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The Impact of Music and Noise-Cancellation on Sedation Requirements During Total Knee Replacement: A Randomized Controlled Trial

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Abstract

Background: Music has emerged as a well-received medical intervention. Patients may be uncomfortable during total joint replacement, which can result in high sedation requirements. These requirements place elderly patients at risk for delirium. This study compares the effect of noise-cancellation versus music medicine on sedation requirements, pain, and opioid consumption during elective total knee replacement. **Methods:** This prospective, double-blinded, randomized clinical trial was conducted at Virginia Commonwealth University Medical Center between July 2018 and July 2019. All participants underwent primary total knee arthroplasty with a combined spinal-epidural as their primary anesthetic and received noise-cancelling, wireless headphones. Patients in the control group received the noise-cancellation feature only, while patients in the experimental group were permitted to listen to music of their choice. Patients signaled a request for sedation by squeezing a noise-making rubber hippopotamus toy. The primary outcomes included whether sedation was requested by the participant, the number of sedation demand doses requested, and the amount of propofol sedation administered during the procedure. Secondary outcomes included postoperative pain scores, total opioid consumption, and time to first opioid request. **Results:** Seventy-one percent (n = 36) of patients agreed to participate in the study. Forty-four percent of participants in the noise-cancellation group and 19% of participants in the music group requested sedation ($P = .25$). The median propofol consumption was not different between groups (0 [0-6.7] μg/kg/min vs 0 [0-0] μg/kg/min, $P = .101$ for noise cancellation vs music, respectively). Pain scores and opioid consumption were not different between groups. **Discussion:** To date, this is the first study to use Bluetooth communication, noise-cancellation, and an Internet-based music streaming service to determine whether this technology has an impact on outcomes during major orthopedic surgery. **Conclusion:** As an isolated intervention, the benefits of music in a complex operating room environment may be overstated. However, music integration with noise-reduction technology and patient-controlled sedation may lead to a safer and more satisfying anesthetic. More research is needed to determine the nonpharmacologic interventions that will produce positive outcomes for the geriatric population.

Keywords

anesthesia, adult reconstructive surgery, geriatric medicine, acute pain medicine, regional anesthesia, music therapy

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Introduction

Patient safety is essential when joint replacement is performed under spinal anesthesia, and many health-care providers underestimate the risks associated with sedation. According to the American Society of Anesthesiologists (ASA) closed claim database on monitored anesthesia care, respiratory depression as a result of oversedation is the most common mechanism of injury leading to death or permanent brain damage.[1] For the

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geriatric population, there is a cognitive cost for providing sedation during operative procedures.[2] When compared to light sedation, deep sedation results in a higher incidence of postoperative delirium in elderly patients undergoing hip fracture repair.[3] Inaccurate expectations of the benefits and harms of sedation can influence decision-making and may contribute to overuse.[4]

Loud noises, such as those common in orthopedic surgery, are anxiety-provoking for patients during total joint replacement. Sedation is necessary to maintain patient comfort.[5] Sounds from the orthopedic bone hammer and oscillating saw can reach up to 105 db, which is equal in magnitude to the sounds heard when standing near a helicopter. Up to 50% of orthopedic surgery operating room (OR) staff have some degree of noise-induced hearing loss.[6]

Music has emerged as a well-received medical intervention. It decreases anxiety, heart rate, and blood pressure when played during an awake craniotomy.[7] It also decreases pain scores and increases satisfaction even when patients are under general anesthesia.[8] For preoperative nerve block procedures, music is an effective alternative to midazolam.[9] Two approaches to music in the perioperative setting include music therapy and music medicine. With music therapy, a trained professional selects tempo-controlled melodies designed to have a calming effect. Music medicine, on the other hand, is more widely accessible and uses patient-selected music as a distraction tool.[10,11]

Advances in music technology open up new opportunities to improve implementation for our patients. First, noise-cancellation devices receive auditory input and release opposing sound waves that reduce the amplitude and frequency of undesired sounds. Next, Bluetooth (Bluetooth Special Interest Group, Kirkland, Washington) employs wireless technology that allows for a headphone connection to a music device up to 10 m away. Lastly, music streaming services have surged in popularity. With enhanced wireless Internet technology in the OR, patients and staff have an instant music selection from a remote digital library.

To date, no studies have determined whether music has an additional benefit in the setting of noise-cancellation in the OR. We hypothesize that when patients receive music during total knee replacement, they will be less likely to require sedation during the procedure. Overall, the mean sedation requirement will be reduced in patients who receive music. We also hypothesize that music will decrease pain scores and opioid consumption postoperatively.

Methods

Study Design

This prospective, double-blinded, randomized clinical trial was conducted at Virginia Commonwealth University Medical Center in Richmond, Virginia, between July 2018 and July 2019. This study was approved by the University's institutional review board (IRB#HM20010566) and written informed consent was obtained from all subjects participating in the trial. The trial was registered prior to patient enrollment at clinical trials.gov (NCT03486106, Principal investigator: B.W.T., Date of registration: April 3, 2018). The study was sponsored and fully funded internally by the Virginia Commonwealth University Department of Anesthesiology. Data were collected and analyzed by the investigators; all authors had access to the data. The study was overseen by a data monitoring committee. This manuscript adhered to the applicable Consolidated Standard of Reporting Trials (CONSORT) guidelines.

Patient Population

Institutional review board approval was obtained prior to undertaking this study. Included were patients aged at least 18 years scheduled to undergo primary total knee arthroplasty by a single orthopedic surgeon (G.J.G.). Also required for participation were eligibility for spinal anesthesia and mental capacity to consent and follow study instructions. We excluded members of regulated vulnerable populations (ie, prisoners, parturients), those with contraindications to spinal anesthesia, morbid obesity, specific allergies (propofol, midazolam, and morphine), preoperative daily morphine equivalent greater than 60 mg and patients with impaired hearing. Participants were recruited preoperatively in the surgical clinic, anesthesia clinic, or on the day of surgery in the preoperative surgical unit. Formal written consent was obtained on the day of surgery.

Procedures, Randomization, and Masking

In preparation for study recruitment, simple randomization for 2 study arms was prepared through Research Randomizer (randomizer.org). Treatment allocations were documented and distributed using a sealed envelope system. The anesthesia providers, surgeons, and other OR staff were blinded to the study arm. All patients received noise-canceling, wireless headphones (Bose QuietComfort 35 II; Bose Corporation, Framingham, Massachusetts) which were placed by a study administrator in the OR following completion of a standard presurgical briefing. Patients in the control group received the noise-cancellation feature only. Patients in the experimental group were permitted to listen to the music of their choice during surgery. Music preference was solicited at the time of enrollment and used to select a genre/channel on Spotify Premium, which is a paid, commercial-free Internet music streaming service. The service was used in compliance with the Spotify Terms of Contract, which permits noncommercial, nonprofit use. An iPod Touch (Apple, Cupertino, California) served as the music device and connected to the Spotify service through wireless Internet in the OR. The iPod Touch transferred the music to the headphones via a Bluetooth wireless connection. Once set according to patient preference, music channel and volume could not be changed. Headphones were placed in the OR following the presurgical safety briefing and removed at the end of surgery. Anesthesia provider, surgeon, and other OR staff were blinded to the study arm. Documentation in the electronic medical record was completed by the anesthesia provider per standard protocol. Data collection was performed through a chart review by a blinded investigator

Figure 1. A noise-making rubber hippo toy served as a signaling device, allowing for patient-controlled sedation. Noise-cancelling headphones are also displayed.

(K.K.X.) who did not consent the participants or administer the sedation.

Study participants received a combined spinal-epidural (CSE) as their primary anesthetic. Spinal doses included 15 mg of bupivacaine and 0.2 mg of preservative-free morphine. Up to 2 mg of intravenous (IV) midazolam was given for anxiolysis during placement. Peripheral nerve blocks were not performed. In addition, all patients received premedication with acetaminophen, celecoxib, gabapentin, and scopolamine. These premedications are standard of care at our institution and not considered a study feature. Vitals signs were monitored according to standard protocol.

In addition to CSE placement which provides complete surgical anesthesia, standard of care for knee arthroplasty includes IV sedation according to the anesthesiologist or nurse anesthetist's discretion. The amount of sedation given is typically based on clinical judgment taking into account the patient's degree of discomfort or anxiety during the procedure. In our study, patients were given sedation on-demand rather than according to the anesthesia provider's determination. Patients signaled a request for sedation by squeezing a noise-making rubber hippopotamus toy which remained in their hand throughout surgery (Figure 1). Each request for sedation resulted in administration of a 0.3 mg/kg bolus dose of IV propofol. The bolus dose was rounded to the nearest 5 mg increment and manually administered by syringe. For patient safety, only one dose per 2-minute window was allowed. Sedation was withheld if the anesthesia provider determined that the patient was oversedated as indicated by physical examination and/or hemodynamic monitors. In the event that 5 propofol boluses were requested, a continuous infusion of propofol was initiated at 25 μg/kg/min. Patients were permitted to make additional requests for sedation, but if more than 5 requests were made, then the infusion was increased to 50 μg/kg/min. In the event that another 5 requests for sedation were made, then the next steps were to be determined based on consultation between the anesthesia providers and investigators.

Our study did not impact standard management of clinical scenarios which generally warrant conversion to general anesthesia. Examples of such circumstances include hemodynamic instability, regurgitation of gastric content, obtundation, excessive agitation, and inadequate spinal anesthesia.

After the surgical procedure, the study participants received acetaminophen, celecoxib, and gabapentin at scheduled intervals per standard protocol. Additionally, oxycodone was available every 4 hours per patient request, and IV hydromorphone was available for breakthrough pain that could not be controlled by oral medications alone.

Outcomes

The primary outcomes of our study included whether the participants requested sedation via activation of the signaling device, and if sedation was requested, the amount of propofol sedation and the number of propofol demand doses administered during the surgical procedure. In order to adjust for weight and anesthesia time, the outcome was calculated and reported in micrograms of propofol per kilogram per minute.

Secondary outcomes included pain scores, opioid consumption, and time to first opioid request within a 24-hour period after the procedure. Numerical pain scores are routinely taken via the standard of care nursing assessment immediately after surgery and every 4 hours afterward. Average and maximum pain scores over a 24-hour time period were documented for data analysis. Total opioid consumption over 24 hours was calculated for each participant and converted into milligram morphine equivalents. Time to first opioid request was recorded, which was defined as the time between leaving the OR and administration of the first oral opioid.

Demographic data included participant age, gender, weight, body mass index (BMI), and ASA classification. Procedure characteristics included anesthesia time, defined in the intraoperative record as "in the OR" time to "surgery stop" time, and surgical duration, defined as "surgery start" to "surgery stop" time.

Statistical Analysis

All statistical analyses were specified in a statistical analysis plan and were conducted using GraphPad Prism, version 8.0 (GraphPad Software, San Diego, California). An a priori power analysis was performed prior to study recruitment via a sample size calculator that used validated equations from statistics literature (clincalc.com).[12] The average sedation requirement for total knee arthroplasty has not been described in the literature. According to the gold standard anesthesia reference, the propofol infusion rate required to obtain adequate sedation for any unspecified procedure is 50 μg/kg/min $\pm$ 25 μg/kg/min.[13] With an anticipated propofol requirement of 25 μg/kg/min or less in the music group, and assuming a parametric distribution, a sample size analysis with an α of 0.05 and β of 0.2 revealed a necessary sample size of 16 in each group.

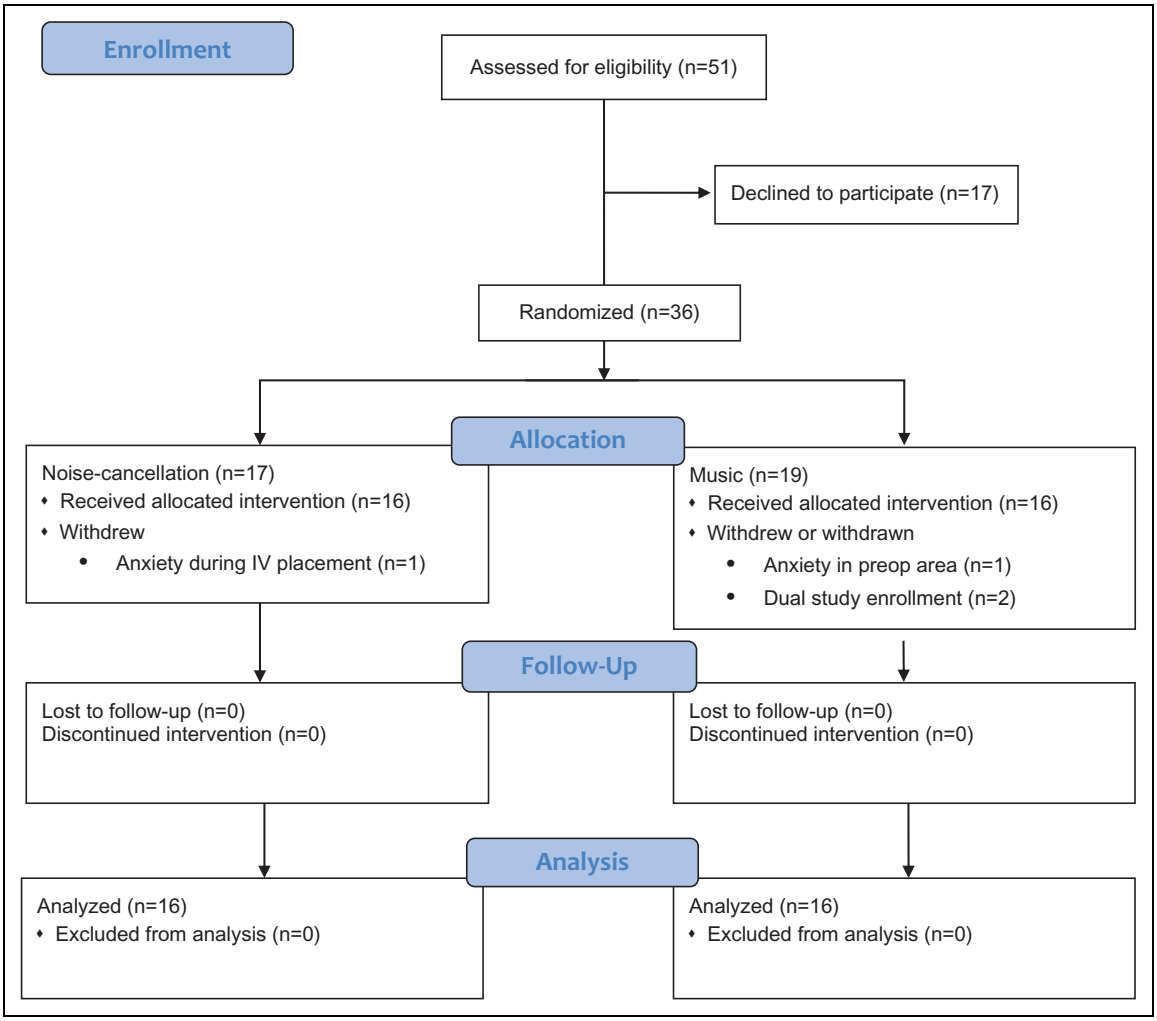

Figure 2. Consolidated Standard of Reporting Trials 2010 flow diagram for study recruitment.

A Shapiro-Wilk test was performed to determine the normality of distribution for data groups with continuous variables. Normally distributed data were reported as mean ± standard deviation. Non-normally distributed data were reported as median (interquartile range).

To determine statistical significance for normally distributed data, a 2-tailed, unpaired, Student *t* test was performed. For non-normally distributed data, a Mann-Whitney *U* test was performed. Fisher exact test was performed for data with discrete variables. A P value <.05 was considered statistically significant.

A Kaplan-Meier survival curve was created to reflect time to the first request for oral opioid medication. A log-rank test was performed to determine hazard ratio, 95% confidence interval of the ratio, and P value.

Results

Recruitment

Study participants were recruited from a single academic medical center over a 1-year period from July 16, 2018, to July 15, 2019. A CONSORT diagram[14] (Figure 2) demonstrates the participant flow through the study. Fifty-one patients were assessed for enrollment. Seventy-one percent (n = 36) of patients agreed to participate in the study. After consent and randomization, 1 participant in the noise-cancellation group withdrew due to anxiety during routine IV placement. One participant from the music group withdrew due to anxiety before entering the OR and 2 participants were withdrawn by a study investigator due to inadvertent dual enrollment in another research study.

Demographics and Procedure Characteristics

Age, gender, BMI, ASA classification, anesthesia time, and surgical duration were not different between groups (Table 1).

Operating Room Outcomes

The number of participants requiring sedation, the average propofol consumption, and number of sedation demand doses were not different between groups (Table 2). Conversion to general anesthesia did not occur with any study participants.

Table 1. Demographic and Procedural Characteristics.[a]

Parameter	Control (n = 16)	Music (n = 16)	*P* Value
Age, years	62 [59-72]	67 (8)	.37
Gender, female (n)	12	7	.15
Weight (kg)	94 (14)	91 (21)	.72
Body mass index (kg/m^2)	33 (5)	30 (6)	.61
ASA status (I/II/III)	0/5/11	0/7/9	.19
Anesthesia time (minutes)	139 (29.7)	161 (32.2)	.05
Surgical duration (minutes)	103 (25.6)	119 (26)	.09

Abbreviations: ASA American Society of Anesthesiologists.
[a]Normally distributed data were reported as mean (standard deviation). Non-normally distributed data were reported as median [interquartile range]. A Student *t* test was performed for normally distributed data. A Mann-Whitney *U* test was performed for non-normally distributed data. Fisher exact test was performed for data with discrete variables. A value of $P < .05$ was considered statistically significant.

Table 2. Operating Room Outcomes.[a]

Parameter	Control (n = 16)	Music (n = 16)	*P* Value
Participants requesting sedation (%)	44	19	.25
Mean propofol usage (μg/kg/min)	5.1 (8.7)	3.5 (8.9)	.10
Median propofol usage (μg/kg/min)	0 [0-6.7]	0 [0-0]	.10
Propofol demand doses (#)	0 [0-3]	0 [0-0]	.21

[a]Normally distributed data were reported as mean (standard deviation). Non-normally distributed data were reported as median [interquartile range]. A Student *t* test was performed for normally distributed data. A Mann-Whitney *U* test was performed for non-normally distributed data. Fisher exact test was performed for data with discrete variables. A value of $P < .05$ was considered statistically significant.

Table 3. Pain Management Outcomes.[a]

Parameter	Control (n = 16)	Music (n = 16)	*P* Value
Average pain score	2.4 [0.72-4.5]	1.6 [0.79-3.5]	.47
Maximum pain score	5.5 (2.8)	5.3 (2.5)	.80
24-h opioid consumption (MME)	18.3 [7.5-43.1]	20.8 (18.8)	.58

Abbreviation: MME, milligram morphine equivalents.
[a]Normally distributed data were reported as mean (standard deviation). Non-normally distributed data were reported as median [interquartile range]. A Student *t* test was performed for normally distributed data. A Mann-Whitney *U* test was performed for non-normally distributed data. Fisher exact test was performed for data with discrete variables. A value of $P < .05$ was considered statistically significant.

Pain Management Outcomes

Average pain score, maximum pain score, and 24-hour opioid consumption were not different between groups (Table 3).

With opioid request as a "survival" outcome, survival curves were not different between groups over 24-hours (hazard ratio: 1.1 [0.52-2.3], $P = .63$; Figure 3). None of the patients required IV breakthrough medication.

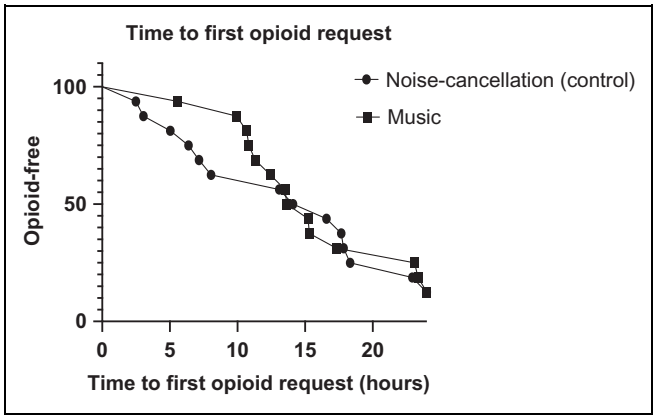

Figure 3. Kaplan-Meier survival curve reflecting time to first opioid request. Hazard ratio 1.1 [0.52-2.3], $P = .633$.

Discussion

To date, this is the first study to use Bluetooth communication, noise-cancellation, and an Internet-based music streaming service to determine whether this technology has an impact on outcomes during major orthopedic surgery. Our hypothesis was not supported by the findings of this study. When noise-reduction technology is employed, the addition of music does not provide additional benefit during total knee replacement. Fewer music patients required sedation and mean propofol consumption was reduced, but these findings did not reach statistical significance. Postoperatively, pain scores and opioid consumption in the first 24 hours after surgery were not different.

Despite these findings, the effect of noise-cancellation technology in both groups is notable. Fifty-six percent of patients in the noise-cancellation group and 81% of patients in the music group were able to avoid sedation altogether. This may have positive implications on the geriatric population, who are more likely to develop delirium if they receive sedation in the OR.[3] The mean propofol requirement for these groups was 5.1 and 3.5 μg/kg/min for the noise-cancellation and music groups, respectively. Historical control data from our institution, which was not collected for research, shows that sedation is used for nearly 100% of patients and that the propofol sedation requirement is approximately 50 μg/kg/min. This data is consistent with previous literature that reports a propofol requirement between 40 and 50 μg/kg/min in patients undergoing total joint replacement under spinal anesthesia.[5] With this amount of sedation, noise in the OR becomes tolerable. The noise level in ORs is consistently above the limits established by federal regulatory agencies.[15] More research is needed to quantify the impact of high-fidelity noise-cancellation when compared to standard practice.

Most anesthesia providers are willing to offer music, and most patients are willing to receive music during surgery, especially patients who have high pain scores at baseline.[16] The majority of our eligible patients agreed to participate in our music study. Music is accessible for free with an Internet

connection, is low-risk, and can be easily switched on-off to minimize disruption in the OR. Headphones provide targeted music intervention for the patient while minimizing distraction for OR staff during critical portions of the procedure.

Our patient-controlled, provider-delivered, propofol sedation technique is unique. The patient-signaling device, a hippo toy, costs less than US$10, whereas a pharmacy-made patient-controlled analgesia (PCA) device would cost over US$200 for total knee arthroplasty.[17] In either case, an anesthesia care team is required for major orthopedic procedures, so this cost is fixed. Administration of propofol by an anesthesia provider also adds a layer of clinical judgment that makes this technique safer than an automated PCA. Due to its simplicity, this method has potential for implementation across various institutions.

Advances in technology allow for safe incorporation of music into a patient's OR experience. A direct connection between headphones and a music device is not recommended. If the music device is plugged into an electrical outlet, the headphones could become a grounding source, placing the patient at risk of electric shock when electrocautery is used. A Bluetooth connection provides a wireless signal between headphones and a music device and therefore removes the risk of electricshock. Prior to initiation of this experiment, a team of bioengineers tested our music apparatus in a simulation lab to ensure patient safety.

A major limitation of the study was that we could not provide a nonactive blinded study arm without noise-cancelling headphones. The institutional review board felt that participants in this study arm would be highly likely to experience excessive anxiety that would not be worth the benefit of additional research data. However, there is sufficient data from previous research that provides a benchmark to assess the effectiveness of the study interventions. Other limitations include a small sample size, for which an a priori power analysis was performed, and a lack of study monitoring for music possibly played on OR speakers. Lastly, the participants did not receive general anesthesia and therefore were not blinded to the study intervention.

Conclusion

Music listening is an enjoyable activity with few downsides, but as an isolated intervention, its benefits in a complex OR environment may be overstated. Regardless, this study has promising results that incorporate both noise-reduction technology and patient-controlled sedation that may lead to a safer and more satisfying anesthetic, especially in the geriatric population. More research is needed to determine the optimal combination of nonpharmacologic interventions that will produce positive patient outcomes.

Authors' Note

Clinicaltrials.gov Registration Number: NCT03486106. In compliance with the approved protocol from our institutional review board, individual-level information will not be shared with other researchers. Therefore, data will not be available in a repository. Bryant W. Tran designed, planned, and conducted this study; he led the team who acquired the data, interpreted the results, and wrote the manuscript. Maliha Y. Nowrouz helped to create the study design and plan; she helped conduct the study, and wrote the "Methods" section of the manuscript. Sabrina K. Dhillon helped to create the study design, conduct the study, and edit the manuscript. Katherine K. Xie helped to collect the data from the electronic medical records and edit the manuscript. Kathryn M. Breslin helped to conduct the study and prepare the tables and figures for the manuscript. Gregory J. Golladay helped to create the study design and write and edit the manuscript.

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Declaration of Conflicting Interests

The author(s) declared the following potential conflicts of interest with respect to the research, authorship, and/or publication of this article. Bryant W. Tran is member of the editorial board for the Geriatric Orthopaedic Surgery and Rehabilitation journal. Gregory J. Golladay is a paid consultant for OrthoSensor, Inc. He receives royalties, represents the company in paid presentations, owns stock options, and receives research support from OrthoSensor, Inc. He also receives research support from KCI Company and Cerus Corporation. He is a member of the editorial board for the *Journal of Arthroplasty* and Deputy Editor for Arthroplasty Today. He is the Publications Committee Chair for the American Association of Hip and Knee Surgeons and is a member of the Virginia Orthopaedic Society Board.

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