Journal of Orthopaedics 20 (2020) 338–341

Contents lists available at ScienceDirect

Journal of Orthopaedics

journal homepage: www.elsevier.com/locate/jor

Cartiva case series: The efficacy of the cartiva synthetic cartilage implant interpositional arthroplasty at one year

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ARTICLE INFO

Keywords:
Arthritis
Hallux rigidus
Cartiva
PROMs
Synthetic cartilage implant

ABSTRACT

Background: The Cartiva synthetic cartilage implant (SCI) is licenced for use in management of symptomatic hallux rigidus in several countries including the UK. As of now, there are no independent series for treatment of hallux rigidus utilising polyvinyl alcohol implants.

Methods: Patients at a single centre with symptomatic hallux rigidus who underwent Cartiva implant interpositional arthroplasty were identified. First metatarsophalangeal joint arthritis was radiographically graded according to the Hattrup and Johnson (HJ) classification. Pre-operative and post-operative patient-reported outcomes (PROMs) were evaluated using the Foot and Ankle Ability Measure (FAAM) activities of daily living subscale and the Manchester-Oxford Foot Questionnaire (MOXFQ).

Results: 55 patients (14M, 41F) (37R and 18L) were followed up for an average of 21 months (min = 12, max = 38). 14 patients suffered from HJ2/moderate arthritis and 41 patients with grade HJ3/severe arthritis.

Post-operative mean FAAM scores showed statistically significant improvement ($p < 0.0001$). Patients reported a 40% increase in functionality during activities of daily living.

All 3 MOXFQ Domain scores improved significantly ($p < 0.02$). The Index score improved by 34 points ($p < 0.0001$).

There was no correlation between length of follow up or age and PROMs ($r = 0.129$). No statistical difference was demonstrated between sexes. Clinically, however, males and older patients exhibited better outcomes.

Conclusions: Our study shows excellent results with statistically significant improvements in functional outcomes, and promising short-term follow-up with low early revision rates. Durability and survivability of the implant will continue to be studied in this cohort.

1. Introduction

The Cartiva Synthetic Cartilage Implant (SCI) was created to act as an interpositional arthroplasty implant for the management of hallux rigidus.[1] It is a polyvinyl alcohol implant has similar biomechanical properties as normal human cartilage and measures 10 mm × 10 mm.[1] The Cartiva SCI hopes to reduce pain and maintain the range of motion in the joint allowing patients to return to their normal day-to-day functionality without compromise. Currently, there are no independent series for treatment of hallux rigidus utilising polyvinyl alcohol implants. The Cartiva Motion study is an industry-funded originator series randomised trial which demonstrated statistically significant improvements in functionality and reduction in pain at two and five years. Previous implants have been tried and studied. These implants, such as the HemiCap, Silastic or BioPro toe and others, had high failure rates due to loosening, material failure and subsidence.[2]

Hallux rigidus is the result of severe first metatarsophalangeal joint (FMTPJ) arthritis with osteophyte formation.[3] This leads to pain, swelling, reduced range of motion and stiffness in the joint. It is a common condition in those over 50 years old.[4] Patients can be left limited in their functionality, suffering with constant pain affecting their productivity and sporting activities.

Treatment of hallux rigidus normally involves operative and non-operative techniques. Non-operative techniques involve shoe and lifestyle modification whereas operative techniques can be subdivided into joint sparing (cheilectomy and interpositional arthroplasty) and joint sacrificing (osteotomy and arthrodesis).[5] The gold standard management technique is arthrodesis as it results in good post-operative

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https://doi.org/10.1016/j.jor.2020.05.009
Received 21 February 2020; Received in revised form 10 April 2020; Accepted 3 May 2020
Available online 30 June 2020

Table 1
Patient demographics.

Number of Patients	Age/Mean (min, max)	Follow up months/Mean (min, max, SD)	Gender	Foot	Hattrup and Johnson Grade
55	56 (30, 80)	21 (12, 38, SD ± 6.0)	14 male 41 female	37 Right 18 Left	HJ 2 = 14 HJ 3 = 41

outcomes and no pain. Arthrodesis however compromises joint movement which can be devastating to some patients.[5]

Patient reported outcome measures are the best method of evaluating the efficacy of surgical outcomes. Validated outcome measures such as the Manchester Oxford Foot and Ankle questionnaire (MOXFQ)[6] and the Foot and Ankle Ability Measure (FAAM)[7] allow us to determine the success of foot and ankle surgical interventions.

The aim of this prospective case series study is to analyse the efficacy of the Cartiva SCI interpositional arthroplasty in the treatment of hallux rigidus utilising patient reported outcome measures (PROMs).

2. Methods

Audit approval was obtained from the Wythenshawe Hospital audit department.

Inclusion criteria included adult patients over 18 years of age at a single centre with symptomatic hallux rigidus who underwent primary Cartiva SCI implant procedure were identified. Patients with previous surgery to the 1st metatarsal and traumatic osteoarthritis patients were excluded.

First MTPJ arthritis was radiographically graded preoperatively, utilising PACS, according to the Hattrup and Johnson (HJ) classification.[8] First MTPJ arthritis is graded between 1 and 3, where Grade 1 is mild changes to the MTPJ with minimal osteophytosis, Grade 2 are moderate changes to the MTPJ including narrowing of the joint with osteophytosis of the metatarsal head and/or phalanx and subchondral sclerosis and/or cysts, and Grade 3 are severely arthritis MTPJ with loss of joint space, marked osteophytosis and subchondral bone changes.

At a minimum of 1 year post surgery, patient-reported outcomes were evaluated using the Foot and Ankle Ability Measure activities of daily living[7] (FAAM ADL) subscale and the Manchester-Oxford Foot Questionnaire[6] (MOXFQ).

FAAM ADL consists of 21 questions relating to daily activities and the difficulty encountered within the past week is scored by the patients between “No difficulty” and “Extremely difficult” or “Unable to do”, where “No difficulty” is given a score of 4, “Unable to do” a score of 0 and the remaining answers a score in between. The total score is divided by 84, however, for every question the patient marks as “Unable to do” are not scored in the final tally, and this score is then multiplied by 100 to express as a percentage. Finally, a subjective score from the patient is given between 0 and 100 regarding their current level of function compared to their prior level of function.

MOXFQ is a 16 question questionnaire which evaluates a person's foot and ankle functionality across three domains: Walking/Standing (7 questions), Pain (5 questions) and Social Interaction (4 questions). 5 responses are allowed between “None of the time” and “All of the time”, which are scored between 0 and 4 respectively. The total is divided by the maximum score per domain. A combined score can be calculated as an overall score of functionality and is known as the Index score.

Pre-operative scores were taken on the day of surgery and post-operative data was collected starting from the patients first clinic visit and followed-up by phone call questionnaires.

GraphPad Prism[9] was utilised to perform Wilcoxon matched-pairs signed-rank test to identify statistically significant results as determined by a p value of < 0.05.

Surgical technique involved a dorsal approach to the metatarsal head. Nerve and tendon were protected. Preparation of the metatarsal head including removal of dorsal osteophytes and implant inserted utilising press fit technique. Implant left at least 3 mm proud on all occasions. Intra-operatively, we aimed to achieve 90° of dorsiflexion in every case.

3. Results

In total, 55 adult patients were identified who fell within the criteria of the study. The cohort was divided into 14 male and 41 female patients, with 37 right feet and 18 left feet treated using Cartiva SCI. Patients were followed up for an average of 21 months (SD ± 6.0). 14 patients suffered from HJ grade 2/moderate arthritis and 41 patients with HJ grade 3/severe arthritis (Table 1).

Post-operative mean FAAM ADL scores showed statistically significant improvement ($p < 0.0001$). Objective scores improved from an average of 64% pre-operatively to 87% post-operatively. Patients reported an improvement of their subjective score of functionality of an average of 46% during activities of daily living after surgery (Table 2).

There was a statistically significant ($p < 0.0001$) improvement in average MOXFQ Index scores of 34 points, from an average of 58 pre-operatively to 24 post-operatively. Average MOXFQ Domain scores showed statistically significant improvements in all 3 domains ($p < 0.02$). Walking/Standing improved from 58 points to 25 points, pain improved from 66 to 25 points and social interaction improved from 46 to 20 points (Fig. 1).

There was no correlation between length of follow up or age and PROMs ($r = 0.129$). No statistically significant difference was demonstrated between sexes. Males exhibit better outcomes than females and older patients experienced better outcomes than their younger counterparts.

Two patients with psoriatic inflammatory arthritis and one patient with primary severe sesamoid osteoarthritis showed little improvement or deteriorated post-operatively.

There was one Cartiva-to-Cartiva revision at 14 months post-op and one revision to arthrodesis at 17 months post-operatively (Fig. 2). Fifteen patients (27.3%) underwent manipulation under anaesthesia and steroid and local anaesthetic injection at 12 weeks post-operatively due to stiffness. No patient had repeat manipulation or injection. This cohort displayed no complications, including infection, wound

Table 2
Foot and Ankle Ability Measure Activities of Daily Living Subscale (FAAM ADL) scores.

DOMAIN	FAAM Activities of daily living			STATISTICAL ANALYSIS	
	PRE-OPERATIVE	POST-OPERATIVE	TOTAL	SHAPIRO-WILKS NORMALITY TEST	WILCOXON SIGNED RANK TEST
SCORE **SUBJECTIVE SCORE**	64% (35%–98%) 41%	87% (37%–100%) 87%	23% 46%	NO	$P < 0.0001$

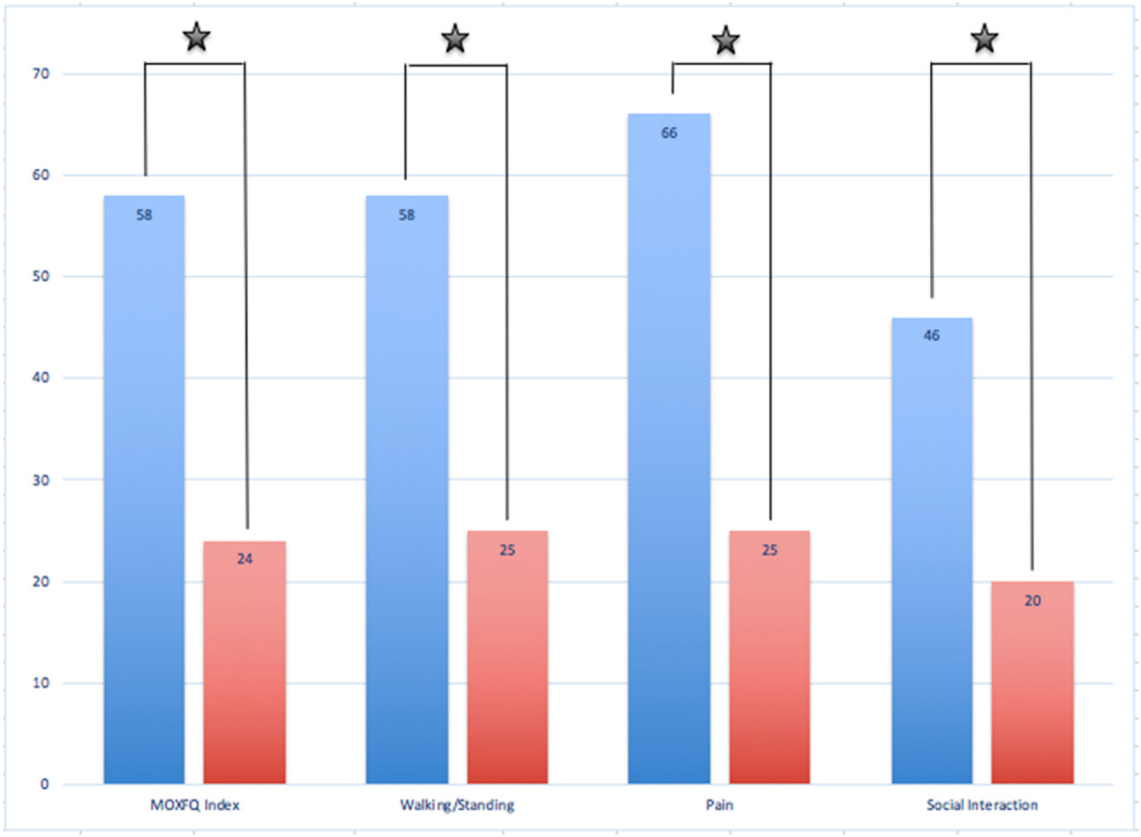

Fig. 1. Manchester Foot and Ankle Questionnaire (MOXFQ) scores.

breakdown or material failure.

There was an 89.4% patient satisfaction with the use of Cartiva.

4. Discussion

First metatarsophalangeal arthritis is a very common condition which causes pain and significantly impacts a person's day to day activities. The gold standard of treatment remains a joint arthrodesis

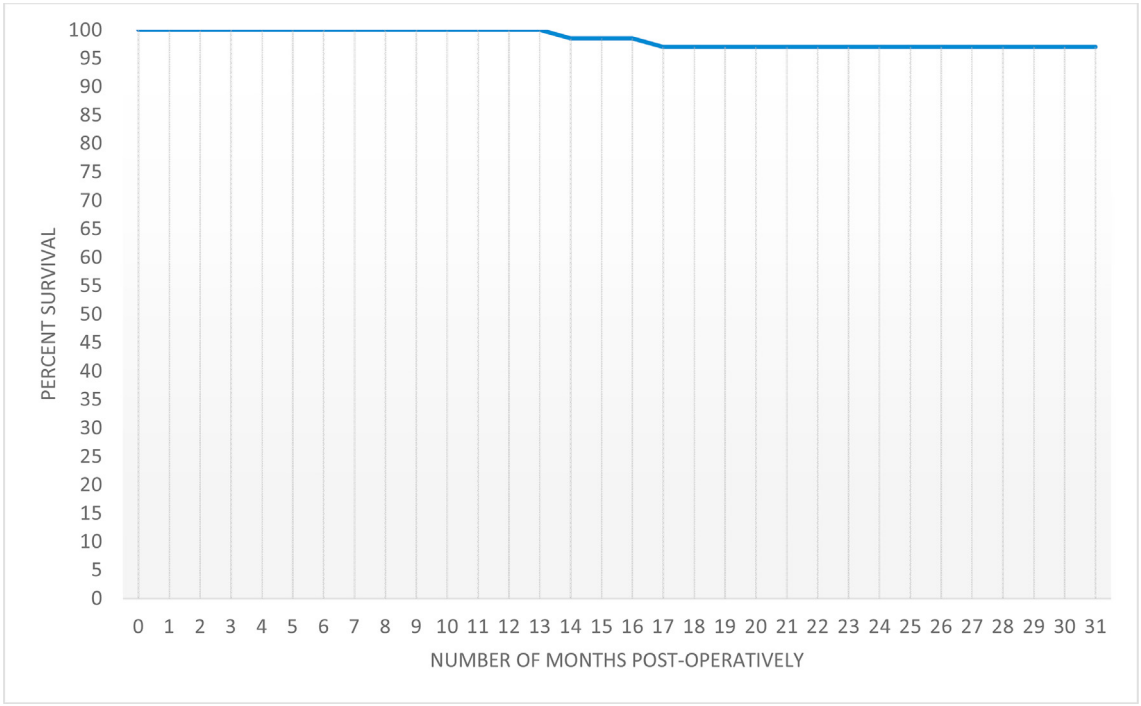

Fig. 2. Kaplan-meier survival plot.

which reduces pain but limits joint movement which impacts on a person's sporting ability and particularly for affects their shoe choice, particularly in women.

Our study demonstrates excellent results with statistically significant improvements in functional outcomes after Cartiva SCI. Foot and Ankle Ability Measure Activities of Daily Living scores improved by an average of 23% in the post-operative period with an average of a 46% increase in the subjective score, illustrating that patients experienced a genuine improvement in their functionality with the Cartiva implant. In particular, when patients were asked if they would recommend the surgery to family members or friends, only five patients (9.1%) answered 'NO', with the same results shown when patients were asked if they would have the same operation again. Six patients had Cartiva SCI performed on the contralateral foot. Two patients at the time of writing have been scheduled to have contralateral Cartiva SCI interpositional arthroplasty.

The Manchester-Oxford Foot and Ankle Questionnaire demonstrated markedly statistically significant improvements across all domains. Pain in particular was significantly reduced. The consistency of outcomes, regardless of length of follow up, suggests that positive early results indicate continued good function. There was a statistically significant improvement in Social Interaction scores. However, there was dissatisfaction within the population of females who enjoy wearing high heeled shoes as they were unable to return to normal use of their favourite shoes post-operatively. Despite the reduction in pain and improved mobility of the joint at mean twenty one months follow-up, the use of high heeled shoes still proved too difficult. This will continue to be followed up in this study.

The only current literature available on Cartiva SCI interpositional arthroplasty for treatment of hallux rigidus is the originator randomised controlled trial, Cartiva Motion Study. Our FAAM ADL scores were comparable to this study at one year post-op; 85% vs 87%. Thus far there are no non-originator series. Comparing our Cartiva SCI interpositional arthroplasty to the Hemicap exhibited similar results with regards to reduction in plain and functional scores. The Hemicap study demonstrated excellent long term follow-up scores at five years and high satisfaction rates. The cases reported in our study will continue to be followed up and compared.

There was one Cartiva-to-Cartiva revision at fourteen months post-op, with use of calcaneal bone graft, as the implant had sunk into the metatarsal. Patient was a thirty year old white female ballet dancer with grade HJ2 osteoarthritis with evidence of osteopenia and a BMI of eighteen. Young high demand patients with poor bone quality are not suitable for Cartiva SCI.

There was one revision to arthrodesis at seventeen months post-op, in a sixty one year old black male patient with grade HJ2. Unfortunately, this patient moved out of area and is now under the care of a different hospital by their orthopaedic department. We contacted the centre where the patient had revision surgery and it was disclosed to us, with patient consent, that he had been experiencing increasing pain and reduced range of motion in the 1st MTPJ. Revision surgery to arthrodesis is made possible by the small amount of bone resection required to fit the primary Cartiva implant.

There were five female patients (9.1%) who were not satisfied with the surgery. Three patients suffered with psoriatic arthritis, one other patient suffered with primary severe sesamoid osteoarthritis. These patients did not improve with use of Cartiva as it does not treat the inflammatory nature of the arthritis or relieve sesamoid OA pain. Cartiva may not be indicated to treat inflammatory arthritis of the 1st MTP and additional imaging, such as CT scanning, may be required to assess sesamoid osteoarthritis if there is clinical suspicion. Careful examination and patient selection is key. Due to the press-fit technique of implant introduction into the metatarsal head, post-menopausal women and osteoporotic patients require careful planning and possibly bone grafting to reduce risk of subsidence and loosening.

5. Conclusion

Our study shows excellent results with statistically significant improvements in functional outcomes and promising short-term follow-up with low early revision rates. Pain in particular was significantly reduced. Less than a third of patients developed post-operative stiffness requiring a manipulation under anaesthesia. Patient selection is key. Additional imaging may be required to assess sesamoid osteoarthritis. Cartiva SCI may not be indicated in patients suffering from inflammatory arthritis. Durability and survivability of the implant will continue to be studied in this cohort.

Funding received

This research did not receive any specific grant from funding agencies in the public, commercial, or not-for-profit sectors.

Declaration of competing interest

None of the authors have conflicts of interest to disclose.

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