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

Amir T. Namin1, Mohammad S. Jalali2,*, Vahab Vahdat1, Hany S. Bedair3, Mary I. O’Connor4, Sagar Kamarthi1, Jacqueline A. Isaacs1

1Northeastern; 2MIT Sloan, 3Harvard Medical School, 4Yale Medicine
* Corresponding: jalali@mit.edu

ABSTRACT

Background: More than 6 million people were living with knee replacement implants in the US as of 2017. This number is expected to increase to more than 3.5 million/year by 2030. The cost-effectiveness of total joint replacement procedures has been broadly studied; however, there is a compelling need to improve beyond the value afforded by off-the-shelf knee implants.

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 model is developed to reproduce the historical data on primary and revision knee replacement implants obtained from the literature and the Nationwide Inpatient Sample. In simulation analyses, rate of 90-day readmission, 3-year revision surgery, hospitalization and recovery period, time savings in operating rooms, and the associated cost within three years of primary knee replacement implants were used as comparison indicators.

Results: The results compared the adoption of CIM and its economic and patient outcome impacts to off-the-shelf implants under different insurance coverage for CIM implants. The simulation results indicate that, by 2025, an adoption rate of 90% for CIM implants will reduce the number of readmissions and revision surgeries by 62% and 39%, respectively, and save hospitals and surgeons 6% on procedure time, resulting in cumulative savings of approximately $40 billion in healthcare costs.

Conclusions: CIM implants have the potential to deliver high-quality care while decreasing total costs, but their adoption requires the expansion of current insurance coverage.

Introduction

The number of total knee replacements performed in the U.S. doubled from 2005 to 2015, with a disproportionate increase among younger adults1,2. Currently, 6.7 million people are living with knee implants—about 20% more than...
the number of people living with heart failure\textsuperscript{3,4}. The number of patients needing knee replacements is projected to grow to 3.5 million people per year by 2030\textsuperscript{5,6}. Approximately 60\% of total hip and knee arthroplasties (THAs & TKAs) are covered by Medicare\textsuperscript{7}, and these procedures cost the U.S. federal government more than $7 billion for hospitalizations alone in 2014\textsuperscript{8}. The Centers for Medicare and Medicaid Services\textsuperscript{9} 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 to reduce the costs of procedures and lengths of stay for THAs and TKAs without sacrificing quality of care\textsuperscript{10,11}. This 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 Customized Individually Made (CIM) Knee Implants

Reports have indicated that patient satisfaction with off-the-shelf (OTS) implants can range from 75\% to 92\%\textsuperscript{12-18}. There are various reasons for patient dissatisfaction, including functional outcomes. Customized implants have the potential to improve mechanical alignment, bone coverage, bone preservation, knee strength, range of motion, and axial rotation\textsuperscript{19-24}. A 3D model, which is prepared by converting a series of 2D scanned images of the patient’s knee joint, is used to fabricate a CIM implant and instrumentation by using additive manufacturing/3D printing technologies. Better bone coverage could lead to less bleeding from exposed bone surfaces and result in less postoperative knee swelling, potentially resulting in an accelerated healing process, shorter hospitalization, and faster recovery\textsuperscript{25,26}. The drawbacks of CIM implants include higher implant cost, lack of long-term evidence for clinical outcomes, longer manufacturing time, need for customized instrumentation, and higher exposure to radiation in the process of axial imaging such as CT scanning for preparation of the 3D model\textsuperscript{27}.

Major Obstacles to the Adoption of CIM Implants

CIM implants have been slowly adopted in operating theaters since their introduction around 2011\textsuperscript{28}. 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; this stems from their training, familiarity, and comfort level with OTS. The new procedure involves malpractice liability insurance costs and possible legal risks. CIM implants cost more than
OTS implants, and third-party payers and insurance companies do not provide coverage for CIM procedures. Hospitals and surgeons are often locked into established contracts with OTS vendors. And as a new product/technology, CIM implants face natural resistance to adoption.

The higher upfront costs of CIM compared to OTS implants tend to discourage hospitals and third-party payers from adopting CIM technologies. 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, post-discharge nursing and physical therapy services. For such bundled payments, hospitals make a profit only if expenses are less than the fixed reimbursement. Since CIM TKA implants are likely to cost 20%-30% more than OTS TKA implants due to the cost of preoperative imaging and more expensive manufacturing processes, hospitals often resist adoption of CIM implants. Since the 90-day bundled payment is not impacted by CIM TKAs, hospitals and third-party payers tend not to consider the potential long-term savings that could accrue from use of CIM implants as a result of shorter hospitalization, fewer revision surgeries, and fewer readmissions.

Understanding reimbursement on the national level is challenging because of health plan complexity and high variability of 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 to investigate the outcomes for CIM vs. OTS TKAs, considering the coverage of insurance bundled payment programs. While the average reimbursement rate for OTS procedures is estimated based on the current bundled payment policies of insurance companies, the frequency of 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 a variety of “what-if” scenarios. The simulation model forecasts the dynamics of CIM and OTS adoption and how CIM implants can emerge in an established market. Prior research has reported that CIM implants can improve some categories of patient outcomes. This benefit of CIM implants is incorporated in the 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, both these barriers change dynamically with the ratio of CIM adopters to OTS users and manufacturers’ production plans to fabricate CIM products. The model explores
how different factors interact to potentially improve patient outcomes and produce savings that can be distributed among all the stakeholders by using CIM implants.

While we focus on the adoption dynamics of CIM implants, applicability to a broad range of adoptions of any new customized therapies is one of the main benefits of our modeling approach.

Methods

The Model

System dynamics (SD)\textsuperscript{36,37} has been widely used to study dynamic and complex problems in public health and health policy\textsuperscript{38-42}. An SD model is a compartmental stock and flow structure with causal feedback mechanisms that rely on a set of differential and algebraic equations. The classical approach to evaluating market adoption developed in 1969 by Bass\textsuperscript{43} predicted S-shaped growth for adoption. Extensions of the Bass model have been shown to be useful for modeling innovation diffusion\textsuperscript{44-46}; therefore, they have been widely used to model diffusion in a broad range of products and issues, such as new pharmaceutical products\textsuperscript{47}, durable products\textsuperscript{48}, pricing strategies\textsuperscript{45}, technological products\textsuperscript{49}, and the positive/negative influence of social awareness and word of mouth for customers on waitlists\textsuperscript{50}.

Though the structure of our model is based on the Bass model, it is significantly expanded to consider 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 a variety of what-if scenarios, e.g., alternative coverage policies for CIM implants, from 2018 to 2025, which can be expanded for trajectories beyond 2025. Figure 1(a) illustrates a high-level overview of the system dynamics model, presenting the main causal loops, and Figure 1(b) presents the flow of patients in the simulation model.

The two main factors that influence the adoption of CIM implants are out-of-pocket surgery costs for patients and surgeons’ pro-CIM recommendations\textsuperscript{35}. These two factors are incorporated in the model—see the two causal links impacting “CIM adoption rate by patients” in Figure 1(a). The feedback loops represent how these two factors change dynamically within the model. The upper half of Figure 1(a) links insurance policies to total costs of healthcare, from the perspectives of patients, hospitals and insurance companies, through the adoption of CIM implants. The lower half of Figure 1(a) presents the impacts of manufacturers, sales representatives, and surgeons’ preference on the adoption of CIM implants.
Insurance companies, whether private or public, are responsible for covering the majority of the costs of total joint replacements. Since the costs of CIM implants are higher than those of OTS implants—due to expensive manufacturing processes and preoperative imaging—hospitals often hesitate to select more expensive products due to their set fee bundled contracts with insurance companies for the episode of care, i.e., TKA procedures in this study. This creates the balancing feedback loop (Loop B in Figure 1(a)) 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 insurance coverage on costs for insurance providers and
hospitals, considering better patient outcomes in some categories through CIM adoption. Higher adoption of CIM could lead to improvement in some categories of patient outcomes, which in turn would result in shorter hospitalization and quicker recovery time, as well as reductions in revision surgeries and readmissions\textsuperscript{25,31}; these positive changes would eventually decrease the costs for all the stakeholders.

The extent of bundled payment coverage for CIM, surgeons’ preference for CIM, and the terms and conditions of CIM vendor-established contracts with hospitals and surgeons would influence surgeons’ recommendations in favor of CIM implants. Higher insurance 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 preferences, as informed by the outcomes of previous procedures, which creates the third reinforcing feedback loop (R3). Evidence of better surgery performance and outcomes would make surgeons more likely to recommend CIM implants and instrumentation; however, it takes time for surgeons to observe the performance of new products and make decisions about their adoption. Currently, surgeons’ preference for OTS is reinforced by their level of comfort, training, familiarity with OTS, and greater availability of information regarding OTS clinical outcomes.

Another factor that influences surgeons’ recommendations of CIM is vendor-established contracts with hospitals and surgeons, which reflects manufacturers’ willingness or unwillingness to shift to CIM (Loop R4). Over the long run, manufacturers’ willingness to produce CIM is affected by market share. If manufacturers observed an increase in the market share of CIM implants driven by their better patient outcomes, OTS implant producers would become more interested in incorporating customized elements into their standard sizes—albeit with significant time lags. Moreover, patients’ willingness to adopt CIM implants due to their social awareness is also considered a factor of influence in the simulation model; it is not shown here in Figure 1(a), but reported in the Appendix.

Figure 1(b) presents the flow of patients from the early stages, when knee replacements are recommended, through post-operative recovery. Figure 1(b) has two main sections: surgery and post-surgery. Each section contains connected stages showing the possible flow of patients. In the model, patients are initially separated into two groups depending on the surgery they undergo, OTS or CIM. This distribution changes over time, since it is driven by surgeons’ recommendations of CIM and patients’ adoption rates of CIM implants, as discussed above and shown in Figure 1(a).

After surgery, patients are discharged to professional nursing facilities, rehabilitation centers, or home, with or without health services. Early research shows a statistically significant difference in the discharge destination distribution after hospitalization for CIM TKAs vs. OTS TKAs: CIM TKA patients are more likely to be discharged
to home, resulting in savings for insurers and patients\(^{25}\). The driving factors of the discharge destination, for both OTS and CIM implants, are early patient function, pain control, social support, conducive home environments, willingness to discharge, and medical comorbidities. In our model, early patient function, as a combination of average range of motion, axial rotation of the knee, and average implant lift-off, is used as a measure of patient outcome after TKA procedures. After surgery, patients may be readmitted within 90 days or undergo revision surgeries within a three-year period. We considered these two periods due to 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, based on implant functionality/patient outcome\(^{19,23-25}\).

The model is fully documented for further evaluation and reproduction in the online appendix in six sections: time series data, model parameter values, formulation, calibration and validation, sensitivity analysis, and an online simulator platform on Forio. The documentation follows the preferred model reporting requirements (PSRR), a guideline for reporting simulation-based studies\(^{52}\).

Moreover, the model is provided for further analysis in an interactive online environment at: forio.com/simulate/anamin/ps-knee-implants-and-instruments (for access to the full features of the model, we recommend using the main model files reported in Appendix Section 6).

**Data, Model Calibration, and Model Validation**

Aggregated historical data obtained from various studies in the literature\(^{53-58}\), much of it based on the National Inpatient Sample (NIS), is used for the validation of the model. Sections 1 and 2 of the Appendix present time series data, parameter values, and their references in detail. The model reproduces the historical patterns along with the projected trends for data sources as shown in Figure 2—more details on validation are provided in Appendix Section. The simulation model begins with a status quo base case scenario representing the current state of knee replacements in the U.S., and then uses the projected numbers, from those data sources, for future trends from 2018 to 2025.
In the absence of published literature, some of the parameters are estimated using the partial calibration method, where the optimal values of the unknown parameters are estimated by calibrating the parts of the model with historical data and matching the numbers of primary and revision surgeries performed over time. Section 4 of the Appendix includes the details. The calibrated model is then tested to compare the numbers of patients at different stages, including surgery, hospitalization, recovery, readmission, and revision surgery, to the aggregated historical data from 1990 to 2011. To increase confidence in the model, various validation and verification tests are performed: unit consistency, equation robustness in extreme conditions, and behavior validity. Different sensitivity analyses illustrated that the simulation outcomes are comparably robust for changes in the assumptions and estimated parameters, i.e., sensitivity analysis of changes in the assumptions for performance improvement in the design and use phase—during the surgery—of either type of implant indicates the model robustness to those changes. Detailed information on sensitivity analyses is provided in Section 5 of the Appendix.

Results

Baseline

The base case scenario reflects the current market share of CIM implants (less than 5%) and follows the status quo with respect to CIM adoption from 2018 to 2025. The costs of knee replacement procedures are estimated considering the complete procedure, duration of hospitalization and recovery, and numbers 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\textsuperscript{64}. The coverage of third-party payers’ fixed rate bundled payment programs for CIM procedures define the insurance policy scenarios.

\textit{Simulated Intervention}

Figure 3 presents the dynamics over time, from 2018 to 2025, of the numbers of readmissions and revision surgeries for all patients under the base 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 since CIM implants are about 20\%-30\% more expensive than OTS implants, the fixed rate bundled payments could still cover more than 60\% of CIM procedures\textsuperscript{29,30}. Therefore, we consider three levels of coverage for CIM procedures: 50\%, 70\%, and 90\%. Meanwhile, the insurance coverage for OTS implants remains constant at 90\%\textsuperscript{31-34}, it is set at the highest payment reimbursed for CIM in the policy analysis. The base case represents the continuation of the current conditions for CIM implants—being used in around 5\% of cases. It could be hypothesized that once coverage for CIM increases to, say, 90\%, the coverage rate for OTS could decrease from the status quo. However, the OTS coverage was kept constant, considering a pessimistic situation, because decreases in OTS coverage would be another driver for CIM adoption, resulting in even better performance outcomes than those presented.

Due to uncertainties regarding the levels of coverage of insurance bundled payments for CIM procedures, patient outcomes/functionality, and possible improvements in CIM implants in the future, an online version of the model is developed in an interactive environment, which provides the possibility of running the model quickly under various user-created scenarios (forio.com/simulate/anamin/ps-knee-implants-and-instruments). More information on the online simulator can be found in Appendix Section 6.

\textit{Readmissions and Revision Surgeries}

The decisive elements for readmission and revision surgery rates in the model are the initial rates obtained from the literature\textsuperscript{9,65}, combined with patient outcomes/functionality considered in the model after primary knee replacements—see Appendix Section 3 for detailed information. 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\textsuperscript{24,66}. Figure 3(a) illustrates the percentage change in the number of readmitted patients within 90 days after primary knee replacements for different levels of coverage of insurance bundled payment programs for CIM. The percentage change in the number of revision
surgeries within 3 years after primary knee replacements for different policies is shown in Figure 3(b). 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 numbers of readmissions and revision surgeries occurs for 90% CIM coverage. By 2025, the number of readmissions could be reduced by approximately 62% (1,409,610) when CIM coverage is increased to 90% from the coverage rate in the base case (5%). In addition, a reduction of approximately 39% (264,060) in revision surgeries could be expected under 90% CIM coverage. The results show that CIM implants have a potential to significantly reduce the numbers of readmissions and revision surgeries. It is worth mentioning that readmissions and revisions are two independent events with different financial implications, because the costs for revision surgeries are much higher, as indicated in Figure 3(c).

Cost Effectiveness

Figure 3(c) shows total cumulative cost estimates by the year 2025 (based on the dollar value in 2017). It compares the cumulative costs of knee replacement procedures for both OTS and CIM under different insurance policies—i.e., coverage of insurance bundled payment programs—for CIM implants. The total cumulative costs include costs for the procedure (product, surgeons, and operating rooms), hospitalization (in hospital, nursing facility/rehab and home), 90-day readmissions, and 3-year revision surgeries. None of the policies would cost more than the base case, due to the higher long-term costs associated with OTS implants. Healthcare costs for all the stakeholders for items such as hospitalization, 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. According to Figure 3(c), the higher the coverage rate for CIM, the higher the cost savings for every scenario. The highest cumulative savings of approximately $40 billion (about 6% of the total costs) could be achieved under 90% coverage for CIM for all the stakeholders together by 2025.
Figure 3

(a) Percentage of patients readmitted (OTS and CIM) within 90 days 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%, are presented. The highest percentage of readmissions occurs in the base case. As the CIM coverage rate increases, the number of readmissions decreases. (b) 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 implants. As the CIM coverage rate increases, the number of revision surgeries decreases. (c) Total cumulative costs for all the stakeholders in 2025 (based on the dollar value in 2017) 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 2025. 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 decreasing revision surgeries can have the most positive impact on cost savings.

SOURCE Authors’ analyses of results from the simulation model. NOTES (a) Percentage of patients readmitted (OTS and CIM) within 90 days 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%, are presented. The highest percentage of readmissions occurs in the base case. As the CIM coverage rate increases, the number of readmissions decreases. (b) 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 implants. As the CIM coverage rate increases, the number of revision surgeries decreases. (c) Total cumulative costs for all the stakeholders in 2025 (based on the dollar value in 2017) 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 2025. 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 decreasing revision surgeries can have the most positive impact on cost savings.

Adoption, Total Cost per Patient, and Time Savings

As expected, Figure 4(a) illustrates that an increase in the coverage of insurance bundled payment programs for CIM would catalyze the adoption of these implants by patients. In the base case, the adoption rate would remain similar to the current situation. The coverage of insurance bundled payment programs of 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 adoption at 70% and 90% coverage rates are driven by the higher adoption rate among incoming patients
who are willing to use CIM due to perceived better performance and financial feasibility of CIM implants. Under these coverage rates, a higher number of surgeons and patients will be willing to adopt CIM, because it is financially more attractive. After the initial rapid increases, the system stabilizes and the adoption rate increases smoothly.

Figure 4(b) shows nationwide average total costs per patient (based on dollar value in 2017) under different policies within 3 years of primary knee replacement. Total costs include the costs of the procedure, hospitalization, readmission, and revision surgery. As expected, Figure 4(b) indicates that 90% CIM coverage of insurance bundled payment programs has better potential to reduce the cost per patient over time due to the performance improvements resulting from CIM implants. Since hospitalization time, readmission, and revision surgery rates are related to patient outcomes/functionality, cost savings are achieved with only 50% adoption, and the savings significantly increase for higher coverage rates: $1,700 per patient for 70% and $2,300 for 90%.

CIM procedures can save time for hospitals, not only because of shorter hospitalization, but also because of shorter procedure time. Figure 4(c) represents the plots of total surgery time savings per month under different levels of coverage of insurance bundled payment programs for CIM procedures. Further investigations are required to analyze the time savings from an additional revenue standpoint, since the cost of staff, overhead, operating rooms, and the number of patients receiving the service vary among providers. According to Figure 4(c), the most surgery time savings could be achieved through a 90% coverage rate, compared with the base case (5%). The cumulative surgery time saved could reach over 40,000 hours per month for knee replacements nationwide. It is notable that the plots in Figure 4(a) and Figure 4(c) follow a similar pattern. This similarity confirms that when more patients adopt CIM implants, more time savings per surgery can be achieved.


Discussion

Controlling healthcare costs is essential. Bundled payment programs for total hip and knee arthroplasties 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 impact long-term outcomes or costs. This highlights the need for more effective long-term healthcare strategies that are beneficial to all the stakeholders. The results of the modeling analysis indicate that if the coverage of bundled payments for CIM procedures was at 90%, the healthcare system could achieve cumulative savings of $40 billion by 2025.

Joint replacement is a multi-stage process, from pre-procedure preparation to post-operative 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. Our findings show that a higher 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 and insurance providers’ expenditures.
Taking into account the substantial growth in the number of patients needing primary knee replacements, as well as the significant age reduction among new patients\(^1\), the number of revision procedures will also grow considerably in the near future. The shrinking number of surgeons available to take care of these patients makes the need to decrease the number of revision procedures even more critical\(^7\). 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 hospitalization times after primary knee replacements; so 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 (e.g., liability, R&D, 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, and pain management, could influence patient outcomes.

Limitations

First, the current simulation model, like most models, cannot portray full reality, but the validated model can potentially help uncover complexities in the healthcare system around TKAs. The analyses compare the relative potential of different insurance policies rather than predicting precisely the long-term effect of these policies. Second, the simulation model did not consider indirect costs and delays associated with administrative processes. Indirect costs may include lost wages due to patients’ disability from the procedures. Administrative processes may include delays due to the U.S. Food and Drug Administration (FDA) approval process. All hospital entities have to use FDA-approved medical devices\(^7\); however, FDA regulations for 3D printed medical devices are expected to increase in the near future, which could put increased pressure on the adoption of these products\(^7\). In the model, we assumed that the FDA would approve new CIM implant manufacturers and their products within a period of four months.

We considered performance improvements of CIM implants, the design phase and the use phase during surgery, as a “moving target,” since the evaluation process takes time and may not reflect the latest effects of product modifications on performance\(^4\). OTS implants have been on the market for a long time, and 3D printed patient-specific surgical
guidance for OTS implants and robotically assisted surgery\textsuperscript{13,20,26,73-76} have enhanced their improvements up to the present; CIM implants were introduced only a few years ago. For this reason, we consider the potentials for improvements of CIM implants in the design phase and the use phase during surgery to be 5\% per year: 2.5\% higher than OTS. However, to increase our confidence in the model, sensitivity analyses were done on the performance improvement assumptions for each type of implant. According to the sensitivity analysis results presented in Appendix Section 5, the model is relatively robust to changes in performance improvements. Furthermore, the online simulator platform, mentioned in the model section, provides decision-makers with the flexibility to incorporate various performance improvement rates for either type of implant (OTS or CIM), initially or midway through the simulation run, and observe the results.

All these assumptions and limitations notwithstanding, the simulation model facilitates systematic study to better understand the effects of knee replacement procedure coverage policies. As presented in the previous sections, the model’s accuracy is validated considering these assumptions.

**Conclusion**

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 costs and patient outcomes when new information becomes available. The benefit of the model is that it allows decision-makers to test different coverage policies based on their preference. For instance, they can consider a dynamic scenario for their coverage rate for CIM procedures based on 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 policymakers 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 and 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 utilization of CIM knee implants.

This study provides a first systematic step towards better understanding of the dynamics of adoption of CIM knee implants and instrumentation. More broadly, the current modeling approach and systems thinking perspective could be utilized to consider the adoption of any new customized therapies, i.e., personalized medicine.
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