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The Adoption of New Medical Technologies: The Case of Customized Individually Made Knee Implants

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ABSTRACT

Objectives: To investigate the impact of insurance coverage on the adoption of customized individually made (CIM) knee implants and to compare patient outcomes and cost effectiveness of off-the-shelf and CIM implants. **Methods:** A system dynamics simulation model was developed to study adoption dynamics of CIM and meet the research objectives. The model reproduced the historical data on primary and revision knee replacement implants obtained from the literature and the Nationwide Inpatient Sample. Then the dynamics of adoption of CIM implants were simulated from 2018 to 2026. The rate of 90-day readmission, 3-year revision surgery, recovery period, time savings in operating rooms, and the associated cost within 3 years of primary knee replacement implants were used as performance metrics. **Results:** The simulation results indicate that by 2026, an adoption rate of 90% for CIM implants can reduce the number of readmissions and revision surgeries by 62% and 39%, respectively, and can save

hospitals and surgeons 6% on procedure time and cut down cumulative healthcare costs by approximately \$38 billion. **Conclusions:** CIM implants have the potential to deliver high-quality care while decreasing overall healthcare costs, but their adoption requires the expansion of current insurance coverage. This work presents the first systematic study to understand the dynamics of adoption of CIM knee implants and instrumentation. More broadly, the current modeling approach and systems thinking perspective could be used to consider the adoption of any emerging customized therapies for personalized medicine.

Keywords: health systems, insurance, knee replacement, technology diffusion

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Introduction

The number of total knee replacements performed in the United States doubled from the year 2005 to 2015, with a disproportionate increase among younger adults.^{1,2} Currently, 6.7 million people are living with knee implants—about 20% more than the number of people living with heart failure.^{3,4} The number of patients needing knee replacements is projected to grow to 3.5 million per year by 2030.^{5,6} Approximately 60% of total hip and knee arthroplasties (THAs and TKAs) are covered by Medicare,⁷ and these procedures had cost the US federal government more than \$7 billion for hospitalizations alone in 2014.⁸ The Centers for Medicare & Medicaid Services⁹ has targeted total joint replacement as a high-volume and high-cost procedure that should be subject to

cost and quality control. Accordingly, bundled payment programs have been introduced in an attempt to reduce the costs of procedures and shorten length of stay for THAs and TKAs without sacrificing quality of care.^{10,11} The emphasis on value in the bundled payment model demonstrates the importance of investigating the role of new technologies, such as additively manufactured customized individually made (CIM) knee implants and instrumentation, in increasing the efficiency and cost effectiveness of knee procedures.

The Benefits and Drawbacks of CIM Knee Implants

Reports have indicated that patient satisfaction with off-the-shelf (OTS) implants can range from 75% to 92%.^{12–18} Customized

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implants have the potential to improve mechanical alignment,^{19,20} implant fit,^{19–21} bone coverage (overhang/underhang) and restoration,²¹ bone preservation,²² knee strength, range of motion, and axial rotation.^{23–25} A 3-dimensional model, which is prepared by converting a series of 2-dimensional scanned images of the patient's knee joint, is used to fabricate a CIM implant and instrumentation by using additive manufacturing/3-dimensional printing technologies. Better bone coverage could lead to less bleeding from exposed bone surfaces and less postoperative knee swelling, potentially resulting in an accelerated healing process and faster recovery.^{26,27} The drawbacks of CIM implants include (typically) expensive than OTS implant, lack of long-term evidence for clinical outcomes, need for customized instrumentation, higher exposure to radiation in the process of axial imaging such as computed tomography scanning, and increased complexity of the implant ordering system.²⁸

Major Obstacles to the Adoption of CIM Implants

CIM implants have been slowly adopted in operating theaters since their introduction around 2011.²⁹ The widespread adoption of CIM implants faces many barriers. There is no long-term proven evidence that CIM implants can directly improve patient outcomes, whereas OTS implants have proven clinical outcomes. Surgeons have to maintain backup implants in case, during the procedure, they discover any errors such as contamination or damage in the CIM implants. Surgeons tend to prefer OTS implants because of their training, familiarity, and comfort level with OTS. The new procedure involves potential increased malpractice liability insurance costs and legal risks because of ordering and administrative issues. CIM implants cost more than OTS implants, and third-party payers do not provide coverage for CIM procedures. Hospitals and surgeons are often locked into established contracts with OTS vendors. Furthermore, CIM implants, as an emerging technology, face natural resistance to adoption.

The higher upfront costs of CIM implants compared with OTS implants tend to discourage the adoption of CIM technology. Hospitals are typically paid a fixed amount as a “bundled payment” from both Medicare and third-party payers for all costs associated with TKA surgery and 90 days of care thereafter, including costs associated with implants, operating rooms, nursing, inpatient stay, postdischarge nursing, and physical therapy services. For such bundled payments, hospitals gain profit only if expenses are less than the fixed reimbursement. Because CIM TKA implants are likely to cost 20% to 30%^{30,31} more than OTS TKA implants because of the cost of preoperative imaging and expensive manufacturing processes, hospitals often resist the adoption of CIM implants. Moreover, potential long-term savings that could accrue from the use of CIM implants (eg, as a result of fewer revision surgeries) are not relevant in a 90-day bundled payment.

Understanding the reimbursement dynamics on a national level is challenging because of health plan complexities and high variability in costs in knee replacement procedures depending on geographical location, types of services provided, and other factors. In this study, we use a system dynamics simulation model to produce a comparative quality analysis and investigate the outcomes for CIM versus OTS TKAs, considering the coverage of insurance bundled payment programs. Although the average reimbursement rate for OTS procedures is estimated on the basis of the current bundled payment policies,^{32–35} the coverage for CIM procedures is investigated at different levels.

The simulation model is developed to study the long-term effects of the dynamic evolution of knee replacement procedures, coverage, and possible health quality improvement under various “what-if” scenarios. The simulation model forecasts the

dynamics of CIM and OTS adoption and how CIM implants can emerge in an established market. Benefits of CIM implants on some categories of patient outcomes^{19–24,26,27} are incorporated in the simulation model. Established contracts between hospitals/surgeons and OTS manufacturers and natural resistance to adoption of a new product/technology are considered barriers to CIM adoption in the model. Over time, these barriers change dynamically with the ratio of CIM adopters to OTS users and manufacturers' production plans to fabricate CIM products.³⁶ The model explores how different factors interact to potentially improve patient outcomes and produce savings that can be distributed among the stakeholders by using CIM implants.

Although our modeling approach focuses on the adoption dynamics of CIM implants, it is applicable to evaluate a broad range of emerging customized therapies in the era of personalized medicine.

Methods

The Model

System dynamics has been widely used to study complex problems in public health and health policy.^{37–46} Also, the classical approach to evaluating market adoption developed by Bass⁴⁷ predicted S-shaped growth for adoption. Extensions of the Bass model have been shown to be useful for modeling innovation diffusion,^{48–50} and have been widely used to model diffusion in a broad range of products and issues.^{40,51–55} Although the structure of our system dynamics model is based on the Bass model, it includes additional factors related to coverage control, performance-related improvements, and information distribution. Furthermore, the evaluation stage in the adoption process and its interrelated dynamics have been incorporated.

The model simulates changes under various what-if scenarios, for example, alternative coverage policies for CIM implants from 2018 to 2026, which can be expanded for trajectories beyond 2026. [Figure 1](#) illustrates a high-level overview of the model, presenting the causal loop diagram (CLD) and patient flow.

The 2 main factors that influence the adoption of CIM implants are out-of-pocket surgery costs for patients and surgeons' pro-CIM recommendations. The feedback loops represent how these 2 factors change dynamically within the model. The upper half of the CLD links the coverage for CIM to total costs of healthcare through the adoption of CIM implants. The lower half presents the impacts of manufacturers, sales force, and surgeons' preference on the adoption of CIM implants.

Hospitals often hesitate to select more expensive products because of their set-fee bundled contracts with insurance companies for the episode of care, that is, TKA procedures in this study. This creates the balancing feedback loop (loop B in CLD) for hospitals and insurance companies' expenditures and coverage rates, which explains insurers' short-term focus. In contrast, the revision surgery and readmission reinforcing loop (loop R1) presents the long-term effects of coverage rate considering better patient outcomes in some categories through CIM adoption. Wider adoption of CIM would lead to improvement in some categories of patient outcomes, which in turn would result in quicker recovery, as well as reductions in revision surgeries and readmissions^{26,56}; these positive changes would eventually decrease the costs for all the stakeholders.

Higher coverage for CIM TKAs would encourage CIM adoption and increase the chances that surgeons would recommend CIM (loop R2). The next essential factor affecting surgeons' recommendations is their preference, as evidenced by the outcomes of previous procedures, which creates the third reinforcing feedback

[org/10.1016/j.jval.2019.01.008](https://doi.org/10.1016/j.jval.2019.01.008). The driving factors of the discharge destination, for both inpatient/outpatient OTS and CIM implant procedures, are early patient performance, pain control, social support, conducive home environments, willingness to discharge to a specific destination, and medical comorbidities.⁶²

In our model, early patient performance, as a function of average range of motion, axial rotation of the knee, and implant lift-off in early and late flexion, is used as a measure of patient outcome after TKA procedures. After surgery, patients may be readmitted within 90 days or may undergo revision surgeries within a 3-year period. We considered these 2 periods because of their common use and data availability. Although patients may experience complications that force them to have unscheduled readmissions or revision surgeries, in the model, the severity of those complications varies between patients using OTS and CIM implants, on the basis of implant functionality/patient outcome.^{19,22,23,26}

The model is fully documented for further evaluation and reproduction in the Appendix (MDIR) in [Supplemental Materials](#). The documentation follows a guideline for reporting simulation-based studies.⁶³

Data, Model Calibration, and Model Validation

We used aggregated historical data obtained from the literature^{64–69} and the National Inpatient Sample. The Appendix (MDIR) in [Supplemental Materials](#) presents time series data, parameter values, and their references. The model reproduces the historical patterns along with the projected trends for data sources (Fig. 2) (more details on validation are in Section 4 in the Appendix [MDIR] in [Supplemental Materials](#)). The simulation model begins with a status quo base-case scenario representing the current state of knee replacements in the United States, and then uses the projected numbers, derived from data sources, for future trends.

In the absence of published literature, some of the parameters are estimated using the partial calibration method^{40,70,71} (see Section 4 in the Appendix [MDIR] in [Supplemental Materials](#)). The calibrated model is then tested to compare the number of patients at different stages, including surgery, hospitalization and recovery, readmission, and revision surgery, with the aggregated historical data from 1990 to 2012. To increase confidence in the model, various validation tests are performed: unit consistency, equation robustness in extreme conditions,⁷² and behavior validity.^{73,74} Sensitivity analyses also illustrated that the simulation outcomes are comparably robust for changes in the assumptions

and estimated parameters (see Section 3 in the Appendix [SI] in [Supplemental Materials](#)).

Results

Baseline

The base-case scenario reflects the current market share of CIM implants (<5%)⁷⁵ and follows the status quo with respect to CIM adoption. The costs of knee replacement procedures are estimated considering the complete procedure, duration of hospitalization and recovery, and the number of unscheduled readmissions and revision surgeries. These factors are weighed against patient outcomes/functionality for a full cost-benefit analysis. The initial levels of vendor-established contracts with hospitals and surgeons, and natural resistance to adoption of CIM implants as a new product/technology, are considered medium to high in the model.⁷⁶ The coverage of third-party payers' fixed-rate bundled payment programs for CIM procedures defines the insurance policy scenarios.

Simulated Intervention

Figure 3 presents the dynamics of the number of readmissions and revision surgeries for all patients under the base-case scenario and levels of bundled payment coverage of CIM procedures. Considering high variability in costs of knee replacement procedures for several reasons (discussed earlier), and because CIM implants are about 20% to 30% more expensive than OTS implants, the fixed-rate bundled payments could still cover more than 60% of CIM procedures.^{30,31} Therefore, we consider 3 levels of coverage for CIM procedures: 50%, 70%, and 90%. Meanwhile, the insurance coverage for OTS implants remains constant at 90%^{32–35}; it is set at the highest payment reimbursed for CIM implants in the policy analysis. The base case represents the continuation of the current conditions for CIM implants—being used in about 5% of cases. It could be hypothesized that once the coverage rate for CIM implants increases to, say, 90%, the coverage rate for OTS implants could decrease from the status quo. Nevertheless, the OTS coverage was kept constant, considering a pessimistic situation, because decrease in OTS coverage would be another driver for CIM adoption, resulting in even better performance outcomes than those presented.

Because of uncertainties regarding the levels of coverage of insurance bundled payments for CIM procedures, patient outcomes/functionality, possible improvements in CIM and OTS

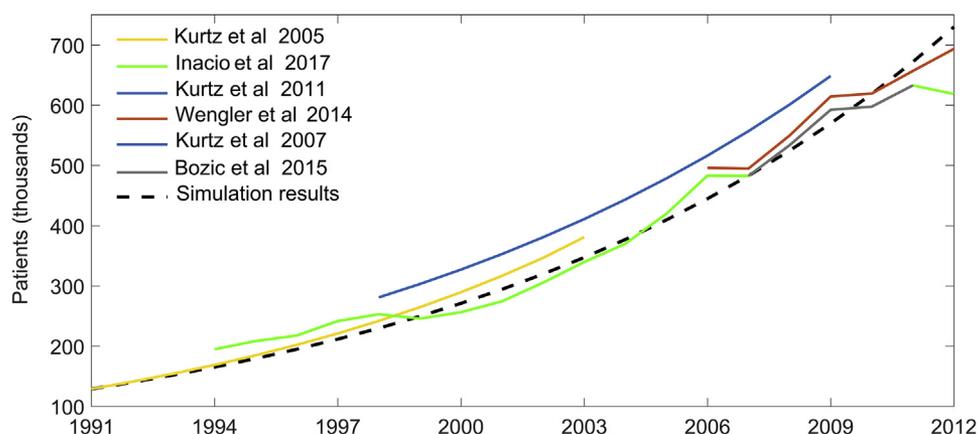


Fig. 2 – Historical data on numbers of patients.^{64–69} Historical and reproduced numbers of patients from different sources.

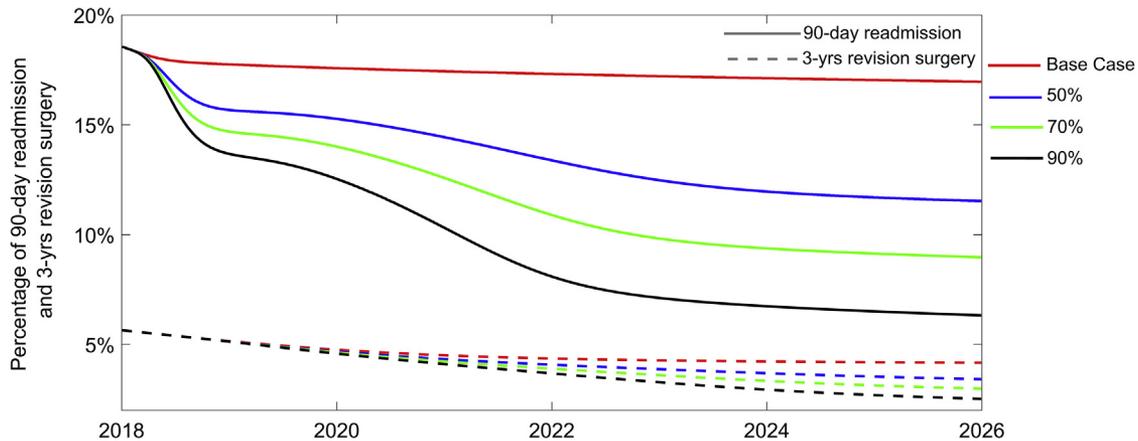


Fig. 3 – Percentage of patients readmitted (OTS and CIM) within 90 days and percentage of patients undergoing revision surgeries (OTS and CIM) within 3 years after primary procedures under different levels of coverage of insurance bundled payment programs for CIM procedures. Three insurance policies, covering CIM implants at 50%, 70%, and 90%, in addition to the base case are presented. The highest percentage of readmissions and revision surgeries occurs in the base case. As the CIM coverage rate increases, the number of readmissions and revision surgeries decrease. CIM indicates customized individually made; OTS, off-the-shelf.

implants in the future, and relative price of CIM and OTS implants, an online version of the model is developed in an interactive environment, which enables running the model quickly under various user-created scenarios (<http://jalali.mit.edu/medical-tech-adoption>) (more information is given in Section 5 in the Appendix [MDIR] in Supplemental Materials).

Readmissions and Revision Surgeries

The decisive elements for readmission and revision surgery rates in the model are the initial rates obtained from the literature,^{9,77,78} which change over time with patient outcomes/functionality after primary knee replacements (see Section 3 in the Appendix [MDIR] in Supplemental Materials). Patient outcomes/functionality are determined by standardizing range of motion and axial rotation for each type of implant to healthy knee performance, along with the average rate of condyle lift-off in early and late flexion for each type of implant.^{23,79} Figure 3 illustrates the percentage change in the number of readmitted patients within 90 days and the number of revision surgeries within 3 years after primary knee replacements for different levels of coverage of insurance bundled payment programs for CIM. The highest percentage of patients who were readmitted or underwent revision surgeries occurs in the base case, which represents the current scenario for CIM. The lowest number of readmissions and revision surgeries occurs for 90% CIM coverage, in which, by 2026, the number of readmissions and revision surgeries could be reduced by approximately 62% (285 962) and 39% (44 157), respectively. It is worth mentioning that readmissions and revisions are 2 independent costs events with different financial implications, because the costs for revision surgeries are much higher, as indicated in Figure 4.

Cost Effectiveness

Figure 4 shows the total cumulative cost estimates by the year 2026. It compares the cumulative costs of knee replacement procedures for both OTS and CIM under different coverage for CIM implants. The total cumulative costs include costs for the procedure (product, surgeons, and operating rooms), recovery (in hospital, home, nursing facility, and rehabilitation center), 90-day readmissions, and 3-year revision surgeries. None of the scenarios would cost more than the base case, because of the higher long-term costs associated with OTS implants. Healthcare costs for

the stakeholders for items such as recovery, readmissions, and revision surgeries in CIM are lower than those for OTS. These lower costs compensate for the higher costs of CIM implants relative to the cost of OTS. As shown in Figure 4, the higher the coverage rate for CIM, the higher the cost savings for every scenario. The highest cumulative savings of approximately \$38

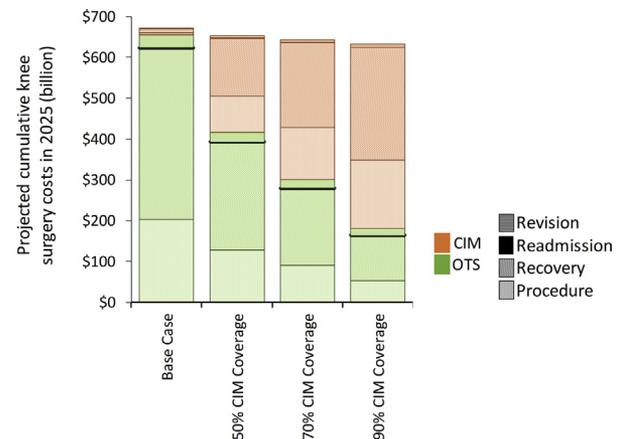


Fig. 4 – Total cumulative costs for all the stakeholders in 2026 (on the basis of the dollar value in 2018) under different coverage policies for CIM implants. The base case represents the current conditions for CIM implant coverage of 5%. Three coverage rates are considered, 50%, 70%, and 90%, for CIM implants from 2018 to 2026. Each bar stacks up several boxes, which represent (from bottom to top) OTS surgery costs, OTS recovery costs, OTS readmission costs (the bold line), OTS revision surgery costs, CIM surgery costs, CIM recovery costs, CIM readmission costs (the bold line), and CIM revision surgery costs. The differences among the bars illustrate the amount of savings that can be achieved under each coverage rate for CIM implants. This figure indicates that shortening the recovery period along with decreasing revision surgeries can have the most positive impacts on cost savings. CIM indicates customized individually made; OTS, off-the-shelf.

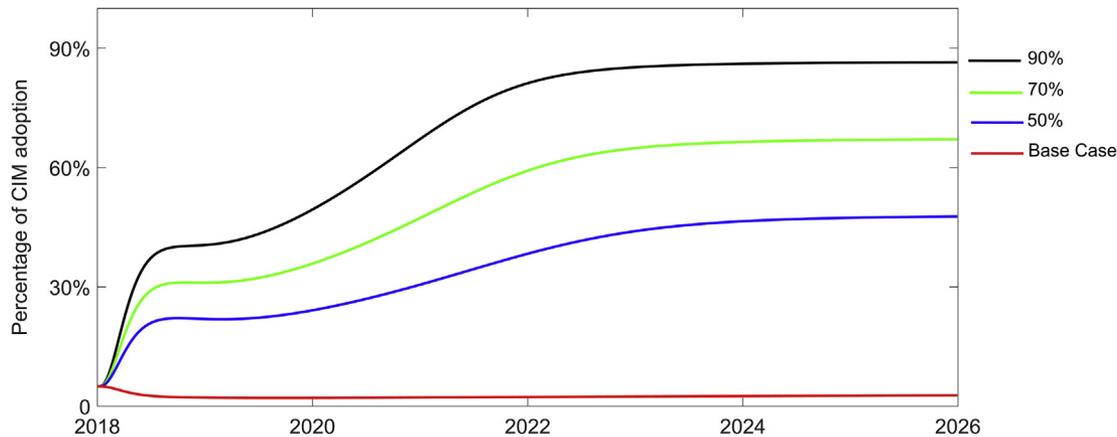


Fig. 5 – Patient adoption rate. The initial value of adoption is equal to the current market share of CIM implants (<5%). Three levels of coverage of insurance bundled payment programs for CIM implants, 50%, 70%, and 90%, are presented. An increase in insurance coverage raises adoption rates of CIM implants. The base line indicates the base case, which shows the current conditions for CIM. Sharp increases under the 70% and 90% coverage rate scenarios are due to increases in the initial number of patients willing to adopt CIM. CIM indicates customized individually made.

billion (about 6% of the total costs) could be achieved under 90% coverage for CIM for all the stakeholders together by 2026.

Adoption

Figure 5 illustrates that an increase in the coverage of insurance bundled payment programs for CIM would catalyze the adoption of these implants by patients. The coverage of insurance bundled payment programs at 70% and 90% greatly increase adoption rates because more hospitals, surgeons, and incoming patients are willing to opt for CIM implants. The sudden increases in CIM adoption at 70% and 90% coverage rates are driven by the higher number of incoming patients willing to use CIM because of perceived better performance and financial feasibility. Under these coverage rates, a higher number of surgeons and patients will be willing to adopt CIM. After the initial rapid increases, the system stabilizes and the adoption rate increases smoothly.

Total Cost per Patient

Figure 6 shows nationwide average total costs per patient under different policies within 3 years of primary knee replacement.

Total costs include the costs of the procedure, recovery, readmission, and revision surgery. Figure 6 indicates that 90% coverage of insurance bundled payment programs for CIM has better potential to reduce the cost per patient over time because of the performance improvements resulting from CIM implants. Because recovery time, readmission, and revision surgery rates are related to patient outcomes/functionality, cost savings can be achieved with only 50% adoption, and the savings significantly increase for higher coverage rates: \$1600 per patient for 70% and \$2200 for 90% (see also surgery time savings in the Appendix [SI] in Supplemental Materials).

Discussion

Bundled payment programs for THAs and TKAs are expected to reduce the costs while ensuring the quality of these procedures. These bundled payments focus on costs within 90 days of the surgical procedure and are not designed to have an impact on long-term outcomes or costs. This highlights the need for more effective long-term healthcare strategies.⁸⁰ The results of our modeling and analysis indicate that if the coverage of bundled

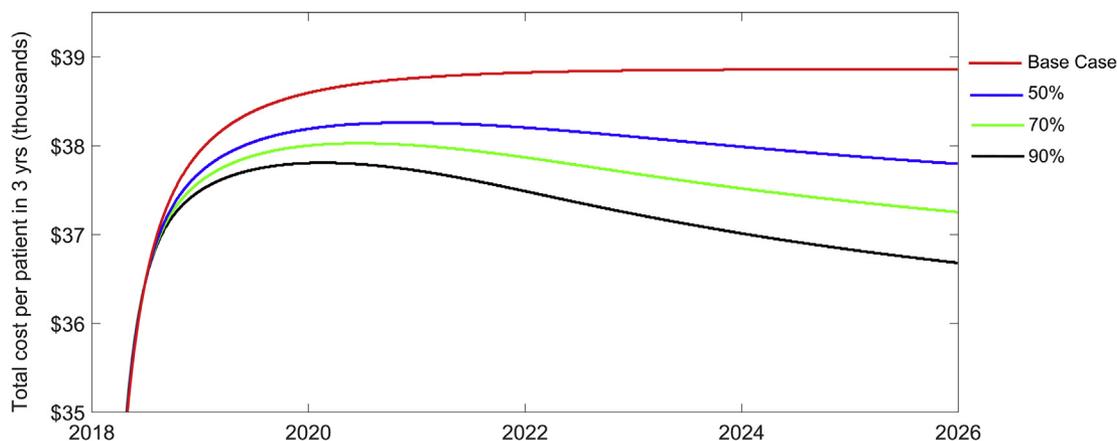


Fig. 6 – Total cost per patient under different coverage policies for CIM implants. This figure shows the trend of nationwide average total cost per patient within 3 years of primary TKA (on the basis of the dollar value in 2018). The savings under 90% CIM coverage rate are higher than those in other scenarios because of CIM's potential for improvements in patient outcomes/functionality and consequent reductions in recovery time, readmission rate, and revision surgery rate. CIM indicates customized individually made; TKA, total knee arthroplasty.

payments for CIM procedures is at 90%, the healthcare system could achieve cumulative savings of \$38 billion by 2026.

Joint replacement is a multistage process, from preprocedure preparation to postoperative recovery and avoidance of complications. In the process, various stakeholders have different objectives. Therefore, achieving effective strategies requires a systematic perspective, considering the major factors at all stages of the process and their interconnections, as reflected in the model presented in this work.

We considered an integrated framework for the economic and potential patient outcomes of OTS and CIM knee implants under different scenarios. An adoption rate of CIM implants is driven by surgeons' recommendations and out-of-pocket surgery cost for patients, which is mainly dependent on the levels of coverage of insurance bundled payment programs for CIM procedures. Higher adoption rates could not only improve some categories of patient outcomes but also decrease hospital costs, insurance providers' economic burden, and patients' out-of-pocket expenditures.

Taking into account the substantial growth in the number of patients needing primary knee replacements, as well as the significant reduction average age of new patients,¹ the number of revision procedures will grow considerably in the near future. The shrinking number of surgeons available to take care of these increasing volumes of patients makes the need to decrease the number of revision procedures even more critical.⁸¹ The results of our analyses indicate that substantial reductions in the number of revision surgeries could be achieved through higher adoption of CIM implants.

Furthermore, CIM implants could significantly reduce 90-day readmissions, procedure times, and recovery after primary knee replacements. Consequently, higher coverage for CIM procedures could be expected to reduce costs for hospitals and other stakeholders in the entire healthcare system around TKA. We expect that greater attention to the potential benefits of CIM implants would promote personalized healthcare.

It is worth noting that the reimbursement rates have dropped to a flat, narrow range over the past few years. This trend puts some financial constraints on hospitals and service providers. Future modeling studies could examine how several categories of implants and instrumentation manufacturing costs (eg, liability, research and development, marketing, overhead, and insurance costs) could be incorporated in the final cost of the products. Moreover, future research could compare how advancements in different areas of joint replacement procedures, such as operative techniques, anesthesia, pain management, and outpatient TKA in ambulatory surgical centers, could influence patient outcomes.

The limitations of our study are discussed in the Appendix (SI) in [Supplemental Materials](#).

Conclusions

The goal of the present study was to take a systematic look at the adoption of CIM knee implants. The objective was not to explore how to improve treatment, but rather to perform what-if analyses. The flexible nature of the model lends itself to extending it to study innovative policies and interventions focused on economic burden and patient outcomes when new information becomes available. The model allows decision and policy makers to test different coverage policies on the basis of their preference. For instance, they can consider a dynamic scenario for their coverage rate for CIM procedures on the basis of their initial investment and savings throughout the simulation time. They can also test the effect of time delays on the preparation of the infrastructure. The results may help policy makers consider CIM implants as an attractive option for improving patient outcomes while reducing the total costs of healthcare associated with TKA. The results

could inform decision making among the Centers for Medicare & Medicaid Services, private insurance providers, and hospitals, spurring them to consider adoption of CIM implants and to offer alternative payment methodologies that would encourage widespread use of CIM knee implants.

Supplemental Materials

Supplementary data associated with this article can be found in the online version at <https://doi.org/10.1016/j.jval.2019.01.008>.

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