TITLE PAGE

Title of Project
Incorporating Patient-Reported Outcomes into Shared Decision Making with Patients with Osteoarthritis of the Knee

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1. STRUCTURED ABSTRACT

Background: Treatments for knee osteoarthritis (OA) range from medications and physical therapy to elective total knee replacement. Although several orthopaedic decision aids exist, few incorporate patient-reported outcomes (PROs) and machine-learning–based predictive analytics to provide a personalized approach to shared decision-making (SDM).

Methods: We conducted a hybrid type 2 study to assess both the clinical effectiveness and implementation process of a personalized machine-learning–based SDM tool in patients with knee OA. In a randomized controlled trial (RCT) at an orthopaedic practice, the intervention consisted of a patient decision aid incorporating education, preference elicitation, and a personalized risk/benefit estimate; the control group received patient education only. Patients were followed for up to 9 months. Outcomes included decision quality, conflict, and regret; functional status; and treatment concordance. We assessed implementation at a second orthopaedic surgery practice by using intervention mapping, with one-on-one interviews of patients and staff.

Results: Among 201 patients in the RCT, those in the intervention group showed higher decision quality, lower decision conflict, and lower decision regret at 6 months; higher levels of capability at 6-9 months; and greater treatment concordance. At the implementation site, patients and providers reported that use of the SDM tool facilitated a patient-centered approach to treatment planning. Time and personnel constraints were identified as challenges in sustaining SDM in clinics.

Conclusion: Machine-learning–based decision support tools can facilitate SDM in patients with knee OA considering total knee replacement.

Key Words:
Patient-reported outcomes, shared decision-making, knee osteoarthritis, machine learning, artificial intelligence, intervention mapping, implementation

2. PURPOSE

Our objective was to assess both the clinical effectiveness and implementation process of a patient decision aid for patients with knee osteoarthritis (OA) presenting to 2 orthopaedic clinics. Specifically, we sought to:

Aim 1: Evaluate the clinical effectiveness and impact of the patient-reported outcome-guided predictive analytic decision aid in terms of decision quality and treatment choice for patients with knee OA.

Aim 2: Using intervention mapping as an implementation strategy, implement and evaluate the feasibility and acceptability of the tool and process in a second clinical setting with a different clinical population, clinical group, and electronic health record.

3. SCOPE

Background

Shared decision making

Shared decision making (SDM) is a process in which clinicians and patients work together to make informed health care decisions that align with patients' preferences and values. The use of SDM is gaining traction in relation to total knee replacement (TKR) surgery vs. non-operative management for patients with osteoarthritis (OA) of the knee. OA of the knee represents a substantial proportion of the global burden of disease with cases projected to increase 75% by 2050 compared to 2020. Recent systematic reviews highlight knee OA as a growing public health concern and underscore the need for more personalized treatment plans to effectively manage growing populations experiencing this condition. Care for knee OA is largely preference sensitive and discretionary where multiple treatment options exist, including TKR surgery, which remains one of the most performed operations in the United States. By 2030, 7.4 million are expected to have an artificial knee. The decision and timing of TKR surgery is not determined exclusively by objective clinical findings, but rather by patient preferences, values, and goals, making SDM critical in the treatment decision.

In the case of TKR, SDM tools and processes are becoming available. At Dell Medical School at UT Austin, Kevin Bozic, MD, MBA, and colleagues, have been leaders in SDM in musculoskeletal care. Their prior randomized controlled trial demonstrated the effectiveness of SDM on informed decision making in patients with OA of the hip or knee, showing that patients randomized to receive decision and communication aids prior to their initial clinic visit with an orthopaedist reported significantly higher rates of reaching informed decisions and higher confidence levels in their decision compared with control-arm patients. Another recent advance in TKR decision making is utilizing machine learning to predict outcomes of TKR surgery. To this point, though, it has not been applied to patients contemplating TKR vs. non-operative treatment. Bozic and colleagues have piloted a structured, data-driven and patient-centered predictive analytic tool and process for supporting SDM, Joint Insights (OM1, Boston, USA), which was evaluated and disseminated in this project.

Implementing patient-reported outcomes in clinical decision-making

Patient-reported outcomes (PROs) are reports of the status of a patient's health condition that come directly from the patient without interpretation by a clinician or researcher. Historically, patient-reported outcome measures (PROMs) were used primarily in research, but they are gaining popularity in patient-centered care delivery. Recognition of the potential for PROMs to improve SDM by increasing engagement, helping set priorities for discussion, and providing further information to inform decision making is growing, yet evidence is lacking on how to make PROMs actionable for patient care and how best to integrate PROMs within existing clinical informatics systems. A recent survey of surgeons and researchers found that the 2 highest-priority PRO research areas were using PROMs in decision making and integrating PROMs in the electronic health record (EHR). This project assessed implementation of PROs, clinical data, and a novel machine-based learning predictive analytic tool – along with attempts to integrate it into the EHRs – at 2 different practices to inform SDM for patients with knee OA contemplating TKR surgery.

Context

UT Health Austin Musculoskeletal Institute
The UT Health Austin Musculoskeletal Institute opened in October 2017 and, from its inception, has measured general and condition-specific PROs on every patient. Patients with knee pain complete the Patient Health Questionnaire-2 (a 2-item screener for depression, which triggers a more comprehensive PHQ-9 on a positive screen), the Generalized Anxiety Disorder-2 (a screener for anxiety, which triggers a GAD-7 when positive), the PROMIS Global (a general health measure), and the Knee injury and Osteoarthritis Outcome Score for Joint Replacement (KOOS JR). PROMIS Global-10 is a 10-item measure assessing health-related quality of life with

items about overall physical and mental health including social connections and physical capabilities. The KOOS, JR is a 7-item measure of knee joint-related stiffness, pain, and function; interval scores range from 0 to 100, with 0 representing poorest knee health and 100 best knee health. These PRO assessments are completed by patients in English or Spanish using a third-party PRO tool vendor either before the clinic visit via e-mailed links to the surveys or upon arrival to the clinic, where they are collected on iPads. Scores are then inputted automatically into the Athena EHR for review and use by patients and providers.

Clinicians at the Musculoskeletal Institute have begun to incorporate PRO scores into a standalone prognostic tool for SDM (Joint Insights) regarding operative vs. non-operative treatment for patients with knee OA. Joint Insights uses the PRO scores and clinical data to estimate the probability of a successful clinical outcome with TKR. Specifically, the tool generates a report that shows the likelihood of improving after surgery, likelihood of not improving or getting worse, and likelihood of experiencing complications from surgery. The tool also shows the chance of improvement of specific symptoms such as knee stiffness and overall knee pain. The patient and provider then use this information to arrive at an appropriate treatment course. A limitation of the PRO collection process and prognostic tool, however, is that they have not been fully integrated into the EHR, presenting systems issues that need to be addressed and tested across multiple EHRs before scaling and spreading this technology.

UT Heath San Antonio Medical Arts & Research Center
Prior to this project, PROM use at the UT Health San Antonio orthopaedic practices was in the formative stages, and the predictive analytic tool was not available there. Furthermore, UT Health San Antonio uses a different EHR, Epic. An advantage of Epic is its patient-friendly portal, MyChart, through which PROs can be collected in advance of the visit; alternatively, PROs can be collected via tablets or by paper and pencil during the clinic visit. Although UT Health San Antonio was primed to adopt more widespread use of PROMs and tools to guide SDM, successful implementation requires a clinician to champion its use; informatics support; and additional workflow considerations.

Setting

UT Health Austin Musculoskeletal Institute
The Musculoskeletal Institute averages about 12 new patients presenting with knee OA per week. Patients are seen by a care team that may include an associate provider (nurse practitioner), physical therapist, social worker, nutritionist, and/or surgeon depending on the patient's needs. Approximately 60% are women, 50% of patients are part of the Medical Access Program (MAP), which provides access to care for uninsured low-income residents of Central Texas, and 32% are Spanish-speaking.

UT Heath San Antonio Medical Arts & Research Center
This clinic has 1 orthopaedist who performs the vast majority of the TKR surgeries. This clinic sees approximately 16-26 new patients with knee OA per week, in addition to returning patients with OA. As in Austin, approximately 61% of patients are women, but in contrast to Austin, only 2% are uninsured and 12% report that Spanish is their primary language.

Participants

Aim 1 (to evaluate the clinical effectiveness and impact of the PRO-guided predictive analytic decision aid) was conducted at UT Health Austin. We recruited 222 new adult patients seeking care for OA-related knee pain between February 2021 and November 2022. Inclusion criteria were age between 45 and 89 years, fluency in English or Spanish, a primary diagnosis of advanced knee OA (determined using radiographic Kellgren-Lawrence [KL] grade 3 or 4 where grade 0 represents no OA and grade 4 severe OA), ability to provide informed consent, and medical fitness for possible TKR. Further, only patients with a body mass index (BMI) between 20 and 46 kg/m^2, and baseline KOOS JR between 0 and 85 were included. The limits for age, BMI, and KOOS JR scores were set based on threshold requirements for the computational model within the

machine learning-based decision aid. Patients with knee problems due to other conditions (e.g., trauma, rheumatoid arthritis, inflammatory arthropathy); advanced OA affecting other lower extremity joints requiring care first; any prior lower extremity total joint arthroplasty involving the hip, knee, or ankle; and prior musculoskeletal care for OA by an orthopaedic specialist, were excluded.

For Aim 2 (implementation and evaluation of PRO collection and predictive analytic tool implementation) at UT Health San Antonio, we enrolled 25 new patients with knee OA pre-PRO and tool implementation and another 25 new patients post-PRO and tool implementation. We also interviewed an orthopedic surgeon, nurse practitioner, orthopedic residents and medical assistants, with a total of 7 interviews pre-implementation and 5 post-implementation.

4. METHODS

Study Design

We undertook a 2-site study utilizing a hybrid type 2 study design to assess both the clinical effectiveness and implementation process of PRO collection and the machine learning-based predictive analytic tool for SDM. This mixed-method study of a PRO-guided predictive analytic tool included a randomized controlled trial (RCT) of effectiveness, as well as semi-structured interviews with providers.

Aim 1: For the RCT, all new patients with knee OA were approached to enroll in the clinical effectiveness. The enrollment target was 180, but to account for loss to follow-up, we aimed to enroll 200. The intervention arm received both educational material and a personalized report of their chances of improvement with TKR, whereas the control group received just the educational material.

Patient-level data collected included demographic data (age, sex, and race/ethnicity), clinical data (BMI and medical comorbidities), and the PROMs: PHQ, GAD, PROMIS, and KOOS-JR. The full machine learning-based decision analytic tool includes 3 modules within a software platform: digital patient education (knowledge module), interactive preference assessment (preference module), and a machine-learning model that generated person-specific estimations of risks, benefits, and treatment outcomes (forecasting module). The primary outcome measure was the Knee OA Decision Quality Instrument (K-DQI). Secondary outcome measures included the CollaboRATE survey (assessing collaborative decision-making), Decision Conflict Scale (DCS), Decision Regret Scale (DRS), the KOOS JR score (assessing level of capability at 3 months and 6-9 months follow-up), numerical rating scales for patient and provider satisfaction with the consultation, consult duration in minutes, TKR rates, and treatment concordance.

We stratified patients who enrolled in the RCT on 3 variables known or suspected to be highly predictive of decision quality and/or treatment choice: ethnicity (Hispanic/non-Hispanic), insurance (MAP/non-MAP), and day of clinic visit (surgeon 1’s clinic day vs. surgeon 2’s clinic day). This stratification ensured balance of these 3 variables between intervention and control groups over time and within stratum. A random block-size randomization strategy was utilized within each stratum with blocks of 4 or 6 to assign patients to either the intervention or control group.

Aim 2: At UT Health San Antonio, we conducted baseline interviews with providers and staff to assess needs and identify likely barriers and facilitators in accordance with intervention mapping. Then, at the time of tool roll out, we interviewed providers, clinic staff, and patients to assess their perspectives on feasibility; acceptability; perceived barriers and facilitators; and preferences for the tool’s integration into workflow and the EHR (e.g., location, linkage to other data). Patient, provider, and staff interviews were audio-recorded for transcription and analysis.

Evaluation was guided by the Consolidated Framework for Implementation Research (CFIR), a widely-used conceptual framework that describes key factors impacting implementation success across 5 domains: 1) intervention characteristics; 2) inner setting (e.g., within the clinic); 3) outer setting (e.g., patient needs and

resources); 4) characteristics of individuals involved (e.g., providers and patients); and 5) the implementation process. We created structured summaries from transcribed recordings to capture the emergence of CFIR domains and constructs from provider, staff, and patient perspectives. We then transposed domain content from summaries into a matrix to allow for structured content comparison across participants and domains (i.e., matrix analysis), an effective method for rapid and rigorous summary of findings to aid in formative and implementation evaluation. In accordance with intervention mapping, we then identify key barriers and facilitators emerging across each CFIR construct identified, separating out by stakeholder group (clinic staff, providers).

5. RESULTS

Principal Findings

Aim 1

We analyzed data from a final total of 201 patients (101 patients in the intervention group (mean [SD] age 64.9 [10.1] years; 53.5% women); 100 patients in the control group (mean [SD] age 63.4 [8.0] years; 60% women). Patients in the intervention group showed higher decision quality (mean [SD] K-DQI process score 84.4 [25.2] versus 71.4 [29.8], P=0.0011). In addition, patients in the intervention group showed lower decision conflict (DCS score 1.0 [3.1] versus 3.3 [5.8], P=.0029), lower decision regret at 6 months (DRS score 18.2 [19.5] versus 27.2 [24.2], P=0.0051), increased levels of capability at 6-9 months (KOOS JR interval score 69.5 [17.3] versus 47 [18.4], P<0.0001), and greater treatment concordance (91.1% versus 76%, P=0.0043) compared with the control group. In the intervention group, levels of collaborative decision-making, capability at 3 months, patient and clinician satisfaction, consult duration, TKR rates, and decision regret at 3 months were not significantly different from the control group (CollaboRATE score, 25.6 [3.9] versus 25 [3.6]; KOOS JR interval score at 3 months, 51.4 [20.1] versus 48.3 [17.4]; NRS patient satisfaction 9.7 [1.2] versus 9.5 [1.1]; NRS clinician satisfaction 9.2 [1.1] versus 9.1 [1.3]; consult duration (minutes) 24.0 [10.7] versus 22.5 [10.6]; TKR rate 24.8% versus 15.0%), and decision regret at 3 months (DRS 3 months 22.4 [20.0] versus 25.9 [20.4]).

Aim 2

Patients

Patients had similar priorities and hopes for knee OA management in both pre- and post-implementation phases of the SDM tool. Prior to implementation, patients typically reported satisfaction with their provider and with the treatment planning course as decided by the provider during the clinic visit. A key theme in the patient data, however, was the lack of discussion of rehabilitation and other non-surgical therapy as an important component of knee OA management. In contrast, post-implementation, patients indicated that providers gave a thorough explanation of all the treatment options available, including non-surgical options. They felt the use of the SDM tool and its output helped them ask more questions to the providers and provided them an opportunity to participate in the treatment planning process. Patients typically found the education material to be very detailed and supportive of decision making but indicated that it would have been helpful to have more time to read and process the information. They suggested inputting their information into the tool prior to coming to the clinic, rather than at the clinic.

Providers

Prior to implementation, providers expressed enthusiasm in the use of PROMs and SDM in their practice but anticipated difficulty with implementation given the need to move patients through their busy clinic quickly. Providers generally felt that patients' needs were being met under the pre-implementation care model, however, so they had a mixed perception of the relative advantage of adding the SDM tool. Post-implementation, providers indicated that the scores helped them prepare for the conversation with patients.

Depending on the individual patient's PRO scores, they anticipated either shorter or longer conversations to discuss the appropriateness of a surgical procedure vs. non-surgical options. Providers felt that the tool had the potential to be used to triage patients to improve the efficiency of their clinic. When there was concordance between the scores and treatment decision, it was anticipated to be helpful from a medico-legal standpoint. Key challenges identified to implementing and sustaining the SDM tool and process in the clinic were lack of time and the need for dedicated staff to help administer the tool. Providers also expressed limited understanding of the machine-learning algorithm powering the tool, making it challenging to discuss the scores with the patients. Integrating the tool into the EHR and providing the materials to patients to complete prior to the visit were seen as potential solutions to reduce provider burden.

Integration of Joint Insights into the Austin EHR (Athena)

While we did not achieve a full integration of the solution, we made substantial steps toward this end and are close to a "go live" of the integrated tool. Technical integration of Joint Insights was completed and validated as of December 13, 2024. The next step is a Go-Live Risk Assessment. Once completed, the integrated version will go live in early 2025, pending leadership approval and sign off. Steps completed to get to this point include:

- Technical integration
    - Navigating data transfer requirements between Joint Insights and Athena to enable generation of the personalized report.
    - Development of a final clinic / EHR version of the personalized report.
- Clinical integration
    - Pathway mapping to ensure Joint Insights can run seamlessly within the current clinic flow resulted in the final plans for
        - The pre-clinic team huddle to highlight in advance all patients appropriate for Joint Insights
        - Medical Assistants / in-clinic fellows to ensure these patients are given the application via an iPad (and these team members to be able to respond to any error messages stating data are missing so they can correct it)
        - Orthopaedic surgeons to initiate the order (push) to generate the report.

The integrated tool allows for the following:

- The patient's Joint Insights report is made available to the provider as a lab order within the EHR. The EHR integration enables "digital labs" (i.e., "lab" results based on digital inputs that can be provided purely via a machine interface) as a new function within the EHR.
- Patient information for the digital lab order is provided without adding to the provider's work burden: Relevant inputs are read directly from the data entered into the EHR during the clinical encounter.
- Measures are computed from answers collected directly from patients via a PRO software experience, collected during the visit or prior to the visit
- Data collected from PRO software is directly funneled into the patient's record, requiring no intervention from the provider staff.
- The Joint Insights "digital lab" report is computed within moments of the lab request using a new API-based implementation, hosted by OM1. The report is delivered to and stored in the patient's EHR record and can be viewed by the provider within moments of the request by the provider's office.
- A patient education + knowledge assessment module is made available within the PRO experience. Results can be viewed in the EHR.
- This integrated EHR implementation can be leveraged for other digital lab reports, supporting other clinical applications for surgery or other treatments and interventions.

Limitations

Integration of the tool into the EHRs at both sites took much longer than anticipated, due to a confluence of factors. First, due to the Covid-19 pandemic, our IT teams were focused on projects prioritizing Covid testing, treatment, and vaccination. The UT Austin IT team also experienced substantial staff turnover during the first part of the project period, impacting our ability to make progress on an implementation plan. Finally, we worked with our IT team and OM1 to navigate Texas requirements for security assessment for Texas state agencies (the Texas Risk and Authorization Management Program or TX-RAMP). Realizing that integration of the tool would take substantially longer than anticipated, we began the RCT before tool implementation into the EHR began. The entire RCT was conducted with the stand-alone tool and integration did not begin until the final year of the project. Note that this limitation does not affect the integrity of the RCT but rather made conducting the trial more burdensome to our research team. Similarly, in San Antonio, we conducted the tool incorporation and evaluation part of the project using the stand-alone web-based version of the tool.

Discussion

The management of advanced knee OA can be improved by incorporating a more personalized approach to treatment selection utilizing SDM combined with self-reported data on health outcomes provided by PROMs. The decision-making process can be further augmented by incorporating machine-learning-based tools, such as Joint Insights, to provide personalized predictions of health outcomes following TKR. This data-driven and technology-enabled approach can augment the SDM process as demonstrated in this study where the predictive analytic tool showed improved decision quality and levels of medium to longer term knee capability of knee OA compared with patient education only. Challenges involved with disseminating and implementing use of PRO collection, predictive analytic tool integration, and SDM in this study can guide future widespread implementation efforts.

6. LIST OF PUBLICATIONS and PRODUCTS

Conference Abstracts

Poster Presentations

Prasanna S, Tsevat J, Wang A, Lill S, Finley E. Patient and provider goals in treatment planning for knee osteoarthritis - a case study. AcademyHealth Annual Research Meeting, Washington, DC, June 2022.

Trutner Z, Uhler L, Aksan N, Custer J, Bozic K, Jayakumar P, Tsevat J. Decision regret and health outcomes among patients with knee osteoarthritis following use of a technology-enabled patient decision aid. Society for Medical Decision Making, Seattle, WA, October 2022.

Prasanna S, Tsevat J, Romero R, Jayakumar P, Uhler L, Lill S, Brunner J, Finley E. Factors impacting readiness for implementation of an electronic shared decision-making tool for knee osteoarthritis: A tale of two orthopedic surgery clinics. AcademyHealth 16th Annual Conference on the Science of Dissemination and Implementation, Washington, DC. December 2023.

Jayakumar P, Hortert A, Sayegh G, Uhler L, Koenig KM, Rathouz P, Bozic KJ. Comparing AI-enabled personalized decision support versus educational material on decision quality, shared decision-making, patient experience, and levels of capability in adults with knee osteoarthritis considering joint replacement surgery: a randomized clinical trial. Accepted for presentation at the American Academy of Orthopaedic Surgeons 2025 Annual Meeting, San Diego, CA. March 10-14, 2025

Symposia/Panel Presentations

Jayakumar P. Transforming the User Experience in Orthopaedic Care using Artificial Intelligence, Mixed Reality, and Digital Phenotyping: TechTalk. American Academy of Orthopaedic Surgeons (AAOS), Chicago, IL. March 2022.

Shah R, Jayakumar P, Trutner Z, Bini S. Practical Artificial Intelligence; Realistic Ways It Can Help Orthopaedic Surgeons and the Challenges It Will Face. American Academy of Orthopaedic Surgeons (AAOS), Las Vegas. March 2023. Instructional Course Lecture 2023;72:101-110. PMID: 36534850

Jayakumar P et al., Artificial Intelligence: Transforming Management of Musculoskeletal Conditions Across the Care Continuum. Computer Assisted Orthopaedic Surgery (CAOS), Groningen, Netherlands. June 2024.

Jayakumar P et al., Clinical Applications of AI in Orthopaedics and Surgery. Artificial Intelligence and Sarcoma Care Session. International Society of Limb Salvage. Brisbane, Australia. October 2024.

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Manuscripts

Published:

Lin E, Uhler LM, Finley EP, Jayakumar P, Rathouz PJ, Bozic KJ, Tsevat J. Incorporating patient-reported outcomes into shared decision-making in the management of patients with osteoarthritis of the knee: a hybrid effectiveness-implementation study protocol. BMJ Open. 2022 Feb 21;12(2):e055933. doi: 10.1136/bmjopen-2021-055933. PMID: 35190439.

Ready for submission to a peer-reviewed journal:

Jayakumar P, Lin E, Trutner Z, Uhler LM, Koenig KM, Tsevat J, Rathouz P, Bozic KJ. Advancing Shared Decision Making in Osteoarthritis Care using ‘digital twins’: A randomized clinical trial comparing an AI-enabled decision aid versus patient education on decision quality, capability, and user experience.