Disclosure of Financial Conflicts of Interest

An Evaluation of Orthopaedic Surgery Patients' Understanding

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Abstract

Background Industry and orthopaedic surgeons often partner to develop new technology, which can lead to orthopaedic surgeons having financial conflicts of interest (FCOI). It is essential these FCOI be conveyed clearly to patients. It is unclear, however, whether and to what degree patients understand the ramifications of physician FCOI.

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Each author certifies that his or her institution approved or waived approval for the human protocol for this investigation and that all investigations were conducted in conformity with ethical principles of research.

This study was performed at University of Connecticut Health Center, Farmington, CT, USA.

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Questions/purposes We evaluated (1) patients' concerns regarding their surgeon having FCOI or the presence of institutional FCOI, (2) the effect of surgeon FCOI on patients' willingness to have surgery, and (3) patients' understanding of FCOI.

Methods We asked 101 patients (66% female) receiving total joint arthroplasty from the orthopaedic practices of two surgeons at an academic health center to complete a descriptive, correlational designed survey at their 6-week followup appointment. The data collected included patient demographics, knowledge of FCOI, and the influence of FCOI on patient attitudes toward surgery and their surgeon.

Results A minority of patients (13%) reported discussing FCOI with prior physicians and only 55% agreed or strongly agreed a surgeon should disclose FCOI. Only 15% of patients believed such conflicts would make them less likely to have their surgeon operate on them. Level of education was weakly correlated (Spearman's rho = 0.29) with patient understanding of FCOI.

Conclusions Overall, patients had a poor understanding of FCOI. Both level of education and previous discussions of FCOI predicted better understanding. This study emphasizes communication of FCOI with patients needs to be enhanced.

Introduction

Over the past several years, there have been increased concerns about the impact of financial conflicts of interest (FCOI) on both the surgeon-patient relationship and the outcomes of total joint arthroplasty procedures. There is a general agreement within the orthopaedic community that these financial conflicts need to be disclosed to patients [1, 2, 6, 10].

Although physicians believe the disclosure of FCOI can improve trust between the patient and their physician, the best method to provide this information to patients has not been identified [13]. A number of studies have been conducted evaluating patient attitudes toward disclosure of FCOI related to clinical research [3, 8, 13, 14]. Three of these studies presented hypothetical situations and then surveyed patients on the potential impact FCOI had on patient trust and the desire to participate in a clinical research project [3, 8, 13]. Most patients had little understanding of FCOI despite extensive discussion. Patients wanted [4, 5] to be informed of FCOI, but this had little impact on their decision as to whether or not to participate in a clinical trial. However, it is unclear whether and to what extent patients understand disclosures communicated to them by their surgeon. We were unable to identify other studies in the literature that evaluated patients' understanding of FCOI in other areas of orthopaedic surgery or in other areas of medicine.

We therefore evaluated (1) patients' concerns regarding their surgeon having FCOI or the presence of institutional FCOI, (2) the effect of surgeon FCOI on patients' willingness to have surgery, (3) patients' understanding of disclosure of FCOI after reading and signing a specially designed form provided to patients at the time of their preoperative visit, and (4) potential relationships among various demographic variables and responses to survey items to identify factors that may contribute to patients' understanding of FCOI.

Patients and Methods

From September 2010 to September 2011, we asked all patients 18 years old or older scheduled for primary THA and TKA from the orthopaedic practices of two joint arthroplasty specialists (JRL, GGP) at an academic health center to participate in our study. During the study period, we operated on 247 patients with primary THA and TKA. The patients were told their surgeon was doing a study to gain further understanding of patients' knowledge of and attitudes toward potential FCOI. One hundred one of the 247 patients (41%) agreed to participate (Table 1). The mean ($\pm$ SD) age was 63 ± 13 years (range, 27–88 years); 66% were female; 69% of patients held a college degree or higher; and 83.2% identified themselves as white. One patient did not provide demographic information. The patients underwent 42 (42%) primary THAs and 55 (55%) TKAs. The specific joint operated on could not be identified for four patients. This study received an exempt status from the institutional review board. Neither of the surgeons had received either royalties or research support from an implant manufacturer. One of the surgeons (JRL) has a

consulting agreement with an implant manufacturer, but it was not related to the use of implants used in these patients.

All patients in the department of orthopaedic surgery are given a form entitled "Written Patient Disclosure: Orthopaedic Inventions and Know-How" (Appendix 1; supplemental materials are available with the online version of CORR) to read and sign before their operative procedure. This form educates patients with respect to potential FCOI that surgeons may have related to their surgery. All patients receive this form from the medical assistant when they come to the office to give informed consent for their operative procedure. Just before the 6-week followup visit, the surgeons asked the patients if they wanted to participate in this study by filling out a survey. Patients were given the opportunity to ask questions regarding the purpose of the survey with their surgeon. The patients were assured their responses would remain anonymous and would have no impact on their care. The surveys were not reviewed by the surgeon at the time of the office visit. If the patient agreed to participate in the study, he or she was given the survey by a medical assistant and asked to fill it out. At their 6-week followup visit, the study patients completed a descriptive, correlational designed survey entitled "Disclosure of Financial Conflicts of Interest Survey" (Appendix 2; supplemental materials are available with the online version of CORR®). The following issues were assessed: patient demographics including age, sex, education level, race, and type of surgery; previous knowledge of FCOI; and the effect of FCOI on patients' interest in having that surgeon operate on them. In addition, we evaluated the patients' understanding of the Written Patient Disclosure: Orthopaedic Inventions and Know-How form via a quiz on the content of the form. These sections addressed the patients' understanding of the

Table 1. Demographic data for patients undergoing total joint arthroplasty

Characteristic	Value
Number of patients*	100
Age (years) [†]	63 ± 13.3 (27–88)
Sex (female:male)	66 (66%):34 (34%)
Education	
< 9 th grade	1 (1%)
Some high school	5 (5%)
High school	5 (5%)
College	49 (49%)
Master's degree	17 (17%)
Doctoral degree	3 (3%)

* There were 101 patients in the study population, but demographic data were missing from one patient; values are expressed as mean $\pm$ SD, with range in parentheses; the remaining values are expressed as the number of patients, with percentages in parentheses.

form through direct questions and contained a quiz on the content of the form. Most of the questions used a Likert-type scale with a score of 1 representing strong disagreement with the statement and a score of 5 representing strong agreement with the statement.

We calculated descriptive statistics for demographic variables and survey forms, including percentage of patients seen by each surgeon, percentage of patients having each type of surgery, percentage of patients who had previously discussed disclosure of FCOI with another clinician, and percentage of patients who remembered signing the conflict of interest form. Patients who did not answer these questions were not included in the calculation of the average score for this section. The average score for all participants on the quiz at the end of the survey was calculated. Patients were given 1 point for each correct answer, for a maximum quiz score of 6. Patients who left this section blank were not included in calculating the average score for all patients. However, patients who commented they did not know the answers to questions were given a 0 for their quiz score.

To answer the four primary research questions, we performed descriptive statistical tests (central tendencies and frequencies) and bivariate analyses (correlations). For Question 1, patient concern regarding their surgeon having FCOI or the presence of institutional FCOI, the frequencies of responses to Items 5 through 9 in Section IV of the survey were summarized. This process was repeated for Question 2, the effect of surgeon FCOI on patient willingness to have surgery, using Items 1 through 6 in Section V of the survey. For Question 3, patients' understanding of disclosure of FCOI after reading and signing a specially designed form provided to the patient at the time of their preoperative visit, the mean and SD of the quiz score were calculated. For Question 4, exploration of factors that may contribute to a patient's understanding of FCOI, correlation analysis was performed to identify association between patient understanding and collected demographic variables and

responses to survey questions. The quiz score was selected to serve as a proxy variable for patient understanding of FCOI. Spearman rank correlation coefficients were calculated for age, sex, and education in relation to quiz score and for each Likert item on the survey. For questions regarding previous discussion of FCOI and memory of signing the disclosure form in which responses were dichotomous in nature (yes/no), point biserial correlation coefficients were calculated. An alpha level of 0.05 was considered significant for all correlation analyses. We performed all statistical analyses using Stata® 12 (Release 12; StataCorp LP, College Station, TX, USA).

Results

Thirteen patients (13%) had received information regarding FCOI from a surgeon in the past. Thirty-four patients (39%) had not heard of FCOI related to clinical research whereas 41 patients (47%) had previous knowledge of FCOI and 12 patients gave a neutral answer (Table 2, Appendix 3; supplemental materials are available with the online version of CORR). Seventy-three patients (81%) were either not concerned or minimally concerned if their surgeon had FCOI whereas six patients (7%) were very concerned. Similarly, 71 patients (79%) were not worried or had minimal worries about institutional FCOI, and eight patients (9%) indicated concern. Twenty-nine patients (33%) did not want their surgeon to disclose FCOI whereas 48 patients (55%) believed surgeons should make patients aware of FCOI. Twenty-one patients (24%) indicated they would trust a surgeon less if he or she had FCOI, 39 patients (44%) disagreed with this statement, and 28 patients recorded a neutral response.

The effect of surgeon FCOI on patient willingness to be operated on by that particular surgeon was also evaluated (Table 3). Thirteen patients (14%) indicated, if their surgeon had developed a prosthesis used in their surgery, they

Table 2. Patients' opinions regarding physician FCOI

Question*	Number of patients responding	Patient response [†]				
		1	2	3	4	5
5) Surgeon disclosure of FCOI	88	25 (28%)	4 (5%)	11 (13%)	8 (9%)	40 (46%)
6) Extent of surgeon FCOI	90	21 (23%)	7 (8%)	15 (17%)	12 (13%)	35 (39%)
7) Trust and surgeon FCOI	88	32 (36%)	7 (8%)	28 (32%)	7 (8%)	14 (16%)
8) Problem with surgeon having FCOI	90	39 (43%)	9 (10%)	17 (19%)	7 (8%)	18 (20%)
9) Trust surgeon to use best product	97	13 (13%)	2 (2%)	3 (3%)	8 (8%)	71 (73%)

* Summarized versions of Questions 5 to 9 from Section IV of Disclosure of Financial Conflicts of Interest Survey; refer to the full survey in Appendix 2 for the complete wording of each question; [†]responses to this section's self-reported patient questions were developed as Likert scales: a score of 1 indicates a patient strongly disagrees with the statement, a score of 3 indicates neutrality, and a score of 5 indicates a patient strongly agrees with the statement; numbers of patients responding with each score are listed, with percentages in parentheses based on the number of patients responding to a given question; FCOI = financial conflicts of interest.

Table 3. Impact of surgeon FCOI on patients' willingness to undergo total joint arthroplasty

Question*	Number of patients responding	Patient response [†]				
		1	2	3	4	5
1) Surgeon developed prostheses	86	8 (9%)	5 (5%)	29 (34%)	14 (16%)	30 (35%)
2) Surgeon receives revenue from company	90	18 (20%)	18 (20%)	34 (38%)	8 (9%)	12 (13%)
3) Surgeon has stock in company	90	27 (30%)	13 (14%)	28 (31%)	8 (8%)	14 (15%)
4) Surgeon may receive future revenue	89	22 (25%)	17 (19%)	31 (35%)	7 (8%)	12 (14%)
5) Surgeon paid for product used in surgery	88	24 (27%)	14 (16%)	33 (38%)	3 (3%)	14 (16%)
6) Surgeon paid for product not used in surgery	87	14 (16%)	8 (9%)	39 (45%)	8 (9%)	18 (21%)

* Summarized versions of Questions 1 to 6 from Section V of Disclosure of Financial Conflicts of Interest Survey; refer to the full survey in Appendix 2 for the complete wording of each question; [†]responses to this section's self-reported patient questions were developed as Likert scales: a score of 1 indicates a patient would be less likely to have a surgeon operate on them; a score of 3 indicates neutrality, and a score of 5 indicates a patient would be more likely to have a surgeon operate on them; numbers of patients responding with each score are listed, with percentages in parentheses based on the number of patients responding to a given question; FCOI = financial conflicts of interest.

would be less willing to have this surgeon perform the operation. However, 44 patients (51%) would be more willing to be operated on by a surgeon who developed a prosthesis used in their surgery. In contrast, patients had concerns about surgeon relationships with companies. Thirty-six patients (40%) answered they would be less likely to be operated on by a surgeon if he or she received revenue from a company. Patients were concerned ($n = 38$, 43%) if the surgeon was paid by a company that manufactured a product used in the surgery but were less concerned ($n = 22$, 25%) if the company did not make a product to be used in the surgery.

At the 6-week followup visit, 42 patients (45%) remembered signing the Written Patient Disclosure: Orthopaedic Inventions and Know-How form preoperatively. The patients' understanding of this form was also evaluated (Appendix 4; supplemental materials are available with the online version of CORR). The mean quiz score for all patients was 3.48 ± 1.83 of a possible 6 (Appendix 5; supplemental materials are available with the online version of CORR). Neither age nor sex was associated with the quiz score. Remembering signing the form was not associated with total understanding. The results of the quiz scores were not influenced by which surgeon performed the procedure. Level of education had a weak positive correlation with total understanding of the form (Spearman's $\rho = 0.29$, $p = 0.02$).

Discussion

There is general agreement that it is essential for surgeons to disclose FCOI to their patients. However, the best method to communicate this information has not been identified. We therefore determined (1) patients' concerns regarding their surgeon having FCOI or the presence of institutional FCOI, (2) the effect of surgeon FCOI on the

patients' willingness to have surgery, (3) patients' understanding of disclosure of FCOI after reading and signing a specially designed form provided to patients at the time of their preoperative visit, and (4) potential relationships among various demographic variables and responses to survey items to identify factors that may contribute to patients' understanding of FCOI.

This study does have some clear limitations. First, patients were left to take the survey on their own in examination rooms while waiting for their physician. Although the patients had their privacy and their answers were anonymous, the results may have been more reliable if they were observed by a research coordinator to ensure they were answering all the questions. Second, the patient demographics of our practice tend to be skewed toward well-educated whites, which is not representative of most orthopaedic groups nationwide. Third, approximately 59% of patients were not interested in filling out the survey and this could bias our results in some way that cannot be determined. It could be argued patients with some interest in FCOI would be more likely to fill out the form, which suggests the overall population of patients would have even less knowledge and interest in FCOI. Finally, we evaluated only patients with arthroplasty in this study, and therefore, we cannot extend our findings to patients treated with nonarthroplasty procedures. Despite these limitations, our findings suggest changes need to be made in the manner in which patients learn about FCOI. In addition, unlike most studies that analyze patients' understanding of FCOI, we did not use hypothetical situations. Instead, we evaluated the attitudes of patients that received information regarding FCOI and had just received a total joint arthroplasty.

Our results were quite surprising to us. Patients had less knowledge of FCOI than we expected and patients' concerns regarding FCOI were less than we had hypothesized. Only 47% of patients reported they were aware of FCOI before participating in this study, and only 55% of our

patients wanted to learn of these FCOI [3, 4, 8]. The majority of patients in our study had not had prior conversations related to FCOI with other physicians, as only 13% had heard of them before from a clinician. These findings have been noted in other areas of medicine [5, 11, 12].

Patients' concerns related to FCOI were variable. The majority of patients (81%) had no or minimal concerns if the surgeon had FCOI or if there were potential institutional FCOI (79%). Although 55% believed surgeons should disclose FCOI, 33% did not believe it was necessary. Many patients (51%) would be more likely to be operated on by a surgeon who had developed a prosthesis. Furthermore, only 40% of patients answered they would be concerned if a surgeon had a financial relationship with a company. These findings suggest patients may believe a surgeon's participation in the development of a prosthesis is associated with a higher level of clinical expertise and the surgeon would have a better understanding regarding the use of the prosthesis, which could lead to better outcomes. However, some patients were not aware surgeons may receive royalties from a manufacturer for developing a prosthesis and that this poses FCOI. It appears patients may not truly comprehend the different types of financial relationships that surgeons may have with manufacturers and that these relationships can influence surgeon behavior. Since patients seemed to be less concerned if a surgeon was receiving royalties from a manufacturer than if he or she had a "financial relationship" with a company, this suggests patients did not understand a surgeon designer may not only have FCOI but perhaps a bias to use a prosthesis because he or she helped participate in the design of the implant.

Khan et al. [7] performed a study to evaluate patients' attitudes regarding surgeon and medical device manufacturer's collaborations. Patients with spine problems filled out an eight-question survey in the office. The majority of patients (94.3%) believed it was beneficial to them to have surgeons act as consultants to industry and a majority (66%) believed it was appropriate for surgeons to receive remuneration for this work. In addition, approximately 73% of patients would want to know whether their doctor designed the device used in the surgery and 89% believed it was reasonable for a doctor to recommend a device he or she had designed [7].

We were surprised the majority of the patients in our study were not concerned about surgeons having FCOI or the potential for institutional FCOI. Our expectation was that this would be a concern to the majority of patients. The patients' attitudes may reflect their trust in their particular surgeon or that they were satisfied with their outcome. These findings should not be interpreted to mean FCOI are not important. The results suggest, even after reading a form, some patients do not understand different types of FCOI.

Prior discussion of FCOI predicted a higher level of understanding of the form. There was a weak correlation between level of education and comprehension of the form. These findings highlight the importance of using a disclosure of FCOI form at the appropriate reading level for a general patient population and that increased exposure to information related to FCOI enhances understanding of this topic.

Our findings suggest just providing written material at an office visit is not sufficient for many patients to totally understand FCOI. Only 45% of our patients recalled receiving the FCOI form and many others did not fully understand the potential impact that FCOI could have on their care. Similar findings have been noted when assessing patient's understanding of informed consent for surgical procedures. In a recent review of this literature, Muslow et al. [9] found in patients undergoing general surgery there was poor understanding of the surgical procedure even though consent had been obtained, and the authors suggested different teaching aids should be made available to patients to increase comprehension. The authors suggested a computer-based simulation could be used to enhance patient understanding related to informed consent.

Although the opportunity to review FCOI information with a physician or a physician extender during an office visit may improve comprehension, patients may be uncomfortable discussing these issues with their surgeon. A more detailed description of FCOI may be necessary for some patients. The availability of other reading materials related to FCOI may be helpful. Perhaps comprehension would be improved if patients read the form at home before coming to the office visit so they had more time to read it. Finally, the use of a video or an online teaching module may be helpful. It is critical that orthopaedic surgeons analyze their method of disclosing FCOI to improve patient understanding, enhance the patient-doctor relationship, and avoid legal liability and patient dissatisfaction in the future.

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