"Without data you are just another person with an opinion" - W. Edwards Deming

Executive summary

moveUP digital therapeutics is on a mission to drastically improve health management through the smart application of data and technology. At moveUP we are convinced that healthcare will go through a drastic transformation, whereby the payment model will evolve from the fee-for-service model to an outcome based one (pay for performance model). This transition towards value-based health care means that clinical benefit and value for money should be demonstrated for every intervention. In turn, data collection to measure outcomes and drive innovation is becoming a central issue for all stakeholders. moveUP have the ambition to be at the heart of this transformation, focusing initially on orthopaedic pathologies, starting with total hip and knee arthroplasty (THA and TKA).

Although hip replacement is only second to cataract surgery in terms of health benefits 7-23% of patients are not entirely satisfied with the final outcome. The figure is 10-34% for knee replacement patients. This can be mostly explained by chronic pain due to variability of care at every step of the pathway. With the increasing drive to reduce length of stay and the growing popularity of day surgery joint replacements there is even less visibility of struggling patients which poses safety concerns without a way of monitoring patients' progress. At the same time, shorter hospital stay driven by workforce shortages and other economic reasons can negatively impact the patient experience too, especially when it comes to the lack of advice on recovery and rehabilitation.

Humanity when faced with challenges often responds by developing novel technologies. In our age data science offers a solution to some of the problems health care is struggling with. The growing ubiquity of smartphones and wearable devices even within the over 60 age group allows the collection of the necessary real-life data cheaply and conveniently.

moveUP takes advantage of this progress in technology and have developed a digital coach and monitoring solution to manage patients' expectations, fears and beliefs before, during and after surgery to improve satisfaction and quality of care. More than 400 data points are captured per patient via an activity tracker and daily questionnaires on a mobile app providing a complete picture of their medical profile, physical activities, psycho-social profile and expectations. The data in turn is used to monitor patient progress, ensure safety and drive rehabilitation. Machine learning on the granular data helps to predict outcomes, support clinical decisions and optimise and personalise treatment. Health care professionals can gain previously unattainable insight into the pathway for quality control and service improvement.

moveUP Therapy is at the forefront of the new paradigm combining research evidence and real-life data: evidence-based, personalised, data driven medicine. In this model the available research evidence serves as a starting point for the development of treatment protocols. After clinical

implementation the protocol is continuously updated using real life feedback data from patients. The feedback serves a double purpose: it is used to optimise and personalise the treatment for the individual patient and to refine and adjust the protocol for patients coming after. In this way both research evidence and real-life data can be used to make treatment decisions less prone to subjective biases, driving down unjustified variability and ultimately allow for automatisation.

Remote healthcare has come to the fore more than ever in the aftermath of the Covid epidemic. The moveUP remote monitoring and rehabilitation solution brings both health and economic benefits at the best of times, but even more so in context of a restructured health care system battling with the pandemic.

With ongoing research and development including a 1M Euro research project in collaboration with Vrije Universiteit Brussels moveUP is on course to become a leader in the application of machine learning in the context of orthopaedic surgery and rehabilitation. Further developments are ongoing to expand the service to other common orthopaedic pathologies, bariatrics, thoracic surgery and oncology.

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1. Introduction

Medicine has evolved organically over the course of history along with the societies it was embedded in. Empirical or trial-and-error medicine is being replaced by "evidence-based medicine". Although the name would suggest that health care professionals consider all the evidence related to the clinical problems they face this is often not the reality on the ground. Even if it was the case they would select and interpret the available evidence differently based on their personal experiences and biases. The situation is compounded by the fact that good quality evidence is extremely time consuming and expensive to produce so only the big questions are pursued in this way. The best evidence comes from randomised clinical trials, but quite often even these deliver limited and 'synthetic' snapshot data. The current model of health care therefore is better described as "expert driven" with inevitable variability. Some of this is wholly justified as different cultures, patient expectations may lead to different treatment decisions for the same pathology, but often unexplained and reflect the biases of the health care professional.

In recent years, the focus of researchers and policy-makers has shifted from processes towards a more patient centred approach by looking at the entire patient experience. This involves a more holistic approach paying attention to all pre- and post-operative measures to further improve the overall outcome and experience for patients. Similarly to hospital care, pre- and postoperative standards of care and rehabilitation vary significantly across the spectrum. (1)

Dissatisfaction & chronic pain after joint replacement

An example of variability of care is the diverse outcomes after joint replacement surgery. Hip replacement is often referred to as the surgery of the (20th) century. Since its introduction in the seventies, it has evolved from complex surgery with unpredictable results reserved for the elderly to a common surgical procedure with more predictable results for all age groups. Despite the advancements in surgical and anaesthetic techniques, implants and other technology, still a substantial number of patients remain unsatisfied after hip and knee replacements for various reasons. The most important factor determining the outcome is the presence of chronic pain which occurs in 7-23% after Total Hip Arthroplasty (THA) and 10-34% after Total Knee Arthroplasty (TKA). (2) The cause of chronic pain is multifactorial, but it could certainly be reduced using data to help the decision making from the indication through to rehabilitation at every step of the treatment pathway.

In the Belgian context, Segal et al. showed that important variations still exist between Belgian care pathways for TKA patients. Not all evidence-based key interventions are implemented or planned which may lead to quality and safety issues. In recent years structural changes have been made in the reimbursement for low variability hospital care, which also applies to uncomplicated TKA and THA surgery. These measures include a penalty for unnecessary consultations in an attempt to improve consistency and drive down costs.

Lack of insight into clinical practice

Routine outcome data collection is still not universal even in developed countries and where some exists it is confined to Patient Reported Outcome Measures (PROMs) at a few points in time. Outside of academic centres and clinical research poor compliance reduces further the value of the data collected. A lot more data is gathered in the pre-operative period to assess (mainly anaesthetic) risk, but this is not in a suitable structure for machine learning to predict outcomes and to optimise treatment.

Enhanced recovery programs

To improve outcome, patient satisfaction and efficiency, a lot of work has been done to optimise surgical and anaesthetic techniques and to standardise hospital care through multimodal enhanced recovery programs such as the introduction of multi-disciplinary care pathways and fast-track surgery with early mobilization. (3) Research, including meta-analyses, has shown that 'Enhanced Recovery programmes After Surgery' (ERAS) and early rehabilitation after TKA and THA surgery is associated with a shorter length of stay (LOS), lower overall costs with no evidence of an increased rate of complications or increase of 30-day readmission rate. With the advent of day case joint replacement services on a large scale in some countries, safety and optimal rehabilitation are becoming increasingly important.

Mobile Health (mHealth) and remote rehabilitation

It is becoming clear that after certain surgical procedures face to face rehabilitation does not add significant value over home exercise. NICE in the UK recommends that after routine joint replacement patients should have self-directed rehabilitation. (4) Countries facing workforce shortages and lack of facilities are forced to adopt home rehabilitation for these reasons.

Marcolino et al. state that in healthcare in general, mHealth is increasingly being used for

- patient communication and monitoring
- to reduce the burden of diseases linked with poverty
- to improve access to health services, clinical diagnosis and treatment adherence
- for chronic disease management

mHealth could improve the quality of care at a low cost even though conclusive evidence is still lacking. (5)

The use of mHealth in orthopaedic care has been growing steadily over the last few years. After total joint arthroplasty multiple reviews have found a positive impact on efficacy. (6–9) Considering the growing burden of care due to the expected increase in hip and knee arthroplasty surgery, tele-rehabilitation can be a cost-effective model of care. (7) This is confirmed by a systematic review by Koutras et al. who found a positive impact of using eHealth and mHealth after major joint arthroplasty surgery on costs, time and hospital visits. (10) In an

RCT, Moffet et al. found that satisfaction levels of patients using tele-rehabilitation vs home visits were very high and did not differ between groups. These results combined with emerging evidence of clinical effectiveness and cost-effectiveness, support the use of tele-rehabilitation to improve the efficiency and accessibility of care for orthopaedic patients. (11) mHealth solutions can potentially address multiple problems in orthopaedic care and rehabilitation:

- The growing burden on health care funds due to the expected increase of arthroplasty surgeries by offering a cost-effective rehabilitation solution
- The lack of evidence for type and intensity of physiotherapy on short- and long-term outcomes by using real life data to improve treatment protocols
- The need for further standardisation and optimisation of pre- and postoperative measures by using group data to identify pre- and postoperative risk factors
- No superiority of costly in-patient rehabilitation over home-based exercise therapy, by offering easily accessible care while still allowing for high treatment adherence and efficacy.

In the aftermath of the Covid-19 pandemic infection control rules require patients to stay away from communal buildings such as hospitals and rehabilitation facilities to avoid being infected and to stop the virus spreading. Home rehabilitation however needs to be safe and consistent so patients recover smoothly and problems and complications are identified early. mHealth solutions are an obvious way to provide high quality care safely.

Economic challenges

Driven by both demographic and non-demographic factors, the number of orthopaedic surgical procedures, particularly hip and knee replacements, is growing rapidly at a rate of more than 5% per year. It is expected that between 2015 and 2050 the absolute number of hip implants in OECD countries will rise by 50%. (12) The same trend can be seen in total knee arthroplasty surgery with also vast improvements in techniques and increasing numbers of implants. (13) Given the expected increase in the number of joint replacement patients, pressure on healthcare budgets are expected to rise. It is estimated that by 2030 the arthroplasty market will be worth $75Bn.

The emergence of value-based health care is a response to the widening gap between what is possible with new medical technology and the price societies are able to pay for health care services. To control costs payers are moving from fee-for-service payments to performance systems via bundled payments: a total budget is allocated for the entire pathway, from pre-surgery examination to discharge or even to full recovery, determined by validated outcome measures. It is therefore increasingly important that clinical benefit and value for money is demonstrated for any intervention. In turn the collection of data to measure outcomes is becoming a central issue for all stakeholders of the health care economy.

2. moveUP digital therapies

What is digital therapeutics?

“Digital therapeutics (DTx), a subset of digital health, are evidence-based therapeutic interventions driven by high quality software programs to prevent, manage, or treat a medical disorder or disease.” - Wikipedia

Digital therapeutics are a combination of evidence-based medicine and digital technology to support decision making, predict outcomes, drive down variability of care and personalise treatments. They are fundamentally different from simple adherence, diagnostic, or tele-health services as their focus is on delivering direct therapeutic interventions. They also have the ability to integrate with mobile platforms, sensors and wearables as well as existing health care IT infrastructure such as medical record systems.

DTx products need to follow technology best practices both in terms of design, clinical validation, usability, and data security. Unlike simple consumer apps DTx solutions are strictly regulated.

The field of DTx is as diverse as medicine itself, but they all help engage and empower patients, support healthcare providers in achieving better and more efficient care through high quality, safe, and effective data-driven therapies.

What is moveUP?

moveUP is a digital therapy for remote, personalised, data driven hip and knee replacement rehabilitation. Further pathways in orthopaedics and beyond are being developed and rolled out according to our development roadmap. moveUP was borne out of the frustration over the inability to control the postoperative recovery after joint replacement surgery resulting in high incidence of chronic pain and dissatisfaction especially after knee arthroplasty. Since its inception the project has grown to cover data collection for the whole patient pathway and include predictive features and support for clinical decision making. The granular data moveUP collects allows unprecedented insight into the recovery process which can be used for research, service improvement and clinical audit.

The growing ubiquity of smartphones and wearable devices even within the 55-65 age group (4 on 5 own a smartphone, 1/5 wearable) and older (1 out of 2 smartphone, 1/10 wearable) allows the collection of a huge amount of real-life data cheaply and conveniently.(14) moveUP take advantage of this technological revolution and collects more than 400 data points during the entire joint replacement patient journey via the moveUP app, a commercially available activity tracker and remote monitoring.

The moveUP Therapy, is based on AI-driven protocols, that continuously adapt the treatment based on this data. It guides the patient through an optimal, personalised pathway before and after their hospital stay. This continuous, data-driven follow-up allows complications to be detected quickly, anticipate and prevent undesired situations such as persistent pain leading to higher patient satisfaction. Thanks to the automation provided by the AI models, these benefits come at a

reasonable cost. After 2 years of tests, pilots and studies, the moveUP platform and its orthopaedic therapy obtained CE marking as a Class 1 medical device with ISO 13485 certification in 2017. The cloud-based system is ISO 27001 certified for data security. The hip and knee replacement protocols are now being used in over 17 hospitals in Belgium and piloted in The Netherlands, France and the UK where moveUP aims to become the reference in its field.

The moveUP digital therapy enables healthcare providers to control the whole patient journey. It contributes to better patient selection, reduce chronic pain and dissatisfaction, while increasing efficiency of care. Structured, real-life data collection during the patient journey and the application of machine learning on this data allows to constantly improve the efficiency and the outcome of the treatment pathway. At the same time moveUP also engages and empowers patients so they can play a more active part in their rehabilitation.

3. The data we collect

The moveUP therapies are driven by more than 400 data points collected during the whole patient journey. These fall into distinct categories and fit every stage of the patient's treatment pathway:

- Before surgery: patient's profile and expectations, medical history. Baseline step count, and range of movement, Performance based outcome measures (PBOMs) and pain levels via daily questionnaires. Patient reported outcome measures (PROMs)
- During hospital stay type of surgery, anaesthesia, reported pain, medication and discharge assessment.
- During rehabilitation: step count, pain, joint warmth and swelling, medication use, walking aids, wellbeing, rehab exercise adherence and coping, range of movement, PROMs.
- After discharge from care: PROMs and patient reported experience measures (PREMs) are collected at 6 weeks, 3 months, 6 months, 1 year, 2 years and beyond to assure patients are doing well, there are no signs of complications and to benchmark long term outcomes.

Performance based outcome measures (PBOMs)

Performance-based measures require the patient to perform a set of movements or tasks. Scores can be based on either an objective measurement (e.g., numbers steps taken or range of movement) or a qualitative assessment that is assigned a score (e.g., normal or abnormal mechanics). Both PBOMs and PROMs capture a current status and these measures do not necessarily equate with each other. While patient reported outcome measures capture a patient's perception, beliefs, social and/or health factors, performance-based measures allow insight into underlying physiologic factors. (15)

Currently, moveUP uses two performance measures: daily step count and weekly ROM analysis for TKR patients.

Continuous activity data (step count)

We ask patients to wear an easy to fit activity tracker paired with their smart phone. It is waterproof with a battery life of at least six months so patients do not need to take it off for any reason and can wear it 24/7.

The activity tracker is a good objective indicator of the patient's activity as it is worn in 97.7% of the cases. The most common reason for not wearing it, is 'forgotten' (2%), other reasons are 'day of surgery', as hospital policies quite often do not allow these devices in the operating theatre, and 'not working' both less than 1%. Patients need to wear the tracker day and night, subsequently also allowing to measure sleep duration and number of times the patient wakes up. The activity tracker is validated for commercial use and moveUP will only allow the use of other wearables after a certification process.

The average number of steps per day varies hugely between patients. The value of activity data therefore is not in the absolute but in the relative comparison. Ideally, patients start to collect data two weeks before surgery. Patient's baseline daily activity recording is done on D-14 and D-7 prior to surgery. The week immediately before surgery we see an increase in activity compared to the week D-14 to D-7 as patients want to get a lot of housework done which they will not be able to do in the first weeks postoperatively. The daily step count is represented by the blue bars on the medical dashboard.

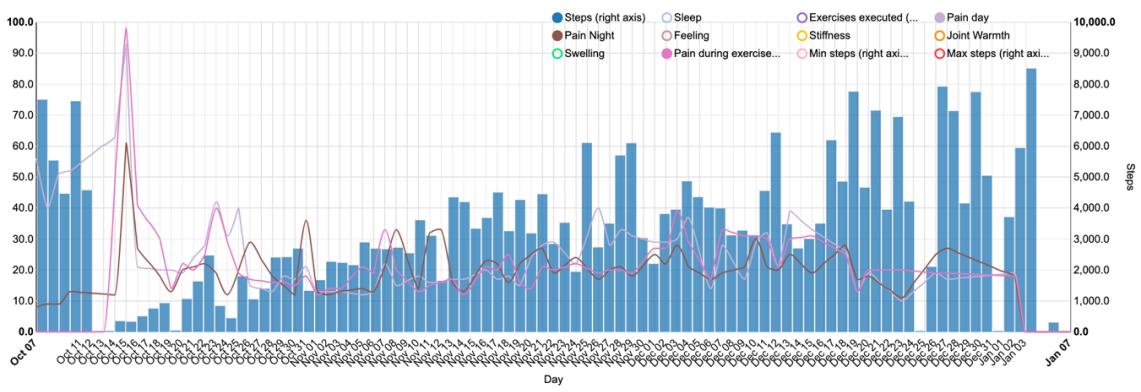


Fig. 1: Continuous data of patient 1253 – reference 10.000 steps

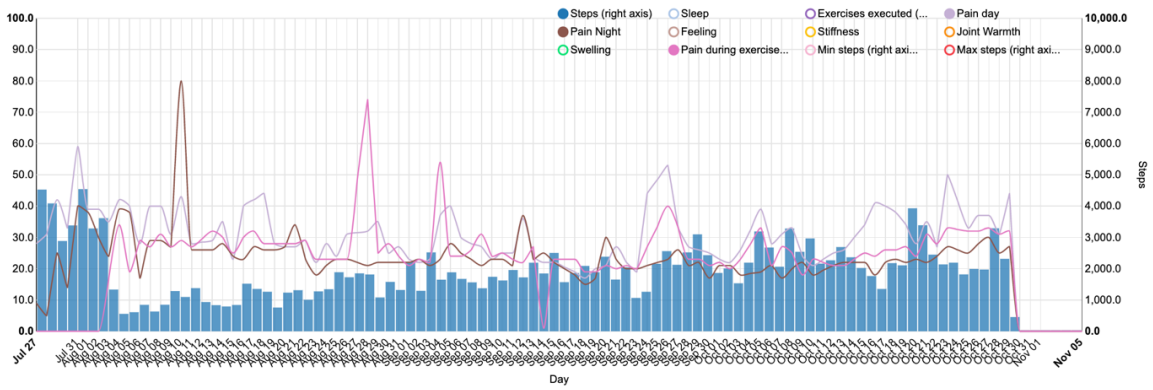


Fig. 2: Continuous data of patient P433 – reference 10.000 steps

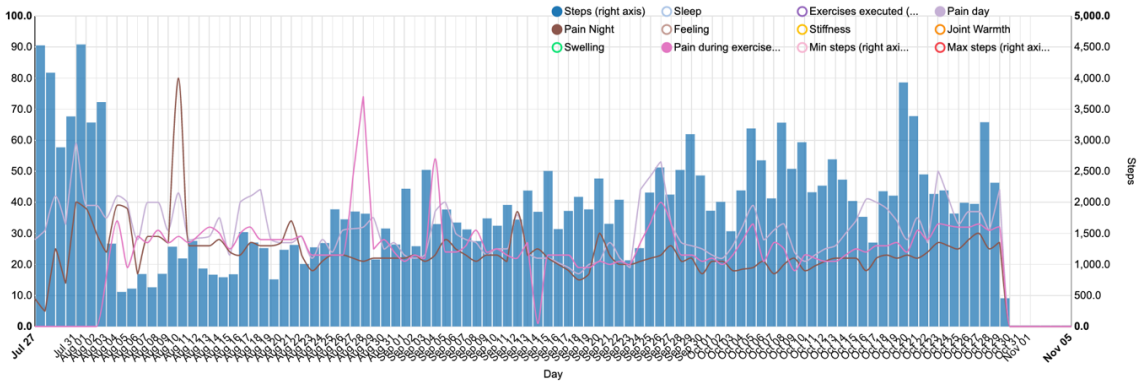


Fig. 3: Continuous data of patient P433 – reference 5.000 steps

When comparing the graph of patient 1253 with the first graph of PP433 the second patient seems less active both before and after surgery. However, after adjusting the scale to 5.000 steps the graphs are easily comparable.

The step count is used to measure the overall activity of patients which feeds into the adjustment of the rehabilitation program. Should pain levels, medication use or inflammatory parameters remain high or increasing - among other measures - the patient may be asked to reduce their activity to allow the operated joint to settle down.

An important milestone, when patients regain their pre-surgery activity level can also be used as an outcome measure.

Automated range of movement analysis

Range of movement (ROM) is an important measure of joint function and is followed closely during TKR rehabilitation. Patients are asked to take a video of their knee going from maximum extension to maximum flexion every week and upload it to the moveUP platform. The automated, AI driven video analysis allows an objective measurement of the ROM with 96.7% accuracy. This model increases the reproducibility of the measurement and the efficiency of physiotherapy, hence classified as clinical decision support system (CDSS). Figure 4 depicts the cumulative ROM from week 1 to 4 postoperatively. The ROM is measured as the difference between maximum flexion

and extension. As expected, the first post-operative week delivers the worst results, with less than 50% of patients being able to achieve 90 degrees of flexion or more.

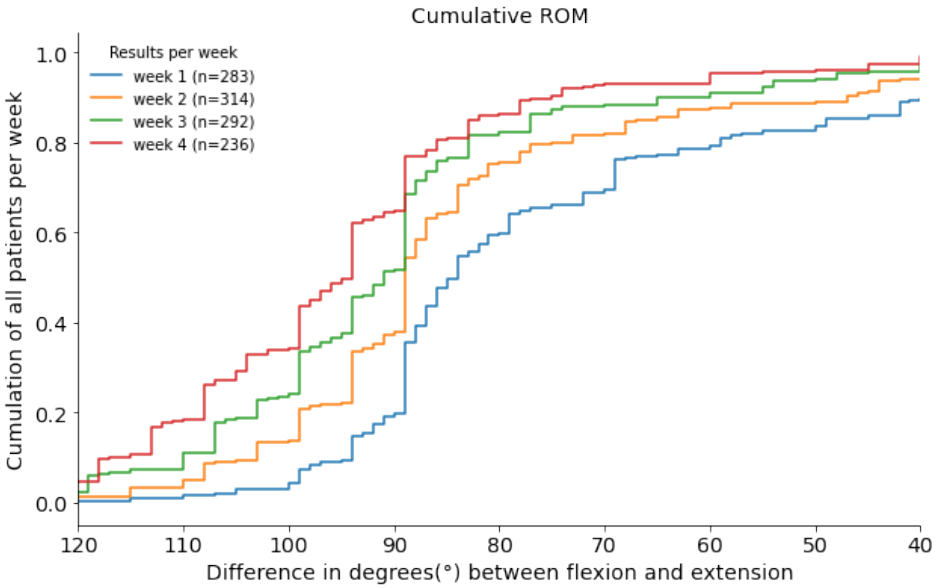


Fig. 4: Cumulative range of motion (maximum flexion - maximum extension) of all knee patients in the moveUP database. The results of week 1-4 postop are displayed.

In case the ROM unexpectedly stops improving during the course of the rehabilitation, the team can investigate the cause and intervene at the earliest opportunity if deemed necessary.

Daily data collection

We ask patients to complete a daily questionnaire which becomes available after 4 PM each day. The questionnaire includes the following categories: pain, swelling, stiffness, general feeling, joint temperature, stiffness, medication use, activities of daily living (ADL), exercise adherence and use of walking aids.

Pain

Pain is the main symptom of osteoarthritis and the goal of any intervention is to help patients get rid of it. It is therefore the single most important measure of success following joint replacement surgery and a good indicator of a patient's progress. moveUP collects three pain scores daily: night pain, rest pain and pain after exercise. A digital version of the Visual Analogue Scale (VAS) is utilised, where patients need to indicate their pain on a slider ranging from 0 (best) to 100 (worse). The three different pain scores are colour coded on the medical dashboard: the brown line (pain at night), the magenta line (pain during day) and the purple line (pain after exercises).

The pain data is used to adjust the activity and exercises for the subsequent days. Over-exercise can result in increasing inflammation and pain so the patient is advised to reduce their activity i.e. walk less and/or change some of the exercises or the number or repetitions. On the other hand, if pain is under control activity can be increased.

The pain score also provides input into the flagging system to detect complications such as infection resulting in increasing pain.
The pain score is also used to set up a patient milestone: pain stop. In the literature significant (moderate and severe) pain is defined by a pain score of 40 or more on the VAS scale.(16) If pain levels are below the threshold for three days in a row the pain stop milestone is hit. If the pain increases again above the threshold value for three consecutive days, the pain stop milestone is delayed. Figure 5 shows the cumulative results of the pain stop milestones for different types of surgeries in the moveUP database. Knee arthroplasty seems to be more painful for longer than hip arthroplasty which is in line with literature data. moveUP can easily quantify this difference using pain data captured on a daily basis.

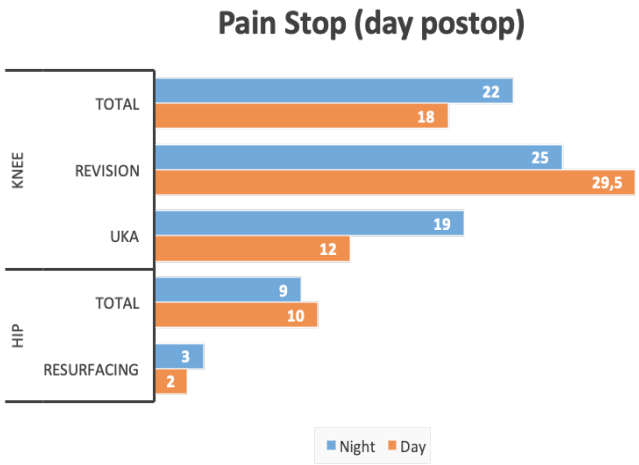


Fig. 5: The median pain stop milestone for different types of surgeries.

Medication use

Pre- and post-operative pain medication intake is a good indicator of pain control and the progress of the patient through rehabilitation. Even large national databases of Sweden and United Kingdom (National Joint Registry) do not provide information about medication use. moveUP however, provides detailed information on patient reported daily pain killer and anti-inflammatory use during rehabilitation.

The WHO classifies pain medication into three groups: Group 1 consists of Paracetamol and Non-Steroidal Anti-Inflammatory Drugs (NSAID) to control mild pain and the inflammatory process. Group 2 includes light opioids (Tramadol, Codeine) to treat moderate pain and Group 3 represents strong opioids (Morphine, Oxycodone etc.) to control severe pain episodes.

moveUP collects data on each group of pain killers on a daily basis building up a picture of medication use. We use the data to guide the rehabilitation as described in the pain section and to detect possible complications such as infection indicated by increasing pain levels and medication use.

Swelling, stiffness, warmth and general feeling

Along with pain scores patients need to indicate how much swelling, stiffness and warmth they have in the operated joint as well as their general feeling. We use a slider ranging from 0 (best) to 100 (worse). Swelling, stiffness and warmth indicate inflammation which should gradually subside following surgery. This data along with pain and medication use feeds into the adjustment of the activity levels and exercises to keep patients on track and avoid under- or over-exercising. A sudden increase in these variables may also indicate a complication such as infection.

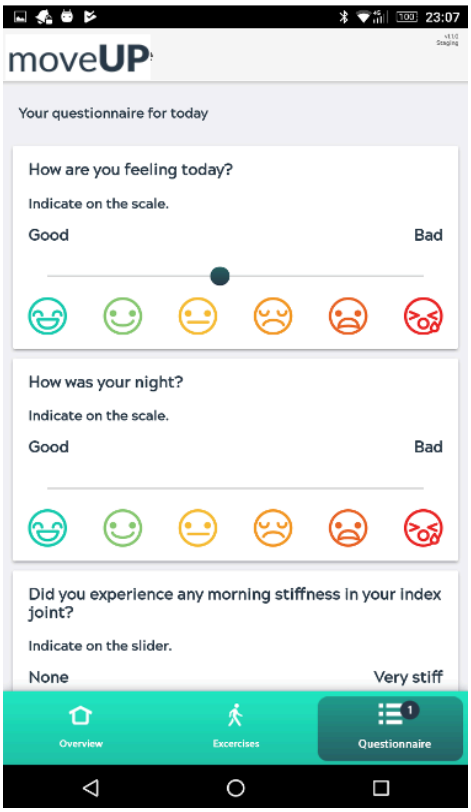


Fig. 6: Snapshot of how the patients can indicate their daily parameters on a slider.

Exercise adherence

It is important to understand how compliant patients are with the recommended exercise program otherwise all our efforts are in vain and we can come to the wrong conclusion with regards to a patient's progress. moveUP therefore asks patients to give feedback on how many repetitions they were able to do for each of the prescribed exercises. The flagging system on the medical dashboard helps quickly identify patients in need of encouragement and puts the other data in perspective. On average, moveUP patients are 85% compliant with the daily exercises.

Activities of daily living (ADL) and walking aids

Besides getting relief from pain, returning to activities of daily living are the most important factors defining patient satisfaction after joint replacement surgery. Stopping the use of walking aids is also a major milestone following arthroplasty. moveUP collects these data to gain insight into how quickly patients are able to return to their normal activities. The data can be used to inform and guide patients as well as for clinical audit.

Periodic data: Patient Reported Outcome Measures (PROMs)

PROMs are standardised and validated questionnaires allowing international benchmarking.

moveUP uses the Knee Osteoarthritis Outcome Score (KOOS), Hip Osteoarthritis Outcome Score (HOOS), Oxford Knee Score (OKS), Oxford Hip Score (OHS) and the Forgotten Joint Score (FJS). The Osteoarthritis Outcome Scores are subdivided into five different categories; pain, symptoms, activities of daily living (ADL), sports and quality of life (QOL). Additionally, this score includes another frequently used PROM i.e. Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC). The OKS and OHS evaluate the outcome of the surgery on a scale from 0 to 48, with a higher score indicating better outcome. The FJS rates the extent to which the patient is aware of the operated joint during various activities from 0 (worse) to 100 (best).

4. How we use the data

moveUP collects most of the data in a structure that allows machine learning to be applied. This takes different forms at each stage of the patient journey.

Preoperative phase

At this stage moveUP collects data on baseline function, motivation, medical profile, physical activities (level and type), psycho-social profile and expectations. This is used to plan the rehabilitation and increasingly to support peri-operative decision making and to predict outcomes. The moveUP index (a composite score taking into account several PROMs data and personal profile factors) helps to predict how successful the proposed surgery is likely to be and measures the progression made in a single score.

Postoperative phase

Based on the baseline data, step count and daily feedback the activity and exercises are adapted to keep the patient on the ideal path to recovery using the moveUP AI models. These are used as “augmented intelligence” tools to support and guide the physiotherapist who can overrule the decisions made by the algorithm if they feel necessary.

The type of models used for the exercise prediction are decision trees as these are easily interpretable for health care professionals. 'Black box models' are more difficult to integrate into clinical practice, because it is not known why the model suggests certain exercises and based on what data. Regulatory uncertainty is also an obstacle in this regard.

For each exercise, there is a separate decision tree. The data used in the decision tree are based on what the most relevant features are according to the model. The features can be: profile data (e.g.: type of surgery), data from daily questionnaires, PROMs, step count or other derivative data calculated from primary measurements (e.g.: average pain from day 3-7).

The physiotherapist needs to look at the preoperative PROMs to help define the post-op treatment approach. Daily adaptation of the therapy is based on pain scores, exercise coping and signs of inflammation. The postoperative PROMs are also used for treatment adaptions and advice on a higher time frame. Based on the answers in the PROMs it is clear which functional tasks the patient is struggling with the most, (e.g.: difficulty putting on shoes or socks —> work on deep flexion and rotation mobility in hip).

We know from experience, that patients with lower PROMS scores tend to have more complaints in the beginning and a slower build-up might be needed. When looking at the literature, patients with relatively lower PROMS preoperatively, tend to make more improvement after surgery (higher rise in PROM scores), compared to patients with higher scores preoperatively.

5. moveUP and the transformation of the standard model of care (SoC)

The conventional patient journey for joint replacement is divided into the following parts:

- Pre-intervention
- Intervention
- Post-intervention
- The end of care episode with or without long-term follow up

The current model of care is based on snapshots of data collection and intervention. The patient is seen in the outpatient clinic where the diagnosis is made and the severity of the condition is established based on the history, physical examination, imaging and laboratory studies. Once the surgery is scheduled, the patient is advised to attend a pre-surgery class together with other patients. Following surgery patients usually stay 2-5 days on the orthopaedic ward, then allowed to return home. Enhanced recovery and day surgery pathways have also been developed in some countries further reducing hospital stay. After discharge from hospital patients attend physiotherapy sessions which can be as often as 3-5 times a week (up to 60 sessions is available in Belgium after joint replacement surgery). More care-dependent patients will first go to inpatient rehabilitation centres for a 3 to 4-week period before going back to their home environment where rehabilitation can be continued under supervision of a peripheral

physiotherapist (PT). At the other end of the spectrum patients are given advice on "self-directed" rehabilitation and not routinely seen by physiotherapists unless their progress is insufficient, as is the current policy in the UK.
The first appointment with the surgeon is usually made after 6 to 8 weeks after surgery. If the surgeon feels that there is still some progress to be made, extra physiotherapy sessions are prescribed, and the patient is seen after another 6 weeks for a second appointment. If the patient made sufficient progress and is happy with the outcome they are discharged from care. In most countries there is no systematic long term follow-up, although national registries collect data on revisions and some of them on PROMs.
The events and progress between appointments are not always recorded and if they are this is in retrospect relying on the patients' subjective recollection. Events occurring after the end of the care episode are not recorded at all. The effect of these unknowns is also unknown.
In order to be able to better understand and control the patient journey data collection should be continuous, automatic and structured. moveUP transforms the standard model by adopting these principles, feeding the data into AI models and using it to drive the postoperative rehabilitation.

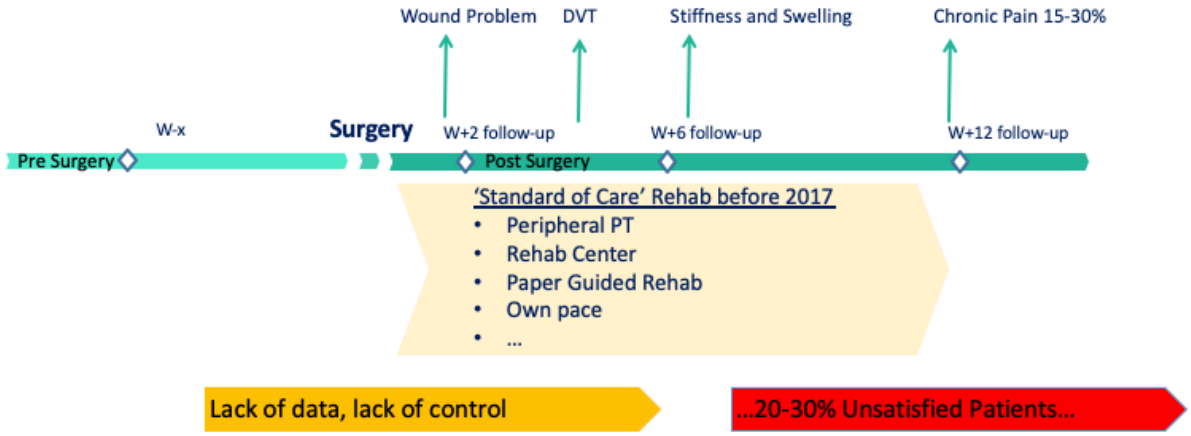


Fig. 7: Example of the TKA patient journey in AZ Maria Middelares before 2017.

Current standard of care (SoC)

As described above, the SoC patient-surgeon contact is restricted to the pre-surgery consultation, the surgery, the inpatient follow-up (1-5 days) and a few post-operative visits. During these consultations the surgeon obtains a snapshot of the patient's status. Figure 8a shows an overview of the information obtained, uncovering a large black-box between the patient-surgeon contacts. The patient could give the surgeon a retrospective view of the preceding weeks, but it may not be accurate and important information is often missed.

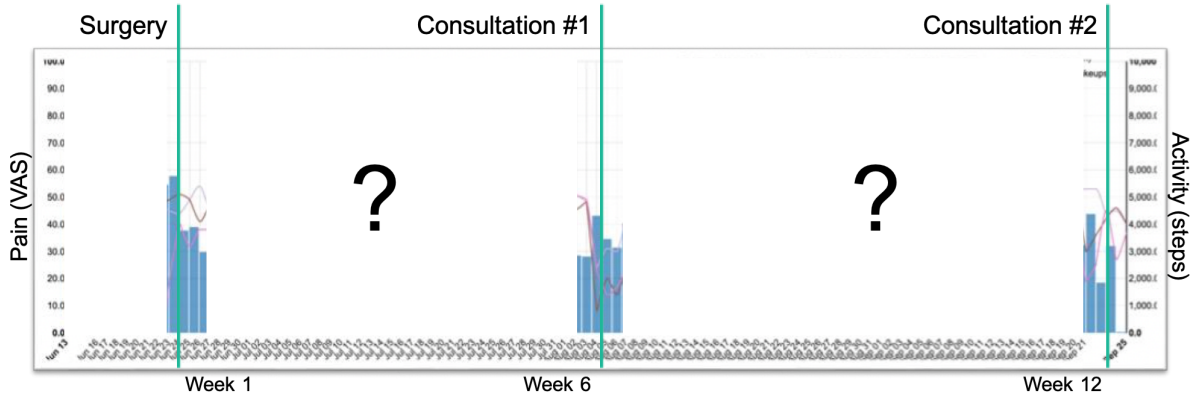


Fig. 8a: Current SoC, only functional outcome at 6-12 weeks and PROMs collection.

The 24/7 monitoring tool should overcome this black-box problem between consultations. Figure 8b depicts the wealth of patient rehabilitation data when adding daily monitoring to SoC consultations. Comparing figure 8a with 8b (same patient data) indicates that the pain drop on the day of the 6 weeks' consultation was temporary (about four days). This illustrates that without the daily monitoring tool, the surgeon receives a snapshot which does not reflect the patient's overall progress.

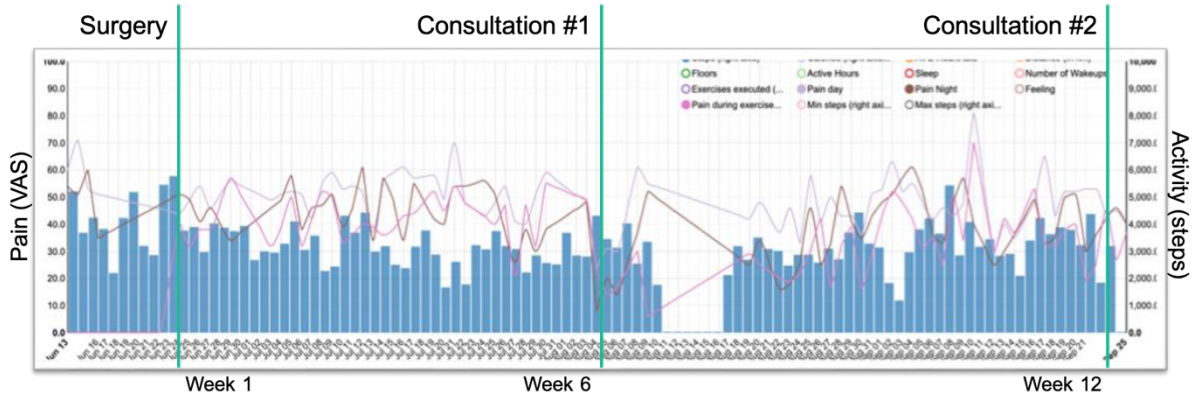


Fig. 8b: SoC added with 24/7 monitoring tool.

<u>The monitoring tool in action</u>

Figure 8c displays an example of the benefits of daily monitoring. This patient still had substantial pain (>40 on VAS) at 6 weeks following surgery. The 24/7 monitoring allows the surgeon to track the issue. In this case the activity level of the patient (blue bars) increased too soon, not allowing the joint to recover from surgery. The surgeon advised the patient to decrease his activity level resulting in an immediate drop in pain levels. At consultation 2 (week 12) the patient was again able to increase his activity without experiencing any pain.

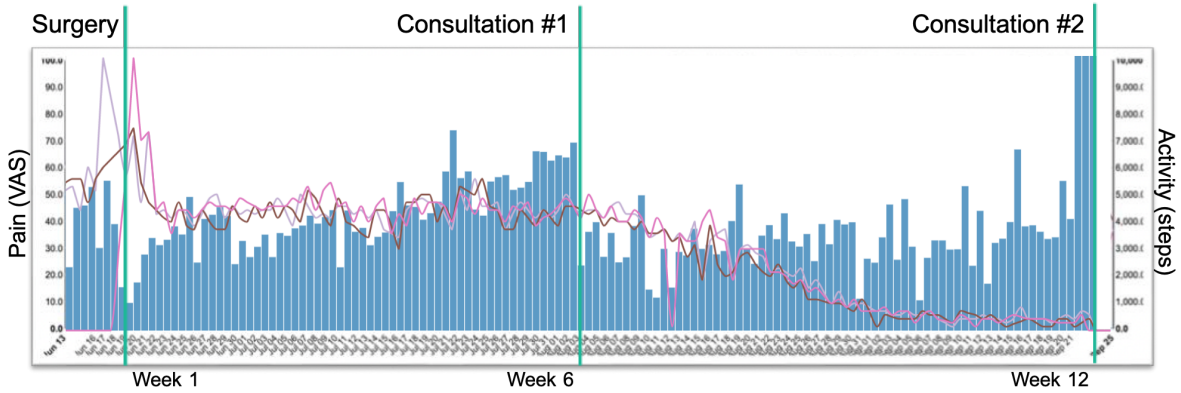


Fig. 8c: Example of a positive application of the monitoring tool.

SoC and 24/7 monitoring with moveUP Coach

Based on the daily data, personalised rehabilitation can be provided under the supervision of a physiotherapist who is in contact with the patient and intervenes if necessary.
Figure 8d shows an example of well controlled rehabilitation after surgery. The pain peak after surgery quickly disappears and there are no recurring significant pain peaks thanks to the daily monitoring and adaptation of therapy.

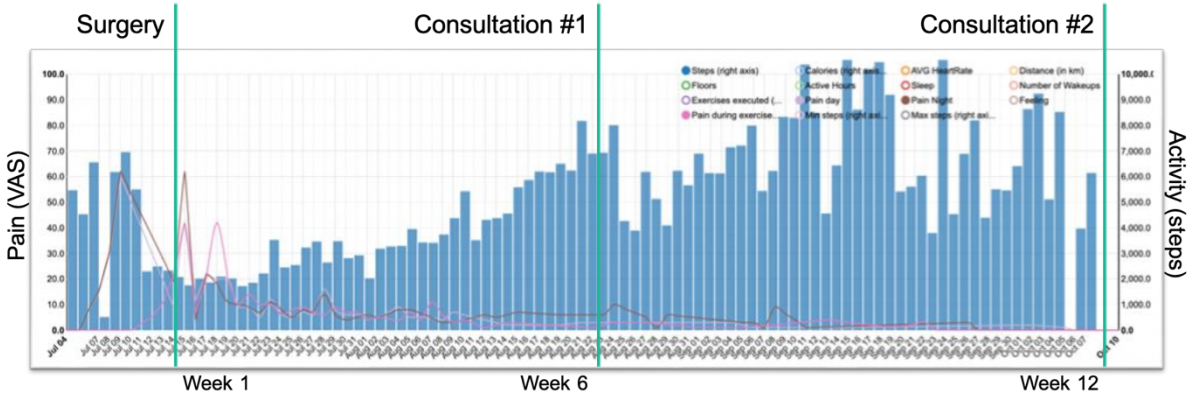


Fig. 8d: SoC and 24/7 monitoring tool added with moveUP Coach

6. Rehabilitation tool

The moveUP solution can be used at 4 different levels

– moveUP PROMs is a data collection tool to collect pre-assessment information and PROMs

– moveUP Companion is a data collection & patient education tool. It enables surgeons to collect patient information before consultation, helps in the assessment and diagnosis of

patients, to monitor and benchmark outcomes and overall quality of care. Patients receive relevant, personalised information and education on their treatment and progress.

– moveUP Coach adds a coaching solution to Companion. It enables the HCP to monitor how their patients progress on a live dashboard in terms of pain and function, and interact with them to offer advice or adjust their treatment. The dashboard supports multiple healthcare providers where issues can be escalated (PT > Nurse > Junior doctor > Surgeon) as applicable in individual hospital settings. The flagging system enables patients to be referred via the platform to the correct HCP. Patients and the HCP can interact via a secure messaging function.

– moveUP Therapy adds an evidence based, standardised and validated rehabilitation protocol to Coach. Automation allows to increase efficiency for healthcare providers and reduce variability of care. Automatic prioritisation of patients, adaptation of exercises and activity allows the HCP to focus on patients who need it the most.

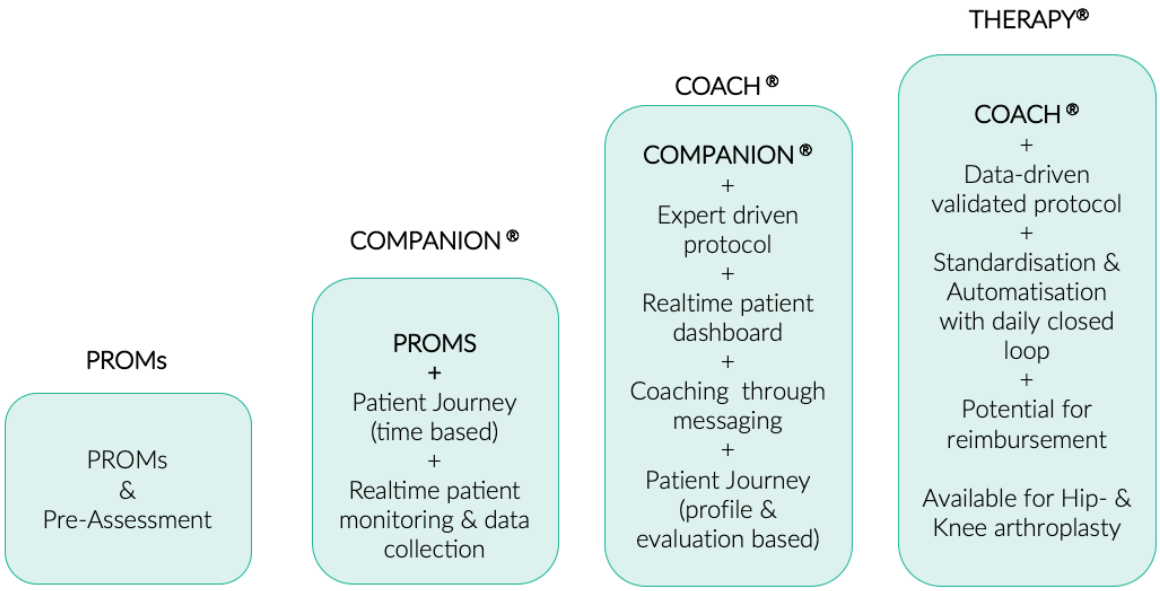


Fig. 9: Overview of the four different levels available in the moveUP solution.

The patient interacts with the system via an intuitive app on their smartphone or tablet. The patient is asked to report data on parameters detailed in the previous sections on a daily basis. Objective activity data (step count) is collected through a wearable device. Other objective data can be collected through video's, pictures and questionnaires.
Subjective data is collected through questionnaires and a messaging function.
Together with a profile dataset of the patient, this data is uploaded daily to a cloud server where the virtual clinic software runs. The virtual clinic is supervised by physiotherapists with access to other HCPs such as nurses and doctors. They verify the input of the patients and the output of the smart algorithms. The daily treatment of the patient is defined by a combination of automated, data driven decision making and clinical judgement by the care team, with the

ultimate goal being full automatisation as our algorithms evolve.

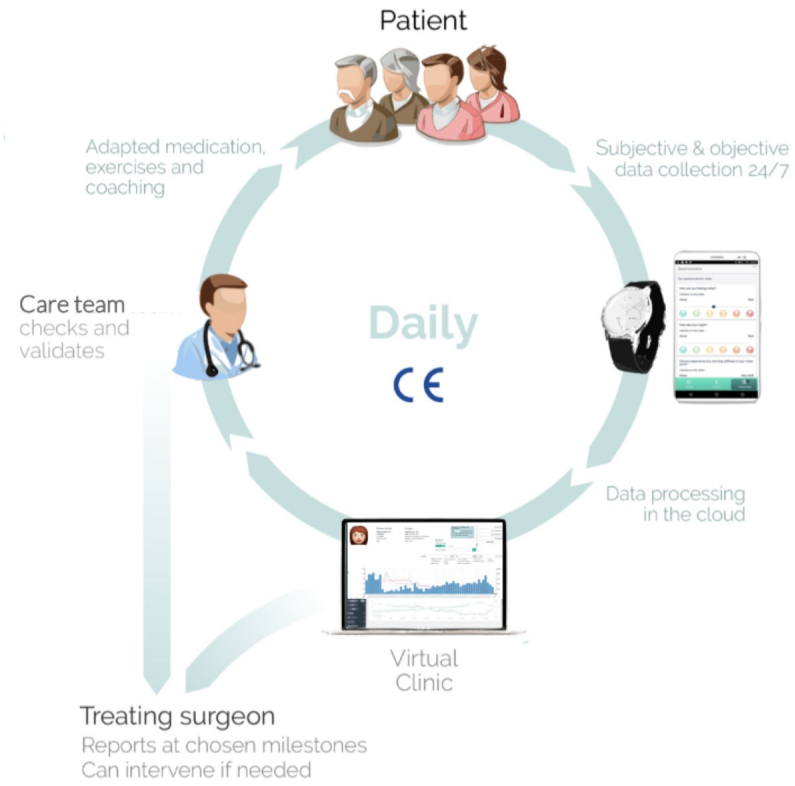


Fig. 10: Explanation of the use of the daily monitoring tool and moveUP Coach

7. Safety and clinical effectiveness

The safety of any health care product is of paramount importance. Digital therapies have to comply with strict regulations as required by relevant legislation. moveUP is registered as a CE Class 1 medical device and as such fulfils all applicable safety requirements. Beyond the necessary documentation and processes moveUP had to demonstrate the safety and clinical effectiveness of the platform in real life clinical use. Not only regulatory bodies and payers had to be convinced though, as the general opinion of health care providers (paramedical and medical) at the time was that a remote digital solution would be inferior both in terms of outcomes and safety. There was concern regarding the rise of complications, possibly leading to an increase in readmissions. Both adverse events can lead to unsatisfied patients and increased healthcare costs. To investigate these issues, a prospective cohort study including 200 patients from 3 centres was conducted over a six-month period in 2018. All patients followed a fully digital rehabilitation moveUP pathway.

Two inclusion criteria were applied:

1) the patient is discharged straight to their home after surgery

2) the patient should be able to perform activities of daily living independently at home

Outcome measures included readmissions and complications as well as PROMs (KOOS, HOOS, OKS and OHS). For comparison, literature and national registry data was used. The moveUP readmission data for the first 430 patients were collected at six months post-surgery, matching the selected papers. When papers compared a new technique against a conventional control group, the results of the conventional group were used. Readmissions for both medical and surgical reasons were included.
Limitations of the study are acknowledged as inherent in the design without a control group. Inclusion and exclusion criteria also vary between the papers and are usually stricter than those of our study. On the other hand, registries include all patients introducing an opposite bias.

Results

Complications. 426 moveUP patients completed this questionnaire. Complication rates were slightly lower than the median value found in the international literature based on 21 papers, published between 2004 and 2018. (17–31) The majority of complications collected are bleeding, phlebitis, inflammation and pain.

Fig. 11: moveUP complication rate compared with literature

Readmissions. 371 moveUP patients completed this questionnaire and 4 of them were readmitted to hospital (1.9%). (24,25,28,30,32–44) This was the lowest compared to literature data based on 16 papers published between 2006 and 2018.

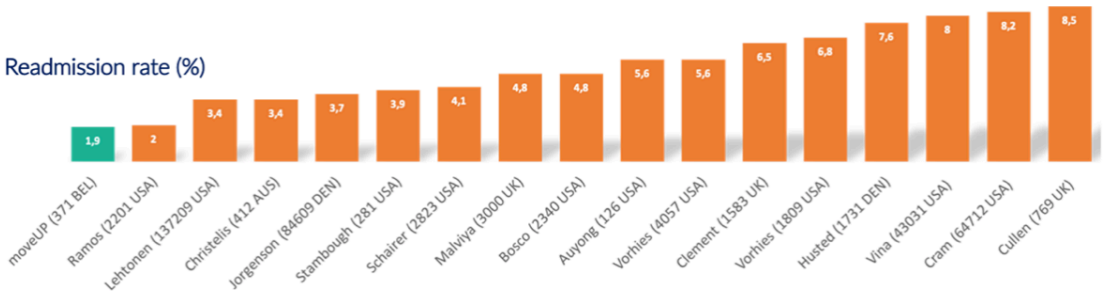


Fig. 12: moveUP readmission rate compared with literature

The discrepancy between readmission and complication rate proves the value of the moveUP solution in this domain. The daily follow up allows problems to be identified before they become severe enough complications requiring readmission. The close follow-up could also result in increased reporting of minor complications, not normally recorded. This may indicate that the incidence of post-operative complications is under-diagnosed if the data is not collected prospectively on a daily basis.

PROMs results. AJRR (American Joint Replacement Registry) is a national institution for primary and revision hip and knee replacement data collection. The presented data of AJRR was published in the annual report of 2018, based on data gathered in 2017. (45) The data obtained from the national knee registry of Sweden is published in the 2018 annual knee report, consequently this data was collected in 2017. (46) Unfortunately, the HOOS data is not captured or published in the annual hip report in Sweden. Figure 13 allows comparison between moveUP and registry data as wells knees vs hips.

Fig. 13: An overview of the KOOS and HOOS of moveUP patients compared to national registries (Sweden and America, AJRR). Both the pre-operative average values (baseline) and post-operative average values (1 year) are displayed.

Table 1 provides more insight into the KOOS and HOOS data. As previously described, both scores are subdivided into five categories. The category 'sports' is excluded from the investigation, since there is inconsistency in publishing this category in the literature. Hence only pain, symptoms, ADL and QOL are listed and tested against SoC. A t-test with α chosen 0.05 is used to align with literature. The majority of the p-values showed no significant difference between moveUP and SoC with two exceptions: moveUP scores were lower for ADL for knee patients compared to the national results of America. However, for hip patients moveUP performs significantly better than the AJRR concerning QOL.
What stands out is the fact that the mean results of Sweden and AJRR differ significantly (α = 0.05). This might be explained by cultural differences in scoring (e.g. Americans are more likely to give higher scores) and treatment differences (e.g. the surgical approach and rehabilitation pathway might differ between different countries).

Score		moveUP mean(SD)	Sweden mean(SD)	p-value	AJRR mean(SD)	p-value
KOOS	pain	81.7(19.3)	81(19)	.69	84.1(18.7)	.23
	symp	79.9(17.8)	78(17)	.24	80.9(17.3)	.60
	ADL	81.1(18.4)	80(19)	.55	85.3(18.0)	**.03**
	QOL	69.0(25.6)	65(23)	.07	71.2(26.0)	.42
HOOS	Pain	91.4(13.7)			88.5(15.8)	.07
	symp	89.5(13.2)			87.1(13.9)	.10
	ADL	91.3(13.4)			88.4(15.6)	.07
	QOL	85.3(18.6)			78.1(21.9)	**<.01**

Table 1: Comparison between moveUP and the national registries of the KOOS and HOOS

subcategories at 1 year postop. Significance calculated at α = 0.05.

Analogous to the KOOS and HOOS, both OKS and OHS are tested against SoC. National registries of Sweden and America do not include Oxford Scores, hence other registries were used to provide a basis for SoC. The Dutch national registry (2018) LROI contains both scores based on data collected in 2017. (47) A second source of OKS and OHS is a regional database used in a paper by Hamilton (United Kingdom), published in 2018 (48). Data were collected through informed consent for inclusion between 2007 and 2011. Figure 14 depicts an overview of the Oxford Scores for both registries and moveUP. The absolute results at 1 year post-operatively showed higher scores for moveUP than either registries, with potential significance shown in table 2. The table contains both pre-operative and post-operative data but also the difference between pre- and post-operative results. The absolute OKS and OHS moveUP values exceed those in the regional UK registry and, except postoperative OKS, also those of LROI. The relative values (difference) on the other hand do not indicate significant differences between moveUP and SoC (α = 0.05).

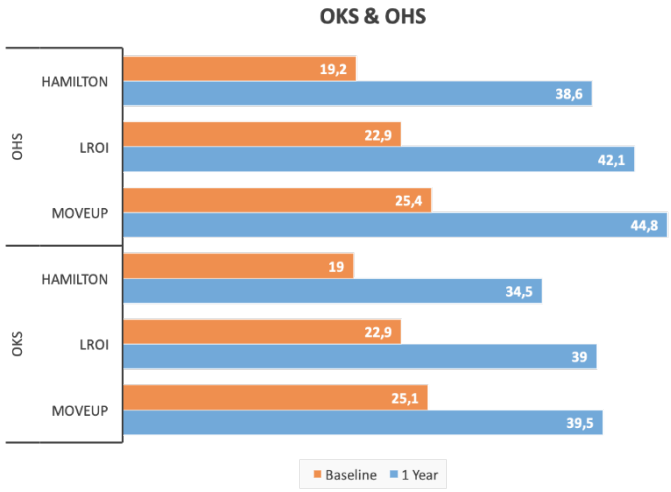


Fig. 14: An overview of the OKS and OHS of moveUP patients compared to national/regional registries (The Netherlands and UK, Hamilton). Both the pre-operative average values (baseline) and post-operative average values (1 year) are displayed.

Score		moveUP mean(SD)	Hamilton mean(SD)	p-value	LROI mean(SD)	p-value
OKS	preop	25.2(8.5)	19.0(7.5)	**<.01**	22.9(7.7)	**<.01**
	postop	39.0(8.6)	34.5(10.0)	**<.01**	39.0(10.1)	.97
	diff	13.0(9.9)	15.5(12.5)	.14	16.1(12.7)	.07
OHS	preop	25.3(8.5)	19.2(8.5)	**<.01**	22.9(7.7)	**<.01**
	postop	44.9(8.6)	38.6(9.4)	**<.01**	42.1(6.6)	**<.01**
	diff	18.2(9.9)	19.4(12.7)	.44	19.2(10.1)	.42

Table 2: Comparison between moveUP and the national registries of the oxford scores preop (baseline), 1 year postop and the improvement at 1 year postop. Significance calculated at α = 0.05.

8. Clinical audit and benchmarking

Clinical audit and benchmarking are the most widely used quality improvement methodologies used in healthcare. The wealth of data moveUP collects allows for more detailed insight compared to conventional audits based on snapshot data at predefined points in time. As the data is entered by patients or collected automatically via the activity tracker the audit is continuous and automated resulting in better quality and vastly improved efficiency. The following examples demonstrate how this feature can be used.

Pain medication use.

Pain audits are labour intensive and costly if done using paper-based VAS scales. moveUP collects pain scores and medication data daily, providing an automatic audit on an ongoing basis.

The WHO classification includes three groups of pain killers: Group 1 consists of Paracetamol and Non-Steroidal Anti-Inflammatory Drugs (NSAID) to control mild pain and the inflammatory process. Group 2 consists of weak opioid medication (Tramadol, Codeine) to tackle moderate pain and Group 3 consists of strong opioid medication (like Morphine, Oxycodone) necessary to control severe pain episodes.

Figures 15 and 16 show the opioid (level 2 and 3) and non-opioid (group 1) use for respective TKA and THA patients. Data shown represent medication use at the start of the rehabilitation, 6 weeks, and 3 months postoperatively. A patient who used the analgesic at least twice a week, is indicated as user for that week.

225 knee patients and 293 hip patients were included in the audit, 6 weeks postoperatively 275 and 382 patients and 3 months postoperatively 150 knee and 130 hip patients respectively provided data.

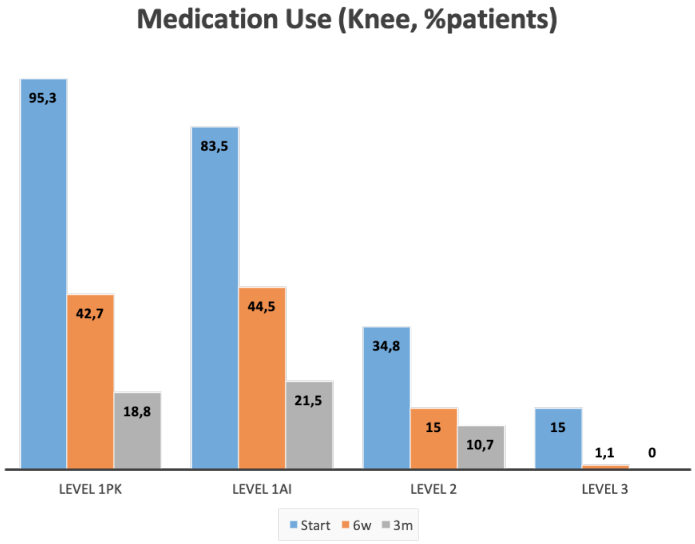


Fig. 15: An overview of the analgesic use of knee patients postoperatively. Level 1 PK covers the non-opioid painkiller use, level 1 AI covers NSAID use.

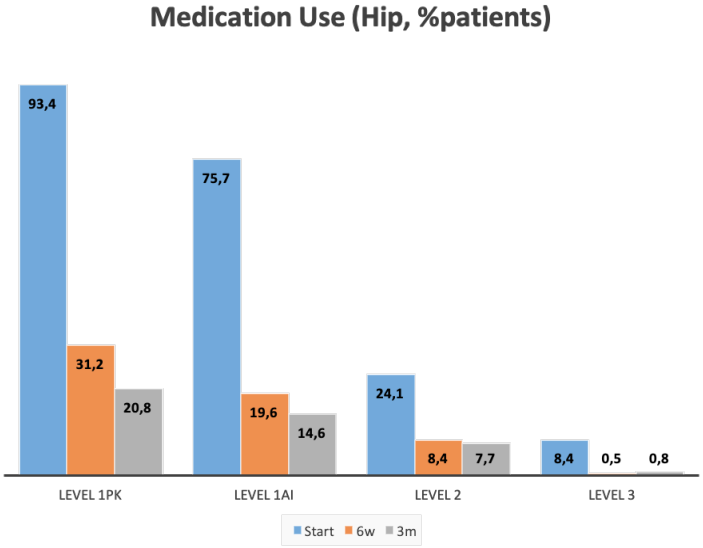


Fig. 16. An overview of the analgesic use of Hip patients postoperative. Level 1 PK covers the non-opioid painkiller use, level 1 AI covers NSAID use.

	Knee(%)					Hip(%)				
week	n	level 1	level 2	level 3	Analgesic	n	level 1	level 2	level 3	Analgesic
-1	222	38.7	8.1	0.5	41.9	293	39.6	12.3	0.0	44.4
1	339	99.1	34.8	15.0	99.4	452	97.8	24.1	8.4	98.5
2	348	97.1	36.8	2.6	98.0	469	95.9	22.4	1.5	96.8
3	328	93.9	29.0	1.8	95.1	454	78.4	17.8	0.9	80.8
4	321	81.3	20.9	2.5	83.8	446	59.6	13.9	0.9	61.4
5	301	74.8	20.3	2.3	77.1	413	48.7	10.2	0.5	50.1
6	274	65.0	15.0	1.1	67.5	382	41.4	8.4	0.5	43.5
7	258	62.0	12.4	1.2	64.0	346	34.1	7.8	0.3	35.8
8	242	52.1	13.6	1.2	56.2	305	31.5	6.9	0.3	33.4
9	226	49.1	12.8	1.3	52.2	271	29.5	6.3	0.4	31.4
10	200	48.0	11.0	1.5	51.5	210	29.0	6.2	0.5	31.9
11	186	44.6	10.2	0.5	47.8	177	33.3	5.6	0.6	36.2
12	169	44.4	8.3	0.6	46.2	154	29.9	5.2	0.6	32.5

Table 3: Medication use of patients pre- and post-operative, listed per week. Analgesic medication is subdivided into level 1 (non-opioids), level 2 (light opioids) and level 3 (strong opioids)

Table 3 provides a detailed overview of the weekly medication use between week -1 (preop.) and week 12 (postop.).
The medication use for hip patients in the preoperative setting is slightly higher than the medication use for knee patients. Post-operative data show different results: non opioid use in THA patients decreases faster compared to TKA patients during the early rehabilitation phase. Opioid use is common during the first week after surgery with a clear difference between TKA and THA patients. These differences are also maintained during the rehabilitation which suggests that TKA is associated with a more painful and difficult rehabilitation.
This corresponds with the literature confirming that primary THA is associated with superior short-term outcomes compared to primary TKA. (49) THA patients on average take less analgesic medication at six weeks compared to the preoperative use. TKA patients however seem to have similar analgesic intake at week 12 compared to pre-operative levels.

Anti-inflammatory medication is commonly used after hip and knee replacement surgery. There is some controversy regarding their use. Specialists in internal medicine and anaesthesia try to avoid these drugs because of fear of side effects. In contrast, orthopaedic surgeons like using them as they effectively reduce swelling and pain perception and contribute to a quicker return to normal activities after a surgery. As the moveUP platform is used in different hospitals with different protocols on the use of NSAIDs, benchmarking could yield useful insights (e.g. table 4, fig. 17 and fig. 18).

	3 project-hospitals	All knee patients
# days on Zaldiar	5	5
# days on Tradonal	17	16
# days on Paracetamol	26	28
# days on NSAID	20	33
# days to get pain under control	14	13
# days to reach pre-op activity level	21	22
# days to start driving	32	36
Average Compliance	74%	80%
Median compliance	84%	89%

Table 4: Tabular benchmarking of 3 project-hospitals against the whole moveUP knee population. Topic: Milestones

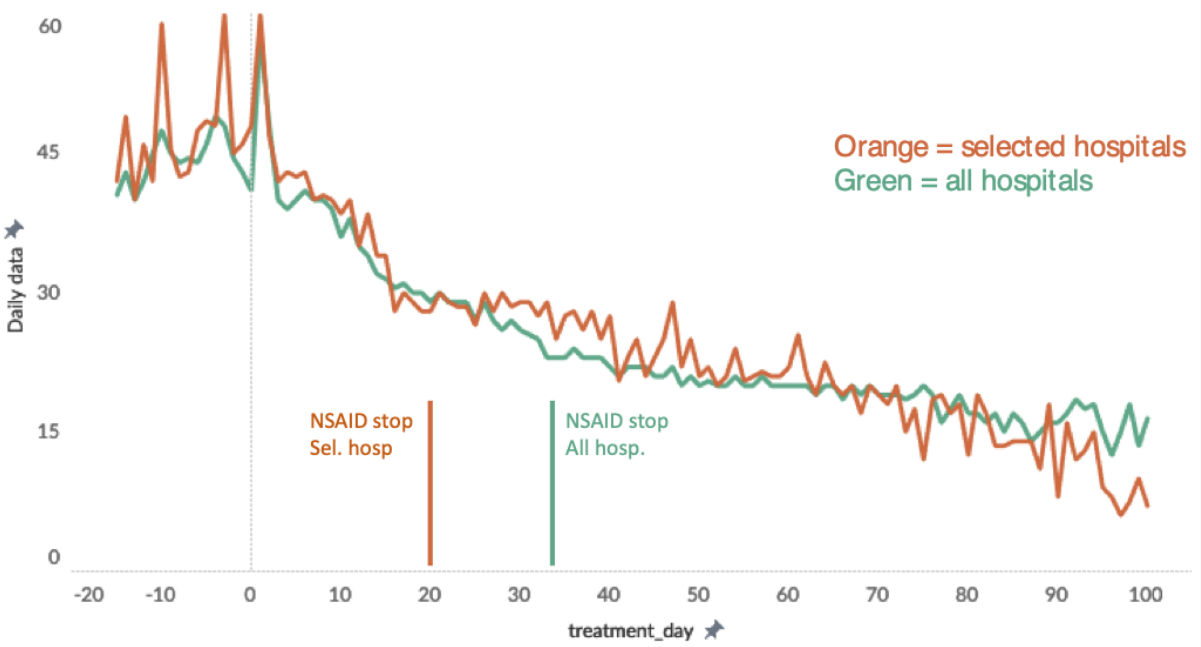


Fig. 17: Graphical benchmarking of 3 project-hospitals against the whole moveUP knee population. Topic: Daily pain

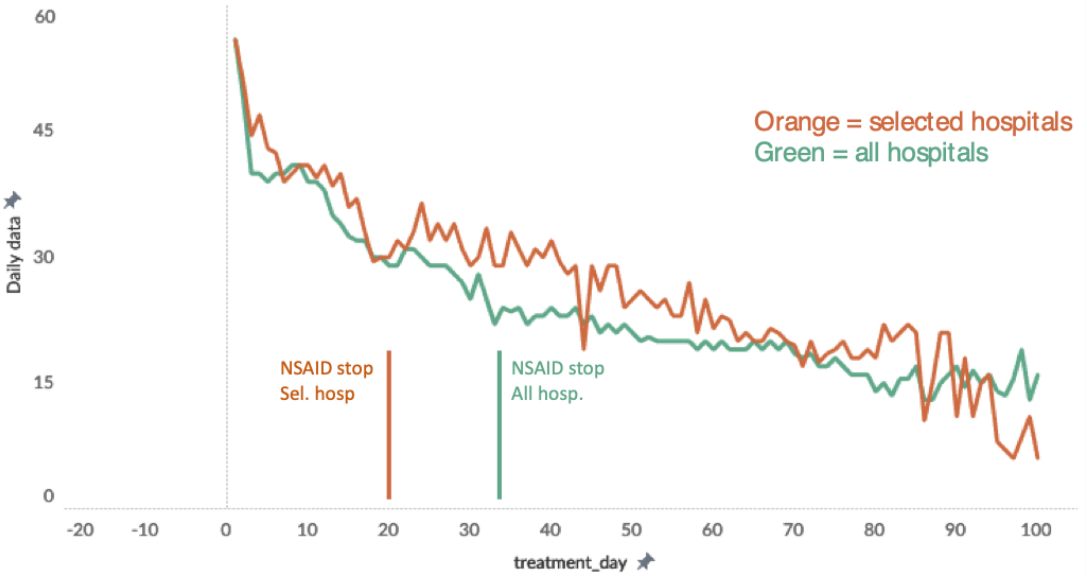


Fig. 18: Graphical benchmarking of 3 project-hospitals against the whole moveUP knee population. Topic: Pain during exercises

The last two graphs (fig.17 and fig. 18) suggest longer NSAID use (33 vs 20 days) to be related to lower pain levels in the second month of recovery.

Cultural differences play a significant role in medication use. Goesling et al. investigated the opioid use in TKA and THA patients (n=574) and provided pre- (TKA/THA: 26.3%/31.1%) and post-operative data at 1 month (TKA/THA: 26.4%/30.4%), 3 months (TKA/THA: 24.2%/30.3%) and 6 months (TKA/THA: 18.8%/12.9%). (50) The corresponding values for moveUP can be found in table 3: week -1 (preop), week 4 and week 12. Preoperative values are similar to the moveUP database, but postoperative values are significantly higher in the study (USA). The reversal (preop versus postop) in medication use between TKA and THA patients after surgery is also present in the study. Future studies might compare the absolute values concerning medication intake and subsequently draw conclusions regarding potential cultural differences.

Pain perception in patients with chronic low back pain

It is well documented that total knee replacement patients experience more pain for longer than hip replacement patients. It has also been demonstrated that chronic low back pain impacts pain perception and medication use. Daily data collection allows to quantify this difference at every stage of the recovery process.

Figure 19 shows the daily evolution of pain for hip and knee patients with and without low back pain (LBP). The graph confirms earlier findings of prolonged pain medication use in knee patients. The influence of pre-existing low back pain is also demonstrated.

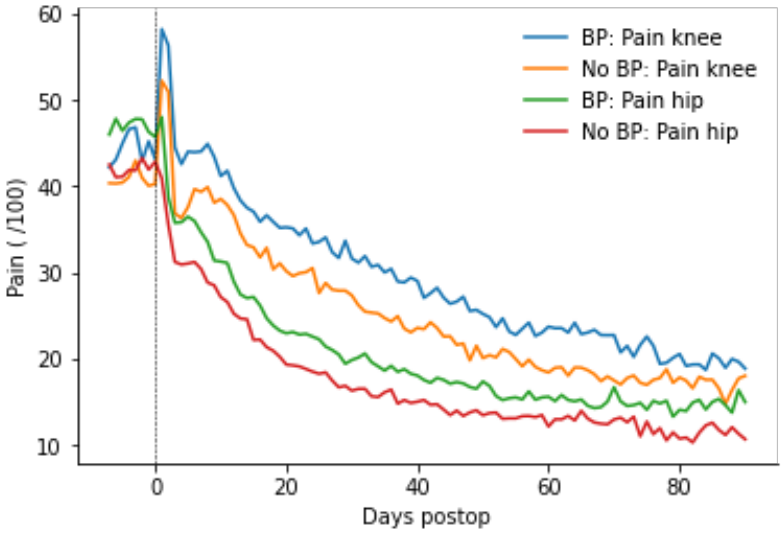
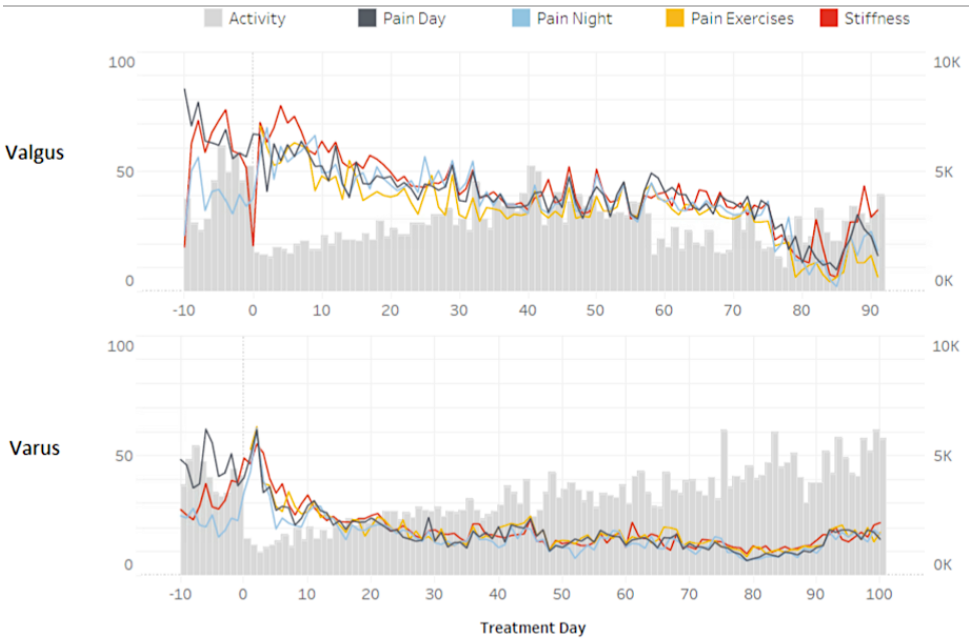


Fig. 19: Difference in pain levels experienced by patients with or without LBP. The difference between hip and knee replacement surgery is also obvious. Data is provided from 7 days pre- until 90 days post-surgery.

Audit of outcomes in patients with different characteristics

TKA surgeries are performed for end stage degenerative disease of the knee. The two main possible deformities that are corrected during these surgeries are varus (bow) and valgus (knock) knees.
When analysing PROMs data in the literature similar results are reported for both. Anecdotally however, patients with valgus knees tend to have a more difficult rehabilitation. In a series of 251 knees operated on in the setting of a clinical study (ODEP) no differences were found in the ROM, KOOS and OKS. The forgotten joint scores (FJS-12) however, were significantly lower for valgus knees compared to varus knees. The figure below shows a typical overview of daily data in the moveUP dashboard and additional PROMs data in the table. Activity (daily steps) is displayed in a bar plot, while the lines represent pain levels during the day, night and after exercises as well as subjective stiffness. The two figures are averages for total knee replacements with prior valgus and varus respectively. Patients with a valgus knee have a much less predictable recovery with more variability and higher pain levels in the first three months. Using simple snapshot PROMs data, these granular differences are impossible to uncover.



Patient Reported Outcome		Valgus			Varus		
		PreOp	Week 6	Month 3	PreOp	Week 6	Month 3
Oxford Knee Score		24	25	35	27	32	36
KOOS	Symptoms	46	60	68	55	69	75
	Pain	43	60	63	50	72	78
	ADL	43	65	71	52	67	73
	QoL	28	50	63	35	55	60
Forgotten Joint Score		16		35	24		58

Fig. 20: The graphs show the averages for respectively valgus and varus. The table gives an overview of the PROMs at three time points.

Audit of surgical techniques.

For several decades the reference axis used to position the components of a TKA implant has been the mechanical axis (MA). In the last few years however, the kinematic alignment (KA) principle has gained popularity. The effect of a switch between these two techniques can be audited using moveUP platform. One of the surgeon authors of this white paper, Dr. Van Overschelde switched to the KA technique in 2019 and has since performed 139 KA cases, the majority of which were followed up by the moveUP system.

When one starts off with a new technique there is always a learning curve that influences the results. From previous experience in this case the learning curve was expected to be around 30 patients.
This finding is reflected in the below table using the FJS-12 and comparing the first 30 KA patients with the next 100.

FJS scores min 6M	Mean	Median
First 30 KA	56	48
Other KA	55	60

FJS scores min 1Y	Mean	Median
First 30 KA	56	51
Other KA	60	67

Table 5: FJS scores of the first 30 KA patients versus the next 100.

When comparing the MA with the KA results at 6 months follow up, the results are supporting the switch to the KA technique. With a higher percentage in the group of patients who tend to completely forget they have an artificial knee (FJS score between 80 and 100)

FJS Score - 6M	<40	40-60	60-80	80-100
KA	39%	18%	21%	23%
MA	46%	21%	25%	8%

Table 6: Comparison of KA patients against MA patients by grouping the patients based on the FJS score at 6 months.

THR approach audit

Total hip arthroplasty can be performed via different surgical approaches. Traditionally the antero-lateral (ALA) and postero-lateral (PA) approaches were the two main approaches used. In the last 10 years the direct anterior approach (DAA) was reintroduced and is gaining popularity. Proponents claim to see less pain and quicker recovery after DAA but so far literature data based on PROMs at 6 weeks has not supported this notion. Collecting daily data allows to discover differences in the early recovery period as shown in figure 21. This audit data can be used to formulate the relevant questions for the design of high quality research on this topic where moveUP can be used to collect the data.

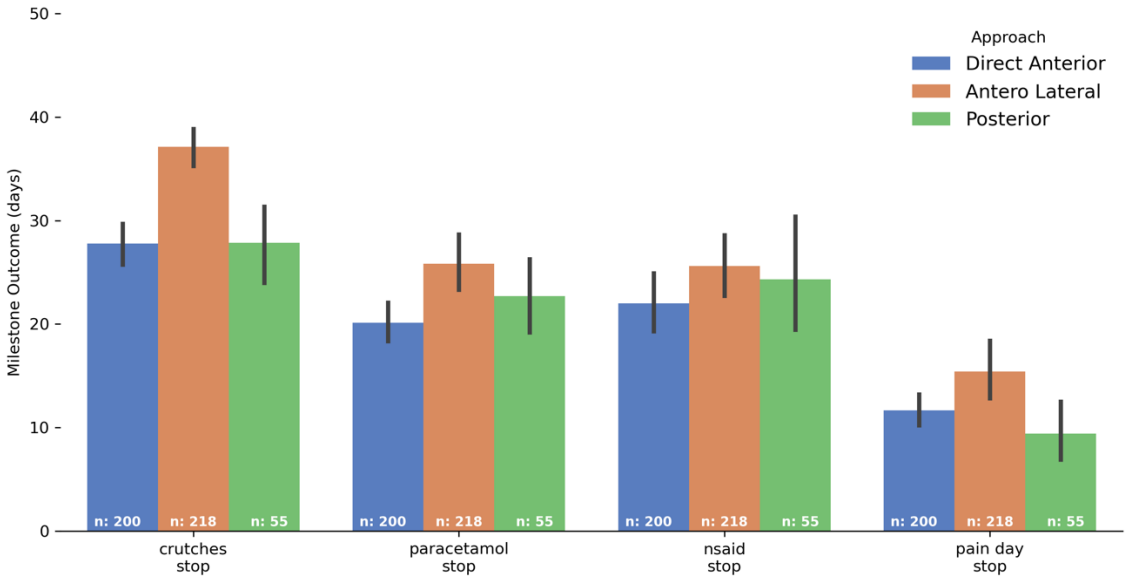


Fig. 21: Comparison of multiple THR approaches based on specific milestones.

Hospital benchmarking using the net promoter score

The Net Promoter Score (NPS) is the percentage of customers rating their likelihood to recommend a company, a product, or a service to a friend or colleague as 9 or 10 ("promoters") minus the percentage rating this below 6 ("detractors") on a scale from 0 to 10. The score is a widely used simple method to measure customer satisfaction and is becoming popular in the health sector worldwide demonstrated by the compulsory “Friend and family” test for NHS providers in the UK. It can also be used for benchmarking hospitals as shown in the figure below. One of our partner hospitals AZ Maria Middelares is scoring highly amongst our other users.

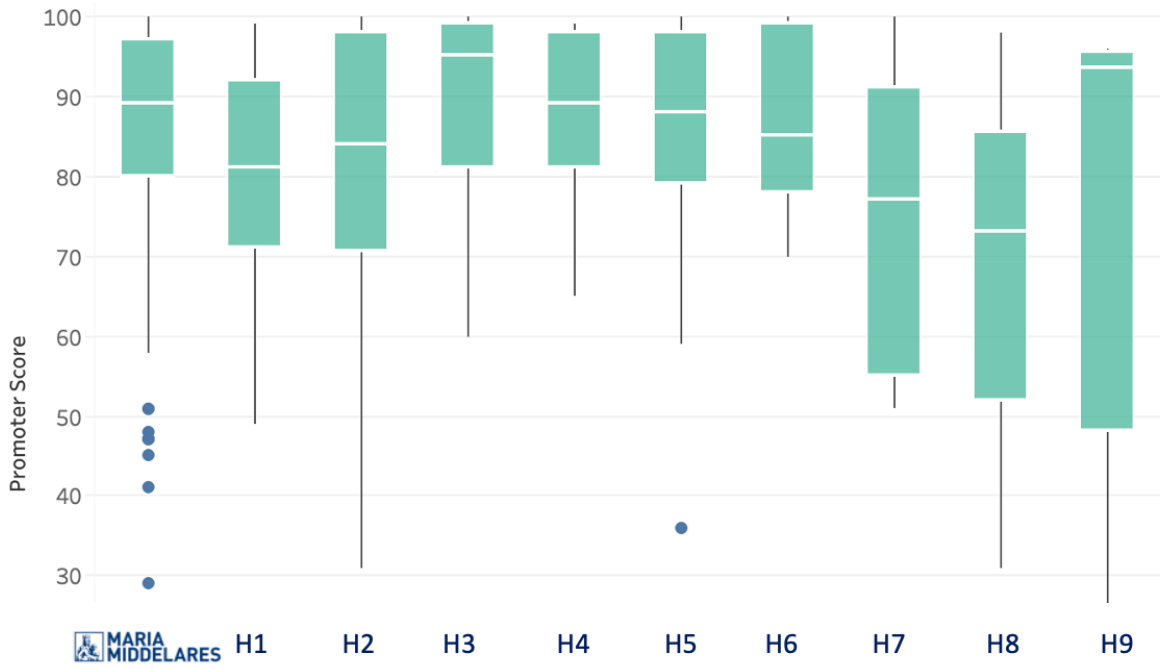


Fig. 22: Hospital benchmarking based on the net promotor score.

Long term data collection

The ultimate goal of any treatment is a happy and satisfied patient. Given the final result is often only reached 1 to 2 years after surgery, long term follow-up is needed to evaluate the success of joint replacements. This long term monitoring is also useful to understand how patients function and to detect possible late failures in need of intervention.

9. The moveUP Index: from decision support tool to prediction

Shared decision making is becoming the norm in healthcare with doctor and patient collaborating to formulate the treatment plan. For this process to work the availability of good quality and easy to understand data is of paramount importance.
The moveUP Index is based on the data of more than 1000 patients who have completed a full moveUP digital rehabilitation journey and have a minimum follow up of 1 year fully documented. The Index can take a value from 0 (worse)-100 (best). We aimed to determine a threshold value to help decide whether or not to proceed with surgery. The percentage of possible increase in the moveUP Index relative to the preoperative value can be used to predict the outcome.
The following case studies demonstrate the use of the Index.

Visualisation of THA with smooth recovery and excellent outcome

The preoperative moveUP Index for patient PP497 was 37,62. At 6 weeks, three months, six months and 1 year the values were 64,5, 85,6, 79,7 and 83,6 respectively. At 6 weeks the Index

doubled from the preoperative value. As demonstrated on the graph, the daily pain scores during the active digital rehabilitation phase are going down very rapidly after surgery.
In this particular case there was a 122% increase in moveUP index. During the preoperative assessment in the outpatient clinic this example can be used to explain the expected postoperative rehabilitation pathway and outcome to a patient with similar preoperative moveUP index.

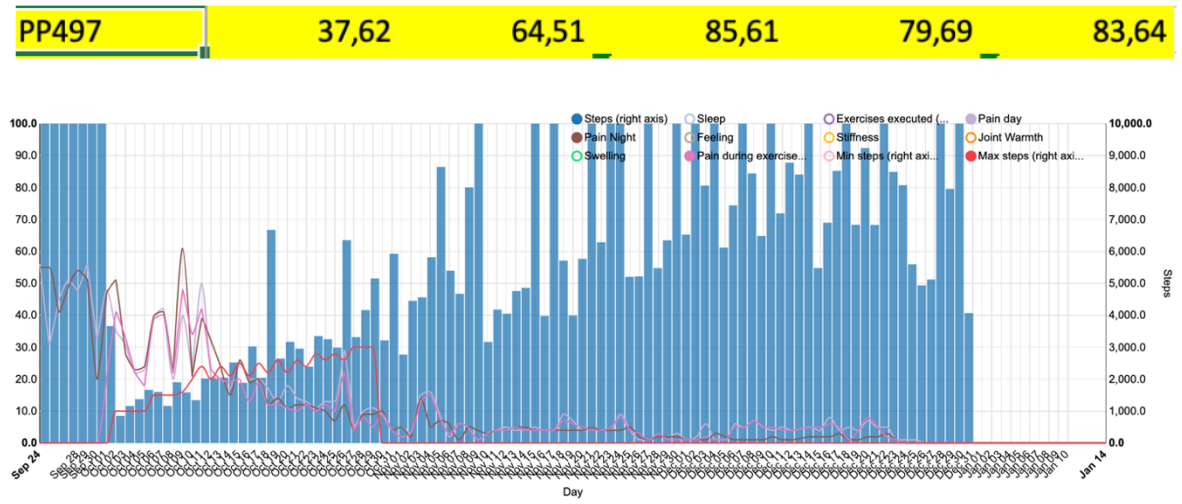


Fig. 23a: THA with smooth recovery and excellent outcome

<u>Visualisation of THA with longer rehabilitation and less favourable outcome</u>

This example shows a preoperative moveUP Index that differs substantially from the previous example. The resultant pathway is less smooth than the first one and the relative gain in the moveUP Index during the first year (13%) is also less compared to the preoperative value.

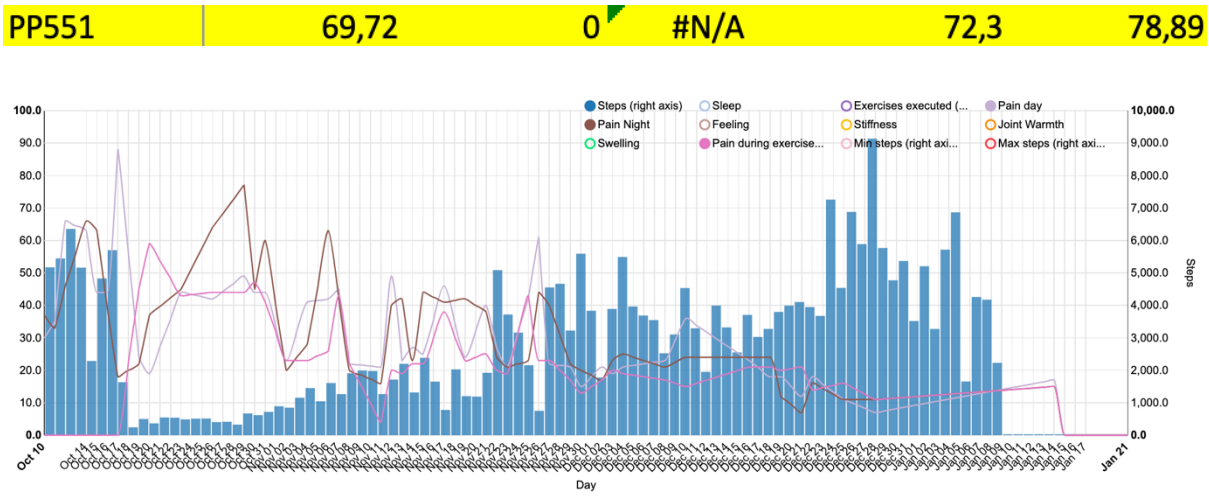


Fig. 23b: THA with longer rehabilitation and less favourable outcome

Visualisation of TKA with quick recovery and excellent outcome

TKA patients can have a similar experience to THA patients given the correct diagnosis and timing of surgery. Appropriate guidance and coaching to gradually build up the activity is important to control the inflammatory process and to allow the pain to subside completely. This is only possible by collecting daily data on the relevant parameters. As illustrated in this example there is a rapid decline in the pain parameters and a progressive buildup of activity. In this particular case there was a 107% increase in the moveUP Index as early as 6 weeks.

752	42,23	87,62	85,1	90,11	90,79

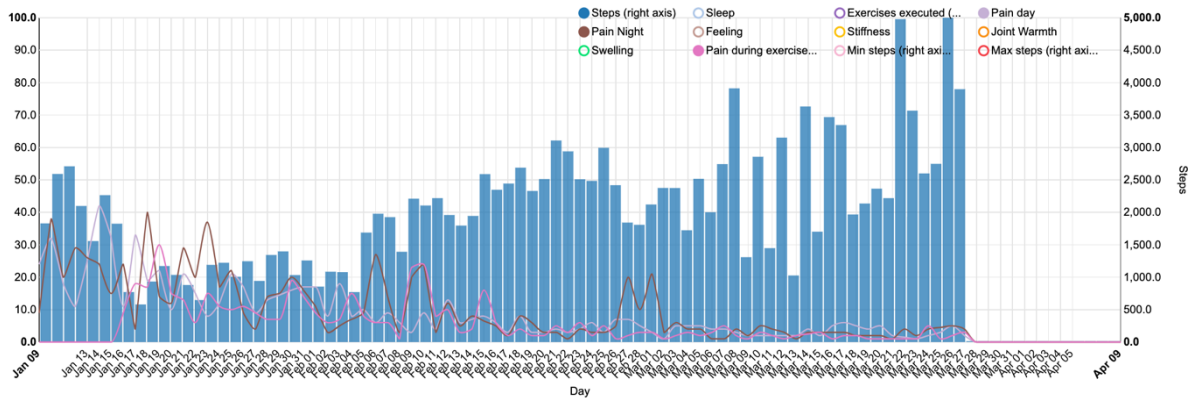


Fig. 23c: TKA with quick recovery and excellent outcome

Visualisation of TKA with slower rehabilitation but still favourable outcome

This case illustrates the effect of a less gradual buildup of the activity with a longer period needed for the inflammatory process to subside and for the pain to ease. In this particular case there was a 41% increase in the moveUP index at 6 weeks and a 91% increase at 1 year postoperatively.

TP595	45,7	64,51	75,71	80,3	87,46

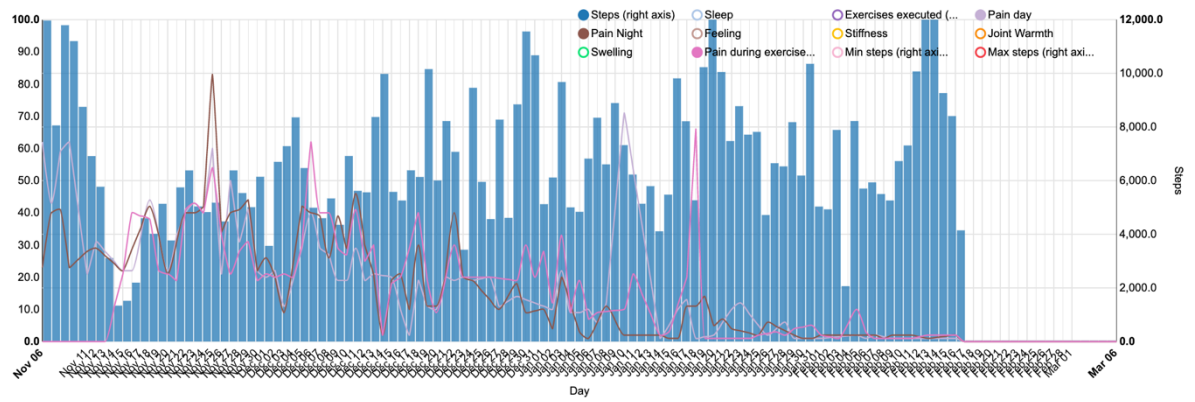


Fig. 23d: TKA with slower rehabilitation but still favourable outcome

Visualisation of TKA with prolonged rehabilitation and less favourable outcome

This case illustrates the importance of a decision support tool in the current context of shared decision making. As the preoperative data show, there is considerable night pain and relatively low activity presumably due the knee pain. The X-ray, clinical exam and patient history were all supporting the decision to perform surgery on this patient. Had the preoperative moveUP Index been calculated (this index was not available at the time of the decision to go ahead with surgery) it would have been clear that the possible gain will be limited and thus the result perceived by the patient might be less favourable. In this particular case there was a drop in moveUP index at 6 weeks despite good guidance and a progressive buildup of the activity levels. At 1 year postoperatively there was only a 17% increase in moveUP Index.

PP349	62,59	61,23	#N/A	#N/A	73,71

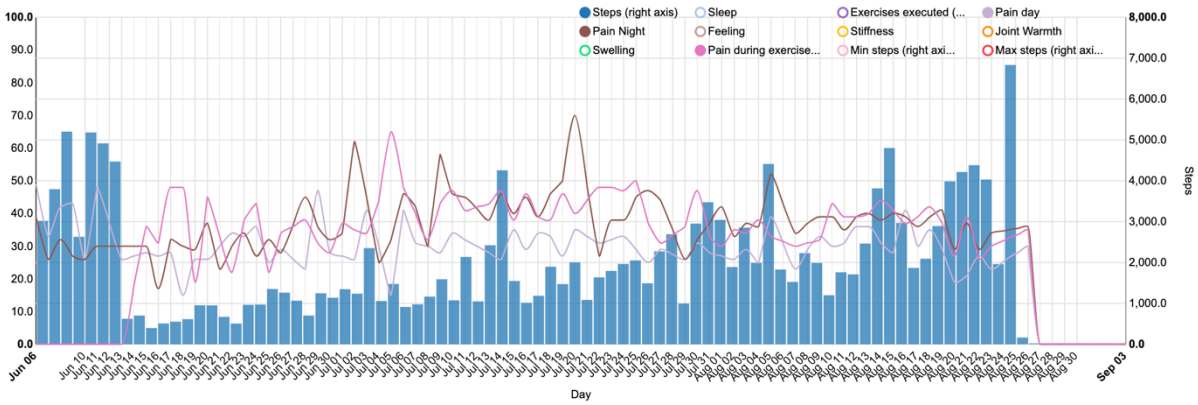


Fig. 23e: Visualisation of TKA with prolonged rehabilitation and less favourable outcome

These examples illustrate the value that a decision support tool can have in deciding whether or not to operate on a patient. Based on history, clinical examination and imaging it is not always possible to decide with 100% certainty whether or not surgery would bring significant enough benefit. The moveUP Index can be used as the fourth parameter to support decision making when discussing a surgical procedure with a patient. The numeric value of the moveUP Index as

well as the expected result (expected gain in moveUP index) are explained. This score can also be used for the informed consent in order to individualise the process.
The moveUP Index is currently used as a decision support tool in the shared decision making process. It is a first step in the development of a reliable decision tool and eventually a prediction tool for the future. The moveUP index will undergo independent clinical validation before being released to all users of the platform.

10. Patient feedback on the moveUP solution

moveUP put a strong emphasis on engaging with patients and listening to their feedback to constantly improve the functionalities and usability of the platform. The latest data showed high compliance and satisfaction with 85% exercise adherence and daily data provision compliance, 90% recommending it to family and friends and a net promoter score of 78. A breakdown of the different domains of satisfaction can be seen in the figure below.

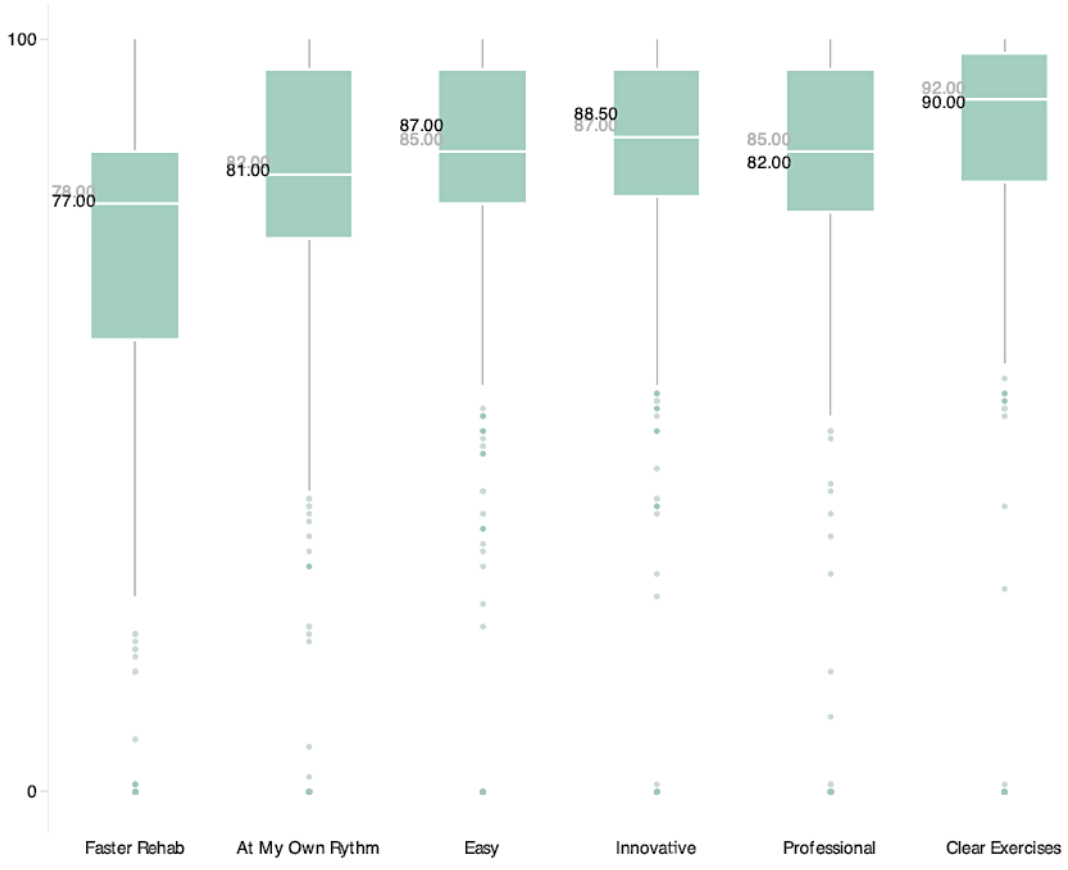


Fig. 24: Satisfaction of the moveUP population within different domains

11. Ongoing research and development

moveUP are actively working on further AI automation tools to improve our clinical decision support system (CDSS) and develop predictive features.

A 1M Euro research project in collaboration with the Vrije Universiteit Brussels is under way to develop smart phone camera based gait analysis, predictive features using patient profile and feedback data and automated x-ray analysis. The results of this research will be used to develop more precise prediction models and to move the treatment process further from expert driven to data driven. Some of the key features of the development roadmap are pain prediction, exercise automation and predicting recovery milestones.

Next day pain prediction. Based on historical data - data from the previous day and the trend of daily data - an AI model predicts whether a patient will suffer substantial pain in the coming days. The model helps the HCP to identify patients needing extra attention on that specific day. At the same time, predicting substantial pain might allow the prevention of it with early intervention (predictive medicine).

Exercise automation. Patients receive daily exercises based on a (PT adaptable) protocol. The goal of developing an AI model is to predict the perfect set of exercises for each patient based on the protocol and historical adaptations of pathways of other patients. The model has been trained on thousands of manual adaptations made by physiotherapist active on the moveUP platform, and now able to propose the optimal exercises with high accuracy. The model supports the PT and is therefore classified as CDSS but full automatisation is theoretically possible.

Recovery milestones. Depending on the pre-surgery profile, the model helps to predict when the patient will reach certain milestones, such as stopping using walking aids, pain killers or starting driving again. This feature can be used to guide patients and manage expectations as well to support shared decision making and personalised consenting.

Quality of care and health economics research

The Hip and Knee Unit of AZ Maria Middelares in Gent is running a Randomised Clinical Trial (RCT) together with the Economics Department of University of Hasselt to evaluate the safety, efficacy and health economics of doing hip and knee replacement surgery as a day case. Möbius has developed a cost monitor to analyse the costs within the hospital whereas the moveUP application will record the daily expenditures outside the clinic together with daily measurements of quality of care. This RCT started in Q4 of 2020 and will be used to guide the discussions about bundled payment of the full hip and knee replacement surgery pathway.

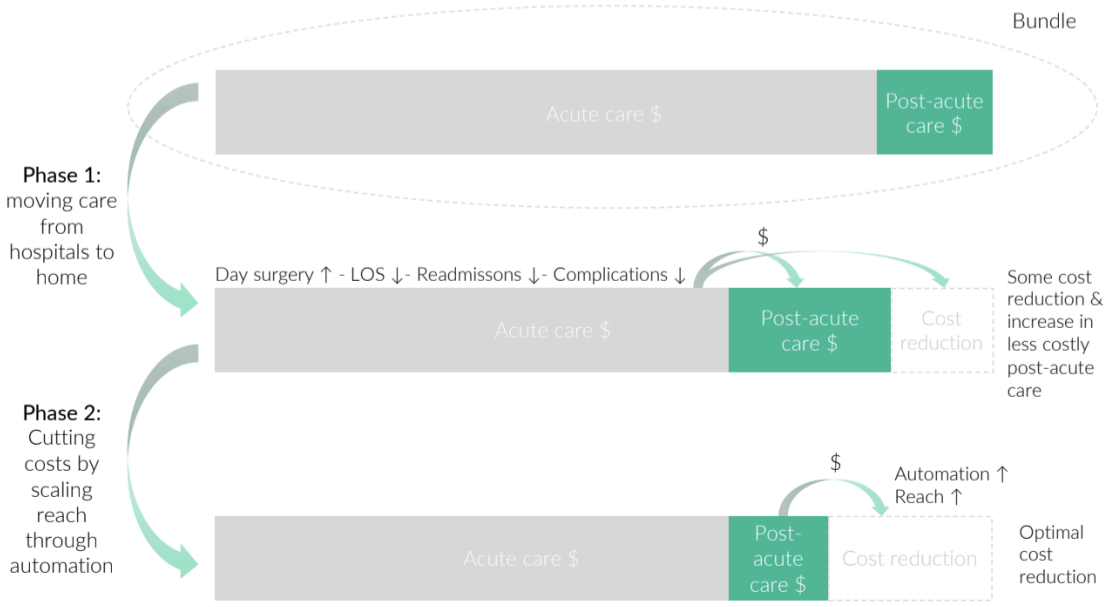


Fig. 25: Evolution in phases taking into account the ongoing R&D.

12. Covid-19

The Covid-19 pandemic has an enormous negative impact on the World Economy including the healthcare business and important consequences for patients. All elective surgical procedures, including primary hip and knee replacement surgeries were cancelled in mid-March 2020. Non-urgent clinical appointments were also postponed. This resulted in patients operated on just before the lockdown had no access to conventional follow-up or physical rehabilitation sessions and new patients, suffering from severe pain, were not able to get appropriate care.

The Belgian authorities similarly to other countries allowed remote consultations by health care providers to be reimbursed (medical and paramedical HCP). Surgeons and physical therapists could therefore use the moveUP platform to help them better prepare for consultations and to understand their patients' progress.

From the 4th May 2020 elective interventions restarted (in Belgium). However, the government requires hospitals to keep a minimum number of both normal and intensive care beds available in order to guarantee the admission of Covid-19 patients. It became a priority to keep hospital stay as short as possible and preferably not to operate on patients who may require intensive care postoperatively. moveUP supports both appropriate patient selection with the aid of the moveUP Index and safe early discharge from hospital by providing a safety net through monitoring and personalised remote digital coaching. The virtual clinic (b.clinic) as an outsourcing option gives health care providers flexibility to switch to remote rehabilitation as required.

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