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Abstract An aging population coupled with longer life expectancy has resulted in an exponential growth in total hip and total knee replacements (THR) (TKR). Especially during the 2020 COVID-19 pandemic, support for patients recovering form THR and TKR was difficult due to reduction in face-to-face visits. To address this and enable Australians to have a better patient experience, the following proffers a tele-assessment solution, ARIADNE (Assist foR hIp AnD kNEe), that can provide high quality care, with access for all and support for high value outcomes.

Keywords: total hip replacement (THR), total knee replacement (TKR), telehealth, remote monitoring, tele-assessment, tele-rehabilitation, value-based care, healthcare valu proposition

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1 Introduction

In Australia, the exponential growth of joint replacements, in particular total hip (THR) and total knee replacements (TKR), is projected to reach an unsustainable burden by 2030 (Ackerman et al., 2019), which has many severe and far-reaching implications for healthcare delivery and for the demand on public and private hospitals. Given several key contributing factors, most notably an aging population and longer life expectancy (Nutt & Solan, 2017), the most prudent way to address this is to leverage technology solutions that can support cost-effective, efficient and effective care delivery post-surgery. We proffer tele-assessment, a noted void in current telemedicine solutions for orthopaedic care, as such a solution.

A key bottleneck in the recovery from THR and TKR is the return to appropriate postural and functional control (Russell, Buttrum, Wootton, & Jull, 2011). The current standard clinical pathway involves 12 to 60 face to face visits over a period of three months (The Brigham and Women's Hospital, 2010). This is not only costly and difficult to manage, especially for isolated and disadvantaged populations (The Brigham and Women's Hospital, 2010), but if not done successfully leads to poor clinical outcomes and low patient satisfaction (Jansson, Harjumaa, Puhto, & Pikkarainen, 2020). Moreover, clinical best practice notes that this 3-month window post-surgery is imperative for optimal recovery and best results (Aasvang, Luna, & Kehlet, 2015). To address this critical aspect on the THR and TKR patient journey, and support quality clinical outcomes and patient satisfaction as well as ease the burden for our healthcare system, we design, develop and test ARIADNE (Assist foR hIp AnD kNEe), a pervasive tele-assessment solution that can support clinical tele-assessment to assess postural and functional control to support post-surgery THR and TKR recovery. ARIADNE will enable objective, remote examination and monitoring of patient functional performance during their typically long rehabilitation journey, something that to date is missing from current telemedicine solutions especially in orthopaedic care. By implementing such a pervasive tele-assessment solution within traditional practice, we have the potential to: a) improve existing practice patterns, b) shorten the recovery trajectory, c) increase the likelihood for optimal clinical outcomes, and d) support a superior patient experience.

Background

Total hip or knee replacement is a common surgical intervention for treating advanced hip/knee Osteoarthritis (OA). As a strategy to address the burden of disease of OA in Victoria and optimally align health services to consumers' needs and evidence, the Department of Health and Human Services (Victoria) commissioned the development of a Model of Care (MoC) for Osteoarthritis of the Hip and Knee. A MoC is an evidence and consultation-informed framework that describes what and how health services and other resources should be delivered locally to people who live with specific health conditions. In 2018 (Victorian Musculoskeletal Clinical Leadership Group, 2018), the MoC recommended the "Innovation in service delivery model". The model was designed to establish: 1) telehealth services to improve consumers' access to specialist clinics for the purposes of clinical assessment, management planning and treatment, and 2) web-based and smartphone app tools that deliver accurate health information and support behaviour change to consumers and care providers. The development of ARIADNE is designed to addresses the above acknowledgement of the importance of a telemedicine platform to improve health care services for rehabilitation following THR and TKR. (Department of Health, 2010; Victorian Musculoskeletal Clinical Leadership Group, 2018).

Tele-rehabilitation via online video communication is an emerging area attracting increased attention as a potential alternative to conventional, face to face rehabilitation, suggested to be an option for people located remotely to reduce the need for frequent travel (Russell et al., 2011). A recent systematic review concluded that tele-rehabilitation can lead to better healthcare at lower costs (Klaassen, van Beijnum, & Hermens, 2016). An example is the tele-rehabilitation system eHAB (NeoRehab, Brisbane, Australia) that enables real-time video conferencing to the patient's home and includes features such as recording instruction and exercises (Richardson, Truter, Blumke, & Russell, 2017). Similarly, MyRehab offers a tele-rehabilitation communication system via text or voice messages and video-conference, evaluated in a RCT with THR and TKR patients (Eichler et al., 2017).

Indeed, tele-rehabilitation partially addresses some of the requirements of the MoC. However, a critical missing element in current solutions is tele-assessment which supports an objective remote postural and functional assessment integrated with web-based management and planning capabilities. ARIADNE addresses this key void by being able to transform standard care with a face to face assessment, mostly available only in major cities with experts, to provide remote assessment access and quality of care to a wider and remote community. Thus, ARIADNE, will significantly enhance Australian health care services, ensuring objective postural and functional examination can be performed. It will provide the foundation for future telemedicine platforms for clinical trials and treatment monitoring.

To further improve upon the Australian telehealth system the following objectives need to be addressed:

1. An <u>examination</u> into the measurement consistency and agreement of a newly established tele-assessment system with respect to a face to face clinical based reference condition.
2. A <u>determination</u> of the feasibility and the extent to which the tele-assessment can be used by clinicians and patients to achieve effectiveness (accuracy and completeness), efficiency (resources needed for effectiveness) and satisfaction (comfort and acceptability).
3. An <u>assessment</u> of the cost-effectiveness associated with tele-assessment including those related to healthcare, purchase of equipment, mobile phone data usage, and costs associated with establishing and delivering the service, and analysing the results.

Overview of ARIADNE

In orthopaedics, performance measures following THR and TKR are required to identify patient functional competency and physical progress. In existing clinical practice, these postural and functional measures include: 1) range of motion, 2) postural balance, 3) chair rise, 4) 40 meter fast paced walk, and 5) timed up and go (TUG) (Victorian Musculoskeletal Clinical Leadership Group, 2018), and are executed face to face while the clinician manually records the duration and number of repetitions to complete the task. A more robust objective, but to date only used in research and not in clinical settings due to availability and accessibility, is quantifying performance using Inertial Measuring Units (IMU) motion sensors comprising accelerometers and gyroscopes (Galan-Mercant, Baron-Lopez, Labajos-Manzanares, & Cuesta-Vargas, 2014; Pham et al., 2018; Witchel et al., 2018) to measure linear acceleration and angular velocity, respectively. Once the raw data is captured, the level of performance is quantified by a further well-defined signal processing methods (Adusumilli et al., 2017; Galan-Mercant et al., 2014; Pham et al., 2018; Steinberg, Adams, Waddington, Karin, & Tirosh, 2017; Steinberg, Tirosh, Adams, Karin, & Waddington, 2017).

ARIADNE has been developed and designed to support the above requirements and is built from previous work by one of the authors around web based repository applications Gaitabase and PROMsBase (Tirosh, Baker, & McGinley, 2010; Tirosh, Tran, et al., 2019), and leverages his research on the use of IMU motion sensor signals to capture, process, and interpret postural and functional performance (Kuo, Culhane, Thomason, Tirosh, & Baker, 2009; Steinberg, Adams, et al., 2017; Steinberg, Tirosh, et al., 2017; Tirosh, Orland, Eliakim, Nemet, & Steinberg, 2017, 2019, 2020). Gaitabase has been used by world leading gait laboratories for clinical gait analysis, having 22 different centres in 8 different countries on four different continents. PROMsBase is routinely used at Western Health in Victoria to collect patients' satisfaction and wellbeing data pre and post joint replacement procedures with over 8,000 questionnaires from over 10,000 surgery procedures now collected.

In order to be clinically useful as a tele-assessment platform, we extended the technology with unique integration methods of the web based repository system coupled with the motion sensor IMU data captured from a mobile phone. During assessment, the clinician remotely connects to the motion capture app installed on the patient's mobile phone that is strapped above the ankle (to measure joint angle) or at the lower back (to measure postural control) using an ankle or waist strap, respectively. Once connected, the clinician remotely operates the app while the patient performs the specific functional task as instructed by the clinician. Once the task is completed the clinician remotely saves the mobile sensors data that is automatically uploaded to the web-based application for further processing and analysis. Both the clinician and the patient can login to the web application and generate performance and progress reports. Figure 1 shows an example of the motion sensors data analysis during the clinical tasks.

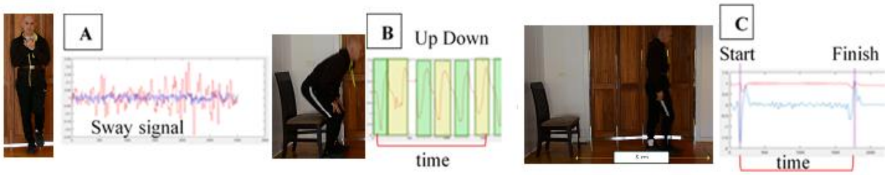

Figure 1. Example of motion sensor data during Tele-assessment of (A) postural balance, (B) sit stand, and (C) TUG tests.

Methodology

To test the proposed tele-assessment solution this section outlines the research plan. Tele-assessment is the missing piece in telemedicine care for orthopaedic rehabilitation. Unique aspects of ARIADNE include that it: a) can provide remote, quantified, and postural and function control, and b) provide early detection of deviation, problems and potential complications. Our pilot study will serve to incorporate key co-design principles to ensure clinician and patient input in the design and development of ARIADNE, and then test the definitive solution in terms of: (a) desirability (patients and clinicians), and clinician and patient usability and acceptance, (b) reliability (ability to deliver consistently on key clinical outcomes) and "fit for purpose", and (c) cost-effectiveness.

The tele-assessment platform ARIADNE is very simple to use as it integrates a web-based database and interface platform and motion sensor data that is captured remotely from the patient's mobile phone while the patient performs their essential postural and functional measures, including (Victorian Musculoskeletal Clinical Leadership Group, 2018): 1) range of motion, 2) postural balance, 3) chair rise, 4) 40 meter fast paced walk, and 5) timed up and go (TUG). The motion sensor data is processed to objectively quantify the patient's performance level.

Overview of design

To ensure a robust solution it is essential to conduct a feasibility pilot study to measure the desirability, usability, reliability, Minimal Detectable Change (MDC), fit for purpose, and cost-effectiveness, and better access, quality and value of the tele-assessment platform for THR and TKR patients. The tele-assessment will be utilised during the conventional THR and TKR standard care pathway.

Protocol

We have secured HREC (Human Research Ethics Committee) approval and now planning for final ARIADNE co-design session with 2 clinicians and 4 patients (2 TKR and 2 THR). Prior to tele-assessment at **T0**, clinicians and patients will participate in an educational focus group session. In this session participants will be educated on the use of ARIADNE with preparation for their joint replacement journey.

Tele-assessments will be performed on 10 occasions including; base-line pre surgery-1 (**T1**), pre surgery-2 (**T2**), and at 1 (**T3**), 2 (**T4**), 3 (**T5**), 4 (**T6**), 5 (**T7**), 6 (**T8**), 9 (**T9**), and 12 (**T10**) weeks post-surgery. The duration of each tele-assessment session is 20 minutes. In each session, the patient will start the app that automatically connects to the clinician web portal. The patient will then insert the mobile phone in the waist pouch and attach it around their waist. The clinician will instruct the patient to perform the tasks (balance, TUG, chair rise, range of motion) while the mobile app captures the motion data and automatically uploads it to the web portal for storage and further analysis. At **T2** and **T10** patient questionnaires will be administered to assess usability of ARIADNE. In addition, at **T10** a clinician focus group will be conducted.

Outcome and data analysis: At the completion of the study the following aims will be achieved:

Primary Aim (a): assess desirability and usability of ARIADNE:

The Unified Theory of Acceptance and Use of Technology (UTAUT) will be used as the theoretical framework underpinning the research, to understand and empirically test the factors that influence the end-users' acceptance and adoption of the tele-assessment services in THR and TKR patients. The UTAUT includes four determinants; performance expectancy (PE), effort expectancy (EE), social influence (SI), and facilitating conditions (FCs), which can explain 70% of the variance of behavioural intentions (Hoque & Sorwar, 2017), while other models explained approximately 40% of technology acceptance (Lim, 2003). It has been widely adopted in different areas including mobile health such as to investigate the intention to use Physical Activity Apps (Liu et al., 2019), but to our knowledge there is no published study applying UTAUT to the investigation of tele-assessment use intention in joint replacement patients. To specify, PE refers to the services of the clinician in the clinician–patient interaction in tele-assessment. EE refers to patients' perceived ease of interacting with physicians in tele-assessment. SI refers to the impact of other people's feelings, views, and behaviours on the behavioural intention of patients interacting with clinicians in telehealth. FC refers to users' perceptions of their ability to perform the behaviour and measure the degree to which the tele-assessment fits with their existing values, previous experiences and current needs. Each determinant includes related questions with a 5-point Likert-type response format that ranges from "strongly disagree" (1) to "strongly agree" (5) to measure each construct covering the variables in the research model. The UTAUT will be completed at **T1**, **T8** and **T10**. Separate analyses will be conducted for older and younger groups of participants in order to test usability and efficacy across all age levels.

Primary Aim (b): assess reliability using MDC:

The outcome measure for each postural and functional task is calculated by processing the motion sensor signal from the mobile device. The outcome measures are the hip and knee joint maximum range of motion, the magnitude of body sway for the postural balance test, the time taken to complete five repetitions of the sit-to-stand manoeuvre test, and time taken to complete the TUG and 40 meter fast paced walk tests.

Reliability and MDC will be analysed from the tele-assessment outcome measures (described above) when comparing outcomes between the pre surgery-1 and the pre surgery-2 sessions. The reliability will be estimated using repeated-measures analysis of variance and the intra-class correlation coefficient. Standard error of measure (SEM) and Minimal Detectable Change (MDC) will be calculated utilising the same methodology as our previous study using IMU measurements in gait (Tirosh, Orland, et al., 2019). SEM will be calculated as SD x $\sqrt{1}$ – ICC, where SD is the standard deviation of all scores from the participants. SEM is also presented as a SEM% by dividing the SEM with the average of the test and retest values. The MDC will be calculated as SEM x 1.96 x $\sqrt{2}$ to construct 95% CI. Multi-level analysis will be used to test for significant differences across younger and older age groups separately for THR and TKR patients. This is an intention-to-treat method which allows for irregular assessment measures, allowing for the control of other variables as needed.

Primary Aim (c): *evaluate if ARIADNE is fit for purpose*:

Empirical evidence shows that users will not simply accept and use the technology if it does not fit their needs and improve their performance (Gebauer & Ginsburg, 2009; Junglas & Watson, 2008). Hence, to assess the fit for purpose of ARIADNE, we apply *task-technology fit*, the degree to which a technology assists an individual in performing his or her task. To measure the level of "fit for purpose" of ARIADNE, during the focus group session conducted at **T10**, we will ask clinicians to compare their experience with ARIADNE to that without tele-assessment; i.e. as per their normal delivery of care. This will enable us to understand key task characteristics, how the technology supported those tasks, and whether clinician users perceived ARIADNE to perform better, as good as, or worse than face to face assessments.

Identified Risks

Risk #1 – Poor desirability and reliability of the tele-assessment platform: The tele-assessment platform is built for the purpose of assessing joint replacement intervention postural and functional control outcomes. Thus, it is important for the platform to be desirable and reliable. This risk is mitigated from findings of previous studies on the desirability and reliability of using IMU in measuring postural and functional performance of the proposed tasks in a range of population types including: healthy older adults (Chan, Keung, Lui, & Cheung, 2016; Keogh et al., 2019), Parkinson's disease (Pham et al., 2018), multiple sclerosis (Witchel et al., 2018), and TKR (Huang, Liu, Hsu, Lai, & Lee, 2020), with very good to excellent desirability and reliability. These studies and a systematic review (Keogh et al., 2019) used mobile phone motion sensors, suggesting that mobile phones are non-inferior compared to the other postural and functional measurement techniques. Furthermore, our unpublished preliminary experiment validating our tele-assessment knee range with the gold standard video analysis showed excellent correlation ($r = 0.98$) and very good agreement with clinically acceptable bias of 5.4 degrees with 17.3 and -6.4 degrees for upper and lower 95% confidence bounds respectively.

Risk #2 – Security of the data: to increase data security the data will be stored on Nectar cloud and will be backed up daily. Nectar is an online infrastructure for researchers to store, access, and analyse data remotely, and is managed and funded by the Australian Government through the National Collaborative Research Infrastructure Strategy.

Risk #3 – Participants can feel directionless and overwhelmed with the technology: to reduce participant anxiety with the digital technology, the patient advocate team member will provide coaching and mentoring support to participants, enabling them to optimise self-management.

Risk #4 – Falls, limited space, and poor environmental set up at home or difficulties to attach the phone to the ankle and/or waist: patients' home visits will occur to inspect and set up the testing environment, and reduce potential hazards.

Risk #5 - Poor Internet connection: the necessary internet connection will utilise the mobile device internet access provider. Data collection is performed using the app installed on the patient's mobile device, thus a poor network will not disrupt data capture and quality.

Results to Date:

The assessment of the fidelity, efficacy and fit for purpose of the developed ARIADNE solution requires many stages and is thus a longitudinal study. On the receipt of ethics approval, initial phases of the design science research methodology have been conducted with a small group of patients and clinicians respectively to fine tune the solution. This is an important key step to ensure high clinician and patient use as well as ensure the developed solution will support the required needs for rehab of THR and TKR patients. The ARIADNE solution now has patient and clinician approval and based on a small pilot study demonstrated ease of use and fit for purpose. While not statistically significant, this directional data provides support to progress to the next phase with confidence. The next key step is to conduct a large scale clinical trial to capture key data around the impact of the solution to support THR and TKR patients in their rehabilitation. Once the clinical trial is concluded it will then be possible to address issues around deployment of the solution into appropriate clinical contexts.

Discussion:

ARIADNE is designed to remotely capture, analyse, and interpret body motion using the accelerometer and gyroscope motion sensors embedded in today's mobile phones. The mobile phones we have today have 3-axial accelerometer and gyroscope components. The accelerometer allows the measurement of linear acceleration in three orthogonal directions (x, y, and z) and the gyroscope allows the measurement of angular velocity in the x, y, and z axes. The linear acceleration and angular velocity signals can be processed and used to analyse body motion and further provide interpretation of the movement quantity and quality, such as level of stability during quiet standing. The ability to remotely connect to a patient's mobile phone and capture accelerometer and gyroscope data creates new opportunities for clinicians, sport trainers, and engineers to remotely quantify and analyse the performance level of any posture and/or movement task.

Conclusions:

Our designed solution, ARIADNE, represents a novel and unique approach to telehealth rehabilitation in orthopaedic care for THR and TKR patients. To date, current telehealth solutions in this space do not address tele-assessment, which means that there is a significant limitation in the current post-operative critical 12-week period for THR and TKR patients. Hence, ARIADNE not only addresses this key void, but it serves to also potentially help to address a major conundrum facing healthcare delivery around THR and TKR. If the results of the clinical trial provide a positive endorsement for ARIADNE, then we would have successfully developed a unique, COVID-19 safe, tele-assessment solution that addresses a key gap in post-surgical recovery for THR and TKR patients.

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