The Roles of Funding Source, Clinical Trial Outcome, and Quality of Reporting in Orthopedic Surgery Literature

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Abstract

Compared with nonfunded or peer-reviewed funded projects, industry-sponsored clinical trials have traditionally been associated with more positive results. This relationship has been extensively studied in the nonsurgical literature. Although a few authors have addressed specialties, little has been reported on orthopedic clinical trials and their association with funding, study outcome, and efforts to reduce bias after randomization across journals of multiple subspecialties.

For the study reported here, we selected 5 major orthopedic subspecialty journals: *Journal of Bone and Joint Surgery (American Volume), Spine, Journal of Arthroplasty, Journal of Orthopaedic Trauma,* and *American Journal of Sports Medicine.* We chose a 2-year limit for investigation (2002–2004); included all original randomized clinical trials reported in these 5 journals; and examined these trials for their study design, funding source, outcome, bias potential, and conclusion reached.

Support for the 100 eligible orthopedic clinical trials was stated as coming from industry (26 trials, 26%), nonprofit sources (19 trials, 19%), and mixed sources (5 trials, 5%); no support was stated in 46 trials (46%), and support was not reported in 4 trials (4%). Of the 26 trials reporting industry support, 22 (85%) were graded as indicating an outcome favorable to the new treatment. The association between industry funding and favorable outcome was strong and significant ($P<.001$). In almost half of the studies reported in *Journal of Bone and Joint Surgery* and *Spine,* measures taken to reduce bias were not documented.

Our results indicate that there is a significant positive association between reported clinical trial outcome and funding source in the orthopedic surgery literature across subspecialties. There appears to be poor recording of how to reduce bias in the selected journals.

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Since the early 1980s, specific attention through various studies has been given to the relationship between industry and science. These studies have evaluated both medical–industry and academic–industry research collaborations.[1-5] The medical/surgical research community has identified financial conflict of interest as a pressing issue. The medical literature provides several examples in which physicians with financial ties to manufacturers were significantly less likely to criticize the safety or efficacy of a particular product or intervention.[6,7] Friedberg and colleagues[8] found that pharmaceutical company–sponsored studies were less likely than nonprofit-sponsored studies to report unfavorable qualitative conclusions. Conversely, industry sponsorship often carries the burden of perceived bias and lack of credibility simply because the research has direct, transparent linkages with implant/device marketing activities.[9]

An estimated 70% of all clinical trials performed in the United States are industry-supported.[10] Over the past several years, advances in orthopedic surgery have led to closer links with multiple commercial industries. This development reflects the fact that government funding in orthopedic surgery has diminished and that commercial funding has in many cases become a necessary if not attractive option for orthopedic surgeon-scientists. The prevalence and impact of industry sponsorship within orthopedic research have only recently been evaluated.[11,12]

Ezzet[12] reviewed the adult total joint literature in consecutive articles. Prevalence of commercial funding in these studies was 50%. Clinical studies of total hip arthroplasty implants received commercial funding in 75% of cases. Those commercially funded studies resulted in a positive outcome in 93% of cases compared with 37% in studies that were independently funded. Investigators who received royalties reported no negative outcomes related to the respective devices.

Considering that much of this commercially supported work is used by practicing orthopedic surgeons and scientists, making an informed decision based on such studies is challenging. The conflict-of-interest disclosure was created for

readers as a means of recognizing potential bias in scientific literature. Unfortunately, such disclosures do not address the possibility that negative results are potentially suppressed.

In the study reported here, we evaluated the correlation between funding source and positive outcome in the orthopedic surgery literature and evaluated meticulousness and quality of reporting.

Materials and Methods

Article Identification

For this study, we selected 5 major orthopedic subspecialty journals: *Journal of Bone and Joint Surgery (JBJS, American Volume), Spine, Journal of Arthroplasty (JA), Journal of Orthopaedic Trauma (JOT),* and *American Journal of Sports Medicine (AJSM)*. We chose a 2-year limit for investigation (2002–2004) because we deemed this recent period to be the most consistent with regard to individual journal disclosure policies. All original randomized controlled clinical trials reported in these 5 journals were conducted within this period. Eligibility for our study was determined by searching Medline on PubMed. Each journal name was entered with, successively, *random**, *clinical trial**, *prospective**, and *controlled**. A cohort of studies was then identified from a large pool, and each selected complete text article was then hand-searched or searched online. Only randomized controlled trials described in full reports were selected for this study. Required article elements were an abstract, a Materials and

Table I. Modified Jadad Score Used to Assess Bias Within Randomized Clinical Trials

Question	Response	Maximum Points Awarded
Was the study described as randomized?	Yes	2
	No	0
Was the study described as double-blinded?	Yes	2
	No	0
Was there a description of withdrawals and dropouts?	Yes	1

Table II. Journals and Number of Studies That Met Inclusion Criteria Within Period 2002–2004

Journal	No. Randomized, Clinical Trials That Met Inclusion Criteria
Journal of Bone and Joint Surgery (American Volume)	36
Spine	31
Journal of Arthroplasty	15
Journal of Orthopaedic Trauma	5
American Journal of Sports Medicine	13

Table III. Cross-Tabulation of Funding Sources by Primary Outcomes for All Journals[a]

	Primary Outcome				
Funding Source	Unclear	Neutral	Unfavorable	Favorable to Conventional Treatment	Favorable to New Treatment
Not reported	0	0	0	1 (25%)	3 (75%)
None	3 (7%)	15 (33%)	4 (9%)	6 (13%)	18 (39%)
Nonprofit	1 (5%)	8 (42%)	1 (5%)	2 (11%)	7 (37%)
Mixed	0	2 (40%)	1 (20%)	1 (20%)	1 (20%)
Industry	1 (4%)	2 (8%)	0	1 (4%)	22 (85%)

[a]Data are number of articles (row percentages).

Table IV. Cross-Tabulation of Funding Sources by Primary Outcomes for All Journals After Collapsing Categories[a]

	Primary Outcome	
Funding Source	Other	Favorable to New Treatment
None, nonprofit, or mixed	41 (61%)	26 (39%)
Industry	3 (12%)	22 (88%)

[a]Data are number of articles (row percentages).

Table V. Funding Sources by Study Outcomes for the 5 Journals for Period 2002–2004

Funding Source	Primary Outcome: Unfavorable	Unclear	Neutral	Favorable to Conventional Treatment	Favorable to New Treatment	Total
			Spine			
None	2	1	4	0	3	10
Nonprofit	0	0	4	0	2	6
Industry	0	0	0	1	11	12
Mixed	0	0	1	0	0	1
Not reported	0	0	0	0	2	2
						31
			Journal of Bone and Joint Surgery (American Volume)			
None	0	1	4	5	6	16
Nonprofit	1	1	3	1	5	11
Industry	0	0	0	0	6	6
Mixed	1	0	0	1	1	3
Not reported	0	0	0	0	0	0
						36
			Journal of Arthroplasty			
None	2	1	2	0	5	10
Nonprofit	0	0	1	0	0	1
Industry	0	0	2	0	1	3
Mixed	0	0	1	0	0	1
Not reported	0	0	0	0	0	0
						15
			Journal of Orthopaedic Trauma			
None	0	0	1	1	1	3
Nonprofit	0	0	0	1	0	1
Industry	0	0	0	0	1	1
Mixed	0	0	0	0	0	0
Not reported	0	0	0	0	0	0
						5
			American Journal of Sports Medicine			
None	0	0	4	0	3	7
Nonprofit	0	0	0	0	0	0
Industry	0	1	0	0	3	4
Mixed	0	0	0	0	0	0
Not reported	0	0	0	1	1	2
						13

Methods section, clearly defined statistics, and a conclusion. No attempt was made to limit selection by any other criteria, such as randomized study design, control groups, placebos, disease categories, treatment arms, or study populations. From each trial, relevant data (eg, author lists, competing interests, declaration of conflict, funding source, primary outcome) were extracted.

Funding Source

Funding sources for included studies were drawn from Acknowledgments sections of reports. Reliability of the funding source was directly dependent on reporting by individual investigators. Funding sources were subdivided into 5 categories: *none, nonprofit, industry, mixed, and not reported*. When multiple sources of funds were listed, the study was classified as having mixed funding. The no-funding classification was applied only when a report explicitly noted lack of funding.

Results of the Trials

We categorized the primary outcomes of the trials according to the study authors' interpretations of how the investigational and control groups fared against each other, as stated in Discussion and Conclusion sections. The 5 outcome categories were:

1. *Unfavorable*. The authors of the randomized controlled trial concluded that the new treatment tested was inferior to the gold standard and had an unfavorable result (including complications in the new treatment cohort) at the end of the trial.
2. *Unclear.* The results of the study were unclear, and no benefit or disadvantage to the tested treatment was explicitly stated in the Discussion or Conclusion section.
3. *Neutral*. The authors' results were not weighted toward the new treatment or toward the gold standard, and similar efficacy was established.
4. *Favored conventional treatment*. The authors clearly stated within the Discussion or Conclusion section that, though there were no adverse events within the new treatment cohort, results indicated that the gold-standard treatment was superior to the new treatment.
5. *Favored new treatment*. The authors clearly stated within the Discussion or Conclusion section that results indicated that the new treatment was superior to the gold-standard treatment.

Table VI. Modified Jadad Scores of ≥4 After Collapsing Categories With Regard to Funding Source[a]

Journal	Funding Source	
	Industry	None/Nonprofit
Journal of Bone and Joint Surgery (American Volume)	6 (35%)	11 (65%)
Spine	12 (67%)	6 (33%)
Journal of Orthopaedic Trauma	1	1
American Journal of Sports Medicine	3 (50%)	3 (50%)
Journal of Arthroplasty	1 (25%)	4 (75%)

[a]Data are number of articles with modified Jadad scores of ≥4 (row percentages).

The quality of reporting, as described by Jadad and colleagues,[13] consists of 3 questions that relate directly to the control of bias within a study: (1) Was the study described as randomized? (2) Was the study described as double-blinded? (3) Was there a description of withdrawals and dropouts? It is very difficult in randomized trials in orthopedic surgery to have double-blinded studies with the investigator and the patient unaware what type of implant was used. To maintain consistency between all studies extracted, we modified the Jadad score to give credit to reports that maintained some form of blinding, not necessarily double-blinding (Table I). As a result, when evaluating the included studies, we used the 3 questions to elicit yes or no answers. Points awarded to questions 1 and 2 depended on the quality of the description of the methods used to generate the sequence of randomization and/or on the quality of the description of the blinding method used. For example, when a trial had been described as randomized and/or blinded, but there was no description of the methods used to generate the sequence of randomization or the blinding conditions, just 1 point was awarded in each case. When the method of generating the sequence of randomization and/or blinding had been explicitly described, 1 more point was given to each item if the method was appropriate. A method to generate randomization sequences was regarded as adequate when it allowed each study subject to have the same chance of receiving either the conventional treatment or the new treatment, and when the investigators could not predict which intervention was next. Blinding was considered appropriate and was awarded 1 point when it was stated that the study subject could not identify the intervention being assessed. Conversely, when the method of generating the sequence of randomization and/or blinding was described but not appropriate, the relevant question was not given any points. An additional point was awarded when a study was double-blinded.

Points were potentially assigned regarding withdrawals and dropouts. No points were assigned when withdrawals and dropouts were not explicitly included in the results. One point was awarded to trials that documented the number of withdrawals and dropouts and clearly stated reasons in the Results section. When this scoring system was used to assess reporting quality, each question yielded a composite score ranging from 0 to 5. A higher score was thus reflective of better methodologic quality.

Interobserver and Intraobserver Variability

A consensus-building approach was used before each article was assessed by 2 different authors for funding type, trial outcome, and reporting quality. One hundred percent concordance was achieved for each variable. One author re-reviewed the articles at a later time and found 100% concordance for all 3 variables.

Statistics

Data were summarized as 2-way or multiway cross-tabulations. To test for associations between industry support and favorable outcome, we collapsed funding source to 2 levels (industry, none/nonprofit/mixed) and outcome to 2 levels (favorable to new treatment, other). When the source was not reported, or the outcome was graded as unclear, the data were not included in association tests. Pearson χ^2 was used to test for significant associations. Logistic regression was used to test for an association between industry support and outcome while adjusting for trial quality by modified Jadad score. Data were analyzed with Systat version 8.0 (Systat Software, Inc., Chicago, IL).

Results

One hundred orthopedic clinical trials were found to meet the inclusion criteria: 36 in *JBJS [Am],* 31 in *Spine,* 15 in *JA,* 13 in *AJSM,* and 5 in *JOT* (Table II). Support for these eligible trials was stated as coming from industry (26 trials, 26%), nonprofit sources (19 trials, 19%), and mixed sources (5 trials, 5%); no support was stated in 46 trials (46%), and support was not reported in 4 trials (4%). Of the 26 industry-supported trials, 22 (85%) were graded as indicating an outcome favorable to the new treatment (Tables III, IV). The association between industry funding and favorable outcome was strong and significant (Table III, $\chi^2 = 17.7$, $P<.001$). The unadjusted odds ratio was 11.6 (95% confidence interval, 3.1-42.5). The odds ratio showed little change after adjustment for the modified Jadad score (odds ratio, 10.9; 95% confidence interval, 2.6-44.7), indicating that trial quality did not affect the relationship between funding and outcome. The number of clinical trials was low for some journals, making it difficult to analyze the relationship between funding and outcome by journal.

The most striking results were evident in the *JBJS [Am]* and *Spine* data (Table V). All 6 industry-funded clinical trials (100%) out of the 36 trials included from *JBJS*

CONSORT Statement 2001 - Checklist

Items to include when reporting a randomized trial

PAPER SECTION And topic	Item	Descriptor	Reported on Page #
TITLE & ABSTRACT	1	How participants were allocated to interventions (*e.g.*, "random allocation", "randomized", or "randomly assigned").	
INTRODUCTION Background	2	Scientific background and explanation of rationale.	
METHODS Participants	3	Eligibility criteria for participants and the settings and locations where the data were collected.	
Interventions	4	Precise details of the interventions intended for each group and how and when they were actually administered.	
Objectives	5	Specific objectives and hypotheses.	
Outcomes	6	Clearly defined primary and secondary outcome measures and, when applicable, any methods used to enhance the quality of measurements (*e.g.*, multiple observations, training of assessors).	
Sample size	7	How sample size was determined and, when applicable, explanation of any interim analyses and stopping rules.	
Randomization -- Sequence generation	8	Method used to generate the random allocation sequence, including details of any restrictions (*e.g.*, blocking, stratification)	
Randomization -- Allocation concealment	9	Method used to implement the random allocation sequence (*e.g.*, numbered containers or central telephone), clarifying whether the sequence was concealed until interventions were assigned.	
Randomization -- Implementation	10	Who generated the allocation sequence, who enrolled participants, and who assigned participants to their groups.	
Blinding (masking)	11	Whether or not participants, those administering the interventions, and those assessing the outcomes were blinded to group assignment. If done, how the success of blinding was evaluated.	
Statistical methods	12	Statistical methods used to compare groups for primary outcome(s); Methods for additional analyses, such as subgroup analyses and adjusted analyses.	
RESULTS Participant flow	13	Flow of participants through each stage (a diagram is strongly recommended). Specifically, for each group report the numbers of participants randomly assigned, receiving intended treatment, completing the study protocol, and analyzed for the primary outcome. Describe protocol deviations from study as planned, together with reasons.	
Recruitment	14	Dates defining the periods of recruitment and follow-up.	
Baseline data	15	Baseline demographic and clinical characteristics of each group.	
Numbers analyzed	16	Number of participants (denominator) in each group included in each analysis and whether the analysis was by "intention-to-treat". State the results in absolute numbers when feasible (*e.g.*, 10/20, not 50%).	
Outcomes and estimation	17	For each primary and secondary outcome, a summary of results for each group, and the estimated effect size and its precision (*e.g.*, 95% confidence interval).	
Ancillary analyses	18	Address multiplicity by reporting any other analyses performed, including subgroup analyses and adjusted analyses, indicating those pre-specified and those exploratory.	
Adverse events	19	All important adverse events or side effects in each intervention group.	
DISCUSSION Interpretation	20	Interpretation of the results, taking into account study hypotheses, sources of potential bias or imprecision and the dangers associated with multiplicity of analyses and outcomes.	
Generalizability	21	Generalizability (external validity) of the trial findings.	
Overall evidence	22	General interpretation of the results in the context of current evidence.	

www.consort-statement.org

Figure 1. CONSORT Statement 2001 Checklist. Items to include when reporting a randomized trial. Copyright, CONSORT group.

[Am] reported a favorable outcome; when the no-funding and nonprofit categories were collapsed and analyzed for outcome, only 11 (41%) of 27 trials reported a favorable outcome ($P<.001$, Mantel-Haenszel). Similarly, 11 (92%) of the 12 industry-supported trials out of the 31 trials included from *Spine* reported a favorable outcome; when the no-funding and nonprofit categories were collapsed and analyzed for outcome, only 5 (31%) of 16 trials reported a favorable outcome ($P<.001$, Mantel-Haenszel). Of the 15 trials from *JA,* 10 did not receive any funding support, and 5 (50%) of the 10 reported favoring new treatment over conventional treatment; of the 3 industry-supported trials, 2 had a neutral outcome, and 1 favored the new treatment over the conventional treatment. Of the 13 trials from *AJSM,* 4 were industry-supported, and 3 of those favored the new treatment. Only 5 trials from *JOT* met our inclusion criteria, and the sample was deemed too small to draw any meaningful conclusions.

As already stated, the modified Jadad score evaluates the quality of reporting and methods used to reduce as much bias as possible within a clinical trial. A composite score (0-5 points) is used, with a higher score representing a more rigorously documented methodology. According to our analysis of the quality of all 36 clinical trials from *JBJS [Am],* 19 (53%) received a score of 4 or more. Of the 31 clinical trials from *Spine,* 18 (58%) received a score of 4 or more. In the 2-year period chosen for this study, 7 (54%) of 13 studies from *AJSM,* 2 (40%) of 5 studies from *JOT,* and 4 (27%) of 15 studies from *JA* directly documented their control of bias.

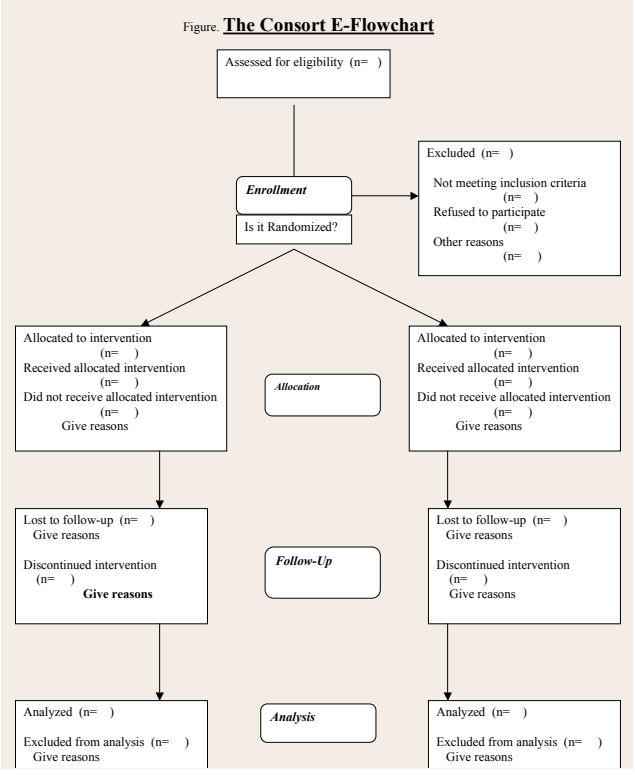

Figure 2. CONSORT (Consolidated Standards of Reporting Trials) E-Flowchart. Copyright, CONSORT group.

When funding source was collapsed into 2 levels (industry, none/nonprofit/mixed), 67% of industry-funded studies from *Spine* and 35% of industry-funded studies from *JBJS [Am]* received a score of 4 or more (Table VI).

Discussion

As orthopedics continue to advance as a specialty, the number and complexity of clinical questions will grow. The funding required to study and answer these questions is often a limiting factor. The role of industry sponsorship of orthopedic research has also grown. Because of this variable, the potential for bias in reporting data is undeniable. The medical literature has already identified these potential biases and noted that industry funding for research has been associated with increased positive results.[14-17]

The goal of this study was to examine how funding sources relate to orthopedic surgery randomized clinical trial outcomes across 5 journals in orthopedic surgery specialties and, more specifically, whether industry-funded studies report more positive clinical trial results than do studies with other funding sources. Previous investigators have examined the spectrum of research in a single subspecialty journal (inclusive of basic science, case series, biomechanics studies)[11] or across medical and surgical journals of several specialties (including medicine, general surgery, plastic surgery, neurosurgery and orthopedic surgery).[18] Our results indicate that there is a significant positive association between reported clinical trial outcome and funding source in the orthopedic surgery literature. There also appears to be a trend toward journal-dependent association between study outcome and funding source. Of the 26 industry-supported trials, 22 (85%) showed outcomes favorable to the new treatment ($P<.001$). These results are consistent with previous results in other fields of medical research, as noted earlier.[1-5]

Almost half of the *JBJS [Am]* and *Spine* reports on randomized trials did not document (in their Materials and Methods sections) attempts to reduce bias. Information on the extent of bias and attempts to reduce it is important to both informed and lay readers who want to draw reasonable clinical conclusions.

There is a positive relationship between funding and outcomes and higher methodologic quality in *Spine* over the period chosen—possibly a result of the increased number of Food and Drug Administration (FDA)–driven, industry-sponsored Investigational Device Exemption clinical trial data available for publication. The stringent methodologies demanded by the FDA for these trials may have led to better control or reduction and reporting of bias, but no data support this hypothesis.

It may be naïve to think that the current orthopedic literature is not skewed toward positive results, especially considering the amount of time and money required for well-designed clinical studies. No doubt the process begins at the level of preclinical investigations. Any commercial product that shows preclinical promise is aggressively pursued toward the clinical trial arena. Conversely, nega-

tive results do not warrant further resource expenditure. Expensive randomized clinical trials are embarked on with at least a solid notion of product success or an equivalence to the conventional treatment. Alternatively, certain industry-sponsored research contracts may have clauses giving ownership rights over the data collected. On a smaller scale (nonrandomized or controlled), negative data may never be published. It must also be noted that unpublished data may also be data judged not clinically useful or relevant.

Large, prospective, multicenter collaborative trials that involve hundreds of patients and critically evaluate treatments are ultimately the goal for orthopedic clinical research. These trials will redefine practice and change patient care—effects similar to those in the medical subspecialties. In the light of decreased funding from national agencies, such as the National Institutes of Health (NIH), the interaction between orthopedic investigators and biotechnical industry remains critical. Orthopedic investigators who conduct appropriately powered large clinical trials have no choice but to approach industry. As the orthopedic surgery literature continues to evolve, most readers assume that authors accurately report their findings. However, variations in study design, execution, potential physician bias, and financial agreements between sponsoring agencies and authors' institutions can have a major impact on the direction and interpretation of results.[19] These data must be clearly stated within each report and must be considered in reviews of presented or published work.

Despite efforts over several decades, reports on randomized clinical trials are still inadequate.[20,21] For example, in a review of 122 articles on randomized controlled clinical trials that evaluated the effectiveness of selective serotonin reuptake inhibitors as first-line management for depression, only 1 article (0.8%) adequately described randomization.[22] Inadequate reporting makes interpretation of randomized trials difficult; similarly, reporting the quality of randomized clinical trials in orthopedic surgery must be addressed by including the key domains of concealment of treatment allocation, blinding of outcomes assessment and double-blinding, and handling of withdrawals and study dropouts.

Inadequate reporting borders on unethical practice when biased results receive false credibility. In this regard, investigators and editors developed the CONSORT (Consolidated Standards of Reporting Trials) statement to help authors of randomized clinical trials improve reporting by using a checklist (Figure 1) and a flow diagram (Figure 2).[23] The checklist has 22 items that encompass the content of the Title, Abstract, Introduction, Methods, Results, and Discussion sections of reports. These items were chosen because empirical evidence indicated that not reporting this information was associated with biased estimates of treatment effect and that this information is required to judge the reliability and relevance of the data. The flow diagram shows information from 4 trial stages (enrollment, intervention allocation, follow-up, analysis) and depicts the number of participants in the trial according to each intervention group included in the primary data analysis. An overview of the recruitment process and reason for withdrawals allows the reader to judge whether the authors have performed an intention-to-treat analysis.

Of the Web sites for the 5 journals studied here, only the *JBJS [Am]* and *Spine* sites specifically instruct authors to follow CONSORT guidelines. This situation is relevant, as recent literature has demonstrated that journals' adoption of CONSORT guidelines is associated with improved reporting of randomized clinical trials.[24]

We acknowledge that the small number of trials reviewed here may limit the interpretations that can be made from associating a journal-dependant trend with study outcome and funding source. The period chosen for review (2002–2004) represented 2-year publication data when authorship guidelines and journal disclosure policies were initially consistently published within the 5 journals. This period may also introduce a time-related bias, as clinical trials reported in each journal after 2004 may reflect better quality of reporting. As already noted, however, our study specifically examined outcome and funding source in orthopedic randomized clinical trials, so our *n* may reflect the fewer randomized clinical trials reported in our specialty.

In conclusion, our study results show that funding sources for clinical research in orthopedic surgery have an impact on study outcomes. They also show that many studies do not appropriately identify potential bias within their methods. As these variables may affect clinical judgments and practice, practicing orthopedic physicians must keep them in mind.

Authors' Disclosure Statement

The authors report no actual or potential conflict of interest in relation to this article.

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Commentary

In "The Roles of Funding Source, Clinical Trial Outcome, and Quality of Reporting in Orthopedic Surgery Literature," Khan and colleagues demonstrate that orthopedic clinical trials sponsored by industry are significantly more likely to report positive results than trials not sponsored by industry. Our internal cynic may suspect that industry is suppressing unflattering results, but we should not rush to judgment. While industry may suppress results in some cases, randomized trials require a significant investment, and industry is more likely to sponsor trials of products that they are confident work well. Many of the less promising devices have already been abandoned along the research-and-development trail.

Nevertheless, the devil may be in the details. Khan and colleagues also demonstrate that there is poor reporting of efforts to reduce bias in the orthopedic clinical-trials literature. Because of this, it is difficult to objectively determine the quality of a trial's design in minimizing bias, which is the exclusive purpose of a rigorous study protocol—to reduce bias in order to discover the truth. And ultimately truth is the goal of any scientific inquiry. There may be an incentive in industry-sponsored trials to weight the deck in favor of the treatment of interest by comparing it with a clearly inferior treatment. Without the ability to adequately peer-review a study's details, it is impossible to know whether industry-sponsored studies are designed with a bias favoring their intervention.

Perhaps a more insidious concern is the motivation for the sponsorship of clinical trials. Ultimately, there is little reason to have faith in the altruism of industry. For obvious reasons, research results are a means to an end—to get devices approved for sale and to market devices to consumers. As such, there may be an impulse to repress unfavorable findings or to hide potential biases in vague methodology descriptions in published articles. It is, therefore, incumbent upon the orthopedic community, and peer-reviewed journals in particular, to properly vet the quality of study design and the interpretation of study findings for industry-sponsored trials.

Fortunately, the NIH and FDA have begun mandating the enrollment of trials for devices not yet approved at http://clinicaltrials.gov; however, this reporting is voluntary for trials of devices already approved. Several journals already require that studies be registered in this system before considering them for publication, even for studies of already approved devices. Orthopedic journals should set this same requirement.

Additionally, orthopedic researchers should insist on freedom of publication as a condition of accepting industry funding to conduct a trial, because this will help eliminate the risk of industry suppression of results. As suggested by Khan and colleagues, full disclosure of funding source and financial incentives should be mandatory for publication.

Ultimately, industry and peer-reviewed research represent awkward bedfellows hampered by the financial realities of our system, but let us not lose sight of the fact that truth trumps profit every time. At least it should.

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This paper will be judged for the Resident Writer's Award.