Mid-term efficacy of the Cartiva synthetic cartilage implant in symptomatic hallux rigidus

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Aims

The Cartiva synthetic cartilage implant (SCI) entered mainstream use in the management of first metatarsophalangeal joint (MTPJ) arthritis following the positive results of large trials in 2016. Limited information is available on the longer-term outcomes of this implant within the literature, particularly when independent from the originator. This single-centre cohort study investigates the efficacy of the Cartiva SCI at up to five years.

Methods

First MTPJ arthritis was radiologically graded according to the Hattrup and Johnson (HJ) classification. Preoperative and sequential postoperative patient-reported outcome measures (PROMs) were evaluated using the Manchester-Oxford Foot Questionnaire (MOXFQ), and the activities of daily living (ADL) sub-section of the Foot and Ankle Ability Measure (FAAM).

Results

Patients were followed up for a mean of 66 months (SD 7.1). Of an initial 66 cases, 16 did not return PROM questionnaires. A total of six failures were noted, with survival of 82%. Overall, significant improvement in both objective scores (MOXFQ and FAAM ADL) was maintained versus preoperatively: 18.2 versus 58.0 ($p > 0.001$) and 86.2 versus 41.1 ($p > 0.001$), respectively. The improvement was noted to be less pronounced in males. Subjective scores had deteriorated since early follow-up, with an interval decrease in patient satisfaction from 89% to 68%. Furthermore, a subset of cases demonstrated clinically important interval deterioration in objective scores. However, no specific patient factors were found to be associated with outcomes following analysis.

Conclusion

This study represents the longest-term independent follow-up in the literature. It shows reassuring mid-term efficacy of the Cartiva SCI with better-than-expected survival. However, deterioration in scores for a subset of patients and lower satisfaction may predict ongoing failure in this group of patients. Additionally, males were noted to have a lower degree of improvement in scores than females. As such, ongoing observation of the SCI to assess durability and survivability, and identify predictive factors, is key to improving patient selection.

Take home message

- The Cartiva implant demonstrates good efficacy at medium term follow-up, and can be considered an option for potential motion-sparing management of advanced Hallux rigidus.
- Concern remains as to the failure rate of this implant compared to the gold-standard of arthrodesis.
- In the absence of further long-term data, careful patient selection and joint decision-making should be emphasized.

Introduction

Advanced arthritis of the first metatarsophalangeal joint (MTPJ) presents as hallux rigidus. It is relatively common in the adult population (one in 40 for those aged over 50 years) and leads to pain and limited range of motion

(ROM). This leads to difficulty with day-to-day activities, sports, and social interaction.[1] As such, it has a considerable impact on quality of life within this population.

The gold standard for treatment of symptomatic hallux rigidus has been arthrodesis. This procedure provides reliable pain relief and improvement in function, yet does not promote normal forefoot biomechanics and is associated with adjacent joint arthritis.[2] Prior efforts to resurface the joint with metallic implants or with silastic implants, have been found to have higher rates of failure than arthrodesis. Additionally, revision following failure after such procedures has been found to be challenging due to significant bone loss.[3]

The Cartiva synthetic cartilage implant (SCI; Stryker, USA) is a polyvinyl alcohol device with properties analogous to articular cartilage. Once implanted, it recreates the original joint space, reducing symptoms while preserving functionality of the first MTPJ. The originator has published a randomized controlled trial demonstrating significant improvement in pain and function up to five years following implantation.[4,5] Brandao et al[6] published the first non-originator prospective series supporting the above findings.

The aim of this independent prospective study is to evaluate the mid-term efficacy of the Cartiva SCI in the treatment of hallux rigidus. These data are of relevance because of the recent National Institute for Health and Care Excellence (NICE) guidelines on the continued use of the Cartiva SCI implant;[7] due to the limited high-quality evidence for efficacy, the procedure should only be carried out in the context of research or audit.

Methods

Audit approval was given by Wythenshawe Hospital (UK). Patient-reported outcome measures (PROMs) data were gathered as part of routine management in accordance with national guidelines, with ongoing departmental audit.[7]

All adult patients with symptomatic hallux valgus who had undergone Cartiva SCI at a single centre (Wythenshawe Hospital) were included. SCI was considered in those patients where dorsal impingement was not a primary feature of their presentation. Exclusion criteria were previous surgery or trauma. Of those initially identified (n = 75), nine did not provide answers at early follow-up and therefore 66 cases were included in this mid-term study.

Procedures were conducted by two foot and ankle surgeons (AF, AP) within a large teaching hospital (Wythenshawe). The dorsal approach was taken to the first metatarsal head, protecting nerve and tendon. Dorsal osteophytes were removed, and the metatarsal head was prepared with bony autograft for press-fit implant insertion. Implants were left at least 3 mm proud and 90° dorsiflexion was achieved at the time of surgery. Where required, patients underwent manipulation and steroid injection at 12 weeks for early stiffness (n = 15; 27%). No repeat injections were required.

The efficacy of the implant was evaluated using robust and validated PROMs pre- and postoperatively. Demographic data, including age and sex, were recorded, in addition to the severity of arthritis and relevant associated conditions (Table I).

Table I. Patient demographics for study cases.

Variable	Data (n = 66)*
Mean age at operation, yrs (min to max)	56 (30 to 80)
Sex, n (%)	
Male	19 (28.8)
Female	47 (71.2)
Hattrup & Johnson grade, n (%)	
HJ2	17 (25.8)
HJ3	49 (74.2)
Operated side, n (%)	
Right	44 (66.7)
Left	22 (33.3)

*Number of feet - five bilateral cases.

The Manchester-Oxford Foot Questionnaire (MOXFQ) evaluates function across three domains: Walking/Standing (seven questions), Pain (five questions), and Social Interaction (four questions).[8] Each section can be calculated independently and given a score out of 100, but a combined overall index score is promoted to give a more generalizable indicator of outcome. Higher scores indicate poorer outcomes.[9]

The Foot and Ankle Ability Measure (FAAM) comprises two domains:[10] sport, and activities of daily living (ADL), the latter of which was assessed. The ADL subscore comprises 21 questions assessing daily activity over the previous week. Responses are scored 4 to 0 in order of increasing difficulty. Where an activity is affected by any other disability, the patient may respond 'not applicable' and the question is removed from the final score. A score is therefore calculated for those activities limited only by the foot/ankle problem and converted to a percentage, with 100% representing full function. The minimal important difference is eight points.

PROMs were collected preoperatively on the day of surgery, at early follow-up (mean 20 months; SD 6.7) and at mid-term follow-up at five years. The questionnaires were taken in clinic and remotely where attendance within the correct timescale was not possible.

Statistical analysis

SPSS version 29 (IBM, USA) was used to carry out relevant statistical analysis. Freidman tests were used to analyze the continuous, non-parametric data series. Post-hoc between-pairs comparison with Bonferoni correction was then applied to identify the important interval for statistically significant data series. Survival was estimated with a Kaplan-Meier function. Further statistical analysis was conducted to evaluate the relationship between patient factors and subjective scores (Pearson correlation/independent *t*-tests), and further to evaluate those cases at risk of failure (independent-samples *t*-test for continous data, chi-squared test for categorical data) with subsequent binary logistic regression. G*Power (Heinrich Heine University Düseldorf, Germany) was employed for power calculations.[11]

Results

Survival

Of the 66 cases, two had failed previously and 16 were lost to follow-up after patients declined or were uncontactable. Responses were gathered for the remaining 48 feet (total 50 feet; 75% follow-up). The mean length of follow-up was 66 months (SD 7.1). A further four failures were noted over the intervening period, bringing the observed total to six, representing 82% survival. The predicted mean survival was 78 months (73 to 83) based on the data available in this cohort (Figure 1).

Functional scores

An a priori power analysis indicated a sample size of 34 with a moderate effect size, indicating our cohort was of sufficient size. Post-hoc checks indicated our actual effect size to be larger, and therefore the study was powered above 80% for the primary outcome.

The mean MOXFQ index demonstrated sustained improvement compared to the preoperative score, with a score of 18 compared to 58 preoperatively (Table II). While this difference was statistically significant ($p < 0.001$, Friedman test), pairwise comparisons demonstrated no significant further improvement from early follow-up, indicating that most of the benefit is perceived by patients in the first two years, with minimal consequent improvement (Figure 2). Overall, 86% of cases demonstrated a clinically important improvement in scores.[8]

Pain scores followed the same pattern, with a postoperative score of 21 compared to a preoperative score of 66 ($p < 0.001$). While a marginally better pain score was observed at mid-term follow-up than early follow-up, this difference was not significant. It is important to note that while this represents the overall trend, a proportion of cases (17/44) experienced deterioration in pain scores compared to early follow-up, with ten of these reaching clinically important deterioration (12+ point difference).[12] The remainder experienced stability or further improvement. Overall, however, only five cases failed to demonstrate clinically important improvement following SCI, and continued to experience persistent pain at years (11.4%).

FAAM ADL scores in particular remained constant and maintained a statistically significant improvement compared to preoperatively ($p < 0.001$). Overall, 96% of cases demonstrated sustained clinically important improvement (Figure 3). On the other hand, FAAM subjective scores were found to have dropped, with a significant difference noted from early to medium-term follow-up ($p < 0.001$), Pairwise comparisons supported the significant improvement from baseline to early follow-up alone, and loss of statistical improvement from preoperative baseline to mid-term follow-up. A corresponding drop in patient satisfaction to 68% was noted.

Patient factors

The relationship between patient factors (age, arthritis severity, sex, and operated side) and the efficacy of Cartiva SCI was explored by interpreting PROMs scores for both improvement and predictors of failure. The improvement in PROMs scores at mid-term follow-up from preoperative baseline was calculated and shown to follow a normal distribution. No significant relationship was identified on statistical testing between age, operated side, and arthritis grade, suggesting that these factors may be independent.

Comparison between sexes revealed a consistently higher degree of improvement in PROMs scores for females, and this was statistically significant for the ADL subscale ($p = 0.008$). Age, arthritis severity, and operated side did not predict degree of improvement (Table III).

In order to explore predictors of failure, those cases with both a clinically important deterioration in pain score and FAAM objective scores were considered 'at risk' for failure and grouped with the failed implants (n = 10 + 6; 32%). Univariate analysis of patient factors did not, however, demonstrate any significant predictors of failure at mid-term follow-up (Table IV). None of these patient characteristics were independently predictive of failure on subsequent multivariate binary logistic analysis.

Table II. Functional scores preoperatively and at follow-up.

Domain	Preop	Early	Mid	Difference	p-value*
MOXFQ Index	58.0	23.9	18.2	39.82	< 0.001
MOXFQ Pain	65.9	24.6	21.0	44.89	< 0.001
FAAM ADL	41.1	85.7	86.3	45.16	< 0.001
FAAM Subjective	62.1	85.2	71.9	9.79	< 0.001

*Freidman tests; all p-values are significant.
ADL, activities of daily living; FAAM, Foot and Ankle Ability Measure; MOXFQ, Manchester-Oxford Foot Questionnaire.

Discussion

The SCI arthroplasty provides an alternative to the traditional gold standard of arthrodesis, which is well recognized in the successful management of pain but leads to reduced ROM. The perceived functional benefit from an increased ROM with SCI has been its greatest strength, but limited information on the longer-term efficacy and, indeed, safety has been reported.[13]

This study represents the longest-term follow-up from an independent non-originator series. The improvement in PROMs appears to be broadly maintained at five years, although subjective scoring was paradoxically lower. Some patients reported stiffness resulting in difficulty wearing heeled shoes, and this may have influenced these scores in spite of objective good function. Additionally, decline in generalized health and remote arthropathy appeared to have a more negative impact on subjective scoring. Most importantly, the data suggest that those patients who experienced an interval deterioration in pain symptoms from early to mid-term follow-up gave deteriorating subjective scores and were less satisfied.

Overall, our survival results are similar to other published data.[4,5,14] Survival of the implant was 82% in our study versus 84.9% over a very similar mean follow-up period. Survival predictors were slightly better than expected at a mean of 78 months (6.5 years). It should be noted that a trend towards an early cluster of failures was noted, and therefore censored and skewed data of this nature are likely to have underestimated survival. However, our survival function did not reach 0.5 (50%) within the follow-up period, therefore

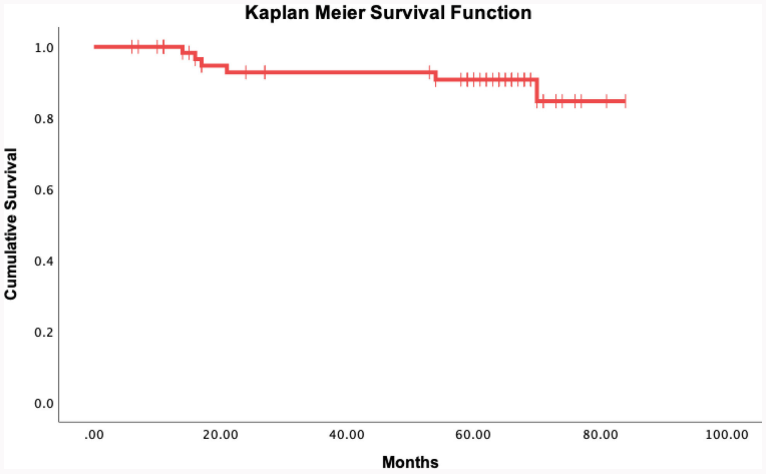

Fig. 1
Kaplan-Meier survival estimate of the Cartiva implant. Censored subjects are represented by vertical dash.

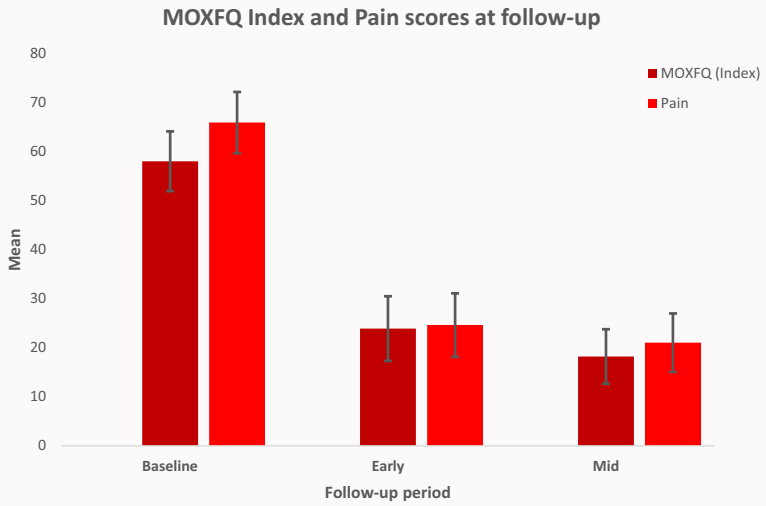

Fig. 2
Manchester-Oxford Foot Questionnaire (MOXFQ) index and pain scores. 95% CIs displayed as error bars.

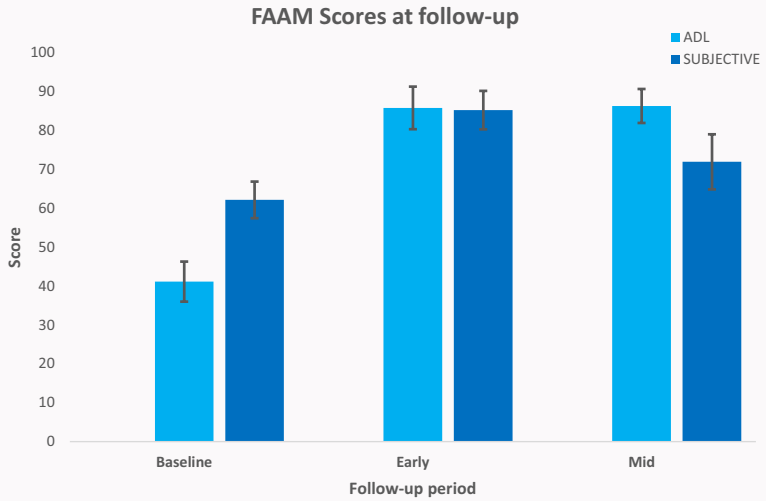

Fig. 3
Foot and Ankle Ability Measure (FAAM) activities of daily living and subjective scores. 95% CIs represented by error bars.

Table III. Relationship between change in scores at five years and patient factors.

Variable	Mean difference in MOXFQ index, 95% CI		Mean difference in FAAM ADL, 95% CI		Mean difference in FAAM objective, 95% CI	
Age, yrs*	0.077 (-0.255 to 0.366); p = 0.619		0.033 (-0.267 to 0.326); p = 0.833		0.253 (-0.047 to 0.512); p = 0.097	
Sex†						
Female (n = 31)	43.8	Δ13.5 (-2.4 to 29.4); p = 0.093	50.5	Δ18.1 (5.2 to 31.0); p = 0.008	11.8	Δ6.8 (-9.9 to 23.5); p = 0.415
Male (n = 13)	30.3		32.4		5.0	
Hattrup grade†						
2 (n = 11)	36.9	Δ3.8 (-14.1 to 21); p = 0.608	38.3	Δ9.2 (-3.9 to 22.3); p = 0.163	0.9	Δ11.9 (-7.9 to 31.6); p = 0.222
3 (n = 33)	40.7		47.5		12.8	
Operated side†						
Left (n = 16)	31.4	Δ13.3 (-2.3 to 28.9); p = 0.115	51.4	Δ9.9 (-4.1 to 23.8); p = 0.146	5.8	Δ6.3 (-12.3 to 24.9); p = 0.492
Right (n = 28)	41.6		41.6		12.1	

Positive scores represent improvement in patient-reported outcome measures from baseline.
*Pearson correlation coefficient.
†Two-sided *t*-test.

median survival cannot be calculated. Of the six failures, one female patient was noted to undergo early catastrophic failure with revision at 14 months. This patient was an athlete with a BMI of 18 kg/m^2 and evidence of osteopenia. On the other hand, another failure in a 60-year-old male was secondary to direct trauma despite having no prior significant deterioration at 70 months (5.8 years). The remaining four patients underwent revision for pain and/or persistent stiffness without documented evidence of subsidence, the oldest of whom was a 61-year-old male.

Although some of the data produced by the originators are encouraging, other studies have shown cheilectomy alone to be equivalent or better than SCI,[15,16] and patient satisfaction to be equivocal.[17] However, SCI may offer a better ROM.[18] Although the SCI is considered safe, longer-term follow-up and comparative studies may be required to further evaluate the ongoing efficacy of the SCI. In moderate disease, where efficacy is comparable, cheilectomy is generally a technically simpler and cheaper surgical procedure.

Patient selection is key in the success of any orthopaedic procedure. Previous findings in the literature suggest that the outcome appears to be independent of patient factors, including sex, age, and severity of arthritis.[19] Analysis of these patient factors within our dataset found that age, sex, and arthritis did not predict failure. When analyzing the effect on scores, age and arthritis severity were not predictors. With regard to sex, both males and females improved significantly, but the level of improvement at mid-term follow-up was found to be higher in females, and this was significant in the FAAM ADL function. However, post-hoc power testing revealed that this was likely underpowered due to the relatively smaller number of males. Higher joint reaction forces proportional to the size of the implant could explain this less profound improvement in males, and bring about earlier symptomatic subsidence and instability.[20] Some evidence in the literature supports better outcomes in medium-grade arthritis,[21] but this was not the case in our cohort.

Persistent pain in SCI appears to be an ongoing concern. Such patients have been previously evaluated with imaging and featured evidence of instability, ongoing oedema, and loss of the joint space.[20] Our data support findings that pain can be an ongoing issue, and may ultimately be the reason for self-referral and definitive revision to arthrodesis from SCI arthroplasty. Among those dissatisfied, there was no radiological evidence of lucency, osteolysis, or subsidence. Four feet did, however, demonstrate progression of arthritis at five years. The literature describing radiological changes has been mixed, with some finding no evidence,[22] while another, albeit smaller, cohort described up to 90% subsidence at two years.[23]

Table IV. Patient characteristics for deteriorating and stable implants at mid-term follow-up.

Variable	At risk/failure	Stable	p-value
Mean age, yrs (95% CI)	53.8 (48.8 to 58.8)	57.4 (54.0 to 60.8)	0.224*
Male:female ratio, n	4:12	12:22	0.467†
Hattrup grade (2:3), n	5:11	10:24	0.895†
Left:right foot ratio, n	7:9	9:25	0.222†

*Two sided *t*-test.
†Chi-squared test.

With regard to this study, some limitations require acknowledgement. We were unable to gather mid-term data on 14 (25%) of the 66 feet. This introduces the risk of bias and reduces the power of our findings. However, following interrogation of electronic records, we were able to ascertain that no failures to revision occurred in those patients who were unable to return PROM scores. As such, our survival data are accurate. We intend to continue follow-up with this cohort.

Limitations in the ability of PROM scores to detect changes should also be acknowledged. Although the MOXFQ and FAAM are validated scores, there was discrepancy between objective and subjective components, suggesting that they may be insensitive to some factors which patients consider more important. Additionally, the FAAM ADL score requires omission of questions where the answer is influenced by an issue other than the implant in question. As such,

interval deterioration in secondary general and musculoskeletal health conditions has the potential to introduce a degree of bias into the result. While our study was adequately powered for the primary outcome measures, the analysis of patient factors was underpowered to detect a moderate effect size and therefore some relationships may not have been adequately dismissed.

This case series demonstrates ongoing significant symptomatic relief and function at five-year mid-term follow-up following Cartiva SCI for hallux rigidus, with comparable failure rates to the available literature. The majority of PROMs improvement was noted in the initial 24 months, with overall PROMs stable at mid-term. However, nearly 40% of feet had experienced mid-term interval deterioration in pain scores.

On the other hand, estimated survival of the implant was higher than expected at 78 months. Nevertheless, deterioration in the symptoms of a subset of cases may predict further failures in the next five years. Some recent reports have called into question the efficacy of this implant given its equivocal subjective clinical outcomes, evidence of radiological deterioration, and moderate failure rate.[24] Longer-term follow-up is required to establish more accurate survival and help underline themes in patient selection in order to offer this procedure to the most appropriate patient groups and appropriately counsel patients. The data presented in this series are the largest non-originator series which is of relevance when interpreting the current NICE guidelines in shared decision-making.

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The datasets generated and analyzed in the current study are not publicly available due to data protection regulations. Access to data is limited to the researchers who have obtained permission for data processing. Further inquiries can be made to the corresponding author.

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This data was collected under routine audit and therefore no ethical approval was required.

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