ROSA® Hip

VALUE ANALYSIS BRIEF
Clinical & Economic Value
of the **ROSA Hip System**

ZIMMER BIOMET

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1. Executive Summary*

Hip osteoarthritis (OA) is a progressive disease, with pain and functional limitations impairing quality of life (QoL) and eventually exhausting pharmacotherapy options.[1,2] For hip OA that has progressed to severe end-stage disease, total hip arthroplasty (THA) is the gold standard treatment.[3-5] More than 450,000 THA procedures are performed annually in the U.S.,[6] and the rate of THA utilization is expected to continue increasing, with an **estimated ~635,000 THA procedures projected in 2030**.[7-9]

Although THA typically produces substantial improvements in pain and function—as evidenced by a 10-year implant survivorship of 95%[10]—a subset of patients experience suboptimal outcomes and complications.[11-13]

- Readmissions and surgical site infections ≤90 days of surgery have been reported in 7.9% and 2.1% of patients, respectively[12,13]
- Certain complications can necessitate revision surgery, including dislocations (which account for 15% to 31% of revision procedures), infections, inflammatory reactions, instability, aseptic loosening, and mechanical complications[14-17]
- Revision THA accounts for approximately 15% of all THA procedures and is projected to increase to 96,700 annually in the U.S. by 2030[18-20]

While OA of the hip is a costly disease that accounts for a large volume of hospital expenditures,[21,22] economic studies have demonstrated the cost effectiveness of THA across age groups and implant types, including newer generation dual-mobility implants.[23-26] However, **hip dislocations are a leading cause of revision THA**, which is significantly more expensive than primary THA due to higher hospital costs and increased resource use.[27,28] Operating room (OR) time remains dependent on surgeon and patient factors (e.g., learning curve, patient body mass index [BMI]),[29-31] but is significantly longer and more variable with revision procedures;[32] thus, OR efficiency remains a key area of focus in THA.

The three commonly used surgical approaches for THA include the direct anterior approach, direct lateral approach, and posterior approach.[34] There is a trend towards increasing use of the direct anterior approach, which provides soft tissue preservation, faster recovery, and low risk of dislocation, but presents challenges in component positioning and requires a longer operation time vs. other approaches.[34-42] Despite advances in surgical techniques and implant design, **there remains an unmet need for accurate and reproducible results** for patients undergoing THA procedures.[16,43]

While the use of robotic technology in hip arthroplasty has also trended upwards,[44,45] and patients have expressed a preference for robot-assisted orthopedic surgery over conventional methods,[46] rapid and seamless integration of new technology into current surgical processes is needed to optimize the learning curve and minimize disruption to surgeon workflow.[47] Additionally, bundled payment models have resulted in hospitals and surgeons increasingly sharing the risk of post-operative complications and associated expenses,[33] driving investment in technology with the potential to maximize efficiency and improve quality reporting metrics.[24,48]

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

Compared to conventional instrumentation, the **ROSA Hip System®** is a **personalized robotics system** designed to enhance the **accuracy and reproducibility** of direct anterior THA procedures by assisting with pre-operative preparation and intra-operative positioning of implant components.[49,50]

- Precisely assists with accurate acetabular component orientation and leg length through robotic guidance[50]
- Provides real-time data to evaluate leg length and offset decision making intra-operatively[49]
- Resulted in 100% of cases within the Lewinnek and Callanan Safe Zones (fewer outliers compared to conventional instrumentation)[50]
- Fits seamlessly into existing fluoroscopy-based workflows for the direct anterior approach, with a customizable workflow designed to minimize the learning curve[49]

Robotic-assisted THA* has been shown to increase surgical accuracy and decrease outliers vs. conventional methods, with decreased or comparable rates of revision surgeries and complications such as dislocation.[51-55] Robotic THA has also been associated with improved functional and QoL outcomes vs. conventional procedures, as well as high patient satisfaction.[51,52,54] Index length of stay (LOS), readmissions, and blood transfusion rates can be lower for robotic vs. conventional THA, leading to lower facility costs.[56,57]

ROSA Hip offers several key features designed to improve surgical workflow and optimize OR efficiency for THA procedures:[49]

- No requirement for pins or reference arrays to simplify setup and potentially minimize additional time to procedure
- Integrated with ONE Planner™ Hip, a web-based surgical software, to plan a hip replacement case using pre-operative X-ray patient images[49]
- Decreased radiation exposure as no CT scans are required
- Auto landmarking and overlay tool supports a streamlined procedure

In addition to THA, the ROSA Robotics platform can include additional modalities for total knee and partial knee arthroplasty, with the potential to optimize efficiencies for medical facilities.[58]

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2. Clinical Burden of Hip Osteoarthritis*

Key Takeaways:

- ◊ The prevalence of symptomatic hip OA in the U.S. ranges from 4.2% to 9.7% and increases with age[59-62]
- ◊ Total Hip Arthroplasty (THA) is the gold standard treatment for hip OA that has progressed to a severe end-stage disease[1,3-5]
- ◊ More than 450,000 THA procedures are performed annually in the U.S.,[6] and approximately 635,000 annual procedures are predicted by 2030,[9] as patients <65 years drive increased demand[7,63,64]
- ◊ Although THA is a successful treatment for end-stage hip OA, with 10-year implant survivorship of 95%,[10] a subset of patients experience suboptimal outcomes and complications;[11-13] readmissions and surgical site infections ≤90 days of surgery have been reported in 7.9% and 2.1% of patients, respectively[12,13]
- ◊ Certain complications can necessitate revision surgery, including dislocations (which account for 15% to 31% of revision procedures), infections, inflammatory reactions, instability, aseptic loosening, and mechanical complications[14-17]
- ◊ Revision THA accounts for approximately 15% of all THA procedures and is projected to increase to 96,700 annually in the U.S. by 2030[18-20]
- ◊ The incidence of revision THA is increased in patients between 45 and 65 years of age, with the highest lifetime risk of revision in younger patients[65,66]

2.1 Increasing Burden of Hip OA

OA is the most common form of arthritis and is a leading cause of disability in the U.S.[67-69]

- Among American adults, the **prevalence of symptomatic OA of the hip ranges from 4.2% to 9.7%**[59,60]
  - o The Johnston County Osteoarthritis Project, a prospective longitudinal cohort study of 2,997 adults (≥45 years of age; primarily rural) found that 9.7% of the adults had symptomatic hip OA[59]
  - o The Framingham Osteoarthritis Study, a prevalence survey of 978 adults (≥50 years of age; primarily urban) reported that 4.2% of the adults had symptomatic hip OA[60]
- The prevalence of hip OA increases with age, resulting in a **lifetime risk of ~25%**[61,62]

Hip OA is a progressive disease, with pain and functional limitations impairing quality of life (QoL) and eventually exhausting pharmacotherapy options.[1,2]

- In a cross-sectional study of patients with hip or knee OA (N=2,170; n=623 U.S.), over half of patients with hip OA reported moderate or severe pain; approximately 20% of hip OA patients had moderate or severe pain despite opioid use[1]

For hip OA that has progressed to severe end-stage disease, **total hip arthroplasty (THA) is the gold standard treatment.**[3-5]

- THA is typically recommended for patients with severe end-stage symptomatic hip OA who have not received adequate pain relief or functional improvement from non-operative interventions[4-6,70]

THA is the standard of care for severe end-stage hip OA

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2.2 Increasing Need for THA

More than 450,000 THA procedures are performed annually in the U.S.,[6] and the rate of THA utilization is expected to continue increasing through 2030.[7,8]

- Analysis of National Hospital Discharge Survey (NHDS) data showed that the number of THAs performed among inpatients aged ≥45 years more than doubled between 2000 to 2010[63]
- Based on a historical trend analysis using the Nationwide Inpatient Sample (NIS) database, primary THA was predicted to grow by 75% between 2010 and 2020[64]
- By 2030, the volume of THA procedures is projected to increase to approximately 635,000, according to a retrospective review of discharge data obtained from the NIS, the Healthcare Cost and Utilization Project (HCUP), and the Agency for Healthcare Research and Quality (AHRQ) between 2000 and 2014[49]

Patients aged <65 years have been a key driver of increased THA demand.[7]

- Based on NHDS data, the number of THA procedures among inpatients aged ≥75 years increased by 92% from 2000 to 2010 and increased by 205% for those aged 45 to 54 years[63]
- According to the NIS, 25% of patients who underwent primary THA in 1993 were <65 years; this proportion increased to 40% in 2006, and was projected to increase to 52% by 2030[71]

Patient comorbidities predict progression to THA.[2]

- A systematic review of factors associated with hip OA progression concluded that the presence of comorbidities, higher baseline Kellgren-Lawrence grade, superior or lateral femoral head migration, and subchondral sclerosis were predictive of faster progression to THA[2]

Annual demand for THA procedures in the US is projected to reach ~635,000 by 2030

2.3 THA Outcomes

THA is a successful treatment for end-stage hip OA, typically producing substantial improvements in pain and function;[72] however, a subset of patients experience suboptimal outcomes and complications.[11-13]
Among THA recipients, **rates of readmissions and surgical site infections ≤90 days post-surgery were 7.9% and 2.1%, respectively.**[12,13]

- A retrospective study using U.S. Medicare claims (N=288,314; 2012 to 2014) found that the rate of readmissions occurring ≤90 days post-THA was 7.9% across all surgical approaches; post-acute services utilized ≤90 days post-THA days included home health agencies (68.1%), skilled nursing facilities (28.5%), and inpatient rehabilitation facilities (6.4%)[12]
- The rate of surgical site infections ≤90 days post-surgery was 2.1% for primary THA recipients in a retrospective analysis of data from MarketScan and Medicare databases (N=163,547; 2009 to 2015)[13]

The American Academy of Orthopaedic Surgeons (AAOS) published clinical practice guidelines on the management of hip OA, highlighting **obesity, age, and mental health disorder as risk factors for worse outcomes following THA.**[11]

- Obese patients may achieve lower absolute outcome scores vs. non-obese patients, but have a similar level of patient satisfaction and relative improvement in pain and function post-THA (strength of evidence: moderate); obese patients have increased incidence of superficial wound infection, post-operative dislocation, and blood loss post-THA (strength of evidence: limited)

- Increased age is associated with lower functional and QoL outcomes in patients undergoing THA (strength of evidence: moderate); increased age may be associated with higher risk of mortality in patients undergoing THA (strength of evidence: limited); younger age may be associated with higher risk of revision in patients undergoing THA (strength of evidence: limited)
- Depression, anxiety, and psychosis are associated with decreased function, pain relief, and QoL in patients post-THA (strength of evidence: moderate)

Surgical site infections and readmissions ≤90 days occur in a subset of THA recipients

2.4 Complications Leading to THA Revisions

Although U.S. data has shown approximately **95% implant survivorship after 10 years**,[10] certain complications of THA can necessitate revision surgery.

- Between 2012 and 2019, the most common causes of THA revision surgeries as reported by the American Joint Replacement Registry (AJRR) (N=49,024) were infection and inflammatory reactions (19.3%), followed by dislocation/instability (17.4%), aseptic loosening (15.8%), and mechanical complications (15.0%)[14]
- A retrospective chart review conducted on 535 THA revisions from January 2010 to May 2019 reported mechanical failure (36.5%), metallosis (21.4%), dislocation (14.6%), periprosthetic fracture (10.4%), infection (9.9%), wound complications (3.4%), and other (3.8%) as major mechanisms of failure that resulted in THA revisions; average time to THA revision was 8.5 years[15]

Hip dislocation is one of the leading causes of THA revisions, accounting for 15% to 31% of revision procedures.[14-17]

- A study using NIS data to identify all THA revisions performed in the U.S. from 2009 to 2013 (N=258,461 THA revisions) reported that 17.3% of THA revisions were due to dislocations[16]
- Analysis of data derived from the Swedish Hip Arthroplasty Register of 1,302 THA revisions performed between 2005 and 2010 found that 30.6% of THA revisions were due to dislocations; more than half (69%) of the THA revisions due to dislocations were performed ≤1 year post THA[17]

Although there has been a shift in the rate and cause of **early failure, early THA failures still occur** (≤5 years post-primary THA), most commonly due to infections, fractures, and dislocation/instability.[14,15,73]

- The AJRR reported that 54% of revision surgeries between 2012 and 2019 (N=8,095) occurred <3 months after the index THA, with the most common reasons for revisions within 3 months being infections and inflammatory reactions (32.5%), fractures (24.3%), and instability (21.7%)[14]
- Based on a retrospective chart review of THA revisions (n=136), 30.9% of cases occurred ≤2 years post primary THA, most likely due to infection and periprosthetic fracture[15]
- A retrospective study assessing 282 early THA revision cases (24.1% of all THA revisions) between 2001 and 2011 noted aseptic loosening (29.0%), infection (19.5%), instability (19.1%), metallosis (13.8%), miscellaneous diagnosis (9.2%), and periprosthetic fracture (9.2%) as causes resulting in early failure (≤5 years) of primary THA; the mean time to early THA failure was 1.81 years[73]

Infection, dislocation, and aseptic loosening after primary THA are common causes of revision surgery

2.5 THA Revision Rates

Across database and registry studies, THA revision accounts for approximately 15% of all THA procedures.[18,19]

- A retrospective study evaluating revision THAs (n=235,857) identified between October 2005 and December 2010 using the NIS database reported a 23% increase in revision THA (from 40,555 in 2006 to 49,857 in 2010); revision burden ranged from 15.4% in 2006 to 14.6% in 2010[18]
- A systematic review assessing data from clinically relevant literature and published national arthroplasty registers from Sweden, Norway, Finland, Denmark, Australia, and New Zealand identified 77,036 THA revisions (15%) reported between 1979 and 2009[19]

Incidence of THA revision has increased in patients between 45 and 65 years of age, and **lifetime risk of a revision THA is highest in younger patients.**[65,66]

- A retrospective study using NIS data to identify all THA revisions from 2007 to 2013 (n=320,496 THA revisions) reported a 41.9% increase in the incidence of THA revision in patients between 45 and 64 years of age, adjusted for population growth; a greater increase was reported in the 55 to 64 years old age group (58.8%) vs. the 45 to 54 years old age group (17.4%)[66]
- Analysis of implant survival in patients who underwent THA (n=63,158) from the UK Clinical Practice Research Datalink between 1991 and 2011 reported:[65]
    - 10-year implant survival rate was 95.6% and 20-year implant survival rate was 85% in patients; implant survival was higher in older patients
    - Estimated lifetime risk of revision (LTRR) increased in younger patients; LTRR in patients with a mean age of 70 years ranged from 4.4% to 7.7%, while LTRR in patients with a mean age of 60 years was approximately 15%

The **total number of THA revisions is projected to increase.**[20]

- Statistical projections based on NIS data predicted a 137% increase in the total number of THA revisions in the U.S. by 2030 (from 40,800 in 2005 to 96,700 in 2030)[20]

Revision THAs are expected to more than double by 2030

3. Economic Burden of Hip Osteoarthritis*

Key Takeaways:

- ◊ OA of the hip is a costly disease that accounts for a large volume of hospital expenditures[21,22]
- ◊ U.S.-based economic evaluations have demonstrated the cost effectiveness of THA across age groups and implant types, including newer generation dual-mobility implants[23-26]
- ◊ Due to variable reimbursement rates and bundled payment models, hospitals and surgeons increasingly share the risk of THA complications and associated expenses[12,33,74]
- ◊ Hip dislocations are a leading cause of revision THA, which is significantly more expensive than primary THA due to higher hospital costs and increased resource use[27,28]
- ◊ Revision THA costs vary widely by patient complications and comorbidities, and bundled payment models may not adequately account for this heterogeneity[33,75]
- ◊ OR time remains dependent on surgeon and patient factors (e.g., learning curve, patient BMI)[29-31] and is significantly longer and more variable with revision procedures;[32] thus, OR efficiency remains a key area of focus in THA

3.1 Costs Associated with Hip OA and THA

Hip OA is a costly disease: per the Burden of Musculoskeletal Diseases in the U.S. (BMUS), the total **incremental cost associated with OA was $136.8 billion** per year between 2008 and 2014 (most common site is knee followed by hip, which accounts for 14% of OA-related hospital discharges).[21]

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

Published calculations using AHRQ data estimated that $13.7 billion in hospital expenditures were associated with THA in 2009 (284,708 total hospital discharges).[22]

Hospital Medicare reimbursement for THA is substantially lower than private payer reimbursement.[74]

- As of 2017, average reimbursement rates for total joint arthroplasty were $14,747 vs $30,099 for Medicare and private insurance, respectively[74]
- In a Medicare claims study of THA designed to benchmark 90-day economic outcomes, mean wage-adjusted payments for index hospitalizations were $12,825; additional 90-day post-acute care payments included $2,952 for skilled nursing facility, $2,095 for home health, $965 for inpatient rehab, and $1,269 for readmissions[12]

The adoption of bundled payment models in joint arthroplasty has resulted in **hospitals and surgeons increasingly sharing the risk** of post-operative complications and associated expenses.[33]

- Per a recent Medicare claims analysis, surgeon charges per THA procedure in 2017 ranged from $5,150 to $7,288, while reimbursement per procedure ranged from $1,016 to $1,093[33]

THA complications pose a potential cost burden to hospitals in the context of bundled

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3.2 Cost Effectiveness of THA

Across economic analyses of hip OA, **THA has demonstrated broad cost effectiveness** vs. non-surgical management.[76,77]

- In a U.S. retrospective cohort study, THA was shown to be cost effective, with an incremental cost-effectiveness ratio (ICER) of $39,453 vs. presurgical baseline, and 1.34 lifetime quality-adjusted life-years (QALYs) gained (discounted at 3% per year)[23]
- In a U.S.-based Markov model, THA was a dominant treatment strategy vs. non-operative treatment, with overall cost savings and an incremental QALY increase of 5.5[24]

Primary THA with newer generation dual-mobility implants (designed to reduce the risk of dislocation) can be cost saving vs. conventional implants.[26]

- In a U.S. Markov cohort model, THA with a dual-mobility implant was associated with lower accrued costs ($39,008 vs. $40,031 U.S. dollars) and higher QALYs (13.18 vs. 13.13) relative to conventional implants, assuming that dual-mobility implants met clinical and economic benchmarks (e.g., annualized incremental probability of revision from unforeseen failure remained below 0.29%; costs exceeded conventional implants by ≤$1,023)[26]

Although the ICER increases with age, **THA is also cost effective in elderly patients** (≥80 years) compared with non-surgical management.[25]

- Based on a U.S. Markov model comparing THA to non-operative management in patients ≥80 years with end-stage hip OA, THA was associated with an ICER of $7,307 per QALY. Sensitivity analysis demonstrated the cost effectiveness of THA below threshold values of 0.14 for both peri-operative mortality risk and primary THA failure risk, and below a base-rate mortality threshold of 0.19 (corresponding to the average annual mortality of 93-year-old individual)[25]
- In another U.S. Markov model, when stratified by age, THA was dominant vs. non-operative treatment for ages 40-64, after which the ICER increased by age group ($371 for 65-69 years; $5,618 for 70-74 years; $10,748 for >75 years)[24]

Conventional THA is cost effective across a broad range of patients and implant types

3.3 Cost Burden of Revision THA

Revision THAs are significantly more expensive than primary THAs, with higher hospital costs and healthcare resource use.[27,28]

- In a retrospective analysis from NYU Langone, revision THA was associated with significantly higher hospital operating direct cost (29.2% greater), hospital operating total cost (28.8% greater), direct hospital cost (24.7% greater), and total hospital cost (26.4% greater) ($p<0.05$)[27]
- In a retrospective study from Duke University, revision THA was approximately 19% more costly than primary THA, including significantly greater direct costs, nursing services, surgery services, and medical/surgical supply costs ($p<0.05$)[28]

Dislocations requiring revision THA are particularly costly, increasing hospital costs by 148% vs. primary THA.[78]

- A Mayo Clinic study of patients who experienced a dislocation following primary THA (N=99) reported that 37% of patients required subsequent revision surgery, with average hospital costs per patient (for ≥1 closed reduction and subsequent revision THA) that were 148% higher than an uncomplicated primary THA[78]

Hospital charges and reimbursements are higher with revision THAs; however, **bundled payment models may not adequately account for the case heterogeneity observed with revision procedures.**[33,75]

- Patients with complications and comorbidities that have shown large variations in marginal cost impact are grouped into single DRG codes[75]

Hip dislocation is a leading cause of costly revision surgery

3.4 OR Efficiency with THA

OR efficiency remains a challenge with THA, further contributing to the economic burden.[29,32,79]

- THA procedures routinely require three to six instrument trays, resulting in estimated sterile processing costs of up to $1,206 per procedure[79]

Average operative time for a conventional THA is 93 minutes, with **surgeon learning curve and patient body mass index (BMI) significantly impacting operating time.**[29-31]

- In a single-center retrospective study, surgery times were significantly longer for obese class III patients vs obese class II ($p=0.011$), obese class I, overweight, normal weight, or underweight (all $p<0.001$); for obese class II patients, surgery times were significantly longer than overweight, normal weight (both $p<0.001$), or underweight ($p=0.038$) patients; for obese class I patients, surgery times were significantly longer than overweight or normal weight patients ($p<0.001$ for both)[30]
- A retrospective single-surgeon analysis reported a significant decrease in surgical time between the first 25 THA procedures performed and the second 25 performed ($p=0.0052$)[31]

OR time can be longer and more variable with revision THAs, with various factors (e.g., implantation of a new femoral component, significant bone loss) increasing actual OR time beyond surgeon-predicted OR time.[32]

Based on AJRR data, the average length of stay for a primary THA procedure in the U.S. was 1.9 days in 2019.[14]

- An extended length of stay (average 5.8 days) has been reported in patients receiving revision THA[18]

Optimizing OR efficiency and simplifying surgical workflow remain key unmet needs in THA

4. Evolution of THA Treatment Landscape

Key Takeaways:

- ◊ The three commonly used surgical approaches for THA include the direct anterior approach, direct lateral approach, and posterior approach[34]
- ◊ Although there is a trend towards increasing use of the direct anterior approach among surgeons and patients, correct component positioning can pose a challenge[35,36 37-39]
- ◊ An increasing number of THA procedures are performed in the outpatient setting,[80] and value-based reimbursement models may further drive additional uptake of outpatient procedures[48]
- ◊ Outpatient THA is more cost effective and is associated with a similar rate of functional outcomes, complications, and readmissions vs. inpatient THA[80-83]
- ◊ There is a trend towards increased use of robotic technology in hip arthroplasty[44,45]
- ◊ Rapid and seamless integration of technology into current surgical processes is needed to optimize the learning curve and minimize disruption to surgeon workflow[47]

4.1 THA Approaches

There are three commonly used surgical approaches for THA: the direct anterior approach, direct lateral approach, and posterior approach.[34]

Approach	Advantages	Disadvantages/Risks & Complications
Direct anterior	• Muscle-sparing • Low dislocation rates • Earlier restoration of gait kinematics • Can be performed with or without use of specialized table or fluoroscopy • Provides earlier restoration and function	• Intra-operative fractures • Nerve injury • Longest operation time compared to other approaches
Direct lateral	• Low dislocation rates • Adequate exposure of both proximal femur and acetabulum • Provides extensile exposure to femur	• Abductor muscle insufficiency • Intra-operative fractures • Nerve injury • Longer operation time vs. posterior approach
Posterior	• Adequate visualization of both femur and acetabulum • Spares abductor muscles during exposure of femur and acetabulum • Provides extensile exposure to femur and acetabulum	• Higher dislocation rates when compared with other approaches • Nerve injury

Sources: Cha et al. 2020, Petis et al. 2015, Moerenhout et al. 2020, Wang et al. 2018, Barrett et al. 2013, Kamath et al. 2018, Yoo et al. 2019, Alecci et al. 2011, Goebel et al. 2012, Masonis et al. 2002, Witzleb et al. 2009.12,34,40,41,84-90

Numerous comparative studies have assessed the outcomes and complications of THA procedures performed with each approach.

- Direct anterior **vs. posterior approach**:
  - o A prospective, randomized, multicenter clinical study conducted between February 2011 and July 2013 demonstrated a trend toward **faster functional recovery with the direct anterior approach** vs. posterior approach over a period of 4 weeks post-operatively (Harris Hip Score [HHS]: 76.7 vs. 68.7; p=0.08); implants were well positioned in both groups[84]
  - o According to a meta-analysis based on randomized controlled trials (RCTs) (n=9 RCTs totally 754 patients; direct anterior group, n=377; posterior group, n=377), the direct anterior approach is associated with an early functional recovery, less pain scores, shorter incision length, and reduced blood loss vs. the posterior approach[85]
  - o A network meta-analysis that analyzed complications between the direct anterior vs. the posterior approach reported the following:[40]
    - ◊ **Longer operation time for the direct anterior approach vs. posterior approach** (standardized mean difference [SMD] 0.45 [95% confidence interval [CI]: 0.24, 0.66]; p<0.001)
    - ◊ Higher blood loss during direct anterior THA vs. posterior and lateral approach (SMD 0.60 [95% CI: 0.39, 0.82]; p=0.002)
  - o A prospective randomized trial comparing the direct anterior approach (n=43) vs. direct posterior approach (n=44) at 6 weeks, 3 months, 6 months, and 12 months following surgery demonstrated:[41]
    - ◊ **Longer duration of surgery in the direct anterior approach vs. posterior approach** (23.8 minutes longer)
    - ◊ Shorter mean length of hospital stay for the direct anterior approach (2.28 days) vs. posterior approach (3.02 days; p=0.037)
    - ◊ More patients who underwent direct anterior THA were walking limitlessly, climbing stairs normally, and had higher HHS at 6 weeks vs. the patients who underwent posterior THA; differences dissipated by 3 months and remained insignificant at the 12-month timepoint
  - o A study using Medicare claims data from 2012 to 2014 to assess 90-day economic outcomes of THA via the direct anterior approach (n= 1,794) vs. matched control patients (all other THA approaches; n=897) demonstrated that **the direct anterior approach group had significantly lower post-acute care resource** use ($4,139 vs $7,465; p<0.0001), lower hospital length of stay (2.06 vs 2.98 days; p<0.0001), and readmissions (5.0% vs. 7.9%; p=0.013) when compared with the control group[12]
- Direct anterior vs. lateral approach:
  - o A systematic review of 7 RCTs and 5 comparative studies (n=429 patients; direct anterior approach group, n=211; anterolateral group, n=218) reported significantly higher gait speed (SMD=0.17 [95% CI: 0.12, 0.22]; p<0.01) and peak hip flexion (odds ratio [OR]=1.90 [95% CI: 1.67, 2.13]; p<0.01) ≤3 months post-surgery in the direct anterior approach group vs. the anterolateral group[86]
  - o A retrospective study in Italy, comparing peri- and intra-operative outcomes of primary THA performed via a direct anterior approach (n=221) vs. lateral approach (n=198) reported **less pain, reduced length of stay in hospital** (7 days vs. 10 days), and **longer mean duration of operation** (8 minutes longer) with the direct anterior approach vs. the lateral approach group (p<0.05), and increased peri-operative blood loss in the direct lateral vs. direct anterior approach group[87]
  - o A retrospective cohort study in 200 patients undergoing THA via the direct anterior approach vs. the lateral approach reported less perceived pain on day 1 following surgery as measured by the VAS (0.41±0.8 vs. 0.66±1.1, p=0.036), faster achievement of range of motion (6.4 days vs. 7.4 days), and significantly less length of hospital stay (average 10.2 days vs. 13.4 days) with the direct anterior approach vs. the lateral approach[88]

- Direct lateral vs. posterior approach:
  - A review that included 2 prospective and 12 retrospective studies reported the rate of dislocation to be 3.23% for the posterior approach and 0.55% for the direct lateral approach, and abductor insufficiency ranging from 0% to 16% for the posterior approach and from 4% to 20% for the direct lateral approach[89]
  - A prospective study evaluating the short-term outcomes of patients undergoing THA via direct lateral (n=30) vs. posterior (n=30) approach reported no significant differences in HHS, Western Ontario and McMaster Universities Arthritis Index (WOMAC), and SF-36 scores between the two groups throughout the 3-month period following THA; the rate of dislocations and fractures also did not differ significantly between the two groups[90]
  - A network meta-analysis reported longer operation time for the lateral approach vs. posterior approach (SMD 0.96 [95% CI: 0.74, 1.18]; p<0.001)[40]

There is a **trend towards increasing use of the direct anterior approach**, which provides soft tissue preservation and low risk of dislocation, but requires a longer operation time vs. other THA approaches and presents challenges in component positioning.[34-42]

- U.S. database analyses have shown an increase in the proportion of THAs performed using the direct anterior approach from 4% (2001-2011) to 17% (2012-2014)[42,91]
- In a 2019 survey of 996 arthroplasty surgeons, 56.2% of the surgeons performed THAs using the direct anterior approach[35]
- While the direct anterior approach is a popular surgical technique among both surgeons and patients, correct component positioning can pose a challenge[35-39]
  - A study of 29 patients who had undergone THA procedures using the direct anterior approach demonstrated that combined femoral and acetabular component anteversion within the safe zone (25° to 50°) was achieved in 79% of patients[92]
  - A retrospective study of THAs using the direct anterior approach (N=537; 2013-2017) demonstrated that 80% of the cups were within the combined safe zone (inclination [30° to 50°]; anteversion [10° to 30°]); malpositioned cups were primarily anteverted (8.5%) or vertical (10%)[37]

Accurate component positioning is key to successful outcomes with the direct anterior approach

4.2 Outpatient THA

The number of THA procedures being performed in the outpatient setting has increased in the U.S.[80]

- Outpatient discharges were noted for 2.9% of THA procedures in a retrospective analysis of the US Humana PearlDiver database (N=75,780; 2007 to 2016), with overall incidence rates of 10.5 per 100,000 for outpatient THA and 352.3 per 100,000 for inpatient THA[80]
  - The incidence of outpatient THA procedures increased from 2.0 per 100,000 in 2007 to 4.0 per 100,000 in 2015, although the relative incidence of outpatient vs. inpatient procedures did not significantly change[80]

Outpatient THA is associated with a **similar rate of functional outcomes, complications and readmissions vs. inpatient THA.**[80-82]

- In a randomized trial of outpatient vs. inpatient THA in the U.S. (N=220), there were no significant differences between each group for mean pain VAS scores (1.7 vs. 1.7; p=0.77), HHS (75 vs. 75; p=0.77), or readmissions due to complications (2 vs. 1; p=1.0) at 4 weeks post-surgery[81]

- A systematic review and meta-analysis comparing outpatient vs. inpatient THA (published up to 2018, 64,484 total patients) found no significant differences in the risk of any post-surgical complication (risk ratio [RR]=0.82; p=0.96), and no differences in the risk of readmissions (RR=0.72; p=0.51), reoperations (RR=1.38; p=0.31), or blood transfusions (RR=0.59; p=0.35)[82]
- The rate of common (≥0.5%) complications at 1 year post-surgery were comparable between outpatient vs. inpatient THA procedures in a retrospective analysis of the U.S. Humana PearlDiver database (N=75,780; 2007 to 2016), including component revisions (2.75% vs. 2.33%; p>0.05), hip dislocations (2.01% vs. 1.67%; p>0.05), and irrigation and debridement procedures (0.92% vs. 1.27%; p>0.05)[80]

Outpatient THA was more cost effective than inpatient THA in a US-based cost-effectiveness model, using a willingness-to-pay (WTP) of $50,000/QALY.[83]

- Recent inclusion of outpatient THA in the Comprehensive Care for Joint Replacement (CJR) value-based reimbursement model may further drive additional uptake of outpatient procedures[48]

In the future, THA may be increasingly performed in the outpatient setting

4.3 Utilization of Robotics in THA

Adoption of robotic technology is already prevalent in hip arthroplasty.[44]

- Arthroplasty requires a very high degree of precision in preparing and positioning implants, and is particularly well-suited to robotic assistance[44]
- As a new generation of robotic systems is introduced into the field of total hip arthroplasty, careful consideration of clinical and cost effectiveness will be needed to maximize return on investment[44]

A study using the New York Statewide Planning and Research Cooperative System database demonstrated **increasing utilization of technology assistance in hip arthroplasty** from 0.5% (n=75/14,813) in 2008 to 5.2% (n=1,010,19,496) in 2015 (p<0.001).[45]

- Utilization among providers also grew during this period; the use of technology assistance in hip arthroplasty in hospitals increased from 6.3% in 2008 to 14.0% in 2015, and the proportion of surgeons using technology in hip arthroplasty also increased from 1.6% in 2005 to 7.6% in 2015[45]

Despite advances in surgical techniques and implant design, there remains an **unmet need for reproducible results** for patients undergoing THA procedures.[16,43]

- A systematic literature review (SLR) evaluating the importance of acetabular cup positioning in preventing dislocations following primary THA reported that narrow target zone ranges may be reproduced clinically using technologies designed to assist accurate cup placement[93]
    - o Due to variations in study design, surgical procedures, and patient population, the SLR reported difficulties in measuring and comparing positioning across studies and could not draw broad conclusions on whether cup positioning has an influence on post-operative dislocations[93]

Technologies that aid in component positioning have the potential to improve component positioning, which may reduce the risk of dislocation

4.4 Patient Preference for Robotics

As direct allocation of consumer health care dollars increases, the accelerated rise in patient financial responsibilities presents an emerging threat for hospital margins.[94] 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
- Based on the results of a 30-question online survey of orthopedic surgery practices (N=588):[46]
  - o 34% of respondents reported a clear preference for robotic-assisted surgery over a conventional manual approach
  - o Nearly half (49%) would choose a low-volume surgeon assisted by robotic technology over a high-volume surgeon using conventional methods
  - o 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%)
- Results from a 24-question global survey (n=699 U.S. respondents; n=45 non-U.S. respondents) conducted in 2016 indicated that 72% of respondents believed that robotic-assisted surgery was safer, faster, and less painful, or offered better results than minimally invasive conventional surgery[95]

Patient surveys have noted a preference for robot-assisted orthopedic surgery over conventional methods

4.5 Volume and Reimbursement Considerations

Increased patient volume is a key goal for hospitals and ambulatory surgery centers, and 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.[96,97]

However, while the volume of arthroplasty procedures has increased, **Medicare reimbursement to physicians has decreased for the majority of procedures.**[33,98]

- Based on a study of the Medicare Fee-for-Service billing from 2000 to 2019, the number of hip arthroplasty procedures increased by 100%, while physician reimbursement decreased 38.9% per procedure[98]
- Another study of Medicare reimbursement trends from 2012 to 2017 reported inflation-adjusted decreases in physician reimbursement of 10.7% for primary THA and 6% for revision THA[33]

Hospital Medicare reimbursement rates for THA have also decreased, while private payer reimbursement rates have increased: between 2012 and 2017, Medicare rates decreased by 1.6% while private payer rates increased by 7.4%.[33,74]

Initiatives aimed at reducing Medicare expenditures (e.g., the CJR model), which drive cost savings via bundled payments and value-based reimbursement, could further incentivize **investment in technology that offers the potential to improve quality reporting metrics.**[24,48]

Higher volume and lower reimbursement rates may encourage investment in surgical assistive technology, particularly multi-application platforms

4.6 Focus on Care Team Well-being and Retention

The Triple Aim framework (www.ihi.org), a widely accepted approach to optimizing performance of the U.S. health care system, is based around three interdependent goals: improved population health, improved patient care, and lower costs.[99] 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.[99]

- **Burnout is highly prevalent among orthopedic surgeons:** U.S. 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)[100,101]
  - Staff burnout threatens both patient care and staff satisfaction[99]
  - Dissatisfied physicians are more likely to leave their practice, and the cost of surgeon turnover is high[99]
- **Prioritization of care team well-being highlights the importance of considering work environment** (e.g., workflow, ergonomics, and staff satisfaction) when considering technology investments[47,99]
  - Work-related injuries are common among OR staff: a survey of 50 peri-operative 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[47]
  - Lifting and manipulating heavy instrument trays, in particular, contributes to musculoskeletal injuries among OR staff[47]
  - Adoption of new technology should not disrupt surgeon workflow or impose unnecessary processes and should aid with routine tasks/ergonomics[47]

New technologies should integrate seamlessly into existing surgical processes to minimize disruption to staff

5. ROSA Hip System

Key Takeaways:

- ◊ Compared to conventional instrumentation, ROSA Hip is a personalized robotics system designed to enhance the accuracy and reproducibility of direct anterior THA procedures by assisting with pre-operative preparation and intra-operative positioning of implant components[49,50]
- ◊ ROSA Hip enables direct anterior surgeons to evaluate and execute a surgical plan based on real-time feedback and the patient's unique anatomy, while seamlessly integrating into the surgeon's workflow[49]
- ◊ ROSA Hip patients who utilize the mymobility® Care Management Platform throughout their episode of care receive a connected experience through mymobility's customized protocols, communication, and monitoring. As compared to the standard of care, using mymobility for qualified patients has shown to decrease the number of post-operative physical therapy visits[49,102]

5.1 Product Features

ROSA Hip is a personalized robotics system designed to enhance the accuracy and reproducibility of direct anterior THA procedures by assisting with **pre-operative preparation and intra-operative positioning of implant components.**[49,50]

- Precisely assists with accurate acetabular component orientation and leg length through robotic guidance[50]
- Provides real-time feedback of patient's unique anatomy, allowing intra-operative evaluation of leg length and offset decision making[49]
- May minimize additional time to procedure due to a simplified set-up without pins or reference arrays[50]
- Utilizes ONE Planner™ Hip, a web-based surgical software, to plan a hip replacement case using pre-operative X-ray patient images to assess implant components and neck cut, restore leg length and offset, and evaluate pelvic tilt[49]
- Trial panel enables surgeons to evaluate best possible implant combinations for each patient[49]
- Auto landmarking and overlay tool support a streamlined procedure[49]

Compared to conventional techniques, positioning of components has been shown to be **more accurate and reproducible using the ROSA Hip System:**[50]

- Fewer positioning outliers were reported for ROSA Hip-assisted THA procedures compared to conventional THA[50]
- 100% of cases within the Lewinnek and Callanan Safe Zones (fewer outliers compared to conventional instrumentation)[50]

ROSA Hip is compatible with several clinically proven implant systems, so procedures can be tailored to individual patient needs while maintaining a simple surgical workflow.[49,103-110]

- Compatible with the Avenir Complete® Hip System and G7® Acetabular systems, which provide a comprehensive range of stems, shells, and liners (including Dual Mobility)[103-105,108]
- Also compatible with Taperloc® Complete Hip System, Avenir® Hip System, and Echo® Hip System[105,109,110]

As a data-driven robotic system, ROSA Hip also integrates with the OrthoIntel Orthopedic Intelligence Platform and mymobility Care Management Platform for pre-op communication and post-op monitoring, enabling a significant decrease in post-operative physical therapy visits for patients undergoing joint arthroplasty.[49,102]

- 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 or TKA demonstrated that patients using mymobility achieved comparable early outcomes without the need for a formal physical therapy program[102]

6. Evidence of THA Robotic Systems*

Key Takeaways:

- ◊ Robotic-assisted THA has been shown to increase surgical accuracy and decrease outliers vs. conventional methods, with decreased or comparable rates of revision surgeries and complications such as dislocation[51-55]
- ◊ Robotic THA has been associated with improved functional and QoL outcomes vs. conventional procedures, as well as high patient satisfaction[51,52,54]
- ◊ A small number of cases is typically required to overcome the learning curve for robotic THA, with comparable surgical time vs. conventional THA for an experienced OR team[55,111,112]
- ◊ Index LOS, readmissions, and blood transfusion rates can be lower for robotic vs. conventional THA, leading to lower facility costs[56,57]

6.1 Clinical Value

Increased surgical accuracy and fewer outliers in implant placement have been reported for THA performed with robotics systems vs. conventional methods.

- Compared to manual procedures, robotic-assisted THA enabled significantly more patients to achieve an overall component position within the Lewinnek safe zone (OR: 8.6; p=0.002) or Callanan's safe zone (OR: 6.3; p=0.003) for a randomized study in the UK (N=120)[51]
- A retrospective analysis of patients who received THA procedures in the American Hip Institute's Hip Replacement Registry (N=174; 2008 to 2013) found that robotic-assisted THA significantly reduced the global offset vs. manual THA (2.96 mm vs. 4.48 mm, p<0.001), and also reduced the risk of the acetabular cup placement falling outside of safe zones (Lewinnek, RR: 0.11, p=0.002; Callanan, RR: 0.21, p=0.001)[52]
- In a randomized study comparing a robotic system vs. manual techniques for THA in Korea (n=54), robotic THA enabled significantly smaller mean stem misalignment (0.3° vs. 2.2°, p=0.005) and significantly fewer stem alignment outliers (≥3° misalignment, 0% vs. 24%, p=0.022) compared to manual procedures. Mean leg length discrepancy was also significantly smaller for robotic THA compared to manual rasping techniques (1.9 vs. 4.9 mm, p=0.011)[53]
- A meta-analysis of two studies comparing efficacy and safety outcomes for robotic vs. conventional THA (2005 to 2017) found a significantly higher rate of ideal cup placement per Lewinnek/Callanan save zone (OR: 5.64, p<0.00001) for robotic THA vs. conventional surgical techniques[54]
- Robotic-assisted THA enabled significantly lower positioning variance vs. manual THA (inclination angle variance: 14.0° vs. 37.5°, p<0.01; anteversion angle variance: 19.5° vs. 56.3°, p<0.01), as well as significantly more acetabular implants within the safe zone (Lewinnek: 90% vs. 55%, p<0.01; Callanan: 82% vs. 45%, p<0.01; surgeon-defined safe zone: 97% vs. 76%, p<0.01) in a retrospective analysis of patients in the U.S. (N=394, 2008 to 2014)[55]

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

THA performed with robotic systems have demonstrated **decreased or similar rates of revision surgeries and complications** vs. conventional THA, including dislocations.

- In a retrospective analysis of patients receiving THA in the U.S. Mariner database (N=9,260; 2010 to 2018), the rate of revision surgeries were comparable for robotic THA vs. conventional THA at 90 days, 1 year, and 5 years post-surgery ($p>0.498$ for all). The rate of dislocations were also similar between robotic and conventional THA at all timepoints up to 5 years post-surgery ($p\geq0.312$ for all timepoints)[56]
- At a minimum 5-year follow-up, a non-significant reduction in the rate of revision surgeries was reported for robotic THA vs. manual THA (revision surgeries: 4.5% vs. 9.1%, $p=0.479$) in a retrospective analysis of patients of the American Hip Institute's Hip Replacement Registry (N=174; 2008 to 2013)[52]
- Among 115 THA procedures retrospectively analyzed in a Chinese hospital (2018 to 2019), the rates of complications were statistically similar between robotic and manual THA procedures, including dislocations (two dislocations requiring manual reduction for manual THA vs. no dislocations in the robotic THA) and infections (one case of acute periprosthetic joint infection for manual THA and no major infections for robotic THA)[113]
- A meta-analysis of studies comparing efficacy and safety outcomes for robotic vs. conventional THA (N=7 studies representing 1,516 patients, 2005 to 2017) found a significantly lower risk of intra-operative complications (OR: 0.12, $p<0.0001$) and total complications (OR: 0.43, $p=0.03$) for robotic THA vs. conventional surgical techniques[54]

Functional outcomes, satisfaction and QoL following robotic THA **are improved or comparable** vs. THA performed with conventional methods.

- In a randomized study comparing robotic-assisted vs. manual techniques for THA in the UK (n=120), robotic THA enabled significantly higher mean Oxford Hip Score (44.4 vs. 41.9, $p=0.038$) and Forgotten Joint Score (78.0 vs. 56.9, $p<0.001$) compared to manual THA at six months post-operation[51]
- A retrospective analysis of the American Hip Institute's Hip Replacement Registry (N=132 for matched cohort; 2008 to 2013) found that patients who received robotic THA reported significantly higher PROs vs. manual THA after a minimum of 5 years post-surgery, including better mean scores for HHS (90.57 vs. 84.62, $p<0.001$), Forgotten Joint Score-12 (82.69 vs. 70.61, $p=0.002$), Veterans RAND-12 Physical (50.30 vs. 45.92, $p=0.002$), and SF-12 Physical (48.92 vs. 44.01, $p=0.001$)[52]
    - Satisfaction at the minimum 5-year follow-up was high for both robotic and conventional THA (8.91 vs. 8.52 out of 10, $p=0.35$)
- After a minimum of 16 months post-surgery, robotic THA enabled significantly better functional outcomes vs. conventional THA for patients in a retrospective analysis of a single U.S. institution (N=189; 2015 to 2017), including significantly improved mean WOMAC (11.7 vs. 17.7; $p<0.001$) and HHS scores (86.7 vs. 83.6; $p<0.05$)[114]
- A meta-analysis comparing pooled functional outcomes (HHS, Merle d'Aubigne Hip Scores, and Japanese Orthopedic Association Scores) for robotic vs. conventional THA at 24 months post-surgery (N=5 studies, 2005 to 2017) were comparable for robotic THA vs. conventional surgical techniques, with a weighted mean difference of 0.09 for robotic–conventional THA ($p=0.38$)[54]

The learning curve for robotic THA is generally overcome after a small number of cases, allowing surgical teams to rapidly gain confidence in the procedure.

- The learning curve for a robotic THA system was overcome after 12 cases per cumulative summation analysis in a prospective study of 100 THA procedures in the UK[111]
    - o Significant time decreases during the learning stage included time for OR setup (p<0.001), bone registration (p<0.001), and acetabular reaming (p<0.001), and the overall mean operative time for robotic THA was similar to conventional THA (59.0 vs. 54.7; p=0.14)
    - o Surgical team confidence levels per the Spielberger State-Trait Anxiety Inventory (STAI) followed a similar pattern to the learning curve, with a significant inflection point after 12 cases (p<0.001). Overall mean STAI scores were statistically comparable between robotic and conventional THA across all subscales (p>0.26 for all)
- In a retrospective study of 395 robotic THA procedures in Italy (2014 to 2018), OR time for robotic THA procedures significantly decreased with greater institutional experience with robotic systems (from 107 minutes in 2014 to 83 minutes in 2018; p<0.01)[112]
- Retrospectively comparing the first 98 robotic THA procedures performed by a single U.S. surgeon vs. 198 conventional procedures performed by the same surgeon plus a senior investigator (2008 to 2014) found no significant differences in mean surgical times for robotic vs. conventional techniques (114 vs. 113 minutes, p=0.11)[55]

6.2 Economic Value

Short-term impacts such as **length of stay (LOS), readmissions, and blood transfusion are improved** by robotic THA versus conventional THA, **leading to lower costs.**

- LOS was significantly shorter for patients who received any robotic THA vs. conventional THA (3.4 days vs. 3.7 days; p=0.001) in a retrospective analysis of patients in the U.S. Mariner database (N=9,260; 2010 to 2018), with significantly lower total costs at 90 days ($13,892 vs. $15,576; p=0.001) as well as 1 year ($19,778 vs. $21,537; p=0.001)[56]
- In a retrospective analysis of THA recipients in the U.S. Medicare 100% Standard Analytic Files (N=5,608; 2015 to 2018), patients who received robotic-assisted procedures incurred significantly lower 90-day episode-of-care costs vs. conventional THA procedures ($19,734 vs. $20,519; p=0.0095), driven by significantly lower utilization of inpatient readmissions (0.64% vs. 2.68%; p<0.0001), admissions to skilled nursing facilities (20.79% vs. 24.99%; p=0.0041), and a fewer number of home health agency visits (14.06 vs. 15.00; p=0.0133)[57]
    - o The LOS for 90-day post-surgery admissions also trended shorter for robotic THA vs. conventional THA, including inpatient readmissions (7.15 vs. 7.91 days; p=0.8029) and skilled nursing facility stays (17.98 vs. 19.64 days; p=0.5080)

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.**[44]

7. How ROSA Hip Differs from Other Robotic Systems

ROSA Hip is designed to simplify workflow and potentially **increase surgical efficiency:**[49]

- No requirement for pins or reference arrays, to simplify setup and potentially minimize additional time to procedure
- Decreased radiation exposure as no CT scans are required
- Auto landmarking and overlay tool supports a streamlined procedure

ROSA Hip is **flexible for surgeons' preferred, existing methods**.[49]

- ROSA Hip fits seamlessly into existing fluoroscopy-based workflows for the direct anterior approach
- Customizable workflow is designed to minimize the learning curve

ROSA Hip is integrated with **ONE Planner Hip**, a web-based pre-operative planning software to plan a hip replacement case by using pre-operative X-ray patient images to plan implant components and neck cut, restore leg length and offset, and evaluate pelvic tilt.[49]

Real-time feedback assists surgeons with acetabular component positioning and impaction, while also intra-operatively quantifying cup orientation, leg length, femoral offset, and global offset.[115]

7.1 Value of ROSA Robotics Across Applications

In addition to THA, the ROSA Robotics platform can include **additional modalities for total knee and partial knee arthroplasty**, with the potential to optimize efficiencies for medical facilities.[58]

- Multi-modal robotics platforms have a reduced OR footprint compared to multiple single-purpose robotics systems,[58] and have the potential to decrease technology acquisition costs and streamline service, repair, and staff education[116]
- All applications of ROSA Robotics are part of the ZBEdge™ integrated technology suite. Intra-operative data from all ROSA Robotics applications can be viewed in the OrthoIntel Orthopedic Intelligence Platform, which combines pre-, intra- and post-operative data from ZBEdge Connected Intelligence Suite to help surgeons uncover clinical insights effortlessly. This meaningful data is intended to help healthcare professionals optimize care by efficiently exploring the connection between surgery and outcomes.[49]

7.2 ROSA Hip Return on Investment

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

- Facility procedural volume
- Annual growth estimates
- Utilization rates of robotic vs. non-robotic THA
- 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.

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