiver to respond on behalf of children. Responses from the Likert scale will reflect the overall enjoyment of participants riding an adaptive bike with instrumentation (Appendix H). A paper copy of their responses will be stored in a file and will be protected in a locked cabinet.

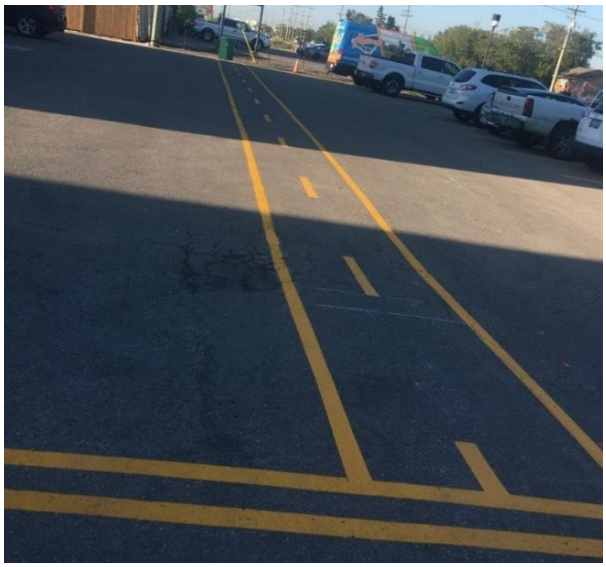


Figure 71 Outdoor biking path

Data Analysis

To assess the reliability of assessment tools to capture select physical measure One-way Analysis of variance (ANOVA) can be performed. The reliability statistic most often reported for continuous measurements is the intra class correlation coefficient (ICC). The ICC is a special type of correlation coefficient and is a number that can go from -1 to +1. High positive values of ICC reflect good reliability. There are different formulas to calculate ICC under numerous study designs.

Ethics Approval

The phase II study has received an ethics approval by Health Research Ethics Board (HREB): Certificate number HS23582; H2020:024.

Appendix F: Consent Form

College of Rehabilitation Sciences
Department of Occupational Therapy
R106 – 771 McDermot Avenue
Winnipeg, Manitoba
Canada R3E 0T6
Phone: [redacted]
Fax: [redacted]

UNIVERSITY OF MANITOBA | Rady Faculty of Health Sciences

Research Participant Information and Assent Form

Title of Study:
Capturing Change: Understanding the Physical and Psychosocial impacts of Adaptive Bikes: Phase 2 Development of an Adaptive Bike Assessment

Principal Investigator
Jacquie Ripat, Ph.D.
Associate Professor
Department of Occupational Therapy
College Rehabilitation Sciences
University of Manitoba
[redacted]

Co-Investigators

Dr. Danny Mann, Department of Biosystems Engineering University of Manitoba	Dr. Cheryl Glazebrook Faculty of Kinesiology & Recreation Management University of Manitoba

Funder: This study has been submitted to Mitacs Accelerate for funding.

You are being asked to participate in a research study. Please take your time to review this consent form and discuss any questions you may have with the study staff. You may take your time to make your decision about participating in this study and you may discuss it with your friends, family, or your health care provider before you make your decision. This consent form

may contain words that you do not understand. Please ask the study staff to explain any words or information that you do not clearly understand.

Purpose of Study
The overall aim of this study is to assess the validity and feasibility of an adaptive bike assessment designed to track physical performance. These findings will be used to develop an evidence informed set of assessment tools and protocols for evaluating the impact of adaptive cycling on the physical and psychosocial function of children with neuromuscular conditions.

Participant Selection
A total of up to 10 participants with Cerebral Palsy (GMFCS Level 2, 3, 4), Down syndrome or Autism will participate in this study. Participants will be ages be between the ages 5-21, are currently enrolled in elementary, middle or high school, and have experience using an adaptive bicycle. Participants who report a cardiac condition history or an unstable health condition will be excluded from this study.

Study procedures
If you participate in this study, you will attend 1 session for approximately 2 hours. First, a research assistant will fit you for the adaptive bike assessment (assessment components and body placement will be identified in *Figure 1.1* below). You will then complete 30 meters of self-paced cycling at a comfortable speed for 3 trials. While you cycle, physical performance data will be collected through the sensors. A member of the research team will observe you while cycling and ensure safety throughout the process.

Figure 1.1: Adaptive bike assessment details

Instrument	Description	Placement	Function
Altius Analytics Labs	This video analysis software enables the collection of angle movement of knee and hip.	No physical sensor or marker required.	This device will measure the participant's relative change in angle at the knee and hip while they cycle using a video.
1BodiTrak PRO pressure mapping system.	This wireless device measures the pressures at the interface area where two surfaces meet.	The pressure mapping system will be attached to the bike seat and back.	This device will measure the participant's postural symmetry as they cycle.
Go Pro ™ camera	This wireless device captures video footage.	This device will be placed on the side of the adaptive bike.	This will provide researchers with video camera footage to analyse rider's ROM in Altius.
Power Meter Pedals	This device measures the power output of a cyclist.	This device will be placed under the	This will provide cycling performance

		adaptive bicycle platform pedals	data (Power output, speed, pedal cadence)
Garmin Fitness watch	This device is a multi-sport tracking GPS watch which also records wrist-based heart rate data.	This device will be placed the participant's wrist as they cycle	This will provide wrist-based heart rate data while the participant cycles.

Risks and Discomforts

To reduce the risks and discomforts associated to cycling, all testing will be held in a closed area with minimal distractions and obstacles (Freedom Concepts Inc., 2087 Plessis Rd). We request you dress appropriately for the testing (comfortable and breathable clothing) to ensure comfort while exercising. Participants will also be required to wear a helmet while cycling to prevent injury in the case of falls or crashes.

A research assistant will be present to supervise and intervene, if necessary, to prevent falls or crashes; but to avoid undue fatigue and stress we ask that you report any discomfort or stress immediately to study staff.

Some risks include mild muscle fatigue. You are encouraged to take breaks or shorten data collection if necessary. You may also experience some mild skin irritation from the abrasion/adhesive from the sensors.

Benefits

There may or may not be direct benefit to you from participating in this study. Participants will receive a 20$ honorarium for their participation in the study.

Costs

All the procedures, which will be performed as part of this study, are provided at no cost to you. Parking fees will be reimbursed.

Confidentiality

We will do everything possible to keep your personal information confidential. Your name will not be used at all in the study records. A list of names and addresses of participants will be kept in a secure file so we can send you a summary of the results of the study and the honorarium. If the results of this study are presented in a meeting, or published, nobody will be able to tell that you were in the study. The collection and access to personal information will be in compliance with provincial and federal privacy legislations. All data will be kept on a secure, password-protected computer or hard drive and will not be used beyond this study without your consent. Data collected from this study, will be maintained for two years following completion of this study, at which time they will be erased or destroyed.

Some people or groups may need to check the study records to ensure that the study is being conducted in an ethical manner and as described in the submission approval. All of these people have a professional responsibility to protect your privacy. These people or groups are:

- The Health Research Ethics Board of the University of Manitoba which is responsible for the protection of people in research and has reviewed this study for ethical acceptability
- Quality assurance staff of the University of Manitoba and who ensure the study is being conducted properly

All records will be kept in a locked secure area and only those persons identified will have access to these records. If any of your research records need to be copied to any of the above, your name and all identifying information will be removed. No information revealing any personal information such as your name, address or telephone number will leave the University of Manitoba.

Voluntary Participation/Withdrawal from the Study

Your decision to take part in this study is voluntary. You may refuse to participate, or you may withdraw from the study at any time. The study staff may decide to remove you from this study without your consent if they feel your on-going engagement in the study could pose a significant risk to your safety and health. We will tell you about any new information that may affect your health, welfare, or willingness to stay in this study. You are not waiving any of your legal rights by signing this consent form nor releasing the investigator(s) or the sponsor(s) from their legal and professional responsibilities.

You can stop participating at any time. However, if you decide to stop participating in the study, we encourage you to talk to the study staff first and discuss any concerns.
You can also opt to receive a summary of the study results from the principal investigator. The results will be provided to you after the study completion.

Questions

You are free to ask any questions that you may have about this study.
If any questions come up during or after the study, or if you have a research-related injury, you can contact the study staff: Dr. Jacquie Ripat at 204-789-3303.

For questions about your rights as a research participant, you may contact the University of Manitoba, Bannatyne Campus Research Ethics Board Office at 204-789-3389.

Do not sign this consent form unless you have had a chance to ask questions and have received satisfactory answers to all your questions.

Statement of Consent

1. I have read all 5 pages of the consent form.
2. I have had a chance to ask questions and have received satisfactory answers to all of my questions.
3. I understand that by signing this consent form I have not waived any of my legal rights as a participant in this study.
4. I understand that my records, which may include identifying information, may be reviewed by the research staff working with the Principal Investigator and the agencies and organizations listed in the Confidentiality section of this document.
5. I understand that I may withdraw from the study at any time and my data may be withdrawn prior to publication.

6. I understand I will be provided with a copy of the consent form for my records.
7. I agree to participate in the study.

I understand that information regarding my personal identity will be kept confidential, but that absolute confidentiality is not guaranteed. I authorize the inspection of any of my records that relate to this study by The University of Manitoba Research Ethics Board for quality assurance purposes. By signing this consent form, I have not waived any of the legal rights that I have as a participant in a research study.

I would like to have a copy of the study results when the study is completed. Yes ___ No ___

If yes, please provide an email or mailing address
_____

Participant signature: _____ Date: _____

Participant printed name: _____

I, the undersigned, have fully explained the relevant details of this research study to the participant named above and believe that the participant has understood and has knowingly given their consent

Printed Name: _____ Date: _____

Signature: _____

Role in the study: _____

Appendix G: Assent Form

College of Rehabilitation Sciences
Department of Occupational Therapy
R106 – 771 McDermot Avenue
Winnipeg, Manitoba
Canada R3E 0T6
Phone: 204-789-3897
Fax: 204-789-3927

UNIVERSITY OF MANITOBA | Rady Faculty of Health Sciences

Research Participant Information and Assent Form

Title of Study:
Capturing Change: Understanding the Physical and Psychosocial impacts of Adaptive Bikes: Phase 2 Development of an Adaptive Bike Assessment

Investigators:
Dr. Jacquie Ripat, Ph.D.
Dr. Danny Mann
Dr. Cheryl Glazebrook

Why are you here?

The researchers want to tell you about a study for individuals who use adaptive bikes. They want to see if you would like to be in this study. This form tells you about the study. If there is anything you do not understand, please ask your parent, your guardian, or the study staff.

Why are they doing this study?

They want to learn more about an adaptive bike assessment that was created to track physical performance. The results from this study will be used to develop a set of tools to test how adaptive bicycles affect children with Cerebral Palsy, Down syndrome, or Autism.

What will happen to you?

If you want to be in the study these things will happen:

1. The study will last about 2 hours. You will be asked to come to the Freedom Concepts, 2087 Plessis Rd for one visit.
2. Once you have arrived a research assistant will fit you for an adaptive bike assessment. The parts of the adaptive bike assessment include:

- an adaptive bike (fitted for you);

- a bike power sensor (placed on the bike pedals);
- a pressure mapping system (placed on your bike seat);
- a Go Pro camera (placed on the side of an adaptive bike);
- and a watch with a heart rate monitor (placed on your wrist).

3. You will then complete 30 meters of cycling at your own pace. You will do this 3 times.
4. While you cycle, the adaptive bike assessment will gather information about your performance.
5. A member of the research team will observe you while cycling and will be available for your safety.

Will the study hurt?

While cycling, your muscles may feel tired. If at any point during the study you feel sick or tired, you are encouraged to take breaks or stop if necessary.

You may also feel some mild skin irritation from the adhesive from the sensors.

To reduce risks while you are cycling, we will be testing in a closed area without distractions and obstacles. We request you wear comfortable and breathable clothing while you cycle. All participants are required to wear a helmet while cycling to prevent injuries in the case of falls.

A member of the research team will supervise and stop the activity, if necessary, to prevent falls or crashes. If at any point you feel uncomfortable, please tell study staff.

Will you get better if you are in this study?
This study will not make you feel better or get well.

What if you have any questions?
You can ask questions any time, now, or later. You can talk to the research team, your family or someone else.

Who will know what I did in the study?
Any information you give to study staff will be kept private. Your name will not be on any study paper and no one but the study staff will know that it was you who was in the study.

Do you have to be in the study?
You do not have to be in the study. No one will be mad at you if you don't want to do this.

If you do not want to be in this study, just say so. We will also ask your parents/guardian if they would like you to be in the study. Even if you parents want you to be in the study you can still say no.

Even if you say yes now you can change your mind later. It is up to you.

Do you have any questions?

What questions do you have?

Assent

I want to take part in this study. I know I can change my mind at any time.

_____ Verbal assent given Yes ☐
Print name of child

[If verbal assent obtained the process must be clearly documented in the research or medical file]

Written assent if the child chooses to sign the assent.

_____ _____ _____
Signature of Child Age Date

[The following statement and signature is required]:

I confirm that I have explained the study to the participant to the extent compatible with the participants understanding, and that the participant has agreed to be in the study.

_____ _____ _____
Printed name of Person obtaining assent | Signature of Person obtaining assent | Date

Appendix H: Participant Enjoyment Evaluation Form

Do you enjoy riding a bike in the school?

Did you enjoy the bike ride today?