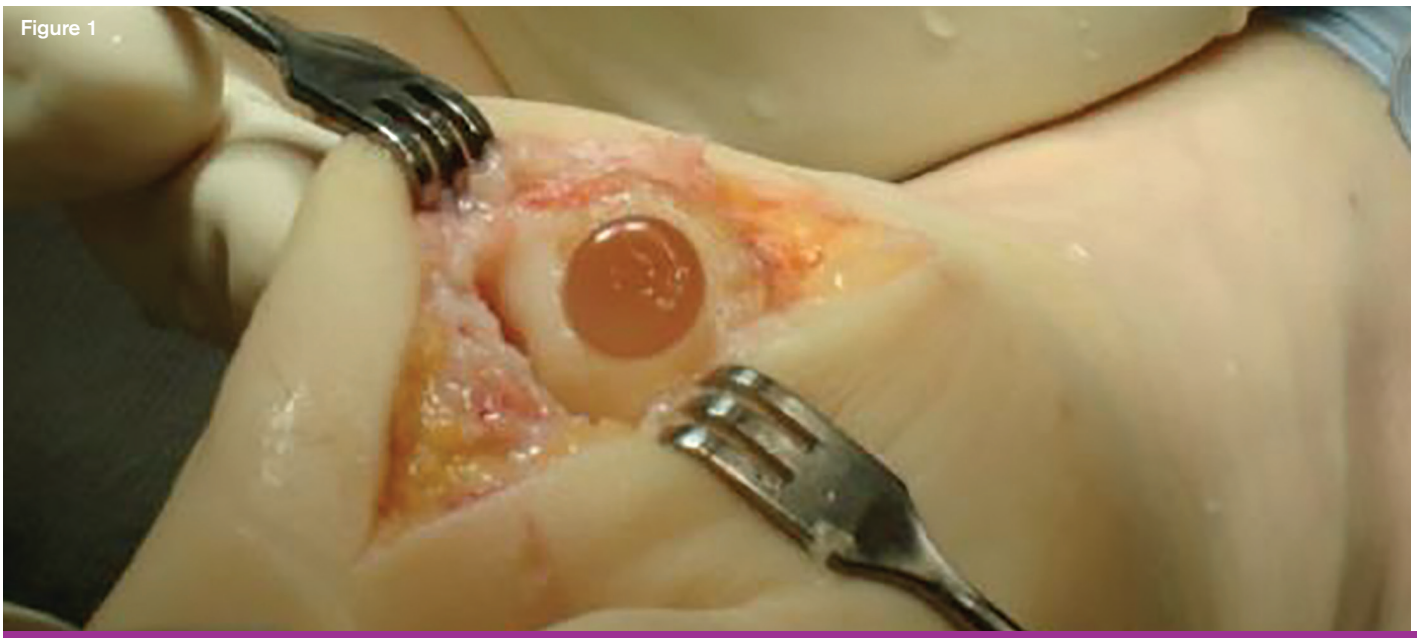

Figure 1

# OUTCOMES OF CARTIVA® IMPLANT SURGERY PERFORMED ON LESSER METATARSOPHALANGEAL JOINT (2ND AND 3RD) IN A NATIONAL HEALTH SERVICE PODIATRIC SURGERY SERVICE

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**The most common joint disease worldwide is osteoarthritis (OA), which affects 18% of females and 10% of males over 60 years old [(1)]. OA causes pain, loss of function and disability, and it has a large socio-economic cost worldwide. This cost in developed countries is estimated to between 1.0% and 2.5% of gross domestic product[1,2].**

## BACKGROUND

Hallux rigidus (HR) is the most common OA pathology in the foot and affects the first metatarsophalangeal joint (MTPJ)[3]. Primarily, OA changes similar to HR can also occur in the second MTPJ, leading to painful limited dorsiflexion[4]. There is less research conducted on the second MTPJ, and primary OA in the second MTPJ has not been reported in the literature[5]. However, the presence of a hallux valgus (HV) deformity increases the chances of developing secondary OA in the second MTPJ due to the transfer of load into this joint the HV deformity.

The main biomechanical differences between the first and second MTPJ is that the first MTPJ carries two-fifths of the total body weight and the remaining MTPJs share the remaining load[6]. This higher biomechanical load on the first MTPJ suggests it would be the hardest to address surgically[7].

Cartiva® is a synthetic cartilage implant that is durable and made from polyvinyl alcohol (PVA) and saline. It is designed to mimic cartilage-like visco-elasticity compatible with the biomechanical properties of human cartilage[8]. The implant is introduced into the bone and replaces the damaged cartilage with a new smooth surface. As a result, the Cartiva® implant relieves pain and stiffness whilst maintaining the range of motion of the joint[9].

Cartiva® implants have shown good results in the knee, talus and first MTPJ[10-12]. Cartiva® treatment can also be used on the lesser MTPJs, however a review of the literature shows only a few studies have been conducted in the use of Cartiva® implants in these joints. This suggests further research in this field is required to increase the evidence base, which investigates the possible associated improvements in quality and patient safety[13].

Cartiva® procedures are performed on both primary and secondary OA due to the occurrence of joint degeneration at the end stage. The division of OA into primary and secondary types occurs because some prior injuries or diseases can lead to the development of OA as a secondary cause[14]. Freiberg's disease, first described in 1914, is a relatively rare osteonecrotic condition, which in its later stages is classed as secondary OA as degenerative joint changes occur[15].

Freiberg's disease leads to an avascular necrosis of the metatarsal head, which classically affects the second metatarsal, though it can be found in the third, fourth and fifth metatarsal head. It predominantly occurs in teenagers undergoing skeletal growth and is more common in females (ratio 5:1). Freiberg's disease is also seen in adults and should remain a differential diagnosis in individuals with metatarsalgia; surgeons should be familiar with this pathology and its treatment[15].

Smillie[16] reported the first classification system covering five stages in Freiberg's disease. Stage five, total joint degeneration or secondary OA[17], is where this pathology is included in the population group for this service review. Grading of primary OA in the second MTPJ is described by Cho et al [4] as the classification of second toe rigidus. This grades zero to three and correlates to how many of the following deformities are present within the joint: joint-

Figure 1. Baumhauer, JB, Singh, DS, & Glazebrook, MG (2016). Intraoperative clinical photograph of 10-mm implant in first metatarsal head. https://www.cartiva.net/wp-content/uploads/2019/06/Baumhauer_2016_CartivaPivotalTrialPublication.pdf

space narrowing, subchondral sclerosis, osteophyte and subchondral cystic formation[4]. Although joint alterations on X-ray and stage classification for both primary and secondary OA differ, due to initial joint space widening in Freiberg`s disease and narrowing in OA[4], core treatment options remain the same. Surgical procedures would be classified as either joint sparing or salvage for early-stage OA, or joint destructive surgical procedures for end-stage OA[1,17]. Joint destructive surgical options for OA can be grouped into three categories: resection arthroplasty, arthrodesis and implant arthroplasty[18]. Surgical treatment should focus on the level of joint degeneration in the MTPJ. The imaging aids surgical planning in assessing the appropriate surgical procedure for the level of joint damage[19].

Studies using Cartiva® implants used on the first MTPJ report good results in resolving pain and maintaining mobility (see Figure 2). Baumhauer et al, in their prospective randomised controlled clinical trial, compared the safety and effectiveness of small (8/10 mm) hydrogel synthetic cartilage bone implants in 152 patients versus first MTPJ arthrodesis in 50 patients[7].

**Figure 2**

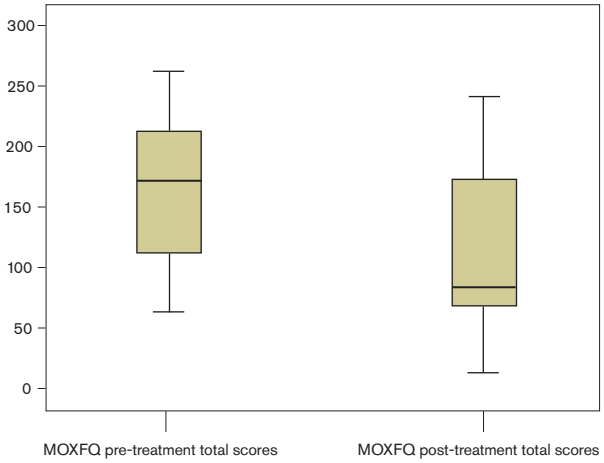


**Figure 2** Total score boxplot.

This study reported equal pain relief and functional outcomes with both procedures and concluded that the synthetic implant was an excellent alternative in patients who wished retain first MTPJ motion. The percentage of secondary surgical procedures was similar in the two groups at 2 years, and less than 10% of the implant group required revision to arthrodesis[(7)]. After this 'Motion' study, the use of Cartiva® in the first MTPJ was approved in 2016 by the Food and Drug Administration (FDA) in the USA. Daniels et al[3] repeated the 'Motion' study by reviewing patients from three of the 12 centres originally involved over a 5 year period, concluding that the Cartiva® implant demonstrated a lasting result. However, one implant was reported to be removed 2 years post-operatively, and the other Cartiva® implants showed no wearing, loosening or changes in position. However, both studies were funded by the company manufacturing the implant, which introduces potential bias due to this conflict of interest. Unlike total joint implants, Cartiva® implants are small in size, resulting in minimal loss of bone length[20]; in addition to this, if the Cartiva® implant needs to be removed, no shortening of the metatarsal bone occurs, therefore arthrodesis can still be performed at a later date should this be necessary. Cartiva® implants are cheaper than an arthrodesis[21], and they require less surgery time than an arthrodesis (40% or 23 minutes less), which reduces the risk of complications while improving recovery rates[7;22].

There is no published evidence on the use of Cartiva® implants on second MTPJ, and application of this in the USA has not yet been approved; however, in the European Union (EU) and Canada, application has been possible for nearly 15 years[21]. This research question is based on the relative knowledge of previously provided research of Cartiva® used on the first MTPJ and the retrospective surgery outcomes of 10 patients, focusing on the Patient Reported Outcomes Measures (PROMs). Consent was granted by the Sheffield Teaching Hospital (STH) Foundation Trust to use anonymised patient data for this study. No further ethical approval was required.

The review of the literature confirms that there is a gap in evidence-based literature and reviews. The aim of this service evaluation was to expand the evidence-based research available on lesser MTPJ Cartiva® surgery with recent outcomes and to address the lack of evidence in the literature on this topic. Currently, the author is aware of one study in progress, soon to be published, which is a 2 year retrospective follow-up of Cartiva® implant for second MTPJ OA. Further studies like this, multi-centred over a long follow-up period, are crucial to expand the limited body of evidence available on this procedure.

## METHODOLOGY AND METHODS

A quantitative descriptive design was adapted for this service evaluation, using numerical data extracted from the Manchester Oxford Foot Questionnaire (MOXFQ) and Patient Satisfaction Questionnaire (PSQ-10). The author chose not to include the first question of PSQ-10 due to time restrictions. Service evaluations are crucial to measure the effectiveness of services and can be used to monitor health services and ensure appropriate standards are being achieved[23].

## DATA COLLECTION

Patient Reported Outcome Measures (PROMs) are collected by the podiatric surgery unit as part of each patient's treatment using PASCOM-10[24]. Patient data are anonymised, as required by the tool; and PASCOM-10 is used within most podiatric surgery units to measure outcomes and procedures[25]. The 16-item MOXFQ questions include three sections: foot pain (five items), standing/walking difficulties (seven items) and social interaction (four items); all are recorded three months prior and six months post-surgery[26]. Each item is scored from zero to four, with zero representing the best and four the worst state; the scores are then converted to a metric-scale (0 representing no symptoms and 100 representing severe symptoms)[26].

A single summary index score can also be used to represent the MOXFQ because it is possible to improve or deteriorate within the three domains of the MOXFQ,[27]. The PSQ-10 contains 10 questions divided into four domains: improvement in foot condition, patient understanding, patient critical assessment and post-operative service delivery[28]. These data are collected at the 6 month review and are scored differently to the MOXFQ. A lower score suggests improvement in the MOXFQ, whereas with the PSQ-10 the lower the score the poorer the outcome. It is scored with a maximum of 100 signifying satisfaction, and a score below 70 indicating poor patient satisfaction[24]. The data were not assessed against clinical standards/recommendations for this procedure, which would make it an audit. To the author's knowledge there are no national data or clinical standards for this specific lesser MTPJ procedure, only recommendations applicable to the first MTPJ, where found[29].

| Age | Sex | ASA | Pathological Joint | Surgery Code | Other procedure simultaneously | Tourniquet time | Revision surgery |
|---|---|---|---|---|---|---|---|
| 47 | F | 1 | Second L | 50.4 Prosthetic spacer in MTP lesser toes | Midshaft scarf without Akin (1) | 51 min | |
| 50 | F | 1 | Second L | 50.6 Prosthetic resurfacing of metatarsal head | N/A | 34 min | 51 Prosthetic removal toe joint |
| 69 | F | 2 | Second L | 50.6 Prosthetic resurfacing of metatarsal head | Tendon lengthening: small tendon of foot (1) | 32 min | |
| 79 | F | 1 | Second R | 50.6 Prosthetic resurfacing of metatarsal head | N/A | 39 min | |
| 30 | F | 1 | Second L | 50.6 Prosthetic resurfacing of metatarsal head | N/A | 30 min | |
| 44 | F | 2 | Second R | 50.6 Prosthetic resurfacing of metatarsal head | Cheilectomy dorsal metatarsal head only (1) | 28 min | |
| 63 | F | 1 | Second R | 50.6 Prosthetic resurfacing of metatarsal head | Arthoplasty excisional lesser toe single PIPJ (1) | 25 min | |
| 24 | F | 2 | Third L | 50.6 Prosthetic resurfacing of metatarsal head | N/A | 0 min | |
| 68 | F | 1 | Second R | 50.6 Prosthetic resurfacing of metatarsal head | Scarf rotational osteotomy midshaft with Akin and arthoplasty excisional lesser toe single (PIPJ) (2) | 79 min | |
| 36 | F | 1 | Second R | 50.6 Prosthetic resurfacing of metatarsal head | N/A | 33 min | |
| **51** | **F** | **1** | | | | **35 min** | **Average** |

Table 1. Patient Demographics

The sampling method used for this study was a purposive, total population sample where all patients who underwent this procedure within this service between 6 June 2015 and 24 April 2019 were included. Inclusion criteria included patients who underwent an arthroplasty with a Cartiva® implant in the lesser MTPJ due to primary or secondary OA. All patients were 18 years and older. Exclusion criteria included first MTPJ Cartiva® implants. Data were extracted manually from PASCOM-10. Twenty-two procedures involving a Cartiva® implant were extracted from PASCOM-10. After applying exclusion criteria, 13 patients met the inclusion criteria, of which one was lost to follow-up and two remain in progress for follow-up, leaving a sample size of 10 patients.

## DATA ANALYSIS

PASCOM-10 automatically produces reports for selected cohorts of patients that have undergone specific procedures. This is an efficient form of data collection as it allows the automatic extraction of data, thus avoiding human error[24]. However, due to the specificity of this study topic, the automatic retrieved data were analysed and calculated upon the cohort of 22 patients, of which only 10 patients could be used in this study. This meant that the calculations had to be repeated manually with the Statistical Package for the Social Sciences (SPSS). Diagnosis was recorded for one patient and the grade of the pathology was not recorded by the unit on PASCOM-10; therefore, no recommendations can be given for what procedure may be preferably used in a particular grade of OA. A recommendation to all PASCOM-10 users is to be mindful of the limitations when inputting data due to human error as this can impact on future research.

| Remaining patients included in the study | Not yet been followed up | Lost to follow-up | Study Period | Follow-up period |
|---|---|---|---|---|
| 10 | 2 | 1 | 02/06/15 - 24/04/19 | 6 months |

Table 2. Patient Demographics

From the extracted data, descriptive statistics could be calculated within both SPSS and MS Office Excel 2019. Both the Wilcoxon test and the paired sample t-test was used to conduct comparative testing, due to uncertainty about the extent of the deviation of response from the data of 'Normality' in a small sample size (10 pairs). The similarity of responses suggests that the assumptions required for the t-test were met for the standing/walking and pain MOXFQ data. Subsequent analysis will proceed with the t-test. The Wilcoxon signed rank test was used to conduct comparative testing for the social interaction values of the MOXFQ, due to the low sample size (10 pairs) and deviations from normality of data; the data appeared skewed on this measure when performed on the t-test. Therefore, the Wilcoxon signed rank

| | | | | 95% Confidence Interval of the Difference | | |
|---|---|---|---|---|---|---|
| | | Median Mean | Standard Deviation | Lower | Upper | P Value |
| Pair 1 | MOXFQ pre-treatment total | 164.5 | 61.9 | | | |
| | MOXFQ post-treatment total | 116.7 | 71.2 | | | |
| | Total MOXFQ pre-/ post-treatment | 47.8 | 64.19 | 1.9 | 93.6 | **0.043** |

Table 6. Total MOXFQ Paired Samples Statistics

| Band (PSQ) | Count | Percentage (%) |
|---|---|---|
| 0 -10 | 0 | 0 |
| 11-20 | 0 | 0 |
| 21-30 | 0 | 0 |
| 31-40 | 0 | 0 |
| 41-50 | 1 | 10 |
| 51-60 | 0 | 0 |
| 61-70 | 2 | 20 |
| 71-80 | 0 | 0 |
| 81-90 | 5 | 50 |
| 91-100 | 2 | 20 |
| Total | 10 | 100 |
| **Average PSQ score:** | | **82.5** |

Table 7. PSQ-10 Total Score (Q2-Q10)

test was chosen for the social interaction values.

The 13 patients included within this study all presented to the podiatric surgery team, with lesser MTPJ pain as a primary complaint. The procedures took place between 6 June 2015 and 24 April 2019, with a standard follow-up scheduled six months post-surgery. Of the original 13 patients, one was lost to follow up and two patients had undergone the procedures, but had not been followed-up at six months, leaving a cohort of 10 patients. All patients were female, with an average age of 51. Of these patients, 90% were second MTPJ and 10% were third MTPJ procedures. The average surgery time was 35 minutes, with reported 10% revision rates (see Tables 1 and 2).

The standing and walking MOXFQ score decreased from 56.10 to 46.00, with a change of 10.100 of median and a P-value of 0.197.

The pain MOXFQ decreased from 59.00 to 39.00, with a median change of 20.000 for the median and a significant change in P-value of 0.011 (P-value is significant if below 0.05). The standard deviation for the pain data range increased pre-surgery to post-surgery, from 21.577 to 23.190.

The Wilcoxon Signed Rank test was used for the social interaction values. The pre-to-post-surgery change was a median of zero (Z=-1.72; P=0.085).

The total MOXFQ scores decreased from 164.500 to 116.700. Table 6 summarises the output from a paired sample t-test conducted to assess the significance of the difference between pre- and post-scores on the total MOXFQ measure. It shows a change of 47.800 of median MOXFQ survey score and a P-value score of 0.043 for this data set, which was deemed significant. The standard deviation pre-surgery to post-surgery increased from 61.89103 to 71.21181.

The PSQ score shows the average score to be 82.5, with 50% of the population group allocating a score between 80 and 90 (Table 7).

Table 8 shows the number of complications reported post-surgery. Of the sample of 10 patients, 60% reported no complications. In total there were seven sequelae reported, due to one patient reporting four individual sequelae.

## DISCUSSION

### MOXFQ

The literature states that the MOXFQ has proven to be a trustworthy measurement tool[30,27,31]. When combined, the three data sets (standing and walking, pain, and social interaction) produced a P-value of 0.043, which was also statistically significant in terms of improvement after treatment (Table 6). When the three domains are reviewed separately, not all data sets produced statistically significant P-values. Reduction in pain was the most significant change in terms of pre-to-post-operative treatment. This is consistent with the Bullough and Dicarlo study[32], which reports that the main complaint for this pathology is pain, especially for the secondary OA population group. Non-significant change value occurred for the MOXFQ standing/walking and social interaction domains, which may be due to the low sample size. In the future this could be improved by collecting a larger range of test data.

### PSQ-10

In this cohort, 80% were satisfied and reported they would repeat the procedure under the same conditions. However, 10% reported no improvement and a further 10% reported deterioration after the procedure (Table 7). There is a poor evidence base on the reliability of the PSQ-10 available, and further research on PROMs would aid its reliability.

## POST-TREATMENT SEQUELAE

From the remaining sample of 10 patients who underwent lesser MTPJ Cartiva® surgery, seven post-operative sequelae were recorded (see Table 8). This is due to one patient reporting four individual sequellae: pain at 6 weeks, pain at 3 months, revision surgery and a painful scar line. Two other patients reported temporary pain at 3 months and one patient reported temporary pain at 6 weeks. The remaining 60% reported no complications. This relatively high complication rate post-surgery is consistent with the literature, which states that temporary high complications do not negatively affect the total satisfaction rate[23].

The average surgery time using the Cartiva® implant on the lesser MTPJs was 35 minutes, with 10% revision rates reported. Similar revision rates have been reported in first MTPJ Cartiva® surgery after a 3 year follow-up study by Baumhauer et al[7]; direct comparison is not possible due to the difference in joints. Overall the MOXFQ, PSQ-10 and post-operative sequellae showed a higher satisfaction

| Code | Name | Sequellae | Sequellae % |
|---|---|---|---|
| NA | No observed sequella | 6 | 46.15 |
| INFS | Infection: suspected/not proven | 0 | 0.00 |
| PNSS | Pain: surgical site beyond six weeks | 2 | 15.38 |
| RxP | Pain: excessive post treatment pain (first 72 hours) | 0 | 0.00 |
| JPS | Pain: joint pain and stiffness after 3 months | 3 | 23.08 |
| OED | Healing: swelling beyond 4 months | 0 | 0.00 |
| NA | Deleted (revision) | 1 | 7.69 |
| SCR | Pain: Scar line hypertrophy/keloid | 1 | 7.69 |
| | **Total** | **13** | **100.00** |

Table 8. Post Treatment Sequellae

post-treatment, with a significant reduction in pain. Dawson et al[33] concluded that PROMs provide subjective data on topics that are crucial to a patient's contentment with the service and with the performed procedure, such as pain, health-related quality of life, function and mobility. PROMs allow for these subjective measurements of patient health to be recorded with diminished clinician bias as they are provided by the patients themselves[27]; patient satisfaction is one of the main goals within any surgery, and the use of PROMs has proven to be crucial to enable the service to review its quality of care.

## CONCLUSION

The aim of this service evaluation was to evaluate and to expand the evidence available on Cartiva® surgery for the lesser MTPJ. Only 10% of the sample had revision surgery over a 4 year period. According to the PROMs results of this study, patients improved significantly after the procedure; the total MOXFQ covering three areas (standing and walking, pain, and social interaction) improved significantly after treatment. The most significant change post-operative treatment was the improvement in pain, and 'treatment satisfaction' was reported by 80% of the patients. These results show that the Cartiva® implant offered relief and a high patient satisfaction rate in mild-to-severe second and third MTPJ OA degeneration, and can be used to estimate a power calculation for a future full-scale follow-up study. Further investigations on a larger sample size and with use of multi-centre data with a longer follow-up period would increase transferability of the results. Expanding the available literature promotes evidence-based practice and therefore improved patient safety and quality of care. PROMs have been proven to be crucial to enable the service to review its quality of care and to ensure patient satisfaction. Further research on PROMs and their reliability, especially on PSQ-10, should be encouraged in order to promote service quality. ■

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