Systematic review

Fragility Index as a Measure of Randomized Clinical Trial Quality in Adult Reconstruction: A Systematic Review

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A R T I C L E   I N F O

Article history:
Received 29 March 2021
Received in revised form 8 August 2021
Accepted 29 August 2021

Keywords:
Total joint arthroplasty
Fragility index
Randomized controlled trials
Statistical significance

A B S T R A C T

Background: The Fragility Index (FI) and Reverse Fragility Index are powerful tools to supplement the P value in evaluation of randomized clinical trial (RCT) outcomes. These metrics are defined as the number of patients needed to change the significance level of an outcome. The purpose of this study was to calculate these metrics for published RCTs in total joint arthroplasty (TJA).

Methods: We performed a systematic review of RCTs in TJA over the last decade. For each study, we calculated the FI (for statistically significant outcomes) or Reverse Fragility Index (for nonstatistically significant outcomes) for all dichotomous, categorical outcomes. We also used the Pearson correlation coefficient to evaluate publication-level variables.

Results: We included 104 studies with 473 outcomes; 92 were statistically significant, and 381 were nonstatistically significant. The median FI was 6 overall and 4 and 7 for significant and nonsignificant outcomes, respectively. There was a positive correlation between FI and sample size (R = 0.14, P = .002) and between FI and P values (R = 0.197, P = .000012).

Conclusions: This study is the largest evaluation of FI in orthopedics literature to date. We found a median FI that was comparable to or higher than FIs calculated in other orthopedic subspecialties. Although the mean and median FIs were greater than the 2 recommended by the American Academy of Orthopaedic Surgeons Clinical Practice Guidelines to demonstrate strong evidence, a large percentage of studies have an FI < 2. This suggests that the TJA literature is on par or slightly better than other subspecialties, but improvements must be made.

Level of Evidence: Level I; Systematic Review.

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Introduction

Total hip arthroplasty (THA) and total knee arthroplasty (TKA) are 2 of the most commonly performed orthopedic surgeries in the world [1–4]. Current data suggest an increase by 143% in TKA performed annually in the United States by 2050, [4] with similar numbers for THA [2]. Given this scenario, researchers are constantly looking for ways to evaluate and improve techniques and outcomes in these patient populations, often in the form of randomized controlled trials (RCTs). Analyzing RCTs can, thus, facilitate establishing a standard for both clinical practice guidelines and future research.

In evaluating these studies, the P value is the most used tool. However, the P value provides information solely relevant to an outcome’s relation to the null hypothesis. It is unable to comment on sample size or strength of association. Thus, the Fragility Index (FI) and Reverse Fragility Index (RFI) have emerged as supplemental tools to assess clinical trial results. The FI and RFI are defined as the number of patients (or events) that would need to have an alternative outcome to convert an outcome from significant to nonsignificant or vice versa. A large FI suggests a robust outcome, as it
would require many changed events to have a different outcome. Alternatively, a small FI suggests less confidence in an outcome, as very few events would be required to change its P value. The FI, thus, provides information on effect size, demonstrating how each event impacts the P value.

The FI has increasingly been used to evaluate orthopedic surgery clinical trials. The American Academy of Orthopaedic Surgeons (AAOS) published clinical practice guidelines for evaluating research, stating that an article with a median FI of 2 would be considered “strong research” [5]. The FI for orthopedic subspecialties is generally low, with reported FIs ranging from 2 to 5, with sports literature thus far being the most robust with an FI of 5 [6–10].

A recent study by Ekhtiari et al. described the FI of statistically significant outcomes in 34 RCTs in total joint arthroplasty (TJA) [11]. However, their sample was small, and this article seeks to expand that research. Research by Kahn et al. and McCormick et al. recently described the “reverse fragility index,” which determines FI in nonstatistically significant outcomes in general and orthopedic research, respectively [12,13]. This allows the FI to be applied to a much larger body of research. The aim of our study was to evaluate the quality of RCTs in the orthopedic subspecialty of adult reconstruction using FI and RFI as metrics.

Material and methods

Study design and eligibility

The authors performed a systematic review of all RCTs using methods akin to those described in previous analyses of statistical fragility [5–10,14]. The top 25 highest impact orthopedic surgery and arthroplasty journals were determined via Incites Journal Citation Reports. These journals were queried for all RCTs in knee or hip arthroplasty published in the last 10 years in English.

Inclusion criteria were articles written in English between January 1, 2010, and September 1, 2020, that investigated surgical interventions for primary TJA and required the use of a 1:1 parallel, 2-arm randomization procedure, with at least 1 dichotomous outcome. Articles were excluded if they did not meet any of these criteria. Titles and abstracts were screened independently by 2 different authors (K.L.M. and A.G.) to ensure studies met inclusion criteria. If there was disagreement, a third author (C.L.H.) read the article as well. All articles were reviewed in their entirety to record all dichotomous, categorical outcomes for further analysis. The following study characteristics were collected for analysis: study size, number of patients lost to follow-up, outcome type, reported P values, and journal of publication. We used PubMed, Embase, and Medline to search, and the specific search criteria are summarized in Table 1.

Calculation of FI

The FI is defined as the lowest number of outcomes that must be changed in a stepwise fashion using FI and RFI as metrics. Additionally, the reverse fragility index (RFI) was calculated for each categorical, dichotomous outcome using Fisher’s exact test as described by Walsh et al. [14]. For statistically significant outcomes, discrete outcome events were switched from the larger outcome group to the smaller group in a stepwise fashion until the P value was greater than 0.05. For statistically insignificant P values, events in the smaller outcome group were changed in a similar manner, until the P value was less than .05 and, thus, statistically significant.

Statistical analysis

As stated previously, all P values were recalculated using Fisher’s exact test. A Student’s t-test was used to calculate the difference between the aforesaid study variables. Finally, the Pearson Correlation Coefficient was used to evaluate associations between FI and P values of included studies, as well as the associations between publication-level variables. All statistical analyses were performed using Microsoft Excel 2016 (Microsoft, Redmond, WA) and SPSS Version 23 (IBM, Armonk, NY).

Results

Characteristics

A total of 1069 articles were identified. After abstract review, 459 studies were excluded because they did not evaluate surgical interventions (eg, postoperative pain management, rehabilitation protocols). An additional 502 studies were excluded because they lacked dichotomous, categorical outcomes, and 5 studies for being focused on hemiarthroplasty and unicompartmental surgery. Ultimately, 104 studies were included for analysis with a total of 473 outcomes (Fig. 1). A full list of the included articles can be found in the appendices. The top 3 referenced journals were the Journal of Arthroplasty with 37 studies (35.6% of total articles), Clinical Orthopaedics and Related Research with 23 studies (22.1%), and Bone & Joint Journal with 14 articles (13.5%) (Table 2). The most often reported outcome type was postoperative complications (154 outcomes, 33%), as shown in Table 3.

Fragility index

Among the 473 outcomes assessed, the median FI was 6 (mean 6.7, range 1–40). Of the 91 statistically significant outcomes, the median FI was 4 (mean 5.6, range 1–26) (Fig. 2). The median FI for the 382 nonstatistically significant outcomes was 7 (mean 7.0, range 1–40) (Fig. 3). The FI was less than or equal to 3 in 98 outcomes (Fig. 4). There was a statistically significant difference between statistically significant and statistically insignificant outcomes (P = .0007). The number of subjects lost to follow up can be seen in Appendices Tables 1–3. Number of patients lost to follow-up was found to be greater than FI for 181 outcomes (38.3%). There was a positive correlation between FI and sample size (R = 0.14, P = .002), and between FI and P values (R = 0.197, P = .000012). There was no, however, correlation between FI and number of patients lost to follow-up (R = 0.022, P = .62) (Table 4).

Discussion

We identified 104 studies and 473 outcomes in our systematic analysis. This is the largest study to date examining FI for surgical clinical trials in TJA and, moreover, in any orthopedic subspecialty, as well as the first study to evaluate nonstatistically significant outcomes in TJA literature through the use of the RFI. We found a median FI of 6 for all 473 outcomes assessed, with a median FI of 4 and RFI of 7 for statistically significant and nonstatistically significant outcomes.
outcomes, respectively. These median FIs are comparable to or greater than those reported for other orthopedic subspecialties, which ranged from 2 to 5 [6-10]. As stated previously, the AAOS released guidelines which consider an FI above 2 as “strong evidence” [5]. According to that guidance, the FI and RFI calculated here demonstrate strong evidence and robust P values. In this investigation, FI/RFI ranged from 1 to 40. The largest value was an RFI of 40, assigned to an RCT investigating the effect of triclosan-coated sutures on surgical site infection after TKA and THA [15]. In addition, there were positive correlations between FI and sample size (R = 0.14, P = .002), and between FI and P values (R = 0.197, P = .000012). We would expect to see these results, as it suggests that the larger a sample size is, the more confident one can be in the P value. The further the P value moves from the null hypothesis in either direction, the more changes in event are needed to change the significance level and the stronger the result.

This study contradicts that of Ekhtiari et al. that was recently published [11]. In it, the authors performed a literature search to identify RCTs performed for primary or revision surgery and ultimately included 34 RCTs from the past decade in TJA literature and found that the median FI was 1, meaning that reversing the outcome of just one subject would change any statistically significant outcome to not statistically significant. Furthermore, they found that the FI was lower than that in any other reported orthopedic subspecialty. In their discussion, they argue that as TJA is such a common procedure and has widely accepted indications and

| Table 2 | Number of included publications by journal. |
|---------|---------------------------------------------|
| Journal | Number of publications                      |
| Journal of Arthroplasty | 37                          |
| Clinical Orthopaedics and Related Research | 23                          |
| Bone & Joint Journal | 14                          |
| Journal of Bone and Joint Surgery | 12                          |
| Knee Surgery Sports Traumatology Arthroscopy | 9                           |
| Acta Orthopaedica | 6                           |
| International Orthopedics | 3                           |

| Table 3 | Categorization of dichotomous recorded outcomes. |
|---------|-------------------------------------------------|
| Outcome            | Count, N (%)          |
| Postoperative complication | 154 (32.6)         |
| Alignment: radiographic findings | 114 (24.1)         |
| Patient pain/function | 86 (18.2)           |
| Failure of surgery/required reoperation | 49 (10.4)          |
| Other radiological findings | 44 (9.3)           |
| Transfusion | 19 (4.0)          |
| Patient satisfaction | 7 (1.5)            |
techniques, future trials should not be hampered by small sample sizes. Our data do corroborate their last point. Based on our calculations, FI does correlate strongly with increasing sample size. In evaluating the FI of both significant and nonsignificant outcomes, however, we found a much higher median FI of 6 overall, and 4 and 7 for significant and nonsignificant outcomes, respectively. Both these values are greater than what their study reported [11]. Our research evaluated different studies—we chose to evaluate solely primary TJA RCTs describing surgical interventions in the top 25 highest impact orthopedic journals, with manuscripts in English. However, we included more than triple the number of studies (104 rather than 34) by including insignificant outcomes and calculating the RFI, the number of patients needed to change outcomes in a study, to change a nonstatistically significant variable into one that is statistically significant. It is possible that this increased FI/RFI is in part due to using higher impact journals.

However, these data should be interpreted with caution. One hundred and eighty-one (38.3%) of the outcomes analyzed in this review had FIs greater than the number of patients lost to follow-up. Combining both FI and RFI, there are 65 outcomes with an FI or RFI \( \leq 2 \), which represents 14% of the outcomes studied here (Fig. 4). We attempted to control for this by using median values rather than means, and by including more studies, we were able to show a strong overall median FI; but there is certainly still room for improvement. For comparison, a recent review of RCTs in cardiology showed that the median FI of 123 manuscripts was 13 [16].

![Figure 2. Frequency of fragility index values of significant outcomes histogram.](image1)

![Figure 3. Frequency of fragility index values of nonsignificant outcomes histogram.](image2)
The FI has inherent limitations. A major limitation of this metric is its inability to evaluate nondichotomous outcome variables. Many outcomes in TJA research are reported with continuous metrics including radiographic angles and patient-reported outcomes, which the FI is unable to assess. As a result, a significant portion of studies had to be excluded (Seventy-eight percent of studies evaluated were excluded for not having dichotomous outcomes.). Because of this the FI, while useful in the appropriate setting, has a relatively limited application. Previously, the FI was even more limited, only applicable to significant outcomes and expanded the FI’s usefulness, but it is still limited by design as a statistical tool. Further work needs to be carried out to expand its use or to determine complementary tools.

TJAs remain some of the most common procedures in the world today [1-4]. As of 2010, 0.83% of the population and 1.52% of the population have undergone THA and TKA, respectively. This number is growing, with estimations that THAs will grow by 71% by 2030 to 635,000 procedures annually and that TKAs will grow by 85% to 1.26 million procedures [1]. Given this, research is extremely important to ensure safe and accessible TJAs as demand increases.

Despite its limitations, we believe the FI and RFI provide value in assessing outcomes in clinical research and holding our field accountable for the research we perform. Given the evidence shown here, although mean and median FI/RFI values were greater than the AAOS benchmark of 2, there are still a wide number of studies with numbers below that, and we must continue to be diligent in how we design trials evaluating TJAs.

**Table 4**

| Publication-level associations between fragility index and study variables. |
|------------------------------------------------------|
| Study variables | Pearson correlation coefficient | P value |
|----------------|-------------------------------|---------|
| Patient sample size | 0.140 | .002a |
| Journal impact factor | -0.0263 | .56 |
| Number of journal citations | -0.096 | .035a |
| Patients lost to follow-up | 0.022 | .62 |
| All P values | 0.197 | .000012a |
| Significant P values | -0.028 | .78 |
| Nonsignificant P values | 0.177 | .000045a |

* a Statistically significant.

**Conclusions**

This study is the largest evaluation of FI in orthopedics literature to date. We found a median FI/RFI of 4 for recently published TJA literature, which is comparable to or higher than FIs calculated in other orthopedic subspecialties. Although, overall, these numbers suggest strong evidence, there is still a large minority of studies with poor methodology. These data should be interpreted with caution, and we must continue to demand more sound research designs from our subspecialty.

**Conflicts of interest**

C. L. Herndon is a board member in AAOS.

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Appendix Table 1
Analyzed total hip arthroplasty articles.

| Journal | Author | Year | Comparison | Patients enrolled | Lost to follow-up | Outcomes (no.) | FI* |
|---------|--------|------|------------|-------------------|-------------------|----------------|-----|
| ACTA    | Gustafson et al. [1] | 2014 | Metal-on-metal hip resurfacing vs metal-on-polyethylene THA Electrochemically deposited vs conventional plasma-sprayed hydroxyapatite femoral stem | 54 | 10 | 14 | 6 |
|         | Flatøy et al. [2] | 2016 | | 55 | 30 | 2 | 9 |
| BJJ     | Vendittoli et al. [3] | 2013 | Hybrid hip resurfacing vs metal-on-metal uncemented THA | 219 | 55 | 6 | 5 |
|         | Lee et al. [4] | 2014 | 28-mm vs 32-mm Ceramic heads | 120 | 107 | 1 | 13 |
|         | van der Veen et al. [5] | 2015 | Metal-on-metal vs metal-on-polyethylene THA | 104 | 6 | 1 | 9 |
|         | Schücher et al. [6] | 2017 | Bisphosphonate solution vs saline | 60 | 2 | 3 | 5 |
|         | Ando et al. [7] | 2018 | Large vs conventional femoral head | 185 | 69 | 1 | 2 |
|         | Sköldenberg et al. [8] | 2019 | Argon-gas gamma-sterilized vs vitamin E-doped, highly crosslinked polyethylene | 42 | 4 | 1 | 2 |
| CORR    | Della Valle et al. [9] | 2010 | Mini-incision vs two-incision THA | 72 | 0 | 3 | 8 |
|         | Goosen et al. [10] | 2011 | Minimally invasive vs classic posterolateral approach | 120 | 0 | 10 | 7 |
|         | Corten et al. [11] | 2011 | Cemented vs cementless | 250 | 0 | 5 | 6 |
|         | Weber et al. [12] | 2014 | Fluoroscopy vs imageless navigation | 125 | 9 | 4 | 7 |
|         | Engh et al. [13] | 2016 | Ceramic-on-metal vs metal-on-metal | 72 | 9 | 2 | 5 |
|         | Parratte et al. [14] | 2016 | Computer-assisted vs conventional | 60 | 0 | 1 | 10 |
|         | Kim et al. [15] | 2016 | Ultrashort vs conventional anatomic cementless femoral stem | 212 | 12 | 3 | 16 |
|         | Hopper et al. [16] | 2018 | Crosslinked vs conventional polyethylene | 230 | 0 | 4 | 4 |
|         | Nakamura et al. [17] | 2018 | Robot-assisted vs hand-rasped stem | 130 | 15 | 1 | 4 |
|         | Taunton et al. [18] | 2018 | Direct anterior vs mini posterior THA | 116 | 15 | 1 | 4 |
|         | Mjaaland et al. [19] | 2019 | Direct anterior vs direct lateral THA | 164 | 11 | 2 | 9 |
|         | Bascarevic et al. [20] | 2010 | Alumina-on-alumina ceramic vs metal on highly cross-linked polyethylene | 150 | 0 | 23 | 6 |
| Int. Orthop. | | | | | | | |
| JOA     | Amanullah et al. [21] | 2011 | Ceramic-ceramic vs ceramic-polyethylene | 357 | 45 | 19 | 6 |
|         | Beaupre et al. [22] | 2013 | Ceramic-on-ceramic vs ceramic-on-crossfire polyethylene | 92 | 14 | 1 | 3 |
|         | Barrett et al. [23] | 2013 | Direct anterior vs posterolateral THA | 87 | 0 | 20 | 7 |
|         | Gurgel et al. [24] | 2014 | Computer-assisted vs conventional THA | 40 | 0 | 1 | 9 |
|         | Lass et al. [25] | 2014 | Imageless navigation system vs conventional THA | 130 | 5 | 1 | 7 |
|         | Hamilton et al. [26] | 2015 | 28-mm vs 36-mm Femoral heads | 345 | 113 | 1 | 3 |
|         | Wegryn et al. [27] | 2015 | Tantalum vs titanium cup | 111 | 25 | 2 | 4 |
|         | Gao et al. [28] | 2015 | Tranexamic acid with epinephrine vs tranexamic acid alone | 110 | 3 | 11 | 7 |
|         | Suarez et al. [29] | 2015 | Bipolar sealer vs standard electrocautery | 118 | 0 | 1 | 1 |
|         | Sculco et al. [30] | 2016 | Perioperative corticosteroids vs placebo | 40 | 13 | 7 | 7 |

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| Journal | Author | Year | Comparison | Patients enrolled | Lost to follow-up | Outcomes (no.) | FI* |
|---------|--------|------|------------|------------------|-------------------|----------------|-----|
|         | North et al. [31] | 2016 | Topical vs intravenous tranexamic acid | 139 | 0 | 1 | 1 |
|         | Cheng et al. [32] | 2017 | Direct anterior vs posterior approach THA | 75 | 2 | 15 | 5 |
|         | Guild et al. [33] | 2017 | Hybrid plasma scalpel vs bipolar sealer | 232 | 0 | 1 | 29 |
|         | Abdel et al. [34] | 2017 | Two-incision vs mini-posterior approach THA | 72 | 1 | 4 | 8 |
|         | Gielis et al. [35] | 2019 | Short vs wedge-shaped straight stem | 150 | 10 | 8 | 7 |
|         | Brun et al. [36] | 2019 | Direct lateral vs minimal invasive anterior approach THA | 164 | 0 | 8 | 5 |
| JBJS    | Barsoum et al. [37] | 2011 | Bipolar sealer vs standard electrocautery | 140 | 0 | 2 | 9 |
|         | Howie et al. [38] | 2012 | 28-mm vs 36-mm Femoral heads | 645 | 30 | 1 | 2 |
|         | Devane et al. [39] | 2017 | Highly cross-linked vs ultra-high-molecular-weight polyethylene | 122 | 31 | 1 | 5 |
|         | Kayupov et al. [40] | 2017 | Oral vs intravenous tranexamic acid | 89 | 6 | 1 | 10 |

Acta, Acta Orthopaedica; BJJ, Bone & Joint Journal; CORR, Clinical Orthopaedics and Related Research; Int. Orthop., International Orthopedics; JBJS, Journal of Bone and Joint Surgery; JOA, Journal of Arthroplasty.

* Average for all outcomes rounded to the nearest digit.
### Appendix Table 2
Analyzed total knee arthroplasty articles.

| Journal | Author | Year | Comparison | Patients enrolled | Lost to follow-up | Outcomes (no.) | FL* |
|---------|--------|------|------------|-------------------|-------------------|----------------|-----|
| Acta    | Meijerink et al. [41] | 2011 | CKS vs PFC TKA designs | 82 | 0 | 3 | 3 |
|         | Stilling et al. [42] | 2011 | High-porosity trabecular metal vs low-porosity titanium-pegged porous fiber-metal polyethylene backing tibial components | 50 | 4 | 1 | 6 |
|         | Wilson et al. [43] | 2012 | Trabecular metal vs cemented tibial component | 70 | 25 | 1 | 11 |
| BJJ     | Van Leeuwen et al. [44] | 2018 | Patient-specific positioning guides vs conventional method | 109 | 15 | 6 | 4 |
|         | Breeman et al. [45] | 2013 | Mobile vs fixed-bearing TKA | 539 | 7 | 14 | 8 |
|         | van Jonbergen et al. [46] | 2014 | Circumpatellar electrocautery vs no treatment | 300 | 98 | 1 | 1 |
|         | Boonen et al. [47] | 2016 | Patient-matched positioning guides and conventional instruments | 180 | 17 | 1 | 2 |
|         | Schotanus et al. [48] | 2016 | MRI vs CT patient-specific guides in TKA | 140 | 3 | 11 | 7 |
|         | Powell et al. [49] | 2018 | Mobile vs fixed-bearing TKA | 167 | 82 | 2 | 3 |
|         | Lachiewicz and O’Dell [50] | 2019 | Standard vs highly crosslinked polyethylene | 265 | 56 | 5 | 8 |
|         | MacDessi et al. [51] | 2020 | Kinematic vs mechanical alignment | 128 | 0 | 21 | 9 |
| CORR    | Hernández-Vaquero et al. [52] | 2011 | Navigation vs jig-based TKA | 97 | 24 | 5 | 7 |
|         | Charoencholvanich et al. [53] | 2011 | Tranexamic acid vs placebo | 100 | 0 | 1 | 9 |
|         | Laffosse et al. [54] | 2011 | Midline vs anterolateral skin incision | 64 | 2 | 3 | 5 |
|         | Cip et al. [55] | 2013 | Autotransfusion vs control | 151 | 11 | 1 | 12 |
|         | Rob et al. [56] | 2013 | Patient-specific instrumentation vs conventional method | 100 | 10 | 6 | 2 |
|         | Fernandez-Fairen et al. [57] | 2013 | Porous tantalum cementless vs cemented tibial component | 145 | 13 | 3 | 6 |
|         | Pongcharoen et al. [58] | 2013 | Medial parapatellar vs midvastus approach TKA | 59 | 0 | 13 | 8 |
|         | Song et al. [59] | 2013 | Robot-assisted vs conventional TKA | 100 | 0 | 5 | 9 |
|         | Ponsornskul et al. [60] | 2014 | Infrapatellar fat pad excision vs no excision | 90 | 13 | 3 | 2 |
| Int. Orthop. | Sah [61] | 2015 | Bidirectional barbed vs standard sutures | 50 | 0 | 3 | 7 |
|         | Young et al. [62] | 2017 | Kinematic vs mechanical alignment | 114 | 0 | 3 | 8 |
|         | Kim et al. [63] | 2018 | Navigation vs conventional TKA | 296 | 14 | 9 | 11 |
|         | Chen et al. [64] | 2014 | Whole vs half course tourniquet use | 64 | 0 | 1 | 8 |
|         | Ha et al. [65] | 2019 | Resurfacing vs nonresurfacing of the patella | 66 | 4 | 2 | 6 |
| JOA     | Hamilton et al. [66] | 2011 | High flex vs standard rotating platform TKA | 142 | 6 | 1 | 2 |
|         | Plymale et al. [67] | 2012 | Unipolar vs bipolar hemostasis in TKA | 113 | 0 | 1 | 9 |
|         | Georgiadis et al. [68] | 2013 | Topical tranexamic acid vs placebo | 101 | 0 | 5 | 6 |
|         | Kusuma et al. [69] | 2013 | Bovine thrombin vs no treatment | 80 | 0 | 1 | 4 |
|         | Liow et al. [70] | 2014 | Robot-assisted vs conventional TKA | 60 | 0 | 3 | 4 |
|         | Nam et al. [71] | 2014 | Extramedullary vs accelerometer navigational cutting guides | 100 | 6 | 4 | 5 |
|         | Randelli et al. [72] | 2014 | Topical novel fibrin vs no treatment | 62 | 0 | 1 | 6 |
|         | Patel et al. [73] | 2014 | Intravenous vs topical tranexamic acid | 100 | 0 | 1 | 7 |
|         | Gao et al. [74] | 2015 | Tranexamic acid with epinephrine vs tranexamic acid alone in TKA | 103 | 0 | 7 | 7 |
|         | Fricka et al. [75] | 2015 | Cemented vs cementless TKA | 100 | 3 | 3 | 5 |
|         | Shi et al. [76] | 2016 | Fixed vs individualized valgus correction | 133 | 0 | 3 | 17 |

(continued on next page)
| Journal                | Author                  | Year | Comparison                                                                 | Patients enrolled | Lost to follow-up | Outcomes (no.) | FL* |
|-----------------------|-------------------------|------|----------------------------------------------------------------------------|--------------------|-------------------|----------------|-----|
| Ahn et al. [77]       | 2016                    |      | Reduction osteotomy vs piecrusting for medial release                      | 106                | 0                 | 1              | 4              |
| Chan et al. [78]      | 2017                    |      | Bidirectional barbed vs traditional sutures in TKA                         | 117                | 0                 | 6              | 5              |
| Wang et al. [79]      | 2017                    |      | Tranexamic acid vs placebo                                                | 200                | 0                 | 4              | 4              |
| Kim et al. [80]       | 2017                    |      | High flex vs standard TKA                                                 | 994                | 34                | 2              | 11             |
| Teeter et al. [81]    | 2017                    |      | Measured resection vs gap balancing TKA                                   | 23                 | 0                 | 1              | 3              |
| Gharabei et al. [82]  | 2017                    |      | Navigation vs conventional TKA                                            | 190                | 4                 | 10             | 6              |
| Tammachote et al. [83]| 2018                    |      | Customized cutting block vs conventional TKA                              | 108                | 2                 | 9              | 7              |
| Cip et al. [84]       | 2018                    |      | Navigation vs conventional TKA                                            | 200                | 141               | 11             | 5              |
| Dong et al. [85]      | 2018                    |      | Patellar resurfacing and circumpatellar electrocautery                    | 53                 | 5                 | 2              | 8              |
| Thiengwittayaporn et al. [86] | 2019 |      | Patellar resurfacing vs nonresurfacing                                   | 84                 | 4                 | 1              | 10             |
| JBJS                  | Hui et al. [87]         | 2011 | Oxidized zirconium vs cobalt-chromium femoral component                   | 40                 | 6                 | 1              | 9              |
| Huang et al. [88]     | 2011                    |      | Computer-assisted navigation vs conventional TKA                          | 113                | 0                 | 4              | 2              |
| Hinarejos et al. [89] | 2013                    |      | Erythromycin and colistin cement vs standard cement                       | 3000               | 52                | 3              | 8              |
| Schimmel et al. [90]  | 2014                    |      | Bicruciate substituting vs conventional posterior stabilizing implant     | 124                | 0                 | 1              | 4              |
| Verburg et al. [91]   | 2016                    |      | Mini-midvastus vs conventional TKA                                       | 100                | 0                 | 3              | 5              |
| Petursson et al. [92] | 2018                    |      | Computer assisted vs conventional TKA                                     | 190                | 23                | 11             | 4              |
| Abdel et al. [93]     | 2018                    |      | Intravenous vs topical tranexamic acid                                    | 664                | 24                | 2              | 13             |
| KSSTA                 | Nam et al. [94]         | 2019 | Cemented vs cementless TKA                                               | 147                | 6                 | 2              | 14             |
| Demey et al. [95]     | 2011                    |      | Cemented vs uncemented femoral component                                 | 130                | 9                 | 5              | 6              |
| Pang et al. [96]      | 2011                    |      | Computer-assisted gap balancing vs conventional measures                  | 140                | 0                 | 4              | 6              |
| Jung et al. [97]      | 2013                    |      | Intramedullary vs extramedullary alignment                               | 91                 | 0                 | 3              | 6              |
| Lee et al. [98]       | 2013                    |      | Tranexamic acid + indirect factor Xa inhibitor vs direct factor Xa inhibitor alone stabilized design | 72                 | 0                 | 4              | 6              |
| Breugem et al. [99]   | 2014                    |      | Fixed vs mobile posterior stabilized design                               | 103                | 3                 | 3              | 6              |
| Izumi et al. [100]    | 2015                    |      | Transcutaneous electrical nerve stimulation vs control                    | 90                 | 0                 | 1              | 1              |
| Chen et al. [101]     | 2015                    |      | Pin-less navigation vs conventional surgery                               | 100                | 0                 | 3              | 1              |
| Olivier et al. [102]  | 2016                    |      | MRI-based vs computer-assisted TKA                                        | 80                 | 0                 | 5              | 6              |
| Collados-Maestre et al. [103] | 2017 |      | Single radius vs multiradius TKA                                         | 240                | 3                 | 3              | 2              |

* Average for all outcomes rounded to the nearest digit.
Appendix Table 3
Analyzed total hip and total knee arthroplasty articles.

| Journal | Author | Year | Comparison | Patients enrolled | Lost to follow-up | Outcomes (no.) | FI* |
|---------|--------|------|------------|-------------------|-------------------|----------------|-----|
| BJJ     | Sprowson et al. [104] | 2018 | Triclosan-coated vs standard sutures | 2546 | 109 | 20 | 9 |

BJJ, Bone & Joint Journal.

* Average for all outcomes rounded to the nearest digit.