Patients' perspective on function after total knee arthroplasty: analyses of patient-reported outcome measures

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Declaration

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Abbreviations

ADL	Activities of daily living
ASA	American Society of Anesthesiologists
AUC	Area under the curve
BMI	Body mass index
CI	Confidence interval
COSMIN	Consensus-Based Standards for the Selection of Health Status Measurement Instruments
EQ-5D-3L	EuroQol five dimensions three levels
ES	Effects size
FJS-12	Forgotten Joint Score
GRRAS	Guidelines for Reporting Reliability and Agreement Studies
HAAS	High-Activity Arthroplasty Score
HSS-KRES	Hospital for Special Surgery Knee Replacement Expectations Survey
ICC	Intraclass Correlation Coefficient
ISAR	International Society of Arthroplasty Registries
KL	Kellgren and Lawrence classification of osteoarthritis
KOOS	Knee injury and Osteoarthritis Outcome Score
KOOS-12	KOOS 12-item short form
KOOS-JR	Knee injury and Osteoarthritis Outcome Score for Joint Replacement
KSS	Knee Society Score
MCID	Minimal clinically important difference.
OECD	Organisation for Economic Co-operation and Development
PaRIS	Patient-Reported Indicator Surveys
PASS	Patient acceptable symptom state
PPHS	PhD Program Health Sciences
PROM	Patient-reported outcome measure
QoL	Quality of life
REDCap	Research Electronic Data Capture
ROC	Receiver operating characteristics
SD	Standard deviation
SDC	Smallest detectable change
SEM	Standard error of measurement
SIRIS	Swiss National Joint Arthroplasty Registry

SRM	Standardised response means
THA	Total hip arthroplasty
TKA	Total knee arthroplasty
VAS	Visual analogue scale
WOMAC	Western Ontario and McMaster Universities Arthritis Index

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Summary

Patient-reported outcome measures (PROMs) are validated questionnaires completed by patients. They are essential to assess what is meaningful to patients and provide insight into the patients' perspective. One in five patients with total knee arthroplasty (TKA) is dissatisfied with the result of their surgery. To better understand the underlying reasons, we began to collect PROMs routinely from our patients scheduled for TKA. They complete a series of PROMs preoperatively, at four months, and annually for up to five years postoperatively. This overall PROMs collection project was the basis for the entire thesis. Four sub-projects are embedded in it.

The first project involved the High-Activity Arthroplasty Score (HAAS), a questionnaire that measures a wider range of functional abilities, particularly in more active patients. As a validated German version was not yet available, we aimed to translate and cross-culturally adapt the HAAS. After forward and backward translation, we examined the psychometric properties in 52 patients 12 months after primary TKA. The German version of the HAAS showed good validity and reliability. It can be easily self-administered and is recommended to measure high-intensity activities in patients after TKA.

One motivation for collecting routine PROMs was a new generation of implants, customised individually made (CIM) TKA. They were introduced to address anatomical variability with the aim of restoring individual anatomy and potentially improving patient satisfaction and function. In the second project, we conducted a matched-pair analysis based on a propensity score matching on 85 CIM and 85 off-the-shelf (OTS) TKA. Follow-up was at four months, one year and two years. We found high patient satisfaction with no differences between patients with CIM and OTS TKA. Both implant systems improved subjective and objective function, pain and health-related quality of life. Patients with CIM TKA showed superior results with regard to demanding activities.

In the third project, we assessed the responsiveness of different PROMs in patients with TKA. Responsiveness is the ability of a measure to detect change over time and was determined by effect size (ES), standardised response means (SRM), area under the receiver operating characteristics (ROC) curve (AUC), floor and ceiling effects, and hypothesis testing. We analysed data from 309 TKA at four months, one year and two years follow-up. We compared the Knee injury and Osteoarthritis Outcome Score (KOOS), KOOS-12, Forgotten Joint Score (FJS-12), HAAS and EQ-5D-3L. We demonstrated high

responsiveness, which varied between the different measures. The KOOS-12 and FJS-12 showed the largest internal and external responsiveness, although ceiling effects occurred with the KOOS-12.

Finally, in the fourth project, we examined the relationship between preoperative expectations and postoperative satisfaction and other PROMs in TKA patients. We analysed data from 193 TKA at baseline, 4 months and 12 months. Patient expectations were measured using the Hospital for Special Surgeries Knee Replacement Expectation Survey (HSS-KRES). Preoperative expectations were high but did not correlate with postoperative satisfaction or any of the pre- or postoperative PROMs. While it is worth educating patients about realistic expectations, high patient expectations do not always seem to be a warning sign.

In summary, PROMs are essential to better reflect the patient perspective. PROMs help to focus on patient priorities and increase patient involvement in the treatment process. This is especially true for TKA procedures, which are commonly performed but still have a substantial number of dissatisfied patients. We believe that our research is a valuable contribution to further promote the potential of PROMs and their use in everyday medical practice.

Zusammenfassung

Patient-reported outcome measures (PROMs) sind validierte Fragebögen, die von Patientinnen und Patienten ausgefüllt werden. Sie sind wichtig, um zu bewerten, was für Patientinnen und Patienten von Bedeutung ist, und geben Einblick in deren Perspektive. Einer von fünf Patienten mit einer Knie-Totalendoprothese (TKA), ist mit dem Ergebnis der Operation unzufrieden. Um die Gründe hierfür besser zu verstehen, haben wir damit begonnen, routinemässig PROMs von unseren Patientinnen und Patienten vor einer TKA zu erheben. Sie füllen PROMs präoperativ, nach vier Monaten und jährlich bis zu fünf Jahren postoperativ aus. Dieses Gesamtprojekt zur PROMs-Erhebung bildete die Grundlage für die gesamte Dissertation. Darin eingebettet sind vier Teilprojekte.

Das erste Projekt bezog sich auf den High-Activity Arthroplasty Score (HAAS), ein Fragebogen welcher ein breiteres Spektrum an funktionellen Fähigkeiten misst, insbesondere für aktivere Patientinnen oder Patienten. Da eine validierte deutsche Version noch nicht verfügbar war, haben wir den HAAS übersetzt und kulturübergreifend angepasst. Nach der Vorwärts- und Rückwärtsübersetzung untersuchten wir die psychometrischen Eigenschaften bei 52 Patientinnen und Patienten 12 Monate nach einer primären TKA. Die deutsche Version des HAAS zeigte eine gute Validität und Reliabilität. Sie kann leicht selbst ausgefüllt werden und wird zur Messung von intensiveren Aktivitäten nach TKA empfohlen.

Eine Motivation für die routinemässige Erhebung von PROMs war eine neue Generation von Implantaten, personalisierte individuell angefertigte (CIM) TKA. Sie wurden eingeführt, um die anatomische Variabilität zu berücksichtigen, mit dem Ziel, die individuelle Anatomie wiederherzustellen und möglicherweise die Zufriedenheit und Funktionsfähigkeit von Patientinnen und Patienten zu verbessern. Im zweiten Projekt führten wir eine Matched-Pair-Analyse basierend auf einem Propensity-Score-Matching an 85 CIM- und 85 Standard-TKA durch. Die Nachuntersuchungen erfolgten nach vier Monaten, einem Jahr und zwei Jahren. Wir stellten eine hohe Patientenzufriedenheit fest, wobei es keine Unterschiede zwischen CIM- und Standard-TKA gab. Beide Implantatsysteme verbesserten die subjektive und objektive Funktion, die Schmerzen und die gesundheitsbezogene Lebensqualität. Patientinnen und Patienten mit CIM-TKA zeigten bessere Ergebnisse bei anspruchsvollen Tätigkeiten.

Im dritten Projekt haben wir die Responsivität verschiedener PROMs bei Patientinnen und Patienten mit TKA bewertet. Die Responsivität ist die Fähigkeit eines Instrumentes, Veränderungen im Laufe der Zeit zu erkennen, und wurde anhand von Effektgröße (ES), standardisiertes Antwortmittel (SRM), Fläche unter der ROC-Kurve (AUC), Boden- und Deckeneffekte und Hypothesentests ermittelt. Wir analysierten die Daten von 309 TKA nach vier Monaten, einem Jahr und zwei Jahren. Wir verglichen den Knee injury and Osteoarthritis Outcome Score (KOOS), KOOS-12, Forgotten Joint Score (FJS-12), HAAS und EQ-5D-3L. Wir konnten eine hohe Responsivität nachweisen, die zwischen den verschiedenen Instrumenten variierte. Der KOOS-12 und der FJS-12 zeigten die grösste interne und externe Responsivität, obwohl beim KOOS-12 Deckeneffekte auftraten.

Abschliessend, untersuchten wir im vierten Projekt den Zusammenhang von präoperativen Erwartungen und postoperativer Zufriedenheit und weiterer PROMs bei Patientinnen und Patienten mit TKA. Wir analysierten die Daten von 193 TKA vor der Operation, nach 4 und nach 12 Monaten. Die Erwartungen der Patientinnen und Patienten wurden mit dem Hospital for Special Surgeries Knee Replacement Expectation Survey (HSS-KRES) erhoben. Präoperative Erwartungen waren hoch, korrelierten jedoch nicht mit der postoperativen Zufriedenheit oder einem der prä- oder postoperativen PROMs. Obwohl es sicher sinnvoll ist, Patientinnen und Patienten über realistische Erwartungen aufzuklären, scheinen hohe Erwartungen nicht immer ein Warnsignal zu sein.

Zusammenfassend lässt sich sagen, dass PROMs wesentlich sind, um die Perspektive von Patientinnen und Patienten besser widerzuspiegeln. PROMs helfen dabei, sich auf die Prioritäten von Patientinnen und Patienten zu fokussieren und diese stärker in den Behandlungsprozess einzubeziehen. Dies gilt insbesondere für TKA Operationen, welche häufig durchgeführt werden, aber immer noch eine beträchtliche Anzahl unzufriedener Patientinnen und Patienten aufweisen. Wir glauben, dass unsere Forschung einen wertvollen Beitrag zur weiteren Förderung des Potenzials von PROMs und ihrer Verwendung in der täglichen medizinischen Praxis darstellt.

Chapter 1

Introduction

"*Listen to your patient; he is telling you the diagnosis.*"

Source unknown, often attributed to Sir William Osler (1849-1919)

Total knee arthroplasty and patient satisfaction

Total knee arthroplasty (TKA) is a frequently performed elective treatment for end-stage osteoarthritis of the knee. It is generally an effective [90,143] and cost-effective treatment [43] for improving pain and function and demonstrates high success rates, especially when assessed by objective outcome measures.

All arthroplasty registries have recorded an increase [112] and projections available for different countries forecast a further significant increase in TKA rates if the current trend continues [102,184]. The ageing of the society is one reason, and the fact that the indications for TKA have expanded to include younger patients is another [194]. There has been a marked increase in the number of TKAs performed in patients under the age of 65 [109,198]. In fact, younger patients represent the fastest growing population of TKA recipients and are expected to account for more than 50% of TKAs by 2030 [204]. In Switzerland, approximately 22 000 patients undergo TKA each year [149]. The incidence of 260 per 100000 population was the highest among the Organisation for Economic Co-operation and Development (OECD) countries in 2019 [150].

Despite the success of TKA, about 20% of patients are dissatisfied with the outcome of the procedure as determined by subjective outcome measures [12,26,68,91,145]. Pain and functional limitations are the two main reasons for dissatisfaction [73]. This 20% rate has persisted despite advances in surgical technique, implant design, and health care improvements such as rapid recovery protocols [7,8,68]. In 1999, the Swedish Knee Registry was the first to ask patients “How satisfied are you with your knee replacement?” [167,208]. The answer was less positive than expected: only 81% of patients who had their TKA between 1981 and 1995 were satisfied [167]. By 2022, not much had changed: 82% of TKA patients were very satisfied or satisfied with the surgery [198].

Substantial efforts have been made to understand the factors and predictors that lead to dissatisfaction [8,55,68,92,124,139,158,178]. A variety of factors have been identified, including female gender [57], higher body mass index (BMI) [8,57,98,128], younger age [7,24,26,128], lower socioeconomic status [15], comorbidities [8,36,57,97], anxiety or depression [13,36,57,92,177], personality [34,183,222], extended hospital stay [26], unmet expectations [14,18,26,27,74,116,123,197,211], high preoperative expectations [18,100], poor preoperative function [68,177], and poor postoperative function [13,36,92,177,207,211]. Nevertheless, the ability to predict a satisfied patient is still poor [158,227] and patient satisfaction after TKA remains a challenge [208].

The importance of the patients' perspective

Traditionally, the success of TKA has been assessed by objectives measures deployed by the surgeon. In recent decades, there has been a shift towards a greater emphasis on the patients' perspective, particularly due to evidence supporting disparities between patient and surgeon outcome ratings [86,125]. Compared to their surgeons, TKA patients tend to be less satisfied with the outcome of their treatment [26,76,110].

The collection and analysis of patient-reported outcome measures (PROMs) is essential to better understand the patient perspective and to identify pre- and post-operative factors that contribute to patient satisfaction. The outcome of orthopaedic surgery should be measured not only with objective endpoints, but also with endpoints that are relevant to patients. From a patient-centred perspective, a TKA is only successful if the patient is satisfied with the outcome. The ultimate goal must be to have a satisfied patient in the long term [167].

PROMs were developed in the 1990s to reduce the risk of bias in surgeon-rated outcome [208]. They are a set of questionnaires and related techniques designed to capture patients' own views of their health and the benefits they receive from health care [65]. PROMs collect subjective information directly from the patient and transform immeasurable subjective qualities into quantitative measures [106]. They can be categorised as generic or condition-specific and should be combined as they provide complementary information [168].

The use of validated PROMs contributes to a patient-centred approach and ensures that improvements in pain, function, quality of life and other endpoints important to patients are assessed. PROMs facilitate an emphasis on patient priorities and can be a tool for increasing patient involvement in the treatment process [106]. When used routinely, they can improve communication with patients, help monitor changes in health status, support clinical care decisions, and assess treatment effectiveness [1,9,49]. The value of PROMs has been summarised by the Canadian Institute of Health Information and the OECD Patient-Reported Indicator Surveys (PaRIS), as described in Table 1 [31,151].

Table 1: The value of PROMs

Stakeholder	Uses
Health system policy-makers/ system managers	• Compare outcomes locally, nationally, internationally and over time. • Identify variations in quality of care and leaders in best practice for mutual learning. • Evaluate and drive quality improvement initiatives. • Compare different care models and clinical pathways for outcome analysis. • Support health service allocation decisions informed by the relative cost of achieving desired outcome states (“value-based care”). • Inform health services programming, planning and policies.
Health care organisations	• Monitor organisation and provider performance; compare with peer organisations; identify organisations with high outcome scores for engagement and learning opportunities. • Identify and engage providers who would benefit from further support.
Health care providers	• Direct feedback can be used to modify the care path and provide evidence toward improving or maintaining a high level of care. • Support improved clinician–patient communication and raise awareness of problems that would otherwise be unidentified. • Facilitate performance comparisons and quality improvement initiatives.
Patients	• Provide opportunity for patients to provide input from their perspective and to be more aware of expected outcomes and how they compare. • Provide opportunity for patients to provide feedback independent of their provider’s view; potentially identify themselves as having a less-than-satisfactory outcome. • Enhance communication with care providers; improve patient involvement in care planning and decision-making; flag potential issues to providers that may require modification of their treatment plan.

Source: Canadian Institute of Health Information [31], OECD Patient-Reported Indicator Surveys (PaRIS) [151]

The need to collect patient-reported outcome measures (PROMs)

The first nationwide collection of PROMs started with the Swedish Hip Arthroplasty Registry in 2002 [83,170]. This was followed by many other registries. A recent report found 14 local or national registries collecting PROMs after TKA [23]. In Switzerland, the Swiss National Joint Arthroplasty Registry (SIRIS) collects information on implants, providers and patients, but does not yet collect PROMs [185]. Some cantons have recently made the collection of PROMs mandatory for certain diseases [63], but in an international comparison, Switzerland ranks very poorly in the implementation of PROMs [175].

Therefore, in 2017, we started to routinely collect PROMs from our patients scheduled for elective partial knee arthroplasty or TKA. In the design phase, we followed international guidelines [32,82] and the recommendations of the PROMs Working Group of the International Society of Arthroplasty Registries (ISAR) [168,169]. To maximise participation rates, we aimed to select a reasonable set of PROMs to avoid overburdening patients.

This overall project of collecting PROMs from our patients laid the foundation for further research projects and my PhD. The protocol related to this is the first publication of my thesis and is printed in **Chapter 3**.

The new PROM for highly active patients

In selecting the PROMs to be used later, the focus was not only on traditional PROMs, such as the Knee injury and Osteoarthritis Outcome Score (KOOS) or the EQ-5D, but also on newer PROMs, such as the Forgotten Joint Score (FJS-12), which promise greater responsiveness in younger patients. After we started collecting PROMs, we came across the High-Activity Arthroplasty Score (HAAS). This questionnaire was designed to capture the broader range of functional abilities of younger and more active patients with TKA or total hip arthroplasty (THA) [194]. As mentioned above, the indications for TKA have expanded to include younger and more active patients. Traditional PROMs often focus on pain and symptoms and are not sufficient to discriminate between patients with normal and higher levels of function, such as participation in recreational and sports activities [194].

We also noticed that our patients tended to be younger and more active, especially those who received a customised individually made (CIM) prosthesis. We were therefore interested in using the HAAS and incorporating it into our routine set of PROMs. Studies have demonstrated adequate measurement properties with good validity and reliability

[48,59,87,194] and low ceiling effects [87]. The HAAS was originally developed in English [194], with other translations available [48,58,133].

A validated German version of the HAAS was not yet available. We felt there was a need for a better assessment of function in highly active TKA patients and wanted to use the HAAS in our German-speaking patients. This research gap led to the translation and cross-cultural adaptation of the English HAAS into a German version. At the same time, we were interested in the psychometric properties of the German HAAS in patients 12 months after primary TKA. The publication on this project can be found in **Chapter 4**.

The customised approach: comparison of two different implants

In recent decades, technological advances have led to the development of CIM TKA. These implants have been available since 2011 [39] and have been used in our patients since 2015. The rationale behind CIM TKA is to address the anatomical variability and to restore the individual anatomy, resulting in improved knee kinematics. It has been shown that there is a high variability in the morphology of knee joints [19,20,29,80,99]. Conventional off-the-shelf (OTS) TKA does not fully restore normal biomechanics and functional limitations may occur [146]. OTS TKA can result in implant overhang, malalignment and abnormal kinematics [25,113,118,182]. In theory, CIM TKA may offer a solution to these problems. They are designed to overcome these limitations with the aim of improving clinical outcomes and patient satisfaction.

CIM implants are manufactured based on a computed tomography scan. The individualised implant is then manufactured and the surgeon is provided with individualised instruments and a planning overview (iView®). A very detailed description of the surgical procedure has been published previously [190]. Studies have shown early encouraging results with CIM TKA in terms of knee alignment [5,220], kinematics [229], function [189] and patient satisfaction [163,174]. However, recent systematic reviews found conflicting evidence with superior and inferior results for CIM TKA and highlighted the need for better methodological studies [136,138,210].

Comparative studies remain limited. A prospective study of CIM TKA with a matched control group focusing on patient satisfaction and other PROMs is currently not published. This research gap led to our study with the manuscript in **Chapter 5**. Thanks to the above-mentioned translation project, we were also able to analyse the results in relation to the HAAS for the first time.

The comparison of responsiveness of PROMs

There are many validated PROMs available to assess the outcome of TKA and selecting the most appropriate can be challenging. Responsiveness is an important factor when considering the psychometric properties of a measure. By definition, the responsiveness of a PROM is its ability to detect change over time [69,131]. Responsiveness is particularly important because changes in health and quality of life in chronic conditions are usually small and require specific and sensitive measures.

Some traditional, long-established knee-specific PROMs, such as the KOOS, are recommended in TKA patients but are known to have deficits in responsiveness [38]. A newer short form, the KOOS-12, has shown promising early results in terms of good responsiveness and no ceiling effects [50,61], but as with any new measure, further research is needed [61]. In addition, the literature suggests that recently developed PROMs such as the FJS-12 or the HAAS are more discriminating, particularly in younger and more active patients [21,194].

As we used a range of PROMs, we wanted to take advantage of this opportunity and aimed to compare the different PROMs in terms of their responsiveness. PROMs such as the KOOS-12, FJS and HAAS are still new concepts. Studies are needed to investigate their psychometric properties and their performance at different follow-up intervals.

The responsiveness of different PROMs has been partially evaluated in patients with TKA. However, comparative analyses of simultaneously recorded PROMs are still limited [66,134]. In particular, a comparison of the performance of newer PROMs such as KOOS-12, FJS-12 and HAAS with traditional PROMs or clinician-reported measures was needed and led to our study. The corresponding manuscript is printed in **Chapter 6**.

The patient expectations

The concept of satisfaction is complex and influenced by many factors, but especially by expectations and outcome [121]. In the medical context, patient expectations have been defined as the anticipation that certain events are likely to occur during or as a result of medical care [205]. Knowing patient expectations is an important part of shared decision-making before TKA. It will help to improve communication between surgeon and patient and could help to prevent potentially dissatisfied patients. Dissatisfaction might be a result of unrealistically high expectations rather than the result of a poor treatment outcome.

The issue of patient expectations is receiving increasing attention, particularly in elective orthopaedic surgery, where the patient's perspective strongly influences the decision to undergo surgery [119]. With an ageing population expecting to lead active lives after retirement, patient expectations of improvement after TKA will become even more important. In addition, the proportion of younger TKA patients with potentially higher expectations is increasing. This highlights the need to understand the interaction between patient expectations, satisfaction and outcome, particularly in young, active patients. The literature suggests that patients tend to have high, overly optimistic and unrealistic expectations of TKA [123,154], and that patients tend to have higher expectations than their surgeons [64].

The interaction between preoperative patient expectations and postoperative patient satisfaction is not well understood. Patient satisfaction after TKA is strongly influenced by the extent to which patient expectations are met [72,115,145,176], but there is conflicting evidence on the association between expectations and postoperative outcome. Systematic reviews on this topic found inconsistent results [14,71,72]. The most recent review reported an association between expectations and satisfaction in four out of eight studies [72]. Later, a large cohort study found an association between expectations of kneeling and psychological well-being and satisfaction at one year [77]. Others showed that higher expectations predicted greater improvements in PROMs, but not satisfaction [85], and that patients with more optimistic expectations had better surgical outcome [56].

It remains unclear whether high expectations are associated with a higher risk of dissatisfaction after TKA. To improve outcome for TKA patients, we need a better understanding of the relationship between patient expectations and satisfaction. This research gap led to the study described in **Chapter 7**. In preparation, a literature review identified the Hospital for Special Surgery Knee Replacement Expectations Survey (HSS-KRES) as the appropriate PROM to capture patient expectations. We added it to the existing set of PROMs and have been using it routinely ever since.

Personal contribution

I had the great opportunity to become the first research associate at the practice LEONARDO, which has recently been split into practice LEONARDO and practice MEIN KNIE. Thus, I contributed substantially to all parts of the research projects included in this dissertation from the very beginning.

In the planning phase, I researched and pre-selected the PROMs to be used and organised the necessary licences. I designed the methods and submitted applications, and amendments if needed, to the ethics committee.

In the execution phase, I was responsible for the project management and project coordination, including the data collection. To enhance the data collection, we implemented a secure web application for creating and managing online surveys (REDCap) [162]. I was responsible for setting up and maintaining the REDCap database. For more advanced questions, I was supported by a computer scientist. I organised the forward and backward translation within the translation project and added the expectations questionnaire (HSS-KRES) to implement the patient expectations project.

In the analysis phase, I performed all statistical analyses and plotted all graphs and charts. I drafted all manuscripts, coordinated the critical review by all co-authors and submitted and revised all manuscripts.

Chapter 2

Study objectives

Collection of PROMs

The objective of the overall research project was to implement PROMs into our daily medical routine to gain a better understanding of the patients' perspective. The aim of the first article was to provide the protocol for our study to collect PROMs from patients undergoing knee arthroplasty.

Embedded in the overall project were the following four sub-projects, each with a specific study objective.

The German version of the High-Activity Arthroplasty Score (HAAS)

The study objective was to translate, cross-culturally adapt and validate the German HAAS in patients one year after primary TKA.

Satisfaction after total knee arthroplasty: a prospective matched-pair analysis

The purpose of this study was to compare PROMs, especially patient satisfaction, of patients with CIM and OTS TKA in a matched-pair analysis with a two-year follow-up.

Comparison of responsiveness of PROMs

The aim of this study was to evaluate the responsiveness of the objective KSS and different PROMs, namely the KOOS, KOOS-12, FJS-12, HAAS and the EQ-5D, at four months, one year and two years in patients with primary TKA.

Patient expectations and patient satisfaction

The aim of this study was to assess patient expectations and their correlation with patient satisfaction at 4 and 12 months after TKA. We hypothesised that patients with higher expectations would be less satisfied with their TKA.

Chapter 3

Patient-reported outcome measures (PROMs) following knee arthroplasty: a prospective cohort study protocol

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Abstract

Introduction

To evaluate the quality of clinical practice, patient reported outcome measures (PROMs) are important as certain questions could only be answered by the patient himself. PROMs help to get a better understanding what is meaningful to a patient and directly affects daily functioning. To move beyond traditional measures, we are interested in what matters to patients and developed this project. The aim of this article is to provide the protocol for our study collecting PROMs in daily medical practice from patients who undergo knee arthroplasty.

Methods and analysis

This study is a single site, observational, prospective cohort study. We will recruit patients scheduled for a knee arthroplasty in our medical office, situated in a private clinic. After signed informed consent, patients complete self-reported questionnaires before the surgery, after 4 months, 1 year, 2 years, 3 years, 4 years and 5 years. We will use the following PROMs: Knee injury and Osteoarthritis Outcome Score (KOOS), Forgotten Joint Score, EQ-5D and satisfaction. Additionally, the surgeon will complete the objective Knee Society Score. Administration of the questionnaires will be electronically or paper-based.

We will assess differences between pre- and postoperative data with paired t-test for continuous variables and Wilcoxon signed-rank test for categorical variables. To assess subgroup differences we will use unpaired t-test for continuous variables and Mann-Whitney-U-test for categorical variables. To assess possible presence of bias we will conduct sensitivity analyses.

Ethics and dissemination

The study has been reviewed and approved by the local ethics committee in Basel, Switzerland. Written informed consent will be obtained from all patients. We will disseminate the results of the study through peer-reviewed journals, national and international conference presentations and presentations to relevant stakeholders through appropriate channels.

Keywords

Knee arthroplasty, knee replacement, patient reported outcome measures, orthopaedic surgery, prospective cohort study

Article Summary

Strengths and limitations of this study

- Our results return a direct feedback from patients with knee arthroplasties, short to long term.
- The findings will help to understand why some patients with knee arthroplasties are not satisfied and can be compared to other data from registries with PROMs.
- The Swiss arthroplasty registry SIRIS does not apply PROMs, our study helps to collect important data.
- Participants are recruited from a single private medical office consisting of a team of three subspecialised knee surgeons. The sample size may not be representative for all patients in Switzerland, but is likewise a homogenous sample

Introduction

Patient-reported outcomes are an important element to evaluate the quality and the results of clinical practice, as they directly and without any interpretation report a patient's health status [206]. Certain questions, e.g. regarding health-related quality of life or functioning in daily life, could only be answered by the patient himself. Patient reported outcome measures (PROMs) are standardised measures to capture and translate the patients' perspective into objective numerical data. The Organisation for Economic Co-operation and Development (OECD) promotes people-centredness of primary care services [32] and the International Consortium for Health Outcomes Measurement (ICHOM) is developing more standard sets to measure PROMs [82].

PROMs help to get a better understanding of outcomes that are most meaningful to patients and have direct relevance to their everyday functioning. Patients with arthroplasties differ in what they consider important: the ability to run, kneel or squat has not the same relevance for all patients [215]. Despite high implant survival rates and good overall outcome of knee arthroplasties, up to 20% of the patients are still unsatisfied with their results after surgery [68].

Each year, 21,000 patients undergo total knee arthroplasty (TKA) in Switzerland [152]. The frequency of 250 per 100,000 population is the highest among the OECD countries [152]. The Swiss National Joint Registry captures implant specific outcomes of almost all TKA procedures in Switzerland, but until now the registry does not capture PROMs [185]. To move beyond traditional measures, we are interested in what matters to patients and developed this project. The aim of this article is to provide the protocol for our study collecting PROMs in daily medical practice from patients undergoing knee arthroplasty.

Methods and analysis

Study design, setting and recruitment

This study is a single site, observational, prospective cohort study with a follow-up of five years. Recruitment will take place in our medical office, situated in a private clinic. Three experienced knee surgeons will consecutively recruit patients scheduled for elective partial or total knee arthroplasty. As part of daily routine, we will ask all patients eligible to participate. The participation is voluntary and will not affect patients' further treatment. The inclusion and exclusion criteria are described in Table 1

Table 1	Inclusion and exclusion criteria
Inclusion	► Patients scheduled for elective partial or total knee arthroplasty. ► Age >18 years. ► Any diagnosis, any implant design.
Exclusion	► Insufficient knowledge of German, English, Italian or French to understand the consent form and the questionnaires.

A trained research associate (NV) will be responsible to instruct patients about the needs and goals of the project, to distribute and collect the questionnaires and to manage and analyse collected data.

Procedures and follow-up

After signed informed consent, we will ask patients to complete the self-reported questionnaires not before three weeks before the surgery. Postoperative, we will distribute questionnaires after 4 months, 1 year, 2 years, 3 years, 4 years and 5 years. Questionnaires are predominantly electronically or otherwise paper-based, whereby a trained research associate will enter the data into our database. In general, all study data will be collected and managed using REDCap (Research Electronic Data Capture), a secure web-based software hosted on a secured server placed in Switzerland. Authorised study personnel only will have access to uncoded patient data.

During the routine medical screening, surgeons will as well complete a questionnaire: before the surgery, after 4 months, 1 year and 5 years. We will collect demographic data and data concerning surgery details from patients' medical records. Independent of our study, every patient scheduled for a total knee or hip arthroplasty at our clinic, is eligible to participate in the national arthroplasty registry (Swiss Implant Registry, SIRIS). For those patients who agreed to take part in the registry we will have standardised data on their general state of health, previous surgeries and details on the implant.

Our data collection will be joint-based, rather than patient-based. Thus, patients with bilateral surgery will complete questionnaires for each knee joint. In case of an unreturned questionnaire, we will send out a reminder or call the patient. To assess external validity, we will collect anonymised information about age and sex for those patients not willing to take part in the study. A detailed summary about outcome measures and their distribution over time is outlined in Table 2.

Table 2 Outcome measures and time of completion

Outcome measures	Instrument	Time of completion						
		Before surgery	4 months	1 year	2 years	3 years	4 years	5 years
Demographic data		x						
Patient-reported, knee specific								
Symptoms	KOOS symptoms	x	x	x	x	x	x	x
Pain	KOOS pain	x	x	x	x	x	x	x
Activities of daily living	KOOS ADL	x	x	x	x	x	x	x
Sports and recreational activities	KOOS sports	x	x	x	x	x	x	x
Knee related quality of life	KOOS QoL	x	x	x	x	x	x	x
Forgotten Joint	FJS-12	x	x	x	x	x	x	x
Satisfaction with surgery	Likert scale		x	x	x	x	x	x
Overall knee improvement	Likert scale		x	x	x	x	x	x
Surgery again	Yes/no		x	x	x	x	x	x
Patient-reported, generic								
Health-related quality of life	EQ-5D-3L	x	x	x	x	x	x	x
Clinician-completed								
Knee function	KSS	x	x	x				x
Degree of osteoarthritis	Kellgren-Lawrence Scale	x						
Satisfaction with surgery	Likert scale		x	x				x

ADL, activities of daily living; EQ-5D-3L, EuroQol five dimensions three levels; FJS-12, Forgotten Knee Joint Score; KOOS, Knee injury and Osteoarthritis Outcome Score; KSS, Knee Society Score; QoL, quality of life.

Outcome measures

For patients with knee osteoarthritis, numerous validated questionnaires are available to assess several aspects of functioning and health-related quality of life. Such questionnaires typically comprise items on joint function, pain, stiffness, and treatment satisfaction. We screened the literature for international guidelines [32,82], common PROMs in other relevant studies and national arthroplasty registries [217] and followed the recommendation to combine generic and specific PROMs [168]. We tried to find a reasonable balance between the amount of PROMs applied and the burden for the patient to answer all items in order to increase our participation rate. As a result, we decided to use three validated PROMs and one validated clinician completed questionnaire.

Objective Knee Society Score (KSS)

The Knee Society Score consists of different parts, we will only use the objective Knee Society Score (KSS) [147]. Four items regarding alignment, stability, and joint motion completed by the surgeon and three patient reported items on symptoms contribute to the KSS. The total score ranges from 0 to 100 points with a higher score indicating better outcome. The Knee Society Score is valid, responsive, reliable and consistent in patients with arthroplasties [42,95].

Knee injury and Osteoarthritis Outcome Score (KOOS)

The Knee injury and Osteoarthritis Outcome Score (KOOS) is developed to assess the patient's opinion about their knee and associated problems [171]. The KOOS consists of 42 items divided into five subscales on pain, symptoms, activities of daily living (ADL), sports and recreational activities, and quality of life (QOL). Each subscale ranges from 0 to 100 points, with a higher score indicating better outcome. A total score has not been validated and is not recommended. Adequate measurement properties have been demonstrated [38].

Forgotten Joint Score (FJS-12)

The Forgotten Joint Score (FJS-12) measures through 12 items the new concept of patients' ability to forget the artificial joint in everyday life [21]. The total score ranges from 0 to 100 points with a higher score indication better outcome. The measurement properties have been evaluated and confirmed for patients with arthroplasties in several studies [16,66,202]. The FJS-12 showed less ceiling effects than the KOOS and might be more discriminating in patients with total knee arthroplasties [201].

EQ-5D-3L

The three-level version of the EQ-5D is one of the most widely used instruments for measuring generic health-related QOL [53,54] and is also the most commonly used generic PROM amongst arthroplasty registries [169]. The EQ-5D-3L captures five dimensions (mobility, self-care, usual activities, pain/discomfort and anxiety/depression) based on three levels of severity (no problems, moderate problems, extreme problems). To derive the summary index score a value set of the general population of a country or region is required. In the absence of a value set for Switzerland, we will apply the European value set. The index score ranges from 0 to 1 with a higher value indication better health.

Additionally, a visual analogue scale (EQ-VAS) records the patient's self-rated health on a vertical VAS with the endpoints "The best health you can imagine" (100 points) and "The worst health you can imagine" (0 points). The different EQ-5D instruments have been proven to be valid, reliable and responsive in numerous conditions and populations [53].

Satisfaction

Besides the usage of validated questionnaires, it is recommended to use an extra item to measure global satisfaction. Such an item presents with a good face validity and gives the patient the opportunity to summarise his point of view [168]. We will ask patients on a five-point Likert scale how satisfied they are with the result of the surgery (very satisfied,

satisfied, neutral, unsatisfied, or very unsatisfied). To objectify this outcome, surgeons will answer this question as well.

We will also ask patients, if they would undergo the surgery again (yes or no) and how they rate their current overall improvement in their knee joint compared to the state before the surgery on a seven-point Likert scale (very much better, substantially better, a little better, no change, a little worse, substantially worse, or very much worse). Health transition items are another type of PROMs to reflect a self-perceived change over a defined period.

Outcomes

We will calculate the total score for each outcome measure according their published algorithms. For all outcome measures, we will report end and change scores. Our primary outcome will be patients' satisfaction with the result of the surgery; whereas all other patient and clinician reported outcomes, adverse events and revision surgery will be secondary outcomes.

Sample size and study duration

The volume of knee arthroplasties at our medical office is approximately 130 arthroplasties in 120 patients per year (bilateral surgery possible). We estimate that only few patients are not eligible because of language barriers as the questionnaires are available in four languages (German, English, Italian, and French). We will ask all eligible patients to participate and assume that 20 % will reject. Finally, we will recruit about 100 patients per year and aim for at least a 90 % follow-up rate in the first two years after surgery. A small proportion (3%) will be patients with revision surgery whose data will be analysed separately from patients with primary knee arthroplasty.

The recruitment period will be five years, data collection period ten years (five years per patient), respectively. In total, we aim to collect data from 500 knee arthroplasties.

Missing data

We will regard the instructions on how to handle missing answers for each outcome measure. For each of the KOOS subscales at least half of the answers are mandatory, for the FJS-12 two-thirds are mandatory to calculate a mean score. All answers are mandatory for the EQ-5D to compute the index value. We will report the frequency of missing data for each outcome measure and each follow-up.

Statistics

We will perform statistical analyses with IBM SPSS Statistics for Windows, Version 26.0. (Armonk, NY: IBM Corp.). Descriptive statistics will be presented, including means and standard deviation (SD) for all continuous variables, and frequency counts and percentages for categorical variables. As bilateral knee arthroplasties are possible, we will report joint-based data, rather than patient-based data.

The Kolmogorov-Smirnov test will be used to verify normal distribution. To assess differences between pre- and postoperative data we will use paired t-test for continuous variables and Wilcoxon signed-rank test for categorical variables. To assess subgroup differences we will use unpaired t-test for continuous variables and Mann-Whitney-U-test for categorical variables. To assess possible presence of bias we will conduct sensitivity analyses. We will perform all tests two-tailed and consider p values ≤ 0.05 as statistically significant.

Burden and practical considerations

We estimated that patients need maximum 10 to 15 minutes and surgeons 2 to 3 minutes to complete the questionnaires. Questionnaires for patients are available in four different languages and administered electronically or paper-based. For a private medical office the administrative burden and costs involved in routinely collection of PROMs for knee arthroplasty patients are significant. A research associate coordinates all procedures and put the collection of PROMs into daily medical practice. Technical issues needed to be resolved to implement a database that is able to capture study data and send out questionnaires to patients and surgeons.

Ethics and dissemination

Our study is in accordance with the World Medical Association Declaration of Helsinki [219] and was approved by the local ethics committee in Basel, Switzerland (reference: 2016-01777) [192]. All patients will have to sign a written informed consent. The findings of the study will be published in peer-reviewed journals and presented at national and international conferences. Moreover, we will communicate the results to relevant stakeholders like patients, clinicians, health-care providers or policymakers through appropriate channels.

Patient and public involvement

Patients and the public were not directly involved in planning, design and development of the study. However, the results will be published and publicly available.

Discussion

We hereby described the methods of our study to collect PROMs from patients undergoing knee arthroplasty. Our aim is to contribute to the implementation of PROMs collection into daily medical routine. For a private medical office, it is a burden regarding costs and time to realize such a project. However, we are interested in the *real* results of our patients and want to identify, and if possible to reduce, factors leading to unhappy patients after a knee arthroplasty. In addition, we want to answer the question, if different types of implants, off-the-shelf versus customised individually made implants, show any differences in their outcomes.

We selected a balanced combination of validated generic und disease specific PROMs that are commonly used and likewise present in national arthroplasty registries. Beyond traditional PROMs like KOOS and EQ-5D, we added the FJS-12. It comprises a relatively new and convincing concept of joint awareness and measures the ability to forget the artificial joint, while having less ceiling effects [200]. Distribution of questionnaires will predominantly be electronically. Thus, we avoid transcription errors while distribution is more efficient and less time consuming. We are optimistic, that the need for paper administration will diminish with time since also elderly get familiar with new technologies [168].

Besides the evaluation of the patients perspective, PROMs can be used to engage patients in medical decision-making [148]. Patients may have little experience participating in medical or health decisions and may not recognize the important role they play in clarifying their values and incorporating them into decisions [111]. In summary, we believe that the results of our study will be useful for all stakeholders, like clinicians, patients or policy makers to enhance the understanding of the impact of knee osteoarthritis or knee arthroplasty on the patient.

Chapter 4

The German version of the High-Activity Arthroplasty Score is valid and reliable for patients after total knee arthroplasty

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Abstract

Purpose

The indications for a total knee arthroplasty (TKA) broadened to younger and more active patients. The High-Activity Arthroplasty Score (HAAS) is a self-administered instrument focussing on the wider range of functional abilities of more active patients. The HAAS was developed in English and is not available in German yet. This study aims to translate, cross-cultural adapt and assess the psychometric properties of the German HAAS in patients 12 months after primary TKA.

Methods

After forward and backward translation, we examined the final version regarding its psychometric properties in patients 12 months after primary TKA. The HAAS was sent out to 70 patients together with routine questionnaires comprising the Knee injury and Osteoarthritis Outcome Score (KOOS), the Forgotten Joint Score (FJS-12), the EuroQol (EQ-5D-3L) and two numerical pain rating scales. Acceptability, reliability, responsiveness, content and construct validity as well as floor and ceiling effects were evaluated.

Results

Fifty-two patients were recruited. The HAAS was well accepted with a mean time to completion of 2.4 minutes. Cronbach's alpha for internal consistency was 0.749, test-retest reliability was excellent with an Intraclass Correlation Coefficient (ICC) of 0.961. The smallest detectable change was 1.5. Good content validity was confirmed. A strong correlation was found between the HAAS and KOOS sport (r = 0.661) and a medium correlation for all other KOOS subscales (r = 0.324 to 0.453), the FJS-12 (r = 0.425), the EQ-5D-3L (r = 0.427) and pain (r = -0.439 to -0.308). The HAAS showed no floor and ceiling effects.

Conclusions

The German version of the HAAS provides good validity and reliability. It can be easily self-administered and is recommended to capture high-intensity activities in patients after TKA.

Keywords

High-Activity Arthroplasty Score, cross-cultural adaptation, German validation, total knee arthroplasty, total knee replacement, patient-reported outcome measure

Level of Evidence

Diagnostic study, Level I

Introduction

Patient-reported outcome measures (PROMs) capture and translate patients' perspectives into objective numerical data. PROMs help to conceive which outcomes are meaningful and relevant to patients. For patients with a total knee arthroplasty (TKA) several PROMs have been developed and are well established [169,217].

Over time, the indications for TKA comprises both younger patients who are more demanding and older patients who are more active [194]. The number of TKAs in patients under the age of 65 years notably increased in recent years [109,199]. They represent the fastest growing population of TKA recipients and are expected to account for more than 50% of knee replacement procedures by the year 2030 [204].

As a consequence, outcomes after surgery improved and patients' expectations increased [216]. PROMs after TKA must therefore adapt to meet the changing expectations [218]. Traditional PROMs for patients with TKA often focus on pain and symptoms and are prone to ceiling effects because of a very narrow spectrum at the top end of the scale [194]. They are not appropriate to discriminate between patients with normal and higher level of function, for example, participation in recreational and sports activities [194]. New instruments with more discriminative power and less floor and ceiling effects are needed to distinguish between patients with good and excellent scores.

The High-Activity Arthroplasty Score (HAAS) was developed to overcome the aforementioned deficits and to explicitly address the wider range of functional abilities of younger and more active patients with TKA or total hip arthroplasty (THA) [194]. Studies proved adequate measurement properties with good validity and reliability [48,59,87,194] and low ceiling effects [87]. The original HAAS was developed in English [194] and translations are available in Italian [133], French [48], and Dutch [58]. A validated German version of the HAAS is not available so far, but necessary to facilitate PROMs particularly for highly active patients with TKA in the German speaking population.

The objectives of this study were the translation, cross-cultural adaptation and assessment of the psychometric properties of the German HAAS in patients 12 months after primary TKA. It was hypothesised that the German HAAS will show adequate psychometric properties regarding reliability, responsiveness and validity.

Materials and methods

Study design and properties

This is a single-centre, prospective, observational study. The assessment and reporting followed the Consensus-Based Standards for the Selection of Health Status Measurement Instruments (COSMIN) checklist [131] and the Guidelines for Reporting Reliability and Agreement Studies (GRRAS) [105]. The study was approved by the local ethics committee (ID: 2016-01777).

The HAAS questionnaire

The HAAS questionnaire, developed in 2010, is self-reported and comprises the four items walking, running, stair climbing, and the activity level [194]. The response level for each item ranges from normal function to serious limitation. The patient selects the highest possible level of his functional ability for each item. A point system for each item is applied whereby a higher score indicates a higher functional ability. The total score ranges from 0 to 18 points. The original version provides no instruction regarding missing answers. Therefore all answers were set as mandatory and thus missing answers avoided.

Translation and cross-cultural adaptation

The process followed the guidelines of cross-cultural adaptation of self-report measures consisting of the following stages: translation, synthesis, back translation, expert committee review, and pretesting [17]. First, two bilingual authors with German mother tongue and fluent in English (equivalent to language level C1), independently translated the English version of the HAAS into German (NV, RK). In a consensus meeting the translations were then combined to one German version. Subsequently, two bilingual persons from our non-medical staff with English mother tongue and fluent in German (equivalent to language level C1 and C2) independently translated the German version back into English. Both were blind to the original HAAS. In a subsequent consensus meeting, the expert committee, comprising the four translators and the senior author, reviewed the translations, reached a consensus and finalised the German version of the HAAS (Figure 1). This version was pre-tested in a group of five patients with TKA and found that no further adjustments were needed.

Figure 1: High Activity Arthroplasty Score – German Version

Bitte geben Sie Ihr höchstes Funktionslevel in jeder der vier Kategorien an.

Gehen

5 Auf unregelmässigem Boden länger als eine Stunde
4 Ohne Probleme auf flachem Boden, mit Schwierigkeiten auf unregelmässigem Boden
3 Ohne Probleme auf flachem Boden, nicht möglich auf unregelmässigem Boden
2 Auf flachem Boden für mindestens 30 Minuten
1 Kurze Entfernungen (bis zu 20 m) ohne Hilfe
0 Kurze Entfernungen mit Gehilfe oder gar nicht möglich

Rennen

4 Mehr als 5 km
3 Langsames Joggen bis zu 5 km
2 Ohne Anstrengung über die Strasse rennen
1 Wenn nötig, ein paar Schritte rennen, um dem Verkehr auszuweichen
0 Rennen geht nicht

Treppensteigen

3 Zwei Stufen auf einmal
2 Ohne Geländer
1 Nur mit Geländer oder Stock
0 Treppensteigen geht nicht

Aktivitätslevel

6 Leistungssport, z. B. Tennis (Einzelspiel), Rennen > 10 km, Radfahren > 80 km
5 Freizeitsport, z. B. Tennis (Doppelspiel), Skifahren, Joggen < 10 km, anstrengendes Aerobic
4 Anstrengende Freizeitaktivitäten, z. B. Wandern, wenig anstrengendes Aerobic, schwere Gartenarbeit oder körperliche Arbeit
3 Mässige Freizeitaktivitäten, z. B. Golf, leichte Gartenarbeit, leichte körperliche Arbeit
2 Leichte Freizeitaktivitäten, z. B. kurze Spaziergänge, Boccia
1 Nur notwendige Aktivitäten ausserhalb des Hauses, z. B. ein kurzer Weg zum Einkaufen
0 Ohne Hilfe kein Verlassen des Hauses möglich

Sample size

Following the rule of 10 patients per scale item, at least 50 participants were required to sufficiently assess reliability parameters [196]. It was anticipated three out of four patients eligible would be willing to participate and consecutively the next 70 patients eligible were asked to join this study.

Patients

Setting and recruitment

Routinely, patients from our private practice complete the following PROMs before and 12 months after their TKA: Knee injury and Osteoarthritis Outcome Score (KOOS), Forgotten

Joint Score (FJS-12), the EuroQol five dimensions three levels (EQ-5D-3L) and pain with level walking and pain with stairs or inclines [213]. According to their preference, patients receive the questionnaires paper-based or electronically via a secured study database (REDCap®). For this study, we asked 70 consecutive patients who completed the questionnaires electronically to participate. Those who gave their consent completed all PROMs including the HAAS and additionally answered four questions to measure content validity. After 10 days, they received the HAAS again to measure test-retest reliability. For practical reasons we included patients with electronically administered questionnaires only to ensure a test-retest interval of 10 days. Recruitment took place from July 2019 to November 2020. Over the same period, 37 patients completed paper-based questionnaire that were not analysed for this study for the stated reasons (Supplementary Material 1). Patients with a bilateral TKA participated only once.

Inclusion- and exclusion criteria

We included patients from our practice, fluent in German, 12 months after primary TKA who completed their PROMs questionnaire, including the HAAS, electronically. Patients were of all ages. This is contrary to the original validation [194], but consistent with Jenny et al. who showed the HAAS can be used in elderly patients as well [87]. Patients with revision surgery, major diseases or relevant co-morbidities that could impact physical activity were excluded.

Acceptability

Patients could pass a comment in the case of any problems with the HAAS. Time to completion could only be measured indirectly during the second assessment via Redcap®. For this, we recorded the time from viewing until submitting the electronic questionnaire.

Reliability

Reliability assesses the extent to which an instrument is stable, reproducible and free of measurement error. It comprises internal consistency, test-retest reliability, and measurement error [131].

Internal consistency

Internal consistency refers to the degree of interrelatedness among the items [40,131]. It is measured by Cronbach's alpha and should ideally be between 0.7 and 0.95 [40,195,196].

Test-retest reliability

Test-retest reliability reflects the variation in a measurement taken by an instrument on the same subject under the same conditions [104]. The interval between the repeated measurements should be long enough to prevent recall, though short enough to prevent clinical change. One to two weeks is recommended, we decided to send out the questionnaire again after 10 days [196]. Test-retest reliability was assessed by the Intraclass Correlation Coefficient (ICC) with a two-way random effects absolute agreement model because it regards systematic errors as part of the measurement error [126,196]. Based on the 95% confident interval (CI) of the ICC, the reliability was classified as poor (< 0.5), moderate (0.5 to 0.75), good (0.75 to 0.9), or excellent (> 0.90), respectively [104].

Measurement error

The standard error of measurement (SEM) reflects the systematic and random error of an instrument that are not attributed to true changes [132]. Patients received no treatment between the first and the second assessment of the HAAS. These assessments were used to determine the SEM. The SEM was measured applying the formula $SEM = SD \cdot \sqrt{(1 - R)}$, where SD is the pooled SD from the HAAS score and R is the test-retest reliability [196,209].

Responsiveness

Responsiveness, or sensitivity of change, is the ability of an instrument to detect important changes over time. The smallest detectable change (SDC) was measured with the formula $SDC = 1.96 \cdot \sqrt{2} \cdot SEM$, which reflects the smallest within-person change above measurement error [196].

Content validity

Content validity is defined as the extent to which the concepts of interest are comprehensively represented in the questionnaire. Patients were asked to report on their perception of the measurement aim (“Do you think the aim of this questionnaire is to ascertain high-intensity activities?”), target population (“Do you think this questionnaire refers to your condition?”), relevance (“Do you think the items are relevant to evaluate high-intensity activities?”) and completeness (“Do you think the items comprehensively reflect high-intensity activities?”). The hypotheses were considered acceptable if the proportion of confirming answers was > 85 % [196].

Construct validity

Construct validity determines to what degree an instrument measures what it is intended for. It was hypothesised a priori, that 12 months after TKA the HAAS will show a medium to strong correlation with the German versions of the KOOS [96], the FJS-12 [16], with pain and with the EQ-5D-3L [53]. We presumed the correlation with KOOS symptoms and pain to be lower than with KOOS activities of daily living (ADL) or KOOS sport. It was analysed by the Spearman's correlation. Correlation effect sizes were classified as low ($r > 0.1$), medium ($r > 0.3$) or strong ($r > 0.5$) [37].

KOOS

The KOOS consists of 42 items divided into five subscales on pain, symptoms, ADL, sports and recreational activities, and quality of life (QoL) [96]. Each subscale ranges from 0 to 100 points, with a higher score indicating better outcome. A total score has not been validated and is not recommended.

FJS-12

The FJS-12 measures through 12 items the new concept of patients' ability to forget the artificial joint in everyday life [16]. The total score ranges from 0 to 100 points with a higher score indication better outcome.

EQ-5D-3L

The EQ-5D-3L is generic measure for health-related QoL [53]. It captures five dimensions (mobility, self-care, usual activities, pain/discomfort and anxiety/depression) based on three levels of severity (no problems, moderate problems, extreme problems). To derive the summary index score a value set of the general population of a country or region is required. In the absence of a value set for Switzerland, we applied the European value set. The index score ranges from 0 to 1 with a higher value indicating better health.

Additionally, a visual analogue scale (EQ-VAS) records the patient's self-rated health on a vertical VAS with the endpoints "The best health you can imagine" (100 points) and "The worst health you can imagine" (0 points).

Pain

Pain was measured as pain with level walking and pain with stairs or inclines. Both on a numerical rating scale from 0 to 10 with a higher score indicating severer pain.

Floor and ceiling effects

We considered floor and ceiling effects to be present if more than 15% of the patients achieved the lowest or highest possible score [196].

Statistics

All statistical analyses were performed with IBM SPSS Statistics for Windows, Version 27.0 (Armonk, NY: IBM Corp). Results are presented with mean and standard deviation (SD). Differences between participants and non-participants were analysed with t-tests for continues variables and Mann-Whitney-U-tests for categorical variables.

Results

Patient characteristics

The questionnaires were electronically sent out to 70 patients. Of these, 52 patients participated and their questionnaires were analysed (response rate: 74%). Patients' characteristics are described in Table 1. Patients who refused to participate were not different from participants according to age, sex, body mass index, bilateral surgery, insurance or civil status. Baseline PROMs scores were not different, except for KOOS symptoms and EQ-5D VAS with lower scores for participants (Table 1).

Acceptability

The HAAS was well accepted, problems with comprehension of the questionnaire or the instruction did not occur. Adaptations were not necessary. Time to completion was 2.4 min (SD 1.6, range 0.18 to 8.55). Missing responses did not occur as all answers in the electronic questionnaire were mandatory.

Reliability

Cronbach's alpha for internal consistency was 0.749. Mean scores for the first and second assessment were 11.7 (SD 2.6) and 12.0 (SD 2.9), respectively. The first assessment was 12 months after primary TKA. The second assessment was send out 10 days later and resulted in a mean test interval of 11 days (1.7 SD, range 10 to 17). Test-retest reliability was excellent with an ICC of 0.961 (95% CI 0.921 to 0.976). The SEM was 0.54 points.

Table 1: Demographic characteristics and baseline PROMs

		Participants n = 52	Non-participants n = 18	P value
Age (SD, range)		65 years (7.6, 46 to 79)	68 years (8.1, 51 to 80)	0.200
Body mass index (SD, range)		28.1 kg/m^2 (5.1, 20.8 to 49.6)	27.9 kg/m^2 (5.5, 21.6 to 41.2)	0.875
Sex	Male	26 (50%)	11 (65%)	0.225
	Female	26 (50%)	6 (35%)	
Surgery	Unilateral	38 (73%)	14 (82%)	0.385
	Bilateral	14 (27%)	3 (18%)	
Insurance	Private/semiprivate	11 (21%) / 21 (40%)	2 (11%) / 7 (39%)	0.300
	Basic insurance	20 (39%)	9 (50%)	
Civil status	Not married	2 (4%)	1 (6%)	0.768
	Married	37 (71%)	13 (72%)	
	Divorced	6 (12%)	2 (11%)	
	Widowed	2 (4%)	-	
	Unknown	5 (10%)	2 (11%)	
KOOS (SD, range)	Symptoms	43 (16.0 14 to 82)	52 (20, 14 to 89)	0.049
	Pain	44 (17.2, 17 to 92)	47 (14.3, 25 to 89)	0.492
	ADL	51 (17.0, 10 to 86)	55 (15.1, 33 to 99)	0.373
	Sport	20 (16.9, 0 to 65)	21 (18.2, 0 to 70)	0.746
	QoL	24 (14.6, 0 to 63)	26 (14.0 0 to 63)	0.593
FJS-12 (SD, range)		14 (10.9, 0 to 48)	17 (17.5, 0 to 71)	0.357
EQ-5D-3L (SD, range)		0.617 (0.18, 0.231 to 1.0)	0.614 (0.15, 0.298 to 0.846)	0.954
EQ-5D VAS (SD, range)		60 (22.6, 15 to 100)	72 (13.5, 50 to 90)	0.012
Pain (SD, range)	Level walking	5.7 (2.6, 0 to 10)	5.3 (2.6, 0 to 10)	0.495
	Stairs/inclines	6.5 (2.9, 0 to 10)	6.4 (2.5, 1 to 10)	0.746

SD = standard deviation; n = number; KOOS = Knee injury and Osteoarthritis Outcome Score; ADL = Activities of daily living; QoL = Quality of life; FJS-12 = Forgotten Joint Score; EQ-5D-3L = EuroQol five dimensions three levels; VAS = visual analogue scale

Responsiveness

The SDC, representing the smallest change in score that is presumably reflecting the true change above measurement error, was 1.5.

Content validity

Content validity was given: the conforming answers to the four content validity questions were all above 85% (range 87 to 100%).

Construct validity

The correlations between the HAAS and other PROMs are presented in Table 2. Our a priori hypotheses were confirmed, indicating that all PROMs measure the same construct. Strong correlation was found for KOOS sport, for all other PROMs medium correlation was found.

Floor and ceiling effects

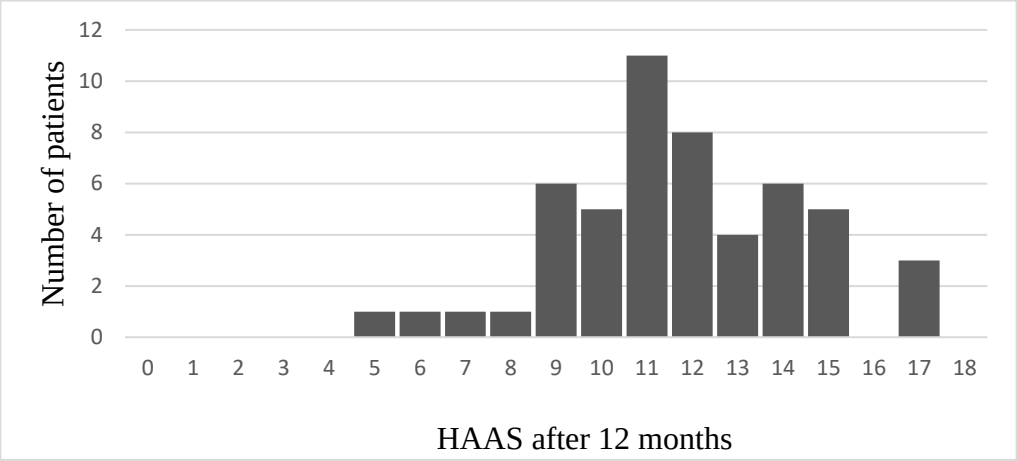
The HAAS showed no floor and ceiling effects, since no patient achieved the minimum or maximum score. The distribution of the HAAS total scores is shown in Figure 2. Floor and ceiling effects of all PROMs are shown in Table 2 and in detail in Supplementary Material 2. Floor effects were found for pain with level walking and pain with stairs or inclines, ceiling effects were found for KOOS ADL and the EQ-5D-3L.

Table 2: PROMs after 12 months with mean, SD, floor and ceiling effect and correlation to HAAS

		Mean score 12 months (SD)	Floor/ceiling effect in %	Spearman's rho (p value)	Correlation
HAAS		11.7 (2.6)	0/0	-	-
KOOS	Symptoms	76 (16.3)	0/10	0.324 (0.019)	medium
	Pain	84 (15.2)	0/14	0.336 (0.015)	medium
	ADL	86 (14.2)	0/17	0.453 (0.001)	medium
	Sport	66 (24.3)	0/10	0.661 (0.000)	strong
	QoL	70 (21.9)	0/10	0.443 (0.001)	medium
FJS-12		63 (28.6)	0/6	0.425 (0.002)	medium
EQ-5D-3L		0.851 (0.15)	0/41	0.427 (0.002)	medium
EQ-5D VAS		80 (15.1)	0/2	0.403 (0.003)	medium
Pain	Level walking	0.8 (1.5)	65/0	-0.439 (0.001)	medium
	Stairs or inclines	1.9 (2.1)	33/0	-0.308 (0.026)	medium

HAAS = High-Activity Arthroplasty Score; KOOS = Knee injury and Osteoarthritis Outcome Score; ADL = Activities of daily living; QoL = Quality of life; FJS-12 = Forgotten Joint Score; EQ-5D-3L = EuroQol five dimensions three levels; VAS = visual analogue scale; SD = standard deviation

Figure 2: Distribution of the HAAS total scores



Discussion

The most important finding of this study is, that the German version of the HAAS is valid and reliable for patients after primary TKA. The translation and cultural adaption of the German version of the HAAS revealed no problems. The results indicate a successful adaption process following international guidelines. The HAAS is successful in self-administration and easily applicable during daily clinical practice. Based on the findings of this validation study, the German version of the HAAS is an internal consistent, valid and reliable instrument without floor and ceiling effects for patients after primary TKA.

The HAAS is a short questionnaire easy to comprehend for patients. Our patients experienced no difficulties with the completion. In the original version, Talbot et al. discussed the relatively subjective “activity level” item. Patients might have problems to find the right category addressing their recreational activities. In our study, none of the patients reported any difficulties with this item. Moreover, the score is easy to calculate and to administer. With a time to completion of approximately two minutes it is only a small burden to the patient. However, time to completion could only be estimated by the time a patient was logged in at his electronic device. This is prone to error because the patient might not have logged out immediately after completing the questionnaire. Only the Italian version also measured time to completion and found similar values to ours (1.6 min SD 0.5) [133].

When assessing reliability, the Cronbach’s alpha for internal consistency was as intended > 0.7. Cronbach’s alpha was lower in the French version (0.58) [48], but higher in the original

(0.86) [194], the Italian (0.91) [133] and Dutch version (0.838) [58]. Test-retest reliability was excellent and in accordance with the Italian version (ICC = 0.95). The SEM was preferably low. Comparisons to other versions were not possible, none of the authors reported a SEM. The SDC was also preferably low and in fact lower than in the Italian version (1.8) [133].

The German HAAS proved to be valid regarding content and construct validity. Content validity was so far only confirmed in the Italian version [133]. We found a moderate to strong correlation between the HAAS and all KOOS subscales. As predicted, the correlation to KOOS symptoms and KOOS pain was lower than to KOOS ADL and KOOS sport, which confirms the HAAS focuses rather on physical activity instead on symptoms or pain. Assessment of content validity in the Dutch version found very similar correlations regarding KOOS subscales (r = 0.182 to 0.674), EQ-5D-3L (r = 0.447) and pain (r = -0.357) [58]. The Italian version reported higher correlation for all KOOS subscales and pain (r = -0.79 to -0.91).

As expected, no floor or ceiling effects were found. Thus, the discriminatory power of the HAAS to distinguish between patients with good and excellent results was confirmed. This is in accordance with all other language versions and other publications [87].

The strengths of our study are as follows: an a priori sample size estimation was calculated and a homogenous group of patients recruited. The use of electronic questionnaires prevented missing answers for the HAAS, ensured a consistent test-retest interval and allowed to measure time to completion. Moreover, we confirmed sufficient content validity, which was not measured in the original version.

Still, our study has some limitations. First, due to missing longitudinal data the responsiveness could only be estimated through the SDC. Other adequate measures like the minimal important difference or effect sizes are missing. Second, only patients who completed the HAAS electronically were included, which might bear a selection bias. Third, the HAAS was not yet validated for patients with THA. Originally, the HAAS is intended for patients after TKA and after THA.

The present study is the first to provide a German translation and validation of the HAAS. This is clinically relevant to capture self-reported functional abilities of younger or more active German speaking patients after TKA.

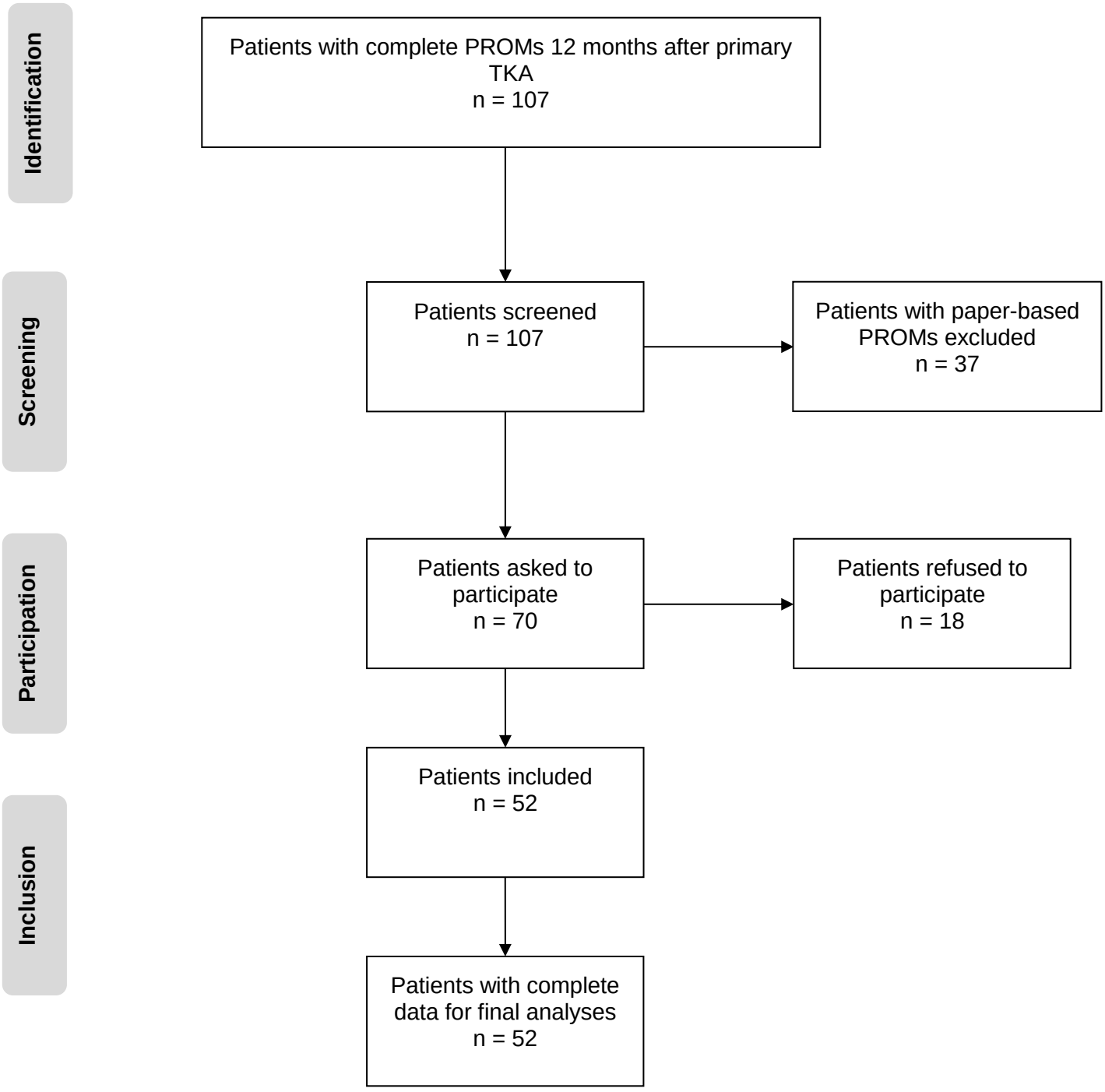
Conclusions

The German version of the HAAS provides good validity and reliability. It can be easily self-administered and is recommended to capture high-intensity activities in patients after TKA.

Appendix

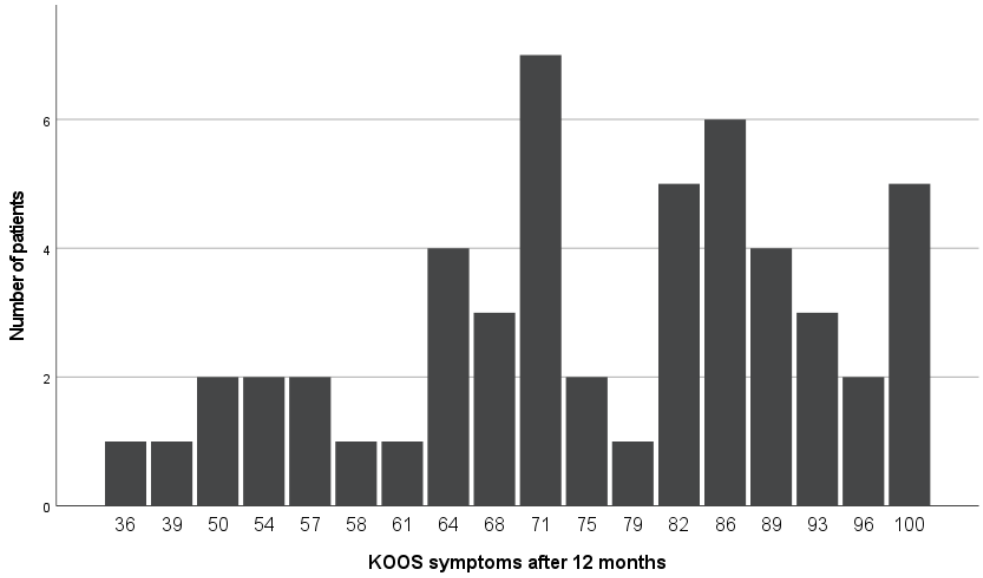
Additional material

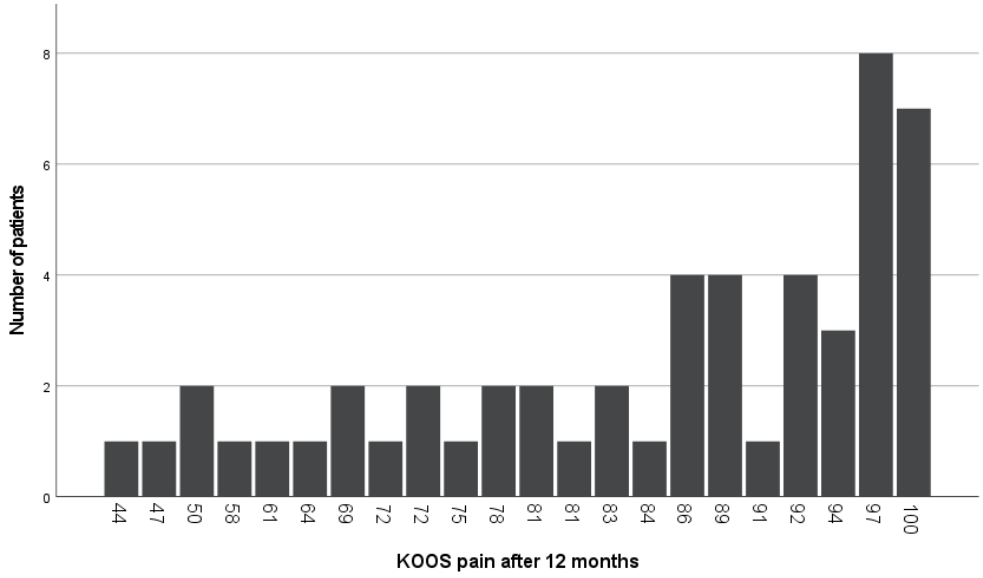
Flowchart of recruitment

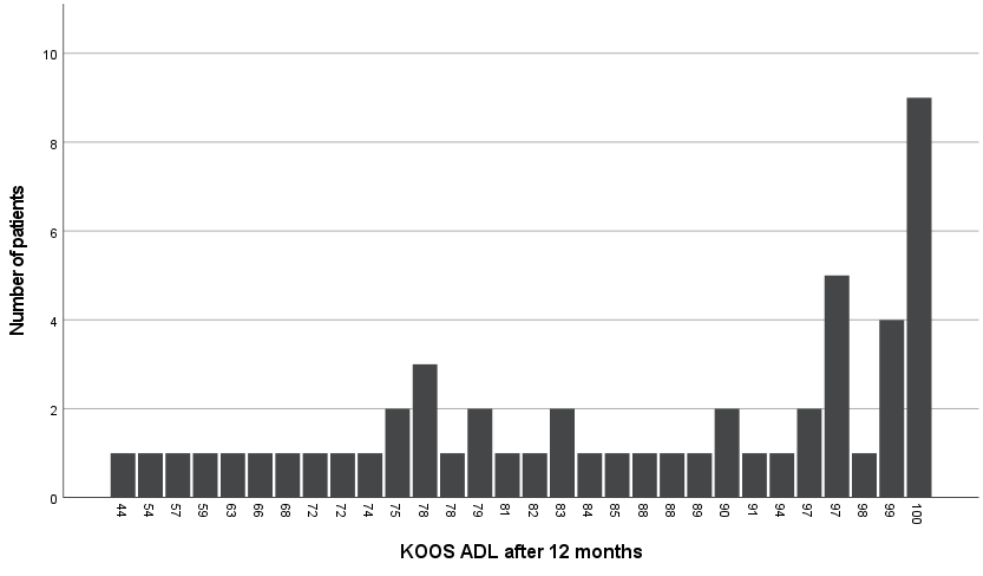


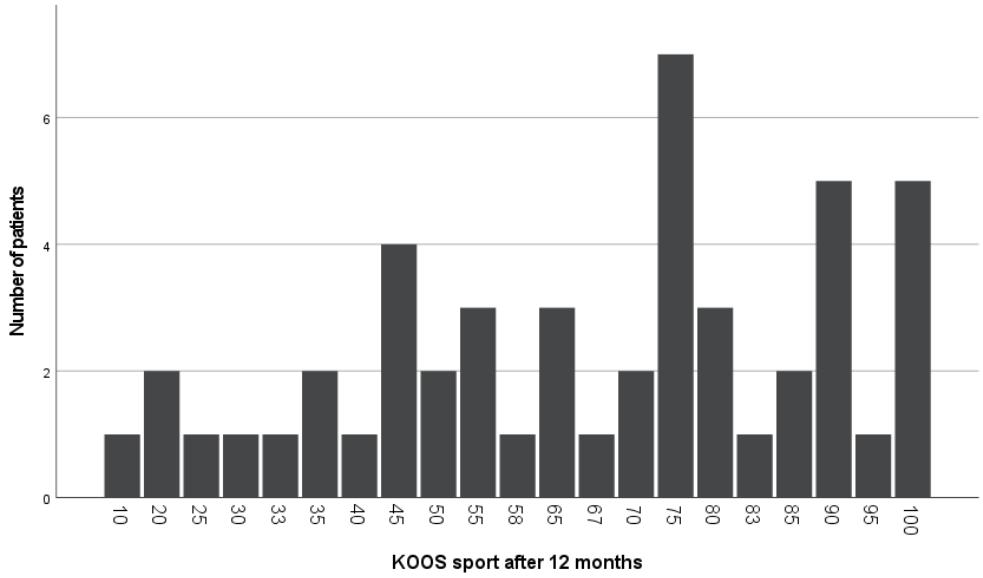
PROM = patient-reported outcome measure, TKA = total knee arthroplasty

Distribution of all patient-reported outcome measures





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25
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65
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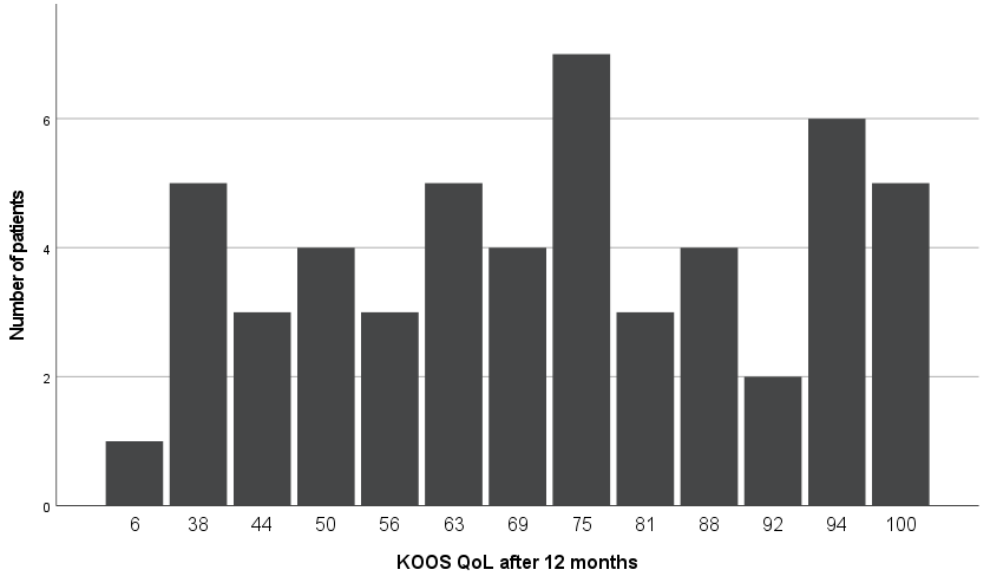
75
80
83
85
90
95
100
KOOS sport after 12 months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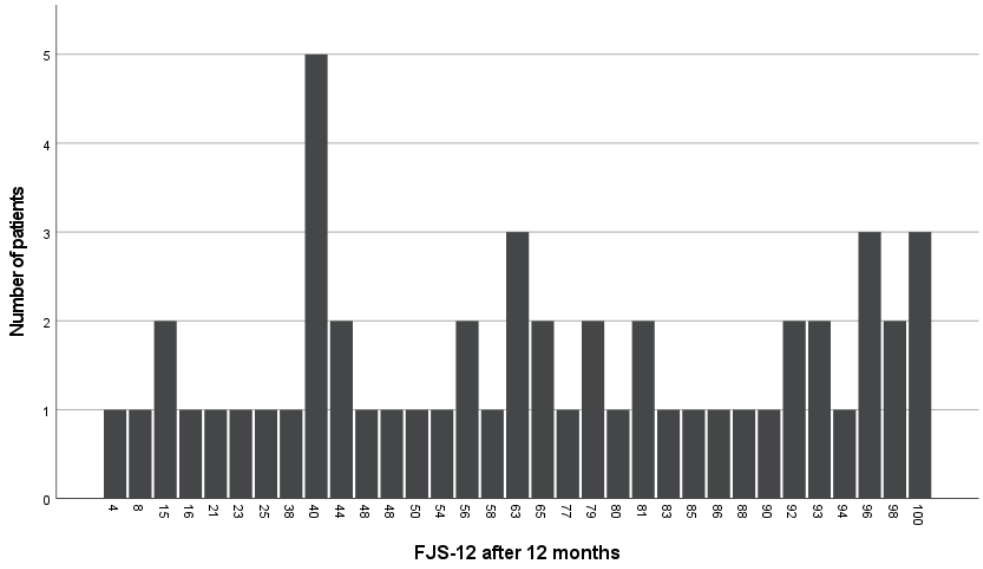
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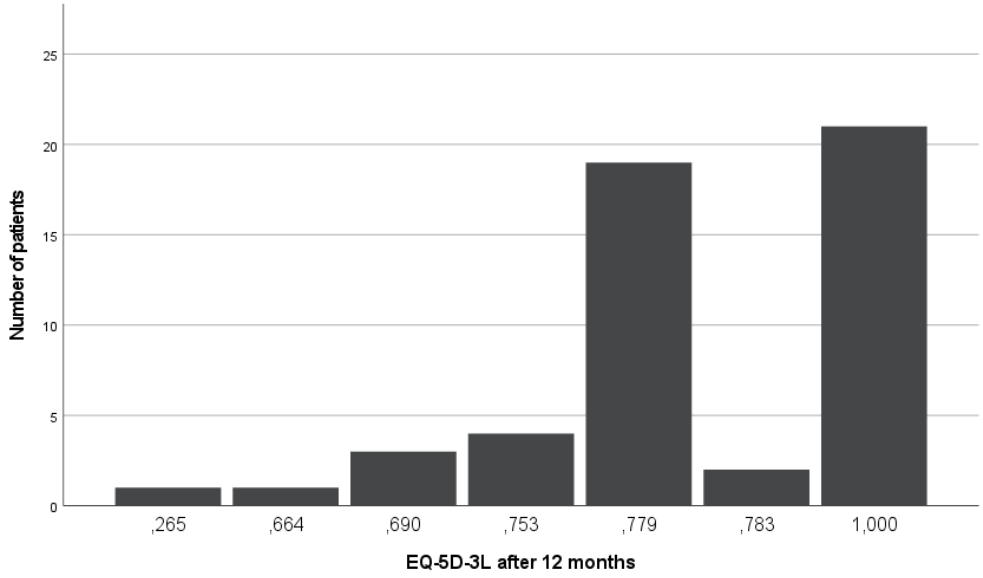
FJS-12 after 12 months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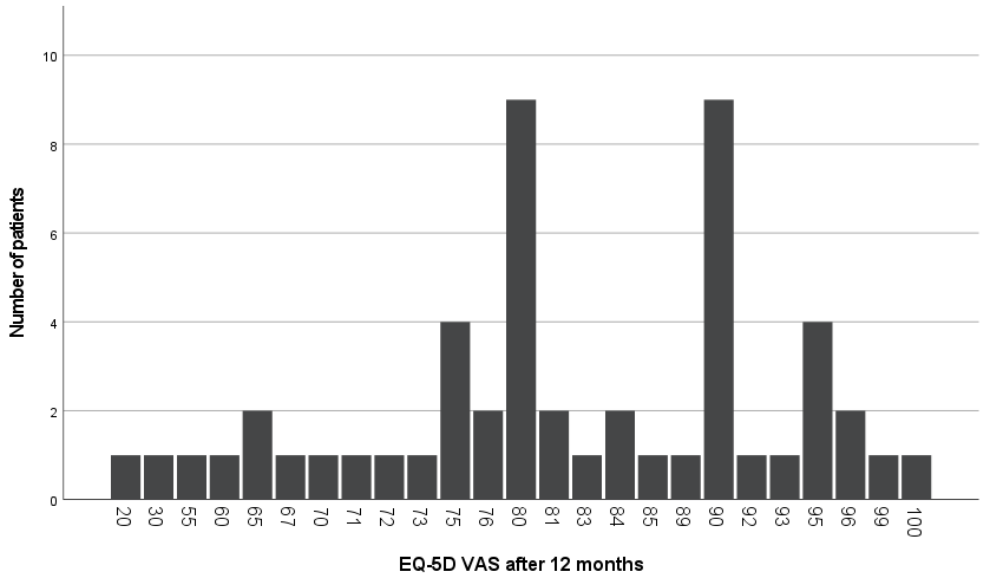
EQ-5D-3L after 12 months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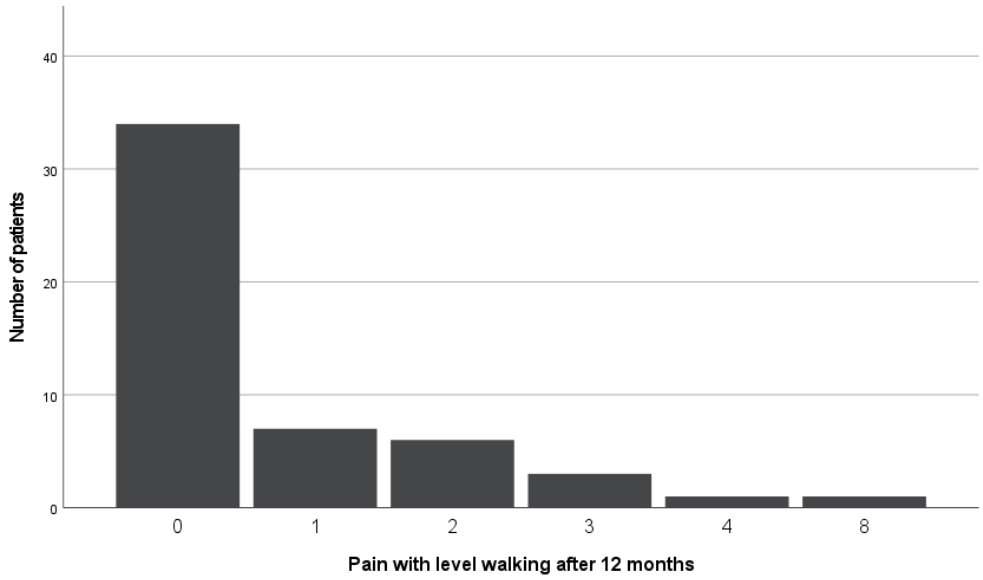
99
100
EQ-5D VAS after 12 months


Number of patients
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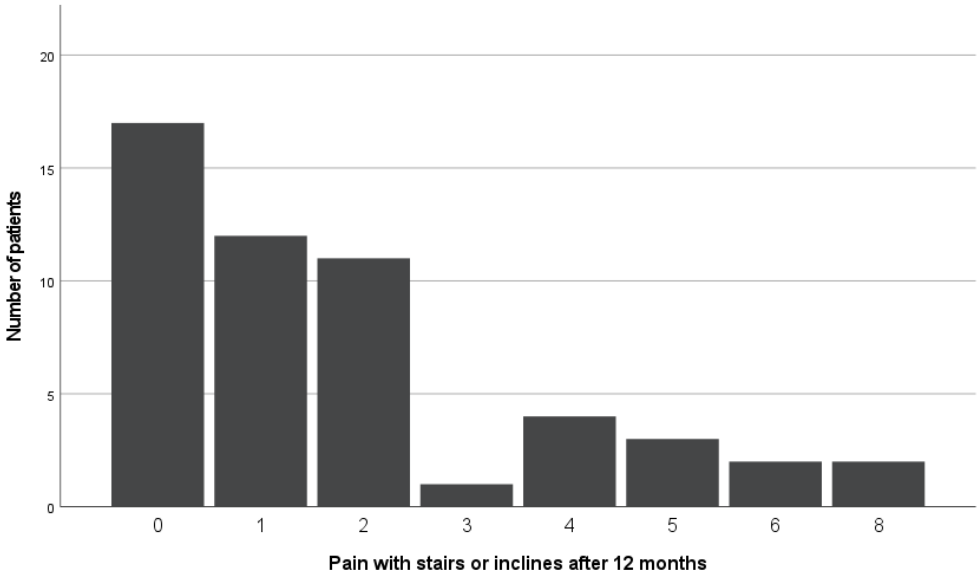
3
4
8
Pain with level walking after 12 months


Number of patients
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10
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2
3
4
5
6
8
Pain with stairs or inclines after 12 months

Chapter 5

Satisfaction after total knee arthroplasty: a prospective matched-pair analysis of patients with customised individually made and off-the-shelf implants

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Abstract

Purpose

Customised individually made (CIM) total knee arthroplasty (TKA) was introduced to potentially improve patient satisfaction and other patient-reported outcome measures (PROMs)**.**

Methods

We performed a prospective cohort study with a propensity score matching of 85 CIM and 85 off-the-shelf (OTS) TKA. The follow-up was four months, one year and two years. The primary outcome was patient satisfaction. Secondary outcomes were as follows: overall improvement, willingness to undergo the surgery again, Knee injury and Osteoarthritis Outcome Score (KOOS), Forgotten Joint Score (FJS-12), High Activity Arthroplasty Score (HAAS), EQ-5D-3L, EQ-VAS, Knee Society Score (KSS) and surgeon satisfaction.

Results

Patient satisfaction ranged from 86% to 90% and did not differ between CIM and OTS TKA. The EQ-VAS after four months and the HAAS after one year and two years were higher for CIM TKA. KOOS, FJS-12 and EQ-5D-3L were not different at follow-up. The changes in KOOS symptoms, pain and daily living were higher for OTS TKA. The KSS was higher for patients with CIM TKA. Surgeon satisfaction was high and not different between both groups.

Patients who were satisfied after two years were preoperatively not different from not satisfied patients. Postoperatively, all PROMs were better for satisfied patients. Patient satisfaction was not correlated to patients' characteristics, implant or preoperative PROMs and medium to strong correlated with postoperative PROMs.

Conclusion

Patient satisfaction was high with no differences between patients with CIM and OTS TKA. Both implant systems improved subjective and objective function, pain and health-related quality of life. Regarding demanding activities patients with CIM TKA showed superior results.

Keywords

Total knee arthroplasty, custom, patient-specific, patient-reported outcome measure, patient satisfaction, matched-pair analysis

Level of evidence

II, prospective cohort-study

Introduction

To reach a high percentage of satisfied patients after a total knee arthroplasty (TKA) is still challenging. Despite the success of TKA in patients with end stage osteoarthritis, about 20% of patients remain not satisfied after a TKA [26,91,208]. Multiple influencing factors and predictors were found [8,55,68,92,124,158,178], whereby persistent pain and limited function are the two leading reasons for patient dissatisfaction [73]. To better understand the patients' perspective, the analysis of patient-reported outcome measures (PROMs), with patient satisfaction in particular, is inevitable. From a patient-centred point of view a TKA is only successful if the patient is satisfied with the result.

Customised individually made (CIM) TKAs have been introduced in 2011 as an alternative for patients undergoing TKA [39]. CIM implants are manufactured based on a computed tomography scan of the affected leg. The underlying concept is to respect the anatomical variability and to restore the individual anatomy and consequently to improve knee kinematics. Off-the-shelf (OTS) TKAs can cause implant overhang, malalignment and abnormal kinematics [25,113,118,182]. CIM TKAs were designed to overcome these limitations and to improve clinical outcome and patient satisfaction. The high variability in morphology supports the evolution towards CIM TKA to potentially achieve better bone-implant fit [19,20].

Studies have shown encouraging results of CIM TKA regarding knee alignment [5,220], improved function [189] and patient satisfaction [163,174]. Recent systematic reviews found conflicting evidence with superior and inferior results for CIM TKA [136,138,210]. However, they highlighted the need for better methodological studies.

A prospective study about CIM TKA with matched-pair control group focussing on patient satisfaction or other PROMs is currently not published. Thus, the purpose of this study was to compare PROMs, especially patient satisfaction, of patients with CIM and OTS TKA in a matched-pair analysis with a follow-up of two years.

Materials and methods

Study design, setting and recruitment

This is a single-side, observational, prospective cohort study with matched-pair analyses comparing patients with CIM and OTS TKA. The study was conducted in accordance with the World Medical Association Declaration of Helsinki [219] and approved by the local ethics committee (reference: 2016-01777).

Patients were recruited in our medical practice. Routinely, all of our TKA patients were asked to complete a set of PROMs. Details regarding recruitment and procedures are published elsewhere [213]. In the current study we included consecutive patients with a primary cruciate-retaining CIM TKA (iTotal® CR G2, Conformis Inc., Billerica, MA, US) or primary cruciate-retaining OTS TKA (Attune® CR mobile-bearing, DePuy Synthes, Raynham, MA, US) who completed PROMs before the surgery and after two years. Patients with major re-operation or revision were excluded. All patients gave their written informed consent for the study participation.

Implants and surgery technique

The CIM TKA implant is based on a preoperative computed tomography. The surgeon is then provided with an individualised implant and individualised instruments. The concept and surgical technique are described elsewhere [190]. The planning algorithm of CIM TKAs results in a hip-knee-ankle angle of 180° and a limited joint line obliquity provided by uneven medial and lateral inlay heights.

The Attune implant applied in the control group is the most commonly used OTS implant in Switzerland [186]. All TKAs were performed between January 2017 and December 2020 by three well experienced senior surgeons (MPA, TR and RK). All patients underwent the identical peri- and postoperative anaesthesia and pain management protocol. A medial parapatellar approach without tourniquet was used for all surgeries. The same postoperative rehabilitation protocol was applied for all patients and included immediate full weight-bearing on crutches until sufficient muscular stabilisation was gained.

Data collection

We collected data during routine visits before the surgery, after four months, one year and two years using Research Electronic Data Capture (REDCap®). Table 1 provides a detailed overview about measures and data collection. Patients' characteristics were extracted from the medical records. Osteoarthritis was classified according to Kellgren and Lawrence (KL) grade from 0 (no osteoarthritis) to 4 (severe osteoarthritis) [103] and comorbidities according the American Society of Anesthesiologists (ASA) from ASA I (normal healthy) to ASA V (moribund) [6].

The primary outcome was patient satisfaction on a five-point Likert scale. Patients were summarised as satisfied (patients who answered “very satisfied” or “satisfied”) and not satisfied (patients who answered “neutral”, “unsatisfied” or “very unsatisfied”). Secondary

outcomes were all other PROMs: overall improvement (patients who answered “very much better” or “substantially better” were classified as improved and all other patients as not improved), the willingness to undergo the surgery again, the Knee injury and Osteoarthritis Outcome Score (KOOS), the Forgotten Joint Score (FJS-12), the High Activity Arthroplasty Score (HAAS), and the EQ-5D-3L for health-related quality of life including a visual analogue scale (VAS).

Table 1: Measures and data collection

Measure and scale	Data collection			
	Before	4 months	1 year	2 years
PROM				
Patient satisfaction, 5-point Likert scale very satisfied, satisfied, neutral, unsatisfied, very unsatisfied		x	x	x
Overall improvement, 7-point Likert scale very much better, substantially better, a little better, no change, a little worse, substantially worse, very much worse			x	x
Surgery again Yes, no			x	x
KOOS [171] pain, symptoms, daily living, sports, quality of life 0 (worst) to 100 (best) points	x	x	x	x
FJS-12 [202], ability to forget the artificial joint in everyday life 0 (worst) to 100 (best) points	x	x	x	x
HAAS [212], high-intensity activities 0 (worst) to 18 (best) points		x	x	x
EQ-5D-3L [53], health-related quality of life 0 (worst) to 1 (best)	x	x	x	x
EQ-VAS [53], health-related quality of life 0 (worst) to 100 (best)	x	x	x	x
Surgeon reported				
KSS-Knee [179], objective knee function 0 (worst) to 100 (best) points	x	x	x	
Surgeon satisfaction, 5-point Likert scale very satisfied, satisfied, neutral, unsatisfied, very unsatisfied		x	x	

PROM: patient-reported outcome measure, KOOS: Knee injury and Osteoarthritis Outcome Score, FJS-12: Forgotten Joint Score, HAAS: High-Activity Arthroplasty Score, VAS: Visual Analogue Scale, KSS: Knee Society Score

Additionally, surgeons completed the objective part of the Knee Society Score (KSS), also known as KSS-Knee, and rated their satisfaction with the surgery. Similarly to patient satisfaction “very satisfied” and “satisfied” were summarised as satisfied. The KSS was not available after two years, because it required a follow-up visit, which was not routine for all patients.

Postoperative complications a like thromboembolic event, infection, re-operation, revision or decease were recorded as adverse events. Revision was defined as a re-operation to replace some or all parts of the original TKA.

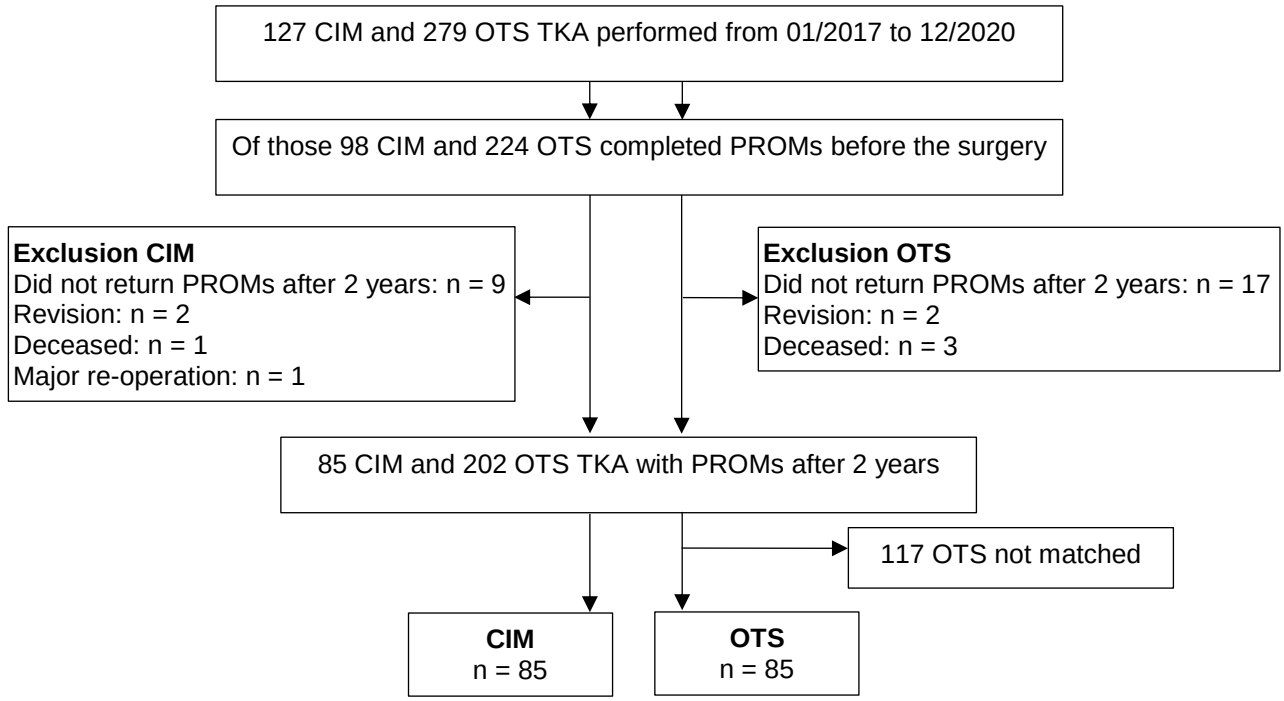
Sample size and matching

The a priori power calculation was based on a calculated effect size of 0.5 and resulted in a sample size of 85 TKAs per group to assure a power of 0.9 with a two-sided alpha of 0.05. To reduce the bias resulting from a non-randomised study design and to eliminate differences in patients' characteristics, we performed a propensity score matching based on the variables age, body mass index (BMI), sex, KL grade and ASA score. From 287 TKA with PROMs after two years available, we matched 85 CIM to 85 OTS TKA (Figure 1).

Statistics

Descriptive statistics comprise mean and standard deviation (SD) for continuous variables, frequency count and percentage for categorical variables. Differences between pre- and postoperative data were tested with paired t-test. Differences between groups were measured with unpaired t-test for continuous variables and with Mann-Whitney U test or Chi-Square test for categorical variables. Bivariate linear correlations were analysed with the Spearman test, whereby effect sizes were interpreted as low ($r \approx 0.1$), medium ($r \approx 0.3$) or strong ($r \approx 0.5$) [37]. For statistical analyses we used IBM SPSS statistics for Windows, Version 29, Armonk, NY: IBM Corp and R, Version 4.1.3 [160]. Matching was performed with the MatchIt package in R, Version 4.5.3.

Figure 1: Flow chart of recruitment



CIM: customised individually made, OTS: off-the-shelf, TKA: total knee arthroplasty, PROMs: patient-reported outcome measures, n: number of patients

Results

Recruitment and baseline measures

We analysed matched-pair data of 85 CIM TKA (70 patients, 34 women) and 85 OTS TKA (78 patients, 33 women). Details to recruitment are described in Figure 1 and patients' characteristics in Table 2. Patients with CIM TKA had more often a supplementary insurance which is required in Switzerland to cover costs for a CIM TKA. Patients with CIM TKA had more often a staged bilateral surgery and at baseline higher PROMs and a lower KSS (Table 2).

Postoperative measures

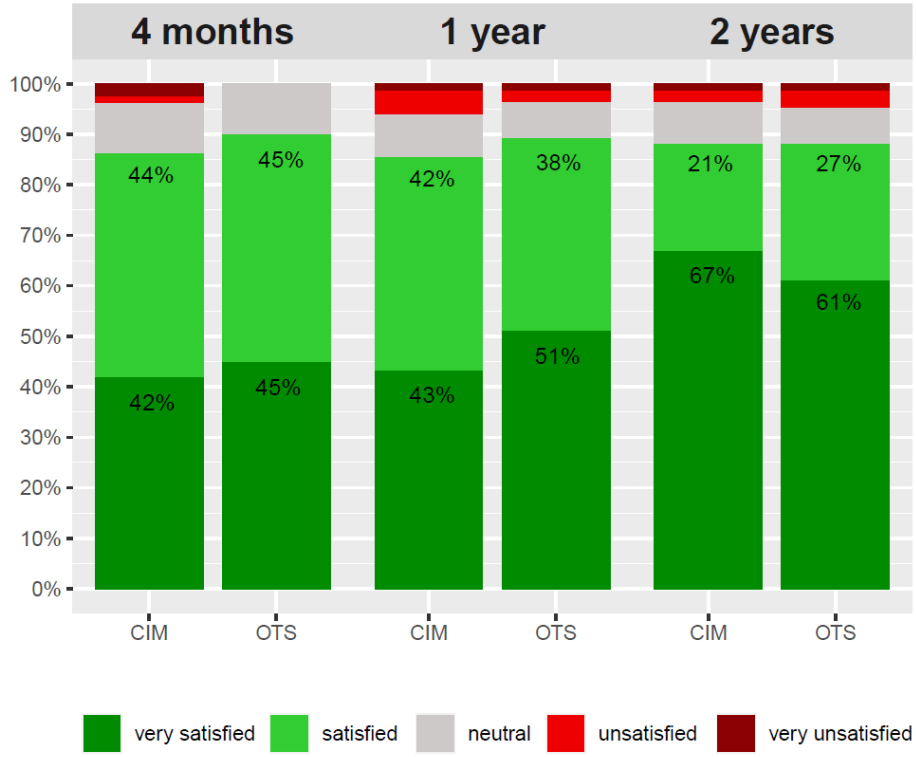
PROMs

Patient satisfaction ranged from 86% to 90% and did not differ between CIM and OTS TKA (Table 3 and Figure 2). Eight patients (5%) were not satisfied after one year but satisfied after two years and 7 patients (4%) were satisfied after one year but not satisfied after two years. All other patients (91%) did not change regarding patient satisfaction. Almost all

patients reported an overall improvement and would undergo the surgery again (Table 3). All other PROMs improved for all patients from baseline to each follow-up (four months, one year and two years), as well as from four months to one year and from one year to two years ($p < .001$, respectively). Sole exception was the EQ-VAS with a mean change of -0.7 points from one year to two years ($p = .218$).

When patients with CIM and OTS TKA compared, the EQ-VAS after four months and the HAAS after one year and two years were clearly higher for patients with CIM TKA (Table 3, Figure 3). All other PROMs were not different in their end scores. Change scores of PROMs were higher for patients with OTS TKA from baseline to any follow-up with clearly higher values for KOOS symptoms, pain and daily living (Table 5, additional material).

Figure 2: Patient satisfaction at follow-up



CIM: customised individually made, OTS: off-the-shelf

KSS and surgeon satisfaction

The KSS improved for all patients from baseline to four months and from baseline to one year ($p < .001$, respectively). The KSS end and change scores were higher for patients with CIM TKA ($p < .001$, Table 3 and additional material: Table 5). Surgeon satisfaction ranged from 91% to 96% and did not differ between CIM and OTS TKA (Table 3). The correlation between patient and surgeon satisfaction was strong (four months: $r = .418$, $p < .001$; one year: $r = .483$, $p < .001$).

Satisfied compared to not satisfied patients

Patients who were satisfied after two years did not differ at baseline from patients who were not satisfied (Table 4). At each follow-up, all PROMs and the KSS were higher for patients who were satisfied after two years (Table 4 and Figure 4). Likewise, the change scores for all PROMs and the KSS were higher for satisfied patients (additional material: Table 6).

Patient satisfaction was at no follow-up correlated with patients' characteristics (age, BMI, sex, insurance, side, bilateral surgery, KL grade, ASA), implant or baseline measures. The correlation between patient satisfaction and measures after one year was medium for HAAS ($r = .365$, $p < .001$) and strong for KOOS, FJS-12, EQ-5D-3L, EQ-VAS and KSS ($r > .411$, $p < .001$). The correlation between patient satisfaction and measures after two years was medium for HAAS ($r = .356$, $p < .001$) and EQ-VAS ($r = .333$, $p < .001$) and strong for KOOS, FJS-12, EQ-5D-3L ($r > .432$, $p < .001$).

Adverse Events

By the time of the last follow-up, one patient with CIM TKA and three patients with OTS TKA deceased. Four revisions occurred: two CIM TKA after 17 and 26 months and two OTS TKS after eight and nine months, respectively. The revision rate was 2.4% in both groups. One patient with CIM TKA needed a major re-operation due to a quadriceps rupture after 19 months. These patients were excluded from the analysis (Figure 1).

From those patients included in the matched-pair analysis, three patients with CIM TKA and one patient with OTS TKA had an adverse event. Two patients, one with CIM and one with OTS TKA, needed a diagnostic arthroscopy to exclude an infection (both negative) and two patients with CIM TKA needed an arthrolysis.

Table 2: Patients' characteristics and baseline measures.

	CIM n = 85	OTS n = 85	Difference	
	mean (±SD)	mean (±SD)	P value	[95% CI]
Patients' characteristics				
Age, years	66.7 (±8.6)	66.3 (±9.1)	.792	[-2.3 to 3.0]
BMI, kg/m^2	26.4 (±3.2)	26.7 (±3.9)	.617	[-1.4 to 0.8]
Sex, n (%)			.756	
Women	37 (44%)	34 (40%)		
Men	48 (56%)	51 (60%)		
Insurance, n (%)			< .001	
Basic	5 (6%)	57 (67%)		
Supplementary	80 (94%)	28 (33%)		
Side, n (%)			.575	
Left	36 (42%)	39 (46%)		
Right	49 (58%)	46 (54%)		
Surgery, n (%)			.008	
Unilateral	55 (65%)	71 (84%)		
Bilateral	30 (35%)	14 (16%)		
KL grade, n (%)			0.857	
2		1 (1%)		
3	19 (22%)	20 (24%)		
4	66 (78%)	64 (75%)		
ASA Classification, n (%)			0.494	
I/II	76 (89%)	72 (85%)		
III	9 (11%)	13 (15%)		
Length of stay, days	6.1 (±1.2)	6.3 (±1.1)	.375	[-0.5 to 0.2]
Baseline measures				
KOOS symptoms	51.5 (±17.1)	47.0 (±20.2)	.123	[-1.2 to 10.1]
KOOS pain	50.2 (±16.2)	43.2 (±15.4)	.004	[2.2 to 11.8]
KOOS daily living	58.2 (±15.6)	51.2 (±18.4)	.009	[1.8 to 12.1]
KOOS sports	24.0 (±16.1)	20.0 (±16.6)	.124	[-1.1 to 9.1]
KOOS quality of life	26.8 (±12.9)	25.1 (±14.3)	.421	[-2.4 to 5.8]
FJS-12	18.0 (±12.3)	15.4 (±13.3)	.203	[-1.4 to 6.5]
HAAS (not administered)	-	-		
EQ-5D-3L	0.65 (±0.16)	0.62 (±0.18)	.269	[-0.02 to 0.08]
EQ-VAS	65.5 (±21.8)	60.0 (±22.2)	.115	[-1.3 to 12.2]
KSS	53.1 (±11.4)	58.0 (±13.3)	.010	[-8.7 to -1.2]

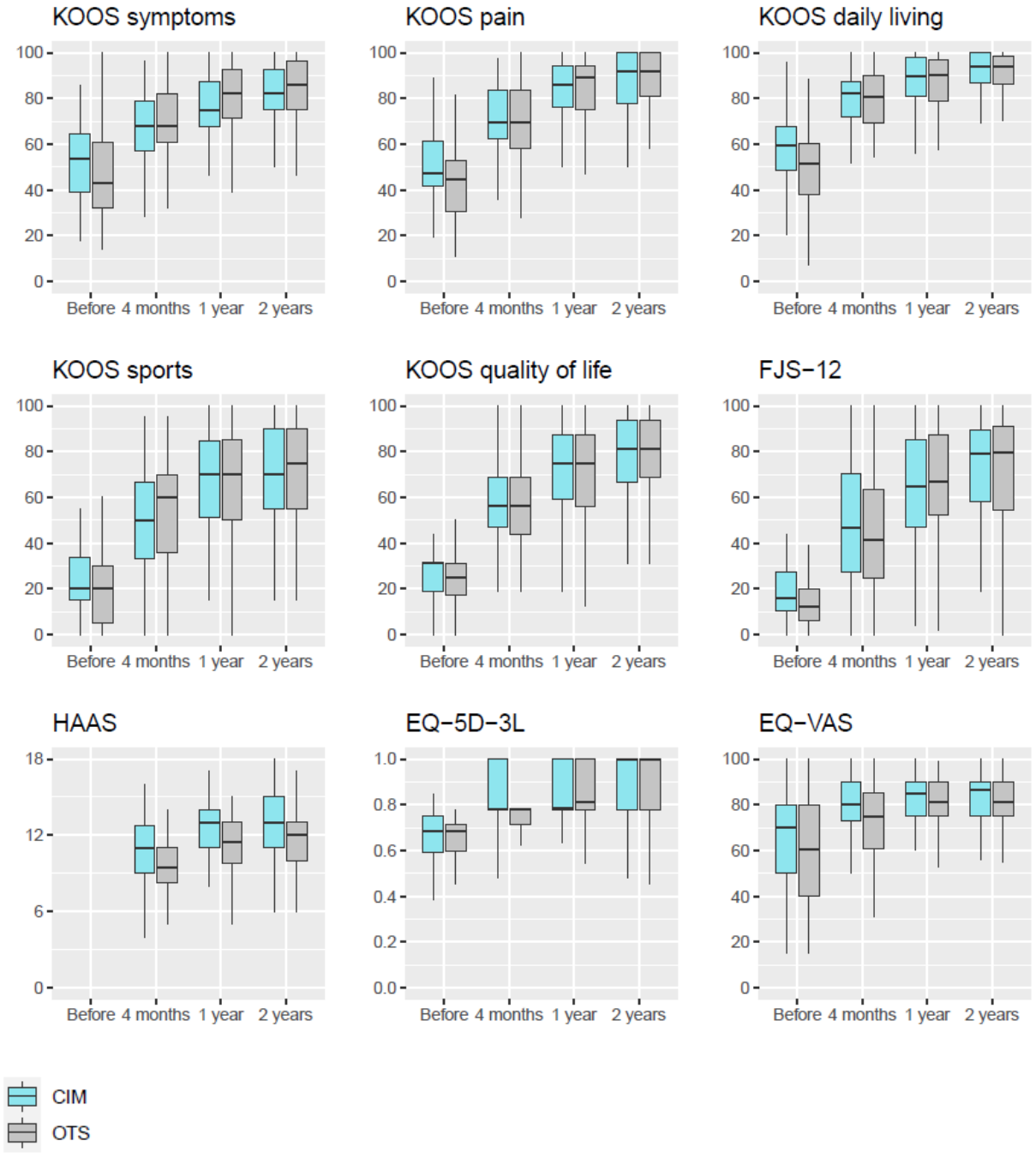
CIM: customised individually made, OTS: off-the-shelf, n: number of patients, SD: standard deviation, BMI: body mass index, KL: Kellgren and Lawrence grade of osteoarthritis, ASA: American Society of Anesthesiologists, KOOS: Knee injury and Osteoarthritis Outcome Score, FJS-12: Forgotten Joint Score, HAAS: High-Activity Arthroplasty Score, VAS: Visual Analogue Scale, KSS: Knee Society Score

Table 3: Postoperative outcome measures of patients with CIM and OTS TKA.

	CIM n = 85		OTS n = 85		Difference	
	mean	(±SD)	mean	(±SD)	P value	[95% CI]
4 months						
Satisfied patient, n (%)	70	(86%)	72	(90%)	.725	
KOOS symptoms	67.3	(±16.1)	68.4	(±16.4)	.676	[-3.9 to 6.0]
KOOS pain	70.8	(±16.1)	70.4	(±16.9)	.894	[-5.4 to 4.7]
KOOS daily living	78.7	(±14.1)	78.7	(±14.5)	.997	[-4.3 to 4.3]
KOOS sports	48.9	(±23.7)	53.8	(±23.0)	.208	[-2.8 to 12.7]
KOOS quality of life	56.2	(±20.4)	57.1	(±20.3)	.763	[-5.3 to 7.2]
FJS-12	47.6	(±25.7)	44.8	(±25.8)	.481	[-10.8 to 5.1]
HAAS	10.4	(±2.8)	9.8	(±2.3)	.288	[-1.6 to 0.5]
EQ-5D-3L	0.83	(±0.15)	0.79	(±0.15	.105	[-0.08 to 0.01]
EQ-VAS	79.7	(±13.1)	72.1	(±18.19	.003	[-12.5 to -2.7]
KSS	90.9	(±6.6)	85.0	(±8.9)	< .001	[-8.3 to -3.5]
Satisfied surgeon, n (%)	75	(91%)	76	(92%)	.753	
1 year						
Satisfied patient, n (%)	71	(86%)	75	(89%)	.844	
Improved patient, n (%)	63	(83%)	64	(88%)	.643	
Surgery again, n (%)	70	(92%)	69	(96%)	.496	
KOOS symptoms	75.3	(±17.0)	80.4	(±15.5)	.043	[0.2 to 10.1]
KOOS pain	81.9	(±16.6)	83.9	(±15.2)	.420	[-2.9 to 6.8]
KOOS daily living	86.3	(±13.7)	86.1	(±14.4)	.939	[-4.5 to 4.1]
KOOS sports	66.0	(±21.5)	64.9	(±24.7)	.758	[-8.5 to 6.2]
KOOS quality of life	69.8	(±21.4)	71.3	(±21.8)	.654	[-5.1 to 8.1]
FJS-12	65.0	(±25.5)	65.4	(±26.4)	.913	[-7.5 to 8.4]
HAAS	12.3	(±2.6)	11.2	(±2.4)	.016	[-2.0 to -0.2]
EQ-5D-3L	0.87	(±0.14)	0.87	(±0.13)	.562	[-0.03 to 0.05]
EQ-VAS	81.4	(±14.7)	80.2	(±13.5)	.606	[-5.5 to 3.1]
KSS	94.6	(±6.1)	89.0	(±8.0)	< .001	[-8.0 to -3.4]
Satisfied surgeon, n (%)	75	(96%)	70	(92%)	.382	
2 years						
Satisfied patient, n (%)	75	(88%)	75	(88%)	.883	
Improved patient, n (%)	78	(92%)	76	(89%)	.890	
Surgery again, n (%)	75	(90%)	77	(96%)	.211	
KOOS symptoms	80.8	(±14.8)	83.4	(±16.6)	.293	[-2.2 to 7.3]
KOOS pain	87.1	(±14.7)	86.2	(±17.5)	.720	[-5.8 to 4.0]
KOOS daily living	90.6	(±12.3)	89.1	(±14.5)	.463	[-5.6 to 2.6]
KOOS sports	69.9	(±21.6)	72.0	(±22.5)	.563	[-5.0 to 9.1]
KOOS quality of life	76.2	(±21.2)	76.3	(±22.5)	.991	[-6.6 to 6.7]
FJS-12	72.7	(±23.5)	70.8	(±26.6)	.621	[-9.5 to 5.7]
HAAS	12.9	(±2.6)	11.7	(±2.6)	.004	[-2.0 to -0.4]
EQ-5D-3L	0.93	(±0.12)	0.91	(±0.13)	.254	[-0.06 to 0.02]
EQ-VAS	81.5	(±15.7)	79.9	(±14.8)	.487	[-6.3 to 3.0]

CIM: customised individually made, OTS: off-the-shelf, n: number of patients, SD: standard deviation, CI: confidence interval, KOOS: Knee injury and Osteoarthritis Outcome Score, FJS-12: Forgotten Joint Score, HAAS: High-Activity Arthroplasty Score, VAS: Visual Analogue Scale, KSS: Knee Society Score

Figure 3: Boxplots of PROMs for CIM and OTS TKA.



CIM: customised individually made, OTS: off-the-shelf, KOOS: Knee injury and Osteoarthritis Outcome Score, FJS-12: Forgotten Joint Score, HAAS: High-Activity Arthroplasty Score, VAS: Visual Analogue Scale

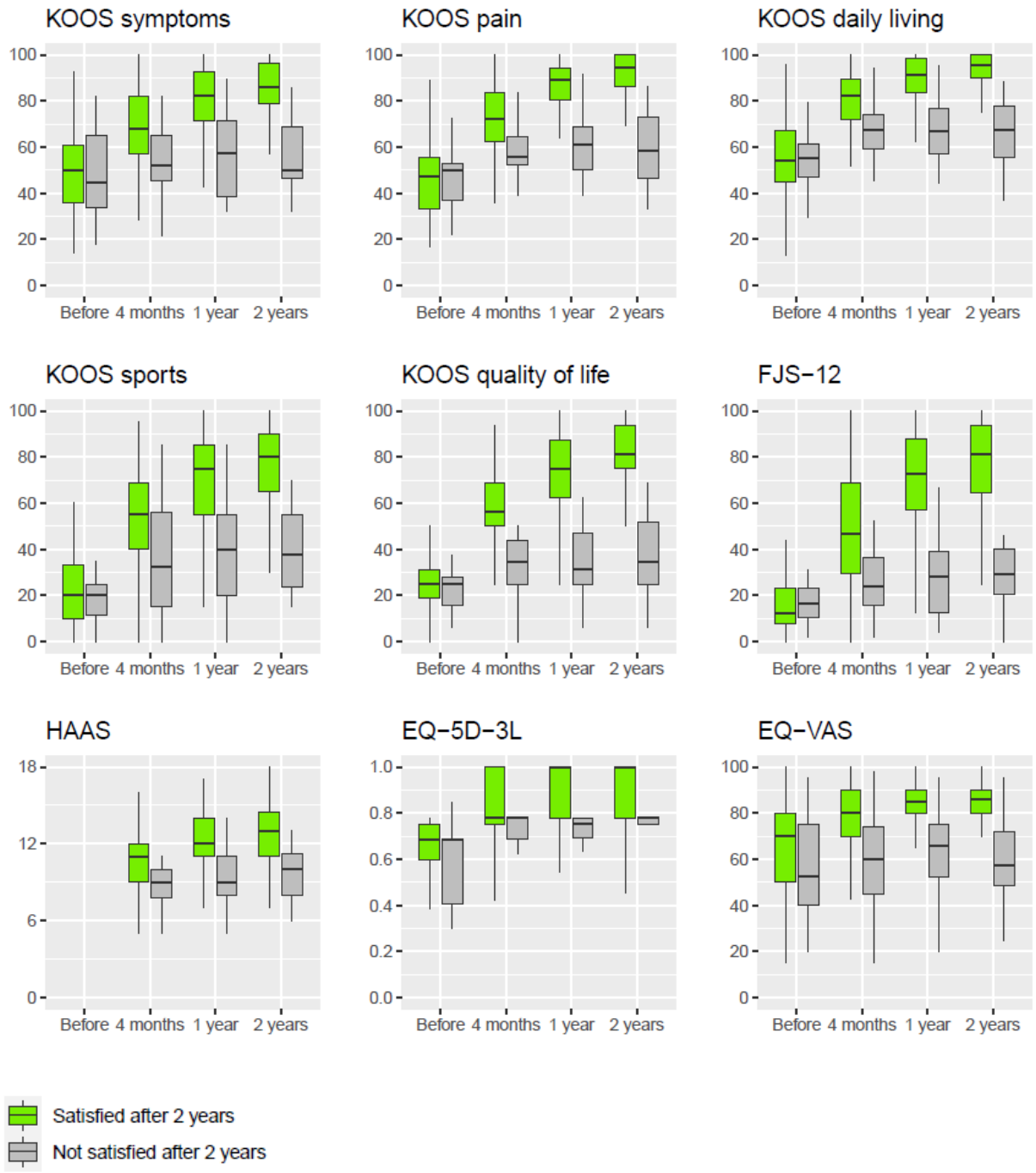
Table 4: Comparison of satisfied and not satisfied patients at two years follow-up.

	Baseline			4 months			1 year			2 years		
	Satisfied at 2 years n = 150	Not satisfied at 2 years n = 20		Satisfied at 2 years n = 150	Not satisfied at 2 years n = 20		Satisfied at 2 years n = 150	Not satisfied at 2 years n = 20		Satisfied at 2 years n = 150	Not satisfied at 2 years n = 20	
	mean (±SD)	mean (±SD)	P	mean (±SD)	mean (±SD)	P	mean (±SD)	mean (±SD)	P	mean (±SD)	mean (±SD)	P
Patients' characteristics												
Age, years	66.3 (±8.7)	67.6 (±10.3)	.564									
BMI, kg/m^2	26.5 (±3.6)	26.8 (±3.5)	.771									
Women, n (%)	61 (41%)	10 (50%)	.474									
Basic insurance, n (%)	56 (37%)	6 (30%)	.625									
Unilateral TKA, n (%)	110 (73%)	16 (80%)	.600									
CIM TKA, n (%)	75 (50%)	10 (55%)	1.000									
KL grade 4, n (%)	116 (77%)	14 (70%)	.480									
ASA I/II, n (%)	132 (88%)	16 (80%)	.318									
Length of stay, days	6.2 (±1.1)	6.6 (±1.3)	.148									
Measures												
Satisfied patient, n (%)	-	-		131 (92%)	11 (58%)	.001	139 (95%)	7 (35%)	< .001			
Improved patient, n (%)	-	-		-	-		120 (93%)	7 (35%)	< .001	148 (99%)	6 (30%)	< .001
Surgery again, n (%)	-	-		-	-		126 (98%)	13 (68%)	< .001	144 (99%)	8 (44%)	< .001
KOOS symptoms	49.4 (±18.6)	48.2 (±20.8)	.792	69.8 (±15.2)	53.2 (±16.2)	< .001	80.7 (±14.0)	57.0 (±18.1)	< .001	85.6 (±11.8)	55.7 (±16.4)	< .001
KOOS pain	46.7 (±16.0)	47.0 (±17.3)	.945	72.2 (±15.8)	58.9 (±16.6)	< .001	85.9 (±13.6)	60.8 (±14.2)	< .001	90.3 (±12.3)	59.7 (±15.5)	< .001
KOOS daily living	54.8 (±17.1)	53.9 (±19.5)	.836	80.4 (±12.9)	65.9 (±17.2)	< .001	88.8 (±11.6)	67.0 (±15.5)	< .001	93.1 (±9.1)	65.7 (±15.8)	< .001
KOOS sports	22.0 (±16.2)	21.9 (±18.7)	.984	53.8 (±22.0)	33.7 (±25.9)	< .001	69.4 (±20.3)	38.7 (±22.8)	< .001	75.7 (±18.2)	38.6 (±18.3)	< .001
KOOS quality of life	26.1 (±13.5)	24.7 (±14.7)	.682	59.2 (±19.0)	38.1 (±20.6)	< .001	75.1 (±17.7)	37.5 (±18.2)	< .001	81.6 (±16.2)	36.6 (±16.5)	< .001
FJS-12	16.5 (±12.5)	18.5 (±15.4)	.591	48.8 (±25.4)	28.0 (±20.5)	< .001	70.1 (±22.6)	29.1 (±19.1)	< .001	77.4 (±20)	29.9 (±18)	< .001
HAAS*	-	-		10.3 (±2.6)	8.6 (1.9)	.028	12.2 (±2.3)	9.2 (±2.5)	< .001	12.7 (±2.5)	9.9 (±2.3)	< .001
EQ-5D-3L	0.64 (±0.17)	0.59 (±0.16)	.242	0.82 (±0.15)	0.75 (±0.16)	.077	0.89 (±0.12)	0.75 (±0.16)	< .001	0.94 (±0.11)	0.78 (±0.13)	< .001
EQ-VAS	63.6 (±22.0)	56.3 (±22.3)	.206	78.4 (±13.6)	57.1 (±21.4)	< .001	83.0 (±11.8)	64.1 (±18.0)	< .001	83.8 (±11.8)	58.1 (±18.7)	< .001
KSS*	55.2 (±12.7)	58.2 (±11.3)	.332	88.4 (±8.5)	84.7 (±6.5)	.061	92.8 (±7.2)	84.4 (±6.5)	< .001	-	-	
Satisfied surgeon, n (%)	-	-		135 (93%)	16 (80%)	.120	131 (98%)	14 (70%)	< .001	-	-	

n: number of patients, SD: standard deviation, BMI: body mass index, TKA: total knee arthroplasty, CIM: customised individually made, KL: Kellgren and Lawrence grade of osteoarthritis, ASA: American Society of Anesthesiologists score for comorbidity, KOOS: Knee injury and Osteoarthritis Outcome Score, FJS-12: Forgotten Joint Score, HAAS: High-Activity Arthroplasty Score, VAS: Visual Analogue Scale, KSS: Knee Society Score

** HAAS not administered preop, KSS not administered at 24mo FU*

Figure 4: Boxplots of PROMs for satisfied and not satisfied patients after two years.



KOOS: Knee injury and Osteoarthritis Outcome Score, FJS-12: Forgotten Joint Score, HAAS: High-Activity Arthroplasty Score, VAS: Visual Analogue Scale

Discussion

The most important finding was, that patient satisfaction after two years was high and not different between patients with CIM and OTS TKA. Preoperative, patients with a CIM TKA tend to have less subjective impairment and presented with higher PROMs. Postoperative, patients with CIM TKA had a higher EQ-VAS after four months and a higher HAAS after one year and two years. All other PROMs were not different regarding the end scores between CIM and OTS TKA. The level of overall change of the scores were higher for OTS TKA, especially for KOOS symptoms, pain and daily living.

The objective KSS was postoperatively higher for CIM TKA. Surgeon satisfaction was not different between CIM and OTS TKA and was strongly correlated to patient satisfaction. Patients that were satisfied after two years were clearly better regarding all PROMs and the KSS compared to patients that were not satisfied after two years.

Our findings regarding patient satisfaction are within the spectrum of current TKA studies or registry reports [8,73,91,198]. The results are also in line with other CIM TKA studies. The largest retrospective study to date included 540 CIM TKA and found a satisfaction rate of 89% after a mean follow-up of 2.8 years (range 0.1 to 7.0) [174]. The authors reported a KOOS for Joint Replacement (KOOS-JR) of 82 points and a revision rate of 1.5%. The only study with a long-term follow-up so far, found very good and stable results over five years [189]. Patient satisfaction was not analysed, but they found a mean KSS of 92 points, a mean WOMAC of 11 points and a revision rate 1.4% after five years. A study with posterior-stabilised CIM TKA (iTotal® PS, Conformis Inc., Billerica, MA, US) reported a high satisfaction rate of 90% for 100 CIM TKA after a mean follow-up of 1.9 years (range 1.5 to 2.4) [141].

Comparative CIM TKA studies are still sparse. Our own group found no differences after one year in an unmatched comparison of 74 CIM and 169 OTS TKA [214]. The satisfaction rate was similar to the present study (CIM 87%, OTS 89%). Others found superior clinical results and higher fulfilment of expectations for patients with CIM TKA after one year, although in a small sample of 33 CIM and 31 OTS TKA [228]. Another study examined PROMs of 47 CIM and 47 OTS TKA in the same patient undergoing staged bilateral surgery. After a mean follow-up of 2.3 years (range 0.7 to 3.8) they found better values for CIM TKA regarding KOOS-JR, FJS-12, pain, mobility, stability and normal feeling of the knee. In summary, 72% of the patients preferred the CIM TKA, 21% saw no difference and 6% preferred the OTS TKA [173].

We found a strong correlation between patient satisfaction and PROMs at follow-up, which is in accordance with other studies [8,227]. In contrast to others we found no correlation between dissatisfaction and younger age [8 55,178], higher BMI [8,158], female sex [158] or low preoperative PROMs [8].

The majority of improvement in all PROMs and the KSS occurred quite early, within the first four months. Until the four months follow-up, we found an obvious difference in all measures for patients that were later satisfied or not satisfied. Others also reported early different satisfaction profiles already after six weeks [227] or after three months [62]. PROMs could support the early identification of unsatisfied patients and enable clinicians to apply timely targeted intervention to improve patient outcomes [227]. Nevertheless, all measures in our study improved considerably until the two years follow-up. But the proportion of patients who moved from being satisfied after one year to being not satisfied after two years, and vice versa, was rather small (9%). Others as well found no changes in patient satisfaction from six months to two years [227] or only rare changes from one year to three years [60].

Since 2018, another CIM TKA system is available, the Symbios Origin® implant (Symbios, Yverdon-les-Bains, Switzerland) [193]. After promising first results [135], a large improvement in the KSS was recently shown with a mean KSS of 94 points after one year [161]. Another study published a high satisfaction rate of 94% after a mean follow-up of 2.8 years [67]. KOOS and FJS-12 results of this study were similar or slightly lower compared to our results after two years. Others found satisfactory early clinical and radiographic outcomes for this CIM TKA in patients with prior osteotomies or extra-articular fracture sequelae [44].

The strength of our study is the prospective matched-pair design that was not published for CIM TKA yet. We applied a profound set of PROMs and analysed the data at multiple follow-ups while having a reasonable number of drop outs. Nevertheless, our study has some limitations. First, although the data was prospectively collected, a selection bias is possible due to the lack of randomisation. On the other hand, one has to realise that patients in a private clinic setting would not accept this scientifically interesting randomisation. For practical reasons this bias is therefore unavoidable.

To limit the bias and to assure a certain degree of homogeneity, we performed a propensity score matching. The follow-up of two years is only mid-term. But CIM TKAs are still relatively new and not wide spread. However, for studies with PROMs as

primary outcome, it was shown that a one year follow-up is also adequate as results remain consistent in longer follow-up periods [156,172]. Regarding implant survival, a longer follow-up is preferable. Our two-year revision rate was 2.4% in both groups, which is lower than the reported overall two-year revision rate of 3.5% in the Swiss Implant Registry (iTotal: 2.3%, Attune: 4.2%) [186]. The loss to follow-up of patients who did not return their PROMs questionnaire amounted to 9% after two years. Despite constant efforts, including mail or e-mail reminders and telephone calls, achieving a high PROMs response rate on multiple time points has proven to be challenging [159].

Conclusions

In this matched-pair analyses, we found a high patient satisfaction after one year and after two years, which did not differ between patients with CIM and OTS TKA. The HAAS, which is designed to capture improvements in activities reaching recreational sports levels, was superior for patients with CIM TKA. All other PROMs were not different. Both implant systems apparently improved subjective and objective function, pain as well as health-related quality of life.

Appendix

Additional material

Table 5: Changes of outcome measures for CIM and OTS TKA.

	CIM n = 85		OTS n = 85		Difference	
	mean	(±SD)	mean	(±SD)	P value	[95% CI]
Changes from baseline to 4 months						
KOOS symptoms	15.9	(±22.7)	21.1	(±23.9)	.149	[-12.4 to 1.9]
KOOS pain	20.3	(±20.9)	26.9	(±19.4)	.037	[-12.8 to -0.4]
KOOS daily living	20.0	(±20.4)	27.1	(±19.2)	.023	[-13.2 to -1.0]
KOOS sports	24.1	(±28.8)	33.8	(±23.7)	.032	[-18.7 to -0.8]
KOOS quality of life	29.3	(±25.1)	32.2	(±22.2)	.442	[-10.1 to 4.4]
FJS-12	29.6	(±29.4)	29.2	(±24.7)	.941	[-8.2 to 8.8]
EQ-5D-3L	0.17	(±0.19)	0.18	(±0.20)	.838	[-0.07 to 0.05]
EQ-VAS	14.0	(±24.0)	12.1	(±24.5)	.625	[-5.8 to 9.5]
KSS	38.0	(±12.8)	26.6	(±14.0)	< .001	[7.2 to 15.5]
Changes from baseline to 1 year						
KOOS symptoms	24.3	(±23.3)	33.2	(±21.9)	.011	[-15.8 to -2.0]
KOOS pain	31.8	(±21.4)	40.5	(±17.6)	.004	[-14.8 to -2.8]
KOOS daily living	28.2	(±18.7)	34.6	(±19.3)	.031	[-12.3 to -0.6]
KOOS sports	42.1	(±27.2)	45.0	(±24.7)	.497	[-11.4 to 5.6]
KOOS quality of life	42.8	(±24.5)	46.8	(±22.6)	.283	[-11.2 to 3.3]
FJS-12	46.5	(±28.9)	49.8	(±26.5)	.441	[-11.9 to 5.2]
EQ-5D-3L	0.21	(±0.19)	0.26	(±0.17)	.137	[-0.10 to 0.01]
EQ-VAS	16.0	(±24.1)	19.7	(±21.7)	.300	[-11.0 to 3.4]
KSS	41.1	(±13.1)	31.5	(±14.8)	< .001	[5.1 to 14.0]
Changes from baseline to 2 years						
KOOS symptoms	29.3	(±23.2)	36.3	(±20.8)	.042	[-13.7 to -0.3]
KOOS pain	36.9	(±21.4)	42.9	(±18.5)	.053	[-12.1 to 0.1]
KOOS daily living	32.5	(±19.1)	37.5	(±18.9)	.087	[-10.8 to 0.7]
KOOS sports	45.8	(±26.3)	50.5	(±23.7)	.254	[-13.0 to 3.5]
KOOS quality of life	49.4	(±24.1)	52.1	(±22.3)	.461	[-9.7 to 4.4]
FJS-12	54.7	(±28.4)	55.8	(±26.0)	.791	[-9.5 to 7.3]
EQ-5D-3L	0.28	(±0.19)	0.29	(±0.20)	.779	[-0.07 to 0.05]
EQ-VAS	16.3	(±24.8)	19.9	(±23.6)	.341	[-11.1 to 3.9]

CIM: customised individually made, OTS: off-the-shelf, n: number of patients, SD: standard deviation, CI: confidence interval, KOOS: Knee injury and Osteoarthritis Outcome Score, FJS-12: Forgotten Joint Score, VAS: Visual Analogue Scale, KSS: Knee Society Score

Table 6: Changes of outcome measures for satisfied and not satisfied patients after two years.

	Satisfied at 2 years n = 150		Not satisfied at 2 years n = 20		Difference	
	mean	(±SD)	mean	(±SD)	P value	[95% CI]
Changes from baseline to 4 months						
KOOS symptoms	20.3	(±22.4)	5.0	(±26.8)	.006	[4.5 to 26.1]
KOOS pain	25.2	(±19.6)	11.9	(±22.7)	.006	[3.9 to 22.7]
KOOS daily living	25.1	(±19.4)	12.0	(±21.5)	.016	[2.6 to 23.6]
KOOS sports	31.1	(±25.0)	12.7	(±33.6)	.007	[5.0 to 31.8]
KOOS quality of life	33.0	(±22.6)	13.2	(±24.7)	< .001	[7.5 to 32.2]
FJS-12	32.0	(±25.9)	10.1	(±28.9)	< .001	[9.2 to 34.5]
EQ-5D-3L	0.17	(±0.20)	0.18	(±0.18)	.958	[-0.10 to 0.09]
EQ-VAS	14.6	(±22.5)	1.1	(±33.0)	.025	[1.7 to 25.3]
KSS	33.0	(±14.6)	26.6	(±12.5)	.061	[-0.3 to 13.3]
Changes from baseline to 1 year						
KOOS symptoms	31.5	(±21.3)	8.8	(±25.5)	< .001	[12.5 to 33.0]
KOOS pain	39.2	(±18.0)	13.8	(±20.9)	< .001	[16.8 to 34.0]
KOOS daily living	33.9	(±18.2)	13.1	(±16.7)	< .001	[12.3 to 29.3]
KOOS sports	47.4	(±23.3)	18.0	(±28.8)	< .001	[17.6 to 41.0]
KOOS quality of life	48.8	(±20.7)	13.5	(±20.9)	< .001	[25.4 to 45.3]
FJS-12	53.2	(±24.3)	10.1	(±22.3)	< .001	[31.4 to 54.7]
EQ-5D-3L	0.24	(±0.18)	0.16	(±0.19)	.063	[-0.00 to 0.17]
EQ-VAS	19.0	(±21.6)	8.3	(±31.2)	.064	[-0.6 to 21.9]
KSS	37.8	(±14.4)	26.2	(±13.3)	< .001	[4.9 to 18.4]
Changes from baseline to 2 years						
KOOS symptoms	36.2	(±19.6)	7.50	(±24.9)	< .001	[19.2 to 38.2]
KOOS pain	43.6	(±16.8)	12.8	(±22.9)	< .001	[22.5 to 39.1]
KOOS daily living	38.1	(±16.7)	11.8	(±20.2)	< .001	[18.2 to 34.3]
KOOS sports	52.8	(±21.3)	16.9	(±26.1)	< .001	[25.2 to 46.6]
KOOS quality of life	55.6	(±18.4)	12.5	(±21.7)	< .001	[34.1 to 52.1]
FJS-12	60.9	(±21.9)	11.9	(±25.0)	< .001	[38.2 to 59.7]
EQ-5D-3L	0.29	(±0.19)	0.21	(±0.18)	.068	[-0.01 to 0.18]
EQ-VAS	19.9	(±23.1)	3.2	(±28.1)	.005	[5.1 to 28.5]

n: number of patients, SD: standard deviation, CI: confidence interval, KOOS: Knee injury and Osteoarthritis Outcome Score, FJS-12: Forgotten Joint Score, VAS: Visual Analogue Scale, KSS: Knee Society Score

Chapter 6

Comparison of responsiveness of patient-reported outcome measures after total knee arthroplasty

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Abstract

Background

The aim of this study was to evaluate the responsiveness of different patient-reported outcome measures (PROMs) in patients with primary total knee arthroplasty (TKA).

Methods

In this prospective observational study we assessed patients with TKA before the surgery, after four months, after one year and after two years. Measures were the objective Knee Society Score (KSS) and the following PROMs: Knee injury and Osteoarthritis Outcome Score (KOOS), KOOS-12, Forgotten Joint Score (FJS-12), High-Activity Arthroplasty Score (HAAS) and EQ-5D-3L. Responsiveness was determined by effects size (ES), standardised response means (SRM), area under the receiver operating characteristics (ROC) curve (AUC), floor and ceiling effects and hypotheses testing.

Results

We analysed data from 309 TKA (272 patients, 56% female). ES and SRM for the change in KSS, KOOS, KOOS-12, FJS-12 and EQ-5D-3L from baseline to any follow-up were large (> 0.8). The largest responsiveness from baseline to follow-up was found for the KSS, KOOS/KOOS-12 quality of life, KOOS-12 summary, KOOS-12 pain and FJS-12 (2.0 > ES < 3.9, 1.4 > SRM < 2.4). The AUC from baseline to any follow-up was ≥ 0.7 for KOOS, KOOS-12 and FJS-12 (range 0.71 to 0.95) and < 0.7 for KSS and EQ-5D-3L (range 0.65 to 0.74). We found floor or ceiling effects in the KOOS, the KOOS-12 and EQ-5D-3L, but not in the KSS, the FJS-12 and the HAAS.

Conclusion

Our study demonstrated that responsiveness differed between the various measures. The KOOS-12 and FJS-12 showed the largest internal and external responsiveness, although ceiling effects occurred in the KOOS-12.

Keywords

Total knee arthroplasty, responsiveness, osteoarthritis, patient-reported outcome measure, floor and ceiling effects

Introduction

Adequate responsiveness of a patient-reported outcome measure (PROM) is essential in the evaluation of treatment efficacy [164]. Responsiveness assesses longitudinal validity and is one of the measurement properties that reflects the quality of an outcome measure [130]. Distinct from reliability and validity, it was introduced in 1985 [101]. Responsiveness is defined as the ability of a measure to detect change over time in the construct to be measured [69,131]. The assessment requires repeated measurements over time may vary across different settings and populations [164]. When comparing different PROMs, a more responsive PROM is more likely to detect change over time. Responsiveness can be measured as internal responsiveness, which is the ability to measure change over a given time frame (e.g. before and after an intervention) and external responsiveness, which reflects the extent to which changes in a measure correspond to changes in a reference measure of health status [81].

To evaluate the outcome of total knee arthroplasty (TKA) numerous validated PROMs exist. Selecting the most appropriate measure is still challenging for clinicians and researchers. Among arthroplasty registries that apply PROMs, the Knee injury and Osteoarthritis Outcome Score (KOOS) is one of the most knee-specific measures and the EQ-5D is one of the most common generic measure used [23]. Both measures are well established in patients with TKA, but seem to have deficits regarding their responsiveness in terms of floor and ceiling effects [38,225]. A newer short form, the KOOS-12 showed promising first results regarding good responsiveness and no ceiling effects [50,61], but as with any new measure additional research is needed [61]. The Forgotten Joint Score (FJS-12) and the High-Activity Arthroplasty Score (HAAS) were recently developed to distinguish patients with good outcomes from patients with excellent outcomes, thus resulting in a better discriminatory power in younger and more active patients [21,194]. For the FJS-12, a current review found less floor and ceiling effects but conflicting evidence regarding the responsiveness recommended further studies [3].

Responsiveness of different PROMs has partly been evaluated in patients with TKA. However, comparative analyses of simultaneously captured PROMs are still sparse [66,134]. In particular, a comparison of the performance of newer PROMs, like KOOS-12, FJS-12 and HAAS, in relation to traditional PROMs or clinician-reported measures is needed. Despite their value in reflecting the patients' perspective on treatment outcome, PROMs are often not routinely implemented in the clinical setting.

The aim of this study was to evaluate the responsiveness of different PROMs at four months, one year and two years in patients with primary TKA.

Material and Methods

Participants

This prospective observational study involved consecutively recruited patients undergoing TKA at our medical office. Routinely, all patients were asked to complete a set of PROMs. For this study, we included patients if they completed PROMs before the surgery and after two years. Further details to recruitment and procedures are published elsewhere [213]. We excluded patients with a major re-operation at the affected leg or with revision surgery. Revision was defined as a second surgery to replace some or all parts of the original TKA. All surgeries were done by three senior knee surgeons (MPA, TR, RK) between January 2017 and January 2021.

The study was conducted in accordance with the World Medical Association Declaration of Helsinki [219] and was approved by the local ethics committee in Basel, Switzerland (reference: 2016–01777). All patients gave their written informed consent.

Data collection and measures

Data was collected at baseline and at follow-up after four months, one year and two years using Research Electronic Data Capture (REDCap®). Patients' characteristics were extracted from the medical records. The degree of osteoarthritis was determined by the Kellgren and Lawrence grade and physical status was determined by the American Society of Anesthesiologists (ASA) classification. Surgeons completed the Knee Society Score (KSS) at baseline and during routine visits after four months and one year. Patients completed the KOOS, the FJS-12 and the EQ-5D-3L at baseline and the KOOS, the HAAS, the FJS-12, the EQ-5D-3L, overall improvement and satisfaction at each follow-up, respectively. The KOOS-12 was calculated at baseline and at each follow-up from the full-length KOOS.

We determined the total scores of each measure regarding the rules on the number of missing items allowed. For the KSS all items needed to be complete, for the KOOS and KOOS-12 subscales at least 50%, for the FJS-12 at least 67% and for the EQ-5D-3L all items. For the HAAS no rules are published, therefore, we set all items as mandatory.

Knee Society Score (KSS)

The objective part of the KSS is completed by the surgeon and consists of four items regarding alignment, medial-lateral stability, anterior-posterior stability and joint motion [95,147]. The KSS ranges from 0 (worst) to 100 (best) points. The KSS was assessed during routine visits only and is thus missing after two years when a routine visit is not standard at our medical office.

Knee injury and Osteoarthritis Outcome Score (KOOS)

The KOOS is a wide-spread, traditional questionnaire that involves 42 items in the subscales pain (9 items), symptoms (7 items), activities of daily living (17 items), sports (5 items) and quality of life (4 items) [171]. Each subscale ranges from 0 (worst) to 100 (best) points.

KOOS 12-item short form (KOOS-12)

The KOOS-12 is a new 12-item short form that reduces respondent burden by 70% from the full-length KOOS [61]. It comprises the subscales pain, function, and quality of life with four items each. The quality of life subscale equals the KOOS quality of life subscale. A summery score can be derived as the average of the three subscale scores. Each subscale and the summery score ranges from 0 (worst) to 100 (best) points.

Forgotten Joint Score (FSJ-12)

The FJS-12 was introduced in 2012 and captures the new concept of patients' ability to forget the artificial joint in everyday life [16,21]. The FJS-12 comprises 12 items about joint awareness and ranges from 0 (worst) to 100 (best) points. The loss of awareness of the artificial joint is seen as crucial to improve patient satisfaction [21]. The FJS-12 proved high discriminatory power especially in well-performing patients [21].

High-Activity Arthroplasty Score (HAAS)

The HAAS questionnaire comprises the four items walking, running, stair climbing, and the activity level and is administered postoperatively only [194,212]. It was developed in 2010 to assess subtle variations in functional ability after lower limb arthroplasty with particular regard to highly functioning individuals [194]. The response level for each item ranges from normal function to serious limitation, the total score ranges from 0 (worst) to 18 (best) points.

EQ-5D-3L

The three-level version of the EQ-5D is a generic measure that captures health-related quality of life on five dimensions: mobility, self-care, usual activities, pain/discomfort and anxiety/depression. After application of a value set, the score ranges from 0 (worst) to 1 (best) [53]. We applied the European value set because a Swiss value set is not available.

Global rating of improvement

Global rating of improvement was measured on a seven-point Likert scale (very much better, substantially better, a little better, no change, a little worse, substantially worse or very much worse). The use of a 7 to 11-point Likert scale is recommended for an adequate global rating scale [93]. It was used as the transition item to measure external anchor-based responsiveness. For that purpose patients were dichotomised into improved (patients who rated "very much better" or "substantially better") and not improved (patients who rated "little better", "no change" or "little worse"). Furthermore, the anchor and the measure should capture similar constructs and should have a moderate to strong correlation of $r \geq 0.5$ [46].

Satisfaction

Patient satisfaction was assessed on a five-point Likert scale (very satisfied, satisfied, neutral, unsatisfied or very unsatisfied). Patients were dichotomised into satisfied (patients who rated “very satisfied” and “satisfied”) and not satisfied (patients who rated “neutral”, “unsatisfied” or “very unsatisfied”). As it is recommended to use multiple anchors to examine responsiveness [165], we used patient satisfaction as a second anchor to perform a sensitivity analysis.

Responsiveness

To report responsiveness no gold standard is available and different parameters are widely used [81]. For internal responsiveness we analysed the effect size (ES) and the standardised response mean (SRM). For external responsiveness we determined the area under the receiver operating characteristics (ROC) curve (AUC).

Effect size (ES)

The ES is a standardised measure of change also known as Cohen's *d* [37]. The ES is the mean change in a score divided by the standard deviation (SD) at baseline or earlier assessment. The SD at baseline is untainted by the treatment effect and better reflects

the population SD, instead of a pooled SD when SDs in both groups differ [52]. An ES of about 0.2 is considered a small change, 0.5 a moderate change and 0.8 a large change [37]. A larger ES value reflects a larger responsiveness of the outcome measure. Therefore, the ES should be small in patients reporting no or small improvement and larger in patients reporting larger improvement.

Standardised response mean (SRM)

The SRM is defined as the mean change in a score divided by the SD of the score change. The SRM is preferred over ES as it uses the SDs of the change scores as the denominator and reflects the variability of the change scores [153]. Thus, a measure with high variability in change scores in relation to mean change will have a small SRM [81]. An SRM of about 0.2, 0.5 and 0.8 indicates a small, moderate or large responsiveness, respectively [81].

Area under the receiver operating characteristics (ROC) curve (AUC)

ES and SRM are distribution-based methods relying on data distribution and ignoring patients' judgement on effectiveness of the treatment. To consider patient relevant information, we used the anchor-based method for external responsiveness and plotted the ROC curve to determine the AUC [47,81]. As the external criterion, i.e. the anchor, we used the patients' global rating of improvement and classified patients into improved (very much better, substantially better) and not improved (little better, no change, little worse). Thus, responsiveness is described in terms of sensitivity, which is the probability of a measure to correctly classify patients who improved on the external criterion of change, and specificity, which is the probability of a measure to correctly classify patients who did not improved [81]. In other words, it assesses the ability of a measure to discriminate between change and no change.

The ROC curve plotted the values for sensitivity (true positive) against 1-specificity (false positive) for each PROM change score. The AUC was then analysed to determine the ability of each PROM to discriminate improved from not improved patients. The AUC ranges from 0.5 (no ability on discriminating improvement and no improvement) to 1.0 (perfect ability) [47]. An AUC of ≥ 0.70 is considered to be adequate [196].

Floor and ceiling effects

The ability to detect changes is limited when floor or ceiling effects are present because changes cannot be measured in these patients [196]. A measure suffers from ceiling

effects when a substantial proportion of patients achieve the highest possible score and further improvement cannot be detected. We compared the floor or ceiling effects of the different measures and considered them to be present if more than 15% of the patients achieved the lowest or highest possible total score [196].

Hypothesis testing

Responsiveness is considered as longitudinal validity and analogous to construct validity, longitudinal validity should be assessed by testing predefined hypotheses if no gold standard is available [196]. The measured ES or SRM only has meaning as a measure of responsiveness if the magnitude of the treatment effect of the intervention is assumed beforehand to avoid over- or underestimation of the real change [130].

TKA is a very effective procedure in patients with knee osteoarthritis and we anticipated rather high change scores, especially in the first year after TKA. Our hypotheses were as follows:

1. For all measures, the mean change scores from baseline to any follow-up will be rather high and therefore ES and SRM will be large > 0.8.
2. The positive effect for patients will decrease over time, thus ES and SRM will be moderate ≈ 0.5 from four months to one year and small ≈ 0.2 from one year to two years.
3. KOOS, KOOS-12, FJS-12 and HAAS measure a similar, but not the same, knee-specific construct. Their change scores will have a strong positive correlation with r ≈ 0.5.
4. The change scores of the generic measure EQ-5D-3L will have a medium positive correlation with r ≈ 0.3 to the change scores of all other knee-specific measures (KSS, KOOS, KOOS-12, FJS-12 and HAAS).

Statistical analyses

We used IBM SPSS statistics for Windows, Version 29, Armork, NY: IBM Corp and R, Version 4.1.3 with R studio [160]. Descriptive statistics are presented with mean and SD or frequency count and percentage, respectively. Differences between follow-up data were tested with two-sided paired t-test for continuous variables and Wilcoxon signed rank test for categorical variables. Differences in subgroups were measured with two-sided unpaired t-test for continuous variables and with Mann–Whitney U test or Chi-Square test for categorical variables. Bivariate linear correlations were analysed with the

Pearson test for continuous variables and the Spearman test for categorical variables. The correlation effect sizes were classified as low (r = 0.1), medium (r = 0.3) or strong (r = 0.5) [37]. At least 50 patients are the recommended minimum sample size to adequately assess responsiveness [196]. A post hoc power analysis based on the ES at follow-up with two-sided alpha of 0.05 resulted in a power of > 0.99.

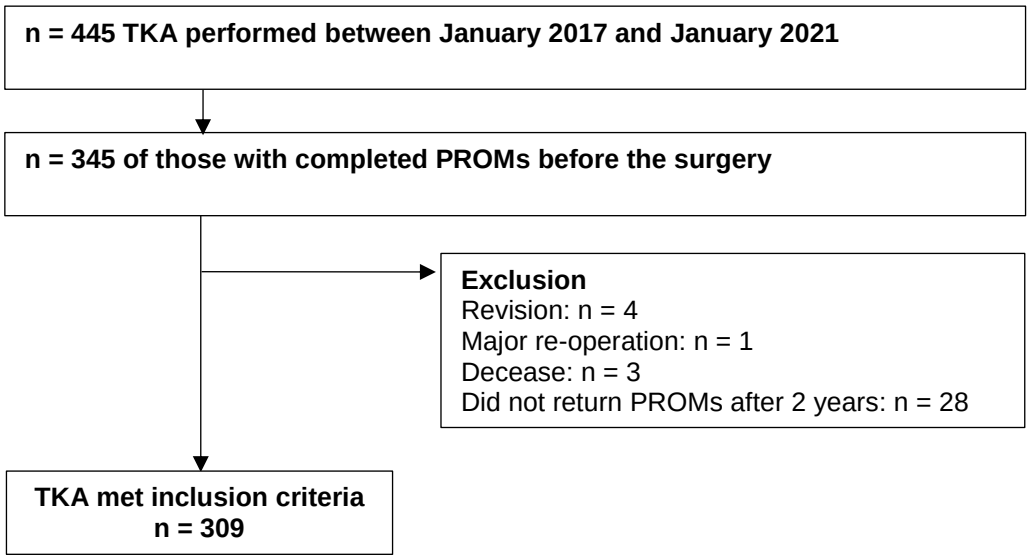
Results

Recruitment

In total, we included data from 309 TKA (272 patients, 56% women). We excluded five patients because of re-operation or revision, three patients because of decease and 28 patients because they did not return the PROMs questionnaire after two years. The detailed recruitment process is shown in Figure 1. Details to patients' characteristics are displayed in Table 1. Patients who did not want to complete PROMs did not differ regarding patients' characteristics compared to patients included in the study (0.176 < p > 0.723). The 28 patients who did not return their questionnaire after two years did not differ regarding patients' characteristics or baseline PROMs compared to the patients included in the analyses (0.206 < p > 0.577).

Table 2 shows the KSS and PROMs at baseline and follow-up. The KSS and all PROMs clearly increased from baseline to follow-up, from four months to one year and two years as well as from one year to two years (p < 0.001, Table 3).

Figure 1: Flow chart of recruitment



n = number; TKA = Total knee arthroplasty; PROM = Patient-reported outcome measure

Table 1: Patients' characteristics at baseline.

		n = 309
Age, mean ±SD (range)		68.7 years ±8.9 (42.4 to 88.2)
BMI, mean ±SD (range)		28.0 kg/m^2 ±4.7 (19.5 to 49.6)
Sex, n (%)		
	Women	167 (54)
	Men	142 (46)
Surgery, n (%)		
	Unilateral	235 (76)
	Bilateral	74 (24)
Side, n (%)		
	Right	166 (54)
	Left	143 (46)
Kellgren and Lawrence grade, n (%)		
	1	1 (0.3)
	2	5 (2)
	3	71 (23)
	4	232 (75)
ASA classification, n (%)		
	I/II	251 (81)
	III	56 (18)
	IV/V	2 (1)
Length of stay, mean ±SD (range)		6.4 days ±1.1 (1 to 10)

n = number; SD = standard deviation; BMI = Body mass index; ASA = American Society of Anesthesiologists.

Table 2: KSS and PROMs at baseline and follow-up.

	Baseline		4 months		1 year		2 years	
	mean	SD	mean	SD	mean	SD	mean	SD
KSS*	54.9	±13.4	87.4	±8.5	91.0	±8.1		
KOOS symptoms	47.7	±17.7	69.2	±16.0	78.2	±15.2	82.3	±14.4
KOOS pain	44.8	±15.3	71.9	±16.4	82.6	±15.8	85.6	±15.8
KOOS daily living	52.2	±16.8	78.2	±13.8	85.3	±13.9	88.1	±13.4
KOOS sports	21.1	±17.9	51.4	±24.6	64.3	±25.5	68.9	±24.3
KOOS quality of life	25.5	±14.4	58.3	±20.3	70.5	±21.4	75.2	±21.4
KOOS-12 summary	39.0	±13.4	68.5	±15.9	79.2	±15.9	83.0	±15.6
KOOS-12 pain	39.9	±15.0	69.7	±17.9	80.9	±17.1	84.6	±17.2
KOOS-12 function	51.5	±18.7	77.6	±15.5	86.4	±13.7	89.0	±12.9
KOOS-12 quality of life	25.5	±14.4	58.3	±20.3	70.5	±21.4	75.2	±21.4
FJS-12	15.3	±13.3	45.5	±25.4	62.9	±27.3	67.0	±27.4
HAAS**			9.3	±2.7	10.8	±3.0	11.3	±3.2
EQ-5D-3L	0.63	±0.18	0.80	±0.15	0.87	±0.14	0.91	±0.12
Improved patients			82%		88%		91%	
Satisfied patients			89%		88%		88%	

KSS = Knee Society Score; KOOS = Knee injury and Osteoarthritis Outcome Score; FJS-12 = Forgotten Joint Score; HAAS = High-Activity Arthroplasty Score; SD = standard deviation.

* KSS not administered at 2 years, ** HAAS not administered at baseline

Internal responsiveness

ES and SRM for the change in all measures from baseline to any follow-up were large (> 0.8), demonstrating the ability to detect a large improvement after TKA (Table 3). ES and SRM for the change in all measures increased over time, in other words got larger from baseline to four months, from baseline to one year and from baseline to two years (Table 3). ES and SRM from four months to one year were moderate to large (range 0.4 to 0.8), from one year to two years were small (range 0.2 to 0.4) and from four months to two years were large (range 0.7 to 0.9) (Table 3).

Besides the objective KSS, ES and SRM at each follow-up were highest for KOOS/KOOS-12 quality of life, KOOS-12 summary, KOOS-12 pain and FJS-12 (Table 3). The HAAS is measured postoperatively only which complicates a comparison by the missing baseline values. But throughout follow-up, ES and SRM were comparable to KOOS, KOOS-12 and FJS-12 (Table 3).

External responsiveness

Overall, the majority of patients reported an improvement: 82% at four months, 88% at one year and 91% at two years follow-up (Table 2). At each follow-up the correlation of the global rating of improvement, as the transition item, with end and change scores of the KSS and all PROMs was medium to strong ($p < 0.001$). The AUC values from baseline to any follow-up were adequate for all knee-specific PROMs (range 0.71 to 0.95), confirming the predictive ability of the measures to classify patients as improved or not improved. AUC values for the objective KSS ranged from 0.65 to 0.71 and for the generic EQ-5D-3L ranged from 0.65 to 0.74 (Table 3). The predictive ability for those measures is questionable. The same applies for the HAAS: although baseline values are missing, AUC values ranged from 0.55 to 0.62, suggesting uncertain predictive ability.

Similarly to ES and SRM, the AUC values increased over time and got larger from baseline to four months, from baseline to one year and from baseline to two years (Table 3).

Floor and ceiling effects

No floor or ceiling effects were found for the KSS, KOOS-12 summary, FJS-12 and HAAS. A floor effect was present in the KOOS sports at baseline and ceiling effects were present in some KOOS and KOOS-12 subscales and the EQ-5D-3L (Table 4).

Table 3: Mean change of measures and responsiveness data.

	Difference baseline to 4 months						Difference baseline to 1 year						Difference baseline to 2 years					
	mean	SD	P value	ES	SRM	AUC	mean	SD	P value	ES	SRM	AUC	mean	SD	P value	ES	SRM	AUC
KSS*	32.5	±15.0	< 0.001	2.43	2.17	0.65	36.1	±14.9	< 0.001	2.69	2.43	0.71						
KOOS symptoms	21.4	±22.0	< 0.001	1.21	0.98	0.71	30.6	±21.1	< 0.001	1.72	1.45	0.71	34.6	±20.2	< 0.001	1.95	1.71	0.79
KOOS pain	26.9	±19.8	< 0.001	1.77	1.36	0.84	37.6	±19.3	< 0.001	2.47	1.95	0.85	40.7	±19.8	< 0.001	2.67	2.05	0.91
KOOS daily living	25.7	±19.5	< 0.001	1.55	1.32	0.78	32.7	±18.5	< 0.001	1.97	1.77	0.79	35.7	±18.0	< 0.001	2.14	1.97	0.84
KOOS sports	30.2	±27.7	< 0.001	1.69	1.09	0.77	43.3	±27.3	< 0.001	2.41	1.59	0.76	47.2	±27.0	< 0.001	2.67	1.75	0.85
KOOS quality of life	32.8	±23.8	< 0.001	2.28	1.37	0.83	44.7	±24.1	< 0.001	3.13	1.86	0.86	49.8	±24.4	< 0.001	3.45	2.04	0.95
KOOS-12 summary	29.3	±19.4	< 0.001	2.20	1.51	0.85	39.9	±18.6	< 0.001	3.00	2.14	0.87	44.0	±18.9	< 0.001	3.28	2.34	0.95
KOOS-12 pain	29.6	±21.1	< 0.001	1.99	1.40	0.83	40.8	±20.5	< 0.001	2.73	1.99	0.85	44.6	±21.2	< 0.001	2.98	2.11	0.93
KOOS-12 function	26.0	±22.1	< 0.001	1.40	1.18	0.73	34.8	±20.8	< 0.001	1.87	1.67	0.74	37.3	±20.6	< 0.001	2.01	1.81	0.80
KOOS-12 quality of life	32.8	±23.9	< 0.001	2.28	1.37	0.83	44.7	±24.1	< 0.001	3.13	1.86	0.86	49.8	±24.4	< 0.001	3.45	2.04	0.95
FJS-12	30.2	±26.0	< 0.001	2.27	1.16	0.79	47.2	±28.0	< 0.001	3.58	1.69	0.84	51.8	±28.3	< 0.001	3.89	1.83	0.93
HAAS**																		
EQ-5D-3L	0.18	±0.20	< 0.001	0.94	0.87	0.74	0.23	±0.19	< 0.001	1.33	1.19	0.65	0.28	±0.20	< 0.001	1.56	1.42	0.69

	Difference 4 months to 1 year						Difference 1 year to 2 years						Difference 4 months to 2 years					
	mean	SD	P value	ES	SRM	AUC	mean	SD	P value	ES	SRM	AUC	mean	SD	P value	ES	SRM	AUC
KSS*	3.8	±7.3	< 0.001	0.42	0.52	0.61												
KOOS symptoms	8.9	±12.8	< 0.001	0.56	0.69	0.70	4.4	±11.5	< 0.001	0.27	0.38	0.66	13.2	±15.3	< 0.001	0.82	0.86	0.68
KOOS pain	10.8	±13.5	< 0.001	0.65	0.80	0.71	3.2	±12.5	< 0.001	0.19	0.26	0.69	14.0	±16.0	< 0.001	0.84	0.88	0.79
KOOS daily living	7.0	±11.9	< 0.001	0.51	0.60	0.67	2.8	±9.2	< 0.001	0.20	0.30	0.65	10.0	±12.2	< 0.001	0.72	0.82	0.71
KOOS sports	12.9	±20.9	< 0.001	0.52	0.62	0.60	4.3	±17.3	< 0.001	0.18	0.25	0.59	17.7	±23.3	< 0.001	0.71	0.76	0.68
KOOS quality of life	12.4	±18.9	< 0.001	0.60	0.66	0.66	4.9	±16.0	< 0.001	0.22	0.31	0.75	17.3	±21.1	< 0.001	0.83	0.82	0.85
KOOS-12 summary	10.9	±13.0	< 0.001	0.67	0.84	0.70	4.0	±10.4	< 0.001	0.24	0.38	0.75	14.8	±15.1	< 0.001	0.91	0.98	0.83
KOOS-12 pain	11.4	±15.6	< 0.001	0.63	0.73	0.68	3.9	±14.0	< 0.001	0.22	0.28	0.75	15.2	±18.0	< 0.001	0.83	0.85	0.81
KOOS-12 function	8.9	±13.3	< 0.001	0.57	0.67	0.66	2.7	±9.6	< 0.001	0.19	0.28	0.60	11.5	±14.1	< 0.001	0.74	0.82	0.65
KOOS-12 quality of life	12.4	±18.9	< 0.001	0.60	0.66	0.66	4.9	±16.0	< 0.001	0.22	0.31	0.75	17.3	±21.1	< 0.001	0.83	0.82	0.85
FJS-12	17.2	±21.5	< 0.001	0.69	0.80	0.69	4.6	±19.6	< 0.001	0.15	0.23	0.71	21.6	±25.4	< 0.001	0.85	0.85	0.82
HAAS	1.4	±2.6	< 0.001	0.56	0.53	0.55	0.57	±2.0	< 0.001	0.17	0.28	0.58	1.9	±2.7	< 0.001	0.74	0.72	0.62
EQ-5D-3L	0.06	±0.15	< 0.001	0.47	0.37	0.54	0.04	±0.12	< 0.001	0.29	0.34	0.57	0.10	±0.14	< 0.001	0.73	0.73	0.70

KSS = Knee Society Score; KOOS = Knee injury and Osteoarthritis Outcome Score; FJS-12 = Forgotten Joint Score; HAAS = High-Activity Arthroplasty Score; SD = standard deviation; ES = effect size; SRM = standardised response mean; AUC = area under the curve.
* KSS not administered at 2 years, ** HAAS not administered at baseline

Table 4: Floor and ceiling effects of measures.

	Baseline		4 months		1 year		2 years	
	Floor in %	Ceiling in %	Floor in %	Ceiling in %	Floor in %	Ceiling in %	Floor in %	Ceiling in %
KSS*	0	0	0	5	0	13		
KOOS symptoms	0	0	0	1	0	6	0	11
KOOS pain	0	0	0	2	0	14	0	**24**
KOOS daily living	0	0	0	1	0	14	0	**22**
KOOS sports	**19**	0	4	1	2	6	1	11
KOOS quality of life	6	0	0	5	0	11	0	**19**
KOOS-12 summary	0	0	0	1	0	6	0	14
KOOS-12 pain	0	0	0	7	0	**22**	0	**34**
KOOS-12 function	0	1	0	7	0	**29**	0	**39**
KOOS-12 quality of life	6	0	0	5	0	11	0	**19**
FJS-12	9	0	2	2	0	6	1	10
HAAS**			0	0	0	0	0	1
EQ-5D-3L	0	3	0	**28**	0	**47**	0	**61**

KSS = Knee Society Score; KOOS = Knee injury and Osteoarthritis Outcome Score; FJS-12 = Forgotten Joint Score; HAAS = High-Activity Arthroplasty Score.

Floor and ceiling effects: >15% of the patients achieved the lowest or highest possible total score.

* KSS not administered at 2 years, ** HAAS not administered at baseline

Hypotheses testing

The results in relation to our hypotheses were as follows:

1. For all measures ES and SRM were > 0.8 from baseline to any follow-up. The hypothesis was confirmed.
2. ES and SRM were moderate ≈ 0.5 from four months to one year and small ≈ 0.2 from one year to two years. The hypothesis was confirmed.
3. KOOS, KOOS-12 and FJS-12 change scores had a strong positive correlation with each other ($0.427 > r < 0.915$, $p < 0.001$). HAAS change scores showed only a medium positive correlation to KOOS, KOOS-12 and FJS-12 change scores ($0.149 > r < 0.376$, $p < 0.05$). The hypothesis was partly confirmed.
4. The generic EQ-5D-3L change scores had a medium positive correlation to the change scores of the knee-specific KSS, KOOS, KOOS-12, FJS-12 and HAAS ($0.130 > r < 0.537$, $p < 0.001$). The hypothesis was confirmed.

Satisfaction and sensitivity analysis

Patient satisfaction was 89% after four months, 88% after one year and 88% after two years (Table 2). At each follow-up the correlation with end and change scores of the KSS and all PROMs was medium to strong ($p < 0.001$). We found a small mismatch between the global rating of improvement and satisfaction. For example after one year, five patients reported to be “substantially better”, which classified them as improved, but answered “neutral” regarding satisfaction, which classified them as not satisfied. We therefore also applied satisfaction as the external anchor and reanalysed the AUC. All AUC values were comparable to the primary analysis (Table 5, additional material). The AUC values from baseline to any follow-up were again adequate for all knee-specific PROMs (range 0.77 to 0.90), confirming the measures ability to predict patients as satisfied or not satisfied. The AUC for the objective KSS (range 0.71 to 0.73) and for the generic EQ-5D-3L (range 0.67 to 0.72) were slightly better.

Discussion

The most important findings of this study are that the objective KSS and knee-specific PROMs, namely the KOOS, the KOOS-12 and the FJS-12, are highly responsive for patients after TKA. When quantified through ES and SRM, these measures showed large responsiveness at four months, one year and two years follow-up. The analysis of the HAAS is deficient by the missing baseline values, but during follow-up ES and SRM were comparable to the other knee-specific PROMs.

Responsiveness was correlated with joint specificity: the generic EQ-5D-3L was against knee-specific PROMs less responsive, but ES and SRM were still large to capture change over time. External responsiveness was adequate for the KOOS, the KOOS-12 and the FJS-12. We found floor or ceiling effects in the KOOS, the KOOS-12 and EQ-5D-3L, but not in the KSS, the FJS-12 and the HAAS.

During follow-up, we detected the greatest magnitude of improvement already in the first four months. The improvement was continuing to one year follow-up and flattening towards two years follow-up. There is an ongoing debate, whether it is sufficient for clinical studies to present PROMs after one year or two years. Regarding our study, one year results showed the most of the improvement but two years data is still showing changes. Our data collection is still on-going and it might be worth to evaluate responsiveness data in the long-term. Other authors found no differences in PROMs

between one year and two years follow-up [127,156], only minimal improvement during the second and third year [33] or even consistent PROMs up to five years [172]. While long-term follow-up after TKA remains important for implant survivorship, it appears that PROMs show the most improvement already in the first months [1,35] and are after one year as reliable and meaningful as PROMs after two years [180]. Poor PROM results after six months should alert surgeons and can be used to identify patients at greater risk of early revision surgery [1].

If applicable, our results are within the findings of other studies. For the KOOS a high level of responsiveness was shown, but also floor and ceiling effects [38,61,66,155]. Recently, a study with 1392 patients showed similar mean change scores after one year for the subscales pain, daily living and quality of life with slightly smaller ES and SRM (1.8 > ES < 2.2 and 1.3 > SRM < 1.9) [61]. Ceiling effects at one year follow-up were found for KOOS daily living (16% and 19%) and KOOS pain (25% and 28%) [51,61]. Ceiling effects at two years follow-up were found for KOOS symptoms (19%), KOOS pain (33%), KOOS daily living (29%) and KOOS quality of life (21%) [51].

For the KOOS-12 large ES and SRM were shown for all subscales and the summary score at six months follow-up (1.8 > ES < 2.4 and 1.6 > SRM < 1.8) [2] and at one year follow-up (2.1 > ES < 2.7 and 1.8 > SRM < 2.1) [50,61]. Ceiling effects were not present in the KOOS-12 summary score [2,51,61] but in the KOOS-12 pain (21% and 32%), KOOS-12 function (18% and 23%) after six months and one year, respectively [2,61]. In summary, the KOOS-12 is a time-saving alternative to the full length version with separate relevant domains and the advantage of a summary score. The minimal important difference was previously determined [188].

A systematic review about the FJS-12 highly recommends the use for patients with high levels of function after TKA but found conflicting evidence for responsiveness. Two out of four studies had a positive rating to responsiveness, one had a negative rating and one had an indeterminate rating. Low floor or ceiling effects were found with a mean value of 8.9% [3]. A previous study found 9.0% patients with the maximum score after one year and 14.8% after two years [51].

Only few literature is available for the HAAS. To our knowledge, no anchor-based responsiveness data was published yet. Distribution-based sensitivity to change, in terms of the smallest detectable change, was found to be 1.8 points [133] and 1.5 points [212]. This value describes the smallest change in a score that is likely to reflect a true

change above measurement error. Mean HAAS scores in the literature were comparable to our findings: after one year 11.7 points [212], after two years 11.0 points [144] and 11.7 points [108]. Floor or ceiling effects were not reported so far [133,194,212]. Different from our hypothesis, the HAAS change scores were not strongly correlated to the change scores of KOOS, KOOS-12 and FJS-12, indicating that a related but dissimilar construct is measured.

The EQ-5D-3L is the most used version of the EQ-5D and as a generic health status measure not restricted to a particular disease or joint and responds to co-existing conditions. Such generic measures may have their limitations when applied to specific diseases, but they allow comparisons across various diseases and treatments. We found large responsiveness from baseline to follow-up although with smaller ES and SRM compared to the knee-specific PROMs. The EQ-5D-3L was shown to be sensitive to clinically meaningful change after TKA. Based on national data from the UK a SRM of 1.1 was found after 6 months [94]. Another study with 721 patients found an ES of 1.0, SRM of 0.9 and AUC of 0.8 after one year [181]. Similar to our results they detected the most improvement during the first three months [181]. The mean improvement in knee registries ranged from 0.12 to 0.25 after six months to one year [83]. However, the responsiveness is limited by the highest ceiling effects we found during follow-up. This is consistent with others who found ceiling effects of 30% after one year [225] or 39% to 81% after two months to two years [66]. To improve sensitivity and to reduce ceiling effects, the EQ-5D-5L with five instead of three severity levels was introduced [28,79]. By the time we started our study, this version was relatively new and not widely used. Nowadays it is recommended to apply the more discriminating EQ-5D-5L in identifying health-related quality of life changes in patients with THA or TKA [89]. To better detect small changes after THA or TKA, the Swedish Arthroplasty Register has decided to change from the EQ-5D-3L to the EQ-5D-5L [198].

Strengths and limitations

Our study provides a profound comparison of prospective PROMs data collected simultaneously at four months to two years. We compared an objective, knee-specific and generic measures and included traditional measures (KSS, KOOS and EQ-5D-3L), newer measures (KOOS-12 and FJS-12), and measures with currently limited data available (HAAS).

Besides these strengths our study has some limitations. The study sample may suffer from a selection bias, because it was from a single private institution, and may present a more economically advantaged population. However, the study sample itself is homogenous and consistent over the follow-up of two years. Potentially, a recall bias and response shift may have been introduced by the use of the global rating of improvement as transition item. Even if widely used, it is known that transition items are influenced by the current status [70]. Retrospective self-reports, e.g. transition items, tend to have a stronger correlation with the current health status than with the past health status because the current status influences the retrospective perception of change [164]. Hence, we also applied satisfaction as transition item and found no crucial differences regarding external responsiveness.

In addition, our analyses are limited to patients who completed PROMs before and after their TKA. A respondent bias is therefore conceivable. We found no differences between patients who completed PROMs and patients who did not want to complete them or were lost to follow-up. Additionally, registry data showed only small differences between responders and non-responders even if data collection is captured electronic-only [75].

Conclusions

In conclusion, our study demonstrated that responsiveness differed between the various measures. Knee-specific measures were more responsive than generic measures. The KOOS-12 und FJS-12 showed the largest internal and external responsiveness. Nevertheless, ceiling effects occurred in the KOOS-12 subscales and may limit improvement monitoring after TKA.

Appendix

Additional material

Table 5: AUC based on satisfaction as external anchor.

	Baseline to 4 months	Baseline to 1 year	Baseline to 2 years	4 months to 1 year	1 year to 2 years	4 months to 2 years
	AUC	AUC	AUC	AUC	AUC	AUC
KSS*	0.71	0.73		0.66		
KOOS symptoms	0.79	0.77	0.77	0.68	0.66	0.69
KOOS pain	0.81	0.88	0.81	0.73	0.63	0.72
KOOS daily living	0.78	0.83	0.79	0.68	0.56	0.65
KOOS sports	0.80	0.83	0.79	0.62	0.54	0.62
KOOS quality of life	0.84	0.88	0.88	0.71	0.63	0.77
KOOS-12 summary	0.85	0.90	0.86	0.73	0.64	0.74
KOOS-12 pain	0.78	0.89	0.81	0.69	0.64	0.70
KOOS-12 function	0.80	0.79	0.77	0.69	0.54	0.63
KOOS-12 quality of life	0.84	0.88	0.88	0.71	0.63	0.77
FJS-12	0.82	0.85	0.89	0.70	0.64	0.75
HAAS**				0.62	0.58	0.66
EQ-5D-3L	0.68	0.67	0.72	0.61	0.49	0.65

KSS = Knee Society Score; KOOS = Knee injury and Osteoarthritis Outcome Score; FJS-12 = Forgotten Joint Score; HAAS = High-Activity Arthroplasty Score; AUC = area under the curve.

* KSS not administered at 2 years, ** HAAS not administered at baseline

Chapter 7

Patients with total knee arthroplasty have high expectations that do not correlate with patient satisfaction

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Abstract

Background

The relationship between preoperative patient expectations and postoperative patient satisfaction remains poorly understood. The aim of this study was to analyse the association between expectations and satisfaction and further patient-reported outcome measures (PROMs) in patients with a total knee arthroplasty (TKA).

Questions/Purposes

(1) What are patients' preoperative expectations and which items are most relevant to patients? (2) Do expectations correlate with satisfaction? (3) Do expectations correlated with patient characteristics or with PROMs? (4) Is satisfaction correlated with patient characteristics or with PROMs?

Methods

This is a monocentric, observational, prospective cohort study involving patients undergoing TKA. We analysed data from 193 TKA (179 patients, 54% women). Data was collected at baseline, after 4 months and after 12 months. Patient expectations were measured using the Hospital for Special Surgeries Knee Replacement Expectation Survey (HSS-KRES). We also assessed patient satisfaction, the Knee injury and Osteoarthritis Outcome Score (KOOS), the Forgotten Joint Score (FJS-12), the High-Activity Arthroplasty Score (HAAS), the EQ-5D-3L and the objective Knee Society Score (KSS). Bivariate linear correlations were analysed using the Pearson or Spearman test.

Results

The mean HSS-KRES was 82.2 points (range 26.9 to 100.0), and the items with the highest expected improvement were “No need for walking aids”, “Straighten the knee” and “Pain relief”. The HSS-KRES did not correlate with satisfaction at either 4 or 12 months and did not differ between patients who were satisfied at 12 months (82.5 points) and those who were not (80.4 points, p = .461). The HSS-KRES did not correlate with patient characteristics or any of the pre- or postoperative PROMs or the KSS. Patient satisfaction was high (4 months: 91%, 12 months: 85%) and did not correlate with patient characteristics or any of the preoperative PROMs or the KSS. Patient satisfaction was medium to strongly correlated with postoperative PROMs and the KSS.

Conclusion

Preoperative expectations were high, but not correlated with postoperative satisfaction. In other words, high patient expectations are not always a warning sign. We also found no correlation between expectations and patient characteristics or pre- and postoperative PROMs.

Keywords

Patient expectations, satisfaction, patient-reported outcome measure, total knee arthroplasty

Introduction

Total knee arthroplasty (TKA) is a common and effective treatment for end-stage knee osteoarthritis. However, approximately one in five patients is dissatisfied with the outcome [26,68,92]. Substantial efforts have been made to understand the factors associated with dissatisfaction after TKA and several predictors have been analysed [68,92,124,158]. Nevertheless, the ability to predict satisfied patients remains poor [227].

Patient-reported outcome measures (PROMs) are the basis for gaining insight into the patients' perspective and better understanding satisfaction after TKA. Lately, there has been a shift from recommending a TKA based on objective osteoarthritis signs to focusing on PROMs including patients' readiness and expectations [154]. The topic of patients' expectations is receiving increasing attention, particularly for elective orthopaedic surgery, where patients' perspectives strongly influence the decision to undergo surgery [119]. Knowledge of expectations promotes a better patient education, shared decision-making, and ensures that patients and surgeons have similar goals [119]. In the medical setting, patient expectation has been defined as the anticipation that given events are likely to occur during or as a result of medical care [205]. Dissatisfaction may be the result of unrealistically high expectations rather than poor treatment outcomes. Patients tend to have high, overly optimistic and unrealistic expectations of TKA [123,154], and patients tend to have higher expectations than their surgeons [64].

The relationship between preoperative patient expectations and postoperative patient satisfaction remains poorly understood. According to the literature, patient satisfaction after TKA is strongly influenced by the extent to which patient expectations are met [72,115,145,176]. But there is conflicting evidence on the association between expectations and postoperative outcome. In TKA patients, systematic reviews found no consistent association between patient expectations and outcomes [71] or patient expectations and satisfaction [14,72]. Whereas a subsequent large cohort study found an association between expectations about kneeling and psychological well-being and the level of satisfaction at one year [77]. Others have found that patients with more optimistic expectations have better surgical outcomes [56].

It is unclear whether high, unrealistic expectations are associated with a higher risk of dissatisfaction after TKA. A better understanding of the relationship between patient expectations and satisfaction is needed to improve outcomes for patients with TKA. Thus, the aim of this study was to assess preoperative patient expectations and their

correlation with patient satisfaction at 4 and 12 months after TKA. We hypothesised that patients with higher expectations would be less satisfied with their TKA.

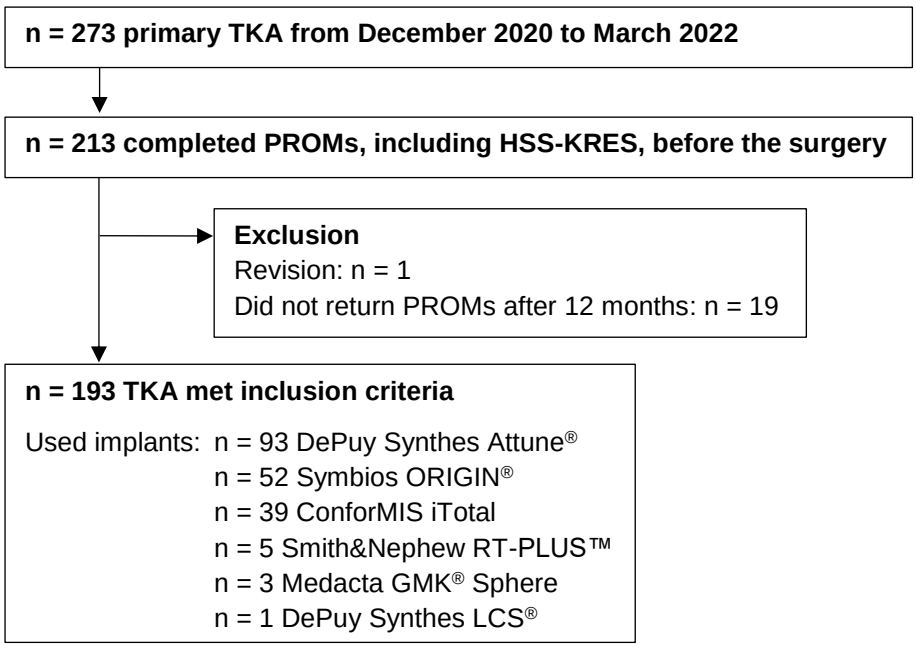
Patients and methods

Setting, recruitment and data collection

This is a monocentric, observational, prospective cohort study approved by the local ethics committee (reference: 2016-01777). The study was conducted in accordance with the World Medical Association Declaration of Helsinki [219].

All patients were recruited at our practice and gave written informed consent to participate. Routinely, we ask all patients scheduled for a knee arthroplasty to complete a set of PROMs. Details of recruitment and procedures have been published previously [213]. Since December 2020, our patients have also completed a preoperative expectations questionnaire. For this study, we included all patients with a primary TKA who completed a set of PROMs, including patient expectations, before the surgery and after 12 months. Patients who underwent revision surgery were excluded. TKAs were performed between December 2020 and March 2022 by well experienced senior surgeons (MPA, TR, RK). Figure 1 outlines the recruitment process and the implants used.

Figure 1: This flow charts depicts the recruitment process.



n: number, TKA: total knee arthroplasty, PROM: patient-reported outcome measure, HSS-KRES: Hospital for Special Surgeries Knee Replacement Expectation Survey

We collected data during routine visits before the surgery, after 4 and 12 months using Research Electronic Data Capture (REDCap®). Patient characteristics were extracted from medical records. Osteoarthritis was graded from 0 (no osteoarthritis) to 4 (severe osteoarthritis) according to Kellgren and Lawrence [103]. Comorbidities were graded following the American Society of Anesthesiologists (ASA) from ASA I (normal healthy) to ASA V (moribund) [6].

Measures

The most widespread measure to capture patient expectations prior to TKA is the Hospital for Special Surgeries Knee Replacement Expectation Survey (HSS-KRES). The HSS-KRES was originally a value-based format in which patients were asked to rate the importance of their expectations [121,122]. It was later modified into a probability-based format, asking patients how much improvement they expect [120].

The HSS-KRES is self-administered before the surgery and consists of 17 items with the response options: “back to normality or complete improvement” (4 points), “not back to normality but a great improvement” (3 points), “not back to normality but a moderate improvement” (2 points), “not back to normality but a small improvement” (1 point) or “this expectation does not apply to me/I do not have this expectation” (0 points). The total score is converted to a scale from 0 to 100, with higher values indicating higher expectations [120]. We found no rule about the number of missing items allowed and calculated the total score if at least two thirds, i.e. 12 items, were completed.

Further PROMs we collected were: patient satisfaction, overall improvement, willingness to undergo the surgery again, the Knee injury and Osteoarthritis Outcome Score (KOOS), the Forgotten Joint Score (FJS-12), the High-Activity Arthroplasty Score (HAAS) and the EQ-5D-3L including the EQ-VAS (Figure 2). Regarding patient satisfaction, we summarised patients who answered "very satisfied" or "satisfied" as satisfied. Regarding overall improvement, we summarised patients who answered “very much better” or “substantially better” as improved. In addition to the subjective measures mentioned above, surgeons completed the objective part of the Knee Society Score (KSS). Details of the measures and data collection are displayed in Figure 2.

Figure 2: This scheme outlines the measures and data collection.

Measure	Scale	Data collection		
		Baseline	4 months	12 months
HSS-KRES [120] Expectations about improvement	0 (low) to 100 (high) points	x		
Satisfaction	5-point Likert scale: very satisfied, satisfied, neutral, unsatisfied, very unsatisfied		x	x
Overall improvement	7-point Likert scale: very much better, substantially better, a little better, no change, a little worse, substantially worse, very much worse		x	x
Surgery again	Yes, no		x	x
KOOS [171] Subscales: pain, symptoms, daily living, sports, quality of life	0 (worst) to 100 (best) points	x	x	x
FJS-12 [202] Ability to forget the artificial joint in everyday life	0 (worst) to 100 (best) points	x	x	x
HAAS [212] High-intensity activities	0 (worst) to 18 (best) points		x	x
EQ-5D-3L [53] Health-related quality of life	0 (worst) to 1 (best)	x	x	x
EQ-VAS [53] Health-related quality of life	0 (worst) to 100 (best)	x	x	x
KSS [179] Objective knee function	0 (worst) to 100 (best) points	x	x	x

HSS-KRES: Hospital for Special Surgeries Knee Replacement Expectation Survey, KOOS: Knee injury and Osteoarthritis Outcome Score, FJS-12: Forgotten Joint Score, HAAS: High-Activity Arthroplasty Score, VAS: Visual Analogue Scale, KSS: Knee Society Score

Statistics

Statistical analyses were performed using IBM SPSS statistics for Windows, version 29, Armonk, NY: IBM Corp and R, version 4.1.3 [160]. Differences between pre- and postoperative data were tested using paired t-test. Differences between groups were measured with unpaired t-test, one-way analysis of variance, Mann-Whitney U test or Chi-Square as appropriate. Bivariate linear correlations were analysed with Pearson test for continuous variables and Spearman test for categorical variables. The correlation effect size was classified as low (r = 0.1), medium (r = 0.3) or strong (r = 0.5) [37].

The sample size calculation to detect a correlation of at least r = 0.2 between the HSS-KRES and satisfaction resulted in a sample of 193 patients to ensure a power of 0.8 with a two-sided alpha of 0.05.

Patients' characteristics

We analysed data from 193 TKA (179 patients, 54% women). We excluded one patient because of revision and 19 patients because they did not complete PROMs after 12 months (Figure 1). Patients' characteristics are summarised in Table 1.

Table 1: Patients' characteristics.

Patients' characteristics	n = 193	
Age, mean years (±SD)	67.6	(±9.2)
Body mass index, mean kg/m^2 (±SD)	28.0	(±5.1)
Sex, n (%)		
Women	106	(55%)
Men	87	(45%)
Side, n (%)		
Left	88	(46%)
Right	105	(54%)
Surgery, n (%)		
Unilateral	165	(85%)
Bilateral	28	(15%)
Kellgren and Lawrence grade, n (%)		
2	2	(1%)
3	29	(15%)
4	162	(84%)
ASA Classification, n (%)		
I	29	(15%)
II	128	(66%)
III	36	(19%)
Length of stay, mean days (±SD)	5.8	(±1.2)

n: number, SD: standard deviation, ASA: American Society of Anesthesiologists

Results

Patient expectations and most relevant items

The mean preoperative HSS-KRES was 82.2 points and ranged from 26.9 to 100.0 (Table 2). Overall, expectations were high: 59% of the patients had a HSS-KRES ≥ 80 points and 40% had a HSS-KRES ≥ 90 points (Table 2). On average, patients expected improvement in 15 items (range 9 to 17) and improvement back to normality in 10 items (range 0 to 17). Patients most frequently expected (any expectation) the items "Go down stairs" (99.5%), "Ability to walk" (99.5%), "Pain relief" (99.0 %) and "Go down stairs" (99.0%) and least often the items "Be employed" (67.1%) and "Sexual activity" (64.3%).

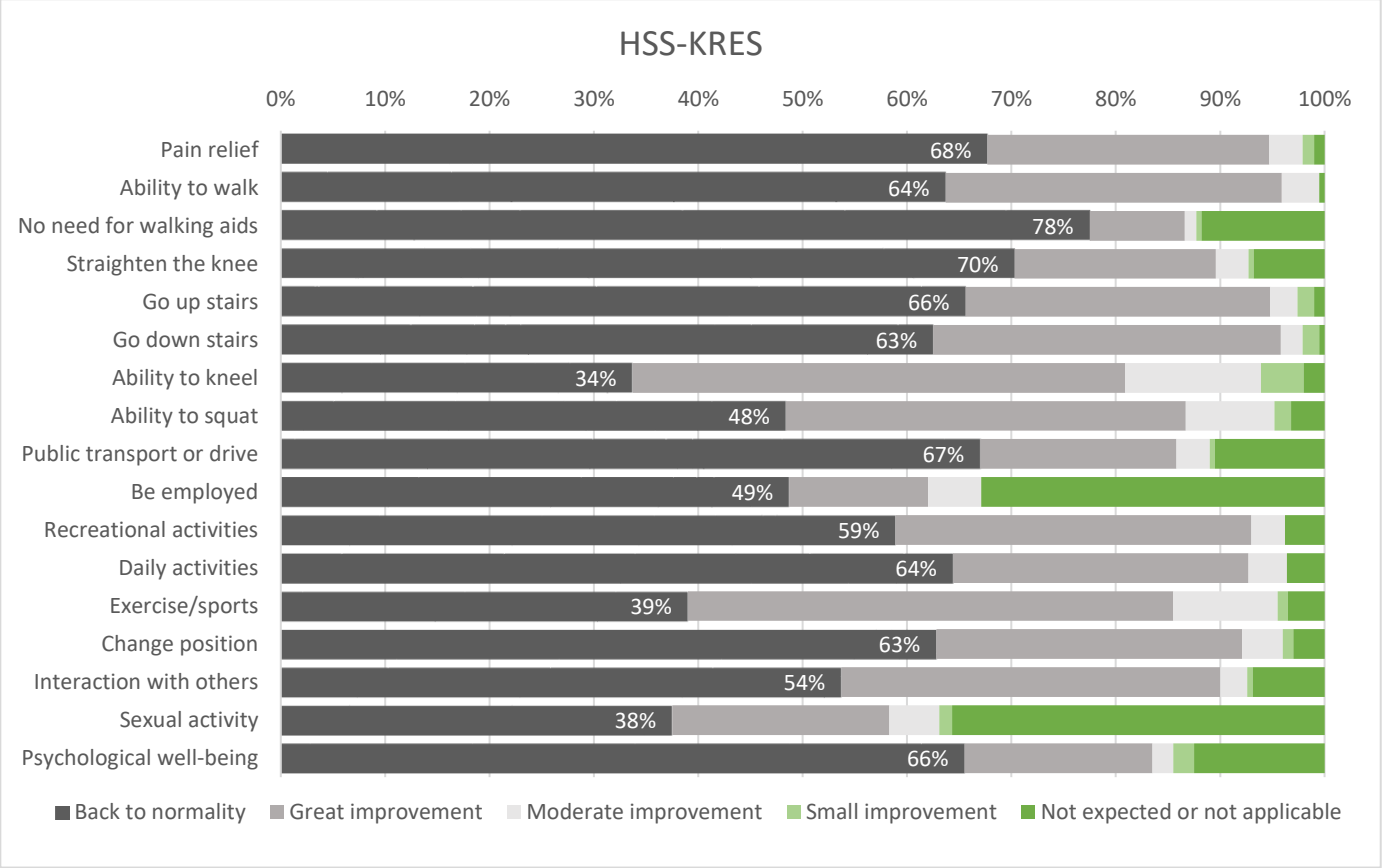
The items “No need for walking aids”, “Straighten the knee” and “Pain relief” were the items with the most improvement, i.e. back to normality, expected (Figure 3 and Table 4 in additional material).

Table 2: Results of pre- and postoperative measures.

	Baseline n = 193 mean (±SD)	4 months n = 193 mean (±SD)	12 months n = 193 mean (±SD)
HSS-KRES	82.2 (±15.7)		
HSS-KRES in categories, n (%)			
≥ 80 points	114 (59%)		
≥ 90 points	77 (40%)		
Satisfied patients, %		91%	85%
Improved patients, %		79%	87%
Surgery again, %		99%	95%
KOOS symptoms	49.4 (±17.7)	68.1 (±17.2)	77.8 (±15.1)
KOOS pain	44.9 (±16.6)	72.8 (±16.2)	82.8 (±15.5)
KOOS daily living	54.6 (±18.9)	79.9 (±13.2)	85.8 (±13.9)
KOOS sports	20.7 (±19.2)	53.8 (±25.9)	66.0 (±23.0)
KOOS quality of life	24.8 (±14.5)	60.8 (±20.2)	70.8 (±22.5)
FJS-12	17.4 (±14.6)	49.1 (±27.4)	63.8 (±27.2)
HAAS		9.5 (±2.7)	10.7 (±3.0)
EQ-5D-3L	0.61 (±0.19)	0.81 (±0.12)	0.88 (±0.15)
EQ-VAS	63.8 (±19.4)	73.8 (±15.6)	79.2 (±13.9)
KSS	53.8 (±14.5)	88.6 (±8.4)	92.1 (±6.7)

n: number, SD: standard deviation, HSS-KRES: Hospital for Special Surgeries Knee Replacement Expectation Survey, KOOS: Knee injury and Osteoarthritis Outcome Score, FJS-12: Forgotten Joint Score, HAAS: High-Activity Arthroplasty Score, VAS: Visual Analogue Scale, KSS: Knee Society Score

Figure 3: This diagram shows the HSS-KRES rating per item of all patients.



Correlation between expectations and satisfaction

The HSS-KRES was not correlated with satisfaction after 4 months ($r = -.065$, $p = 0.386$) or satisfaction after 12 months ($r = -.115$, $p = .112$). The HSS-KRES did not differ in patients who were satisfied after 4 months (81.6 points) compared to patients who were not satisfied (81.4 points, $p = .955$) and it did not differ in patients who were satisfied after 12 months (82.5 points) compared to patients who were not satisfied (80.4 points, $p = .461$).

Correlation between expectations and patients' characteristics or PROMs

The HSS-KRES did not correlate with any of the patients' characteristics listed in Table 1 or with any of the pre- or postoperative PROMs or the KSS (additional material, Table 5). When analysing the 17 HSS-KRES items separately, we found no correlation between each item and patient satisfaction after 4 months ($-.114 < r > .098$) or patient satisfaction after 12 months ($-.058 < r > .100$).

Correlation between satisfaction and patients' characteristics or PROMs

Patient satisfaction was high, with 91% of patients being very satisfied or satisfied after 4 months and 85% after 12 months. Patient satisfaction after 4 and 12 months was not correlated with any of the patients' characteristics listed in Table 1 or any of the preoperative measures (PROMs and KSS), including the HSS-KRES ($r < .103$ and $r < .126$, respectively). Patient satisfaction after 4 months was medium to strong correlated with measures, after 4 months ($.370 < r > .562$, $p < .001$). Patient satisfaction after 12 months was medium to strongly correlated with measures after 4 months ($.202 < r > .549$, $p < .001$) and measures after 12 months ($.367 < r > .725$, $p < .001$).

Overall improvement was high, with 79% of patients reporting being much or very much better after 4 months and 87% after 12 months (Table 2). All other PROMs and the KSS clearly improved from baseline to 4 months ($p < .001$), from baseline to 12 months ($p < .001$) and from 4 months to 12 months ($p < .001$; Table 2).

Subgroup analyses

The HSS-KRES and satisfaction after 12 months did not differ between women and men or between younger and older patients (Table 3). The HSS-KRES was higher in patients with a customised individually made (CIM) implant (Symbios ORIGIN®: 85.1, ConforMIS iTotal: 85.0) compared to an off-the-shelf (OTS) implant (DePuy Synthes Attune®: 79.3), while satisfaction after 12 months did not differ (Table 3). Satisfaction after 12 months did not differ between patients with higher and lower preoperative expectations (Table 3).

Table 3: Subgroup analyses.

			HSS-KRES		Satisfied patients at 12 months	
		n	mean (±SD)	P value	n (%)	P value
Sex	Women	106	81.0 (±16.2)	.224	93 (88%)	.312
	Men	87	83.7 (±15.1)		71 (82%)	
Age	< 65 years	79	82.6 (±16.1)	.768	68 (86%)	.839
	≥ 65 years	114	81.9 (±15.4)		96 (84%)	
Implant*	DePuy Synthes Attune®	93	79.3 (±16.9)	.045	80 (86%)	.568
	Symbios ORIGIN®	52	85.1 (±13.8)		45 (87%)	
	ConforMIS iTotal	39	85.0 (±14.7)		31 (80%)	
Expectations	HSS-KRES ≥ 80	114	93.1 (±6.1)	< .001	97 (85%)	.999
	HSS-KRES < 80	79	66.4 (±11.2)		67 (85%)	
Expectations	HSS-KRES ≥ 90	77	96.8 (±3.1)	< .001	68 (88%)	.313
	HSS-KRES < 90	116	72.5 (±13.0)		96 (83%)	

HSS-KRES: Hospital for Special Surgeries Knee Replacement Expectation Survey, n: number, SD: standard deviation

** we excluded the 3 implants less often used (Smith&Nephew RT-PLUS™, Medacta GMK® Sphere, DePuy Synthes LCS®)*

Discussion

The most important finding of this study was that patients had high preoperative expectations, which did not correlate with postoperative satisfaction. In addition, we found no correlation between preoperative expectations and any of the pre- or postoperative outcome measures, namely the KOOS, FJS-12, HAAS, EQ-5D and the KSS. Our hypothesis that patients with higher expectations would be less satisfied was not supported. Patients had high expectations prior to their TKAs but these expectations seemed to be less determining for postoperative outcome.

Other studies using the probability-based format of the HSS-KRES reported similar high patient expectations [85,142,157,203,223]. Jain et al. found a mean HSS-KRES of 76.6 ±18.0 in 83 patients and no correlation with patient satisfaction as well. In contrast to our findings, they reported the HSS-KRES to be predictive for postoperative improvement in PROMs [85]. In their large registry study, Ponzio et al. reported a mean HSS-KRES of 79.2 ±17.6 for 1008 active patients and of 79.8 ±18.7 for 1008 inactive patients. Consistent with our findings, preoperative expectations and postoperative outcome including satisfaction were not associated [157]. On the other hand, Neuprez et al. found a mean HSS-KRES of

69.1 ±13.7 in 58 TKA, which was the single best positive predictor for patient satisfaction [142].

The value-based format of the HSS-KRES is still widely used. The approach differs because patients score the importance of each item, but results are fairly similar [77,140,176,187,224]. Recently, Hawker et al. studied 1266 patients and reported a median score of 85.3 (interquartile range 75.0 to 92.7). The total HSS-KRES was not predictive for satisfaction, but preoperative expectations regarding the items kneeling and psychological well-being were associated with satisfaction at one year [77].

We found no association between expectations and patients' characteristics or preoperative PROMs. Previous studies have reported inconsistent results in this regard. Higher expectations were associated with poor preoperative PROMs [176,224,226], low disease burden [84], younger age [78,176,218,221,226], being male [176] and lower expectations were associated with higher body mass index [137]. By contrast, others found no association between expectations and preoperative PROMs [85,187], age [41,85,117,187], sex [41,85,117,187] and body mass index [85,187]. Regarding the different implants, patients with CIM TKA had relevant higher expectations with no effect on patient satisfaction. The impact of CIM TKA on patient satisfaction is still controversial and recent studies have shown conflicting results [67,135,214].

To date, there is no consensus on how to measure expectations or satisfaction [14]. Measuring patient satisfaction is not straightforward, and satisfaction is highly dependent on the patient's individual perspective. To be satisfied with surgery may mean for one patient the outcome was excellent, whereas for another patient it may mean the outcome was satisfactory [119]. Promoting realistic expectations is particularly important for patients before TKA. Numerous studies have shown that satisfaction is associated with the fulfilment of expectations [72,115,145,176]. Surgeons should ask their patients about their mandatory expectations for a successful TKA and counsel them about the likelihood of these expectations being met to avoid unrealistic expectations [115]. In this regard, Tolk et al. recently demonstrated the potential of additional education on realistic expectations. It had a modifying effect on preoperative expectations and led to a higher postoperative expectation fulfilment and satisfaction rate. In their intervention group the mean HSS-KRES of 69.1 ±18.2 decreased after an education module about realistic expectations (mean difference -6.9, $p < 0.001$). Expectation fulfilment rate (70%) and patient satisfaction rate (74%) was clearly higher compared to the control group

(expectation fulfilment: 59%, satisfaction: 57%) [203]. In contrast, the randomised controlled trial of Culliton et al. revealed no effect of an additional e-learning tool about realistic expectations on the outcomes met expectations and satisfaction [42].

The association between met expectations and satisfaction would support the concept of lowering patients' expectations. However, other authors recommend that patients' expectations of postoperative TKA outcomes should be as high as possible in order to benefit from the positive effects of anxiety reduction, better treatment adherence and beneficial coping mechanisms associated with higher expectations [85,203]. Consistent with this, optimism has been shown to be positively associated with preoperative joint function and postoperative outcome in TKA patients, whereas pessimism is associated with the opposite [222]. According to the authors, preoperative assessment of patients' general personality traits should be considered to respond to patients' pessimistic expectations and potentially improve postoperative outcome in TKA [222].

The complexity of the situation is also demonstrated in the study by Munn et al., which showed that met expectations moderate the relationship between pain and satisfaction [139]. An interaction was found between met expectations and pain and met expectations and function: as met expectations increased, pain and function predicted satisfaction less strongly. This suggests that there may be more value in improving pain for patients with low met expectations [139].

We prospectively assessed the association between expectations and satisfaction after TKA, using a broad set of PROMs to better understand the patients' perspective. Nevertheless, we found no correlation between expectations and satisfaction or between expectations and any of the patients' characteristics or pre- and postoperative PROMs. Despite all the care taken, our study has some limitations. We did not assess fulfilment of expectations which might have been a moderating variable and might have shown an association to preoperative expectations or postoperative satisfaction. The follow-up of one year is relatively short. However, PROMs have been shown to be as reliable and meaningful after one year as they are after two years [180], and to remain consistent even with longer-term follow-up [156,172]. The response rate of our patients to routine preoperative PROMs 78%, with a reasonable drop-out rate of 9%. Despite our ongoing efforts, including postal or email reminders and telephone calls, achieving a high response rate to PROMs at multiple time points has proven challenging [159]. Finally, the generalisability of the findings may be limited to some extent. Our study took place in a

private hospital in Switzerland and the results may not be representative of patients in other settings.

Conclusions

We found no correlation between preoperative expectations and postoperative satisfaction. We also found no correlation between expectations and patient characteristics or pre- and postoperative PROMs. In conclusion, we found that high preoperative patient expectations do not lead to a higher risk of dissatisfied patients. Nevertheless, we believe that expectations should be discussed with the patient in a shared decision-making process and are a relevant aspect prior to elective TKA surgery.

Appendix

Additional material

Table 4: HSS-KRES rating details.

n = 193, in %	Back to normality or complete improvement	Not back to normality but a …			Not expected or not applicable
		Great improvement	Moderate improvement	Small improvement	
Pain relief	68%	27%	3%	1%	1%
Ability to walk	64%	32%	4%	-	1%
No need for walking aids	77%	9%	1%	1%	12%
Straighten the knee	70%	19%	3%	1%	7%
Go up stairs	66%	29%	3%	1%	1%
Go down stairs	63%	33%	2%	2%	1%
Ability to kneel	34%	47%	13%	4%	2%
Ability to squat	48%	38%	9%	2%	3%
Public transport or drive	67%	19%	3%	1%	11%
Be employed	49%	13%	5%	-	33%
Recreational activities	59%	34%	3%	-	4%
Daily activities	64%	28%	4%	-	4%
Exercise/sports	39%	47%	10%	1%	4%
Change position	63%	29%	4%	1%	3%
Interaction with others	54%	36%	3%	1%	7%
Sexual activity	38%	21%	5%	1%	36%
Psychological well-being	66%	18%	2%	2%	13%

Table 5: HSS-KRES correlation with pre- and postoperative measures.

	HSS-KRES					
	Baseline		4 months		12 months	
	r	P value	r	P value	r	P value
Patients' characteristics						
Age	.021	.771				
BMI	-.070	.333				
Sex	-.091	.206				
Kellgren and Lawrence grade	.006	.938				
ASA classification	-.084	.247				
Measures						
Satisfaction			-.065	.386	-.115	.112
Overall improvement			.097	.193	.068	.348
Surgery again			.095	.211	-.017	.815
KOOS symptoms	-.018	.803	-.032	.666	-.044	.539
KOOS pain	-.091	.208	-.039	.602	-.019	.797
KOOS daily living	-.073	.310	-.032	.664	.007	.927
KOOS sports	-.002	.983	-.077	.345	.013	.869
KOOS quality of life	-.054	.454	-.021	.784	-.046	.528
FJS-12	-.024	.743	-.054	.471	-.003	.967
HAAS			-.033	.655	.057	.439
EQ-5D-3L	-.090	.214	.068	.362	.010	.890
EQ-VAS	.010	.889	.025	.740	.080	.272
KSS	-.111	.127	-.096	.200	-.029	.737

HSS-KRES: Hospital for Special Surgeries Knee Replacement Expectation Survey, ASA: American Society of Anesthesiologists, KOOS: Knee injury and Osteoarthritis Outcome Score, FJS-12: Forgotten Joint Score, HAAS: High-Activity Arthroplasty Score, VAS: Visual Analogue Scale, KSS: Knee Society Score, r: correlation coefficient

Chapter 8

Related publications

Customised, individually made total knee arthroplasty shows promising 1-year clinical and patient reported outcomes

Moret CS, Hirschmann MT, Vogel N, Arnold MP. Customised, individually made total knee arthroplasty shows promising 1-year clinical and patient reported outcomes. Arch Orthop Trauma Surg. 2021 Dec;141(12):2217-2225. doi: 10.1007/s00402-021-04045-1. Epub 2021 Jul 16.

Introduction: Customised individually made (CIM) implants for total knee arthroplasty (TKA) were introduced about 10 years ago. These implants aim to reduce the risk of prosthesis-related issues resulting from anthropometric differences between different knees. The purpose of this study was to analyse the short-term clinical outcome and patient reported outcome measures (PROMs) of a specific CIM implant, the ORIGIN® knee replacement system (Symbios, Yverdon-les-Bains, Switzerland), which was introduced in 2018.

Materials and methods: This is a prospective cohort study of patients undergoing primary posterior-stabilised (PS) CIM TKA using the specific ORIGIN® knee replacement system, (Symbios, Yverdon-les-Bains, Switzerland). TKAs were performed from February 2019 to October 2020. Data was collected preoperatively and postoperatively at 4 and 12 months. Outcome measures included the objective part of the Knee Society Score (KSS) with the range of motion (ROM) and the following PROMs: the Knee injury and Osteoarthritis Outcome Score (KOOS), the Forgotten Joint Score (FJS-12), the EuroQol, five dimensions, three levels (EQ-5D-3L) with the EuroQol visual analogue scale (EQ-VAS) and patient satisfaction. Differences in pre- to preoperative data were assessed with paired sample t tests. A p value < 0.05 was considered significant.

Results: Twenty-five CIM TKA (20 patients, 8 female) were included. The mean age at surgery was 66 years (SD, 6.9). At 4 and 12 months, significant improvements in the KSS ($p < 0.001$), the ROM ($p < 0.001$), all KOOS subscales ($p < 0.001$), the FJS ($p < 0.001$) and the EQ-5D-3L ($p < 0.026$) were found. Satisfaction rate was 91% and 88% at 4 and 12 months, respectively. Intraoperative complications did not occur and no revision surgeries were undertaken.

Conclusions: The present study demonstrated significant improvements in the KSS and specific PROMs 1 year after CIM TKA. This study suggests that CIM TKA is a safe and suitable option, which can yield good clinical outcome and PROMs at least during short-term follow-up.

No difference in patient-reported satisfaction after 12 months between customised individually made and off-the-shelf total knee arthroplasty

Wendelspiess S, Kaelin R, Vogel N, Rychen T, Arnold MP. No difference in patient-reported satisfaction after 12 months between customised individually made and off-the-shelf total knee arthroplasty. Knee Surg Sports Traumatol Arthrosc. 2022 Sep;30(9):2948-2957. doi: 10.1007/s00167-022-06900-z. Epub 2022 Feb 12.

Purpose: A subset of patients is usually not satisfied after a total knee arthroplasty (TKA). Customised individually made (CIM) TKA are deemed to overcome drawbacks of classical off-the-shelf (OTS) TKA, but evidence is still sparse. The aim of this study was to compare satisfaction of patients with CIM and OTS TKA.

Methods: This prospective cohort study compared clinical and patient-reported outcome measures (PROM) between patients with CIM and OTS TKA. The primary outcome was patient satisfaction after 12 months. Secondary outcomes were the Knee Society Score (KSS), the Knee injury and Osteoarthritis Outcome Score (KOOS), the Forgotten Joint Score (FJS-12) and the EQ-5D-3L after 4 and 12 months.

Results: Data were analysed from 74 CIM TKA and 169 OTS TKA between January 2017 and September 2020. Patients with CIM TKA were slightly younger, more often male, had a lower body mass index, a lower KSS and partially higher preoperative PROMs. Patient satisfaction after 12 months was high and comparable (CIM 87%, OTS 89%). All PROMs improved for both groups ($p < 0.001$) and did not differ after 12 months ($p > 0.063$). The majority of patients improved above the minimal important difference (range 65 to 89%) and reported a clear overall improvement (CIM 86%, OTS 87%). The postoperative KSS, notably regarding knee stability, was higher for CIM TKA ($p < 0.001$).

Conclusion: No difference was found in patient satisfaction between CIM and OTS TKA after 12 months. In both groups, patient satisfaction was high and PROMs improved considerably.

Chapter 9

Discussion and outlook

Main findings

This dissertation firstly presents the protocol for the overall project to collect routine PROMs from patients with knee arthroplasty. Embedded in the overall project were four sub-projects, each with a specific study objective. The main findings can be summarised as follows:

First, the German version of the HAAS is valid and reliable for patients after primary TKA. Translation and cultural adaption followed international guidelines and did not reveal any problems. The HAAS can be successfully self-administered and is easy to use in daily clinical practice. It is short, easy to understand and the total score is simple to calculate. In conclusion, we have shown that the German HAAS is an internally consistent, valid and reliable measure without floor and ceiling effects for patients after primary TKA.

Second, we found high patient satisfaction after two years and no differences between patients with CIM and OTS TKA. Before surgery, patients with CIM TKA had less subjective impairment and higher PROMs. At follow-up, patients with CIM TKA had a higher EQ-VAS after four months and a higher HAAS after one and two years. All other PROMs did not differ between CIM and OTS TKA with respect to end scores. Surgeon satisfaction was strongly correlated with patient satisfaction and did not differ between CIM and OTS TKA. Patients who were satisfied after two years were clearly better on all PROMs compared to patients who were not satisfied after two years.

Third, the objective KSS and knee-specific PROMs, namely the KOOS, KOOS-12 and FJS-12, are highly responsive in patients after TKA. When quantified by ES and SRM, these measures showed high responsiveness at four months, one year and two years follow-up. Analysis of the HAAS was limited by missing baseline values, but responsiveness during follow-up was comparable to the other knee-specific PROMs. Responsiveness was higher in the knee-specific PROMs, but ES and SRM in the generic EQ-5D-3L were still large to capture change over time. External responsiveness was adequate for the KOOS, KOOS-12 and FJS-12. We found floor or ceiling effects in the KOOS, KOOS-12 and EQ-5D-3L, but not in the KSS, FJS-12 and HAAS.

Fourth, patients with TKA had high preoperative expectations, which did not correlate with postoperative satisfaction. There was also no correlation between preoperative expectations and any of the pre- or postoperative outcome measures, namely KOOS,

FJS-12, HAAS, EQ-5D and KSS. Our hypothesis that patients with higher expectations would be less satisfied was not supported. Patients had high expectations before their TKAs, but these expectations did not appear to be important for postoperative outcome.

Over the course of the four sub-projects mentioned above, we have extended our set of PROMs. A final list of the PROMs applied can be found in Table 1 in the appendix.

The value, criticism and future challenges of PROMs

With the shift to a value-based and patient-centred health care, PROMs will continue to have a prominent role in outcome assessment, shared decision-making and determining the effectiveness of procedures such as TKA. In clinical trials, PROMs have taken over as the primary outcome, with less emphasis on the disease state itself and more on how the patient feels or experiences the condition and its impact on function and quality of life [106].

Although collecting PROMs can be time consuming and costly, PROMs are an important part of research projects, and even more valuable if already routinely collected. The feedback from our patients was mostly positive, despite the extra work involved in completing questionnaires on a regular basis. Patients appreciated being asked for their opinion and most took advantage of this opportunity. This is reflected in a stable preoperative response rate of around 80% over the last few years. Unfortunately, this means that one in five patients is not interested in completing PROMs before surgery, for whatever reason. It is unclear what response rate is acceptable, a rate of 60% has been recommended [168]. Maximum effort has been shown to increase pre- and postoperative response rates enormously, but it is unclear whether the additional costs are justified from a value-based health care perspective [159]. PROM completion rates also vary widely across registries, ranging from 3% to 91% [83]. This highlights the logistical difficulties of collecting PROMs from large numbers of patients. Hopefully, as technology advances and digital literacy increases, the collection of PROMs will become more convenient and more efficient in the future.

Despite their recognised value, PROMs are not without criticism. They are prone to reporting and response bias, and certain nuances that patients wish to express may not be covered. In addition, the concept of patient satisfaction is extremely heterogeneous, subjective and not straightforward to assess [119]. There is still no gold standard for

measuring patient satisfaction, and quantifying satisfaction in a valid way is challenging [125]. As with PROMs in general, unvalidated measures may provide misleading data.

The value of a single-item question on pain, function or satisfaction is controversial. A single-item knee pain VAS has been shown to sufficiently identify patients at higher risk of early revision [1]. It may also reduce patient attrition, but it may not capture the depth or nuance of patients' perspectives on surgical outcome [166], and more comprehensive surveys are needed to capture the full picture. While higher satisfaction is associated with better PROMs and greater postoperative improvement, a certain percentage of patients score poorly while reporting a high satisfaction [114]. This demonstrates the difficulty of interpreting the meaning of a single satisfaction question, as it may be biased by factors unrelated to the intervention [114].

To select the appropriate PROM and to use it in an appropriate way is of utmost importance [107]. Potential problems in the use and reporting of PROMs are common in sports research [107] and also in RCTs [88], which may affect the validity of reported results. Moreover, there is often more than one appropriate measure, and the variety of PROMs available makes comparative analysis difficult. One solution is certainly a national registry, which offers the possibility of aggregating and standardising the collection of PROMs. Comparability between registries, in terms of collection of specific PROMs, follow-up and demographics to allow adjustment for confounders, is necessary to enable comparisons between registries to improve arthroplasty care internationally [83]. Even though the Swiss Registry does not yet collect PROMs, progress is being made and projects on the implementation of PROMs are on the rise. [4,10,11]

To facilitate the interpretation of PROMs, thresholds are required to define clinically meaningful improvement to the patient such as the minimal clinically important difference (MCID), or the patient acceptable symptom state (PASS). Although now well established, there are considerable inconsistencies among MCIDs reported for PROMs in patients with TKA [45]. Consensus and standardisation on the calculation method may have implications for optimal patient selection and PROM-based quality measurement, ultimately improving patient satisfaction and outcome [22].

Despite the importance of PROMs, it is worth to recognise that additional performance measures are necessary to fully characterise the functional improvement of patients after TKA. Performance measures provide objective information on how patients actually function that is not captured by PROMs [129,191]. Just recently, a study showed significantly

faster times for all functional tests in patients with CIM TKA, while PROMs showed no differences compared to patients with OTS TKA [30].

Conclusions

We successfully introduced PROMs for TKA patients into our routine practice. We made a new questionnaire, the HAAS, available to German-speaking patients to better assess function after TKA even in more active patients. Although we found no differences in PROMs after two years between patients with CIM and OTS TKA, technical advances require research to verify their applicability. We showed that CIM TKA is an excellent alternative to achieve substantial improvement and high satisfaction. By comparing the responsiveness of PROMs, we were able to provide important guidance that could help in the selection of the appropriate PROM. We found no correlation between expectations and satisfaction. Patients had high expectations that did not seem to be relevant for postoperative outcome. However, as this is still a controversial topic, we were able to make a contribution to research. In the future, it would certainly be interesting to investigate the relationship between fulfilled expectations and satisfaction.

In conclusion, we have shown that routinely collected PROMs are powerful tools that substantially impact research and ensure a greater focus on the patients' perspective. We are confident that our project is a valuable contribution to further promote the importance of PROMs and their use in daily medical practice.

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Appendix

Table 1: Overview about measures and time of completion

Measure	Scale	Time of Completion						
		before surgery	4 months	1 year	2 years	3 years	4 years	5 years
Patient-reported outcome measure (PROM)								
Knee-specific PROM								
Satisfaction with surgery	5-point Likert scale (very satisfied, satisfied, neutral, unsatisfied, very unsatisfied)		x	x	x	x	x	x
Overall knee improvement	7-point Likert scale (very much better, substantially better, a little better, no change, a little worse, substantially worse, very much worse)		x	x	x	x	x	x
Surgery again	Yes/no		x	x	x	x	x	x
KOOS symptoms	0 (worst) to 100 (best)	x	x	x	x	x	x	x
KOOS pain	0 (worst) to 100 (best)	x	x	x	x	x	x	x
KOOS daily living	0 (worst) to 100 (best)	x	x	x	x	x	x	x
KOOS sports	0 (worst) to 100 (best)	x	x	x	x	x	x	x
KOOS quality of life	0 (worst) to 100 (best)	x	x	x	x	x	x	x
Forgotten Joint Score (FJS-12)	0 (worst) to 100 (best)	x	x	x	x	x	x	x
High-Activity Arthroplasty Score (HAAS)	0 (worst) to 18 (best)		x	x	x	x	x	x
Hospital For Special Surgery Knee Replacement Expectations Survey (HSS-KRES)	0 (lowest) to 100 (highest)	x						
Generic PROM								
EQ-5D-3L	0 (worst) to 1 (best)	x	x	x	x	x	x	x
EQ-VAS	0 (worst) to 100 (best)	x	x	x	x	x	x	x
Clinician completed								
Knee Society Score (KSS)	0 (worst) to 100 (best)	x	x	x				x
Satisfaction with surgery	5-point Likert scale (very satisfied, satisfied, neutral, unsatisfied, very unsatisfied)		x	x				x

Curriculum vitae

PROFESSIONAL EXPERIENCE

• since 01/2016	RESEARCH ASSOCIATE Practice Leonardo, Hirslanden Klinik Birshof, 4142 Münchenstein, Switzerland
• 07/2014 – 11/2015	RESEARCH ASSOCIATE asim, Insurance medicine, Research & Education, University Hospital, 4031 Basel, Switzerland
• 01/2001 – 06/2014	PHYSIOTHERAPIST Self-employed and employed, Germany

SCHOOL AND VOCATIONAL EDUCATION

• 2020 – 2023	PhD CLINICAL RESEARCH University of Basel, Switzerland PhD Thesis: Patients' perspective on function after total knee arthroplasty: analyses of patient reported outcome measures.
• 2011 – 2013	MASTER OF PUBLIC HEALTH Ludwig-Maximilians-Universität München, Germany Master thesis: Health-related quality of life is associated with physical activity in adolescents. A cross-sectional study with adolescents who are normal weight, obese and young athletes. Research internship: Obesity in children and adolescents
• 2008 – 2011	BACHELOR OF SCIENCE IN PHYSIOTHERAPY University of Applied Sciences Fulda and Philipps-Universität Marburg, Germany Bachelor thesis: Effectiveness of active exercises for CMD – a systematic review.
• 1999 – 2002	Physiotherapist education, Medizinische Berufsfachschule Klinikum Chemnitz, Germany

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