

Outcomes Following Interposition Arthroplasty of the First Metatarsophalangeal Joint for the Treatment of Hallux Rigidus: A Systematic Review

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Abstract

Background: Interposition arthroplasty of the first MTP joint has recently experienced renewed interest as a treatment for hallux rigidus. The purpose of this study was to systematically review the rapidly expanding literature on PRO following interposition arthroplasty of the first MTP joint.

Methods: PubMed Central, Embase, and the Cochrane Central Register for Controlled Trials (CENTRAL) were searched. Inclusion criteria included length of time to follow-up, number of patients, outcome measure, and use of allogeneic or autogenous soft tissue or a synthetic matrix as interposition.

Results: 20 studies were included in the review, comprising 498 patients and 539 feet with mean time to follow-up of 4.5 years. The most common substance used for interposition in the included studies was autogenous first MTPJ capsular tissue, a technique reported on in 12 (60.0%) of the included articles. In studies reporting preoperative and postoperative outcomes by way of a standardized outcome scoring system, mean group improvements exceed minimal clinically important differences in the majority of studies. Eighty-five percent of the studies included in this review were of Level IV quality evidence, and of this subset of studies, 70.6% were of a retrospective nature. Progression to further surgery was observed in 3.8% of toes. The most common complication reported was transfer metatarsalgia of I or more lesser toes, observed in up to 57.9% of patients in one study.

Conclusion: Interposition arthroplasty appears to be a viable option for the treatment of moderate to severe hallux rigidus in patients looking to salvage motion through the first metatarsophalangeal joint. A wide array of autogenous, allogeneic, and synthetic implant materials have surfaced in recent years, but long-term follow-up and prospective, comparative study designs with low risk of bias are limited.

Level of Evidence: Level IV, systematic review of Level III-IV studies

Keywords: hallux rigidus, interposition arthroplasty, first MTP joint, hallux disorders, soft tissue arthroplasty, systematic review

Introduction

Hallux rigidus has been treated operatively with a variety of procedures, including fusion, cheilectomy, osteotomy, implant arthroplasty, resection arthroplasty, and interposition arthroplasty. Cheilectomy and first metatarsal/proximal phalangeal osteotomy have a role in operative management of symptomatic early-stage hallux rigidus, whereas arthrodesis and arthroplasty are indicated in the management of more advanced pathology.³⁷ Despite fusion being the “gold standard” procedure for the treatment of severe hallux

valgus, it leads to a limitation of motion through the first metatarsophalangeal joint that is unacceptable to some patients.⁴⁰ Silicone, ceramic, and metallic hemi- and total-

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joint implants have high rates of revision associated with fragmentation, loosening, malalignment, subluxation, and reactive inflammatory and cystic pathology, which makes these implants poor choices in comparison with arthrodesis.^{22,28,44,46,53,54,56,58}

In an effort to offer the patient with hallux rigidus an alternative to fusion, various techniques for an “interposition arthroplasty” have been proposed. Interposition arthroplasty is a modification of the Keller resection arthroplasty with the addition of a “spacer,” a modification intended to make the procedure a viable option for the more active patient.²⁴ Despite the description of the successful interposition of dorsal capsule and extensor hallucis brevis in the first MTP joint space for the treatment of advanced hallux rigidus, many modifications to this technique have surfaced.²⁵ There has been burgeoning interest in the role of autogenous and allogeneic soft-tissue biomaterials and synthetic analogs as both spacers and functional cartilaginous substitutes.^{3,18} The purpose of this review was to systematically review the current state of the literature related to patient outcomes after interposition arthroplasty of the first metatarsophalangeal joint in the treatment of hallux rigidus.

Methods

Search Strategy

The Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) statement was used in designing the study, and article selection proceeded in accordance with the multitiered system defined by this statement.⁴² Articles were derived from a search of 3 databases: PubMed Central, Embase, and Cochrane Central Register of Controlled Trials (CENTRAL). The search strategy (Supplementary Table 1) was employed on December 12, 2017. As a result, publications made available online after this date were not included in the review. Two reviewers (B.E., D.C.) completed title review of articles independently. Where there was divergence of opinion on inclusion of an article in the next stage of the screening protocol, the disagreement was resolved by including the article in further review. At the time of full-text review, the references of each article were searched and studies that were not captured by the combined result of the initial database searches were each evaluated for eligibility.

Study Eligibility Criteria and Data Extraction

Prospective and retrospective studies evaluating the role of interposition arthroplasty in the treatment of hallux rigidus were evaluated for inclusion based on a number of predetermined criteria (Figure 1). All articles that met the review’s inclusion criteria were scrutinized for data points thought to be critical to a systematic presentation of patient outcomes. Data were extracted by 2 reviewers independently, and any discrepancies in extraction were resolved after further discussion. When complications and frequency of need for

further surgery on the ipsilateral hallux were not explicitly addressed by a study, this was differentiated from a report of “zero incidence” and instead documented as “not reported” (N/R).

Quality Assessment of Included Studies

Quality assessment of all included studies was performed using the Modified Coleman Methodology Score (MCMS), a comprehensive tool for assessing both nonrandomized and comparative, randomized studies (Supplementary Table 2).^{1,9,13} As a quality assessment tool, it has been reported to be highly reproducible ($r=0.99$).⁵⁹ Level of evidence was gauged in accordance with the outline provided by the Oxford Center for Evidence Based Medicine.⁶¹

Statistical Analysis

The majority of studies were heterogeneous and nonrandomized, 1-armed case series. Quantitative analysis could not be performed given the paucity of studies examining interposition arthroplasty in a comparative setting. For multi-armed studies of a comparative nature containing subgroups undergoing one of several treatments for the arthritic first metatarsophalangeal joint, the “interposition arthroplasty” subgroup was treated separately for qualitative analysis. Because of the heterogeneity of studies with respect to operative procedure, patient population, and outcome measure, meta-analysis was not possible.

Results

Study Inclusion

Five hundred eighty articles were pulled from the combined database search, of which 172 appeared in more than 1 database. A total of 408 distinct articles were subject to title review. Articles were selected according to a well defined screening procedure (Figure 2). Ultimately, 20 studies were included (Table 1).

Study Quality Assessment and Levels of Evidence

The average MCMS for the included studies was 49.7 ± 9.2 (range, 33-63) indicating subpar methodological quality of the available literature (Table 2). Of the 17 studies of Level IV quality evidence, 12 (70.6%) defined their study populations retrospectively and/or collated and analyzed outcome scores based on a retrospective review of patient medical records. Of the 3 Level III studies, 2 concluded that interposition arthroplasty affords equivalent clinical outcomes to alternative surgical treatments (arthrodesis and Keller resection arthroplasty) and 1 reported inferior outcomes in the setting of comparison with cheilectomy (Table 3).^{34,36,51}

Table 1. Study Level of Evidence, Demographics, Interposition Type, Complications, and Reoperations.

| Study | LOE | Patients/ Feet | Age (y) | Males/ Females | Time to Follow-up (y) | Interposition | Revision Rate (%) | Complication Count ^{a,b} (n) |
|--------------------------------------|-----|-------------------|------------|-------------------|--------------------------|---------------------------------------------------------------------------------|----------------------|------------------------------------------|
| Vulcano et al (2018) ⁷⁰ | IV | 42/42 | 64 | 8/34 | 11.3 | Distally based autogenous dorsal capsule with EHB | 9.5 | 0 |
| Ayndardi et al (2017) ² | IV | 133/133 | 58 | 31/102 | 5.2 | Acellular dermal matrix allograft (n=56) | 3.8 | 31 |
| Daniels et al (2017) ¹⁶ | IV | 27/27 | 56 | 6/21 | 5.4 | Proximally based autogenous dorsal capsule with EHB (n=77) | 3.7 | 2 |
| Siclari et al (2017) ⁵⁵ | IV | 45/45 | 52 | 20/25 | 2.0 | Polyvinyl alcohol (PVA) hydrogel | 0.0 | 0 |
| Givissis et al (2017) ²⁰ | IV | 13/18 | 69 | 0/13 | 9.1 | Polyglycolic acid-hyaluronan implant | 5.6 | 5 |
| Clews et al (2015) ¹² | IV | 34/44 | 56 | N/R | 3.8 | Fascia lata allograft | N/R | N/R |
| Gould et al (2015) ²¹ | IV | 13/15 | 65 | 2/11 | 1.8 | Proximally based autogenous dorsal capsule, EHB, and extensor capsularis tendon | 6.7 | 11 |
| Hyer et al (2012) ²⁹ | IV | 6/6 | 54 | 1/5 | 5.4 | Autogenous fascia lata graft | 0.0 | 0 |
| DelaCruz et al (2011) ¹⁷ | IV | 12/13 | 49 | 4/8 | 1.4 | Acellular dermal regenerative matrix | N/R | 0 |
| Heller et al (2011) ²⁷ | IV | 31/31 | 48 | 24/7 | 4.6 | Meniscus allograft | 3.2 | 2 |
| Sanhudo et al (2011) ⁵⁰ | IV | 20/25 | 61 | 4/16 | 3.8 | Gelfoam sponge (absorbable gelatin powder) | N/R | 6 |
| Mackey et al (2010) ³⁶ | III | 10/10 | 64 | 5/5 | 5.3 | Proximally based autogenous dorsal capsule with EHB | 0.0 | N/R |
| Ozan et al (2010) ⁴⁵ | IV | 17/19 | 61 | 3/14 | 1.8 | Proximally based autogenous dorsal capsule with EHB | N/R | 32 |
| Schenk et al (2009) ⁵¹ | III | 14/22 | 55.3 | 6/8 | 1.4 | Proximally based autogenous dorsal capsule with EHB | N/R | 17 |
| Hahn et al (2009) ²³ | IV | 22/22 | 58 | 5/17 | 2.0 | Distally based autogenous medial capsule | N/R | 2 |
| Can Agkun et al (2008) ¹⁰ | IV | 11/13 | 65 | 3/8 | 2.3 | Proximally based autogenous dorsal capsule with EHB | 0.0 | 4 |
| Kennedy et al (2006) ³¹ | IV | 18/21 | 56 | N/R | 3.2 | Proximally based autogenous dorsal capsule with EHB | 4.8 | 3 |
| Roukis et al (2003) ⁴⁸ | IV | 12/15 | 52 | 8/4 | 1.4 | Distally based autogenous capsule, periosteum, and EHB | 0.0 | 0 |
| Coughlin et al (2003) ¹⁵ | IV | 7/7 | 56 | 0/7 | 3.5 | Autogenous ipsilateral gracilis tendon (n=3) | 0.0 | 8 |
| Lau et al (2001) ³⁴ | III | 11/11 | 59 | 6/5 | 2.0 | Autogenous ipsilateral peroneus longus or fascia lata (n=4) | 9.1 | 7 |
| | | | | | | Proximally based autogenous dorsal capsule with EHB | | |

Abbreviations: EHB, extensor hallucis brevis; LOE, level of evidence; N/R, not reported.

^aComplications were expressed as counts as opposed to percentages of a study population, as when manuscripts reported multiple types of complications, often these were not specified as occurring in discrete vs overlapping patients.

^bComplication counts are relatively high for some studies, probably because of inequivalence across studies as to what constituted a complication (ie, Ozan et al deem "loss of ground contact of the big toe" a complication).

Demographic Characteristics of Included Study Populations

A total of 498 patients and 539 feet underwent interposition arthroplasty of the first metatarsophalangeal joint with placement of an allogeneic, autogenous, or synthetic matrix as a joint spacer. The average age of the patients reported on was 57.6. Average time to follow-up for all patients was 4.5 years, with the average time to follow-up for included studies spanning the range of 1.4 to 11.3 years (Table 1).

Interposition arthroplasty was performed as an operative intervention most commonly in a patient population with

advanced degenerative changes at the first metatarsophalangeal joint. Thirteen (65.0%) studies described their study groups by way of the comprehensive Coughlin and Shurnas classification for grading first MTP joint damage.^{8,32} Operative intervention was most common in a population with grade 3 to 4 joint damage. The less comprehensive Hattrup and Johnson and Roukis classification systems were used less commonly, with grade 3 hallux rigidus patients, according to each respective classification system, the most common candidates for interposition arthroplasty.^{26,47}

| Inclusion Criteria | Exclusion Criteria |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <ol style="list-style-type: none"> 1. Full-text version of the study available in the English language in peer-reviewed journal 2. Treatment proceeded by way of interposition of soft-tissue or a synthetic "spacer" 3. Operative technique provided in the study manuscript 4. Clinical outcomes reported using at least one standardized outcome scoring measure (i.e. American Orthopaedic Foot & Ankle Society (AOFAS), Foot and Ankle Ability Measure (FAAM)) 5. Mean time to follow-up ≥ 1 year and ≥ 6 patients available at this time | <ol style="list-style-type: none"> 1. Case reports, technique articles, expert opinions, biomechanical studies, animal studies, concept reviews, and systematic reviews 2. Comparative outcome studies not including an interposition arthroplasty treatment arm 3. Patient series with more recent follow-up available |

Figure 1. Review inclusion and exclusion criteria.

Table 2. Aggregate Quality Assessment of Included Investigations.

| Quality Measure | Number of Studies (of Total) |
|--------------------------------------------------|------------------------------|
| Mean time to follow-up, n (%) | |
| <2 years | 5 (25) |
| 2-5 years | 9 (45) |
| 5-10 years | 5 (25) |
| >10 years | 1 (5) |
| Level of evidence, n (%) | |
| I | 0 (0) |
| II | 0 (0) |
| III | 3 (15) |
| IV | 17 (85) |
| Modified Coleman Methodology Score (MCMS), n (%) | |
| <55 (poor) | 14 (70) |
| 55-69 (fair) | 6 (30) |
| 70-84 (good) | 0 (0) |
| 85-100 (excellent) | 0 (0) |
| Study design, n (%) ^a | |
| Prospective | 6 (33) |
| Retrospective | 12 (67) |

^aEvaluated for 18 studies, as for 2 case series, it was unclear whether the study groups were defined prospectively or retrospectively.

In the 10 studies that reported on history of prior surgery on the ipsilateral hallux, 5 studies had some portion of the treatment group undergoing interposition arthroplasty as a revision procedure at the hallux. Prior surgeries included failed Keller resection arthroplasty, total toe replacement, phalangeal resurfacing implant, Chevron osteotomy, plantarflexion osteotomy, bursectomy, cheilectomy, dorsal osteophyte excision, and an interphalangeal fusion.

Interposition Material and Metatarsophalangeal Joint Decompression

The most common substance used for interposition in the included studies was autogenous first MTPJ capsular tissue

with or without the extensor hallucis brevis tendon, a technique reported on in 12 (60.0%) of the included articles (Table 1). There was some variability in the technique used for interposing autogenous capsular tissue. While a proximally based, dorsal capsule was most commonly used, 2 studies described interposition of a distally based capsule and 1 study reported interposition of medial capsular tissue sutured to the lateral capsule.^{23,48,60} The remaining studies reported interposition of a number of allogeneic and autogenous soft tissue types and synthetic matrices (Table 1).^{2,15,16,17,20,21,27,29,55} After 2010, a trend was noted toward increased usage of interpositional substances other than autogenous first MTPJ capsule (61.5% of studies after 2010 vs 7.7% of studies up through 2010).

Of the 12 included studies describing autogenous first MTPJ capsular interposition, 3 (25.0%) studies explicitly defined the proximal phalangeal resection procedure as $\geq 25\%$ of the bony substance with concomitant removal of intrinsic plantar attachments.^{34,45,51} The remaining studies describe less extensive proximal phalangeal excision with explicit mention of preservation of plantar attachments. Significant variability was noted in description of decompressive procedures of the metatarsal head, with resection ranging from isolated anatomic recontouring to "aggressive" dorsal cheilectomy.

Complications and Reoperation

The most common complication reported was transfer metatarsalgia of 1 or more lesser toes, with the range of incidence from 0.0% to 57.9%. Less frequent complications reported included calluses under the lesser metatarsal heads (27.3%-42.8%),^{15,34} stress fracture of one of the lesser toes resulting from transfer metatarsalgia (4.8%-9.1%),^{10,21,23,31,34} sensory neuroma or hyperpigmentation at the site of autograft harvesting (6.7%-14.3%),^{15,21} radiographic evidence of osteonecrosis of the first metatarsal head (7.7%-40.8%),^{10,51} numbness at the dorsum of the hallux or generalized hypoesthesia of the hallux (9.1%-15.8%),^{10,45,51} infection with or without need

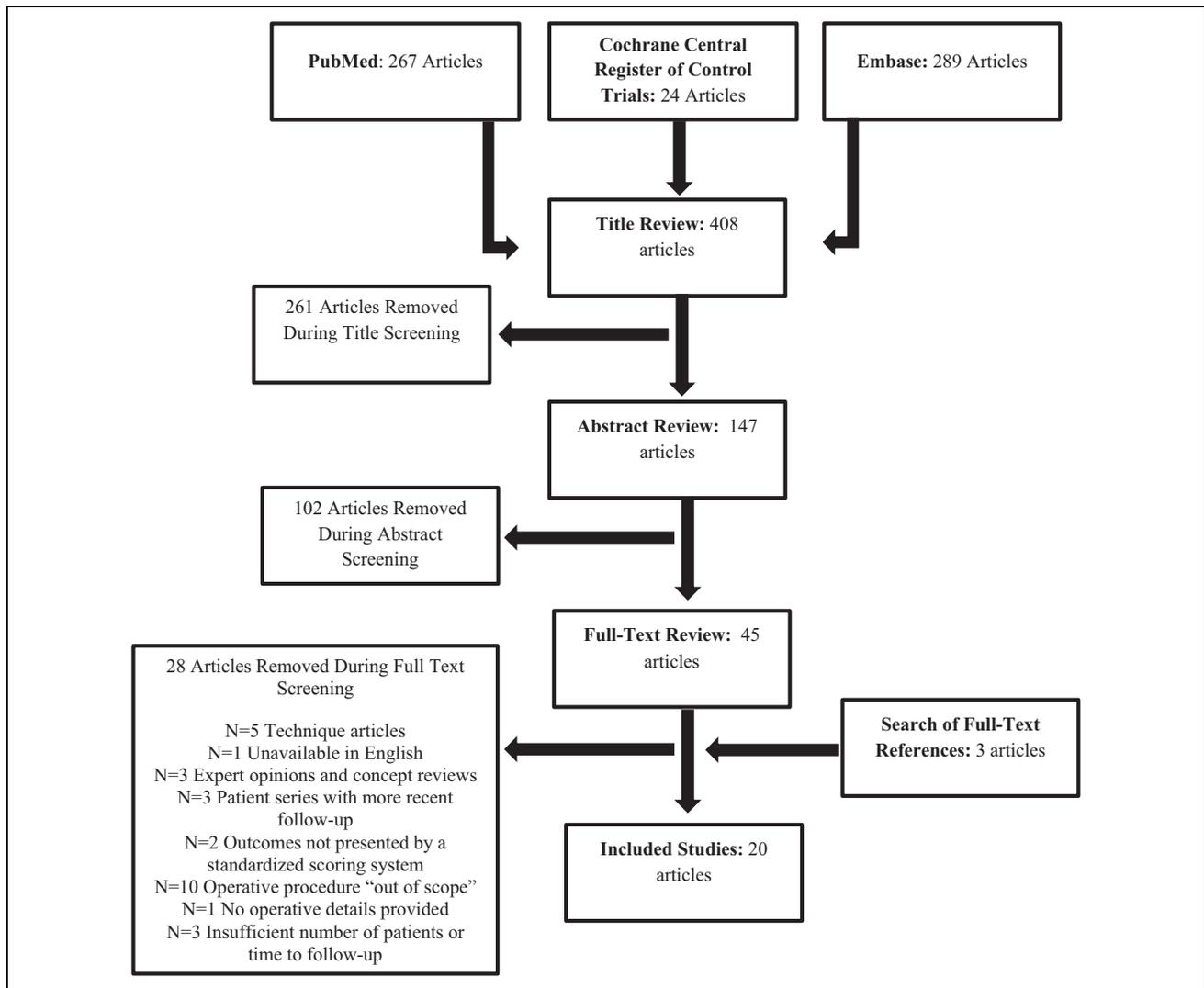


Figure 2. Screening procedure for study selection.

for subsequent debridement (1.5%-6.7%),^{2,20,21} cock-up deformity (4.5%),² proximal phalangeal cystic development (8.7%),¹⁶ claw-toe deformity (5.6%),²⁰ extensor hallucis longus (EHL) tendon entrapment (3.1%),²⁷ capsular ossification (4.5%),⁵¹ and regional pain syndrome (4.5%).⁵¹

In the 14 studies explicitly describing need for further surgery on the ipsilateral first MTPJ, 15 (3.8%) toes progressed to a subsequent operation. These further operations included arthrodesis (range of progression frequency, 2.3%-9.5%),^{2,16,20,27,60} revision interposition arthroplasty (0.75%),² manipulation under anesthesia to improve range of motion (4.8%),³¹ debridement of the joint with EHL tenolysis (0.75%),² and debulking of an oversized graft and further proximal phalangeal resection (6.7%).²¹

Standardized and Subjective Outcome Measures

The most commonly used outcome scoring measure was the American Orthopaedic Foot & Ankle Society Hallux

Metatarsophalangeal-Interphalangeal Scoring System (AOFAS-HMI). Two (10.0%) studies used a modified, reweighted version of the scale (Table 4).^{29,48} The minimal clinically important difference (MCID) for the AOFAS-HMI total score has only been studied in the setting of hallux valgus corrective surgery but is reported with some uncertainty, spanning the range of 7.9 to 30.2.¹¹ Of the 8 studies reporting preoperative and postoperative scores by way of an unmodified AOFAS-HMI scale, 6 (75.0%) reported mean improvement in the AOFAS-HMI total score exceeding 30.2 points, with the 2 additional studies reporting mean improvements of 23.0 and 24.6, respectively.^{10,15,17,20,27,45,51,55} The validated Foot Function Index (FFI), Foot and Ankle Ability Measure (FAAM), the Visual Analog Scale for Pain (Pain VAS), and the Short Form-36 Health Survey (SF-36) were the next most commonly used standardized outcome scoring measures. Of the 4 studies reporting pre and postoperative scores by one of these measures, all reported mean improvements exceeding the MCIDs for their respective

Table 3. Comparative Investigations Included in this Review with an Interpositional Arthroplasty Treatment Arm.

| Study | Level of Evidence | Treatment Groups | Outcome Measures | Study Conclusions |
|-----------------------------------|-------------------|---------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Mackey et al (2010) ³⁶ | III | 1. IA (n=10) 2. Fusion (n=12) | AOFAS-Total: 89.55, FAAM-ADL: 92.18, FAAM-Sport: 87.5, PPP (great toe): 33 N/cm ² , FS: 9.3 kg AOFAS-Total: 64.48, FAAM-ADL: 84.58, FAAM-Sport: 71.35, PPP (great toe): 67 N/cm ² FS: 10.79 kg | The modified oblique Keller capsular interpositional arthroplasty appears to afford equivalent clinical outcomes to fusion but affords a more normal plantar pressure pattern during ambulation. |
| Schenk et al (2009) ⁵¹ | III | 1. IA (n=22) 2. RA (n=30) | Increase in AOFAS-Total: 32, increase in ROM: 19.3° Patient graded outcome as excellent: 63%, good: 14%, fair: 18%, poor: 5% Increase in AOFAS-Total: 38, Increase in ROM: 24.0° Patient graded outcome as excellent: 63%, good: 10%, fair: 17%, poor: 10% | No significant benefit in clinical or radiographic outcome is observed for the capsular interposition arthroplasty over the Keller resection arthroplasty. |
| Lau et al (2001) ³⁴ | III | 1. IA (n=11) 2. Cheilectomy (n=24) | AOFAS-Total: 71.6, FFI-Pain: 27.7, Pain VAS: 3.9, Patient satisfaction: 72.7%, Great toe weakness: 72.7% of patients AOFAS-Total: 77.3, FFI-Pain: 21.0, Pain VAS: 2.9, Patient satisfaction: 87.5%, Great toe weakness: 16.7% of patients | Cheilectomy is a reliable treatment for moderate hallux rigidus. Management of severe arthritis with interposition arthroplasty has less reliable results and ought to be considered a "salvage" procedure. |

Abbreviations: AOFAS, American Orthopaedic Foot & Ankle Society; FAAM-ADL, Foot and Ankle Ability Measure Activities of Daily Living Subscale; FAAM-Sport, Foot and Ankle Ability Measure Sports Subscale; FS, flexion strength measured at distal phalanx; IA, interposition arthroplasty; PPP (great toe), peak plantar pressure under great toe; RA, resection arthroplasty; ROM, range of motion; VAS, Visual Analog Scale.

Table 4. Patient-Reported Standardized and Subjective Outcomes.

| Study | Preoperative Standardized Outcome Scores | Postoperative Standardized Outcome Scores | Additional Subjective Outcomes |
|-------------------------------------|-------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------|
| Vulcano et al (2018) ⁶⁰ | Pain VAS: 7.9, SF-12 Physical: 42.0, SF-12 Mental: 50.7, FFI-Total: 98.3 | Pain VAS: 1.8, SF-12 Physical: 64.2, SF-12 Mental: 54.6, FFI-Total: 49.6 Satisfaction VAS: 7.4/10 | Would have surgery again: 39/42 (92.9%) |
| Ayndardi et al (2017) ² | Pain Verbal Analog: 7.5, FFI-Total: N/R | Pain Verbal Analog: 2.0, FFI-Total: 77.1 | Excellent: 87/133 (65.4%), good: 32/133 (24.1%), fair or poor: 14/133 (10.5%); return to fashionable/regular footwear: 101/133 (75.9%) |
| Daniels et al (2017) ¹⁶ | Pain VAS: 6.41, FAAM-Sports: 39.2, FAAM-ADL: 61.4, SF-36 PCS: 39.5, SF-36 MCS: 55.6 | Pain VAS: 0.57, FAAM-Sports: 89.4, FAAM-ADL: 95.3, SF-36 PCS: 52.2, SF-36 MCS: 54.5 | Would undergo procedure again: 25/26 (96.2%); level of function: normal: 17/26 (65.4%) nearly normal: 8/26 (30.8%) abnormal: 1 (3.8%) |
| Siclari et al (2017) ⁵⁵ | AOFAS-Total: 49.8, AOFAS-Pain: 8.4, AOFAS-Function: 29.3, AOFAS-Alignment: 12.0 | AOFAS-Total: 92.3, AOFAS-Pain: 40.0, AOFAS-Function: 37.3, AOFAS-Alignment: 15.0 | Pain free after 12 months: 45/45 (100%) |
| Givissis et al (2017) ²⁰ | AOFAS-Total: 43.4, AOFAS-Pain: 17.5, AOFAS-Function: 25.9, AOFAS-Alignment: 2.9 | AOFAS-Total: 77.3, AOFAS-Pain: 30.6, AOFAS-Function: 35.3, AOFAS-Alignment: 11.4 | Would have surgery again: 9/13 (69.2%), a lot/adequately satisfied: 9/13 (69.2%), not at all satisfied: 4/13 (30.8%) |
| Clews et al (2015) ¹² | N/R | FHSQ Foot Pain: 80.3, FHSQ Foot Function: 88.1, FHSQ Footwear: 48.0, FHSQ General Foot Health: 68.6 | Satisfied or very satisfied: 28/34 (82.3%) |
| Gould et al (2015) ²¹ | N/R | Pain VAS: 1.0 | Returned to wearing low-heeled, fashionable shoes: 7/8 (87.5%) Returned to wearing high heels: 1/8 (12.5%) |

(continued)

Table 4. (continued)

| Study | Preoperative Standardized Outcome Scores | Postoperative Standardized Outcome Scores | Additional Subjective Outcomes |
|--------------------------------------|------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Hyer et al (2012) ²⁹ | Modified AOFAS-P/F: 38.0/68.0 | Modified AOFAS-P/F: 65.8/68.0 | Considered surgery successful: 6/6 (100%) |
| DelaCruz et al (2011) ¹⁷ | AOFAS-Total: 52.5 | AOFAS-Total: 90.0 | N/R |
| Heller et al (2011) ²⁷ | AOFAS-Total: 35 | AOFAS-Total: 74 | Patient graded outcome as: excellent: 9/30 (30.0%), good: 11/30 (36.7%), medium: 9/30 (30.0%), poor: 1/30 (3.3%) |
| Sanhudo et al (2011) ⁵⁰ | N/R | AOFAS-Total: 93.6, AOFAS-Pain: 36.4, AOFAS-Function: 42.5, AOFAS-Alignment: 14.7 | Completely satisfied: 15/20 (75.0%), partially satisfied: 5/20 (25.0%), would undergo same procedure again: 20/20 (100%) |
| Mackey et al (2010) ³⁶ | N/R | AOFAS-Total: 89.6, FAAM Sports: 92.2, FAAM-ADL: 87.5 | N/R |
| Ozan et al (2010) ⁴⁵ | AOFAS-Total: 60.7, AOFAS-Pain: 20.0, AOFAS-Function: 27.5, AOFAS-Alignment: 15.0 | AOFAS-Total: 85.3, AOFAS-Pain: 37.9, AOFAS-Function: 32.4, AOFAS-Alignment: 15.0 | Patient graded outcome as very good: 9/19 (47.4%), good: 7/19 (36.8%), moderate: 1/19 (5.3%), poor: 2/19 (10.5%) |
| Schenk et al (2009) ⁵¹ | AOFAS-Total: 57.0, AOFAS-Pain: 15.0, AOFAS-Function: 30.0, AOFAS-Alignment: 12.0 | AOFAS-Total: 80.0, AOFAS-Pain: 36.0, AOFAS-Function: 39.0, AOFAS-Alignment: 15.0 | Patient graded outcome as excellent: 14/22 (63.6%), good: 3/22 (13.6%), fair: 4/22 (18.2%), poor: 1/22 (4.6%) |
| Hahn et al (2009) ²³ | N/R | AOFAS-Total: 77.8, AOFAS-Pain: 28.2, AOFAS-Function: 34.9, AOFAS-Alignment: 14.2, SF-36: 72.9 | N/R |
| Can Agkun et al (2008) ¹⁰ | AOFAS-Total: 29.1 | AOFAS-Total: 93.6 | Patient graded outcome as: excellent: 11/13 (84.6%), good: 2/13 (16.4%), fair: 0/13 (0.0%), poor: 0/13 (0.0%) Would undergo the procedure again: 11/11 (100%) |
| Kennedy et al (2006) ³¹ | N/R | AOFAS-Total: 78.4, SF-36: 96.3 | Would undergo the procedure again: 17/18 (94.4%), less pain than preoperatively: 18/18 (100%), little or no pain: 16/18 (88.9%) moderate pain with exercise: 2/18 (11.1%) |
| Roukis et al (2003) ⁴⁸ | Modified AOFAS-Total: 25.0, Modified AOFAS-Pain: 10.4, Modified AOFAS-Function: 14.6, Modified AOFAS-Alignment/Cosmesis: 0.0 | Modified AOFAS-Total: 85.8, Modified AOFAS-Pain: 33.5, Modified AOFAS-Function: 33.3, Modified AOFAS-Alignment/Cosmesis: 19.0 | Would undergo the procedure again: 12/12 (100%) Would recommend procedure to a friend: 12/12 (100%) |
| Coughlin et al (2003) ¹⁵ | Pain VAS: 7.1, AOFAS-Total: 46 | Pain VAS: 1.6, AOFAS-Total: 86 | Patient graded outcome as excellent: 4/7 (57.1%), good: 3/7 (42.9%), walk in comfortable shoes without impingement: 7/7 (100%) |
| Lau et al (2001) ³⁴ | Pain VAS: 8.2 | Pain VAS: 3.9, AOFAS-Total: 71.6, AOFAS-Pain: 22.7, AOFAS-Function: 33.9, AOFAS-Alignment: 15.0, FFI-Pain: 27.7 | Satisfied: 8/11 (72.7%), unsatisfied: 3/11 (27.3%) Would undergo the procedure again: 9/11 (81.8%) |

Abbreviations: AOFAS-Total, American Orthopaedic Foot & Ankle Society Hallux Metatarsophalangeal Interphalangeal Scoring System Total Score; FAAM-ADL, Foot and Ankle Ability Measure Activities of Daily Living Subscale; FAAM-Sports, Foot and Ankle Ability Measure Sports Subscale; FFI-Total, Foot Function Index total score; FHSQ, Foot Health Status Questionnaire; Modified AOFAS P/F, Modified American Orthopaedic Foot & Ankle Society score to select for pain and function (out of 68); Modified AOFAS-Total, Modified American Orthopaedic Foot & Ankle Society HMI score with "cosmesis" added to the "alignment" section and reweighted subscales (pain: 40 points, function: 40 points, cosmesis/alignment: 20 points); Pain VAS, Visual Analog Scale for Pain; Satisfaction VAS, Satisfaction Visual Analog Scale; SF-36-MCS, Short Form-36 Mental Component Summary; SF-12 Mental, Short Form-12 Mental Component; SF-36 PCS, Short Form-36 Physical Component Summary; SF-12 Physical, Short Form-12 Physical Component Summary.

scoring systems (MCIDs: FAAM-ADL, 8; FAAM-Sports, 9; Pain VAS, $\geq 30\%$ difference; FFI-Total, 7).^{33,35,39}

Ten (50%) studies reported both preoperative and postoperative range of motion measurements with statistical treatment of the observed changes in range of motion. Nine (90.0%) of these studies reported statistically significant improvements in dorsiflexion from preoperation to postoperation whereas the 2 studies quantifying change in plantarflexion noted no improvements in this measure. A wide variety of additional subjective outcomes were collected across the included studies in an effort to measure patient satisfaction and level of function (Table 4).

Discussion

Interposition arthroplasty appears to be a viable option for the treatment of moderate to severe hallux rigidus in a patient population looking to salvage motion through the first metatarsophalangeal joint. In studies reporting preoperative and postoperative outcomes with an outcome scoring system, mean group improvements exceed MCIDs in the majority of studies. Subjective patient-reported outcomes suggest a high percentage of postoperative satisfaction, and improved postoperative range of motion in dorsiflexion is frequently noted.

Nonetheless, these findings should be interpreted with caution. The large majority (85.0%) of the studies included in this review were of Level IV quality evidence, and of this subset of studies, 70.6% were of a retrospective nature. Only 14 (70.0%) of the included studies captured both preoperative and postoperative scoring measures on their treatment groups. Using a retrospective chart review to collate AOFAS-HMI scores is a practice that has been subject to criticism in the past, given its tendency to underestimate the tabulated value and subsequently inflate the impression of a treatment's efficacy.⁵² There is conflicting evidence in the literature as to the true construct validity and reliability of the AOFAS scoring system, and its historically central place as a proxy for surgical outcome from treatment of the hallux has been questioned.^{5,30,38,57} Additionally, in the comparative setting with arthrodesis, the AOFAS scoring system is a limited construct, given its partial assessment of outcome as a function of mobility.

Currently, there is significant interest in defining the relative efficacy of first metatarsophalangeal joint fusion in comparison to a motion-salvaging, interpositional technique. Only 1 study included in this review offered such a comparison: a Level III retrospective study concluding that interposition of autogenous dorsal capsule affords a more normal pattern of plantar pressure during standard gait than does arthrodesis with equivalent clinical outcomes.³⁶ However, use of the AOFAS-HMI as a scoring system, the retrospective character of the study, and underpowered sample sizes for cross-treatment comparisons all limit the study's conclusions. More recently, a prospective, randomized,

noninferiority trial was conducted to assess the efficacy of polyvinyl alcohol hydrogel implant in the setting of a side-by-side comparison with arthrodesis.⁶ The investigation concluded that the implant is safe and affords equivalent functional outcomes and pain relief as does arthrodesis through short-term follow-up. As a prospective randomized trial with a prospectively defined endpoint, use of validated outcome scoring measures, high rate of follow-up, a standardized surgical procedure, and a multicentered and geographically inclusive design, the study in many ways has set a gold standard for how surgical options for hallux rigidus might be evaluated moving forward. A subset of the hydrogel implant group has now reached minimum 5-year follow-up, and, as noted in this review, the implant has demonstrated high rates of survival (96.3%) at midterm.¹⁶ Nevertheless, whether these success rates will be reproduced in studies born from third-party investigators is unknown and such studies will be received with great interest.

Beyond the above-mentioned prospective, randomized study, only 2 additional studies included in this review reported outcomes based on the grade of degenerative change at the first MTP joint. One study reported significant improvement ($P < .01$) in patients with grade 3 over grade 4 hallux rigidus (Coughlin and Shurnas Classification).⁵⁰ However, the clinical significance of the differences in those postoperative outcome scores is unclear. Radiographic grade was found to make no difference with regard to outcome in another study.³¹ Although patient selection is thought to be important in optimizing surgical outcome, the mainstay classification schemes for grading hallux rigidus severity do not appear to correlate with intraoperative findings, pain, and active range of motion.⁷ Future studies exploring the role of interposition arthroplasty and arthrodesis in a comparative setting might benefit from exploring outcome as a function of intraoperative appearance of the joint, preoperative pain levels, and range of motion rather than by levels of the existing classifications for grading joint deterioration. The difficulty with a randomized assignment of interposition arthroplasty and arthrodesis is the strong preferences patients may hold to maintain postoperative motion through the hallux. As randomization can lead to a significant rate of study dropout (23.0%), high-quality, nonrandomized, prospective cohort studies might be a more feasible option for exploring this comparison.⁶

The resection arthroplasty with subsequent interposition of autogenous soft tissue has long been described, even prior to the dates of publication of the studies included in this review. Both "bundle soft tissue" interposition arthroplasty and capsular interposition techniques have a long history in the literature, with very early descriptions of this "bundle soft tissue" technique including interposition of gastrocnemius-soleus tendon, extensor hallucis longus tendon, gracilis tendon, and plantaris tendon bundles.^{4,14,41} However, the most recent systematic review dedicated to exploring outcomes from these interpositional techniques pre-dated the rapid emergence of outcome-centered

investigations exploring the role of allogeneic soft tissue and synthetic, pliable substrates as joint spacers.⁴⁹ Many of these studies have surfaced in the literature in recent years, as the movement toward both promoting chondrostimulation and regeneration and developing matrices to serve as functional chondral replacement has gained momentum.^{18-21,27,29,55} Interestingly, studies reporting on opportunities for biopsy of autogenous interposed capsular tissue in the setting of surgery needed on the lesser rays after interposition arthroplasty have noted the appearance of a viable fibrocartilaginous flap in the first MTP joint.^{2,43}

Despite all of these innovative and promising efforts, only 1 of the studies included in this review evaluated autogenous and allogeneic interpositional material comparatively, noting no difference in failure rate or incidence of transfer metatarsalgia between the placement of autogenous dorsal capsule and acellular dermal matrix allograft.² Immunogenic reactions have been reported anecdotally with allografting of the first MTP joint, whereas autogenous “bundle soft tissue” placement has been associated with donor site morbidity.^{15,21} Although the isolated dorsal and medial autogenous capsular interpositional techniques can minimize these potential complications, the local capsular interpositional techniques may not provide sufficient tissue for grafting, particularly of the sesamoid-metatarsal articulation. Additionally, although the technique has evolved over time to minimize the extent of phalangeal resection and to preserve plantar proximal phalangeal attachments, transfer metatarsalgia is still observed with some frequency as a postoperative complication. At this time, despite an array of available interpositional materials, there is limited evidence suggesting the improved efficacy of one implant over the many others. The relative importance of the quality and extent of debridement and decompressive technical work vs graft choice also remains unclear.

There are a number of limitations of this review, primarily related to the quality of the current literature that is available on this subject, which in many ways is an important finding in and of itself. The paucity of prospective, multi-armed studies using a reliable and validated common scoring measure prevented the possibility of meta-analyses and firm treatment recommendations. Additionally, the generalizability and sustainability of the included studies’ findings are difficult to gauge, given that the treatment populations were fewer than 30 patients in 75% of the included studies and 70% of the studies evaluated patients at less than midterm follow-up time.

In conclusion, interposition arthroplasty appears to be a viable option for the treatment of moderate to severe hallux rigidus in patients looking to salvage motion through the first metatarsophalangeal joint. A wide array of autogenous, allogeneic, and synthetic implants have debuted in recent years, but long-term follow-up and prospective, comparative studies are lacking. Patient-reported outcomes suggest high postoperative satisfaction, and improved postoperative range of

motion in dorsiflexion is frequently noted regardless of interpositional material and operative technique.

Declaration of Conflicting Interests

The author(s) declared no potential conflicts of interest with respect to the research, authorship, and/or publication of this article. ICMJE forms for all authors are available online.

Funding

The author(s) received no financial support for the research, authorship, and/or publication of this article.

Supplemental Material

Supplemental material for this article is available online.

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