DIGITAL CARE PATHWAY
for Total Knee Arthroplasty

Value Analysis Brief

ZIMMER BIOMET

Table of Contents

1. Executive Summary

Osteoarthritis (OA) of the knee is a progressive disease affecting approximately 15 million Americans, half of whom will eventually undergo total knee arthroplasty (TKA).[1,2]

To date, more than 754,000 TKA procedures are performed annually and predicted to rise to 1.27 million by 2025.[3,4]

The fastest growing TKA demographic is patients 50 to 65 years of age, who account for over 40% of all procedures[5-7] (Figure 1). These patients pose a long-term challenge due to activity demands, extended follow-up, and current limitations of implant survivorship.[8-10]

Changing Demographics[5]

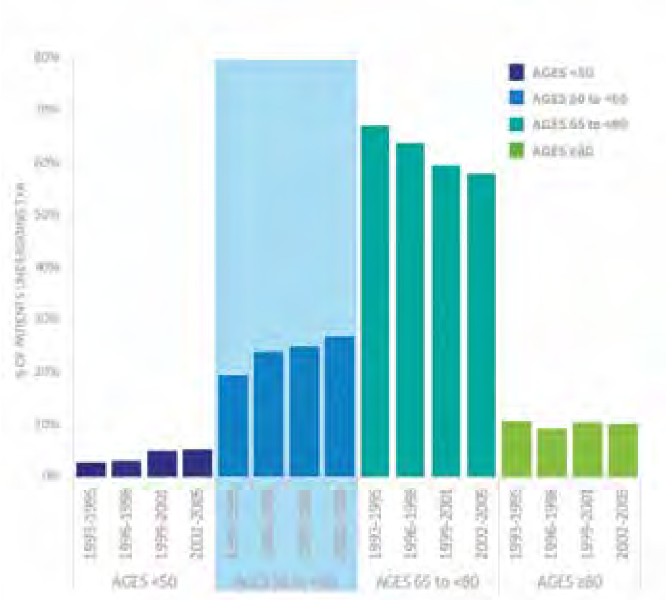

Figure 1

Moreover, despite the effectiveness of TKA, 30% to 40% of patients report reluctance or unwillingness to undergo the procedure, which may be addressed by consultation with a surgeon and education on the procedure and expected outcomes.[11-13]

Post-operative complications (e.g., pain, stiffness, and swelling) are common following TKA, affecting over 50% of patients.[14, 15] Despite advancements in surgical techniques and implants, post-TKA patient dissatisfaction has shown little improvement.[21] With the ongoing shift from fee-for-service to pay-for-performance reimbursement in joint arthroplasty, patient experience—and integration of patient-generated data—will be a key differentiator for healthcare providers.[24-28]

- **In ~4% of patients, persistent knee stiffness requires manipulation under anesthesia (MUA),** a procedure that can improve range of motion (ROM) if performed early (10-12 weeks);[80,82,83] however, patients who undergo MUA are 2 to 3 times more likely to eventually require a revision TKA.[16-18]
- **Revision TKA, which accounts for ~8% of all TKA** procedures, poses a substantial clinical burden to patients, particularly younger, active patients, who may require multiple revisions over their lifetime.[7,8,19,20]
- **Overall, 1 in 5 patients report dissatisfaction with their TKA procedures,** with even higher rates (1 in 4) reported by patients <55 years.[21-23] Despite advancements in surgical techniques and implants, post-TKA patient dissatisfaction has shown little improvement over the previous 15 to 20 years.[21]

TKA is associated with a considerable economic burden, as US hospital **expenditures total nearly $30 billion annually.[29]**

Revision TKA is particularly costly, with higher hospital costs and healthcare resource use (HCRU) than primary TKA.[30] Although hospitalization is a key driver of costs, post-acute care accounts for nearly half of total episode-of-care costs,[31-33] and traditional physical therapy (PT) services comprise ~80% of 90-day outpatient costs.[34,35]

Reduced profit margins for TKA present an increasing challenge to hospitals, due to bundled payment models and reduced reimbursement rates.[36,37] However, while implementation of bundled payment plans has decreased post-acute care costs, these costs still accounted for ~42% of total episode-of-care costs as of 2016.[31] Initiatives to reduce post-acute care costs can require a substantial investment for providers (e.g., pre-operative protocol optimization, peri-operative education, and interdisciplinary communication), but these costs are often not reimbursable.[31,38]

Evolution of the TKA care pathway, including the trend towards reduced length of stay (to a mean 1.7 days), the disproportionate burden of in-person rehabilitation, and increased patient demand for digital health services, highlights the need for more integrated and effective post-TKA follow-up.[19,27,32,39,40] Patients increasingly prefer and expect digital engagement in the healthcare setting, a trend accelerated by the COVID-19 pandemic, but availability of these services has lagged demand.[37,41-43] Effective digital care pathways can directly improve patient experience, a key driver of value-based reimbursement (e.g., comprising 20% of the total Value-Based Purchasing [VBP] score under the CMS pay-for-performance reimbursement model), and impact outcomes that matter to patients, such as earlier discharge, home recovery, and earlier return to activity.[24,41,42,44] Patient satisfaction also impacts physician satisfaction and retention,[45,46] which is increasingly relevant as burnout rates among orthopedic surgeons approach 70%, and streamlining daily workflow (e.g., via technology) offers a promising strategy for reducing burnout.[47-50] From the provider perspective, bundled payments and value-based reimbursement may further incentivize investment in technology with the potential to improve quality reporting metrics.[51-53]

To address the need for digital care pathways in joint arthroplasty, Zimmer Biomet has developed ZBEdge™ Dynamic Intelligence™ with the power to elevate and unlock the full potential of Zimmer Biomet's cutting-edge suite of integrated digital technologies, robotics and implant solutions.

- **The mymobility® Care Management Platform** connects providers with their patients for pre-operative engagement, post-operative check-ins, and remote monitoring of metrics, such as mobility and gait quality, exercise adherence, and heart rate*.[56] Patients who used mymobility required fewer 90-day PT visits, readmissions, and ER visits versus those who received conventional engagement, with comparable clinical outcomes.[58]
- **The ROSA® Robotics System** is designed to enhance the accuracy and reproducibility of joint arthroplasty procedures by assisting with pre-operative preparation, bone resection, positioning of implant components. Connectivity features include an application programming interface (API) and digital recording/hand-off of applied resection techniques.[59]
- **The OrthoIntel Orthopedic Intelligence Platform** provides interactive and customizable reports for the data collected in ZBEdge, allowing clinicians to explore the direct impact of pre-operative and intra-operative data on outcomes.[55]

*Heart Rate Data is collected by Apple Watch® and is displayed in the mymobility app.

Persona IQ, the latest digital innovation within ZBEdge Dynamic Intelligence, is a first-to-world smart knee implant that collects and transmits meaningful post-operative gait metrics.[60,63]

Persona IQ features a 3D accelerometer and gyroscope designed to automatically capture objective kinematic data (Figure 2) for at least 10 years post-surgery, providing an adjunct to other physiological parameters assessed by the physician to support the goal of patient compliance.[60,61]

The objective kinematic data from Persona IQ is automatically available and accessible through the mymobility Care Management Platform for both patients and providers to review post-operatively.

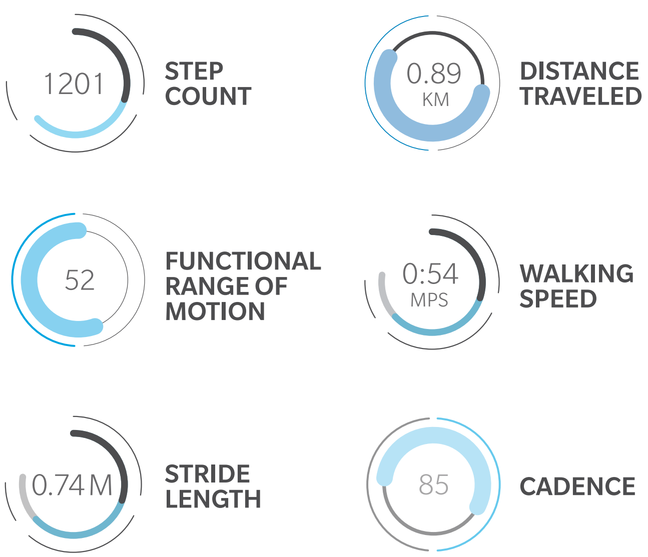

Figure 2

Connected digital TKA care pathway technologies also support remote patient engagement and collection of holistic healthcare data. This connectivity is particularly critical given that 90% of post-operative recovery takes place outside the purview of healthcare providers.[62]

- Remote patient engagement prior to joint arthroplasty can significantly shorten post-operative length of stay (LOS) and improve patient compliance with follow-up, compared to conventional pre-operative preparation.[40,62]
- Remote guidance and follow-up after joint arthroplasty can significantly reduce rehospitalizations, complications, and costs (up to 61% decrease)[33] compared to standard in-person follow-up.[40,63,64]

Patients report high satisfaction and compliance with remote monitoring, describing the devices as "motivating" and noting savings in time and money.[65-67] Clinical parameters collected remotely by mobile sensors (e.g., gait variables) after joint arthroplasty procedures have also been found to correlate with patient satisfaction and patient-reported outcomes (PROMs).[67-69] Thus, remote collection of post-operative data can facilitate analysis of patient recovery while streamlining follow-up care, reducing the burden on patients and providers.[67-70]

Zimmer Biomet is committed to maintaining patient privacy and ensuring data security. Patients and providers retain ownership of their own data, which is used only for agreed upon services and purposes compatible with providing those services. Patient and provider data is protected by robust safeguards, including encryption in transit and at rest, scheduled security risk assessments, and third party penetration testing.

ZBEdge has not been evaluated for clinical or economic outcomes, and none of the products in ZBEdge were utilized in the studies cited in this section. mymobility or Persona IQ were not evaluated in these studies as it relates to Remote Patient monitoring.

WARNING - The kinematic data from this device have not been demonstrated to have clinical benefit. It is not intended to be utilized for clinical decision-making, and no data have been evaluated by FDA regarding clinical benefits.

2. Total Knee Arthroplasty Market

Key Takeaways:

- ◊ Osteoarthritis (OA) of the knee is a progressive disease affecting approximately 15 million Americans, half of whom will eventually undergo Total Knee Arthroplasty (TKA).[1,2]
- ◊ Utilization of TKA in the US continues to accelerate, with the number of TKA procedures predicted to rise from 754,000 in 2017 to 1.27 million by 2025.[3,4]
- ◊ Younger adults (<65 years of age) represent the fastest growing demographic, accounting for over 40% of all TKAs.[5-7]
- ◊ Younger patients present a challenging demographic for long-term TKA outcomes, due to increased activity demands, the need for extended follow-up, and existing limitations of implant survivorship.[8-10]
- ◊ Despite the effectiveness of TKA, approximately 30% to 40% of patients report reluctance or unwillingness to undergo the procedure; consultation with a surgeon and education on the procedure and expected outcomes have been linked to increased patient willingness.[11-1]

2.1 Epidemiology of Osteoarthritis

Osteoarthritis (OA) is the most common form of arthritis and a leading cause of disability in the US.[71,72]

- Approximately 15 million Americans are affected by symptomatic OA of the knee, including nearly 9 million with advanced knee OA.[2]
- The overall prevalence of OA in the US is increasing, and this trend is expected to continue given aging and obesity projections.[73]

Knee OA is a progressive disease, and it is projected that **approximately half of all patients will eventually undergo a TKA.**[1]

- In 2017, more than 754,000 TKA procedures were performed in the US; by 2025, this number is predicted to rise to 1.27 million.[3,4]
- Approximately 30% to 40% of patients report reluctance or unwillingness to undergo TKA. Key factors contributing to willingness include understanding of the procedure, expectations for surgical outcomes (e.g., expecting a shorter hospital stay), and consultation with a surgeon.[11-13]

The overall incidence of TKA procedures is projected to rise to 1.27 million by 2025.[3,4]

2.2 Changing Demographics

Working age adults (18 to 64 years) account for over half of all patients with OA in the US.[74]

- The prevalence of knee OA increases with age, leading to a 9.3% cumulative risk of developing symptomatic knee OA by the age of 60.[75]
- The majority of patients with OA are between 18 and 64 years of age (57.4%), totaling 18.5 million working age adults, and approximately 5.7 million with OA of the knee.[74]

Utilization of TKA in the US continues to accelerate, and **adults <65 years of age represent the fastest growing demographic,** accounting for over 40% of all TKAs[5-7] (Figure 3).

Changing Demographics[5]

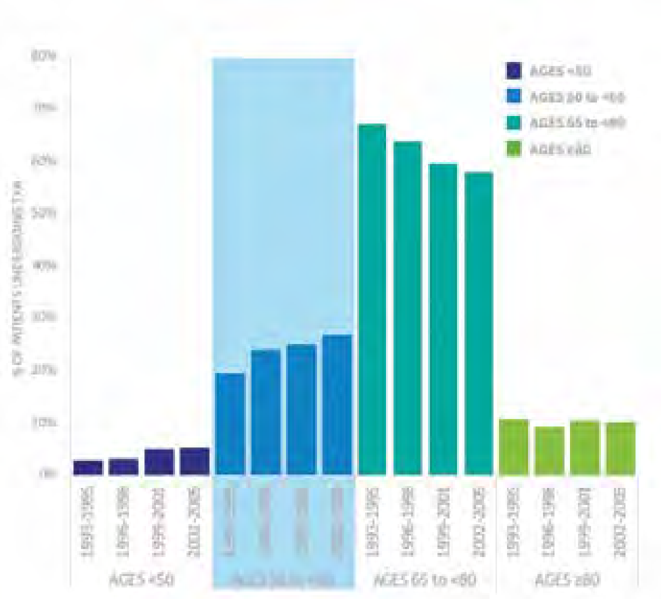

Figure 3

- Based on analysis of data from the Nationwide Inpatient Sample (NIS), TKA utilization increased dramatically in the US between 1999 and 2008, with utilization more than doubling among the overall population and tripling among individuals aged 45 to 64. In 2008, 43% of all TKA procedures (N=615,050) were performed in patients aged 18 to 64 years.[6]

- Another study based on NIS data found that primary TKA utilization increased substantially in patients <65 years of age between 1993 and 2006, from 25% to 41%. Based on existing trends, patients <65 were projected to account for 55% of primary TKAs by 2030.[7]

- Analysis of data from the Mayo Clinic Total Joint Registry (N=7,229) also showed an increase in the proportion of patients <65 years undergoing primary TKA over a period of 13 years (1993 to 2005), from 22.4% to 31.9%. The proportion of patients <50 years of age also increased significantly, from 2.9% to 5.2% ($p<0.001$).[5]

- A US claims analysis reported a decrease in the mean age of patients who underwent primary TKA between 2007 and 2016 (from 68.3 years in 2007 to 66.7 years in 2016; $p=0.003$).[31]

- Analysis of data from the Canadian Joint Replacement Registry indicated that the largest increase in TKA rates between 2006 and 2007 occurred in the 45- to 65-year age group.[76]

Younger patients present a challenging demographic for long-term TKA outcomes, due to increased activity demands (e.g., return to work, sports, etc.) and the existing limitations of implant survivorship.[8-10]

TKA utilization has shown greater racial diversity in recent years, potentially reflecting improved access to care in under-served demographics.[77]

- A study assessing the national trends of primary TKA using the NIS database found that the proportion of TKA recipients who belonged to minority groups increased between 2009 and 2015 in the US:[77]
  - o Black patients: 2.3% increase ($p<0.001$)
  - o Hispanic patients: 1.7% increase ($p<0.001$)
  - o Asian or Pacific Islander patients: 1.0% increase ($p<0.001$)

TKAs are increasingly performed in younger adults (<65 years) who require longer-term follow-up and support.

3. Clinical Burden of Total Knee Arthroplasty

Key Takeaways:

◊ More than 50% of patients who undergo TKA experience post-operative complications (e.g., persistent pain, stiffness, and swelling,[14,15] and up to 20% of patients report that their knee does not feel "normal," commonly associated with mid-flexion instability.[78,79]

◊ Stiffness of the knee, a common post-TKA complication, requires manipulation under anesthesia (MUA) in approximately 4% of patients;[18,80,81] this percentage increases to over 10% in patients <45 years of age.[16-18]

◊ MUA improves range of motion (ROM) if performed early, but function of the knee remains inferior to the general arthroplasty population.[80,82,83]

◊ Patients who received MUA were 2 to 3 times more likely to undergo revision TKA[18,81]

◊ Early causes of TKA failure have shifted from primarily implant-dependent to more surgeon-influenced mechanisms, which can be improved with surgical training, connected (intelligent) instrumentation, and access to real-time patient data.[19,84-88]

◊ Revision TKA, which accounts for approximately 8% of all TKA procedures, poses a substantial clinical burden to patients.[7,8,19,20]

◊ The burden of revision TKA is particularly acute in younger, more active patients, who may require multiple revisions over their lifetime due to the survivorship limitations of TKA implants.[7,8,20]

◊ Approximately 20% of patients report dissatisfaction with their TKA procedures, due to suboptimal clinical outcomes and poor alignment of outcomes with expectations; rates of dissatisfaction are higher in younger patients (<55 years of age), 25% of whom are dissatisfied following TKA.[21-23]

◊ Despite advancements in surgical techniques and implants, little improvement has been observed in levels of post-TKA patient dissatisfaction.[21]

◊ With the ongoing shift from fee-for-service to pay-for-performance reimbursement in joint arthroplasty, patient experience will be a key differentiator for healthcare providers.[24,25]

◊ Integration of patient-generated data is critical to improving patient outcomes across the continuum of care,[26-28] and remote patient monitoring, in particular, has demonstrated potential to holistically identify and manage post-operative risks following joint arthroplasty;[28] however, gathering such data has been done in only a limited and investigational capacity.

3.1 Post-operative Complications

Post-operative **complications occur in more than half of TKA patients,** ranging from persistent pain, stiffness, instability, and swelling, to surgical site infection, blood loss, and thromboembolism.[14,15,79]

- A retrospective cohort study assessed electronic medical records of 1,552 patients who underwent orthopedic surgery in 2010 at the University of Michigan Health System. The most commonly reported adverse event in TKA recipients (n=252) was prolonged pain, which affected nearly one-third of patients.[14]
- Up to 20% of patients report that their knee does not feel "normal" following TKA, which is commonly associated with mid-flexion instability.[78,79]

- An Australian registry study that retrospectively assessed data from 5,662 patients who underwent TKA between 2012 to 2018, showed that 53.6% of TKA recipients reported complications (14.4% major; 46.6% minor). Minor complications included joint stiffness (18.5%), swelling (15.6%), and paraesthesia (15.6%), while the most common major complications were arthroplasty-related readmission (6.0%) and reoperation (2.5%).[15]
  - o Readmissions were due to infections (2.1%), manipulation under anesthesia (1.9%) and deep vein thrombosis (0.4%).[15]
  - o Reoperations were due to joint stiffness (1.5%) or infection (0.5%).[15]

Stiffness is a common post-operative complication of TKA **requiring MUA in approximately 4% of patients,** a procedure often linked to suboptimal rehabilitation.[18,80,81]

- Reduced ROM at discharge (total ROM <90°) is treated with MUA[80] in approximately 4% of TKA recipients.[18,81]
  - o A Norwegian retrospective study of patients treated with MUA following primary TKA (n=23) reported a median total ROM at discharge of 70°.[80]
  - o A retrospective study of the Pearl Diver patient record database (Sambandam et al. 2022; n=232,014 patients who underwent TKA in the US between 2010 and 2018) reported that 3.9% of patients required MUA within 1 year.[18]
  - o An earlier retrospective study of the Pearl Diver patient record database (Werner et al. 2015; n=141,016 patients who underwent TKA in the US between 2005 and 2011) reported a similar trend, with 4.2% of patients receiving an MUA 6 months post-TKA.[81]
- MUA improves ROM, particularly if performed early, but function often remains inferior to the general arthroplasty population.[80,82,83]
  - o A retrospective cohort analysis of patients who underwent primary TKA (N=4,581) at a specialist joint replacement center in the UK between 1996 and 2006 evaluated the effectiveness of early (<20 weeks; n=56) vs late (>20 weeks; n=30) MUA, finding a significantly higher flexion gain at 1 year post-MUA in the early MUA group vs the late MUA group 1 year (p=0.003).[82]
  - o In the Norwegian retrospective study described above, total ROM was improved at a mean 2.5 years following MUA (p<0.001), and regression analysis showed a significant correlation between time to MUA and subsequent improvement (i.e., earlier MUA improved outcomes); however, despite improvement in ROM, patients did not achieve normal knee function at follow-up.[80]
- Patients who undergo MUA also report more pain than those who did not undergo MUA.[89]
  - o A German retrospective study of patients treated with post-TKA MUA between 2009 and 2011 (N=51) found that patients reported significantly more pain at 7 days following MUA than a matched-pair control group of TKA recipients who had not received MUA (p=0.018). At final follow-up (approx. 3 years post-TKA), fewer patients from the MUA group reported complete lack of pain vs the control group (28.1% vs 75.7%, respectively; p=0.001), significantly higher proportion of patients required pain medication (78.1% vs 16.2%, respectively; p<0.001).[89]
- Post-TKA **stiffness and MUA are more common in younger patients,** with MUA rates over 10% in patients <45 years of age.[16-18]
  - o Based on the most recent US data (Sambandam et al. 2022), retrospective assessment of patients who underwent MUA within 1 year following TKA (n=9,156 patients) found that MUA rate decreased as age increased, with the highest MUA rate observed in patients aged 40 to 44 years (11%) and the lowest MUA rate in patients aged 80 to 84 years (0.8%).[18]

- o A prospective study using data from the Michigan Arthroplasty Registry Collaborative Quality Initiative registry of patients who underwent primary TKA between 2014 and 2018 (N=3,556 TKAs) reported that the probability of MUA decreased by 4% for every 1-year increase in age (odds ratio [OR]: 0.96; 95% confidence interval [CI]: 0.94, 0.98; p<0.001), and did not differ by implant or fixation type.[17]
- o A retrospective review of the Mayo Clinic Total Joint Registry assessed the risk factors associated with stiffness post-TKA in patients who underwent TKA between 1990 and 2016 (N=12,735); multivariate analysis identified younger age (<65 years) as one of the independent risk factors associated with stiffness post-TKA (adjusted hazard ratio [HR]: 2.34; 95% CI: 1.86, 2.93; p<0.001).[16]

- MUA is a painful and costly procedure, often requiring general anesthesia, followed by 2 to 3 days in the hospital on a continuous passive motion machine.[80]

Patients who undergo MUA after TKA have worse long-term clinical outcomes, worse implant survivorship, and nearly triple the risk of requiring a revision TKA.[18,81,90,91]

- Patients who received MUA were 2 to 3 times more likely to undergo revision TKA:[18,81]
  - o Sambandam et al. 2002 reported that patients who received MUA ≤1 year following TKA were 2.9 times more likely to undergo revision TKA at 2 years of follow up (p<0.05), based on comparison of the MUA cohort (n=538) with the matched non-MUA cohort (n=194).[18]
  - o An earlier analysis of the same database, Werner et al. 2015, found that patients who received post-TKA MUA were 2.4 times more likely to undergo revision TKA within 7 years vs non-MUA controls (p<0.0001).[81]
- A retrospective study of data from the American Joint Replacement Registry (2012 to 2019), in patients ≥65 years of age who underwent an MUA following primary TKA (n=3,918), reported that a total of 3.4% of patients required a revision after a median 9 months, most commonly for mechanical complications, infection, instability, or pain.[90]
- A retrospective analysis of US registry data from patients who underwent primary TKA between 2003 and 2007 (N=2,790) demonstrated that additional MUAs significantly increased the risk of revision surgery (relative risk of 9.7 after 2 MUAs and 27.02 after ≥3 MUAs; p<0.001 for both) at a mean follow-up of 9.7 years, and significantly decreased survivorship (89.4% vs 97.2% for MUA and non-MUA, respectively; p<0.001).[91]

Post-operative complications are common following TKA, ranging from pain and instability to stiffness requiring additional procedures.

The most common reasons for TKA failure include aseptic loosening, instability, and infection.[19,84,85]

- Early causes of TKA failure have shifted from primarily implant-dependent (e.g., polyethylene wear) to more surgeon-influenced mechanisms; infection, instability, arthrofibrosis, and malalignment are early causes of TKA failure that could be improved with surgical training and instrumentation.[19,84-87]
- Surgeons currently lack access to real-time patient data that could aid in diagnosis and potentially improve outcomes.[88]

TKA is increasingly performed in the outpatient setting,[19] which has been associated with an increased risk of peri- and post-operative complications in some studies.[92,93]

- A retrospective study of data from the Humana subset of the Pearl Diver database compared patients who underwent outpatient TKA (n=4,391) and inpatient TKA (n=128,951) between 2007 and 2015. After adjusting for age, sex, and comorbidities, outpatient TKA significantly increased the risk of noninfectious component revision (OR: 1.22; 95% CI: 1.01, 1.47; p=0.039), prosthesis explantation (OR: 1.35; 95% CI: 1.07, 1.72; p=0.013), irrigation and debridement (OR: 1.50; 95% CI: 1.28, 1.77; p<0.001), and stiffness requiring MUA (OR: 1.28; 95% CI: 1.17, 1.40; p<0.001) at 1 year; similar trends were reported at 6 months. Additionally, the risk of post-operative deep vein thrombosis (DVT) (within 60 days) and acute renal failure (within 14 days) were higher after outpatient vs inpatient TKA (OR: 1.42; 95% CI: 1.25, 1.63; p<0.001 and OR: 1.13; 95% CI: 1.01, 1.25; p=0.026, respectively).[92]

- A population-based study of patients who underwent TKA between 1997 and 2009 was conducted using data obtained from the Medicare 5% Limited Data Set. Patient data were stratified based on length of stay (LOS): 1 to 2 days (n=7,755), 3 to 4 days standard-stay (n=71,341), ≥5 days (n=23,134), and outpatient patients (n=454). The results indicated a correlation between outpatient TKA and increased risk of readmission within 90 days (0.9%); a similar trend was observed with shorter-stay TKA (i.e., 1 to 2 day) and increased risk of revision (0.4%).[93] The results indicated a correlation between outpatient TKA and increased risk of readmission within 90 days (0.9%); a similar trend was observed with shorter-stay TKA (i.e., 1 to 2 day) and increased risk of revision (0.4%).[93]

3.2 Burden of TKA Revision

Revision (rTKA), which accounts for ~8% of all TKA procedures, poses a substantial clinical and economic burden to patients, and revisions within three months are most common in younger patients.[19]

- Per the American Academy of Orthopaedic Surgeons-American Joint Replacement Registry (AAOS-AJRR) 2021 annual report, rTKA accounted for 7.8% of knee arthroplasty procedures in 2020, and this percentage has remained relatively stable over the previous decade.[19]

- rTKA performed in the first three months is most common in patients <50 years of age (0.6%), vs 0.4% in patients aged 50 to 59 years and 0.3% in patients aged 60 to 69 years.[19]

- According to two studies approximately one-third of all revisions occur within 2 years of primary TKA.[85,86]
  - 35.3% in ≤2 years; mean time to revision 5.9 years[85]
  - 37.6% in ≤2 years[86]

- More than one-third of rTKAs require revision of all components.[94]

- Comorbidities (e.g., diabetes, obesity, coronary artery disease) add an additional clinical burden to many patients undergoing revision rTKA;[95] based on a US retrospective study conducted between 2005 and 2010, approximately 15% of patients undergoing rTKA have a severity of illness score (based on the number and severity of comorbid conditions) classified as “major”.[96]

Due to survivorship limitations of TKA implants, rTKAs are particularly burdensome for younger patients.[7,8,20]

- Based on pooled registry and case series data, primary TKAs have a 25-year survivorship of 82.3%.[8]

- Patients <65 years of age accounted for 48% of rTKAs in the US in 2010, projected to increase to nearly two-thirds by the year 2030.[7,20]

- The risks of rTKA are particularly pronounced in younger, more active patients, who may require multiple revisions over their lifetime.[20]

- TKA survivorship is further reduced with increasing number of revisions, as demonstrated by the results of a single-center German study (p=0.003; mixed model univariate test). TKA survivorship varied as follows:[97]

- o Primary TKA to first revision: 53 months
- o First to second revision: 29 months
- o Second to third revision: 49 months
- o Third to fourth revision: 37 months
- o Fourth to fifth revision: 25 months
- o Fifth revision to follow-up: 23 months

Revision procedures are expected to become more prevalent with the changing demographics of TKA, increasing the clinical burden and risk to patients.

3.3 Patient Experience and Satisfaction

An estimated **1 in 5 patients report dissatisfaction with their TKA procedure,** driven by both suboptimal clinical outcomes and poor alignment of outcomes with expectations.[21,22]

- Key drivers of TKA dissatisfaction include the degree of improvement in function, degree of pain relief following surgery, and unmet expectations; notably, patients who were less active post-TKA were more likely to be dissatisfied.[21]
  - o Pre-operative factors: Patient-reported function, pain, and mental health; delayed TKA[21]
  - o Intra-operative factors: Implanting technique (amount of proximal tibial resection)
  - o Post-operative factors: Patient-reported outcome measures (PROMs) and general health scores, pain, function, complications, and unmet expectations
- A Canadian cross-sectional study of patients who received primary TKA between 2001 and 2005 (N=1,703) reported post-TKA dissatisfaction with aspects of pain relief (15% to 28%) and function (16% to 30%) in a sizeable proportion of patients. Key contributors to patient dissatisfaction included unmet expectation, a low 1-year Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC)†, a low pre-operative WOMAC pain score when sitting or lying down, and complications resulting in hospital admission.[98]
- An Australian prospective cohort study of patients who underwent TKA between 2013 and 2015 (N=1,017) noted that post-operative complications were significantly associated with patient dissatisfaction (OR: 3.4; 95% CI: 1.88, 6.13; p<0.001) and patient-rated TKA success (OR: 2.39; 95% CI: 1.59, 3.57; p<0.001.[99]
- Parameters contributing to post-operative patient satisfaction include knee alignment, range of motion (ROM), and gait parameters (e.g., walking speed and flexion).[26,100]
  - o The Patient Acceptable Symptom State (PASS) post-TKA has been determined to be 1.2 m/s for walking speed and 50° for maximal knee flexion[100]
- Despite advancements in surgical techniques and implants, little improvement has been observed in levels of post-TKA patient dissatisfaction.[21]

Younger TKA patients (<55 years of age) report even higher dissatisfaction rates (1 in 4), correlated with persistent pain and unmet expectations.[23]

- In a prospective study of patients <55 years of age who underwent TKA between 2008 and 2013 (N=157), 24.9% of patients were unsure or dissatisfied with their procedure at 1 year post-TKA. Based on multivariate analysis, significant predictors of dissatisfaction included poor pre-operative Oxford Knee Score (OKS), poor improvement in OKS, and post-operative stiffness; pain relief and met expectations were found to correlate highly with overall patient satisfaction.[23]

† WOMAC scores range from 0 (worst) to 100 (best).

20% of patients report dissatisfaction following TKA, with dissatisfaction rates up to 25% in younger patients (<55 years).

With a shift from fee-for-service to pay-for-performance reimbursement in joint arthroplasty, patient experience will be a key differentiator for healthcare providers.[24,25]

Integration of patient-generated data throughout the care pathway is critical to improving patient outcomes across the continuum of care, but gathering such data has been done in only a limited and investigational capacity.[26-28,101]

- Physicians often overestimate pain and function outcomes relative to patients.[26] In a retrospective study of 375 patients who underwent primary TKA between 2000 and 2009, results of the 2011 Knee Society Scoring System found that:[26]
  - Patient-derived function scores correlated weakly with physician-derived scores.
  - Patient-derived symptoms scores correlated poorly with physician-derived scores.
- Patient Reported Outcome Measures (PROMs) are important measures that can be used to inform shared decision making, bridging the gap between which outcomes are considered important to surgeons vs patients.[101]
- Measurement of patient experience across the care pathway requires further standardization and validation.[27]
- Remote monitoring post-joint arthroplasty has shown the potential to identify and manage post-operative risks (e.g., hypotensive symptoms) on a pilot basis, but the utility and integration of real-time clinical monitoring has yet to be fully realized.[28]

4. Operational and Economic Burden of Total Knee Arthroplasty

Key Takeaways:

◊ TKA is associated with an estimated $30 billion in hospital expenditures annually in the US.[29]

◊ Although hospitalization is a key driver of TKA costs, post-acute care accounts for nearly half of total episode-of-care costs.[31-33]

◊ Formal physical therapy (PT) accounts for up to 8% of episode-of-care costs, with over 80% of 90-day outpatients costs following TKA spent on PT services.[34,35]

◊ Early initiation of rehabilitation, however, has been linked to shorter LOS and reduced total costs following joint arthroplasty.[102]

◊ Reduction in post-acute care costs can require a substantial investment of provider time (e.g., pre-operative protocol optimization, peri-operative education, and interdisciplinary communication), but the costs of these initiatives are often not reimbursable.[31,38]

◊ Reduced profit margins for TKA pose an increasing burden to providers, with bundled payment models and decreased reimbursement constraining revenue.[36,37]

◊ While bundled payment plans have decreased post-acute care costs, these costs still accounted for ~42% of total episode-of-care costs as of 2016.[31]

◊ Revision TKAs are significantly more expensive and associated with higher hospital costs and healthcare resource use (HCRU) than primary TKAs.[30]

◊ The annual economic burden of TKA revision in the US is $2.7 billion in hospital charges alone and is projected to exceed $13 billion by 2030.[20,103]

TKA is associated with a considerable economic burden, with **annual US hospital expenditures of nearly $30 billion.**[29]

- Published calculations using Agency for Healthcare Research and Quality (AHRQ) data associated TKA with an estimated $28.5 billion in hospital expenditures in 2009.[29]

The economic burden of TKA is driven by both hospitalization and post-acute care costs, which account for nearly half of total episode-of-care costs.[31-33]

- Post-acute care costs (acute rehabilitation, skilled nursing, home health, outpatient clinic visits) represent the largest driver of variability in Medicare spending.[104]
- While bundled payment plans have decreased post-acute care expenditures, these costs still accounted for **~42% of total episode-of-care costs as of 2016.** In a retrospective analysis of the Humana claims database, among patients who underwent primary TKA between 2007 and 2016:[31]
  - o Average episode-of-care cost per patient decreased from $46,754 to $31,856 ($p<0.001$)[31]
  - o Average post-acute care costs decreased from $20,224 to $13,498 ($p<0.001$)[31]
  - o The largest contributors to post-acute care costs were home health ($5,531 per patient), skilled nursing care ($3,248 per patient), and outpatient visits ($1,700 per patient), as of 2016[31]
- TKA post-operative follow-up (e.g., in-person outpatient rehabilitation visits) results in a cost burden to both the provider and the patient.[32,33]

- Reduction in post-acute care costs often require a substantial investment of provider time, including pre-operative protocol optimization, peri-operative education, and interdisciplinary communication; despite these initiatives, however, surgeon fees declined by $574 from 2007 to 2016.[31]
    - o The costs of surgeon-led post-acute care initiatives are not reimbursable via fee-for-service models.
    - o With an additional 9% cut in surgeon fees for primary joint arthroplasty implemented in 2021, these costs will increasingly be taken on by healthcare providers.[38]

Traditional physical therapy (PT) is a key driver of post-acute care costs following TKA, with over 80% of 90-day outpatient costs spent on PT services.[34,35]

- Both payers and patients incur substantial costs over the year following TKA, with the majority of costs attributed to outpatient PT.34 Based on a study evaluating 90-day and 1-year HCRU for patients who underwent TKA between 2013 and 2017 (n=326):[34]
    - o In the 90 days following TKA, the mean number of outpatient visits was 27.1, and 77% of these visits were for PT. Mean total medical costs were $3,720, 84% of which were attributed to outpatient costs.
    - o Similar trends were observed in the year following TKA: the mean number of outpatient visits was 48.9, and 70% of these visits were for PT. The mean total medical costs were $8,930, and of the outpatient costs (60%), 71% were attributed to PT visits.
- Formal PT accounts for up to 8% of the episode-of-care (EOC) costs following primary arthroplasty.[35]
    - o Based on a claims analysis of patients enrolled in a private insurance plan (n=2,971) or Medicare Advantage (n=1,070) who underwent primary arthroplasty between 2015 and 2017, the highest PT costs were reported in patients using both home and outpatient PT ($2,091 and $1,891 for private insurance and Medicare Advantage, respectively, out of total bundle costs of $41,751.75 and $24,686.33).[35]
    - o In the Virtual Exercise Rehabilitation In-home Therapy (VERITAS) trial, traditional PT was associated with median 90-day costs of $2,805.[33]

Delayed or inadequate rehabilitation may increase HCRU and costs following TKA.[102]

- A 2016 systematic literature review and meta-analysis of knee and hip arthroplasty linked early initiation of rehabilitation to shorter LOS and reduced total costs, compared with standard rehabilitation.[102]

Performing TKA in a hospital outpatient or ambulatory surgical center setting offers a less expensive alternative to inpatient TKA, but only in carefully selected patients.[93,105]

- Hospital outpatient and ambulatory surgical center TKAs were associated with significantly reduced 30- and 90-day costs in a commercial claims database study (n=40,574 TKAs)[105]
    - o 30-day mean medical and pharmacy costs were $35,728 (inpatient TKA), $29,154 (hospital outpatient TKA), and $29,945 (ambulatory surgical center TKA) (P-value of analysis of variance: $p<0.001$)
    - o Similar trends were observed for 90-day mean medical and pharmacy costs.
- Outpatient and short stay (1 to 2 days) TKAs produce substantial cost savings vs longer inpatient stays, but with an increased revision risk. Based on results from a population-based study of TKAs performed between 1997 and 2009 (Medicare 5% Limited Data Set), incremental payments for OA-associated costs were $8,527 lower in the outpatient TKA group (n=454) and $1,967 lower with the short stay TKA (n=7,755), relative to the standard stay (3 to 4 days) group (n=71,341).[93]

- Based on multivariable analysis of data from patients undergoing joint arthroplasty (THA; N=112), pre-operative pain level and patient expectations were the primary drivers of LOS (p=0.001 and p<0.001, respectively),[106] highlighting the need for improved patient engagement and the potential value of remote patient monitoring.[106,107]

Revision TKAs contribute disproportionally to the cost burden of TKA; revision TKAs are significantly more expensive than primary TKAs, with higher hospital costs and HCRU.[30]

- A US retrospective study of patients who underwent TKA between 2007 and 2009 (n=2,383) found that mean 90-day healthcare costs were nearly double for revision vs primary TKAs ($40,782 vs $22,194, respectively).[30]
- Based on NIS data from 2005 to 2006 (N=60,436 revisions), revision TKA was associated with a mean LOS of 5.1 days and average total charges of $49,360. All-component revision was the most common type of revision (35.2%), followed by arthrotomy/prosthesis removal (15.2%), and tibial component revision (9.5%).[94]
- A broader assessment of NIS data from 2005 to 2010 (N=301,718 revisions) found that patients undergoing revision TKA required a mean (SD) LOS of 4.8 days (10.5) and a mean (SD) hospitalization cost of $23,130 ($36,643); the longest LOS and highest costs were associated with periprosthetic joint infection and fracture.[96]
- In a more recent study of NIS data (2009 to 2013; 337,597 revisions), the mean LOS for revision TKA had decreased to 4.5 days, while the mean total charges had increased to $75,028.[108]
- Per the AAOS-AJRR 2021 annual report, while LOS for overall TKA has decreased over the last decade, LOS following revision TKA has stayed relatively steady (from mean 3.6 days in 2012 to 3.4 days in 2010).[19]
- The cost burden of revision TKA is particularly high in older patients: a US single-center study of patients who underwent revision TKA between 2018 and 2020 characterized factors that contribute to hospital costs in patients aged 60 to 69 (n=158), 70 to 79 (n=94), and ≥80 (n=24), reporting that older patients undergoing revision TKA are more likely to require a longer stay (p<0.0001), inpatient rehabilitation, and/or discharge to a skilled nursing facility.[109]
    - o LOS: 2.8 days (60 to 69 years of age), 3.4 days (70 to 79 years of age), 3.8 (≥80 years of age).[109]
    - o Inpatient rehabilitation: 1.9% of patients aged 60 to 69 years, 8.5% of patients aged 70 to 79 years, 8.3% of patients aged ≥80 years.[109]
    - o Discharge to a skilled nursing facility: 12.6% of patients aged 60 to 69 years, 27.7% of patients aged 70 to 79 years, 75% of patients aged ≥80 years.[109]
- While Medicare is the primary payer for the majority of revision TKAs (59.5%), private payers account for 30.9%.[94]

In the US, the annual economic burden of TKA revision is $2.7 billion in hospital charges alone.[20]

- Based on a historical trend analysis using the NIS database, the number of revision TKAs was projected to increase by 7-fold from 2005 to 2030;[103] even with a more conservative projection of a 5-fold increase, the annual economic burden would exceed $13 billion by 2030.[20]

Reduced profit margins for TKA pose an increasing burden to hospitals, with significant variability in risk-adjusted costs observed by specific region and hospital.[36,37]

- Hospital revenue from TKA has decreased over time in the US, largely due to Managed Medicare reimbursement rates. Based on a Lahey Clinic analysis of primary TKAs conducted between 1991 and 2008:[36]
    - Inflation-adjusted hospital revenue decreased by 8% per case for Medicare Fee-for-Service patients.
    - Inflation-adjusted hospital revenue decreased by 22% per case for Managed Medicare patients.
- Adoption of bundled payment models and reduction in reimbursement rates contribute to increasing revenue constraints.[37]
- Considerable variation in risk-adjusted episode payments, post-acute care utilization, and readmission rates is observed between hospitals, with high and low-performance outliers comprising up to 30% of hospitals in a given region.[110]

TKA and revision TKA pose an increasing revenue challenge to providers in the context of bundled payment models.

5. Evolution of the Digital Care Pathway

Key Takeaways:

- ◊ Length of Stay LOS following TKA has decreased steadily over time (to a mean of 1.7 days), highlighting the need for more integrated and effective post-TKA follow-up.[27,39,40]
- ◊ Data-driven devices and and remote patient monitoring platforms have the potential to reduce or replace hospital-based rehabilitation, decreasing the burden of routine follow-up on patients and providers.[32,70]
- ◊ Patients increasingly prefer and expect digital engagement in the healthcare setting, a trend accelerated by the COVID-19 pandemic, but availability of these services has lagged demand.[37,41-43]
- ◊ The COVID-19 pandemic has also accelerated an existing shift towards outpatient joint arthroplasty, and highlighted the demand and necessity for remote patient monitoring.[37,43]
- ◊ Value-based payment reforms to Medicare reimbursement aim to incentivize quality and advancement of care and have become a key consideration for hospitals and ambulatory surgery centers.[111]
- ◊ Effective digital care pathways can directly improve patient experience, a key driver of value-based reimbursement (e.g., comprising 20% of the total Value-Based Purchasing [VBP] score under the CMS pay-for-performance reimbursement model), and impact outcomes that matter to patients, such as earlier discharge, recovery in home setting, and earlier return to usual activity levels.[24,41,42,44]
- ◊ Patient satisfaction further impacts physician satisfaction and retention,[45,46] which has become increasingly critical as burnout rates among orthopedic surgeons have increased to nearly 70%.[47,48]
- ◊ Bundled payments and value-based reimbursement models in joint arthroplasty may further incentivize hospital investment in technology that offers the potential to improve quality reporting metrics.[51-53]

Several aspects of the TKA care pathway (e.g., the trend towards reduced LOS, the burden of in-person rehabilitation visits, and increased patient demand for digital health services) **highlight the need for more integrated and effective post-TKA follow-up.**[32]

- Length of Stay (LOS) following TKA has decreased steadily over time (to a mean of 1.7 days); while this trend is consistent with patient preferences, it leaves a gap in post-TKA follow-up and support.[27,39,40]
    - o A US retrospective study of the National Surgical Quality Improvement Program (NSQIP) assessed the overall LOS trend in patients who underwent TKA between 2006 and 2016 (N=221,764). Patient data was stratified into 3 cohorts (2006 to 2009, 2010 to 2013, and 2014 to 2016) based on the year of primary TKA. Multivariate analysis demonstrated a significant decrease in LOS ($p<0.001$) between 2006 and 2016, which was primarily attributed to rapid recovery protocols; shorter LOS was particularly prevalent in younger, healthier, and more functionally independent patients. A similar trend was observed in decreased operative time ($p<0.001$), likely due to advances in TKA surgical techniques (i.e., minimally invasive techniques) and potentially related to decreased LOS.[39]
        - – Mean LOS: 3.7 days (2006-2009), 3.3 days (2010-2013), 3.0 days (2014-2016).
        - – Mean operative time: 100 minutes (2006-2009), 95 minutes (2010-2013), 92 minutes (2014-2016).

- Based on the AAOS-AJRR 2021 annual report (N=625,900 knee arthroplasties), mean LOS following TKA decreased from 2.9 days in 2012 to 1.7 days in 2020.[19]
    - A US prospective study of patients who underwent primary TKA between 2015 and 2017 (N=476) demonstrated significantly shorter post-operative LOS in patients who utilized telephone-based surgery preparation (mean LOS: 2.0 days) vs patients who received standard surgery preparation (mean LOS: 2.7 days; $p<0.001$).[40]
    - When surveyed, patients have shown a preference for shorter LOS following TKA; however, remaining doubts and concerns related to early discharge underscore the need for ongoing support.[27]
- Data-driven devices and services (e.g., remote patient monitoring) post-TKA have the potential to reduce or replace hospital-based rehabilitation, thereby decreasing the burden of routine follow-up.[32]
    - Traditional outpatient rehabilitation includes 6 weeks of clinic-based appointments, with driving assistance required (as patients are not permitted to drive for 6 weeks post-surgery), and progression/regression (knee flexion and extension) measured using a standard hand-held goniometer.
    - Self-reported diaries pose a challenge in verifying patient compliance with prescribed home exercises.
    - Remote monitoring devices could provide more holistic objective and subjective assessments of patient progress (knee flexion/extension) and patient compliance, while mitigating lengthy hospital outpatient times, wait times, and the burden of patient travel associated with conventional hospital-based follow-up appointments.

Recent surveys have also shown that **patients increasingly prefer and expect digital engagement in the healthcare setting,** a trend accelerated by the COVID-19 pandemic.[37,41-43]

- High patient demand exists for digital healthcare (e.g., digital communication with their provider, monitoring their condition via an app), but availability of these services has lagged demand.[41,42]
- The 2020 Healthcare Consumer Study surveyed a total of 1,502 respondents in October 2020 to evaluate US consumers' level of digital engagement and their expectations/standards. Results from this study demonstrated that patients (typically between the ages of 18 and 54):[41]
    - Prefer to interact through a patient portal.
    - Prefer online appointment scheduling.
    - Are likely to consider switching physicians if they lack digital services (e.g., touchless check-in, virtual care).
- The COVID-19 pandemic has further highlighted the demand and necessity for remote patient monitoring, accelerating the shift towards digital care pathways and digital health tools.[37,43]
    - The pandemic accelerated an existing shift towards outpatient joint arthroplasty.[37]
    - Use of and demand for Patient Engagement Platforms (PEPs) have also grown during the pandemic, a trend expected to continue post-pandemic.[43]
    - PEPs enable remote patient monitoring and telemedicine, and also provide educational resources, at-home therapeutic alternatives, proactive and effective patient communication, and meaningful connections between patients and providers.[43]
    - PEPs enable rapid wound assessment via image sharing, which can lead to proactive treatment modifications.[43]

Effective digital care pathways can directly improve patient experience, a key driver of value-based reimbursement, and impact outcomes that matter to patients (e.g., earlier discharge, recovery in the home setting, and earlier return to usual activity levels).[24,41,42,44]

- Connected digital pathways are critical to continuity of care, given that 90% of post-operative recovery takes place outside the purview of healthcare providers.[62]

- **Patient experience as measured by the Press Ganey survey makes up 20% of the total Value-Based Purchasing (VBP) score,** which was implemented by CMS as a pay-for-performance reimbursement model. Factors that influence hospital rating include communication with nurses, communication about medications, staff responsiveness, and pain management.[24]

- Value-based drivers of surgical instrument purchasing include both surgical factors (surgeon preference, technique compatibility, prior training) and patient factors (disease-related improvement, safety, LOS, readmission/complication rates, quality of life [QoL] outcomes, and patient satisfaction).44

Value-based payment reforms to Medicare reimbursement, which aim to incentivize quality and advancement of care, have become a key consideration for hospitals and ambulatory surgery centers.[111]

- Joint arthroplasty has been an early target of value-based reimbursement reforms, highlighting the importance of patient risk assessment and efforts to decrease complications.[111]

- While the overall volume of arthroplasty procedures has increased in the US over the past two decades, Medicare reimbursement to physicians has decreased across nearly all procedures (including TKA).[115]
  - o Medicare reimbursement for primary TKA decreased by 17% from 2012 to 2017, while the reimbursement rate (payment to charge ratio) decreased by 14% across all TKA procedures.[116]

- Increased expenses and decreased physician fees have strained the finances of orthopedic surgery practices and this balance may grow increasingly difficult to strike.[117]

Patient satisfaction also impacts physician satisfaction and retention, which have become increasingly critical to orthopedic surgery practices.[45,46, 112-114]

- Burnout is reported in as high as 60% of orthopedic surgeons, increasing to nearly 70% during the COVID-19 pandemic.[47,48]

- A US cross-sectional survey study (N=155 physicians) conducted in 2012 assessed the impact of patients' experience on physicians' perception of overall job satisfaction and clinical practice. Of the physicians surveyed, 59% indicated that their compensation was linked to patient satisfaction and 78% reported job satisfaction was either moderately or severely affected by patient satisfaction.[45]

- Increased physician satisfaction is associated with decreased burnout and decreased risk of leaving the practice, based on the results of a prospective study of US physicians (N=168) between 2011 and 2014.[46]

- Streamlining daily workflow (e.g., by use of technology) has the potential to reduce burnout in orthopedic surgeons.[49,50]

- Results from several US studies highlight that the rising demand for arthroplasty has coincided with a downward trend in arthroplasty specialists, indicating a potential future shortage.[112-114]

The trend towards bundled payments and value-based reimbursement models in joint arthroplasty may further incentivize hospital investment in technology that offers the potential to improve quality reporting metrics.[51-53]

- Success in a bundled payment model is based on the target price and the cost of the episode of care; however, aggressive target pricing and continuous efficiency improvements may be challenging for programs to maintain.[52,53]

- The shift towards outpatient TKA, which is not eligible for the CJR bundle, removes the healthiest and least costly patients from the bundle, and target prices may therefore underestimate the true cost.[51]

Effective digital care pathways have the potential to improve patient experience and reduce burnout in orthopedic surgeons.

6. ZBEdge™ Dynamic Intelligence™ Digital Care Pathway Solutions

Key Takeaways:

◊ ZBEdge Dynamic Intelligence with the power to elevate and unlock the full potential of Zimmer Biomet's cutting-edge suite of integrated digital technologies, robotics and implant solutions.

◊ The mymobility Care Management Platform connects providers and patients, and has been shown to significantly reduce PT visits compared to traditional follow-up; mymobility was also associated with reduced readmissions, emergency room visits, and surgery-related anxiety, with high patient satisfaction and clinical outcomes comparable to traditional follow-up.[58,118]

◊ The ROSA Robotic Platform is designed to enhance the accuracy and reproducibility of joint arthroplasty procedures by assisting with pre-operative preparation, bone resection, and intra-operative positioning of implant components; connectivity features include an application programming interface (API) and digital recording/hand-off of applied resection techniques.[59]

◊ ZBEdge also includes OrthoIntel Orthopedic Intelligence Platform that enables providers to explore the direct impact of pre-operative and intra-operative data on treatment outcomes.[55]

◊ Persona IQ is a first-to-world smart knee implant that automatically collects and transmits meaningful post-operative gait metrics, integrating seamlessly into ZBEdge.[60,61]

◊ Persona IQ features a 3D accelerometer and gyroscope designed to automatically capture objective kinematic data (e.g., functional ROM, stride length, step count, and step cadence) for at least 10 years post-surgery, providing an adjunct to other physiological parameters assessed by the physician and supporting the goal of patient compliance.[60,61]

6.1 ZBEdge Dynamic Intelligence Solutions

ZBEdge Dynamic Intelligence with the power to elevate and unlock the full potential of Zimmer Biomet's cutting-edge suite of integrated digital technologies, robotics and implant solutions.

- The WalkAI™ Predicted Progress Exceptions is an artificial intelligence (AI) model that identifies patients who are off-track and at risk of a slow 90-day post-operative recovery gait speed as early as 15 days post-operatively compared to their matched cohort.

- Zimmer Biomet maintains robust practices to ensure that patient privacy is maintained, including strong safeguards to protect patient data such as encryption (applied in transit and at rest) and regular security risk testing.

ZBEdge Dynamic Intelligence with the power to elevate and unlock the full potential of Zimmer Biomet's cutting-edge suite of integrated digital technologies, robotics and implant solutions.

ZBEdge™ by ZIMMER BIOMET

The mymobility® Care Management Platform connects providers with their patients via a compatible mobile device (iPhone Devices with optional Apple Watch or Android Devices) or web-based application, providing pre-operative engagement, postoperative check-ins, and remote monitoring for metrics such as mobility and gait quality, patient engagement (e.g. exercise adherence, PROM survey adherence), and heart rate*.[56]

Use of **mymobility has been associated with a reduction in PT visits, readmissions, and emergency room visits,** with clinical outcomes and recovery of physical activity comparable to traditional follow-up, and patients reporting a better overall experience with reduced surgery-related anxiety.[58,118]

- In a randomized controlled trial of primary knee arthroplasty (N=452; 76.3% TKA), mymobility enabled TKA recipients to achieve a significant decrease in post-operative PT visits within 3 months of follow-up compared to patients without mymobility (patients requiring ≥1 visit: 65.8% vs 93.9% respectively; p<0.001).[58]
  - o TKA recipients who received mymobility were also observed to have a numerical decrease in 90-day emergency room visits (3.1% vs 6.5%) and readmissions (3.1% vs 5.4%) compared to patients without mymobility.[58]
  - o Clinically significant outcomes with mymobility (as assessed by 90-day ROM, Knee Injury and Osteoarthritis Outcome Score for Joint Replacement [KOOS JR], EQ-5D-5L, Single Leg Stance, Timed Up and Go test, and passive flexion) were noninferior to traditional care.[58]
  - o Step and stair counts were also collected through the mymobility Platform in this study, and revealed that approximately 50% of individuals using mymobility recovered their pre-operative step counts within 1.5 months post-surgery (baseline median 4,160 steps to median 4,504 steps at 1.5 months), which continued to improve through 6 months post-surgery (median 5,517 steps; p<0.001 versus baseline). Similar trends were observed for stair counts, with 64% returning to pre-operative levels within 3 months, and significant improvement from baseline at 6 months (p=0.003). These recovery curves were noted to be similar to previously reported PROMs curves for patients following joint arthroplasty.[118]
- Users of mymobility were satisfied with their treatment, with 80% of individuals rating their treatment as better than previous medical/ surgical experiences, and 63% describing their surgery-related anxiety as better than previous procedures.[56,119,120]

↑80%

Compared to your other medical and surgical experiences, how did the mymobility app affect this experience?

↑63%

Compared to your other medical and surgical experiences, how did the mymobility app affect the anxiety you felt with this surgical experience?

*Heart Rate Data is collected by Apple Watch® and is displayed in the mymobility app.
§ Patients must have Internet access and a text-capable mobile device or a compatible smartphone to use mymobility; not all smartphone app features are available with web-based version. Not all patients are candidates for the use of this product and surgeons should evaluate individually to determine which patients are appropriate for therapy at home. Apple, iPhone and Mac are registered trademarks of Apple, Inc. Google and Android are trademarks of Google, LLC.

The **ROSA® Robotics System** is designed to enhance the accuracy and reproducibility of joint arthroplasty procedures by assisting with pre-operative preparation, bone resection, and intra-opreative positioning of implant components. Connectivity features include an application programming interface (API) and digital recording/hand-off of applied resection techniques.[59]

The **OrthoIntel Orthopedic Intelligence Platform** provides interactive and customizable reports for the data collected in ZBEdge, allowing clinicians to explore the direct impact of pre-operative and intra-operative data on outcomes.[55]

- The impact of pre-/intra-operative data (including hip-knee angle and joint laxity) on post-operative step counts and KOOS JR scores was explored in a retrospective study of patients who underwent ROSA robotic-assisted TKA procedures and used mymobility for follow-up (N=131, July 2020 to February 2021); although no significant associations were found between tightness and KOOS JR scores at follow-up, medial laxity in flexion <1 mm was associated with significantly decreased step counts at 6 weeks post-surgery (p=0.035).[121]

6.2. Persona IQ Smart Implant

- Persona IQ, the newest digital innovation within ZBEdge, is a first-to-world smart knee implant that collects and transmits meaningful post-operative gait metrics.[60,6] Persona IQ combines the Persona® Knee System and the CANARY canturio™ te (CTE) Stem Extension with CHIRP™ Technology. [60,61]

- Persona IQ is indicated for use in patients undergoing a cemented TKA procedure who are normally indicated for at least a 58 mm sized tibial stem extension. Objective kinematic data generated by Persona IQ are not intended to support clinical decision making.[60,61]

- Persona IQ features a 3D accelerometer and gyroscope as well as a 10-year lithium carb-monofluoride battery and near-field antenna, which can transmit kinematic data (Figure 5).[123]

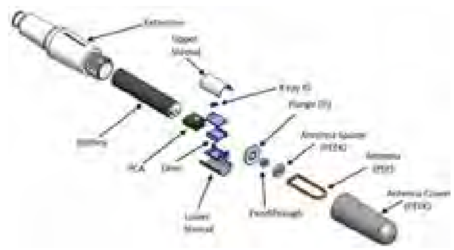

Figure 5

  o No GPS capabilities are included in Persona IQ.

- The 3D accelerometer and gyroscope measure kinematic outcomes such as functional ROM (including tibia and functional knee ROM), stride length, step count, and step cadence, as well as estimated distance traveled and average walking speed (based on step count, cadence, and stride length) (Figure 6).[60]

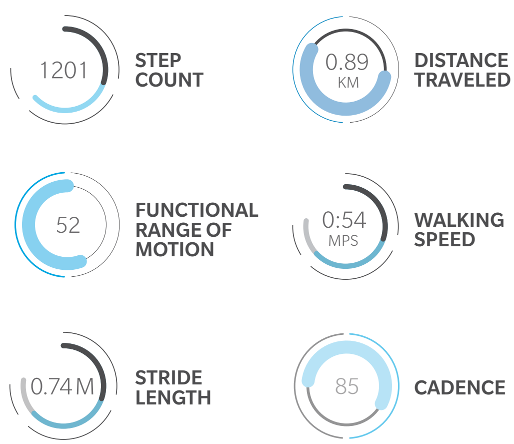

Figure 6

WARNING - The kinematic data from this device have not been demonstrated to have clinical benefit. It is not intended to be utilized for clinical decision-making, and no data have been evaluated by FDA regarding clinical benefits.

- 3D motion analysis is considered the gold standard for knee kinematics, and 3D inertial gait data can provide insights into outcomes beyond 2D knee flexion/extension parameters, such as knee alignment and load distribution (which in turn are related to tibial insert wear).[124,125]

- Data from Persona IQ is wirelessly transmitted to a Home Base Station, which in turn automatically sends the data to a HIPAA-compliant Cloud Management platform over Wi-Fi.[126] This automatic data transmission by Persona IQ ensures a consistent cadence of data collection and supports the goal of patient compliance (Figure 7).

Figure 7

- The objective kinematic data from Persona IQ is automatically available and accessible through the mymobility Care Management Platform for both patients and providers.

Persona IQ Contraindications

- The CTE stem extension is contraindicated for use in patients who are undergoing procedures or treatments at or in the proximity of the CTE using therapeutic ionizing radiation, which can result in shortened battery life or premature failure of electronic components. Damage to the CTE by therapeutic ionizing radiation may not be immediately detectable.[60]

- The Zimmer Biomet Persona Knee System components are contraindicated for use in patients who have:[60]

  - Previous history of infection in the affected joint and/or other local/systemic infection that may affect the prosthetic joint
  - Insufficient bone stock on femoral or tibial surfaces
  - Skeletal immaturity
  - Neuropathic arthropathy
  - Osteoporosis or any loss of musculature or neuromuscular disease that compromises the affected limb
  - A stable, painless arthrodesis in a satisfactory functional position
  - Severe instability secondary to the absence of collateral ligament integrity

Smart: Persona IQ incorporates built-in sensors to capture objective kinematic data over the course of patient monitoring and treatment post-surgery, to act as an adjunct to other physiological parameters assessed by the physician.[60,61]

Connected: Data from Persona IQ integrates into the mymobility Care Mangement Platform, providing remote access for providers monitoring patient recovery and treatment post-surgery.[60]

- Provides a direct view of patient-level data for at least 10 years
- Supports the goal of patient compliance

Simple: Instrumentation and workflow for Persona IQ remains the same as the standard Persona® The Personalized Knee® implant, and kinematic data is collected automatically and provided to both providers and patients via an easy-to-use interface on the mymobility Care Management Platform. [60]

7. Value of Connected Digital Care Pathway for Arthroplasty††

Key Takeaways:

◊ Remote patient engagement prior to joint arthroplasty can significantly shorten post-operative LOS and improve compliance with follow-up, compared to conventional pre-operative preparation.[40,63]

◊ Remote guidance and follow-up after joint arthroplasty can significantly reduce rehospitalizations, complications, and costs compared to standard in-person follow-up.[33,64]

◊ Collection of post-operative data via wearable sensors can facilitate robust analysis of patient recovery while streamlining follow-up care and reducing patient burden.[67-70]

◊ Patients report high satisfaction and compliance with remote monitoring, describing wearable devices as "motivating," and noting savings in time and money.[62,66,67]

Digital healthcare technologies such as telemonitoring and personalized healthcare programs have the potential to target underserved patient populations and create new markets where they previously did not exist, providing a competitive advantage for first-to-market technologies.[127,128] Two key areas in which connected digital care pathways can add value to the TKA care pathway are remote engagement with patients and remote collection of data.

7.1. Benefits of Remote Patient Engagement

Remote patient engagement improves post-operative compliance and provides increased independence for both patients and providers, reducing the constraints of traditional consultation and in-person visits.[32,63]

- In a US retrospective study of arthroplasty recipients (N=17,133, 2014 to 2017), patients who used a mobile app for post-operative follow-up were more engaged, with significantly higher PROMs compliance and post-operative log-in frequency, versus individuals who only used email for submitting questionnaires ($p \leq 0.010$ for all age categories)[63]
    - The highest levels of mobile app engagement were observed in patients aged 51 to 60, who had an average of 17 post-operative logins per patient through follow-up.[63]
    - The largest improvement in PROMs compliance was noted in patients aged 18 to 30, with a 44% increase in completion rates between patients with and without the app.[63]

Pre-operative remote engagement is viewed as helpful by the majority of patients undergoing orthopedic surgery, and **can significantly shorten post-operative LOS** compared to standard pre-surgical patient engagement.[40,64,129,130]

- Compared to patients who received standard surgery preparation, telephone-based preparation (termed "prehabilitation") enabled significantly shorter post-operative LOS (mean: 2.0 vs 2.7 days; $p<0.001$) and significantly fewer discharges with home assistance (42.8% vs 77.2%; $p<0.001$), in a US prospective study of 476 TKA recipients. Benefits in discharge disposition were also observed, with remote surgery preparation associated with:[40]

†† ZBEdge Dynamic Intelligence has has not been evaluated for clinical or economic outcomes, and none of the products in the ZBEdge Dynamic Intelligence were utilized in the studies cited in this section

- o Significantly fewer discharges with home assistance (42.8% vs 77.2%; p<0.001).
- o Significantly fewer discharges to home with health aide (21.1% vs 31.8%; p=0.04).
- o Significantly fewer discharges to a skilled nursing facility (1.8% vs 21.8%; p<0.0001).

- A US survey of THA or TKA recipients who used a web/smartphone app for pre- and post-operative rehabilitation (N=207; 54% TKA) found that 80% of patients were satisfied with the app-based prehabilitation (mean overall satisfaction score of 23.2 on a scale of 0 to 29), with 86% of patients reporting they would recommend the app to friends.[129]
- Patients who received remote follow-up in a randomized controlled trial of TKA or THA (N=55) rated their likelihood to recommend remote monitoring as a mean of 8.8 out of 10.[64]
- In a digital care feasibility study of patients undergoing spinal surgery (N=24), the majority of patients who received remote pre- and post-surgical engagement through a smartphone app reported the app to be helpful with both surgery preparation (88%) and recovery (66%).[130]

The majority of joint arthroplasty recipients who received remote follow-up reported they were motivated by the program, and the majority would not have preferred standard in-person outpatient visits.[65,66]

- In a survey of joint arthroplasty recipients in the UK who were monitored remotely through mail and telephone starting 6 weeks after the procedure (N=1,523; n=56 subgroup surveyed), 89% of patients reported they were "satisfied" or "very satisfied" with the remote follow-up program, and only 18% of patients reported they would have preferred typical in-person outpatient appointments. 86% of patients surveyed noted that remote monitoring saved them time and/or money, primarily due to transportation issues.[62]
- A pilot study that used remote patient monitoring via a wearable device to collect PROMs, kinematic data, and home exercise program compliance for patients undergoing primary TKA (N=25) found that all respondents at 3 months described the remote monitoring as "engaging" or "motivating", and the mean daily compliance with home exercise was 62%.[62]

Compared to joint arthroplasty recipients who received standard outpatient follow-up, remote guidance and follow-up was associated with **significantly fewer complications and incurred significantly lower costs** within 90 days of discharge.[33,64]

- TKA or THA recipients in the Anthem Blue Cross database (N=558, 45% TKA, 2011 to 2016) who received remote guidance and telemonitoring experienced significantly fewer complications (7.0% vs 15.3%; relative risk [RR]: 0.456; p=0.004) and incurred significantly less 90-day total costs per patient ($651.25 vs $1,307.77 [USD]; p=0.006) compared to joint arthroplasty recipients who received standard outpatient follow-up.[64]
- In the Virtual Exercise Rehabilitation In-home Therapy (VERITAS) trial, a randomized controlled trial that compared post-TKA outcomes with virtual PT (n=143) vs traditional home and/or clinic based PT (n=144), virtual PT was associated with a 61% reduction in total costs compared to standard PT ($1,782 vs $4,527; p<0.001), driven both by fewer PT visits and reduced rehospitalizations.[33]

Joint arthroplasty recipients who received **remote patient monitoring required significantly fewer rehospitalizations** compared to those with standard follow-up procedures.[33,63]

- In a randomized controlled trial of patients receiving TKA or THA (N=242), patients who received remote follow-up experienced a significantly lower rehospitalization rate compared to standard follow-up (3.4% vs 12.2%; p=0.01) and a significantly reduced mean number of rehospitalizations (4.2 vs 13.0; p=0.02).[63]
- In the VERITAS trial, significantly fewer total rehospitalizations within 12 weeks post-surgery were reported for TKA recipients who received remote PT compared to patients who received standard PT (12 vs 30; p=0.007).[33]

Patients monitored remotely after joint arthroplasty have fewer complications and require fewer rehospitalizations compared to conventional follow-up.[66]

7.2. Value of Remote Data Collection

Sensors built into implant systems have been shown to provide useful data in the orthopedic space, allowing motion data to be collected under a wide variety of activities, and facilitating longer-term monitoring.[131] Accelerometers that can detect multiple dimensions also improve the precision and detail of collected data compared to single sensor measurements.[132] Remote patient care can support a more holistic approach to post-TKA follow-up, aligning with the preference of surgeons to **streamline follow-up care and reduce inefficiencies** while reducing patient burden.[70]

- A survey of US surgeons who perform joint arthroplasty procedures (N=195 procedures, 45% TKA) reported that 72% of post-operative visits were rated as appropriate for remote follow-up instead of conventional in-person visits, and overall only 67% of follow-up visits were rated as "worthwhile." Surgeons generally noted that specific issues and problems warranted in-person visits, while routine follow-up appointments delivered less value and could be done remotely. [70]
  - Conventional follow-up also burdens patients and caregivers; wait times, travel time/distance, and financial costs were the most commonly cited reasons for patient dissatisfaction with conventional follow-up appointments, which were estimated to require a mean of 5.35 person hours per visit (including friends and family who accompanied the patients). 46% of this time was being taken off work, leading to an estimated indirect cost of $68.85 per visit in lost wages.[70]

Post-surgical **clinical parameters collected by mobile sensors (e.g., gait variables) correlate with patient satisfaction and PROMs.[67-69]**

- Inertial gait variables measured from a wearable sensor correlated well with clinical variables including KOOS scores and Six-Minute WalkTest (6MWT) in a study of US TKA recipients (N=18); the authors noted the strength of this association, which was estimated to drive up to 89% of the variability in clinical outcomes.[69]
  - Gait variables accounted for 89.3%, 54.6%, 70.3%, and 63% of the variance in KOS-ADLS (Activities of Daily Living Scale), KOOS-Pain, KOOS-Symptom, and of KOOS-QOL scores, respectively.
- In a study using a wearable mobility sensor to monitor the recovery of knee arthroplasty recipients who were aged 50 to 70 years and physically active (University of California Los Angeles [UCLA] activity score >5; N=6), higher running speed and improved maximum power of deceleration correlated with greater improvement of Knee Society Score (KSS) and Oxford Knee Score (OKS) from baseline vs 12 months post-surgery.[68]
- In a pilot study of remote heart rate/blood pressure monitoring in patients who underwent outpatient joint arthroplasty (N=17), heart rate and/or blood pressure issues were detected in 5 patients, with all issues successfully resolved after following recommended hydration protocols. Overall, 94% of patients (17/18) were compliant with the monitoring, and patients reported high satisfaction with using the device, with a mean satisfaction score of 8.94 out of 10 for ease of use, 9.67 out of 10 for home coaching, and 8.35 out of 10 for belief that the protocol improved patient safety. Among the patients who developed post-operative hypotensive symptoms (approximately 30%), remote monitoring allowed for implementation of hydration and delayed ambulation protocols, preventing potential adverse consequences associated with post-discharge hypotension (e.g., falls, fainting, peri-prosthetic fractures).[67]

Remote patient monitoring post-TKA is associated with high patient compliance and satisfaction.[24,37,41-44]

Remote patient monitoring is currently reimbursed through Medicare on a monthly basis, including device supply for scheduled recordings and/or programmed alert(s) transmission to monitor the musculoskeletal system (CPT code 98977) and clinical staff/physician/other qualified healthcare professional time requiring interactive communication with the patient/caregiver lasting ≥20 minutes (CPT code 98980). For more reimbursement resources, please see the coding guides available at https://www.zimmerbiomet.com/en/support/reimbursement/coding-guides.html.

In summary, connected digital care pathways have the potential to reduce post-acute care costs, improve patient satisfaction and compliance, and alleviate the burden of post-TKA follow-up, while meeting increased patient demand for remote engagement and provider demand for actionable patient data.[24,37,41-44] ZBEdge Dynamic Intelligence with the power to elevate and unlock the full potential of Zimmer Biomet's cutting-edge suite of integrated digital technologies, robotics and implant solutions.[54-58,60,61]

8. References

1. Losina E, Paltiel AD, Weinstein AM, et al. Lifetime medical costs of knee osteoarthritis management in the United States: impact of extending indications for total knee arthroplasty. Arthritis Care Res (Hoboken). Feb 2015;67(2):203-215.

2. Deshpande BR, Katz JN, Solomon DH, et al. Number of Persons With Symptomatic Knee Osteoarthritis in the US: Impact of Race and Ethnicity, Age, Sex, and Obesity. Arthritis care & research. 2016;68(12):1743-1750.

3. AAOS. Total Knee Replacement. 2021; https://orthoinfo.aaos.org/en/treatment/total-knee-replacement/.

4. Singh JA, Yu S, Chen L, Cleveland JD. Rates of Total Joint Replacement in the United States: Future Projections to 2020-2040 Using the National Inpatient Sample. The Journal of rheumatology. Sep 2019;46(9):1134-1140.

5. Singh JA, Lewallen DG. Time trends in the characteristics of patients undergoing primary total knee arthroplasty. Arthritis Care Res (Hoboken). Jun 2014;66(6):897-906.

6. Losina E, Thornhill TS, Rome BN, Wright J, Katz JN. The dramatic increase in total knee replacement utilization rates in the United States cannot be fully explained by growth in population size and the obesity epidemic. J Bone Joint Surg Am. Feb 1 2012;94(3):201-207.

7. Kurtz SM, Lau E, Ong K, Zhao K, Kelly M, Bozic KJ. Future young patient demand for primary and revision joint replacement: national projections from 2010 to 2030. Clin Orthop Relat Res. Oct 2009;467(10):2606-2612.

8. Evans JT, Walker RW, Evans JP, Blom AW, Sayers A, Whitehouse MR. How long does a knee replacement last? A systematic review and meta-analysis of case series and national registry reports with more than 15 years of follow-up. The Lancet. 2019;393(10172):655-663.

9. Kuijer PPFM, van Haeren MM, Daams JG, Frings-Dresen MHW. Better return to work and sports after knee arthroplasty rehabilitation? Occupational Medicine. 2018;68(9):626-630.

10. Witjes S, van Geenen RC, Koenraadt KL, et al. Expectations of younger patients concerning activities after knee arthroplasty: are we asking the right questions? Quality of life research : an international journal of quality of life aspects of treatment, care and rehabilitation. Feb 2017;26(2):403-417.

11. Vina ER, Ran D, Ashbeck EL, et al. Patient preferences for total knee replacement surgery: Relationship to clinical outcomes and stability of patient preferences over 2 years. Semin Arthritis Rheum. Aug 2016;46(1):27-33.

12. Kwoh CK, Vina ER, Cloonan YK, Hannon MJ, Boudreau RM, Ibrahim SA. Determinants of patient preferences for total knee replacement: African-Americans and whites. Arthritis Res Ther. Dec 3 2015;17:348.

13. Allen KD, Golightly YM, Callahan LF, et al. Race and sex differences in willingness to undergo total joint replacement: the Johnston County Osteoarthritis Project. Arthritis Care Res (Hoboken). Aug 2014;66(8):1193-1202.

14. Gagnier J, Morgenstern H, Kellam P. A retrospective cohort study of adverse events in patients undergoing orthopaedic surgery. Patient Safety in Surgery. 05/11 2017;11.

15. Heo SM, Harris I, Naylor J, Lewin AM. Complications to 6 months following total hip or knee arthroplasty: observations from an Australian clinical outcomes registry. BMC musculoskeletal disorders. Sep 10 2020;21(1):602.

16. Owen AR, Tibbo ME, van Wijnen AJ, Pagnano MW, Berry DJ, Abdel MP. Acquired Idiopathic Stiffness After Contemporary Total Knee Arthroplasty: Incidence, Risk Factors, and Results Over 25 Years. J Arthroplasty. Aug 2021;36(8):2980-2985.

17. Knapp P, Weishuhn L, Pizzimenti N, Markel DC. Risk factors for manipulation under anaesthesia after total knee arthroplasty. Bone Joint J. Jun 2020;102-b(6_Supple_A):66-72.

18. Sambandam S, Mounasamy V, Wukich D. Patients undergoing manipulation after total knee arthroplasty are at higher risk of revision within 2 years. Eur J Orthop Surg Traumatol. Jan 2022;32(1):145-150.

19. AAOS-AJRR. Annual Report. 2021.

20. Bhandari M, Smith J, Miller LE, Block JE. Clinical and economic burden of revision knee arthroplasty. Clin Med Insights Arthritis Musculoskelet Disord. 2012;5:89-94.

21. Gunaratne R, Pratt DN, Banda J, Fick DP, Khan RJK, Robertson BW. Patient Dissatisfaction Following Total Knee Arthroplasty: A Systematic Review of the Literature. J Arthroplasty. Dec 2017;32(12):3854-3860.

22. Nakano N, Shoman H, Olavarria F, Matsumoto T, Kuroda R, Khanduja V. Why are patients dissatisfied following a total knee replacement? A systematic review. International Orthopaedics. 2020/10/01 2020;44(10):1971-2007.

23. Scott CE, Oliver WM, MacDonald D, Wade FA, Moran M, Breusch SJ. Predicting dissatisfaction following total knee arthroplasty in patients under 55 years of age. Bone Joint J. Dec 2016;98-b(12):1625-1634.

24. Siqueira MBP, Chughtai M, Khlopas A, et al. Does Gender Influence How Patients Rate Their Patient Experience after Total Knee Arthroplasty? J Knee Surg. Sep 2017;30(7):634-638.

25. Anil U, Elbuluk AM, Ziegler J, Schwarzkopf R, Long WJ. Hospital Consumer Assessment of Healthcare Providers and Systems Scores Do Not Predict Outcomes After Total Hip Arthroplasty. J Arthroplasty. Feb 2018;33(2):337-339 e336.

26. Matsuda S, Kawahara S, Okazaki K, Tashiro Y, Iwamoto Y. Postoperative alignment and ROM affect patient satisfaction after TKA. Clin Orthop Relat Res. Jan 2013;471(1):127-133.

27. Jones EL, Wainwright TW, Foster JD, Smith JR, Middleton RG, Francis NK. A systematic review of patient reported outcomes and patient experience in enhanced recovery after orthopaedic surgery. Ann R Coll Surg Engl. Mar 2014;96(2):89-94.

28. Mouli VH, Carrera CX, Schudrowitz N, Flanagan Jay J, Shah V, Fitz W. Post-Operative Remote Monitoring for Same-Day Discharge Elective Orthopedic Surgery: A Pilot Study. Sensors (Basel). Aug 26 2021;21(17).

29. Murphy L, Helmick CG. The impact of osteoarthritis in the United States: a population-health perspective: A population-based review of the fourth most common cause of hospitalization in U.S. adults. Orthopedic nursing. Mar-Apr 2012;31(2):85-91.

30. Burnett Iii RA, Yang J, Courtney PM, Terhune EB, Hannon CP, Della Valle CJ. Costs of unicompartmental compared with total knee arthroplasty. The Bone & Joint Journal. 2021/06/01 2021;103-B(6 Supple A):23-31.

31. Burnett RA, 3rd, Serino J, Yang J, Della Valle CJ, Courtney PM. National Trends in Post-Acute Care Costs Following Total Knee Arthroplasty From 2007 to 2016. J Arthroplasty. Jul 2021;36(7):2268-2275.

32. Msayib Y, Gaydecki P, Callaghan M, Dale N, Ismail S. An Intelligent Remote Monitoring System for Total Knee Arthroplasty Patients. J Med Syst. Jun 2017;41(6):90.

33. Prvu Bettger J, Green CL, Holmes DN, et al. Effects of Virtual Exercise Rehabilitation In-Home Therapy Compared with Traditional Care After Total Knee Arthroplasty: VERITAS, a Randomized Controlled Trial. J Bone Joint Surg Am. Jan 15 2020;102(2):101-109.

34. Hung A, Li Y, Keefe FJ, et al. Ninety-day and one-year healthcare utilization and costs after knee arthroplasty. Osteoarthritis Cartilage. Oct 2019;27(10):1462-1469.

35. Yayac M, Moltz R, Pivec R, Lonner JH, Courtney PM, Austin MS. Formal Physical Therapy Following Total Hip and Knee Arthroplasty Incurs Additional Cost Without Improving Outcomes. J Arthroplasty. Oct 2020;35(10):2779-2785.

36. Healy WL, Rana AJ, Iorio R. Hospital economics of primary total knee arthroplasty at a teaching hospital. Clin Orthop Relat Res. Jan 2011;469(1):87-94.

37. Clarivate | DRG. Large-Joint Reconstructive Implants. 2021.

38. Krueger CA, Courtney PM. Projections of the Impact to Arthroplasty Surgeons With Changes to the 2021 Medicare Physician Fee Schedule-A Looming Crisis of Access to Care? J Arthroplasty. Jul 2021;36(7):2412-2417.

39. Sarpong NO, Boddapati V, Herndon CL, Shah RP, Cooper HJ, Geller JA. Trends in Length of Stay and 30-Day Complications After Total Knee Arthroplasty: An Analysis From 2006 to 2016. J Arthroplasty. Aug 2019;34(8):1575-1580.

40. Chughtai M, Shah NV, Sultan AA, et al. The role of prehabilitation with a telerehabilitation system prior to total knee arthroplasty. Ann Transl Med. Feb 2019;7(4):68.

41. Cedar. Healthcare Consumer Experience Study. 2020.

42. Imison C, Castle-Clarke S, Watson R, Edwards N. Delivering the benefits of digital healthcare, Nuffield Trust. 2016.

43. Bini SA, Schilling PL, Patel SP, et al. Digital Orthopaedics: A Glimpse Into the Future in the Midst of a Pandemic. The Journal of arthroplasty. 2020;35(7S):S68-S73.

44. Nassiri AM, Garrett CG, Dail TL, et al. Should I Buy This? A Decision-Making Tool for Surgical Value-Based Purchasing. Otolaryngol Head Neck Surg. Sep 2020;163(3):397-399.

45. Zgierska A, Rabago D, Miller MM. Impact of patient satisfaction ratings on physicians and clinical care. Patient preference and adherence. 2014;8:437-446.

46. Linzer M, Sinsky CA, Poplau S, Brown R, Williams E. Joy In Medical Practice: Clinician Satisfaction In The Healthy Work Place Trial. Health Aff (Millwood). Oct 1 2017;36(10):1808-1814.

47. Arora M, Diwan AD, Harris IA. Burnout in orthopaedic surgeons: a review. ANZ Journal of Surgery. 2013;83(7-8):512-515.

48. Kale N, Stamm M, Higgins M, Mulcahey M. Spread Too Thin: How has the COVID-19 Pandemic Contributed to Burnout Among Academic Orthopaedic Surgeons? 02/24 2022.

49. OrthoEvidence. When Busy Isn't Enough: Seven Steps Towards Working More Efficiently. 2021; https://myoe.blob.core.windows.net/docs/Insight_39.pdf. Accessed July 5, 2022.

50. National Academies of Sciences E, and Medicine,. Taking Action Against Clinician Burnout: A Systems Approach to Professional Well-Being. Washington, DC: The National Academies Press; 2019.

51. Davis CM, 3rd, Swenson ER, Lehman TM, Haas DA. Economic Impact of Outpatient Medicare Total Knee Arthroplasty at a Tertiary Care Academic Medical Center. J Arthroplasty. Jun 2020;35(6S):S37-S41.

52. Springer BD, McInerney J. Medicare bundles for arthroplasty : a journey back to fee for service? Bone Joint J. Jun 2021;103-b(6 Supple A):119-125.

53. CMS. Comprehensive Care for Joint Replacement (CJR) Model Three-Year Extension and Changes to Episode Definition and Pricing (CMS-5529-F). 2021.

54. Zimmer Biomet. ZBEdge (website). 2022; https://www.zimmerbiomet.com/en/products-and-solutions/zb-edge.html. Accessed May 11, 2022.

55. Zimmer Biomet. OrthoIntel Brochure. 2021.

56. Zimmer Biomet. mymobility Brochure. 2021.

57. Zimmer Biomet. Data on File: Persona IQ Pitch Deck. 2022.

58. Crawford DA, Duwelius PJ, Sneller MA, et al. 2021 Mark Coventry Award: Use of a smartphone-based care platform after primary partial and total knee arthroplasty: a prospective randomized controlled trial. The Bone & Joint Journal. 2021;103-B(6 Supple A):3-12.

59. Zimmer Biomet. Data on File - ROSA Hip Detailed Brochure. 2021.

60. Zimmer Biomet. Persona IQ (website). 2022; https://www.zimmerbiomet.com/en/products-and-solutions/specialties/knee/persona-iq.html. Accessed May 11, 2022.

61. Zimmer Biomet. Persona IQ Surgical Technique Guide. 2021.

62. Bell K, Warnick E, Nicholson K, et al. Patient Adoption and Utilization of a Web-Based and Mobile-Based Portal for Collecting Outcomes After Elective Orthopedic Surgery. American Journal of Medical Quality. 2018;33(6):649-656.

63. Mehta SJ, Hume E, Troxel AB, et al. Effect of Remote Monitoring on Discharge to Home, Return to Activity, and Rehospitalization After Hip and Knee Arthroplasty: A Randomized Clinical Trial. JAMA Network Open. 2020;3(12):e2028328-e2028328.

64. Rosner BI, Gottlieb M, Anderson WN. Effectiveness of an Automated Digital Remote Guidance and Telemonitoring Platform on Costs, Readmissions, and Complications After Hip and Knee Arthroplasties. J Arthroplasty. Apr 2018;33(4):988-996 e984.

65. El Ashmawy AH, Dowson K, El-Bakoury A, Hosny HAH, Yarlagadda R, Keenan J. Effectiveness, Patient Satisfaction, and Cost Reduction of Virtual Joint Replacement Clinic Follow-Up of Hip and Knee Arthroplasty. J Arthroplasty. Mar 2021;36(3):816-822 e811.

66. Ramkumar PN, Haeberle HS, Ramanathan D, et al. Remote Patient Monitoring Using Mobile Health for Total Knee Arthroplasty: Validation of a Wearable and Machine Learning-Based Surveillance Platform. J Arthroplasty. Oct 2019;34(10):2253-2259.

67. Mouli VH, Carrera CX, Schudrowitz N, Flanagan Jay J, Shah V, Fitz W. Post-Operative Remote Monitoring for Same-Day Discharge Elective Orthopedic Surgery: A Pilot Study. Sensors. 2021;21(17):5754.

68. Calliess T, Bocklage R, Karkosch R, Marschollek M, Windhagen H, Schulze M. Clinical evaluation of a mobile sensor-based gait analysis method for outcome measurement after knee arthroplasty. Sensors (Basel). Aug 28 2014;14(9):15953-15964.

69. Youn I-H, Leutzinger T, Youn J-H, Zeni JA, Knarr BA. Self-Reported and Performance-Based Outcome Measures Estimation Using Wearables After Unilateral Total Knee Arthroplasty. Frontiers in Sports and Active Living. 2020-September-25 2020;2.

70. Barrack TN, Abu-Amer W, Schwabe MT, et al. The burden and utility of routine follow-up at one year after primary arthroplasty. The Bone & Joint Journal. 2020;102-B(7_Supple_B):85-89.

71. Cisternas MG, Murphy L, Sacks JJ, Solomon DH, Pasta DJ, Helmick CG. Alternative Methods for Defining Osteoarthritis and the Impact on Estimating Prevalence in a US Population-Based Survey. Arthritis Care Res (Hoboken). May 2016;68(5):574-580.

72. Neogi T. The epidemiology and impact of pain in osteoarthritis. Osteoarthritis and cartilage. 2013;21(9):1145-1153.

73. Hootman JM, Helmick CG, Barbour KE, Theis KA, Boring MA. Updated Projected Prevalence of Self-Reported Doctor-Diagnosed Arthritis and Arthritis-Attributable Activity Limitation Among US Adults, 2015-2040. Arthritis Rheumatol. Jul 2016;68(7):1582-1587.

74. US Bone and Joint Initiative. The Burden of Musculoskeletal Diseases in the US (BMUS), 2020. 2020; https://www.boneandjointburden.org/print/book/export/html/978. Accessed April 19, 2022.

75. Losina E, Weinstein AM, Reichmann WM, et al. Lifetime risk and age at diagnosis of symptomatic knee osteoarthritis in the US. Arthritis care & research. 2013;65(5):703-711.

76. Bohm ER, Dunbar MJ, Bourne R. The Canadian Joint Replacement Registry-what have we learned? Acta Orthop. Feb 2010;81(1):119-121.

77. Gwam C, Rosas S, Sullivan R, Luo TD, Emory CL, Plate JF. The Who, What, and Where of Primary TKAs: An Analysis of HCUP Data from 2009 to 2015. J Knee Surg. Apr 2020;33(4):378-386.

78. Noble PC, Conditt MA, Cook KF, Mathis KB. The John Insall Award: Patient Expectations Affect Satisfaction with Total Knee Arthroplasty. Clinical Orthopaedics and Related Research®. 2006;452.

79. Stambough JB, Edwards PK, Mannen EM, Barnes CL, Mears SC. Flexion Instability After Total Knee Arthroplasty. J Am Acad Orthop Surg. Sep 1 2019;27(17):642-651.

80. Randsborg PH, Tajet J, Negard H, Rotterud JH. Manipulation under Anesthesia for Stiffness of the Knee Joint after Total Knee Replacement. Arthroplast Today. Sep 2020;6(3):470-474.

81. Werner BC, Carr JB, Wiggins JC, Gwathmey FW, Browne JA. Manipulation Under Anesthesia After Total Knee Arthroplasty is Associated with An Increased Incidence of Subsequent Revision Surgery. J Arthroplasty. Sep 2015;30(9 Suppl):72-75.

82. Desai AS, Karmegam A, Dramis A, Board TN, Raut V. Manipulation for stiffness following total knee arthroplasty: when and how often to do it? Eur J Orthop Surg Traumatol. Oct 2014;24(7):1291-1295.

83. Colacchio ND, Abela D, Bono JV, Shah VM, Bono OJ, Scott RD. Efficacy of manipulation under anesthesia beyond three months following total knee arthroplasty. Arthroplast Today. Dec 2019;5(4):515-520.

84. Lombardi AV, Jr., Berend KR, Adams JB. Why knee replacements fail in 2013: patient, surgeon, or implant? Bone Joint J. Nov 2014;96-b(11 Supple A):101-104.

85. Schroer WC, Berend KR, Lombardi AV, et al. Why are total knees failing today? Etiology of total knee revision in 2010 and 2011. J Arthroplasty. Sep 2013;28(8 Suppl):116-119.

86. Sharkey PF, Lichstein PM, Shen C, Tokarski AT, Parvizi J. Why are total knee arthroplasties failing today--has anything changed after 10 years? J Arthroplasty. Sep 2014;29(9):1774-1778.

87. Thiele K, Perka C, Matziolis G, Mayr HO, Sostheim M, Hube R. Current failure mechanisms after knee arthroplasty have changed: polyethylene wear is less common in revision surgery. J Bone Joint Surg Am. May 6 2015;97(9):715-720.

88. Seyler TM, Marker DR, Bhave A, et al. Functional problems and arthrofibrosis following total knee arthroplasty. J Bone Joint Surg Am. Oct 2007;89 Suppl 3:59-69.

89. Yao D, Bruns F, Ettinger S, et al. Manipulation under anesthesia as a therapy option for postoperative knee stiffness: a retrospective matched-pair analysis. Arch Orthop Trauma Surg. Jun 2020;140(6):785-791.

90. Brigati DP, Huddleston J, Lewallen D, et al. Manipulation Under Anesthesia After Total Knee: Who Still Requires a Revision Arthroplasty? J Arthroplasty. Jun 2020;35(6S):S348-S351.

91. Crawford DA, Adams JB, Morris MJ, Berend KR, Lombardi AV, Jr. Manipulation under Anesthesia after Knee Arthroplasty Is Associated with Worse Long-Term Clinical Outcomes and Survivorship. J Knee Surg. Jun 2021;34(7):739-744.

92. Arshi A, Leong NL, D'Oro A, et al. Outpatient Total Knee Arthroplasty Is Associated with Higher Risk of Perioperative Complications. J Bone Joint Surg Am. Dec 6 2017;99(23):1978-1986.

93. Lovald ST, Ong KL, Malkani AL, et al. Complications, mortality, and costs for outpatient and short-stay total knee arthroplasty patients in comparison to standard-stay patients. J Arthroplasty. Mar 2014;29(3):510-515.

94. Bozic KJ, Kurtz SM, Lau E, et al. The epidemiology of revision total knee arthroplasty in the United States. Clin Orthop Relat Res. Jan 2010;468(1):45-51.

95. Halawi MJ, Gronbeck C, Metersky ML, et al. Time Trends in Patient Characteristics and In-Hospital Adverse Events for Primary Total Knee Arthroplasty in the United States: 2010-2017. Arthroplast Today. Oct 2021;11:157-162.

96. Bozic KJ, Kamath AF, Ong K, et al. Comparative Epidemiology of Revision Arthroplasty: Failed THA Poses Greater Clinical and Economic Burdens Than Failed TKA. Clin Orthop Relat Res. Jun 2015;473(6):2131-2138.

97. Kirschbaum S, Erhart S, Perka C, Hube R, Thiele K. Failure Analysis in Multiple TKA Revisions-Periprosthetic Infections Remain Surgeons' Nemesis. Journal of clinical medicine. Jan 13 2022;11(2).

98. Bourne RB, Chesworth BM, Davis AM, Mahomed NN, Charron KD. Patient satisfaction after total knee arthroplasty: who is satisfied and who is not? Clin Orthop Relat Res. Jan 2010;468(1):57-63.

99. Khatib Y, Badge H, Xuan W, Naylor JM, Harris IA. Patient satisfaction and perception of success after total knee arthroplasty are more strongly associated with patient factors and complications than surgical or anaesthetic factors. Knee Surg Sports Traumatol Arthrosc. Oct 2020;28(10):3156-3163.

100. Bonnefoy-Mazure A, Lubbeke A, Miozzari HH, et al. Walking Speed and Maximal Knee Flexion During Gait After Total Knee Arthroplasty: Minimal Clinically Important Improvement Is Not Determinable; Patient Acceptable Symptom State Is Potentially Useful. J Arthroplasty. Oct 2020;35(10):2865-2871 e2862.

101. Liu JB, Pusic AL, Temple LK, Ko CY. Patient-reported outcomes in surgery: Listening to patients improves quality of care. Bull Am Coll Surg. Mar 2017;102(3):19-23.

102. Masaracchio M, Hanney WJ, Liu X, Kolber M, Kirker K. Timing of rehabilitation on length of stay and cost in patients with hip or knee joint arthroplasty: A systematic review with meta-analysis. PloS one. 2017;12(6):e0178295.

103. Kurtz S, Ong K, Lau E, Mowat F, Halpern M. Projections of primary and revision hip and knee arthroplasty in the United States from 2005 to 2030. J Bone Joint Surg Am. Apr 2007;89(4):780-785.

104. Mechanic R. Post-acute care--the next frontier for controlling Medicare spending. N Engl J Med. Feb 20 2014;370(8):692-694.

105. Waterman F, Cisternas M, Korrer S, Wilson A. Analysis of patient characteristics, health care costs by surgical venue, and opioid utilization for common orthopedic procedures in the United States. J Manag Care Spec Pharm. May 2021;27(5):586-595.

106. Halawi MJ, Vovos TJ, Green CL, Wellman SS, Attarian DE, Bolognesi MP. Preoperative pain level and patient expectation predict hospital length of stay after total hip arthroplasty. J Arthroplasty. Apr 2015;30(4):555-558.

107. Krause A, Sayeed Z, El-Othmani M, Pallekonda V, Mihalko W, Saleh KJ. Outpatient Total Knee Arthroplasty: Are We There Yet? (Part 1). Orthop Clin North Am. Jan 2018;49(1):1-6.

108. Delanois RE, Mistry JB, Gwam CU, Mohamed NS, Choksi US, Mont MA. Current Epidemiology of Revision Total Knee Arthroplasty in the United States. J Arthroplasty. Sep 2017;32(9):2663-2668.

109. Fang C, Pagani N, Gordon M, Talmo CT, Mattingly DA, Smith EL. Episode-of-Care Costs for Revision Total Joint Arthroplasties by Decadal Age Groups. Geriatrics (Basel). 2021;6(2):49.

110. Schilling PL, He J, Chen S, Placzek H, Bini S. Risk-Adjusted Cost Performance for 90-Day Total Knee Arthroplasty Episodes: Data and Methods for Comparing U.S. Hospitals Nationwide. J Bone Joint Surg Am. Jun 3 2020;102(11):971-982.

111. Goldman AH, Kates S. Pay-for-performance in orthopedics: how we got here and where we are going. Curr Rev Musculoskelet Med. Jun 2017;10(2):212-217.

112. Haglin JM, Arthur JR, Deckey DG, Makovicka JL, Pollock JR, Spangehl MJ. Temporal Analysis of Medicare Physician Reimbursement and Procedural Volume for all Hip and Knee Arthroplasty Procedures Billed to Medicare Part B From 2000 to 2019. J Arthroplasty. Jul 2021;36(7s):S121-s127.

113. Nayar SK, MacMahon A, Mikula JD, Greenberg M, Barry K, Rao SS. Free Falling: Declining Inflation-Adjusted Payment for Arthroplasty Surgeons. J Arthroplasty. Mar 2021;36(3):795-800.

114. Mayfield CK, Haglin JM, Levine B, Della Valle C, Lieberman JR, Heckmann N. Medicare Reimbursement for Hip and Knee Arthroplasty From 2000 to 2019: An Unsustainable Trend. J Arthroplasty. May 2020;35(5):1174-1178.

115. Hariri S, York SC, O'Connor MI, Parsley BS, McCarthy JC. A resident survey study of orthopedic fellowship specialty decision making and views on arthroplasty as a career. J Arthroplasty. Sep 2011;26(6):961-968 e961.

116. Iorio R, Robb WJ, Healy WL, et al. Orthopaedic surgeon workforce and volume assessment for total hip and knee replacement in the United States: preparing for an epidemic. J Bone Joint Surg Am. Jul 2008;90(7):1598-1605.

117. Fehring TK, Odum SM, Troyer JL, Iorio R, Kurtz SM, Lau EC. Joint replacement access in 2016: a supply side crisis. J Arthroplasty. Dec 2010;25(8):1175-1181.

118. Anderson M, Van Andel D, Israelite CL, Nelson C. The Recovery Curve for Physical Activity Following Primary Knee Arthroplasty Using Passively Collected Objective Measures with a Smartphone-Based Care Platform and Smart Watch. Orthopaedic Proceedings. 2021;103-B(SUPP_9):15-15.

119. Zimmer Biomet. mymobility Clinical Study Preliminary Data. 569 Hip and Knee patients completing survey through 08/04/2020. Questions answered between 14- and 44-days post op. Interim Study Data. Study ongoing. 2020.

120. Zimmer Biomet. mymobility Clinical Study Preliminary Data. 774 Hip and Knee patients completing survey through 08/04/2020. Questions answered between 14- and 44-days post op. Interim Study Data. Study ongoing. 2020.

121. Anderson M, Lonner J, Van Andel D, Ballard JC. Passive Data Collection Across the Six-Week Episode of Care: The Next Evolution in Contemporary Patient Outcome Monitoring in Total Knee Arthroplasty. Orthopaedic Proceedings. 2021;103-B(SUPP_9):14-14.

122. Zimmer Biomet. Zimmer Biomet and Canary Medical Announce FDA De Novo Classification Grant and Authorization to Market the World's First and Only Smart Knee Implant. 2021.

123. Zimmer Biomet. Persona IQ Physician Instructions for Use. 2022.

124. Picerno P. 25 years of lower limb joint kinematics by using inertial and magnetic sensors: A review of methodological approaches. Gait & Posture. 2017/01/01/ 2017;51:239-246.

125. Komnik I, Weiss S, Fantini Pagani CH, Potthast W. Motion analysis of patients after knee arthroplasty during activities of daily living – A systematic review. Gait & Posture. 2015/02/01/ 2015;41(2):370-377.

126. Canary. Canary Tibial Extension with CHIRP System Patient Manual. 2020.

127. Christensen C, Waldeck A, Fogg R. How Disruptive Innovation Can Finally Revolutionize Healthcare. 2017.

128. Haleem A, Javaid M, Singh RP, Suman R. Telemedicine for healthcare: Capabilities, features, barriers, and applications. Sensors International. 2021/01/01/ 2021;2:100117.

129. Knapp PW, Keller RA, Mabee KA, Pillai R, Frisch NB. Quantifying Patient Engagement in Total Joint Arthroplasty Using Digital Application-Based Technology. J Arthroplasty. Sep 2021;36(9):3108-3117.

130. Ponder M, Ansah-Yeboah AA, Charalambous LT, et al. A Smartphone App With a Digital Care Pathway for Patients Undergoing Spine Surgery: Development and Feasibility Study. JMIR Perioper Med. 2020/10/16 2020;3(2):e21138.

131. D'Lima DD, Fregly BJ, Colwell CW, Jr. Implantable sensor technology: measuring bone and joint biomechanics of daily life in vivo. Arthritis Res Ther. Jan 31 2013;15(1):203.

132. Sliepen M, Lipperts M, Tjur M, Mechlenburg I. Use of accelerometer-based activity monitoring in orthopaedics: benefits, impact and practical considerations. EFORT Open Reviews. 03 Dec. 2019 2019;4(12):678-685.

Warning: The kinematic data obtained from Persona IQ have not been demonstrated to have clinical benefit. It is not intended to be utilized for clinical decision-making, and no data have been evaluated by FDA regarding clinical benefits.

WalkAI Exceptions are visible through the mymobility® clinician experience and are only for hip or knee replacement patients using the mymobility app with an iPhone 8 or higher using iOS 14 or newer.

This material is intended for health care professionals. Distribution to any other recipient is prohibited. For indications, contraindications, warnings, precautions, potential adverse effects, and patient counseling information, see the package insert or contact your local representative; visit www.zimmerbiomet.com for additional product information.

Patients must have Internet access and a text capable mobile device or a compatible smartphone to use mymobility; not all smartphone app features are available with web-based version. Not all patients are candidates for the use of this product and surgeons should evaluate individually to determine which patients are appropriate for therapy at home.

ZIMMER BIOMET

3938.1-US-en-Issue Date 2022-12

canturio™ Exclusively Distributed By

Zimmer, Inc.
1800 West Center St.
Warsaw, Indiana 46581-0587
USA

zimmerbiomet.com

canturio™ Legal Manufacturer

Canary Medical USA LLC
2710 Loker Ave. West
Suite 350
Carlsbad, CA 92010
Customer Service: 1-833-692-2627

canarymedical.com