FOREFOOT DEFORMITY SURGICAL RECONSTRUCTION OUTCOMES IN PEOPLE LIVING WITH RHEUMATOID ARTHRITIS IN SOUTH AFRICA

by

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Contents

Declaration

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Abstract

Introduction: Involvement of the forefoot is common among patients with Rheumatoid Arthritis. It results in severe deformities with significant disabilities.

Aim: The aim of this study was to compare and assess in patients with Rheumatoid Arthritis in a South African population the outcomes of severe forefoot deformity reconstruction surgery in the short- to medium-term and in particular focusing on radiological, clinical, and functional outcomes.

Patients and Methods: A retrospective review of 19 patients who received reconstructive forefoot surgery for forefoot deformities resulting from Rheumatoid Arthritis was undertaken. They all underwent Modified Hoffman Surgical Reconstruction (first MTPJ fusion and lesser toe resection arthroplasty). The patient records between 2013 and 2016 were reviewed. Pre-operative and post-operative outcome scores were collected. Final post-operative radiographs were analyzed. Patients completed Short Form 36 and AOFAS forefoot scores. Post-operative scores were collected 6 months post-op.

Results: There were 19 patients in the study with a minimum 6 months follow up. Of the 19 patients 17 (89.5%) were females and 2 (10.5%) males. The mean age was 54.9 ± 9.6 years (range: 34 – 69 years). Most patient outcomes (SF36, AOS alignment, VAS Pain percentage, and VAS Disability percentage) significantly improved with a p value < 0.05, when comparing the pre-operative versus post-operative variable scores. However, only AOS Alignments showed no significant difference between pre-operative and post-operative scores ($p>0.05$).

Conclusion: Reconstructive forefoot surgery with the Modified Hoffman Surgical Reconstruction provides marked radiological correction, with significant improvements in the quality of life of the cohort of patients.

Keywords: Forefoot reconstruction, outcomes, Rheumatoid Arthritis, South Africa.

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PART A

LITERATURE REVIEW

Introduction

The present chapter offers a review of literature on the different types of surgery procedures to improve rheumatoid forefoot deformities. The chapter initially focuses on rheumatoid arthritis (RA) forefoot prevalence and the types of commonly reported deformities in RA forefoot. The chapter will also look into the common operative procedures adopted globally for the correction of RA forefoot deformities and their positive and negative outcomes. The present literature review is expected to provide us with the most up to date information about the efficiency of the surgical interventions used in reconstruction of forefoot in patients with deformities arising from RA. We also identify the major research gaps from the available knowledge in this chapter.

Rheumatoid arthritis, cause, symptoms and medical treatment

Rheumatoid arthritis (RA), an inflammatory disease that is progressive and a polyarticular pathology leading to chronic cartilage erosion and degeneration resulting in pain and functional limitation.[1-3] The prevalence rate of RA is estimated to be 0.3%–1.2% with more likelihood in women and aged the population.[4] The pathology incurs remarkable health and cost burdens as an estimated 50% of arthritic population become professionally inactive after 10 years of disease onset.[5] The forefoot joints are the most affected zones and often the initiation sites of the disease.[6] The forefoot deformities are noticed in almost all the patients within the first 10 years of disease onset, involving 70% to 80% of the metatarsophalangeal (MTP) joints.[7-9] In fact pain due to synovitis of MTP joints starts within the first three years of chronic RA and therefore serve as the initial RA symptom.[10-11]

The common secondary forefoot deformities include hallux valgus (HV), fifth MTP joint varus deformity, subluxation and dislocation of MTP joint of lesser toes.[12-14] Continuous walking creates laxity in MTP joints with consequent chronic dorsal MTP joint dislocation and permanent dorsiflexion at the MTP joints.[12] This is associated with the simultaneous plantar flexion of the distal phalanges resulting in the diminished support to the first ray by the lesser metatarsals. This gives rise to the progressive first metatarsal deviation and hence HV.[12] The anatomical alterations, particularly the hyperextension of the MTP joints, result in obvious biomechanical changes like the stretched plantar plate and protruded metatarsal heads.

Alterations in the plantar fat pad shifts the pressure to the metatarsal heads and inferior subcutaneous tissues leading to metatarsalgia, callouses and painful bursae, and overall difficulty in walking.[12-13] Further with the development of HV, an increase in the intermetatarsal angle (IMA) occurs between the first and second ray, resulting in the loss of the weight-bearing function of the first ray and deformities, fracture, subluxation, or dislocation of the second metatarsal due to synovitis.

Treatment strategies begin with a variety of conservative treatments. These treatments include non-steroidal anti-inflammatory drugs (NSAIDS), disease modifying anti-rheumatic drugs (DMARDS), specialized orthotics and footwear. The objective of these treatments is to alter the disease progression and reduce pain and stiffness.[15] However, 5-22% patients have to undergo surgical treatment procedures due to persistent arthralgia and localised synovitis, progressive deformity and debilitating joint functions.[16] The overall objectives of the surgical treatment include pain relief, prevention of further deformity and deterioration, improved function and health related quality of life.

Surgical treatment options

In this section we review the different types of surgical procedures to improve the rheumatoid forefoot deformities burden. We conducted our literature search on Pubmed, Google, and Google scholar. We identified literature published in English language following search items: (‘‘Rheumatoid arthritis feet” OR ‘‘Rheumatoid foot”) AND (‘‘Forefoot reconstruction” OR ‘‘surgery” OR “surgical management” OR “surgical procedures”) AND (“arthrodesis” OR “arthroplasty” OR “fusion”) AND (“hallus valgus”) AND (“foot function” OR “forefoot deformities”). Inclusion criteria involved adults above 18 years of age with confirmed RA forefoot deformities. All types of studies including systematic reviews, literature reviews, and retrospective cohorts; and randomized and non-randomized clinical studies reporting surgical outcomes of RA forefoot were included. Exclusion criteria involved case studies done on single patient, studies reporting some combination outcomes of conservative and surgical treatments, studies performed on other forms of arthritis like juvenile or osteoarthritis, and studies where treatment options other than surgery (orthopaedic shoes or physiotherapy) were studied as primary treatment. Further manual search was also conducted within citations of the searched articles to include relevant articles.

Surgical procedures for diseased first MTP joint include arthrodesis fusion, resection arthroplasty to correct hallux valgus deformity, and arthrosis, silastic or metal arthroplasty.[17-22] The first original forefoot reconstruction surgery was performed by Hoffman et al. in 1912

based on resection arthroplasty. The procedure involves the excision of all four metatarsal heads of lesser toes through a distal transverse plantar incision.[19] While the procedure was reported to relax the soft tissues, the primary concerns were increased risk of neurovascular damage, remission of HV and stiffness in MTPJ post-operatively.[23] In continuation with the Hoffmann procedures, other resection arthroplasty techniques have been developed by Hueter, Mayo, Keller, and Clayton.[24-27] Combinations of these procedures were also evaluated. The comparative outcomes of Mayo and Keller procedures demonstrated better outcomes in the Keller procedure, with comparatively reduced degree of forefoot pain, lesser toe deformities, HV recurrence, and functional stability.[27] The superiority of Keller procedure is largely confined to the maintenance of alignment and sesamoids position, restricted resection of the phalanx base to retain the flexor function, and performing a secure capsulorrhaphy.[28] Despite many of the mentioned advantages, stiffness was reported in more than one third of the joints in the Keller procedure. A combination of Mayo and Keller procedures documented superior outcomes than each of the individual techniques, however walking ability remained unchanged in all the groups.[29] Overall, while a few sets of studies rejected the use of these techniques due to poor outcomes with respect to deformity and pain recurrence as well as deterioration of the hallux, other studies have reported higher rates of satisfaction and pain relief.[30-34] The Clayton procedure involved a dorsal transverse incision accompanied by five longitudinal extensions and extensor tendon transections. The functional outcomes of the Clayton procedure demonstrated restricted standing on tip toes by 21% patients, and the presence of fibular drift and metatarsal stumps with recurrent splayfoot deformity.[35] The Tillmann procedure modified the Hueter-Mayo procedure involving a dorsomedial and a plantar approach for the hallux valgus (HV), and lesser toes metatarsal heads resection respectively.[36] Further, the complete forefoot arthroplasty technique of Tillmann also modified the Hoffmann technique through resection arthroplasty of MTP joints II to V.[19, 37] The technique also involved tenolysis, and realignment of the tendons by additional resection of the proximal phalangeal base. In-addition, the sesamoids are also resected. To provide stability to the alignment and to sort flexion contractures of the proximal or distal interphalangeal joints, temporary Kirschner wire fixation and manipulation of the contracted joints are employed.[36, 38, 39] A recent retrospective study analyzed the post-operative outcomes of complete forefoot correction done by the Tillmann method for a follow up of 20 years.[40] The pain outcomes represented no forefoot pain in 35% participants while 40% and 23% patients demonstrated pain under strain and in resting stage respectively. Recurrent HV was demonstrated in 61.45% patients that varied from mild to severe with a reoperation rate of 43.3% after 10.5 ± 7.3 years of primary operation. Further, decreased forefoot function was also reported. The author's recommendation for the

technique as a solid surgical option was based upon the satisfaction level of patients (80%) which should be cautiously handled despite the higher rate of HV remission, reoperation rate, and decreased foot function. Correction of claw toe is usually done by the Stainsby procedure involving the bony resection of the lesser toe and realignment of the freed plantar plate underneath the metatarsal heads. The stabilization of the toe was achieved through the use of intramedullary wire. The technique first described by Briggs and Stainsby allows the repositioning of the metatarsal heads and prevents their sinking in the fat pads of the foot thereby preserving the weight bearing capacity of the metatarsal head.[41, 23] Overall it is suggested that both the Weil and Stainsby procedure offers an advantage over excision arthroplasty through preservation of the plantar attachment and weight bearing capabilities of the lesser rays.[42]

The gold standard procedure for deformity correction and pain relief is the first MTPJ arthrodesis. The process involved fusion of both joint surfaces at an approximate angle of 10-15 degrees of valgus and 10 degrees of dorsiflexion from plantar surface. Appropriate fusion of the first MTP joint results in a permanent correction of the deformity with diminished incidence of future deformities. The process restores the weight bearing capacity along the medial border of the foot. To facilitate bony union, a number of temporary fixation techniques have been developed including simple lag screws and dorsal low profile plates. Usually, the type of fixation decides the use of a dorsal or medial approach for the joint. Mann and Thompson further introduced dorsal incisions and the use of Kirschner wire for stabilization of the lesser toe deformities.[43] The first MPTJ arthrodesis is used either alone or in combination with lesser MTPJ resection. While lesser MPTJ resection produced short-lived outcomes when performed alone, its combination with the 1st MTPJ fusion produced good results with respect to correction of the HVA, pain relief, function, and subjective relevant outcome measure in the majority of the rheumatoid forefoot.[44-49] A Study conducted by Bass et al. revealed the functional outcomes of 1st MTP fusion combined with Stainsby procedures of the lesser toes.[50] A significant improved AOFAS score was documented after 12 months of follow up. The significant improvement in IMA and HVA were notified by 6 months only. By 12 months, all lesser toe deformities and all fusions were united. Post-operative complications were noticed in 25% of the patients. The study revealed the positive outcomes of a new technical combination. While the first MTP joint arthrodesis resulted in the stabilization of the first ray and realignment of plantar fat pads beneath the metatarsal heads, the joint preservation strategy of the Stainsby procedure provided effective pain relief, and corrects the distribution of plantar plate pressure over metatarsal heads. Retrospective surgical procedure conducted by Whitt et al. revealed radiographic fusion in 90% of the patients with a decrease of 23.8° and 3.7° in HVA and IMA respectively.[51] The

surgical intervention performed by the authors includes first MTP joint arthrodesis, lesser metatarsal head resection, and lesser proximal interphalangeal joint (PIPJ) fusion. The study revealed an overall higher complication rate of 45% with respect to non-union (10%), infection (20%), revision (1%), and digital amputation secondary to infection (10%). The authors continued to favour the superiority of first MTP joint fusion with lesser metatarsal head resection and digital fusion over newly introduced joint preservation techniques due to excellent long-term clinical outcomes, significant radiographic improvement, rapid bony fusion, and low surgery revisions as well as complications.

On the contrary, the study conducted by Grondal et al. notified no major differences in functional outcomes of 1st MTPJ fusion and the Mayo resection procedure.[52] The main advantage of the first MTP joint fusion is the protection of the lesser MTP joints from dorsiflexion forces. It is hypothesized that fusion of first MTP joint remarkably reduces the contact time of the foot with the ground due to the decreased movement in the first ray. Furthermore, the RA associated load transmission to the lesser toes was also reduced after fusion leading to the switch of this load to the original fat pad of the big toes.[43, 53] Conversely, the major drawbacks include the higher demand of surgical expertise and a non-union rate ranging from 0–30 %. However, it has been reported that the latter setback was remedied with modified advanced techniques.[28, 45, 54-56] Revision surgeries are seldom needed in the case of dorsiflexion or plantarflexed malunions. In an interesting study, Mulcahy et al. compared the outcomes of arthrodesis and resection arthroplasty (Clayton, Hoffman, and Keller procedure).[55] The overall as well as sub-group SF-36, pain scale, and HV angle outcomes showed no significant differences among the tested procedures. Procedures involving stable 1st ray showed significant better foot function, improved plantar pain, and HVA and IMA score when compared with procedures involving major resections. There were those among the several patients who underwent the Keller procedure that had to undergo maximum re-operation, while some patients of the Clayton group had maximum plantar pain due to highest degree of resection. Overall, the authors ruled out the general belief of no significant differences in the post-operative outcomes with respect to the surgical methods adopted. The study clearly identified the differences in the results and functional outcomes based upon the surgical methods. In the context of arthrosis versus resection arthroplasty, the authors favoured arthrosis offering preservation function of the bigger and lesser toes. The study reported best aesthetic outcomes with improved forefoot function and distribution of forefoot pressures in unoperated 1st MTP joint together with MT head resection and K-wire stabilization of the lesser toes. A recent systematic review by Ortega-Avila et al. evaluated the effective surgical treatments for rheumatoid forefoot and/or ankle through non-randomized controlled trials and cohort studies.[57] The systematic review

identified first MTP joint arthrodesis and/or resection arthroplasties of the MTP joints as the most widely used techniques to correct rheumatoid forefoot deformities. The authors documented the best outcomes with respect to pain relief and enhanced functionality through the different combinations of these techniques. However, the authors noticed no clear evidence to the application of these outcomes in all the metatarsal heads or just the first metatarsal head due to low methodological quality of the included studies. Although a trend towards the first MTP joint preservation was noticed over resection arthroplasty based upon the reduced pain intensity in the selected choice, interestingly this difference is not reflected in the case of functionality.[58, 59] Nevertheless, the overall surgical outcomes irrespective of the adopted technique are often very beneficial.[60-62]

The other form of surgical intervention used in the rheumatoid forefoot management is distal-joint-preserving surgery.[63] The procedure is useful to treat mild to moderate HV and provide stable solutions for HVA, joint mobility, and deformities. However, the technique is not the right fit for management of rheumatoid forefoot with severe stiffness, joint destruction, or progressive degenerative changes. A popular example of distal-joint-preserving surgery is the Lapidus procedure involving fusion of the first tarsometatarsal joint.[64] The Lapidus procedure is extensively used to treat hypermobile 1st ray and often concluded as a preventive surgery measure.[65-66] However, it is also recommended to cautiously assess the risks of surgery specifically in the case of the fusion of a seemingly normal joint proximally. Joint-preserving surgery was made popular by Barouk through the use of a Weil osteotomy, involving elevation of the metatarsal head in combination with lengthening of extensor tendon.[67] Weil osteotomy has been reported to be biomechanically more stable as opposed to other proximal osteotomies.[68] Takakubo et al. developed Modified Mann proximal crescentric osteotomy for HV correction. The authors demonstrated improved patient reported outcome measures with relatively few complications and HV recurrence.[69] Joint preserving surgery has been concluded to provide better functional outcomes in early or intermediate RA with respect to deformities correction, foot function, and cosmesis.[70-71] However, similar to the first MTP joint fusion technique, this procedure is also technically very demanding.

Another surgical technique to preserve first MTP joint mobility and to treat HV and associated degenerative changes in MTP joint include use of metallic and silastic implants.[72-74, 20, 21, 75] Different forms of silastic implants like hemiarthroplasties, Swanson hinges, and spacer devices have been rejected due to variety of complications including osteolysis, loosening, and inflammatory synovitis.[76-78] Despite the complications, benefits in terms of HV correction and pain relief with a minimum rate of revision surgery have also been demonstrated.[77, 78] The granulomatous reaction against silicone particulate matter can be

prevented by the use of titanium grommets between the bone and silicone.[74] Another option is to replace the poly-silicone implants with metallic hemi-implants.[22] In an interesting comparative study, functional outcomes also favoured the resection arthroplasty of the first MTP joint over hinged silicone implant arthroplasty.[79] This is further supported by the inadequate pain relief, recurrence of deformity and metatarsalgia, and specialized technical requirements.

Few surgical options like debridement of plantar callosities and synovectomy were also found to exert limited clinical benefit.[80-84] There are however a bare minimum of cohort studies to demonstrate their outcomes.

Evaluation of the benefits of any surgical procedure is incomplete without the assessment of complications occurrence with the operative treatment. One of the key complications associated with all surgical procedures for treatment of rheumatoid forefoot is the incidence of infection and delayed wound healing. Different cohort studies demonstrated the infection rate to be as low as 7% and as high as 39% depending upon the surgical approach and use of pharmaceutical agents.[46, 85, 86] Other factors that predispose the patients towards infection include vasculitis, weakened soft tissue, and long term use of immunosuppressants. Rheumatoid forefeet majorly involve deformities in multiple toes therefore requiring longer operative time, multiple incisions, and surgical wounds all leading to delayed wound healing.[87] While vasculitis can lead to gangrene development, osteopenia significantly contributes in bony malunion. All these complications individually or in combination contribute to compromised surgical outcomes as well disease recurrence.[12]

Research gap and proposed research

There is limited evidence of research on forefoot reconstructive surgical outcomes with respect to the radiological, clinical, functional, Quality of Life (QOL) and pain improvement scores in South African RA patients. Accurate post-surgical detection of complications and outcomes depends on rigorous and efficient follow up of patients to minimize loss to follow up.[88] It is envisaged that this present study will contribute significantly to closing the research gaps in the area of forefoot reconstruction surgery for better treatment and management of these deformities. Furthermore, the research outcomes of the current study will also shed light on the required improvements in evidence-based surgical practices for RA patients and in informing decisions on channelling appropriate resources towards appropriate management and care for patients.

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PART B
MANUSCRIPT (IN PRESS WITH JOURNAL)

The manuscript below will be submitted to the South African Orthopaedics Journal. The format and referencing style is in accordance to the instructions prescribed by the journal to the authors of the journal (see attached instructions in Part C).

Title page

Title:

FOREFOOT DEFORMITY SURGICAL RECONSTRUCTION OUTCOMES IN PEOPLE LIVING WITH RHEUMATOID ARTHRITIS IN SOUTH AFRICA

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In terms of conflict we the authors declare none what so ever.

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Blinded abstract

Introduction: Involvement of the forefoot is common among patients with Rheumatoid Arthritis. It results in severe deformities with significant disabilities.

Aim: The aim of this study was to compare and assess in patients with Rheumatoid Arthritis in a South African population the outcomes of severe forefoot deformity reconstruction surgery in the short to medium-term, in particular focusing on radiological, clinical and functional outcomes.

Patients and methods: A retrospective review of 19 patients who received reconstructive forefoot surgery for forefoot deformities resulting from Rheumatoid Arthritis was undertaken. They all underwent Modified Hoffman Surgical Reconstruction (first MTPJ fusion and lesser toe resection arthroplasty). The patient records between 2013 and 2016 were reviewed. Pre-operative and post-operative outcome scores were collected. Final post-operative radiographs were analyzed. Patients completed Short Form 36 and AOFAS forefoot scores.

Results: There were 19 patients in the study with a minimum 6 months follow up. Of the 19 patients 17 (89.5%) were females and two (10.5%) males. The mean age was 54.9 ±9.6 years (range: 34 - 69 years). Most patient outcomes (SF36, AOS alignment, VAS Pain percent, and VAS Disability percentage) significantly improved with a p value < 0.05, when comparing the pre-operative versus post-operative variable scores. However, only AOS Alignments showed no significant difference between pre-operative and post-operative scores ($p>0.05$).

Conclusion: Reconstructive forefoot surgery with the Modified Hoffman Surgical Reconstruction provides marked radiological correction, with improvements in the quality of life of the cohort of patients significantly.

Keywords: Forefoot reconstruction, outcomes, Rheumatoid Arthritis, South Africa

Introduction

Rheumatoid arthritis (RA) is a progressive polyarticular inflammatory disease leading to the chronic cartilage degeneration and erosion ending up in pain and functional limitation.[1-3] The prevalence rate of RA is estimated to be 0.3%–1.2% with more likelihood in women and aged population.[4] The pathology incurs remarkable health and cost burdens as an estimated 50% of arthritic population become professionally inactive after 10 years of disease onset.[5] The forefoot joints are the most affected zones and often the initiation sites of the disease.[6] The forefoot deformities are noticed in almost all patients within 10 years of disease onset involving the metatarsophalangeal (MTP) joints 70% to 80% of the time.[7-9]In fact pain due to synovitis of MTP joints started within the first three years of chronic RA and therefore served as the initial RA symptom.[10, 11]

The common secondary forefoot deformities include hallux valgus (HV), fifth MTP joint varus deformity, subluxation and dislocation of lesser toes MTP joint.[12-14] The anatomical alterations particularly the hyperextension of the MTP joints results in obvious biomechanical changes like the stretched plantar plate and the protruded metatarsal heads leading to metatarsalgia, callouses and painful bursae and overall difficulty in walking.[12, 13] Further with the development of HV, an increase in the intermetatarsal angle (IMA) occurrs between the first and second ray resulting in the loss of the weight-bearing function of the first ray and deformities, fracture, subluxation, or dislocation of the second metatarsal due to synovitis.[13]

Treatment strategies begin with a variety of conservative treatments including non-steroidal anti-inflammatory drugs (NSAIDS), disease modifying anti-rheumatic drugs (DMARDS), specialized footwear and orthotics with the objectives to alter the disease progression and reduce pain and stiffness.[15] However, 5 – 22% patients had to undergo surgical treatment procedures due to persistent arthralgia and localised synovitis, progressive deformity and disabilitating joint functions.[16] The overall objectives of the surgical treatment include pain relief, prevention of further deformity and deterioration, improved function and health related quality of life.

The surgical procedures for diseased first MTP joint include arthrodesis fusion, resection arthroplasty to correct hallux valgus deformity and arthrosis, silastic or metal arthroplasty.[17-22] A recent systematic review by Ortega-Avila et al. identified first MTP joint arthrodesis and/or resection arthroplasties of the MTP joints as the most widely used techniques to correct rheumatoid forefoot deformities.[23] The authors of this study as well as of other previous studies documented the best outcomes in the different combinations of first MTPJ arthrodesis and lesser MTPJ resection techniques with respect to the correction of

HVA, pain relief, function, and subjective relevant outcome measures in majority of the rheumatoid forefoot.[24-32] A study conducted by Bass et al. revealed the improved AOFAS score, IMA and HVA, and complete bony unions after 12 months of follow up for new technical combination involving 1st MTP fusion combined with Stainsby procedures of the lesser toes.[33] Post-operative complications were noticed in 25% patients. A retrospective study conducted by Whitt et al. revealed radiographic fusion in 90% patients with a decrease of 23.8° and 3.7° in HVA and IMA respectively.[34]The surgical intervention performed by the authors included the first MTP joint arthrodesis, resection of lesser metatarsal head, and fusion of lesser proximal interphalangeal joint (PIPJ). The study revealed an overall higher complication rate of 45%. On the contrary, the study conducted by Grondal et al and Mulcahy et al. notified no major differences in functional outcomes of arthrodesis and resection arthroplasty.[35,36]

The key complications associated with all surgical procedures for treatment of rheumatoid forefoot is the incidence of infection and delayed wound healing. Different cohort studies demonstrated the infection rate to be as low as 7% and as high as 39% depending upon the surgical approach and use of pharmaceutical agents.[26,37,38] Other factors that predispose the patients towards complications include vasculitis, weakened soft tissue, long-term use of immuno suppressants, longer operative time, multiple incisions, and surgical wounds all leading to delayed wound healing, gangrene development, osteopenia, bony malunion, compromised surgical outcomes, as well disease recurrence.[39,12]

In the recent years, orthobiologics has improved the quality of life of rheumatoid patients. In refractory cases however, surgical correction is the only treatment option available but there is limited evidence on the outcomes of forefoot reconstruction in South Africans suffering from RA particularly on improvement of Quality of Life (QOL) and pain improvement scores based on Short Form (SF 36). Accurate detection of post-surgical complications and outcomes depends on rigorous follow up of patients to minimize loss to follow up.[40]

The main objective of this study was to objectively evaluate the patient reported outcomes (PROMS) the short- and mid-term outcomes of the Modified Hoffman Surgical Reconstruction procedure [41], focusing on radiological, clinical, and functional outcomes among Rheumatoid Arthritis with severe forefoot deformity at Groote Schuur Hospital in Cape Town, South Africa.

Materials and Methods

This was a case series of 19 patients that underwent Modified Hoffman Surgical Reconstruction for severe forefoot deformities secondary to RA between 2013 and 2016 at Groote Schuur Hospital in Cape Town, South Africa following the approval from the ethical board committee and approval of synopsis.

We reviewed the data of skeletally mature patients with a minimum follow up of 9 months in our clinic following Modified Hoffman reconstruction procedure. We excluded any patients that lacked capacity and patients who were operated in our hospital but had incomplete records in our hospital data base or were lost to follow up. We performed modified Hoffman surgical reconstruction following the criteria laid out by Bauman et al. for severe forefoot deformity which includes persistent arthralgia and localised synovitis, progressive deformity and debilitating joint function. The patients were followed for a minimum of six months in our clinic postoperatively. Short term outcomes were labelled at six weeks while outcomes at six months were termed as mid-term outcomes.

The primary outcome was the American Orthopaedic Foot and Ankle Society (AOFAS)-forefoot scale. The AOFAS-forefoot scale has three subcomponents namely: pain, function and alignment. The score ranges from 0 – 100 with 100 being the best outcome. The secondary outcome was the quality of life health questionnaire (SF-36) having a mental and physical subcomponent scales. Tertiary outcomes were the Visual Analogue scale (VAS), radiological outcomes such as union and non-union, and complications following the procedure.

Radiological union was defined as the absence of pain and presence of callus in three of the four cortices seen on the AP and lateral radiographs. The x-rays were performed in weight-bearing position and assessed by an orthopaedic consultant in the foot and ankle specialty. Non-union was defined as no callus formation at nine months.

Modified Hoffman Surgical technique

Our patient is positioned supine on the operating table. A general anaesthetic and ankle block is administered followed by an above knee tourniquet after prophylactic antibiotic has been given. Antibiotics are given for up to 24 hours' post-surgical procedure. Anaesthesia is then administered (general plus ankle block) and the tourniquet is inflated. Antiseptic solution used to clean the leg, sterile drapes are applied and the tourniquet is inflated after exsanguination.

First we expose the first metatarsophalangeal joint with a dorsomedial incision whilst protecting the dorsal digital nerve laterally and taking care not to apply unnecessary skin tension throughout the procedure. We then sub-periosteally strip the capsule from neck exposing up to the shaft on either side of the joint with preservation of the sesamoids. The first metacarpophalangeal joint cartilage is denuded using conical reamers and arthrodesed with a single lag screw and locking plate fixation.

After fixation of the big toe is complete, we start with the second toe and proceed laterally. Two dorsal incisions are made between the second/third metatarsals and another between the third/forth metatarsals, giving access to metatarsalphalangeal joints. Long and short foot extensor tendons are divided if more exposure is needed, and subperiosteal dissection of interosseous muscles is done to expose the neck of the metatarsals. The neck cuts are made at the ends of the metatarsal shafts which leave second metatarsal longest, to form a gentle arc with a saw perpendicular to the shaft axis and heads removed and smoothening of remaining surface to avoid sharp edges that may cause meta-tarsalgia. Lastly we stabilise the metatarsophalangeal joint with Kirschner wires that extend from the toe tip going into same metatarsal shaft after interposing extensor digitorus brevis.

Careful tensionless closure of the surgical wound with interrupted undyed vicryl done as the risk of skin necrosis is high. Perfusion is assessed after the tourniquet has been released. Sterile gauze is applied as a sling around the toes, and taped plantarly in a boot post-op to avoid the toes riding up dorsally when swelling sets in. We intentionally leave the tips visible to allow for perfusion assessments in the ward.

Physiotherapists mobilise our patients' post-surgery in a heel bearing shoe as tolerated, wound inspection and suture removal is done at 10-14 days, and finally K-wire removal is at 3 weeks post-surgery. Figure 1 shows photographs: pre-operative, intra-operative and at 6 weeks' post-operation. The pre-operation Stage 1 photographs show an anteroposterior view of a forefoot, showing the position of each incision. The incision for the first ray is dorsomedial. The other two incisions lie between the second and third and the fourth and fifth metatarsals. Stage 2 photographs show the postoperative radiograph of the first MTP joint arthrodesis, and lesser toe with metatarsal head resections. Stage 3 photographs show 6 weeks, post-operative radiograph.

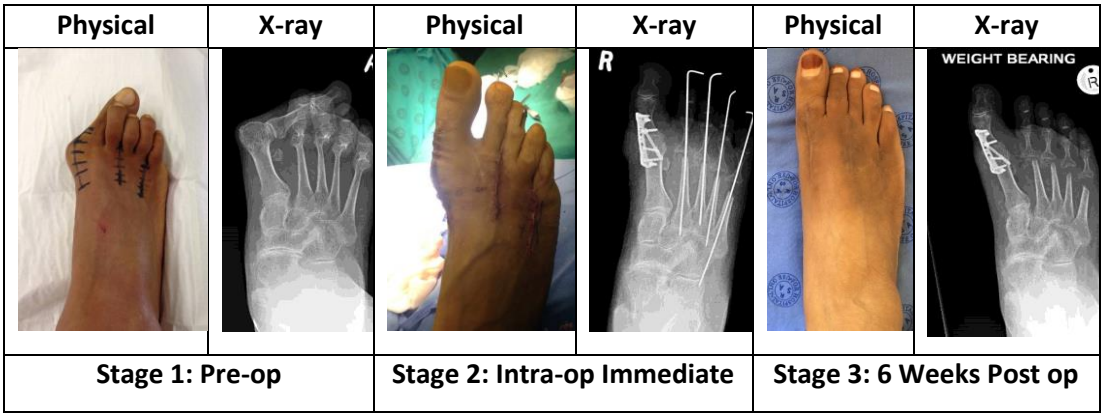

Figure 1: First MTP joint arthrodesis and lesser toe with metatarsal head resections.

The patients' demographic data was also recorded, which included: age, gender, height, weight and body mass index (BMI), duration of the symptoms, and any pre-existing comorbid conditions. The data was analysed on STATA Version 13 software, the continuous data was reported as mean and standard deviation, or median and interquartile ranges, depending on the normality of the data following a Shapiro–Wilk and Shapiro–Francia test.

Paired or matched t-test were used to analyse the mean differences between preoperative and postoperative outcomes. A 95% Confidence interval was defined as the lowest or minimum true minimum clinical improvement difference between pre- and post-surgery SF-36 and VAS outcomes.

Logistic regression was used to check the effects of demographic and baseline observations on surgical outcomes, and especially to investigate any association between BMI and surgical outcomes. A p-value of less than 0.05 was considered statistically significant with a confidence interval of 95%.

Results

The study included 19 patients with a mean age of 54.95 ±9.6 years having 89.5% (17/19) female participants that underwent modified Hoffman surgical correction for rheumatic forefoot deformities with a minimum follow up of six months between January 2013 and December 2016.

On pre-assessment, 47.4% (9/19) patients were obese with a body mass index (BMI) of over 30 kg/m^2. On simple logistic regression analysis at pre-assessment, three significant associations were established between baseline BMI and baseline SF-36 physical component score, AOFAS-forefoot score, and VAS for pain. Likewise, a statistically significant relationship

was present in height and the SF-36 physical component scale, and finally between weight and the SF-36 physical component scale, see Table 1.

Table 1: Simple logistic regression analysis – association between outcomes (height, weight and BMI) against minimum clinical improvement.

Dependent Variable	Independent Variable	Odds Ratio	95% Conf. Interval	P Value
Physical Functioning (SF36 PF)	height	4.01	3.04 - 5.28	0.036
Physical Component Score (SF36 PCS)	weight	0.87	0.76 - 0.99	0.042
Physical Component Score (SF36 PCS)	BMI	0.65	0.42 - 0.99	0.047
Ankle Osteoarthritis Scale (AOS) Total lesser toe	BMI	1.49	1.02 - 2.19	0.040
Visual Analogue Scale (VAS) Pain	BMI	0.65	0.42 - 0.99	0.043

The modified Hoffman surgical procedure showed a statistically improved VAS for pain at 6 months, ($p<0.05$) see Figure 2. Furthermore, VAS for disability was significantly improved at 6 months, ($p<0.05$) see Figure 3.

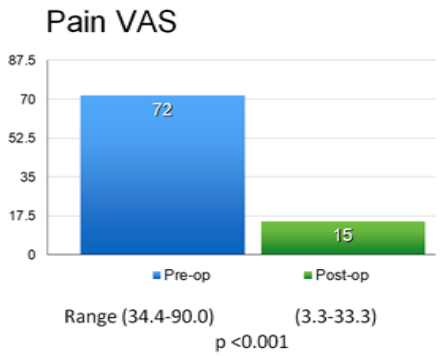

Figure 2: Comparison of pre-post outcomes of the Pain VAS (calculated via paired t-test).

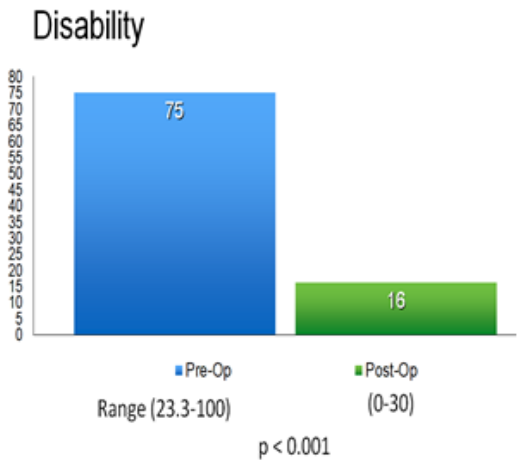

Figure 3: Comparison of pre-post outcomes of the Disability VAS (calculated via paired t-test).

The preoperative hallux valgus angel (HVA) was 44 degrees (11-71) which significantly improved ($p<0.05$) after modified Hoffman reconstruction to 12.1 degrees (8-23). Similarly, the intermetatarsal angel (IMA) improved from 12 degrees (3-20) preoperatively to 9 degrees (4-12) postoperatively ($p<0.05$).

In addition, patients also experienced an improvement in the SF-36 physical component score from a mean baseline of 33 (15-55) to 43 (10-90) at the 6 months' period. However, this did not translate into a statistically significant shift ($p> 0.05$).

Following the modified Hoffman surgical correction for the forefoot deformity, patients did experience a clinical improvement in their SF-36 mental score 72 at the 6 months follow up period when compared to 55 when seen at pre-assessment.

Radiographic union at 2 months for modified Hoffman was 94% while there was one case that was classified a nonunion of the hallux that was treated with compression plating and locking screws and was supplemented by a bone graft at twelve weeks. All the fractures united at six months. Finally, we recorded one postoperative infection during the immediate postoperative period which was successfully treated via oral antibiotics. There were no cases reported with a recurrence of deformity or metatarsalgia following surgical correction.

Discussion

To the best of our knowledge this is only study that quantitatively evaluates the outcomes of modified Hoffman surgical correction for severe forefoot deformities in patients with Rheumatoid arthritis within the South African population at 6 months follow up.

The modified Hoffman surgical procedure involves fusion of the hallux and excisional arthroplasty of the lesser toes. A number of surgical techniques including arthrodesis, resection, or arthroplasty have evolved post Hoffmann's original surgery in 1912.[19] The profound variations occurred in incision types, degree of resection of lesser toes, 1st MTP joint fusions and overall stabilization methods. With respect to the first MTP joint, all these techniques were reported to produce good clinical outcomes specifically in terms of pain relief.[17, 25, 38, 43-63]

However, there is a great paucity of data about the clinical outcomes of reconstructive surgeries of the forefoot in the South African population especially suffering from rheumatoid arthritis and the current study is the first to document forefoot reconstruction outcomes in the South African population.

Hallux valgus Angle (HVA) and Inter-metatarsal angles (IMA) are the primary assessment components of rheumatoid forefoot demonstrating the progressive deformity associated with the disease. Correction of 15 to 30 degrees in HVA is recommended for the first MTP joint to prevent recurrence, pain, and disability.[48, 59, 64-73] The present study noticed 100% and 94.7% improvement in HVA and IMA, suggesting the efficacy of the adopted surgical procedure. While the HVA significantly decreased from 44.1 to 12.1 degrees, IMA reduced from 12.1 to 8.9 post-operatively. The HVA outcomes of this present study are in agreement with previous studies conducted by Matsumoto et al. and Bass et al. following the modified Hoffmann protocol.[33, 74] Both studies demonstrated significant reduction in mean HV angle from 41.4 ± 16.4 to 19.2 ± 11.7 and 48 to 14 degrees in a follow up of approximately 6 years and 12 months respectively. Similarly, comparable IMA outcomes (15 to 10 degrees) were also documented by Bass et al. with 100% corrections in all lesser toe deformities and all fusions re-unions.[33] Another retrospective study conducted by Whitt et al. revealed radiographic fusion in 90% patients with a decrease of 23.8° and 3.7° in HVA and IMA respectively.[34] The surgical intervention performed by the authors includes the fusion of first MTP joint, resection of lesser metatarsal heads, and fusion of lesser proximal interphalangeal joints (PIPJ). Another study by Mulcahy et al. compared the outcomes of arthrodesis and resection arthroplasty performed by four procedures namely: arthodesis group, Clayton procedure, Hoffman procedure, and Keller procedure.[36] In the context of the HVA and IMA scores, procedures involving stable 1st ray showed a significant better effect when compared with procedures involving major resections. Overall, the current findings support the higher efficacy of the modified Hoffmann surgical procedure in improvement of the HVA and IMA scores, resulting in the surpass of required minimum clinical improvement difference (MCID), and pre reconstructive surgery versus post-reconstructive surgery.[76]

Our patients showed a significant improvement on the AOFAS and general health SF36 scores. The total AOFAS score of the big toe and the lesser toe has significantly improved to 69.6 from 30.5 and 74.5 from 35.5 respectively. This improvement is better than the previously reported outcomes. For instance, Bass et al. reported a significantly improved AOFAS score (72 from 46) in rheumatoid forefoot managed through 1st MTP fusion combined with Stainsby procedures of the lesser toes.[33] the study conducted by Coughlin demonstrated an average AOFAS score of 69 out of 90 on first MTPJ arthrodesis and lesser metatarsal heads resection.[25] In the current series, all the SF-6 components score ranged 38.2 – 55.7 pre-operatively, which were significantly improved post-operatively in the range of 72.2 – 85.9. This improvement in SF-36 components was further justified by the significant MCID levels see Table 2.

Table 2: Comparison of previously published literature with our study.

	Bass et al. 2014	Coughlin et al. 2000	Mukabeta & McCollum et al.
Study sample	13	32	19
HVA	48 to 14	38 to 20	44 to 20
IMA	15-9	11-8	12-9
AOFAS (hallux)	46 to 72	69	45 to 61
Union	All by 12 months	All by 74 months	All by 6 months
Complications	3/13 (23%)	15/32 (47%)	4/19 (14%)

HVA- Hallux Valgus angle; IMA- Intermetatarsal angle; AOFAS (American Orthopaedics Foot and Ankle Society).

Similar benefits were also documented in the case of VAS pain and disability percentages post-operatively. While the VAS pain percent significantly improved from 71.6 to 15.1%, the VAS disability percent reduced from 75.2 to 16.3%.

The Simon et al. retrospective study demonstrated no forefoot pain, pain under strain, and in resting stage in 35%, 40% and 23% patients who underwent complete forefoot corrections done by the Tillmann method (Hueter-Mayo procedure), involving a dorsomedial and a plantar approach for the hallux valgus (HV) and lesser toes metatarsal heads resection respectively.[78] Furthermore, decreased forefoot function was also reported. This is to be notified that the authors documented 20 years follow up outcomes, and therefore the mean tentative age of the patients at the time of surgery was 24.6 ± 3.5 years which differed effectively from the current study. Even further, the present VAS disability outcome was comparable with that of Coughlin who demonstrated limitations in daily activities in only 8.5% of patients.[25] The only variable where we are not able to achieve statistically significant differences post-operatively was the AOFAS alignment both in the bigger and lesser toes. However, stable corrections in HVA and IMA were noticed previously radiographically. The present AOFAS alignment outcomes are hard to compare as none of the previous studies documented this outcome. It is suggested that this malalignment was may be due to lateral pressure from the hallux that might have occurred due to unstable first MTP joint following excisional arthroplasty.

Our complication rate was also lower, as we had one case each of non-union and one case of wound infection which settled on revision surgery, oral antibiotics and wound care. At 6 months zero patients had recurrence of deformity or metatarsalgia. Previous published reports documented a much higher overall complication rate. For instance, studies published

by Bass et al. and Whitt et al. reported the post-operative complication in 25%, and 45% patients, respectively.[33,75] Bass et al. achieved corrections in all lesser toe deformities and all fusions re-unions in 12 months, while we were able to attain the outcomes in six months.[33] Similarly, the reoperation rate was 30% and 43.3% in studies conducted by Coughlin and Simon et al, which was approximately 5% in our case. [33,78] This is to be expected with the passage of time and recurrence of the disease, leading reoperations. Although we have a shorter follow up in the current study, we expect few of our patients to return back in the following years as the disease recurs. Therefore, the findings of our study cannot be generalized in the long-term as these patients will require surveillance.

Together, the highly restricted complication rate directly influenced the attainment of MCID in the current study and suggested the efficiency of the adopted protocol at least in the South African population. It is worthwhile to discuss the outcomes of Mulcahy et al. who have highlighted the better efficacy outcomes of procedures involving stable 1st ray over procedures involving major resections in terms of foot function, improved plantar pain, and HVA and IMA score.[36] The modified Hoffman procedure resides under the category of major resection procedure involving resection of all five lesser metatarsal heads. Although the authors demonstrated maximum re-operation and plantar pain in patients who underwent the Keller and Clayton procedure respectively, the present study rules out the overall superiority of procedures involving stable 1st ray, over procedures involving major resections of the specifically modified Hoffmann procedure of ours.

Our study established an inversely proportional relationship with the BMI and Physical Component Score (SF36 PCS) and VAS Pain score, and a linear relationship with AOFAS for the lesser toe. This is in concomitance with the previous reports which also demonstrated the inconsistent impact of BMI on HV incidence outcomes. While few studies reported the protective role of higher BMI in HV incidence other reported higher HV incidence with increasing BMI.[79-82] It is therefore recommended to conduct further cohort studies for clear outcomes.

The major study limitations include its retrospective nature, small patient population, and the limited clinical follow up of 6 months. Nevertheless, the current study managed to prove the hypothesis that reconstructive surgery performed according to the modified Hoffmann protocol in patients suffering from severe forefoot deformities due to Rheumatoid arthritis improved radiological, clinical and functional outcomes or QOL / VAS. This study is critical to inform a reliable technique in the management of forefoot deformities as they are often done first before hip and knee to ensure patient is able to weight bear comfortably. Thirdly, the study used valid and reproducible outcome measures such as the

VAS and AOFAS and SF-36 scores. However, for validation of our findings we recommend a multi-centre randomized trial with a large patient's data set.

Finally, we recommend a stable fusion in the arthritic hallux valgus, preferably with a locking plate combined with the resections of 2-4 metatarsal heads, and realignment plus stabilization with k-wires – this gives us a reliable and consistent result at 6 months.

Further work is needed in these areas to find more reliable joint preservation correction methods as joint arthroplasty or fusion does not restore normal mechanics in a few patients whom often times are young with no arthritic changes.

Conclusion

In summary, modified Hoffman reconstruction is a viable treatment option for the South Africans suffering from severe forefoot deformities secondary to rheumatoid arthritis as it is a stable repair with a high success rate with a low complication profile that objectively shows improved midterm outcomes.

Conflict of interest

None to declare.

Ethical statement

We reviewed hospital records, and the data was dealt with in an anonymized manner and only patient unique identity numbers were used. This study was a retrospective study; hence formal consent from the patients or participants was not needed.

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Author contributions

All the authors (Takura Mukabeta, George Nyandoro, David North and Graham McCollum) contributed to the research study from its inception up until the manuscript writing.

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PART C
ADDENDA

Relevant journal information and instructions to authors

Aims of the journal

The South African Orthopedic Journal is a scientific and medical publication that advances musculoskeletal medicine scientific knowledge. This journal particularly advances knowledge of all orthopedic surgery sub–disciplines. These disciplines include: hip, knee, spine, shoulder and elbow, hand, tumour and sepsis, and foot ankle surgery; including pediatric surgery. The journal publishes scholarly articles involving clinical and basic and theoretical research, (ii) review articles, (iii) expert opinions (iv) editorials and (v) letters to editor.

Criteria for publication

The criteria for publication include the following:

(i) The manuscript must be within the scope and aims of the journal.

(ii) The methods used must be described sufficient in detail, repeatable and of a high technical standard. In addition, the statistical analysis must also be done properly to a high scientific standard.

(iii) The results must have not been published in other journals.

(iv) Conclusions must be drawn from the results.

(v) The manuscript must be written in scientific British English and of high standard.

(vi) Ethical standards in medical field must have been met.

(vii) The manuscript must follow the instructions provided in the instructions to authors section.

Instructions to authors

Structure and content of submission

The manuscript body must be of 3500 words inclusive of abstract and exclusive of references. Authors are advised to follow the structure below in preparing the manuscript for submission:

i) The title page should show the title, authors and affiliations, corresponding author and declarations.

ii) A blinded manuscript with the abstract which is a summary of the manuscript encompassing the research background, methods, results, and conclusion. Below the abstract must be key words of the study.

iii) The introduction which highlights the background of the research and research gap, the methods, results, discussion and conclusion sections are to be included as major sections of the article.

iv) Statements of sources of funding sources, conflict of interest, ethical statements, and acknowledgements are to be included after the conclusion.

v) The references are to be inserted after the statements above.

vi) Tables and figures in correct format must be included each as separate files.

Title page

i) Title

The title must be informative, concise and clearly describing clearly the subject and the purpose of the manuscript.

ii) Author names and affiliations

The full name of each author with a letter as a superscript in front showing the authors affiliation must be provided below the title. The affiliations of the authors including the full address and the country of the affiliation must be indicated below the names of the authors and the e–mail address of each author must be provided if available. The corresponding author must be clearly shown as he will be responsible for handling all correspondence during all stages of the review process and post publication.

iii) Declaration

On the title page the authors must declare the contribution of each author as well as compliance with ethical practice. The authors must confirm that the work submitted is original and has not been plagiarized. In addition, the authors must highlight any conflict of interest. Finally, the authors must declare all the funding sources for the research.

Blinded abstract

i) Abstract

The abstract must have a maximum of 350 words summarizing the aim, patients and methods, results and the conclusions. In the abstract

references must not be included. A maximum six key words must be included below the abstract

Introduction

This section should provide the background of the study clearly indicating the research problem or the research gap to be addressed by the study to the medical and scientific community at large. Current literature must reveal the research gap and the importance of study to the medical and scientific community at large. The literature must be brief and up to date. The last paragraph of the introduction must highlight the research question or hypothesis.

Patients (or Materials) and methods

The methods used in the study must be stated clearly, the selection criteria used in choosing the methods and the expected outcome measures. The following aspects of the research study need to be described clearly. The study design and research methodology must be clearly outlined, whether randomization was applied in the methods or not. In case they were controls, how were the controls selected. The authors must state clearly the period of study under review and the number of participants/patients or subjects under investigation. The authors must give reasons on the selected number of participants or subjects. The criteria for inclusion and exclusion of participants or subjects must be clearly indicated. The case and outcome definitions must be clearly indicated. The description of the procedures or interventions done to patients including pre-operative and post-operative procedures or protocols must be clearly described. The outcome scores must be clearly indicated together with the minimum follow–up period of the study must be indicated. The statistical analysis done together with the detailed statistical test and package must be revealed. In addition, the authors must reveal why they chose these tests and at what level of significance are the tests considered.

The authors need also to provide sufficient detail so that other researchers can be able to replicate the study. The information must be presented in the narrative form using past tense. Furthermore, the reader

should be able to understand the manuscript from the introduction, the methods and be able to identify and describe all potential sources of bias within the study such as referral, diagnosis, exclusion, recall or treatment bias. This includes the manner in which investigators selected the patients. Consecutive inclusion implies all patients with a given diagnosis are included, while selective implies patients with a given diagnosis but selected according to certain explicit criteria (e.g., state of disease, choice of treatment). The authors must state standard procedures; they must only include new procedure, interventions or alterations to standard procedures. Where relevant, tables or figures may be included to provide information more clearly. Finally, data must not be included in the methods section.

Results

The authors must present and describe important results for interpretation and analysis thereof. Details on the number of patients or subjects included and excluded, including their reasons for inclusion and exclusion must be stated. The mean and range of the follow up period must be clearly stated. The results section should be divided into sub sections, for example Treatment, Functional Outcome, Complications, etc. Relevant data must be shown or presented as mean, with ranges and standard deviations (SDs) must not be included. In studies with participants or subjects involving less than 100, authors must avoid using percentages. P values or survivorship analysis must be used to back up results. All Kaplan–Meier data should be presented with the confidence intervals. P values must be presented in their absolute terms. In situations where the P values do not depict the entire picture, confidence intervals can be presented.

Discussion

In this section, the authors should discuss the research question or hypothesis stated in the introduction section. This is the section where results are interpreted and any areas of weakness must be clearly expressed. Authors must avoid repeating results. In this section the discussion points must reveal the relevance of the work and its contribution to the body of knowledge. The authors must reveal what was deduced from the results and

analysis and its implication on the medical practice. In addition, authors must use relevant literature to support or criticize their findings, placing the results of the study in the context of previous work in this area. The authors must present the limitations of their study and suggest areas of further research and how the study can be improved in the future. Authors must avoid coming up with statements from non–significant trends unless the study can significantly answer the research question.

Conclusion

The authors must provide a statement that summarizes the findings and the implication of the findings to the scientific and medical community at large. The authors must make sure that concluding statement must be supported by the research findings and data from the specific study presented.

Conflict of interest

In this section, any conflict of interest must be declared by the authors. The format presented below must be used to declare any conflict of interest by the authors. If there are no conflicts to declare the authors must state so.

"Author A.B. (*use initials of relevant author, not full name in order for the document to remain blinded*) has received research grants from Company A. Author B.C. has received a speaker honorarium from Company X and owns stock in Company Y. Author C.D. is a member of committee Z."

Ethical statement

For studies involving human subjects the following statement below must be included and informed consent forms must have been obtained, unless the study is a retrospective study where consent is not required:

"All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards."

"For consent and if identifying information about the participants is included in the manuscript the following statement must be included."

"Additional informed consent was obtained from all individual participants for whom identifying information is included in this article."

Studies involving use of animals studies the statement below must be included.

"All applicable international, national, and/or institutional guidelines for the care and use of animals were followed.' If the study did not involve human or animal subjects state that: 'This article does not contain any studies with human participants or animals performed by any of the authors."

Funding sources

Any funding received by the authors must be listed in the manuscript. Authors are advised to use the format below. If no funding was received authors must state so.

"This work was supported by the xxxx (grant numbers xxxx,yyyy)."

Acknowledgements

This is the section where people involved or contributed to the research but were unable to earn authorship can be acknowledged and thanked for their assistance and contribution. This section is placed soon after the discussion section just before the references section.

References

References should be presented in the format required by the journal and must see examples on the Journal home page. The references must be numbered in the manner that they first appear or are mentioned in the text (consecutively). In the reference section, the citations are to be listed in the numerical order presented in the text.

Tables and figures

Table and figures must be excluded from the main text file of the main manuscript. Rather they must be submitted as individual files separately. Each table or each figure can be included as a separate file at the end of the manuscript. Each table must have a heading and each figure must have a legend.

Questionnaire/data capture instrument

Instrument 1

Forefoot Surgery Assessment Form

(Pages 1 & 2 to be completed by surgeon. Pages 3-4 and SF36 to be completed by patient. Surgeon to calculate AOS score).

Name:_____ **DOB:**___	**Date of Assessment:**
Sex:____ *Patient Label*	

Height:_____cms **Weight:**_____Kg **Smoker:** ❑ YES ❑ NO

Operation Side: ❑ Left ❑ Right

Operation:_____

Pre-operative diagnosis:

HALLUX	LESSER TOES				
❑ Hallux valgus		II	III	IV	V
❑ Hallux rigidus	Claw/hammer/mallet	❑	❑	❑	❑
❑ Post-traumatic OA	Metatarsalgia	❑	❑	❑	❑
❑ Primary OA	Transfer lesion	❑	❑	❑	❑
❑ Rheumatoid Arthritis / Inflammatory Arthritis					

Previous Operations on Foot:

❑ Forefoot (specify)
❑ Midfoot (specify)
❑ Hindfoot/Ankle (specify)

Other Joints involved:

❑ Subtalar arthrosis	Left	Right
❑ Subtalar arthrodesis	Left	Right
❑ Triple fusion	Left	Right
❑ Midfoot fusion	Left	Right
❑ Hip arthrodesis	Left	Right
❑ Knee arthrodesis	Left	Right
❑ Ankle arthrodesis	Left	Right

Past Medical History:

❑ Steroid treatment	❑ Ischaemic Heart Disease / Peripheral
❑ Immune suppression	❑ Vascular Disease
❑ Diabetes	❑ COPD
❑ DVT	❑ Other

AOS SCORE

PAIN

The line next to each item represents the amount of pain you typically had in each situation. On the far left is "No pain" and on the far right is "Worst pain imaginable". Place a mark on the line to indicate how bad your **forefoot pain** was in each of the following situations during the **past week**. If you were not involved in one or more of these situations, place an "X" in the column under the heading "N/A".

How severe was your forefoot pain:

				N/A
1	At its worst?	No pain	Worst pain imaginable	
2	Before you get up in the morning?	No pain	Worst pain imaginable	
3	When you walked barefoot?	No pain	Worst pain imaginable	
4	When you stood barefoot?	No pain	Worst pain imaginable	
5	When you walked wearing shoes?	No pain	Worst pain imaginable	
6	When you stood wearing shoes?	No pain	Worst pain imaginable	
7	When you walked wearing shoe inserts or braces?	No pain	Worst pain imaginable	
8	When you stood wearing shoe inserts or braces?	No pain	Worst pain imaginable	
9	At the end of the day?	No pain	Worst pain imaginable	

To be completed by Surgeon _____/_____ = ____%

DISABILITY

The line next to each item represents the amount of difficulty you had in performing an activity. On the far left is "No difficulty" and on the far right is "So difficult unable". Place a mark on the line to indicate how much difficulty you had performing each activity because of your **forefoot** during the **past week**. If you did not perform an activity during the past week, place an "X" in the column under the heading "N/A".

How much difficulty did you have:

				N/A
1	Walking around the house?	No difficulty	So difficult unable	
2	Walking outside on uneven ground?	No difficulty	So difficult unable	
3	Walking four or more blocks?	No difficulty	So difficult unable	
4	Climbing stairs?	No difficulty	So difficult unable	
5	Descending stairs?	No difficulty	So difficult unable	
6	Standing on tip toes?	No difficulty	So difficult unable	
7	Getting out of a chair?	No difficulty	So difficult unable	
8	Climbing up or down curbs?	No difficulty	So difficult unable	
9	Walking fast or running?	No difficulty	So difficult unable	

To be completed by Surgeon _____/_____ = ____%

SUBJECTIVE ASSESSMENT FOR COMPLETION BY PATIENT

Pain

Please tick one square in each of the boxes below that best describes the pain relating to your *big toe*.

- ❑ None
- ❑ Mild, occasional
- ❑ Moderate, daily
- ❑ Severe, almost always present

Please tick one square in each of the boxes below that best describes the pain relating to your *small toes*.

- ❑ None
- ❑ Mild, occasional
- ❑ Moderate, daily
- ❑ Severe, almost always present

Function

Activity limitations and support requirement (eg walking stick)

- ❑ No limitations, no support
- ❑ No limitation of daily activities, limited recreational activities, no support
- ❑ Limited daily and recreational activities, cane
- ❑ Severe limitation of daily and recreational activities, walker, crutches, wheelchair, brace

Footwear requirements

- ❑ Fashionable, conventional shoes, no insert required
- ❑ Comfort footwear, shoe insert
- ❑ Modified shoes or brace

OBJECTIVE ASSESSMENT FOR COMPLETION BY SURGEON

	Hallux	Lesser Toes
ROM		
MTP joint motion (doriflexion plus plantarflexion)		
Normal or mild restriction (75° or more)	❑	❑
Moderate restriction (30° - 74°)	❑	❑
Severe restriction (less than 30°)	❑	❑
IP joint motion (plantarflexion)		
No restriction	❑	❑
Severe restriction (less than 10°)	❑	❑
MTP-IP stability (all directions)		
Stable	❑	❑
Definitely unstable or able to dislocate	❑	❑
Callus related to MTP-IP		
No callus or asymptomatic callus	❑	❑
Callus, symptomatic	❑	❑
Alignment		
Good, hallux well aligned	❑	❑
Fair, some degree of hallux malalignment observed, no symptoms	❑	❑
Poor, obvious symptomatic malalignment	❑	❑

Instrument 2 AOFAS forefoot score

STEP 3: FIGURING SCORES:

RAND recommends the following straightforward approach to scoring the RAND 36-Item Health Survey.

All questions are scored on a scale from 0 to 100, with 100 representing the highest level of functioning possible. Aggregate scores are compiled as a percentage of the total points possible, using the RAND scoring table (STEP I chart).

The scores from those questions that address each specific area of functional health status (STEP II chart) are then averaged together, for a final score within each of the 8 dimensions measured. (eg pain, physical functioning etc.)

For example, to measure the patients energy/fatigue level, add the scores from questions 23, 27, 29, and 31. If a patient circled 4 on 23, 3 on 27, 3 on 29 and left 31 blank, use table 1 to score them.

An answer of 4 to Q23 is scored as 40, 3 to Q27 is scored as 60, and 3 to Q29 is scored as 40. Q31 is omitted. The score for this block is 40+60+40 =140. Now we divide by the 3 answered questions to get a total of 46.7. Since a score of 100 represents high energy with no fatigue, the lower score of 46.7% suggests the patient is experiencing a loss of energy and is experiencing some fatigue.

All 8 categories are scored in the same way. Using this questionnaire at the beginning and during the course of care, we can track the progress of the 8 parameters mentioned in the STEP II chart. Pretty nifty, eh?

STEP 2: AVERAGING ITEMS TO FORM 8 SCALES:

SCALE	NUMBER OF ITEMS	AFTER RECORDING AS PER TABLE 1, AVERAGE THE FOLLOWING ITEMS
Physical functioning	10	3, 4, 5, 6, 7, 8, 9, 10, 11, 12
Role limitations due to physical health	4	13, 14, 15, 16
Role limitations due to emotional problems	3	17, 18, 19
Energy/ fatigue	4	23, 27, 29, 31
Emotional well being	5	24, 25, 26, 28, 30
Social functioning	2	20, 32
Pain	2	21, 22
General health	5	1, 33, 34, 35, 36

How to Score the Rand SF-36 Questionnair

STEP 1: SCORING QUESTIONS:

QUESTION NUMBER	ORIGINAL RESPONSE	RECORDED VALUE
1, 2, 20, 22, 34, 36	1	100
	2	75
	3	50
	4	25
	5	0
3, 4, 5, 6, 7, 8, 9, 10, 11, 12	1	0
	2	50
	3	100
13, 14, 15, 16, 17, 18, 19	1	0
	2	100
21, 23, 26, 27, 30	1	100
	2	80
	3	60
	4	40
	5	20
	6	0
24, 25, 28, 29, 31	1	0
	2	20
	3	40
	4	60
	5	80
	6	100
32, 33, 35	1	0
	2	25
	3	50
	4	75
	5	100

Instrument 3

Attention - DO NOT enter patient data on this form if the header does not contain *preprinted* HALT PKD ID number, clinical center ID, and visit number.

Participant ID:_____ *haltid* **Clinical Center:** _____*clinic* **Date of Visit** ___/___/_____ *dvm / dvd / dvy*

visit: ___**Form was not completed** *misfr*

Missing Data Codes:	A-Participant Refused	B-Reading Not Possible	C-Institutional Error

QUALITY OF LIFE QUESTIONNAIRE (SF- 36v2 ™ Health Survey) Form # 3

4. During the past 4 weeks, how much of the time have you had any of the following problems with your work or other regular daily activities as a result of your physical health ?

	All of the time	Most of the time	Some of the time	A little of the time	None of the time
a. Cut down on the amount of time you spent on work or other activities *cuttm*	4 ☐	3 ☐	2 ☐	1 ☐	0 ☐
b. Accomplished less than you would have liked *dolss*	4 ☐	3 ☐	2 ☐	1 ☐	0 ☐
c. Were limited in the kind of work or other activities *lmtknd*	4 ☐	3 ☐	2 ☐	1 ☐	0 ☐
d. Had difficulty performing the work or other activities (for example, it took extra effort) *dffwrk*	4 ☐	3 ☐	2 ☐	1 ☐	0 ☐

5. During the past 4 weeks, how much of the time have you had any of the following problems with your work or other regular daily activities as a result of any emotional problems (such as feeling depressed or anxious)?

	All of the time	Most of the time	Some of the time	A little of the time	None of the time
a. Cut down the amount of time you spent on work or other activities *ecuttm*	4 ☐	3 ☐	2 ☐	1 ☐	0 ☐
b. Accomplished less than you would like *edolss*	4 ☐	3 ☐	2 ☐	1 ☐	0 ☐
c. Did your work or activities less carefully than usual *elsscr*	4 ☐	3 ☐	2 ☐	1 ☐	0 ☐

6. During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups? *extent*

Not at all	Slightly	Moderately	Quite a bit	Extremely
0 ☐	1 ☐	2 ☐	3 ☐	4 ☐

Attention - DO NOT enter patient data on this form if the header does not contain *preprinted* HALT PKD ID number, clinical center ID, and visit number.

Participant ID:_____ *haltid* **Clinical Center:** _____*clinic* **Date of Visit** ___/___/_____
dvm / dvd / dvy

visit: ___**Form was not completed** *misfrm*

Missing Data Codes:	A-Participant Refused	B-Reading Not Possible	C-Institutional Error

QUALITY OF LIFE QUESTIONNAIRE (SF- 36v2 ™ Health Survey) Form # 38

This survey asks for your views about your health, how you feel and how well you are able to do your usual activities. Answer every question by checking the appropriate response. There are no right or wrong answers. If you are unsure abou how to answer a question, please give the best answer you can.

1. In general, would you say your health is: *health*

Excellent	Very Good	Good	Fair	Poor
0 ☐	1 ☐	2 ☐	3 ☐	4 ☐

2. Compared to one year ago, how would you rate your health in general now? *rthlth*

Much better	Somewhat better	About the same	Somewhat worse	Much worse
0 ☐	1 ☐	2 ☐	3 ☐	4 ☐

3. The following questions are about activities you might do during a typical day. Does your health now limit you in these activities? If so, how much?

	Yes, limited a lot	Yes, limited a little	No, not limited at all
a. Vigorous activities, such as running, lifting heavy objects, participating in strenuous activities. *vgract*	2 ☐	1 ☐	0 ☐
b. Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf *mdract*	2 ☐	1 ☐	0 ☐
c. Lifting or carrying groceries *lcgroc*	2 ☐	1 ☐	0 ☐
d. Climbing several flights of stairs *cmstair*	2 ☐	1 ☐	0 ☐
e. Climbing one flight of stairs *csstair*	2 ☐	1 ☐	0 ☐
f. Bending, kneeling, or stooping *bdknstp*	2 ☐	1 ☐	0 ☐
g. Walking more than a mile *wlkml*	2 ☐	1 ☐	0 ☐
h. Walking several hundred yards *wlkyd*	2 ☐	1 ☐	0 ☐
i. Walking one hundred yards *wlkoyd*	2 ☐	1 ☐	0 ☐
j. Bathing or dressing yourself *bthdrs*	2 ☐	1 ☐	0 ☐

Attention - DO NOT enter patient data on this form if the header does not contain *preprinted* HALT PKD ID number, clinical center ID, and visit number.

Participant ID:_____ *haltid* **Clinical Center:** _____*clinic* **Date of Visit** ___/___/_____
dvm / dvd / dvy

visit: ___**Form was not completed** *misfrm*

Missing Data Codes:	A-Participant Refused	B-Reading Not Possible	C-Institutional Error

QUALITY OF LIFE QUESTIONNAIRE (SF- 36v2 ™ Health Survey) Form # 38

7. How much bodily pain have you had during the past 4 weeks? *pnxtnt*

None	Very mild	Mild	Moderate	Severe	Very severe
0 ☐	1 ☐	2 ☐	3 ☐	4 ☐	5 ☐

8. During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)? *pnintf*

Not at all	Slightly	Moderately	Quite a bit	Extremely
0 ☐	1 ☐	2 ☐	3 ☐	4 ☐

9. These questions are about how you feel and how things have been with you during the past 4 weeks. For each question, please give the one answer that comes closest to the way you have been feeling.

How much of the time during the Past 4 weeks….	All of the time	Most of the time	Some of the time	A little of the time	None of the time
a. Did you feel full of life? *flife*	4 ☐	3 ☐	2 ☐	1 ☐	0 ☐
b. Have you been very nervous? *nervs*	4 ☐	3 ☐	2 ☐	1 ☐	0 ☐
c. Have you felt so down in the dumps that nothing could cheer you up? *edown*	4 ☐	3 ☐	2 ☐	1 ☐	0 ☐
d. Have you felt calm and peaceful? *ecalm*	4 ☐	3 ☐	2 ☐	1 ☐	0 ☐
e. Did you have a lot of energy? *fenrgy*	4 ☐	3 ☐	2 ☐	1 ☐	0 ☐
f. Have you felt downhearted and depressed? *edprss*	4 ☐	3 ☐	2 ☐	1 ☐	0 ☐
g. Did you feel worn out? *wrnout*	4 ☐	3 ☐	2 ☐	1 ☐	0 ☐
h. Have you been happy? *ehppy*	4 ☐	3 ☐	2 ☐	1 ☐	0 ☐
i. Did you feel tired? *etred*	4 ☐	3 ☐	2 ☐	1 ☐	0 ☐

10. During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives, etc.)? *sinterf*

All of the time	Most of the time	Some of the time	A little of the time	None of the time
4 ☐	3 ☐	2 ☐	1 ☐	0 ☐

Attention - DO NOT enter patient data on this form if the header does not contain *preprinted* HALT PKD ID number, clinical center ID, and visit number.

Participant ID:_____ *haltid* **Clinical Center:** _____*clinic* **Date of Visit** ___/___/_____
dvm / dvd / dvy

visit: ___**Form was not completed** *misfrm*

Missing Data Codes:	A-Participant Refused	B-Reading Not Possible	C-Institutional Error

QUALITY OF LIFE QUESTIONNAIRE (SF- 36v2 ™ Health Survey) Form # 38

11. How TRUE or FALSE is each of the following statements for you?

	Definitely True	Mostly True	Don't Know	Mostly False	Definitely False
a. I seem to get sick a little easier than other people *esysck*	4 ☐	3 ☐	2 ☐	1 ☐	0 ☐
b. I am as healthy as anybody I know *hlthy*	4 ☐	3 ☐	2 ☐	1 ☐	0 ☐
c. I expect my health to get worse *hlthwrs*	4 ☐	3 ☐	2 ☐	1 ☐	0 ☐
d. My health is excellent *hlthgd*	4 ☐	3 ☐	2 ☐	1 ☐	0 ☐

Thank you for completing this very important questionnaire!

****

Reviewed by Designated Personnel (signature required): _____ **Date:** ____/____/____
cmidnum **Month** *cdm* **Day** *cdd* **Year** *cdy*

Data Entry Status: Please check to indicate that the above information has been entered ☐

Primary Entered by: _____ *deidnum* Date: __ __/__ __/__ __ __ __ *dem / ded / dey*

Consent forms and any related participant information sheets

Not applicable, since this study was a patient folder and x-ray review that was operated on from 2013 to 2016.

Research Protocol

Department of Orthopedics

H49 Old Main Building

Groote Schuur Hospital
021 4045108

Research Protocol synopsis

TITLE: RECONSTRUCTIVE SURGERY OUTCOMES FOR SEVERE FOREFOOT DEFORMITIES IN PATIENTS WITH RHEUMATOID ARTHRITIS AT GROOTE SCHUUR HOSPITAL, CAPE TOWN-SOUTH AFRICA: A LONGITUDINAL STUDY FROM 2013 TO 2016

Principal investigator: Dr G McCollum

Mmed Student: Dr T Mukabeta

Rheumatoid arthritis (RA) is a chronic autoimmune mediated, inflammatory and systemic disease[1-7]. RA is prevalent in females (3% women) due to sex hormone imbalances[1, 8]. The synovial membrane that lines the joints is infiltrated by white blood cells, B cells, Macrophages, and T cells, while neutrophils dominate the synovial fluid[8]. This triggers chronic inflammation, eventually destroying joint cartilage and bones[8].

Pathogenesis of arthritis is more dominant in females than in males [7-8]. Thus, RA is a joint disease associated with cartilage, bone damage and disability[8]. Twenty percent (20%) of RA patients present with foot pain and deformity[2]. Studies in United States of America (USA) showed varying RA work disability prevalence ranging between 32% and 50% at 10 years of disease duration [10-12], the forefoot being the most commonly affected [3].

RA affects the metatarso-phalangeal joints[1-2], ligaments and capsule leading to chronic instability, [3-5] subluxation and joint destruction and eventually severe hallux valgus[13] with possible dislocation of the lesser MPJ's [10-12]. The plantar and dorsal parts of the forefoot are exposed to local pressure[4-5]. Eventually the deformities result in disability, difficulties when wearing shoes, excruciating pain, and ulceration on pressure points.

Surgery would be another alternative only when conservative management fails[13]. The aims of the surgery include pain relief, improved ambulation, prevention of skin breakdown from pressure areas, and improved shoe wear. The different types of forefoot surgery available for the hallux are: arthrodesis, arthroplasty, corrective osteotomies, and excision [2-14]

There is limited evidence of research into Forefoot Reconstructive surgery from South Africa among RA patients. This was the first extended review of clinical records in Reconstructive surgery in South

Africa with a rigorous follow up to gather information on forefoot surgery outcomes. Follow up of the patients will be done to establish the impact of this surgery in terms of morbidity, mortality and cure, psycho-social and economic effects after surgery procedures.

Purpose: The study aims to retrospectively review the reconstructive surgery outcomes among patients suffering severe forefoot deformities for Rheumatoid arthritis

Methodology: A retrospective follow up of 19 patients who had reconstructive forefoot surgery to correct forefoot deformities for Rheumatoid arthritis. The patient records from year 2013 to 2016 will be reviewed, pre-operative outcomes (baseline), post-operative including x-rays will be determined. The time between pre and post-operative was 6 months. Patients completed: SF36 PF, SF36 RP, SF36 RE, SF36 VT, SF36 MH, SF36 SF, SF36 BP, SF36 GH, SF36 PCS, SF36 MCS, AOS Pain, AOS alignment, AOS Function, AOS Total, VAS pain percent, and VAS disability percent forefoot score preoperatively and postoperatively; and these will be utilized.

Inclusion criteria: Patients with accessible relevant Medical File Record at Groote Schuur Hospital at the time of the study.

Exclusion criteria: Medical File Records with incomplete information on patient details and post-surgical care will be excluded from the study.

Procedure: This study will be a retrospective review of reconstructive surgical records between January 2013 and December 2016. Pre- and post-operative pain scores taken just before surgery and at six month follow up from patient files will be used in this study. Data will be handled in an anonymized manner. The final data which will be sent for analysis will not contain any information linking to the identity of any individual patient.

Risk: There will be no risks as the study involves hospital folder review.

Data Security: Data de-identification will be done by removing names and addresses before sharing with the statistician. Data will be stored with password protection and patient files were always kept under lock and key. After 10 years, each patient's data will be assigned a numerical code for identification.

Informed consent: There will be no informed consent process, as this is a retrospective study.

Privacy and confidentiality: The department of the hospital itself is accessible only by an activated electronic card, exclusively available for staff. All the records are locked in the filing department.

Declaration: There will be no external or internal funding for the study.

UNIVERSITY OF CAPE TOWN
Faculty of Health Sciences
Human Research Ethics Committee

Room E53-46 Old Main Building
Groote Schuur Hospital
Observatory 7925
Telephone [021] 406 6492
Email: sumayah.ariefdien@uct.ac.za
Website: www.health.uct.ac.za/fhs/research/humanethics/forms

12 January 2018

HREC REF: 811/2017

Dr G McCollum
Department of Orthopaedic Surgery
H-Floor
OMB

Dear Dr McCollum

PROJECT TITLE: RECONSTRUCTIVE SURGERY OUTCOMES FOR SEVERE FOREFOOT DEFORMITIES IN PATIENTS WITH RHEUMATOID ARTHRITIS AT GROOTE SCHUUR HOSPITAL, CAPE TOWN-SOUTH AFRICA: A LONGITUDINAL STUDY FROM 2013-2016 (MMeD-candidate-Dr T Mukabeta)

Thank you for your response letter dated 09 January 2018, addressing the issues raised by the Human Research Ethics Committee (HREC).

It is a pleasure to inform you that the HREC has **formally approved** the above-mentioned study.

Approval is granted for one year until the 30 January 2019.

Please submit a progress form, using the standardised Annual Report Form if the study continues beyond the approval period. Please submit a Standard Closure form if the study is completed within the approval period.
(Forms can be found on our website: www.health.uct.ac.za/fhs/research/humanethics/forms)

We acknowledge that the student: Dr T Mukabeta will also be involved in this study.

Please quote the HREC REF in all your correspondence.

Please note that the ongoing ethical conduct of the study remains the responsibility of the principal investigator.

Please note that for all studies approved by the HREC, the principal investigator **must** obtain appropriate institutional approval, where necessary, before the research may occur.

Yours sincerely

Signature Removed

PROFESSOR M BLOCKMAN
CHAIRPERSON, FHS HUMAN RESEARCH ETHICS COMMITTEE

Federal Wide Assurance Number: FWA00001637.

HREC 811/2017

Institutional Review Board (IRB) number: IRB00001938
This serves to confirm that the University of Cape Town Human Research Ethics Committee complies to the Ethics Standards for Clinical Research with a new drug in patients, based on the Medical Research Council (MRC-SA), Food and Drug Administration (FDA-USA), International Convention on Harmonisation Good Clinical Practice (ICH GCP), South African Good Clinical Practice Guidelines (DoH 2006), based on the Association of the British Pharmaceutical Industry Guidelines (ABPI),and Declaration of Helsinki (2013) guidelines.
The Human Research Ethics Committee granting this approval is in compliance with the ICH Harmonised Tripartite Guidelines E6: Note for Guidance on Good Clinical Practice (CPMP/ICH/135/95) and FDA Code Federal Regulation Part 50, 56 and 312.

UNIVERSITY OF CAPE TOWN

FACULTY OF HEALTH SCIENCES
Human Research Ethics Committee

FHS016: Annual Progress Report / Renewal

HREC office use only (FWA00001637; IRB00001938) This serves as notification of annual approval, including any documentation described below.			
☑ Approved	Annual progress report	Approved until/next renewal date	28-02-2021
☐ Not approved	See attached comments		
Signature Chairperson of the HREC	Signature Removed	Date Signed	27/2/2020

Comments to PI from the HREC
Thank you for the deviation shared

Principal Investigator to complete the following:

1. Protocol Information

Date (when submitting this form)			
HREC REF Number	811/2017	Current Ethics Approval was granted until	30/01/2019
Protocol title	**RECONSTRUCTIVE SURGERY OUTCOMES FOR SEVERE FOREFOOT DEFORMITIES IN PATIENTS WITH RHEUMATOID ARTHRITIS AT GROOTE SCHUUR HOSPITAL, CAPE TOWN-SOUTH AFRICA: A LONGITUDINAL STUDY FROM 2013 TO 2015**		
Protocol number (if applicable)			
Are there any sub-studies linked to this study?	☐ Yes × No		
If yes, could you please provide the HREC Ref's for all sub-studies? **Note:** A separate FHS016 must be submitted for each sub-study.			

(Note: Please complete the Closure form (FHS010) if the study is completed within the approval period)

Principal Investigator	Dr Graham Mccollum
Department / Office Internal Mail Address	Ga.mccollum@uct.ac.za

1.1 Does this protocol receive US Federal funding?	☐ Yes	× No
1.2 If the study receives US Federal Funding, does the annual report require full committee approval? **Note:** Any annual approvals for **Full Committee** review MUST be submitted on the monthly HREC submission dates. (Please send electronic copy for full committee review to hrec-enquiries@uct.ac.za)	☐ Yes	× No
If yes in 1.2 please complete section 1.3 below for invoicing purposes		
1.3 Annual Approval for **full committee** review	- R 3450 (inclusive of vat)	

For invoicing purposes, please provide:	
Sponsor's name	
Contact person	
Address	
Telephone number	
Email Address	

2. List of documentation for approval

3. Protocol status (tick ✓)

☐	Open to enrolment
☐	Closed to enrolment (tick ✓)
☐	Research-related activities are ongoing
☐	Research-related activities are complete, long-term follow-up only
☐	Research-related activities are complete, data analysis only
☐	Main study is complete but sub-study research-related activities are ongoing

(Note: Please complete the Closure form (FHS010) if the study is completed within the approval period)

☐	Study is closed → Please submit a Study Closure Form (FHS010)

4. Enrolment

Number of participants enrolled to date	19
Number of participants enrolled, since last HREC Progress report (continuing review)	0
Additional number of participants still required	0

5. Refusals

Total number of refusals (participants invited to join the study, but refused to take part)	0

6. Cumulative summary of participants

Total number of participants who provided consent	0
Number of participants determined to be ineligible (i.e. after screening)	0
Number of participants currently active on the study	0
Number of participants completed study (without events leading to withdrawal)	0
Number of participants withdrawn at participants' request (i.e. changed their mind)	0
Number of participants withdrawn by PI due to toxicity or adverse events	0
Number of participants withdrawn by PI for other reasons (e.g. pregnancy, poor compliance)	0
Number of participants lost to follow-up. Please comment below on reasons for loss of follow-up.	0
Number of participants no longer taking part for reasons not listed above. Please provide reasons below:	0

7. Progress of study

Please provide a brief summary of the research to date including the overall progress and the progress since the last annual report as well as any relevant comments/issues you would like to report to the HREC:
Data collection completed,journal article prepared and submitted for publication. We intend to present our dissertation using Publication-ready format,and should be ready hopefully by mid 2020. We would like to renew our ethics approval to allow us to complete the final stages.

(Note: Please complete the Closure form (FHS010) if the study is completed within the approval period)

8. Protocol violations and exceptions (tick ✓ all that apply)

×	No prior violations or exceptions have occurred since the original approval
☐	Prior violations or exceptions have been reported since the last review and have already been acknowledged or approved
☐	Unreported minor violations that have occurred since the last review, as well as significant deviations not yet reported, are attached for review

9. Amendments (tick ✓ all that apply)

×	No prior amendments have been made since the original approval
☐	Prior amendments have been reported since the last review and have already been approved
☐	New protocol changes/ amendments are requested as part of this continuing review (See note below)

Note: If new protocol changes are being requested in this review, please complete an amendment form (FHS006).
Specific changes in the amended protocol and consent/assent forms must be **bolded**, *italicised* or tracked and all changes must include a rationale.

10. Adverse events

10.1 Please provide below or attach a narrative summary of serious adverse events and/ or unanticipated problems since the last progress report. Please indicate changes made to the protocol and informed consent document(s) as a result (if not already reported to the HREC). Please comment on whether causality to any study procedure or intervention could be established.
N/A

10.2 Have participants received appropriate treatment/ follow-up/ referral when indicated (e.g. in the case of abnormal or incidental clinical findings, distress or anxiety)?		
☐ Yes	☐ No	× Not applicable
If yes, please describe:		

11. Summary of Monitoring and Audit Activities (tick ✓)

11.1 Was this study monitored or audited by an external agency (e.g. SAHPRA, FDA)?		
☐ Yes	☐ No	× Not applicable

11.2 Did a Data and Safety Monitoring Board publish a report?		
☐ Yes	☐ No	× Not applicable

11.3 If yes, please identify the agency and attach a summary of the findings.

(Note: Please complete the Closure form (FHS010) if the study is completed within the approval period)

Agency Name		Report attached	☐ Yes	☐ No	× Not applicable
		DSMB report attached	☐ Yes	☐ No	× Not applicable

11.4 Has there been any agency, institutional or other inquiry into non-compliance in this study, or any finding of non-compliance concerning a member of the research team?	
☐ Yes	× No
If yes, please explain:	

12. Level of risk (tick ✓)

12.1 In light of your experience of this research, please indicate whether the level of risk to participants has:	
☐	Increased
☐	Decreased
×	Shown no change
If there has been a change, please explain:	

12.2 Please provide a narrative summary of recent relevant literature that may have a bearing on the level of risk.

13. Statement of conflict of interest

Has there been any change in the conflict of interest status of this protocol since the original approval? (tick ✓)	
☐ Yes	× No
If yes, please explain and if necessary, attach a revised conflict of interest statement (Section #7 in the New Protocol Application Form FHS013):	

14. Signature

My signature certifies that the above is complete and correct.			
Signature of PI		Date	

(Note: Please complete the Closure form (FHS010) if the study is completed within the approval period)

UNIVERSITY OF CAPE TOWN

FACULTY OF HEALTH SCIENCES
Human Research Ethics Committee

Form FHS011: Study deviation

HREC office use only (FWA00001637; IRB00001938)			
This serves as acknowledgement of a protocol deviation as described below.			
Chairperson of the HREC signature	Signature Removed	Date	26/2/20

Principal Investigator to complete the following:

1. Protocol Information

Date (when submitting this form)	28/02/2020
HREC REF Number	811/2017
Project Title	RECONSTRUCTIVE SURGERY OUTCOMES FOR SEVERE FOREFOOT
Protocol number (if applicable)	
Principal Investigator	DR GRAHAM MCCOLLUM
Department / Office Internal Mail Address	bulelwa.klaas2@westerncape.gov.za

2. Protocol deviation description

Please describe the deviation below, including the reason why the deviation occurred.
We did not apply for a renewal of the ethics certificate in time. We submitted our paper for publication and I thought maybe to wait applying for renewal until the journal paper had been accepted.I realise this to be an error.

3. Follow-up actions

3.1 Please describe any follow-up action(s) taken or planned as a result of this deviation e.g. DSMB reporting, report to sponsor, informing participants.
We will make sure to apply for ethics renewal just before it expires.
3.2 Please describe what action(s) have or will be taken to prevent similar deviations in future.
We will make sure to apply for ethics renewal just before it expires.

4. Principal Investigator's acknowledgement of responsibility

This signature indicates the PI has reviewed the deviation, taken appropriate follow-up action and implemented or plans to implement preventative steps where possible.

Signature of PI	Signature Removed	Date	26/02/2020.