

Supporting Information

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

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Section 1: Surgery Time Savings

CIM procedures can save time for hospitals, not only because of shorter recovery, but also because of shorter procedure time (1-4). Figure SI1 represents the plots of nationwide 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 SI1, the most surgery time savings could be achieved through a 90% coverage rate, compared with the base case. The cumulative surgery time saved could reach over 45,000 hours per month for knee replacements nationwide. It is notable that the plots in Figure 5 (adoption) and Figure SI1 follow a similar pattern. This similarity confirms that when more patients adopt CIM implants, more time savings per surgery can be achieved.

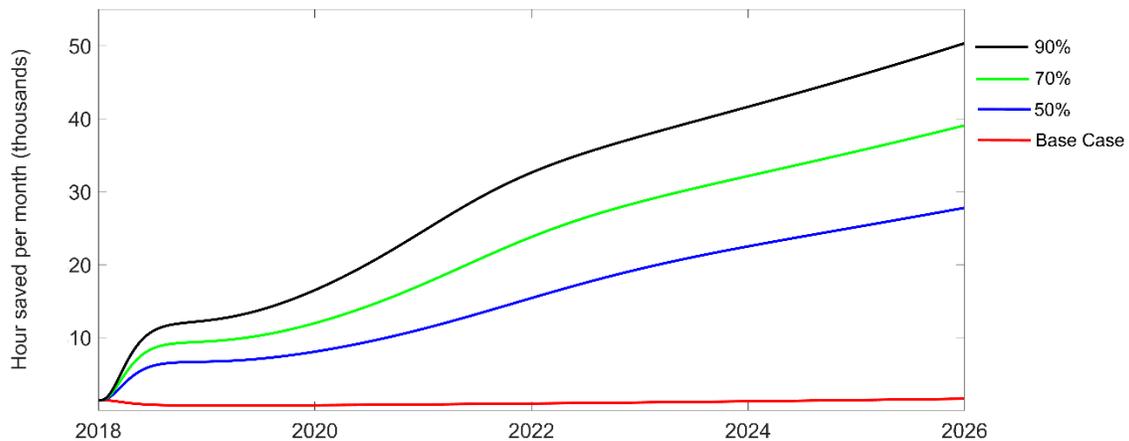


Figure SI1: Surgery time savings per month under different levels of coverage of bundled payment programs for CIM implants. The highest time saving could be achieved under the 90% CIM coverage rate. Understandably, there would be no time savings for the base case. The similarity between the trends of surgery time savings and adoption rates (Figure 5) indicates that higher CIM adoption rates could lead to higher time savings per surgery.

Section 2: Study 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 and bureaucratic burdens of ordering system. All hospital entities have to use FDA-approved medical devices (5); 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 (6). In the model, we assumed that the FDA would approve new CIM implant manufacturers and their products within a period of four months. Complexity of ordering system may include selection of implant (partial, total, cruciate retaining, etc.) and transferring the CT data to a manufacturer which can cause bureaucratic burdens and limit the adoption.

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 (7). 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 (8-14) 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 the next section, the model is relatively robust to changes in performance improvements. In addition, 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.

Outpatient total joint arthroplasty has become more popular in recent years because of the economic benefits due to lower costs associated with reduced length of stay (15-17). The Center for Medicare and Medicaid Services removed TKA from inpatient-only list beginning January 2018 (18). However, according to the American Association of Hip and Knee Surgeons (AAHKS) (19), outpatient TKA should only be utilized for patients who are healthy enough to have a procedure in such settings. The patient should also have an appropriate home support for being discharged with no hospitalization. Similar to any other episode of care, there are advantages and disadvantages associated with outpatient TKA, i.e., reduced costs and discharge on the day of surgery which could lead to either patient satisfaction or dissatisfaction if it causes more complications such as implant failure, stiffness, more readmissions and potentially revision surgeries (20). In our generic model, we considered that OTS and CIM implants can be used in either inpatient or outpatient setting uniformly, however, if the dynamic changes and more patients become interested in outpatient procedures, the model can be expanded to distinguish between inpatient and outpatient settings.

All these assumptions and limitations notwithstanding, the simulation model facilitates a systematic study to better understand the effects of knee replacement procedure coverage policies. As presented in the Modeling Documentation and Instruction for Reproducibility, the model's accuracy is validated considering these assumptions.

Section 3: Sensitivity Analysis

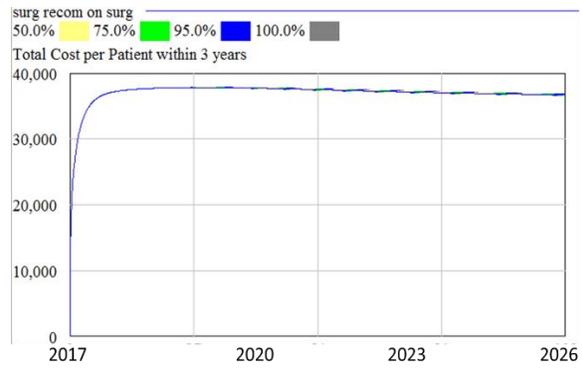
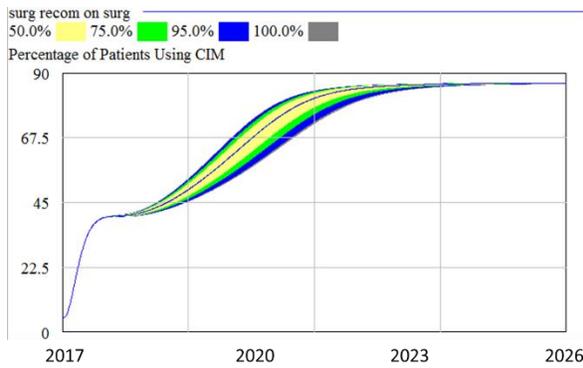
To ensure the reliability of our model, a series of sensitivity analysis has been done on the assumed parameters. For the sensitivity analysis, the values of listed parameters in Table SI1 change by $\pm 50\%$ under 90% coverage for CIM implants, to investigate the effects on the model outputs (total cost per patient within 3 years (Y1) and percentage of patients using CIM implants (Y2)). In addition, sensitivity analysis results considering $\pm 50\%$ change in all parameters at the same time are also provided. All the results are presented in Table SI1.

Table SI1: Sensitivity Analysis Results on Assumed Model Parameters

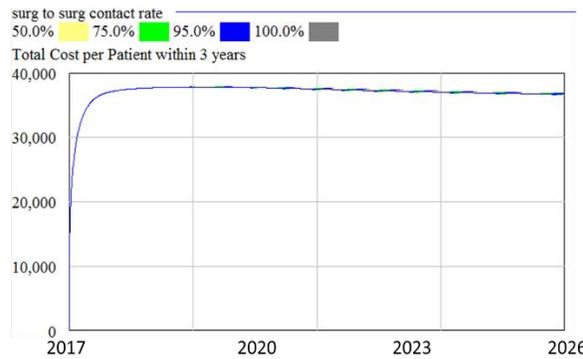
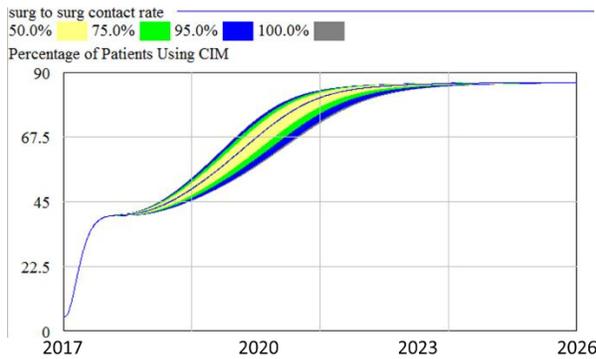
Parameters	Input	Output	
	Change in Parameter	Change in Total \$/patient (Y1)	Change in Percentage of Patients Using CIM (Y2)
Surgeons Recommendation Effectiveness on Surgeons for CIM	$\pm 50\%$	$\pm 0.32\%$	$\pm 0.04\%$
Surgeons to Adopters (surgeons) Contact Rate	$\pm 50\%$	$\pm 0.15\%$	$\pm 0.11\%$
Time to Make Decision (surgeons to adopt)	$\pm 50\%$	$\pm 0.37\%$	$\pm 0.35\%$
Surgeons Recommendation-Effectiveness on Patients for CIM	$\pm 50\%$	$\pm 0.69\%$	$\pm 0.30\%$
CIM Performance Improvement per Doubling the Cooperation	$\pm 50\%$	$\pm 0.34\%$	$\pm 0.02\%$
OTS Performance Improvement per Doubling the Cooperation	$\pm 50\%$	$\pm 0.01\%$	$\pm 0.01\%$
Manufacturer Delay to React to the Market share to Adopt New Technology	$\pm 50\%$	$\pm 0.34\%$	$\pm 0.04\%$
Multiplication of OTS Product Cost for Price of CIM implant	$\pm 50\%$	$\pm 8.89\%$	$\pm 0.01\%$
Time for Sales Force to promote CIM implants	$\pm 50\%$	$\pm 0.02\%$	$\pm 0.01\%$
All Parameters together	$\pm 50\%$	$\pm 9.15\%$	$\pm 2.98\%$

The results of the sensitivity analyses indicate that the most sensitive parameter for total cost per patient within 3 years (Y1) and percentage of patients using CIM implants (Y2) are “Multiplication of OTS Product Cost for Price of CIM implant” and “Time to Make Decision (surgeons to adopt)” respectively.

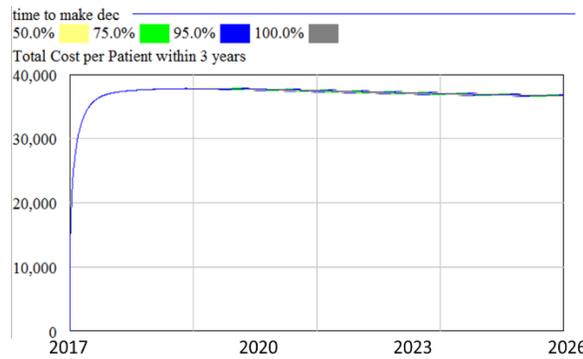
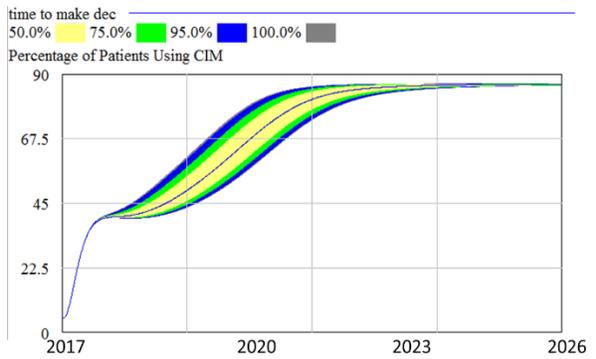
Simulation results based on 200 Monte Carlo simulation runs for 50%, 75%, 95%, 100% intervals are provided in Figure SI2.



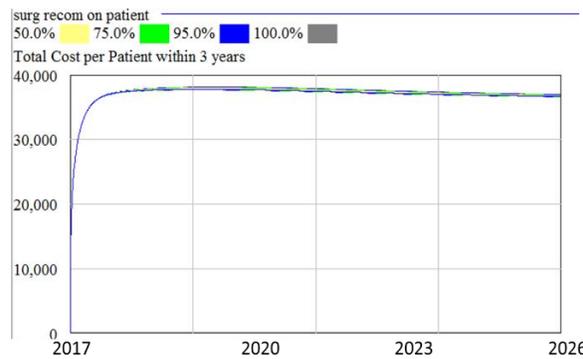
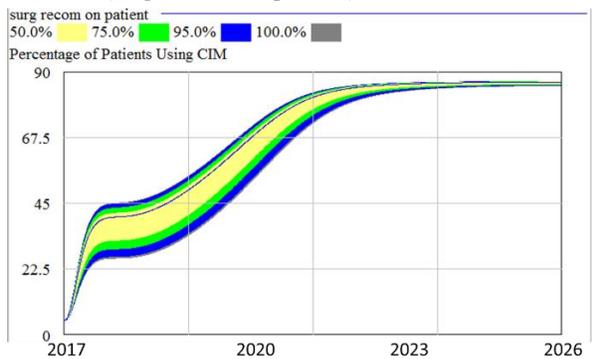
a) Sensitivity of patients using CIM and total cost/patient to $\pm 50\%$ change in “Surgeons Recommendation Effectiveness on Surgeons for CIM implants”



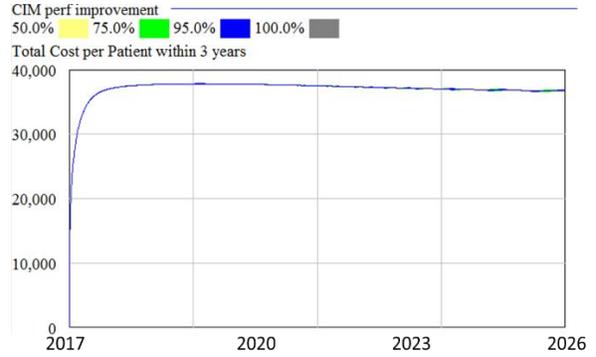
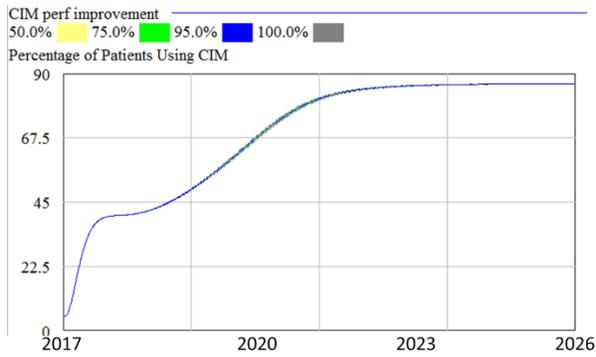
b) Sensitivity of patients using CIM and total cost/patient to $\pm 50\%$ change in “Surgeons to Adopters (surgeons) Contact Rate”



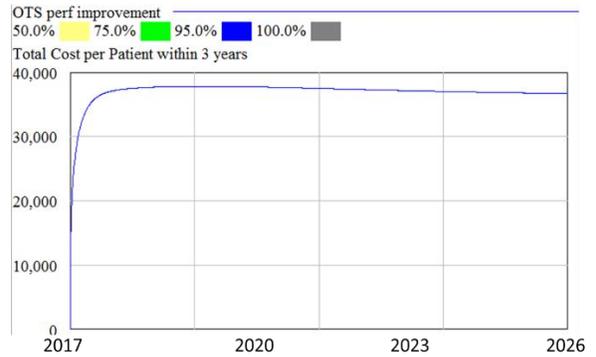
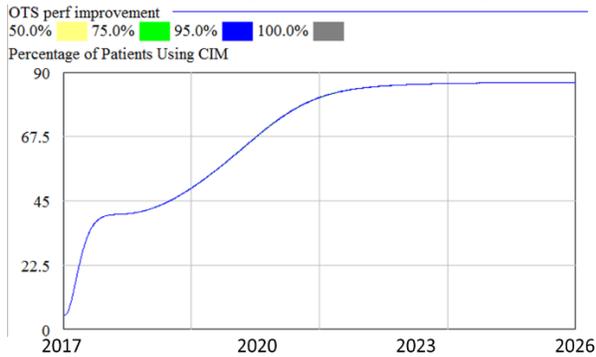
c) Sensitivity of patients using CIM and total cost/patient to $\pm 50\%$ change in “Time to Make Decision (surgeons to adopt CIM)”



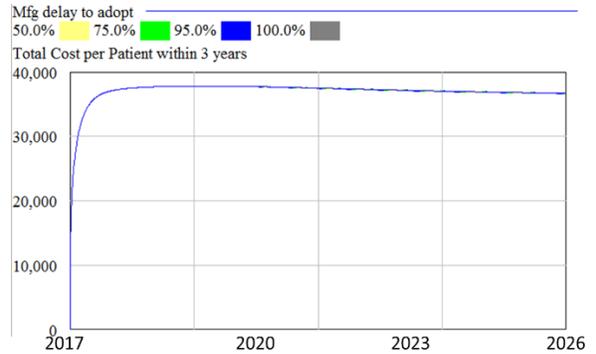
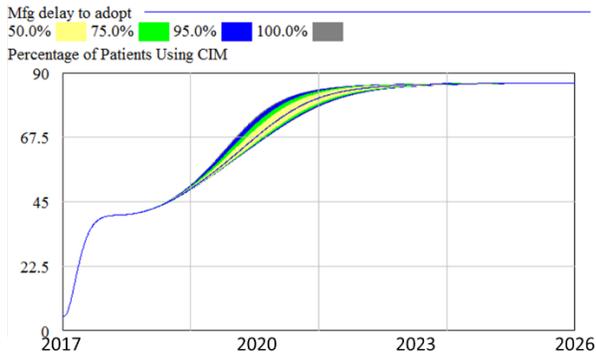
d) Sensitivity of patients using CIM and total cost/patient to $\pm 50\%$ change in “Surgeons recommendation effectiveness on Patients for CIM”



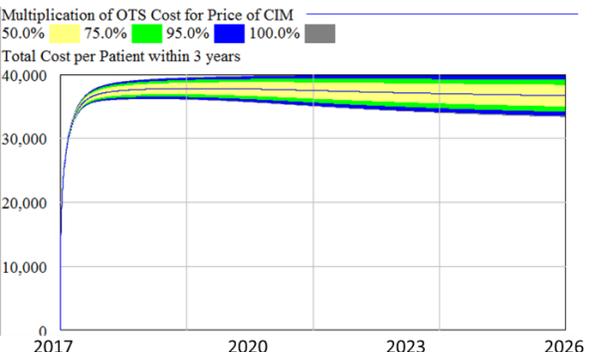
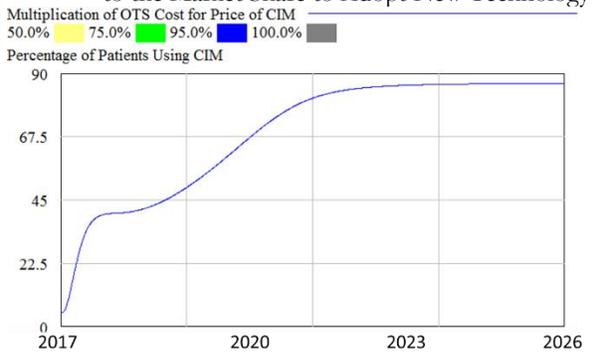
e) Sensitivity of patients using CIM and total cost/patient to $\pm 50\%$ change in “CIM Performance Improvement per Doubling the Cooperation between Manufacturers and Surgeons”



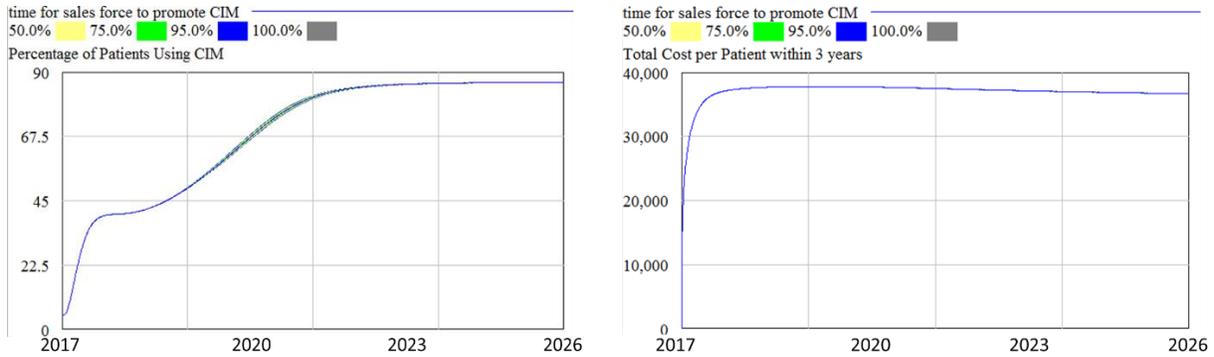
f) Sensitivity of patients using CIM and total cost/patient to $\pm 50\%$ change in “OTS Performance Improvement per Doubling the Cooperation between Manufacturers and Surgeons”



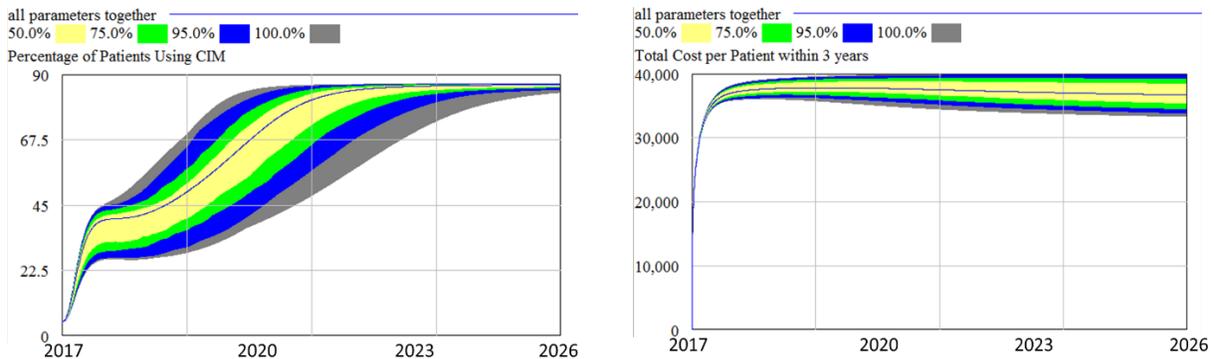
g) Sensitivity of patients using CIM and total cost/patient to $\pm 50\%$ change in “Manufacturer Delay to React to the Market Share to Adopt New Technology”



h) Sensitivity of patients using CIM and total cost/patient to $\pm 50\%$ change in “Multiplication of OTS Product Cost for Price of CIM Implants”



i) Sensitivity of patients using CIM and total cost/patient to $\pm 50\%$ change in “Time for CIM Sales Force to Adjust (promote CIM implants)”



j) Sensitivity of patients using CIM and total cost/patient to $\pm 50\%$ change in “All the parameters together”

Figure SI2: Sensitivity Analysis Results

The results illustrate that there could be a change between 3% and 9% if all parameters change by 50%. This can ensure that the model is relatively robust to the changes in all assumed parameters. We hope that the outcomes of this study encourage more systematic methods for analyzing the effects and consequences of different policies on the adoption of new knee implant technologies.

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