

The Surgeon as a Consultant for Medical Device Manufacturers

What Do Our Patients Think?

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Study Design. Patient survey.

Objective. To evaluate patient perspective on surgeons as consultants for industry and medical device manufacturers.

Summary of Background Data. Relationships between surgeons and medical device manufacturers are becoming increasingly common. Little is known, however, about how patients perceive these relationships.

Methods. Patients in the waiting area of an orthopedic surgery clinic were given a simple 1-page, 8-question anonymous questionnaire. Their responses were tabulated and analyzed for 3 variables: gender, age, and education level.

Results. A total of 245 patients completed the questionnaire. An overwhelming majority (94.3%) believed that surgeon-industry relationship is beneficial to patients, and a majority (66.5%) of patients thought that physicians should be compensated for this role. Women were more likely than men to want this relationship to be regulated by physicians instead of the government or hospitals. Patients older than 55 years were less likely to be in favor of physicians being compensated than younger patients. The more educated the patient, the less likely he/she was in favor of allowing physicians to regulate physician-industry relationship.

Conclusion. Patients support surgeons in the role of consultants for industry. Gender, age, and education level influence the way that patients perceive this issue.

Key words: industry, conflict of interest, consultant.
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The involvement of physicians and surgeons in the design and manufacturing aspects of medical devices and instruments has led to questions about potential conflict of interest issues.¹ In recent years, this topic has been the subject of numerous articles in the popular and scientific press.^{2–4} Most of this discussion has been generated by researchers, physicians, and ethicists, but little data exist in the literature about how patients view this issue.

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The goal of this patient survey-study was to understand how patients perceive the relationship between surgeons and medical device manufacturers. To our knowledge, this subject has not been studied from the patients' perspective in this way previously.

Methods

Patients in the waiting area of the orthopedic spine surgery clinic were given the option of answering a simple 1-page, 8-question anonymous questionnaire (Table 1) on a voluntary basis. The questions were developed and refined by the authors in conjunction with an epidemiologist (J.I.) with the goal of making them easy to understand for an audience of varying educational and socioeconomic backgrounds, and to also minimize bias in the phrasing of the questions.

The questionnaire was given to all patients, including patients who had or were planning to have surgery and those who were undergoing nonoperative treatment. Data from all questionnaires were compiled and tabulated. The data were analyzed using SPSS software (Chicago, IL).

Results

A total of 245 patients (51.0% female, 49.0% male; average age 55.5 ± 14.5 years) filled out the complete questionnaire. The cumulative responses of the patients are shown in Table 1.

An overwhelming majority of patients (94.3%) thought that the advisory role of physicians to medical device manufacturers was beneficial to them (Q1), and a large majority (66.5%) believed that physicians should be compensated for this role (Q2). Slightly fewer than half (48.2%) thought that physician-medical device manufacturer relationship should be regulated, while 19.2% believed that it should not be subject to any regulations (Q3). Of those who thought that such a relationship should indeed be regulated, most (32.2%) were of the opinion that physicians rather than hospitals or the government should control such regulation (Q4). A large majority (72.7%) of patients wanted to know if the device being recommended by their physician was actually designed by him/her (Q5), and the overwhelming majority (89.4%) of patients believed that the physician should be allowed to recommend the use of a device that he/she helped design (Q6).

Patient responses were further analyzed based on gender (female *vs.* male), age (55 years or younger *vs.* >55 years), education level (high-school *vs.* college *vs.* graduate/postgraduate), and whether or not they had/were

Table 1. Patient Questionnaire and Responses for All Patients

Q1	Do you think it is beneficial for you if doctors can advise the medical device manufacturers to improve/design medical instrumentation?	Yes 94.3%	No 0%	Unsure 5.7%	No answer 0%
Q2	Do you think that the doctors should be compensated for this advisory role?	Yes 66.5%	No 9.4%	Unsure 23.3%	No answer 0.8%
Q3	Do you think the relationship between the doctors and the device manufacturers should be regulated?	Yes 48.2%	No 19.2%	Unsure 31.8%	No answer 0.8%
Q4	If you believe that the relationship between the doctors and the medical device manufacturer should be regulated, which authority should do this?	Doctors 32.2%	Hospitals 20.0%	Government 13.5%	No answer 34.3%
Q5	If a medical device is necessary for your care and your doctor recommends its use, would you like to know if your doctor was involved in its design?	Yes 72.7%	No 2.0%	Doesn't Matter 25.3%	No answer 0%
Q6	Do you believe that a doctor should be allowed to recommend the use of a device he/she helped to design?	Yes 89.4%	No 1.2%	Unsure 9.0%	No answer 0.4%
Q7	Will you be having surgery?/Have you had surgery by the surgeon you are visiting today?	Yes 63.7%	No 26.9%	Unsure 0.8%	No answer 8.6%
Q8	What is your highest education level?	High School 46.5%	College 33.9%	Graduate/Post-graduate 19.2%	No answer 0.4%

going to have surgery. A *P* value of <0.05 was considered statistically significant. Data analysis revealed the following statistically significant results:

Gender Differences

Females were more likely than males to prefer the physician-medical device manufacturer relationship to be regulated by physicians instead of the hospitals or the government (Q4: 56.3% *vs.* 40.5%, *P* = 0.008).

Age Differences

Patients 55 years or younger were more likely than those >55 years old to think that physicians should be compensated acting as consultants to industry (Q2: 70.7% *vs.* 63.3%, *P* = 0.01). Patients >55 years old were more likely to have had/be scheduled for surgery (Q7: 79.3% *vs.* 60.2%, *P* = 0.001).

Education Level Differences

The more educated the patient, the less likely he/she was of the opinion that the relationship between physicians and medical device manufacturers should be regulated by physicians (Q4: high-school graduates 61.7%, college graduates 38.8%, graduate/postgraduates 33.3%; graduate/postgraduate *vs.* high-school graduates, *P* = 0.009). Similarly, more educated patients were less likely to want physicians to be compensated for their role as advisors, although this did not achieve statistical significance (Q2: 57.4% *vs.* 75.0%, *P* = 0.06).

Surgical Status Differences

Patients who had/were going to have surgery were more likely to believe that the relationship between physicians and medical device manufacturers should be regulated by the physicians compared with those who did not/were not going to have surgery (Q4: 55.3% *vs.* 41.9%, *P* = 0.01).

Discussion

As the complexity of medical technology continues to increase, industry has aggressively sought after physicians to serve as consultants.⁵ The field of orthopedic

surgery in particular, which relies heavily on medical implants and devices, has witnessed a great deal of such collaboration between orthopedic surgeons and industry. Although this partnership has undeniably benefitted patients, it has also raised concerns about potential conflict of interest issues and the appropriateness of such relationships.⁶⁻⁸ This subject needs to be understood from the patients' perspective. Understanding this issue from their viewpoint can help us alleviate their anxiety, address their concerns, and reemphasize the fact that the most important role of a surgeon is that of a patient advocate.

The results of this study show that, despite adverse publicity in the popular press in the past few years about physicians and conflict of interest issues,⁹ the public is overwhelmingly in favor of allowing surgeons to work with industry because of its potential beneficial effects for patients. Interestingly, the majority of patients seem to be in favor of allowing surgeons to be compensated for this role. This suggests that patients still retain a great deal of confidence in the ethics and judgments of their medical caregivers. However, patients do have some underlying anxiety about the role of the surgeon as an industry consultant, evidenced by the fact that almost half of them indicated that this relationship should be regulated. Yet, by a large margin, they believe that physicians instead of the government should regulate these relationships, underscoring the public's faith in the medical profession to regulate it self. The other salient feature of this study is that our patients were comfortable with the surgeon recommending a device that he/she helped design. However, a large majority preferred being informed if the surgeon was responsible for designing such a device. Other studies have similarly demonstrated that the public does indeed prefer to know about such issues in advance.¹⁰ All these data seem to suggest that, despite the headlines in the popular press to the contrary, the public continues to have confidence in the ethical foundation of the surgeons who treat them.

An interesting finding of this study is the fact that the education level of the patients correlated inversely with their willingness to allow physicians/surgeons to be compensated for their advisory role to the industry. They also were less likely to want physicians to regulate themselves, and preferred outside regulation. We speculate that perhaps the more educated patients are more knowledgeable and informed with respect to potential conflict of interest issues under these circumstances. They may be more mindful of the ability of financial incentives to influence the judgment and opinion of their physician with respect to certain medical devices and implants. This might explain their reluctance to allow for physicians/surgeons to be financially compensated for advising industry.

This study raises important issues that need to be explored further. For example, should surgeons disclose industry relationships to patients? If so, what form should such disclosure take? Who should regulate/monitor such patient disclosure? It would be intriguing to see what patients in other settings (general surgery, neurosurgery, *etc.*) think about this subject. It is a reassuring sign for the medical profession that such a large percentage of our patients trust our ability to remain impartial despite potential conflicts of interest.

■ Conclusion

Most patients believe that the physician relationship with medical device manufacturers is beneficial to them, and they trust physicians to regulate themselves instead of the government. Physicians should be mindful of this public trust and should ensure that potential conflicts of interest (financial or otherwise) do not undermine it. Failure to maintain this public confidence may lead to an erosion of the patient–physician relationship. Therefore, surgeons should maintain objectivity, and they should put the interests of their patients before those of the industry to safeguard this confidence. Larger studies with

more sophisticated epidemiologic methods should be conducted to understand this important issue in greater detail from the patients' point of view, so their concerns can be better understood and addressed.

■ Key Points

- An overwhelming majority of patients believe that the relationship between surgeons and industry benefits their health care.
- A large majority of patients are in favor of allowing surgeons of being compensated for this role.
- Age, gender, and education level influence patients' attitudes about this issue.

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