Zimmer Computer-Assisted Surgery in Total Knee Arthroplasty

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List of Abbreviations

BMI Body Mass Index
CAS Computer-Assisted Surgery
CDC Center of Diseases Control and Prevention
OA Osteoarthritis
OR Operating Room
THA Total Hip Arthroplasty
TKA Total Knee Arthroplasty
1. Executive Summary

Total knee arthroplasty (TKA) has become the most common technique to relieve pain and improve function in patients with osteoarthritis. The success of this technique depends on achieving the proper component alignment (0°±3° of the mechanical axis), ligament balancing, experience of the surgeon, and prosthetic design. The conventional technique is considered the “gold standard” but inaccurate implantation rates of up to 30% and several complications have been reported in TKA. Computer-assisted surgery (CAS) in TKA has demonstrated to overcome the limitations of the conventional technique; assisting to provide better alignment, function improvement, more precise soft tissue balance, less pain, and significantly less complications and tissue damage. Furthermore, CAS has shown to be cost-effective, reducing blood transfusions by 50%, providing faster rehabilitation and shorter days of stay, and generating a substantial improvement of quality of life.

Key Findings

Clinical Burden

- Osteoarthritis (OA) affects 10% of the population worldwide who are over 60 years; and with higher prevalence in women.
- TKA has become a well-established technique to relieve pain, improve function and provide a high level of patient satisfaction in OA.
- By 2030, total hip and knee arthroplasties will increase by 174% and 673%, and revision rates by 137% and 601%, respectively.
- The prevalence of joint arthroplasties is higher in patients over 65 years old, in women between 28-30 years old and in the Caucasian population.
- Conventional instrumentation is considered the “gold standard” but inaccurate implantation rates of up to 30% have been reported using this technique in TKA, independently of the surgeon’s experience.

Computer-Assisted Surgery

- CAS has demonstrated to be more accurate compared to the conventional technique in TKA and may provide faster rehabilitation and reduction of length of hospital stay.
- CAS has demonstrated statistically significant improvement in functional scores during mid-term (5 years) clinical studies; achieving a more precise balance of the joint and avoiding the high rate of soft-tissue release observed in TKA using the conventional technique.
- CAS has shown a significant decrease in blood loss, limited bone injury, and less pain compared to the conventional technique in TKA.
- Although a steep learning curve has been associated with CAS in TKA, several studies have proven that only 20 to 30 cases are required to overcome this stage.

Economic Burden

- CAS is associated with decreased blood transfusions by 50% compared to conventional technique in TKA; representing savings for around $134,000 per year per every 1,000 cases.
- Faster rehabilitation and shorter days of stay (up to 2 days) has been demonstrated after TKA using CAS; representing savings up to $900 (per case) in hospital costs.
- CAS showed a reduction of fat or bone marrow embolism compared to the conventional technique.
- So far, the literature has not reported that CAS significantly increases the probability of infection compared to the conventional technique in TKA.
- CAS is cost-effective in TKA and provides a substantial improvement of quality of life.

From a health-economics point of view, CAS has been linked to longer OR time, additional steps, and laborious and complex procedures; but cost-effective analysis clearly demonstrates favorable results supporting this technology in TKA. Aligned with results, CAS has several other advantages compared to the conventional technique in TKA; these include reduced blood transfusions by 50%, faster rehabilitation and shorter days of stay, less pain, and providing a substantial improvement of quality of life.
Clinical Burden
Osteoarthritis (OA) is a degenerative disease which compromises the integrity and function of the joint.\(^{40-42}\) This disease affects 10% of the world population who are over 60 years,\(^{23,24}\) representing 27 million of individuals in the United States.\(^{25}\) The incidence of OA has been increasing worldwide with higher prevalence in women.\(^{25}\) The etiology of OA is unknown but hereditary and developmental factors have been associated to the pathology.\(^{44}\) Symptoms of OA appear gradually and the treatment is focused on relieving symptoms and improving function.\(^{45}\)

TKA has become a well-established technique to relieve pain, improve physical function and provide high level of patient satisfaction in OA, when other treatments are not indicated.\(^{1,2}\)

Incidence and Prevalence of Joint Arthroplasty
The incidence of primary total hip and knee arthroplasty is significantly increasing worldwide.\(^{26-28,46,47}\) Factors such as awareness of joint arthroplasty benefits, obesity, elder population growth, and patient comorbidities have been associated with the increased demand in hip and knee arthroplasties in the United States.\(^{47}\) MEDICARE allocated 8% of its annual budget in expenditures associated with TKA revisions from 1997 to 2003.\(^{48}\) It has been projected that by 2030, the demand of total hip and knee arthroplasties will increase by 174% and 673%; and revision rates by 137% and 601%, respectively.\(^{26}\)

Age, Gender and Ethnicity in Joint Arthroplasty
In the last ten years, the incidence in total joint replacement has increased in elderly (>65 years) and in younger (<65 years) patients.\(^{26,27}\) Primary THA and TKA (65 years) will increase by 50% in 2011 and 2016, respectively. Revision rates for TKA (65 years) will increase by 50% in 2011; and in 2030 the number of THA and TKA in patients under 65 years old is projected to increase to 52% of primary THAs and 55% to 62% of primary or revision TKA, respectively.\(^{27}\) Total joint arthroplasties have been reported to be more frequent and with worse symptoms in women compared to men.\(^{28-30}\) Higher TKA prevalence has been reported in white patients compared to black and Hispanic populations.\(^{28}\)

Computer Assisted Surgery in Total Knee Arthroplasty
The success of knee arthroplasty depends on the component alignment (0°±3° of the mechanical axis), proper ligament balancing,\(^{3,4}\) experience of the surgeon, soft tissue balancing and prosthetic design.\(^{5}\) Inaccurate implantation rates of up to 30% have been reported using the conventional technique in TKA,\(^{6,7}\) and it has also been demonstrated that the incidence of inaccurate implantation can be independent of the surgeon’s experience.\(^{9}\) CAS has proved to overcome the limitations of the conventional technique and to help in providing better alignment accuracy in TKA.\(^{4,8-11}\)

Limb and Prosthesis Alignment
Inaccurate implantation rates up to 30% have been reported, when the conventional technique and mechanical jigs were used.\(^{5,7}\) Prosthetic loosening rate of 24% was registered when the alignment was >3° but only 3% when <3° from neutral.\(^{49}\) CAS has proven to be significantly more accurate in achieving lower extremity alignment;\(^{17}\) including complex cases where conventional instrumentation cannot be used.\(^{17}\) Patients with better limb alignment may experience faster rehabilitation and a reduction of length of hospital stay of up to 2 days.\(^{22}\)

Functional scores evaluate the effectiveness in restoration of normal joint function after joint replacement. The majority of the literature does not demonstrate significant differences in early post-operative stability and functional scores comparing CAS vs. conventional technique in TKA.\(^{12}\) Mid-term (5 years) studies showed a statistically significant difference in functional scores and range of motion between techniques,\(^{12}\) with greater improvement when CAS was used.\(^{1}\)

Soft-tissue balance and joint line
Proper alignment and balance in TKA requires precise bony resection and soft-tissue release.\(^{50-51}\) Inadequate ligament release may result in instability, loosening, and premature wear of the implant.\(^{52}\) Surgeons traditionally rely on their experience and “feel” to obtain accurate intraoperative soft tissue balance when performing TKA using the conventional technique.\(^{53}\) CAS provides a quantitative measure for range of motion and soft-tissue release in real-time, allowing to achieve a more precise balance of the joint and avoiding excessive soft-tissue release as observed in TKA using the conventional technique.\(^{13,14}\)
Operating Room Time

The majority of the studies show that the use of CAS in TKA extends the length of the surgical procedure compared to the conventional technique. This difference in OR time (P < 0.05) has been reported to be 7 to 20 min. However, Pang et al. showed no statistically significant difference in OR time (140 TKA: CAS, 110±14 min.; conventional, 95±12 min.). Additional OR time might be justified by the significant improvement in alignment and accuracy of implantation as well as reduction in intra-operative complications.

Pain

Pain is the main symptom of osteoarthritis which brings the patient to the surgeon and represents 20% of the cases after TKA. Pain scores showed statistically significant improvement after TKA but most of the studies showed no difference comparing navigation vs. conventional technique. However, statistically significant less pain was demonstrated in some studies using CAS in TKA; and also when comparing incorrect rotational alignments of the femoral component and post-operative pain after TKA.

Survival Rate

Proper ligament balancing and component alignment are important parameters to restore optimal function and theoretically to guarantee the longevity of the implant. Inaccurate implantation rates of up to 30% have been reported using the conventional technique. The average survival rate of total knee components has been shown to be 98% at ten years and up to 90% at fifteen years. Most of the literature shows that obtaining proper prosthesis and limb alignment will result in an optimal function restoration and consequently a longer implant life. CAS demonstrates more accurate prosthesis alignment; and theoretically this technique may extend the implant life and improve patients’ quality of life.

Learning Curve

A steep learning curve due to change in technique and surgery workflow has been described as disadvantages associated with CAS in TKA; however a comparison with the learning curve of TKA using the conventional technique is not performed. There is an improvement in the OR time after the CAS learning curve is overcome. The learning curve for CAS has been estimated between the first 20 to 30 cases. Additionally, CAS allows beginners to achieve similar results compared to experienced surgeons alike from the very first case in terms of alignment, functional scores, and range of motion.

Complications

The incidence of complications after TKA will delay the recovery of the patients and increase the hospital costs. Up to 8% of cases show intraoperative and postoperative complications at short- and mid-term follow-up; due to loosening, infection, instability, dislocation or fracture. Several complications such as fat and bone marrow embolism, blood loss, infections, post-operative stiffness related to the anesthesia, ischemic attack, pain, and deep vein thrombosis have been commonly associated with the conventional technique. CAS has shown a decrease in blood loss and the level of bone injury in TKA.

Economics Burden

The demand of TKA in the United States is projected to grow to 3.48 million procedures per year by 2030. From 1991 to 2008, Medicare hospital payment for joint arthroplasty increased 30% and inflation 59%, for the same period of time. The increase of Medicare payments to hospitals for TKAs was a lower rate compared to inflation.

Blood loss

It is proven that total knee arthroplasty results in significant blood loss. CAS reduces blood loss following TKA and may reduce the need for postoperative transfusion. Hinajeros et al. reported 9% of blood transfusion in TKA using CAS compared to 23% using the conventional technique; at least 1 unit of blood was used in each case. CAS reduces the use of allogenic blood transfusion by 50% and considering the average cost (in US, Medicare 2009) of blood use of $134 per patient; the use of CAS in TKA represents savings for around $1,161,600 in one year.

Operating Room Time

The additional time generated by the use of CAS in TKA has been shown as 7 to 20 min. compared to the conventional technique; however this difference is not statistically significant in several cases. OR time using CAS in TKA with extra-articular deformity is shorter than any conventional navigated TKA in the presence of deformities.
Days of stay
In 2005, 3.4 million (9%) of all hospitalizations in the US were generated by musculoskeletal procedures and these stays were on average half a day longer and $5,500 more expensive (average $13,200) relative to all hospitalizations. CAS has demonstrated better alignment (0°±2°) in TKA, with faster rehabilitation and shorter days of stay (up to 2 days). In many health systems, reimbursement factors determine the days of stay. Hypothesizing an average of $450 per non-surgical day, and 12,000 TKAs using CAS per year; savings of $5,400,000 approximately were represented by the use of CAS in TKA during 2009 in the US.

Infections
On average, hospital stays with infections were 19.2 days longer and nearly $43,000 more expensive than stays without infections by 2007 ($9,377) in the US. Infections are the worst and most common cause of revision TKA (25.2%) followed by implant loosening (16.1%). Furthermore, the number of infections after revision TKA is projected to increase from 6,400 in 2005 to 175,500 in 2030. Moreover, revision TKA with infection requires an average of 2.4 additional hospitalizations and 3.4 additional operations. Hospital stays are 3.7 times longer compared to primary TKA and 2.7 times longer compared to an aseptic revision; which represents $1,700 and $1,215 for non-surgical days respectively. The operating room time revision TKA is 3.4 times greater compared to a primary TKA and 1.8 times greater than aseptic revision. Hospitalization charges are 1.52 significantly greater in patients with revision TKA infection compared to an aseptic revision. Based on the literature search used for this document, it has not been reported that CAS increases the probability of infection compared to the conventional technique in TKA.

Complications
Health care costs are directly associated with the frequency and severity of patient complication during and after TKA. Although the prevalence of complications and revisions are reported as <8% after joint arthroplasty, it is important to highlight the high rate (90%) of success and patient satisfaction of these surgeries.

Complications and surgery volume
Annual rates of mortality (<1%) and select complications (<8%) have been inversely associated with surgeon and hospital volumes of TKAs performed. Lower pneumonia rates alone or mortality, myocardial infarction, pulmonary embolism, deep joint infection, and pneumonia combined rates were found in high TKA volume hospitals and surgeons.

Emboli
Emboli is one of several complications commonly associated with the conventional technique following TKA, and low-volume procedure hospitals. One of the advantages of CAS in TKA is the reduction of fat or bone marrow embolism due to the fact that this technique preserves the intramedullary canal. Kalairajah et al. demonstrated a statistically significant reduction (P=0.0003) in cranial embolism using CAS (mean=0.64) compared to conventional technique (mean=10.7) in TKA. The use of CAS in TKA reduces the probability of cranial embolism by 16.7 fold and represents potential savings of around $710,000 (2009 Medicare data) for every 100 patients operated.

Mortality
Several studies have shown association between low volume hospitals (<25 TKAs per year) and higher mortality rate (30%) in patients undergoing to TKA. Men showed higher 30-day mortality rates compared to women (1.8% and 0.4%, respectively); but at 90-days the mortality rates were similar (1.1% and 1.0%, respectively). Bilateral procedures were associated with higher 30-day mortality rates compared to unilateral, and no differences were observed in 90-day mortality rates. Caucasian and the presence of osteoarthritis were associated with 90-day mortality rates. So far, there is no significant difference in mortality rate between CAS and the conventional technique in TKA.
Cost-effectiveness

Limited number of publications about cost-effectiveness of CAS in TKA is available in the literature. Although, CAS has been associated to longer OR time, additional steps, and laborious and complex procedures; some cost-effective analysis clearly demonstrate favorable results supporting CAS in TKA.\textsuperscript{19,20} Dong and Buxton concluded that CAS may offer better quality-adjusted life years and represents a cost-saving technology in the long-term.\textsuperscript{19} Novak et al. showed that CAS is potentially cost-effective or cost-saving in TKA; however, clinical outcomes and implant longevity have to be assessed in long-term studies.\textsuperscript{39} Finally, Higashi et al. reported that CAS is cost-effective in TKA, affirming that navigation provides a substantial improvement of quality of life at reasonable costs.\textsuperscript{20}

Other important facts:

• Musculoskeletal procedures generated over 3.4 million hospital stays by 2005 (9% of all hospitalization) in the United States and representing $31.5 billion in expenses (over 10% of all hospital care).\textsuperscript{90}

• Knee arthroplasty, hip replacement, and spinal fusion are the most common musculoskeletal procedures, accounting for about 1.2 million hospital stays.\textsuperscript{90}

• In 2005, days of stay in musculoskeletal procedures were on average about a half-day longer compared to the average of all procedures (5.0 days versus 4.6 days), and over $5,500 more expensive ($13,200 per stay versus $7,600 per stay).\textsuperscript{90}

• The volume of knee arthroplasties and hip replacements increased by 69% and 32% percent, respectively, from 1997 to 2005.\textsuperscript{90}
2 Clinical Burden

2.1 Osteoarthritis Clinical Characteristics and Presentation

Key Findings

• Osteoarthritis is a degenerative disease which compromises the integrity and function of the joint.\(^{40-42}\)
• Osteoarthritis generally leads to joint stiffness, inflammation and pain; affecting knees, hips, hands and spine.\(^{45}\)
• Total knee arthroplasty is a well-established technique to relieve pain, improve physical function and enhance quality of life in patients with osteoarthritis.\(^{1,2}\)

Osteoarthritis (OA) is a degenerative disease characterized by destruction of hyaline cartilage, thickening of the synovial capsule and hypertrophy of the bone; which compromises the integrity and function of the joint.\(^{40-42}\) The World Health Organization estimates that OA affects 10% of the world population who are over 60 years old.\(^{23;24}\) The Center of Diseases Control and Prevention (CDC) calculates that around 27 million individuals are affected by OA in the United States.\(^{43}\) The incidence of OA has been increasing worldwide, as well as in the United States with higher prevalence in women compared to men, according to the American Academy of Orthopaedic Surgeons.\(^{25}\)

The etiology of OA is unknown but hereditary and developmental factors have been associated to the joint degeneration. Mechanical and molecular mechanisms have been identified as essential to maintain the ultra-structural organization of the cartilage extracellular matrix and function of the joint. Cell-matrix interactions which regulate responses to growth factors; cytokines and mechanical stress have to be in perfect balance to guarantee the cell adhesion mechanism of the cartilage.\(^{44}\) The tissue damage generally leads to joint stiffness, inflammation and pain; commonly affecting knees, hips, hands and spine.\(^{45}\)

Symptoms of OA appear gradually and usually after the age of 40 years old. OA is classified as idiopathic (localized or generalized) or secondary (depending on the medical trigger such as traumatic, congenital, metabolic, endocrine, or neuropathic factor). So far, there is no cure for OA and the treatments available are focused on relieving symptoms and improving function.\(^{45}\) Additionally, TKA and THA have become a well-established technique to relieve pain, improve physical function and provide high level of patient satisfaction, when other treatments are not indicated in OA.\(^{1,2}\)

2.2 Epidemiology

Key Findings

• The incidence of primary total hip and knee arthroplasty has been significantly increasing worldwide.\(^{26-28;46;47}\)
• From 2005 to 2030, the estimated growth for primary total knee and hip arthroplasties are 673% (3.5 million / year) and 174% (572,000 / year), respectively, in the United States.\(^{26}\)
• The numbers of hip revisions are expected to double from 2005 to 2026 and the demand of knee revisions is expected to double by 2015, in the United States.\(^{26}\)
• Overall, total knee and hip revisions are expected to grow 137% and 601%, respectively, from 2005 to 2030 in the United States.\(^{26}\)
• Awareness of the benefits of arthroplasty, obesity, increase in elder population and patient comorbidities are some of the factors associated as responsible of the increased demand in hip and knee arthroplasties in the United States.\(^{47}\)
• The incidence of joint arthroplasties have increased not only in older (>65 years) but also in younger (<65 years) patients.\(^{26;27}\)
• Total joint arthroplasties are more frequent in women compared to men.\(^{28;29}\)
• The demand of TKA in white patients is higher compared to black and Hispanic populations.\(^{28;91}\)

2.2.1 Incidence and Prevalence of Joint Arthroplasty

The incidence of primary total hip and knee arthroplasty has been significantly increasing worldwide.\(^{26-28;46;47}\) Factors such as awareness of joint arthroplasty benefits, obesity, elder population growth, and patient comorbidities have been associated with the increased demand in hip and knee arthroplasties in the United States.\(^{47}\) Kurtz et al. reported a significant increase of primary (50%) and revision rates (8.2%) in total knee arthroplasties from 1990 to 2002 in the United States.\(^{47}\) In addition, Ong et al. reported that MEDICARE allocated 8% of its annual budget in expenditures associated with TKA revisions from 1997 to 2003.\(^{48}\) It has been projected that by 2030, the demand of total hip and knee arthroplasties will increase by 174% (572,000 surgeries / year) and 673% (3.5 million surgeries / year), (Figure 1); and revision rates by 137% and 601%, respectively (Figure 2).\(^{26}\)
Clinical Burden

2.2.2 Age, Gender and Ethnicity in Joint Arthroplasty

In the last ten years, the incidence of total joint replacement has increased not only in older (>65 years) but also in younger (<65 years) patients.26,27 By 2011, a large percentage of the American population reached >65 years of age and the demand for joint replacement increased significantly.27 Kurtz et al. projected that the portion of primary THA and TKA versus the sum of all types among patients under 65 years old will increase by 50% in 2011 and then by another 50% in 2016. Revision rates for TKA in patients less than 65 years old will increase 50% by 2011; and by 2030 the number of THA and TKA in patients under 65 years old is projected to increase by 52% for primary THAs and by 55% and 62% for primary and revision TKA, respectively (Figure 3).

Figure 1. The projected number of primary total hip arthroplasty (THA) and total knee arthroplasty (TKA) procedures in the United States from 2005 to 2030. Primary TKA will significantly increase compared to primary THA by 2030. (Adapted from Kurtz et al. 2007)26

Figure 2. The projected number of revision total hip arthroplasty (THA) and total knee arthroplasty (TKA) procedures in the United States from 2005 to 2030. TKA revisions will significantly increase compared to THA revisions by 2030. (Adapted from Kurtz et al. 2007)26

Figure 3. Projected relative proportion of younger patient (<65 years) undergoing for primary and revision total joint replacement by 2030. Primary THA and TKA, as well as revision TKA will increase by 2030. (Adapted from Kurtz et al. 2009)27
Gender is an important factor to consider in TKA due to demographic and morphometry variations. Total joint arthroplasties have been reported to be more frequent in women compared to men, and women are at a greater risk for worse symptoms. McDonald et al. studied 3,817 patients (5,279 primary TKA) and found that almost two thirds of the cohort were females. Tanavalee et al. evaluated 314 patients with primary TKA and found an average female/male ratio of 5.1:1. These findings, supported by Robertsson et al., evaluated 27,372 knees and reported that three quarters of the patients were women. McDonald et al. also demonstrated statistically significant differences (P<0.001) in height, weight, body mass index, obesity and pre-operative limb alignment between gender (Figure 4).

It has been reported that the existence of disparities in health care associated to certain racial and ethnic groups in the United States are not due to comorbidities, such as diabetes, hypertension, cancer, HIV, etc. (reviewed by Morgan et al.). Race and ethnicity have been considered variables associated with joint replacement and higher TKA prevalence has been shown in white patients compared to black and Hispanic populations. Wilson et al. analyzed the Medicare hospitalization data and showed that white patients were more likely to undergo TKA compared to black patients. Furthermore, Katz et al. reported that white patients underwent TKA more frequently compared to black patients, between 1998 and 2000 in the United States. Moreover, Jain et al. demonstrated that the proportions of black and Hispanic patients requiring TKA were lower compared to white patients relative to the general population (Figure 5). These racial differences should be considered for future health care assistance and budget allocation strategies.

**Figure 4.** Patient demographics by gender. Women show statistically significant differences in height, weight, body mass index (BMI), obesity, alignment compared to men. (Adapted from McDonald et al. 2008)

<table>
<thead>
<tr>
<th></th>
<th>Age</th>
<th>Height (cm) mean</th>
<th>Weight (kg) mean</th>
<th>BMI mean</th>
<th>Morbidly obese (%)</th>
<th>Previous operation (%)</th>
<th>Varus alignment (%)</th>
<th>Valgus alignment (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Men (n=1100)</td>
<td>69.02</td>
<td>159.53</td>
<td>82.36</td>
<td>32.43</td>
<td>15.4</td>
<td>60.2</td>
<td>55.2</td>
<td>18.6</td>
</tr>
<tr>
<td>Women (n=2179)</td>
<td>68.53</td>
<td>175.33</td>
<td>119.99</td>
<td>36.39</td>
<td>6.4</td>
<td>68.8</td>
<td>64.5</td>
<td>8.2</td>
</tr>
</tbody>
</table>

**Figure 5.** Race distribution trends of patients undergoing total knee arthroplasty in the United States between 1990 and 2000. White population higher incidence of TKA compared to Black, Hispanic and others populations. (Adapted from Jain et al. 2005)
2.3 Computer Assisted Surgery in Total Knee Arthroplasty

Key Findings

- TKA is a well-established technique to relieve pain and improve physical function and provide high level of patient satisfaction in osteoarthritis.\(^1\,^2\)
- Inaccurate implantation rates of up to 30% have been reported using the conventional technique in TKA,\(^6\,^7\) and independent of the surgeon’s experience.\(^9\)
- CAS has demonstrated better alignment accuracy in TKA compared to the conventional technique,\(^4\,^8-11\) with a reduction of outliers to less than 10%.\(^99\)
- CAS increases operating time by only 7 to 20 min. in TKA procedures but this additional time might be justified by the significant improvement in alignment and accuracy of implantation as well as reduction in intra-operative complications.\(^33\)
- CAS reduces the probability of fat embolism and blood loss due to the preservation of the intramedullary canal, instead of using intramedullary rods as required by the conventional technique.\(^36\)
- CAS improves beginner surgeon skills, achieving the same level of accuracy as experts in term of alignment.\(^66\)

2.3.1 Overview

Total knee arthroplasty is a well-established technique to relieve pain, improve physical function and provide high level of patient satisfaction in osteoarthritis.\(^1\,^2\) The success of knee arthroplasty depends on achieving the proper ligament balancing and correct component alignment (0°±3° of the mechanical axis),\(^3\,^4\) the experience of the surgeon, soft tissue balancing and prosthetic design;\(^5\) and it will be translated to the longevity of the implant.\(^59\) Device loosening rates of up to 24% have been reported when the implant is positioned >3° from the mechanical axis compared to a rate of only 3% when the device is ≤3°.\(^49\) Inaccurate implantation rates of up to 30% have been reported using the conventional technique in TKA,\(^6\,^7\) and it has also been demonstrated that this inaccuracy can be independent of the surgeon’s experience.\(^9\)

Several limitations are associated to the conventional technique including: X-ray templating which always carries a margin of error, difficulties determining intraoperative landmarks, the use of conventional tools which may not fit to specific patients and mechanical alignment relying on direct visual criteria.\(^100\) Furthermore, factors such as deformities, narrow canal, obesity, and severe bowing limits the use of the conventional technique.\(^18\,101\) Comparison between intra- and extramedullary-guide systems has not shown advantages in reducing outliers.\(^102\,103\) The average survival rate of total knee components was shown to be 98% at ten years\(^60\) and up to 90% at fifteen years.\(^61\,62\) Prosthesis malalignment has been reported as a factor for premature failures,\(^104\,105\) patellofemoral disorders,\(^59\,106\) and uneven wear of the polyethylene liner.\(^105\,107\) CAS overcomes the limitations of the conventional technique by helping to provide better alignment accuracy, and to reduce outliers and complications\(^99\) compared to the conventional technique in TKA.\(^4\,^8-11\)
Clinical Burden

2.3.2 Limb and Prosthesis Alignment

Inaccurate implantation rates up to 30% have been reported when conventional technique and mechanical jigs are used.\(^6\)\(^7\) The tourniquet, drapes, and subcutaneous fat make it difficult to achieve a proper tibiofemoral alignment.\(^1\) Moreover, it has been described that prosthesis loosening rate was 24%, when the deviation from neutral alignment was >3°; but the loosening rate was only 3% when less than 3° from neutral.\(^6\)\(^9\) CAS has proven to be significantly more accurate and reliable in achieving lower extremity alignment compared to the conventional technique.\(^1\) Furthermore, CAS offers improved accuracy in complex cases such as posttraumatic femoral deformity and retained femoral hardware, where conventional instrumentation is more difficult to used.\(^1\)

Maniar et al. demonstrated that CAS improves alignment accuracy (0°±3° of the mechanical axis) compared to the conventional technique, even early in the learning curve. Conventional technique accuracy rate was 66% (18% outliers) compared to navigation 100%, with no outliers (Figure 6).\(^1\) Pang et al. showed a statistically significant better alignment (P=0.02) and fewer outliers (P=0.01) comparing CAS to the conventional technique in 140 TKA after 2 years.\(^1\) Furthermore, Longstaff et al. demonstrated that the improvement in the coronal femoral alignment (0°±2°) has significantly better functional and clinical Knee Society scores at 1 year postoperatively (153.6 vs. 136.7) compared to outliers; and patients with better limb alignment may experience faster rehabilitation and a reduction of length of hospital stay of up to 2 days.\(^2\)

In addition, Ishida et al. showed that navigation significantly improved alignment in relation to the mechanical axis and femoral rotational at mid-term evaluation (5-years post-operative follow up) (Figure 7).\(^1\) Moreover, Choong et al. demonstrated that coronal alignment within a range of 0°±3° improves quality of life and functional outcomes compared to alignment angles out of that range.\(^1\) Jenny et al. proved that navigation provided the same level of implantation accuracy in both beginners or experienced surgeons (>1000 surgeries).\(^3\) And, Cheng et al. showed that CAS improves postoperative alignment and reduces complication in TKA as result of a meta-analysis of eighty-five articles.\(^1\)

![Figure 6](image1.png)  
**Figure 6.** Total Knee Arthroplasty success rates for different criteria. MA = mechanical axis, FCA = femoral component alignment and TCA = tibial component alignment. CAS-Early (first 100 TKA) and CAS-Late (last 100 TKA). CAS improves alignment compared to conventional technique in TKA. (Adapted from Maniar et al. 2011)\(^1\)

![Figure 7](image2.png)  
**Figure 7.** Varus/valgus alignment of the long leg axis at final follow-up. Neutral alignment in relation to the coronal mechanical axis of the limb is recorded as 0°, negative values imply valgus and positive values imply varus. Larger number of patients achieved 0° to -2° when CAS was used. (Adapted from Ishida et al. 2011)\(^1\)
Overall, the majority of the publications report improved accuracy and alignment using CAS compared to the conventional technique in TKA; and these two factors have may be responsible for the stability and longevity of the implant.\textsuperscript{75,109,110}

Despite of the improvement in mid-term functional scores demonstrated by use of optical navigation, the success of CAS with respect to clinical performance needs further investigation. Long-term, randomized trials to demonstrate the role of this technique in the improvement of functional scores in TKA are required.

### 2.3.3 Soft-tissue balance

Proper alignment and balance in TKA requires precise bony resection and soft-tissue release. Inadequate ligament release may result in instability, loosening, and premature wear of the implant.\textsuperscript{52} Surgeons traditionally rely on their experience and “feel” to obtain accurate intraoperative soft tissue balance when performing TKA using the conventional technique.\textsuperscript{53}

In TKA using either CAS or conventional technique, two different approaches have been described to achieve either femoral component rotation or overall prosthetic alignment: the measured gap resection technique, in which bone landmarks are used to guide resections equal to the distal and posterior thickness of the femoral component, or the gap-balancing technique, in which equal collateral ligament tension in flexion and extension is employed as a guide for final bone cuts.\textsuperscript{111} Freeman et al. proposed the gap-balancing technique more than 30 years ago;\textsuperscript{112} and Insall et al. also supported this concept more recently.\textsuperscript{113} The measured resection technique was introduced during the 1980s by Hungerford, Kenna and Krackow and has been used for many surgeons.\textsuperscript{114}

CAS helps in achieving a proper soft-tissue release in real-time, allowing a more precise balance of the joint and avoiding over release of soft-tissue as observed in TKA using the conventional technique.\textsuperscript{13,14} Hakki et al. showed the mechanical axis and the discrepancy in the measured medial and lateral joint spaces as the measurements to assess the need for ligament release.\textsuperscript{14} Moreover, they proposed that over release found in TKA using conventional technique may be due to temptation to undertake any amount of collateral ligament release in all deformed knee to achieve neutral alignment.\textsuperscript{14}

Taken together, the majority of the literature shows that CAS using the gap-balancing technique provides a better soft-tissue balance compared to the conventional technique in TKA.
2.3.4 Operating Room Time

OR time is an important factor when evaluating surgical techniques due to the significant impact on overall procedure cost. Several studies show the use of CAS may extend the length of the surgical procedure.\textsuperscript{54,55} But others demonstrated that the CAS increases operating time by only 7 to 20 min. in TKA procedures\textsuperscript{18,73} with no statistically significant difference compared to the conventional technique.\textsuperscript{11}

Bathis et al. reported an additional 14 min. for CAS vs. conventional technique in TKA.\textsuperscript{73} Ghothesen et al. showed an average of an additional 15 min. in 1,465 CAS compared to 8,214 conventional TKA performed in Norway between 2005 and 2008.\textsuperscript{74} Additionally, Jenny et al. demonstrated a difference of 21 min. ($P<0.0001$) between CAS mean OR time compared to the conventional group; this difference might be associated with registration of landmarks for the CAS subjects.\textsuperscript{56}

On the other hand, comparing CAS to the conventional technique in 140 randomized TKA, Pang et al. showed no statistically significant difference in OR time (CAS, 110±14 min.; conventional, 95±12 min.) (Figure 9).\textsuperscript{11} And although, Catani et al. demonstrated that mean tourniquet time using CAS in TKA with extra-articular deformity (98 min.) was 20 min. longer compared to CAS in TKA without deformities and 30 min. longer compared to conventional technique; this OR time was shorter than any conventional TKA with deformities.\textsuperscript{18}

![Graph showing demographics and operating room time in TKA](image)

**Figure 9.** Demographics and operating room time in TKA. No statistically significant difference between navigation and conventional technique in TKA was demonstrated. (Adapted from Pang et al. 2011)\textsuperscript{11}

It is well known that CAS increases operating time of about 7 to 20 min. for TKA procedures. Nevertheless, additional OR time might be justified by the significant improvement in alignment and accuracy of implantation as well as reduction in intra-operative complications.\textsuperscript{33}
2.3.5 Pain

TKA is the most common technique to relieve pain and improve function in patients with osteoarthritis of the knee when conservative treatments fail. Pain is the main symptom of osteoarthritis that brings the patient to the surgeon and represents 20% of the cases after TKA. Pain scores showed statistically significant improvement after TKA in most of the studies, but only few have reported an association between malalignment and post-operative chronic pain in TKA.15,115,116

Ishida et al. compared pain score in 27 TKA using navigation vs. 27 TKA using conventional technique and found no statistically significant difference between the two groups 5 years post-operatively.1 Additionally, Czurda et al. evaluated 123 CAS and 207 conventional TKA and found a relevant but no significant (P=0.06) difference in chronic pain (12% and 20%, respectively) after 2 years. However, the Mann-Whitney test showed a statistically significant difference between both techniques, demonstrating a relationship between incorrect rotational alignments of the femoral component and post-operative pain after TKA. Furthermore, Lehnen et al. analyzed 165 TKAs; and demonstrated that CAS provides statistically significant less pain and stiffness, as well as greater overall patient satisfaction compared to the conventional technique.15

Taken together these studies demonstrated that CAS generates less pain compared to the conventional technique in TKA. In addition, it is logical to hypothesize that by providing a more accurate limb and implant alignment compared to the conventional technique, CAS may significantly improve post-operative pain levels in TKA procedures.

2.3.6 Survival Rate

Proper ligament balancing and component alignment are the most important parameters to restore optimal function3,4 and to guarantee the longevity of the implant.59 Inaccurate implantation rates of up to 30% have been reported using the conventional technique.67 Therefore, prosthesis malalignment has been reported as one of the factors for premature failures104 and early loosening.117 The average survival rate of total knee components has been shown to be 98% at ten years60 and up to 90% at fifteen years.61,62

Parrate et al. analyzed 398 primary TKA using the conventional technique from 1985 to 1990 and reported that forty five (15.4%) of 292 implants (0°±3°) and fourteen (13%) of 106 outlier implants (≥3°) were revised after 15 years; but no statically significant difference was found (P=0.88) between groups.63 Furthermore, Chalidis et al. showed an implant survivorship rate of 96.7% after 16 years using conventional technique in 345 patients (n=393 primary TKA).64 Additionally, Adbeen et al. demonstrated a survival rate of 92.4% at 19 years in 100 primary TKA using the IB-1 prosthesis (Zimmer, Warsaw, IN) (Figure 10).65

![Implant Survivorship](image)

**Figure 10.** Best-Case implant survivorship using revision as end point. Survivorship percentage after 19 years was 92.41% in TKA. (Adapted from Adbeen et al. 2010)65

In general, most of the literature shows that obtaining proper prosthesis and limb alignment may result in an optimal function restoration and consequently a longer implant survival. CAS demonstrates more accurate prosthesis alignment; which should extend the implant survival and improve patients’ quality of life.
2.3.7 Learning Curve

The learning curve expresses the relationship between surgeon experience and time required for acquiring abilities vs. the progress to achieve degree of expertise. Learning curves are driven by several assumptions such as the unit of time required to complete a given task, the unit time decreased at a decreasing rate; and the reduction in time follows a predictable pattern (reviewed by Cheng et al.\textsuperscript{32}). A steep learning curve due to change in technique and surgery workflow has been described as factors associated with CAS in TKA,\textsuperscript{31} but no comparison with the learning curve of TKA using the conventional technique has been assessed.

Maniar et al. demonstrated that there is an improvement in OR time after the CAS learning curve is overcome. This study shows that OR time increases 16 min. during the learning curve and only 8 min. after the training period (first 100 TKA) compared to conventional TKA technique (50-90 min., avg. 68 min). They also suggest that having a strict protocol for positioning of equipment and instruments, and clearly defining the sequence of steps with a trained staff are helpful strategies to save OR time.\textsuperscript{10} Moreover, Ong et al. significantly reduced the OR time from 61 min. to 50 min. after overcoming the CAS learning curve (first 50 TKAs).\textsuperscript{118}

Jenny et al. compared the learning curve in beginner vs. experienced TKA navigation centers, including 13 European orthopedic institutions and involving 368 TKAs. They found no significant differences in clinical and radiographic outcomes between the experts and the beginners in navigated techniques except for a slightly greater OR time among the CAS group for beginners compared to experienced surgeons.\textsuperscript{33} This significant increase in operating time for beginner surgeons decreases after 30 implantations, with a residual difference of 7 min. (Figure 11).\textsuperscript{33}

These results are supported by Smith et al., they analyzed the CAS learning curve in beginner (first 50 TKAs) vs. expert (>1000 TKAs) surgeons and demonstrated that from the first case, beginners achieved the same level of accuracy as experts in term of alignment in the coronal and sagittal planes. Furthermore, OR-time was significantly longer in beginner surgeons but only in the first 20 cases (92 vs. 72 min., \(P<0.001\)), and by the 30th to 50th navigated TKAs there was no significant difference in OR time (72 vs. 74 min., \(P=0.944\)) between surgeon-experience levels. The only difference between surgeon experience levels is OR time, where the learning curve is overcome after the first 20 surgeries.\textsuperscript{146} Moreover, Cheng et al. analyzed 32,200 TKA records from the Taiwan National Health Insurance database and concluded that there are significant differences in infection and mortality rates between low and high volume institutions and established a threshold to achieve the lowest infection and complication rate as low as 20 TKA procedures.\textsuperscript{32}

Overall, most of the publications show an increase in OR time using CAS vs. conventional technique; however this difference becomes insignificant after surgeons overcome the learning curve. This learning curve has been defined as the first 20 to 30 TKAs for new navigation surgeons, but no learning curve has been evaluated for the conventional technique in TKA. CAS provides the same standards for beginner and experienced surgeons alike from the very first case in terms of alignment, functional scores, and range of motion. In conclusion, the concept of a “steep” learning curve associated with CAS might be a perception due to the complexity of the technology instead of a scientifically proven fact.
2.3.8 Complications

The incidence of complications after TKA will delay the recovery of the patients and increase the hospital costs; generating also significant patient morbidity and socioeconomic costs.\textsuperscript{46} Despite the advances in surgical techniques, implant designs, and instrumentation, up to 8\% of cases show intraoperative and postoperative complications at short- and mid-term follow-up;\textsuperscript{67} due to loosening, infection, instability, dislocation or fracture.\textsuperscript{68} Some complications have been commonly associated with the conventional technique and include fat and bone marrow embolism, blood loss, infections, post-operative stiffness related to the anesthesia, ischemic attack, pain, and deep vein thrombosis.\textsuperscript{11}

Cheng et al. reported in their 2011 meta-analysis of eighty-five articles that CAS improves the accuracy of postoperative alignment along with the reduction of blood loss, decreased morbidity and limited bone injury in TKA.\textsuperscript{16} Kim et al. proposed that CAS reduces the probability of fat or bone marrow embolism due to the fact that this technique does not require the use of intramedullary guides. These guides may increase pressure and trigger potential activators of the coagulation cascade.\textsuperscript{15} These findings are supported by Catani et al. who reported that CAS reduces the probability of fat embolism and blood loss due to the preservation of the intramedullary canal compared to the conventional technique.\textsuperscript{36}

Ishida et al. did not report any complications after 5 years of TKA using either CAS or conventional technique in 54 patients.\textsuperscript{1} Moreover, Jenny et al. demonstrated that intraoperative complications associated with the navigation system did not occur more frequently in beginners compared to experienced surgeons; they assessed 368 TKA (218 in beginner and 150 experienced) in terms of implantation accuracy, clinical outcomes, OR-time and complications.\textsuperscript{33} Conversely, Bonutti et al. indicated that using navigation in TKA may increase the incidence of complications, such as femoral shaft fracture resulting from femoral tracker placement.\textsuperscript{119} However, this publication reports results from only two cases with displaced femoral fractures at optical pin placement as result of routine navigated TKA. The majority of the literature reports no or less number or severity of complications when CAS is used compared to the conventional technique in TKA.
3 Economic Burden

Key findings
• In 2005, musculoskeletal procedures generated over 3.4 million hospital stays (9% of all hospitalization) in the United States and represent $31.5 billion in expenses (over 10% of all hospital care in the US).90
• Knee and hip arthroplasties, and spinal fusions are the most common musculoskeletal procedures, accounting for about 1.2 million hospital stays.90
• In 2005, days of stays in musculoskeletal procedures were on average about half-day longer compared to the average of all procedures (5.0 days versus 4.6 days), and over $5,500 more expensive ($13,200 per stay versus $7,600 per stay).90
• The volume of knee and hip arthroplasties increased by 69% and 32%, respectively, from 1997 to 2005.90
• Musculoskeletal procedures are more frequent on females and older patients (mean age 60 years).90
• CAS reduces by 50% the use of allogenic blood transfusion21 and considering the average cost of blood used is $134 (2009 US Medicare); the use of CAS in TKA represents savings of around $134,000 per year if 1,000 cases are performed.
• OR time using CAS in TKA with extra-articular deformity is shorter than any conventional navigated TKA in the presence of deformities.18 The additional OR time associated to CAS in TKA (7-10 min.) without deformities might be justified by the significant improvement in alignment and accuracy of implantation as well as reduction in intra-operative complications.33
• Faster rehabilitation and shorter days of stay (up to 2 days less) has been demonstrated after TKA using CAS,22 representing savings up to $900 per case in hospital costs.37

3.1 Blood loss
It is proven that total knee arthroplasty results in significant blood loss;70,71 and several methods such as tourniquet,120 diathermy coagulation,121 plugging of the intramedullary femoral canal,122 positioning of the knee123 and the use of anti fibrinolytic drugs124 have been developed to reduce blood transfusions.

Several publications suggest that CAS reduces blood loss following TKA and may reduce the need for postoperative transfusion.16,18,34-36 Millar et al. demonstrated a statistically significant (P<0.001) reduction in blood loss using CAS (n=30; 1014±312 ml) compared to the conventional technique (n=30; 1287±330 ml) in TKA of obese patients (Figure 12). In addition, the rate of blood transfusion in the CAS group was lower compared to the conventional group, however, no significant different was found.125 Moreover, Schnurr et al. found a statistically significant decrease in blood loss using CAS in TKA; and demonstrated a 50% reduction of allogenic blood transfusion.21 In the same trend, Kalairajah et al. also found a statistically significant difference (P=0.001) in blood loss using CAS compared to conventional technique in TKA. Finally, Hinajeros et al. reported 9% blood transfusion in TKA using CAS compared to 23% using the conventional technique.72

The demand of TKA in the United States is projected to grow to 3.48 million procedures per year by 2030.26 From 1991 to 2008, Medicare hospital payment for joint arthroplasty increased 30% and inflation 59%, for the same period of time. 69 The increase of Medicare payments to hospitals for TKAs was a lower rate compared to inflation. Thus, more detailed studies and reimbursement strategies are needed to demonstrate the cost-effectiveness of navigation in TKA.

Figure 12. Total blood volume loss in patients with BMI<30 and BMI>40 using CAS and conventional technique in TKA. There is a statistically significant reduction in blood loss in the CAS group compared to the conventional technique, independently of obesity. *P<0.05, **P<0.01, *** P<0.001. Body mass index (BMI), milliliters (ml). (Adapted from Millar et al. 2011)125
In 2009, more than 620,000 primary knee procedures were performed in the US and approximately 2% (12,400 TKA procedures) of those surgeries were realized using CAS. Based on Schnurr et al. results, showing that CAS reduces in 50% the use of allogenic blood transfusion and considering the average cost of blood used of $134 per patient (2009 Medicare); the use of CAS in TKA represents savings for around $1,161,600 in one year, derived from the use of blood.

3.2 Operating Room Time
Extended OR time has been associated to the use of CAS compared to the conventional technique. The additional time generated by the use of CAS in TKA has been shown to be from 7 to 20 min. compared to the conventional technique; however, several studies show that this difference is not statistically significant. OR time using CAS in TKA with extra-articular deformities has been reported to be shorter than any conventional TKA in the presence of deformities. Nevertheless, additional OR time might be justified by the significant improvement in alignment and accuracy of implantation as well as reduction in intra-operative complications; which could extend the life of the implant.

3.3 Days of stay
In 2005, 3.4 million (9%) of all hospitalizations in the US were generated by musculoskeletal procedures and these stays were on average half day longer and $5,500 more expensive (average $13,200) relative to all hospitalizations (avg. 4.6 days and avg. cost $7,600, respectively). Hospital costs for musculoskeletal procedures were $31.5 billion in 2004, representing around 10% of total hospital care in the US.

CAS has shown to provide more accurate and reliable limb and prosthesis alignment compared to the conventional technique. Longstaff et al. demonstrated that better alignment (0°±2°) generated by CAS in TKA is associated with faster rehabilitation and shorter days of stay (up to 2 days). In many health systems, reimbursement factors determine the days of stay. Hypothesizing that patients undergoing to CAS TKA are discharged 2 days earlier after satisfactory rehabilitation, a mean hospital cost of $450 per non-surgical day, and 12,000 TKA using CAS per year; savings around $5,400,000 approximately are represented by the use of CAS in TKA during 2009 in the US.

3.4 Complications
Health care costs are directly associated with the frequency and severity of patient complications during and after TKA. Although the prevalence of complications and revisions are reported as <8% after joint arthroplasty, it is important to highlight the high rate (90%) of success and patient satisfaction of these surgeries. Reported complications following knee arthroplasty includes myocardial infarction (0.8%), pulmonary embolism (0.8%), deep joint infection (0.4%), and pneumonia (1.4%).

3.4.1 Complications and surgery volume
Annual rates of mortality (1%) and select complications (<8%) have been inversely associated with surgeon and hospital volumes of TKAs performed. Katz et al. demonstrated statistically significant difference in mortality and complication rates between high and low TKA volume performed by centers and surgeons in 2000 in the US. Lower pneumonia rate alone or mortality, myocardial infarction, pulmonary embolism, deep joint infection, and pneumonia combined rates were found in high TKA volume hospitals and surgeons. Up to date, the literature reviewed for this document has not reported that CAS increases the complication rate or severity compared to the conventional technique in TKA.

3.4.2 Embolism
Embolism is one of several complications commonly associated with the conventional technique following TKA, and low-volume procedure hospitals. One of the advantages of CAS in TKA is the reduction of fat or bone marrow embolism due to the fact that this technique preserves the intramedullary canal, avoiding the coagulation cascade activation and the increase of intramedullary pressure.

Kalairajah et al. demonstrated statistically significant reduction (P=0.0003) in cranial embolism in the CAS group compared to conventional technique in TKA. The CAS group showed that no patients had more than two detectable emboli, 35% had one embolism, and 14% had two emboli. In the conventional technique group, the number of emboli ranged from 1 to 43 and six patients had more than 2 detectable emboli (Figure 13). The nature of the emboli could not be detected using a non-invasive transcranial Doppler device. Almost all emboli occurred soon after the introduction of the intramedullary rod in the conventional group; and at the implant insertion in the CAS group.
Based on Kalairajah et al. results, CAS reduces the probability of cranial embolism in 16.7 folds,\textsuperscript{16} and using an average cost of embolism per case of $7,373 (2009 Medicare data);\textsuperscript{128} therefore the use of CAS in TKA represents potential savings for around $710,000 for every 100 patients operated.

### 3.4.3 Infections

Musculoskeletal disorders are responsible for millions of severe chronic pain and physical disability cases;\textsuperscript{129} and the demand for TKA has been increasing substantially over the past decade worldwide.\textsuperscript{130} Musculoskeletal infections after joint replacement represent an important patient safety, financial, and societal cost problems.\textsuperscript{131} Infections significantly increase the length of stay and costs. On average, hospital stays with infections were 19.2 days longer and nearly $43,000 more expensive than stays without infections by 2007 ($9,377).\textsuperscript{83}

Infections were the most common cause of revision TKA (25.2\%) followed by implant loosening (16.1\%) between 2005 and 2006 (Figure 14).\textsuperscript{83} The rate of deep infection following TKA has been reported to be up to 4\% and is projected to increase at a faster rate for total knee arthroplasty (6\%) than for total hip arthroplasty (1\%).\textsuperscript{129} Periprosthetic joint infections is one of the worse complications of total joint replacement. Using the U.S. Nationwide Inpatient Sample (1990-2003), Kurtz et al. demonstrated that the number of infections after revision total knee arthroplasty is projected to increase from 6,400 in 2005 to 175,500 in 2030.\textsuperscript{27,84}

Revision TKA for an infection requires an average of 2.4 additional hospitalizations and 3.4 additional operations. Hospital stays are 3.7 times longer ($1,700 total for non-surgical days) compared to primary TKA and 2.7 times longer ($1,215 total for non-surgical days) compared to an aseptic revision.\textsuperscript{85}

The OR time revision TKA is 3.4 times greater compared to a primary TKA and 1.8 times greater than an aseptic revision.\textsuperscript{86} Furthermore, hospitalization chargers are 1.52 significantly greater in patients with revision TKA infection compared to an aseptic revision.\textsuperscript{26}

Additional factors such as direct costs for medical malpractice claims ($6.5 billion in the US, 2001); indirect costs (loss of productivity, morbidity and mortality); and intangible costs (pain, suffering and quality of life) have to be considered to assess the economic and social impact of infections following TKA.\textsuperscript{131}

CAS has shown no difference in infection rates compared to the conventional technique in TKA; even though a potential pin-site infection has been related to CAS.\textsuperscript{118}
3.5 Morbidity

Comorbidity is an important factor to consider for complication and mortality rates after TKA, especially in elderly population.\(^7\) Using the Medicare 5% sample (83,011 patients; 1998-2007), Bozic et al. demonstrated that comorbid conditions such as heart failure, metastatic cancer and renal disease are strongly associated to higher 90-day mortality rates in TKA; and congestive heart failure, chronic pulmonary disease, preoperative anemia and diabetes are associated to periprosthetic joint infection (Figure 15).\(^7\)

In favor of CAS, this technique improves rehabilitation and reduces the days of stays,\(^22\) therefore it may decrease morbidity in TKA.

3.6 Mortality

Death is a devastating complication after TKA.\(^7\) Several studies have shown an association between low volume hospitals and higher mortality rates in patients undergoing TKA.\(^80;88\) Katz et al. analyzed 80,904 primary TKA in Medicare beneficiaries (January 1st through August 31st, 2000) and reported 30% higher mortality rate in patients who had the procedure in hospitals with annual TKAs ≤25, however this difference was not statistically significant.\(^77\)

Furthermore, Singh et al. systematically reviewed 80 studies and concluded that the 30-day mortality rate was 0.3% and 90-day 0.7% after TKA. Men showed higher 30-day mortality rate compared to women (1.8% and 0.4%, respectively); but the mortality rate at 90-day were similar (1.1% and 1.0%, respectively). Bilateral procedures were associated with higher 30-day mortality rate compared to unilateral, and no differences were observed in 90-day mortality rates. Caucasian and the presence of osteoarthritis were associated with 90-day mortality rates (Figure 16).\(^89\) There is no report, study or publication that may associate the use of CAS with an increase of mortality rate compared to the conventional technique in TKA.

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**Figure 15.** Comorbid conditions associated to 90-day postoperative mortality and prosthetic joint infection after TKA. (Adapted from Bozic et al. 2011)\(^7\)

**Figure 16.** Association with 30-day and 90-day postoperative mortality in TKA (Adapted from Singh et al. 2011)\(^89\)
3.7 Cost-effectiveness

CAS in TKA is cost-effective and represents a cost-saving technology in the long-term.\textsuperscript{19,20}

There are a limited number of publications about the cost-effectiveness of CAS in TKA. CAS has been associated to longer OR time, additional steps, and laborious and complex procedures; but cost-effectiveness analysis clearly demonstrate favorable results supporting CAS in TKA.\textsuperscript{19,20}

Dong and Buxton concluded that CAS may offer better quality-adjusted life years and is a cost-saving technology in the long-term. Moreover, CAS may reduce revision rates and complications through more accurate and precise alignment.\textsuperscript{19} The average cost for a primary TKA using conventional technique was estimated in $6,796 and additional $309 if CAS was used.\textsuperscript{19} Novak et al. showed that although CAS gives a cost of $1500 per TKA, this technique is potentially cost-effective or cost-saving in total knee arthroplasty; however, clinical outcomes and implant longevity have to be assessed in long-term studies.\textsuperscript{39} In support to these results, Higashi et al. reported that CAS is cost-effective in TKA, affirming that navigation provides a substantial improvement of quality of life at reasonable costs.\textsuperscript{20}
4 Product Information

Zimmer® Computer Assisted Surgery techniques combine advanced computer technology with a surgeon’s skills to help improve the outcomes of knee and hip replacement surgery. CAS, also known as Surgical Navigation, is defined as a surgery that is performed using a computer as a guiding and validation tool. The system provides precise positional implant guidance when replacing damaged surfaces of bones, based on a patient’s anatomy, and suggests the appropriate implant size to be used.

4.1 Computer Assisted Solution

When it comes to performing arthroplasties, Zimmer CAS believes that Computer Assisted Surgery should not limit your surgical flexibility. Our versatile Navigation Solutions are designed to improve your surgical precision and efficiency.

4.1.1 Indication for Use/Intended Use

The ORTHOsoft® Knee Universal system is indicated for use as a stereotaxic instrument to assist in the positioning of Total Knee Replacement components intra-operatively. It is a computer controlled image-guidance system equipped with a three-dimensional tracking sub-system. It is intended to assist the surgeon in determining reference alignment axis in relation to anatomical landmarks, and in precisely positioning the alignment instruments relative to this axis by displaying their locations.

4.1.2 Advantages of Zimmer CAS over conventional technique in arthroplasty

- Helps to improve accuracy of implant alignment and placement.\(^8,10,15,25,99\)
- Facilitates minimally invasive surgeries resulting in faster patient recovery time.\(^22\)
- Provides reproducible results and helps eliminating outliers.\(^99\)
- Associated with short-term risks of revision surgery and long-term implant wear.\(^59,74,109,110\)
- Associated with decreased risks of embolism.\(^15,18,38\)

4.1.3 Sesamoid® Plasty Navigation System: Improved Design, Ideal Size

Our portable navigation system features an integrated touch screen monitor and a compact infrared camera. Its unique design allows it to fit in the smallest operating rooms.
4.1.4 Smart Instrumentation: Improved Efficiency through Instrument Reduction

Our versatile CAS instruments offer precise adjustment features for an improved level of precision. They come in one small tray and are fully compatible with your conventional instrumentation designed to reduce instruments volume, minimize surgeons’ learning curve and improve OR efficiency.

4.1.5 NavitrackER® Reference Markers: A Revolution in Tracking Technology

Forget about visibility issues: our markers provide surgeons with an improved level of tracking performance designed to eliminate the need for intra-operative camera adjustments. With a visibility of 135° and a coating highly resistant to biologic fluids, the NavitrackER Reference Marker makes navigating simple.

4.1.6 Affordable Solutions: Purchasing Options that Will Fit in Your Budget

- Evaluation programs with complete staff and surgeon training
- Up-Front purchase of software, instruments and hardware
- Pay-Per-Use and Pay-Per-Day Models
- Lease and Rental Models

For CAS coding or reimbursement questions: Zimmer Reimbursement Hotline at 1-866-946-0444

4.1.7 Zimmer CAS Applications

Performance Paired with Flexibility

- Customizable to Match Your Standard Technique
- Personalized profiles to control the time you invest in navigation based on your needs
- User-Friendly to Minimize Your Learning Curve
- Application control from the sterile field, easy to follow step-by-step graphics
- Universal for Improved Flexibility
- Universal workflows (Exclusive options are also available for Zimmer implants users)
**Knee**
- Simple workflows & advanced soft tissue balancing options available
- Fast single-point anatomy digitization
- Intra-operative alignment feedback

**Leg Length & Offset Hip**
- Precise leg length assessment with minimal time investment
- No femoral tracker, patient setup in lateral decubitus
- Compatible with the *Kinectiv®* Modular Neck Technology

**Unicondylar Knee**
- Unique prediction of alignment before the cuts are performed
- Surgical workflows supporting multiple implant philosophies

**Cup**
- Cup navigation workflow available

**Partial Hip Resurfacing**
- Planned K-Wire positioning through virtual templating
- Jig centering and guide wire insertion with one single navigated instrument
- Unique notch detection feature
General Information and Contact Information

General Information
Caution Federal (U.S.) law restricts this device to sale by or on the order of a physician.

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