

Industry Payments to Foot and Ankle Surgeons and Their Effect on Total Ankle Arthroplasty Outcomes

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Abstract

Background: The Centers for Medicare & Medicaid Services (CMS) Open Payments public database provides a means for increased transparency of physicians' financial relationships with industry. Total ankle arthroplasty is a procedure with long-term clinical implications and variable outcomes. We compared physician-reported conflict-of-interest (COI) disclosures in the journal *Foot & Ankle International (FAI)* to CMS database information to evaluate for discrepancies.

Methods: Articles published in *FAI* reporting clinical outcomes of total ankle arthroplasty from 2015 and 2019 were reviewed. Payment information in the CMS database was cross-referenced with disclosure statements and International Committee of Medical Journal Editors (ICMJE) forms associated with the manuscript. Statistical analysis was performed to determine if industry payments were appropriately disclosed or influenced outcomes.

Results: We reviewed 173 articles pertaining to ankle arthroplasty, with 27 meeting inclusion criteria. Of 120 total authors with 98 unique authors, 114 (95%) disclosed appropriately in disclosure statements. Twenty-two studies (82%) had appropriate declarations for the entire manuscript. For the 27 senior authors, only 2 discrepancies between manuscript disclosure and the Open Payments public database were noted, showing 13 total disclosures in the Open Payments public database vs 11 disclosed in the manuscript. There was no relationship between industry payments and the outcome of the manuscript ($P = .725$).

Conclusion: The majority of author disclosure statements accurately reflected the Open Payments public data. Additionally, payments were not significantly associated with positive outcomes reported for the specific implant. Overall, authors publishing on ankle arthroplasty in *FAI* are disclosing appropriately.

Level of Evidence: Level IV, systematic review; survey study; literature review.

Keywords: Affordable Care Act, ankle replacement arthroplasty, conflict of interest, financial disclosure

Introduction

As part of the Affordable Care Act, the Physician Payments Sunshine Act was established in 2010, authorizing the creation of the Open Payments public database, a publicly accessible electronic record of physician financial relationships with industry intended to provide increased transparency and accountability for payments received by health care providers.¹⁵ Payments greater than \$10 made to physicians from drug and device manufacturers are required to be reported to the database. These payments are assigned to one of 3 categories: general payments, ownership interests, and

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research payments.²⁵ Royalties and license fees account for up to 69% (\$74.4 million) of all payments from device companies to orthopedic surgeons, with consulting fees making up to 13% (\$13.9 million) of payments. Nonconsulting services account for 5% (\$5.8 million) in payments.²⁹

A study in 2013 showed that 50.1% of orthopedic surgeons had a financial relationship with industry, receiving \$80.2 million in a 3-month period.⁷ An analysis of the Open Payments Database between 2014 and 2017 found that 802 orthopedic foot and ankle surgeons received nearly \$39 million from industry through 29 442 transactions.²⁶ Financial conflicts of interest have been associated with pro-industry-biased research findings,^{8,16,18,23,28} poor study design,^{6,27} and restrictions on study design and collaboration.^{2,11} Industry payments create potential conflicts of interest involving orthopedic implants. It is important for patients and readers to know if authors are accurately disclosing their potential conflicts of interest, as there is the potential for these financial conflicts to affect the outcomes of clinical data published on ankle arthroplasty.

Prior studies found inconsistencies in the accuracy of physician self-reporting of disclosures. Comparing physician-reported and industry-reported disclosures, inconsistencies as high as 35% and 50% have been recorded.^{3,5,12,14,23,24,31} Furthermore, a 2007 study analyzed podium presentations at the AAOS annual meeting and showed a significantly higher rate of positive outcomes when the presenter received royalty, consultant, or employee payments.²³ In terms of patient perceptions, 75% of patients believed that surgeons who were paid as consultants, receiving research funding, or receiving product design royalties were the top experts in the field, with two-thirds of patients believing that such endorsements helped surgeons serve patients better.³²

In 2011, to address concerns about conflict of interest disclosures in the literature, the editors of 20 orthopedic journals, including *Foot & Ankle International (FAI)*, met and signed a consensus statement and agreed to adopt the International Committee of Medical Journal Editors (ICMJE) form for full financial disclosure.⁹ This policy provides readers with detailed information about the type and nature of financial disclosure by authors. The goals of using this form are to clarify author reporting responsibilities, facilitate the reporting process, and lead to a fuller and clearer understanding of potential author conflicts of interest on the part of the reader.⁹

Previous studies have identified potential inaccuracies in voluntary self-disclosures of payments at orthopedic surgery national meetings and in journal publications.^{3,12,19,23} Other studies have demonstrated an association between industry funding and favorable outcomes.^{1,4,17,21} On the contrary, a recent study on total shoulder implants showed that industry payments did not lead to statistically significant increases in the publication of positive results.³⁰ With this in mind, we present a review of total ankle arthroplasty studies published in *FAI* from 2015 to 2019 to examine disclosures, industry

payments reported to the Centers for Medicare & Medicaid Services (CMS) Open Payments database, and the reported outcomes of the published manuscripts. We hypothesized that reported outcomes would not be affected by the presence of industry payments.

Methods

Search and Screening Methods

We performed an electronic search for all articles published in *FAI* between 2015 and 2019. All articles were screened in 2 different stages by a single author. In the first stage, all articles discussing total ankle replacement were included. In the second stage, every article was reviewed and included if they were primary research articles that had 1 or more authors affiliated with a US institution, discussed outcomes (clinical and/or functional), and was associated with 1 or more implants made by a single company. Inclusion and study review was performed by a single author consulting with additional authors in cases of ambiguity or uncertainty until consensus was reached. Articles were excluded if they had no authors affiliated with a US institution or if they discussed implants made by multiple companies.

Data Collecting Methods

All articles that passed the second screening stage were included in our final qualitative synthesis. For these articles, we recorded implant information and manufacturer. The articles were reviewed to determine the study's evaluation of the implant based on previously cited methodologies.^{10,22} Study outcomes were evaluated and manuscripts were placed into one of 3 categories (positive, negative, and neutral) according to a methodology adapted from Hasenboehler et al,¹³ with adjustments based on a study by Noordin et al.²² Two researchers sorted each manuscript independently, any discrepancies between the reviewers were discussed, and a final determination was made.

Each author on a manuscript was then reviewed for any disclosure statements regarding the "significant company," meaning the company manufacturing the prosthetic implant being reviewed in the study. Disclosure statements were obtained by viewing the ICMJE forms attached to the online versions of the article. If the ICMJE forms associated with an article could not be found, the declaration of conflicting interests section located at the end of the online article was used to record any disclosures. Note that this disclosure recording section was simply marked as yes or no, so any disclosure made toward the significant company would be regarded as a full disclosure.

All authors were then searched using the Open Payments Database search tool to find out if they had indeed received payments from the significant company. Any author not found in the Open Payments database was assumed to have received no payments from any biomedical company.

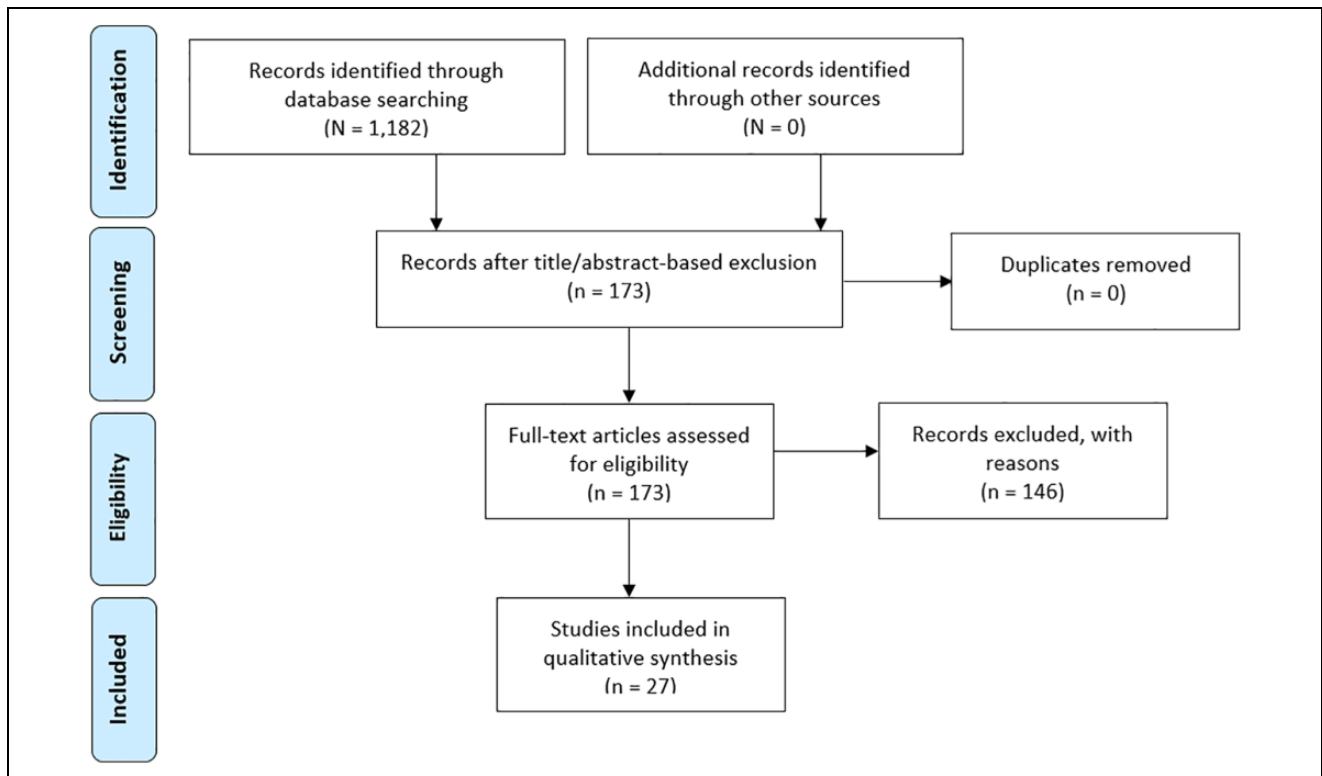


Figure 1. Preferred reporting items for systematic review and meta-analyses (PRISMA) flowchart of the literature screening process performed in this study.

Furthermore, authors found, but without any payments listed from the significant company, were assumed to have received no payments from that company. Open Payments data from the year preceding publication of the article was used to account for the time that was necessary to research, produce, and submit an article to a journal. Years prior to this were not considered as the financial relationship may have been discontinued and thus no longer affect the publication. The year of manuscript publication and proceeding years were also not included as these financial relationships may not have existed throughout the duration of the study and thus were unlikely to influence outcome. Only payments listed as royalties and/or licensing, consulting, services other than consulting, and speaking fees were recorded, as these payment categories may be indicative of long-term financial relationships. Therefore, authors receiving payments from the significant company that were not listed in one of the aforementioned payment types were noted to have received no payment from the company of interest.

Data Comparison

Each author's CMS payment data was then compared to their disclosure statement and assessed for relationship to the study's overall assessment of the implant being reviewed to determine the existence of any nondisclosed conflicts of

interest, as well as any possible association between payment and opinion.

Statistical Analysis

For all authors, as well as independently for senior authors, we analyzed discordance between ICMJE disclosures and payments found in the database using the McNemar test. The association between ICMJE disclosures and positive/nonpositive results was assessed using a chi-squared test, for all authors and separately for senior authors, focusing specifically on the various types of payments. A comparison of total payments made, in positive vs nonpositive studies, was made using a *t* test, for all authors and separately for senior authors.

Results

The PRISMA guidelines were followed for the identification of the articles.²⁰ The results of our initial search and screening can be seen in Figure 1. We observed a total of 1182 articles published to the online version of *FAI* from the beginning of 2015 to the end of 2019. Screening for articles pertaining to ankle arthroplasty based on title and abstract alone left a total of 173 articles. Further screening based on the full-text review and exclusion of manuscripts without US

Table 1. Comparison of Self-Reported Disclosures for Both Senior Authors and All Authors With the Open Payments Database.^a

	Disclosed in Manuscript	Reported in Open Payments Database	P Value
Senior authors (n = 27)			
No. (%) receiving payments	11 (40.7)	13 (48.1)	.617
Total payment, \$, mean (range)	NA	53 629 (0-820 434)	
All authors (n = 120)			
No. (%) receiving payments	26 (21.7)	29 (24.2)	.505
Total payment, \$, mean (range)	NA	50 742 (0-963 615)	

^aOf the 27 senior authors, 11 (40.7%) made a conflict of interest disclosure in the manuscript and 13 (48.1%) had relevant payments recorded in the Open Payments Database. For this group, the specific payment information was not available in the manuscript; however, it was available in the database. Here, it showed a mean of \$53 629 with a range of \$0 to \$820 434.

authors resulted in 27 research articles available to use in our qualitative synthesis.

These articles included a total of 120 credited authors corresponding to 98 unique authors. Twenty-nine of the 120 (24.2%) total authors received industry payments from a company relevant to the publication. Only 3 (2.5%) authors did not appropriately disclose their relationships in the manuscript or the ICMJE. For the 27 senior authorships, only 2 authors failed to disclose appropriately with the Open Payments database showing 13 total disclosures, 11 of which were disclosed appropriately in the manuscript. A comparison of self-reported disclosures for both senior authors and all authors with the Open Payments database is displayed in Table 1.

There was no statistically significant relationship between receiving a payment and disclosing in the manuscript ($P = .617$ and $.505$ for senior and all authors, respectively).

For all authors, there was no association of opinion/outcome with whether a disclosure was made ($P = .21$), nor with payments received for consulting ($P = .424$), for services other than consulting ($P = .109$), or for speaking fees ($P = .632$). Having received royalty payments and an opinion other than positive outcome were found to be significantly related ($P = .003$), indicating authors with royalty income were less likely to have a positive outcome. Receiving royalty income did not appear to influence these authors to publish positive results.

Over the 5-year period, the total payment received by all authors the year prior to manuscript publication totaled \$6.1 million. Senior authors received a total payment of \$1.4 million. The mean value of payments to senior authors was \$53 629, whereas the mean payment to all authors was \$50 742. The amount paid by industry to senior authors of each of the manuscripts analyzed in our study is shown in Figure 2. Comparison of disclosed payments by study outcomes is shown in Table 2.

Of the 27 total studies, 21 had a positive outcome for the implant evaluated, whereas 6 had an outcome other than positive (neutral or negative). We found that total payments in nonpositive studies exceeded payments in positive studies. The relationship between industry payment and the outcome of the manuscript was not statistically significant

for senior authors ($P = .619$) or all authors ($P = .725$). Total payments to all authors for nonpositive studies totaled \$3.4 million vs \$2.7 million for positive studies ($P = .08$). Senior author payments in nonpositive studies also exceeded positive studies, with the nonpositive group receiving \$970 255, whereas the positive studies received \$477 723, though this did not reach statistical significance ($P = .34$). There was high variance in author payments within and between both groups, indicating that payment amount, total or average, is not a universal metric influencing opinions, and also impacts inference, leading to nonsignificant results. Altogether, this reinforces the notion that financial gain for the studies evaluated was not a particularly important factor in author opinion.

Discussion

Industry payments are a clear element of support to some orthopedic surgeons. Prior studies have found inconsistencies in the accuracy of physician self-reporting of disclosures, in distinction to the findings of the present study.^{3,5,12,14,23,24,31}

Several studies evaluated the impact of industry payments on study outcomes. One showed a significantly higher rates of positive outcomes when presenters received royalty, consultant, or employee payments.²³ Another showed that 75% of patients believed that surgeons who were being paid as consultants, receiving research funding, or receiving product design royalties were the top experts in the field, with two-thirds of patients believing that such endorsements helped surgeons serve patients better.³²

A recent study by Somerson et al³⁰ evaluating conflicts of interest in shoulder arthroplasty manuscripts found that approximately half of senior authors (46%) received royalty payments, with more than 90% disclosing appropriately. They found that authors of studies with a positive outcome received a mean of \$115 610, which was almost twice the mean payment of \$62 306 received by authors of studies with nonpositive outcomes; however, this difference did not attain statistical significance.³⁰ In our study, the presence of disclosures or relevant industry transfers of value were not associated with a statistically significantly greater likelihood of positive outcomes. We found that, overall, orthopedic

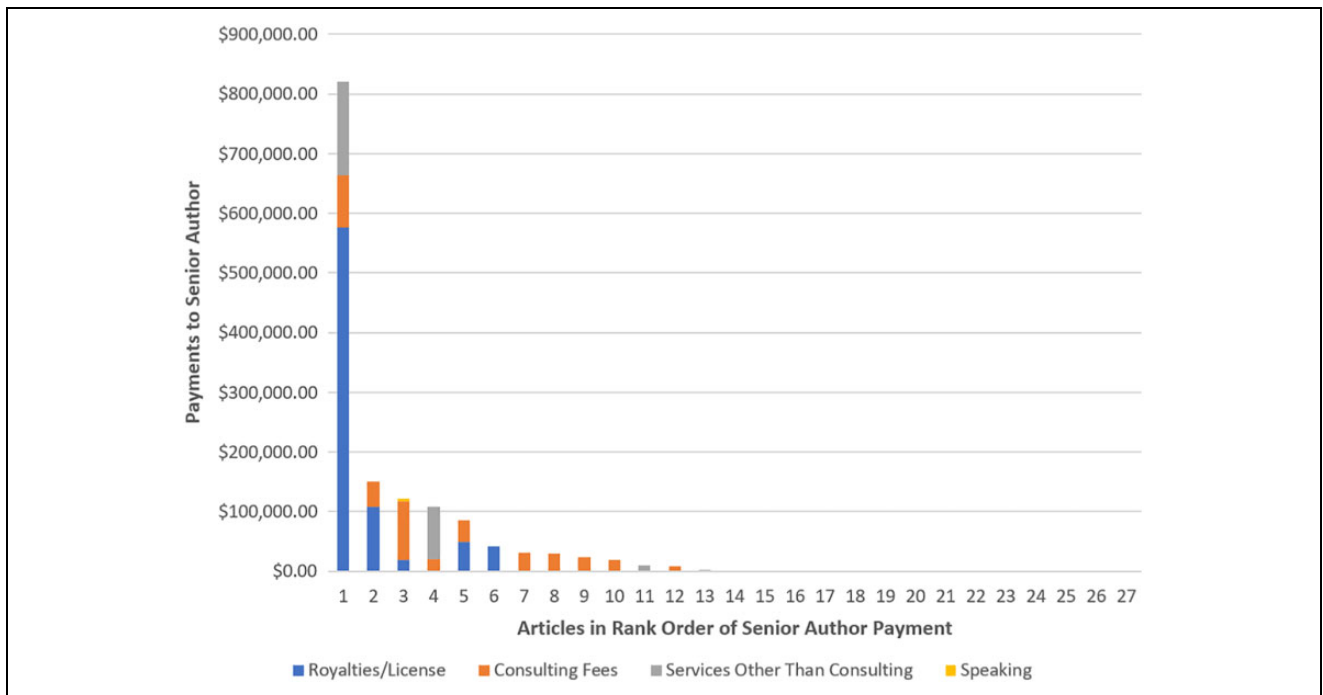


Figure 2. Categories and rank order of senior author payment from the open payments database for the 27 senior authors.

Table 2. Comparison of Disclosed Payments by Study Outcome.^a

	With Positive Outcome	Without Positive Outcome	P Value
Senior authors (n = 27)	21	6	.908
No. receiving payments	9	2	
All authors (n = 120)	92	28	.21
No. receiving payments	19	7	

^aOf the 27 total senior authors, 21 recorded positive outcomes for ankle arthroplasty in their manuscripts. Of this 21, 9 of the authors had received relevant payments, demonstrating that author receipt of payment did not show a statistically significant difference with regard to study outcome.

surgeons are appropriately disclosing their industry relationships in *FAI* when reporting on total ankle arthroplasty results. Additionally, we noted that disclosures are often vague in the disclosure section of the manuscript in this journal, but implementation of the ICMJE form provides for a more thorough conflict of interest analysis when reviewing each author, which provided increased transparency of disclosures in more recent volumes.

There are several limitations to this study. Studies with authors from outside of the United States were excluded because their disclosures were not available for review in the CMS database. Given that our analysis was performed in an international journal, this exclusion narrowed the number of available articles for our review. Second, studies

evaluating multiple implants were excluded, as we were not able to decide on the outcome for each implant. Third, our sample size was only 27 articles after exclusion criteria were applied. The lack of statistical significance in payment amounts and outcomes may be due to a lack of statistical power. Finally, all articles come exclusively from *FAI*, so our findings cannot be extrapolated across the field of orthopedics.

Conclusion

Previous studies have identified discrepancies between payment disclosures made by authors and those published in the Open Payments database. Given limited resources and time constraints, it is difficult for all journals to verify disclosure accuracy. We compared physician-reported conflict of interest disclosures in *FAI* with Open Payments database information to evaluate for discrepancies. The majority of author disclosure statements accurately reflected the database. Payments were not significantly associated with positive outcomes reported for the specific implant. Overall, authors publishing on ankle arthroplasty in *FAI* are disclosing appropriately per our review.

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Ethics Approval

Ethical approval was not sought for the present study because this study does not involve human subjects.

Declaration of Conflicting Interests


The author(s) declared the following potential conflicts of interest with respect to the research, authorship, and/or publication of this article: Vinod K. Panchbhavi, MD, FACS, reports Consulting fees, consultant for Stryker Orthopaedics. ICMJE forms for all authors are available online.

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