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The efficacy of a Smart Insole in Osteoarthritis/ Total Knee Arthroplasty Patients.

Introduction.

The aim of this literature review is a preliminary assessment of what evidence-based research exists for the efficacy of a smart insole in the triage and rehabilitation of knee osteoarthritis (KOA) and knee arthroplasty (KA) patients.

A smart insole has the potential to be a key improvement to KOA patients' quality of life (QoL) via rehabilitation and surgical prioritisation. The literature strongly advocates that smart insoles that monitor plantar pressure, gait, and activity levels can help healthcare professionals (HCPs) triage and rehabilitate KOA and KA patients.

The review has been organized into the following categories:

- Path Insight
- Assessment of Normal Balance and Gait Parameters
    - Balance, Gait and Falls
- What is Knee Osteoarthritis (KOA)?
    - Pathophysiology
    - Treatments
        - Non-surgical
        - Surgical - What is a Knee Arthroplasty?
        - Who Gets a Knee Arthroplasty? (KA Prioritisation)
            - KA Waits, Quality of Life, & Mental Health
- Gait Changes in KOA
    - Gait Changes Through Disease Progression
    - Gait Changes Following KA
- Post-KA Rehabilitation
    - Current State of Post-KA Rehabilitation
    - The Future of KA Rehabilitation

Path Insight.

Path Insight is a smart insole designed to fit into everyday enclosed shoes. The insole is characterised as smart, as it is connected to a smartphone app for the user and a digital downstream dashboard for healthcare professionals. The data is collected during everyday wear and gives insights using AI into a person's function in a useful format for patient education and to support clinical decision making.

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The insole collects data through sensors innervating the insole, in the form of plantar pressure, temperature and gait analysis.

Additionally, Path Insight's associated app tracks self-reported psychosocial health and fear of falling using validated tools to better understand and review trends of mental health during pregnancy.

Assessment of Normal Balance and Gait Parameters.

Path Insight monitors a wide range of balance and gait parameters, measuring very specific aspects of a person's gait which can be used to support clinical decision making and for patient education on function, inclusive of;

- Cadence
- Walking speed
- Gait cycle time
- Stance
- Stance loading
- Stance foot flat
- Stance pushing
- Swing
- Double support time
- Stride length
- Full walking distance
- Stride velocity
- Peak angle velocity
- Max swing speed
- Turning angle
- Lift-off angle
- Swing width
- 3D path length
- Support base
- Pressure loads across the foot
- Pressure distribution over time
- Posture differentiation (sitting, standing, walking)
- Peak pressure
- Gait speed
- Horizontal shear
- Centre of Pressure (COP)
- Postural Sway
- Ground reaction force (GRF)
- Rotational force (torque)

This allows Path Insight to develop a comprehensive understanding of the users' general wellness, health, calculate falls risk, and detect falls.

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What is Knee Osteoarthritis (KOA)?

Pathophysiology.

Knee osteoarthritis (KOA) is the progressive loss and damage of cartilage covering the bones in the knee joint, most common in the elderly. KOA symptoms often progress, becoming more severe, frequent, and debilitating, although the rate of this deterioration varies from person to person. Common symptoms include knee pain with gradual onset that worsen with activity, knee stiffness, swelling, and pain after sitting/resting for extended periods of time (Hsu et al. 2021).
KOA is the most common type of arthritis diagnosed, and its prevalence will continue to increase as life expectancy and obesity rise. About 10% of over-60s have symptomatic KOA. In those over 70, up to 40% have it, with more women suffering from it than men (Hsu et al. 2021). Interestingly, not everyone who shows signs of KOA in their X-ray scans will have symptoms. Reviews have found that 15–81% of patients with radiographic findings of KOA are symptomatic (Bedson et al. 2008).

Treatments.

There are two main courses of treatment for KOA; surgical and non-surgical.

Non-surgical.

Non-surgical treatments include:

- Patient education
- Activity modification
- Physical therapy
- Weight loss
- Knee bracing
- Nonsteroidal anti-inflammatory drugs (NSAIDs)
- Etc.

The first-line treatment for all patients with symptomatic KOA is patient education and physical therapy. UK National Institute for Health and Care Excellence (NICE) guidelines recommend

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education, advice, information access, exercise and weight loss as core treatments for all osteoarthritis patients (Collins et al. 2019). The American Academy of Orthopedic Surgeons (AAOS) recommends supervised and home exercises for such patients. The benefits of exercise are lost after 6 months if the exercises cease. Weight loss via diet control and low-impact aerobic exercise can also help symptomatic KOA patients (Hsu et al. 2021).

Surgical - What is a Knee Arthroplasty?

If an individual has symptomatic KOA in at least 2 of the 3 compartments of the knee and fails more conservative treatments, surgical procedures such as knee arthroplasties (KAs) can be used. KAs, also known as knee replacements, are a method of reconstructing the knee joint by removing the damaged parts and replacing them with prostheses (Hsu et al. 2020). Total knee arthroplasties (TKAs) are highly cost-effective, costing £5623 per quality-adjusted life-year (QALY) gained per patient (Dakin et al. 2012).

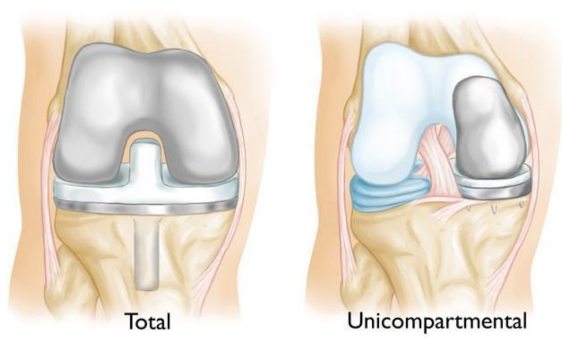

Fig. 1: Image of total and unicompartmental/partial knee arthroplasties from https://orthoinfo.aaos.org/en/treatment/unicompartmental-knee-replacement/ (AAOS website).

Who Gets a Knee Arthroplasty?

The NHS states that “you may be offered knee replacement surgery if:

- you have severe pain, swelling and stiffness in your knee joint and your mobility is reduced
- your knee pain is so severe that it interferes with your quality of life and sleep
- everyday tasks, such as shopping or getting out of the bath, are difficult or impossible
- you're feeling depressed because of the pain and lack of mobility

- you cannot work or have a social life (NHS, 2019)”

According to the United Kingdom NICE guidelines, for a patient to be eligible for a KA, there must be significant, prolonged symptoms with supporting clinical and radiological signs (Adie et al. 2019). However, beyond this, there is currently no specific threshold for KA patient prioritisation (Adie et al. 2019). In countries including Canada (Laberge et al. 2019) and the UK (Dieppe et al. 2008) hospitals often use a 'first-come-first-served' rule or adopt their own policies on KA prioritisation. Patients describe that doctors seem to pay excessive attention to age and excessive complaining from other patients rather than objective measures of QoL (Dieppe et al. 2008).

KA rates are increasing and there is a mismatch between the need and provision of this surgery. A UK study published in 2008 estimated that the need for TKAs is around 55,000/annum compared with provision which is about 30,000/annum (Dieppe et al. 2008). This has resulted in a significant backlog. Although in 2004 the UK government set the goal a reduce waiting times from ‘18 months to 18 weeks’ and this was largely achieved for some time, this goal has not been reached for 5 years now (https://www.health.org.uk/publications/long-reads/returning-nhs-waiting-times-to-18-weeks). The onset of the pandemic has exacerbated this due to the cancellation of elective surgeries with estimates suggesting it will take up to 48 months to reduce the waiting list for hip and knee arthroplasties to pre-pandemic numbers (Oussedik et al. 2021). 54% of patients state their arthritic pain has increased since surgery cancellation and 60-68% report emotional distress from delays (Brown et al. 2020; Wilson et al. 2020). KA delays correlate to greater pain, difficulty with functional tasks, less improvement post-surgery, and reduced quality of life (QoL) (Mahdi et al. 2020; Desmeules et al. 2012; Rossi et al. 2009). Moreover, TKAs without delay cost ~£1,418 less as they do not include non-operative treatment costs (Mather et al. 2014).

As Fig.2 demonstrates, the usual clinical pathway of a patient from KOA to a KA has several steps. There are often two main initial routes to orthopaedic consultation; patients who wait until their symptoms are unbearable (holding off), and patients who seek help preemptively (Sansom et al. 2010). Those who seek help will usually do so in their GP’s office. If the GP deems the patient’s state to be severe enough to be eligible for KA, they will refer them to an orthopaedic surgeon. Each of these steps come with their own barriers to KA availability (See Fig. 2).

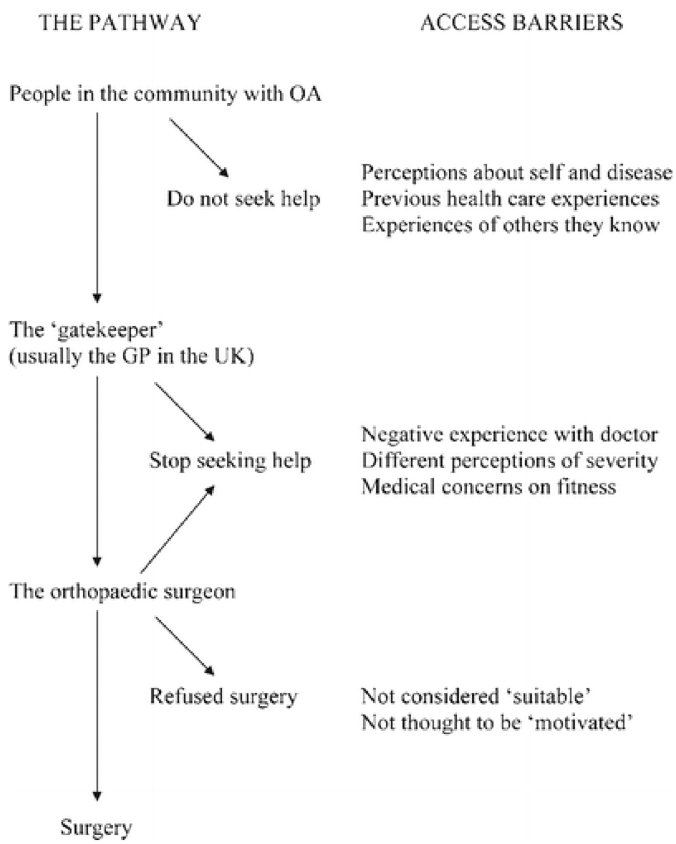

Fig 2: Image of care pathway for joint replacement patients and the barriers to KA (Dieppe et al. 2008).

This lack of prioritization mechanisms in combination with the backlog/high demand of KAs, results in inequalities for KA provision. For example, rates of surgery vary by 25–30% between the different health regions of England and women are less likely to have received drug therapy, be referred for specialist care, or be considered for KAs than their male counterparts, despite women having lower rates of revision surgery (Dieppe et al. 2008; Adie et al. 2019). These sex-related differences remain when factors such as co-morbidities and willingness to undergo surgery are accounted for. This suggests that there may be some sex discrimination in primary care (Dieppe et al. 2008). Literature evidence that patients with higher socioeconomic statuses are prioritised by the NHS with waiting times up to 14% shorter than their disadvantaged counterparts [Gutacker et al. 2014, Laudicella et al. 2012]. There is also a mismatch in thresholds for KA referral due to a lack of proper prioritisation mechanisms between surgeons and general practitioners (GPs). GPs, who act as ‘Gatekeepers’ seem to have higher standards for who deserves a KA, meaning that some people who the surgeons would deem eligible for KAs are not referred to the surgeon (See Fig.2; Dieppe et al. 2008).

All of the above highlights the need for improved decision aids for KA prioritisation. In agreement, NICE recommends decision aids to support people referred for elective joint replacement in making decisions about their treatment.

Gait Changes in KOA.

Gait Changes Through KOA Progression.

Gait changes.

Patients with KOA demonstrate reduced gait parameters (stride length and gait velocity are reduced by 13.4% and 23.4%, respectively) arising from joint stiffness or reduced muscle strength in the knees [27], and plantar pressure changes which contribute to foot pronation and pain (Røsland et al. 2015, Zhang et al. 2017). The inability to prioritise patients for KA can be solved by classifying KOA and other pathologies severity based on spatiotemporal gait analysis. The literature proposes for stride length and cadence to be used for classification of KOA severity, where shorter stride length and lower cadence is associated with higher severity (Elbaz et al. 2014). A progressive decrease in cadence, walking speed, mean stride length, swing phase duration and single support phase, and increased stance phase duration and first double support phase correlates with increased KOA severity (Yadav et al. 2019).

KOA patients show the below changes in gait as their disease progresses (in terms of both radiological findings and pain levels) /compared to healthy controls:

- Reduced:
    - Stride length (Astephen et al. 2008; Hafer et al. 2020; Duffell et al. 2017; Yadav et al. 2019; Cheing & Hui-Chan 2001)
    - Step length (Wiik et al. 2017)

○ Walking velocity (Hafer et al. 2020; Wiik et al. 2017; Duffell et al. 2017; Yadav et al. 2019; Cheing & Hui-Chan 2001)
○ Cadence (Hafer et al. 2020; Yadav et al. 2019; Cheing & Hui-Chan 2001)
● Increased:
○ Stance and stride time (Astephen et al. 2008)
○ Stance % during gait (Astephen et al. 2008; Hafer et al. 2020; Yadav et al. 2019)
○ Gait asymmetry (Robadey et al. 2018; Wiik et al. 2017; Bączkowicz et al. 2018)
○ Gait width (Wiik et al. 2017)
○ Centre of pressure trajectory lengths in early KOA vs no KOA in single foot stance (Duffell et al. 2014)

It should be noted when discussing gait asymmetry in KOA that if a patient has symptomatic unilateral KOA (in one leg), this will result in asymmetries in knee biomechanics while bilateral (both legs) pain is associated with symmetry (Creaby et al. 2012).

Machine learning models analysing changes in gait have been able to predict KOA severity as measured by WOMAC pain scores (Kwon et al. 2020). Other machine learning methods for detecting KOA have been developed using parameters such as vertical, anterior-posterior, and mediolateral GRFs collected after KOA patients walked on a walkway containing force plates. This method had a 5-fold cross-validated accuracy of 72.61% ± 4.24% (Kotti et al. 2017).

Plantar Pressure Changes.

It seems that individuals with KOA tend to have increased foot pronation. For example, some papers have found that plantar pressures in the midfoot and first metatarsophalangeal joint (MPJ) are higher in women with KOA than those without (Zhang et al. 2017). Other papers have found that KA patients have much higher plantar pressure in the non-operated foot and the heel region of that foot compared to healthy individuals (Heil et al. 2019).

Røsland et al. found significant correlations between the maximum force applied by the medial forefoot and pressure pain thresholds, conditioning pain modulation, and WOMAC and BPI pain scores in KOA patients as well as a (non-significant) tendency for the percentage maximal force in the lateral forefoot to increase with increasing pain. This suggests that the maximal force under the medial forefoot decreases as the pain increases (Røsland et al. 2015).

Gait Changes Following KA.

Gait parameters seem to improve following KAs. A recent systematic review concluded that TKAs consistently improve postural stability compared to the pre-surgery state (de Lima et al. 2021). Gait speed, stride length, knee flexion/extension range, and maximal knee flexion all increase 1-year post-TKA compared to pre-TKA (Bonnefoy-Mazure et al. 2020). However, in Bonnefoy-Mazure et al. only maximal knee flexion post-TKA was found to influence the level of patient satisfaction (Bonnefoy-Mazure et al. 2020). Contradicting this, Bączkowicz et al. found an indirect correlation between gait velocity and function WOMAC subscores (Bączkowicz et al. 2018). Suh et al. found that gait speed and gait endurance are positively correlated to cadence and stride length while negatively correlated to timed up-and-go, stair-climbing test ascent, stair-climbing test descent, visual analogue scale, WOMAC pain indices, stiffness and function levels following TKAs. In other words, they found that the faster and more you can walk after KA, the greater your cadence, stride length, and functionality and the lower your pain and stiffness levels (Suh et al. 2019). Some papers, such as Heil et al., contradict this, showing no significant changes in postural sway or plantar pressure pre and post KA (Heil et al. 2019).

Despite improvements in gait parameters, post-KA compared to pre-KA, TKA patients still have worse balance compared to their healthy counterparts (de Lima et al. 2021; Bączkowicz et al. 2018). Following TKAs, Bączkowicz et al. found that patients have slower gait compared to healthy control (Bączkowicz et al. 2018). Gait asymmetries in step length have been noted 15 weeks after surgery possibly due to the habit of using crutches in the early postoperative period (Bączkowicz et al. 2018).

There are also some differences in gait between individuals with TKAs and those with unicompartmental KAs (UKAs). While a recent meta-analysis showed that UKA and TKA patients were similar in terms of vertical GFR, walking speed, and cadence while stride length is shorter in TKA patients compared to UKA patients (Nha et al. 2018; Agarwal et al. 2019).

Post-KA rehabilitation.

Current State of Post-KA Rehabilitation.

The goal of postoperative care for TKA patients is to restore the greatest possible mobility and muscle control to the knee. Adequate rehabilitation is important for achieving successful TKA outcomes (Collins et al. 2019). The exact rehabilitation programme differs from surgeon to surgeon. In-bed rehabilitation starts on day one of surgery. Full weight-bearing is also possible under the supervision of a therapist with a walker. More active rehabilitation exercises, such as straight leg raises, can start one day after surgery (Hsu et al. 2021). The average hospital stay for a TKA is about 1-2 nights. Usually, patients have to show that they can safely walk with an assistive device on flat ground and stairs as well as show the ability to get into bed from sitting or standing positions and good pain control before being discharged from the hospital and going home or to a skilled nursing facility (Hsu et al. 2021).

After leaving the hospital, patients get a postoperative visit at the two-week mark, where the wound is checked and surgical staples are removed. If not already begun, at this point outpatient physical therapy starts. Patients increase their walking, independence in daily activities, and work on their range of motion and quadriceps strength. It usually takes patients 4-6 weeks to improve to the point where they can resume driving and operate car gas pedals safely and rapidly. After 4-10 weeks they can get back to work, depending on what their job is. Patient follow-up is usually at 6 weeks, 3 months, and one year after surgery. Once strength, mobility, and balance are regained, patients can resume low-impact sporting activities although high-impact activities are discouraged (Hsu et al. 2021).

However, rehabilitation communication is still not ideal with many KA patients with ongoing pain blaming themselves for this pain and believing that they must either have done too much or too little exercise in the immediate postoperative period (Dieppe et al. 2008). Although post-surgery rehabilitation improves outcomes and can be more cost-effective than usual care for at least 9 out of 10 patients, >50% of patients fail to continue recommended aftercare following inpatient rehabilitation (Sibold et al. 2011). NICE recommends the need for further research on long-term follow-up and monitoring after joint replacement surgery (NICE 2020).

The Future of KA Rehabilitation.

Rehabilitation has been shown to significantly improve QoL. Early-phase aquatic therapy, enhanced physiotherapy protocols, and fast-track treatment improve quality of life according to SF-36 and EQ-5Q questionnaires (Papalia et al. 2020). Heikkilä et al. showed the enrolling patients in a 12-months progressive home exercise program starting two months post-KA increased (improved) maximal mean velocity maximal mean cadence and reduced operated leg stance time significantly compared with no-exercise controls (Heikkilä et al. 2017). Furthermore, a recent meta-analysis found that early initiation of rehabilitation following KA is associated with shorter lengths of stays in hospital, lower overall cost, with no evidence of more adverse reactions (Masaracchio et al. 2017).

Enhanced recovery after surgery (ERAS) or fast-track programmes were developed by a Danish surgeon, H. Kehlet in the 1990s (Kehlet et al. 1997). ERAS advocates a set of measures to optimise treatment before, during, and after surgery to reduce postoperative physical and psychological trauma and stress, and thus accelerate recovery. Berg et al. found that in TKA fast-track programmes there were three chronological phases (Berg et al. 2019):

1. Preparation (approx. 3 months): Planning and patient preparation from operation decision to hospital admission
2. Hospital stay for surgery (1-3 days): Time from arrival to discharge
3. Recovery: Starts after hospital discharge and includes rehabilitation, regaining function, and returning to daily life activities(For more information see Fig. 3.)

This type of fast-track programme reduces hospital stay length and complications which result in the length of hospital stays longer than 4 days without increasing readmission or mortality in those >85 years old (Petersen et al. 2020).

Telemedicine further shortens hospital stays in fast-track programmes. A Danish clinical trial found that providing a telemedicine solution to hip replacement patients cut lengths of stay from 2.1 to 1.1 days (Vesterby et al. 2017). In a qualitative study, surveyed healthcare professionals proposed several parts of the KA care pathway which could benefit from telemedicine. They stated that prior to surgery, patients should be educated about the eligibility criteria for surgery and healthcare professionals should be informed about patient-reported outcome measures including, willingness for joint replacement, comorbidities, physical functioning/performance, health behaviour, etc (Jansson et al. 2019). Following the COVID-19 pandemic, KA care has shifted further towards telemedicine (Windsor et al. 2021).

Telehealth can aid several aspects of patient experience highlighted in Fig. 3. For example, it can be involved in prioritising patients according to functional outcomes and thus providing patients with a surgery date at an earlier time point. This is particularly important as patients report major anxiety around surgery dates with some stating "The heart pounds when the letter comes it pounds enormously … because you don't know what the date will be. And when you see the date, you're so happy … you've finally got a date, that you can mentally begin to focus on something" (Berg et al. 2019).

Telemedicine can also provide standardised patient education prior to surgery about what to expect. Some patients report not being aware of the loud sawing sounds that they will experience if they opt for spinal anaesthesia as opposed to general anaesthesia, with many stating that they would like to avoid the unpleasant experience of being conscious while they are being operated on (Berg et al. 2019).

Rehabilitation can also be significantly optimised by telemedicine as previously mentioned with the patient noting a need for improved information about post-operative care: "I would have liked to know more about the period after the surgery. No one told me about that. Maybe I had needed to be more prepared because it was very hard, at least the first 3-4 weeks" (Berg et al. 2019). Patients also note a lack of follow-up stating "In any event it concerns how one goes and what one can expect. Limping like this. Yes, I think it's a bit strange that the doctor didn't try to get information about how the operation had gone in greater detail, about how the patient is feeling after the operation" (Berg et al. 2019).

There are now a few tech solutions targeting KA care. IDEEA(r), GaitSmart, SHIMMER3 IMU, and ActivPAL3(tm) are technologies that involve placing multiple sensors on the thighs, ankles, and feet or even taping sensors onto patients' skin. However, attaching multiple sensors can be complicated, bulky, and unseemly, making patients less likely to use them and limiting use to in-clinic.

While some of these solutions, such as GaitSmart, do provide personalised rehabilitation exercises for KA patients, they are too complicated for continuous monitoring and thus the only function for in-clinic use. Providing only in-clinic monitoring makes such devices less likely to help physicians prioritise patients or motivate exercising devices that continuously patients and provides regular notification updates on their gait improvements such as actibelt(r) (gait analyzing belt) and mymobility (Apple Watch app). These, however, have lesser accuracy overall and do not directly measure aspects such as pronation, an element directly linked to KOA pain, such as pronation. Currently, no pressure-sensing insoles for gait analysis pre- or post-KA are available on the market.

Clinical pathway	Generic categories	Subcategories
Phase 1: preparation—from surgery decision until hospital admission	1.1 Confirmation that surgery is needed	1.1.1 Fear of not being accepted for surgery 1.1.2 Satisfaction when decision was made 1.1.3 Importance of shared decision-making
	1.2 Planning the date of surgery	1.2.1 Frustration when not knowing the date, and satisfaction when knowing it 1.2.2 Desire to influence the timing of surgery 1.2.3 Fear that the operation may be canceled
	1.3 Planning the anesthesia	1.3.1 Fear of being awake and having unpleasant experiences during surgery 1.3.2 Fear of complications of spinal anesthesia 1.3.3 Importance of shared decision-making
	1.4 Information about care and outcome of surgery	1.4.1 Diversity in information needs 1.4.2 Scanty information about the recovery 1.4.3 Influenced by information from other sources
Phase 2: hospital stay for surgery	2.1 Admission on the day of surgery	2.1.1 Recognition and a feeling of familiarity 2.1.2 Affirmation and seen by the staff
	2.2 Early mobilization after surgery	2.2.1 Mentally prepared and safe to be mobilized 2.2.2 Hesitation but ready to cooperate
	2.3 Early discharge	2.3.1 Acceptance and satisfaction 2.3.2 Objections and worries
Phase 3: recovery—after discharge from hospital	3.1 Managing daily life	3.1.1 Safety when having support at home 3.1.2 Diversity in pain control
	3.2 Rehab program and recovery	3.2.1 Different needs for personal coaching 3.2.2 Uncertainty about progress
	3.3 Feedback and follow-up	3.3.1 Concerns about unfulfilled expectations 3.3.2 Need for further explanations from the surgeon

Fig.3: Summary of patients' experiences in the care of total hip and knee replacement (Berg et al. 2019)

Conclusion.

Path Insight has a variety of potential applications in the KOA population. Not only can its ability to prioritise patients for KAs help decision making for healthcare professionals and tackle the massive KA backlog, via the use of both pain questionnaires and objective gait metrics, it can help reduce inequalities and biases in KA prioritisation. Furthermore, Path Insight's app will be able to provide patients with standardised clinician-approved information on what to expect before, during, and after surgery. Finally, via monitoring patients' gait metrics, Path Insight will be able to provide personalised physiotherapist-approved prehabilitation and rehabilitation exercises in order to get KOA and KA patients back on their feet.

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