ROSA® KNEE

VALUE ANALYSIS BRIEF

Clinical and Economic Value of the **ROSA Knee System**

ZIMMER BIOMET

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1. Executive Summary

1.1. Unmet Need

- Elective total knee arthroplasty (TKA) procedures are very common and effective treatments for patients with debilitating knee arthritis.[1,2] However, roughly only 85% of patients are satisfied with their primary TKA.[3] This suggests more can be done to relieve pain and restore function in a substantial proportion of patients.
- Several macro trends continue to exert pressure on facility financials: shift to outpatient setting, physician burnout, increased consumerization of health care, and alternative payment models. As with other industries, the winners in a consumer-driven health care market will be the providers who understand consumer motivations and respond to them proactively.

1.2. ROSA Knee System

- The ROSA Knee System is a robotic platform that aims at assisting orthopedic surgeons with bony resections, as well as assessing the state of the soft-tissues to facilitate implant positioning during a total knee arthroplasty.
- ROSA Knee uses x-ray for preoperative planning, which is designed to reduce cost, time, and patient radiation exposure associated with CT scans required by other orthopedic robotic systems.
- With ROSA Knee, surgeons may choose between three of the most distinguished knee implant systems in the world, including Persona®, Vanguard® and NexGen®. This facilitates the ability to personalize implant selection with patient-specific needs.[4–6]
- Utilizing ROSA Knee with the Persona Knee implant system typically reduces the number of instrument trays by 33%, potentially saving sterile processing costs, reducing lifting requirements by perioperative staff, and adding workflow efficiencies.[7,8]

1.3. Clinical Value of Other Robotic TKA Systems

- Improved implant alignment in TKA may translate to improved survivorship.[9] Robotic TKA has demonstrated increased surgical accuracy and fewer outliers in implant placement.[10-13]
- Approximately, only 85% of patients are satisfied with their primary TKA.[3] Evidence continues to emerge demonstrating improved functional and patient-reported outcomes associated with robotic TKA, although longitudinal work is needed to see if this translates to reduced mid- and long-term revision or reoperation rates.[14-17]

1.4. Economic Value of Other Robotic TKA Systems

- Several authors have reported short-term economic results demonstrating decreased index facility costs, decreased lengths-of-stay, fewer readmissions, and decreased post-acute service utilization associated with robotic TKA.[17-19] Additional longitudinal evidence is needed to determine the mid- and long-term cost effectiveness of robotic TKA.
- Studies have shown brief surgeon and staff operative time learning curves with robotic TKA, ranging from 7 to 20 cases in duration.[14,18,20,21]

2. Background

2.1. Epidemiology of Osteoarthritis

Osteoarthritis (OA) is the most common form of arthritis and a leading cause of disability worldwide and affects more than 30 million adults in the United States.[22,23] The overall economic burden of OA in the United States is estimated to be more than $60 billion per year, with work-related impacts as high as $13 billion annually.[24]

To tackle the increasing number of adults living with osteoarthritis, the volume of primary total joint arthroplasty (TJA) procedures has risen in recent decades. In 2019, nearly one million primary total knee arthroplasty procedures were performed in the United States, with an estimated growth rate of 4% per year.[25] The Medicare population makes up a large portion of the surgical volume, accounting for approximately 490,000 primary TKAs in 2017.[1]

2.2. Challenges in Primary Total Knee Arthroplasty

2.2.1 Patient Dissatisfaction after Total Knee Arthroplasty

TKA has revolutionized the treatment approach for patients with debilitating knee arthritis.[2,26] Yet, despite substantial advances in primary TKA patient selection, surgical technique, and implant design, numerous studies indicate roughly only 85% of patients are satisfied with their primary TKA.[3] These reports suggest that TKA is not achieving its goal of relieving pain and restoring function in a substantial proportion of patients.

Increasing evidence is also emerging that patients and doctors do not always agree on health-related quality-of-life improvements after therapeutic interventions.[3,27,28] A systematic review by Gunaratne (2017) reported that patient dissatisfaction in primary TKA pertains to several key factors – patient expectations prior to surgery, the degree of improvement in knee function, and pain relief following surgery.[29]

Identifying factors associated with patient dissatisfaction following TKA enables the surgeon and care team to align on a personalized perioperative care plan. In the operating room, surgeons must continue to strive to achieve an aligned and balanced knee, implanted with minimal soft tissue disruption to limit surgical complications.[29] Outside the surgical suite, surgeons must coordinate with nursing care teams and physiotherapy colleagues to manage patient expectations and emphasize the limitations of TKA in restoring premorbid functionality.[30]

2.2.2 Burden of Revisions

TKA is an effective treatment for patients with end-stage osteoarthritis and boasts strong clinical outcomes.[31] Yet, the burden of revision TKAs in the United States continues to increase. Currently, the estimated annual economic burden is $2.7 billion on the US health care system, and it might rise as high as $13 billion per year by 2030, largely due to increases in primary TKA volume.[32,33]

2.2.2 **Burden of Revisions** (cont.)

A large database study by Delanois et al. (2017) evaluated the Healthcare Cost and Utilization Project (HCUP) National Inpatient Sample (NIS) database to identify all revision TKA procedures performed between 2009 and 2013.[31] Clinical, economic, and demographic data were collected and analyzed for 337,597 procedures. The mean total charge for revision TKAs was $75,028.07, and the mean length-of-stay was 4.5 days. Infection (20.4%) and mechanical loosening (20.3%) were the most common etiologies for revision.[31]

As a result, it is of paramount importance for orthopedists to establish new ways to mitigate these economic and patient burdens. It is particularly important for surgeons to align implants accurately, since component malalignment may be attributed to mechanical loosening.[9] In multiple studies, bone resection errors of up to 4° in the coronal plane and 11° in the sagittal plane have been reported to occur during TKA.[34,35] Consequently, malalignment has been demonstrated in up to 30% of TKAs performed without technology assistance, with considerable variability among less experienced surgeons.[34]

2.3. Changing Orthopedic Landscape

As the demand for TKA increases, the health care system must adapt. The next several sections will address shifts in the orthopedic landscape – many of which are already having a considerable impact on healthcare utilization, surgery setting, surgeon satisfaction and burnout, and provider alignment with consumer preferences:

- **2.3.1.** Moving from Triple to Quadruple Aim
- **2.3.2.** Shift to Outpatient Setting
- **2.3.3.** Consumer-Driven Health Care & High-Deductible Health Plans
- **2.3.4.** Center of Excellence Models

Key Takeaways:

- Nearly half of orthopaedic surgeons experience burnout.[36] When evaluating new technology, providers should consider how new equipment or software might disrupt a surgeon's natural workflow. Another key consideration is how technology impacts surgeon and staff ergonomics, either by assisting with routine tasks and/or reducing the number of trays lifted by perioperative staff.[37]
- Consumers are directly allocating their health care dollars more than ever. In turn, patients are asking more from their care providers, seeking additional services and premium technology in the operating room. Just like in other industries, the winners in a consumer-driven health care market will be those who understand consumer motivations and respond to them proactively.
- Increasing evidence demonstrates patients undergoing TKA with high-volume physicians and hospitals achieve better outcomes.[38,39] Providers and payers are aligning to this evidence by developing center of excellence (COE) models which tout high surgical volumes and streamlined operations.[40] If these COE models prove successful and continue proliferating, facilities will likely increase investments in surgical assistive technology that enables surgeons to reduce variation and focus on accuracy and reproducibility.

2.3.1 Moving from Triple to Quadruple Aim

The Triple Aim framework was developed by the Institute for Healthcare Improvement (IHI) in Cambridge, Massachusetts (www.ihi.org). Since its introduction into health care lexicon, the Triple Aim concept has spread through the health care system. Berwick et al. (2008) explain the Triple Aim as having three interdependent goals: "improving the individual experience of care; improving the health of populations; and reducing the per capita costs of care for populations."[40]

However, literature suggests leaders and providers of health care should consider adding a fourth dimension—improving the work life of those who deliver care—to the compass points of better care, better health, and lower costs (Figure 2-1).[42]

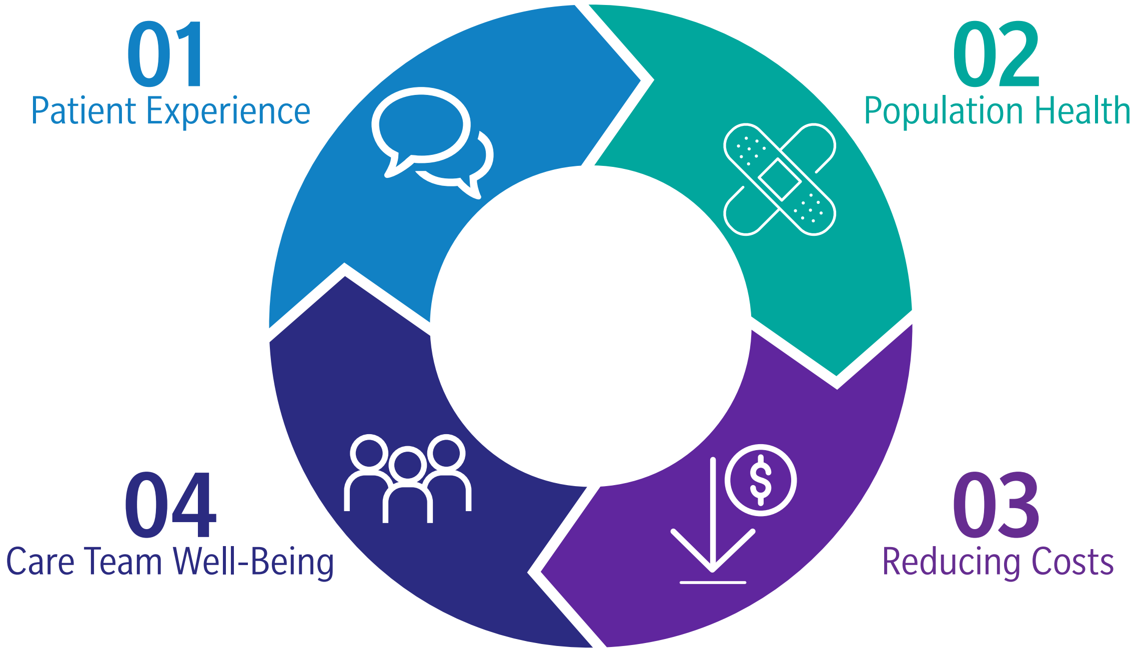

Figure 2-1: The Quadruple Aim introduces the importance of provider work-life considerations

In exchange for rising health care costs, society is expecting more and more of physicians and practices. Bodenheimer et al. (2014) reported, "Patients want their health to be better, to be seen in a timely fashion with empathy, and to enjoy a continuous relationship with a high-quality clinician whom they choose." These increasing demands on physicians and staff have led to high rates of surgeon- and staff-reported burnout.[42]

Shanafelt et al. (2012) found that nearly half of orthopaedic surgeons experienced symptoms of burnout—slightly less than physicians in emergency medicine, general internal medicine, and family medicine subspecialties.[36] This finding is consistent with several studies in the orthopaedic literature that have examined burnout symptoms in practicing surgeons, academic leaders, and trainees around the world.[43,44]

Sheikhzadeh et al. (2009) surveyed 50 perioperative nurses to determine ergonomic risk factors in the operating room environment. The authors reported a high prevalence of work-related musculoskeletal disorders, with lower back pain the most prevalent complaint (84%), followed by ankle/foot (74%) and shoulder (74%) pain.[37] In addition, lower back pain (31%) and ankle/knee (24%) pain were found to be the main causes of absenteeism from work.

2.3.1 Moving from Triple to Quadruple Aim (cont.)

According to a recent RAND Corporation survey, the principal driver of physician satisfaction is the ability to provide quality care.[45] Physician dissatisfaction, therefore, is an early warning sign of a health care system creating barriers to a high-quality practice.

Burnout among the health care workforce threatens patient-centeredness and the Triple Aim. Dissatisfied physicians and nurses are associated with lower patient satisfaction.[42] Unhappy physicians are also more likely to leave their practice, and the cost of surgeon turnover is high.[42]

When evaluating technology investments, providers should consider how a new piece of equipment or software might disrupt a surgeon's natural workflow or impose unnecessary processes. Another key consideration is how adoption of new technology will impact surgeon and staff ergonomics, either by assisting the surgeon with routine tasks and/or reducing the number of trays lifted by perioperative staff.[37] Technologies that meet these aims without imposing on the surgeon's workflow are likely to improve operative efficiency and surgeon and staff satisfaction.

2.3.2 Shift to Outpatient Setting

Effective January 1, 2018, TKA (Current Procedural Terminology code 27447) was removed from the inpatient-only (IPO) list for Medicare beneficiaries. This ruling was based on emerging evidence showing the feasibility of TKA already performed on an outpatient basis in non-Medicare patients.

Despite the immense amount of planning required to select appropriate patients and minimize risks associated with outpatient surgery, the rate of arthroplasty procedures in the outpatient setting is increasing. Between 2012 to 2015, there was a 47% increase in elective outpatient total joint arthroplasty (OTJA), and it is expected that there will be a 77% growth over the next ten years, with inpatient TJA growing only 3% during the same period (Figure 2-2).[46]

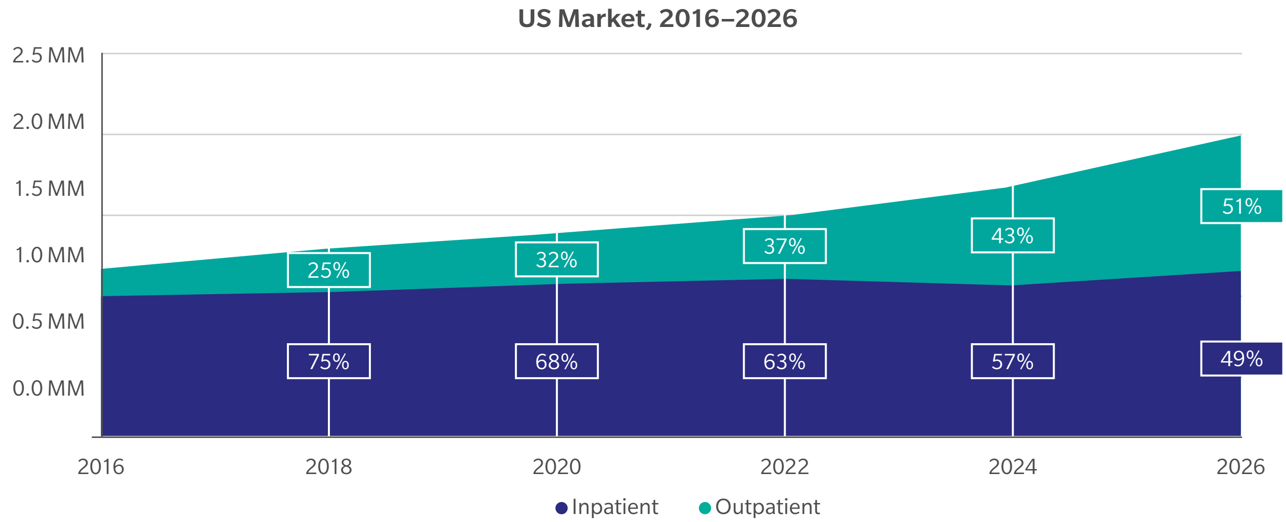

Figure 2-2: Outpatient primary total joint arthroplasty growth will far exceed inpatient growth[46]

Note: "Analysis excludes 0-17 age group, Inpatient forecast indicates discharges; outpatient forecast indicates volumes. Discharges and volumes are for osteoarthritis only and include partial knee replacements. Sources: impact of Change v16.0: HCUP National Inpatient Sample (NIS). Healthcare Cost and Utilization Project (HCUP). 2013. Agency for Healthcare Research and Quality. Rockville, MD; Optum Insight. 2014; The following 2014 CMS Limited Data Sets (LDS); Carrier. Denominator. Home Health Agency. Hospice. Outpatient, Skilled Nursing Facility; The Nielsen Company. LLC, 2016; Sg 2 Analysis. 2016."[46]

In an ambulatory care facility, outpatient total joint replacement requires an efficient and streamlined OR and central processing. Bert et al. (2017) reported, "Two areas, staff training and instrumentation, significantly impact the success of outpatient total joint replacement procedures and the ability to reduce costs."[46]

2.3.2 **Shift to Outpatient Setting** (cont.)

Staff training is critical to realizing the benefits offered by outpatient TKA. Perioperative staff should know each surgeon's procedural preferences and specific instrument sequencing to facilitate optimal procedure durations and operating room turnover times.

Cost reduction is also a significant consideration in the outpatient setting. Bert et al. (2017) reported, "Streamlining the OR via the standardization of instrument trays can decrease setup time and reduce the costs associated with sterilizing instruments that go unused...while also reducing procedure time."[46]

2.3.3 Consumer-Driven Health Care & High-Deductible Health Plans

As employers ask their workforce to bear a greater share of health care costs, consumers will decide the allocation of their health care dollars more than ever. In turn, patients will ask more from their care providers, seeking additional value from conveniences like online scheduling, email communication, retail clinics, and premium technology in the operating room.

Consumerization of healthcare has been a growing trend in the United States for some time, but the past decade brought a sharp rise in the increase of high-deductible health plans (HDHPs). The percentage of individuals under age 65 with private health insurance enrolled in a high-deductible health plan increased, from 25.3% in 2010 to 47.0% in the first three months of 2018 (Figure 2-3).[47] Even for patients without HDHPs, the increases in deductible and maximum out-of-pocket amounts have been significant. For example, the Department of Health and Human Services (HHS) in the United States has proposed the 2020 maximum out-of-pocket costs for Affordable Care Act (ACA) compliant insurance plans be increased to $8,200 for an individual, and $16,400 for a family.[48] This represents a 29% increase over the first year of ACA-compliant plans in 2014 ($6,350 individual, $12,700 family).[48]

" Percentage of persons under age 65 enrolled in a high-deductible health plan without a health savings account or in a consumer-directed health plan, among those with private health insurance coverage: United States, 2010-March 2018."[47]

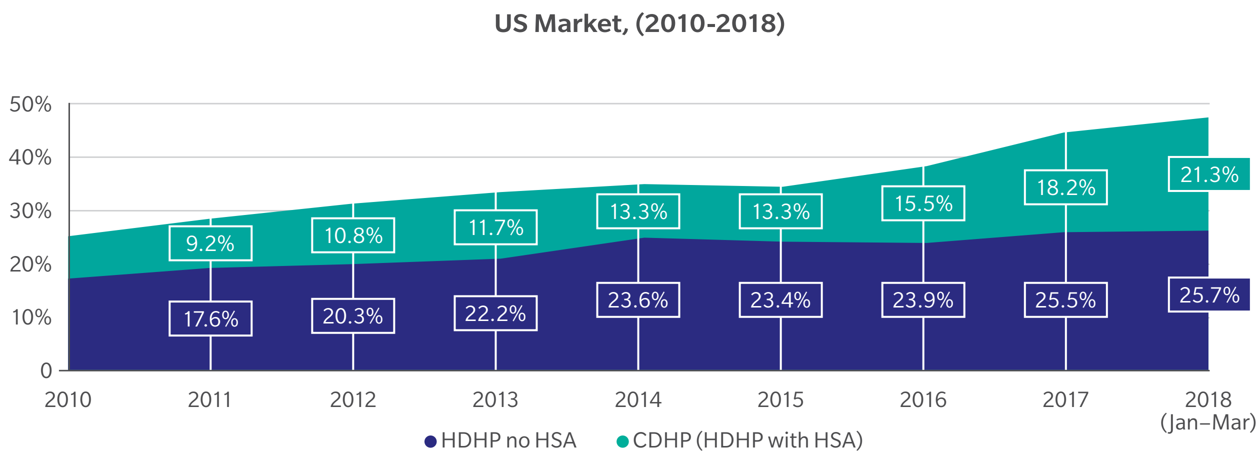

Figure 2-3: Increasing trend of high-deductible health plans in the United States[47]

NOTES: "CDHP is consumer-directed health plan. Which is a high-deductible health plan (HDHP) with a health savings account (HSA). HDHP no HSA is a high-deductible health plan without an HSA. The individual components of HDHP's may not add up to the total due to rounding. Data are based on household interviews of a sample of the civilian non-institutionalized population. SOURCE: NCHS, National Health Interview Survey, 2010–2018, Family Core component."[47]

The growth of high-deductible health plans (HDHPs) offers individuals lower monthly insurance premiums, but comes with higher out-of-pocket medical expenses until the deductible is met. An HDHP may be used with or without a health savings account (HSA), which allows pre-tax income to be saved to help pay for the higher costs associated with an HDHP.

2.3.3 Consumer-Driven Health Care & High-Deductible Health Plans (cont.)

The typical consumer does not have an accurate working definition of value when it comes to health care, especially as it pertains to surgery. As individuals continue to swap low premiums for high deductibles, the accelerated rise in patients' financial responsibilities presents an emerging threat for hospital margins. In 2016, the Health Care Cost Institute reported that individuals with high deductible health plans spend 13% less on health care than individuals with traditional plans.[49]

Additionally, when patients have to pay more out of their own pockets for care, they start shopping. In other words, they weigh tradeoffs in price and quality before they buy, often deciding to substitute cheaper treatments for more expensive ones. Just like in any other industry, the winners in a consumer-driven market will be those who understand consumer motivations and respond to them proactively. The patient experience has already become a key differentiator.

2.3.4 Center of Excellence Models

Increasing evidence supports the finding that patients undergoing a TKA with high-volume physicians and facilities achieve better outcomes.[38,39] In TKA, studies have associated higher surgeon volume with lower mortality, infection, and transfusion rates; shorter procedure times; decreased lengths of stay; and superior patient-reported outcomes.[50,51] Providers and payers are aligning to this growing body of evidence by developing center of excellence (COE) models which tout high surgical volumes and streamlined operations.[40] However, there is no single definition for a COE, so the term does not have a universal certification or set of standards when used by providers.[52]

Mehrotra et al. (2013) described a variety of methods used to designate centers of excellence.[53] The most frequently used criteria is surgical volume, but that only explains part of the variation in outcomes.[54] Other parameters which have been used to designate COEs are surgeon-staff training metrics, performance on process quality metrics, discharge planning, and nursing-patient ratios.[53,55] Evidence exists to support each of these possible criteria; however, systematic evaluation on whether COEs have better longitudinal outcomes and reduced costs is still needed.

Recently, several large self-insured companies have created their own Center of Excellence programs which contract directly with health care providers across the United States for surgical services for their employees.[56] If these COE models prove successful and continue proliferating, facilities will likely increase investments in surgical assistive technology that enables surgeons to reduce variation and focus on accuracy and reproducibility.

2.4. Technology Trends in Orthopedics

2.4.1 History and Development

Robotic technology was first introduced to lower extremity total joint replacement in the late 1980s.[34] In the mid-1990s, Masri et al. (1995) reported use of a passive pre-robotic device that was used to hold the knee during the procedure. The device was found to reduce costs, up to CAD $142 per TKA, and the technology was broadly marketed after EU approval.[57] Yet, despite widespread availability and expansion, these systems were seldom used.[58]

Several reasons limited the acceptance and adoption of early orthopedic robots in the 1990s. First, their use required insertion of fiducial markers before 3D scanning. Second, surgeons and surgical staff needed to learn new workflows, which led to longer operating times and higher costs. Third, the autonomous features of early robotic systems led to a lack of direct involvement from the surgeon. In the end, these usability factors led to low utilization in the mid-2000s and commercial withdrawal of several early orthopedic robotic systems.[34]

2.4.2 Current & Future State of Robotics in Joint Arthroplasty

The development of robotic surgery in orthopedics was based on earlier clinical experience with computer-assisted navigation, and orthopedic robotics has been around for over two decades. In nearly all industries, people question the value of robotic technology early in its lifecycle.[19,59] However, in nearly every industry, robotics has improved consistency, reduced variation in processes, lowered costs, and altered the deployment of human capital. While robotics continues to grow as a valuable supporting tool for surgeons in delivering patient-specific joint replacements, its role is likely to expand as the current era of value-based care shapes the future of healthcare.[59]

While there is debate on the role of robotics in health care, the adoption of robotic technology is prevalent in joint arthroplasty. As further evidence of the growing interest in robotic assistance, between 2008 and 2015, utilization of robotics in hip and knee arthroplasty increased from 16.2% to 29.2% of hospitals and from 6.2% to 17.1% of surgeons in the state of New York.[61] A separate study in 2014 reported that approximately 1 in 14 TKAs (7.0%) performed in the United States utilized computer navigation or robotic assistance, up from only 1.2% in 2005.[62]

Other robotic-arm assisted technology has reportedly demonstrated bone cut accuracy and precision to plan, component alignment and soft-tissue balancing.[63,64] Furthermore, other robotic technology has been associated with a relatively short learning curve, high ability to predict implant sizes, and reduced early post-operative pain.[15,17,21,65]

These advances have the potential to enhance surgical outcomes and may also reduce episode-of-care (EOC) costs for patients, payers and hospitals. Additionally, total joint arthroplasty has been a target of value-based reimbursement platforms such as Comprehensive Care for Joint Replacement (CJR) and the Bundled Payment Care Initiative (BPCI), which most believe are the future of value-based models. Therefore, demonstrating the economic outcomes associated with robotic-arm assisted arthroplasties is critical.

3. Product Profile: ROSA Knee System

Designed to Adapt to Surgeons' Preferred Workflow

ROSA Knee is designed to adapt to each surgeon's preferred workflow and supports a wide range of surgical philosophies with features such as soft tissue balancing and femoral rotation tools.

These advancements along with offering some of the most distinguished implant systems: Persona®, Vanguard® and NexGen®, surgeons are equipped to deliver personalized patient care.

Delivering High Accuracy of Resections[67]

Patient outcomes can be driven by the precision and accuracy of each step within the surgical procedure. The ROSA Knee System is designed to improve surgeon accuracy by providing precise bone resections and presents dynamic data of patient's anatomy throughout the procedure.[67]

A nationwide report has shown that 8 years post-surgery, guidance technologies like ROSA Knee showed 25% less revisions due to loosening of the implant than the ones placed using conventional instruments.[68]* In addition, patients treated with guidance technology like ROSA Knee have shown better function at 3 months and 12 months post-operatively.[69]* Post-operative pain levels for those patients were also lower than patients treated conventionally.[69]*

Optimizing Clinical Efficiency

Flexible imaging modalities, including x-ray based imaging and image-free options allow surgeons and patients convenience in preparing for surgeries and reducing imaging cost. Preoperative planning with ROSA Knee's 2D x-ray to 3D bone modeling X-Atlas™ technology reduces instrumentation in the OR and facilitates custom plans based on patient's unique anatomy.[67]

*ROSA Knee has not been clinically evaluated for effects on revision rates, loosening, function or pain.

4. Clinical and Economic Value of Other Robotic TKA Systems

4.1. Clinical Evidence Summary

There is growing evidence to support the adoption of robot-assisted approaches for TKA. While there is often heterogeneity and contradictory findings on any topic in the medical literature, there is early, solid evidence that robot-assisted TKA may be associated with two key clinical value drivers:

4.1.1. Reduced variability in implant positioning*
4.1.2. Improved functional and patient-reported outcomes*

Key Takeaways:

- Many implant failures can be attributed to misalignment and imbalanced ligament structure.[9] Some robotic TKA has demonstrated increased surgical accuracy and reduction of outliers in implant placement.[10-13]
- Approximately only 85% of patients are satisfied with their primary TKA.[3] Evidence continues to emerge demonstrating improved functional and patient-reported outcomes associated with some robotic TKA, although longitudinal work is needed to see if this translates to reduced mid- and long-term revision or reoperation rates.[14-17]

4.1.1 Reduced Variability in Implant Positioning

Computer-assisted surgery and, more recently, robot-assisted surgery have been introduced with the goal of improving implant positioning. Improved positioning may translate to improved survivorship, as varus tibial component alignment greater than 3° has been associated with early failure.[9] A study by Berend et al. (2004) evaluated 3152 TKA at 2-14 years of follow-up, finding that there was a 17.2 times increased failure with tibias in greater than 3° of varus and a 168 times increased failure with tibias in greater than 3° of varus and patient body mass index (BMI) > 33.7. BMI was not found to be associated with failure if alignment was neutral.[9]

A systematic literature review and meta-analysis by Ren et al. (2019) compared the alignment precision and implant positioning of other robotic and conventional TKA. The authors found seven studies with a total of 486 patients and 517 knees. Compared with conventional surgery, robotic TKA showed better outcomes in precise mechanical alignment and implant position ($p < 0.05$), with lower outliers ($p < 0.05$), and less drainage ($p < 0.05$).[10] No significant differences were observed when comparing operative time, range of motion and complication rates.

In a separate 10-year follow-up study by Cho et al. (2019), the authors reported excellent survival with both robotic and conventional TKA and similar clinical outcomes at long-term follow-up. In terms of radiological outcome, robotic TKA showed significantly better accuracy and consistency with fewer outliers compared with conventional TKA ($p < 0.05$).[11]

*ROSA Knee has not been clinically evaluated for reduced variability or improved functional and PROM scores.

4.1.2 Improved Functional and Patient-Reported Outcomes

As value-based payment models and high-deductible health plans (HDHPs) continue to shape health care design and delivery, the emphasis on patient-reported outcomes and functional measures will continue to grow. Evidence continues to emerge supporting improved functional and patient-reported outcomes associated with robotic TKA in some centers, although more longitudinal work is needed to see if this translates to reduced mid- and long-term revision or reoperation rates.

A systematic literature review by Khlopas et al. (2018) evaluated a number of potential advantages with robotic TKA, including patient satisfaction.[14] The authors reported on a number of early studies demonstrating improved patient satisfaction and improved functional results.

Marchand et al. (2017) used the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC), in which higher scores indicate poorer outcomes, to compare 20 consecutive robotic TKAs to 20 consecutive non-robotic TKAs based on pain, physical function, and total patient satisfaction.[15] Patients in both cohorts underwent similar postoperative rehabilitation, which included early ambulation and physical therapy. Patient satisfaction was assessed at six months postoperatively. Patients who underwent robotic TKA had significantly lower mean pain scores (3 ± 3 points [range, 0 to 8 points] vs 5 ± 3 [range, 0 to 10]), and better overall satisfaction (7 ± 8 points [range, 0 to 22 points] vs 14 ± 8 points [range, 0 to 27 points], $P < .05$) when compared to non-robotic TKA patients.[15] Robotic TKA patients were also found to have greater postoperative physical function as well (4 ± 5 points [range, 0 to 14 points] vs 9 ± 5 points [range, 0 to 17 points]) when compared to non-robotic TKA patients.[15]

Liow et al. (2017) analyzed a prospectively-randomized cohort of 60 TKA patients (31 robotic; 29 conventional) and found subtle improvements in patients' health-related quality of life with robotic assistance.[16] The robotic TKA group displayed a trend towards higher scores in SF-36 health-related quality-of-life measures, with significant differences in SF-36 vitality ($p = 0.03$), role emotional ($p = 0.02$) and a larger proportion of patients achieving SF-36 vitality minimally clinical important difference (MCID) (48.4% vs 13.8%, $p = 0.009$).[16] No significant differences in Knee Society Score (KSS), Oxford Knee Score (OKS), or satisfaction/expectation rates were noted.

Kayani et al. (2018) conducted a prospective cohort study with 40 consecutive patients undergoing non-robotic TKA followed by 40 consecutive patients receiving robotic-arm assisted TKA.[17] Inpatient functional outcomes and time to hospital discharge were collected in all study patients, and the authors found that robotic-arm assisted TKA was associated with reduced postoperative pain ($p < 0.001$), decreased analgesia requirements ($p < 0.001$), decreased reduction in postoperative hemoglobin levels ($p < 0.001$), shorter time to straight leg raise ($p < 0.001$), decreased number of physiotherapy sessions ($p < 0.001$) and improved maximum knee flexion at discharge ($p < 0.001$) compared with non-robotic TKA.[17] In this study, there were no systematic differences in baseline characteristics between the two treatment groups. Surgery was undertaken by a single surgeon using the same approach with identical implant designs, and inpatient rehabilitation was performed using a standardized program with the same rehabilitation team.

4.2. Economic Evidence Summary

In addition to clinical advantages, there is also growing economic evidence supporting the adoption of robot-assisted approaches for TKA. The current economic evidence demonstrates that the use of robotic TKA may be associated with three key economic value drivers:

4.2.1. Decreased index facility costs and length-of-stay*
4.2.2. Lower post-acute care costs and utilization*
4.2.3. Brief surgeon and staff learning curves*

Key Takeaways:

- Several authors have reported short-term economic results demonstrating decreased index facility costs and lengths-of-stay associated with robotic TKA.[17–19] Additional longitudinal evidence is needed to determine the mid- and long-term cost effectiveness of robotic TKA.
- An analysis of Medicare 100% data demonstrated promising results regarding discharge disposition, post-acute services, and readmissions associated with robotic vs non-robotic TKA. The authors reported robotic TKA patients had a significant 90-day readmission reduction of 33% ($p = 0.0423$), when compared with non-robotic TKA patients.[19]
- Studies have shown a beginner in technology-assisted TKA can reproduce the results of an expert from the outset, with operative times decreasing after only a handful of cases.[71] Surgeon learning curves associated with robotic TKA have been reported at 7 to 20 cases in duration.[14,18,20,21]

4.2.1 Decreased Index Facility Costs and Length-of-Stay

While there are several reported clinical improvements associated with robotic surgery (e.g. improved precision, higher patient satisfaction scores), broader uptake of robotic surgery into orthopedic practice will depend on its short-term economic value.[59]

In a study of a single surgeon's first 40 consecutive robotic-assisted TKA procedures, Naziri et al. (2019) reported a decreased length-of-stay associated with the robotic group (1.27 days vs. 1.92 days, $p < 0.0001$).[18]

Kayani et al. (2018) also demonstrated an inpatient length-of-stay reduction of approximately 30 hours with robotic versus non-robotic TKA in a prospective cohort study with 40 patients in each group. Median time to hospital discharge in robotic-arm assisted TKA was 77 hours [interquartile range (IQR) 74 to 81] compared with 105 hours [IQR 98 to 126] in non-robotic TKA ($p < 0.001$).[17]

In an evaluation of 90-day episode-of-care (EOC) costs associated with robotic TKA versus non-robotic TKA, Cool et al. (2019) identified patients in Medicare 100% data and analyzed index costs, lengths-of-stay, discharge disposition and readmission rates.[19] A 1:5 propensity-based match was performed to account for baseline differences between the two groups (519 – robotic TKA; 2595 – non-robotic TKA). The authors reported several promising economic results:

- Overall 90-day EOC costs for robotic TKA patients were found to be significantly less than that for non-robotic TKA patients (US$18,568 vs US$20,960). These amounts showed that robotic TKA patients had an 11% (US$2391) lower average cost associated with their 90-day post-index period of care ($p < 0.0001$).[19]
- Overall index facility costs to the payer for robotic TKA patients were found to be significantly less than those for non-robotic TKA patients (US$12,384 vs US$13,024; $p = 0.0001$).[19] These amounts for robotic TKA patients showed a 5% (US$640) lower cost associated with their index facility costs. In addition, robotic TKA was associated with a significantly lower index length-of-stay than the non-robotic TKA (1.84 vs 2.53 days; $p < 0.0001$).[19]

*ROSA Knee has not been evaluated for facility costs, length of stay, post-acute care costs, or surgeon learning curves.

4.2.2 Lower Post-Acute Care Costs and Utilization

The previously mentioned study by Cool et al. (2019), which evaluated of 90-day episode-of-care (EOC) costs associated with robotic TKA vs non-robotic TKA, also reported promising results with respect to discharge disposition, post-acute services, and readmissions.[19]

- Over 90% of patients in both cohorts utilized post-acute services, with the robotic TKA group accruing $1744 (25%) less costs than non-robotic TKA (US $5234 vs US $6978; p < 0.0001) per patient.[19] The authors suggested post-acute savings could be potentially attributed to robotic TKA patients being discharged to home health aid (56.65% vs 46.67%; p < 0.0001) or home with self-care (27.55% vs 23.62%; p = 0.0566) more frequently, and skilled nursing facilities (SNF) less frequently (12.52% vs 21.70%; p < 0.0001).[19]
- Robotic TKA patients also utilized fewer post-acute services. The robotic TKA group was 47% less likely to have a SNF admission and 16% less likely to utilize emergency room (ER) services in the 90-day post-index period (13.68% vs 25.78%; p < 0.0001 and 11.18% vs 13.29%; p = 0.1726, respectively).[19]
- The robotic TKA patients also had a significant 90-day readmission reduction of 33% (p = 0.0423), when compared with non-robotic TKA patients.[19]

4.2.3 Brief Surgeon and Staff Learning Curves

The number of cases it takes a surgeon to overcome the learning curve associated with a new technology is an important consideration for economic decision makers. Several studies have demonstrated that a beginner in technology-assisted TKA can overcome the learning curve quickly.[70]

In a systematic review and meta-analysis by Ren et al. (2019), the authors analyzed three RCTs which recorded operative time with robotic versus non-robotic TKA.[10,12,13,71] Non-robotic TKA was shown to have a shorter operative time, but the difference was not statistically significant (p=0.08). With regards to the learning curve, an early study by Siebert et al. (2002) reported, over the course of a total of 70 surgeries, the time required per robotic TKA operation declined from nearly 220 to 90 min.[72]

A separate systematic literature review by Khlopas et al. (2018) suggested surgeons can expect a short learning curve of roughly 15 cases in order to achieve similar operative times to those of non-robotic TKA.[14]

In a prospective-cohort, single-surgeon study with 60 consecutive non-robotic TKAs followed by 60 consecutive robotic-arm assisted TKAs, Kayani et al. (2019) reported robotic TKA was associated with a learning curve of seven cases for operative times (p = 0.01) and surgical team anxiety levels (p = 0.02).[20] The authors also reported that cumulative robotic experience did not affect accuracy of implant positioning, limb alignment, posterior condylar offset ratio, posterior tibial slope, and joint line restoration. Robotic TKA improved accuracy of implant positioning (p < 0.001) and limb alignment (p < 0.001) with no additional risk of postoperative complications compared to non-robotic TKA.[20]

In another recent prospective-clinical study, Sodhi et al. (2018) analyzed 240 patients who underwent robotic TKA by two high-volume surgeons without any prior robotic experience.[21] For both surgeons, the mean operative times for their first 20 robotic-assisted cases were significantly greater than those for their last 20 robotic-assisted cases as well as compared to 20 non-robotic controls (surgeon 1: mean, 81 vs 70 vs 68 minutes; surgeon 2: mean, 117 vs 98 vs 95 minutes, P < .05). However, when comparing their last 20 robotic TKA operative times to 20 non-robotic TKA cases, no difference was noted for both surgeon 1 (70 vs 68 minutes, P> .05) and surgeon 2 (98 vs 95 minutes, P > .05).[21] Similarly, when collectively comparing the last robotic cases for both surgeons to the non-robotic TKA controls, no differences in operative times were found (84 vs 81 minutes, P > .05). Based on these results the authors reported a learning curve of a few months in order to achieve similar operative times between robotic TKA and non-robotic TKA.

In a study of a single surgeon's first 40 consecutive robotic-assisted TKA procedures, Naziri et al. (2019) reported no difference in surgical time between the second set of 20 robotic-assisted TKAs versus the entire non-robotic TKA group (78.3 mins vs. 81.1 mins, p = 0.254).[18]

Marchand et al. (2019) investigated 335 robotic-assisted TKAs and reported the robotic software was able to accurately predict both femoral and tibial component sizes within 1 size of what was actually used, 98% of the time.[65] The authors reported that knowing implant sizes within 1 size preoperatively allowed for a substantial reduction in surgical trays (11 vs. 3), which markedly reduced operating room setup time, resources required, and overall operating costs.[65]

5. How ROSA Knee Differs from Other Robotic Platforms

Key Takeaways:

- ROSA Knee uses x-ray for preoperative planning, which may help minimize cost, time, and patient radiation exposure associated with CT scans required by other orthopedic robotic systems.[66]
- Utilizing ROSA Knee with the Persona Knee implant system typically reduces the number of instrument trays by 33%, potentially saving sterile processing cost, reducing lifting requirements by perioperative staff, and adding workflow efficiencies.[7]
- With ROSA Knee, surgeons may choose between three of the most distinguished knee implant systems in the world, including Persona, Vanguard and NexGen. This facilitates the ability to personalize implant selection with patient-specific needs.[4-6]

5.1. Pre-Operative Planning

5.1.1 No CT Required with X-Atlas 2D to 3D Proprietary Planning Process

The X-Atlas imaging protocol used with ROSA Knee does not require a CT scan. This is a clear differentiator versus other systems on the market. Rather, ROSA Knee uses an FDA-cleared algorithm which stitches together two long leg x-rays to generate a 3D model of the patient's knee. Landmarks are identified on the 3D model by a team of in-house specialists at Zimmer Biomet and a personalized preoperative plan is generated. Intraoperatively, the plan is changed in real-time based on landmarks taken by the surgeon which incorporate the patient's cartilage.

Regarding imaging costs, many insurance companies do not reimburse for CT scans for non-diagnostic preoperative imaging, since it is not considered medically necessary. By using x-ray, the ROSA Knee imaging protocol may reduce costs and time associated with CT and MRI scans required by other orthopedic robotic systems.

5.2 Intra-Operative Execution

5.2.1 Reduced Instrumentation and Sterile Processing Department Costs

Direct costs associated with sterile reprocessing of orthopedic instrument trays has been estimated at $58 per tray.[8] With the ROSA Knee System, surgeons using the Persona Knee implant system typically reduce their number of instrument trays from six to four, adding potential cost savings and workflow efficiencies.[7]

5.2.2 Variety of Implant Choices to Accommodate Physician Preference

A recent survey study on physician preference items (PPI) in orthopedic surgery by Burns et al. (2018) found that physicians' preference in vendor selection is heavily influenced by technology/implant factors and sales/service factors.[73] Specifically, the most important technological considerations associated with PPI in this study encompassed patient outcomes and implant longevity, scientific evidence, and the design and ease of both the implant and its instrumentation.

5.2.2 **Variety of Implant Choices to Accommodate Physician Preference** (cont.)

With ROSA Knee, surgeons may utilize some of the most distinguished knee implant systems in the world: Persona The Personalized Knee, Vanguard Knee System, and NexGen Complete Knee Solution.

- The Persona femoral component comes in 21 distinct profiles, with 2 mm increments available in standard and narrow sizes, providing the most comprehensive femoral sizing scheme on the market.
- The Vanguard Knee System offers Surgical Simplicity with complete component interchangeability.
- The NexGen Complete Knee System is one of the most widely used and clinically proven total knee systems in the world and has achieved the lowest revision rate (Cemented, Cementless and Hybrid Fixation) in the 2019 Australian Registry.[5,6]

Utilization of ROSA Knee to implant these knee systems gives the surgeon additional intraoperative information that will assist in more personalized placement of implants.

5.2.3 Real-time Soft Tissue Management

ROSA Knee provides the surgeon with the patient's intraoperative range of motion (ROM), gaps in flexion and extension, and the joint laxity throughout the ROM. This information is provided in real time as the surgeon flexes and extends the knee prior to making cuts, during trialing, and after implant placement. Decisions can be made about the resection while incorporating the soft tissue information.

With ROSA Knee real-time soft-tissue balancing, surgeons can determine resections based on each patient's soft tissue as well as bony anatomy. This also allows the surgeon to personalize rotation of the femoral component based on ligament tension. Other robotic systems on the market collect soft tissue information by taking snapshots of the knee in two positions (flexion and extension), so the surgeon cannot collect data about how the knee is responding as it is being manipulated in the procedure.

5.2.4 Surgeons Keep their Existing Workflow

With ROSA Knee, surgeons aren't required to learn a new surgical method or use different instrumentation to achieve their desired TKA. Whether surgeons prefer measured resection, gap balancing, or hybrid approaches, ROSA Knee incorporates a customized workflow that allows surgeons to remain in control and maintain important tactile feedback while cutting bone.

In addition to the implant sales representative, some other robotic systems on the market require the presence of a product specialist to preoperatively plan the case and to be present in the OR to execute the case. In contrast, ROSA Knee surgical plans are created preoperatively by trained engineers for plan accuracy and reproducibility across all ROSA Knee cases. As a result, no additional personnel are needed with ROSA Knee –the surgeon, OR staff, or Zimmer Biomet sales rep can operate the ROSA Knee touchscreen user interface without a dedicated specialist.

6. ROSA Knee System Return on Investment (ROI)

Zimmer Biomet has developed a customizable business case tool that assists each facility in assessing their potential ROI with the ROSA Knee System. A high-level overview is provided in this section. The full tool is available from Zimmer Biomet upon request.

Figure 6-1: ROSA Knee Pro Forma tool cover page

The ROSA Knee pro forma tool builds a facility-specific business case on the following parameters – facility procedural volume, annual growth estimates, utilization rates of robotic versus non-robotic TKA, payer mix, reimbursement amounts, and care setting. Operational expenses, such as disposable costs and sterile processing savings, are also included.

Once the facility's business case has been built in the ROSA Knee ROI tool, the user can export a PDF report and slide deck for use during value analysis committee meetings or executive justification presentations at the facility or system level.

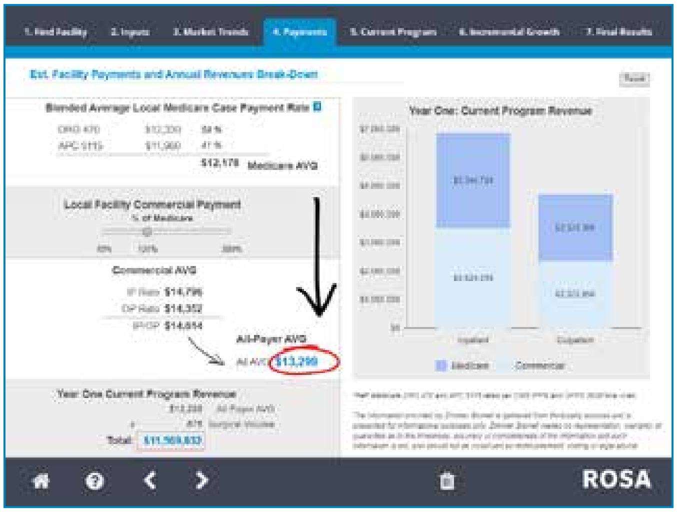

Figure 6-2: Estimating all-payer reimbursement average with ROSA Knee Pro Forma tool

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