



## AMERICAN ACADEMY OF ORTHOPAEDIC SURGEONS

### **The Surgical Treatment of Ankle Arthritis A Technology Overview**

**Adopted by the American Academy of Orthopaedic Surgeons  
Board of Directors  
December 4, 2010**

This *Technology Overview* was prepared by an AAOS physician task force using systematic review methodology and summarizes the findings of studies published as of June 1, 2010 on the surgical treatment of ankle arthritis. As a summary, this document does not make recommendations for or against the use of surgical techniques for ankle arthritis. It should not be construed as an official position of the American Academy of Orthopaedic Surgeons. Readers are encouraged to consider the information presented in this document and reach their own conclusions concerning the use of surgical intervention for ankle arthritis.

The American Academy of Orthopaedic Surgeons has developed and is providing this *Technology Overview* as an educational tool. Patient care and treatment should always be based on a clinician's independent medical judgment given the individual patient's clinical circumstances.

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This technology overview was developed by an AAOS physician volunteer task force based on a systematic review of the current scientific and clinical information and accepted approaches to treatment and/or diagnosis. This technology overview is not intended to be a fixed protocol, as some patients may require more or less treatment or different means of diagnosis. Clinical patients may not necessarily be the same as those found in a clinical trial. Patient care and treatment should always be based on a clinician's independent medical judgment, given the individual patient's clinical circumstances.

**Disclosure Requirement**

In accordance with AAOS policy, all individuals whose names appear as authors or contributors to this technology overview filed a disclosure statement as part of the submission process. All panel members provided full disclosure of potential conflicts of interest prior to developing the key questions contained within this technology overview.

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# **SURGICAL TREATMENT OF ANKLE ARTHRITIS**

## **SUMMARY OF PUBLISHED RESULTS**

The available literature on surgical treatment of ankle arthritis is not expansive enough to be conclusive. Bearing this in mind, summaries of the data that pertain to the four key questions addressed in this Technology Overview are presented below:

All questions pertain to patients with ankle arthritis in whom non operative treatment has failed.

### **KEY QUESTION 1**

What are the clinical results of total ankle replacement?

- Based on low and very low quality evidence, treatment of ankle arthritis with either a generation 2 or generation 3 total ankle arthroplasty results in an improvement in pain and function.

### **KEY QUESTION 2**

What are the clinical results of ankle arthrodesis?

- There is limited data from multiple studies comparing preoperative assessment to postoperative assessment of patients treated with ankle arthrodesis. Very low quality data suggests that ankle arthrodesis results in an improvement in patient-oriented outcomes (e.g. device failure, reoperation, pain relief, patient satisfaction, walking ability).

### **KEY QUESTION 3**

What are the factors that predict outcomes of total ankle replacement?

- The literature does not conclusively demonstrate predictors of better or worse patient-oriented outcomes (e.g. device failure, reoperation, pain relief, patient satisfaction, walking ability) for total ankle arthroplasty.

### **KEY QUESTION 4**

Do patients treated with ankle arthroplasty have different clinical outcomes than patients treated with ankle arthrodesis?

- There is limited data from multiple studies directly comparing the efficacy of total ankle arthroplasty to arthrodesis in patients with arthritis. The disparate pre-operative ankle function scores and demographic characteristics between the groups enrolled in the relevant comparative studies prohibits meaningful comparisons and confounds the interpretation of the data. Analysis of adverse events that corrected for preoperative differences in patients characteristics, provide conflicting results.

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## I. INTRODUCTION

End-stage ankle arthritis is a debilitating condition that results in functional limitation and poor quality of life.<sup>1</sup> Ankle fusion has been the traditional treatment of ankle arthritis and is effective at relieving pain but may result in functional limitation from loss of range of motion and an increased long-term risk for arthritis in adjacent hindfoot joints.<sup>2</sup> Total ankle arthroplasty has been utilized in past attempts to overcome the limitations of ankle fusion but early implant designs resulted in high rates of failure.<sup>3</sup> More recently, newer implant designs have been introduced and published articles have demonstrated promising short and medium-term results using these devices (see Key Question 1). Based on these reports, there has been a renewed interest in ankle arthroplasty as an alternative to fusion that may improve outcomes and diminish the risk of subtalar arthritis. Despite the increasing use of ankle arthroplasty in clinical practice, significant debate remains regarding the role of ankle replacement in the treatment of ankle arthritis.

The purpose of this technology overview is to summarize the current state of knowledge about the outcomes of the surgical treatment of ankle arthritis with either arthroplasty or fusion. Specifically, a systematic review of the literature was undertaken with the goal of investigating key questions about the comparative results of ankle fusion and ankle arthroplasty, as well as patient factors that may contribute to the prognosis of patients undergoing ankle replacement. This information is useful both for informing current clinical practice and identifying areas where further scientific investigation is needed to determine the appropriate indications for ankle replacement.

## II. METHODS

### METHODS OVERVIEW

This technology overview evaluates the efficacy of surgical interventions, ankle arthrodesis and total ankle arthroplasty, for the treatment of ankle arthritis. This section describes the methods used to prepare this technology overview.

This document summarizes the best available evidence pertaining to four key questions regarding the surgical treatment of ankle arthritis; however, we do not provide treatment recommendations regarding this topic. Please see Appendix IV for additional details regarding the methods used to prepare this technology overview.

### INCLUDED ARTICLES

Our search for articles was expansive. Using comprehensive literature searches ensures that the evidence we consider is not biased towards any particular point of view. We searched four electronic databases: PubMed, EMBASE, CINAHL, and the Cochrane Central Register of Controlled Trials (please see Literature Searches for additional information). We supplemented searches of electronic databases with manual screening of the bibliographies of all relevant publications.

The study attrition diagram located in Appendix III provides details about the inclusion and exclusion of studies. The topics included in the literature search but not addressed in this technology overview are provided in Appendix IV.

### QUALITY OF THE LITERATURE

Evaluating the quality of evidence is vitally important when reading the clinical literature. Doing so tells us how much confidence we can have in the evidence. We have more confidence in high quality evidence than in low quality evidence.

We evaluated quality on a per outcome basis rather than a per study basis. Just as different studies can be of different quality, a single study may report highly reliable results for one outcome and less reliable results for another. For example, data from nearly all enrolled patients might be reported for one outcome, but data from only a small percentage of enrolled patients reported for another. In this case, the study is of higher quality for the former outcome. Evaluating studies on an outcome-by-outcome basis is recommended by the GRADE working group<sup>4</sup> and others.<sup>5</sup> We noted the quality of each outcome addressed in this overview. For detailed information regarding how we arrived at the Quality of Evidence, please see Appendix V.

In this Technology Overview we also noted the Level of Evidence for each outcome, screening/diagnostic test, or prognostic variable reported. Use of Levels of Evidence is discouraged; instead the reader should consider the overall strength of the body of evidence. We provided them only as a rough guide for those familiar with such evidence hierarchies. For detailed information regarding how we arrived at the Level of Evidence of Evidence, please see Appendix V.

## **OUTCOMES CONSIDERED**

We included patient-oriented outcomes over surrogate outcomes. This is because patient-oriented outcomes are outcomes that matter to patients and indicate, without the need for extrapolation, whether an intervention is effective.<sup>6</sup> Patient-oriented outcomes include outcomes like pain, quality of life, ability to perform activities of daily living, and revision surgery. Unlike use of patient-oriented outcomes, use of surrogate outcomes can be misleading, and can even make harmful treatments look beneficial.<sup>7</sup>

### III. KEY QUESTIONS AND SUPPORTING EVIDENCE

#### KEY QUESTION 1

##### What are the clinical results of total ankle replacement?

The purpose of Key Question One was to determine whether patients improve following total ankle replacement. The intention of this question was not to determine the best type of ankle replacement device (for this analysis please see Key Question 3), but was to assess the clinical outcomes following total ankle replacement. Because total ankle devices have changed considerably throughout their evolution, we have grouped the results according type of device as indicated by Vickerstaff, et al.<sup>3</sup> We have only included generation 2, generation 3 devices in this overview. We did not include constrained and unconstrained devices.

##### ***SUMMARY OF RESULTS- GENERATION 2 DEVICES***

Six studies with Low and Very Low quality outcomes<sup>8,9,10,11,12,13</sup> evaluated ankle arthroplasty with generation 2 devices (results of generation 3 devices and generation 2 and 3 combined results follow). Please see Table 1 for a list of generation 2 devices included in this systematic review by primary study author. To address the efficacy of generation 2 devices we reported: statistically significant improvement in clinical outcomes at final follow-up, patient opinion of results 4.8-5 years following surgery, percent of patients with surviving device, and adverse events following total ankle replacement.

**Table 1 Devices by Author- Generation 2**

<u>Author</u>	<u>Device Design</u>
Ali, et al. (2007)	Buechel Pappas
Nagashima, et al. (2004)	TNK
Hosman, et al. (2007)	Agility
Henricson, et al. (2007)	Buechel Pappas
Pyevich, et al. (1998)	Agility
Buechel, et al. (2003)	Buechel Pappas

Patients statistically significantly improved at postoperative follow-up (range 2.8-5 years) in five of six outcomes; pain at two durations (2.8 and 5 years), walking ability (2.8 years), AOFAS score (5 years), and motion (2.8 years). The authors did not find a statistically significant improvement at final follow-up in patient function (please see Table 2). The studies were powered sufficiently to detect a difference, which suggests that patients' function truly did not improve 2.8 years following surgery.

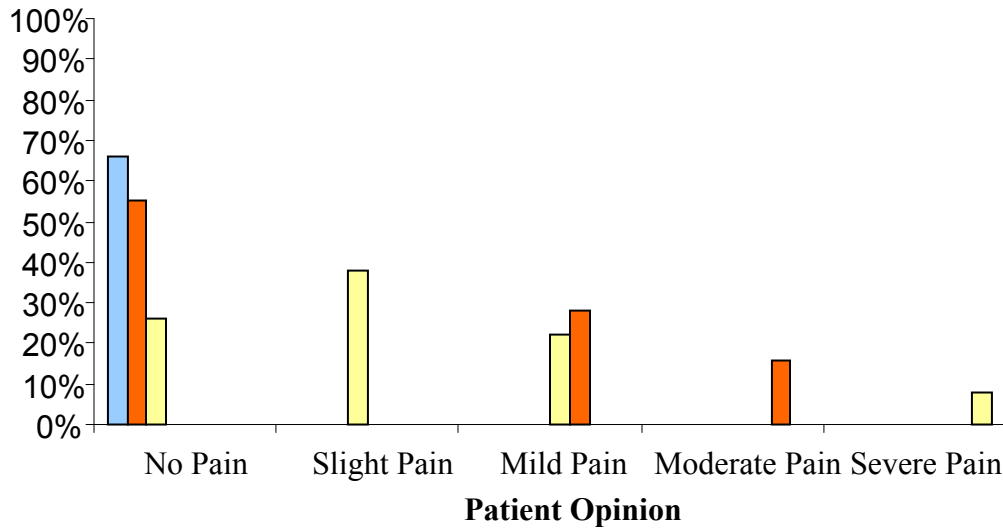
**Table 2 Patient Improvement from preoperative assessment- Generation 2**

<u>Study</u>	<u>N</u>	<u>Strength of Evidence</u>	<u>LoE</u>	<u>Duration of Follow-up</u>	<u>Outcome</u>	<u>Statistically Significant Improvement</u>
Nagashima, et al. (2004)	19	Low	IV	2.8 Years	Pain	Yes
Nagashima, et al. (2004)	19	Low	IV	2.8 Years	Function	○
Nagashima, et al. (2004)	19	Low	IV	2.8 Years	Walking ability	Yes
Ali, et al. (2007)	34	Low	IV	5 Years	AOFAS score	Yes
Nagashima, et al. (2004)	19	Low	IV	2.8 Years	Motion	Yes
Buechel, et al. (2003)	50	Very Low	IV	5 Years	Pain	Yes

○=No statistically significant improvement from preoperative score at final follow-up

Figure 1 and Figure 2 summarize patients' opinion following ankle arthroplasty with generation 2 devices in three studies. The majority of patients had little pain, increased mobility, and were satisfied with results 4.8-5 years following surgery (see Appendix for tables relevant to this figure).

**Figure 1 Patient Opinion of Pain by Percent of Patients- 4.8-5 Years Following Surgery- Generation 2**

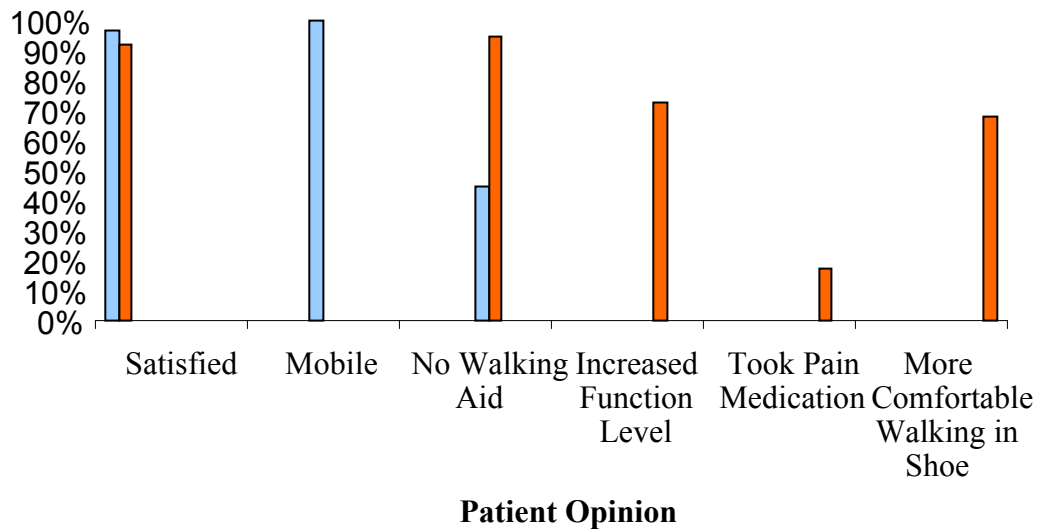


Results from 3 studies at 5 and 4.8 years

All results are Very Low in quality

Blue = Ali, et al. Orange = Pyvich, et al. Yellow = Buechel, et al. (in order left to right)

**Figure 2 Patient Opinion of Results by Percent of Patients 4.8-5 Years Following Surgery- Generation 2**



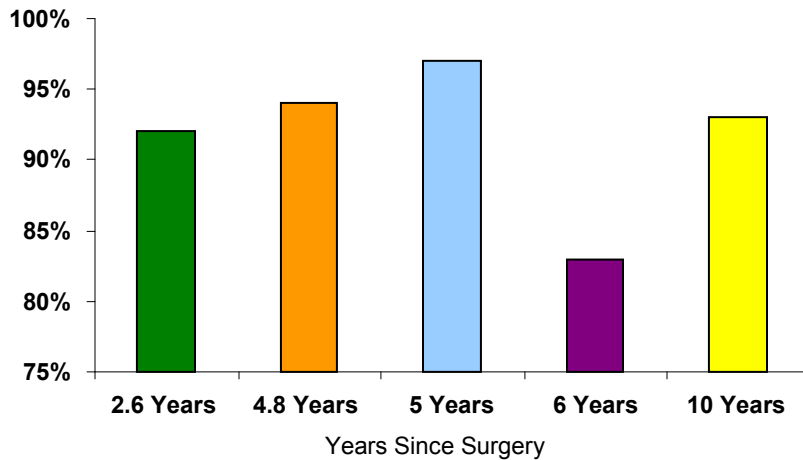
Results shown are from 3 studies with durations ranging from 4.8 to 5 years.

All results are Very Low in quality.

Blue = Ali, et al. Orange = Pyvich, et al. (in order left to right)

Device survival ranged from 83% to 94% ten years following surgery. The authors defined failure as the lack of replacement of device component, revision to ankle arthrodesis, or below the knee amputation. Please see Appendix X for tables detailing the number of patients in each group, exact percentage, and study author.

**Figure 3 Device Survival by Year-Generation 2**



All results are Very Low in quality.

Green= Hosman, et al., Orange= Pyevich, et al., Blue= Ali, et al., Purple= Henricson, et al., Yellow= Buechel, et al. (in order left to right)

The two most common reported adverse events were superficial wound infections, (reported in 5.8% of patients at 5 years and 2% of patients at 4.8 years) and delayed wound healing (reported in 10.5 % of patients at 2.8 years and 14% of patients at 4 months). Please see Table 3 for additional adverse events.

**Table 3 Adverse Events- Generation 2**

<u>Study</u>	<u>N</u>	<u>Strength</u>	<u>LoE</u>	<u>Duration of Follow-up</u>	<u>Outcome</u>	<u>% of Patients</u>
Ali, et al. (2007)	34	Very Low	IV	5 Years	Superficial wound infection	5.8%
Pyevich, et al. (1998)	82	Very Low	IV	4.8 Years	Superficial wound infections	2%
Nagashima, et al. (2004)	19	Very Low	IV	2.8 Years	Delayed wound healing	10.5%
Buechel, et al. (2003)	50	Very Low	IV	4 Months	Delayed wound healing	14%
Pyevich, et al. (1998)	82	Very Low	IV	4.8 Years	Isolated decreased sensation	7%
Buechel, et al. (2003)	50	Very Low	IV	3 Years	Malleolar fracture	6%
Buechel, et al. (2003)	50	Very Low	IV	3 Years	Infection	4%

<u>Study</u>	<u>N</u>	<u>Strength</u>	<u>LoE</u>	<u>Duration of Follow-up</u>	<u>Outcome</u>	<u>% of Patients</u>
Buechel, et al. (2003)	50	Very Low	IV	1 Years	Reflex sympathetic dystrophy	4%
Buechel, et al. (2003)	50	Very Low	IV	7 Years	Talar component subsidence	2%
Buechel, et al. (2003)	50	Very Low	IV	5 Years	Severe bearing wear	2%

The results from the included studies suggest that patients improve following total ankle arthroplasty with generation 2 devices. However, our confidence is low in these results because the quality of evidence is Low and Very Low. Our confidence in outcome results is directly related to the quality of evidence; we have less confidence in results from low quality outcomes than from results from high quality outcomes. Because the outcomes that address this question are Low and Very Low in quality, their results are not reliable. If these studies were performed over again with perfect methodology, it is likely that the results would differ. We expect the results from outcomes of high quality to be verified when replicated.

**SUMMARY OF RESULTS- GENERATION 3 DEVICES**

Ten studies with Low and Very Low quality outcomes<sup>10, 11, 14-18,19 ,20, 21</sup> evaluated ankle arthroplasty using generation 3 devices in patients with ankle arthritis. Please see Table 4 for a list of devices included in this analysis by primary study author (results of procedures using generation 3 and generation 2 devices combined follow).

**Table 4 Devices by Author- Generation 3**

<u>Author</u>	<u>Device Design</u>
Zerahn, et al. (2004)	STAR
Schutte, et al. (2008)	STAR
Henricson, et al. (2007)	STAR, AES, HINTEGRA
Fevang, et al. (2007)	STAR, TPR
Hintermann, et al. (2004)	HINTEGRA ankle
Valderrabano, et al. (2004)	HINTEGRA ankle
Wood, et al. (2008)	STAR
Hosman, et al. (2007)	STAR
Skytta, et al. (2010)	AES
Kofoed, et al. (1995)	STAR

Patients statistically significantly improved at follow-up (range 1-2.5 years) in eight out of nine outcomes: pain at 1 and 2.5 years, VAS Daily Function at one year, VAS Walking at one year, FFI Activity at 2.3 years, FFI Total, and AOFAS score at 2 years. The authors<sup>14</sup> do not report statistically significant improvement from baseline for “VAS shoe adaptation”. This study was powered sufficiently to detect a difference; therefore, it is likely that there was no improvement at 1.75 years.

**Table 5 Improvement from Preoperative Assessment- Generation 3**

<u>Study</u>	<u>N</u>	<u>Strength of Evidence</u>	<u>LoE</u>	<u>Duration of Follow-up</u>	<u>Outcome</u>	<u>Statistically Significant Improvement</u>
Zerahn, et al. (2004)	16	Low	IV	1 Year	VAS pain	Yes
Schutte, et al. (2008)	49	Low	IV	2.3 Years	FFI pain	Yes
Zerahn, et al. (2004)	16	Low	IV	1 Year	VAS daily function	Yes
Zerahn, et al. (2004)	16	Low	IV	1 Year	VAS walking	Yes
Schutte, et al. (2008)	49	Low	IV	2.3 Years	FFI activity	Yes
Schutte, et al. (2008)	49	Low	IV	1 Year	FFI total	Yes
Zerahn, et al. (2004)	16	Low	IV	1.75 Years	VAS shoe adaption	○

<u>Study</u>	<u>N</u>	<u>Strength of Evidence</u>	<u>LoE</u>	<u>Duration of Follow-up</u>	<u>Outcome</u>	<u>Statistically Significant Improvement</u>
Hintermann, et al. (2004)	122	Low	IV	2 Years	AOFAS	Yes
Valderrabano, et al. (2004)	68	Very Low	IV	2 years	AOFAS	Yes

○= No statistically significant improvement from baseline

FFI= Foot Function Index

AOFAS= American Orthopaedic Foot and Ankle Society

Table 6 and Table 7 summarizes patients' opinion of pain and satisfaction two years following surgery. While only 54% of patients were "pain free" at two years, between 83.6% and 86% of patients were satisfied with results at two years.

**Table 6 Percent of Patients with Pain- Generation 3**

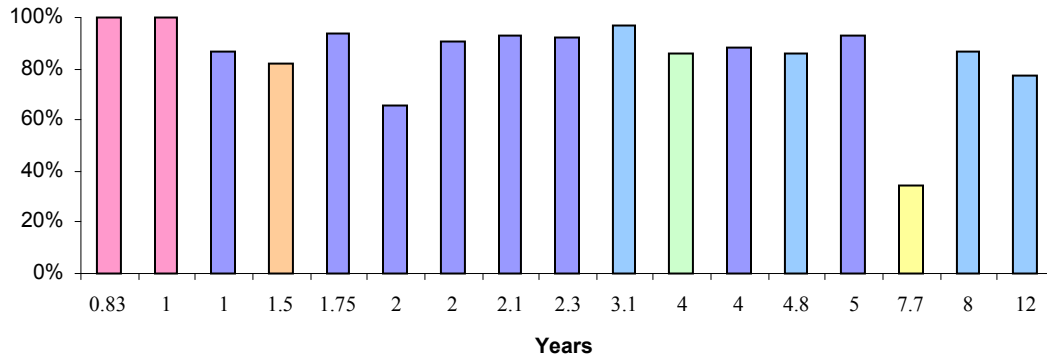
<u>Study</u>	<u>N</u>	<u>Strength</u>	<u>LoE</u>	<u>Duration of Follow-up</u>	<u>Outcome</u>	<u>% of Patients</u>
Valderrabano, et al. (2004)	68	Very Low	IV	2 Years	Pain free	54%
Wood	163	Very Low	IV	3 Years	Pain and stiffness	4%

**Table 7 Patient Satisfaction- Generation 3**

<u>Study</u>	<u>N</u>	<u>Strength</u>	<u>LoE</u>	<u>Duration of Follow-up</u>	<u>Outcome</u>	<u>% of Patients</u>
Hintermann, et al. (2004)	122	Very Low	IV	2 Years	Satisfied	83.6%
Valderrabano, et al. (2004)	68	Very Low	IV	2 Years	Satisfied	86%

Figure 4 summarizes the percent of patients with a functioning device by the number of years following surgery (please see Appendix VIII for tables relevant to this figure). Of seventeen assessments of survival, fourteen patient populations had survival of greater than 80%. The follow-up for groups with less than 80% device survival included: 2 years, 7.7 years, and 12 years.

**Figure 4 Device Survival- Generation 3 devices**



Each bar represents an individual study; device designs vary. See Appendix VIII for tables relevant to this graph.

Skin necrosis was the most common adverse event reported (3% of patients in one study and 37.5% in another). See Table 8 for additional results.

**Table 8 Summary of Adverse Events- Generation 3**

<u>Study</u>	<u>N</u>	<u>Strength</u>	<u>LoE</u>	<u>Duration of Follow-up</u>	<u>Outcome</u>	<u>% of Patients</u>
Hintermann, et al. (2004)	122	Low	IV	2.3 Years	Skin necrosis	3%
Kofoed	16	Very Low	IV	Not reported	Skin necrosis	37.5%
Wood, et al. (2008)	163	Very Low	IV	3 Years	Major delay of wound healing	3%
Wood, et al. (2008)	163	Very Low	IV	At surgery	Fractured malleolus at the time of surgery	5%
Wood, et al. (2008)	163	Very Low	IV	3 Years	Fractured malleolus at later date	6%
Wood, et al. (2008)	163	Very Low	IV	3 Years	Established or threatened aseptic loosening	8.5%
Wood, et al. (2008)	163	Very Low	IV	3 Years	Edge loading of the bearing	5.5%
Kofoed, et al. (1995)	16	Very Low	IV	Not reported	Deep infection	6.25%
Kofoed, et al. (1995)	16	Very Low	IV	6 Years	Revised to arthrodesis	6.25%
Kofoed, et al. (1995)	16	Very Low	IV	8 Years	Aseptic loosening	25%

Like the results from generation 2 devices, these results suggest that patients improve following ankle arthroplasty using generation 3 devices. Again, our confidence is low in these results because the evidence is Low and Very Low in quality.

**SUMMARY OF RESULTS- GENERATION 2 AND GENERATION 3 COMBINED**

One study<sup>22</sup> combined generation 2 and generation 3 devices. Please see Table 8 for devices included in this analysis.

**Table 9 Devices by Author-Generation 2 and Generation 3 Combined**

<u>Author</u>	<u>Device Design</u>
Naal, et al (2009)	Buechel Pappas or Mobility

Patients improved in AOFAS Activity Level and AOFAS total score 3.7 years following surgery. There was no statistically significant improvement in the percent of patients active in sports at 3.96 years. This study was powered to detect a significant improvement; therefore, this is a true lack of increase in patient activity in sports.

**Table 10 Patients Improvement from Preoperative Assessment- Generation 2 and Generation 3**

<u>Study</u>	<u>N</u>	<u>Strength of Evidence</u>	<u>LoE</u>	<u>Duration of Follow-up</u>	<u>Outcome</u>	<u>Statistically Significant Improvement</u>
Naal, et al (2009)	107	Low	IV	3.7 Years	Percent of patients active in sports	○
Naal, et al (2009)	107	Low	IV	3.7 Years	AOFAS activity level	Yes
Naal, et al (2009)	107	Low	IV	3.7 Years	AOFAS score	Yes

○=No statistically significant improvement at final follow-up.

**OVERALL CONCLUSION**

Of eighteen total outcomes assessed, fifteen were statistically significant in favor of total ankle arthroplasty. Overall, patients were satisfied, pain decreased, and mobility increased. Revision rates were fairly low as were adverse events. The results of ankle arthroplasty using generation 2 or generation 3 devices suggest that patients improve following surgery; however, this evidence is Low in quality and is not reliable.

**ARTICLES CONSIDERED**

**Table 11 Articles Considered- Ankle Arthroplasty**

<u>Author</u>	<u>Title</u>	<u>Included or Reason for Exclusion</u>
Schutte, et al. 2008	Short-term results of our first 49 Scandanavian total ankle replacements (STAR)	Included
Wood, et al. 2008	Total ankle replacement: medium-term results in 200 Scandinavian total ankle replacements	Included

<u>Author</u>	<u>Title</u>	<u>Included or Reason for Exclusion</u>
Ali, et al. 2007	Intermediate results of Buechel Pappas unconstrained uncemented total ankle replacement for osteoarthritis	Included
Hintermann, et al. 2004	The HINTEGRA ankle: rationale and short-term results of 122 consecutive ankles	Included
Nagashima, et al. 2004	Total ankle arthroplasty for deformity of the foot in patients with rheumatoid arthritis using the TNK ankle system: clinical results of 21 cases	Included
Zerahn, et al. 2004	Bone mineral density, gait analysis, and patient satisfaction, before and after ankle arthroplasty	Included
Buechel, et al. 2003	Ten-year evaluation of cementless Buechel-Pappas meniscal bearing total ankle replacement	Included
Pyeovich, et al. 1996	Total ankle arthroplasty: A unique design: Two to twelve-year follow-up	Included
Kofoed, et al. 1995	Cylindrical cemented ankle arthroplasty: a prospective series with long-term follow-up	Included
Naal, et al. 2009	Habitual physical activity and sports participation after total ankle arthroplasty	Included
van, et al. 2009	Total ankle prostheses in rheumatoid arthropathy	Included
Fevang, et al. 2007	257 ankle arthroplasties performed in Norway between 1994 and 2005	Included
Henricson, et al. 2007	The Swedish Ankle Arthroplasty Register: An analysis of 531 arthroplasties between 1993 and 2005	Included
Hosman, et al. 2007	A New Zealand national joint registry review of 202 total ankle replacements followed for up to 6 years	Included
Skytta, et al. 2010	Total ankle replacement: a population-based study of 515 cases from the Finnish Arthroplasty Register	Included
Besse, et al. 2009	Clinical evaluation and radiographic assessment of bone lysis of the AES total ankle replacement	Retrospective case series
Takenouchi, et al. 2009	Long-term results of ankle arthrodesis using an intramedullary nail with fins in patients with rheumatoid arthritis hindfoot deformity	Not relevant- nail fins in ankle arthrodesis
Lee, et al. 2009	Ligament reconstruction and calcaneal osteotomy for osteoarthritis of the ankle	Not all patients receive the same treatment
Sayed-Noor, et al. 2009	Joint Arthroplasties other than the Hip in Solid Organ Transplant Recipients	Systematic Review
Kurup, et al. 2008	Medial impingement after ankle replacement	Retrospective case series
Lee, et al. 2008	Ankle arthroplasty alternatives with allograft and external fixation: preliminary clinical outcome	Not relevant, arthroplasty alternatives
Michael, et al. 2008	Biomechanics of the ankle joint and clinical outcomes of total ankle replacement	Insufficient Quantitative Data

<u>Author</u>	<u>Title</u>	<u>Included or Reason for Exclusion</u>
Giannini, et al. 2007	The treatment of severe posttraumatic arthritis of the ankle joint	Difference treatments grouped together
Huowitz, et al. 2007	Outcome analysis of agility total ankle replacement with prior adjunctive procedures: two to six year follow-up	Retrospective case series
Valderrabano, et al. 2007	Total ankle replacement in ankle osteoarthritis: An analysis of muscle rehabilitation	Include
San, et al. 2006	Eight-year results of a minimally constrained total ankle arthroplasty	Retrospective case series
Knecht, et al. 2004	The Agility total ankle arthroplasty. Seven to sixteen-year follow-up	Retrospective case series
Nishikawa, et al. 2004	Total ankle replacement in rheumatoid arthritis	Retrospective case series
Spirt, et al. 2004	Complications and failure after total ankle arthroplasty	Retrospective case series
Mann, et al. 1998	Arthrodesis of the ankle: a critical analysis	Retrospective case series
Levi, et al. 1997	Deep refection following total ankle arthroplasty	Retrospective case series
Amendola, et al. 1996	Ankle arthroscopy: outcome in 79 consecutive patients	Not specific to ankle arthritis
Alvine, et al. 1991	Total ankle arthroplasty: new concepts and approaches	1 <sup>st</sup> generation implant
Bennett, et al. 1991	Triple arthrodesis in adults	Retrospective case series
Kirkpatrick, et al. 1991	Revision arthrodesis for tibiotalar pseudarthrosis with fibular onlay-inlay graft and internal screw fixation	Retrospective case series
McGuire, et al. 1988	Comparative analysis of ankle arthroplasty versus ankle arthrodesis	Difference in baseline characteristics
Unger, et al. 1988	Total ankle arthroplasty in rheumatoid arthritis: a long-term follow-up study	Retrospective case series
Helm, et al. 1986	Long-term results of total ankle replacement	1 <sup>st</sup> generation implant
Lachiewicz, et al. 1984	Total ankle replacement in rheumatoid arthritis	Retrospective case series
Stauffer, et al. 1981	Total ankle arthroplasty: four years' experience	Retrospective case series
Demottaz, et al. 1979	Clinical study of total ankle replacement with gait analysis. A preliminary report	Less than 50% follow-up
Delagoutte, et al. 2002	Retrospective analysis of 110 ankle prostheses	Retrospective

<u>Author</u>	<u>Title</u>	<u>Included or Reason for Exclusion</u>
Wood, et al. 2003	Total ankle replacement. The results in 200 ankles	Data is presented in later included article

## STUDY QUALITY

**Table 12 Study Quality- Arthroplasty Efficacy**

<b>Study:</b>	<b>Zerahn</b>	<b>Zerahn</b>	<b>Zerahn</b>	<b>Zerahn</b>
<b>Outcome:</b>	<b>Shoe Wear</b>	<b>VAS Function</b>	<b>VAS Pain</b>	<b>Walking</b>
Strength of Evidence Based on Quality	●●○○	●●○○	●●○○	●●○○
	Low	Low	Low	Low

Circles represent domains evaluated. Filled circles represent domains that are unflawed.

**Table 13 Study Quality – Arthroplasty Efficacy**

<b>Study:</b>	<b>Nagashima</b>	<b>Nagashima</b>	<b>Nagashima</b>	<b>Nagashima</b>	<b>Ali</b>
<b>Outcome:</b>	<b>Pain</b>	<b>Motion</b>	<b>Walking</b>	<b>Function-Evanski and Waugh</b>	<b>AOFAS Activity</b>
Strength of Evidence Based on Quality	●●○○	●●○○	●●○○	●●○○	●●○○
	Low	Low	Low	Low	Low

Circles represent domains evaluated. Filled circles represent domains that are unflawed.

**Table 14 Study Quality – Arthroplasty Efficacy**

<b>Study:</b>	<b>Hintermann</b>	<b>Schutte</b>	<b>Schutte</b>	<b>Schutte</b>	<b>Schutte</b>
<b>Outcome:</b>	<b>AOFAS</b>	<b>Revision %</b>	<b>FFI Pain</b>	<b>FFI Activity</b>	<b>FFI total</b>
Strength of Evidence Based on Quality	●●○○	●●○○	●●○○	●●○○	●●○○
	Low	Low	Low	Low	Low

Circles represent domains evaluated. Filled circles represent domains that are unflawed.

**Table 15 Study Quality – Arthroplasty Efficacy**

<b>Study:</b>	<b>Naal</b>	<b>Naal</b>	<b>Naal</b>
<b>Outcome:</b>	<b>Sports Activity</b>	<b>AOFAS</b>	<b>AOFAS Activity</b>

Strength of Evidence Based on Quality	●●○○	●●○○	●●○○
	Low	Low	Low

Circles represent domains evaluated. Filled circles represent domains that are unflawed.

**Table 16 Study Quality – Arthroplasty Efficacy**

Study:	Hintermann	Hintermann	Hintermann	Buechel	Buechel
Outcome:	Revision	% Satisfaction	Adverse Events	Survival	% Pain
Strength of Evidence Based on Quality	●○○○	●○○○	●○○○	●○○○	●○○○
	Very Low	Very Low	Very Low	Very Low	Very Low

Circles represent domains evaluated. Filled circles represent domains that are unflawed.

**Table 17 Study Quality – Arthroplasty Efficacy**

Study:	Ali	Ali	Ali	Kofoed	Kofoed
Outcome:	% Pain	% Revision	% Mobility	Estimated survival	Adverse Events
Strength of Evidence Based on Quality	●○○○	●○○○	●○○○	●○○○	●○○○
	Very Low	Very Low	Very Low	Very Low	Very Low

Circles represent domains evaluated. Filled circles represent domains that are unflawed.

**Table 18 Study Quality – Arthroplasty Efficacy**

Study:	Kofoed	Wood	Pyvich	Pyvich	Pyvich
Outcome:	% Revision	Revision	% Satisfied	% Used a cane	% Function
Strength of Evidence Based on Quality	●○○○	●○○○	●○○○	●○○○	●○○○
	Very Low	Very Low	Very Low	Very Low	Very Low

Circles represent domains evaluated. Filled circles represent domains that are unflawed.

**Table 19 Study Quality – Arthroplasty Efficacy**

<b>Study:</b>	<b>Henricson</b>	<b>Henricson</b>	<b>Henricson</b>	<b>Henricson</b>
<b>Outcome:</b>	<b>Failure STAR</b>	<b>Failure AES</b>	<b>Failure STAR</b>	<b>Failure HINTEGRA</b>
Strength of Evidence Based on Quality	●○○○	●○○○	●○○○	●○○○
	Very Low	Very Low	Very Low	Very Low

Circles represent domains evaluated. Filled circles represent domains that are unflawed.

**Table 20 Study Quality – Arthroplasty Efficacy**

<b>Study:</b>	<b>Henricson</b>	<b>Hosman</b>	<b>Hosman</b>	<b>Hosman</b>
<b>Outcome:</b>	<b>Failure Mobility</b>	<b>Failure Mobility</b>	<b>Failure Ramses</b>	<b>Failure STAR</b>
Strength of Evidence Based on Quality	●○○○	●○○○	●○○○	●○○○
	Very Low	Very Low	Very Low	Very Low

Circles represent domains evaluated. Filled circles represent domains that are unflawed.

**Table 21 Study Quality – Arthroplasty Efficacy**

<b>Study:</b>	<b>Pyevich</b>	<b>Pyevich</b>	<b>Pyevich</b>	<b>Pyevich</b>	<b>Ali</b>	<b>Buechel</b>
<b>Outcome:</b>	<b>% Used Pain Medication</b>	<b>% Pain Free</b>	<b>% Shoe</b>	<b>% Revision</b>	<b>% Satisfaction</b>	<b>Adverse Events</b>
Strength of Evidence Based on Quality	●○○○	●○○○	●○○○	●○○○	●○○○	●○○○
	Very Low	Very Low	Very Low	Very Low	Very Low	Very Low

Circles represent domains evaluated. Filled circles represent domains that are unflawed.

**Table 22 Study Quality – Arthroplasty Efficacy**

<b>Study:</b>	<b>Skytta</b>	<b>Pyevich</b>	<b>Ali</b>
<b>Prognostic:</b>	<b>Survival Rate</b>	<b>Adverse Events</b>	<b>Adverse Events</b>
Strength of Evidence Based on Quality	●○○○	●○○○	●○○○
	Very Low	Very Low	Very Low

Circles represent domains evaluated. Filled circles represent domains that are unflawed.

**Table 23 Study Quality – Arthroplasty Efficacy**

<b>Study:</b>	<b>Valderbanno</b>	<b>Valderbanno</b>	<b>Valderbanno</b>	<b>Valderbanno</b>
<b>Prognostic:</b>	<b>AOFAS</b>	<b>Pain</b>	<b>Satisfaction</b>	<b>Revision</b>
Strength of Evidence Based on Quality	●○○○	●○○○	●○○○	●○○○
	Very Low	Very Low	Very Low	Very Low

Circles represent domains evaluated. Filled circles represent domains that are unflawed.

## KEY QUESTION 2

### What are the clinical results of ankle arthrodesis?

The purpose of Key Question Two was to determine whether patients improve following ankle arthrodesis. We identified four prospective case series<sup>23-26</sup> that addressed this question. We reported: statistically significant improvement at follow-up, union and fusion rate, time in the hospital, and reported adverse events. Because we included all relevant studies regardless of arthrodesis surgical technique, we included this information in Table 24. Patient characteristics for the included studies are available in Table 25.

**Table 24 Surgical Technique- Ankle Arthrodesis**

<u>Author</u>	<u>Surgical Technique</u>
Partio, et al. (1992)	Medial and lateral approaches.
Ogilvie and Harris (1993)	Arthroscopically assisted technique not suitable for the correction of clinically important varus or valgus deformity of the tibiotalar joint
Ferkel, et al. (2005)	Arthroscopic ankle arthrodesis using thigh holder and soft-tissue distraction. Standard anteromedial, anterolateral, and posterolateral arthroscopic portals are used.
Sealey et al. (2009)	Not Reported

**Table 25 Patient Characteristics- Arthrodesis**

<u>Author</u>	<u>N</u>	<u>Study Inclusion Criteria</u>	<u>Diagnosis</u>	<u>Age</u>	<u>Sex (m/f)</u>
Partio et al. (1992)	11	Not Reported	Post traumatic ankle arthritis, Rheumatoid Arthritis	24-71	(4/8)
Ogilvie Harris et al. (1993)	19	Minimum or no deformity of the ankle but had severe functional impairment. Pain was not helped by conservative measures.	Post traumatic arthritis, Osteoarthritis, Osteoarthrosis due to infection	27-59	14/5
Ferkel et al. (2005)	35	Failure of more than 6 months of conservative treatment, minimal or mild correctable deformity in the coronal plane, and no active infections.	Post traumatic ankle arthritis, Rheumatoid Arthritis osteochondritis dissecans	Mean 53	(14/21)
Sealey et al. (2009)	45	Isolated post traumatic ankle arthritis present; no previous nor	Isolated Post traumatic ankle	41.6	30/18

subsequent hindfoot surgery; pre arthritis  
and postoperative lateral  
radiographs available, final  
clinical and radiographic  
arthrodesis present

**SUMMARY OF RESULTS**

Patients SF-36 Physical, Mental, and Total scores statistically significantly improved one year following surgery. Please see Table 26 through Table 28. Adverse events reported in the four included studies, are summarized in Table 28.

**Table 26 Improvement from preoperative assessment- Arthrodesis**

<u>Study</u>	<u>N</u>	<u>Strength of Evidence</u>	<u>LoE</u>	<u>Duration of Follow-up</u>	<u>Outcome</u>	<u>Statistically Significant Improvement</u>
Sealey et al. (2009)	45	Very Low	IV	1 Year	SF-36 physical component	YES
Sealey et al. (2009)	45	Very Low	IV	1 Year	SF-36 mental component	YES
Sealey et al. (2009)	45	Very Low	IV	1 Year	SF-36 total score	YES

**Table 27 Summary of Results- Arthrodesis**

<u>Study</u>	<u>N</u>	<u>Strength of Evidence</u>	<u>LoE</u>	<u>Duration of Follow-up</u>	<u>Outcome</u>	<u>Result</u>
Partio, et al. (1992)	12	Very Low	IV	1 Year	Union	92%
Ogilvie Harris et al. (1993)	19	Very Low	IV	31 Months	Union	89%
Ferkel et al. (2005)	35	Very Low	IV	72 Months	Delayed union or Nonunion	8.5%
Partio et al. (1992)	12	Very Low	IV	Not applicable	Time to union	6-16 weeks
Ferkel et al. (2005)	35	Very Low	IV	72 Months	Fusion rate	97%
Ferkel et al. (2005)	35	Very Low	IV	Not Applicable	Time until fusion	11.8 weeks
Ogilvie Harris et al. (1993)	19	Very Low	IV	Not Applicable	Median stay in hospital	3 days
Ferkel et al. (2005)	35	Very Low	IV	72 Months	Screw Removal	31.4%

**Table 28 Adverse Events- Arthrodesis**

<u>Study</u>	<u>N</u>	<u>Strength</u>	<u>LoE</u>	<u>Duration of Follow-up</u>	<u>Outcome</u>	<u>Percent of Patients</u>
Partio, et al. (1992)	12	Very Low	IV	1 Year	Superficial infection	8%
Partio, et al. (1992)	12	Very Low	IV	1 Year	Scar necrosis	8%

**OVERALL CONCLUSION**

The results from the included studies suggest that patients improve following ankle arthrodesis. However, only one study with Very Low quality reported results according to statistical significance. Results that only report the percent of patients are difficult to interpret. Our confidence in these results is low. Additional high quality research is needed to evaluate the efficacy of ankle arthrodesis.

**ARTICLES CONSIDERED**

**Table 29 Articles Considered- Arthrodesis**

<u>Author</u>	<u>Title</u>	<u>Included or Reason for Exclusion</u>
Ferkel, et al. 2005	Long-term results of arthroscopic ankle arthrodesis	Included
Ogilvie-Harris, et al. 1993	Arthroscopically assisted arthrodesis for osteoarthrotic ankles	Included
Sealey, et al. 2009	Sagittal plane motion of the hindfoot following ankle arthrodesis: a prospective analysis	Included
Partio, et al. 1992	Talocrural arthrodesis with absorbable screws, 12 cases followed for 1 year	Included
Lance, et al. 1979	Arthrodesis of the ankle joint. A follow-up study	Retrospective case series
Zwipp, et al. 2010	High union rates and function scores at midterm follow-up with ankle arthrodesis using a four screw technique	Retrospective case series
Takenouchi, et al. 2009	Long-term results of ankle arthrodesis using an intramedullary nail with fins in patients with rheumatoid arthritis hindfoot deformity	Not relevant- nail fins in ankle arthrodesis
Lee, et al. 2009	Ligament reconstruction and calcaneal osteotomy for osteoarthritis of the ankle	Not all patients receive the same treatment
Smith, et al. 2007	Arthrodesis of the ankle in the presence of a large deformity in the coronal plane	Retrospective case series
Thomas, et al. 2006	Gait analysis and functional outcomes following ankle arthrodesis for isolated ankle arthritis	Retrospective case series

<u>Author</u>	<u>Title</u>	<u>Included or Reason for Exclusion</u>
Labitzke, et al. 2005	[Ankle arthrodesis using the cable technique]	Retrospective case series
Buchner, et al. 2003	Ankle fusion attributable to posttraumatic arthrosis: A long-term follow-up of 48 patients	Retrospective case series
Fuchs, et al. 2003	Quality of life 20 years after arthrodesis of the ankle. A study of adjacent joints	Not specific to ankle arthritis
Anderson, et al. 2002	Arthrodesis of the ankle for non-inflammatory conditions--healing and reliability of outcome measurements	Not relevant-validity of scale
Coester, et al. 2001	Long-term results following ankle arthrodesis for post-traumatic arthritis	Retrospective case series
Maenpaa, et al. 2001	What went wrong in triple arthrodesis? An analysis of failures in 21 patients	Retrospective case series
Acosta, et al. 2000	The results of a primary and staged pantalar arthrodesis and tibiototalcalcaneal arthrodesis in adult patients	Less than 10 patients per group
Easley, et al. 2000	Isolated subtalar arthrodesis	Retrospective case series
Pell, et al. 2000	Clinical outcome after primary triple arthrodesis	Not specific to ankle arthritis
Mann, et al. 1998	Arthrodesis of the ankle: a critical analysis	Retrospective case series
Mann, et al. 1998	Isolated subtalar arthrodesis	Not specific to ankle arthritis
Flamme, et al. 1997	Long-term follow-up after arthrodesis of the ankle and the hindfoot	Not relevant hindfoot
Frey, et al. 1994	A review of ankle arthrodesis: predisposing factors to nonunion	Retrospective case series
Cheng, et al. 1993	Ankle arthrodesis	Retrospective case series
Abdo, et al. 1992	Ankle arthrodesis: a long-term study	Less than 50% follow-up
Papa, et al. 1992	Pantalar and tibiototalcalcaneal arthrodesis for post-traumatic osteoarthritis of the ankle and hindfoot	Retrospective case series
Bennett, et al. 1991	Triple arthrodesis in adults	Retrospective case series
Kirkpatrick, et al. 1991	Revision arthrodesis for tibiotalar pseudarthrosis with fibular onlay-inlay graft and internal screw fixation	Retrospective case series
Moran, et al. 1991	Ankle arthrodesis in rheumatoid arthritis. 30 cases followed for 5 years	Retrospective case series
Morgan, et al. 1985	Long-term results of tibiotalar arthrodesis	Retrospective case series
Lachiewicz, et al. 1984	Total ankle replacement in rheumatoid arthritis	Retrospective case series

<u>Author</u>	<u>Title</u>	<u>Included or Reason for Exclusion</u>
Ahlberg, et al. 1981	Late results of ankle fusion	Not specific to ankle arthritis
Wood, et al. 2003	Total ankle replacement. The results in 200 ankles	Data presented in a more recent included study

## STUDY QUALITY

**Table 30 Study Quality- Arthrodesis Efficacy**

<b>Study:</b>	<b>Partio</b>	<b>Partio</b>	<b>Partio</b>	<b>Partio</b>	<b>Ogilvie-Harris</b>
<b>Outcome:</b>	<b>Adverse events</b>	<b>Return to work</b>	<b>Changed work</b>	<b>Union</b>	<b>Union</b>
Strength of Evidence Based on Quality	●○○○	●○○○	●○○○	●○○○	●○○○
	Very Low	Very Low	Very Low	Very Low	Very Low

Circles represent domains evaluated. Filled circles represent domains that are not flawed.

**Table 31 Study Quality- Arthrodesis Efficacy**

<b>Study:</b>	<b>Ogilvie-Harris</b>	<b>Ferkel</b>	<b>Ferkel</b>	<b>Ferkel</b>	<b>Sealey</b>
<b>Outcome:</b>	<b>Hospital stay</b>	<b>Mazur Score</b>	<b>Screw removal</b>	<b>Fusion</b>	<b>SF-36</b>
Strength of Evidence Based on Quality	●○○○	●○○○	●○○○	●○○○	●○○○
	Very Low	Very Low	Very Low	Very Low	Very Low

Circles represent domains evaluated. Filled circles represent domains that are unflawed.

### KEY QUESTION 3

#### What are the factors that predict outcomes of total ankle replacement?

The purpose of this question was to determine which factors successfully predict outcomes for patients treated with total ankle replacement. We addressed the following factors:

1. Type of device
2. Age
3. Preoperative weight
4. Infection
5. Preoperative fracture
6. Side of surgery
7. Sex
8. Deformity
9. Disease
10. Previous operations
11. Ankylosis of the hindfoot
12. Surgeon experience\*
13. Year of surgery\*
14. Hospital surgery volume\*

\*These factors were reported only from studies meeting the inclusion criteria i.e. answering a question in this technology overview.

Table 32 summarizes the results of all analyses. Of the fourteen factors, one (infection) predicted outcome of ankle arthroplasty, patients with infection had worse outcomes than those without. However, this was based on one Very Low quality outcome. There were conflicting results for five prognostic factors: type of device, age, deformity, disease diagnosis, and surgeon experience. For these prognostic factors some results indicated that the prognostic factor predicted outcome, while others found no association between the factors and the outcome of surgery. There was no association between surgery outcome and the remaining eight prognostic factors: preoperative weight, preoperative fracture, side of surgery, sex, previous operations, ankylosis of the hindfoot, year of surgery, hospital surgery volume. Please see Appendix VIII for the data relevant to this Key Question.

#### SUMMARY OF RESULTS:

**Table 32 Summary of Results- Prognostic Factors**

<u>Prognostic Factor</u>	<u>Number of Studies</u>	<u>Strength</u>	<u>Result</u>
Type of Device	2	High/Moderate	☐
Age	8	Very Low	☐
Preoperative Weight	2	Very Low	○
Infection	1	Very Low	●

<u>Prognostic Factor</u>	<u>Number of Studies</u>	<u>Strength</u>	<u>Result</u>
Preoperative fracture	1	Very Low	○
Side of surgery	1	Very Low	○
Sex	7	Very Low	○
Deformity	4	Very Low	●
Disease	5	Very Low	●
Previous operations	1	Very Low	○
Ankylosis of the hindfoot	1	Very Low	○
Surgeon Experience	3	Very Low	●
Year of Surgery	2	Very Low	○
Hospital surgery volume	2	Very Low	○

○= No statistically significant association

●= Statistically significant association

●= Conflicting results

### ***TYPE OF DEVICE***

#### **Generation 2 vs. Generation 3 Devices**

We included two comparative studies<sup>27,28</sup> that assessed generation 2 to generation 3. The results were conflicting. Of eight outcomes reported by two authors, three were statistically significantly in favor of the generation 3 device (STAR): failure necessitating further surgery by either fusion or revision, Kofoed score >50, and implant in site and Kofoed score >50 (see Table 39), and one outcome in favor of the generation 2 device (Buechel Pappas), pain. There was no statistically significant difference in the number of patients who required a secondary surgery (not including revision or fusion), postoperative function, failure rate, number of removed implants, or the number of revisions.

**Table 33 Summary of Outcomes- Generation 2 vs. Generation 3 Device**

<u>Author</u>	<u>N</u>	<u>Strength</u>	<u>LoE</u>	<u>Duration of Follow-up</u>	<u>Outcome</u>	<u>Favored Group</u>
Wood, et al., et al.(2009)	179	High	II	4 Years	Failure necessitating revision or fusion	STAR
Wood, et al.(2009)	179	High	II	4 Years	Require second surgery other than revision or fusion	○
Wood, et al.(2009)	179	Moderate	II	4 Years	AOFAS pain	Buechel Pappas
Wood, et al.(2009)	179	Moderate	II	4 Years	AOFAS function	○
Wood, et al.(2009)	179	Moderate	II	6 years	Failure rate	○
van der Heide, et al. (2009)	58	Moderate	II	2.7 years	Kofoed score >50	STAR
van der Heide, et al. (2009)	58	Moderate	II	2.7 years	Implant in site and Kofoed score >50	STAR
van der Heide, et al. (2009)	58	Moderate	II	2.7 years	Removal of implant	○

○= No statistically significant difference between groups.

NA= Not applicable. Comparison cannot be performed because of differing follow-up times.

**Table 34 Adverse Events- Generation 2 vs. Generation 3 Device**

<u>Author</u>	<u>N</u>	<u>Strength</u>	<u>LoE</u>	<u>Treatment</u>	<u>Complication</u>	<u>Duration of Follow-up</u>	<u>Favors</u>
Wood, et al.(2009)	179	Moderate	II	Star vs. BP	Osteolytic cavities in the tibia	4 Years	○

○= No statistically significant difference between groups

These results are conflicting. Of the nine High and Moderate quality outcomes, four favor generation 3, one favors generation 2, and there is no difference in the remaining five outcomes. All outcomes compared the STAR device to the Buechel Pappas device. These results may not be applicable to other devices.

**AGE**

Eight studies<sup>10, 15, 29, 30, 12, 31, 11, 16, 17, 32</sup> with Very Low quality outcomes assessed age as a prognostic factor for total ankle arthroplasty outcomes of prosthesis survival, risk of failure, risk of revision, pain, AOFAS score and failure rate. One study<sup>11</sup> reported that patients with a lower age were at an increased risk for revision. However, seven other studies<sup>10, 15, 29, 30, 12, 31, 16, 17, 32</sup> did not report a statistically significant association between age and the reported ankle arthroplasty outcome. The studies were powered sufficiently to detect a statistically significant difference.

**Table 35 Summary of Outcomes- Age**

<u>Author</u>	<u>N</u>	<u>Strength</u>	<u>LoE</u>	<u>Duration of Follow-up</u>	<u>Outcome</u>	<u>Risk Factor</u>	<u>Result</u>
Doets, et al. (2006)	93	Very Low	IV	8 Years	Prosthesis survival	Age over 60	○
Skytta, et al. (2010)	573	Very Low	IV	7 Years	Prosthesis survival	Age	○
Hosman, et al. (2007)	183	Very Low	V	5 Years	Risk of failure	Age	○
Fevang, et al. (2007)	257	Very Low	V	5 Years	Prosthesis survival	Age	○
Henricson, et al. (2007)	531	Very Low	V	6 Years	Risk for revision	Lower Age	p=0.002 RR0.98 (CI 0.96, .099) Lower age implied increased risk for revision
Pyeovich, et al. (1996)	82	Very Low	IV	5 Years	Pain	Age	○

Valderrabano, et al. (2004)	74	Very Low	IV	3.7 Years	AOFAS score	Age	○
Kofoed, et al. (1999)	100	Very Low	IV	1 Year	Failure rate	Age over 50	○

○= No statistically significant association

### ***PREOPERATIVE WEIGHT***

Two studies<sup>12, 33</sup> with Very Low quality outcomes addressed preoperative weight and total ankle arthroplasty outcomes. One study<sup>12</sup> reported no association between preoperative weight and pain following total ankle arthroplasty. A second study<sup>33</sup> compared the number of malleolar fractures and nonunion in patients with a preoperative BMI >30 with those with a BMI <30. There were no statistically significant differences in adverse events between the two groups.

**Table 36 Summary of Outcomes- Body Weight**

<u>Author</u>	<u>N</u>	<u>Strength</u>	<u>LoE</u>	<u>Duration of Follow-up</u>	<u>Outcome</u>	<u>Risk Factor</u>	<u>Result</u>
Pyevich, et al. (1996)	82	Very Low	IV	5 Years	Pain	Weight	○
Schuberth, et al. (2006)	50	Very Low	V	2 Years	Malleolar fractures	BMI>30	○
Schuberth, et al. (2006)	50	Very Low	V	2 Years	Nonunion	BMI>30	○

○= No statistically significant association

### ***INFECTION***

One study<sup>28</sup> reported association between patients with preoperative infection and probability of implant removal at five years postoperative follow-up. This Very Low quality evidence suggests that preoperative infection increased the probability of implant removal at 5 years.

**Table 37 Summary of Outcomes- Infection**

<u>Author</u>	<u>N</u>	<u>Strength</u>	<u>LoE</u>	<u>Duration of Follow-up</u>	<u>Outcome</u>	<u>Risk Factor</u>	<u>Result</u>
van der Heide, et al. (2009)	58	Very Low	V	5 Years	Removal of implant	Infection	Infection increased probability of implant removal

### ***PREOPERATIVE FRACTURE***

One study<sup>28</sup> reported no statistically significant association between patients with preoperative fracture and probability of implant removal at five years postoperative.

**Table 38 Summary of Outcomes- Preoperative Fracture**

<b><u>Author</u></b>	<b><u>N</u></b>	<b><u>Strength</u></b>	<b><u>Duration of Follow-up</u></b>	<b><u>Outcome</u></b>	<b><u>Risk Factor</u></b>	<b><u>Result</u></b>
van der Heide, et al. (2009)	58	Very Low	5 Years	Removal of implant	Preoperative fracture	○

○= No statistically significant association

### ***SIDE OPERATED***

One study<sup>28</sup> reported no statistically significant association between the side of the operation and the probability of implant removal at five years postoperative.

**Table 39 Summary of Outcomes- Side of Operation**

<b><u>Author</u></b>	<b><u>N</u></b>	<b><u>Strength</u></b>	<b><u>Duration of Follow-up</u></b>	<b><u>Outcome</u></b>	<b><u>Risk Factor</u></b>	<b><u>Result</u></b>
van der Heide, et al. (2009)	58	Very Low	5 Years	Removal of implant	Side operated	○

○= No statistically significant association

## **SEX**

Seven studies<sup>12, 15, 29, 31 11, 17, 34, 35, 30, 36</sup> reported no statistically significant association between sex and ankle arthroplasty postoperative outcome.

**Table 40 Summary of Outcomes-Sex**

<u>Author</u>	<u>N</u>	<u>Strength</u>	<u>Outcome</u>	<u>Risk Factor</u>	<u>Duration of Follow- up</u>	<u>Result</u>
van der Heide, et al. (2009)	58	Very Low	Removal of implant	Sex	5 Years	○
Doets, et al. (2006)	93	Very Low	Device survival	Sex	8 Years	○
Fevang, et al. (2007)	257	Very Low	Prosthesis survival	Sex	5 Years	○
Hosman, et al. (2007)	183	Very Low	Risk of failure	Sex	5 Years	○
Skytta, et al. (2010)	573	Very Low	Prosthesis survival	Sex*	7 Years	○
Henricson, et al. (2007)	531	Very Low	Risk for revision	Sex	6 Years	○
Kofoed, et al. (1999)	100	Very Low	Failure rate	Sex	1 Year	○

○= No statistically significant association

\*= Adjusted for device design

### ***FRONTAL PLANE DEFORMITY***

Four studies<sup>27,37, 38, 18</sup> assessed the association of preoperative deformity with total ankle arthroplasty outcomes. Wood<sup>27</sup> reported that patients with deformity had less device survival than those without and that an increase of 5 degrees of deformity decreased the probability of device survival. Doets<sup>34</sup> reported a statistically significant association between patients with >10 degrees of deformity and device survival. There was no association between deformity and risk for failure or revision.

**Table 41 Summary of Outcomes-Pre-Operative Deformity**

<u>Author</u>	<u>N</u>	<u>Strength</u>	<u>Outcome</u>	<u>Risk Factor</u>	<u>Duration of Follow-up</u>	<u>Result</u>
Wood, et al (2009)	200	Very Low	Device Survival	Any deformity	6 Years	In patients with deformity the device survived less
Wood, et al (2009)	200	Very Low	Device Survival	Deformity increase of 5 degrees	6 Years	More deformity results in less probability of device survival
Doets, et al. (2006)	93	Very Low	Device Survival	Deformity >10	8 Years	In patients with deformity the device survived less
Hobson, et al. (2009)		Very Low	Risk of failure	Deformity >10	8 Years	○
Wood, Prem, and Sutton (2008)	200	Low	Revision	Valgus or Vargus orientations	6 Years	○

○= No statistically significant association

***INFLAMMATORY ARTHRITIS (RHEUMATOID)***

Five studies<sup>15, 10, 11, 17, 39</sup> examined preoperative diagnosis as a prognostic factor for total ankle arthroplasty outcomes. One study<sup>39</sup> reported that patients with rheumatoid arthritis had less function than those with osteoarthritis. Four additional studies<sup>15, 10, 11, 17</sup> did not report a statistically significant association between diagnosis and postoperative outcomes.

**Table 42 Summary of Outcomes- Preoperative Diagnosis**

<u>Author</u>	<u>N</u>	<u>Strength</u>	<u>Outcome</u>	<u>Risk Factor</u>	<u>Duration of Follow-up</u>	<u>Result</u>
Fevang, et al. (2007)	257	Very Low	Prosthesis survival	Rheumatoid vs. OA	5 Years	○
Hosman, et al. (2007)	183	Very Low	Risk of failure	RA vs. OA	5 Years	○
Henricson, et al. (2007)	531	Very Low	Risk for revision	RA vs. OA	6 Years	○
Skytta, et al. (2010)	573	Very Low	Prosthesis survival	Disease*	7 Years	○
Kofoed, et al. (1998)	52	Very Low	Pain	RA vs. OA	1 Year	○
Kofoed, et al. (1998)	52	Very Low	Function	RA vs. OA	1 Year	Statistically significant less function in RA group
Kofoed, et al. (1998)	52	Very Low	Mobility	RA vs. OA	1 Year	○

○= No statistically significant association

\*=Adjusted for age and gender

***PREVIOUS OPERATIONS***

One study<sup>10</sup> found no association between previous operations and ankle arthroplasty postoperative outcome.

**Table 43 Summary of Outcomes-Previous Operations**

<u>Author</u>	<u>N</u>	<u>Strength</u>	<u>Outcome</u>	<u>Risk Factor</u>	<u>Duration of Follow-up</u>	<u>Result</u>
Hosman, et al. (2007)	183	Very Low	Risk of failure	Previous Operations	5 Years	○

○= No statistically significant association

***ANKYLOSIS OF THE HINDFOOT***

One study<sup>31</sup> reported no statistically significant association between ankylosis of the hindfoot and ankle arthroplasty failure.

**Table 44 Summary of Outcomes-Ankylosis of the Hindfoot**

<u>Author</u>	<u>N</u>	<u>Strength</u>	<u>Outcome</u>	<u>Risk Factor</u>	<u>Duration of Follow-up</u>	<u>Result</u>
Doets, et al. (2006)	93	Very Low	Device survival	Deformity >10	8 Years	○

○= No statistically significant association

***SURGEON EXPERIENCE***

Two studies<sup>10, 34</sup> reported no statistically significant association between surgeon experience and ankle arthroplasty postoperative outcomes. A third study<sup>11</sup> reported that device survival was statistically significantly less when comparing the first 90 surgeries performed by a surgeon with the following 132 surgeries.

**Table 45 Summary of Outcomes- Surgeon Experience**

<u>Author</u>	<u>N</u>	<u>Strength</u>	<u>Outcome</u>	<u>Risk Factor</u>	<u>Duration of Follow-up</u>	<u>Result</u>
Hosman, et al. (2007)	183	Very Low	Risk of failure	Surgeon Experience	5 Years	○
van der Heide, et al. (2009)	58	Very Low	Removal of implant	Surgeon Experience	5 Years	○
Henricson, et al. (2007)	531	Very Low	Risk for revision	Surgeon Experience	6 Years	Fewer revisions for surgeons who have performed more surgeries

○= No statistically significant association

***YEAR OF SURGERY***

Two studies<sup>10, 15</sup> reported no statistically significant association between year of surgery and ankle arthroplasty postoperative outcome.

**Table 46 Summary of Outcomes- Year of Surgery**

<u>Author</u>	<u>N</u>	<u>Strength</u>	<u>Outcome</u>	<u>Risk Factor</u>	<u>Duration of Follow-up</u>	<u>Result</u>
Fevang, et al. (2007)	257	Very Low	Prosthesis survival	Year of surgery	5 Years	○
Hosman, et al. (2007)	183	Very Low	Risk of failure	Year of surgery	5 Years	○

○= No statistically significant association

Year of surgery prognostic factor is not explicitly described in the published literature<sup>10, 15</sup>.

## HOSPITAL VOLUME

Two studies<sup>17,15</sup> reported no statistically significant association between hospital surgery volume and ankle arthroplasty postoperative outcome.

**Table 47 Summary of Outcomes- Hospital Volume**

<u>Author</u>	<u>N</u>	<u>Strength</u>	<u>Outcome</u>	<u>Risk Factor</u>	<u>Duration of Follow-up</u>	<u>Result</u>
Fevang, et al. (2007)	257	Very Low	Prosthesis survival	Number of surgeries performed at hospital	5 Years	○
Skytta, et al. (2010)	573	Very Low	Prosthesis survival	Hospital Volume*	7 Years	○

○= No statistically significant association

\*Adjusted for implant design.

## ARTICLES CONSIDERED

**Table 48 Articles Considered- Prognostic Factors**

<u>Author</u>	<u>Title</u>	<u>Included or Reason for Exclusion</u>
Hobson, et al. 2009	Total ankle replacement in patients with significant pre-operative deformity of the hindfoot	Included
Wood, et al. 2009	A randomized, controlled trial of two mobile-bearing total ankle replacements	Included
Wood, et al. 2008	Total ankle replacement: medium-term results in 200 Scandinavian total ankle replacements	Included
Fevang, et al. 2007	257 ankle arthroplasties performed in Norway between 1994 and 2005	Included
Henricson, et al. 2007	The Swedish Ankle Arthroplasty Register: An analysis of 531 arthroplasties between 1993 and 2005	Included
Hosman, et al. 2007	A New Zealand national joint registry review of 202 total ankle replacements followed for up to 6 years	Included
Doets, et al. 2006	Total ankle arthroplasty in inflammatory joint disease with use of two mobile-bearing designs	Included
Schuberth, et al. 2006	Perioperative complications of the Agility total ankle replacement in 50 initial, consecutive cases	Included
Pyevich, et al. 1996	Total ankle arthroplasty: A unique design: Two to twelve-year follow-up	Included

van, et al. 2009	Total ankle prostheses in rheumatoid arthropathy	Include
Kofoed, et al. 1998	Ankle arthroplasty for rheumatoid arthritis and osteoarthritis: prospective long-term study of cemented replacements	Include
Kofoed, et al. 1999	Ankle arthroplasty in patients younger and older than 50 years: a prospective series with long-term follow-up	Include
Valderrabano, et al. 2004	Scandinavian total ankle replacement: A 3.7-Year average follow-up of 65 patients	Include
Skytta, et al. 2010	Total ankle replacement: a population-based study of 515 cases from the Finnish Arthroplasty Register	Included
Frey, et al. 2007	The effects of obesity on orthopaedic foot and ankle pathology	Not relevant= obesity and ankle pathology
Kapral, et al. 2007	Remission by composite scores in rheumatoid arthritis: are ankles and feet important?	Less than 10 patients with ankle arthritis
Collman, et al. 2006	Arthroscopic ankle arthrodesis: factors influencing union in 39 consecutive patients	Retrospective case series
Spirt, et al. 2004	Complications and failure after total ankle arthroplasty	Retrospective case series
Frey, et al. 2007	The effects of obesity on orthopaedic foot and ankle pathology	Not relevant= obesity and ankle pathology
Kim, et al. 2009	Total ankle replacement in moderate to severe varus deformity of the ankle	Baseline differences

## STUDY QUALITY

Please see the supplemental quality document for additional information regarding the quality analysis.

**Table 49 Study Quality-Prognostic Factors**

<b>Study:</b>	<b>Wood</b>	<b>Wood</b>	<b>Wood</b>	<b>Wood</b>	<b>Wood</b>
<b>Outcome:</b>	<b>Type of Device Require Second Surgery</b>	<b>Type of Device Surviving Implants</b>	<b>Type of Device Failure Rate</b>	<b>Type of Device Failure</b>	<b>Type of Device AOFAS Pain</b>
Strength of Evidence Based on Quality	●●●●	●●●●	●●●●	●●●●	●●●○
	High	High	High	High	Moderate

Circles represent domains evaluated. Filled circles represent domains that are unflawed.

**Table 50 Study Quality-Prognostic Factors**

<b>Study:</b>	<b>Wood</b>	<b>van der Heide</b>	<b>van der Heide</b>	<b>van der Heide</b>	<b>Takakura</b>
<b>Outcome:</b>	<b>Type of Device AOFAS Function</b>	<b>Type of Device Removal of Implant</b>	<b>Type of Device Kofoed Score</b>	<b>Type of Device Implant in site and Kofoed score &gt;50</b>	<b>Type of Device Revision</b>
Strength of Evidence Based on Quality	●●●○	●●●○	●●●○	●●●○	●●○○

Circles represent domains evaluated. Filled circles represent domains that are unflawed.

**Table 51 Study Quality-Prognostic Factors**

<b>Study:</b>	<b>Hosman</b>	<b>Kofoed 1999</b>	<b>Kofoed 1999</b>	<b>Kofoed 1999</b>	<b>Kofoed 1998</b>
<b>Prognostic:</b>	<b>Type of Device Patient Score</b>	<b>Age</b>	<b>Disease</b>	<b>Sex</b>	<b>Disease</b>
Strength of Evidence Based on Quality	●○○○	●○○○	●○○○	●○○○	●○○○ Very Low
	Very Low	Very Low	Very Low	Very Low	

Circles represent domains evaluated. Filled circles represent domains that are unflawed.

**Table 52 Study Quality-Prognostic Factors**

<b>Study:</b>	<b>Hosman</b>	<b>Kofoed 1999</b>
<b>Prognostic:</b>	<b>Type of Device Patient Score</b>	<b>Age</b>
Strength of Evidence Based on Quality	●○○○	●○○○
	Very Low	Very Low

Circles represent domains evaluated. Filled circles represent domains that are unflawed.

**Table 53 Study Quality-Prognostic Factors**

<b>Study:</b>	<b>Fevang</b>	<b>Skytta</b>	<b>Doets</b>	<b>Hosman</b>	<b>Pyevich</b>
<b>Prognostic:</b>	<b>Age</b>	<b>Age</b>	<b>Age</b>	<b>Age</b>	<b>Age</b>
Strength of Evidence Based on Quality	●○○○	●○○○	●○○○	●○○○	●○○○
	Very Low	Very Low	Very Low	Very Low	Very Low

Circles represent domains evaluated. Filled circles represent domains that are unflawed.

**Table 54 Study Quality-Prognostic Factors**

<b>Study:</b>	<b>Henricson</b>	<b>Pyevich</b>	<b>Schuberth</b>	<b>Wood</b>	<b>Hosman</b>
<b>Prognostic:</b>	<b>Age</b>	<b>Weight</b>	<b>BMI</b>	<b>Deformity</b>	<b>Deformity</b>
Strength of Evidence Based on Quality	●○○○	●○○○	●○○○	●○○○	●○○○
	Very Low	Very Low	Very Low	Very Low	Very Low

Circles represent domains evaluated. Filled circles represent domains that are unflawed.

**Table 55 Study Quality-Prognostic Factors**

<b>Study:</b>	<b>wood/978</b>	<b>Doets</b>	<b>Hobson</b>	<b>Fevang</b>	<b>Henricson</b>
<b>Prognostic:</b>	<b>Deformity</b>	<b>Deformity</b>	<b>Deformity</b>	<b>Diagnosis</b>	<b>Diagnosis</b>
Strength of Evidence Based on Quality	●○○○	●○○○	●○○○	●○○○	●○○○
	Very Low	Very Low	Very Low	Very Low	Very Low

Circles represent domains evaluated. Filled circles represent domains that are unflawed.

**Table 56 Study Quality-Prognostic Factors**

<b>Study:</b>	<b>Hosman</b>	<b>Skytta</b>	<b>Doets</b>	<b>Valderrabano</b>
<b>Prognostic:</b>	<b>Diagnosis</b>	<b>Diagnosis</b>	<b>Ankylosis</b>	<b>Side of Surgery</b>
Strength of Evidence Based on Quality	●○○○	●○○○	●○○○	●○○○
	Very Low	Very Low	Very Low	Very Low

Circles represent domains evaluated. Filled circles represent domains that are unflawed.

**Table 57 Study Quality-Prognostic Factors**

<b>Study:</b>	<b>Hosman</b>	<b>Hosman</b>	<b>Fevang</b>	<b>Valderrabano</b>
<b>Prognostic:</b>	<b>Previous Surgery</b>	<b>Year of Surgery*</b>	<b>Year of Surgery*</b>	<b>Age</b>
Strength of Evidence Based on Quality	●○○○	●○○○	●○○○	●○○○
	Very Low	Very Low	Very Low	Very Low

Circles represent domains evaluated. Filled circles represent domains that are unflawed.

\*Year of surgery prognostic factor is not explicitly described in the published literature<sup>10, 15</sup>.

**Table 58 Study Quality-Prognostic Factors**

<b>Study:</b>	<b>Hosman</b>	<b>Van der Heide</b>	<b>Henricson</b>	<b>Fevang</b>	<b>Skytta</b>
<b>Prognostic:</b>	<b>Surgeon Experience</b>	<b>Surgeon Experience</b>	<b>Surgeon Experience</b>	<b>Hospital Volume</b>	<b>Hospital Volume</b>
Strength of Evidence Based on Quality	●○○○	●○○○	●○○○	●○○○	●○○○
	Very Low	Very Low	Very Low	Very Low	Very Low

Circles represent domains evaluated. Filled circles represent domains that are unflawed.

## KEY QUESTION 4

### Do patients with ankle arthritis treated with total ankle arthroplasty have different clinical results when compared to patients treated with arthrodesis?

The purpose of Key Question Four was to compare the results of total ankle arthroplasty with those of ankle arthrodesis. Three comparative studies<sup>1, 1, 40, 41</sup> addressed this recommendation. To answer this question, we need to compare the results of patients treated with ankle arthroplasty to those of a comparable group treated with ankle arthrodesis. Comparable groups have nonstatistically significant differences in baseline characteristics (age, diagnosis, etc.) and outcomes (pain, function, mobility, etc.). The studies found to address this comparison have patient groups that are not comparable. Based on this evidence, it is impossible to determine whether the differences in results are actually due to treatment. Because the inclusion criteria did not exclude studies with differences in characteristics or outcomes, these studies and their corresponding reported outcomes are included.

In one study<sup>38</sup> the authors corrected for the differences in baseline patient characteristics in their analysis of five outcomes: major revision procedures, number of pulmonary embolisms, total number of infections, number of device related infections, and number of postoperative infections. Results with statistical corrections for baseline differences can be accurate (please see Table 59 and Table 61 for these results). AAOS analyzed the remaining twelve outcomes from this study; however, we were unable to correct for the baseline differences. Two additional studies<sup>41, 40</sup> reported statistically significant differences in baseline patient characteristics and/or baseline outcome measurements. We were unable to correct for these differences; therefore, the quality rating reported for outcomes from these studies are “Very Low”.

Of the five outcomes<sup>1</sup> that were adjusted for baseline differences, two were statistically significant in favor of the arthrodesis group major revision procedures (see Table 59) and device related infections (see Table 61), and there were no statistically significant differences in the remaining three adverse events: pulmonary embolism, total infections, and postoperative infections. This study was powered sufficiently to detect a difference, therefore, this is a true lack of difference between groups. Major revision procedures reported by this author<sup>1</sup> include patients readmitted to the hospital for any one or a combination of the following procedures: revision arthroplasty, ankle arthroplasty, removal of a prosthesis, or ankle arthrodesis.

Please see Table 59 through Table 62 for the additional unadjusted outcomes reported. Because these results do not adjust for baseline differences, no conclusions may be drawn concerning the clinical results of the patient comparison groups.

**Table 59 Revisions or Removal of Device- Arthrodesis vs. Arthroplasty**

<u>Study</u>	<u>N</u>	<u>Strength of Evidence</u>	<u>Adverse Event</u>	<u>Duration of follow-up</u>	<u>Favored treatment</u>
SooHoo, et al. (2007)	5185	Low	Major revision procedure*	0.25 Year	Arthrodesis

SooHoo, et al. (2007)	5029	Low	Removal of implant	0.25 Year	○
SooHoo, et al. (2007)	5029	Low	Revision arthroplasty	0.25 Year	○
SooHoo, et al. (2007)	4614	Low	Major Revision	1 Year	Arthrodesis
SooHoo, et al. (2007)	4614	Low	Ankle fusion	1 Year	○
SooHoo, et al. (2007)	4614	Low	Revision arthroplasty	1 Year	Arthrodesis
SooHoo, et al. (2007)	4614	Low	Removal of implant	1 Year	Arthrodesis
SooHoo, et al. (2007)	4614	Low	Subtalar fusion	1 Year	○
Saltzman, et al. (2009)	194	Very Low	Number of revisions/removals	2 Years	○

○= No statistically significant difference between groups

\*Multivariate logistic regression estimating the impact of surgical technique on outcomes while accounting for age, gender, race, insurance, proxy income, comorbidities, and provider characteristics.

**Table 60 Clinical Results- Arthrodesis vs. Arthroplasty**

<u>Author</u>	<u>N</u>	<u>Strength</u>	<u>Outcome</u>	<u>Duration of Follow-up</u>	<u>Result</u>
Saltzman, et al. (2009)	191	Very Low	Improvement in BP pain	2 Years	○
Saltzman, et al. (2009)	224	Very Low	VAS pain	2 Years	○
Saltzman, et al. (2010)	71	Very Low	AOS-pain	2-6 Years	Arthroplasty
Saltzman, et al. (2010)	71	Very Low	AOS-disability	2-6 Years	○
Saltzman, et al. (2010)	71	Very Low	Sf-36 physical component	2-6 Years	○
Saltzman, et al. (2010)	71	Very Low	SF-36 mental component	2-6 Years	Arthroplasty

<u>Author</u>	<u>N</u>	<u>Strength</u>	<u>Outcome</u>	<u>Duration of Follow-up</u>	<u>Result</u>
Saltzman, et al. (2009)	224	Very Low	# of Patients with secondary interventions	2 Years	○
Saltzman, et al. (2009)	224	Very Low	Secondary intervention other than removal/revision	2 Years	Arthrodesis
Saltzman, et al. (2009)	189	Very Low	Efficacy (BP>40)	2 Years	Arthroplasty
Saltzman, et al. (2009)	194	Very Low	Safety	2 Years	○
Saltzman, et al. (2009)	193	Very Low	Overall success	2 Years	Arthroplasty
Saltzman, et al. (2009)	190	Very Low	Improvement in BP deformity	2 Years	Arthroplasty
Saltzman, et al. (2009)	191	Very Low	Improvement in BP function	2 Years	Arthroplasty
Saltzman, et al. (2009)	191	Very Low	Improvement in BP stairs	2 Years	Arthroplasty
Saltzman, et al. (2009)	191	Very Low	Improvement in BP standing	2 Years	Arthroplasty
Saltzman, et al. (2009)	191	Very Low	Improvement in BP support	2 Years	Arthroplasty
Saltzman, et al. (2009)	191	Very Low	Improvement in BP walking	2 Years	○
Saltzman, et al. (2009)	191	Very Low	Improvement in BP limp	2 Years	○
Saltzman, et al. (2009)	191	Very Low	Improvement in BP total	2 Years	Arthroplasty
Saltzman, et al. (2009)	191	Very Low	Improvement in BP total minus ROM	2 Years	Arthroplasty
Saltzman, et al. (2009)	191	Very Low	Total improvement in BP no ROM	2 Years	Arthroplasty

○= No statistically significant difference between groups

**Table 61 Adverse Events- Arthrodesis vs. Arthroplasty**

<u>Study</u>	<u>N</u>	<u>Strength of Evidence</u>	<u>Adverse Event</u>	<u>Duration of follow-up</u>	<u>Favored treatment</u>
SooHoo, et al. (2007)	5185	Low	Pulmonary embolism*	90 days	○
Saltzman, et al. (2010)	71	Very Low	Deep venous thrombosis	2-6 Years	Arthrodesis
SooHoo, et al. (2007)	5185	Low	Infection –total*	90 days	○
SooHoo, et al. (2007)	5185	Low	Infection - postoperative*	90 days	○
SooHoo, et al. (2007)	5185	Low	Infection - device related*	90 days	Arthrodesis
Saltzman, et al. (2009)	224	Very Low	Operation site infections	2 Years	○
Saltzman, et al. (2009)	224	Very Low	Infections	2 Years	○
SooHoo, et al. (2007)	5029	Low	Infectious arthropathy	0.25 Years	○
SooHoo, et al. (2007)	5029	Low	Below-the-knee amputation	90 days	○
SooHoo, et al. (2007)	5029	Low	Chronic osteomyelitis	90 days	○
SooHoo, et al. (2007)	5029	Low	Acute osteomyelitis	90 days	○
Saltzman, et al. (2009)	224	Very Low	Wound problems	2 Years	○
Saltzman, et al. (2009)	224	Very Low	Wound problems and infection	2 Years	○
Saltzman, et al. (2009)	224	Very Low	Operation site wound problems	2 Years	Arthrodesis

<u>Study</u>	<u>N</u>	<u>Strength of Evidence</u>	<u>Adverse Event</u>	<u>Duration of follow-up</u>	<u>Favored treatment</u>
Saltzman, et al. (2009)	224	Very Low	Operation site nerve injury	2 Years	Arthrodesis
Saltzman, et al. (2009)	224	Very Low	Operation site bone fracture	2 Years	Arthrodesis
Saltzman, et al. (2009)	224	Very Low	Operation site soft tissue edema	2 Years	○
Saltzman, et al. (2009)	224	Very Low	Operation site bony change	2 Years	NA
Saltzman, et al. (2009)	224	Very Low	Bony problems	2 Years	○
Saltzman, et al. (2009)	224	Very Low	Any major complication	2 Years	Arthrodesis
Saltzman, et al. (2010)	71	Very Low	intraoperative medial or posterior malleolar fractures	2-6 Years	Arthrodesis
Saltzman, et al. (2010)	71	Very Low	Superficial wound dehiscence	2-6 Years	○
Saltzman, et al. (2010)	71	Very Low	Nonunion	2-6 Years	○
Saltzman, et al. (2010)	71	Very Low	Tibial stress fracture	2-6 Years	○
Saltzman, et al. (2010)	71	Very Low	Hardware pain	2-6 Years	○
Saltzman, et al. (2010)	71	Very Low	Impingement	2-6 Years	○
Saltzman, et al. (2010)	71	Very Low	Wound dehiscence	2-6 Years	○
Saltzman, et al. (2010)	71	Very Low	Leg Length discrepancy	2-6 Years	○

○= No statistically significant difference between groups

\*Multivariate logistic regression estimating the impact of surgical technique on outcomes while accounting for age, gender, race, insurance, proxy income, co morbidities, and provider characteristics.

A clear conclusion cannot be drawn from these data. Based on the five outcomes that were adjusted for baseline differences, the overall results are conflicting; two outcomes favor the arthrodesis group and three outcomes favor the arthroplasty group. No conclusion may be drawn concerning the remaining outcomes because these results do not adjust for baseline differences.

**Table 62 Articles Considered- Ankle Arthroplasty vs. Arthrodesis**

<u>Author</u>	<u>Title</u>	<u>Included or Reason for Exclusion</u>
SooHoo, et al. 2007	Comparison of reoperation rates following ankle arthrodesis and total ankle arthroplasty	Included
Saltzman, et al. 2010	Treatment of isolated ankle osteoarthritis with arthrodesis or the total ankle replacement: a comparison of early outcomes	Included
Saltzman, et al. 2009	Prospective controlled trial of STAR total ankle replacement versus ankle fusion: initial results	Included
Piriou, et al. 2008	Ankle replacement versus arthrodesis: a comparative gait analysis study	Surrogates outcomes only
McGuire, et al. 1988	Comparative analysis of ankle arthroplasty versus ankle arthrodesis	Uses first generation replacements

## STUDY QUALITY

Please see the supplemental quality document for additional information regarding the quality analysis.

**Table 63 Study Quality- Ankle Arthroplasty vs. Arthrodesis**

Study:	SooHoo	SooHoo	SooHoo
Outcome:	Adverse Events adjusted	Adverse Events 90 days	Adverse Events 1 year
Strength of Evidence Based on Quality	●●○○	●●○○	●●○○
	Low	Low	Low

Circles represent domains evaluated. Filled circles represent domains that are unflawed.

**Table 64 Study Quality- Ankle Arthroplasty vs. Arthrodesis**

Study:	Saltzman 2009	Saltzman 2009	Saltzman 2009	Saltzman 2009	Saltzman 2009
Outcome:	BP Subscales	VAS Pain	Additional Intervention	Efficacy	Safety
Strength of Evidence Based on Quality	●○○○	●○○○	●○○○	●○○○	●○○○
	Very Low	Very Low	Very Low	Very Low	Very Low

Circles represent domains evaluated. Filled circles represent domains that are unflawed.

**Table 65 Study Quality- Ankle Arthroplasty vs. Arthrodesis**

Study:	Saltzman 2009	Saltzman 2009	Saltzman 2009	Saltzman 2009	Saltzman 2010
Outcome:	Success	Adverse Events	Success	Adverse Events	AOS
Strength of Evidence Based on Quality	●○○○	●○○○	●○○○	●○○○	●○○○
	Very Low	Very Low	Very Low	Very Low	Very Low

Circles represent domains evaluated. Filled circles represent domains that are unflawed.

**Table 66 Study Quality- Ankle Arthroplasty vs. Arthrodesis**

<b>Study:</b>	<b>Saltzman 2010</b>	<b>Saltzman 2010</b>
<b>Outcome:</b>	<b>SF-36</b>	<b>Adverse Events</b>
Strength of Evidence Based on Quality	●○○○	●○○○
	Very Low	Very Low

Circles represent domains evaluated. Filled circles represent domains that are unflawed.

**Disclaimer**

As noted above, this document is not intended to convey any official AAOS position on surgical interventions to treat ankle arthritis. We provide this *Technology Overview* as a service to our members in an effort to help them identify and evaluate the available published literature on this topic. We hope that our summary will assist physicians in providing the best possible care to their patients.

AAOS would like to have feedback from its members on this *Technology Overview*. To provide your feedback, please visit <http://research.aaos.org/surveys/Tech-Feedback.htm>

## IV. APPENDIXES

### APPENDIX I INCLUSION CRITERIA

We used the following criteria to determine whether studies should be included in this systematic review:

- Study must be of either the treatment or diagnosis of ankle arthritis
- Study must be a full article
- Study must have been published in the peer-reviewed literature
- Study should have 10 or more patients per group
- Study must be of humans
- Study must not be an in vitro study
- Study must not be a biomechanical study
- Study must not be performed on cadavers
- Study must be published in English
- Study must be published after: 1966
- Study results must be quantitatively presented
- Only studies of the highest level of available evidence are included
- Study must not be a retrospective case series
- Enrolled study population may not include patients with: (Diabetic Neuropathy) Charcot Neuroarthropathy, Severe Infections, Severe Peripheral Vascular Disease, Septic Arthritis (unless reported separately), Osteomyelitis
- Study must include patients older than 17 (all patients unless reported separately)
- Study must have 50% follow-up. Studies with less than 80% follow-up will be downgraded.
- Study must use outcome measures reported by more than one group. The scale must be completed by the patient not the physician or other third party.

## APPENDIX II LITERATURE SEARCHES

To identify studies for this *Overview* we searched MEDLINE and the Cochrane Library through April 24, 2010, Cinal through December 31, 2009 and EMBASE through August 27, 2009.

Our MEDLINE search strategy was:

#1

"Ankle joint"[mh] OR ankle\*[tiab] OR tibiotalar[tiab] OR tibiotalarcalcaneal[tiab] OR talar[tiab] OR talus[tiab] OR "Tarsal Bones"[mh] OR hindfoot[tiab] OR talocalcaneal[tiab] OR calcaneus[tw]

#2

Osteoarthritis[mh:noexp] OR Arthritis[mh:noexp] OR "Arthritis, rheumatoid"[mh:noexp] OR arthriti\*[tiab] OR osteoarthritis\*[tiab]

#3

MRI[tiab] OR "Magnetic Resonance Imaging"[mh] OR "CT scan" OR "CAT scan" OR "Tomography, X-Ray Computed"[mh] OR "Radionuclide Imaging"[mh:noexp] OR "bone scan"[tiab] OR Ultrasonography[mh] OR ultrasound[tiab] OR Radiography[mh:noexp] OR "x-ray"[tiab]

#4

"Arthrodesis"[mh] OR arthrodesis[tiab] OR fusion[tiab] OR Arthroscopy[mh] OR arthroscop\*[tiab] OR debridement[tiab] OR "Arthroplasty, Replacement"[mh:noexp] OR Arthroplasty[mh:noexp] OR arthroplasty[tiab] OR "total ankle" OR Joint Prosthesis[mh:noexp] OR "joint replacement"[tiab] OR ((osteotomy[tiab] OR Osteotomy[mh]) AND (tibia[mh] OR tibial[tiab])) OR cheilectomy[tiab]

#5

(Bone Substitutes[mh] OR Bone Transplantation[mh] OR "bone graft"[tiab] OR allograft[tiab] OR xenograft[tiab] OR BMP[tiab] OR (bone[tiab] AND morphogenetic[tiab] AND (protein[tiab] OR proteins[tiab]))) OR (bone[tiab] AND stimulator\*[tiab]) OR "Platelet-Derived Growth Factor"[mh] OR PDGF[tiab] AND (Arthrodesis[mh] OR arthrodesis[tiab] OR fusion[tiab] OR fused[tiab] OR surgery[tw])

#6

English[lang]

#7

(animal[mh] NOT human[mh]) OR cadaver[mh] OR cadaver\*[titl] OR rats[titl] OR mice[titl] OR comment[pt] OR editorial[pt] OR letter[pt] OR addresses[pt] OR news[pt] OR "newspaper article"[pt] OR "historical article"[pt] OR "case report"[title]

#8

#1 AND (#2 OR #4) AND 1966[pdat]:2009[pdat]

#9

#3 AND (Ankle Joint[mh] OR (#1 AND #2)) AND 1995[pdat]:2009[pdat]

#10

#1 AND #5 AND 1990[pdat]:2009[pdat]

#11

(#8 OR #9 OR #10) AND #6 NOT #7

Haynes RB, McKibbin KA, Wilczynski NL, Walter SD, Were S. [Optimal search strategies for retrieving scientifically strong studies of treatment from Medline: analytical survey](#). BMJ 2005 May 21;330(7501):1179.

Montori VM, Wilczynski NL, Morgan D, Haynes RB, for the Hedges Team. [Optimal search strategies for retrieving systematic reviews from MEDLINE: analytical survey](#). BMJ 2005 Jan 8;330(7482):68-73

Our EMBASE search strategy was:

#1

'Ankle arthrodesis'/de OR 'Ankle arthroscopy'/de

#2

Ankle:de OR ankle\*:ti OR tibiotalar:ti OR tibiotalarcalcaneal:ti OR talar:ti OR talus:ti OR talus/de

#3

Osteoarthritis/de OR Arthritis/de OR 'Chronic arthritis'/de OR 'Rheumatoid arthritis'/exp OR arthriti\*:ti OR osteoarthritis\*:ti

#4

'Nuclear magnetic resonance imaging'/exp OR MRI OR 'CT scan' OR 'CAT scan' OR 'Computer assisted tomography'/de OR 'bone scintiscanning'/de OR 'bone scan' OR echography/exp OR ultrasound OR 'radiography, ankle'/de OR radiography/de OR 'bone radiography'/de OR x-ray <http://embase.com/search/results>

#5

arthrodesis OR fusion OR Arthroplasty/de OR 'total ankle' OR 'Joint prosthesis'/de OR 'Tibia osteotomy'/de OR cheilectomy

#6

('Bone graft'/de OR 'Bone allograft'/de OR Xenograft/de OR xenograft OR 'bone morphogenetic protein'/de OR 'bone morphogenetic protein' OR BMP OR 'bone stimulator' OR 'Platelet derived growth factor'/de OR 'platelet-derived growth factor') AND ('Ankle arthrodesis'/de OR arthrodesis OR fusion)

#7

[English]/lim AND [humans]/lim AND [embase]/lim

#8

cadaver/de OR 'in vitro study'/exp OR 'case report':ti OR 'abstract report'/de OR book/de OR editorial/de OR letter/de OR note/de

#9

#1 OR (#2 AND (#3 OR #5))

#10

#4 AND (ankle/de OR (#2 AND #3)) AND 1995-2009/py

#11

#2 AND #6 AND 1990-2009/py

#12

(#9 OR #10 OR #11) AND #7 NOT #8

Wong SS, Wilczynski NL, Haynes RB. [Comparison of top-performing search strategies for detecting clinically sound treatment studies and systematic reviews in MEDLINE and EMBASE](#). J Med Libr Assoc. 2006 Oct;94(4):451-5. No abstract available.

Our Cochrane Library search strategy was:

**S1**

MH Ankle or MH "Ankle joint" or ankle or tibiotalar or tibiotocalcaneal or talar or talus

**S2**

MH Osteoarthritis or MH Arthritis or MH "Arthritis, Rheumatoid" or arthriti\* or osteoarthritis\*

**S3**

LA English

**S4**

PT "editorial" or PT "letter" or PT "case study" or MM "case studies" or TI "case report"

**S5**

S1 and S2 and S3 not S4

Wong SS, Wilczynski NL, Haynes RB. Optimal CINAHL search strategies for identifying therapy studies and review articles. *J Nurs Scholarsh.* 2006; 38(2):194-9.

Our Cinal search strategy was:

**S1**

MH Ankle or MH "Ankle joint" or ankle or tibiotalar or tibiotocalcaneal or talar or talus

**S2**

MH Osteoarthritis or MH Arthritis or MH "Arthritis, Rheumatoid" or arthriti\* or osteoarthritis\*

**S3**

LA English

**S4**

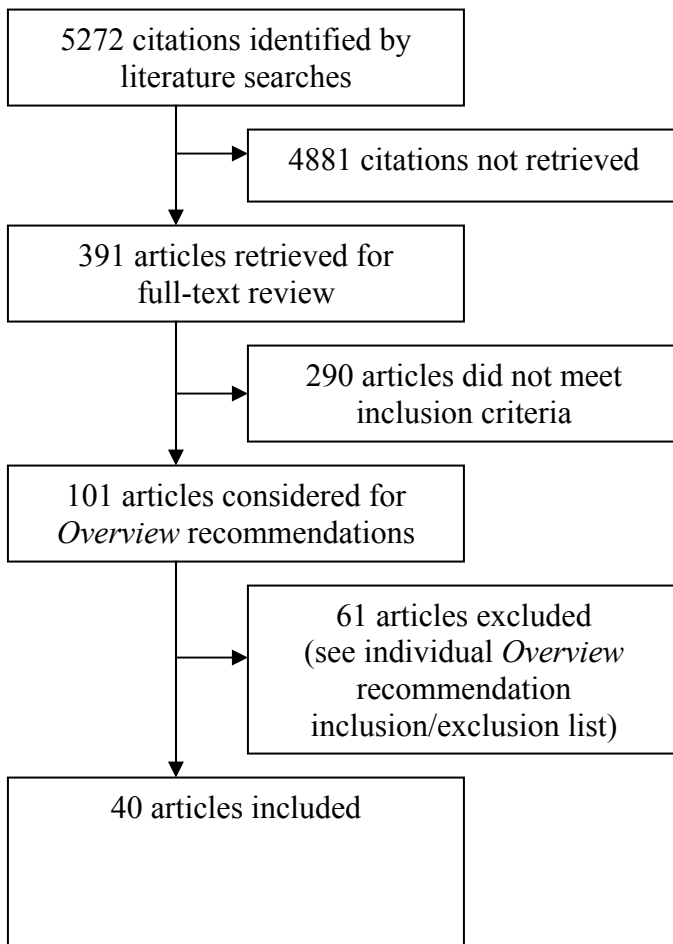
PT "editorial" or PT "letter" or PT "case study" or MM "case studies" or TI "case report"

**S5**

S1 and S2 and S3 not S4

Note: Final CINAHL update was run 12/31/2009 (CINAHL subscription not available in 2010)

### APPENDIX III STUDY ATTRITION



## **APPENDIX IV METHODS**

This report was developed using the methods of a systematic review. Our physician task force developed four key questions regarding the surgical treatment of ankle arthritis based on a systematic review on the treatment of ankle arthritis drafted by AAOS. To develop the systematic review, which was intended for the use in a clinical practice guideline, a physician workgroup developed simulated recommendations and rules used for the inclusion or articles before conducting the literature search. In this technology overview, we maintained all study inclusion criteria but two (non controlled studies must report consecutive enrollment and a controlled study that has baseline differences in outcomes and/or patient characteristics known to influence outcomes must adjust for those differences) (the full list of criteria appears in Appendix I). We addressed the main surgical topics in this Technology Overview and the main non-operative topics in a separate Technology Overview. The topics not addressed in either overview include allograft arthroplasty, internal and external fixation and arthroscopic, open and arthroscopic debridement.

## APPENDIX V JUDGING QUALITY

We evaluated the quality of the data on each outcome using a domain-based approach. Such an approach is used by the Cochrane Collaboration (1) but, unlike the Cochrane Collaboration's scheme (which is for studies with parallel control groups), our scheme allows for evaluation of studies of all designs. The domains we used are whether:

1. The study was prospective (with prospective studies, it is possible to have an *a priori* hypothesis to test; this is not possible with retrospective studies.)
2. The study was of low statistical power
3. The assignment of patients to groups was unbiased
4. There was sufficient blinding to mitigate against a placebo effect
5. The patient groups were comparable at the beginning of the study
6. The treatment was delivered in such a way that any observed effects could reasonably be attributed to that treatment
7. Whether the instruments used to measure outcomes were valid
8. Whether there was evidence of investigator bias

Each quality domain is addressed by one or more questions. These questions are shown in Table 67. This table lists each question domain and the possible questions based on study design. Questions answered with "Yes" in the Table 67 represent the best answers for the study design, questions answered, "No" are questions that are automatically answered as "No" based on the study design.

**Table 67 Quality Questions and Domains for Each of Four Study Designs**

Domain	Question:	Study: Outcome:	Parallel, Contemporary Controls Any	Crossover Trials Any	Historically Controlled Studies Any	Case Series Any
Group Assignment	Stochastic		Yes	Yes	No	No
Group Assignment	Quasi-random Assignment		No	No	No	n/a*
Group Assignment	Matched Groups		No	No	Yes	No
Group Assignment	Consecutive Enrollment		n/a	n/a	n/a	Yes
Prospective	Prospective		Yes	Yes	Yes	Yes
Blinding	Blinded Patients		Yes	Yes	No	No
Blinding	Blinded Assessors		Yes	Yes	No	No
Blinding	Blinding Verified**		Yes	Yes	No	No
Group Comparability	Allocation Concealment**		Yes	Yes	No	No
Group Comparability	>80% Follow-up		Yes	Yes	No	Yes
Group Comparability	<20% Completion Difference		Yes	Yes	No	No
Group Comparability	Similar Baseline Outcome		Yes	n/a	Yes	No
Group Comparability	Comparable Pt. Characteristics		Yes	n/a	Yes	No

<b>Domain</b>	<b>Question:</b>	<b>Study:</b>	<b>Parallel, Contemporary Controls</b>	<b>Crossover Trials</b>	<b>Historically Controlled Studies</b>	<b>Case Series</b>
Group Comparability	Same Control Group Results (cross-over only)		n/a	Yes	n/a	n/a
Group Comparability	Same Experimental Group Results (cross-over only)		n/a	Yes	n/a	n/a
Treatment Integrity	Same Centers		Yes	Yes	Yes	No
Treatment Integrity	Same Treatment Duration in and across All Groups		Yes	Yes	Yes	No
Treatment Integrity	Same Concomitant Treatment to All Groups (controlled studies only)		Yes	Yes	Yes	n/a
Treatment Integrity	No Confounding Treatment (case series only)		n/a	n/a	n/a	Yes
Measurement	Same Instruments		Yes	Yes	Yes	Yes
Measurement	Valid Instrument		Yes	Yes	Yes	Yes
Bias	Article & Abstract Agree		Yes	Yes	Yes	Yes
Bias	All Outcomes Reported		Yes	Yes	Yes	Yes
Bias	No Primary Subgroup Analysis		Yes	Yes	Yes	Yes
Statistical Power	Statistically Significant		High	High	High	High
Statistical Power	Number of Patients in Analysis		See statistical power section			

\* “n/a” refers to “not applicable”. Cells in which non-applicable questions appear are shaded in grey.

\*\*Studies are not penalized for not concealing allocation or not verifying the integrity of blinding. Rather, the answers to these questions act to preserve the quality of outcomes for which the answers to certain questions were “No” or “Unclear”.

To arrive at the quality of the evidence for a given outcome, every quality domain for that outcome reported in any given study is initially judged as not having any flaws and, therefore, the quality of evidence for the effect of that treatment on that outcome is taken as “High.” For all domains except the “Statistical Power” domain, if one or more questions addressing any given domain are answered “No” for a given outcome, that domain is said to have a flaw. A domain is also flawed if there are two or more “Unclear” answers to questions addressing that domain.

Our evaluation of the “Statistical Power” domain considers whether a study had high, moderate or low power. In doing so, we account for whether the results were statistically significant and for the number of patients in the statistical analysis performed on the outcome of interest. The details of these considerations are provided in Table 68.

**Table 68 Details of the evaluation of statistical power**

Power Rating	Condition
High	<p><b><i>ANY OF THE FOLLOWING IS TRUE:</i></b></p> <ul style="list-style-type: none"> <li>• The results of a statistical test were statistically significant</li> <li>• The results were not statistically significant (or it was unclear whether they were significant), and the study was either an uncontrolled study with 34 or more patients in the statistical analysis OR a controlled study in with 128 or more patients in the analysis.</li> <li>• The results will be used in a meta-analysis.*</li> </ul>
Moderate	<p><b><i>ALL OF THE FOLLOWING ARE TRUE:</i></b></p> <ul style="list-style-type: none"> <li>• The results of a statistical test were either not statistically significant or it was unclear whether the results of statistical test were statistically significant.</li> <li>• The study was an uncontrolled study in which data from between 15 and 33 patients were included in the analysis OR the study was a controlled study in which data from between 52 and 127 patients were in the analysis.</li> <li>• No meta-analysis of the relevant data will be performed.</li> </ul>
Low	<p><b><i>ALL OF THE FOLLOWING ARE TRUE:</i></b></p> <ul style="list-style-type: none"> <li>• The results of a statistical test were either not statistically significant or it was unclear whether the results of statistical test were statistically significant.</li> <li>• The study was an uncontrolled study in which data from fewer than 15 patients were included in the analysis OR the study was a controlled study in which data from fewer than 52 patients were in the analysis.</li> <li>• No meta-analysis of the relevant data will be performed.</li> </ul>

\*We make this assumption because one reason for performing a meta-analysis is to compensate for the low statistical power of individual studies. Implicit in this assumption that the power of the meta-analysis that will be conducted is sufficient to detect an effect as statistically significant.

Domain flaws lead to corresponding reductions in the quality of the evidence. The manner in which we conducted these reductions is shown in table. For example, the evidence reported in a randomized controlled trial (RCT) for an outcome of interest begins as being rated as “High” quality. However, if more than one domain is flawed for the evidence addressing this outcome, the quality of evidence is reduced to “Moderate.” The quality remains “Moderate” even if another domain is flawed. However, if a fourth domain is flawed, the quality of evidence for that outcome is reduced to “Low.” The quality of evidence is reduced to “Very Low” if six or more domains are flawed.

Some flaws are so serious that we automatically term the evidence as being of “Very Low” quality if a study exhibits them. These serious design flaws are:

- Non-consecutive enrollment of patients in a case series
- Case series that gave patients the treatment of interest AND another treatment
- Measuring the outcome of interest one way in some patients and measuring it in another way in other patients
- Low Statistical Power

**Table 69 Relationship between Quality and Domain Scores for Studies of Treatments**

Number of Flawed Domains	Quality
0, 1	High
2, 3	Moderate
4, 5	Low
6, 7, 8	Very Low

## **APPENDIX VI DOCUMENTATION OF APPROVAL**

AAOS Task Force Draft Completed	October 8, 2010
Manufacturer Review Completed	October 29, 2010
AAOS Guidelines and Technology Oversight Committee	November 19, 2010
AAOS Evidence Based Practice Committee	November 19, 2010
AAOS Council on Research Quality Assessment and Technology	November 19, 2010
AAOS Board of Directors	December 04, 2010

### **AAOS BODIES THAT APPROVED THIS TECHNOLOGY OVERVIEW**

#### **Guidelines and Technology Oversight Committee**

The AAOS Guidelines and Technology Oversight Committee (GTOC) consists of sixteen AAOS members. The overall purpose of this Committee is to oversee the development of the clinical practice guidelines, performance measures, health technology assessments, and utilization guidelines.

#### **Evidence Based Practice Committee**

The AAOS Evidence Based Practice Committee (EBPC) consists of ten AAOS members. This Committee provides review, planning, and oversight for all activities related to quality improvement in orthopaedic practice, including, but not limited to evidence-based guidelines, performance measures, and outcomes.

#### **Council on Research, Quality Assessment, and Technology**

To enhance the mission of the AAOS, the Council on Research, Quality Assessment, and Technology promotes the most ethically and scientifically sound basic, clinical, and translational research possible to ensure the future care for patients with musculoskeletal disorders. The Council also serves as the primary resource to educate its members, the public, and public policy makers regarding evidenced-based medical practice, orthopaedic devices and biologics regulatory pathways and standards development, patient safety, occupational health, technology assessment, and other related areas of importance.

The Council is comprised of the chairs of the AAOS Biological Implants, Biomedical Engineering, Evidence Based Practice, Guidelines and Technology Oversight, Occupational Health and Workers' Compensation, Patient Safety, Research Development, and US Bone and Joint Decade committees. Also on the Council are the AAOS second vice-president, representatives of the Diversity Advisory Board, the Women's Health Issues Advisory Board, the Board of Specialty Societies (BOS), the Board of Councilors (BOC), the Communications Cabinet, the Orthopaedic Research Society (ORS), the Orthopedic Research and Education Foundation (OREF), and three members at large.

#### **Board of Directors**

The 17 member AAOS Board of Directors manages the affairs of the AAOS, sets policy, and determines and continually reassesses the Strategic Plan.

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#### **Special Acknowledgments**

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## CONFLICT OF INTEREST

All members of the AAOS task force disclosed any conflicts of interest prior to the development of the key questions for this technology overview. Conflicts of interest are disclosed in writing with the American Academy of Orthopaedic Surgeons via a private on-line reporting database.

### AAOS Disclosure Program Information The Task Force on the Surgical Treatment of Ankle Arthritis

**Johnny T Lau, MD:** 2 (Wright Medical Technology, Inc.); 3B (Zimmer); 8 (Foot and Ankle International); 9 (AAOS; American Orthopaedic Foot and Ankle Society; Canadian Orthopaedic Association; Canadian Orthopaedic Association); Submitted on: 06/03/2010. \*

**Nelson Fong SooHoo, MD:** (n) Submitted on: 04/05/2010 and last confirmed as accurate on 09/14/2010. \*

**John G Anderson, MD:** 4 (Pfizer; Pfizer); 9 (American Orthopaedic Foot and Ankle Society; American Orthopaedic Foot and Ankle Society); Submitted on: 10/06/2010. \*

**Simon Carette, MD:** 2 (Journal of Rheumatology); 5A (Pfizer). Submitted on: 02/20/2009 at 10:01 AM.

**Sameh A Labib, MD:** 2 (Arthrex, Inc); 4 (Conformis Inc; Zimmer); 9 (AAOS; American Orthopaedic Foot and Ankle Society); Submitted on: 09/03/2010. \*

**Stephen J Pinney, MD:** 3B (United Health Care); 8 (Foot and Ankle International); 9 (American Orthopaedic Foot and Ankle Society); Submitted on: 04/05/2010. \*

**Steven M Raikin, MD:** 3B (DePuy, A Johnson & Johnson Company); 5 (Biomimetic); Submitted on: 09/11/2010. \*

**William Charles Watters III, MD** 3B (Stryker); 4 (Intrinsic Orthopedics); 8 (Official Disability Guidelines; Spine; The Spine Journal); 9 (American Board of Spine Surgery; North American Spine Society); Submitted on: 05/26/2010 and last confirmed as accurate on 09/14/2010. \*

**Kristy L Weber, MD:** (n) Submitted on: 03/19/2009 at 04:51 PM.

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\* **Disclosure Items Answered:** (n) = Respondent answered 'No' to all items indicating no conflicts. 1= Royalties from a company or supplier; 2= Speakers bureau/paid presentations for a company or supplier; 3A= Paid employee for a company or supplier; 3B= Paid consultant for a company or supplier; 3C= Unpaid consultant for a company or supplier; 4= Stock or stock options in a company or supplier; 5= Research support from a company or supplier as a PI; 6= Other financial or material support from a company or supplier; 7= Royalties, financial or material support from publishers; 8= Medical/Orthopaedic publications editorial/governing board; 9= Board member/committee appointments for a society.

**APPENDIX VIII  
TABLES**

**KEY QUESTION 1**

**Table 70 Patient opinion of pain- Generation 2**

<u>Study</u>	<u>N</u>	<u>Strength</u>	<u>Treatment</u>	<u>Duration of Follow-up</u>	<u>Outcome</u>	<u>% of Patients</u>
Ali	34	Very Low	Arthroplasty	5 Years	Percent of patients pain free or with occasional pain	66%
Pyevich	82	Very Low	Arthroplasty	4.8 Years	No pain (according to patient)	55%
Buechel	50	Very Low	Arthroplasty	5 Years	No pain	26%
Pyevich	82	Very Low	Arthroplasty	4.8 Years	Pain relief (according to patient)	98%
Buechel	50	Very Low	Arthroplasty	5 Years	Slight pain	38%
Buechel	50	Very Low	Arthroplasty	5 Years	Mild pain	22%
Pyevich	82	Very Low	Arthroplasty	4.8 Years	Mild pain (according to patient)	28%
Pyevich	82	Very Low	Arthroplasty	4.8 Years	Moderate pain (according to patient)	16%
Buechel	50	Very Low	Arthroplasty	5 Years	Moderate pain	6%
Buechel	50	Very Low	Arthroplasty	5 Years	Severe pain	8%

**Table 71 Patient satisfaction- Generation 2**

<u>Study</u>	<u>N</u>	<u>Strength</u>	<u>Treatment</u>	<u>Duration of Follow-up</u>	<u>Outcome</u>	<u>% of Patients</u>
Ali	34	Very Low	Arthroplasty	5 Years	Percent of patient happy with surgery	97%
Pyevich	82	Very Low	Arthroplasty	4.8 Years	Patient extremely satisfied	79%
Pyevich	82	Very Low	Arthroplasty	4.8 Years	Patient satisfied	13%
Pyevich	82	Very Low	Arthroplasty	4.8 Years	Patient indifferent	4%
Pyevich	82	Very Low	Arthroplasty	4.8 Years	Patient unhappy with results	4%
Pyevich	82	Very Low	Arthroplasty	4.8 Years	Patient would have the procedure again	95%
Pyevich	82	Very Low	Arthroplasty	4.8 Years	Patient would recommend the procedure to friend	96%

Highlighted area represents one question.

**Table 72 Patient mobility- Generation 2**

<u>Study</u>	<u>N</u>	<u>Strength</u>	<u>Treatment</u>	<u>Duration of Follow-up</u>	<u>Outcome</u>	<u>% of Patients</u>
Ali	34	Very Low	Arthroplasty	5 Years	Percent of patients mobile	100%
Ali	34	Very Low	Arthroplasty	5 Years	Percent of patients requiring no walking aid	45%
Pyevich	82	Very Low	Arthroplasty	4.8 Years	Used cane (according to patient)	5%
Pyevich	82	Very Low	Arthroplasty	4.8 Years	Increase function level (according to patient)	73%
Pyevich	82	Very Low	Arthroplasty	4.8 Years	Patient took pain medication	17%
Pyevich	82	Very Low	Arthroplasty	4.8 Years	More comfortable walking in shoes (according to patient)	68%

**Table 73 Device survival- Generation 2**

<u>Study</u>	<u>N</u>	<u>Strength</u>	<u>LoE</u>	<u>Duration of Follow-up</u>	<u>Outcome</u>	<u>% of Patients</u>
Hosman	117	Very Low	IV	2.6 Years	Device survival	92%
Pyevich	82	Very Low	IV	4.8 Years	Device survival	94%
Ali	34	Very Low	IV	5 Years	Device survival	97%
Henricson	92	Very Low	IV	6 Years	Device survival	83%

<u>Study</u>	<u>N</u>	<u>Strength</u>	<u>LoE</u>	<u>Duration of Follow-up</u>	<u>Outcome</u>	<u>% of Patients</u>
Buechel	49	Very Low	IV	10 Years	Device survival	93%

**Table 74 Device Survival- Generation 3**

<u>Study</u>	<u>N</u>	<u>Strength</u>	<u>LoE</u>	<u>Duration of Follow-up</u>	<u>Outcome</u>	<u>% of Patients</u>
Schutte	49	Very Low	IV	2.3 Years	Device survival	92%
Hinterman	122	Very Low	IV	1.75 Years	Revision	6.6%
Wood	163	Very Low	IV	5 Years	Survival	92.7%
Kofoed	16	Very Low	IV	12 Years	Estimated 12 year survival	70%
Kofoed	16	Very Low	IV	1 Year	Revision	12.5%
Valderrabano	68	Very Low	IV	2 Years	Revision	34%

**Table 75 Device Failure- Generation 3**

<u>Registry</u>	<u>N</u>	<u>Strength of Evidence</u>	<u>LoE</u>	<u>Duration of Follow-up</u>	<u>Device</u>	<u>% of patients</u>
Hosman (New Zealand Registry)	29	Very Low	IV	.83 Years	Mobility	0%
Henricson (Sweden Registry)	23	Very Low	IV	1 Year	Mobility	0%
Hosman (New Zealand Registry)	11	Very Low	IV	1.5 Years	Ramses	18%
Hosman (New Zealand Registry)	45	Very Low	IV	2.1 Years	STAR	7%
Skytta (Finland Registry)	217	Very Low	IV	4.8 Years (0-9.6 Years)	STAR	14%
Fevang (Norway Registry)	216	Very Low	IV	3.1 Years (2.3 Years)	STAR	3%
Henricson (Sweden Registry)	303	Very Low	IV	13 Years*	STAR	23%

Henricson (Sweden Registry)	15	Very Low	IV	8 Years*	STAR with stemmed tibial component	13%
Skytta (Finland Registry)	298	Very Low	IV	2 Years (0-4.7 Years)	AES	9%
Henricson (Sweden Registry)	69	Very Low	IV	4 Years*	AES	12%
Fevang (Norway Registry)	32	Very Low	IV	7.7 (3.2) Years	Norwegian TPR	66%
Henricson (Sweden Registry)	29	Very Low	IV	4 Years*	HINTEGRA	14%

\*Follow-up times were estimated by information provided

**Table 76 Raw Data- Key Question 1**

<u>Study</u>	<u>N</u>	<u>Strength of Evidence</u>	<u>Outcome</u>	<u>Duration of Follow-up</u>	<u>Pre Op</u>	<u>Post Op</u>	<u>Result</u>
Zerahn	16	Low	VAS Daily function	1 Year	median 9 (range 0.2-9.9)	median 3 (range 0-9.3)	0.035
Zerahn	16	Low	VAS Walking	1 Year	median 8.9 (range 4.9- 9.8)	median 2.4 (range 0-.9.4)	0.0043
Zerahn	16	Low	VAS Shoe Adaption	1 Year	median 4.5 (range 0.1-9.6)	median 4 (range 0.0-9.6)	ns
Zerahn	16	Low	VAS Pain	1 Year	median 9.2 (range 2.8-9.8)	median 3.1 (range 0.-9.1)	0.001
Naal	107	Low	Percent of Patients Active in Sports	3.7 Years	62.40%	66.30%	0.56
Naal	107	Low	AOFAS Activity Level	3.7 Years	mean 4.3 (sd 2.2)	mean 6.2 (sd 1.6)	p<0.001

<u>Study</u>	<u>N</u>	<u>Strength of Evidence</u>	<u>Outcome</u>	<u>Duration of Follow- up</u>	<u>Pre Op</u>	<u>Post Op</u>	<u>Result</u>
Naal	107	Low	AOFAS Score	3.7 Years	mean 45.5 (sd 16.6)	mean 84.3 (sd 13.3)	p<0.001
Ali	34	Low	AOFAS	5 years	34.6 (range 20-56)	76 (range 54-100)	p<0.001
Nagashima	19	Low	Pain	2.81 Years	Mean 21.3 (sd 4.8)	Mean 35.4(sd 2.7)	SMD=3.5 (CI-4.6, -2.49)
Nagashima	19	Low	Motion	2.81 Years	Avg 27.3 (sd 5.7)	Avg 35.0(sd 7.0)	SMD = - 1.288 (CI (-1.9, - 0.5)
Nagashima	19	Low	Function	2.81 Years	Avg 27.3 (sd 5.7)	Avg 35.0(sd 7.0)	SMD = - 0.12 (CI - 0.76, 0.50)
Nagashima	19	Low	Walking Ability	2.81 Years	Avg 6.2 (sd 2.7)	Avg 52 (sd 8.4)	SMD =- 1.157 (CI -1.8, - 0.4)
Schutte	49	Very Low	FFI Pain	2.33 Years	54 (not reported)	29 (not reported)	p<0.001
Schutte	49	Very Low	FFI Activity	2.33 Years	62 (not reported)	40 (not reported)	p<0.001
Schutte	49	Very Low	FFI Total	2.33 Years	59 (sd 17)	35 (sd 19)	SMD = 1.3 (CI 0.85- 1.37)
Buechel	50	Very Low	Pain	5 Years	9.8 (sd 5)	32.6 (sd 5)	SMD - 3.5 (CI- 4.1, -2.8)
Hintermann	122	Low	AOFAS Total	0.74 Years	40 (10)	85 (16)	SMD - 3.2 (CI 3.6, -2.9)

SMD= Standardized Mean Difference

## KEY QUESTION 2

**Table 77 SF-36- Ankle Arthrodesis**

<u>Study</u>	<u>N</u>	<u>Strength of Evidence</u>	<u>Treatment</u>	<u>Outcome</u>	<u>Duration of Follow-up</u>	<u>PreOp</u>	<u>PostOp</u>	<u>Result</u>
Sealey	45	Very Low	Arthrodesis	SF-36 physical component	1 Year	26.81 (sd 5.5)	37.03 (sd 6.9)	p<0.001
Sealey	45	Very Low	Arthrodesis	SF-36 mental component	31 months	47.41 (sd 8.4)	53.2 (sd 8.5)	p<0.001
Sealey	45	Very Low	Arthrodesis	SF-36 total score	31 months	37.26 (sd 5.2)	45.12 (sd 7.2)	p<0.001

**Table 78 Raw Data- Key Question 2**

<u>Author</u>	<u>Strength</u>	<u>Outcome</u>	<u>Risk Factor</u>	<u>Result</u>
Wood	Low	Survivorship	Deformity	p=0.02
Wood	Low	Developing edge loading	Deformity increase of 5	Walk test p<0.001
Wood	Low	Developing edge loading	Deformity >15	6.52 greater likelihood (95 CI 3.03, 14.02)
Doets	Very Low	Survival	Deformity >10	0.03
Hobson	Very Low	Risk of failure	Deformity >10	ns
Wood, Prem, and Sutton	Low	Revision	Valgus or vargus orientations	ns
Doets	Very Low	Survival	Undersized tibial component	p=0.02
Doets	Very Low	Survival	Ankylosis of the hindfoot at the time of surgery	ns
Doets	Very Low	Survival	Position of the tibial component in the frontal plane	ns
Pyeovich	Very Low	Pain	Tibia components that were placed more than 4 degrees valgus	ns
Fevang	Very Low	Prosthesis survival	Age	RR= 1 (CI 1, 1)

<u>Author</u>	<u>Strength</u>	<u>Outcome</u>	<u>Risk Factor</u>	<u>Result</u>
Hobson	Very Low	Risk of failure	Age	p>0.05
Hobson	Very Low	Risk of failure	Preoperative deformity> 10	p=0.752
Pyeovich	Very Low	Pain	Age	ns
Doets	Very Low	Survival	Age over 60	ns
Hobson	Very Low	Risk of failure	Age	ns
Henricson	Very Low	Risk for revision	Lower Age	p=0.002 rr 0.98 (CI 0.96, 0.099) Lower age implied increased risk for revision
Pyeovich	Very Low	Pain	Age	ns
Skytta	Very Low	Survival	Age	ns
Pyeovich	Very Low	Pain	weight	ns
Fevang	Very Low	Prosthesis survival	Rheumatoid vs. OA	0.3
Hobson	Very Low	Risk of failure	RA vs. OA	ns
Henricson	Very Low	Risk for revision	RA vs. OA	p=0.1
Wood	Low	Survivorship	Deformity	p=0.02
Wood	Low	Developing edge loading	Deformity increase of 5	Walk test p<0.001
Wood	Low	Developing edge loading	Deformity >15	6.52 greater likelihood (95 CI 3.03, 14.02)
Doets	Very Low	Survival	Deformity >10	0.03
Hobson	Very Low	Risk of failure	Deformity >10	ns
Wood, Prem, and Sutton	Low	Revision	Valgus or Vargus orientations	ns
Doets	Very Low	Survival	Undersized Tibial Component	p=0.02
Doets	Very Low	Survival	Ankylosis of the hindfoot at the time of surgery	ns
Doets	Very Low	Survival	Position of the tibial component in the frontal plane	ns

<u>Author</u>	<u>Strength</u>	<u>Outcome</u>	<u>Risk Factor</u>	<u>Result</u>
Pyevich	Very Low	Pain	Tibia components that were placed more than 4 degrees valgus	ns
Fevang	Very Low	Prosthesis survival	Age	RR= 1 (CI 1, 1)
Hobson	Very Low	Risk of failure	Age	p>0.05
Hobson	Very Low	Risk of failure	Preoperative deformity> 10	p=0.752
Pyevich	Very Low	Pain	Age	ns
Doets	Very Low	Survival	Age over 60	ns
Hobson	Very Low	Risk of failure	Age	ns
Henricson	Very Low	Risk for revision	Lower Age	p=0.002 rr 0.98 (CI 0.96, 0.099) Lower age implied increased risk for revision
Pyevich	Very Low	Pain	Age	ns
Skytta	Very Low	Survival	Age	ns
Pyevich	Very Low	Pain	weight	ns
Fevang	Very Low	Prosthesis survival	Rheumatoid vs. OA	0.3
Hobson	Very Low	Risk of failure	RA vs. OA	ns
Henricson	Very Low	Risk for revision	RA vs. OA	p=0.1

ns= not statistically significant

**KEY QUESTION 3**

**Table 79 Raw Data- Key Question 3**

<u>Author</u>	<u>Strength</u>	<u>Outcome</u>	<u>Risk Factor</u>	<u>Result</u>
Wood	Low	Survivorship	Deformity	p=0.02
Wood	Low	Developing Edge Loading	Deformity increase of 5	Walk test p<0.001
Wood	Low	Developing Edge Loading	Deformity >15	6.52 greater likelihood (95 CI 3.03, 14.02)
Doets	Very Low	Survival	Deformity >10	0.03
Hobson	Very Low	Risk of failure	Deformity >10	ns
Wood, Prem, and Sutton	Low	Revision	Valgus or vargus orientations	ns
Doets	Very Low	Survival	Undersized tibial component	p=0.02
Doets	Very Low	Survival	Ankylosis of the hindfoot at the time of surgery	ns
Doets	Very Low	Survival	Position of the tibial component in the frontal plane	ns
Pyeovich	Very Low	Pain	Tibia components that were placed more than 4 degrees valgus	ns
Fevang	Very Low	Prosthesis survival	Age	RR= 1 (CI 1, 1)
Hobson	Very Low	Risk of failure	Age	p>0.05
Hobson	Very Low	Risk of failure	Pre Operative deformity> 10	p=0.752
Pyeovich	Very Low	Pain	Age	ns
Doets	Very Low	Survival	Age over 60	ns
Hobson	Very Low	Risk of failure	Age	ns
Henricson	Very Low	Risk for revision	Lower age	p=0.002 rr 0.98 (CI 0.96, 0.099) Lower age implied increased risk for revision
Pyeovich	Very Low	Pain	Age	ns

<u>Author</u>	<u>Strength</u>	<u>Outcome</u>	<u>Risk Factor</u>	<u>Result</u>
Skytta	Very Low	Survival		ns
Pyeovich	Very Low	Pain	weight	ns
Fevang	Very Low	Prosthesis survival	RA vs. OA	0.3
Hobson	Very Low	Risk of failure	RA vs. OA	ns
Henricson	Very Low	Risk for revision	RA vs. OA	p=0.1

#### ***KEY QUESTION 4***

**Table 80 Study Results- Arthrodesis vs. Arthroplasty**

<u>Study</u>	<u>N</u>	<u>Strength</u>	<u>Duration of Follow-up</u>	<u>Outcome</u>	<u>n Arthrodesis</u>	<u>n Arthroplasty</u>	<u>Result p=</u>
SooHoo	5029	Low	90 Days	Pulmonary embolism	13	1	0.68
SooHoo	5029	Low	90 Days	Total infection cases	116	13	0.15
SooHoo	5029	Low	90 Days	Postoperative infection	81	8	0.63
SooHoo	5029	Low	90 Days	Device-related infection	43	7	0.03
SooHoo	5029	Low	90 Days	Major revision procedure	16	6	0.01

**Table 81 Study Raw Data- Key Question 4**

<u>Author</u>	<u>N</u>	<u>Strength</u>	<u>Outcome</u>	<u>Duration of Follow-up</u>	<u>Arthro</u>	<u>Fusion</u>	<u>Result p=</u>
Saltzman	224	Very Low	Pain	24 Months	69	32	0.51
Saltzman	224	Very Low	Nerve injury	24 Months	32	5	0.02
Saltzman	224	Very Low	Bone fracture	24 Months	28	2	0.004
Saltzman	224	Very Low	Soft tissue	24 Months	25	NA	0.08
Saltzman	224	Very Low	Decreased ROM	24 Months	10	"Expected"	NA

<u>Author</u>	<u>N</u>	<u>Strength</u>	<u>Outcome</u>	<u>Duration of Follow-up</u>	<u>Arthro</u>	<u>Fusion</u>	<u>Result p=</u>
Saltzman	224	Very Low	Wound problems	24 Months	32	4	0.01
Saltzman	224	Very Low	Infections	24 Months	7	5	0.46
Saltzman	224	Very Low	Bony change	24 Months	12	Not Applicable	NA
Saltzman	224	Very Low	Any major complication	24 Months	14	1	0.05
Saltzman	224	Very Low	Wound problems	24 Months	5	1	0.49
Saltzman	224	Very Low	Infections	24 Months	2	1	0.88
Saltzman	224	Very Low	Bony problems	24 Months	8	0	0.06
Saltzman	224	Very Low	Wound problems and infection	24 Months	1	0	0.51
Saltzman	224	Very Low	# of patients with interventions	24 Months	26	7	0.21
Saltzman	224	Very Low	Intervention type: revision or removal	24 Months	12	7	0.83
Saltzman	224	Very Low	Other intervention	24 Months	18	1	0.02
Saltzman	189	Very Low	Efficacy (BP>40)	24 Months	83	7	<0.001
Saltzman	194	Very Low	Safety	24 Months	101	43	0.17
Saltzman	193	Very Low	Overall success	24 Months	64	7	<0.001
Saltzman	194	Very Low	Number of revisions/removals	24 Months	122	47	0.58
Saltzman	194	Very Low	No major complication	24 Months	128	51	0.13
Saltzman	190	Very Low	Deformity	24 Months	1.9( sd 113)	0.4( sd 1.2)	<0.001
Saltzman	191	Very Low	Function	24 Months	13.4( sd 7.3)	9.7( sd 8)	0.004
Saltzman	191	Very Low	Stairs	24 Months	1.6(sd 2.1)	0.9( sd 2)	0.04
Saltzman	191	Very Low	Standing	24 Months	3.4( sd 2.8)	1.7 ( sd 3.3)	<0.001

<u>Author</u>	<u>N</u>	<u>Strength</u>	<u>Outcome</u>	<u>Duration of Follow-up</u>	<u>Arthro</u>	<u>Fusion</u>	<u>Result p=</u>
Saltzman	191	Very Low	Support	24 Months	1.7 (sd 2.2)	0.8( sd 1.9)	0.02
Saltzman	191	Very Low	Walking	24 Months	2.6 (sd 1.9)	2.7( sd 1.9)	0.75
Saltzman	191	Very Low	Limp	24 Months	4.1 (sd 2.2)	3.4( sd 3.4)	0.11
Saltzman	191	Very Low	Pain	24 Months	21.5(sd 9.6)	19.2( sd 9.4)	0.14
Saltzman	191	Very Low	ROM	24 Months	3.6 (sd 3.7)	-3.7( sd 5.1)	<0.001
Saltzman	191	Very Low	Total	24 Months	40.5(sd 15.1)	26.3( sd 17.1)	<0.001
Saltzman	191	Very Low	Total no ROM	24 Months	36.9 (sd 14.5)	30.0( sd 15.8)	0.01
Saltzman	224	Very Low	VAS pain	24 Months	19.5 (sd 20)	17.9 (sd 20)	0.61
SooHoo	502 9	Very Low	Infectious arthropathy	90 Days	1/470	5/4559	0.591
SooHoo	461 4	Very Low	Subtalar fusion	1 Year	1/423	40/4191	0.054
SooHoo	461 4	Very Low	Major revision	1 Year	1/423	222/4191	0.0001
SooHoo	461 4	Very Low	Ankle fusion	1 Year	11/423	219/4191	0.007
SooHoo	461 4	Very Low	Revision arthroplasty	1 Year	15/423	1/4191	0.0001
SooHoo	461 4	Very Low	Removal of implant	1 Year	10/423	4/4191	0.0001
SooHoo	461 4	Very Low	Ankle arthroplasty	1 Year	8/423	1/4191	0.0001
Saltzman 2010	71	Very Low	Deep venous thrombosis	2-6 Years	2	5	0.003
Saltzman 2010	71	Very Low	Required second surgery	2	15	0	0.003
Saltzman 2010	71	Very Low	Intraoperative medial or posterior malleolar fractures	2	5	0	0.002
Saltzman 2010	71	Very Low	Superficial wound dehiscence	2	1	0	0.172
Saltzman 2010	71	Very Low	Nonunion	2	0	1	0.139
Saltzman 2010	71	Very Low	Tibial stress fracture	2	0	1	0.139

<u>Author</u>	<u>N</u>	<u>Strength</u>	<u>Outcome</u>	<u>Duration of Follow-up</u>	<u>Arthro</u>	<u>Fusion</u>	<u>Result p=</u>
Saltzman 2010	71	Very Low	Hardware pain	2	0	1	0.139
Saltzman 2010	71	Very Low	Impingement	2	0	1	0.139
Saltzman 2010	71	Very Low	Wound dehiscence	2	0	1	0.139
Saltzman 2010	71	Very Low	Leg length discrepancy	2	0	1	0.139

Arthro= Arthroplasty

Fusion= Arthrodesis

## APPENDIX IX REFERENCE LIST

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**APPENDIX X:**

**STUDY QUALITY  
SURGICAL TREATMENT OF ANKLE ARTHRITIS**

**Arthroplasty Efficacy**  
**Quality of Evidence**

<b>Study:</b>	<b>Buechel</b>	<b>Buechel</b>	<b>Buechel</b>
<b>Outcome:</b>	<b>Survival</b>	<b>% Pain</b>	<b>Pain</b>
<b>Method of Group Assignment:</b>			
Stochastic Randomization	No	No	No
Quasi-random Assignment	na	na	na
Matched Groups	No	No	No
Consecutive Enrollment	Yes	Yes	Yes
<b>Study Design and Conduct:</b>			
Control Group Type	Uncontrolled	Uncontrolled	Uncontrolled
Allocation Concealment	No	No	No
Prospective	Yes	Yes	Yes
Group Assignment Score	0.25	0.25	0.25
Blinded Patients	No	No	No
Blinded Assessors	No	No	No
Blinding Verified	No	No	No
>80% Follow-up	Yes	Yes	Yes
<20% Completion Difference	No	No	No
Similar Baseline Outcome Values	No	No	No

**Arthroplasty Efficacy**  
**Quality of Evidence**

<b>Study:</b>	<b>Buechel</b>	<b>Buechel</b>	<b>Buechel</b>
<b>Outcome:</b>	<b>Survival</b>	<b>% Pain</b>	<b>Pain</b>
Comparable Pt. Characteristics	No	No	No
Same Control Group Results (xover)	na	na	na
Same Experimental Group Results (xover)	na	na	na
Same Centers	No	No	No
Same Treatment Duration In And Across All Groups	Yes	Yes	No
Same Concomitant Treatment to All Groups (controlled studies only)	No	No	na
No Confounding Treatment (case series only)	Yes	Yes	Yes
Same Instruments	Yes	Yes	Yes
Valid Instrument	Yes	Yes	No
Consistent Abstract, Results, and Discussion	Yes	Yes	Yes
All Outcomes Reported	No	No	No
A Priori Analysis	Yes	No	No
Statistical Power	High	High	High
Statistically Significant	Unclear	Unclear	Yes
<b>Quality Domain Scores:</b>			
Prospective	1	1	1

**Arthroplasty Efficacy**  
**Quality of Evidence**

<b>Study:</b>	<b>Buechel</b>	<b>Buechel</b>	<b>Buechel</b>
<b>Outcome:</b>	<b>Survival</b>	<b>% Pain</b>	<b>Pain</b>
Power	1	1	1
Group Assignment	0	0	0
Blinding	0	0	0
Group Comparability	0	0	0
Treatment Integrity	0	0	0
Measurement	1	1	0
Investigator Bias	0	0	0
<b>Level of Evidence:</b>	<b>IV</b>	<b>IV</b>	<b>IV</b>
Level of Evidence	●○○○○	●●○○○	●●○○○
	IV	IV	IV
Strength of Evidence Based on Quality	●○○○	●○○○	●○○○
	Very Low	Very Low	Very Low

**Arthroplasty Efficacy**  
**Quality of Evidence**

<b>Study:</b>	<b>Buechel</b>	<b>Nagashima</b>	<b>Nagashima</b>
<b>Outcome:</b>	<b>Adverse Events</b>	<b>Pain</b>	<b>Motion</b>
<b>Method of Group Assignment:</b>			
Stochastic Randomization	No	No	No
Quasi-random Assignment	na	na	na
Matched Groups	No	No	No
Consecutive Enrollment	Yes	Yes	Yes
<b>Study Design and Conduct:</b>			
Control Group Type	Uncontrolled	Uncontrolled	Uncontrolled
Allocation Concealment	No	No	No
Prospective	Yes	Yes	Yes
Group Assignment Score	0.25	0.25	0.25
Blinded Patients	No	No	No
Blinded Assessors	No	No	No
Blinding Verified	No	No	No
>80% Follow-up	Yes	Yes	Yes
<20% Completion Difference	No	No	No
Similar Baseline Outcome Values	No	No	No

**Arthroplasty Efficacy**  
**Quality of Evidence**

<b>Study:</b>	<b>Buechel</b>	<b>Nagashima</b>	<b>Nagashima</b>
<b>Outcome:</b>	<b>Adverse Events</b>	<b>Pain</b>	<b>Motion</b>
Comparable Pt. Characteristics	No	No	No
Same Control Group Results (xover)	na	na	na
Same Experimental Group Results (xover)	na	na	na
Same Centers	No	No	No
Same Treatment Duration In And Across All Groups	No	No	No
Same Concomitant Treatment to All Groups (controlled studies only)	na	na	No
No Confounding Treatment (case series only)	Yes	Unclear	Unclear
Same Instruments	Yes	Yes	Yes
Valid Instrument	No	No	No
Consistent Abstract, Results, and Discussion	Yes	Yes	Yes
All Outcomes Reported	No	Yes	Yes
A Priori Analysis	No	Yes	Yes
Statistical Power	High	High	High
Statistically Significant	Yes	Yes	Yes
<b>Quality Domain Scores:</b>			
Prospective	1	1	1

**Arthroplasty Efficacy**  
**Quality of Evidence**

<b>Study:</b>	<b>Buechel</b>	<b>Nagashima</b>	<b>Nagashima</b>
<b>Outcome:</b>	<b>Adverse Events</b>	<b>Pain</b>	<b>Motion</b>
Power	1	1	1
Group Assignment	0	0	0
Blinding	0	0	0
Group Comparability	0	0	0
Treatment Integrity	0	0	0
Measurement	0	0	0
Investigator Bias	0	0	1
<b>Level of Evidence:</b>	<b>IV</b>	<b>IV</b>	<b>IV</b>
Level of Evidence	●○○○○	●●○○○	●●○○○
	IV	IV	IV
Strength of Evidence Based on Quality	●○○○	●●○○○	●●○○○
	Very Low	Low	Low

**Arthroplasty Efficacy**  
**Quality of Evidence**

<b>Study:</b>	<b>Nagashima</b>	<b>Nagashima</b>	<b>Nagashima</b>
<b>Outcome:</b>	<b>Walking</b>	<b>Adverse Events</b>	<b>Function- Evanski and Waugh</b>
<b>Method of Group Assignment:</b>			
Stochastic Randomization	No	No	No
Quasi-random Assignment	na	na	na
Matched Groups	No	No	No
Consecutive Enrollment	Yes	Yes	Yes
<b>Study Design and Conduct:</b>			
Control Group Type	Uncontrolled	Uncontrolled	Uncontrolled
Allocation Concealment	No	No	No
Prospective	Yes	Yes	Yes
Group Assignment Score	0.25	0.25	0.25
Blinded Patients	No	No	No
Blinded Assessors	No	No	No
Blinding Verified	No	No	No
>80% Follow-up	Yes	Yes	Yes
<20% Completion Difference	No	No	No
Similar Baseline Outcome Values	No	No	No

**Arthroplasty Efficacy**  
**Quality of Evidence**

<b>Study:</b>	<b>Nagashima</b>	<b>Nagashima</b>	<b>Nagashima</b>
<b>Outcome:</b>	<b>Walking</b>	<b>Adverse Events</b>	<b>Function- Evanski and Waugh</b>
Comparable Pt. Characteristics	No	No	No
Same Control Group Results (xover)	na	na	na
Same Experimental Group Results (xover)	na	na	na
Same Centers	No	No	No
Same Treatment Duration In And Across All Groups	Yes	Yes	No
Same Concomitant Treatment to All Groups (controlled studies only)	No	No	No
No Confounding Treatment (case series only)	Unclear	Unclear	Unclear
Same Instruments	Yes	Yes	Yes
Valid Instrument	No	No	No
Consistent Abstract, Results, and Discussion	Yes	Yes	Yes
All Outcomes Reported	Yes	Yes	Yes
A Priori Analysis	Yes	Yes	Yes
Statistical Power	High	High	Moderate
Statistically Significant	Yes	Yes	No
<b>Quality Domain Scores:</b>			
Prospective	1	1	1

**Arthroplasty Efficacy**  
**Quality of Evidence**

<b>Study:</b>	<b>Nagashima</b>	<b>Nagashima</b>	<b>Nagashima</b>
<b>Outcome:</b>	<b>Walking</b>	<b>Adverse Events</b>	<b>Function- Evanski and Waugh</b>
Power	1	1	0.5
Group Assignment	0	0	0
Blinding	0	0	0
Group Comparability	0	0	0
Treatment Integrity	0	0	0
Measurement	0	0	0
Investigator Bias	1	1	1
<b>Level of Evidence:</b>	<b>IV</b>	<b>IV</b>	<b>IV</b>
Level of Evidence	●○○○○	●●○○○	●●○○○
	IV	IV	IV
Strength of Evidence Based on Quality	●●○○○	●●○○○	●●○○○
	Low	Low	Low

**Arthroplasty Efficacy**  
**Quality of Evidence**

<b>Study:</b>	<b>Hintermann</b>	<b>Hintermann</b>	<b>Hintermann</b>
<b>Outcome:</b>	<b>Revision</b>	<b>% Satisfaction</b>	<b>Adverse Events</b>
<b><i>Method of Group Assignment:</i></b>			
Stochastic Randomization	No	No	No
Quasi-random Assignment	na	na	na
Matched Groups	No	No	No
Consecutive Enrollment	Yes	Yes	Yes
<b><i>Study Design and Conduct:</i></b>			
Control Group Type	Uncontrolled	Uncontrolled	Uncontrolled
Allocation Concealment	No	No	No
Prospective	Yes	Yes	Yes
Group Assignment Score	0.25	0.25	0.25
Blinded Patients	No	No	No
Blinded Assessors	No	No	No
Blinding Verified	No	No	No
>80% Follow-up	Yes	Yes	Yes
<20% Completion Difference	No	No	No
Similar Baseline Outcome Values	No	No	No

**Arthroplasty Efficacy**  
**Quality of Evidence**

<b>Study:</b>	<b>Hintermann</b>	<b>Hintermann</b>	<b>Hintermann</b>
<b>Outcome:</b>	<b>Revision</b>	<b>% Satisfaction</b>	<b>Adverse Events</b>
Comparable Pt. Characteristics	No	No	No
Same Control Group Results (xover)	na	na	na
Same Experimental Group Results (xover)	na	na	na
Same Centers	No	No	No
Same Treatment Duration In And Across All Groups	Yes	Yes	Yes
Same Concomitant Treatment to All Groups (controlled studies only)	No	No	No
No Confounding Treatment (case series only)	Yes	Yes	Yes
Same Instruments	Yes	Yes	Yes
Valid Instrument	Yes	Yes	Yes
Consistent Abstract, Results, and Discussion	Yes	Yes	Yes
All Outcomes Reported	Yes	Yes	Yes
A Priori Analysis	Yes	Yes	Yes
Statistical Power	High	High	High
Statistically Significant	Unclear	Unclear	Unclear
<b>Quality Domain Scores:</b>			
Prospective	1	1	1

**Arthroplasty Efficacy**  
**Quality of Evidence**

<b>Study:</b>	<b>Hintermann</b>	<b>Hintermann</b>	<b>Hintermann</b>
<b>Outcome:</b>	<b>Revision</b>	<b>% Satisfaction</b>	<b>Adverse Events</b>
Power	1	1	1
Group Assignment	0	0	0
Blinding	0	0	0
Group Comparability	0	0	0
Treatment Integrity	0	0	0
Measurement	1	1	1
Investigator Bias	1	1	1
<b>Level of Evidence:</b>	<b>IV</b>	<b>IV</b>	<b>IV</b>
Level of Evidence	●○○○○	●●○○○	●●○○○
	IV	IV	IV
Strength of Evidence Based on Quality	●○○○	●○○○	●○○○
	Very Low	Very Low	Very Low

**Arthroplasty Efficacy**  
**Quality of Evidence**

<b>Study:</b>	<b>Hintermann</b>	<b>Schutte</b>	<b>Schutte</b>
<b>Outcome:</b>	<b>AOFAS</b>	<b>Revsion %</b>	<b>FFI Pain</b>
<b>Method of Group Assignment:</b>			
Stochastic Randomization	No	No	No
Quasi-random Assignment	na	na	na
Matched Groups	No	No	No
Consecutive Enrollment	Yes	Yes	Yes
<b>Study Design and Conduct:</b>			
Control Group Type	Uncontrolled	Uncontrolled	Uncontrolled
Allocation Concealment	No	No	No
Prospective	Yes	Yes	Yes
Group Assignment Score	0.25	0.25	0.25
Blinded Patients	No	No	No
Blinded Assessors	No	No	No
Blinding Verified	No	No	No
>80% Follow-up	Yes	Yes	Yes
<20% Completion Difference	No	No	No
Similar Baseline Outcome Values	No	No	No

**Arthroplasty Efficacy**  
**Quality of Evidence**

<b>Study:</b>	<b>Hintermann</b>	<b>Schutte</b>	<b>Schutte</b>
<b>Outcome:</b>	<b>AOFAS</b>	<b>Revsion %</b>	<b>FFI Pain</b>
Comparable Pt. Characteristics	No	No	No
Same Control Group Results (xover)	na	na	na
Same Experimental Group Results (xover)	na	na	na
Same Centers	No	No	No
Same Treatment Duration In And Across All Groups	No	Yes	No
Same Concomitant Treatment to All Groups (controlled studies only)	na	No	na
No Confounding Treatment (case series only)	Yes	Yes	Yes
Same Instruments	Yes	Yes	Yes
Valid Instrument	No	Yes	No
Consistent Abstract, Results, and Discussion	Yes	Yes	Yes
All Outcomes Reported	Yes	Yes	Yes
A Priori Analysis	Yes	Yes	Yes
Statistical Power	High	High	High
Statistically Significant	Yes	Unclear	Yes
<b>Quality Domain Scores:</b>			
Prospective	1	1	1

**Arthroplasty Efficacy**  
**Quality of Evidence**

<b>Study:</b>	<b>Hintermann</b>	<b>Schutte</b>	<b>Schutte</b>
<b>Outcome:</b>	<b>AOFAS</b>	<b>Revsion %</b>	<b>FFI Pain</b>
Power	1	1	1
Group Assignment	0	0	0
Blinding	0	0	0
Group Comparability	0	0	0
Treatment Integrity	0	0	0
Measurement	0	1	0
Investigator Bias	1	1	1
<b>Level of Evidence:</b>	<b>IV</b>	<b>IV</b>	<b>IV</b>
Level of Evidence	●○○○○	●●○○○	●●○○○
	IV	IV	IV
Strength of Evidence Based on Quality	●●○○○	●●○○○	●●○○○
	Low	Low	Low

**Arthroplasty Efficacy**  
**Quality of Evidence**

<b>Study:</b>	<b>Schutte</b>	<b>Schutte</b>	<b>Zerahn</b>
<b>Outcome:</b>	<b>FFI Activity</b>	<b>FFI total</b>	<b>Shoe Wear</b>
<b><i>Method of Group Assignment:</i></b>			
Stochastic Randomization	No	No	No
Quasi-random Assignment	na	na	na
Matched Groups	No	No	No
Consecutive Enrollment	Yes	Yes	Yes
<b><i>Study Design and Conduct:</i></b>			
Control Group Type	Uncontrolled	Uncontrolled	Uncontrolled
Allocation Concealment	No	No	No
Prospective	Yes	Yes	Yes
Group Assignment Score	0.25	0.25	0.25
Blinded Patients	No	No	No
Blinded Assessors	No	No	No
Blinding Verified	No	No	No
>80% Follow-up	Yes	Yes	Yes
<20% Completion Difference	No	No	No
Similar Baseline Outcome Values	No	No	No

**Arthroplasty Efficacy**  
**Quality of Evidence**

<b>Study:</b>	<b>Schutte</b>	<b>Schutte</b>	<b>Zerahn</b>
<b>Outcome:</b>	<b>FFI Activity</b>	<b>FFI total</b>	<b>Shoe Wear</b>
Comparable Pt. Characteristics	No	No	No
Same Control Group Results (xover)	na	na	na
Same Experimental Group Results (xover)	na	na	na
Same Centers	No	No	No
Same Treatment Duration In And Across All Groups	No	No	Yes
Same Concomitant Treatment to All Groups (controlled studies only)	na	na	No
No Confounding Treatment (case series only)	Yes	Yes	Unclear
Same Instruments	Yes	Yes	Yes
Valid Instrument	No	No	No
Consistent Abstract, Results, and Discussion	Yes	Yes	Yes
All Outcomes Reported	Yes	Yes	Yes
A Priori Analysis	Yes	Yes	Yes
Statistical Power	High	High	Moderate
Statistically Significant	Yes	Yes	No
<b>Quality Domain Scores:</b>			
Prospective	1	1	1

**Arthroplasty Efficacy**  
**Quality of Evidence**

<b>Study:</b>	<b>Schutte</b>	<b>Schutte</b>	<b>Zerahn</b>
<b>Outcome:</b>	<b>FFI Activity</b>	<b>FFI total</b>	<b>Shoe Wear</b>
Power	1	1	0.5
Group Assignment	0	0	0
Blinding	0	0	0
Group Comparability	0	0	0
Treatment Integrity	0	0	0
Measurement	0	0	0
Investigator Bias	1	1	1
<b>Level of Evidence:</b>	<b>IV</b>	<b>IV</b>	<b>IV</b>
Level of Evidence	●○○○○	●●○○○	●●○○○
	IV	IV	IV
Strength of Evidence Based on Quality	●●○○○	●●○○○	●●○○○
	Low	Low	Low

**Arthroplasty Efficacy**  
**Quality of Evidence**

<b>Study:</b>	<b>Zerahn</b>	<b>Zerahn</b>	<b>Zerahn</b>
<b>Outcome:</b>	<b>VAS Function</b>	<b>VAS Pain</b>	<b>Walking</b>
<b>Method of Group Assignment:</b>			
Stochastic Randomization	No	No	No
Quasi-random Assignment	na	na	na
Matched Groups	No	No	No
Consecutive Enrollment	Yes	Yes	Yes
<b>Study Design and Conduct:</b>			
Control Group Type	Uncontrolled	Uncontrolled	Uncontrolled
Allocation Concealment	No	No	No
Prospective	Yes	Yes	Yes
Group Assignment Score	0.25	0.25	0.25
Blinded Patients	No	No	No
Blinded Assessors	No	No	No
Blinding Verified	No	No	No
>80% Follow-up	Yes	Yes	Yes
<20% Completion Difference	No	No	No
Similar Baseline Outcome Values	No	No	No

**Arthroplasty Efficacy**  
**Quality of Evidence**

<b>Study:</b>	<b>Zerahn</b>	<b>Zerahn</b>	<b>Zerahn</b>
<b>Outcome:</b>	<b>VAS Function</b>	<b>VAS Pain</b>	<b>Walking</b>
Comparable Pt. Characteristics	No	No	No
Same Control Group Results (xover)	na	na	na
Same Experimental Group Results (xover)	na	na	na
Same Centers	No	No	No
Same Treatment Duration In And Across All Groups	Yes	No	Yes
Same Concomitant Treatment to All Groups (controlled studies only)	No	na	No
No Confounding Treatment (case series only)	Unclear	Unclear	Unclear
Same Instruments	Yes	Yes	Yes
Valid Instrument	Yes	Yes	No
Consistent Abstract, Results, and Discussion	Yes	Yes	Yes
All Outcomes Reported	Yes	Yes	Yes
A Priori Analysis	Yes	Yes	Yes
Statistical Power	High	High	High
Statistically Significant	Yes	Yes	Yes
<b>Quality Domain Scores:</b>			
Prospective	1	1	1

**Arthroplasty Efficacy**  
**Quality of Evidence**

<b>Study:</b>	<b>Zerahn</b>	<b>Zerahn</b>	<b>Zerahn</b>
<b>Outcome:</b>	<b>VAS Function</b>	<b>VAS Pain</b>	<b>Walking</b>
Power	1	1	1
Group Assignment	0	0	0
Blinding	0	0	0
Group Comparability	0	0	0
Treatment Integrity	0	0	0
Measurement	1	1	0
Investigator Bias	1	1	1
<b>Level of Evidence:</b>	<b>IV</b>	<b>IV</b>	<b>IV</b>
Level of Evidence	●○○○○	●●○○○	●●○○○
	IV	IV	IV
Strength of Evidence Based on Quality	●●○○○	●●○○○	●●○○○
	Low	Low	Low

**Arthroplasty Efficacy**  
**Quality of Evidence**

<b>Study:</b>	<b>Ali</b>	<b>Ali</b>	<b>Ali</b>
<b>Outcome:</b>	<b>% Satisfaction</b>	<b>% Pain</b>	<b>% Revision</b>
<b><i>Method of Group Assignment:</i></b>			
Stochastic Randomization	No	No	No
Quasi-random Assignment	na	na	na
Matched Groups	No	No	No
Consecutive Enrollment	Yes	Yes	Yes
<b><i>Study Design and Conduct:</i></b>			
Control Group Type	Uncontrolled	Uncontrolled	Uncontrolled
Allocation Concealment	No	No	No
Prospective	Yes	Yes	Yes
Group Assignment Score	0.25	0.25	0.25
Blinded Patients	No	No	No
Blinded Assessors	No	No	No
Blinding Verified	No	No	No
>80% Follow-up	Yes	Yes	Yes
<20% Completion Difference	No	No	No
Similar Baseline Outcome Values	No	No	No

**Arthroplasty Efficacy**  
**Quality of Evidence**

<b>Study:</b>	<b>Ali</b>	<b>Ali</b>	<b>Ali</b>
<b>Outcome:</b>	<b>% Satisfaction</b>	<b>% Pain</b>	<b>% Revision</b>
Comparable Pt. Characteristics	No	No	No
Same Control Group Results (xover)	na	na	na
Same Experimental Group Results (xover)	na	na	na
Same Centers	No	No	No
Same Treatment Duration In And Across All Groups	No	No	No
Same Concomitant Treatment to All Groups (controlled studies only)	No	No	No
No Confounding Treatment (case series only)	Yes	Yes	Yes
Same Instruments	Yes	Yes	Yes
Valid Instrument	Yes	Yes	Yes
Consistent Abstract, Results, and Discussion	Yes	Yes	Yes
All Outcomes Reported	Yes	Yes	Yes
A Priori Analysis	Yes	Yes	Yes
Statistical Power	High	High	High
Statistically Significant	Unclear	Unclear	Unclear
<b>Quality Domain Scores:</b>			
Prospective	1	1	1

**Arthroplasty Efficacy**  
**Quality of Evidence**

<b>Study:</b>	<b>Ali</b>	<b>Ali</b>	<b>Ali</b>
<b>Outcome:</b>	<b>% Satisfaction</b>	<b>% Pain</b>	<b>% Revision</b>
Power	1	1	1
Group Assignment	0	0	0
Blinding	0	0	0
Group Comparability	0	0	0
Treatment Integrity	0	0	0
Measurement	1	1	1
Investigator Bias	1	1	1
<b>Level of Evidence:</b>	<b>IV</b>	<b>IV</b>	<b>IV</b>
Level of Evidence	●○○○○	●●○○○	●●○○○
	IV	IV	IV
Strength of Evidence Based on Quality	●○○○	●○○○	●○○○
	Very Low	Very Low	Very Low

**Arthroplasty Efficacy**  
**Quality of Evidence**

<b>Study:</b>	<b>Ali</b>	<b>Ali</b>	<b>Ali</b>
<b>Outcome:</b>	<b>% Mobility</b>	<b>Adverse Events</b>	<b>AOFAS Activity</b>
<b><i>Method of Group Assignment:</i></b>			
Stochastic Randomization	No	No	No
Quasi-random Assignment	na	na	na
Matched Groups	No	No	No
Consecutive Enrollment	Yes	Yes	Yes
<b><i>Study Design and Conduct:</i></b>			
Control Group Type	Uncontrolled	Uncontrolled	Uncontrolled
Allocation Concealment	No	No	No
Prospective	Yes	Yes	Yes
Group Assignment Score	0.25	0.25	0.25
Blinded Patients	No	No	No
Blinded Assessors	No	No	No
Blinding Verified	No	No	No
>80% Follow-up	Yes	Yes	Yes
<20% Completion Difference	No	No	No
Similar Baseline Outcome Values	No	No	No

**Arthroplasty Efficacy**  
**Quality of Evidence**

<b>Study:</b>	<b>Ali</b>	<b>Ali</b>	<b>Ali</b>
<b>Outcome:</b>	<b>% Mobility</b>	<b>Adverse Events</b>	<b>AOFAS Activity</b>
Comparable Pt. Characteristics	No	No	No
Same Control Group Results (xover)	na	na	na
Same Experimental Group Results (xover)	na	na	na
Same Centers	No	No	No
Same Treatment Duration In And Across All Groups	No	No	No
Same Concomitant Treatment to All Groups (controlled studies only)	No	na	na
No Confounding Treatment (case series only)	Yes	Yes	Yes
Same Instruments	Yes	Yes	Yes
Valid Instrument	Yes	No	No
Consistent Abstract, Results, and Discussion	Yes	Yes	Yes
All Outcomes Reported	Yes	Yes	Yes
A Priori Analysis	Yes	Yes	Yes
Statistical Power	High	High	High
Statistically Significant	Unclear	Yes	Yes
<b>Quality Domain Scores:</b>			
Prospective	1	1	1

**Arthroplasty Efficacy**  
**Quality of Evidence**

<b>Study:</b>	<b>Ali</b>	<b>Ali</b>	<b>Ali</b>
<b>Outcome:</b>	<b>% Mobility</b>	<b>Adverse Events</b>	<b>AOFAS Activity</b>
Power	1	1	1
Group Assignment	0	0	0
Blinding	0	0	0
Group Comparability	0	0	0
Treatment Integrity	0	0	0
Measurement	1	0	0
Investigator Bias	1	1	1
<b>Level of Evidence:</b>	<b>IV</b>	<b>IV</b>	<b>IV</b>
Level of Evidence	●○○○○	●●○○○	●●○○○
	IV	IV	IV
Strength of Evidence Based on Quality	●○○○	●●○○○	●●○○○
	Very Low	Low	Low

**Arthroplasty Efficacy**  
**Quality of Evidence**

<b>Study:</b>	<b>Kofoed</b>	<b>Kofoed</b>	<b>Wood</b>
<b>Outcome:</b>	<b>estimated survival</b>	<b>% Revision</b>	<b>Revision</b>
<b><i>Method of Group Assignment:</i></b>			
Stochastic Randomization	No	No	No
Quasi-random Assignment	na	na	na
Matched Groups	No	No	No
Consecutive Enrollment	Yes	Yes	Yes
<b><i>Study Design and Conduct:</i></b>			
Control Group Type	Uncontrolled	Uncontrolled	Uncontrolled
Allocation Concealment	No	No	No
Prospective	Yes	Yes	Yes
Group Assignment Score	0.25	0.25	0.25
Blinded Patients	No	No	No
Blinded Assessors	No	No	No
Blinding Verified	No	No	No
>80% Follow-up	Yes	Yes	Yes
<20% Completion Difference	No	No	No
Similar Baseline Outcome Values	No	No	No

**Arthroplasty Efficacy**  
**Quality of Evidence**

<b>Study:</b>	<b>Kofoed</b>	<b>Kofoed</b>	<b>Wood</b>
<b>Outcome:</b>	<b>estimated survival</b>	<b>% Revision</b>	<b>Revision</b>
Comparable Pt. Characteristics	No	No	No
Same Control Group Results (xover)	na	na	na
Same Experimental Group Results (xover)	na	na	na
Same Centers	No	No	No
Same Treatment Duration In And Across All Groups	Yes	No	No
Same Concomitant Treatment to All Groups (controlled studies only)	No	na	na
No Confounding Treatment (case series only)	Yes	Yes	Yes
Same Instruments	Yes	Yes	Yes
Valid Instrument	No	Yes	Yes
Consistent Abstract, Results, and Discussion	Yes	Yes	Yes
All Outcomes Reported	Yes	Yes	Yes
A Priori Analysis	Yes	Yes	Yes
Statistical Power	Moderate	Moderate	High
Statistically Significant	Unclear	Unclear	Unclear
<b>Quality Domain Scores:</b>			
Prospective	1	1	1

**Arthroplasty Efficacy**  
**Quality of Evidence**

<b>Study:</b>	<b>Kofoed</b>	<b>Kofoed</b>	<b>Wood</b>
<b>Outcome:</b>	<b>estimated survival</b>	<b>% Revision</b>	<b>Revision</b>
Power	0.5	0.5	1
Group Assignment	0	0	0
Blinding	0	0	0
Group Comparability	0	0	0
Treatment Integrity	0	0	0
Measurement	0	1	1
Investigator Bias	1	1	1
<b>Level of Evidence:</b>	<b>IV</b>	<b>IV</b>	<b>IV</b>
Level of Evidence	●○○○○	●●○○○	●●○○○
	IV	IV	IV
Strength of Evidence Based on Quality	●○○○	●●○○	●○○○
	Very Low	Very Low	Very Low

**Arthroplasty Efficacy**  
**Quality of Evidence**

<b>Study:</b>	<b>Pyeich</b>	<b>Pyeich</b>	<b>Pyeich</b>
<b>Outcome:</b>	<b>% satisfied</b>	<b>% used a cane</b>	<b>% function</b>
<b><i>Method of Group Assignment:</i></b>			
Stochastic Randomization	No	No	No
Quasi-random Assignment	na	na	na
Matched Groups	No	No	No
Consecutive Enrollment	Yes	Yes	Yes
<b><i>Study Design and Conduct:</i></b>			
Control Group Type	Uncontrolled	Uncontrolled	Uncontrolled
Allocation Concealment	No	No	No
Prospective	Yes	Yes	Yes
Group Assignment Score	0.25	0.25	0.25
Blinded Patients	No	No	No
Blinded Assessors	No	No	No
Blinding Verified	No	No	No
>80% Follow-up	Yes	Yes	Yes
<20% Completion Difference	No	No	No
Similar Baseline Outcome Values	No	No	No

**Arthroplasty Efficacy**  
**Quality of Evidence**

<b>Study:</b>	<b>Pyevich</b>	<b>Pyevich</b>	<b>Pyevich</b>
<b>Outcome:</b>	<b>% satisfied</b>	<b>% used a cane</b>	<b>% function</b>
Comparable Pt. Characteristics	No	No	No
Same Control Group Results (xover)	na	na	na
Same Experimental Group Results (xover)	na	na	na
Same Centers	No	No	No
Same Treatment Duration In And Across All Groups	No	No	No
Same Concomitant Treatment to All Groups (controlled studies only)	na	na	na
No Confounding Treatment (case series only)	Yes	Yes	Yes
Same Instruments	Yes	Yes	Yes
Valid Instrument	Yes	Yes	Yes
Consistent Abstract, Results, and Discussion	Yes	Yes	Yes
All Outcomes Reported	Yes	Yes	Yes
A Priori Analysis	Yes	Yes	Yes
Statistical Power	High	High	High
Statistically Significant	Unclear	Unclear	Unclear
<b>Quality Domain Scores:</b>			
Prospective	1	1	1

**Arthroplasty Efficacy**  
**Quality of Evidence**

<b>Study:</b>	<b>Pyevich</b>	<b>Pyevich</b>	<b>Pyevich</b>
<b>Outcome:</b>	<b>% satisfied</b>	<b>% used a cane</b>	<b>% function</b>
Power	1	1	1
Group Assignment	0	0	0
Blinding	0	0	0
Group Comparability	0	0	0
Treatment Integrity	0	0	0
Measurement	1	1	1
Investigator Bias	1	1	1
<b>Level of Evidence:</b>	<b>IV</b>	<b>IV</b>	<b>IV</b>
Level of Evidence	●○○○○	●●○○○	●●○○○
	IV	IV	IV
Strength of Evidence Based on Quality	●○○○	●○○○	●○○○
	Very Low	Very Low	Very Low

**Arthroplasty Efficacy**  
**Quality of Evidence**

<b>Study:</b>	<b>Pyeich</b>	<b>Pyeich</b>	<b>Pyeich</b>
<b>Outcome:</b>	<b>% used pain medication</b>	<b>% pain free</b>	<b>% shoe</b>
<b><i>Method of Group Assignment:</i></b>			
Stochastic Randomization	No	No	No
Quasi-random Assignment	na	na	na
Matched Groups	No	No	No
Consecutive Enrollment	Yes	Yes	Yes
<b><i>Study Design and Conduct:</i></b>			
Control Group Type	Uncontrolled	Uncontrolled	Uncontrolled
Allocation Concealment	No	No	No
Prospective	Yes	Yes	Yes
Group Assignment Score	0.25	0.25	0.25
Blinded Patients	No	No	No
Blinded Assessors	No	No	No
Blinding Verified	No	No	No
>80% Follow-up	Yes	Yes	Yes
<20% Completion Difference	No	No	No
Similar Baseline Outcome Values	No	No	No

**Arthroplasty Efficacy**  
**Quality of Evidence**

<b>Study:</b>	<b>Pyeovich</b>	<b>Pyeovich</b>	<b>Pyeovich</b>
<b>Outcome:</b>	<b>% used pain medication</b>	<b>% pain free</b>	<b>% shoe</b>
Comparable Pt. Characteristics	No	No	No
Same Control Group Results (xover)	na	na	na
Same Experimental Group Results (xover)	na	na	na
Same Centers	No	No	No
Same Treatment Duration In And Across All Groups	No	No	No
Same Concomitant Treatment to All Groups (controlled studies only)	na	na	na
No Confounding Treatment (case series only)	Yes	Yes	Yes
Same Instruments	Yes	Yes	Yes
Valid Instrument	Yes	Yes	Yes
Consistent Abstract, Results, and Discussion	Yes	Yes	Yes
All Outcomes Reported	Yes	Yes	Yes
A Priori Analysis	Yes	Yes	Yes
Statistical Power	High	High	High
Statistically Significant	Unclear	Unclear	Unclear
<b>Quality Domain Scores:</b>			
Prospective	1	1	1

**Arthroplasty Efficacy**  
**Quality of Evidence**

<b>Study:</b>	<b>Pyeovich</b>	<b>Pyeovich</b>	<b>Pyeovich</b>
<b>Outcome:</b>	<b>% used pain medication</b>	<b>% pain free</b>	<b>% shoe</b>
Power	1	1	1
Group Assignment	0	0	0
Blinding	0	0	0
Group Comparability	0	0	0
Treatment Integrity	0	0	0
Measurement	1	1	1
Investigator Bias	1	1	1
<b>Level of Evidence:</b>	<b>IV</b>	<b>IV</b>	<b>IV</b>
Level of Evidence	●○○○○	●●○○○	●●○○○
	IV	IV	IV
Strength of Evidence Based on Quality	●○○○	●○○○	●○○○
	Very Low	Very Low	Very Low

**Arthroplasty Efficacy**  
**Quality of Evidence**

<b>Study:</b>	<b>Pyeich</b>	<b>Valderrabano</b>	<b>Valderrabano</b>
<b>Outcome:</b>	<b>% revision</b>	<b>Pain</b>	<b>AOFAS</b>
<b>Method of Group Assignment:</b>			
Stochastic Randomization	No	No	No
Quasi-random Assignment	na	na	na
Matched Groups	No	No	No
Consecutive Enrollment	Yes	No	No
<b>Study Design and Conduct:</b>			
Control Group Type	Uncontrolled	Uncontrolled	Uncontrolled
Allocation Concealment	No	No	No
Prospective	Yes	Yes	Yes
Group Assignment Score	0.25	0.00	0.00
Blinded Patients	No	No	No
Blinded Assessors	No	No	No
Blinding Verified	No	No	No
>80% Follow-up	Yes	Yes	Yes
<20% Completion Difference	No	No	No
Similar Baseline Outcome Values	No	No	No

**Arthroplasty Efficacy**  
**Quality of Evidence**

<b>Study:</b>	<b>Pyevich</b>	<b>Valderrabano</b>	<b>Valderrabano</b>
<b>Outcome:</b>	<b>% revision</b>	<b>Pain</b>	<b>AOFAS</b>
Comparable Pt. Characteristics	No	No	No
Same Control Group Results (xover)	na	na	na
Same Experimental Group Results (xover)	na	na	na
Same Centers	No	No	No
Same Treatment Duration In And Across All Groups	No	No	No
Same Concomitant Treatment to All Groups (controlled studies only)	na	na	na
No Confounding Treatment (case series only)	Yes	Yes	Yes
Same Instruments	Yes	Yes	Yes
Valid Instrument	Yes	Yes	Yes
Consistent Abstract, Results, and Discussion	Yes	Yes	Yes
All Outcomes Reported	Yes	Yes	Yes
A Priori Analysis	Yes	Yes	Yes
Statistical Power	High	High	High
Statistically Significant	Unclear	No	No
<b>Quality Domain Scores:</b>			
Prospective	1	1	1

**Arthroplasty Efficacy**  
**Quality of Evidence**

<b>Study:</b>	<b>Pyevich</b>	<b>Valderrabano</b>	<b>Valderrabano</b>
<b>Outcome:</b>	<b>% revision</b>	<b>Pain</b>	<b>AOFAS</b>
Power	1	1	1
Group Assignment	0	0	0
Blinding	0	0	0
Group Comparability	0	0	0
Treatment Integrity	0	0	0
Measurement	1	1	1
Investigator Bias	1	1	1
<b>Level of Evidence:</b>	<b>IV</b>	<b>IV</b>	<b>IV</b>
Level of Evidence	●○○○○	●●○○○	●●○○○
	IV	IV	IV
Strength of Evidence Based on Quality	●○○○	●○○○	●○○○
	Very Low	Very Low	Very Low

**Arthroplasty Efficacy**  
**Quality of Evidence**

<b>Study:</b>	<b>Valderrabano</b>	<b>Valderrabano</b>	<b>Henricson</b>
<b>Outcome:</b>	<b>Satisfaction</b>	<b>Revision</b>	<b>Failure STAR</b>
<b><i>Method of Group Assignment:</i></b>			
Stochastic Randomization	No	No	No
Quasi-random Assignment	na	na	na
Matched Groups	No	No	No
Consecutive Enrollment	No	No	Yes
<b><i>Study Design and Conduct:</i></b>			
Control Group Type	Uncontrolled	Uncontrolled	Uncontrolled
Allocation Concealment	No	No	No
Prospective	Yes	Yes	Yes
Group Assignment Score	0.00	0.00	0.25
Blinded Patients	No	No	No
Blinded Assessors	No	No	No
Blinding Verified	No	No	No
>80% Follow-up	Yes	Yes	Yes
<20% Completion Difference	No	No	No
Similar Baseline Outcome Values	No	No	No

**Arthroplasty Efficacy**  
**Quality of Evidence**

<b>Study:</b>	<b>Valderrabano</b>	<b>Valderrabano</b>	<b>Henricson</b>
<b>Outcome:</b>	<b>Satisfaction</b>	<b>Revision</b>	<b>Failure STAR</b>
Comparable Pt. Characteristics	No	No	No
Same Control Group Results (xover)	na	na	na
Same Experimental Group Results (xover)	na	na	na
Same Centers	No	No	No
Same Treatment Duration In And Across All Groups	No	No	No
Same Concomitant Treatment to All Groups (controlled studies only)	na	na	na
No Confounding Treatment (case series only)	Yes	Yes	Unclear
Same Instruments	Yes	Yes	Yes
Valid Instrument	Yes	Yes	Yes
Consistent Abstract, Results, and Discussion	Yes	Yes	Yes
All Outcomes Reported	Yes	Yes	Yes
A Priori Analysis	Yes	Yes	No
Statistical Power	High	High	High
Statistically Significant	No	No	Unclear
<b>Quality Domain Scores:</b>			
Prospective	1	1	

**Arthroplasty Efficacy**  
**Quality of Evidence**

<b>Study:</b>	<b>Valderrabano</b>	<b>Valderrabano</b>	<b>Henricson</b>
<b>Outcome:</b>	<b>Satisfaction</b>	<b>Revision</b>	<b>Failure STAR</b>
Power	1	1	1
Group Assignment	0	0	1
Blinding	0	0	0
Group Comparability	0	0	0
Treatment Integrity	0	0	0
Measurement	1	1	0
Investigator Bias	1	1	1
<b>Level of Evidence:</b>	<b>IV</b>	<b>IV</b>	<b>IV</b>
Level of Evidence	●○○○○	●●○○○	●●○○○
	IV	IV	IV
Strength of Evidence Based on Quality	●○○○	●○○○	●○○○
	Very Low	Very Low	Very Low

**Arthroplasty Efficacy**  
**Quality of Evidence**

<b>Study:</b>	<b>Henricson</b>	<b>Henricson</b>	<b>Henricson</b>
<b>Outcome:</b>	<b>FailureAES</b>	<b>Failure STAR</b>	<b>Failure Hintegra</b>
<b>Method of Group Assignment:</b>			
Stochastic Randomization	No	No	No
Quasi-random Assignment	na	na	na
Matched Groups	No	No	No
Consecutive Enrollment	Yes	Yes	Yes
<b>Study Design and Conduct:</b>			
Control Group Type	Uncontrolled	Uncontrolled	Uncontrolled
Allocation Concealment	No	No	No
Prospective	Yes	Yes	Yes
Group Assignment Score	0.25	0.25	0.25
Blinded Patients	No	No	No
Blinded Assessors	No	No	No
Blinding Verified	No	No	No
>80% Follow-up	Yes	Yes	Yes
<20% Completion Difference	No	No	No
Similar Baseline Outcome Values	No	No	No

**Arthroplasty Efficacy**  
**Quality of Evidence**

<b>Study:</b>	<b>Henricson</b>	<b>Henricson</b>	<b>Henricson</b>
<b>Outcome:</b>	<b>FailureAES</b>	<b>Failure STAR</b>	<b>Failure Hintegra</b>
Comparable Pt. Characteristics	No	No	No
Same Control Group Results (xover)	na	na	na
Same Experimental Group Results (xover)	na	na	na
Same Centers	No	No	No
Same Treatment Duration In And Across All Groups	No	No	No
Same Concomitant Treatment to All Groups (controlled studies only)	na	na	na
No Confounding Treatment (case series only)	Unclear	Unclear	Unclear
Same Instruments	Yes	Yes	Yes
Valid Instrument	Yes	Yes	Yes
Consistent Abstract, Results, and Discussion	Yes	Yes	Yes
All Outcomes Reported	Yes	Yes	Yes
A Priori Analysis	No	No	No
Statistical Power	High	High	High
Statistically Significant	Unclear	Unclear	Unclear
<b>Quality Domain Scores:</b>			
Prospective			

**Arthroplasty Efficacy**  
**Quality of Evidence**

<b>Study:</b>	<b>Henricson</b>	<b>Henricson</b>	<b>Henricson</b>
<b>Outcome:</b>	<b>FailureAES</b>	<b>Failure STAR</b>	<b>Failure Hintegra</b>
Power	1	1	1
Group Assignment	1	1	1
Blinding	0	0	0
Group Comparability	0	0	0
Treatment Integrity	0	0	0
Measurement	0	0	0
Investigator Bias	1	1	1
<b>Level of Evidence:</b>	<b>IV</b>	<b>IV</b>	<b>IV</b>
Level of Evidence	●○○○○	●●○○○	●●○○○
	IV	IV	IV
Strength of Evidence Based on Quality	●○○○	●○○○	●○○○
	Very Low	Very Low	Very Low

**Arthroplasty Efficacy**  
**Quality of Evidence**

<b>Study:</b>	<b>Henricson</b>	<b>Hosman</b>	<b>Hosman</b>
<b>Outcome:</b>	<b>Failure Mobility</b>	<b>Failure Mobility</b>	<b>Failure Ramses</b>
<b><i>Method of Group Assignment:</i></b>			
Stochastic Randomization	No	No	No
Quasi-random Assignment	na	na	na
Matched Groups	No	No	No
Consecutive Enrollment	Yes	Yes	Yes
<b><i>Study Design and Conduct:</i></b>			
Control Group Type	Uncontrolled	Uncontrolled	Uncontrolled
Allocation Concealment	No	No	No
Prospective	Yes	Yes	Yes
Group Assignment Score	0.25	0.25	0.25
Blinded Patients	No	No	No
Blinded Assessors	No	No	No
Blinding Verified	No	No	No
>80% Follow-up	Yes	Yes	Yes
<20% Completion Difference	No	No	No
Similar Baseline Outcome Values	No	No	No

**Arthroplasty Efficacy**  
**Quality of Evidence**

<b>Study:</b>	<b>Henricson</b>	<b>Hosman</b>	<b>Hosman</b>
<b>Outcome:</b>	<b>Failure Mobility</b>	<b>Failure Mobility</b>	<b>Failure Ramses</b>
Comparable Pt. Characteristics	No	No	No
Same Control Group Results (xover)	na	na	na
Same Experimental Group Results (xover)	na	na	na
Same Centers	No	No	No
Same Treatment Duration In And Across All Groups	No	No	No
Same Concomitant Treatment to All Groups (controlled studies only)	na	na	na
No Confounding Treatment (case series only)	Unclear	Unclear	Unclear
Same Instruments	Yes	Yes	Yes
Valid Instrument	Yes	Yes	Yes
Consistent Abstract, Results, and Discussion	Yes	Yes	Yes
All Outcomes Reported	Yes	Yes	Yes
A Priori Analysis	No	No	No
Statistical Power	High	High	High
Statistically Significant	Unclear	Unclear	Unclear
<b>Quality Domain Scores:</b>			
Prospective			

**Arthroplasty Efficacy**  
**Quality of Evidence**

<b>Study:</b>	<b>Henricson</b>	<b>Hosman</b>	<b>Hosman</b>
<b>Outcome:</b>	<b>Failure Mobility</b>	<b>Failure Mobility</b>	<b>Failure Ramses</b>
Power	1	1	1
Group Assignment	1	1	1
Blinding	0	0	0
Group Comparability	0	0	0
Treatment Integrity	0	0	0
Measurement	0	0	0
Investigator Bias	1	1	1
<b>Level of Evidence:</b>	<b>IV</b>	<b>IV</b>	<b>IV</b>
Level of Evidence	●○○○○	●●○○○	●●○○○
	IV	IV	IV
Strength of Evidence Based on Quality	●○○○	●○○○	●○○○
	Very Low	Very Low	Very Low

**Arthroplasty Efficacy**  
**Quality of Evidence**

<b>Study:</b>	<b>Hosman</b>
<b>Outcome:</b>	<b>Failure STAR</b>
<b><i>Method of Group Assignment:</i></b>	
Stochastic Randomization	No
Quasi-random Assignment	na
Matched Groups	No
Consecutive Enrollment	Yes
<b><i>Study Design and Conduct:</i></b>	
Control Group Type	Uncontrolled
Allocation Concealment	No
Prospective	Yes
Group Assignment Score	0.25
Blinded Patients	No
Blinded Assessors	No
Blinding Verified	No
>80% Follow-up	Yes
<20% Completion Difference	No
Similar Baseline Outcome Values	No

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**Arthroplasty Efficacy**  
**Quality of Evidence**

<b>Study:</b>	<b>Hosman</b>
<b>Outcome:</b>	<b>Failure STAR</b>
Comparable Pt. Characteristics	No
Same Control Group Results (xover)	na
Same Experimental Group Results (xover)	na
Same Centers	No
Same Treatment Duration In And Across All Groups	No
Same Concomitant Treatment to All Groups (controlled studies only)	na
No Confounding Treatment (case series only)	Unclear
Same Instruments	Yes
Valid Instrument	Yes
Consistent Abstract, Results, and Discussion	Yes
All Outcomes Reported	Yes
A Priori Analysis	No
Statistical Power	High
Statistically Significant	Unclear
<b>Quality Domain Scores:</b>	
Prospective	

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**Arthroplasty Efficacy**  
**Quality of Evidence**

<b>Study:</b>	<b>Hosman</b>
<b>Outcome:</b>	<b>Failure STAR</b>
Power	1
Group Assignment	1
Blinding	0
Group Comparability	0
Treatment Integrity	0
Measurement	0
Investigator Bias	1
<b>Level of Evidence:</b>	<b>IV</b>
Level of Evidence	●○○○○
	IV
Strength of Evidence Based on Quality	●○○○
	Very Low

Confidential Draft

**Arthrodesis versus Arthroplasty**  
**Quality of Evidence**

<b>Study:</b>	<b>SooHoo</b>	<b>SooHoo</b>	<b>SooHoo</b>
<b>Outcome:</b>	<b>Adverse Events 1 Year Corrected</b>	<b>Adverse Events 90 days</b>	<b>Adverse Events 1 year Not Corrected</b>
<b><i>Method of Group Assignment:</i></b>			
Stochastic Randomization	Unclear	No	Unclear
Quasi-random Assignment	Unclear	No	Unclear
Matched Groups	Unclear	Yes	Unclear
Consecutive Enrollment	na	na	na
<b><i>Study Design and Conduct:</i></b>			
Control Group Type	Active Parallel	Active Parallel	Active Parallel
Allocation Concealment	No	No	No
Prospective	No	No	No
Group Assignment Score	0.00	0.25	0.00
Blinded Patients	No	No	No
Blinded Assessors	No	No	No
Blinding Verified	No	No	No
>80% Follow-up	Yes	Yes	Yes
<20% Completion Difference	Yes	Yes	Yes
Similar Baseline Outcome Values	Yes	Yes	Yes

**Arthrodesis versus Arthroplasty**  
**Quality of Evidence**

Comparable Pt. Characteristics	No	No	No
Same Control Group Results (xover)	na	na	na
Same Experimental Group Results (xover)	na	na	na
Same Centers	Yes	Yes	Yes
Same Treatment Duration In And Across All Groups	Yes	Yes	Yes
Same Concomitant Treatment to All Groups (controlled studies only)	No	No	No
No Confounding Treatment (case series only)	Yes	na	na
Same Instruments	Yes	Yes	Yes
Valid Instrument	Yes	Yes	Yes
Consistent Abstract, Results, and Discussion	Yes	Yes	Yes
All Outcomes Reported	Yes	Yes	Yes
A Priori Analysis	Yes	Yes	Yes
Statistical Power	High	High	High
Statistically Significant	Yes	Yes	Yes
<b>DOMAIN SCORES:</b>			
<b>Quality Domain Scores:</b>			
Prospective	0	0	0
Power	1	1	1

**Arthrodesis versus Arthroplasty**  
**Quality of Evidence**

Group Assignment	0	0	0
Blinding	0	0	0
Group Comparability	0	0	0
Treatment Integrity	0	0	0
Measurement	1	1	1
Investigator Bias	1	1	1
<b>Level of Evidence:</b>	<b>III</b>	<b>III</b>	<b>III</b>
<b>Quality Summary:</b>	<b>SooHoo</b>	<b>SooHoo</b>	<b>SooHoo</b>
Level of Evidence	●●●○○	●●●○○	●●●○○
	III	III	III
Strength of Evidence Based on Quality	●●○○ Low	●●○○ Low	●●○○ Low

**Arthrodesis versus Arthroplasty**  
**Quality of Evidence**

<b>Study:</b>	<b>Saltzman 2010</b>	<b>Saltzman 2010</b>	<b>Saltzman 2009</b>
<b>Outcome:</b>	<b>SF-36</b>	<b>Adverse Events</b>	<b>Overall Success</b>
<b><i>Method of Group Assignment:</i></b>			
Stochastic Randomization	Unclear	Unclear	Unclear
Quasi-random Assignment	Unclear	Unclear	Unclear
Matched Groups	Unclear	Unclear	Unclear
Consecutive Enrollment	na	na	na
<b><i>Study Design and Conduct:</i></b>			
Control Group Type	Active Parallel	Active Parallel	Active Parallel
Allocation Concealment	No	No	No
Prospective	No	No	Yes
Group Assignment Score	0.00	0.00	0.00
Blinded Patients	No	No	Yes
Blinded Assessors	No	No	Unclear
Blinding Verified	No	No	Yes
>80% Follow-up	Yes	Yes	No
<20% Completion Difference	Yes	Yes	Yes
Similar Baseline Outcome Values	Unclear	Unclear	No

**Arthrodesis versus Arthroplasty**  
**Quality of Evidence**

Comparable Pt. Characteristics	No	No	No
Same Control Group Results (xover)	na	na	na
Same Experimental Group Results (xover)	na	na	na
Same Centers	Yes	Yes	No
Same Treatment Duration In And Across All Groups	Yes	Yes	Unclear
Same Concomitant Treatment to All Groups (controlled studies only)	No	No	Yes
No Confounding Treatment (case series only)	na	na	na
Same Instruments	Yes	Yes	Yes
Valid Instrument	No	No	No
Consistent Abstract, Results, and Discussion	Yes	Yes	No
All Outcomes Reported	Yes	Yes	No
A Priori Analysis	Yes	Yes	Yes
Statistical Power	High	High	High
Statistically Significant	Yes	Yes	Yes
<b>DOMAIN SCORES:</b>			
<b>Quality Domain Scores:</b>			
Prospective	0	0	1
Power	1	1	1

**Arthrodesis versus Arthroplasty**  
**Quality of Evidence**

Group Assignment	0	0	0
Blinding	0	0	1
Group Comparability	0	0	0
Treatment Integrity	0	0	0
Measurement	0	0	0
Investigator Bias	1	1	0
<b>Level of Evidence:</b>	<b>III</b>	<b>III</b>	<b>II</b>
<b>Quality Summary:</b>	<b>Saltzman 2010</b>	<b>Saltzman 2010</b>	<b>Saltzman</b>
Level of Evidence	●●●○○	●●●○○	●●●●○
	III	III	II
Strength of Evidence Based on Quality	●○○○	●○○○	●○○○
	Very Low	Very Low	Very Low

**Arthrodesis versus Arthroplasty**  
**Quality of Evidence**

<b>Study:</b>	<b>Saltzman 2009</b>	<b>Saltzman 2009</b>	<b>Saltzman 2009</b>
<b>Outcome:</b>	<b>BP Subscales</b>	<b>VAS Pain</b>	<b>Additional Intervention</b>
<b><i>Method of Group Assignment:</i></b>			
Stochastic Randomization	Unclear	Unclear	Unclear
Quasi-random Assignment	Unclear	Unclear	Unclear
Matched Groups	Unclear	Unclear	Unclear
Consecutive Enrollment	na	na	na
<b><i>Study Design and Conduct:</i></b>			
Control Group Type	Active Parallel	Active Parallel	Active Parallel
Allocation Concealment	No	No	No
Prospective	Yes	Yes	Yes
Group Assignment Score	0.00	0.00	0.00
Blinded Patients	Yes	Yes	Yes
Blinded Assessors	Unclear	Unclear	Unclear
Blinding Verified	Yes	Yes	Yes
>80% Follow-up	No	No	No
<20% Completion Difference	Yes	Yes	Yes
Similar Baseline Outcome Values	No	No	No

**Arthrodesis versus Arthroplasty**  
**Quality of Evidence**

Comparable Pt. Characteristics	No	No	No
Same Control Group Results (xover)	na	na	na
Same Experimental Group Results (xover)	na	na	na
Same Centers	No	No	No
Same Treatment Duration In And Across All Groups	Unclear	Unclear	Unclear
Same Concomitant Treatment to All Groups (controlled studies only)	Yes	Yes	Yes
No Confounding Treatment (case series only)	na	na	na
Same Instruments	Yes	Yes	Yes
Valid Instrument	No	No	No
Consistent Abstract, Results, and Discussion	No	No	No
All Outcomes Reported	No	No	No
A Priori Analysis	Yes	Yes	Yes
Statistical Power	High	High	High
Statistically Significant	Yes	Yes	Yes
<b>DOMAIN SCORES:</b>			
<b>Quality Domain Scores:</b>			
Prospective	1	1	1
Power	1	1	1

**Arthrodesis versus Arthroplasty**  
**Quality of Evidence**

Group Assignment	0	0	0
Blinding	1	1	1
Group Comparability	0	0	0
Treatment Integrity	0	0	0
Measurement	0	0	0
Investigator Bias	0	0	0
<b>Level of Evidence:</b>	<b>II</b>	<b>II</b>	<b>II</b>
<b>Quality Summary:</b>	<b>Saltzman</b>	<b>Saltzman</b>	<b>Saltzman</b>
Level of Evidence	●●●●○	●●●●○	●●●●○
	II	II	II
Strength of Evidence Based on Quality	●○○○	●○○○	●○○○
	Very Low	Very Low	Very Low

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**Arthrodesis versus Arthroplasty**  
**Quality of Evidence**

<b>Study:</b>	<b>Saltzman 2009</b>	<b>Saltzman 2009</b>	<b>Saltzman 2009</b>
<b>Outcome:</b>	<b>Efficacy</b>	<b>Safety</b>	<b>Success</b>
<b>Method of Group Assignment:</b>			
Stochastic Randomization	Unclear	Unclear	Unclear
Quasi-random Assignment	Unclear	Unclear	Unclear
Matched Groups	Unclear	Unclear	Unclear
Consecutive Enrollment	na	na	na
<b>Study Design and Conduct:</b>			
Control Group Type	Active Parallel	Active Parallel	Active Parallel
Allocation Concealment	No	No	No
Prospective	Yes	Yes	Yes
Group Assignment Score	0.00	0.00	0.00
Blinded Patients	Yes	Yes	Yes
Blinded Assessors	Unclear	Unclear	Unclear
Blinding Verified	Yes	Yes	Yes
>80% Follow-up	No	No	No
<20% Completion Difference	Yes	Yes	Yes
Similar Baseline Outcome Values	No	No	No

**Arthrodesis versus Arthroplasty**  
**Quality of Evidence**

Comparable Pt. Characteristics	No	No	No
Same Control Group Results (xover)	na	na	na
Same Experimental Group Results (xover)	na	na	na
Same Centers	No	No	No
Same Treatment Duration In And Across All Groups	Unclear	Unclear	Unclear
Same Concomitant Treatment to All Groups (controlled studies only)	Yes	Yes	Yes
No Confounding Treatment (case series only)	na	na	na
Same Instruments	Yes	Yes	Yes
Valid Instrument	No	No	No
Consistent Abstract, Results, and Discussion	No	No	No
All Outcomes Reported	No	No	No
A Priori Analysis	Yes	Yes	Yes
Statistical Power	High	High	High
Statistically Significant	Yes	Yes	Yes
<b>DOMAIN SCORES:</b>			
<b>Quality Domain Scores:</b>			
Prospective	1	1	1
Power	1	1	1

**Arthrodesis versus Arthroplasty**  
**Quality of Evidence**

Group Assignment	0	0	0
Blinding	1	1	1
Group Comparability	0	0	0
Treatment Integrity	0	0	0
Measurement	0	0	0
Investigator Bias	0	0	0
<b>Level of Evidence:</b>	<b>II</b>	<b>II</b>	<b>II</b>
<b>Quality Summary:</b>	<b>Saltzman</b>	<b>Saltzman</b>	<b>Saltzman</b>
Level of Evidence	●●●●○	●●●●○	●●●●○
	II	II	II
Strength of Evidence Based on Quality	●○○○	●○○○	●○○○
	Very Low	Very Low	Very Low

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**Arthrodesis versus Arthroplasty**  
**Quality of Evidence**

<b>Study:</b>	<b>Saltzman 2009</b>	<b>Saltzman 2009</b>
<b>Outcome:</b>	<b>Adverse Events</b>	<b>AOS</b>
<b>Method of Group Assignment:</b>		
Stochastic Randomization	Unclear	Unclear
Quasi-random Assignment	Unclear	Unclear
Matched Groups	Unclear	Unclear
Consecutive Enrollment	na	na
<b>Study Design and Conduct:</b>		
Control Group Type	Active Parallel	Active Parallel
Allocation Concealment	No	No
Prospective	Yes	Yes
Group Assignment Score	0.00	0.00
Blinded Patients	Yes	Yes
Blinded Assessors	Unclear	Unclear
Blinding Verified	Yes	Yes
>80% Follow-up	No	No
<20% Completion Difference	Yes	Yes
Similar Baseline Outcome Values	No	No

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**Arthrodesis versus Arthroplasty**  
**Quality of Evidence**

Comparable Pt. Characteristics	No	No
Same Control Group Results (xover)	na	na
Same Experimental Group Results (xover)	na	na
Same Centers	No	No
Same Treatment Duration In And Across All Groups	Unclear	Unclear
Same Concomitant Treatment to All Groups (controlled studies only)	Yes	Yes
No Confounding Treatment (case series only)	na	na
Same Instruments	Yes	Yes
Valid Instrument	No	No
Consistent Abstract, Results, and Discussion	No	No
All Outcomes Reported	No	No
A Priori Analysis	Yes	Yes
Statistical Power	High	High
Statistically Significant	Yes	Yes
<b>DOMAIN SCORES:</b>		
<b>Quality Domain Scores:</b>		
Prospective	1	1
Power	1	1

**Arthrodesis versus Arthroplasty**  
**Quality of Evidence**

Group Assignment	0	0
Blinding	1	1
Group Comparability	0	0
Treatment Integrity	0	0
Measurement	0	0
Investigator Bias	0	0
<b>Level of Evidence:</b>	<b>II</b>	<b>II</b>
<b>Quality Summary:</b>	<b>Saltzman</b>	<b>Saltzman</b>
Level of Evidence	●●●●○	●●●●○
	II	II
Strength of Evidence Based on Quality	●○○○	●○○○
	Very Low	Very Low

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**Arthroplasty Prognostics**  
**Quality of Evidence**

<b>Study:</b>	<b>Kofoed 1998</b>	<b>Wood</b>	<b>Wood</b>
<b>Outcome:</b>	<b>Weight</b>	<b>Require Second Surgery</b>	<b>Surviving Implants</b>
<b><i>Method of Group Assignment:</i></b>			
Stochastic Randomization	No	No	No
Quasi-random Assignment	na	Yes	Yes
Matched Groups	No	No	No
Consecutive Enrollment	No	na	na
<b><i>Study Design and Conduct:</i></b>			
Control Group Type	Uncontrolled	Active Parallel	Active Parallel
Allocation Concealment	No	Yes	Yes
Prospective	Yes	Yes	Yes
Group Assignment Score	0.00	0.50	0.50
Blinded Patients	No	Yes	Yes
Blinded Assessors	No	Unclear	Unclear
Blinding Verified	No	Yes	Yes
>80% Follow-up	Yes	Yes	Yes
<20% Completion Difference	No	Yes	Yes
Similar Baseline Outcome Values	No	Yes	Yes

**Arthroplasty Prognostics**  
**Quality of Evidence**

<b>Study:</b>	<b>Kofoed 1998</b>	<b>Wood</b>	<b>Wood</b>
<b>Outcome:</b>	<b>Weight</b>	<b>Require Second Surgery</b>	<b>Surviving Implants</b>
Comparable Pt. Characteristics	No	Yes	Yes
Same Control Group Results (xover)	na	na	na
Same Experimental Group Results (xover)	na	na	na
Same Centers	No	Yes	Yes
Same Treatment Duration In And Across All Groups	No	Yes	Yes
Same Concomitant Treatment to All Groups (controlled studies only)	na	Yes	Yes
No Confounding Treatment (case series only)	Unclear	Yes	Yes
Same Instruments	Yes	Yes	Yes
Valid Instrument	No	Yes	Yes
Consistent Abstract, Results, and Discussion	Yes	Yes	Yes
All Outcomes Reported	Yes	Yes	Yes
A Priori Analysis	Yes	Yes	Yes
Statistical Power	Low	High	High
Statistically Significant	No	No	No
<b>Level of Evidence:</b>		<b>II</b>	<b>II</b>
<b>Quality and Applicability Summary:</b>		<b>Wood</b>	<b>Wood</b>

**Arthroplasty Prognostics**  
**Quality of Evidence**

<b>Study:</b>	<b>Kofoed 1998</b>	<b>Wood</b>	<b>Wood</b>
<b>Outcome:</b>	<b>Weight</b>	<b>Require Second Surgery</b>	<b>Surviving Implants</b>
Level of Evidence		●●●●○	●●●●○
		II	II
Strength of Evidence Based on Quality		●●●●	●●●●
		High	High

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**Arthroplasty Prognostics**  
**Quality of Evidence**

<b>Study:</b>	<b>Wood</b>	<b>Wood</b>	<b>Wood</b>
<b>Outcome:</b>	<b>Failure Rate</b>	<b>Failure</b>	<b>AOFAS Pain</b>
<b><i>Method of Group Assignment:</i></b>			
Stochastic Randomization	No	No	No
Quasi-random Assignment	Yes	Yes	Yes
Matched Groups	No	No	No
Consecutive Enrollment	na	na	na
<b><i>Study Design and Conduct:</i></b>			
Control Group Type	Active Parallel	Active Parallel	Active Parallel
Allocation Concealment	Yes	Yes	Yes
Prospective	Yes	Yes	Yes
Group Assignment Score	0.50	0.50	0.50
Blinded Patients	Yes	Yes	Yes
Blinded Assessors	Unclear	Unclear	Unclear
Blinding Verified	Yes	Yes	Yes
>80% Follow-up	Yes	Yes	Yes
<20% Completion Difference	Yes	Yes	Yes
Similar Baseline Outcome Values	Yes	Yes	Yes

**Arthroplasty Prognostics**  
**Quality of Evidence**

<b>Study:</b>	<b>Wood</b>	<b>Wood</b>	<b>Wood</b>
<b>Outcome:</b>	<b>Failure Rate</b>	<b>Failure</b>	<b>AOFAS Pain</b>
Comparable Pt. Characteristics	Yes	Yes	Yes
Same Control Group Results (xover)	na	na	na
Same Experimental Group Results (xover)	na	na	na
Same Centers	Yes	Yes	Yes
Same Treatment Duration In And Across All Groups	Yes	Yes	Yes
Same Concomitant Treatment to All Groups (controlled studies only)	Yes	Yes	Yes
No Confounding Treatment (case series only)	Yes	Yes	na
Same Instruments	Yes	Yes	Yes
Valid Instrument	Yes	Yes	No
Consistent Abstract, Results, and Discussion	Yes	Yes	Yes
All Outcomes Reported	Yes	Yes	Yes
A Priori Analysis	Yes	Yes	Yes
Statistical Power	High	High	High
Statistically Significant	No	No	Yes
<b>Level of Evidence:</b>	<b>II</b>	<b>II</b>	<b>II</b>
<b>Quality and Applicability Summary:</b>	<b>Wood</b>	<b>Wood</b>	<b>Wood</b>

**Arthroplasty Prognostics**  
**Quality of Evidence**

<b>Study:</b>	Wood	Wood	Wood
<b>Outcome:</b>	Failure Rate	Failure	AOFAS Pain
<b>Level of Evidence</b>	●●●●○	●●●●○	●●●●○
	II	II	II
<b>Strength of Evidence Based on Quality</b>	●●●●	●●●●	●●●○
	High	High	Moderate

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**Arthroplasty Prognostics**  
**Quality of Evidence**

<b>Study:</b>	<b>Wood</b>	<b>van der Heide</b>	<b>van der Heide</b>
<b>Outcome:</b>	<b>AOFAS Function</b>	<b>Removal of Implant</b>	<b>Kofoed Score</b>
<b><i>Method of Group Assignment:</i></b>			
Stochastic Randomization	No	Unclear	Unclear
Quasi-random Assignment	Yes	Unclear	Unclear
Matched Groups	No	Unclear	Unclear
Consecutive Enrollment	na	na	na
<b><i>Study Design and Conduct:</i></b>			
Control Group Type	Active Parallel	Active Parallel	Active Parallel
Allocation Concealment	Yes	No	No
Prospective	Yes	Yes	Yes
Group Assignment Score	0.50	0.00	0.00
Blinded Patients	Yes	Yes	Yes
Blinded Assessors	Unclear	Unclear	Unclear
Blinding Verified	Yes	Yes	Yes
>80% Follow-up	Yes	Yes	Yes
<20% Completion Difference	Yes	Yes	Yes
Similar Baseline Outcome Values	Yes	Yes	Yes

**Arthroplasty Prognostics**  
**Quality of Evidence**

<b>Study:</b>	<b>Wood</b>	<b>van der Heide</b>	<b>van der Heide</b>
<b>Outcome:</b>	<b>AOFAS Function</b>	<b>Removal of Implant</b>	<b>Kofoed Score</b>
Comparable Pt. Characteristics	Yes	Yes	Yes
Same Control Group Results (xover)	na	na	na
Same Experimental Group Results (xover)	na	na	na
Same Centers	Yes	Yes	Yes
Same Treatment Duration In And Across All Groups	Yes	Yes	Yes
Same Concomitant Treatment to All Groups (controlled studies only)	Yes	No	No
No Confounding Treatment (case series only)	na	Yes	na
Same Instruments	Yes	Yes	Yes
Valid Instrument	No	Yes	No
Consistent Abstract, Results, and Discussion	Yes	Yes	Yes
All Outcomes Reported	Yes	Yes	Yes
A Priori Analysis	Yes	Yes	Yes
Statistical Power	High	Moderate	High
Statistically Significant	Yes	No	Yes
<b>Level of Evidence:</b>	<b>II</b>	<b>II</b>	<b>II</b>
<b>Quality and Applicability Summary:</b>	<b>Wood</b>	<b>van der Heide</b>	<b>van der Heide</b>

**Arthroplasty Prognostics**  
**Quality of Evidence**

<b>Study:</b>	<b>Wood</b>	<b>van der Heide</b>	<b>van der Heide</b>
<b>Outcome:</b>	<b>AOFAS Function</b>	<b>Removal of Implant</b>	<b>Kofoed Score</b>
Level of Evidence	●●●●○	●●●●○	●●●●○
	II	II	II
Strength of Evidence Based on Quality	●●●●○	●●●●○	●●●●○
	Moderate	Moderate	Moderate

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**Arthroplasty Prognostics**  
**Quality of Evidence**

<b>Study:</b>	van der Heide
<b>Outcome:</b>	Implant in site and Kofoed score >50
<b>Method of Group Assignment:</b>	
Stochastic Randomization	Unclear
Quasi-random Assignment	Unclear
Matched Groups	Unclear
Consecutive Enrollment	na
<b>Study Design and Conduct:</b>	
Control Group Type	Active Parallel
Allocation Concealment	No
Prospective	Yes
Group Assignment Score	0.00
Blinded Patients	Yes
Blinded Assessors	Unclear
Blinding Verified	Yes
>80% Follow-up	Yes
<20% Completion Difference	Yes
Similar Baseline Outcome Values	Yes

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**Arthroplasty Prognostics**  
**Quality of Evidence**

<b>Study:</b>	<b>van der Heide</b>
<b>Outcome:</b>	<b>Implant in site and Kofoed score &gt;50</b>
Comparable Pt. Characteristics	Yes
Same Control Group Results (xover)	na
Same Experimental Group Results (xover)	na
Same Centers	Yes
Same Treatment Duration In And Across All Groups	Yes
Same Concomitant Treatment to All Groups (controlled studies only)	No
No Confounding Treatment (case series only)	na
Same Instruments	Yes
Valid Instrument	No
Consistent Abstract, Results, and Discussion	Yes
All Outcomes Reported	Yes
A Priori Analysis	Yes
Statistical Power	High
Statistically Significant	Yes
<b>Level of Evidence:</b>	<b>II</b>
<b>Quality and Applicability Summary:</b>	<b>van der Heide</b>

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**Arthroplasty Prognostics**  
**Quality of Evidence**

<b>Study:</b>	van der Heide
<b>Outcome:</b>	Implant in site and Kofod score >50
Level of Evidence	●●●●○
	II
Strength of Evidence Based on Quality	●●●○
	Moderate

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**Arthroplasty Prognostics**  
**Quality of Evidence**

<b>Study:</b>	<b>Fevang</b>	<b>Skytta</b>	<b>Doets</b>
<b>Prognostic:</b>	<b>Age</b>	<b>Age</b>	<b>Age</b>
<b>Quality:</b>			
Prospective	Yes	Yes	Yes
At Least 10 Patients per Important Variable	Yes	Yes	No
At Least 10 Events	No	Yes	No
All Important Variables Screened for Model	No	No	No
Interactions Tested	No	Yes	No
Collinearity Absent	No	No	No
Primary Analysis (not subgroup or post hoc)	No	Yes	No
Statistically Significant Fit	No	No	No
Article and Abstract Agree	Yes	Yes	Yes
Results Reported for All Studied Variables	No	Yes	Yes
Blinded Data Analysts	No	No	No
<b>DOMAIN SCORES:</b>			
<b>Quality Domain Scores:</b>			
Prospective	1	1	1
Power	0	1	1

**Arthroplasty Prognostics**  
**Quality of Evidence**

<b>Study:</b>	<b>Fevang</b>	<b>Skytta</b>	<b>Doets</b>
<b>Prognostic:</b>	<b>Age</b>	<b>Age</b>	<b>Age</b>
Analysis	0	0	0
Investigator Bias	0	0	0
Model	0	0	0
<b>Level of Evidence:</b>	<b>V</b>	<b>IV</b>	<b>IV</b>
<b>Quality and Applicability Summary:</b>	<b>Fevang</b>	<b>Skytta</b>	<b>Doets</b>
Level of Evidence	●●○○○	●●○○○	●●○○○
	V	IV	IV
Strength of Evidence Based on Quality	●○○○	●○○○	●○○○
	Very Low	Very Low	Very Low

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**Arthroplasty Prognostics**  
**Quality of Evidence**

<b>Study:</b>	<b>Hosman</b>	<b>Pyevich</b>	<b>Henricson</b>
<b>Prognostic:</b>	<b>Age</b>	<b>Age</b>	<b>Age</b>
<b>Quality:</b>			
Prospective	Yes	Yes	Yes
At Least 10 Patients per Important Variable	No	No	No
At Least 10 Events	na	na	na
All Important Variables Screened for Model	No	No	No
Interactions Tested	No	No	No
Collinearity Absent	No	No	No
Primary Analysis (not subgroup or post hoc)	No	No	No
Statistically Significant Fit	No	No	No
Article and Abstract Agree	Yes	Yes	Yes
Results Reported for All Studied Variables	Yes	Yes	Yes
Blinded Data Analysts	No	No	Yes
<b>DOMAIN SCORES:</b>			
<b>Quality Domain Scores:</b>			
Prospective	1	1	0
Power	0	1	0

**Arthroplasty Prognostics**  
**Quality of Evidence**

<b>Study:</b>	<b>Hosman</b>	<b>Pyevich</b>	<b>Henricson</b>
<b>Prognostic:</b>	<b>Age</b>	<b>Age</b>	<b>Age</b>
Analysis	0	0	0
Investigator Bias	0	0	0
Model	0	0	1
<b>Level of Evidence:</b>	<b>V</b>	<b>IV</b>	<b>V</b>
<b>Quality and Applicability Summary:</b>	<b>Hosman</b>	<b>Pyevich</b>	<b>Henricson</b>
Level of Evidence	●●○○○	●●○○○	●●○○○
	V	IV	V
Strength of Evidence Based on Quality	●○○○	●○○○	●○○○
	Very Low	Very Low	Very Low

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**Arthroplasty Prognostics**  
**Quality of Evidence**

<b>Study:</b>	<b>Pyeich</b>	<b>Schuberth</b>	<b>Wood</b>
<b>Prognostic:</b>	<b>Weight</b>	<b>BMI</b>	<b>Deformity</b>
<b>Quality:</b>			
Prospective	Yes	Yes	Yes
At Least 10 Patients per Important Variable	No	No	No
At Least 10 Events	na	na	No
All Important Variables Screened for Model	No	No	No
Interactions Tested	No	No	No
Collinearity Absent	No	No	No
Primary Analysis (not subgroup or post hoc)	No	No	No
Statistically Significant Fit	No	No	No
Article and Abstract Agree	Yes	Yes	Yes
Results Reported for All Studied Variables	Yes	Yes	No
Blinded Data Analysts	No	No	No
<b>DOMAIN SCORES:</b>			
<b>Quality Domain Scores:</b>			
Prospective	1	0	1
Power	1	1	0

**Arthroplasty Prognostics**  
**Quality of Evidence**

<b>Study:</b>	<b>Pyevich</b>	<b>Schuberth</b>	<b>Wood</b>
<b>Prognostic:</b>	<b>Weight</b>	<b>BMI</b>	<b>Deformity</b>
Analysis	0	0	0
Investigator Bias	0	0	0
Model	0	0	0
<b>Level of Evidence:</b>	<b>IV</b>	<b>V</b>	<b>V</b>
<b>Quality and Applicability Summary:</b>	<b>Pyevich</b>	<b>Schuberth</b>	<b>Wood</b>
Level of Evidence	●●○○○	●●○○○	●●○○○
	IV	V	V
Strength of Evidence Based on Quality	●○○○	●○○○	●○○○
	Very Low	Very Low	Very Low

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**Arthroplasty Prognostics**  
**Quality of Evidence**

<b>Study:</b>	<b>Hosman</b>	<b>wood/ 978</b>	<b>Doets</b>
<b>Prognostic:</b>	<b>Deformity</b>	<b>Deformity</b>	<b>Deformity</b>
<b>Quality:</b>			
Prospective	Yes	Yes	Yes
At Least 10 Patients per Important Variable	No	No	No
At Least 10 Events	na	na	na
All Important Variables Screened for Model	No	No	No
Interactions Tested	No	Yes	No
Collinearity Absent	No	Yes	No
Primary Analysis (not subgroup or post hoc)	No	No	No
Statistically Significant Fit	No	No	No
Article and Abstract Agree	Yes	Yes	Yes
Results Reported for All Studied Variables	Yes	Yes	Yes
Blinded Data Analysts	No	na	No
<b>DOMAIN SCORES:</b>			
<b>Quality Domain Scores:</b>			
Prospective	1	1	1
Power	0	0	1

**Arthroplasty Prognostics**  
**Quality of Evidence**

<b>Study:</b>	<b>Hosman</b>	<b>wood/ 978</b>	<b>Doets</b>
<b>Prognostic:</b>	<b>Deformity</b>	<b>Deformity</b>	<b>Deformity</b>
Analysis	0	0	0
Investigator Bias	0	0	0
Model	0	1	0
<b>Level of Evidence:</b>	<b>V</b>	<b>IV</b>	<b>IV</b>
<b>Quality and Applicability Summary:</b>	<b>Hosman</b>	<b>wood/ 978</b>	<b>Doets</b>
Level of Evidence	●●○○○	●●○○○	●●○○○
	V	IV	IV
Strength of Evidence Based on Quality	●○○○	●○○○	●○○○
	Very Low	Very Low	Very Low

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**Arthroplasty Prognostics**  
**Quality of Evidence**

<b>Study:</b>	<b>Hobson</b>	<b>Fevang</b>	<b>Henricson</b>
<b>Prognostic:</b>	<b>Deformity</b>	<b>Diagnosis</b>	<b>Diagnosis</b>
<b>Quality:</b>			
Prospective	Yes	Yes	Yes
At Least 10 Patients per Important Variable	Yes	Yes	No
At Least 10 Events	Yes	No	No
All Important Variables Screened for Model	No	No	No
Interactions Tested	No	No	No
Collinearity Absent	No	No	No
Primary Analysis (not subgroup or post hoc)	No	No	No
Statistically Significant Fit	No	No	No
Article and Abstract Agree	Yes	Yes	Yes
Results Reported for All Studied Variables	Yes	No	Yes
Blinded Data Analysts	No	No	Yes
<b>DOMAIN SCORES:</b>			
<b>Quality Domain Scores:</b>			
Prospective	1	1	0
Power	1	0	0

**Arthroplasty Prognostics**  
**Quality of Evidence**

<b>Study:</b>	<b>Hobson</b>	<b>Fevang</b>	<b>Henricson</b>
<b>Prognostic:</b>	<b>Deformity</b>	<b>Diagnosis</b>	<b>Diagnosis</b>
Analysis	0	0	0
Investigator Bias	0	0	0
Model	0	0	1
<b>Level of Evidence:</b>	<b>IV</b>	<b>V</b>	<b>V</b>
<b>Quality and Applicability Summary:</b>	<b>Hobson</b>	<b>Fevang</b>	<b>Henricson</b>
Level of Evidence	●●○○○	●●○○○	●●○○○
	IV	V	V
Strength of Evidence Based on Quality	●○○○	●○○○	●○○○
	Very Low	Very Low	Very Low

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**Arthroplasty Prognostics**  
**Quality of Evidence**

<b>Study:</b>	<b>Hosman</b>	<b>Valderrbanno</b>	<b>Kofoed</b>
<b>Prognostic:</b>	<b>Diagnosis</b>	<b>Age</b>	<b>age</b>
<b>Quality:</b>			
Prospective	Yes	Yes	Yes
At Least 10 Patients per Important Variable	No	Yes	Yes
At Least 10 Events	na	na	na
All Important Variables Screened for Model	No	No	No
Interactions Tested	No	No	No
Collinearity Absent	No	No	No
Primary Analysis (not subgroup or post hoc)	No	No	No
Statistically Significant Fit	No	No	No
Article and Abstract Agree	Yes	Yes	Yes
Results Reported for All Studied Variables	Yes	Yes	Yes
Blinded Data Analysts	No	No	No
<b>DOMAIN SCORES:</b>			
<b>Quality Domain Scores:</b>			
Prospective	1	1	1
Power	0	1	1

**Arthroplasty Prognostics**  
**Quality of Evidence**

<b>Study:</b>	<b>Hosman</b>	<b>Valderrbanno</b>	<b>Kofoed</b>
<b>Prognostic:</b>	<b>Diagnosis</b>	<b>Age</b>	<b>age</b>
Analysis	0	0	0
Investigator Bias	0	0	0
Model	0	0	0
<b>Level of Evidence:</b>	<b>V</b>	<b>IV</b>	<b>IV</b>
<b>Quality and Applicability Summary:</b>	<b>Hosman</b>	<b>Valderrbanno</b>	<b>Kofoed</b>
Level of Evidence	●●○○○	●●○○○	●●○○○
	V	IV	IV
Strength of Evidence Based on Quality	●○○○	●○○○	●○○○
	Very Low	Very Low	Very Low

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**Arthroplasty Prognostics**  
**Quality of Evidence**

<b>Study:</b>	<b>Valderrbanno</b>
<b>Prognostic:</b>	<b>Age</b>
<b>Quality:</b>	
Prospective	Yes
At Least 10 Patients per Important Variable	Yes
At Least 10 Events	na
All Important Variables Screened for Model	No
Interactions Tested	No
Collinearity Absent	No
Primary Analysis (not subgroup or post hoc)	No
Statistically Significant Fit	No
Article and Abstract Agree	Yes
Results Reported for All Studied Variables	Yes
Blinded Data Analysts	No
<b>DOMAIN SCORES:</b>	
<b>Quality Domain Scores:</b>	
Prospective	1
Power	1

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**Arthroplasty Prognostics**  
**Quality of Evidence**

<b>Study:</b>	<b>Valderrbanno</b>
<b>Prognostic:</b>	<b>Age</b>
Analysis	0
Investigator Bias	0
Model	0
<b>Level of Evidence:</b>	<b>IV</b>
<b>Quality and Applicability Summary:</b>	<b>Valderrbanno</b>
Level of Evidence	●●○○○
	IV
Strength of Evidence Based on Quality	●○○○
	Very Low

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**Arthrodesis Efficacy**  
**Quality of Evidence**

<b>Study:</b>	<b>Partio</b>	<b>Partio</b>	<b>Partio</b>
<b>Outcome:</b>	<b>Adverse Events</b>	<b>Return to work</b>	<b>Changed Work</b>
<b><i>Method of Group Assignment:</i></b>			
Stochastic Randomization	No	No	No
Quasi-random Assignment	na	na	na
Matched Groups	No	No	No
Consecutive Enrollment	Yes	Yes	Yes
<b><i>Study Design and Conduct:</i></b>			
Control Group Type	Uncontrolled	Uncontrolled	Uncontrolled
Allocation Concealment	No	No	No
Prospective	Yes	Yes	Yes
Group Assignment Score	0.25	0.25	0.25
Blinded Patients	No	No	No
Blinded Assessors	No	No	No
Blinding Verified	No	No	No
>80% Follow-up	Yes	Yes	Yes
<20% Completion Difference	No	No	No
Similar Baseline Outcome Values	No	No	No

**Arthrodesis Efficacy**  
**Quality of Evidence**

<b>Study:</b>	<b>Partio</b>	<b>Partio</b>	<b>Partio</b>
<b>Outcome:</b>	<b>Adverse Events</b>	<b>Return to work</b>	<b>Changed Work</b>
Comparable Pt. Characteristics	No	No	No
Same Control Group Results (xover)	na	na	na
Same Experimental Group Results (xover)	na	na	na
Same Centers	No	No	No
Same Treatment Duration In And Across All Groups	Yes	Yes	Yes
Same Concomitant Treatment to All Groups (controlled studies only)	No	No	No
No Confounding Treatment (case series only)	No	No	No
Same Instruments	Yes	Yes	Yes
Valid Instrument	Yes	No	No
Consistent Abstract, Results, and Discussion	Yes	Yes	Yes
All Outcomes Reported	Yes	Yes	Yes
A Priori Analysis	Yes	No	No
Statistical Power	Low	Low	Low
Statistically Significant	Unclear	Unclear	Unclear
Prospective	1	1	1
Power	0	0	0

**Arthrodesis Efficacy  
Quality of Evidence**

<b>Study:</b>	<b>Partio</b>	<b>Partio</b>	<b>Partio</b>
<b>Outcome:</b>	<b>Adverse Events</b>	<b>Return to work</b>	<b>Changed Work</b>
Group Assignment	0	0	0
Blinding	0	0	0
Group Comparability	0	0	0
Treatment Integrity	0	0	0
Measurement	1	0	0
Investigator Bias	1	0	0
<b>Level of Evidence:</b>	<b>IV</b>	<b>IV</b>	<b>IV</b>
<b>Applicability Domain Scores:</b>			
Participants	1	1	1
Interventions & Expertise	0	0	0
Compliance & Adherence	1	1	1
Analysis	1	1	1
Level of Evidence	●●○○○	●●○○○	●●○○○
	IV	IV	IV
Strength of Evidence Based on Quality	●○○○	●○○○	●○○○
	Very Low	Very Low	Very Low

**Arthrodesis Efficacy**  
**Quality of Evidence**

<b>Study:</b>	<b>Partio</b>	<b>Ogilvie-Harris</b>	<b>Ogilvie-Harris</b>
<b>Outcome:</b>	<b>Union</b>	<b>Union</b>	<b>Hospital Stay</b>
<b><i>Method of Group Assignment:</i></b>			
Stochastic Randomization	No	No	No
Quasi-random Assignment	na	na	na
Matched Groups	No	No	No
Consecutive Enrollment	Yes	Yes	Yes
<b><i>Study Design and Conduct:</i></b>			
Control Group Type	Uncontrolled	Uncontrolled	Uncontrolled
Allocation Concealment	No	No	No
Prospective	Yes	Yes	Yes
Group Assignment Score	0.25	0.25	0.25
Blinded Patients	No	No	No
Blinded Assessors	No	No	No
Blinding Verified	No	No	No
>80% Follow-up	Yes	Yes	Yes
<20% Completion Difference	No	No	No
Similar Baseline Outcome Values	No	No	No

**Arthrodesis Efficacy**  
**Quality of Evidence**

<b>Study:</b>	<b>Partio</b>	<b>Ogilvie-Harris</b>	<b>Ogilvie-Harris</b>
<b>Outcome:</b>	<b>Union</b>	<b>Union</b>	<b>Hospital Stay</b>
Comparable Pt. Characteristics	No	No	No
Same Control Group Results (xover)	na	na	na
Same Experimental Group Results (xover)	na	na	na
Same Centers	No	No	No
Same Treatment Duration In And Across All Groups	No	No	Yes
Same Concomitant Treatment to All Groups (controlled studies only)	na	na	No
No Confounding Treatment (case series only)	No	Yes	Yes
Same Instruments	Yes	Yes	Yes
Valid Instrument	No	No	No
Consistent Abstract, Results, and Discussion	Yes	Yes	Yes
All Outcomes Reported	Yes	Yes	Yes
A Priori Analysis	Yes	Yes	Yes
Statistical Power	Low	Moderate	Moderate
Statistically Significant	Unclear	Unclear	Unclear
Prospective	1	1	1
Power	0	0.5	0.5

**Arthrodesis Efficacy  
Quality of Evidence**

<b>Study:</b>	<b>Partio</b>	<b>Ogilvie-Harris</b>	<b>Ogilvie-Harris</b>
<b>Outcome:</b>	<b>Union</b>	<b>Union</b>	<b>Hospital Stay</b>
Group Assignment	0	0	0
Blinding	0	0	0
Group Comparability	0	0	0
Treatment Integrity	0	0	0
Measurement	0	0	0
Investigator Bias	1	1	1
<b>Level of Evidence:</b>	<b>IV</b>	<b>IV</b>	<b>IV</b>
<b>Applicability Domain Scores:</b>			
Participants	1	0	0
Interventions & Expertise	0	0	0
Compliance & Adherence	1	1	1
Analysis	1	1	1
Level of Evidence	●●○○○	●●○○○	●●○○○
	IV	IV	IV
Strength of Evidence Based on Quality	●○○○	●○○○	●○○○
	Very Low	Very Low	Very Low

**Arthrodesis Efficacy**  
**Quality of Evidence**

<b>Study:</b>	<b>Ferkle</b>	<b>Ferkle</b>	<b>Ferkle</b>
<b>Outcome:</b>	<b>Mazur Score</b>	<b>screw removal</b>	<b>Fusion</b>
<b><i>Method of Group Assignment:</i></b>			
Stochastic Randomization	No	No	No
Quasi-random Assignment	na	na	na
Matched Groups	No	No	No
Consecutive Enrollment	Yes	Yes	Yes
<b><i>Study Design and Conduct:</i></b>			
Control Group Type	Uncontrolled	Uncontrolled	Uncontrolled
Allocation Concealment	No	No	No
Prospective	Yes	Yes	Yes
Group Assignment Score	0.25	0.25	0.25
Blinded Patients	No	No	No
Blinded Assessors	No	No	No
Blinding Verified	No	No	No
>80% Follow-up	Yes	Yes	Yes
<20% Completion Difference	No	No	No
Similar Baseline Outcome Values	No	No	No

**Arthrodesis Efficacy**  
**Quality of Evidence**

<b>Study:</b>	<b>Ferkle</b>	<b>Ferkle</b>	<b>Ferkle</b>
<b>Outcome:</b>	<b>Mazur Score</b>	<b>screw removal</b>	<b>Fusion</b>
Comparable Pt. Characteristics	No	No	No
Same Control Group Results (xover)	na	na	na
Same Experimental Group Results (xover)	na	na	na
Same Centers	No	No	No
Same Treatment Duration In And Across All Groups	Yes	No	No
Same Concomitant Treatment to All Groups (controlled studies only)	No	No	na
No Confounding Treatment (case series only)	Yes	Yes	Yes
Same Instruments	Yes	Yes	Yes
Valid Instrument	No	No	No
Consistent Abstract, Results, and Discussion	Yes	Yes	Yes
All Outcomes Reported	Yes	Yes	Yes
A Priori Analysis	Yes	Yes	Yes
Statistical Power	Moderate	Moderate	High
Statistically Significant	Unclear	Unclear	Unclear
Prospective	1	1	1
Power	0.5	0.5	1

**Arthrodesis Efficacy  
Quality of Evidence**

<b>Study:</b>	<b>Ferkle</b>	<b>Ferkle</b>	<b>Ferkle</b>
<b>Outcome:</b>	<b>Mazur Score</b>	<b>screw removal</b>	<b>Fusion</b>
Group Assignment	0	0	0
Blinding	0	0	0
Group Comparability	0	0	0
Treatment Integrity	0	0	0
Measurement	0	0	0
Investigator Bias	1	1	1
<b>Level of Evidence:</b>	<b>IV</b>	<b>IV</b>	<b>IV</b>
<b>Applicability Domain Scores:</b>			
Participants	0	0	0
Interventions & Expertise	0	0	0
Compliance & Adherence	1	1	1
Analysis	1	1	1
Level of Evidence	●●○○○	●●○○○	●●○○○
	IV	IV	IV
Strength of Evidence Based on Quality	●○○○	●○○○	●○○○
	Very Low	Very Low	Very Low

**Arthrodesis Efficacy**  
**Quality of Evidence**

<b>Study:</b>	Sealey
<b>Outcome:</b>	SF-36
<b>Method of Group Assignment:</b>	
Stochastic Randomization	No
Quasi-random Assignment	na
Matched Groups	No
Consecutive Enrollment	No
<b>Study Design and Conduct:</b>	
Control Group Type	Uncontrolled
Allocation Concealment	No
Prospective	Yes
Group Assignment Score	0.00
Blinded Patients	No
Blinded Assessors	No
Blinding Verified	No
>80% Follow-up	Yes
<20% Completion Difference	No
Similar Baseline Outcome Values	No

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**Arthrodesis Efficacy**  
**Quality of Evidence**

<b>Study:</b>	<b>Sealey</b>
<b>Outcome:</b>	<b>SF-36</b>
Comparable Pt. Characteristics	No
Same Control Group Results (xover)	na
Same Experimental Group Results (xover)	na
Same Centers	No
Same Treatment Duration In And Across All Groups	No
Same Concomitant Treatment to All Groups (controlled studies only)	na
No Confounding Treatment (case series only)	Yes
Same Instruments	Yes
Valid Instrument	Yes
Consistent Abstract, Results, and Discussion	Yes
All Outcomes Reported	Yes
A Priori Analysis	Yes
Statistical Power	High
Statistically Significant	Yes
Prospective	1
Power	1

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**Arthrodesis Efficacy**  
**Quality of Evidence**

<b>Study:</b>	<b>Sealey</b>
<b>Outcome:</b>	<b>SF-36</b>
Group Assignment	0
Blinding	0
Group Comparability	0
Treatment Integrity	0
Measurement	1
Investigator Bias	1
<b>Level of Evidence:</b>	<b>IV</b>
<b>Applicability Domain Scores:</b>	
Participants	
Interventions & Expertise	
Compliance & Adherence	
Analysis	
Level of Evidence	●●○○○
	IV
Strength of Evidence Based on Quality	●○○○
	Very Low

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