

# ROSA<sup>®</sup> Partial Knee

## VALUE ANALYSIS BRIEF Clinical and Economic Value of the ROSA Partial Knee System





# Table of Contents

1. Executive Summary .....	2
2. Clinical Burden (PKA vs TKA).....	4
2.1 Economic burden (PKA vs TKA) .....	12
2.2 Evolution of PKA Treatment Landscape .....	15
3. ROSA Partial Knee System.....	19
4. Evidence of Partial Knee Robotic Systems .....	21
5. How ROSA Partial Knee Differs from Other Robotics Systems .....	24
5.1 ROSA Partial Knee Return on Investment .....	24
6. References.....	25

# 1. Executive Summary

Knee osteoarthritis (OA) is a progressive disease, and it is projected that approximately half of all patients will eventually undergo a total knee arthroplasty (TKA).<sup>1</sup> However, for a well-defined subset of patients with anteromedial OA,<sup>2,3</sup> partial knee arthroplasty (PKA) offers **a less invasive alternative to TKA**.

- PKA preserves bone stock and natural ligaments,<sup>4</sup> allowing for normal knee kinematics (stability, balance) and improved physiological function vs TKA.<sup>5-7</sup>
- In comparative studies, PKA has demonstrated better functional outcomes,<sup>8-11</sup> faster recovery time,<sup>9-12</sup> higher patient satisfaction,<sup>13-15</sup> and fewer complications than TKA.<sup>16-19</sup>
- Patients have reported less pain<sup>10,14</sup> and, consequently, less opioid use with PKA vs TKA.<sup>20-22</sup>
- Results from randomized clinical trials have also favored PKA over TKA.<sup>8,23,24</sup>

Although prospective and retrospective studies have shown that **nearly 50% of all knee replacement patients could be candidates for PKA**,<sup>3,25,26</sup> PKA currently accounts for less than 8% of joint arthroplasty procedures in the US.<sup>27-29</sup> Surgical volume is a critical factor in optimizing outcomes, with 20% of PKA utilization established as the minimum threshold for significantly decreasing revision rates in a large registry study.<sup>30</sup>

US-based economic evaluations have demonstrated the cost-effectiveness of PKA, which is associated with **lower hospital direct costs and total costs vs TKA**,<sup>31-35</sup> as well as shorter hospital stays and decreased risk of discharge to a rehabilitation facility.<sup>11,18,31</sup> The shorter procedure times and reduced instrumentation associated with PKA can also promote efficiency in the OR.<sup>31,36,37</sup>

As the treatment landscape for knee arthroplasty evolves, key considerations will include care team well-being and retention,<sup>38-41</sup> particularly in the context of higher patient volume and cost containment pressures,<sup>42-45</sup> and the ongoing adoption of robotic technology.<sup>46</sup> PKA is well-suited to robotic assistance, and utilization of robotic-assisted PKA has increased at more than double the rate of unassisted PKA.<sup>46,47</sup> In a survey study, patients expressed a preference for robotic-assisted orthopedic surgery, suggesting a potential marketing pull for hospitals and surgery centers.<sup>48</sup>

The **ROSA Partial Knee system** is a surgeon-centered robotic platform for enhancing the accuracy, precision, and efficiency of PKA procedures.<sup>49</sup> The ROSA Partial Knee system:

- Collects real-time data on patient's anatomy and soft tissues to provide dynamic tracking, laxity and tissue balance support, and solid resection construction<sup>49</sup>
- Provides a simple and easy-to-use workflow that can adapt to surgeons' individual preferences, building confidence and minimizing the learning curve<sup>49</sup>
- Works with the Persona<sup>®</sup> Partial Knee implant, a fixed bearing knee replacement built upon the clinical heritage of the Miller Galante (M/G) unicompartmental knee system, and Vivacit-E<sup>®</sup> vitamin E highly crosslinked polyethylene for enhanced strength and ultra-low wear<sup>50</sup>
- Integrates with the OrthoIntel Orthopedic Intelligence Platform and mymobility<sup>®</sup> with Apple Watch<sup>®</sup> to enhance pre- and post-operative communication and monitoring.<sup>49</sup>

Persona Partial Knee has not been evaluated for clinical or economic outcomes and was not utilized in the studies summarized in this section

Partial knee robotics systems have been shown to increase surgical accuracy and decrease outliers vs conventional methods, promoting a decrease in revision surgeries and improved implant survivorship.<sup>51-55</sup> Robotic PKA has been associated with very high patient satisfaction, rapid return to sports, and functional and quality of life outcomes that are improved or comparable to conventional PKA.<sup>55-58</sup>

The features of the ROSA Partial Knee system offer unique advantages compared to some other robotic PKA systems:

- X-Atlas™ 2D to 3D process, which generates 3D image-based surgical plans using X-ray imaging instead of CT scans<sup>49,59</sup>
- Flexibility for surgeons' preferred methods (no robot-specific representative needed)<sup>49</sup>
- Real-time soft tissue balancing allows surgeons to adjust component rotation based on ligament tension, taking into account the full range of motion for the knee<sup>60</sup>
- Single robotic platform for knee arthroplasty, with a simple intraoperative transition from PKA to TKA if needed<sup>49,61</sup>

\*\*Patients must have a compatible smartphone and be clinically evaluated as appropriate candidates for remote care to use mymobility

††ROSA Partial Knee has not been clinically evaluated for clinical or economic outcomes and was not utilized in the studies cited in this section

## 2. Clinical Burden (PKA vs TKA)<sup>†</sup>

### Key Takeaways:

- ✓ For a well-defined subset of patients with unicompartmental OA,<sup>2,3</sup> PKA offers a less invasive alternative to TKA; in comparative studies, PKA has demonstrated better functional outcomes,<sup>8-11</sup> faster recovery time,<sup>9-12</sup> and higher patient satisfaction<sup>13,14</sup>
- ✓ Patients who received a PKA have reported less post-operative pain,<sup>10,14</sup> and consequently less opioid use, compared with TKA<sup>20-22</sup>
- ✓ PKA procedures have been associated with significantly fewer complications in head-to-head studies vs TKA, including lower rates of deep infection, venous thromboembolic events, and myocardial infarction<sup>16-19</sup>
- ✓ Nearly 50% of all knee replacement patients could be candidates for PKA,<sup>25,26</sup> however, PKA accounts for less than 8% of joint arthroplasty procedures in the US<sup>27-29</sup>
- ✓ Approximately half of patients in one peer-reviewed survey study expressed a preference for PKA over TKA<sup>62</sup>
- ✓ Surgical volume is a critical factor in optimizing PKA outcomes, with 20% PKA utilization established as the minimum threshold for significantly decreasing revision rates in a large registry study<sup>30</sup>

Osteoarthritis (OA) is the most common form of arthritis and a leading cause of disability in the US.<sup>63,64</sup>

- Approximately 15 million Americans are affected by symptomatic OA of the knee, including nearly 9 million with advanced knee OA<sup>65</sup>
- The overall prevalence of OA in the US is increasing, and this trend is expected to continue given aging and obesity projections<sup>66</sup>
- The prevalence of knee OA increases with age, and the cumulative risk of developing symptomatic knee OA by the age of 60 is 9.3%;<sup>67</sup> however, working age adults (18 to 64 years) account for over half of all patients with OA in the US<sup>68</sup>

Knee OA is a progressive disease, and it is projected that **approximately half of all patients will eventually undergo a total knee arthroplasty (TKA).**<sup>1</sup>

- TKA utilization increased dramatically in the US between 1999 and 2008, with TKA utilization more than doubling among the overall population and tripling among individuals age 45 to 64<sup>69</sup>
- In 2017, more than 754,000 TKA procedures were performed in the US;<sup>70</sup> by 2025, this number is predicted to rise to 1.27 million<sup>71</sup>

However, for a well-defined subset of patients,<sup>72</sup> partial knee arthroplasty (PKA) offers a less invasive alternative that has demonstrated better functional outcomes<sup>8-11</sup> and fewer complications.<sup>16-19</sup>

<sup>†</sup>Persona Partial Knee has not been evaluated for clinical or economic outcomes and was not utilized in the studies summarized in this section

## Optimal Indication

Knee OA confined to a single compartment (medial, lateral, or patellofemoral) is termed unicompartmental osteoarthritis of the knee.<sup>4,73</sup> For patients with isolated medial knee OA, unicompartmental knee arthroplasty (UKA; also termed partial knee arthroplasty, or PKA) offers an attractive alternative to TKA.<sup>72</sup>

- PKA preserves bone stock and natural ligaments,<sup>4</sup> allowing for normal knee kinematics (stability, balance) and improved physiological function vs TKA;<sup>5-7,74,75</sup> in a head-to-head gait comparison study (n=12 TKA; n=12 PKA; n=121 healthy controls), PKA was associated with a higher top walking speed and a more physiological gait than TKA<sup>7</sup>
- PKA has been associated with fewer complications than TKA in comparative studies, including lower rates of deep infection, venous thromboembolic events, and myocardial infarction<sup>16,18,76</sup>

**Patient selection is key to a successful PKA;** Per Berend et al 2015, the consensus patient selection criteria is Anteromedial Osteoarthritis (AMOA; OA limited to the medial compartment).<sup>2,3,77,78</sup>

- AMOA is defined as: bone-on-bone in the medial compartment, full-thickness cartilage in the lateral compartment, functionally intact anterior cruciate ligament (ACL), and functionally normal medial collateral ligament (MCL)<sup>2,3</sup>
- An additional rare indication for PKA is spontaneous osteonecrosis of the knee (SONK)<sup>77</sup>

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*For a well-defined subset of patients with anteromedial OA, PKA offers a less invasive alternative to TKA*

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## Improved Outcomes

PKA has been associated with better function, more natural motion, and a faster recovery time compared with TKA.

- A review of joint registry data (n=3,519 PKA; n=10,557 TKA) demonstrated that 59% more PKA patients achieved excellent results than TKA patients<sup>14</sup>
- Better range of motion has been observed with PKA vs TKA in comparative studies<sup>9,11,12</sup>
  - Significantly better range of motion ( $p=0.0016$ ) was observed 6 weeks following PKA vs TKA in a retrospective matched cohort study (n=103 mobile-bearing PKA; n=103 TKA)<sup>11</sup>
- PKA has produced more physiological functionality and more natural motion, with a near-normal gait<sup>5-7,75</sup>
  - In a head-to-head gait comparison study (n=12 TKA; n=12 PKA; n=121 healthy controls), PKA was associated with a higher top walking speed and a more physiological gait than TKA<sup>7</sup>
  - Patients with both a PKA and a TKA (N=16) favored the PKA side in treadmill gait analysis<sup>6</sup>
- Additional advantages of PKA include a faster recovery time<sup>9-12</sup> and more likely return to low-impact sports<sup>10-12,79,80</sup>
  - In a retrospective case-control study (n=35 PKA; n=35 TKA), patients who received a PKA reported significantly higher post-operative activity level than those who received a TKA ( $p<0.001$ )<sup>80</sup>

Results from **randomized clinical trials have favored PKA** over TKA.

- Results from a large randomized clinical trial using surgeon's choice of implant (TOPKAT; N=528) demonstrated that PKA and TKA produced comparable clinical outcomes, but PKA was more effective, providing 0.240 additional quality-adjusted life-years (QALYs) over 5 years of follow up. Based on the results of this study, the authors suggest that PKA should be considered the first choice for patients with late-stage isolated medial OA.<sup>23</sup>
- A single-center randomized trial (N=102) assessed results over a longer follow-up period, with fixed-bearing PKA recipients demonstrating better patient-reported outcomes and implant survivorship vs TKA at 15 years.<sup>8</sup>
- Another single-center randomized trial (N=80) in patients with early medial OA reported similar improvement in patient-reported outcomes, function, and performance at 2 years, but fewer complications in the fixed-bearing PKA group vs the TKA group.<sup>24</sup>

Patients who received a PKA have reported less pain<sup>10,14</sup> and, consequently, less opioid use.<sup>20-22</sup>

- A US retrospective study reported that patients who underwent PKA were less significantly likely to require a second opioid prescription (50.2% vs 60.5%; p=0.0006), and significantly less likely to report continued opioid use, as defined by >5 prescriptions (5.8% vs 13.7%; p=0.001)<sup>20</sup>
- Another US claims database study found that PKA patients had significantly lower rates of post-operative opioid prescription compared to TKA patients over 1 year of follow-up, with pre-operative opioid use the strongest predictor of prolonged post-opioid use<sup>81</sup>
- In opioid-naïve patients, PKA was associated with less opioid consumption, lower refill rates, and shorter duration of use over the 4-week post-operative period vs TKA<sup>21</sup>
- When pre-operative opioid use was balanced across comparator arms, in a network cohort study designed to emulate the TOPKAT trial, a 35% to 40% cumulative incidence of opioid use was observed in the 3 to 12 months following PKA, compared to 40% to 45% following TKA<sup>22</sup>

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*PKA has been associated with less post-operative pain and opioid use vs TKA*

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Although PKA is frequently associated with higher revision rates than TKA in registry and observational studies,<sup>16,76</sup> the only large randomized trial conducted to date found no difference in revision rates between PKA and TKA.<sup>23</sup>

- In the TOPKAT RCT, which randomized patients with isolated medial knee OA to either PKA or TKA (surgeon's choice of implant), revision rates at 5 years of follow-up were 4% in both groups, with 6% of the PKA group and 8% of the TKA group receiving any re-operation<sup>23</sup>
  - Revisions were predominantly due to unexplained pain (2 patients receiving PKA vs 5 patients receiving TKA) or bearing dislocation (3 patients vs 0 patients, respectively)
- Long-term follow-up with the Oxford® mobile-bearing PKA implant has demonstrated survivorship ranging from 92.4% at 10 years<sup>82-87</sup> to 91.0% at 20 years<sup>88</sup>
- Replacement of an unsuccessful TKA with another TKA is a major reconstruction of the joint, often requiring specific revision implants; thus, surgeons may be less willing to advise re-operation of a TKA than a PKA<sup>16,89</sup>
  - PKA, being less invasive, can typically be converted to TKA with standard primary components
- American Academy of Orthopaedic Surgeons (AAOS) 2015 guidelines for surgical management of knee OA support the use of TKA over PKA to decrease revision risk, but note the need for a large prospective randomized trial<sup>90</sup>
  - Following publication of data from the TOPKAT trial, the UK National Institute for Health and Care Excellence (NICE) released an updated guideline recommending that patients with medial compartment OA be offered a choice of PKA or TKA, based on the relative risks and benefits for each patient<sup>91,92</sup>

Across studies, PKA has been associated with a **reduced rate of complications** compared to TKA, even after adjusting for differences in patient populations.

- AAOS guidelines note that limited evidence supports use of PKA vs TKA to decrease the risk of deep vein thrombosis (DVT) and manipulation under anesthesia for medial compartment OA<sup>90</sup>
- A systematic review identified a significantly increased risk of venous thromboembolic events (risk ratio 0.39; 95% CI 0.27, 0.57;  $p < 0.001$ ) and major cardiac events (risk ratio 0.22; 95% CI 0.06, 0.86;  $p = 0.03$ ) with TKA vs PKA in registry and large database studies<sup>76</sup>
- A US retrospective database review (N=828) reported a low rate of 90-day perioperative complications, with no post-operative variances from normal recovery in 88% of patients<sup>93</sup>
- Higher post-operative morbidity with TKA was also reported in a US retrospective multicenter study (n=2,235 TKA, n=605 PKA): after adjusting for demographic differences, PKA patients had a significantly lower overall risk of complications vs TKA patients (4.3% vs 11.0%; odds ratio 2.8;  $p < 0.0001$ ), as well as stiffness requiring manipulation under anesthesia (0.4% vs 5.0%; odds ratio 13.0;  $p < 0.0001$ ) and post-operative transfusion (0.2% vs 1.6%; odds ratio 8.5;  $p = 0.036$ )<sup>18</sup>
- Based on data from the National Joint Registry of England and Wales (NJR; N=341,749 knee arthroplasty procedures) using propensity score matching to minimize confounding by indication, patients in the PKA group experienced significantly lower rates of intraoperative complications, blood transfusion, thromboembolism, stroke, and myocardial infarction, relative to the TKA group ( $p < 0.02$  for all), and significantly lower rates of reoperation for infection ( $p < 0.0001$ )<sup>16</sup>
- A Swedish registry study (n=15,437 TKA; n=10,624 PKA) found that patients receiving a TKA were 2.6 times more likely to require a reoperation for infection than those receiving a PKA<sup>17</sup>

Registry and database studies have reported a **lower mortality rate** following PKA vs TKA.

- A systematic review of registry and large database studies concluded that TKA was associated with a significantly increased risk of mortality vs PKA (risk ratio 0.27; 95% CI 0.16, 0.45;  $p \leq 0.001$ )<sup>76</sup>
- Based on propensity score-matched survival modeling of NJR data, Liddle et al. 2014 estimated that 100 patients receiving PKA instead of TKA would result in one fewer death over four years<sup>16</sup>
- Morris et al. 2013 reported no deaths during the 90-day perioperative period following PKA, which compares favorably to the published perioperative mortality rate of TKA<sup>93</sup>

Patients were **more likely to be satisfied with a PKA** than a TKA, and more likely to state that they would choose to undergo the procedure again.

- Approximately 20% of patients reported being dissatisfied with their primary TKA in a peer-reviewed systematic literature review; key factors contributing to patient dissatisfaction included degree of improvement in function, degree of pain relief following surgery, and unmet expectations<sup>94</sup>
- Based on data from the NJR, patients who received a PKA were 27% more likely to be highly satisfied than patients who received a TKA<sup>14</sup>
- More patients who received a PKA reported they would undergo the procedure again; at 5 years of follow-up in the TOPKAT trial, 91% of PKA recipients stated that they would undergo the procedure again, vs 84% of TKA recipients<sup>15</sup>
- In a prospective study that assessed joint awareness using the Forgotten Joint Score (FJS), patients who received robotic PKA (n=65) reported significantly less joint awareness than patients who received robotic TKA (n=65) at 1 year (72.2 vs 61.1,  $p=0.02$ ) and 2 years of follow-up (72.4 vs 61.2,  $p=0.01$ )<sup>13</sup>

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*PKA has been associated with fewer complications, reduced risk of mortality, and higher patient satisfaction*

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## Target vs Actual Utilization

Prospective and retrospective analyses have shown that **nearly 50% of all knee replacement patients could be candidates for PKA.**<sup>3,25,26</sup>

- A prospective analysis of 200 knee arthroplasty patients classified 47.6% as PKA candidates<sup>25</sup>
- A retrospective assessment of 97 TKA procedures concluded that 21% of cases could have been treated with PKA<sup>95</sup>
- A retrospective cross-sectional study of 457 patients who received a primary TKA or PKA (Oxford mobile-bearing implant) estimated that 49% of patients were PKA candidates<sup>26</sup>

Utilization of PKA has increased in the US since the early 2000s, including in patients <65 years, as age is no longer considered a selection criteria.<sup>27,96</sup>

- In a study of two large claims databases, the rate of PKA utilization increased in the Medicare population (≥65 years) by 49% over 10 years (2002 to 2011) and in the MarketScan cohort (<65 years) by 25% over 8 years (2004 to 2012)
  - The annual increase in the number of PKA procedures averaged 5.8% in the older population and 25.4% in the younger population, vs increases of 3.6% and 33.9%, respectively, for TKA<sup>96</sup>
- Based on analysis of implant manufacturer data (1998 to 2005), the annual increase in TKA procedures was 9.4% vs 32.5% for PKA<sup>28</sup>

Approximately half of the patients in one study would choose PKA over TKA, suggesting that increased utilization rates are aligned with patient preferences.<sup>62</sup>

- In a discrete choice experiment that presented the evidence-based risks and benefits of each procedure to patients with knee OA (N=300), 58% of patients in the good-function cohort and 46% of patients in the fair/poor-function cohort chose PKA over TKA
  - Complications and revision rates were key factors driving patient preference<sup>62</sup>

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### *Patients have indicated a preference for PKA over TKA*

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Despite strong annual growth rates in PKA utilization and the high percentage of patients meeting inclusion criteria, **PKA accounts for less than 8% of joint arthroplasty procedures in the US**, and this proportion has plateaued in recent years.<sup>27-29</sup>

- 3 published studies have assessed trends in PKA utilization rates in the US:
  - Hansen et al. 2018 (Medicare/MarketScan claims databases): in 2008, PKA prevalence was 5.9% of the TKA prevalence in the Medicare population and 8.9% of the TKA prevalence in the MarketScan population<sup>96</sup>
  - Bolognesi et al. 2013 (Medicare claims database): PKA utilization was 4.5% among Medicare beneficiaries receiving joint arthroplasty from 2000 to 2009<sup>27</sup>
  - Riddle et al 2008 (Implant manufacturer sales data cross-referenced to hospital databases): in 2004, PKA represented 7.7% of all knee arthroplasty procedures<sup>28</sup>
- Based on the most recent data from the American Joint Replacement Registry (AJRR), PKA accounted for 4.1% of all primary knee arthroplasty in 2019<sup>29</sup>

Several factors contribute to the underutilization of PKA. Patient selection is driven primarily by historical precedent, **with current practice lagging the most up-to-date evidence.**

- The original 1989 study by Kozinn & Scott classified 5% of knee arthroplasty patients as PKA candidates,<sup>97</sup> however, a 2015 update removed many key selection criteria (obesity, age, patellofemoral damage limited to the medial facet, chondrocalcinosis)<sup>2</sup>
- Campi et al. 2018 also reviewed the most recent evidence and concluded that traditional contraindications for PKA (patient age, activity, weight, state of patellofemoral joint and chondrocalcinosis) had been disproven<sup>98\*</sup>

Higher reported revision rates with PKA vs TKA have driven **low utilization of PKA**, with surgeons offering the procedure to a limited subset of knee arthroplasty patients ( $\leq 5\%$ ) and therefore performing few each year.<sup>30</sup>

- Reported considerations for higher revision rates for PKA vs TKA include:
  - o Incorrect indication<sup>72</sup>
  - o Lower usage rate/lower patient volume<sup>30,72,77,98</sup>
  - o Relative simplicity of converting a PKA to a TKA, lowering the threshold for revision of a PKA to TKA (vs TKA to revision TKA)<sup>72</sup>
- Observed utilization rates are also reportedly heterogeneous across surgeons, due to different interpretations of the relative benefits and risks of PKA vs TKA<sup>99</sup>

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*Nearly 50% of knee replacement patients may qualify as potential PKA candidates; however, PKA currently accounts for <8% of all arthroplasty procedures in the US*

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\*See package insert for current indications and contraindications for use.

## Treatment Setting (Volume-Outcomes Correlation)

Surgical volume is a critical factor in optimizing PKA outcomes. Registry studies and meta-analyses have repeatedly shown **lower PKA revision rates with higher volume** surgeons and facilities:

- In a study from the NJR (N=41,986 PKAs), designed to determine the optimal usage threshold, the lowest revision rates were achieved with PKA usage between 40% and 60% of knee arthroplasties, with acceptable results observed above 20%
  - Highest rates of revision were observed with the lowest usage (<5%): specifically in the lower usage group (<20%), every 10% of increased usage was correlated with a 21% decreased risk of revision<sup>30</sup>
- Another NJR cohort study (N=23,400 PKAs) showed that low volume centers (defined as ≤50 procedures over 8 years) reported significantly higher revision rates than their high volume (>400) counterparts (1.62 vs 1.16 revisions per 100 component years)
  - Similarly, low volume surgeons (defined as ≤25 procedures over 8 years) reported significantly higher revision rates than the highest volume (>200) surgeons (2.16 vs 0.80 revisions per 100 component years)<sup>100</sup>
    - Risk of revision per center volume (≤50 vs >400): adjusted hazard ratio 1.35 (95% CI 1.10, 1.66; p<0.005)
    - Risk of revision per surgeon volume (≤25 vs >200): adjusted hazard ratio 2.54; 95% CI 1.97, 3.27; p<0.001)
- A meta-analysis of PKA outcomes (1998 to 2016) found that caseload of >24 per year and usage >30% were associated with the lowest revision rates; notably, usage had a greater impact on revision rates than caseload<sup>101</sup>
  - Annual revision rate by caseload (≤6 vs >24 per year): 1.87 vs 0.88 (p=0.02)
  - Annual revision rate by usage (<10% vs >30%): 0.69 vs 1.89 (p<0.001)
- In a Norwegian registry study (N=4,460 PKAs), hospitals performing more than 40 PKA procedures per year had a significantly lower risk of revision than those performing less than 10 per year (adjusted risk ratio 0.59; 95% CI 0.39, 0.90; p=0.01)<sup>102</sup>

In large registry studies, surgeons utilizing PKA for **at least 20% of annual knee arthroplasties** achieved a significant decrease in revision rate,<sup>30</sup> and hospitals performing more than 40 PKAs per year reported a lower risk of revision (vs those performing under 10 per year).<sup>102</sup>

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*20% utilization of PKA is the reported minimum threshold for significantly decreasing revision rates*

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## 2.1 Economic Burden (PKA vs TKA)<sup>†</sup>

### Key Takeaways:

- ✓ OA of the knee is a costly disease, and TKA accounts for the largest percentage of direct medical costs<sup>1,68</sup>
- ✓ US economic evaluations have demonstrated the cost-effectiveness of PKA, which is associated with lower hospital direct costs and lower total costs vs TKA<sup>31-35</sup>
- ✓ PKA has been associated with shorter hospital stays and decreased risk of discharge to a rehabilitation facility in comparative cost-effectiveness analyses<sup>11,18,31</sup>
- ✓ Preferential use of PKA in all eligible US patients has been estimated to produce a lifetime societal savings of \$987 million to \$1.5 billion per annual wave of treated patients<sup>103</sup>
- ✓ PKA procedures can promote efficiency in the OR via shorter procedure times and reduced instrumentation<sup>31,36,37</sup>

OA of the knee is a costly disease: per the Burden of Musculoskeletal Diseases in the US (BMUS), the **total incremental cost associated with OA was \$136.8 billion per year** between 2008 and 2014 (an estimated one-third of which is knee OA).<sup>68</sup>

- Incremental direct costs (medical expenditures): \$2,018 per person per year
- Indirect costs (earnings losses) of \$4,274 per person per year

Overall work-related impacts of OA are considerable: US adults had an aggregate earnings loss attributable to OA of \$71.3 billion annually between 2008 and 2014.<sup>68</sup>

The largest percentage of knee OA-related direct medical costs are attributable to TKA; if TKA eligibility criteria are expanded, costs are projected to increase accordingly<sup>1</sup>

- Published calculations using Agency for Healthcare Research and Quality (AHRQ) data associated TKA with an estimated \$28.5 billion in hospital expenditures in 2009<sup>104</sup>

### Cost-Effectiveness

Numerous economic evaluations have demonstrated the cost-effectiveness of PKA, with **lower hospital direct costs** and **lower total costs** vs TKA.

- A US retrospective review of primary TKA vs PKA (fixed-bearing) found that hospital direct costs were significantly lower for PKA vs TKA (\$7,893 vs \$11,156;  $p < 0.001$ ), with the same trend observed with total costs (hospital direct costs plus overhead; \$11,397 vs \$16,243;  $p < 0.001$ )<sup>31</sup>
- A US cost-effectiveness analysis concluded that, assuming levels of durability and function remain comparable to TKA, PKA is a cost-effective alternative for the treatment of unicompartmental OA, with incremental gains in effectiveness at minimal cost<sup>32</sup>
- The cost-effectiveness of PKA is further supported by a global SLR, which noted that initial cost savings are maintained over patient lifetimes even when accounting for higher rates of revision<sup>33</sup>

<sup>†</sup>Persona Partial Knee has not been evaluated for clinical or economic outcomes and was not utilized in the studies summarized in this section

- Modeling studies have shown that PKA becomes increasingly cost-effective as more older patients qualify for the procedure.
- Based on a Markov model comparing the cost-effectiveness of PKA vs TKA in the US across the age spectrum, PKA dominated TKA in patients  $\geq 65$  years, with lower lifetime costs and higher QALYs; when the percentage of older patients qualifying as candidates for PKA varied from 10.0% to 21.0%, total lifetime societal savings in the year 2015 ranged from \$56 to \$336 million. These savings are predicted to increase to \$84 million to \$544 million in 2020<sup>34</sup>
- Another US-based Markov model assessing the cost-effectiveness of PKA vs TKA in elderly, low-demand patients concluded that PKA is a cost-effective option in this patient population, assuming the annual revision rate remains below 4%; PKA resulted in higher accumulated QALYs (0.05) and lower accumulated costs (\$200) per case<sup>35</sup>

Preferential use of PKA in all US patients with unicompartmental OA could produce up to \$1.5 billion in annual cost savings.

- Based on a Markov model that assessed costs and QALYs as a function of age, an estimated lifetime societal savings of \$987 million to \$1.5 billion (per annual wave of patients) would be produced by preferential use of PKA in all US patients with end-stage unicompartmental knee OA<sup>103</sup>

PKA is associated with **shorter hospital stays** and **decreased risk of discharge to a rehabilitation facility** across studies.

- In a US retrospective cohort study that matched patients receiving a PKA (Oxford mobile-bearing implant) with patients receiving a TKA, hospital stays were significantly shorter in the PKA group vs the TKA group (1.4 days vs 2.2 days;  $p=0.0000$ ), and PKA patients were significantly more likely to be discharged on their first post-operative day (71 vs 28 patients;  $p=0.0000$ )<sup>11</sup>
- A US retrospective multicenter study reported that patients undergoing TKA experienced a significantly longer length of stay (LOS) after their procedure (3.3 days vs 2.0 days;  $p<0.0001$ ) than patients undergoing PKA, and were significantly more likely to be discharged to a rehabilitation facility (18.0% vs 3.1%;  $p<0.0001$ )<sup>18</sup>
- A US retrospective review comparing primary PKA (fixed bearing) and TKA procedures performed by a single surgeon also found a shorter length of stay in the PKA group ( $2.2 \pm 1.1$  vs  $3.8 \pm 2.4$ ;  $p<0.001$ ), with 4% of PKA patients discharged to a rehabilitation facility vs 25% of TKA patients<sup>31</sup>

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*Preferential use of PKA can shorten hospital stays and reduce the proportion of patients discharged to a rehabilitation facility†*

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## OR Efficiency

PKA contributes to OR efficiency via **shorter procedure times**

- An average TKA requires approximately 100 minutes of OR time,<sup>105</sup> with an additional 35 minutes of OR turnover<sup>106</sup>
- A US retrospective review found that both operative minutes ( $81.4 \pm 25.5$  vs  $112.2 \pm 52.1$ ;  $p < 0.001$ ) and anesthesia minutes ( $125.7 \pm 33.2$  vs  $156.4 \pm 53.0$   $p < 0.001$ ) for PKA were significantly shorter than that for TKA<sup>31</sup>

PKA procedures **utilize smaller and fewer instrument trays** vs TKA, streamlining OR workflow and potentially reducing costs

- Up to 8 instrument trays are often used for a conventional TKA with standard instruments, each weighing up to 70 pounds, and preparing and sterilizing each tray requires an average cost of \$75<sup>36</sup>
- Compromised trays, observed in 10% to 18% of TKA procedures, may result in additional time and cost for resterilization<sup>107</sup>
- The Persona Partial Knee implant system requires only 2 instrument trays<sup>37</sup>
- Based on an observational study of joint arthroplasty (N=7 surgeons), reducing the average number of trays from 5.3 to 3.0 saved 17.0 minutes of OR time; the total cost savings (including OR time and sterile processing costs) were estimated at \$763 per case<sup>108</sup>

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*PKA can contribute to OR efficiency via shorter procedures times and reduced instrumentation<sup>‡</sup>*

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<sup>‡</sup>Persona Partial Knee has not been evaluated for clinical or economic outcomes and was not utilized in the studies summarized in this section

## 2.2 Evolution of PKA Treatment Landscape†

### Key Takeaways:

- ✓ Prioritization of care-team well-being, particularly prevention of staff burnout, has emerged as a key consideration for hospitals and ambulatory care facilities<sup>38-41</sup>
- ✓ Higher patient volume and increased specialization may motivate investment in surgical assistive technology<sup>42,43</sup>
- ✓ Adoption of robotic technology, already prevalent in joint arthroplasty, is expected to continue expanding<sup>46</sup>
- ✓ PKA is particularly well-suited to robotic assistance, and utilization of robotic-assisted PKA has increased at more than double the rate of unassisted PKA, per a US database analysis<sup>46,47</sup>
- ✓ PKA procedures are increasingly performed in an outpatient setting, a shift that offers the opportunity for cost savings<sup>44,45,109</sup>
- ✓ Based on the results of a survey study, patients may exhibit a preference for robotic-assisted orthopedic surgery, offering a potential marketing pull for hospitals and surgery centers<sup>48</sup>

### Focus on Care Team Well-being and Retention

The Triple Aim framework ([www.ihl.org](http://www.ihl.org)), a widely accepted approach to optimizing performance of the US health care system, is based around three interdependent goals: improved population health, improved patient care, and lower costs.<sup>38</sup> Most recently, incorporation of a fourth dimension—care team well-being—has emerged as a key consideration for hospitals and ambulatory care facilities, particularly in the context of staff retention.<sup>38</sup>

- **Burnout is highly prevalent among orthopedic surgeons:** US survey studies have found that approximately half of orthopedic surgeons experience symptoms of burnout (e.g., emotional exhaustion, depersonalization, and low sense of personal accomplishment)<sup>40,41</sup>
  - o Staff burnout threatens both patient care and staff satisfaction<sup>38</sup>
  - o Dissatisfied physicians are more likely to leave their practice, and the cost of surgeon turnover is high<sup>38</sup>

†Persona Partial Knee has not been evaluated for clinical or economic outcomes and was not utilized in the studies summarized in this section

- **Prioritization of care team well-being highlights the importance of considering work environment** (e.g., workflow, ergonomics, and staff satisfaction) when considering technology investments<sup>38,39</sup>
  - o Work-related injuries are common among OR staff: a survey of 50 perioperative nurses and technicians (NYU Hospital for Joint Diseases Orthopedic Institute) 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<sup>39</sup>
  - o Lifting and manipulating heavy instrument trays, in particular, contributes to musculoskeletal injuries among OR staff<sup>39</sup>
  - o Adoption of new technology should not disrupt surgeon workflow or impose unnecessary processes, and should aid with routine tasks/ergonomics<sup>39</sup>

## Volume Considerations

Increased patient volume, a key goal for hospitals and ambulatory surgery centers, is a particularly relevant consideration for PKA, given the well-established correlation between usage and outcomes for this procedure.<sup>30</sup>

- While the overall volume of arthroplasty procedures has increased in the US over the past two decades, **Medicare reimbursement to physicians has decreased for all arthroplasty procedures with the exception of PKA**<sup>110</sup>
  - o Based on a study of the Medicare Fee-for-Service billing from 2000 to 2019, the number of total knee and hip arthroplasty procedures increased by 100% over this period, while physician reimbursement decreased 38.9% per procedure; the one exception to this trend was PKA, which showed an increased mean physician reimbursement of 16.6%, adjusted for inflation<sup>110</sup>
  - o Value-based payment reforms to Medicare physician reimbursement, which aim to incentivize quality and advancement of care, will be another key consideration for hospitals and ambulatory surgery centers<sup>110,111</sup>
- The proliferation of center of excellence (COE) models, typically characterized by high surgical volumes and streamlined operations, suggests that providers and payers are aligning to the growing body of evidence linking volume to outcomes in joint arthroplasty<sup>42,43</sup>
- Higher volume and increased specialization may motivate **investment in surgical assistive technology, including multi-application platforms**
- Increased volume of PKA could also result in an increased need for intra-operative flexibility, allowing surgeons to transition from a planned PKA to a TKA if needed<sup>112</sup>

## Outpatient PKA

PKA procedures have been increasingly performed in an outpatient setting, a shift that offers the opportunity for cost savings, but requires particular focus on patient selection.<sup>44,109</sup>

- Ambulatory discharge following PKA has become increasingly prevalent in the US, with **outpatient PKA accounting for the majority of PKA procedures** as of 2016<sup>45,109</sup>
  - Based on a retrospective study of a national claims database, utilization of outpatient PKA (defined as ambulatory surgery center or in-hospital outpatient) increased significantly between 2007 and 2016 (14.5% to 58.1%,  $p < 0.001$ )<sup>109</sup>
- In appropriately selected patients, PKA can be performed in the outpatient setting without increasing the risk of perioperative complications or readmissions<sup>109,113</sup>
  - A retrospective analysis of PKA procedures from the American College of Surgeons National Surgical Quality Improvement Program (ACS-NSQIP) database (2011 to 2013), which used propensity matching to compare day of surgery discharge vs post-operative day 1 discharge, reported no difference in 30-day complications or readmissions<sup>113</sup>
  - Gruskay et al. found a significantly decreased risk of pneumonia (OR 0.23;  $p = 0.008$ ) and post-operative transfusion (OR 0.28;  $p < 0.001$ ) with outpatient vs inpatient PKA, and a trend towards decreased 90-day readmission risk (OR 0.83;  $p = 0.062$ ) in a national private insurance database study (2007 to 2016)<sup>109</sup>
  - A Medicare claims study of PKAs performed between 2007 and 2016 (Bosch et al 2020) reported increased utilization of outpatient PKA without an increased risk of major medical complications (although a higher rate of wound complications and operative debridement was observed in the outpatient group)<sup>45</sup>
- PKA has been associated with a similarly low rate of complications in the hospital outpatient and ambulatory care settings<sup>114</sup>
  - A comparative study of single-surgeon PKA outcomes (2012-2016) noted a low rate of early post-operative complication rate in both settings, with no significant difference in overall complication rate, emergency department visits, or 90-day re-admissions<sup>114</sup>
- Outpatient PKA offers a **key opportunity for cost containment** in the setting of bundled payments and decreasing reimbursement rates<sup>44,45</sup>
  - Per Bosch et al, mean global (90-day) period reimbursement per procedure was \$2,782.13 lower for outpatient vs inpatient PKA ( $p < 0.001$ )
  - From 2007 to 2016, global period reimbursement decreased over time for both inpatient PKA (\$19,860.71 vs \$18,676.75;  $p = 0.004$ ) and outpatient PKA (\$17,317.98 vs \$16,242.42;  $p = 0.069$ )<sup>45</sup>
  - To realize the potential cost benefits of outpatient PKA, streamlining the OR via staff training and instrument standardization is critical to reducing procedure time and maximizing OR efficiency<sup>44</sup>

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*The majority of PKA procedures are now performed in the outpatient setting, providing a key opportunity for cost containment†*

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## Shifts Toward Robotic Systems

The use of robotic technology, already prevalent in joint arthroplasty, is expected to expand further as value-based reimbursement approaches shape the future of the US healthcare system.<sup>46</sup>

- Arthroplasty is particularly well-suited to robotic assistance, due to the very high degree of precision required to prepare and position implants<sup>46</sup>
- Adoption of **robotic technology is widespread in joint arthroplasty**, including PKA, and expected to continue expanding<sup>46</sup>
  - At present, nearly 40% of PKA procedures in the US are robotic-assisted, based on a study of 35,061 Medicare patients who underwent PKA in 2014 (38.8%)<sup>47</sup>
  - A 500% increase in robotic-assistance for knee arthroplasty was reported from 2009 and 2013, per a New York state database analysis (N=151,147), with the increase attributed primarily to PKA; overall, teaching hospitals accounted for 80% of robotic-assisted arthroplasty<sup>115</sup>
  - Annual increases in the proportion of cases using technology assistance were also observed in another New York state database study (N=133,472 primary TKA or PKA): from 2008 to 2015, the proportion of all knee arthroplasty cases with robotic assistance increased from 4.3% to 11.6%
    - The proportion of hospitals and surgeons using robotic-assisted arthroplasty was also noted (from 16.2% of hospitals and 6.2% of surgeons in 2008 to 29.2% and 17.1%, respectively, in 2015), with increases observed across all insurance and volume categories<sup>116</sup>
- Utilization of **robotic-assisted PKA has increased at more than double the rate of manual PKA**<sup>47</sup>
  - In a study of Medicare patients who underwent a PKA between 2005 and 2014 (N=35,061), primary robotic-assisted PKA increased 13.3-fold over the study period, vs a 5.4-fold increase in primary manual PKA<sup>47</sup>
- As a new generation of robotic systems is introduced into the field of knee arthroplasty, careful consideration of clinical and cost-effectiveness will be needed to maximize return on investment<sup>46</sup>

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*PKA is particularly well-suited to robotic assistance, and uptake of robotics is rapidly outpacing unassisted PKA†*

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As direct allocation of consumer health care dollars increases, the accelerated rise in patient financial responsibilities presents an emerging threat for hospital margins.<sup>117</sup> Patient experience will therefore be a key differentiator for hospitals and ambulatory surgery centers, with patients seeking value from services (e.g., premium technology in the OR, integrated apps for communication and post-operative monitoring).

- Patients may exhibit a **preference for robot-assisted orthopedic surgery** over conventional methods, suggesting a potential marketing pull for hospitals and surgery centers<sup>48</sup>
- Based on the results of a 30-question online survey of orthopedic surgery practices (N=588):<sup>48</sup>
  - 34% of respondents reported a clear preference for robotic-assisted surgery over a conventional manual approach
  - Nearly half (49%) would choose a low-volume surgeon assisted by robotic technology over a high-volume surgeon using conventional methods
  - 69% of respondents believed that robotic-assisted orthopedic surgery leads to better outcomes than conventional methods, with fewer complications (69%), less pain (59%), and shorter recovery time (62%)

†Persona Partial Knee has not been evaluated for clinical or economic outcomes and was not utilized in the studies summarized in this section unless stated otherwise

### 3. ROSA Partial Knee System

#### Key Takeaways:

- ✓ The ROSA Partial Knee system is a surgeon-centered robotic platform that enhances efficiency with a simple adaptable workflow designed to provide seamless support during the key steps of a PKA procedure<sup>49</sup>
- ✓ Based on the results of a cadaveric study, ROSA Knee can improve the accuracy and precision of knee arthroplasty compared to conventional methods<sup>118 §</sup>
- ✓ ROSA Partial Knee enhances pre-op communication and post-op monitoring through integration with the OrthoIntel Orthopedic Intelligence Platform and mymobility with Apple Watch for qualified patients<sup>49 ‡</sup>
- ✓ The ROSA Partial Knee system is compatible with the Persona Partial Knee implant, which offers multiple anatomical sizing options, and Vivacit-E vitamin E highly crosslinked polyethylene for enhanced strength and ultra-low wear<sup>50</sup>

#### Product Features

The **ROSA Partial Knee system** is a surgeon-centered robotic platform for **enhancing the accuracy, precision, and efficiency** of PKA procedures.<sup>49</sup>

- Collects real-time data on patient's anatomy and soft tissues to provide dynamic tracking, laxity and tissue balance support, and solid resection construction<sup>49</sup>
- Provides a simple and easy-to-use workflow that can adapt to surgeons' individual preferences<sup>49</sup>
- Designed to provide confidence in performing PKA by supporting surgeons during the key steps of a PKA procedure<sup>49</sup>

ROSA Knee has been shown to assist with intra-operative implant placement in TKA, increasing implant accuracy and precision compared to conventional methods<sup>118 † ‡</sup>

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*The ROSA Partial Knee system is designed to adapt to each surgeon's preferred workflow, building confidence and minimizing the learning curve*

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§ Cadaveric studies are not necessarily indicative of clinical results.

‡ Patients must have a compatible smartphone and be clinically evaluated as appropriate candidates for remote care to use mymobility

ROSA Partial Knee offers a data-driven approach, with insights designed to aid decision-making in the OR and deliver procedures that are efficient and predictable.<sup>49</sup> The ROSA Partial Knee also integrates with **mymobility with Apple Watch** and **OrthoIntel Orthopedic Intelligence Platform** for pre- and post-operative communication and monitoring.<sup>49</sup>

- A multicenter prospective randomized control trial, evaluating the use of smartphone-based care with mymobility with Apple Watch vs standard of care in patients who received PKA (N=107), demonstrated that patients using mymobility achieved comparable early outcomes without the need for a formal physical therapy program, and required fewer readmissions (5.1% vs 0%) and fewer ER visits (6.8% vs 0%) within 90 days<sup>119</sup>

The ROSA Partial Knee system is compatible with the **Persona Partial Knee**, a fixed bearing knee replacement built upon the clinical heritage of the Miller Galante (M/G) unicompartmental knee system with **excellent clinical outcomes**:

- The Persona Partial Knee offers compartment-specific, anatomical shapes for the femoral and tibial components, with seven different sizing options to optimize the fit. The tibial component also uses the Vivacit-E polyethylene bearing surface, which is actively stabilized with vitamin E to help protect against oxidation and maintain wear resistance<sup>50</sup>
- In an analysis of the Persona Partial Knee multicenter study at 2 years (N=110 knees with complete follow-up), survivorship was 98.9% with four revisions in total (three due to infections, one due to unexplained pain). A total of 97.3% of patients were surveyed as being satisfied or very satisfied with the results of their surgery, and 94.4% reported they were satisfied or very satisfied with the improvements in pain following implantation of the Persona Partial Knee<sup>120</sup>
- In a 20-year follow-up of 51 patients who received an M/G unicompartmental knee implant (N=62 knees), total survivorship was 90% with no cases of aseptic loosening or osteolysis<sup>121</sup>
  - o Clinical outcomes also remained positive with M/G unicompartmental implants through long-term follow-up, with a mean HSS score of 78 reported for patients at ≥15 years

## 4. Evidence of Partial Knee Robotics Systems<sup>§</sup>

### Key Takeaways:

- ✓ Robotic-assisted PKA has been shown to increase surgical accuracy and decrease outliers vs conventional methods, potentially decreasing revision surgeries and improving implant survivorship<sup>51-55</sup>
- ✓ Robotic PKA has been associated with very high patient satisfaction, rapid return to sports, and functional and quality of life outcomes that are improved or comparable to conventional PKA procedures<sup>55-58</sup>
- ✓ A small number of cases is typically required to overcome the learning curve for robotic PKA<sup>51,122</sup>
- ✓ Robotic PKA has shown the potential to improve index facility costs, LOS, readmissions, and post-acute service utilization versus conventional PKA<sup>123,124</sup>

### Clinical Value<sup>§</sup>

**Increased surgical accuracy and decreased outliers** in implant placement have been reported for PKA performed with robotics systems vs conventional methods:

- In a prospective randomized controlled trial (N=139), robotic-assisted PKA was associated with significantly improved component positioning, as assessed by lower median errors in all component parameters ( $p < 0.01$ ), and a significantly greater proportion of patients with component implantation within  $2^\circ$  of target position ( $p < 0.02$  across all component positions) vs conventional PKA<sup>52</sup>
- In a case-control study of 80 patients who received robotic-assisted PKA matched with 80 patients who received conventional PKA, significantly fewer postoperative limb alignment outliers were observed in the robotic vs conventional group for both lateral PKA ( $p = 0.018$ ) and medial PKA ( $p = 0.038$ )<sup>53</sup>
- In an SLR and meta-analysis including 10 articles (published up to April 2020; N=1,231 knees), PKA performed with robotic systems had significantly fewer outliers of limb alignment ( $p < 0.001$ ) and outliers of tibial alignment ( $p < 0.001$ ) compared to conventional methods<sup>54</sup>
- Another SLR including 21 studies noted that all 11 studies that compared implant positioning with robotic system PKA vs conventional PKA found increased accuracy with robotic systems<sup>55</sup>

Robotic PKA systems can promote a **decrease in revision surgery and improved implant survivorship** compared to conventional PKA, driven in part by the higher positional accuracy achieved with robotic PKA:

- In a retrospective analysis of patients who underwent robotic or conventional PKA between 2005 and 2014 were identified in the PearlDiver Medicare database (N=35,061), robotic PKA procedures had significantly lower revision incidence (0.99 vs 4.24%,  $p = 0.003$ ) and lower proportion of patients requiring multiple revisions (0.91 vs 4.23%,  $p = 0.005$ ) compared to conventional PKA. Kaplan-Meier survival curve 3 years following the index procedure to all-cause revisions demonstrated that patients who received robotic PKA maintained nearly 100% survivorship compared with conventional PKA patients who had 97.5% survivorship<sup>47</sup>
  - o Optimal tibial and femoral component coronal angles ( $2^\circ$  to  $4^\circ$  for tibial,  $0^\circ$  and  $2^\circ$  for femoral) were associated with a significant implant survival benefit at 15 years compared to non-optimal placements in a prospective analysis of 264 PKA procedures in a hospital registry<sup>125</sup>

<sup>§</sup> ROSA Partial Knee has not been clinically evaluated for clinical or economic outcomes and was not utilized in the studies cited in this section

Robotic PKA has been associated with **very high patient satisfaction**, and **functional and quality-of-life outcomes that are improved or comparable to PKA performed with conventional methods**:

- In a randomized controlled trial of robotic-assisted vs conventional PKA (N=139), significantly improved early pain ( $p=0.04$ ) and function (per American Knee Society Score,  $p=0.0405$ ) were observed in the robotic arm vs the conventional arm at 8 weeks of follow-up; additionally, nearly double the proportion of patients in the robotic arm achieved a forgotten joint (15% vs 8%)<sup>126</sup>
- A retrospective study assessed data from a total of 25 patients who received lateral PKA (11 robotic-assisted PKA and 17 conventional PKA): results from this study demonstrated that robotic surgical technique for lateral PKA provided significantly quicker return to sports than conventional technique ( $4.2 \pm 1.8$ -month improvement;  $p<0.01$ ), with a comparable rate of return to sports (100% vs 94%)<sup>57</sup>
- A prospective multicenter study of 384 patients who received robotic PKA (432 knees) demonstrated 97% implant survivorship over a mean follow-up of 5.7 years (13 revisions were performed, of which 11 knees were converted to total knee arthroplasty and in 2 cases, 1 PKA component was revised)
  - Among all the unrevised patients, 91% were either very satisfied or satisfied with their knee function at follow-up<sup>56</sup>
- No implant failures or implant-related complications were recorded among 51 robotic PKA procedures in a prospective study. Furthermore, 96.1% of patients were satisfied or very satisfied at the latest follow-up, while none were dissatisfied or very dissatisfied. Total WOMAC (Western Ontario and McMaster Universities Arthritis Index) score and each score's component was significantly improved after surgery. Knee alignment was significantly improved; as flexion increased, varus and flexion contracture decreased<sup>58</sup>
- In an SLR of 21 studies, robotic-assisted PKA demonstrated better soft tissue balance, patient function scores and satisfaction in short-term outcomes compared to conventional methods<sup>55</sup>

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*Compared to conventional PKA, robotic PKA systems have shown improved implant survivorship while maintaining high patient satisfaction and preserving functional outcomes*

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Robotic PKA is characterized by **a learning curve that can be overcome after a small number of cases**, allowing surgical teams to **rapidly gain confidence** in the procedure:

- Robotic-arm assisted PKA ( $n=60$ ) was associated with a learning curve of six cases for operating time and surgical team confidence levels in a prospective study<sup>51</sup>
  - Accuracy of implant positioning, posterior condylar offset ratio, posterior tibial slope, native joint line preservation, and post-operative limb alignment were not significantly affected by cumulative surgical experience
- Among 13 surgical teams performing a total 892 robotic PKA procedures, an average of 16 surgeries (range: 4 to 42) were required for surgical teams to consistently reach their respective steady-state surgical times in a single-center study<sup>122</sup>

## Economic Value<sup>5</sup>

Short-term impacts such as **index facility costs, LOS, readmissions, and post-acute service utilization can be improved by robotic PKA** versus conventional PKA, leading to lower costs:

- In a Markov model for US payers, estimated incremental cost-effectiveness ratio (ICER) for robotic vs conventional PKA was \$14,737 per revision avoided in a facility seeing 100 patients a year. Cost-effectiveness was strongly impacted by case volume, with higher case volumes associated with greater cost-effectiveness<sup>123</sup>
- At 24 months after the primary PKA procedure, patients who underwent robotic PKA had fewer revision procedures (0.81% [2/246] vs 5.28% [26/492]; p=0.002), shorter mean overall LOS (duration of initial surgery stay + revisions: 2.00 vs 2.33 days; p>0.05) and incurred lower mean costs (cost of initial surgery + revisions: \$26,001 vs \$27,915; p>0.05) than conventional PKA patients<sup>124</sup>
  - Considering only the index surgery stay, robotic PKA patients also experienced significantly shorter mean LOS (1.77 vs 2.02 days; p=0.0047) and lower mean costs (\$25,786 vs \$26,307; p>0.05) compared to conventional PKA

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*Robotic PKA systems have demonstrated cost-effectiveness vs conventional PKA, especially for facilities with high case volumes*

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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.<sup>46</sup>

## 5. How ROSA Partial Knee Differs from Other Robotics Systems

ROSA Partial Knee provides several features that offer unique advantages compared to some other robotic PKA systems:

- ROSA Partial Knee uses the **X-Atlas™ 2D to 3D process**, which generates 3D image-based surgical plans using **X-ray imaging instead of CT scans**, with the potential to save money and decrease radiation exposure<sup>49,59</sup>
  - CT scans constitute a substantial proportion of ionizing radiation received during medical procedures (average effective dose typically between 2 to 16 mSv)<sup>127,128</sup>
- ROSA Partial Knee is **flexible for surgeons' preferred methods**, and **no robot-specific representative is needed** during the procedure (an implant rep is sufficient)<sup>49</sup>
- Real-time soft tissue balancing allows surgeons to adjust component rotation based on ligament tension, taking into account the full range of motion for the knee (rather than only flexion and extension)<sup>60</sup>
- The ROSA Partial Knee system **supports TKA as well as PKA procedures**, allowing facilities to achieve greater efficiency through a single robotics platform<sup>49,61</sup>
- ROSA offers a **simple intraoperative transition** from PKA to TKA, if needed<sup>49</sup>

### 5.1 ROSA Partial Knee Return on Investment

A pro-forma return on investment (ROI) tool has been developed for the ROSA Partial Knee system, which builds a facility-specific business case for the ROSA Partial Knee system based on the following parameters:

- Facility procedural volume
- Annual growth estimates
- Utilization rates of robotic vs non-robotic PKA
- Payer mix
- Reimbursement amounts
- Care setting
- Operational expenses (including disposable costs and sterile processing costs)

The ROI tool is available from Zimmer Biomet upon request.

§ ROSA Partial Knee has not been clinically evaluated for clinical or economic outcomes and was not utilized in the studies cited in this section

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