

# Patients Who Reviewed a Decision Aid Prior to Major Orthopaedic Surgery Reported Higher Trust in Their Surgeon

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**Background:** Decision aids (DAs) are utilized to ensure that patients are informed and involved in the decision-making process. Although DAs improve decision quality, other aspects of the decision-making process, such as trust and regret, are seldom measured. The objective of the present study was to determine whether patients given a DA prior to orthopaedic surgery had greater trust and lower regret at 6 months postoperatively.

**Methods:** Consecutive patients were identified who underwent a hip or knee replacement or spine surgery from October 2018 to January 2020 and were subsequently surveyed at 6 months postoperatively. Outcomes included the Trust in the Surgical Decision and Decision Regret Scales. The primary analysis compared scores of patients who reviewed at least some of the DA to those who had not received or reviewed it. A sensitivity analysis compared patients with a DA order who reported reviewing it to those who did not. Multivariable models analyzed whether DA exposure predicted trust or regret. An exploratory mediation analysis examined the direct and indirect effects of DA exposure, including through the Shared Decision Making Process score.

**Results:** The response rate was 56% (700 of 1,253). In the primary analysis, the proportion of patients who reported complete trust was 50.9% among those with no DA review and 63.8% among those with DA review (adjusted odds ratio, 1.62; 95% confidence interval, 1.11 to 2.36). A nonsignificant effect was observed comparing a DA order (59.9%) versus no DA order (51.4%; adjusted odds ratio, 1.30; 95% confidence interval, 0.80 to 2.11). Regret was unrelated to DA exposure. In the mediation analysis, 19.3% (95% confidence interval, 3.1% to 35.4%) of the effect of DA review on trust could be attributed to increased shared decision making.

**Conclusions:** Patients who reviewed a DA prior to orthopaedic surgery reported higher trust in their surgeons.

**Clinical Relevance:** Providing patients with a DA prior to orthopaedic surgery can improve trust in the surgeon. Improving trust between patients and surgeons may improve communication and help patients make better health decisions.

Clinical practice guidelines, including those for the treatment of major orthopaedic disorders, emphasize the importance of informing patients about their options and engaging in shared decision making (SDM) to determine the appropriate treatment<sup>1-3</sup>. SDM is an interactive process that integrates the expertise of patients (e.g., how the disease is impacting their life, as well as their goals and preferences), the expertise of clinicians, and clinical evidence to determine the best treatment. SDM helps ensure patients are well informed and receive treatments that match their preferences<sup>4</sup>. SDM supported by patient decision aids

(DAs) has been called “The New Era of Informed Consent,”<sup>5</sup> and a Cochrane review with >100 randomized trials and >30,000 patients has shown that this process leads to better decisions<sup>6</sup>.

Wennberg and others have advanced the notion of “wrong patient surgery” as a medical error; that is, operating on a patient who would not want the procedure if fully informed and involved<sup>7</sup>. The Cochrane review demonstrates that in randomized trials of SDM supported by DAs, 15% to 20% fewer patients undergo surgery when fully informed and involved compared with usual care<sup>6</sup>.

**Disclosure:** The **Disclosure of Potential Conflicts of Interest** forms are provided with the online version of the article (<http://links.lww.com/JBJSOA/A366>).

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Improving trust between patients and clinicians by providing more transparency and better communication around the benefits and harms of treatment can help patients make better health-care decisions, which should mitigate medicolegal risk and improve the quality of care. However, there is as yet no direct evidence that SDM supported by the use of DAs reduces malpractice litigation<sup>8</sup>.

The aim of the present study was to determine whether patients who are given a DA prior to major orthopaedic surgery had (1) greater trust in the operating surgeon and (2) lower decision regret at 6 months postoperatively compared with patients who underwent the same operations but who were not given a DA.

### Materials and Methods

This comparative cohort study included eligible patients who underwent 1 of 4 elective orthopaedic or neurosurgical procedures at 1 of 4 hospitals affiliated with an academic medical center. Consecutive patients were identified with use of a Health Insurance Portability and Accountability Act (HIPAA)-compliant data warehouse. Patients were included if they were  $\geq 40$  years old and had undergone elective primary total hip or knee replacement with a corresponding diagnosis of hip or knee osteoarthritis or were  $\geq 30$  years old and had undergone elective primary spinal fusion, laminectomy, or discectomy with a corresponding diagnosis of lumbar spinal stenosis or a herniated disc. Patients were also required to have a preferred language of English. Patients were excluded who were unable to consent for themselves, had a hip fracture within 12 months prior to hip replacement, had osteonecrosis within 12 months prior to hip or knee replacement, or had absolute indications for spine surgery. Each patient's record was reviewed by research staff to verify eligibility.

#### Description of DAs

The 4 DAs used in this project were developed by Healthwise: *Knee Osteoarthritis: Is it Time to Think about Surgery?*; *Hip Osteoarthritis: Is it Time to Think About Surgery?*; *Lumbar Herniated Disc: Which Treatment Is Right for You?*; and *Lumbar Spinal Stenosis: Which Treatment Is Right for You?* The DAs were available online and as a printed booklet.

#### DA Distribution

The distribution of the DAs occurred as part of routine care. The DAs were prescribed by the surgeon or a member of the surgical team, documented in the electronic medical record of the patient, and delivered to patients electronically via the portal. For patients who were not active on the portal, the DA could be printed and distributed as a paper booklet, and office staff were asked to document such an order in the patient record.

#### Survey

Eligible patients were mailed a cover letter, survey, and \$5.00 incentive. Patients were given the choice of returning the survey

by mail or accessing an electronic version through Research Electronic Data Capture (REDCap; Mass General Brigham) with use of a unique code. A research assistant made follow-up calls and sent a follow-up survey, followed by another reminder call. The mode of survey completion was recorded.

The Mass General Brigham institutional review board approved this study.

#### Survey Measures

##### Trust in the Surgical Decision Scale

This is a validated, 5-item scale that measures the level of patient trust that their surgeon will help them make a good decision about an operation<sup>9</sup>. Each item is scored on a scale of 0 to 4, with the overall score ranging from 0 to 20. Higher scores indicate higher trust.

##### Decision Regret Scale

The Decision Regret Scale is a validated, 5-item scale that measures distress or remorse after a decision with use of a Likert scale<sup>10</sup>. The scores are based on a linear scale of 0 to 100, with lower scores indicting less regret.

##### Shared Decision Making Process Scale

The 4-Item Shared Decision Making Process Scale is endorsed by the National Quality Forum for elective surgical decisions as a measure of patient involvement in decision making<sup>11</sup>. A score is calculated according to responses to 4 items (0-4), with a higher score indicating greater involvement<sup>12,13</sup>.

##### DA Receipt Survey

All patients were asked if they remembered receiving a DA prior to surgery (Table I). If patients reported that they received a DA, they were asked how much of the DA they had viewed, with preset answers including none, some, most, or all of it. Higher self-reported time spent viewing the DA has previously been related to higher knowledge scores<sup>14</sup>. An image of the DA corresponding to their condition, which was quite distinctive, was included to remind patients what the DA looked like.

##### Knowledge

Patients were asked to answer 5 disease-specific, multiple-choice knowledge questions specific to each condition; these questions have been previously validated<sup>15-17</sup>. The items are scored on a scale of 0% to 100%, with higher scores indicating greater knowledge.

##### Covariates

Patients were asked to self-report their overall health, whether they were referred by their primary care physician, their health literacy based on a 1-item screener<sup>18</sup>, their highest level of education completed, and their race and ethnicity.

##### DA Order in the Electronic Medical Record

Order status was obtained via an institutional report created to track DA orders documented in the year prior to surgery (yes or no).

TABLE 1 Decision Aid (DA) Exposure Based on Documentation in the Chart and Patient Self-Report

	Prescribed a DA		Total (N = 700)
	Yes (N = 282)	No (N = 418)	
Self-reported receipt of a DA			
Yes	167	195	362
Self-report of amount of DA reviewed			
All	112	117	229
Most	37	46	83
Some	14	29	43
None	2	3	5
Missing*	2	0	2
No	109	214	323
Missing*	6	9	15
Primary analysis (DA reviewed)†			
Exposed	163	192	355
Not exposed	111	217	328
Sensitivity analysis (DA ordered)†			
Exposed	167	0	167
Not exposed	0	214	214
Discordant (excluded)	109	195	304

\*17 patients with missing responses were not included in the primary analysis. †Exposed = DA received and reviewed all, most, or some; not exposed = DA received and reviewed none or DA not received.

### Defining DA Exposure

DA exposure was originally defined as DA documentation in the electronic medical record. The documentation suggested that 282 (40.3%) of 700 patients had a DA order and that 418 (59.7%) of 700 did not. After being shown a picture of the DA in the survey, 60% of patients with a DA order recalled receiving the DA, whereas 39% without a DA order also indicated that they had received it. Given this discrepancy between the chart documentation and patient recollection, we redefined DA exposure to represent patient self-reporting of the amount of the DA reviewed (i.e., “some,” “most,” or “all” versus “none” or “not received”). For a sensitivity analysis, we created an exposure variable that considered a patient exposed if both the patient reported receiving the DA and the order was documented, and the patient was considered not exposed if they did not receive it and there was no documentation. All discrepant responses were excluded from the sensitivity analysis.

### Statistical Analyses

Data were summarized with use of means with standard deviations (SDs) for continuous variables and frequencies with percentages for categorical variables. For the 2 outcome variables, 58% of the sample reported complete trust in the surgeon (score = 20) and 63% reported no regret (score = 0). Given the skewness of the scores, the measures of trust and regret were dichotomized according to the proportion reporting the highest score for trust and the lowest score for

regret. Logistic regression models with the generalized estimating equations approach were utilized to examine if DA exposure predicted trust or regret after controlling for potential confounders, while accounting for the clustering of patients within surgeons. The prespecified covariates in the models included age, gender, race, education, overall health, referral by primary care physician, and surgical condition. A sensitivity analysis compared respondents whose DA order matched their self-report and excluded those who had discordant data. To understand whether reviewing the DA increased trust through an improvement in shared decision making, we also conducted an exploratory mediation analysis. All analyses were conducted with use of SAS (version 9.4; SAS Institute).

This study was originally designed to collect 600 completed surveys—300 from patients who received a DA and 300 from patients who had not—which would provide 80% power to detect a clinically important absolute difference on the trust scale of 0.25 (SD, 0.33) with a 2-sided alpha error of 5%. This sample size would also be able to detect a 0.33 SD absolute difference (i.e., about 5 points on a 100-point scale) in the regret measure, a relatively small effect. However, as we approached the final sample size of 600, only 30% of the respondents had received a DA. To maximize the number of patients who received a DA, we obtained institutional review board approval to continue recruiting patients who received a DA. By maximizing the number of patients who received a DA during the study interval, we

maintained the planned power for the analyses comparing the trust and regret measures between patients who did and did not receive a DA.

### Source of Funding

This study was supported by a grant from CRICO/Risk Management Foundation of the Harvard Medical Institutions.

### Results

Of 1,541 subjects screened, 288 were ineligible. Of the 1,253 eligible patients, 700 (56%) responded to the survey (Fig. 1). There were similar proportions of female patients among responders and non-responders, but responders were older (66 versus 63 years, respectively;  $p < 0.001$ ), more likely to be White (92.6% versus 87.3%;  $p = 0.002$ ), more likely to have had hip surgery (33.1% versus 26.0%;  $p = 0.008$ ), and less likely to have had herniated disc surgery (7.3% versus 11.2%;  $p = 0.014$ ).

Table I displays frequencies for the 2 exposure definitions. Of the 700 patients, 282 (40.3%) had a recorded DA order. A total of 362 patients (51.7%) reported receiving a DA, of whom 355 (98.1%) reported reviewing some, most, or all of the DA. Our primary analysis compared the 355 patients who reported reviewing at least some of the DA to the 328 who reported reviewing none ( $n = 5$ ) or never receiving the DA ( $n = 323$ ).

Table II describes the patient characteristics by DA exposure. The mean age of patients was 65.8 years, 55.3% were female, 89.4% were White, 63.7% had a college degree, and 69.4% had hip or knee surgery. Those who reviewed the DA were more likely to be male, had slightly less education, had lower health literacy, and were more likely to complete the survey in paper mode. Age, race, ethnicity, overall health, and whether the patient was referred by their primary care provider did not differ by DA exposure.

Table III displays the percentage of patients with top trust and regret scores according to the 2 definitions of DA exposure. Based on the primary analysis, the patients who reviewed the DA were more likely to report complete trust (64%) compared with those who did not (51%;  $p < 0.001$ ). The proportion of patients who reported no regret was similar in all groups. Patients who reviewed the DA did not have

higher knowledge than those who did not review the DA, but did have higher Shared Decision Making Process Scale scores (2.6 versus 2.3;  $p = 0.001$ ). However, in the sensitivity analysis, patients who had a DA order and self-reported reviewing the DA had a higher knowledge score (3.1) than those who had neither been prescribed nor reviewed a DA (2.6;  $p = 0.003$ ).

In the logistic regression models controlling for covariates and condition and accounting for clustering of patients within surgeons, patients exposed to the DA were more likely to report complete trust compared with those who were unexposed (adjusted odds ratio [aOR], 1.62; 95% confidence interval [CI], 1.11 to 2.36;  $p = 0.013$ ). In the sensitivity analyses focused on the subset of patients with a concordant DA order and patient self-report responses, the group that was exposed to a DA was more likely to report complete trust, although the result did not reach significance (aOR, 1.30; 95% CI, 0.80 to 2.11) (Table IV). In both models, better overall health was a significant predictor of complete trust, whereas patients with higher educational attainment were less likely to report complete trust. There was no difference in regret between those exposed or unexposed to a DA in both sets of analyses.

Based on the findings that the group who recalled receiving and reviewing “some, most, or all” of the DA were more likely to report complete trust and had higher Shared Decision Making Process Scale scores, we conducted an exploratory mediation analysis. We found that 19.3% (95% CI, 3.1% to 35.4%) of the effect of DA review on complete trust can be attributed to the increase in SDM Process scores.

### Discussion

This project, which studied the relationship of trust and regret with receipt of a DA prior to major orthopaedic surgery, found that patients who recalled receiving and reviewing a DA were more likely to report complete trust in their surgeon at 6 months postoperatively. There was no relationship between DA exposure and regret.

The importance of trust in health care was discussed in a series of articles published in 2019<sup>19-23</sup>, as well as other articles that focused on medical mistrust and race<sup>24-26</sup>. The impact of SDM and DAs on factors that may drive medicolegal risk, including trust and regret, have received little attention. In a recent trial assessing clinician trust and the use of a DA for surgery versus medical treatment for benign prostatic enlargement, Piercy et al. reported that 58.5% of patients who received a DA indicated that they trusted their urologist more as a result of viewing the DA, and 69.4% thought that the DA would increase the trust of most patients<sup>27</sup>. Few studies have examined the impact that SDM and the use of a DA have on regret. Another study that followed men for 15 years after making a decision about treatment for early-stage prostate cancer reported that one of the strongest predictors of lower long-term regret was participants reporting that they had made an informed treatment decision initially<sup>28</sup>.

The routine use of DAs has resulted in patients who are more informed and involved in their decisions to undergo elective orthopaedic surgery<sup>15,16,29</sup>. However, the task of getting DAs to the right patients at the right time remains a challenge.

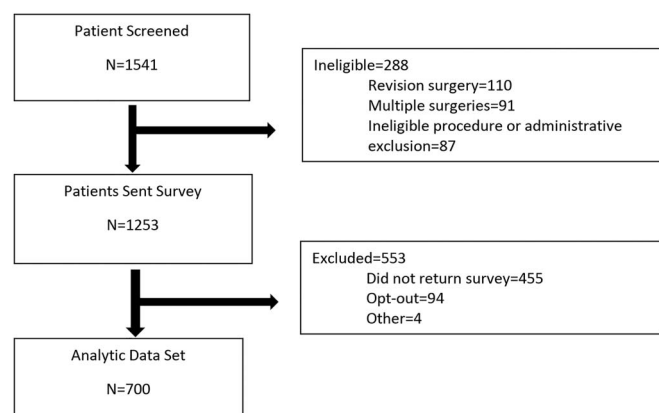


Fig. 1  
Study population flowchart.

**TABLE II Patient Characteristics by Decision Aid (DA) Exposure\***

	Primary Analysis: DA Reviewed			Sensitivity Analysis: DA Ordered			
	Not Exposed	Exposed	P Value	Not Exposed	Exposed	P Value	Discordant (Excluded)
	N = 328	N = 355		N = 214	N = 167		N = 304
Age (yr)	65.7 (10.8)	65.6 (10.0)	0.87	64.4 (11.4)	65.7 (9.7)	0.23	66.5 (9.9)
Female gender	58.8%	51.3%	0.047	62.1%	56.3%	0.25	49.3%
Race or ethnicity			0.24			0.13	
Hispanic	1.2%	1.1%		0.9%	2.4%		0.7%
Non-Hispanic White	91.2%	88.5%		92.1%	87.4%		89.1%
Non-Hispanic Black	1.8%	2.8%		0.9%	1.8%		3.6%
Asian	0.6%	2.0%		0.9%	1.8%		1.3%
Multi-race/other	0.9%	0.8%		1.4%	0.6%		0.7%
Education			0.09			0.99	
High school or less	10.7%	14.1%		11.7%	10.8%		13.8%
Some college	21.3%	23.1%		22.4%	21.6%		22.4%
4-year degree	23.2%	26.5%		25.7%	26.3%		23.4%
>4-year degree	44.2%	34.6%		39.7%	38.3%		39.1%
Literacy screen†			0.02			0.63	
Never	79.3%	73.2%		79.0%	76.6%		73.7%
Rarely	14.6%	15.2%		14.5%	15.0%		15.1%
Some/often/always	6.1%	11.0%		6.5%	7.8%		10.5%
Overall health			0.55			0.14	
Poor	1.2%	0.8%		0.9%	1.2%		1.0%
Fair	9.8%	8.2%		11.2%	4.8%		9.5%
Good	38.4%	35.8%		35.5%	37.1%		38.2%
Very good	36.3%	37.2%		37.9%	36.5%		36.2%
Excellent	14.0%	17.2%		14.5%	19.8%		14.1%
Mode			0.07			0.71	
REDCap	67.7%	60.6%		66.4%	65.3%		61.2%
Paper	31.4%	39.2%		32.2%	34.1%		38.8%
Phone	0.9%	0.3%		1.4%	0.6%		0.0%
PCP referred, yes	26.2%	29.9%	0.27	27.1%	32.9%	0.20	26.3%
Condition			0.047			<0.001	
Herniated disc	8.5%	6.5%		12.6%	4.2%		5.6%
Hip osteoarthritis	29.6%	37.5%		25.7%	44.3%		33.2%
Knee osteoarthritis	35.4%	36.6%		29.9%	44.3%		36.2%
Spinal stenosis	26.5%	19.4%		31.8%	7.2%		25.0%

\*Values are given as the mean with the SD in parentheses or as the percentage. PCP = primary care physician. †"How often does someone help you read instructions, pamphlets, or other written material from your doctor or pharmacy?"

In the present study, many patients (40.8%) did not recall receiving the DAs that were sent via the patient portal. We were surprised that 46.0% of patients who did not have a DA order recalled receiving the DA. We believe that many hard copies of the DAs were passed out in practices without making a notation in the institutional prescription log. For this reason, we chose patient recall of receiving and reviewing a DA as our primary exposure variable. The amount of the DA reviewed is probably the most relevant definition

for studying whether DA exposure increases trust in the surgeon and decreases decision regret postoperatively.

We examined the effect of DA exposure in a sensitivity analysis excluding those with discordance between the chart and self-report. Trust was higher in those who reported that they reviewed a DA compared with those who did not, and it was not different in those who were prescribed a DA and reviewed it compared with those who did not receive or review it. About 60% of patients reported



**TABLE III Percent with Top Trust, and No Regret, Knowledge Scores, and Shared Decision Making Process Scores by Decision Aid (DA) Exposure Status\***

	Primary Analysis: DA Reviewed			Sensitivity Analysis: DA Ordered			
	Not Exposed	Exposed	P Value	Not Exposed	Exposed	P Value	Discordant
	N = 328	N = 355		N = 214	N = 167		N = 304
Complete trust (score = 20)	50.9%	63.8%	<0.001	51.4%	59.9%	0.10	61.1%
No regret (score = 0)	60.3%	65.2%	0.19	63.8%	65.4%	0.74	60.6%
Knowledge score	2.7 (1.4)	2.8 (1.4)	0.30	2.6 (1.4)	3.1 (2.2)	0.003	2.6 (1.4)
Shared Decision Making Process Scale	2.3 (1.2)	2.6 (1.1)	0.001	2.4 (1.1)	2.5 (1.0)	0.28	2.5 (1.1)

\*Values are given as the mean with the SD in parentheses or as the percentage.

no regret. Regret may be driven primarily by surgical outcome, rather than the decision-making process. Our finding that DA review was not associated with higher knowledge was unexpected, as prior studies have generally found that patients exposed to DAs have higher knowledge scores<sup>6</sup>, including in a prior study in this population<sup>29</sup>. We cannot explain this finding, but nonetheless found increased trust with DA exposure.

The Shared Decision Making Process Scale score was higher among patients who recalled receiving and reviewing some, most, or all of a DA compared with reviewing none of or not receiving a DA, even after accounting for potential confounders. The mediation analysis, which examined the effect of reviewing a DA on complete trust, found that some of this effect could be attributed to an increase in SDM. The mean Shared Decision Making Process Scale score in this study was similar to that reported in other orthopaedic trials<sup>14</sup>.

The present study had several limitations. Patients who seek care from this type of facility may differ from patients who seek care at other hospitals. This study was not a randomized trial, so we cannot exclude residual bias as a result of uncontrolled confounding. It is possible that surgeons who are more likely to use DAs may be perceived as trustworthy in other ways. There is limited generalizability because <4% of patients were non-Hispanic Black or Hispanic, and 64% of the population had a college degree. Finally, we can estimate the precision of the probability of no regret with DA exposure by utilizing the probability of regret in the unexposed group (60%). The probability of no regret with DA exposure would be expected to be anywhere between 56% to 70%, based on the confidence intervals around the odds ratio of regret with DA exposure (Table III). If smaller differences in the absence of patient-reported postoperative regret are clinically important, our sample size may have been insufficient to detect them.

**TABLE IV Multivariable Models Predicting Complete Trust (Score = 20) and No Regret (Score = 0)\***

	Complete Trust				No Regret			
	Primary Analysis: DA Reviewed		Sensitivity Analysis: DA Ordered		Primary Analysis: DA Reviewed		Sensitivity Analysis: DA Ordered	
	aOR (95% CI)	P Value	aOR (95% CI)	P Value	aOR (95% CI)	P Value	aOR (95% CI)	P Value
DA exposure (exposed vs. not exposed)	1.62 (1.11-2.36)	0.013	1.30 (0.80-2.11)	0.29	1.15 (0.86-1.55)	0.34	0.79 (0.49-1.29)	0.35
Age (per 10 years)	0.91 (0.78-1.07)	0.27	0.92 (0.75-1.11)	0.37	0.86 (0.76-0.98)	0.021	0.90 (0.71-1.13)	0.35
Education (per level of education)	0.75 (0.61-0.91)	0.004	0.78 (0.63-0.96)	0.021	0.96 (0.77-1.19)	0.70	1.02 (0.74-1.40)	0.91
Overall health (per level [Table II])	1.48 (1.20-1.82)	<0.001	1.44 (1.05-1.96)	0.023	2.06 (1.66-2.57)	<0.001	2.30 (1.72-3.07)	<0.001
Gender (male vs. female)	1.06 (0.69-1.61)	0.80	0.92 (0.57-1.49)	0.74	1.14 (0.86-1.51)	0.35	1.23 (0.89-1.71)	0.22
Race (other vs. non-Hispanic White)	0.69 (0.44-1.08)	0.11	0.59 (0.33-1.06)	0.077	0.42 (0.23-0.77)	0.005	0.39 (0.21-0.73)	0.004
Referred by PCP (yes vs. no)	0.89 (0.62-1.27)	0.51	0.83 (0.54-1.28)	0.41	0.99 (0.70-1.41)	0.97	1.32 (0.81-2.15)	0.26
Condition (OA vs. HD/SS)	0.89 (0.65-1.20)	0.44	1.07 (0.66-1.71)	0.79	1.11 (0.74-1.66)	0.62	1.18 (0.81-1.74)	0.39

\*Models accounted for clustering of patients within surgeon. DA = decision aid, PCP = primary care physician, OA = osteoarthritis, HD = herniated disc, SS = spinal stenosis.

In conclusion, patients who reported receiving and reviewing some, most, or all of a DA prior to orthopaedic surgery were more likely to report complete trust in their surgeon. Simply prescribing DAs to patients before surgery is not enough. Ensuring that patients review DAs may increase trust in the surgeon, which may reduce the risk of malpractice litigation. ■

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