

Thou Shalt not Fuse: Implant Survival Outcomes and Complications Following Arthroplasty in Hallux Rigidus

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ABSTRACT

Aims and background: Hallux rigidus (HR) is a condition characterized by pain and loss of range of motion of the metatarsophalangeal joint (MTPJ) of the great toe caused by degenerative arthritis. The aim of this article is to present the clinical outcomes, survival, and complication profile of the available implants for the salvage of the first MTPJ.

Materials and methods: This study is a narrative review of the current evidence base assessing joint-sparing procedures using interposition implants. A comprehensive literature search was performed in PubMed by two investigators, and data were categorized based on implant option.

Results: Silastic, metallic, and polyvinyl alcohol (PVA) implants were analyzed. The majority of the studies demonstrated satisfactory clinical outcomes and survivorship, and low complication rates for all types of implants. Nevertheless, there are a few reports of poor results after arthroplasty for HR.

Conclusion: Arthroplasty of the first MTPJ for the management of HR yields satisfactory functional outcomes and reasonable pain relief. Future prospective studies are needed to confirm the findings of the present study.

Clinical significance: Arthroplasty may be a safe alternative to an arthrodesis while preserving the range of movement of the first MTPJ.

Keywords: Arthroplasty, Complications, Hallux rigidus, Metatarsophalangeal arthritis, Outcomes, Survival.

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INTRODUCTION

Hallux rigidus (HR) is a common condition characterized by pain and loss of range of motion of the metatarsophalangeal joint (MTPJ) of the great toe caused by degenerative arthritis. HR affects 2.5% of people over the age of 50, and it is twice more common in female patients.¹ Several predisposing factors have been described, including acute trauma and repetitive microtrauma, anatomical variations, such as metatarsus adductus, familial history, shoe wear, and female gender. However, the exact etiology remains unknown.²

Mild and moderate cases of HR have been traditionally treated with conservative measures, such as nonsteroidal antiinflammatory drugs, intraarticular steroid injections, and orthotics or with dorsal cheilectomy.^{3,4} Arthrodesis of the first MTPJ has been widely accepted as the gold standard for the treatment of end-stage HR.⁵ More recently, joint-sparing techniques have been introduced as an alternative treatment option to severe HR. The main advantage of these techniques over arthrodesis is the preservation of the range of movement without the risk of nonunion or malunion.

The first implant for the first MTPJ arthroplasty was designed in 1952 by Swanson and was followed by several modifications. Lack of appreciation of 1st MTPJ biomechanics and appropriate patient selection led to poor medium to long-term outcomes.⁶ Since then, there has been a constant improvement in materials and designs. Currently, there are numerous implants available, including silastic, metallic, as well as the recently introduced polyvinyl alcohol (PVA) implants. The purpose of this article is to present the clinical outcomes, survivorship, and complication profile of the available implants for the salvage of the first MTPJ.

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MATERIALS AND METHODS

This study is a narrative review of the current evidence base assessing the first MTPJ-sparing procedures using interposition implants. A comprehensive literature search in PubMed was performed using the following search terms—"HR," "first MTPJ osteoarthritis," "treatment," "surgery," "arthroplasty," "hemiarthroplasty," "silastic," "metallic," "Swanson" "polyvinyl alcohol," "Cartiva," and "implant" with "AND" and "OR" as Boolean terms. Relevant publications were retrieved as full-text articles, and reference lists of the related articles were hand-searched for any additional eligible studies. Only articles published in peer-reviewed journals and only articles written in English were included in the review. Two investigators extracted the relevant data from the eligible studies. Finally, data were categorized based on implant options to present the

outcomes, survivorship, and complications associated with each one. Detailed characteristics of the included studies in the review are presented in Table 1.

RESULTS

Silastic Implants

The first implants for the first MTPJ arthroplasty were silastic, with a single-stemmed design, and they were used to replace the base of the proximal phalanx. As such, they acted as spacers and were used in conjunction with a Keller excision arthroplasty. Initial reports in the 1980s were associated with extremely high failure rates due to osteolysis and wear, reactive synovitis, and lymphadenopathy,^{6–9} leading to the development of new designs that are now currently in use.

The Swanson Flexible Hinge Toe (Wright Medical Group N.V.) is an implant made from silicon elastomer and consists of a long proximal and a shorter distal stem of rectangular cross-section. The Swanson Flexible Hinge Toe was introduced in 2012 and is the silastic implant currently in use. Clough and Ring, in a retrospective study of 108 implants with a minimum of a 2-year follow-up, reported a survivorship of 97.2%, a satisfaction rate of 90.6%, and an improvement in all functional and pain scores. They had a 2.8% revision rate due to infection or implant breakage. Other complications included superficial wound infection, delayed wound healing, stiffness, and transfer of metatarsalgia.¹⁰

Previous studies for similar double-stemmed silastic implants also showed satisfactory outcomes. In particular, Morgan et al. retrospectively reviewed 108 feet in 83 patients and found a satisfactory American Orthopaedic Foot and Ankle Scoring (AOFAS) system and visual analog scale (VAS) score and an adequate range of movement. They had only three revisions for persistent pain. Interestingly, although they had a 23% osteolysis rate, they found that this was not progressive and did not correlate to the functional outcome.¹¹ Ter Keurs et al., reported pain relief in 95% of the patients in their study and with a reasonable range of movement of more than 30°.¹²

Metallic Implants

There are multiple metallic implant designs available currently, including hemiarthroplasty designs that resurface either the proximal phalanx or the metatarsal head and total arthroplasty designs.

The HemiCAP (Arthrosurface Inc. Franklin, MA) is a metallic implant made from cobalt-chromium alloy that is designed to replace the metatarsal head without the use of cement but with screw-in fixation. The HemiCAP is one of the most widely used metallic implants currently, and there are multiple studies in the literature assessing its outcomes and complication profile. Unfortunately, there are no randomized controlled trials, with the only available data being level four evidence-retrospective case series studies. All studies in the literature reported an improvement in the functional and pain scores, and eight of them demonstrated a statistically significant improvement.^{13–23} Revision rates ranged from 2.4 to 12.3%, and the main reason for the revision was persistent pain. Survivorship of the implant was reported in only one study and was 87.5% in 5 years.¹⁶

The BioPro® (BioPro, Port Huron, Michigan, United States of America) first MTP joint hemiarthroplasty is a press-fit implant designed to replace the proximal phalanx. Giza et al. reported a

significant improvement in the AOFAS and VAS scores with the BioPro® implant and a 10% revision rate due to persistent pain.²⁴ Salonga et al., also reported an improvement in the AOFAS score. They performed 79 procedures, and they had only one revision, also due to persistent pain. Other complications included sesamoiditis, extensor hallucis longus contracture, hallux subluxation or dislocation, and misaligned implants.²⁵ Clement et al., found an 85.6% survivorship rate in 5 years, and they had a 15% revision rate, mainly for persistent pain.²⁶ There are four studies in the literature comparing hemiarthroplasty with the BioPro® implant with an arthrodesis procedure. Two of them showed no difference in the outcomes,^{27,28} one found that arthrodesis is more reliable,²⁹ one found more favorable outcomes with a hemiarthroplasty.³⁰

The ROTOglide™ (Implants International) is an uncemented, nonhinged, three-part, metal-on polyethylene implant that incorporates a sliding and rotating meniscus. Karpe et al., showed a significant improvement in function and pain, with a low complication rate and high patient satisfaction rates.³¹ Similar outcomes were reported by Kofoed et al., who also showed a survivorship rate of 91.5% in 15 years.³²

The Toe-Fit Plus (Smith and Nephew) is another total arthroplasty implant that includes a polyethylene articulation. There are two studies in the literature, and they both reported significant improvement in function and improvement in pain levels, with no complications and no revisions.^{15,20} Erdil et al., found no difference in the outcomes between a total joint replacement and an arthrodesis.¹⁵

Finally, the Metis (Newdeal SA, Integra Life Science ILS, New Jersey, United States of America) is another three-component, uncemented, total arthroplasty design. A study by Horisberger et al. showed a significant improvement in pain levels, but at the same time, a high amount of revision surgeries.³³ Nuesch et al., found that although functional scores were significantly improved with the metis implant, the postoperative range of motion was not significantly greater compared to the preoperative one.³⁴

Polyvinyl Alcohol Implants

Polyvinyl alcohol (PVA) (Cartiva Synthetic Cartilage Implant; Cartiva, Inc) was recently developed to act as an interposition arthroplasty implant for the treatment of HR. The PVA implant is believed to have similar biomechanical properties as the normal human cartilage and measures 10 × 10 mm.³⁵

A recent systematic review by Smyth et al.,³⁶ that included seven publications^{37–43} assessing the clinical results of PVA in the management of HR and a total of 152 patients showed a significant short and intermediate-term (2 and 5 years, respectively) improvement in the Foot and Ankle Ability Measure (FAAM) sports and activity of daily living, as well as VAS pain scores. The 5-year implant survivorship was found to be 96%. The clinical outcomes were found to be similar to an arthrodesis procedure but with a shorter operative time. In this systematic review, the main publication was the one by Baumhauer et al.,³⁷ as the rest of them included subsets of patients of this original randomized controlled trial. Baumhauer et al., reported similar outcomes between an arthrodesis procedure and Captiva, with a 9.2% complication rate in the Captiva group that required revision surgery. It should be noted that although the outcomes at 2 years were similar between the groups, the Captiva group demonstrated clinical and statistically significant functional improvement over the arthrodesis group in the early postoperative period.

Table 1: Detailed characteristics of the included studies in the review

Implant material	Company	Design	Author (year)	Functional outcomes	Pain relief	Survivorship (%)	Complications	
Silastic	Swanson Flexible Hinge Toe	Double-stemmed	Clough and Ring (2020)	Improved MOXFQ ¹ scores (78.1–11.0) 90.6% satisfaction rate	Improved VAS ² scores (7.0–1.3)	Almost 97.2 (5.3 years)	Around 2.8% revision rate Infection, delayed wound healing, stiffness, and transfer metatarsalgia	
	N/A	Double-stemmed	Morgan et al. (2012)	Improved AOFAS ³ scores (77.5) Adequate ROM ⁴ Improved AOFAS-HIM ⁵ scores (83.0)	Improved VAS scores (7.73)	N/A	Three revisions due to persistent pain, 23% osteolysis rate	
PVA	N/A	Double-stemmed	Ter Keurs et al. (2011)	Improved AOFAS-HIM ⁵ scores (83.0)	Around 95% of patient had pain relief	N/A		
	Cartiva	Interposition arthroplasty implant	Baumhauer et al. (2016)	Significantly improved FAAM ⁶ sports and activity of daily living subscores (36.9–81.2 at 1 year, 79.5 at 2 years)	Significantly improved VAS score (6.8–1.78 at 1 year, to 1.45 at 2 years)	Survival probability better than arthrodesis	Around 9.2% revision rate	
Metallic	HemiCAP	Hemiarthroplasty, MT head resurfacing	Engasser et al. (2020)	Significantly improved FAAM scores (71.0–88.2 for FAAM ADL, 44.6–72.0 for FAAM Sports) N/A	Significantly improved VAS score (4.94–3.1)	N/A	Around 18.5% revision rate	
			Shimozono et al. (2021)	Improvement in ROM	Significantly improved VAS score (4.1–3.0)	N/A	Significant radiologic subsidence with lysis	
			Jorsboe et al. (2020)	Improvement in ROM	Most patients pain-free	N/A	N/A	N/A
			Mermerkaya et al. (2018)	Significantly improved AOFAS score (34.0–83.0)	N/A	N/A	Around 12.3% revision rate due to pain	
			Hilario et al. (2017)	Significantly improved ROM Significant change in AOFAS score (36.62–89.16 at 1 year, to 90.6 at 10 years)	AOFAS pain scale (37.78 of 40.0)	N/A	Around 2.4% revision rate	
			Mermerkaya and Adli (2016)	Significantly improved AOFAS score (33.0–87.7)	Significantly improved VAS score (8.5–2.0)	N/A	Around 3.6% superficial infections	
			Circi et al. (2016)	Significantly improved AOFAS score (49.2–80.8)	Significantly improved pain scores ⁷ (16.5–32.5)	N/A	Three out of 12 patients had a revision due to pain	
			Meric et al. (2015)	Significantly improved ROM Significantly AOFAS-HIM scores (33.9–81.6)	Significantly improved VAS score (8.4–1.21)	N/A	One out of 14 patients had a revision due to pain	
			Gheorghiu et al. (2015)	Significantly improved ROM Improved AOFAS score (66.5)	Around 41.7% pain-free 16.7% severe pain	N/A	Around 8.3% revision rate	
			Kline and Hasselman (2013)	Significantly improved AOFAS score (51.4–94.1) Significantly improved SF-36 ⁸ score (66.7–90.6)	N/A	Almost 87.5% (5 years)	Around 13.3% revision rate	

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Implant material	Company	Design	Author (year)	Functional outcomes	Pain relief	Survivorship (%)	Complications
			Dos Santos et al. (2013)	Significantly improved AOFAS score (32.0–77.272) Significantly improved ROM	Significantly improved VAS score (6.636–0.727)	N/A	N/A
			Erdil et al. (2013)	Significantly improved AOFAS-HMI scores (45.42–86.14) Significantly improved ROM No difference with arthrodesis	Significantly improved VAS score (7.86–1.36) No difference with arthrodesis	N/A	No revisions
			Aslan et al. (2012)	Significantly improved AOFAS score (40.94–85.1) Reasonable ROM	Significantly improved VAS score (8.3–2.05)	N/A	No complications
BioPro®		Hemiarthroplasty, proximal phalanx resurfacing	Giza et al. (2010)	Significantly improved AOFAS score (61.0–80.0)	Significantly improved VAS score (4.7–2.5)	N/A	Around 10% revision rated due to pain
			Salonga et al. (2010)	Improved ACFAS ¹⁰ score (94.0) Significant improvement ROM	Around 56.96% pain-free	N/A	Severe pain, sesamoiditis, extensor hallucis longus contracture, hallux subluxation, dislocation, and misaligned implants
ROTOglide™		Total arthroplasty, metal on polyethylene, and uncemented	Clement et al. (2016)	Significantly improved MOXFQ (53.2–33.2) Significantly improved SF-12 ¹¹ score (36.7–44.2)	N/A	Almost 85.6% (5 years)	Around 15% revision rate (infection, osteolysis, pain)
			Karpe et al. (2018)	Significantly improved AOFAS score (41.2–89.1) Significantly improved ROM	Significantly improved AOFAS pain scores (8.8–35.0)		Around 8.8% revision rate
ToeFit Plus		Total arthroplasty, metal on polyethylene, and uncemented	Kofoed et al. (2017) Mermerkaya and Adli (2016)	Significantly improved AOFAS score (40.0–95.0) Significantly improved AOFAS score (31.0–83.0)	N/A Improved VAS score (9.0–2.0)	91.5% (15 years) N/A	Around 8.75% revision rate No complications
Metis		Total arthroplasty, metal on polyethylene, and uncemented	Erdil et al. (2013) Nuesch et al. (2017)	Significantly improved AOFAS-HMI scores (45.42–92.67) Significantly improved ROM No difference with arthrodesis Significantly improved AOFAS score (58.0–84.0) No significant improvement in ROM	Significantly improved VAS score (7.57–1.58) No difference with arthrodesis N/A	N/A N/A	No revisions N/A
			Horisberger et al. (2016)	Significantly improved AOFAS score (55.0–83.5)	Significantly improved VAS score (5.9–1.2)	N/A	Around 24.1% secondary surgeries

¹ Manchester Oxford Foot and Ankle Questionnaire (maximum score 100, most severe); ² Visual analogue scale (maximum score 10, most severe); ³ American Orthopaedic Foot and Ankle Scoring system (maximum score 100, indicating no symptoms); ⁴ Range of motion; ⁵ American Orthopedic Foot and Ankle Society-hallux metatarsophalangeal-interphalangeal score (maximum score 100, indicating no symptoms); ⁶ Foot and Ankle Ability Measure (maximum score 100%, indicating best function); ⁷ Pain scores, maximum score 40, indicating no pain; ⁸ Foot and Ankle Disability Index (maximum score 104, indicating no disability); ⁹ Short-form 36 (maximum score 100, indicating best function); ¹⁰ American College of Foot and Ankle Surgeons Universal Evaluation Scoring Scale (maximum score 100, indicating best function); ¹¹ Short-form 12 (maximum score 100, indicating best function) MT, Metatarsal; ROM, Range of Motion



Engasser et al.,⁴⁴ in retrospective case series of 54 patients with Cartiva, showed a significant improvement in the FAAM and VAS scores at a mean follow-up of 18.9 months. Approximately, 72.5% of the patients reported that they would definitely or probably have the operation again. There were 10 patients (18.5%) that required revision surgery, and in two of them, there was an infection. Similarly, Brandao et al.,⁴⁵ showed a statistically significant improvement in FAAM scores in 55 patients with a minimum of a 1-year follow-up. They reported an 89.4% satisfaction rate with Cartiva. They had one revision surgery, however, 27.3% of the patients underwent manipulation under anesthesia due to stiffness.

The study by Shimozono et al. reports high failure rates with PVA implants with significant radiologic subsidence with lysis around the implant, erosion of the proximal phalanx countersurface, and implant wear.⁴⁶ An analysis of reports to the United States Food and Drug Administration (FDA) showed that the most common complication is implant subsidence, followed by fragmentation, infection, and bone erosion.⁴⁷

DISCUSSION

In this review, we report the outcomes, survivorship, and complication profile of the implants most commonly used for a hallux arthroplasty. The study design and use of outcomes showed heterogeneity across the included studies, and a quantitative meta-analysis of the results was not possible. The assessment of outcomes was categorized based on implant material.

In contrast to previous studies in the 1980s, silastic implants were found to have a satisfactory functional outcome, with excellent survivorship and a very low revision rate. This may be a result of the evolution of the implants that are currently double-stemmed, which prevent silicon material from articulating with the joint and maintaining hallux length. Another important factor for their success is patient selection. An ideal candidate for a silastic implant is an elderly or middle-aged patient that is lightly active but wishes to maintain their first MPTJ range of movement. In addition, silastic implants offer some transverse plane stability but are often unreliable with the correction of severe hallux valgus deformities. Silastic implants have been heavily criticized in the past, after the initial reports of high failure rates 30 years ago, but perhaps it is time to revisit their use with newer generations of design.

There are several metallic implants available with varying designs. Hemiarthroplasty designs include the HemiCAP, which is designed to replace the metatarsal head, and the BioPro®, which is designed to replace the proximal phalanx. There are several studies in the literature, and they have all shown a satisfactory functional outcome and adequate pain relief. Revision rates varied among the included studies from 2.4 to 15%; however, in most of the cases, a revision was performed due to persistent pain. Total arthroplasty implants include the ROTOglide™, the Toe-Fit Plus, and the Metis which all have a similar three-part design that incorporates a polyethylene articulation. Reports for total arthroplasty implants are contradictory, with some studies showing excellent survivorship and others showing the need for secondary surgery in almost one-fourth of the patients.³³

Polyvinyl alcohol (PVA) implants represent a relatively new entity, as they received approval from the FDA in 2016. PVA is considered a form of synthetic cartilage that could be used to provide pain relief in HR while preserving the range of movement. There are several studies in the literature assessing the results of PVA in the management of HR, and the majority of them have

shown satisfactory functional outcomes and excellent survivorship rates. There are, however, reports of high failure rates and early complications.⁴⁶

Arthrodesis of the first MTPJ has been considered the gold standard for the management of severe HR. A recent meta-analysis of 33 studies by de Bot et al., found comparable complications and revision rates in arthrodesis and metallic arthroplasty but superior outcomes in pain relief in patients undergoing an arthrodesis. Functional improvement was assessed with the AOFAS score and was also similar in both groups.⁴⁸ Park et al., performed a meta-analysis to compare implant arthroplasty and arthrodesis for advanced HR. In this study, both metallic arthroplasties and Captiva were included. In line with the study by de Bot et al., they found similar clinical outcomes, patient satisfaction, reoperation rates, and complication rates, but the pain was significantly lower in the arthrodesis group.⁴⁹ The meta-analysis by Stevens et al., on the other hand, showed that arthrodesis is superior in terms of clinical outcomes and pain relief, and is less often accompanied by intervention-related complications and revisions.⁵⁰ A review by Brewster, also reported a similar postoperative AOFAS score between an arthrodesis and a total joint arthroplasty but a lower complication rate in the arthrodesis group.⁵¹ These results should be interpreted with caution as these are meta-analyses of retrospective case series or prospective cohort studies. Also, there was high heterogeneity in the included studies in the arthrodesis fixation techniques and the arthroplasty implants. Finally, there is one randomized controlled trial in the literature by Stone et al., comparing arthroplasty and arthrodesis for HR.⁵² This study showed greater pain relief with an arthrodesis both at 2 and at 15 years postoperatively and more revisions in the arthroplasty group. They found that the functional outcomes were similar between the two groups.

CONCLUSION

Arthroplasty of the first MTPJ for the management of HR yields satisfactory functional outcomes and reasonable pain relief. The complications and revision rates vary in the literature. The level of evidence of the included studies is significantly limited, and future prospective studies with a control group are needed before making definitive recommendations.

Clinical Significance

The findings of the present study show that arthroplasty of the first MTPJ may be a safe alternative to an arthrodesis procedure while preserving the range of movement of the joint. The present study provides guidance to clinicians for the management of HR.

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