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Revisiting the FAITH Trial: A Secondary Analysis Yielding Novel Insights with the Win Ratio

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Background: Many orthopaedic trials use any unplanned reoperation as the primary outcome, but this overlooks how patients experience those outcomes. Using a high-quality hip fracture trial, we demonstrate how the relative importance of multiple patient-important outcomes can be effectively incorporated into data analysis, providing a more comprehensive understanding of treatment impact.

Methods: This secondary analysis of the Fixation using Alternative Implants for the Treatment of Hip Fracture (FAITH) trial included 1,079 patients aged 50 years or older with a low-energy femoral neck fracture who were randomly assigned to treatment with a sliding hip screw or cancellous screws. The original trial used unplanned revision surgery as the primary outcome. Our primary analysis instead used a composite outcome of all-cause mortality at 4 months, ambulation status at 10 weeks (measured by the EuroQol-5 Dimension [EQ-5D] mobility dimension), and days at home within 4 months. We assessed outcomes hierarchically using the win ratio method, comparing each patient with every other patient in the alternative treatment group in a pairwise manner. We conducted sensitivity analyses at 6 and 12 months, and subgroup analyses to explore smoking status and fracture displacement as potential effect modifiers.

Results: Of the 1,079 participants, 741 had EQ-5D data available for the primary analysis at 4 months, yielding 137,114 pairwise comparisons. A sliding hip screw was superior to cancellous screws in 65,158 (47.5%) comparisons, inferior to cancellous screws in 63,378 (46.2%) comparisons, and tied in 8,578 (6.3%), leading to a win ratio of 1.03 (95% confidence interval [CI] 0.86-1.23), but this difference was not statistically significant (p = 0.76). The sensitivity analysis results were similar at 6 and 12 months. In the subgroup analysis, a sliding hip screw was superior to cancellous screws in current smokers, with a win ratio of 1.65 (95% CI 1.02-2.65) at 6 months (p = 0.007).

Conclusion: This analysis approach should be considered for future orthopaedic trials as it was consistent with the FAITH primary analysis findings but yielded a more nuanced interpretation of the patients' experience and offers deeper insights into intervention effectiveness. The bounds of the 95% CI for the primary outcome were within many standard definitions of equivalence, suggesting surgeons can assume similar patient-important outcomes with either treatment.

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Introduction

Many orthopaedic trials use unplanned reoperation as the primary outcome, but this fails to delineate between minor and major reoperations, and does not convey how patients experience those outcomes. The win ratio is a statistical approach used in clinical trials to analyze hierarchical composite outcomes, providing a ranked evaluation of multiple components (e.g., survival, quality of life, and functional status)[1]. Unlike traditional methods such as Kaplan-Meier survival analysis, log-rank test, and Cox proportional hazards regression, the win ratio incorporates the relative importance of each outcome in a *predefined* hierarchy, comparing all possible pairs of participants across treatment groups. In contrast to conventional methods, the win ratio can analyze composites composed of time-to-event, recurrent events, continuous, and categorical outcomes[1]. This allows for a more comprehensive interpretation of data and often greater statistical power to identify and quantify a treatment difference by incorporating all available information within the component outcomes.[2]

Using data from the high-quality hip fracture trial, Fixation using Alternative Implants for the Treatment of Hip Fractures (FAITH)[3], we aimed to demonstrate how the relative importance of multiple outcomes can effectively be incorporated into data analyses by separately evaluating the clinical status of these hip fracture patients, providing a more comprehensive understanding of treatment impact. Our goal is not to diminish the value of this trial but to demonstrate that alternative outcome measures and analytical approaches can yield additional information for the results and potentially enhance statistical power. By adopting this new method of analysis, we hope to offer more comprehensive insights that could guide policymakers and improve the design and interpretation of future orthopaedic trials.

Methods

FAITH Study Overview

Between March 3, 2008, and March 31, 2014, the FAITH trial (ClinicalTrials.gov NCT00761813) enrolled 1,079 patients from 81 clinical centers in the United States, Canada, Australia, the Netherlands, Norway, Germany, the United Kingdom, and India, who were at least 50 years old with a low-energy femoral neck fracture treated by fracture fixation with a sliding hip screw or cancellous screws. The primary outcome was unplanned revision surgery to promote healing, relieve pain, treat infection, or improve function within 24 months of fracture fixation. Ethics approval for this secondary analysis was obtained from the Hamilton Integrated Research Ethics Board (#18542).

Outcomes

For this secondary analysis of the FAITH trial, we constructed a ranked composite outcome that included (1) all-cause mortality, (2) ambulation status at one follow-up time point assessed using the EuroQol-5 Dimension (EQ-5D) mobility dimension[4], and (3) number of days at home (see Appendix Figure S1). Higher priority was given to components that are clinically more important, with mortality considered the most critical outcome, followed by ambulation status, and then days at home. The ranking of these components was supported by patient preference research in this study population[5-8].

The FAITH trial collected the length of stay for hospital admissions for the initial surgery, reoperations, and adverse events throughout the 24-month follow-up period. Using these data points, the days in hospital were calculated for each participant and subtracted from the days alive within the 24-month follow-up period to calculate the number of days at home. We present a breakdown of the average length of hospital stay in FAITH trial participants by reoperation type and reason for reoperation in the Appendix. In the FAITH trial, reoperations that were classified as study events included implant removal; implant exchange—total hip arthroplasty, hemiarthroplasty, or internal fixation; soft tissue procedure; and any other event as determined by the adjudication committee (proximal femoral osteotomy). The reasons for reoperations included painful hardware, implant failure, avascular necrosis, nonunion, deep infection, superficial infection, hip instability, intractable pain due to wear of the acetabulum, periprosthetic femur fracture, or hip dislocation.

Statistical Analysis

Baseline demographics and fracture characteristics were analyzed using descriptive statistics reported as count and percentage or mean and standard deviation (SD) or median and interquartile range, depending on the data distribution.

The primary analyses followed the intention-to-treat principle, analyzing participants in the group to which they were randomly assigned. We hierarchically assessed mortality at 4 months, followed by ambulation status (EQ-5D mobility dimension) at 10-week postrandomization, and the number of days at home within 4-month postrandomization using the win ratio method. The win ratio method is based on the principle that each patient in a clinical trial is compared with every other patient assigned to the alternative treatment in a pairwise manner. Higher importance is given to higher-ranked components of the composite outcome. The pairwise comparison proceeds in a *predefined* hierarchical fashion, starting with all-cause mortality, followed by ambulation status (EQ-5D mobility dimension), and then days at home when patients cannot be differentiated based on a higher ranked comparison. The all-cause mortality component was included as a time-to-event analysis, assuming an earlier event was worse than a later occurrence. Participants with unknown mortality status at the time of assessment were censored at their last known observation. If a participant died within an assessment window, rendering their ambulation status unknown, they were assigned the lowest ambulation level (confined to bed) to not be dropped from the analysis. Finally, the treatment groups were assigned a win, loss, or tie in each pairwise comparison. Initially, the pairs were compared for time until death, truncated at 4 months. If both participants died, the "winner" of the comparison was the one who had a longer time between the time of randomization and the date of death. If the match was tied (both participants died within the same follow-up time or both remained alive until the 4-month visit), the pair were then compared for ambulation status. Finally, if a second tie occurred, participants were compared for days at home, and the participant with the most days at home was declared the "winner." The win ratio is the number of wins in one treatment group divided by the number of wins in the other treatment group with a 95% confidence interval (CI) and p-value calculated using the methods described by Bebu and Lachin[9]. A win ratio greater than 1 indicated a better outcome in the sliding hip screw group.

We conducted 2 sensitivity analyses that followed the primary analysis methods but changed the timing of outcomes:

1. We hierarchically assessed mortality at 6 months, followed by ambulation status (EQ-5D mobility dimension) at 6-month postrandomization, and number of days at home across 6-month postrandomization.

2. We hierarchically assessed mortality at 12 months, followed by ambulation status (EQ-5D mobility dimension) at 12-month postrandomization, and number of days at home across 12-month postrandomization.

We also conducted subgroup analyses investigating smoking status and fracture displacement as possible effects modifier at 4, 6, and 12 months. Smoking status and fracture displacement were included as subgroups in the primary FAITH study[3].

For all analyses, the threshold for statistical significance was $p < 0.05$. We did not adjust the alpha for multiple comparisons. All analyses were conducted in R (version 4.4.2; R Foundation for Statistical Computing).

Results

Demographics and Fracture Characteristics

Of the 1,079 participants enrolled in the FAITH trial, 741 were included in the primary analysis. Most of these participants were female (63.7%) and White (94.3%), with a mean age of 73.2 years (SD 11.5 years). Half of the participants had a normal body mass index (18.5-24.9), and most were either former or nonsmokers (82.5%). Nearly all injuries were sustained from a fall (97.0%), and most fractures were subcapital (62.2%), undisplaced (70.3%), and of Pauwels classification Type II (62.1%) (Table I).

TABLE I Demographics and Fracture Characteristics

	Sliding Hip Screw N = 383	Cancellous Screws N = 358
Age (yrs), mean (SD)	73.4 (11.6)	73.0 (11.5)
Sex, n (%)		
Male	144 (37.6)	125 (34.9)
Female	239 (62.4)	233 (65.1)
Body mass index, n (%)		
Underweight (<18.5)	26 (6.8)	24 (6.7)
Normal weight (18.5-24.9)	193 (50.4)	183 (51.1)
Overweight (25-29.9)	121 (31.6)	109 (30.4)
Obese (30-39.9)	34 (8.9)	35 (9.8)
Morbidly obese (≥40)	6 (1.6)	2 (0.6)
Did not disclose	3 (0.8)	5 (1.4)
Race/ethnicity, n (%)		
Indigenous	1 (0.3)	1 (0.3)
South Asian	4 (1.0)	3 (0.8)
East Asian	4 (1.0)	3 (0.8)
Black	15 (3.9)	8 (2.2)
Hispanic or Latin	1 (0.3)	1 (0.3)
White	357 (93.2)	342 (95.5)
Did not disclose	1 (0.3)	0 (0.0)
Smoking history, n (%)		
Former or nonsmoker	315 (82.2)	296 (82.7)
Current smoker	67 (17.5)	61 (17.0)
Did not disclose	1 (0.3)	1 (0.3)
Mechanism of injury, n (%)		
Fall	369 (96.3)	350 (97.8)
Spontaneous fracture	11 (2.9)	4 (1.1)
Other low-energy trauma	1 (0.3)	3 (0.8)
Did not disclose	2 (0.5)	1 (0.3)
Level of fracture line, n (%)		
Subcapital	259 (67.6)	258 (72.1)
Midcervical	109 (28.5)	88 (24.6)
Basal	15 (3.9)	12 (3.4)
Fracture displacement, n (%)		
Displaced	117 (30.5)	103 (28.8)
Undisplaced	266 (69.5)	255 (71.2)
Pauwel classification, n (%)		
Type I	40 (10.4)	31 (8.7)
Type II	297 (77.5)	279 (77.9)
Type III	46 (12.0)	48 (13.4)

Primary Analysis

Of the 1,079 participants, 741 had EQ-5D data available for the primary analysis at 4 months, yielding 137,114 pairwise comparisons (383 sliding hip screw participants × 358 cancellous screw participants). A sliding hip screw was found to be superior to cancellous screws in 65,158 (47.5%) comparisons, inferior to cancellous screws in 63,378 (46.2%) comparisons, and tied in 8,578 (6.3%), leading to a win ratio of 1.03 (95% CI 0.86-1.23), but this difference was not statistically significant ($p = 0.76$). Mortality (5.5% vs. 7.3%), ambulation status (no problems walking: 18.3% vs. 16.2%, some problems walking: 73.6% vs. 74.9%, confined to bed: 8.1% vs. 8.9%), and days at home (111.7 vs. 111.0) were similar between the sliding hip screw and cancellous screws groups (Fig. 1, Appendix Table S1).

Sensitivity Analyses

At 6 months, 636 participants had EQ-5D data available for the analysis, yielding 101,075 pairwise comparisons. A sliding hip screw was found to be superior to cancellous screws in 46,673

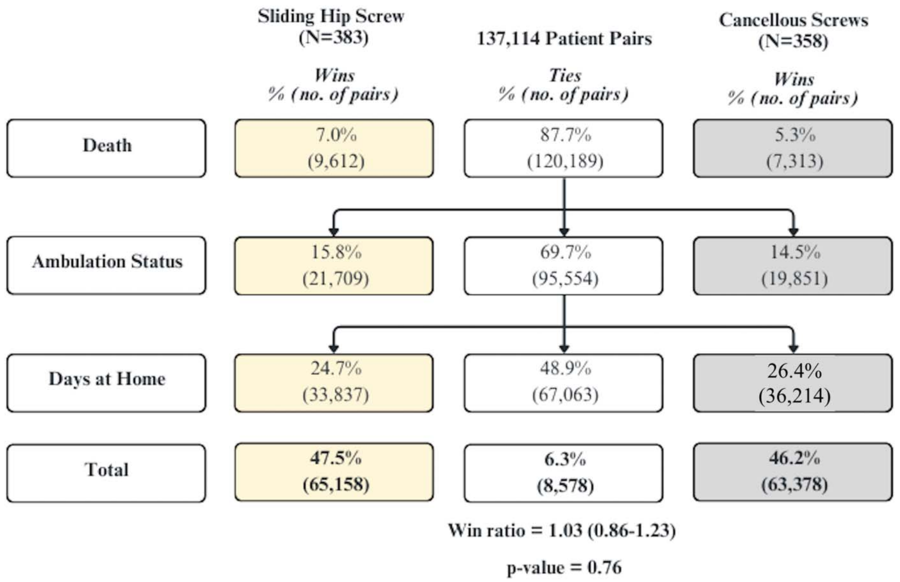

Fig. 1
Primary analysis—win ratio results at 4 months.

(46.2%) comparisons, inferior to cancellous screws in 49,616 (49.1%) comparisons, and tied in 4,786 (4.7%), leading to a win ratio of 0.94 (95% CI 0.78-1.14), but this difference was not statistically significant (p = 0.53) (Fig. 2, see Appendix Table S1).

At 12 months, 655 participants had EQ-5D data available for the analysis, yielding 107,226 pairwise comparisons. A sliding hip screw was found to be superior to cancellous screws in 49,751 (46.4%) comparisons, inferior to cancellous screws in 53,193 (49.6%) comparisons, and tied in 4,282 (4.0%), leading to a win ratio of 0.94 (95% CI 0.78-1.12), but this difference also was not statistically significant (p = 0.48) (Fig. 3, see Appendix Table S1).

Subgroup Analyses—Smoking Status

At 4 months, the win ratio between the sliding hip screw and cancellous screws groups in current smokers was 1.41 (95% CI 0.92-2.17), with the sliding hip screw group experiencing more wins in all outcome components compared with the cancellous screws group (overall: 55.2% vs. 39.1%), but this difference only neared statistical significance (p = 0.09) (Fig. 4, see Appendix Table S1).

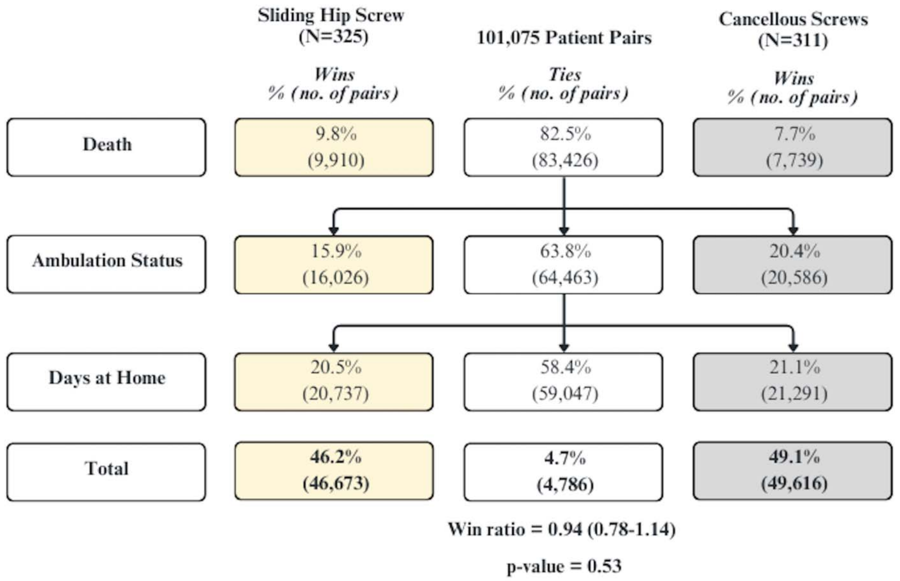

Fig. 2
Sensitivity analysis—win ratio results at 6 months.

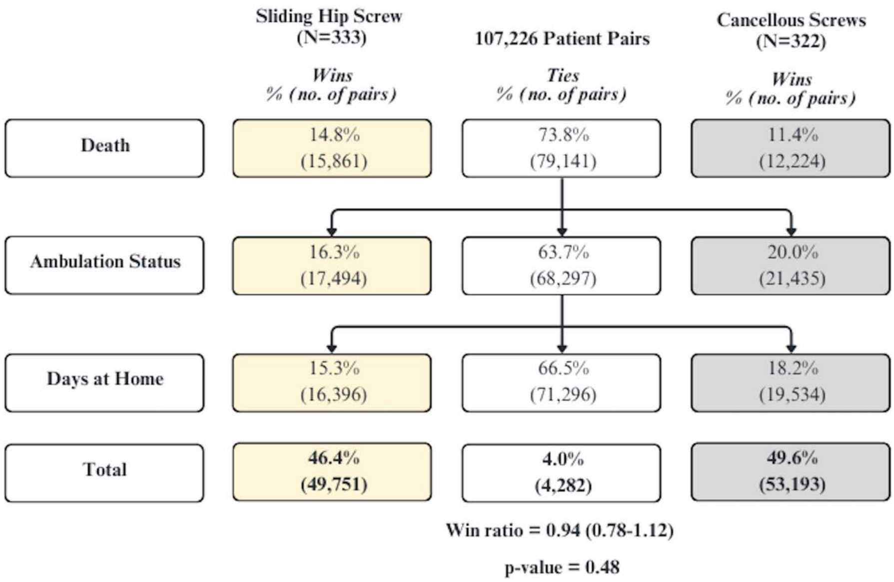

Fig. 3

Sensitivity analysis—win ratio results at 12 months.

At 6 months, treatment with a sliding hip screw was preferred in current smokers, with a win ratio of 1.65 (95% 1.02-2.65; p = 0.007). The sliding hip screw group won on the mortality (15.3% wins vs. 10.8%), ambulation status (25.7% wins vs. 9.1%), and days at home (18.9% wins vs. 16.5%) outcomes (Fig. 4, see Appendix Table S1).

At 12 months, the win ratio between the sliding hip screw and cancellous screws groups in current smokers was 1.29 (95% CI 0.83-2.00), with the sliding hip screw group experiencing more wins overall compared with the cancellous screws group (53.8% vs. 41.7%), but this difference did not reach statistical significance (p = 0.10) (Fig. 4, see Appendix Table S1).

Subgroup Analyses—Fracture Displacement

At 4 months, the win ratio between the sliding hip screw and cancellous screws groups in those with a undisplaced fracture was 1.06 (95% CI 0.86-1.32), with the sliding hip screw group experiencing more wins overall compared with the cancellous screws group (48.4% vs. 45.4%), but this difference did not reach statistical significance (p = 0.53) (see Appendix Table S1).

At 6 and 12 months, the win ratios between the sliding hip screw and cancellous screws groups in those with a undisplaced fracture were 0.90 (95% CI 0.72-1.13) and 0.96 (95% CI 0.77-1.20), respectively, with the sliding hip screw group experiencing more losses overall compared with the cancellous screws group (6 months: 45.2% vs. 50.3%; 12 months: 47.0% vs. 49.0%). These differences did not reach statistical significance (6 months: p = 0.37; 12 months: p = 0.63) (see Appendix Table S1).

Discussion

In this reanalysis of the FAITH trial, the results were consistent with the FAITH primary analysis findings but yielded a more nuanced interpretation of composite data when using a hierarchical composite outcome consisting of all-cause mortality, ambulation status, and number of days at home. The bounds of the 95% CI meet many standard definitions of equivalence (between 0.8-1.25 on a relative scale according to the U.S. Food and Drug Administration guidance)[10], suggesting surgeons can assume similar patient-important outcomes with either treatment.

The win ratio method has been widely adopted in cardiovascular trials over the past decade for analyzing a composite clinical hierarchy of outcomes[11] but has yet to be explored in orthopaedic trial research. The win ratio approach shares similarities with the conventional time-to-first event analyses (such as Cox proportional hazards models) that are typically used in orthopaedic trials in that both approaches compare outcomes between treatment groups by considering the time at which events occur. However, there are key differences in how they handle events and prioritize outcomes. Many orthopaedic trials use unplanned reoperation as the primary outcome, and if using a composite endpoint, such as reoperation and nonunion or malunion, these conventional composite endpoints do not take into account that the component events likely vary in their clinical importance and only consider the first event to occur regardless of its clinical importance[1,11]. Although these time-to-first event analyses provide a straightforward and statistically powerful way to compare treatment effects in clinical trials, they may not always fully capture a trial's overall conclusions[12]. The win ratio is useful because composite outcomes generally have a well-defined hierarchy of components that aligns with their clinical importance, allowing the outcomes to be more patient-centered. Another benefit of win statistics is its ability to also incorporate recurrent events and patient-reported outcomes (continuous or categorical) within a clinical hierarchy[2,13].

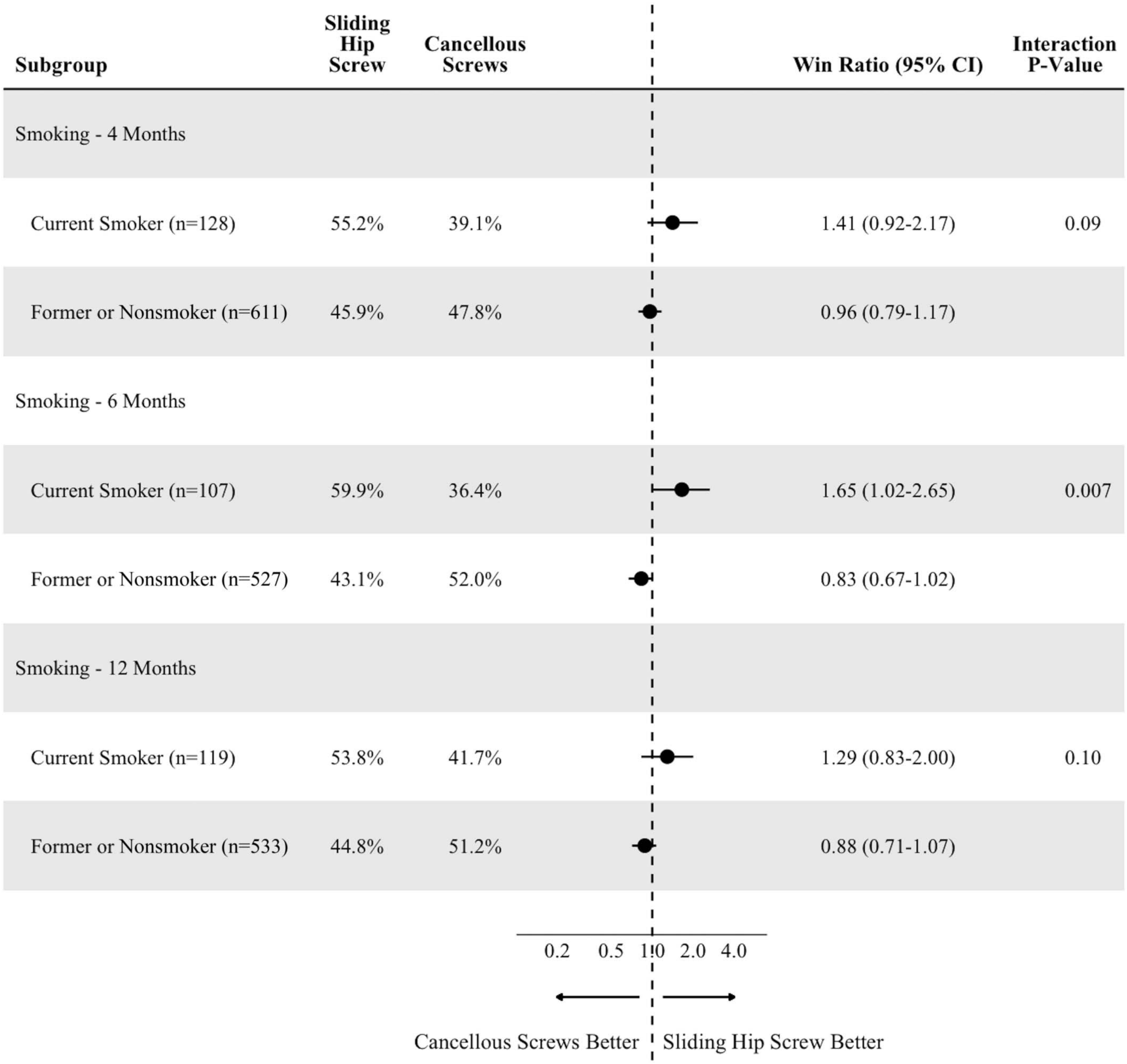

Fig. 4
Subgroup analyses.

Overall, the win ratio approach is an appealing alternative for comparing randomized treatments due to its hierarchical structure, strong statistical power, flexibility, and ability to incorporate patient-important outcomes.

Breaking down wins and losses by component clarifies each outcome's contribution to the overall win ratio, helping determine whether the treatment effect is driven by clinically important events (e.g., mortality) or less critical outcomes (e.g., ambulation status). In our subgroup analysis, the results for current smokers at 6 months appear to be primarily influenced by ambulation status, with 25.7% wins in the sliding hip screw group vs. 9.1% wins in the cancellous screw group. When examining the ambulation status breakdown, the most notable shift occurs between the “some problems walking” and “confined to bed” categories. However, a limitation of this analysis is the use of only 3 ambulation levels. Most patients fall into the “some problems walking” category, which may obscure meaningful differences. In future analyses, a more detailed 4-level classification would be beneficial: (1) ambulates without an aid, (2) ambulates with an aid, (3) ambulates with human assistance, and (4) unable to ambulate, with ambulate defined as walking 10 feet or across a room. Adopting this refined categorization could better differentiate the "some problems walking" group, offering a more comprehensive assessment and potentially revealing differences not apparent in the current analysis.

Our analyses of the FAITH trial data demonstrate how hierarchically assessed composite endpoints are affected by the duration of follow-up. The duration of follow-up affects the number of events observed, the weight of different outcome types, and the balance of wins and losses over time[1,13,14]. Longer follow-up can provide a more complete picture of treatment effects, especially when an intervention has delayed benefits or if secondary outcomes (e.g., functional decline and hospitalizations) become more relevant over time. However, longer observation periods also increase the likelihood of competing risks, often exogenous to the treatments. On the other hand, shorter follow-up may limit the number of events recorded, leading to a higher proportion of ties, potentially diluting the treatment effect. For instance, in our FAITH trial subgroup analyses, the treatment effects among smokers at 4 months may not have been apparent because key complications likely driving the overall FAITH outcomes had not yet occurred within that timeframe, but became apparent at 6 months. Selecting an appropriate follow-up period is crucial to ensuring that win statistics accurately reflect treatment efficacy. Examining how the win ratio evolves over time, along with the distribution of wins and losses across different outcome tiers, helps clarify treatment effects. These patterns may vary over time between treatment groups or across different components of the outcome hierarchy, offering deeper insight into the intervention's impact[13].

This exercise demonstrates the potential of the win ratio method as a valuable alternative to conventional time-to-first event approaches in orthopaedic trials. It should be noted that although the win ratio method provides statistical verification of similarities or differences between the comparisons, the interpretation of clinical significance is left to the authors and readers. Assessing the practical or clinical importance of observed differences relies on informed judgment beyond the statistical results. Although our findings were consistent with the FAITH trial's primary analysis, by accounting for event *predefined* hierarchies and incorporating patient-reported outcomes, the win ratio provides a patient-centered approach to assessing treatment effects. Future orthopaedic trials should consider exploring the application of win ratio statistics for evaluating treatment efficacy to enhance clinical decision-making and patient care.

Appendix

eA Supporting material provided by the authors is posted with the online version of this article as a data supplement at jbjs.org (http://links.lww.com/JBJSOA/A997). This content was not copyedited or verified by JBJS. ■

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