Primary Fusion versus Metatarsal Hemiarthroplasty for the Treatment of Advanced Hallux Rigidus. A Systematic Literature Review.

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Introduction

Hallux Rigidus (HR) is a common degenerative disease of the foot[1-5] presenting with pain, limited motion in the sagittal plane and some form of functional impairment[4]. Estimations have shown an 8% prevalence of symptomatic radiographic first metatarsophalangeal (MTP) osteoarthritis (OA) in community based adults aged 50 years and over, with 72% reporting disabling foot symptoms[6]. Bilateral involvement with clinical and radiological evidence has been shown to be as high as 79%[7].

Treatment solutions target pain relief, improvement of motion (ROM), proper alignment, maintenance of the medial column and toe length, re-establishing normal foot function and gait pattern[8].

The literature shows good agreement for the management of early stage HR with conservative measures such as shoe modification, oral anti-inflammatory medication, activity modification and intra-articular injections[1-4]. Failure of conservative modalities typically results in joint preserving procedures such as cheilectomy, or decompressive osteotomies[4-9].

The treatment of advanced stages of Hallux Rigidus remains controversial; however, arthrodesis continues to be considered the “gold standard” in the literature[10-13] despite reports of risks and complications including revision surgery for hardware removal, non-union, or mal-union, hardware migration, as well as persistent pain or pressure, and changes to forefoot kinematics[14-24].

Historically in the United States, hemiarthroplasty for HR largely involved the phalangeal side until the introduction of metatarsal hemiarthroplasty in 2005 (HemiCAP®, Arthrosurface, Franklin, MA). The purpose of this study was to evaluate the clinical results of advanced Hallux Rigidus with a systematic review comparing primary fusion to the newer metatarsal based hemiarthroplasty using pain, function, satisfaction, and reoperation rate as the primary outcomes.

Material and Methods

A literature search strategy was developed with the intent to isolate studies with homogenous cohorts and clinically relevant endpoints that would allow for a comparison of primary fusion and metatarsal hemiarthroplasty. Various nomenclatures and combinations terms were used to cover the indication and procedure specific spectrum. The following Mesh headings and key words were identified to construct the query and perform a search of the PubMed database (pubmed.gov):

Hallux rigidus Or hallux limitus Or toe arthrodesis Or toe fusion Or metatarsal phalangeal arthrodesis Or metatarsal phalangeal fusion Or metatarsal hemiarthroplasty Or toe hemiarthroplasty Or toe resurfacing Or metatarsal resurfacing Or toe implant.

The search was limited to a single filter with a publication date range arbitrarily set to include publications from 2005 onward (01/01/2005 to 05/10/2016) ensuring consistent use of modern arthrodesis techniques which also coincided with the year metatarsal hemiarthroplasty was introduced. An endpoint in the publication range (date of search) was chosen to improve the reproducibility of this study.

Inclusion and exclusion criteria were defined at the onset of the study to identify suitable publications for inclusion into the final review (Table 1). The indication was limited to hallux rigidus or hallux limitus (HL). Studies were included if the entire cohort or subgroups met these indications and results were reported specifically. Only the English literature was chosen and non-English articles were excluded during the systematic review. Only primary fusion procedures were considered. Each study cohort or subgroup had

to be larger than 10 procedures similar to the meta-analysis performed by Brewster[8]. Results for each intervention or etiology had to be reported separately if multiple procedures or etiologies were included in the study. In order to compare the clinical results, AOFAS scores and / or VAS pain scores were required as well as a demographic description of the study cohort.

In order to reduce bias, the risk of publication overlap was considered and studies with similar authors, cohort sizes, indications, procedures, and treatment date ranges were excluded and only the study with the most data or longest follow-up was considered. All preclinical, basic science, cadaver, or biomechanical studies were excluded. Review articles, technique publications, non-surgical treatments, anatomic or radiographic studies, study design reports, editorial or author comments and alternative etiologies for first MTP degeneration such as rheumatoid arthritis were excluded. Secondary fusions after failed arthroplasty were also excluded to limit comparative bias.

Table 1: Study Selection Criteria

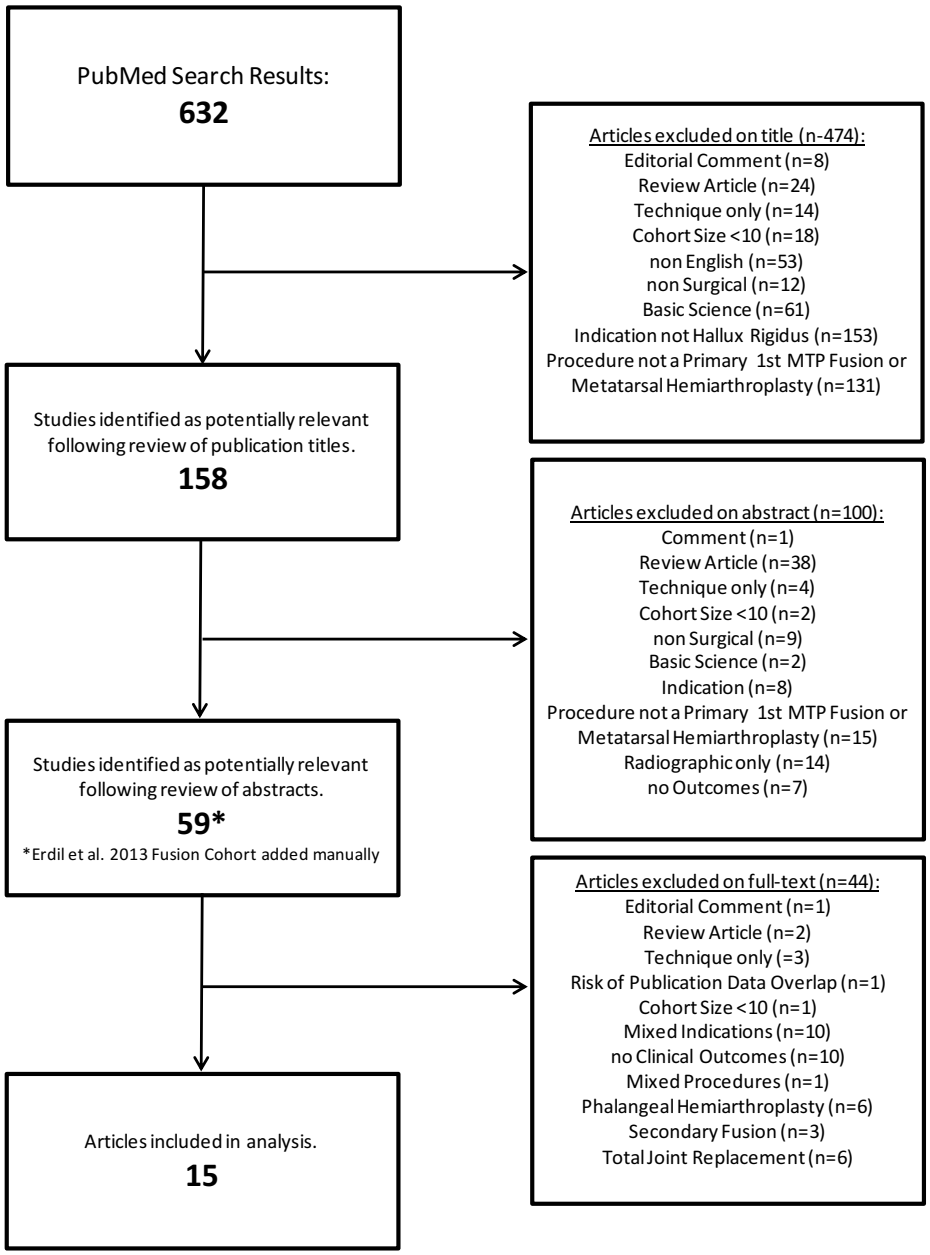
Inclusion Criteria	Exclusion Criteria
• Indication: Hallux Rigidus/Hallux Limitus • Human studies available in English • Primary Arthrodesis/Fusion or metatarsal hemiarthroplasty of the first MTPJ • Series or cohort with n >10 • Results for each intervention type or etiology type were separable if more than one procedure or etiology was included in a study. • AOFAS Scores and/or VAS pain • Documented demographics of patients for comparison purposes • Publication date range: 01/01/2005 to 05/10/2016	• Risk of Publication overlap. For data reported for the same series of patients in different articles, only one series was used (the one with the most data or longest follow-up) • Preclinical, basis science, cadaver or biomechanical study • Review article • Technique only • Non Surgical Treatment • Anatomic study • Radiographic only • Study design only • Editorial comment or author comment • Rheumatoid arthritis main focus • Secondary arthrodesis after failed arthroplasty

The systematic review was performed in three steps (Figure 1): The initial query resulted in 632 articles. During step one, study titles and citations were reviewed. 474 publications did not meet the selection criteria and were excluded. The resulting 158 studies were then reviewed based on their abstract content during step two and 100 additional publications were eliminated. The comparative study by Erdil et al.[1] met all the selection criteria for both the arthrodesis and metatarsal hemiarthroplasty subgroups. The fusion cohort was added manually as a separate entry resulting in an increase from 58 to 59 all of which were reviewed in full text during step three. Upon exclusion of an additional 44 publications, 15 studies were included in the review.

In order to increase the potential for inclusion, AOFAS and/or VAS Pain scores were considered regardless whether they stemmed from the follow-up time point alone or included a baseline assessment. The validity of the AOFAS score has been previously questioned, however its subjective component has been validated in the past by Ibrahim et al.[25]. Based on their findings, the authors believe that the AOFAS clinical rating scales can be used to formulate valid conclusions in patients with foot and ankle problems. Various forms of patient satisfaction were considered for inclusion: Categorical ratings from poor to excellent, categorical ratings from not satisfied to very satisfied or categorical ratings that would indicate if patients would/or would not undergo the procedure again. The reoperation rate, complications, non-union or delayed union reports all were limited to 1st MTP index joint related procedures.

Figure 1: Flowchart of Systematic Review

(Publication range: 01/01/2005 to 05/10/2016)



Results

Prior to the systematic review, a study endpoint review was performed (Table 2): Complete pre- and postoperative VAS pain scores were available in 50.0% of the fusion studies (Pre: 50.0%, Post: 87.5%) compared to 71.4% in the metatarsal hemiarthroplasty studies (Pre: 71.4%, Post: 71.4%). All VAS scores were converted to a scale from 0-10 where applicable. Pre- and postoperative AOFAS scores were available in 25.0% (Pre: 25.0, Post: 62.5%) of the fusion group, compared to 85.7% in the hemiarthroplasty group (Pre: 85.7, Post: 100.0%). Satisfaction data were available in 50.0% of the fusion

studies and 42.9% of HemiCAP studies. Re-operations were addressed in 75% of the arthrodesis studies and 85.7% of the hemiarthroplasty studies. Complications were included in 87.5% of both study groups and 87.5% of the arthrodesis publications reported on non-union or mal-unions. Reoperation, complication, and non-union rates were either accepted verbatim, or calculated on the basis of the procedure volume (Number of reported non-unions divided by the total number of procedures, multiplied by 100). Based on the study selection criteria and PubMed indexing, both treatment options showed a similar publication volume since 2005.

Table 2: Systematic Review - Outcomes Parameters

Publication	Preop Pain VAS	Postop Pain VAS	Preop AOFAS	Postop AOFAS	Satisfaction	Reoperation	Complications	Nonunion/ Delayed union
Fusion								
Raikin 2007[26]	NR	✓	✓	✓	✓	✓	✓	✓
Aas 2008[27]	NR	✓	NR	✓	NR	✓	✓	✓
Simons 2015[28]	NR	NR	NR	✓	✓	✓	✓	✓
Erdil 2013[1]	✓	✓	✓	✓	NR	NR	✓	✓
Maher 2008[29]	✓ *	✓*	NR	NR	NR	✓	NR	NR
Beertema 2006[30]	NR	✓	NR	✓	✓	NR	✓	✓
Gibson 2005[31]	✓*	✓*	NR	NR	✓	✓	✓	✓
Baumhauer 2016[12]	✓*	✓*	NR	NR	NR	✓	✓	✓
HemiCAP								
Carpenter 2010[32]	NR	NR	✓	✓	✓	✓	✓	n/a
Aslan 2012[33]	✓	✓	✓	✓	NR	✓	✓	n/a
Dos Santos 2013[34]	✓	✓	✓	✓	NR	NR	NR	n/a
Kline 2013[35]	✓	✓	✓	✓	✓	✓	✓	n/a
Erdil 2013[1]	✓	✓	✓	✓	NR	✓	✓	n/a
Meric 2015[36]	✓	✓	✓	✓	NR	✓	✓	n/a
Gheorghiu 2015[37]	NR	NR	NR	✓	✓	✓	✓	n/a

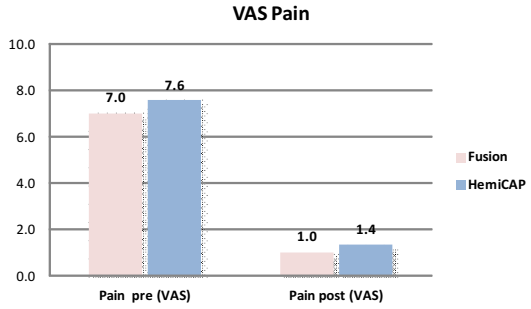
- NR: not reported
- *VAS Pain converted from a scale of 100 to 10
- Carpenter 2010[32]: Pre and postop Pain reported with AOFAS subscore
- Simmons 2015[28]: Follow-up Pain reported with FAOS and FFI subcscores
- Maher 2008[29]: Pre- and postop Pain reported as FHSQ pain domains (combination of frequency and intensity questions); conversion to final score not described
- Beertema 2006[30]: No overall postoperative AOFAS scores provided, Grade III subgroup was chosen

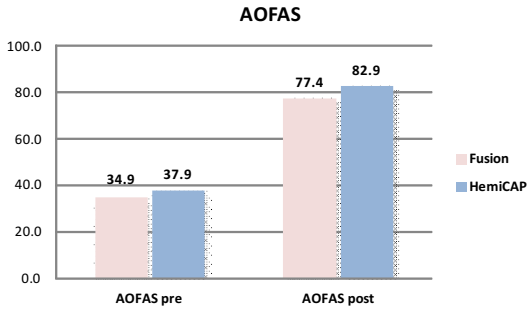
The mean level of evidence for fusion studies was 2.8 (range 1-4) compared to 3.6 in the hemiarthroplasty group (range: 2-4). The combined procedure volume for fusion studies was 372 and 140 for metatarsal hemiarthroplasty procedures. Fusion studies included an average of 46.5 procedures (range: 12-150), whereas hemiarthroplasty studies reported a mean of 20 procedures (range: 11-32). The mean patient age was similar with 54.9 (range 52.0-59.6) years in the arthrodesis group and 56.8 (51.0-62.8) years in the hemiarthroplasty group. The mean follow-up was 42.8 months (range: 7.5-96.0) in the fusion group and 34.0 months (range: 24.2-47.0) in the hemiarthroplasty group.

The mean preoperative VAS pain score improved from 7.0+/- 0.8 (range 6.1-8.0) (n=4) to a postoperative mean score of 1.0+/- 0.5 (range 0.5-2.0) (n=7) in the fusion group the same score improved from 7.6 +/-

0.9 (range 6.6-8.4) (n=5) to 1.4 +/- 0.5 (range 0.7-2.1) (n=5) in the hemiarthroplasty group. The mean baseline AOFAS score improved from 34.9+/- 1.8 (range 33.6-36.1) (n=2) to an average of 77.4 +/- 4.5 (range 73-83.8) (n=5) in the arthrodesis group and from 37.9+/- 7.7 (range 30.8-51.5) (n=6) to 82.9 +/- 8.7 (range 66.5-94.1)(n=7) for the hemiarthroplasty procedures. The average satisfaction rate was 79.1+/- 0.1% (range 0.6-0.9) (n=4) for the fusion group and 85.0+/- 0.3% (range 0.6-1.0) (n=3) in the HemiCAP group. The mean reoperation rate was 10.0 +/- 7.0% (range 0-19) (n=6) in the arthrodesis group and 3.4+/- 5.6% (range 0-13.3) (n=6) in the hemiarthroplasty group (p=0.1). Other complications in the fusion studies included plantar calluses, instability, irritation from hardware, metatarsalgia, erythema/exsudate, and broken hardware. The hemiarthroplasty group reported infection, metatarsalgia and implant subsidence. The clinical endpoint comparison is summarized in Figure 2 and the corresponding Source Data is listed in Appendix A.

Figure 2: Clinical Endpoint Comparison of Fusion vs. Metatarsal Hemiarthroplasty (HemiCAP)





Publication Source (Table 2):

Fusion – Pain

Pre: 1,12,29,31 **Post**:1,1,26,27,29,30,31

HemiCAP – Pain

Pre:1,33,34,35,36 **Post**:1,33,34,35,36

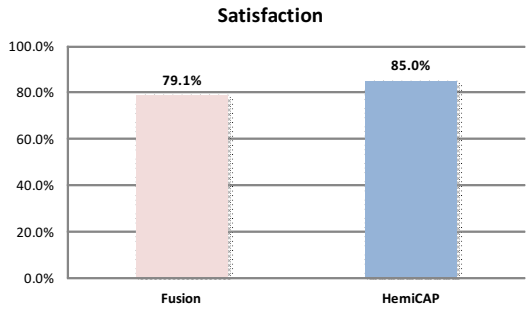
Publication Source (Table 2):

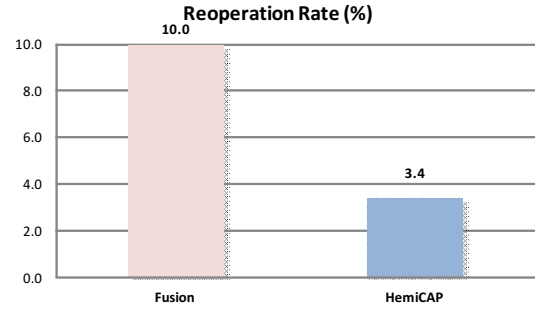
Fusion - AOFAS

Pre: 1,26 **Post**: 1,26,27,28,30

HemiCAP - AOFAS

Pre:1,32,33,34,35,36 **Post**: 1,32,33,34,35,36,37





Publication Source (Table 2):

Fusion – Satisfaction

Post:26,27,30,31

HemiCAP – Satisfaction

Post:32,35,37

Publication Source (Table 2):

Fusion – Reoperation Rate

Post: 12,26,27,28,29,31

HemiCAP - Reoperation Rate

Post: 1,32,33,35,36,37

Discussion

Due to the variability in endpoint reporting across all included studies, the review was performed using existing data components and is therefore limited in its generalizability. Although fusion is mainly used to relieve pain, the hemiarthroplasty group showed a larger impact on VAS pain relief improving by 6.1 points versus 4.9 points in the fusion group. The overall hemiarthroplasty results were comparable to fusion over the study time duration. Motion is a theoretical advantage of the arthroplasty procedure; however range of motion cannot be compared to joint fusion and was therefore not part of this review. Consistent with these results, the average satisfaction rating was higher for metatarsal hemiarthroplasty when compared to the fusion group. Arthrodesis by default is intended to be an end stage procedure, as such, it is surprising that its reoperation rate was nearly 3 times higher than that of the hemiarthroplasty group. Larger cohort sizes and longer follow-up in the fusion studies may explain this observation therefore future studies will need to revisit these findings.

Limitations

The quality of systematic reviews is directly related to the quality of the studies identified in the literature through a structured search and elimination process. Since 2005, the English literature indexed in the PubMed database has produced a relative paucity of high level studies on the treatment of advanced stages of hallux rigidus with clean cohorts that include clinically relevant endpoints such as VAS pain reduction, functional improvement expressed with a well published score such as the AOFAS, patient satisfaction, and reoperation rates.

Overall, the chosen clinical endpoints showed better availability for metatarsal hemiarthroplasty studies. Particularly longitudinal studies with baseline and follow-up AOFAS scores showed a substantially better reporting for hemiarthroplasty (85.7%, vs. 25.0%). Satisfaction ratings were reported in half (fusion) of the studies or less (hemiarthroplasty 42.9%). In order to strengthen the validity of systematic reviews, future meta-analyses on this topic would benefit from longer follow-up, larger cohorts, and higher level evidence in the metatarsal hemiarthroplasty group as well as a widening of the publication date range to include earlier arthrodesis studies with additional pre and postoperative pain and function data utilizing a VAS Pain score and a validated scoring system.

Conclusions

Preliminary results from this systematic review suggest that metatarsal hemiarthroplasty is an acceptable alternative to arthrodesis and provides equal or better clinical results with higher satisfaction and lower complication rates at two to four years after the procedure. Longer follow-up and larger cohorts particularly for hemiarthroplasty and wider publication ranges for arthrodesis studies will be required to substantiate these findings and allow for more definitive conclusions.

Key Words

Indications: Hallux Rigidus, Hallux Limitus
Procedures: Fusion, Arthrodesis, Metatarsal Hemiarthroplasty
Joints: First Metatarsophalangeal Joint

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Appendix A: Systematic Review Data

Authors	Procedure	Level of Evidence	Patients/ Joints	Age at Operation	Follow-up (mths)	Pre-op AOFAS	Post op AOFAS	Preop Pain (VAS)	Postop Pain (VAS)	Satisfaction %	Reoperation Rate (%)
Raikin et al.[26]	Fusion	3	26/27	54.1 (32-73)	30 (13-67)	36.1	83.8	NR	0.7	82	7
Aas et al.[27]	Fusion	4	35/39	52 (34-69)	96 (24-180)	NR	74 +/- 15 (23-90)	NR	1 +/- 2.3 (0-8.4)	NR	12.8
Simons et al.[28]	Fusion	3	132/150	59.6 +/- 9.5	41.5 (13-98)	NR	80.2 (18,1-100)	NR	NR	64	15.2
Erdil et al.[1]	Fusion	3	12/12	58.2 +/- 8.5	35.3 (24-66)	33.6 +/- 3.8	76.1 +/- 5.7	8 +/- 0.7	0.5 +/- 0.7	NR	NR
Maher et al.[29]	Fusion	4	29/29	52 +/- 24.7 (39-74) F 55 +/- 16.2 (44-67) M	7.5 (3.3-23)	NR	NR	7.1 (0-10)	1.3 (0-8.9)	NR	0
Beertema et al.[30]	Fusion	3	34	54 (31-68)	84 +/-38.4 (24-156)	NR	73 (Grade III)	NR	2 (Grade III)	85	NR
Gibson et al.[31]	Fusion	1	21/34	54.2 +/- 10.6 (34-77)	24	NR	NR	6.1 +/- 1.8	1.1	85.3	5.8
Baumhauer et al.[12]	Fusion	1	47/47	54.9 +/- 10.5 (32-78)	24	NR	NR	6.9 +/- 14.3 (3.8 -9.8)	0.6 +/- 1.2 (0-7)	NR	19
Carpenter et al.[32]	HemiCAP	2	30/32	62.8 +/- 9.7 (39-86)	27.3 +/- 9.1 (12-43)	30.8 (10-54)	89.3 (70-100)	NR	NR	100	0
Aslan et al.[33]	HemiCAP	4	25/27	58 (40-71)	37.6 (30-43)	40.9 (25-63)	85.1 (54-98)	8.3	2.05	NR	0
Dos Santos et al.[34]	HemiCAP	4	11/11	51.9 +/- 1.1 (46-58)	44.8 +/-0.1 (36-48)	32 +/- 0 (32-32)	77.3+/- 0.8 (75-80)	6.6 +/ 0.15 (6-7)	0.7 +/-0.3 (0-2)	NR	NR
Kline et al.[35]	HemiCAP	4	26/30	51 (35-74)	27 (17-38)	51.5 +/- 12.6 (35-74)	94.1 +/- 6.2 (82-100)	6.8	1.4	100	13.3
Erdil et al.[1]	HemiCAP	3	14/14	58.14 +/- 6.1	30.2 (24-42)	38.4+/- 6.7	86.1 +/- 6.9	7.9 +/- 0.7	1.4 +/- 0.9	NR	0
Meric et al.[36]	HemiCAP	4	14/14	58.7 +/- 7.4 (52-75)	24.2 +/- 7.2 (12-36)	33.9 +/- 9.8	81.6 +/- 10.1	8.4 +/- 0.9	1.2 +/- 1.2	NR	7
Gheorghiu et al.[37]	HemiCAP	4	11/12	NR	47 (36-48)	NR	66.5 (22-92)	NR	NR	55	0

NR: Not reported