The Economic Value of an Innovative Knee Implant System for Total Knee Arthroplasty

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BACKGROUND

The ATTUNE™ Knee System is a next-generation innovative total knee arthroplasty (TKA) system developed by *DePuy Synthes Joint Reconstruction* for patients with osteoarthritis (OA) requiring TKA. When compared with conventional contemporary TKA systems, innovative TKA systems are expected to improve patient functional status and knee implant survivorship.

OBJECTIVE

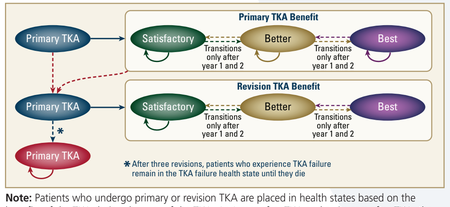
This study aimed to illustrate the expected economic value of a recently developed innovative TKA system among patients with OA requiring knee replacement. In addition to quantifying the cost-effectiveness of the innovative TKA system by comparing the costs and quality-adjusted life-years (QALYs) associated with use of the innovative and contemporary TKA systems, this study assessed the incremental cost-effectiveness of the innovative TKA system in terms of cost per revision avoided and knee-related nonrevision medical costs avoided.

METHODS

A Markov model was developed to explore the cost-effectiveness of an innovative TKA system compared with a contemporary TKA system among patients with OA requiring knee replacement. The model design distinguished between the innovative and contemporary TKA systems in terms of functional status after surgery and implant survivorship.

- Model perspective: United States (US) payer.
- Model comparators: Patients using an innovative TKA system (the ATTUNE Knee System) compared with patients using a contemporary TKA system.
- Sensitivity analysis: The effects of uncertainty associated with all inputs were tested in one-way and probabilistic sensitivity analyses.
- Model structure (Figure 1):
  - Patients enter the model in the Primary TKA health state and move across health states.

Figure 1.Markov Model Structure Diagram



Note: Patients who undergo primary or revision TKA are placed in health states based on the benefits of the TKA during the year of the TKA. At 1 year after TKA and at 2 years after TKA, the model allows the patients to improve to or worsen to a different TKA benefit health state. These movements are depicted in the dashed arrows in the Primary TKA Benefit and Revision TKA Benefit boxes. From year 3, the patients stay in the same TKA benefit health states unless they experience a TKA failure. Patients in any health state are at risk for death.

- Model time horizon: Lifetime
- Model cycle duration: 1 year
  - Primary and revision TKA health states have a 90-day duration, because the intensive treatments and rehabilitation following a TKA typically occur in the 90 days following surgery.
  - TKA benefit health states (Satisfactory, Better, and Best) immediately follow the primary and revision TKA health states and last the remainder of the year of the TKA surgery (365.25 days - 90 days).
- Model assumptions:
  - After three revisions, patients who experience TKA failure remain in the TKA Failure health state until they die.
  - The probability of Revision TKA is modeled separately for the short-term (up to 2 years after TKA) versus the mid- to long-term life of a knee device.
  - The annual revision rate is constant for the first 2 years; the rate then changes and is constant for the remainder of the patients' lifetimes.
  - The probability of a revision is the same for patients in the Satisfactory, Better, and Best health states.
  - Revisions employ the same type of contemporary TKA components, regardless of whether the primary TKA was with an innovative or contemporary TKA implant. The short-term and mid- to long-term probabilities of revision for a revised innovative or contemporary TKA are the same as those for a primary contemporary TKA.
  - The cost of failure experienced before a revision is incorporated into the cost assigned to the Revision TKA health state.
- Model inputs:
  - Population inputs: Based on a systematic literature review of Medicare patients with end-stage knee OA.[1] The model relies on the cohort mean age and sex distribution at model entry to calculate cohort life expectancy.
    - Model entry age: 70 years
    - Male/female patients: 33.3%/66.7%
  - Functional status after primary/revision TKA (Satisfactory, Better, and Best) (Table 1): Estimated based on an analysis of a prospective, randomized, multicenter clinical investigation comparing a high-flexion prosthesis with a standard knee prosthesis in patients who received bilateral TKA.[2-4]
    - Patients with a Western Ontario and McMaster Universities Arthritis Index (WOMAC) score ≥ 60 at 12 months after TKA are categorized as experiencing outcomes corresponding to Better or Best TKA health state.[5]
    - Among those patients, those with a score of at least 85 on the Knee injury and Osteoarthritis Outcome Score (KOOS) Quality of Life (QOL) subscale at 12 months after TKA are categorized as experiencing outcomes corresponding to the Best TKA health state.

Table 1. Distribution of TKA Functional Outcomes After a Primary or Revision TKA

Health State	Innovative TKA	Contemporary TKA
Best	0.541	0.361
Better	0.377	0.512
Satisfactory	0.082	0.127
Total	**1.000**	**1.000**

  - Knee survivorship (Table 2):
    - Contemporary TKA System: Estimated using patient-level survivorship data with the SIGMA® Fixed Bearing Knee System from the National Joint Registry of England and Wales Supplier Feedback Dataset, September 11, 2012.[6]
    - Innovative TKA System: Started with the assertion made by Suter et al.[7] Adjustments were made to revision risk for causes addressed in the design of the ATTUNE Knee System (i.e., wear, loosening, pain, instability, patella maltracking, and stiffness), as an example of potential improvements from an innovative TKA system. (Table 3)
  - Costs and utilities associated with various health states: Pulled from the literature (Tables 4 and 5)
  - Discount rates: 3% for both expected health outcomes and costs

Table 2. Predicted Survivorship of Innovative and Contemporary TKA Systems

Survivorship	Innovative TKA	Contemporary TKA
At 2 years	99.5%	99.4%
At 20 years	94.4%	93.0%

Table 3. Proportion of Each Type of Revision Among All Early/Late Revisions and Reduction in Each Type of Revision Due to an Innovative TKA System

Cause of Revision	Early/Late Revisions in the National Joint Registry of England and Wales	Assumed Reduction Applied for Innovative TKA Revision Rates
Early revisions (up to 2 years)		
Malalignment	16%	0%
Stiffness	1%	50%
Patella maltracking	5%	50%
Instability	14%	50%
Infection	64%	0%
Late revisions (after 2 years)		
Wear	12%	50%
Loosening	24%	50%
Malalignment	0%	0%
Pain	40%	20%
Peri-prosthetic fracture	1%	0%
Implant fracture	1%	0%
Progression	3%	0%
Other	18%	0%

Table 5. Utility Weights for Health States in the Model

Health State	Utility Weight	Duration	Assumption
Primary or Revision TKA	0.690	1 year	Approximated from pre-TKA utility
Best	0.919	1 year	10% higher than the full benefit TKA in Losina et al.,[5] defined by WOMAC score of 60 or above (0.835)
Better	0.835	1 year	Utility for patients with WOMAC score of ≥ 60[5]
Satisfactory	0.760	1 year	Utility for patients with WOMAC score < 60[5]
TKA Failure	0.518	1 year	Assumed to be 25% lower than that from the year of the TKA

N/A = not applicable.

Table 4. Cost Associated With Each Health State During/After Primary TKA

Health-State Cost Category	Model Inputs	Assumption/Calculation for Model Inputs
First year: First 90 days		
Primary TKA		
Incremental cost of ATTUNE implant over the cost of a contemporary TKA	$675	Assumption
Number of hospital days	3.617	Weighted average of the mean number of days for DRG codes associated with primary TKA in HCUP[8] (469: Major joint replacement or reattachment of lower extremity w/ MCC, 470: Major joint replacement or reattachment of lower extremity w/o MCC)
Hospitalization cost per day	$3,293	Weighted average total costs divided by the weighted average number of days in HCUP[8] Inflated from the 2009 value to the 2011 value using the mCPI multiplier, (400.258/375.613)
Other costs	$10,403	Sum of the physician's fee (Medicare reimbursement for CPT 27447; Physicians' Fee Reference, 2011[9]), $1,539, and postacute care costs Postacute care costs were estimated at $12,715 for inpatient postsurgical care costs (inpatient rehabilitation and skilled nursing facility) and $3,305 for home care[5] Because Losina et al.[5] did not report the percentage of patients who required rehabilitation at an inpatient rehabilitation center or a skilled nursing facility, the model assumes 44% based on back-calculation to estimate the percentage of patients who require such resources in the Losina et al. article.[5] $10,403 = ($1,539.47 + $12,715 x 0.44 + $3,305 x (1 – 0.44)), inflated by the ratio of the 2011 and 2006 mCPIs (400.258/336.200)
Revision TKA		
Implant	$9,250	Average cost of all revision TKA prostheses was used for innovative and contemporary TKA[10]
Number of hospital days	4.426	Weighted average of the mean number of days for DRG codes associated with revision TKA in HCUP[8] (466: Revision of hip or knee replacement w/ MCC, 467: Revision of hip or knee replacement w/o CC, 468: Revision of hip or knee replacement w/o CC/MCC)
Hospitalization cost per day	$2,854	Same as Primary TKA
Other costs	$10,631	Sum of the physician's fee (Medicare reimbursement for CPT 27487; Physicians' Fee Reference, 2011[9]), $1,539, and postacute care costs. Postacute care costs were calculated using the same process as for Primary TKA: $10,631 = ($1,767.11 + $12,715 x 0.44 + $3,305 x (1 –0.44)), inflated by the ratio of the 2011 and 2006 mCPIs (400.258/336.200).
First year: Post-90 days		
Satisfactory benefit	$3,409	$3,800 inflated by the ratio of the 2011 and 2006 mCPIs (400.258/336.2) and applied to the remainder of the first year of the surgery (365.25 days less 90 days) (365.25 – 90)/365.25[5]
Better benefit	$2,950	$3,800 – $512 inflated by the ratio of the 2011 and 2006 mCPIs (400.258/336.2) and applied to the remainder of the first year of the surgery (365.25 days less 90 days) (365.25 – 90)/365.25[5]
Best benefit	$2,950	Same as Better benefit
Subsequent years (annual cost)		
Satisfactory benefit	$4,524	$3,800 inflated by the ratio of the 2011 and 2006 mCPIs (400.258/336.2)[5]
Better benefit	$3,914	$3,800 - $512 inflated by the ratio of the 2011 and 2006 mCPIs (400.258/336.2)[5]
Best benefit	$3,914	Same as Better benefit
TKA failure	$6,786	Losina et al.[5] reported the annual cost of TKA failure to be 50% higher than that of primary TKA $3800 x 1.5 inflated by the ratio of the 2011 and 2006 mCPIs (400.258/336.2)

CC = with a complication or comorbidity; CPT = Current Procedural Terminology; DRG = diagnosis-related group; HCUP = Healthcare Cost and Utilization Project; MCC =with a major complication or comorbidity; mCPI = medical Consumer Price Index.

RESULTS

Base-Case Results

The model predicted that an innovative TKA (e.g., the ATTUNE Knee System) could reduce revisions by approximately 19% and that this improvement in survivorship will translate to economic savings that almost offset the increased cost of the implant (cost-neutral with improved health), independent of functional improvements. When considering both improvements in survivorship and patient functioning, the expected increase in the total cost was only approximately $115 per person, while nearly 20% of revisions were predicted to be avoided (Table 6).

Table 6. Expected Lifetime Costs and Health Outcomes for a Hypothetical Cohort of 1,000 Patients (Considering Improvements in Survivorship and Patient Functioning)

Type of Cost and Health Outcome	Innovative TKA	Contemporary TKA	Difference	Relative Difference
Cost of primary TKA implant	—[a]	—[a]	$675,000	—[a]
Expected cost of revision TKA implant	$308,669	$377,009	–$68,340	–18.1%
Expected cost of primary TKA procedures and care	$69,434,095	$69,491,034	–$56,939	–0.1%
Expected cost of revision TKA procedures and care	$1,925,212	$2,359,970	–$434,758	–18.4%
Total cost	$76,842,976	$76,728,013	$114,963	0.1%
Expected number of revisions	45	55	–10	–18.7%
Expected QALYs	10,816	10,593	223	2.11%

[a]Primary implant costs vary by hospital. The results were estimated based on an assumption about the difference in the cost of innovative versus contemporary TKA systems.

To isolate the effect of an innovative TKA system's ability to improve patient functional status on the economic outcomes, a separate scenario analysis was conducted. When limiting the expected benefit of an innovative TKA system to only improvements in patient functioning, the innovative TKA system is still predicted to improve substantially the QALYs of patients undergoing TKA. The incremental cost per QALY gained is approximately $1,550, well below the commonly used threshold incremental cost-effectiveness ratio (ICER) per QALY gained in the US of $50,000[11,12] (Table 7).

Table 7. Expected Lifetime Costs and Health Outcomes for a Hypothetical Cohort of 1,000 Patients (Considering Only Improvements in Patient Functioning)

Type of Cost and Health Outcome	Innovative TKA	Contemporary TKA	Difference	Relative Difference
Cost of primary TKA implant	—[a]	—[a]	$675,000	15%
Expected cost of revision TKA implant	$377,009	$377,009	–$0	–0%
Expected cost of primary TKA procedures and care	$69,172,048	$69,491,034	–$318,986	–0.5%
Expected cost of revision TKA procedures and care	$2,350,424	$2,359,970	–$9,546	–0.4%
Total cost	$77,074,481	$76,728,013	$346,468	0.5%
Expected number of revisions	55	55	–0	–0.00%
Expected QALYs	10,816	10,593	223	2.10%

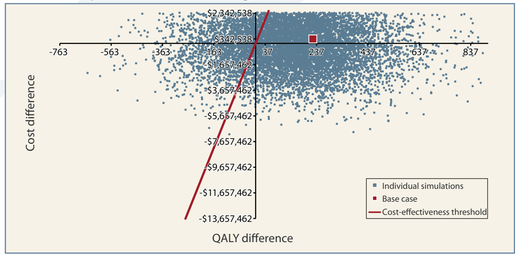
[a]Primary implant costs vary by hospital. The results were estimated based on an assumption about the difference in the cost of innovative versus contemporary TKA systems.

Sensitivity Analyses

Considering improvements in survivorship and patient functioning, in the one-way sensitivity analysis, varying any of the model inputs within the respective 95% confidence intervals (or +/- 20% when such information was unavailable) did not produce a sufficiently large effect on the ICER to take it above the $50,000 per QALY threshold, meaning that the innovative TKA system was potentially cost-effective in each case tested.

In the probabilistic sensitivity analysis, assuming a threshold ICER of $50,000 per QALY gained, the probability that the innovative TKA system would be cost-effective was 88.1% (Figure 2).

Figure 2.Probabilistic Sensitivity Analysis Scatter Plot (Considering Improvements in Survivorship and Patient Functioning)



DISCUSSION

This model was designed to estimate the potential benefit of an innovative TKA system, compared with a contemporary TKA system. The model evaluated the anticipated improvements in revision rate and patient functioning associated with the ATTUNE Knee System on the potential costs and health outcomes of a patient undergoing a TKA. The reduction in wear, stiffness, patella maltracking, pain, instability, and loosening due to the ATTUNE Knee System is anticipated to translate to reduced revision rates when compared with contemporary TKA systems, and the model predicts that the improved survivorship of the ATTUNE Knee System may increase QALYs while offsetting the increased costs of the implant over patients' lifetimes. However, because of the limited data directly supporting the model structure, the model results must be interpreted carefully.

LIMITATIONS

- There is a lack of published data linking functional improvements of knee systems to clinical outcomes.
  - The data on the extent that an innovative TKA system, such as the ATTUNE Knee System may be able to reduce wear cannot be linked directly to the reduction in revisions due to wear.
  - Laboratory results may show reductions in the percentage of patients who experience overhang, but these results must be translated to the reduction in revisions due to overhang-related pain. Therefore, following an approach used in a published study by Suter et al.,[7] the modeled analysis made assumptions on how each type of functional improvement of the knee translates to the number of revisions and used a wide range around the base-case assumption for the sensitivity analyses.
  - The model assumed that the risk of revision was constant from years 1 through 2 and from years 3 through lifetime. If, in real-world scenarios, the revision rates increase or decrease with time, the current analysis may have biased the estimated advantage of an innovative TKA system, such as the ATTUNE Knee System.
- The model bases the analyses on patients, rather than on knees. In the National Joint Registry of England and Wales, knees are the unit of measurement, and some patients may have received a TKA in each knee.[13]

CONCLUSIONS

Although TKA is a successful intervention, there is potential for innovative TKA systems to provide clinical and economic value. Further investigation to quantify the link between improvement in TKA implant design features and clinical outcomes is necessary to improve the understanding of potential clinical and economic benefits of innovative TKA systems.

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REFERENCES

Please see handout, which can be found at the following link: http://www.ispor.org/research_study_digest/research_index.asp.