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Health Policy Analysis

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

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 Services[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 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 Bass[47] 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

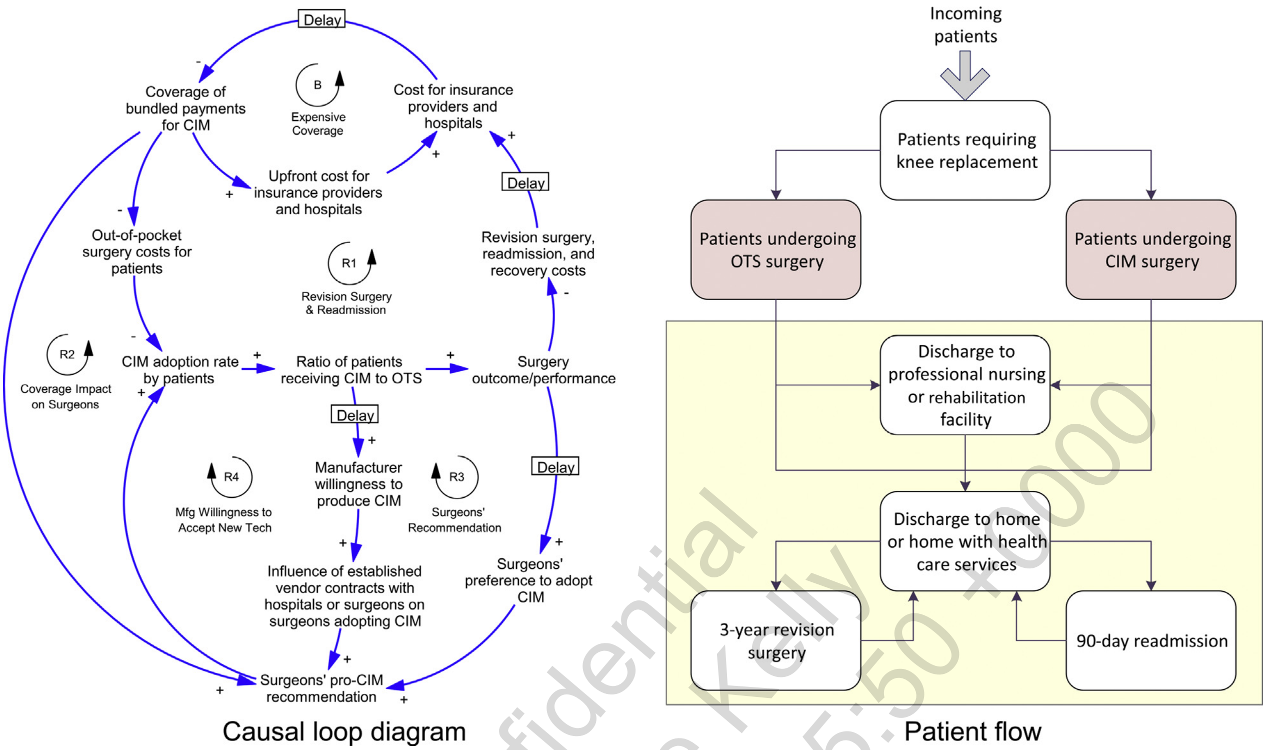

Fig. 1 – High-level version of CLD and patient flow in the system dynamics model. Positive (+) links between any variables in the CLD present changes in the same direction for those variables, whereas negative (−) links illustrate changes in the opposite direction. CIM adoption rates by patients are influenced by out-of-pocket surgery costs for patients and surgeons' recommendations for CIM. Surgery costs for patients are dependent on levels of coverage for CIM, whereas surgeons' recommendations are driven by surgeons' preferences, which are mainly influenced by outcomes of previous patients, stipulations of established contracts with vendors and sales representatives for hospitals and surgeons, and levels of coverage for CIM procedures. The balancing loop (B) and 4 reinforcing loops (R1, R2, R3, and R4) are the main feedback loops in the CLD. Expensive coverage acts as a balancing loop (B) that slows down CIM adoption rates, whereas the reinforcing loops try to promote CIM adoption by improving patient outcomes, shortening recovery, reducing the number of revision surgeries and readmissions, curtailing total healthcare costs, and expanding the CIM market share. Patient flow shows a simplified process for knee replacement surgery for both OTS and CIM implants. The upper part represents the knee replacement surgical procedure, and the lower part describes the patient flow during postoperative recovery. The discharge, readmission, and revision surgery rates vary between OTS and CIM procedures. CIM indicates customized individually made; CLD, causal loop diagram; OTS, off-the-shelf.

loop (loop R3). Evidence of better surgery performance and outcomes would make surgeons more likely to recommend CIM implants and instrumentation; nevertheless, there will be time lag for surgeons to observe the better performance and use new products. 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 encourages or discourages manufacturers to shift to CIM (loop R4). Over the long run, manufacturers' willingness to produce CIM is affected by market share for CIM. 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 a significant time lag. Moreover, patients' willingness to adopt CIM implants because of their social awareness is also considered a factor of influence in the simulation model reported in the Appendix (Modeling Documentation and Instruction for Reproducibility [MDIR]) in Supplemental Materials found at https://doi.org/10.1016/j.jval.2019.01.008.

The patient flow from early stages, when knee replacements are recommended, through postoperative recovery is shown in Figure 1. Surgery and postsurgery are 2 main sections in the patient flow. In the model, patients are initially separated into 2 groups depending on the surgery they undergo, OTS or CIM. This distribution changes over time, because it is dynamically driven by the factors discussed earlier and shown in the CLD.

After surgery, patients are discharged home (with or without home-visiting health services), to skilled nursing facilities, or rarely to rehabilitation centers. Early research shows a statistically significant difference in the discharge destination distribution after hospitalization for CIM versus OTS TKAs: CIM TKA patients are more likely to be discharged home, resulting in savings for insurers and patients.[26] Recently, outpatient TKA, which still needs more clarification in the definition of length of stay,[57–60] has gained momentum because of its potential to minimize the costs among healthy patients; nevertheless, nationwide data demonstrate a higher risk of perioperative surgical and medical complications including component failure, infection, knee stiffness, and deep vein thrombosis,[61] which we discuss further in Section 2 in the Appendix (Supporting Information [SI]) in Supplemental Materials found at 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

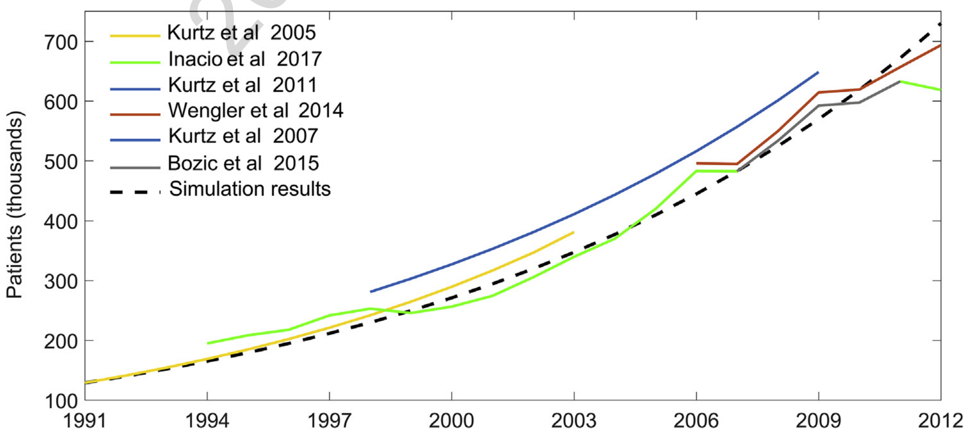

Fig. 2 – Historical data on numbers of patients.[64–69] Historical and reproduced numbers of patients from different sources.

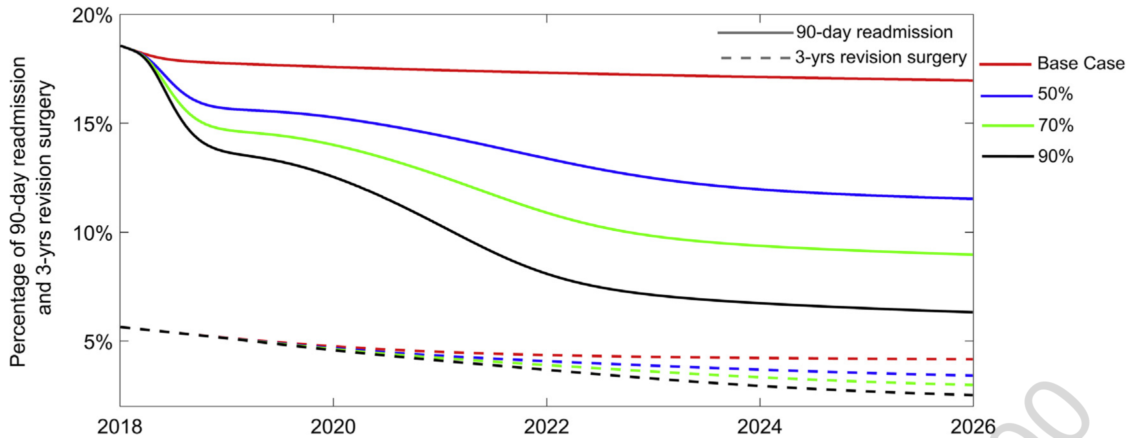

Fig. 3 – Percentage of patients readmitted (OTS and CIM) within 90 days and percentage of patients undergoing revision surgeries (OTS and CIM) within 3 years after primary procedures under different levels of coverage of insurance bundled payment programs for CIM procedures. Three insurance policies, 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 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

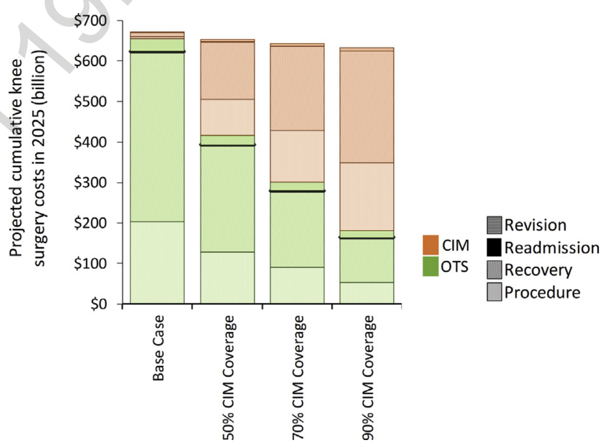

Fig. 4 – Total cumulative costs for all the stakeholders in 2026 (on the basis of the dollar value in 2018) under different coverage policies for CIM implants. The base case represents the current conditions for CIM implant coverage of 5%. Three coverage rates are considered, 50%, 70%, and 90%, for CIM 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.

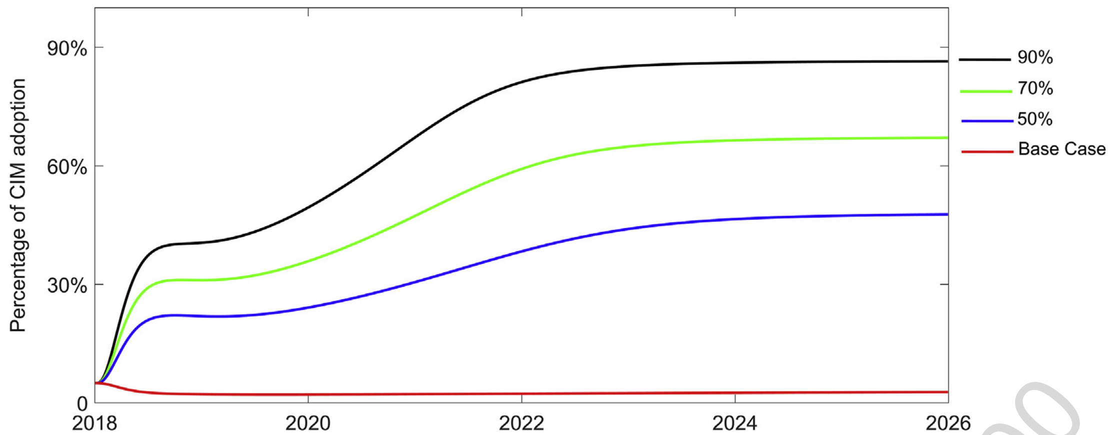

Fig. 5 – Patient adoption rate. The initial value of adoption is equal to the current market share of CIM implants (<5%). Three levels of coverage of insurance bundled payment programs for CIM implants, 50%, 70%, and 90%, are presented. An increase in insurance coverage raises adoption rates of CIM implants. 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

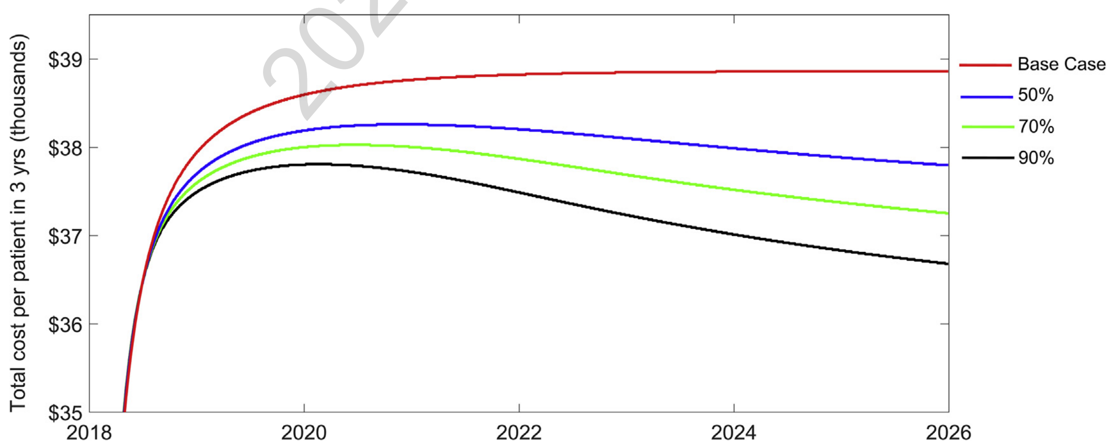

Fig. 6 – Total cost per patient under different coverage policies for CIM implants. This figure shows the trend of nationwide average total cost per patient within 3 years of primary TKA (on the basis of the dollar value in 2018). The savings under 90% CIM coverage rate are higher than those in other 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.

REFERENCES

1. Weinstein AM, Rome BN, Reichmann WM, et al. Estimating the burden of total knee replacement in the United States. *J Bone Joint Surg Am*. 2013;95(5):385–392.
2. Ubel P. Medicare is reducing the cost of knee replacements (here's how that could backfire). Forbes. Forbes.com. Accessed February 2017.
3. Ventola CL. Medical applications for 3D printing: current and projected uses. *P T*. 2014;39(10):704.
4. Centers for Disease Control and Prevention. *Heart Failure Fact Sheet*. Atlanta, GA: Division for Heart Disease and Stroke Prevention, Centers for Disease Control and Prevention; 2016.
5. Maradit Kremers H, Larson DR, Crowson CS, et al. Prevalence of total hip and knee replacement in the United States. *J Bone Joint Surg Am*. 2015;97(17):1386–1397.
6. American Academy of Orthopaedic Surgeons. *Total Knee Replacement Surgery by the Numbers. A Nation in Motion*. Rosemont, Illinois: American Academy of Orthopaedic Surgeons; 2017.
7. Accelerohealth. Length of stay is critical for total hip and knee replacement cost of care; 2014. https://accelerohealth.com/wp-content/uploads/2014/04/Length-of-Stay-is-Critical-for-Joint-Replacement-Cost-of-Care.pdf.
8. Center for Medicare & Medicaid Services. Comprehensive care for joint replacement. CMS.gov. Accessed February 11, 2019; 2018.
9. Ramos NL, Wang EL, Karia RJ, et al. Correlation between physician specific discharge costs, LOS, and 30-day readmission rates: an analysis of 1,831 cases. *J Arthroplasty*. 2014;29(9):1717–1722.
10. Mears SC. How to decrease length of hospital stay after total knee replacement. *J Surg Orthop Adv*. 2016;25(1):2–7.
11. Hart A, Bergeron SG, Epure L, et al. Comparison of US and Canadian perioperative outcomes and hospital efficiency after total hip and knee arthroplasty. *JAMA Surg*. 2015;150(10):990–998.
12. Dunbar MJ, Richardson G, Robertsson O. I can't get no satisfaction after my total knee replacement: rhymes and reasons. *Bone Joint J*. 2013;95-B(11):148–152.
13. Choi Y-J, Ra HJ. Patient satisfaction after total knee arthroplasty. *Knee Surg Relat Res*. 2016;28(1):1–15.
14. Bourne RB, Chesworth BM, Davis AM, et al. Patient satisfaction after total knee arthroplasty: who is satisfied and who is not? *Clin Orthop Relat Res*. 2010;468(1):57–63.
15. Chesworth BM, Mahomed NN, Bourne RB, et al. Willingness to go through surgery again validated the WOMAC clinically important difference from THR/TKR surgery. *J Clin Epidemiol*. 2008;61(9):907–918.
16. Heekin RD, Fokin AA. Incidence of bicompartmental osteoarthritis in patients undergoing total and unicompartmental knee arthroplasty: is the time ripe for a less radical treatment? *J Knee Surg*. 2014;27(1):77–81.
17. Tria Jr AJ. Bicompartmental knee arthroplasty: the clinical outcomes. *Orthop Clin North Am*. 2013;44(3):281–286, vii.
18. Müller M, Matziolis G, Falk R, et al. Die bikompartimentelle Kniegelenkendoprothese Journey Deuce. *Der Orthopäde*. 2012;41(11):894–904.
19. Carpenter DP, Holmberg RR, Quartulli MJ, et al. Tibial plateau coverage in UKA: a comparison of patient specific and off-the-shelf implants. *J Arthroplasty*. 2014;29(9):1694–1698.
20. Dai Y, Scuderi GR, Penninger C, et al. Increased shape and size offerings of femoral components improve fit during total knee arthroplasty. *Knee Surg Sports Traumatol Arthrosc*. 2014;22(12):2931–2940.
21. Levengood GA, Dupee J. Accuracy of coronal plane mechanical alignment in a customized, individually made total knee replacement with patient-specific instrumentation. *J Knee Surg*. 2018;31(8):792–796.
22. Kurtz WB, Slamin JE, Doody SW. Bone preservation in a novel patient specific total knee replacement. *Reconstr Rev*. 2016;6(1).
23. Zeller IM, Sharma A, Kurtz WB, et al. Customized versus patient-sized cruciate-retaining total knee arthroplasty: an in vivo kinematics study using mobile fluoroscopy. *J Arthroplasty*. 2017;32(4):1344–1350.

24. Zeller IM, Kurtz WB, Ta MD, et al. In-vivo kinematics for patients implanted with a customized, patient-specific posterior stabilized total knee arthroplasty vs traditional patient sized off-the-shelf TKA during activities of daily living. *Knee*. 2017;24(6):VIII.
25. Harman MK, Banks SA, Kirschner S, et al. Prosthesis alignment affects axial rotation motion after total knee replacement: a prospective in vivo study combining computed tomography and fluoroscopic evaluations. *BMC Musculoskelet Disord*. 2012;13(1):206.
26. Culler SD, Martin GM, Swearingen A. Comparison of adverse events rates and hospital cost between customized individually made implants and standard off-the-shelf implants for total knee arthroplasty. *Arthroplast Today*. 2017;3(4):257–263.
27. Chua MCH, Chui C-K. Optimization of patient-specific design of medical implants for manufacturing. *Procedia CIRP*. 2016;40:402–406.
28. Steinert AF, Beckmann J, Holzapfel BM, et al. Bicompartmental individualized knee replacement. *Oper Orthop Traumatol*. 2017;29(1):51–58.
29. Gregg A. Perfect knee implants, courtesy of a 3-D printer. Washington Post Business. Washingtonpost.com. Accessed December 2014; 2014.
30. Lewis J. *Custom Conformis Knee Replacement*. London: James Lewis Orthopaedic Knee & Hip Surgeon; 2015.
31. Schrock S. *3D relief: Arlington man among the first to receive custom knee implants*. Star-Telegram. 2014.
32. Romualdez I. The average cost of knee replacement surgery. Pocket Sense. pocketsense.com. Accessed October 2017; 2017.
33. Lewis S. How much does knee replacement cost? Health Grades. Healthgrades.com. Accessed July 2016; 2016.
34. Greengard S. Understanding knee replacement costs: What's on the bill? Healthline. Healthline.com. Accessed October 2017; 2017.
35. Olmos M. Does Medicare cover knee replacement surgery costs? Medicare. Medicare.com. Accessed October 2018; 2010.
36. Rosenthal E. *An American Sickness: How Healthcare Became Big Business and How You Can Take It Back*. London, UK: Penguin Publishing Group; 2017.
37. Homer J, Milstein B, Hirsch GB, et al. Combined regional investments could substantially enhance health system performance and be financially affordable. *Health Aff (Millwood)*. 2016;35(8):1435–1443.
38. Homer JB, Hirsch GB. System dynamics modeling for public health: background and opportunities. *Am J Public Health*. 2006;96(3):452–458.
39. Jalali M, Rahmandad H, Bullock S, et al. Dynamics of implementation and maintenance of organizational health interventions. *Int J Environ Res Public Health*. 2017;14(8):917.
40. Ghaffarzadegan N, Ebrahimvandi A, Jalali MS. A dynamic model of post-traumatic stress disorder for military personnel and veterans. *PLoS One*. 2016;11(10):e0161405.
41. Homer J. A diffusion model with application to evolving medical technologies. *Technol Forecast Soc Change*. 1987;31(3):197–218.
42. Sterman J. System dynamics at sixty: the path forward. *Syst Dyn Rev*. 2018;34(1-2):5–47.
43. Ansah JP, Koh V, Chiu C-T, et al. Projecting the number of elderly with cognitive impairment in China using a multi-state dynamic population model. *Syst Dyn Rev*. 2017;33(2):89–111.
44. Duintjer Tebbens RJ, Thompson KM. Using integrated modeling to support the global eradication of vaccine-preventable diseases. *Syst Dyn Rev*. 2018;34(1-2):78–120.
45. Rogers J, Gallaher EJ, Dingli D. Personalized ESA doses for anemia management in hemodialysis patients with end-stage renal disease. *Syst Dyn Rev*. 2018;34(1-2):121–153.
46. Paul S, Venkateswaran J. Impact of drug supply chain on the dynamics of infectious diseases. *Syst Dyn Rev*. 2017;33(3-4):280–310.
47. Bass FM. A new product growth for model consumer durables. *Manag Sci*. 1969;15(5):215–227.
48. Milling PM. Modeling innovation processes for decision support and management simulation. *Syst Dyn Rev*. 1996;12(3):211–234.
49. Milling PM. Understanding and managing innovation processes. *Syst Dyn Rev*. 2002;18(1):73–86.
50. Ghaffarzadegan N, Rad AA, Xu R, et al. Dell's SupportAssist customer adoption model: enhancing the next generation of data-intensive support services. *Syst Dyn Rev*. 2018;33(3-4):219–253.
51. Paich M, Peck C, Valant J. Pharmaceutical market dynamics and strategic planning: a system dynamics perspective. *Syst Dyn Rev*. 2011;27(1):47–63.
52. Bass FM. The relationship between diffusion rates, experience curves, and demand elasticities for consumer durable technological innovations. *J Bus*. 1980;53(3):16.
53. Maier FH. New product diffusion models in innovation management—a system dynamics perspective. *Syst Dyn Rev*. 1998;14(4):285–308.
54. Keith DR, Sterman JD, Struben J. Supply constraints and waitlists in new product diffusion. *Syst Dyn Rev*. 2016;33(3-4):254–279.
55. Jalali MS, Ashouri A, Herrera-Restrepo O, et al. Information diffusion through social networks: the case of an online petition. *Expert Syst Appl*. 2016;44:187–197.
56. Schairer WW, Vail TP, Bozic KJ. What are the rates and causes of hospital readmission after total knee arthroplasty? *Clin Orthop Relat Res*. 2014;472(1):181–187.
57. Vehmeijer SBW, Husted H, Kehlet H. Outpatient total hip and knee arthroplasty. *Acta Orthop*. 2018;89(2):141–144.
58. Sher A, Keswani A, Yao DH, et al. Predictors of same-day discharge in primary total joint arthroplasty patients and risk factors for post-discharge complications. *J Arthroplasty*. 2017;32(9):S150–S156.e1.
59. Nelson SJ, Webb ML, Lukasiewicz AM, et al. Is outpatient total hip arthroplasty safe? *J Arthroplasty*. 2017;32(5):1439–1442.
60. Bovonratwet P, Webb ML, Ondeck NT, et al. Definitional differences of "outpatient" versus "inpatient" THA and TKA can affect study outcomes. *Clin Orthop Relat Res*. 2017;475(12):2917–2925.
61. Arshi A, Leong NL, D'Oro A, et al. Outpatient total knee arthroplasty is associated with higher risk of perioperative complications. *J Bone Joint Surg Am*. 2017;99(23):1978–1986.
62. Lake S. Is outpatient knee replacement for you? Know who benefits. DukeHealth. dukehealth.org; 2017.
63. Rahmandad H, Sterman JD. Reporting guidelines for simulation-based research in social sciences. *Syst Dyn Rev*. 2012;28(4):396–411.
64. Kurtz SM, Ong KL, Lau E, et al. International survey of primary and revision total knee replacement. *Int Orthop*. 2011;35(12):1783–1789.
65. Kurtz S, Ong K, Lau E, et al. Projections of primary and revision hip and knee arthroplasty in the United States from 2005 to 2030. *J Bone Joint Surg*. 2007;89(4):780.
66. Inacio MCS, Paxton EW, Graves SE, et al. Projected increase in total knee arthroplasty in the United States—an alternative projection model. *Osteoarthritis Cartilage*. 2017;25(11):1797–1803.
67. Bozic KJ, Kamath AF, Ong K, et al. Comparative epidemiology of revision arthroplasty: failed THA poses greater clinical and economic burdens than failed TKA. *Clin Orthop Relat Res*. 2015;473(6):2131–2138.
68. Wengler A, Nimptsch U, Mansky T. Hip and knee replacement in Germany and the USA: analysis of individual inpatient data from German and US hospitals for the years 2005 to 2011. *Dtsch Arztebl Int*. 2014;111(23-24):407–416.
69. Kurtz S, Mowat F, Ong K, Chan N, Lau E, Halpern M. Prevalence of primary and revision total hip and knee arthroplasty in the United States from 1990 through 2002. *J Bone Joint Surg*. 2005;87(7):1487–1497.
70. Homer JB. Partial-model testing as a validation tool for system dynamics (1983). *Syst Dyn Rev*. 2012;28(3):281–294.
71. Hosseinichimeh N, Rahmandad H, Wittenborn AK. Modeling the hypothalamus-pituitary-adrenal axis: a review and extension. *Math Biosci*. 2015;268:52–65.
72. Sterman JD. *Business Dynamics: Systems Thinking and Modeling for a Complex World*. Boston, MA: Irwin McGraw-Hill; 2000.
73. Barlas Y. Formal aspects of model validity and validation in system dynamics. *Syst Dyn Rev*. 1996;12(3):183–210.
74. Senge PM, Sterman JD. Systems thinking and organizational learning: acting locally and thinking globally in the organization of the future. *Eur J Oper Res*. 1992;59(1):137–150.
75. ConforMIS. ConforMIS announces sale of over 50,000 customized knee implants. *ConforMIS News*; October 2016.
76. O'Connor B, Pollner F, Fugh-Berman A. Salespeople in the surgical suite: relationships between surgeons and medical device representatives. *PLoS One*. 2016;11(8):e0158510.
77. American Joint Replacement Registry. *2018 Annual Report*. Rosemont, Illinois: American Joint Replacement Registry; 2018.
78. National Joint Registry. *15th Annual Report 2018*. National Joint Registry for England, Wales, Northern Ireland and Isle of Man. London, UK: National Joint Registry; 2018.
79. Schwarzkopf R, Brodsky M, Garcia GA, et al. Surgical and functional outcomes in patients undergoing total knee replacement with patient-specific implants compared with "off-the-shelf" implants. *Orthop J Sports Med*. 2015;3(7), 2325967115590379.
80. Baicker K, Chandra A. Medicare spending, the physician workforce, and beneficiaries' quality of care. *Health Aff (Millwood)*. 2004;(Suppl 1). W4-184-197.
81. Iorio R, Robb WJ, Healy WL, et al. Orthopaedic surgeon workforce and volume assessment for total hip and knee replacement in the United States: preparing for an epidemic. *J Bone Joint Surg Am*. 2008;90(7):1598–1605.