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Short-term outcomes associated with drain use in shoulder arthroplasties: a prospective, randomized controlled trial

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Background: This study examined the immediate outcomes during the perioperative period associated with drains in the setting of total shoulder arthroplasty or reverse shoulder arthroplasty. We hypothesized that drain use would result in lower postoperative hemoglobin and hematocrit levels that would increase transfusion rates and longer hospital stays that would increase hospital costs.

Methods: The study prospectively randomized 100 patients (55% women; average age, 69.3 years) who underwent total shoulder arthroplasty or reverse shoulder arthroplasty to receive a closed-suction drainage device (drain group, n = 50) or not (control group, n = 50) at the time of wound closure. Basic demographic information and intraoperative and postoperative data were collected.

Results: The groups were similar with respect to basic patient demographics. Postoperatively, drains had no effect on transfusion rates or any perioperative complication ($P > .715$). There were also no significant differences in hemoglobin or hematocrit levels immediately after surgery or on postoperative day 1. On average, patients were discharged from the hospital 1.6 days and 2.1 days postoperatively in the control and drain groups, respectively ($P = .124$). The average cost associated for the control cohort's hospital stay was $35,796 ± $13,078 compared with $43,219 ± $24,679 for the drain cohort ($P = .063$).

Discussion: Drain use after shoulder arthroplasty had no appreciable difference on short-term perioperative outcomes, postoperative anemia, length of hospital stay, or cost. It is possible that the potential negative effects of postoperative drainage are blunted by the routine use of tranexamic acid.

Level of evidence: Level I; Randomized Controlled Trial; Treatment Study

Keywords: Closed-suction drainage; shoulder arthroplasty; postoperative blood loss; hospital cost; hemoglobin; hematocrit

Drain use dates back to the early days of Hippocrates, who in 400 BC drained a surgical wound with a wooden tube.[20] By the 19th century, the first reported closed-suction drainage system was commercially available.[17] Since that time, a rich collection of scientific investigations has been published on the use of closed-suction drainage in total hip (THA) and knee (TKA) arthroplasty. The theoretical benefits of

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closed-suction drainage after these procedures include improved healing, reduced infections, and reductions in hematoma and effusion formation.[1,10,15,23] However, these benefits have not been proven in the hip and knee arthroplasty literature, which has associated drain use instead with increased postoperative blood loss, increased blood transfusions, higher infection risks, and no proven wound healing benefits.[4,5,20-22] Furthermore, from a logistical standpoint, drains can be cumbersome to patients during the hospital stay and have a substantial effect on cost and quality control.

Given the lack of clear benefit of routine drain usage in TKA and THA, it is surprising that there is a paucity of investigations assessing their use in shoulder arthroplasty. This is particularly true because drains are routinely used after shoulder arthroplasty cases without any evidence-based guidelines.[6,7,13] As such, a prospective evaluation of drain use in shoulder arthroplasty is necessary to determine the risks, benefits, and costs associated with this intervention.

To that end, we designed a randomized controlled trial evaluating the short-term perioperative effects of drain use in primary and revision total (TSA) and reverse shoulder arthroplasty (RSA). Outcome measurements were chosen based on previously published lower extremity literature focusing on drain use and included measurements of postoperative anemia, wound complications, including hematoma development, hospital duration, transfusion requirements, any associated surgical or hospitalization complications, and overall cost. We hypothesized that drain use would result in lower hemoglobin (HgB) and hematocrit (Hct) levels, higher transfusion requirements, longer hospital durations, and increased costs but that there would be no differences in wound complications.

Materials and methods

This prospective, randomized controlled trial was conducted at a tertiary referral center and included 100 consecutive shoulder arthroplasty patients from December 2015 to June 2017. All operations were performed by 1 of 3 fellowship-trained shoulder surgeons. Inclusion criteria included adult patients requiring primary or revision TSA or RSA with osteoarthritis, inflammatory arthritis, posttraumatic arthritis, or proximal humeral fracture refractory to nonoperative management. Preoperative history, physical examination, and imaging were reviewed in clinic visits to confirm the diagnosis and determine treatment plans. Exclusion criteria included age ≤18 years, hemiarthroplasty, or inability to provide informed consent. Informed consent was obtained by the surgeon, surgical fellow, or research associate once surgery was indicated.

Patients who elected to proceed with surgical treatment in the form of a TSA or RSA were randomized to not receive a drain (control group) or receive a drain during operative closure. Randomization into the 2 groups was performed using a computer randomization program (www.Random.org; Dublin, Ireland). The randomization assignment was determined immediately before wound closure intraoperatively by the opening of an opaque research envelope by a nonsurgical research associate to keep the surgical team blinded until the final moments before wound closure. The clinical team planned to remove the drains when drainage was <30 mL/12-hour shift or at the discretion of the attending surgeon.

Demographics and preoperative data

Basic patient demographic information and preoperative clinical data were collected and recorded for the entire cohort inclusive of age, sex, body mass index, American Society of Anesthesiologists (ASA) Physical Status Classification, daily use of any anticoagulation, baseline Hct and HgB levels, procedure (primary vs. revision and TSA vs. RSA), and preoperative Disabilities of the Arm, Shoulder and Hand scores.

Intraoperative data

TSA or RSA was performed using 1 of 6 types of shoulder arthroplasty implant: Zimmer BF TSA (Zimmer, Warsaw, IN, USA), Zimmer TM RSA (Zimmer), Arthrex Univers Apex TSA (Arthrex, Naples, FL, USA), DePuy Global Steptech APG TSA (DePuy/Synthes, New Brunswick, NJ, USA), Stryker ReUnion RSA (Stryker, Kalamazoo, MI, USA), and Tornier Aequalis Perform RSA (Tornier, Bloomington, MN, USA). A standard deltopectoral approach was performed in each case.

After arthroplasty implantation and subscapularis repair, a nonsurgical research assistant who was present for the procedure opened the opaque research envelope to determine the patient cohort. For the drain cohort, a 400 mL Davol closed-wound suction evacuator (C.R. Bard, Inc., Covington, GA, USA) was positioned deep to the deltopectoral interval with the suction tubing exiting laterally. This step was skipped in the control cohort. The deltopectoral interval was closed with two #1 nonabsorbable sutures in both cohorts, and a 2-0 absorbable suture was used for the deep dermal layer in simple, interrupted, buried fashion. Subcuticular closure was performed with a 4-0 monofilament, and Dermabond (Ethicon, Somerville, NJ, USA) was applied. Finally, a 4×4 gauze and occlusive Tegaderm (3M, St. Paul, MN, USA) dressing was placed. This dressing was left in place until the first postoperative visit 2 weeks from the date of surgery.

Intraoperative data collected included estimated blood loss (EBL), operative time, and use of tranexamic acid (TXA). EBL was estimated by assessing total suction canister contents and surgical sponge counts and subtracting the total irrigation used both by pulsatile lavage and bulb syringe. Operative time was measured from time of incision to the moment when the dressing was applied. Both of these measurements were performed by the nonsurgical research associate who observed the procedure.

Administration of TXA is standard protocol at our institution, and patients received 1 g of intravenous TXA at the time of the incision and another gram at the point of closure, unless ideal body weight dictated a significantly different weight-based dosage. Exclusion from this protocol was based on a collaborative decision between the attending orthopedic surgeon and anesthesiologist based on specific patient comorbidities.

Postoperative data

Postoperative data collected included HgB and Hct levels collected immediately postoperatively on postoperative day (POD) 0 and on POD 1, hospital duration, total hospital cost, method of deep vein

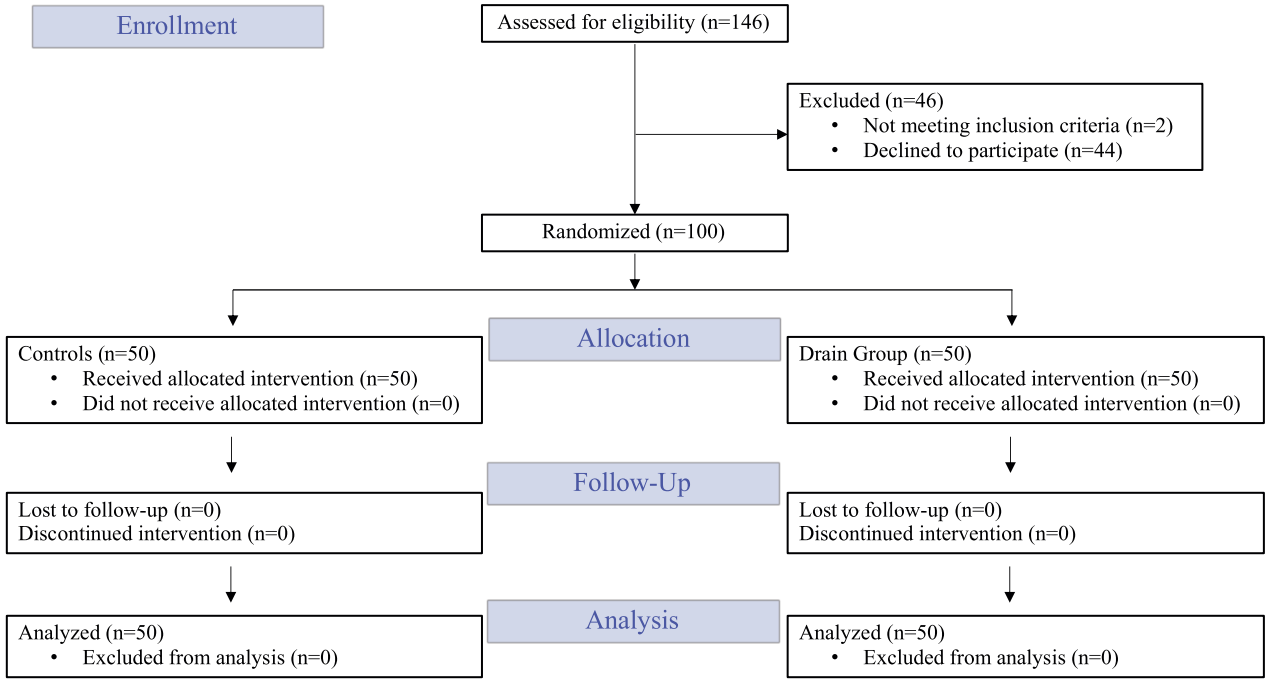

Figure 1 Consolidated Standards of Reporting Trials flow diagram of study.

thrombosis prophylaxis, and any associated perioperative complications. Perioperative complications investigated included blood transfusions, wound compromise, wound drainage, concerning ecchymosis, hematoma, deep vein thrombosis, pulmonary embolism, 90-day superficial and deep infections, death, and reoperation for any reason. Daily drain outputs and POD of drain removal were recorded. Standard of care deep vein thrombosis prophylaxis included 28 days of aspirin (325 mg twice daily), unless a more aggressive regimen was recommended during the patient's preoperative clearance evaluation. All data points were collected by a nonsurgical research associate prospectively.

Statistical analysis

Statistical analyses were performed using GraphPad Prism 7.0a software (GraphPad Software, La Jolla, CA, USA). Statistical significance was determined using a Student 2-tailed *t* test when comparing the means of 2 or more groups or the χ^2 test when analyzing continuous data. Statistical significance was set at $P \leq .05$. A power analysis for this study was performed based on prior investigations looking at differences in hemoglobin levels in TSAs.[7] The latter reported a large effect size (~.8). Specifically, to determine a large effect size, we determined that 26 patients per group was required to achieve 80% power at an α of 0.05.

Results

From December 2015 to June 2017, 146 patients were assessed for eligibility in this investigation, of which 100 patients (55% women) were randomized to receive a drain (n = 50) at the time of closure or not to receive a drain (n = 50; Fig. 1). No patients were lost to follow-up because all patients were admitted to the hospital and monitored for the full extent of their perioperative course. The mean age of patients included in the study was 69.3 ± 9.1 years (range, 48-88 years; Table I). There were no significant differences in any preoperative comparisons between the control and drain group including age, sex, body mass index, ASA classification, baseline HgB, baseline Hct, the proportion of patients on anticoagulation, or preoperative Disabilities of the Arm, Shoulder and Hand scores

Table I Patient demographic and preoperative characteristic comparisons between treatment groups

Variables	Control (n = 50)	Drain (n = 50)	*P* value
Age, yr	68.5 ± 9.2	70.2 ± 9.1	.348
Women	28 (56.0)	27 (54.0)	>.999
Body mass index, kg/m^2	29.9 ± 6.8	29.2 ± 6.3	.588
ASA Physical Status Classification	2.48 ± 0.5	2.46 ± 0.5	.849
Hemoglobin, g/dL	13.2 ± 1.2	13.6 ± 1.4	.089
Hematocrit, %	40.3 ± 3.5	41.4 ± 3.8	.143
Patients on preoperative anticoagulation	3 (6.0)	5 (10.0)	.715
Preoperative DASH score	60.8 ± 17.9	56.0 ± 17.5	.209
Patients undergoing primary arthroplasty	47 (94)	47 (94)	>.999
Patients undergoing TSA	34 (68)	24 (48)	.068

ASA, American Society of Anesthesiologists; *DASH*, Disabilities of the Arm, Shoulder and Hand; *TSA*, total shoulder arthroplasty.
Continuous data are presented as mean ± standard deviation and categorical data are presented as number of patients (%).

Table II Intraoperative and immediate postoperative comparisons between treatment groups

Variables	Control (n = 50)	Drain (n = 50)	*P* value
Surgical duration, min	125.6 ± 31.4	117.8 ± 29.3	.207
Estimated blood loss, mL	239.4 ± 134.0	287.9 ± 199.3	.158
Patients receiving TXA	45 (90.0)	41 (82.0)	.388
Hospital duration, d	1.62 ± 0.8	2.12 ± 2.12	.124
Complications	3 (6.0)	5 (10.0)	.715
Intraoperative fracture	0 (0.0)	1 (2.0)	
Atrial fibrillation	0 (0.0)	1 (2.0	
Transfusion	1 (2.0)	1 (2.0)	
Urinary tract infection	0 (0.0)	1 (2.0	
Clostridium difficile infection	0 (0.0)	1 (2.0)	
Persistent hypertension	1 (2.0)	0 (0.0)	
Superficial infection	1 (2.0)	0 (0.0)	
Deep infection	0 (0.0)	0 (0.0)	
Dressing change required	0	0	>.999

TXA, tranexamic acid.
Continuous data are presented as the mean ± standard deviation, and categorical data are presented as number of patients (%).

($P > .05$). Furthermore, the proportion of patients undergoing a primary vs. a revision and the proportion of patients receiving a TSA vs. RSA performed in each cohort were not significantly different.

Intraoperative comparisons revealed no significant differences in the surgical duration, EBL, or percentage of patients who received intraoperative TXA (Table II). Postoperatively, patients who received a drain had an average hospital duration of 2.1 days compared with 1.6 days for control patients; however, this difference was not significant ($P = .124$). The cost associated with each patient's hospital stay was assessed (Fig. 2). The average cost associated for the control cohort's hospitalization was $35,796 ± $13,078 compared with $43,219 ± $24,679 for the drain cohort, representing a $7,423 difference that was not statistically significant ($P = .063$).

The overall complication rate during the perioperative period was not significantly different between the groups ($P = .715$). Two patients in the drain cohort (4%) experienced an intraoperative complication. This included a humeral fracture during removal of a proximal humeral plate and conversion to TSA that was treated with cable wiring, and atrial fibrillation with a rapid ventricular rate that required pressor support and a postoperative intensive care unit stay. Both groups had a 2.0% postoperative transfusion rate.

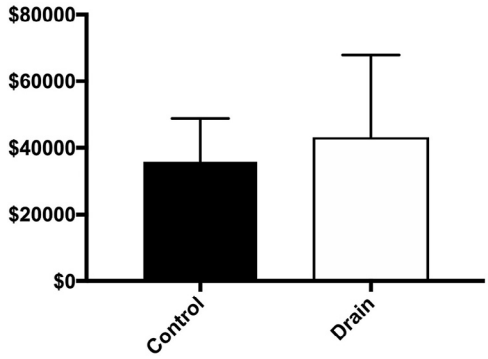

Figure 2 Cost comparison between the control and drain cohorts surgical hospitalization reveals no significant difference. Mean data are presented with the standard deviation (*error bars*).

Other postoperative complications included a urinary tract infection and a positive *Clostridium difficile* infection in 2 separate patients in the drain group, as well as a superficial infection treated via antibiotics alone and persistent hypertension necessitating a cardiology consult in 2 separate patients in the control group. In regards to immediate perioperative wound complications, no patient in either group experienced acute wound dehiscence or compromise, nor did anyone experience drainage or bleeding requiring a dressing change. A hematoma was documented during the hospital course of 1 patient in the control group but did not require treatment and was asymptomatic.

The average duration of wound drainage and the amount of postoperative wound drain output was recorded for the drain cohort. On average, the wound drain was kept in place for 1.26 days, with 64% of drains being removed on POD 1. No drain was kept longer than POD 2. The average amount of wound drainage per patient was 161.7 mL, with average drain outputs on POD 0, POD 1, and POD 2 of 96.5 mL, 74.9 mL, and 35.7 mL, respectively. The amount of drainage between TSA and RSA was not significant at 142.6 mL vs. 185.9 mL ($P = .221$). Drainage did not have an effect on postoperative anemia as assessed by HgB and Hct levels (Fig. 3). Drainage did not influence postoperative HgB or Hct levels. For example, POD 0 and POD 1 HgB levels in the control and drain cohorts were 11.8 and 11.9 g/dL ($P = .784$) and 10.9 and 11.1 g/dL ($P = .688$), respectively. POD 0 and POD 1 Hct levels in the control and drain cohorts were 35.8% and 35.9% ($P = .910$) and 33.2% and 33.4% ($P = .828$), respectively.

Discussion

In this prospective randomized study we evaluated the effects of drainage on the immediate postoperative outcomes of patients undergoing shoulder arthroplasty for a variety of pathologies. With respect to our prestudy hypothesis, drain use had no bearing on postoperative wound complications inclusive of hematoma formation. Contrary to our hypothesis, however, receiving a drain had no effect on postoperative

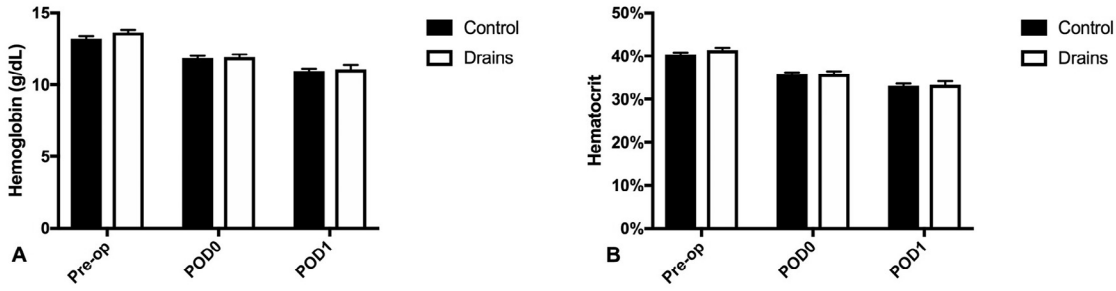

Figure 3 Comparison of preoperative and postoperative (**A**) hemoglobin and **(B)** hematocrit levels between treatment groups. No significant differences were identified. Mean data are presented with the standard deviation (*error bars*). *POD*, postoperative day.

anemia or transfusions levels and was not associated with increased hospital stays or cost. These results suggest that routine drain usage, although safe, is unnecessary for routine shoulder arthroplasty cases.

Although 2 studies previously analyzed drain use in open shoulder surgery, this is the first randomized controlled trial directly comparing outcomes associated with postoperative wound drainage in shoulder arthroplasty. In 1997, Gartsman et al[6] performed a prospective investigation of 300 heterogeneous open shoulder operations, including rotator cuff repairs, glenohumeral stabilizations, and arthroplasties. Similar to the conclusions of the current investigation, the authors found no differences in hematoma formation, wound dehiscence, transfusion, or return to the operating room based on drain use.

More recently, in 2017, Makhni et al[13] provided the first descriptive data comparing closed-suction drainage in homogenous populations of TSA and RSA patients. The authors found that RSA resulted in significantly higher drainage (209 mL vs. 168 mL), greater postoperative anemia, and higher transfusion rates. However, drainage was not an independent risk factor for transfusion in the investigation; instead, a low preoperative HgB level was the most important risk factor for transfusion in both groups.

Interestingly, the wound drainage documented in the current investigation was lower for both RSA and TSA compared with the postoperative drainage identified by Makhni et al.[13] The only noticeable difference between the protocols of the 2 investigations that could explain this difference was the routine use of TXA in the current study. Similarly, in 2015, Gillespie et al[7] performed a randomized controlled trial evaluating the use of TXA in TSA and RSA in which the control and TXA groups both received a postoperative drain that was routinely removed on POD 1. The authors found that TXA decreased postoperative wound drainage by 62 mL on average. The same investigation demonstrated that TXA was associated with decreased postoperative anemia but not transfusions because no patient in either of their treatment groups required a transfusion. In addition, in a study evaluating RSA exclusively, Vara et al[19] found that TXA decreased the average postoperative drainage by 151 mL and the transfusion rate from 14.3% to 5.7%.

The 0% transfusion rate identified by Gillespie et al[7] and the 2% transfusion rate identified in the current investigation is much lower than previously published transfusion rates after shoulder arthroplasty and is most likely directly related to the use of TXA. For example, the transfusion rate documented by Makhni et al[13] in 2017 was 11.7% after RSA and 3.1% after TSA. Others have found rates of transfusion in TSA to be 4.3%,[2] 6.0%,[9] 21.8%,[14] and 38%.[8] Fewer studies have investigated RSA specifically, but transfusion rates of 18.0%[9] and 73.7%[8] have been documented compared with the 5.7% rate of RSA in the setting of TXA identified by Vara et al,[19] as mentioned above. And finally, a recent 2000 to 2009 study on transfusions in shoulder arthroplasties used the National Inpatient Sample to identify an overall transfusion rate of 6.7% after shoulder arthroplasty.[16] As such, given the low transfusion rates seen in the presence of drains in the current investigation and previously by Gillespie et al,[7] we can conclude that postoperative drainage has minimal or no bearing on postoperative anemia and transfusion rates after TSA or RSA in the setting of TXA.

Another key finding of this investigation was that drain use did not increase the average length or cost of patients' hospitalization. Our hypothesis that drains would result in longer hospitalizations and costs stemmed from a 2014 analysis that identified a $538 and $455 higher cost per THA and TKA when performed with a drain, respectively.[3] Taking all costs together, we found that drain use was associated with a total cost of $432,972 to their institution over a 10-week period despite the relatively low cost, $35, of the drain. These higher costs were attributed to the increased length of stays for THA but not TKA and to costs associated with the higher transfusion rates for both operations when drains were used. Although the average cost difference was $7,423 between the 2 cohorts in the current investigation, this difference was not statistically significant ($P = .063$). We now hypothesize that TXA's role in decreasing the overall transfusion rate mitigated the risk of longer, more costly hospital stays by preventing postoperative blood loss normally associated with drain use.

This study does have certain limitations. First, despite being a randomized controlled trial, it could not be double-blinded because the intervention was known to the treatment team and patient. To help decrease the bias associated with

our inability to blind both parties, patients were not assigned to a cohort until closure so that their intraoperative treatment was not influenced.

In addition, the short-term nature of this study does not provide any information about whether using drains produces better outcomes such as increased range of motion or improved functional scores. However, we chose not to investigate this because drains have not been found to influence any of these long-term outcomes in the TKA and THA literature.[11,12,18,20,24]

Finally, the inclusion of multiple implants, surgeons, and the inclusion of primary and revision cases limits the significance of the results.

The strength of this randomized controlled trial includes that it involved all patients undergoing TSA and RSA compared with studies that included only healthy patients or patients who did not have low preoperative HgB levels.[7,19] In addition, this study is similar in size to previous randomized controlled trials documenting similar outcome measurements in shoulder arthroplasty patients as well as randomized controlled trials investigating drains in lower extremity arthroplasty.[7,11,19]

Conclusion

This randomized prospective investigation evaluated the effects of drainage on the immediate postoperative outcomes of patients undergoing TSA and RSA. No differences were identified between the two cohorts, which we hypothesize is due to the introduction of routine TXA use in shoulder arthroplasty, which decreases the risk of transfusion and postoperative blood loss associated with a closed suction drain. Although drain use is safe, we conclude that it is unnecessary for routine shoulder arthroplasty cases.

Disclaimer

Charles M. Jobin reports the following: Acumed, LLC: paid consultant; American Shoulder and Elbow Surgeons: board or committee member; DePuy, A Johnson & Johnson Company: paid consultant; *Journal of the American Academy of Orthopaedic Surgeons*: editorial or governing board; Tornier: paid presenter or speaker; Wright Medical Technology, Inc.: paid consultant; and Zimmer: paid consultant. William N. Levine reports the following disclosures: American Shoulder and Elbow Surgeons: board or committee member; *Journal of the American Academy of Orthopaedic Surgeons*: editorial or governing board; and Zimmer: unpaid consultant. Christopher S. Ahmad reports the following: Arthrex, Inc.: paid consultant, research support; At Peck: stock or stock options; Lead Player: publishing royalties, financial, or material support; Major League Baseball: research support; *Orthopedics Today*: editorial or governing board; and Stryker: research support. The other authors, their immediate families, and any research foundation with which they are affiliated have not received any financial payments or other benefits from any commercial entity related to the subject of this article.

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