SYSTEMATIC REVIEW AND META-ANALYSIS

The role of sham surgery in orthopedic practice: a systematic review and meta-analysis

Khalaf A. Alnowaishiri[1*], Ahmed Saeed M. Alqahtani[2], Bader Sulaiman Althunayyan[3], Ghaida M. Alanbari[4], Hasan Ali AlGharib[5], Mohammed H. Hwaifr[6], Naif M. Alqahtani[7], Turki F. Alrashidi[8], Ismail H. Almogbil[9]

ABSTRACT

Background: To assess whether sham procedures offer comparable outcomes in pain relief, function, quality of life, and adverse events.

Methods: The literature search was conducted across the PubMed, Scopus, and Cochrane Library databases (2014–2024). Eligible studies included randomized controlled trials and observational studies comparing sham and actual orthopedic surgeries. Data were extracted and pooled using Review Manager version 5.1.4, with standardized mean difference (SMD) as the effect size metric. A random-effects model accounted for heterogeneity. Risk of bias was assessed using the Cochrane tool.

Results: Seven studies were included. The meta-analysis showed a statistically significant difference favoring real surgery for pain outcomes (SMD = -0.73; 95% CI: -1.23 to -0.22; $p = 0.005$), with high heterogeneity ($I^2 = 89\%$). Functional outcomes (185 participants across 3 studies) showed no significant difference (SMD = -0.07; 95% CI: -1.04 to 0.89; $p = 0.88$; $I^2 = 90\%$). For quality of life (342 participants across 5 studies), the difference was also non-significant (SMD = -0.09; 95% CI: -0.47 to 0.30; $p = 0.66$; $I^2 = 77\%$).

Conclusion: Sham surgeries produced outcomes similar to real procedures in function, quality of life, and adverse events. However, real surgery provided greater pain relief. These findings suggest that while placebo effects play a role in patient improvement, some orthopedic surgeries still offer meaningful benefits, especially for pain.

Keywords: Orthopedic procedures, pain management, placebos, treatment outcome, quality of life.

Introduction

Sham surgery, also known as placebo surgery, is the imitation of a surgical procedure without performing the actual therapeutic operation. The use of a sham control in clinical research is not unique to orthopedics; it originates from a landmark 1959 trial that compared internal mammary artery ligation with a sham operation for angina pectoris and found no difference between the two, challenging a surgical practice that had been adopted without formal evidence [1]. Since then, sham-controlled designs have been extended across numerous surgical and interventional specialties. In neurosurgery, several sham-controlled trials of fetal cell transplantation and gene therapy for Parkinson's disease using a partial burr-hole as the sham procedure found no significant benefit of the active intervention over sham [2]. Interventional cardiology has similarly relied on sham-controlled designs: the ORBITA trial found that percutaneous coronary intervention for stable angina did not improve exercise time beyond a sham procedure [3], and the SYMPLICITY HTN-3 trial found no significant blood-pressure benefit of renal denervation over sham in patients with resistant hypertension [4]. A systematic review spanning multiple surgical disciplines similarly found that most placebo-controlled surgical trials fail to

Correspondence to: Khalaf A. Alnowaishiri
*Kuwait Institute for Medical Specializations (KIMS), Kuwait City, Kuwait.
Email: Khalnuwaishry@gmail.com
Full list of author information is available at the end of the article.
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demonstrate superiority of the active intervention, while sham procedures themselves carry a non-negligible risk of adverse events [2,5]. These cross-disciplinary findings establish sham-controlled trials as a methodological tool for distinguishing genuine treatment effects from placebo response, of which orthopedic sham surgery represents one specific application.

Sham surgeries are common placeholders in orthopedic studies to assess the actual efficacy of surgical intervention and to separate placebo response from mechanistic bias. Louw et al. [6] conducted a systematic review of six randomized controlled trials (RCTs) comparing real orthopedic surgeries with sham procedures. The results showed that placebo surgeries were as effective as actual surgeries in relieving pain and improving function. However, the authors warn that these findings cannot be extrapolated, as the included studies represented a small subgroup [6].

Sham surgery in clinical studies is a major ethical issue. Its use remains the subject of active debate among clinicians, ethicists, and trialists. Critics argue that it is hard to justify exposing patients to an incision, anesthesia, and the general risks of surgery when the procedure cannot provide any medical benefit. They believe this goes against the principle of non-maleficence, which means avoiding harm to patients. Critics also argue that patients may not fully understand the risks of a procedure that is intentionally designed to have no therapeutic effect, even if they give formal informed consent [7]. Supporters argue that without a sham control, it is impossible to separate the placebo effect of an invasive procedure from its real treatment effect. This could lead to the continued use of surgical procedures that are no more effective than a placebo. They believe that using a sham control is ethically acceptable if there is genuine clinical equipoise and the risks to participants are minimized and clearly explained [8]. Ethical frameworks developed specifically for sham-controlled trials describe the conditions under which their use is justified. These conditions include a scientifically valid research question, an acceptable balance between risks and benefits, and a rigorous informed-consent process. The informed-consent process should clearly explain that participants may receive a sham intervention that is not intended to provide therapeutic benefit [8].

The primary concern is the potential to subject patients to unnecessary surgical risks without demonstrable clinical benefit. Ethical considerations underscore the need for thorough risk-benefit calculations and informed consent to inform decision-making about the use of sham surgeries in research trials [9]. Despite these ethical challenges, sham-controlled studies are vital in orthopedic research. They offer a powerful framework for assessing the real-world impact of surgical interventions, helping mitigate the risks of continuing treatments that show no efficacy beyond placebo. The purpose of this approach is to provide evidence-based best practices that inform the principles of reconstruction, maximizing patient benefit while minimizing health resource wastage [6].

Although sham surgery poses significant ethical and methodological concerns in orthopedic research, it is crucial for confirming the effectiveness of surgical procedures. To assess the position of sham surgery relative to surgical procedures, we performed a systematic review and meta-analysis of current studies regarding the role of sham surgery in orthopedic practice [6]. This study aims to update and strengthen the current evidence by including newer trials and providing a more comprehensive meta-analysis of sham versus real orthopedic surgery. We wanted to clarify whether the conclusions of earlier reviews still valid and to better understand where real surgery offers benefits beyond placebo.

Methodology

Literature search strategy

This review followed the methodological guidance of the Cochrane Handbook for Systematic Reviews of Interventions for the conduct and reporting of systematic reviews of sham- and placebo-controlled intervention trials [10]. A thorough electronic search was conducted using PubMed, Scopus, and the Cochrane databases for studies published between 2014 and 2024. A combination of Medical Subject Headings, including “sham surgery,” “placebo surgery,” “orthopedics,” “orthopedic surgery,” and “systematic review,” was used to comprehensively identify all studies related to the comparative analysis of the role of sham surgery in orthopedics. The references of the selected studies were also reviewed to find any additional articles that may have been missed. This systematic review was registered in PROSPERO (CRD42024582780) and conducted following the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines (Supplementary Materials).

Inclusion/Exclusion criteria

This review includes all studies that compare sham surgery to actual surgical interventions in orthopedics, focusing on at least one of the following outcomes: pain, function, quality of life, or adverse events. Only studies published in English between 2014 and 2024 that addressed any of these outcomes were included. The review encompasses various research designs, including RCTs, prospective and retrospective cohort studies, cross-sectional studies, and observational studies. However, we excluded review articles, case reports, commentaries, editorials, letters to the editor, animal studies, *in vitro* research, conference abstracts, and studies where the data could not be extracted. Additionally, studies not involving orthopedic surgical procedures, lacking a sham surgery component, or published in a language other than English were also excluded.

Selection of articles and data extraction

All records identified from the initial database search were imported into Mendeley (LDN, UK) for deduplication. The deduplicated results were subsequently imported into Rayyan (MA, USA) for relevance assessment based on the title and abstract by four independent authors (NA, GA, BA, and HA). After the initial screening, the full texts of the selected studies were assessed by three authors (TA, MH, and AA) to finalize the inclusion and exclusion criteria. Any disagreements during the screening process were resolved through discussion among all authors. Data were extracted by three independent authors (GA, BA, and HA).

Statistical analysis

Meta-analysis was conducted using Review Manager (RevMan, version 5.1.4; Cochrane Collaboration, London, UK) [11], applying the general inverse-variance module to analyze continuous data, with the standardized mean difference (SMD) serving as the effect size metric. A random-effects model was applied, as we anticipated heterogeneity. I^2 levels were classified into four quartiles: low, low-to-moderate, moderate-to-high, and high heterogeneity, with ranges of 0% to <25%, 25% to <50%, 50% to <75%, and >75%, respectively. To assess the risk of bias in the included studies, the Cochrane risk of bias tool was used to generate both a summary and an individual article risk of bias bar graph. All analyses were performed at the 0.05 significance level. Blinding of participants and personnel to treatment allocation is difficult to achieve in surgical trials, given that a genuine incision-based procedure cannot always be physically or perceptually matched by a sham intervention. This represents a well-recognized methodological limitation of surgical trial design generally, rather than a deficiency specific to the studies included in this review [12].

Continuous outcomes (pain, function, quality of life) were pooled as SMD using the general inverse-variance method. Adverse events were also synthesized within this same inverse-variance framework rather than as a pooled proportion; consequently, the Freeman–Tukey double arcsine transformation, which is intended to stabilize variance in single-arm proportion meta-analyses, did not apply to our two-arm comparative synthesis. We acknowledge that a risk ratio or odds ratio, pooled via the Mantel-Haenszel method, is generally the preferred approach for dichotomous safety outcomes such as adverse events, and we identify this as a limitation of our analysis.

Results

Literature search

Using the search approach previously outlined in the methodology, 2,273 articles were found across multiple databases: PubMed yielded 1703, the Cochrane Library yielded 495, and Scopus yielded 75. After 57 duplicate articles were removed, 2,216 articles underwent screening, and 2,138 were excluded for failing to meet the inclusion criteria. Following an assessment of the remaining 78 papers for eligibility, 71 articles were rejected for various reasons, including failure to include the outcome of interest. Ultimately, seven records were included in the systematic review and meta-analysis. This is shown in the PRISMA flow diagram (Figure 1).

Study characteristics

All seven chosen publications compared sham surgery in orthopedics with real surgical procedures (Table 1). The investigations were published in English between 2014 and 2024 and conducted in various geographical locations.

Meta-analysis

The overall test for subgroup differences revealed substantial heterogeneity in treatment effects across outcomes (χ^2 = 7.79, p = 0.05), suggesting that sham surgery is more effective in some conditions than others (Figure 2). The meta-analysis of pain-related outcomes, comprising seven studies and 705 participants, showed a statistically significant difference favoring comparator surgery over sham (SMD = -0.73; 95% CI: -1.23 to -0.22; p = 0.005). However, heterogeneity among studies was high (I^2 = 89%).

For functional outcomes, three studies with a total of 185 participants were included. The pooled SMD was -0.07 (95% CI: -1.04 to 0.89; p = 0.88), indicating no statistically significant difference between real and sham surgery. Heterogeneity remained substantial (I^2 = 90%). In terms of quality of life, five studies involving 342 participants reported an SMD of -0.09 (95% CI: -0.47 to 0.30; p = 0.66), again showing no significant difference between the two groups. Moderate-to-high heterogeneity was observed (I^2 = 77%). Regarding adverse events, three studies with 298 participants reported a pooled SMD of 3.66 (95% CI: -0.38 to 7.69; p = 0.08), suggesting a trend toward more adverse events in the comparator surgery group, though the difference was not statistically significant. Notably, heterogeneity was extremely high (I^2 = 99%).

Assessment of quality of the included studies

Most domains showed a low risk of bias, particularly in random sequence generation, allocation concealment, and blinding of outcome assessment (Figure 3).

Some studies had unclear risks, including incomplete outcome data and selective reporting. A high risk of bias was noted only in blinding of participants and personnel, reflecting the challenge of maintaining blinding in surgical trials. Overall, the included studies were generally of good methodological quality. However, a study by Roos et al. [15] had a high risk of performance bias (Figure 4). On the other hand, several studies showed unclear risk of bias on various items; 2/7 studies had unclear risk of concealment bias [14,15].

Discussion

In this study, researchers carefully examined the effectiveness of sham surgeries in orthopedic care. This review study found that the results from sham surgeries often match those from real surgeries in terms of pain, how well patients function, and their quality of life. This finding suggests that how patients think and feel about their operation plays a big part in their recovery. Possible improvements observed after surgery may be due to the process itself and post-operative treatment.

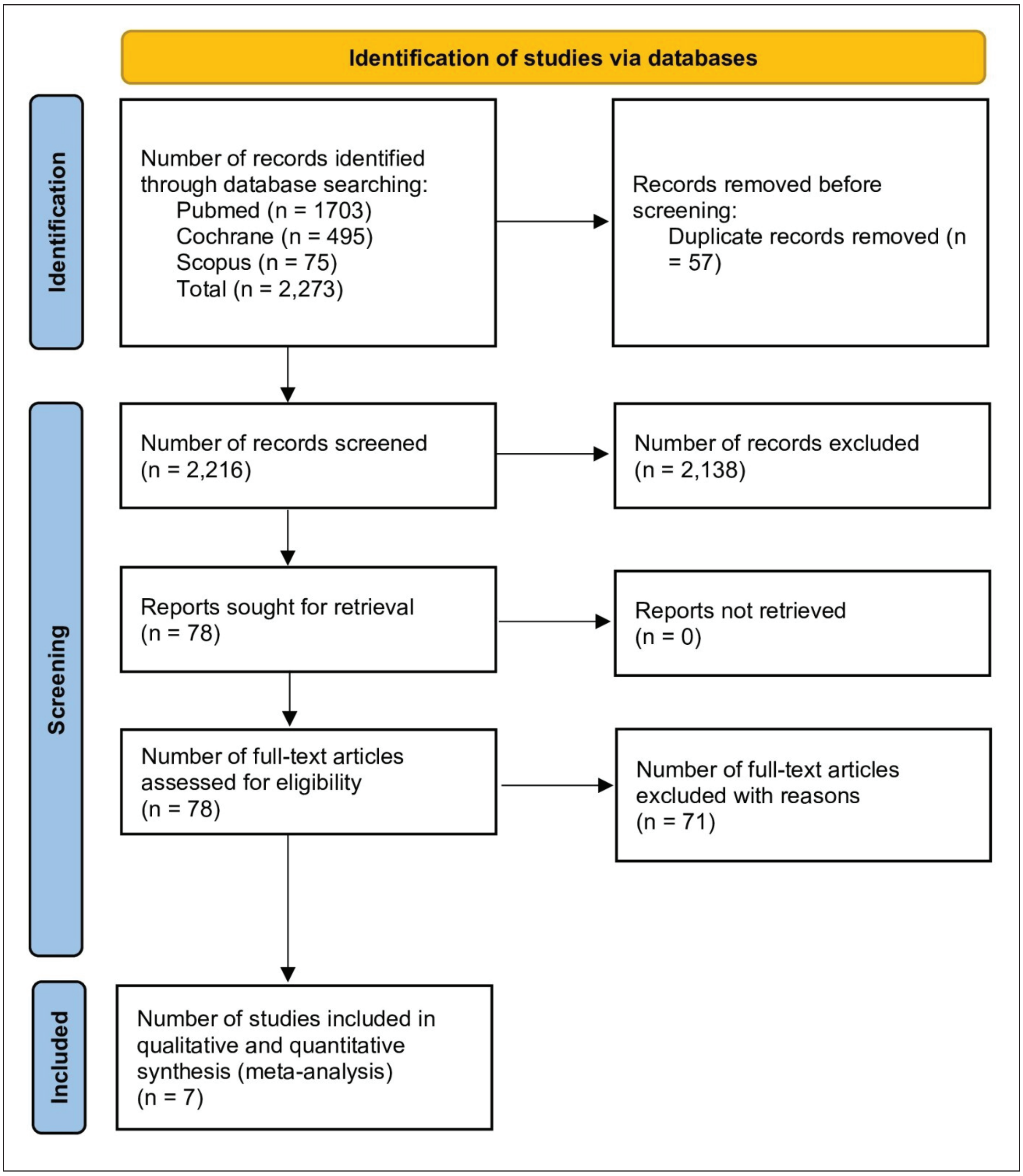

Figure 1. *PRISMA flow diagram showing selection and inclusion of studies.*

These findings are supported by work from Gu et al. [20], who did a meta-analysis showing that sham surgeries lead to short-term improvements in pain, showing how placebo effects and subjective experiences play a big role in surgical results. A similar review by Louw et al. [6] concluded that sham treatments decreased pain and related disability according to patients just as much as actual surgery did, pointing out the significance of the overall hospital environment and a patient's anticipation of recovery. Liu and Yu's research [21] about why placebo analgesia occurs with sham surgery found that the invasive action can elicit strong pain relief through psychological factors, suggesting that such responses may not be caused by specific surgeries.

Paavola and his colleagues [17] studied 67 patients diagnosed with shoulder impingement syndrome by comparing arthroscopic subacromial decompression with diagnostic arthroscopy in their Finnish Subacromial Impingement Arthroscopy Controlled Trial. No significant changes in pain scores or functional ability were noted for either treatment group over 5 years, suggesting that the surgery provided no more benefits than those from a placebo [17]. The results from Beard et al.'s study [22] are in line with this, as outcomes from ASD, placebo surgery, and no treatment were all the same, making the ASD procedure less important. Karjalainen et al. [23] conducted a study that found surgery for ASD does not lead to improvements in pain, daily activities, or quality of life compared to those found in placebo surgery or conservative care. Similarly, a 5-year follow-up study by Bäck et al. [24] found no superior results for the ASD group. These researchers found that the results of subacromial decompression surgery may be largely

Table 1. Characteristics of the included studies.

Authors	Country	Sample size	Study design	Intervention	Outcome/Results	Conclusion
Kroslak et al. [13]	Australia	26	Randomized-controlled trial, double blind	Surgery procedure	Both treatments enhanced grip strength, pronation-supination range, epicondyle discomfort, and the modified Orthopaedic Research Institute–Tennis Elbow Testing System.	For chronic tennis elbow, surgical removal of the degenerative part of the ECRB did not provide any more advantages than sham surgery.
Randers et al. [14]	Norway & Sweden	63	Double-blind, randomized, placebo-controlled study	Sham surgery	Six months after surgery, the operated SIJ decreased by 2.6 points in the surgical group compared to baseline.	At 6 months following surgery, we were unable to demonstrate that minimally invasive SIJ fusion was more effective than sham surgery in treating persistently severe SIJ pain.
Roos et al. [15]	Denmark	44	A sham-controlled randomized trial	APM	At 2 years, both the surgical and sham groups showed clinically significant improvements. The average difference was 8.2 in favor of surgery. However, nine individuals - six undergoing surgery and three undergoing sham - had 11 adverse events.	Only after two years did APM exhibit better benefits than skin incisions; nevertheless, the trial was underpowered, and the high non-blinding and crossover rates make it impossible to generalize the findings.
Fischgrund et al. [16]	US & Germany	225	Randomized, double-blind, sham-controlled multi-center study	Intercept system arm	At 3 months, the ODI significantly decreased in the treatment arm, and 75.6% of patients had a clinically significant improvement over the sham control arm.	CLBP can be safely and effectively treated with radiofrequency ablation of the BVN, which significantly improves pain and disability scores as compared to the sham group.
Paavola et al. [17]	Finland	193	Multicenter, three-group, randomized, double blind, sham-controlled trial.	ASD	There were notable differences in favor of ASD in both arm activity at 24 months and VAS at rest in the secondary comparison (ASD *vs.* exercise therapy). Because patients with poor outcomes were specifically excluded, the comparison is probably skewed in favor of ASD.	Patients with shoulder impingement syndrome do not benefit clinically from ASD over diagnostic arthroscopy (placebo surgery). After 24 months, both groups' functional results and pain levels significantly improved.
Sihvonen et al. [18]	Finland	146	Multicenter, randomized, controlled trial.	APM	Compared to the placebo surgery group, the APM group had a slightly higher chance of developing radiographic knee osteoarthritis. Results reported by the patients, including WOMET, Lysholm knee score, and post-exercise discomfort, did not differ significantly.	When compared to placebo surgery, APM did not improve knee function or symptoms. Additionally, 5 years after surgery, APM was linked to a marginally higher risk of radiographic knee osteoarthritis.
Schrøder et al. [19]	Norway	118	Blinded, three-armed randomized, sham-controlled study	Biceps tenodesis and labral repair	Rowe ratings at 2 years were different for the following groups: labral repair versus sham surgery: 0.6 (95% CI -5.9 to 7.0), $p = 0.86$; biceps tenodesis against sham surgery: 1.6 (95% CI -5.0 to 8.1), $p = 0.64$; and biceps tenodesis versus labral repair: 1.0 (95% CI -5.4 to 7.4), $p = 0.76$. Following labral repair, 5 patients experienced postoperative stiffness, and following tenodesis, four patients experienced it.	For patients with SLAP II lesions, neither biceps tenodesis nor labral repair offered any discernible therapeutic advantage over sham surgery.

APM, Arthroscopic Partial Meniscectomy; ASD, Adjacent Segment Disease; BVN, Basivertebral Nerve; CLBP, Chronic Low Back Pain; ERCB, Endoscopic Radiofrequency Coblation; ODI, Oswestry Disability Index; SIJ, Sacroiliac Joint; SLAP II, Superior Labrum Anterior to Posterior Lesion, Type II.

due to patient expectations, good hospital care, rest, and healing time rather than the procedure itself.

The study by Sihvonen et al. [18], included in our review, investigated the success of arthroscopic partial meniscectomy compared to sham surgery. Both groups showed similar outcomes for pain and activity during the 5-year follow-up. This result is supported by the study comparing exercise therapy with arthroscopic partial meniscectomy (APM) in improving knee function over a 5-year period, and that non-surgical therapies were more effective [25]. A 2023 individual participant data meta-analysis of four RCTs found that surgery did not work better for degenerative tears than sham or non-surgical care [26]. This conclusion is also supported by a recent review by Lee et al. [27], who found that APM does not make a big difference in pain or how well patients can function, and this was true whether or not patients had osteoarthritis. These studies confirm that APM provides very little benefit for patients with degenerative meniscal tears and who prefer conservative therapy.

In 2017, a randomized clinical trial by Schrøder et al. [19] studied patients with type II Superior Labrum Anterior to Posterior (SLAP) lesions who underwent labral repair, biceps tenodesis, or sham surgery. The analysis found few differences between the groups, suggesting that surgery may be no more effective than a placebo in treating SLAP lesions [19]. A systematic review and meta-analysis by Hurley et al. [28] found that biceps

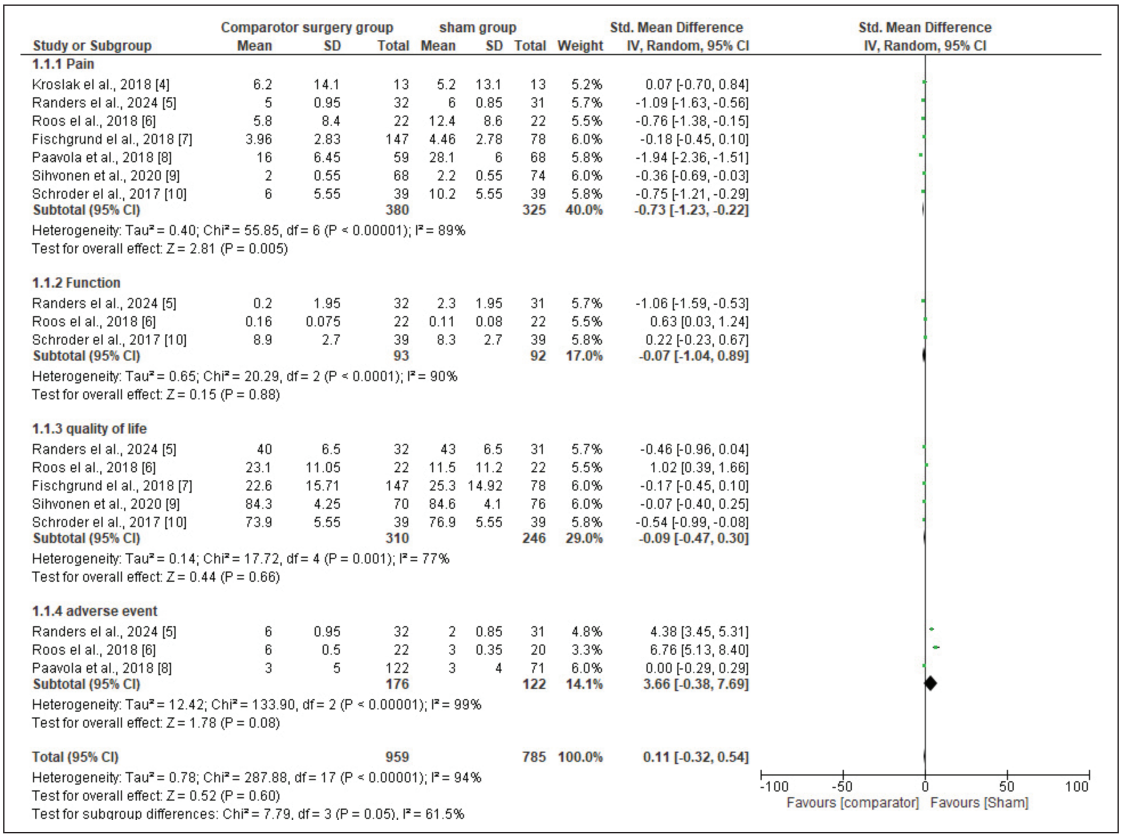

Figure 2. *The difference between surgical procedures and the sham surgery method.*

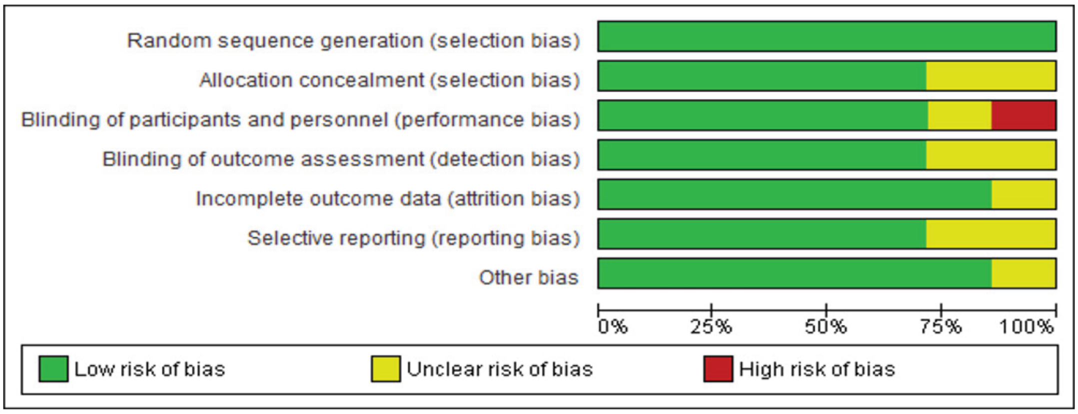

Figure 3. *Risk of bias summary.*

tenodesis led to greater satisfaction and higher return-to-sport rates than SLAP repair, but functional scores were the same for both techniques. Likewise, Ren et al. [29] noted that tenodesis for biceps pathology yielded superior results and greater satisfaction than labral repair, without increasing the risk of complications, indicating that it is a suitable option for less invasive treatment [29]. Another review study, published by Shin et al. [30], revealed that repairs performed for overhead athletes do not differ significantly in return-to-sport rates, function, or complication rates compared to tenodesis. These results suggest that non-operative care or microsurgery, such as biceps tenodesis, may be just as effective for treating type II SLAP lesions.

Randers et al. [14] looked at how sacroiliac joint fusion (SIFJ) performed against a sham surgery. It was found that the benefits of SIFJ were limited, likely due to placebo effects, making it important to carefully select patients for the treatment [14]. A trial by Polly et al. [31] and his team that randomly assigned patients found triangular titanium implants in SIFJ surgery were better at relieving pain, reducing disability, and increasing quality of life than standard non-surgical care, as long as the right patients were chosen [31]. In addition, Karjalainen et al. [23] stated that the procedure yielded better pain and disability scores than conservative care in people with long-standing sacroiliac joint-related low back pain. Similarly, Capel et al. [32] looked into SIFJ procedures and showed that, compared with placebo

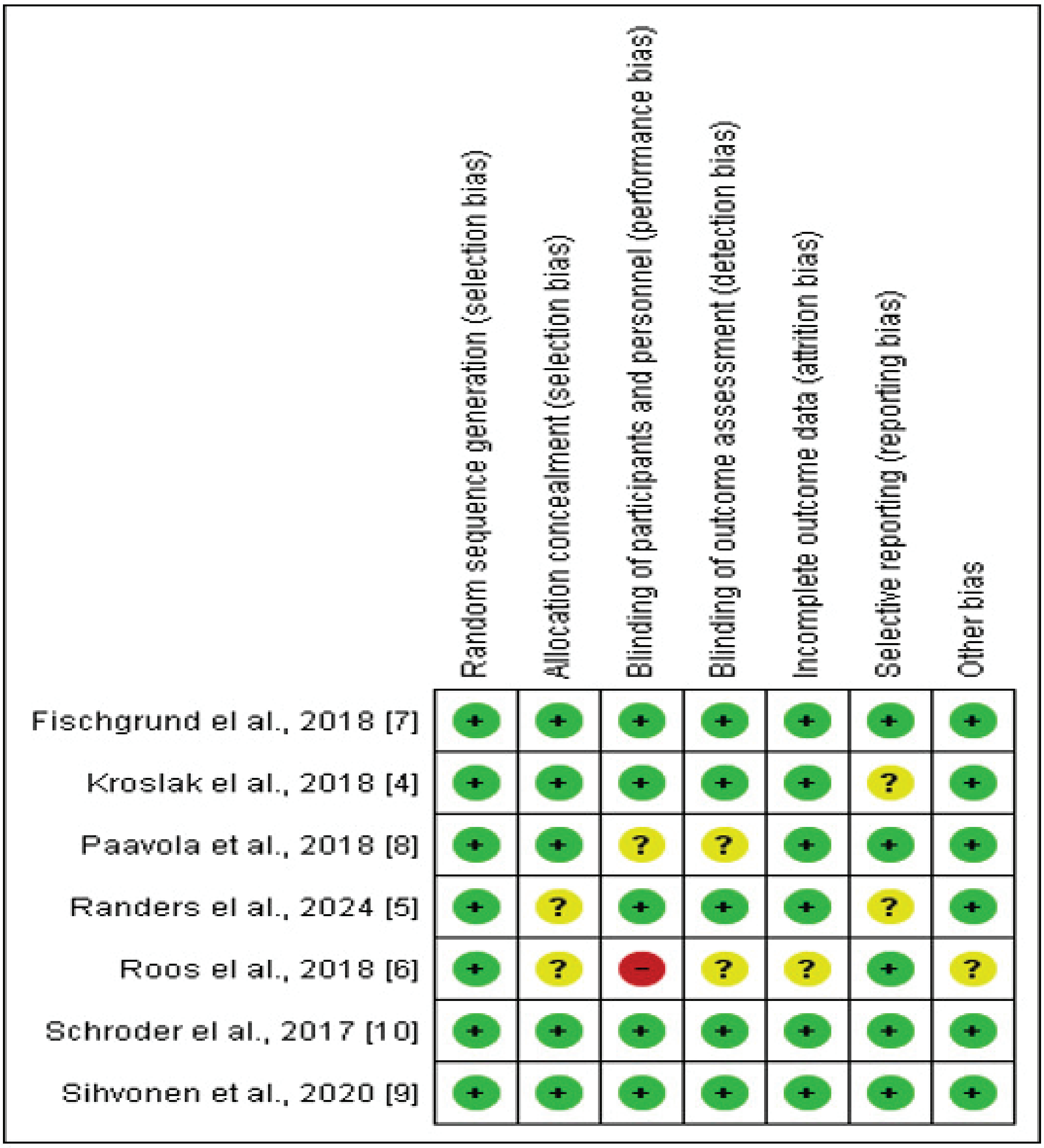

Figure 4. *Risk of bias of items of each study.*

responses, they can reliably help with pain and problems with movement. All these studies suggest that when used appropriately and accurately, SIFJ can be beneficial, although its effects may also be due to the drug's placebo effect.

Doing sham surgeries on patients in trials can cause ethical worries about their consent and the risk of injury without real help. This concern has been debated in the bioethics literature. Freedman's concept of clinical equipoise is often invoked as the ethical precondition that must hold before patients can be randomized to a sham arm at all [33]. Miller has argued that sham surgery is not inherently unethical and can be justified when the research question is methodologically sound, the risk–benefit ratio is acceptable, and informed consent addresses the possibility of receiving a non-therapeutic sham procedure [34]. By contrast, London and Kadane [35] have argued against the use of sham surgery in several contexts, contending that exposing participants to a procedure carrying real physical risk without any prospect of therapeutic benefit is difficult to justify even under conditions of clinical equipoise, particularly when less invasive comparators are available. This unresolved tension between methodological necessity and participant risk continues to shape how sham-controlled orthopedic trials are designed and reviewed by ethics boards. Still, studies like this help determine how much surgery actually helps, rather than the effect of treatment alone. Ensuring that participants understand and agree to the risks is crucial during the planning and execution of sham-controlled trials.

Some of these studies suggest that orthopedic surgery may not be more effective than a placebo, which means we should carefully evaluate the reasons for undergoing surgery. Experts should evaluate both surgical and nonsurgical methods, taking into account the risks and benefits, before deciding on surgical procedures where the results are not well established.

A limitation of our review is that, for dichotomous safety outcomes such as adverse events, we did not use the risk ratio or odds ratio pooled with the Mantel-Haenszel method, which is generally the preferred approach for meta-analysis of these outcomes.

Conclusion

Many times, sham surgeries have the same effects on pain, function, and quality of life as surgical treatments, and they do not lead to more side effects. Although comparator surgeries show lower pain scores, the variability found in study results may indicate that a lot of the benefit is due to a placebo effect. This research demonstrates that less invasive techniques should be considered when superiority for surgery cannot be found. In addition, selecting patients wisely and explaining the options are necessary because sham-controlled tests can raise ethical questions. Therefore, more studies should aim to classify patients most likely to benefit from surgery and to minimize bias in placebo-controlled surgical trials.

List of Abbreviations

APM	Arthroscopic Partial Meniscectomy
ASD	Arthroscopic Subacromial Decompression
BVN	Basivertebral Nerve
CI	Confidence Interval
CLBP	Chronic Low Back Pain
ECRB	Extensor Carpi Radialis Brevis
ESCAPE	Exercise versus Surgery for Chronic Arthroplasty of the Patella/knee (trial name)
FIDELITY	Finnish Degenerative Meniscus Lesion Study (trial name)
FIMPACT	Finnish Subacromial Impingement Arthroscopy Controlled Trial
I^2	Inconsistency Statistic (measure of heterogeneity)
MRI	Magnetic Resonance Imaging
ODI	Oswestry Disability Index
PRISMA	Preferred Reporting Items for Systematic Reviews and Meta-Analyses
PROSPERO	International Prospective Register of Systematic Reviews
RCTs	Randomized Controlled Trials
SIJ	Sacroiliac Joint
SIJF	Sacroiliac Joint Fusion
SLAP	Superior Labrum Anterior to Posterior
SMD	Standardized Mean Difference
VAS	Visual Analogue Scale
WOMET	Western Ontario Meniscal Evaluation Tool

Conflict of interest

The authors declare that there is no conflict of interest regarding the publication of this article.

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Consent to participate

Not applicable, as this study did not involve any individual participants or identifiable data.

Consent for publication

Not applicable.

Ethical approval

This article is a systematic review and meta-analysis of previously published studies. Ethical approval was not required as no new human or animal subjects were involved.

Author details

Khalaf A. Alnowaishiri[1], Ahmed Saeed M. Alqahtani[2], Bader Sulaiman Althunayyan[3], Ghaida M. Alanbari [4], Hasan Ali AlGharib[5], Mohammed H. Hwaifr[6], Naif M. Alqahtani[7], Turki F. Alrashidi[8], Ismail H. Almogbil[9]

1. Kuwait Institute for Medical Specializations (KIMS), Kuwait City, Kuwait
2. College of Medicine, King Khaled University, Abha, Saudi Arabia
3. College of Medicine, Qassim University, Al Qassim, Saudi Arabia
4. College of Medicine, Taif University, Taif, Saudi Arabia
5. College of Medicine, Jouf University, Sakaka, Saudi Arabia
6. College of Medicine, Shaqra University, Shaqra, Saudi Arabia
7. College of Medicine, Prince Sattam bin Abdulaziz University, Alkharj, Saudi Arabia
8. Unaizah College of Medicine, Qassim University, Al Qassim, Saudi Arabia
9. Associate Professor, Qassim University, Qassim, Saudi Arabia

Supplementary content (If any) is available online.

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