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Hip resurfacing arthroplasty in women: A novel ceramic device enables near normal gait function

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ABSTRACT

Background: Gait function improves after Total Hip Arthroplasty (THA) but is not restored to normal levels. Metal-on-metal Resurfacing Arthroplasty (MoM-HRA) is an alternative to THA and has shown to restore normal levels gait function and physical activity but has been restricted to men owing to problems of metal-ion release. Ceramic HRA (cHRA) removes the cobalt-chrome bearing surfaces, thereby eliminating these specific metal-ion concerns and aiming to be safe for females.
Research question: Is there a difference in gait function of female cHRA patients compared to female THA using subjective and objective measures?
Methods: Fifteen unilateral cHRA and 15 unilateral THA, age and BMI matched, completed patient reported outcome measures (PROMs) (Oxford Hip Score, EQ5d and MET score) and underwent gait analysis using an instrumented treadmill pre- (2–10 weeks) and post-operatively (52–74 weeks). Maximum walking speed (MWS), Vertical GRF of the stance phase, GRF symmetry index (SI) and spatiotemporal gait measures were recorded. Patients were compared to age, gender and BMI healthy controls (CON).
Results: There were no differences in PROMs or gait function between groups pre-operatively. Post- operatively, cHRA had a higher MET score (11.2 vs 7.1, $p = 0.02$) and a higher MWS (6.2 vs 6.8 km/hr, $p = 0.003$) compared to THA. cHRA had a similar GRF profile to CON, whereas THA had a reduced push-off force at 70–77 % of the stance phase compared to CON. At faster walking speeds of 6 km/hr walking speed, THA displayed an asymmetric GRF profile (SI<4.4 %) whereas the cHRA patients continued to display a symmetrical gait profile. cHRA was able to increase step length from pre-op levels (63 vs 66 cm, $p = 0.02$) and produced a larger step length compared to THA (73 vs 79 cm, $p = 0.02$).
Significance: Female cHRA returned to levels of gait function and activity similar to healthy controls unlike female THA.

1. Introduction

Physical activity is an important part of health and wellbeing according to World Health Organisation (WHO) guidelines [1]. This can be confirmed using subjective metrics such as the metabolic equivalent of task (MET) [2], and objective gait metrics [3], both relating life expectancy to activity level on a population basis [3,4]. Hip disease, can be successfully treated by total hip arthroplasty (THA), relieving pain, and improving function. The improvement of walking ability and participating in physical activity has been shown to be an important outcome for patients following hip arthroplasty [5]. Many conventional patient reported outcome measures (PROMs) scores are based on a combination of reported pain, distance of walking, mobility, ability to perform activities of daily living, level of physical activity and limping. Despite well documented improvements in function compared to preoperative levels [6], deviations in gait and function often persist post THA surgery and patients with THA may be unable to restore the key elements of function displayed by healthy controls [6].

Metal-on-metal hip resurfacing arthroplasty (MoM-HRA) is a bone-conserving alternative to THA, developed to restore hip mechanics by maintaining the shape and structure of the proximal femur with good long-term results in younger people [7]. By avoiding a stiff metal stem and more closely restoring the femoral head size, HRA restores the capsular biomechanics and range of motion [8], allowing a near-normal

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level of function and physical activity post operatively [9,10].

Subjectively, the higher level of activity enjoyed by patients with MoM-HRA has been documented using PROMs, but only in more demanding subscales such as sports and heavy manual labour [11,12]. Objective evaluations of clinically relevant hip function have tried to confirm these subjective findings after hip arthroplasty using gait analysis. Three randomised controlled studies (RCTs) were unable to detect a difference between MoM-HRA and THA using gait analysis at low walking speeds [13–15], but at higher walking speeds, THA patients had a less symmetric gait profile and walked slower than MoM-HRA patients. In addition, the MoM-HRA patients' gait was close to healthy controls [15], despite similar PROMs, making the case that more sensitive objective measures are warranted.

Any benefits in function claimed for HRA must be balanced with concerns over the use of MoM-HRA implants. Patients (especially females) with poorly positioned HRAs, poorly designed devices and smaller sizes have reported unacceptable incidences of progressive pain leading to early revision [16]. This pain is commonly caused by either adverse local tissue reactions (ALTR) to metal ion particles generated by excessive wear [17]; or soft tissue impingement on the hard metal edges of the components [18]. Consequentially the use of MoM-HRA has been restricted to men with larger femoral heads since 2015.

Biolox®*delta* ceramic is a zirconia-toughened-alumina widely used in THAs and has very low wear characteristics even under edge loading conditions [19], and low rates of complications [20]. Using this material for HRA aims to leverage the positive clinical and functional performance of MoM-HRA compared to THA while avoiding the MoM problems. A ceramic-on-ceramic hip resurfacing (cHRA) was developed and introduced in an MHRA approved clinical investigation [21]. It is hoped that this will allow patients with smaller hips access to HRA once more.

This study investigates the following question: is there a difference in gait function of female cHRA patients compared to female THA and a control group of healthy volunteers using subjective and objective gait metrics pre- and post-operatively? Gait speed and symmetry are common measures of function used in previous studies following hip arthroplasty [9,15]; therefore, our primary null hypothesis was that there would be no difference in the objective measurements of function using patient's maximum walking speed, the symmetry of the ground reaction force (GRF) profiles of operated and non- operated limb, and spatiotemporal gait variables between cHRA, THA and healthy controls. Our secondary null hypothesis was that no difference in Patient Reported Outcome Measures (PROMs) encompassing domains of pain, mobility, functional performance, and activity levels, would be observable between patients receiving the two forms of hip arthroplasty.

2. Methods

2.1. Patients

Fifteen female patients about to receive a unilateral cHRA as part of a larger clinical investigation evaluating the clinical outcome of the device were recruited for this study. The use of gait analysis was approved by the local REC and MHRA (ethics reference number 17/EE/0330, MHRA study number CI/2017/0040) and registered with NIHR [21]. Patients were age and BMI matched with 15 unilateral female THA patients from another ethically approved longitudinal study of gait following hip arthroplasty (ethics reference number 14/NS/1045). All patients had primary osteoarthritis in one hip, they had no other issues affecting their contralateral limb, and were able to complete gait analysis pre- and post-operatively. Patients underwent surgery with the same surgeon using a posterior approach, cHRA patients received the H1 Ceramic Resurfacing (Embody Orthopaedic Limited, London, UK), while patients having THA received the Furlong Evolution (JRI Orthopaedics, Sheffield, UK). Healthy control subjects (CON) were matched for age, sex, and BMI from a longitudinal study of gait (ethics reference number 14/NS/1045), if they had no evidence of hip or knee osteoarthritis, no history of hip or knee surgery or injury, or any other lower limb dysfunction (Table 1).

2.2. Subjective outcome measures

Fifteen cHRA patients and 13 THA patients completed PROMs (Oxford Hip Score (OHS), EQ5D and MET index) pre-operatively (2–10 weeks) and post-operatively (52–74 weeks). Two of the matched THA patients had no pre-operative PROMs recorded. Tables 2 and 3.

2.3. Gait protocol

Fifteen cHRA patients and 15 THA patients underwent treadmill gait analysis pre-operatively (2–7 weeks) and post-operatively (53–67 weeks). This post-operative time point was chosen as it has been shown using PROMs that clinically important improvements and patients achieving an OHS $>$ 42 is achieved by 12 months [22]. An instrumented treadmill (HP/COSMOS, Hab International) collected gait data. The vertical components of ground reaction forces (GRF) were collected on tandem force plates (Kistler) at a sampling frequency of 1000 Hz. Patients began by completing a familiarisation period by walking unassisted on the treadmill at 3 km/hr for five minutes. Once familiarised, the speed of the treadmill was increased to 4 km/hr then further increased by 0.5 km/hr every 45 s until the patient reached their self-determined maximum walking speed (MWS). Data was collected during a 20 s period at each walking speed, and the average of 10 steps for each limb was used for further analysis. Patients wore their own comfortable trainers and were secured into a safety harness throughout the analysis (which did not impede patient mobility); and were able to stop at any point.

2.4. Gait variables

2.4.1. Maximum walking speed

MWS was determined as the fastest walking speed achieved before breaking out into a run or limited by discomfort. MWS was normalized to correct for differences in leg length [23].

2.4.2. Ground reaction force profile

Vertical GRFs were collected with three variables for analysis: maximum weight acceptance, midstance support and maximum push-off. Maximum weight acceptance and maximum push-off are the first and second force peaks in the stance phase with the midstance force being the lowest point between both peaks. Data was filtered using a 4th order Butterworth low-pass filter with a cut-off frequency of 5 Hz, to minimise the impact of noise and was normalized to bodyweight. GRF profiles are reported at 4.5 km/hr pre-operatively and at speeds of 4.5 km/hr and 6.0 km/hr post-operatively as these were the highest common walking speeds. A comparison at 6.5 km/hr was reported between cHRA patients and CON as not all THA patients reached that speed.

2.4.3. Symmetry index

To assess for asymmetry between the two limbs, the conventional

Table 1
Patient and control demographics.

	THA	cHRA	CON	P-VALUE
Age at surgery (years)	61.4 (6.2)	56.1 (9.1)	54.3(12.7)	0.16
Sex (F:M)	15:0	15:0	15:0	N/A
BMI	27.3 (5.3)	26.1 (5)	23.4 (3)	0.09
time pre op (weeks)	4 (1)	2 (0.4)	N/A	**0.01**
time post op (weeks)	67(2)	53 (1)	N/A	**0.02**

Table 2
Spatiotemporal gait variables 4.5 km/hr pre- and 4.5 km/hr post- operatively. Mean (standard deviation).

	cHRA (N = 15)			THA (N = 15)		
	Pre Op	Post Op	P-VALUE	Pre Op	Post Op	P-VALUE
step length (cm)	**63 (2)**	**66 (2)**	**0.02**	63 (4)	64 (3)	0.44
cadence (steps/minute)	49 (2)	48 (2)	0.54	49 (2)	48 (2)	0.61
double support (s)	0.38 (0.4)	0.43 (0.1)	0.65	0.38 (0.3)	0.40 (0.04)	0.89
step width (cm)	**9.5 (1)**	**7.6 (2)**	**0.01**	8.0 (2)	8.1 (2)	0.68

Table 3
Spatiotemporal gait variables at 6 km/hr post- operatively compared to healthy controls. Mean (standard deviation).

	6 km/hr			P-VALUES		
	cHRA	THA	CON	cHRA vs THA	cHRA vs CON	THA vs CON
step length (cm)	79 (3)	73 (3)	79 (3)	**0.02**	0.24	**0.01**
cadence (step/minute)	53 (2)	55 (1)	52 (2)	**0.01**	0.35	**0.02**
double support (s)	0.31 (0.04)	0.30 (0.03)	0.31 (0.03)	0.33	0.41	0.34
step width (cm)	7.5 (1)	8.8 (1)	7.5 (1)	0.57	0.21	0.44

Robinson symmetry index (SI) was calculated at maximum weight acceptance, midstance support and maximum push-off [24]. SI gives a measure of percentage difference between limbs and is calculated as shown in the following equation:

$$SI = \frac{(x1 - x2)}{0.5(x1 + x2)} \times 100$$

$x1$ and $x2$ represent the operated and non-operated limb, respectively. The value of SI= 0 indicates full symmetry between limbs; a higher SI indicates less symmetry. If the SI values exceeded 4.4 % at weight acceptance, 2.9 % at mid stance and 3.2% at push-off, they were considered asymmetrical [25].

2.4.4. Spatiotemporal gait variables

Step length of the operated limb, cadence, double support time and step width were recorded. To correct for differences in leg length, step length was normalized post-collection [23].

2.5. Statistical analysis

The Shapiro–Wilk test demonstrated that OHS and EQ5D scores were not normally distributed; therefore, the Mann–Whitney U test was used with Bonferroni correction where differences were detected. MET index values were normally distributed, therefore independent samples t-tests were used with Bonferroni correction. Gait data were analysed using MATLAB (2014a). Normality of data was examined and confirmed for MWS, GRF and spatiotemporal gait variables using the Shapiro-Wilk test. A series of paired sample t-tests was used to compare discrete values between the cHRA and THA patients pre- and post-operatively, whilst a one-way ANOVA followed by post-hoc comparisons using Bonferroni corrections ($p < 0.05$) was used to compare differences between all three groups. Effect size (Cohen's d) was reported for all statistical differences, with a small effect: d= 0.2, medium effect: d= 0.5 and large effect: d= 0.8. For statistical parametric mapping (SPM), independent samples t-test (between cHRA, THA and CON) were performed to compare the GRF in the time-normalized (0–100 %) stance phase of the gait cycle. The SPM was calculated at each point of the waveform; if it exceeded the critical threshold of < 0.05, it was considered significant in that part of the waveform.

3. Results

3.1. Subjective outcome measures

Both forms of hip arthroplasty were successful, significantly increasing OHS post-operatively (cHRA: 29–48, p = 0.020, d=1.14, THA: 25–45,p = 0.020,d=1.12) and EQ5D (cHRA: 0.6–1.0,p = 0.040, d=1.05, THA: 0.4–0.9, p = 0.020,d=1.11). No significant differences were found between the groups for pre-operative scores, the post-operative scores, or improvement in OHS (20 vs 19,p = 0.440) or EQ5D (0.5 vs 0.4, p = 0.460). Using MET score, cHRA significantly improved from pre-operative levels (5–11.2,p = 0.030,d=0.92), whereas THA did not (5–7.1,p = 0.330). Pre-operatively, both groups scored a mean of 5, while post-operatively, cHRA recorded significantly higher MET scores compared to THA (11.2 vs 7.1,p = 0.020,d=0.83) (Fig. 1).

3.2. Maximum walking speed

CON walked at a mean MWS of 7 ± 0.5 km/hr. Pre-operatively, both arthroplasty groups were slower: THA managed a mean MWS of 5.5 ± 0.4 km/hr, while cHRA managed a mean MWS of 5.1 ± 1.1 km/hr. Post-operatively, THA increased MWS by 13 % to 6.2 ± 0.3 km/hr. while cHRA increased MWS by 33 % to 6.8 ± 0.3 km/hr, cHRA significantly improved more than THA (p = 0.003,d=0.91). No significant difference was found between the groups' pre-operative MWS, while post-operatively, MWS reached significance (one-way ANOVA ($f_{(2,44)}$= 6.008, p = 0.005). When MWS of all three groups was compared, THA patients were more than 10 % slower than both cHRA patients and CON (THA vs cHRA: 6.2 vs 6.8 km/hr,p = 0.003,d=0.67; THA vs CON: 6.2 vs 7.0 km/hr,p = 0.007,d=0.57). No significant difference was found in MWS between cHRA (post-operative) and CON (p = 0.570). Correction for leg length did not change these results.

3.3. Ground reaction force profile

SPM revealed no differences between groups in vertical GRF pre-operatively (Fig. 2). Post-operatively, at slower speeds, the three groups remained simila (Fig. 2). At the highest common speed of 6 km/hr, THA recorded a lower push-off force at 70–77 % of stance phase (Fig. 2). This reached significance when compared to CON (p = 0.02, d=0.47), but no significant differences were detectable between cHRA and THA. At a walking speed of 6.5 km/h, reached by all cHRA patients, CON had a significantly lower GRF at midstance (Fig. 2).

3.4. Gait symmetry

Both patient groups had an asymmetric heel strike (THA 5.7 %, cHRA 6.5 %,p = 0.480) and midstance support (THA:4.4 %, cHRA:3.1 %, p = 0.350) pre-operatively (Fig. 3). Post-operatively, at the slower speed

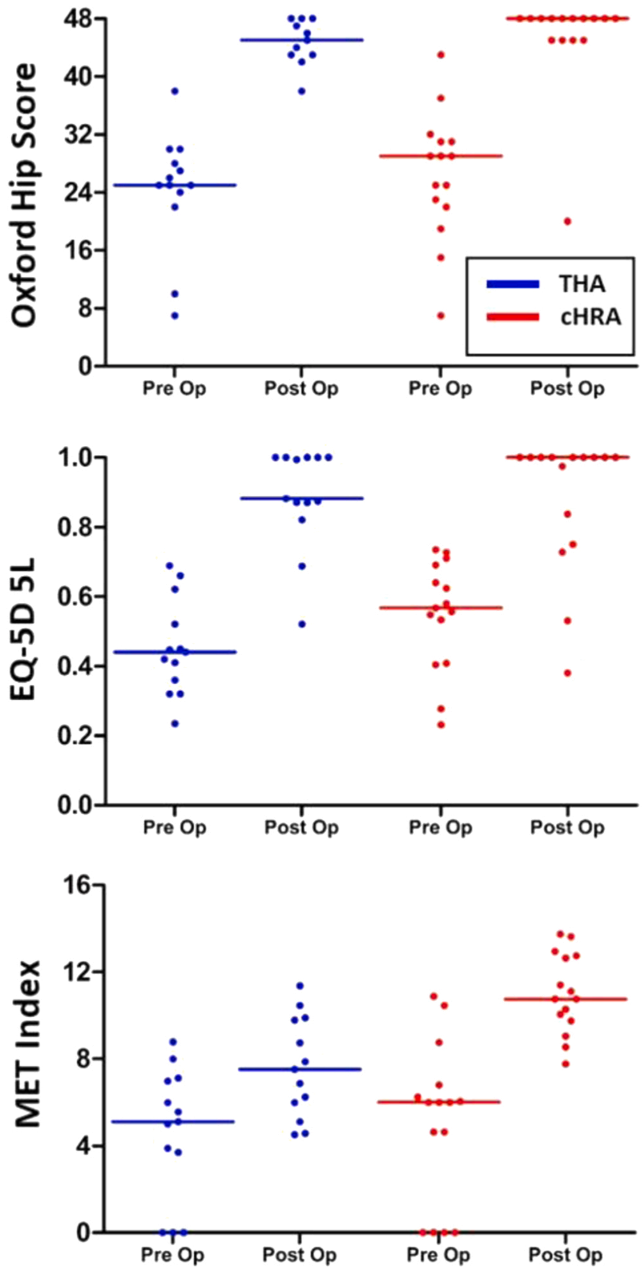

Fig. 1. Patient reported outcome measures for THA and cHRA, pre- and post-operatively. OHS = Oxford Hip Score, EQ5D = EuroQol 5 Dimension, MET INDEX = Metabolic equivalent of task.).

of 4.5 km/hr, neither group limped (Fig. 3), with decreased SI values for heel strike, midstance support and push-off. At the higher speed of 6 km/hr, THA were asymmetric at all 3 points of gait, whereas cHRA continued to display a symmetrical gait profile (Fig. 3). No significant differences were found in SI between groups pre- or post- operatively at 4.5 km/hr. At 6 km/hr, THA were significantly more asymmetric compared to cHRA at heel strike (4.1vs0.4 %, p = 0.001,*d*=0.56), midstance (5.6vs0.9 %,p = 0.020,*d*=0.66) and push-off (4.2vs1.8 %, p = 0.012,*d*=0.43).

3.5. Spatiotemporal variables

Post-operatively, at the slower speed of 4.5 km/hr, no significant differences were found in step length, cadence, double-support or step width in THA compared to pre-op, while cHRA's step length increased significantly pre- to post-operatively (63vs66 cm,p = 0.020,*d*=0.21) and their step width decreased significantly (9.5vs 7.6 cm,p = 0.014, *d*=0.19), although the effect size was small for both of these comparisons. At this slower speed of 4.5 km/hr, no significant differences were found between groups in any spatiotemporal variables at both pre- and post-op time points.

At the faster speed of 6 km/hr, THA's step length increased to 73 cm, while both cHRA and CON's step length increased to 79 cm. The 9 % shorter step length of THA was statistically significant when compared against both cHRA and CO, although the effect size was small (one-way ANOVA (f(2,44)= 7.741), p = 0.001, Bonferroni post-hoc test THA vs cHRA,p = 0.008,*d*= 0.22, THAvsCON,p = 0.003,*d*= 0.22). TH had a cadence of 56 steps/minute, while cHRA had a cadence of 53 steps/minute and CON used 52 steps/minute (one-way ANOVA (f(2,44) = 7.246),p = 0.002). No significant differences were found in spatiotemporal variables between CON and cHRA.

4. Discussion

This small, prospective study sought to explore the objective improvements in gait and subjective improvement in PROMs in female patients following two forms of hip arthroplasty. Both null hypotheses were rejected: female patients with THA were not able to walk as fast as healthy controls following surgery, nor were they able to be as active when measured by MET score, while no significant differences were found between female cHRA and healthy controls in any of the metrics used.

Using gait analysis, no differences in spatiotemporal variables were found between groups at slower walking speeds, reflecting previous HRA gait studies. However, when walking faster, THA patients were unable to increase step length, resulting in an increase in cadence and a lower overall MWS. cHRA patients were able to increase speed in the same way as the healthy control group (increasing step length), again mirroring the published data [9].

Walking speed is a measure of functional ability; a higher post-

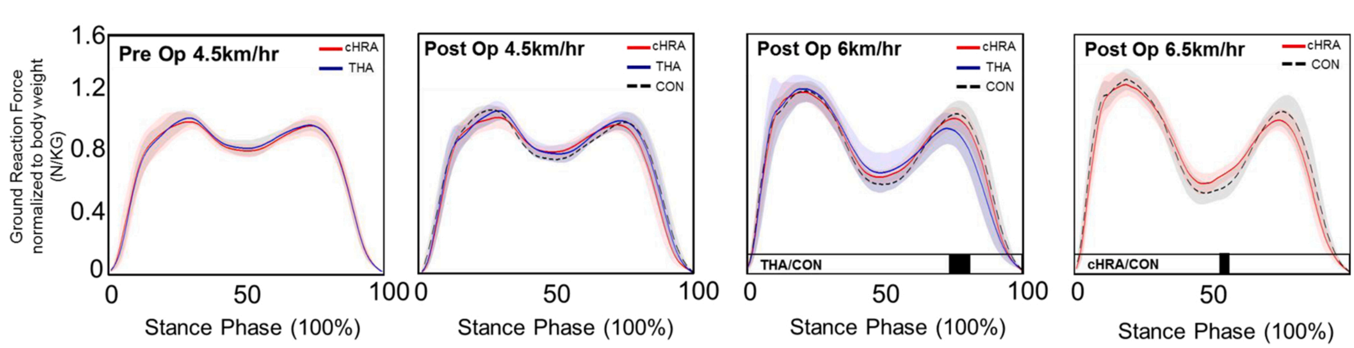

Fig. 2. Normalized to body weight: Ground reaction force profile for THA and cHRA pre- operatively, and post- operatively compared to healthy controls. SPM results are displayed below the figures and black bars indicate significant difference.

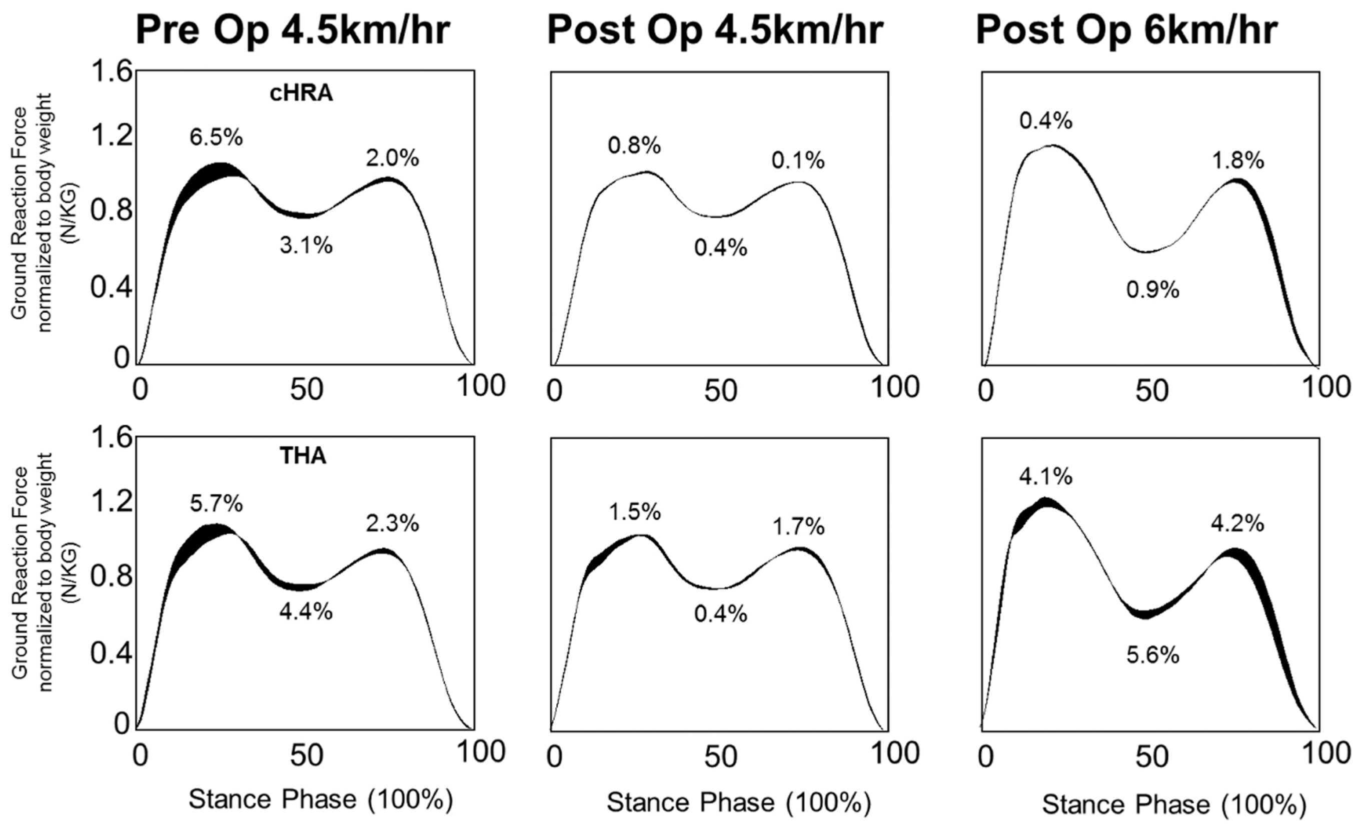

Fig. 3. Normalized to body weight: Ground reaction force profile with Symmetry Index for THA and cHRA pre- operatively, and post- operatively.

operative speed is associated with better functional recovery following hip arthroplasty [26]. In this study, both groups had a similar pre-operative MWS, suggesting no advantage at baseline, and both procedures increased MWS over the minimal clinically important change of 0.36 km/hr [27]. However, for the patients receiving THA, gait was not normal at higher speeds (shorter step length, lower push-off force, higher asymmetry), perhaps reflecting the presence of a femoral stem and the smaller femoral head, depowering hip flexor function in full extension, whereas cHRA had gait close to that of healthy controls [6].

Three RCTs have reported on gait restoration after HRA and THA [13–15]. This study supports their finding of no difference in GRF between groups at slower walking speeds. Two of the previous studies only evaluated at patient's comfortable speed, potentially missing differences with health-related consequences, the only one to use an instrumented treadmill and increased walking speeds reported higher MWS and more symmetrical gait profile at higher walking speeds in men receiving MoM-HRA compared to THA [15], in keeping with this female-only study.

'Normal' gait is characterised by symmetric movement patterns that minimise loads across joints. Commonly, arthritic patients will produce abnormal movement patterns with reduced loading of the affected leg, producing asymmetric GRF profiles. This study showed that THA and cHRA exhibited similar asymmetric patterns pre-operatively. Both procedures were effective in producing a symmetrical GRF profile at slower walking speeds but only the cHRA patients were able to maintain a symmetrical gait profile at faster speeds. In addition, patients with a THA were unable to generate the same push-off force compared to healthy controls or patients with cHRA, despite the same surgical approach to the hip. This might be attributed to the presence of the stem inhibiting appropriate loading during push-off or the bigger head size of HRA acting as a fulcrum for the iliopsoas to generate a higher push-off force. Similar to the extensive literature of gait following THA: while it improves gait, THA is not able to restore gait to normal [6].

The results replicate the higher levels of activity reported in men with MoM-HRA [28]. When using the MET index, the female THA patients increased their activity level from 5 to 7 but this increase was not found to be significant, while after cHRA, the female patients increased their activity level significantly from a mean of 5–11. A MET score of between 5 and 8 is necessary to maintain cardio-respiratory fitness and MET score over 8 is considered to be of high intensity activity [29], with higher scores reducing risk of premature mortality [2].

A strength of this study was the inclusion of prospectively gathered pre-operative data: we did not detect significant differences between our groups pre-operatively, allowing for a direct comparison of improvement. Limitations of the study include cofounding bias due to the absence of randomisation, meaning conclusions must be treated with caution. Additionally, for symmetry index reporting, the contralateral healthy hip was used as a reference to determine the quality of the operated side, although hips are often not completely symmetric. To address this, patients without comorbidities affecting the gait performance of the contralateral leg were included, therefore this small population may not be entirely representative of all people with hip osteoarthritis, who often present with symptoms in both hips. Another limitation is the difference in age at surgery between THA and cHRA; no significant difference was found but the cHRA patients and control participants tended to be younger, which might partly explain the higher function in those groups compared to the THA patients. Finally, the THA patients were assessed post-operatively at 67 weeks compared to 53 weeks for the cHRA patients which may have had an influence on the results in this small pilot study; although results from other studies suggest that PROMs tend to plateau after the 52 week time-point [30].

In conclusion, this small study confirms that both THA and cHRA improve function in women using subjective and objective measures. Women with resurfacings were able to return to levels of activity similar to that of healthy controls. THA were as good as those in the published literature but were not able to achieve the benchmark of normal maximum walking speed and had a difference in physical activity relevant to measures of health and wellbeing recommended by WHO [1].

Declaration of Competing Interest

Amy Maslivec has no conflicts of interest. Camilla Halewood is a paid employee and director of Embody Orthopeadic Limited. Susannah Clarke is a paid employee and director of Embody Orthopeadic Limited. Justin Cobb is a directorof Embody Orthopeadic Limited.

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