

# METHODOLOGY, MECHANISMS & TRANSLATIONAL RESEARCH SECTION

## Review Article

# Sham Surgery in Orthopedics: A Systematic Review of the Literature

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All authors contributed to the study concept and design. Adriaan Louw and Emilio J. Puentedura did the main statistical analysis and interpretation of data. Adriaan Louw, Emilio J. Puentedura and César Fernández-de-las-Peñas contributed to draft the report. Adriaan Louw and Ina Diener obtained funding. Ina Diener provided administrative, technical, and material support. Emilio J. Puentedura and César Fernández-de-las-Peñas supervised the study. All authors revised the text for intellectual content and have read and approved the final version of the manuscript.

## Abstract

**Objective.** To evaluate the evidence for the effectiveness of sham surgery in orthopedics by conducting a systematic review of literature.

**Methods.** Systematic searches were conducted on Biomed Central, BMJ.com, CINAHL, the Cochrane

Library, NLM Central Gateway, OVID, ProQuest (Digital Dissertations), PsycInfo, PubMed/Medline, ScienceDirect and Web of Science. Secondary searching (PEARLing) was undertaken, whereby reference lists of the selected articles were reviewed for additional references not identified in the primary search. All randomized controlled trials comparing surgery versus sham surgery in orthopedics were included. Data were extracted and methodological quality was assessed by two reviewers using the Critical Review Form—Quantitative Studies. Levels of scientific evidence, based on the direction of outcomes of the trials, were established following the Australian National Health and Medical Research Council (NHMRC) Hierarchy of Evidence (Australian National Health and Medical Research Council, 1999).

**Results.** This review includes six randomized controlled trials (RCTs) involving 277 subjects. All six studies were rated as very good on methodological quality. Heterogeneity across the studies, with respect to participants, interventions evaluated, and outcome measures used, prevented meta-analyses. Narrative synthesis of results, based on effect size, demonstrated that sham surgery in orthopedics was as effective as actual surgery in reducing pain and improving disability.

**Conclusions.** This review suggests that sham surgery has shown to be just as effective as actual surgery in reducing pain and disability; however, care should be taken to generalize findings because of the limited number of studies.

**Key Words.** Neuroscience; Orthopedics; Pain; Sham; Surgery

## Introduction

Orthopedic rehabilitation is deeply rooted in a biomedical health model focusing on tissues and tissue injury [1–3]. This biomedical model emphasizes the search for

anatomical or biomechanical faults, which, when corrected, would lead to an expected improvement in pain and disability [1–3]. Unfortunately, strict adherence to the biomedical model has shown limited scientific efficacy in decreasing pain and disability [4,5]. Further, anatomical and biomechanical pathology is poorly correlated to pain. For example, approximately 40% of asymptomatic people have a bulging disc on magnetic resonance imaging (MRI) [6,7], 25–50% of the general population exhibit disc and zygapophyseal degeneration on MRI [8], 40% of asymptomatic people have rotator cuff tears on MRI [9], and there is just a 50% correlation between the presence of knee arthritis and pain [10].

This disparity between tissue health and perception of pain has led to the search for a better paradigm for understanding pain in physical rehabilitation and a greater interest in the neuroscience of pain [11]. The paradigm shift from a tissue-based model of pain has led to the inclusion of the brain and the current neuromatrix model of pain [12–14]. Central to the neuromatrix model is the importance of consciousness and the brain, and how pain is better defined as a measure of potential threat, rather than true tissue health [12,15–17]. The bigger the perceived threat, the greater the experienced pain [15]. The neuromatrix model suggests that various beliefs and cognitions will determine if pain is to be experienced or not [18,19]. Subsequently, altering a patient's beliefs regarding the health of their tissues may powerfully influence their experience of pain [17,20–22].

Orthopedic surgery also usually follows a stringent biomedical model correlating the correction of faulty anatomy or biomechanics with pain relief [23]. At its simplest level, a patient with a bony fracture is thought to experience pain because of the fracture (tissue damage), and surgical repair of the fracture will, logically, lead to eventual elimination of the pain. If the surgical repair of the damaged tissue is required for eventual pain relief then how can the potential result of sham surgery be explained? Sham surgery refers to a faked surgical intervention that omits the step thought to be therapeutically necessary. The earliest report of a sham surgical procedure in 1959 reported that patients undergoing ligation of the internal mammary artery did no better than patients in the sham surgery group receiving only a skin incision under local anesthesia without the ligation procedure [24]. Since then, only a few sham surgical interventions have been published, for Parkinson's disease [25,26], Meniere's disease [27–29] and orthopedic conditions [30–32]. The proposed mechanism behind sham surgery and its efficacy is the expectation of benefit or placebo effect [26,33]. When patients believe they are receiving an invasive surgical procedure with the expectation that their underlying pathology or disease state is being properly corrected, they will report improvement in symptoms and dysfunction. Another explanation for the observed benefits of sham surgery could be that there is a change in the brain's perception of the underlying pathology or disease state, despite the fact that the procedure could not directly affect these

[30,31]. Understandably, sham surgery is very controversial in the community. Opponents of sham surgery raise the ethical issues of withholding surgery from patients, as well as noting the many variables requiring control before it may be demonstrated that the sham procedure truly resulted in a placebo effect [34–37].

Clinical and life experiences suggest that a direct relationship between pathoanatomy and pain does not exist. To further explore this, we decided to conduct a systematic review to evaluate the efficacy of sham surgery in orthopedic medicine. Specific questions asked included: 1) Were there any differences in outcome measures (pain and disability) observed following sham surgery when compared to actual surgical procedures?; and 2) if none were observed, what might account for observed benefits following a sham procedure? The purpose of this review was not to undervalue orthopedic surgery, but rather shed further light on the correlation between pathoanatomy, the brain, and pain experiences.

## Methods

### Literature Database Search

This report closely adheres to the PRISMA method for reporting on systematic reviews. Computerized literature searches between May 2015 and July 2015 were performed on the following databases with no limitations on time frame: PubMed/Medline, Biomed Central, BMJ.com, CINAHL, the Cochrane Library, NLM Central Gateway, EMBASE, OVID, AMED, ProQuest (Digital Dissertations), PsycInfo, ScienceDirect, and Web of Science. Each database has its own indexing terms and functions, and therefore different search strategies were developed for each database by the authors. The main search items included "joint," "orthopedic," "orthopaedic," "placebo," "procedure," "sham" and "surgery." In PubMed, medical subject headings (MeSH) terms were used where possible, with Boolean operators. The search strategies for the remaining databases included synonyms of the main search items. When database facilities allowed search limits, searches were restricted to randomized clinical trials. Secondary searching (Pearling) was undertaken, whereby reference lists of the selected articles were reviewed for additional references not identified in the primary search.

### Inclusion Criteria for Article Selection

Articles chosen to go through the selection process were reviewed by two authors. All titles and abstracts were read to identify potentially relevant articles. Articles were included if they met the inclusion criteria listed in Table 1. When there was uncertainty regarding the eligibility of the article from the abstract, the full text version of the article was retrieved and evaluated for the inclusion criteria. The full text version of all articles that met the inclusion criteria were retrieved for quality assessment and data extraction.

**Table 1** Inclusion criteria used in the systematic review

| Criterion                           | Justification  |
|-------------------------------------|--|
| English language                    | Major journals in this area are published in this language.  |
| No time limit                       | Given the limited number of sham surgeries it was decided to set no time limit.  |
| Humans                              | Since the objective of the study was to determine true placebo effect and change in perception and to make findings clinically meaningful, animal studies were excluded.               |
| No age limit                        | Given the limited number of sham surgeries it was decided to set no age limit.   |
| Randomized controlled trials (RCTs) | Randomized controlled trials were chosen because of their high levels of evidence and to pool results.   |
| Sham surgery                        | This review focused on surgical interventions where one group in the RCT did not receive the actual surgical intervention but a procedure mimicking the actual surgical interventions. |
| Outcomes                            | No limitations were set on the outcomes measures used in the RCTs mainly due to the limited studies in the area.   |

### Assessment of Methodological Quality

Critical appraisal of each included study was conducted by determining: 1) the level of evidence on the Australian National Health and Medical Research Council (NHMRC) Hierarchy of Evidence (Australian National Health and Medical Research Council, 1999); and 2) the methodological quality of each study, using the Critical Review Form—Quantitative Studies [38].

All authors independently scored the studies and where disagreement occurred, consensus was achieved by discussion. Quality scores were divided into five categories: poor (score  $\leq 8$ ), fair (score: 9–10), good (score: 11–12), very good (score: 13–14) and excellent (score: 15–16) [39]. The Critical Review Form—Quantitative Studies [38] includes 17 of the 22 items that are contained in the CONSORT statement [40,41]. It does not include item 1 (study design stated in title or abstract), items 8 to 10 (randomization: sequence generation, allocation concealment and implementation respectively) or item 19 (adverse events). Although the CONSORT statement was not designed to evaluate methodological quality [40], it was documented whether these five

CONSORT criteria were fulfilled by the included RCTs, providing further methodological quality information.

### Data Extraction

Data were initially extracted by the authors using the PICO approach [42]. A study was considered “relevant” when at least one of the outcome measures concerned pain or disability. For being “generally consistent,” at least 75% of the trials that analyzed the same sham surgery had to exhibit the same results (positive, neutral, or negative). The results (to determine the efficacy of sham surgery in orthopedic medicine) were posted in narrative form, and the outcomes were defined as positive (experimental group obtained a significantly greater improvement compared to the control group); neutral (there were no statistically significant differences between groups); or negative (the control group obtained a significant greater improvement compared to the experimental group). An alpha of  $P < 0.05$  was used to define a significant outcome measure. This method is based on four levels of scientific evidence on the quality and the outcome of the trials [43,44].

### Analysis of the Data

Data on the effectiveness of the sham surgery for orthopedics were also extracted for each study. To determine the effect of the sham surgery on each outcome measure, the mean and 95% confidence interval (CI) for the between-group differences was calculated for RCTs, based on the results provided in each article [45]. Moreover, the mean change between pre- and post-treatment (and 95% CI) was calculated for the RCTs. Pain reduction of more than 20%, irrespective of the measurement tool, was considered clinically worthwhile [46,47]. It was expected that there would be heterogeneity in participants, interventions, comparisons and outcomes. Therefore the results of the studies were synthesized in a narrative format.

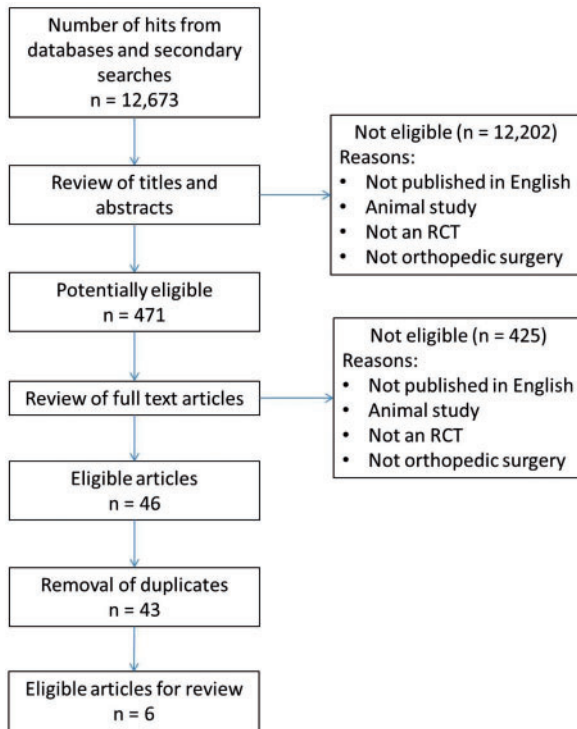
## Results

### Search Strategy Yield

Initially 12,673 hits were gained from databases and secondary searches. After review of the titles and abstracts, those articles that did not meet the inclusion criteria were removed. After reviewing 471 abstracts, the full text of 46 articles were retrieved. Upon further review of the 46 articles, duplicates were removed, non-orthopedic and non-RCT studies excluded, leaving six studies for the systematic review. This systematic review is based on six published studies (Figure 1). All six studies included in this review were RCTs [30–32,48–50].

### Methodological Quality

There was 100% agreement in scoring between the authors conducting the systematic review. Scoring in methodological quality was noted, with scores rated as 14 in



**Figure 1** Retrieval and review process.

four studies (very good) and 15 in two studies (excellent). Table 2 provides details regarding the criteria that were fulfilled on the Critical Appraisal Form—Quantitative Studies. Four of six studies failed to provide adequate description of sample size calculation (criterion 6) and all six studies failed to mention the validity of the outcomes measures chosen to report results (criterion 8).

Table 2 also provides details regarding the fulfilment of the CONSORT criteria. All but two studies reported all the criteria of the CONSORT criteria 1, 8, 9, 10 and 19, with the studies by Moseley [30] and Krosiak [48] failing to report on the adverse events (criteria 19).

#### Clinical Data of Included Trials

Six randomized clinical trials are included in this review, with two on vertebroplasty for osteoporotic compression fractures [31,32]; two on intradiscal electrothermal therapy (IDET) [49,50]; one on arthroscopic debridement for osteoarthritis of the knee joint [30]; and one on open debridement of common extensor tendons for lateral epicondylitis [48]. The average duration of symptoms for the osteoporotic compression fractures ranged from 9.5 [31] to 20 weeks [32]; and for the IDET it was greater than 24 months [49,50]. The study by Krosiak [48] reported an average duration of symptoms of 59 months. Finally, the study by Moseley [30] did not report the average duration of knee symptoms due to knee osteoarthritis but exclusion criteria indicated symptoms to be present > 6 months. In total, sham surgery was

performed on 277 orthopedic patients of whom 52.7% were female. The average age of the patients ranged from  $40.8 \pm 7.5$  years [50] to  $78.9 \pm 9.5$  years [31] with a mean age (calculated as the mean of the mean reported ages) of 56.1 years of age.

#### Sham Surgery Procedure

Details of the specific content of the sham surgery procedures used in the studies are found in Table 3. All trials used similar procedures for sham surgery including: mimicking the actual surgical procedure, skin incisions, use of the same surgical equipment; sounds to mimic the real surgical procedure, smells to mimic the real surgical procedure, similar postoperative instructions and management as the real surgical procedure, and similar time in the operating room as real surgical procedure [30–32,48–50]. Only two studies used no penetration of the joint structure containing the presumed patho-anatomical cause of pain [30–32].

#### Professionals Performing Sham Surgery

Sham surgery was performed by a radiologist (vertebroplasty) [31], a single orthopedic surgeon (knee arthroscopy) [30] and single unspecified surgeon (lateral epicondylitis) [48]. Three studies failed to identify the professionals who performed the surgery [32,49,50].

#### Use of Sham Procedure

All six RCTs provided detailed descriptions of the surgical procedures which were compared to the sham surgery. The orthopedic surgeries can be summarized as skin incision, penetration of the anatomical structure containing the proposed patho-anatomical structures causing pain and dysfunction, use of surgical instruments, and correction of pathoanatomical cause of the structured involved in the patient's pain and disability [30–32,48–50].

#### Outcome Measures

There was great variability in outcome measurements across the studies in terms of the number, type used and the number of occasions they were used (Table 3). Researchers and clinicians utilizing sham surgery were mainly interested in determining if sham surgery affected issues related to pain [30–32,48–50], function [30,32,48–50], quality of life [31,32,49, 50], disability [31,32,49,50], adverse events [31], self-perceived recovery [31,48,49], and general health [32].

Although similar outcome measures were sometimes used for pain, disability and quality of life in the six studies, the measurement of pain with the numerical pain rate scale and visual analog scale varied in their report of the pain rating period, over the course of a previous week [31,49] to average back-pain intensity during the preceding 24 hours [32], thus nullifying the ability to compare the outcomes of the studies. Further, the

**Table 2** Study quality of the randomized controlled trials included in this review using the Criterion-critical review form

| #  | Criterion-critical review form                | Barendse et al. 2001 | Moseley 2002 | Pauza et al. 2004 | Buchbinder et al. 2009 | Kallmes et al. 2009 | Kroslak 2012 |
|----|---|----------------------|--------------|-------------------|------------------------|---------------------|--------------|
| 1  | Purpose clearly stated                        | 1                    | 1            | 1                 | 1                      | 1                   | 1            |
| 2  | Literature review relevant                    | 1                    | 1            | 1                 | 1                      | 1                   | 1            |
| 3  | Study design appropriate to study design aims | 1                    | 1            | 1                 | 1                      | 1                   | 1            |
| 4  | No biases present                             | 1                    | 1            | 1                 | 1                      | 1                   | 1            |
| 5  | Sample description in detail                  | 1                    | 1            | 1                 | 1                      | 1                   | 1            |
| 6  | Sample size justified                         | 0                    | 0            | 1                 | 0                      | 0                   | 1            |
| 7  | Informed consent gained                       | 1                    | 1            | 1                 | 1                      | 1                   | 1            |
| 8  | Validity of outcome measures used             | 0                    | 0            | 0                 | 0                      | 0                   | 0            |
| 9  | Reliability of outcome measures used          | 1                    | 1            | 1                 | 1                      | 1                   | 1            |
| 10 | Intervention described in detail              | 1                    | 1            | 1                 | 1                      | 1                   | 1            |
| 11 | Statistical reporting of results              | 1                    | 1            | 1                 | 1                      | 1                   | 1            |
| 12 | Appropriate statistical analysis              | 1                    | 1            | 1                 | 1                      | 1                   | 1            |
| 13 | Clinical importance reported                  | 1                    | 1            | 1                 | 1                      | 1                   | 1            |
| 14 | Appropriate conclusions                       | 1                    | 1            | 1                 | 1                      | 1                   | 1            |
| 15 | Clinical implications reported                | 1                    | 1            | 1                 | 1                      | 1                   | 1            |
| 16 | Study limitations acknowledged                | 1                    | 1            | 1                 | 1                      | 1                   | 1            |
|    | Total   | 14                   | 14           | 15                | 14                     | 14                  | 15           |
|    | Quality category*                             | Very good            | Very good    | Excellent         | Very good              | Very good           | Excellent    |
|    | Criterion-CONSORT statement**                 |                      |              |                   |                        |                     |              |
| 1  | Study design stated in the title or abstract  | √                    | √            | √                 | √                      | √                   | √            |
| 8  | Randomization: sequence generation            | √                    | √            | √                 | √                      | √                   | √            |
| 9  | Randomization: allocation concealment         | √                    | √            | √                 | √                      | √                   | √            |
| 10 | Randomization: implementation                 | √                    | √            | √                 | √                      | √                   | √            |
| 19 | Adverse events                                | √                    | X            | √                 | √                      | √                   | X            |

\*Quality category: poor (score  $\leq 8$ ); fair (score = 9–10); good (score = 11–12); very good (score = 13–14) and excellent (score = 15–16).

\*\*√ = criterion fulfilled; x = criterion not fulfilled.

initiation, frequency, and duration of the outcomes varied considerably between the studies. Outcomes measures were initiated as soon as 3 days after surgery [32] and as late as 6 months after surgery [50]. The duration of outcome measure reporting ranged from 3 months [32] to 2 years [30].

### Treatment Effectiveness

Data gained from the RCTs could not be pooled into a meta-analysis because of the heterogeneity of the outcomes and comparison groups. Results are reported in narrative form and summarized in Table 4.

#### Pain

All six studies in this review examined sham surgery's effect on pain [30–32,48–50]. A sham knee arthroscopy was just as effective as lavage and debridement in reducing knee pain at 1 and 2 years after the surgery [30].

Percutaneous intradiscal radiofrequency thermocoagulation (90 seconds, 70° C) was no more effective in reducing chronic discogenic low back pain than the sham procedure [49]; however, percutaneous intradiscal electrothermal therapy (4 minutes, 90° C) did reduce pain more than the sham procedure [50]. Sham vertebroplasty surgery was as effective as the actual vertebroplasty in reducing overall pain rating 3 months following the surgery [31,32].

In patients with osteoporotic fractures, undergoing sham vertebroplasty or actual vertebroplasty, there was a decrease use of opioid medication with no significant between-group differences at any follow-up period [31]. Finally, sham surgery was just as effective in reducing pain as a common surgical technique for lateral epicondylitis (surgical excision of the macroscopically degenerated portion of extensor carpi radialis brevis) [48,51].

#### Function

Five of the six studies examined sham surgery's effect on function [30, 32, 48–50]. Sham knee arthroscopy

**Table 3** Participants, interventions and outcomes in the reviewed studies

| Author   | Participants |  | Interventions  |   | Outcomes   |   |   |
|--|--------------|--|--|---|--|---|---|
|  | N            | Sample characteristics   | Diagnostic criteria  | Treatment   | Sham surgery   | Outcome instruments   | Time of assessment  |
| Barendse GAM, van den Berg SGM, Kessels AHF, Weber WEJ, van Kleef M. 2001<br>Spine | 28           | Chronic discogenic low back pain selected on basis of a diagnostic anesthetic anesthesia of lumbar disc<br>Sham group (N = 15): Ave age 45.2 ± 8.4 years; 33.3% males<br>Radiofrequency lesion group (N = 13): Ave age 40.8 ± 7.5 years; 38.5% males | Had to have only one putative painful level on diagnostic anesthetic anesthesia of lumbar disc   | Radiofrequency lesion: Diagnostic anesthetic anesthesia of one disc followed by insertion of a 20-gauge C15 cannula with a 10-mm exposed tip using tunnel vision fluoroscopy. This was followed by a 90-second 70 C radiofrequency treatment.   | Sham: Diagnostic anesthesia of one disc followed by insertion of a 20-gauge C15 cannula with a 10-mm exposed tip using tunnel vision fluoroscopy. No radiofrequency current applied.   | <p><u>Pain:</u></p> <ul style="list-style-type: none"> <li>• Visual analog scale</li> <li>• Global perceived effect</li> <li>• Analgesic intake</li> </ul> <p><u>Function:</u></p> <ul style="list-style-type: none"> <li>• Oswestry Disability Index</li> <li>• Dartmouth COOP Functional Health Assessment Charts/World Organization of Primary Care Physicians (COOP/WONCA)</li> </ul>   | <ul style="list-style-type: none"> <li>• 4 days</li> <li>• 8 weeks</li> </ul>   |
| Moseley, 2002<br>New England Journal of Medicine                                   | 180          | Knee arthroscopy Osteoarthritis (OA) of the knee; Moderate knee pain ≥ 4 on a visual analog scale (VAS) > 6 months of medical treatment<br>Sham group (N = 60): Ave age 52.0 ± 11.1 years; 93.3% males<br>Lavage group (N = 61): Ave                 | Defined by the American College of Rheumatology Radiological (scale 0–4) of 3 knee compartments for a total of 12; ≥ 9 out of 12 for the study | Lavage: Diagnostic arthroscopy followed by a joint lavage of at least 10 liters of fluid. Anything that could be flushed out through arthroscopic opening was removed. No mechanical tools to debride or remove tissues, except mechanically important, unstable meniscus tears were removed and the meniscus was trimmed to smooth out the firm the rim. | Sham: Standard arthroscopic debridement simulated. Knee prepped and draped followed by three 1 centimeter (cm) incisions in the skin. Surgeon asked for all the instruments and manipulated the knee as if the arthroscopy was performed. Saline was splashed to simulate lavage sounds. No instruments entered the portals. Patient kept in the operating room for the same time required | <p><u>Pain:</u></p> <ul style="list-style-type: none"> <li>• Knee Specific Pain Scale (KSPS)</li> <li>• Arthritis pain: Arthritis Impact Measurement Scale (AIMS2-P)</li> <li>• Body pain: (SF-36).</li> </ul> <p><u>Function:</u></p> <ul style="list-style-type: none"> <li>• 5-item walking—bending subscale from the AIMS2 (AIMS2-WB)</li> <li>• SF-36 (As an objective measure, they devised the Physical Functioning Scale (PFS) to record the amount of time in</li> </ul> | <ul style="list-style-type: none"> <li>• 2 weeks</li> <li>• 6 weeks</li> <li>• 3 months</li> <li>• 6 months</li> <li>• 12 months</li> <li>• 18 months</li> <li>• 24 months</li> </ul> |

(continued)

**Table 3** Continued

| Author   | Participants |   | Interventions   |  | Outcomes  |   |
|--|--------------|---|---|--|---|---|
|  | N            | Sample characteristics  | Diagnostic criteria   | Treatment  | Sham surgery  | Time of assessment  |
|  |              | age 51.2 ± 12.2 years; 88.5% males<br>Debridement group (N = 59): Ave age 53.6 ± 12.2 years; 96.6% males  |   | <u>Debridement:</u> Diagnostic arthroscopy followed by 10 liters of fluid lavage. Rough articular cartilage was shaved (chondroplasty), loose debris was removed; all torn or degenerated meniscal fragments were trimmed and the remaining meniscus was smoothed to a firm and stable rim. No abrasion arthroplasty or microfracture. Typically no bone spurs were removed. | for a debridement. Patient spent the night after the surgery in the hospital and cared for nurses unaware of the treatment assignment. Same post-operative protocol of walking aids, exercises and analgesics.  | seconds that a patient required to walk 30 m (100 ft) and to climb up and down a flight of stairs as quickly as possible. Longer times indicate poorer functioning.             |
| Pauza KU, Howell S, Dreyfuss P, Pelozo JH, Dawson K, Bogduk N. 2004<br>The Spine Journal | 64           | Low back greater than leg pain for greater than 6 months<br>Sham group (N = 27): Ave age 40 ± 8 years; 41% male<br>IDET group (N = 37): Ave age 42 ± 10 years; 51% male | Positive provocative discography, and posterior tear of the annulus fibrosus on CT scan | <u>IDET:</u> Conscious sedation and a 17-gauge introducer needle to contact outer annulus under fluoroscopy. Advancement of needle into disc and passage of flexible electrode into disc which was then heated to 90 c following a standard protocol   | <u>Sham:</u> Conscious sedation and a 17-gauge introducer needle to contact outer annulus under fluoroscopy. Instead of introducing the flexible electrode, patient exposed to a fluoroscope monitor demonstrating the passage of an electrode, then generator noises were produced for 16.5 minutes to mimic an active treatment | <u>Pain:</u><br>• Visual analog scale<br>• SF-36: Bodily pain (0–100)<br><u>Function:</u><br>• SF-36: Physical functioning (0–100)<br>• Oswestry disability index<br>• 6 months |
| Buchbinder R, Osborne RH, Ebeling PR, et al. 2009  | 78           | Vertebroplasty<br>Back pain < 12 months; 1 or 2 recent vertebral fractures; vertebral collapse;   | Vertebral collapse of grade 1 or higher on the grading system by Genant et al.          | <u>Vertebroplasty:</u> The left pedicle of the fracture site was identified with the use of a metallic marker. A 25-gauge needle was used to infiltrate the skin   | <u>Sham:</u> Participants who were assigned to the sham intervention underwent the same procedures as those in the vertebroplasty group up to the   | <u>Pain:</u><br>• 1 week<br>• 1 month<br>• 3 months<br>• 6 months<br><u>Quality of life:</u>  |

(continued)

**Table 3** Continued

| Author                          | Participants | Interventions  | Outcomes  |  |  |
|---------------------------------|--------------|--|---|--|--|
|                                 | N            | Sample characteristics   | Diagnostic criteria   |  |  |
|                                 |              | Treatment  | Sham surgery  |  |  |
|                                 |              |  | Outcome instruments   |  |  |
|                                 |              |  | Time of assessment  |  |  |
| New England Journal of Medicine | 40           | <p>Sample characteristics</p> <p>edema, a fracture line or both on magnetic resonance imaging (MRI)</p> <p>Vertebroplasty (N = 38): Age 74.2 ± 14.0 years; 82% female; Duration of back pain (median) = 9.0 weeks</p> <p>Sham (N = 40): Age 78.9 ± 9.5 years; 78% female; Duration of back pain (median) = 9.5 weeks</p> | <p>overlying the pedicle, and a 23-gauge needle was used to infiltrate the periosteum of the posterior lamina. An incision was made in the skin, and a 13-gauge needle was placed posterolaterally relative to the eye of the pedicle. Gentle tapping guided the needle through the pedicle into the anterior two thirds of the fractured vertebral body.</p> <p>Anterior–posterior and lateral images were recorded with the needle in the correct position.</p> <p>Prepared polymethylmethacrylate (PMMA) (approximately 3 ml) was slowly injected into the vertebral body, and satisfactory infiltration of the vertebral body was confirmed radiographically. A bipedicular approach was used only if there was inadequate instillation of cement with the unipedicular approach. Injection was stopped when substantial resistance was met or when the cement reached the posterior quarter of</p> | <p>insertion of the 13-gauge needle to rest on the lamina.</p> <p>The central sharp stylet was then replaced with a blunt stylet. To simulate vertebral body, the vertebral body was gently tapped, and PMMA was prepared so that its smell permeated the room.</p> <p>After the intervention, all participants received usual care. Analgesia was given according to standard practice.</p> | <p>Quality of Life Questionnaire of the European Foundation for Osteoporosis (QUALEFFO), Assessment of Quality of Life (AQoL)</p> <p>European Quality of Life—5 Dimensions (EQ-5D) scale</p> <p>Disability: Modified 23-item version of the Roland–Morris Disability Questionnaire</p> <p>Perceived recovery: With respect to pain, fatigue, and overall health was measured on 7-point ordinal scales ranging from “a great deal worse” to “a great deal better.”</p> <p>Responses of “moderately better” or “a great deal better” were classified as successful outcomes.</p> <p>Adverse events: Adverse events, including incident clinical fractures, were assessed at each time point with the use of open-ended questions.</p> |

(continued)



**Table 3** Continued

| Author   | Participants |  | Interventions       |  | Outcomes   |  |  |
|--|--------------|--|---------------------|--|--|--|--|
|  | N            | Sample characteristics   | Diagnostic criteria | Treatment  | Sham surgery   | Outcome instruments  | Time of assessment   |
| Kallmes DF, Comstock BA, Heagerty PJ, et al. 2009<br>New England Journal of Medicine | 131          | Vertebroplasty Patients 50 years or older; One to three painful osteoporotic vertebral compression fractures between T4 and L5; inadequate relief of pain from standard medical care and pain at least 3 on a scale of 0 to 10. Fractures less than 1 year old based on pain. Fractures on uncertain age required marrow edema on MRI or increased vertebral-body uptake on bone scan. | MRI or bone scan    | <p>the vertebral body; injection was also stopped if cement leaked into extraosseous structures or veins. All participants in the vertebroplasty group received cephalothin, administered intravenously immediately after PMMA injection.</p> <p><u>Vertebroplasty:</u> Patients were brought to the fluoroscopy suite, where conscious sedation was induced and sterile preparation for surgery was performed. Using fluoroscopic guidance, the practitioner infiltrated the skin and subcutaneous tissues overlying the pedicle of the target vertebra or vertebrae with 1% lidocaine and infiltrated the peristeam of the pedicles with 0.25% bupivacaine. 11-gauge or 13-gauge needles were passed into the central aspect of the target vertebra or vertebrae. Bariumopacified PMMA was prepared on the bench and infused under constant lateral fluoroscopy into the vertebral</p> | <p><u>Sham:</u> Patients were brought to the fluoroscopy suite, where conscious sedation was induced and sterile preparation for surgery was performed. Using fluoroscopic guidance, the practitioner infiltrated the skin and subcutaneous tissues overlying the pedicle of the target vertebra or vertebrae with 1% lidocaine and infiltrated the peristeam of the pedicles with 0.25% bupivacaine. During the sham intervention, vertebral and physical cues, such as pressure on the patient's back, were given, and the methacrylate monomer was opened to simulate the odor associated with mixing of PMMA, but the needle</p> | <p><u>Disability:</u> Modified Roland Morris Disability Questionnaire (RDQ).<br/><u>Pain:</u> NRS—ratings of average back-pain intensity during the preceding 24 hours<br/>Pain frequency index<br/>Pain bothersomeness index<br/>The use of opioid medication<br/>Function: Study of osteoporotic Fractures—Activities of daily living (SOF-ADL) scale.<br/><u>Quality of life:</u> The European Quality of Life—5 Dimensions (EQ-5D) scale<br/><u>General health:</u> Physical Component Summary (PCS) subscale of the self-administered Medical Outcomes Study 36-Item Short-Form General</p> | <ul style="list-style-type: none"> <li>• 3 days</li> <li>• 14 days</li> <li>• 1 month</li> <li>• 3 months</li> </ul> |

(continued)

**Table 3** Continued

| Author  | Participants | Interventions   | Outcomes   |   |   |  |
|---|--------------|---|--|---|---|--|
|   | N            | Sample characteristics  | Diagnostic criteria  |   |   |  |
|   |              | Treatment   | Sham surgery   |   |   |  |
|   |              | Outcome instruments   | Time of assessment   |   |   |  |
| Krosiak M. 2013<br>MSurg(Res)<br>Thesis<br>University of Sydney,<br>Australia | 22           | <p>63 sham 74.3 ± 9.6; female = 73% 20 weeks mean pain duration</p> <p>68 vertebroplasty 73.4 ± 9.4; female = 78% 16 weeks pain duration</p> <p>Clinical diagnosis of lateral epicondylitis Sham (N = 11): Ave age 51 (41–77) years; 27.3% male</p> <p>Nirschl (N = 11): Ave age 52 (42–66) years; 36.4% male</p> | <p>Lateral epicondylitis persisting after at least 6 months after medical therapy (physiotherapy or rehabilitation, massage, acupuncture, non-steroidal anti-inflammatories, splinting/bracing, or any elbow injections</p>  | <p>was not placed and PMMA was not infused. After the procedure, both groups of patients were monitored in the supine position for 1 to 2 hours before discharge.</p>   | <p>Health Survey (SF-36), version 2.<br/>Mental Component Summary (MCS) subscale of the self-administered Medical Outcomes Study 36-Item Short-Form General Health Survey (SF-36), version 2.</p> | <p>• 2 weeks<br/>• 6 weeks<br/>• 12 weeks<br/>• 26 weeks</p> |
|   |              | <p>body. Infusion was stopped when the PMMA reached to the posterior aspect of the vertebral body or entered an extraosseous space, such as the intervertebral disk or an epidural or paravertebral vein.</p>   | <p>Sham: Intravenous sedation (midazolam, fentanyl and propofol infusion). Arm prepped and draped in a standard sterile fashion after local anesthetic (bupivacaine 0.5% with adrenaline 1 in 200,000) was infiltrated around the lateral epicondyle. An incision approximately 3 cm long was made over the lateral epicondyle and extensor carpi radialis brevis (ECRB) origin was exposed. Degenerated portion of ECRB identified and excised. Any defect in ECRB closed with 2-0 Vicryl sutures and wound closed with a running subcuticular Monocryl suture.</p> | <p>Pain:<br/>• Frequency of pain<br/>• Level of pain<br/>Function:<br/>• Patient rated level of difficulty picking up objects<br/>• Patient rated level of elbow stiffness<br/>• Patient rated overall elbow rating</p> |   |  |

was just as effective as lavage or debridement in improving function in individuals undergoing arthroscopy at 2-year follow-up [30]. There was no statistical difference between the sham and intradiscal radiofrequency thermocoagulation in either disability scales at 8 weeks [49]. Oswestry Disability Index scores were significantly better at 6 months post IDET compared to sham [50]. Finally, there were no significant differences in functional measures 26 weeks after lateral epicondylitis excision surgery compared to sham surgery [48].

### Quality of Life and General Health

Five of the six studies examined sham surgery's effect on quality of life [31,32,48–50]. Although quality of life outcomes between sham vertebroplasty and actual vertebroplasty fail to reach clinically difference, one week after sham vertebroplasty, patients in the sham surgery group rate their quality of life (QUALEFFO) better than patients having undergone the actual vertebroplasty procedure [31]. There was no significant difference in change of COOP/WONCA scores between the sham and radiofrequency lesion group for discogenic low back pain at 8 weeks [49]. Overall, patient ratings of stiffness and elbow condition were not significantly different between sham and true lateral epicondylitis surgery at 26 weeks [48].

In the only study examining general health following sham surgery, no difference was found in general health between sham vertebroplasty and actual vertebroplasty [32].

### Disability

Four studies examined the effect of sham surgery on disability [31,32,49,50]. Sham vertebroplasty was as effective as actual vertebroplasty in decreasing disability ( $P=0.49$ ) [32]. Furthermore, the two groups did not differ in the post-specified proportion of patients who had clinically meaningful improvement in physical disability related to back pain at 1 month [32]. Sham intradiscal thermal surgery may be just as effective as actual intradiscal thermal surgery in decreasing disability [49,50].

### Perceived Recovery

Three studies reported on perceived recovery following sham surgery [31,48,49]. No difference was found in perceived recovery between the sham vertebroplasty procedure and vertebroplasty procedure [31], between sham intradiscal radiofrequency thermocoagulation and the actual procedure [49], and between sham lateral epicondylitis debridement surgery and the actual procedure [48].

### Adverse Events

Only one study examined the adverse events following sham surgery [31], although all others reported no adverse events. Patients receiving sham vertebroplasty for osteoporotic fractures compared to actual vertebroplasty had no meaningfully different rates in adverse events. Seven participants (three in the vertebroplasty group and four in the sham group) reported an incident of clinical vertebral fracture within 6 months after the study intervention. Three participants (one in the vertebroplasty group and two in the sham group) reported new rib fractures at 1 week [31].

### Discussion


Sham surgery is quite rare and marred with ethical considerations [36,52–54]. To the authors' knowledge, this is the first systematic review investigating the efficacy of sham surgery in orthopedic medicine [52]. Although care should be taken to extrapolate findings from six RCTs consisting of only four types of orthopedic surgeries, the results from the current review indicate that in comparison to real surgery, sham surgery provides similar results in pain and disability. The results indicate that sham surgery in orthopedic medicine led to real changes in patients, similar to the real surgical intervention. For the 277 patients involved in these six studies, those who underwent a sham orthopedic procedure reported outcomes similar to those who had the real surgical intervention. These findings concur with findings in sham surgery for ligation of the internal mammary artery [24], Parkinson's disease [25,26], and Meniere's disease [27–29].


Orthopedic surgery is based on a biomedical health model focusing on tissues and tissue injury [1–3]. This biomedical model seeks to find the anatomy or biomechanics at fault and once surgically corrected, it is expected that the pain and resulting disability will be resolved [1–3]. In all six studies included in the current review, the authors described detailed procedures to maintain blinding and ensure patients would not become aware they were in the sham surgery group, including pre-operative and post-operative education, sounds, duration of procedures, smells and rehabilitation. Pain is complex and recent research highlights the finding that pain is more likely be a measure of potential threat, than of true tissue health [12,15–17]. The greater the perceived threat, the higher the pain experienced [15]. Most patients view pain as an indicator of tissue health and if they believe that activity may further damage their tissue and thus increase pain, they may decrease physical movements as a logical protective mechanism [17]. The surgical experience may likely be interpreted by the patient's brain as the process of correcting faulty tissue. Once completed, the perception of a painful, movement limiting degenerative disc, vertebral fracture, arthritic knee or chronically inflamed elbow is re-evaluated by the brain, resulting in decreased pain and increased function.

**Table 4** Efficacy of sham surgery in orthopedic

| Outcome                     | Barendse et al. 2001 | Moseley 2002 | Pauza et al. 2004 | Buchbinder et al. 2009 | Kallmes et al. 2009 | Kroslak 2012 |
|-----------------------------|----------------------|--------------|-------------------|------------------------|---------------------|--------------|
| Decrease pain ratings       | N                    | N            | -                 | N                      | N                   | N            |
| Improve function            | N                    | N            | -                 | NA                     | N                   | N            |
| Improve quality of life     | N                    | NA           | NA                | N                      | N                   | N            |
| Decrease disability         | N                    | NA           | -                 | N                      | N                   | NA           |
| Adverse events              | NA                   | NA           | NA                | N                      | NA                  | NA           |
| Increase perceived recovery | N                    | NA           | NA                | N                      | NA                  | N            |
| Improve general health      | NA                   | NA           | NA                | NA                     | N                   | NA           |

NA = not applicable.

 Indicates sham surgery was superior to real surgical procedure.

 Indicates sham surgery and the real surgical procedure has similar outcomes.

 Indicates real surgical procedure was superior to sham surgery.

We can hypothesize that the sham surgery likely altered the patient's perception of the health of their tissues. This hypothesis is supported by the results of a study where patients undergoing lumbar discectomy who were shown and given their disc fragment had superior postoperative results compared to traditional discectomy [21]. The authors reasoned that patients who saw their disc fragment received "visual confirmation" that the corrective surgery was successful, much like the visual, auditory and sensory and physical stimuli produced during the sham procedures, thus providing perception of a technically successful surgery. Additionally, the finding of this review is underpinned by recent research evaluating the effect of a cognitive educational approach of explaining pain and pain processing to patients utilizing neurobiology and neurophysiology, with the aim of altering a patient's view of his or her tissues and the reasons for pain perception [12,55,56]. This reconceptualization of pain and the health of their tissues allow patients to report less pain, improve movement, decrease fear and decrease brain activity [12,55,56]. This finding is strengthened by the fact that patients report change in pain and move better after education only, with no physical interventions [17].

The current systematic review is limited by the number of studies as well as the heterogeneous nature of studies which precluded true meta-analyses, which would have been helpful to determine the real effectiveness of sham surgery in orthopedics. Furthermore, the carry-over

of results of intradiscal thermal therapy, knee arthroscopy, vertebroplasty surgical procedures, and lateral epicondylar soft tissue debridement, to other more comprehensive and common orthopedic surgeries such as knee and hip replacement or rotator cuff repairs, is limited.

## Conclusion

The results of the systematic review provide preliminary evidence that sham surgery in orthopedics may provide results similar to the actual surgical interventions. Even though sham surgery remains controversial, the fact that sham surgery yields results similar to real surgery highlights the powerful contributions of the brain to pain modulation. The premise in the biomedical health model that correcting altered anatomy or biomechanics will alter pain and resulting disability is challenged by these sham surgery results. Patients who believed that faulty tissues had been surgically corrected experienced the same relief as patients who had undergone real surgical correction of purportedly damaged tissues. Health practitioners making decisions regarding surgical versus conservative management in orthopedic medicine would do well to consider these results.

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