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A 12-month review of patients with advanced metatarsophalangeal joint osteoarthritis undergoing synthetic cartilage hemi implant arthroplasty

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The aim of this study was to present patient reported outcomes (PROMS) and complications at 6 and 12 months following metatarsophalangeal joint (MTPJ) hemiarthroplasty with a synthetic cartilage hemi implant in patients with advanced MTPJ arthritic degeneration treated by a surgery team in the English National Health Service. Over a 12-month period between January 2016 and February 2017 a total of 20 patients underwent MTPJ hemiarthroplasty with a synthetic cartilage hemi implant. Patients were reviewed at both 6 and 12 months. All outcome data were collected using the PASCOM-10 audit database, an online resource which is able to report clinical and patient reported outcomes for selected cohorts. At 6 months, 65% of patients felt that their original complaint was now better or much better, while 4 patients (20%) felt their foot condition had deteriorated. At 12 months, 60% of patients felt better or much better and only 1 patient (5%) reported a deterioration in their foot condition. At 6 months 80% of patients felt that their original expectations from before surgery had been met or partly met and 95% reported they would be prepared to have surgery performed under the same conditions again; this reduced to 75% and 80% respectively by 12 months. The most common complication was joint pain and stiffness (60%) at 6 months, and 25% of the cohort had the implant revised to a joint destructive procedure by 12 months. Initial results for the synthetic cartilage hemi implant arthroplasty for the surgical treatment of advanced MTPJ arthritic degeneration were disappointing and did not compare well with previous studies. Although validated PROMS demonstrate a subtle improvement in health related quality of life and patient satisfaction at 6 months and 12 months, the results were not convincing and both complication and revision rates were high.

Keywords: metatarsophalangeal, osteoarthritis, implant arthroplasty

Historically arthrodesis for advanced arthritis of the 1st metatarsal phalangeal joint (MTPJ) was considered as the gold standard, with good reduction in pain and high patient satisfaction levels reported [1]. However, sacrificing the range of motion of the MTPJ following arthrodesis is not ideal, it can restrict footwear, interfere with activities that require joint motion, can lead to transfer metatarsalgia, and arthritic degeneration in adjacent joints [2]. A desire to preserve joint motion has prompted the development of several joint implants, unfortunately many have not lived up to expectations and have demonstrated high rates of failure as a result of loosening, malalignment, dislocation, subsidence, implant fragmentation, and

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bone loss [3-4]. The advancement of technology has led to the introduction of novel new implants one of which is the Cartiva® synthetic cartilage hemi implant arthroplasty (SCHIA) (Cartiva® Wright Medical Group N.V.). This is a polyvinyl alcohol (PVA) hydrogel MTPJ hemi implant. PVA has been used with great success in several different medical devices but it is particularly useful as a joint implant material as its viscoelasticity and tensile strength are very similar to healthy human articular cartilage [5-8].

Initial outcomes for the SCHIA appear promising, Buamhauer and colleagues in an industry funded prospective, randomised, multi-centred, clinical trial named 'the Motion study' followed 202 patients at two years and found the implant to be equivalent to 1st MTPJ arthrodesis for advanced hallux rigidus with the added advantage of maintaining dorsiflexion, reducing pain and having few safety concerns [9]. The study used 2:1 randomised allocation in favor of the implant group, 23% of the arthrodesis control group withdrew after initially consenting to randomisation, 152 implant patients and only 50 arthrodesis patients started the trail with a further 4% lost to follow-up by the end of the study. Although unfortunate, this disproportionate ratio of patients between the two groups may bias the results in favor of the implant group. A total of 11% of patients in the implant group underwent revision surgery with 9.2% of the implants failing and having to be converted to a 1st MTPJ arthrodesis. The root cause of the implant failure was not determined or discussed. Although implant patients' VAS pain scores improved by >30% at 1 and 2 years follow-up these scores were higher than the MTPJ arthrodesis group at all time points, though not statistically significant.

In a subset of 27 first MTPJ SCHIA patients followed up at five years, Daniel et al., showed an impressive 96% implant survivorship with only one implant having to be removed and converted to arthrodesis [10]. They also demonstrated continued improvements in function and pain scores over the five-year period compared to baseline scores for those patients with retained implants. Postoperative radiographs evaluation showed no bone loss, loosening or wear of the implant, and patient tolerance and satisfaction were high. They conclude that the SCHIA was a viable alternative to first MTPJ arthrodesis in the treatment of patients with advanced hallux rigidus, however generalizability of these results is limited, as only the first 43% of patients from the original RCT were evaluated, and no control group was included to compare results against. More recently the group have published their complete multi-centred midterm results for the SCHIA. They found that clinical and safety outcomes observed at two years were maintained at 5.8 years [11]. It is difficult to determine the relevance of these results as over 15% of patients were removed from the trial following revision to arthrodesis and it is unclear how a further 12% of patients progressed as they were lost to follow-up, hence results for almost a third of the original cohort were absent from the 5-year study.

Although not quite as common and certainly not as well covered in the literature as hallux rigidus lesser MTPJ degenerative joint disease can be equally debilitating and just as challenging for surgeons to treat [12]. Etiology can follow a similar course as a consequence of trauma, either acute or repetitive, and can lead to an interruption in the blood supply commonly affecting the 2nd metatarsal head, but any metatarsal can be affected resulting in avascular necrosis better known as Freiberg's Infraction [12,13]. Freiberg's is characterised radiographically by fissuring and fracture of the articular cartilage, leading to collapse and flattening of the metatarsal head, and finally resulting in severe arthritic degeneration of the joint, as described by Smillie in 1914 [13]. Surgical management is driven by the stage of the deformity and presence of arthritic degeneration. In advanced lesser MTPJ arthritic degeneration surgeons tend to shy away from arthrodesis and prefer to opt to maintain joint function with either excisional arthroplasty or implant arthroplasty [12]. The SCHIA is available in several sizes and although it has not received clearance in the USA for use in joints other than the 1st MTPJ, there is potential for it to be used as an alternative surgical option for advanced lesser MTPJ degeneration [14].

The initial results from the MOTION study look promising, however further studies are still required to help substantiate their findings. The purpose of this study was to present patient reported outcomes and complications at 6 and 12 months following MTPJ SCHIA in patients with advanced MTPJ arthritic degeneration treated by a foot surgery team in the English National Health Service.

Method

A retrospective case series review of patients and their records was carried out at 6 and 12 months following MTPJ SCHIA. All patients over the age of 18 and who underwent surgery with the synthetic cartilage implant to address painful moderate to severe arthritic degeneration of an MTPJ, were included in the study. Patients with early MTPJ arthritic degeneration with minimal cartilage loss or those who had not previously received conservative care, or had marked transverse plane deformity were not offered surgery with the SCHIA. Over a 12-month period (Between January 2016 and February 2017) a total of 20 patients underwent MTPJ SCHIA. Surgical technique for SCHIA in the 1st MTPJ has previously been described in the literature [4,15]. Our surgical technique for implanting lesser MTPJ synthetic cartilage implants was no different except for the mobilisation of the sesamoid apparatus required in 1st MTPJ's, all surgeries were combined with a dorsal joint cheilectomy. Surgeries were carried out under local anaesthesia with an ankle tourniquet by one of the department's three surgeons. All patients were fit and healthy at the time of surgery and classed as either American Society of Anesthesiologists (ASA) 1 or ASA 2 [16] (Table 1). Mean Body Mass Index (BMI) was 27.9 ranging from (18.7 – 39.1) a third of the cohort had a BMI above 30.

All patients underwent preoperative x-ray evaluation, patients diagnosed with hallux rigidus had their joint degeneration graded using the Coughlin and Shurnas classification system for hallux rigidus [17]. Patients diagnosed with lesser MTPJ degenerative disease were graded according to the Smillie classification system for Freiberg's infraction [13] (Table 1). Subsequently seventeen 1st MTPJ, two 2nd MTPJ and one 3rd MTPJ hemi-arthroplasties were performed using a size appropriate synthetic cartilage implant. As long as wounds were healed patients returned to supportive footwear at two weeks and started a post-operative physiotherapy programme of 1st MTPJ strengthening and range of motion exercises. Patients returned to the clinic on request and were reviewed by the authors at 6 months and 12 months following their surgical procedures. Governance approval for the study design was sought from Nottinghamshire Healthcare NHS Foundation Trust Research and Development Department.

All outcome data were collected using the PASCOM-10 audit database, an online resource which is able to report clinical and patient reported outcomes for selected cohorts [18]. PASCOM-10 benefits from the inclusion of a patient satisfaction questionnaire, the PSQ-10 [16]. For the measurement of patient-reported outcomes, PASCOM-10 uses the Manchester Oxford Foot/Ankle Questionnaire (MOXFQ), which is a validated measure of health-related quality of life (HRQOL) [19]. The MOXFQ assesses patient outcomes across 3 domains; pain, walking/standing, and social interaction with a maximum score of 100 in each domain. High scores signify poor HRQOL [20]. The PASCOM-10 system includes a reporting package, which was used to extract summary descriptive data for the cohort, this was then transferred into Microsoft Excel for further analysis. Descriptive statistics are presented throughout for demographic and outcome data.

Minimal clinically important change (MCIC) scores were interrogated for all MOXFQ domains at each postoperative measurement point (6 months and 12 months). MCIC is an anchor based estimate of score change where a patient notices an actual, rather than statistical improvement in their foot health status. In the context of foot surgery, Dawson et al. [21] determined the MCIC estimate to be a 13-point score change across each of the 3 domains.

Results

All 20 patients completed preoperative MOXFQ questionnaires, 19 patients returned at six months and 18 patients returned at 12 months to complete postoperative MOXFQ, and patient satisfaction PSQ-10 questionnaires. Two patients (10%) were lost to follow-up at 12 months but the remaining 18 patients did return for a final review at a mean 18.95 months (range 11- 24 months). Only one case was a revision procedure following moderate 1st MTPJ degeneration after a hallux valgus correction with scarf and Akin osteotomies. MOXFQ scores improved at 6 months and a further improvement was recorded at 12 months across all three domains compared to baseline scores (See Figure 1). The MOXFQ score change at both 6 and 12 months exceeded the threshold for MCIC demonstrating an actual improvement in patients HRQOL (See Table

2).

Demographics	Measure	Number	Percentage %
	ASA 1	8	40
	ASA2	12	60
	Female	17	85
	Male	3	15
	Mean Age	51 years	
	Age Range	35-72	
Joint involvement	Hallux Rigidus stage 2*	8	47
	Hallux Rigidus stage 3*	8	47
	Hallux Rigidus stage 4*	1	6
Lesser Metatarsal	II**	2	67
	IV**	1	33

Table 1 Patients diagnosed with lesser MTPJ degenerative disease were graded according to the Smillie classification system for Freiberg's infraction. *Hallux Rigidus Classification (0-IV) Coughlin & Shurnas (2003). **Lesser Metatarsal – Smillie Classification (I-V).

Domain	Pre-op	6/12 Post-op	Score change	12/12 Pot-op	Score Change	Minimal clinical important difference
Walking	67	47	20	33	34	16
Pain	80	45	35	32	48	12
Social	60	33	27	20	40	24
Mean PSQ-10		76		78		

Table 2 Six- and 12-month follow-up: Summary of Mean MOXFQ and PSQ10 Scores.

Sequelae	Number	Percentage %
6 Months		
Joint Pain & Stiffness	12	60
Swelling	2	10
Transfer Metatarsalgia	1	5
Implant failure revised to joint destructive procedure	3 1st MTPJ Arthrodesis 1st MTPJ Primus Implant 2nd MTPJ Interplex Rod	15
12 Months		
Joint restriction	4	20
Joint Pain & Stiffness	5	25
Implant failure revised to joint destructive procedure	2 1st MTPJ Arthrodesis	10

Table 3 Six- and 12-month complications.

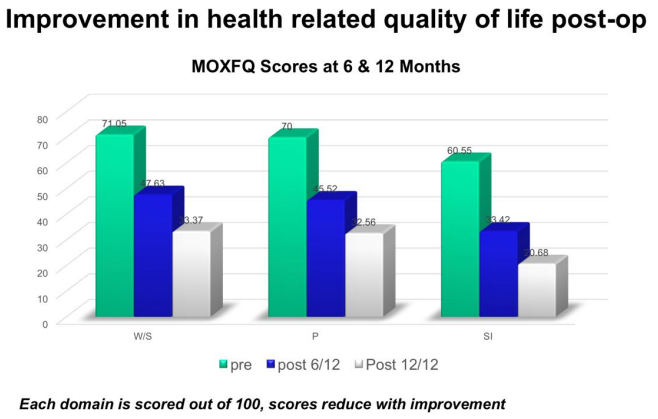

Figure 1 MOXFQ scores improved at 6 months and a further improvement was recorded at 12 months across all three domains compared to baseline scores.

Table 2, illustrates patient satisfaction scores recorded using the PSQ10 questionnaire at both 6 and 12 months, scores did meet the benchmark suggested for UK podiatric surgery of 75 and above [22]. Further descriptive data from the PSQ10 questionnaires demonstrated that at 6 months post operation, 65% of patients felt that their original complaint was now better or much better, while 4 patients (20%) felt their foot condition had deteriorated. At 12 months, 60% of patients felt better or much better and only 1 patient (5%) reported a deterioration in their foot condition. At 6 months 80% of patients felt that their original expectations from before surgery had been met or partly met and 95% reported they would be prepared to have surgery performed under the same conditions again, this reduced to 75% and 80% respectively by 12 months.

Within the first six months following surgery 12 patients, 60% of the cohort, had returned complaining of joint pain and stiffness and subsequently underwent MUA with intra-articular corticosteroid injection. Marked swelling was noted in two patients (10%), and one patient (5%) developed transfer metatarsalgia, there were no episodes of suspected or proven post-operative infection (See Table 3). Three implants failed and had to be revised to a joint destructive procedure in the first 6 months, this equated to 15% of the cohort and by 12 months the revision rate had risen to 25% a significantly higher figure than reported by the MOTION study. A further 25% of patients continued to experience pain and stiffness within the joint, and only 20% noticed an improvement in joint ROM at 12 months. Table 3 details the full list of complications recorded at 6 and 12 months following surgery.

Discussion

In our study population, initial results for SCHIA in the surgical treatment of advanced MTPJ arthritic degeneration were suboptimal and not as good as previous studies stating positive outcomes in over 90% of patients [9-12]. Although validated PROMS demonstrate a subtle improvement in HRQOL and patient satisfaction at 6 months and 12 months, our results were not convincing and both complication and revision rates were high compared to the MOTION study group [9-11]. To our knowledge this is the first study to indicate suboptimal results for the SCHIA.

Level I evidence from Baumhauer et al., demonstrated extremely promising results for the SCHIA. They found that clinical outcomes of pain, function and safety were equivalent to the gold standard 1st MTP joint arthrodesis, for treating advanced hallux rigidus at two-year follow-up, with the added advantage of improving joint dorsiflexion [9]. Two subsequent studies carried out by the MOTION study group showed these positive outcome scores were consistently maintained at 5.8 years when compared with those observed at two years [9-11]. The improvements from baseline exceeded the MCID for each outcome measure for the vast majority of patients at 5.8 years (90.5%-97.2%) [11].

It is difficult to directly compare our results to the previous studies as the study design, methodology and outcomes are dissimilar, however, it is still apparent that our early outcomes for SCHIA did not fare as well as the original study [9]. Within the first six months following surgery 12 patients (60% of the cohort) returned complaining of joint pain and stiffness and subsequently underwent MUA with an intra-articular corticosteroid injection. In a recent retrospective study of 60 patients undergoing 64 SCHIA's for the management of stage 2-4 hallux

rigidus yielded an overall neutral patient satisfaction, mild pain and dysfunction at an average follow up of 15.2 months [23]. Over half of their cohort had at least one injection of corticosteroid for joint pain postoperatively at 2 or more months after surgery, for a total of 79 injections and 82% of injections were given within the first year. As a consequence of our initial results we now routinely counsel patients about the risk of persistent pain and swelling and the potential need for a manipulation under anaesthetic with intra-articular corticosteroid injection within the first 6 months of surgery.

The MOTION study noted few safety concerns at 2 or 5 years, with overall survivorship of the SCHIA reported to be 84.9% at 5.8 years [11]. Our study noted a lower implant survivorship of 75% at 12 months. Surgical revision rate was therefore high in-comparison with 25% of the cohort having the implant removed and converted to a joint destructive procedure as a result of persistent or recurrent joint pain and stiffness.

A 9.2% surgical revision rate and conversion to a 1st MTPJ arthrodesis at 24 months was reported by the MOTION study. Daniel et al., showed an impressive 96% implant survivorship with only one implant having to be removed and converted to arthrodesis [10]. It should be noted that this was a small subgroup of patients taken from the MOTION study followed up at 5 years, and therefore may not be a true representation of the original cohort. Glazebrook et al., did publish the complete midterm results for the MOTION study and, although there was a loss to follow-up of 17%, they reported a more realistic implant survivorship of 84.9% by 5.8 years [11]. Cassinelli et al., also found excellent implant survivorship of 92%, however they had a reoperation rate of 20% in their short-term follow-up study [23]. A third of patients underwent magnetic resonance imaging (MRI) postoperatively due to persistent pain. Revision surgery included implant removal and conversion to arthrodesis (5 patients), lysis of adhesions (4 patients), Moberg osteotomy (1 patient), and implant exchange with bone grafting for impinging soft tissue or implant subsidence (3 patients). It was not made clear if postoperative MRI imaging was helpful in determining if reoperation was necessary and whether it played a part in deciding whether to retain or remove the implant, but it is clear that this would have added a further expense to an already expensive procedure. A longer-term follow-up of these patients would be useful to evaluate the reoperation success rate and to determine how implant removal and arthrodesis compared with the less aggressive procedures, including implant exchange. All of our revision surgeries involved a joint destructive procedure of either MTPJ arthrodesis or total implant arthroplasty, intraoperatively in all cases the implant was found to have subsided below the cortical bone of the metatarsal head with resultant bony contact between the proximal phalanx and metatarsal head. Due to the advanced arthritic degeneration and the fact that the SCHIA had already failed, we felt that a joint destructive procedure would yield the most reliable surgical outcome for these patients.

Rothermel et al., carried out a systematic review of the available literature and compared the cost of SCHIA and 1st MTPJ arthrodesis. The total direct cost of MTPJ arthrodesis was $3632, using a conservative failure rate of 9.2% with subsequent conversion to MTPJ arthrodesis, the total cost of SCHIA was $4565. They concluded that significantly higher inclusive costs were associated with the SCHIA, and sensitivity analysis revealed that MTPJ fusion was more cost-effective even if the failure rate increased to 15% and SCHIA failure rate was 0% [24].

Other than secondary surgeries carried out for implant failure, the original prospective randomised study does not provide any other information on postoperative complications, nor does it give an explanation for implant failure [9]. Cassinelli et al., thought that implant failure was largely a result of the implant subsiding, they recommended only using SCHIA in patients with adequate bone stock and that leaving the implant prominent may reduce the risk of subsidence [23]. Given our study demographics that included 85% women with a mean age of 51, hence a high portion of our cohort were at high-risk of osteoporosis. This may offer some explanation for the high rate of implant subsidence and our high implant failure rate compared to other studies with a lower female to male ratio and age comparison [9-11].

In our study, all patients underwent six-month postoperative x-ray evaluation, typical findings showed marked narrowing of the joint space, proximal impaction of the synthetic cartilage implant

into the head of the metatarsal and there was significant arthritic involvement of the sesamoid apparatus. Daniels et al., reviewed 23 of the 27 patients radiographs at five-year follow-up. They reported no signs of implant loosening or subsidence and no evidence of implant wear. Radiographs did show signs of further arthritic joint degeneration compared to baseline films, however none required further surgery [10].

One of the main reasons patients choose a joint implant procedure over an arthrodesis is to maintain or improve function and joint ROM [2,3,4,8,9,10,11,25]. The MOTION study demonstrated a mean improvement of 27.3% in 1st MTPJ dorsiflexion at 24 months, these improvements in dorsiflexion were maintained at 5.8 years following surgery compared to baseline results [9-11]. In our study 60% of patients noticed an improvement in symptoms at 12 months, however only 20% of patients noticed an improvement in joint ROM, 80% had no improvement or a deterioration in joint ROM with the SCHIA. Cassinelli et al., reported that 14% of patients noticed a restriction in 1st MTPJ ROM postoperatively and were provided with a dynamic splinting device to aid postoperative rehabilitation and improve joint ROM. A further 19% were found to have restricted 1st MTPJ ROM intraoperatively and in these patients in addition to releasing the sesamoids they also added a Moberg dorsiflexion osteotomy of the proximal phalanx in an attempt to restore normal MTPJ ROM and kinematics, none of these patients complained of restricted joint ROM at short-term follow-up [23].

Another explanation for our suboptimal results may at least in some part be due to technical error. We feel that whilst being described as a joint resurfacing implant, in actual fact the synthetic cartilage implant has more of a buffer effect and if the Implant is inserted too deep within the metatarsal head there is a greater risk of subsidence due to the softer trabecular bone found in the metatarsal diaphysis. Leaving the Implant significantly prouder will not only reduce the risk of subsidence, as stated by Cassinelli et al., but also distend the joint and increase the implants buffer effect. We found that SCHIA limited the size of the dorsal metatarsal head exostectomy that could be taken, subsequently dorsal joint impingement was more likely, leading to reduced joint dorsiflexion and increased pain at end range of motion. Reducing the size of the implant or placing the implant more plantarly within the metatarsal head may address this issue, further studies on implant position and subsidence are needed. Finally, in advanced hallux rigidus, the sesamoids are often involved, showing significant hypertrophy on x-rays and clinically being ankylosed to the base of the metatarsal head, causing joint pain and stiffness. In our experience despite releasing the sesamoids intraoperatively, SCHIA does not address the sesamoid apparatus and continued plantar joint pain and stiffness was a recurrent issue in our cohort at 6 and 12 month follow-up.

Limitations of this study lie with its single center retrospective design, small sample size, and short-term follow up, which undermines the reliability of these results. Due to the small cohort of patients we were unable to perform any statistical analysis and instead used descriptive analysis. The low patient numbers were because we quickly stopped using SCHIA to treat advanced arthritic degeneration of the MTPJ's, as a consequence of cost and suboptimal results noted at early follow-up. We are unable to comment regarding mid to long-term results and perhaps patient satisfaction rates, complications and revision rates may all improve with time in our study population and measures have already been put in place to follow these patients up at 3 and 5 years.

We acknowledge that combining the outcomes of the 1st MTPJ and lesser MTPJs may be a methodological error, as they are different pathologies and there is no equivalent of the 1st MTPJ sesamoid apparatus in the lesser MTPJs and, moreover, it is not typically salvageable by arthrodesis. However, reviewing the conditions separately would have reduced the numbers in the study further and we do not believe that combining the results in this case has detracted from the purpose of this study, which was to present our initial experience including patient reported outcomes and complications relating to MTPJ SCHIA.

In conclusion, our initial results for the SCHIA were suboptimal, complication and revision rates were high and did not compare well with previous results published by the MOTION study group. From our experience, we would recommend judicious use of the SCHIA in the surgical treatment of patients with advanced MTPJ arthritic degeneration. We feel that

further work around patient selection, implant positioning and subsidence is necessary.

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