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30

31 **Hip Contact Forces in Asymptomatic Total Hip Replacement Patients**

32 **Differ from Normal Healthy Individuals: Implications for Preclinical**

33 **Testing**

34

35 **Abstract**

36 Background. Preclinical durability testing of hip replacement implants is standardised by
37 ISO-14242-1 (2002) which is based on historical inverse dynamics analysis using data
38 obtained from a small sample of normal healthy individuals. It has not been established
39 whether loading cycles derived from normal healthy individuals are representative of loading
40 cycles occurring in patients following total hip replacement.

41 Methods. Hip joint kinematics and hip contact forces derived from multibody modelling of
42 forces during normal walking were obtained for 15 asymptomatic total hip replacement
43 patients and compared to 38 normal healthy individuals and to the ISO standard for pre-
44 clinical testing.

45 Findings. Hip kinematics in the total hip replacement patients were comparable to the ISO
46 data and the hip contact force in the normal healthy group was also comparable to the ISO
47 cycles. Hip contact forces derived from the asymptomatic total hip replacement patients were
48 comparable for the first part of the stance period but exhibited 30% lower peak loads at toe-
49 off.

50 Interpretation. Although the ISO standard provides a representative kinematic cycle, the
51 findings call into question whether the hip joint contact forces in the ISO standard are
52 representative of those occurring in the joint following total hip replacement.

53

54

55

56 **1. Introduction**

57 The term “normal walking” is commonly referred to in hip implant testing, as
58 simulators generally aim to reproduce the sliding distances and loads encountered in the body
59 while walking. Walking has been chosen specifically as it is the most common activity where
60 the bearing surfaces experience high loads and relative motion (sliding distance); both of
61 these variables directly influence wear (Fisher and Dowson, 1991). The requirements for
62 preclinical durability testing of total hip replacement (THR) implants are standardised by
63 ISO-14242-1 (2002) which is intended to provide inputs defining a ‘representative’ cycle of
64 normal walking in a typical individual. The data for the motion and load defined within the
65 ISO standard for hip wear simulation was based on a historical inverse dynamics model using
66 data obtained from normal healthy individuals (Paul, 1967). It is possible however that hip
67 joint motion and loading patterns in patients following THR may differ from those of normal
68 healthy individuals as a consequence of altered articulating surfaces and changes in soft
69 tissues following reconstruction. It has been reported that THR patients exhibited a reduced
70 gait velocity, a decreased hip mobility (Perron et al., 2000, Madsen et al., 2004) and altered
71 muscle activity patterns (Long et al., 1993). Age has also been shown to influence the hip
72 moment and power during gait (DeVita and Hortobagyi, 2000, Chester and Wrigley, 2008).
73 The extent to which the ISO data are actually ‘representative cycles’ for hip joint loading has
74 not been evaluated. Furthermore, recent attention placed on stratified approaches to treatment
75 has highlighted the need to explore variability between groups even within existing standards
76 (Bloss and Haaga John, 2013). Understanding the current test standard and future studies
77 designed specifically to enhance future standards developments are likely in turn to improve
78 pre-clinical testing.

79 We hypothesized in this exploratory study that the hip joint kinematics and contact
80 forces of patients following THR may differ from healthy normal controls and from the ISO
81 standard, with a view to determining whether future work might be of benefit.

82

83 **2. Methodology**

84 2.1 Clinical

85 Ethical approval was obtained in advance of the study from the Leeds West Ethics
86 Committee. 15 asymptomatic unilateral total hip replacement patients were randomly
87 selected for detailed motion analysis. Asymptomatic THR cases were defined by: no current

88 symptoms in the index hip at the time of testing and no clinical indication of limping as
89 determined by the surgeon, they were >12 months post-operation, were radiologically normal
90 and had no other history of musculoskeletal disorders. All subjects had undergone hip
91 replacement using an anterior approach. Although the specific implant used was not recorded
92 and there was no formal quantification of functional ability, the cohort were representative of
93 those cases who would be deemed clinically to have a good outcome. 38 normal healthy
94 individuals from a dataset compiled using the same motion capture protocols were assigned
95 to a normal cohort. Due to the large age difference between the ISO dataset (mean 19 years)
96 and the anticipated age of our THR cases, the normal cohort was not actively age matched.
97 Instead, subjects were targeted to represent normal function but to lie close to an age in which
98 THR might be considered a surgical option.

99

100 2.1 Gait Analysis

101 Joint kinematics were recorded using a clinical gait analysis system comprising of an
102 eight camera passive marker system (Vicon MX ,T40 cameras,150hz, Oxford Metrics, UK)
103 with force plate data from two Bertec force pates (1000 Hz) (Bertec Corp, OH, USA). A 14
104 marker plug in gait model was used employing 9mm markers attached to the pelvis, thigh,
105 shank and foot as well described previously (Holsgaard-Larsen et al., 2014), and the technical
106 error for this setup within a working volume of 10 x 11 x 2.5 m was calculated as less than
107 0.2 mm. Following an acclimatisation period, gait data were acquired from three passes along
108 an 8 metre walkway with clean strikes on the force plates observed.

109

110 2.3 Biomechanical Analysis

111 Motion capture and ground contact force plate data were imported into a multi-body
112 dynamics modelling system (AnyBody, version 5.0, AnyBody Technology, Aalborg,
113 Denmark) utilising inverse dynamics analysis. The musculoskeletal model of the lower
114 extremity in AnyBody has been previously validated in the literature (Forster, 2004, Manders
115 et al., 2008) and comprises of a human lower extremity model which includes 340 muscles
116 and 11 rigid bodies representing talus, foot, shank, patella and thigh for both legs and the
117 pelvis. The muscle, joint centre and inertial parameters of the lower extremity model in the
118 AnyBody Repository is based on an anthropometric dataset provided by the University of

119 Twente (Horsman and Dirk, 2007). The trunk segments were included in this study for
120 attaching the psoas major muscles, and were constrained to the pelvis.

121 For this study, simple muscle models without force-length-velocity relationships were
122 adopted, as force-length-velocity relationships have been shown to have little influence on
123 the prediction of muscle forces and contact forces of hip joints for normal gait (Anderson and
124 Pandy, 2001). Model scaling and kinematic optimization were performed based on the
125 marker trajectories of each file, reflecting individualized parameters for each participant.
126 Ground reaction force was then applied to the foot segment of the scaled model to perform
127 inverse dynamics analysis. The problem of muscle redundancy was solved by quadratic
128 muscle recruitment (Heintz and Gutierrez-Farewik, 2007, Glitsch and Baumann, 1997) which
129 minimizes the sum of muscle stresses squared. Hip contact force and hip moment for both
130 legs of each subject were calculated after performing inverse dynamics analysis.

131 Gait parameters of the normal healthy cohort and the index limb of the THR patients
132 were compared to the ISO data. The hip joint kinematics and joint loads for the operated and
133 non-operated sides of THR patients were also compared to explore possible effects of
134 unilateral THR on the contralateral limb. In the discussion, further comparison is made
135 between the current results and previous in vivo data derived from instrumented hip
136 prostheses. All comparisons of joint contact forces represent the total force magnitude and
137 calculated joint contact forces were normalized to body weight to control for differences in
138 body weight between subjects.

139

140 2.4 Statistical Analysis

141 Data are presented as mean values, along with the associated 95% confidence intervals
142 (CI) for each cohort to show the variation within each cohort. Data sets were temporally
143 aligned to 101 centiles through spline interpolation in MATLAB (R2013b, MathWorks,
144 Natick, MA, USA). The means of the normal cohort were obtained by averaging the mean
145 result of the two limbs for each subject. Because some of the gait data were not normally
146 distributed, non-parametric statistical tests were used. A Mann-Whitney test was used to
147 determine whether differences in kinematics and kinetics between cohorts were systematic
148 and reached statistical significance, and the comparison between operated and non-operated
149 limbs was conducted through a Wilcoxon test. A significance level $p \leq 0.05$ was regarded as
150 significant throughout.

151 3. Results

152 The demographic characteristics of the control and asymptomatic cohorts are described
153 in Table 1. The velocity, cadence and stride length for the asymptomatic THR cohort was
154 significantly reduced ($P < 0.005$) compared to normal healthy individuals (Table 2). The
155 normal healthy individuals had significantly greater angular excursion in the directions of
156 flexion/extension ($P = 5.7E-3$) and abduction/adduction ($P = 2.2E-5$) than the THR cohort
157 (Table 3). Both groups demonstrated a characteristic peak-trough-peak (F_1 – F_2 – F_3) pattern in
158 the hip contact force, however, this was significantly less dynamic in the asymptomatic THR
159 patients whom exhibited a 22% higher trough ($P = 2.9E-3$) and 35% lower peak loads at toe-
160 off ($P = 1.9E-8$) (Figure 1 and Table 3). Our normal cohort exhibited a very similar pattern
161 and magnitude in kinetics to the ISO data. Using the same modern acquisition methods
162 resulted in the THR cohort yielding 30% lower loads at toe-off (F_3). The differences in peak
163 load at heel strike (F_1) were not significant for these three groups.

164 Within the asymptomatic THR cohort, there were no significant differences in any of
165 the kinematic variables or predicted joint loading patterns between the operated and non-
166 operated sides (Figure 2).

167 Within each cohort, between subject variability was higher (95% CI $> 10\%$ of the mean
168 value) for hip abduction/adduction and internal/external rotation, although there was less
169 between subject variability (95% CI $< 10\%$ of the mean value) in other parameters (Table 3).
170 For the hip contact force, 95% CI were $\sim 5\%$ of the mean value for the normal healthy
171 individuals and $\sim 10\%$ of the mean value for the asymptomatic THR cohort on both the
172 operated and non-operated sides (Figure 1 and Figure 2).

173

174 4. Discussion

175 In this exploratory study, we hypothesized that the hip joint kinematics and contact
176 forces of patients following THR may differ from healthy normal controls and from the ISO
177 standard. Derived from the data by Paul, the ISO standard recommends a maximum load of
178 3kN, and is based on a 75kg patient and equates to a force of approximately four times body
179 weight. A twin peak in the force time curves was predicted by the model with the average
180 peak forces for the normal healthy cohort equalling 3.89 times body weight (mean BW =
181 72kG). Our data for the normal cohort was similar in shape and magnitude to the ISO
182 standard (Table 3, Figure 3) which suggests that the traditional inverse dynamics used in the

183 ISO standard provided a comparable result to the modern acquisition and modelling
184 techniques utilised in this study. As expected the normal healthy individuals recruited to this
185 study were significantly older (mean 45 yrs.) than the subjects used in the inverse dynamics-
186 calculated data published by Paul (mean 19 yrs.), and were arguably more representative of a
187 THR patient although we accept that there was no attempt to match specifically to the THR
188 cohort. Our normal cohort and THR cohort have similar age and BMI to typical healthy and
189 THR populations respectively and thus are not closely matched for age and BMI. As reported
190 by Bennett et al (2008), the difference in age alone would not be expected to account for the
191 difference in gait kinematics between the normal healthy individuals and THR patients.
192 However, other studies have reported age-affected alterations in gait parameters (DeVita and
193 Hortobagyi, 2000, Chester and Wrigley, 2008) and so this warrants consideration. The
194 mismatch in BMI may also be a reason for the difference in gait parameters between our
195 normal healthy cohort and THR cohort. Better stratified studies are required in the future to
196 further characterize the effect of age and BMI, although it was not within the scope of this
197 study.

198 The novelty of this study was that the THR cohort consisted of unilateral asymptomatic
199 THR patients, recruited at a minimum of one year post-operatively and who were carefully
200 screened to have no other history of musculoskeletal disorders and to represent the typical
201 THR patient in our regional tertiary referral centre, deemed to have a good clinical outcome.
202 While the small sample investigated in this study makes the drawing of wide-ranging
203 conclusions inappropriate, the presence of a systematic difference between our THR group
204 and both the ISO cycle and the normal group suggest that further exploration of and
205 development of testing standards might warrant further attention in future. Compared to the
206 normal healthy individuals, there was evidence of a persisting decreased range of motion and
207 reduced hip contact force in the THR patients which suggests that there is at least some
208 residual compromise of function associated with hip arthroplasty even in cases with a
209 clinically good outcome. This reduced mobility is in agreement with prior kinematic studies
210 of THR patients in the literature (Loizeau et al., 1995, Bennett et al., 2008, Beaulieu et al.,
211 2010, Madsen et al., 2004).

212 Contact forces were similar for the operated and non-operated side of the asymptomatic
213 THR patients (Figure 2). The magnitude of the peak forces at heel-strike and to-off was
214 similar to those reported by Foucher et al (2008) who reported values of 3.0 and 2.5 times
215 body weight respectively. The reduced gait dynamics additionally led to a loss in the

216 restoration of the second peak of force at toe-off perhaps related to diminished hip moment
217 outputs (Table 3). As synovial joints are nearly frictionless (Mow and Lai, 1980, Jin et al.,
218 1997, Li et al., 2013), the hip moment, which is related to the hip contact force, is generated
219 mainly to balance ground reaction force and the inertia effect of the moving body segments.
220 As such, hip moments are influenced by gait velocity, cadence and stride length, parameters
221 that were all seen to reduce in asymptomatic THR patients. Consequently, the results confirm
222 that even with carefully selected cohorts of patients exhibiting no other co-morbidities, the
223 altered dynamic inputs observed in asymptomatic THR patients, as compared with the normal
224 healthy individuals, lead to a corresponding reduction in hip range of motion and a lower
225 joint contact force.

226 In vivo peak hip forces have been reported by several authors over the past 25 years
227 using specialised instrumented prostheses with values ranging from 2.4 to 4.1 times body
228 weight recorded during gait (Bergmann et al., 2001, Davy et al., 1988, Kotzar et al., 1991,
229 Bergmann et al., 1993, Brand et al., 1994, Damm et al., 2013a, Damm et al., 2013b,
230 Schwachmeyer et al., 2013). Whilst these reports are based on small numbers of patients,
231 with varying degrees of postoperative recovery, the data provide useful information for
232 comparison. The peak load predicted in this study was 3.35 times body weight (3.04 to 3.66)
233 for the operated side which falls in the middle of the in vivo reported data from the literature.

234 The data published by Bergmann include more additional patient details that may be
235 used for further comparison (Bergmann et al., 2001). Our asymptomatic THR cohort was
236 comparable in age and BMI (64.27 yrs., 30.74) to those described by Bergmann (62.17 yrs.,
237 29.05). A comparison of the average hip contact forces for the asymptomatic THR cohort are
238 made to the in vivo measurements of Bergmann in Figure 3 on the operated side of implanted
239 THR patients. There is some evidence of a bi-modalism in the four patients in the Bergmann
240 dataset as some patients (HS, KW) had two distinct peaks of loading and a more dynamic
241 pattern of gait, similar to our asymptomatic THR cohort, whilst others (PE, IB) had only a
242 single peak possibly interpreted as being indicative of with poorer function. The strict patient
243 selection criteria used in the current study allowed the authors to stratify an asymptomatic
244 THR cohort that screened out poorly functioning patients. When considering the two patients
245 of Bergmann with better function, our average joint force data was comparable during the
246 majority of the gait cycle, although was ~20% greater at heel-strike. We acknowledge that
247 direct comparison to existing datasets is difficult without the additional consideration of

248 clinical data such as the involvement of multiple joints, contralateral THR or other functional
249 compromise such as limb length inequality.

250 Although a surrogate only for direct measurement of joint forces, laboratory collection
251 of kinematics and forces combined with multi-body dynamics facilitates the use of larger
252 cohorts without the need for a specialised implant and the associated ethical challenges
253 involved in instrumented joints. One weakness of the modelling approach, as exemplified in
254 the current study, is that the individual patient geometry was derived by scaling a default
255 patient model. Studies have been conducted investigating factors such as patient specific
256 correction for hip centre, muscle architecture and muscle activation to refine multi-body
257 dynamics solution. The effect on the resulting modelling has been widely discussed (Besier et
258 al., 2003, Carbone et al., 2012) and we acknowledge that without controlling for these factors
259 the current preliminary data must be interpreted with caution. Stansfield et al (2003) and
260 Heller et al (2001) have compared the prediction of joint contact forces for small cohorts
261 using multi-body dynamics against forces derived from direct measurement using
262 instrumented prostheses for validation. These studies have shown that while multi-body
263 dynamics provides an appropriate means of parametric analysis, it generally overestimates
264 the peak joint contact forces by ~10%, due to the lack of a realistic muscle wrapping path
265 around the hip joint within the model (Bergmann et al., 1993, Stansfield et al., 2003, Heller et
266 al., 2001). While the current study set out only to explore tentatively the possibility that THR
267 results in variance in joint loadings from the cycles applied in the ISO standard, any future
268 evaluation should try to address such shortcomings.

269 For our THR cohort, who walk more slowly than healthy controls and have a higher
270 BMI (BMI 27.7 to 33.8) than both the normal cohort and the general population, skin
271 movement artefact may also be considered as important, although skin movement artefacts
272 have been shown to be least sensitive to flexion/extension motions at angles seen in walking
273 (Lu and O'Connor, 1999). In our study, flexion angle contributed the most to hip moment and
274 the resultant contact force.

275 Our results suggest that the asymptomatic THR patients exhibited a similar hip range of
276 motion but a different loading pattern when compared to the ISO standard, while the normal
277 healthy individuals exhibited a similar loading pattern to that used in the ISO standard. The
278 asymptomatic THR patients appeared to walk less dynamically, with significantly lower
279 second peak contact forces and a significantly greater stance phase load. Whilst the THR
280 patients examined in the study had reduced peak loads, the greater stance phase loads

281 observed when combined with slower walking speeds will result in longer joint loading
282 periods that may have a negative influence on bearing lubrication and subsequent wear.
283 Additionally, many total hip replacement patients have concomitant multiple joint
284 involvement or other functional compromises that will likely alter the kinetics and subsequent
285 joint contact forces of the hip (Budenberg et al., 2012). Given the recent emphasis on
286 stratified approaches to health care interventions, these data support the argument for further
287 work which might lead to better representation of the systematic variability of real-world in
288 vivo conditions.

289 In conclusion, the hip contact force during gait in our sample of normal healthy
290 individuals compared well with the ISO loading cycle, while the joint contact forces in the
291 asymptomatic THR patients showed some differences from those used in the ISO standard.
292 These preliminary data suggest that further work is warranted to explore whether THR
293 patients more generally might differ from the ISO standard cycle, and also that future studies
294 could benefit pre-clinical testing by exploring stratification according to differences in
295 loading cycles more systematically.

296

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List of Figures

Figure 1. Mean joint contact forces \pm 95% CI for the operated side of asymptomatic THR patients (THR-O) and normal healthy individuals (Normal), along with the ISO data. The loading pattern in ISO exhibited similar pattern and magnitude to the normal cohort but significantly differed from the THR cohort, with more dynamic pattern and higher magnitude, particularly on F_3 .

Figure 2. Mean joint contact forces \pm 95% CI for asymptomatic THR patients for the operated (-O) and non-operated (NO-) sides. Both sides of THR patients exhibited similar patterns and magnitude of hip contact force.

Figure 3. Mean joint contact force for the operated side of THR patients (THR-O, black line) and results of Bergmann for patients with instrumented THR prostheses (coloured lines) during normal walking (Bergmann et al., 2001). The predicted hip contact force for the operated side of THR patients was similar to patient HS and KW, but different from patient PE and IB in the results of Bergmann.

Figure 1.

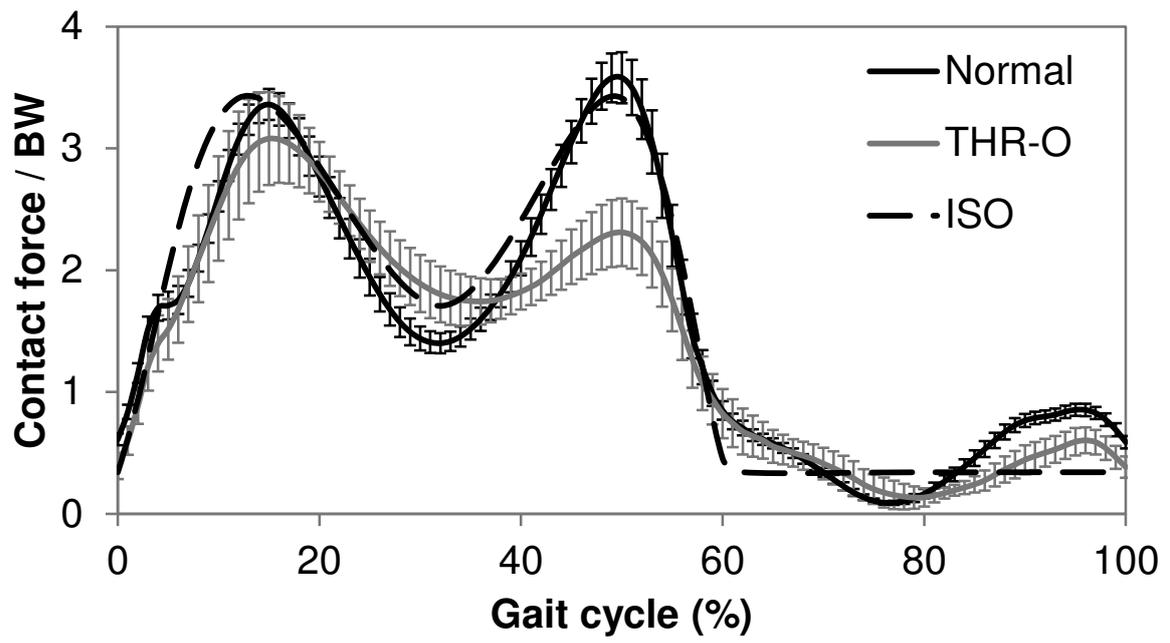


Figure 2.

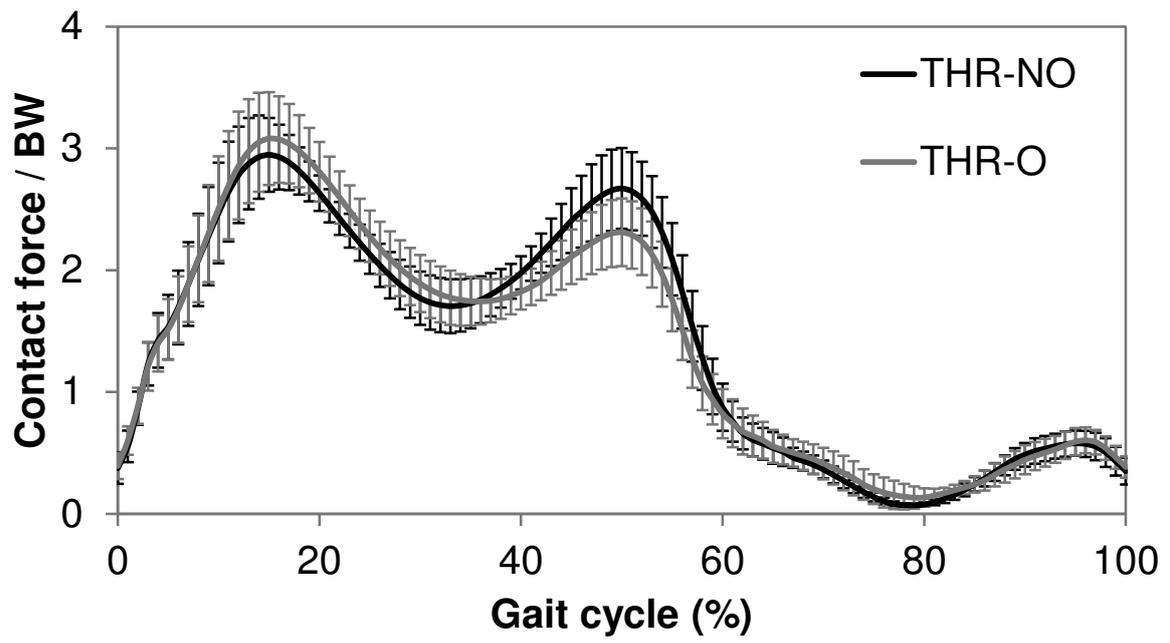
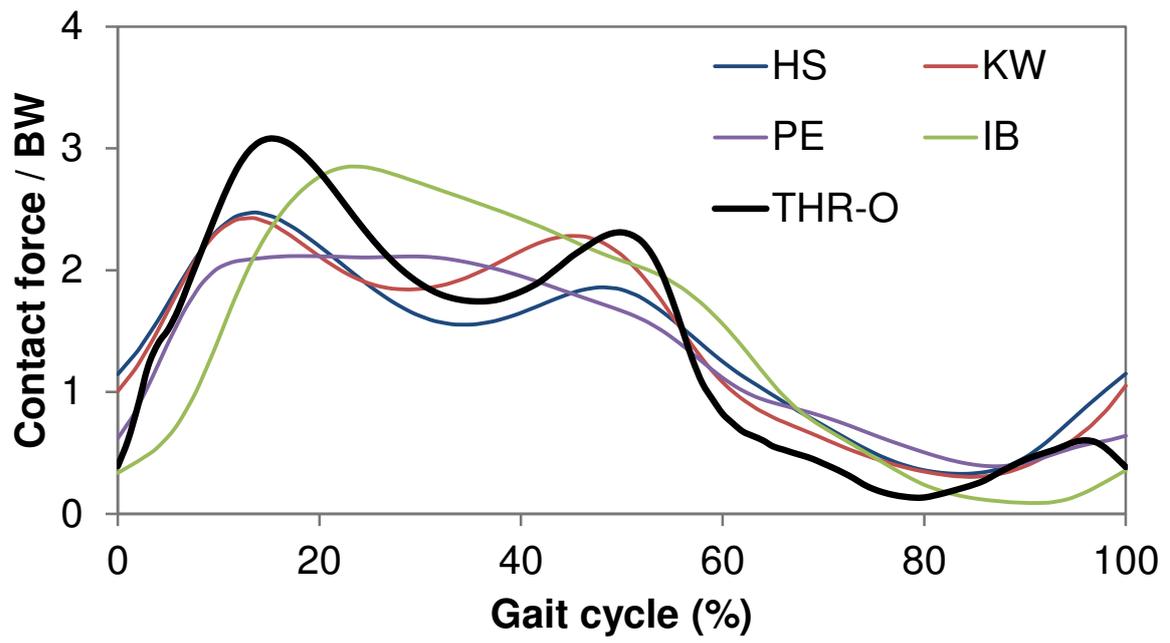


Figure 3.



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Table 1 Mean (95% CI) for gender, age and BMI in the control cohort and asymptomatic THR cohort.

Cohorts	Male / Female	Age (years)	BMI (kg/m ²)
Normal	19 / 19	44.97 (40.92 to 49.03)	24.72 (23.84 to 25.61)
THR	11 / 4	64.27 (58.59 to 69.95)	30.74 (27.72 to 33.77)

Table 2. Mean (95% CI) of gait velocity, cadence and stride length in the normal cohort and asymptomatic THR cohort. Values in these results were reduced for the THR cohort, compared to the normal cohort.

	Velocity (m/s)	Cadence (steps/min)	Stride length (m)
Normal	1.44 (1.39 to 1.50)	121 (119 to 124)	1.43 (1.39 to 1.47)
THR-O	1.09 (1.01 to 1.18)	108 (104 to 112)	1.22 (1.13 to 1.32)
THR-NO			1.23 (1.13 to 1.32)

Table 3. Mean (95% CI) for hip contact force, hip moment, and kinematics (range of motion) for the ISO standard, the normal control cohort and asymptomatic THR cohort for the operated side.

	ISO	Normal	THR-O
F ₁ (/ BW)	3.4	3.42 (3.30 to 3.55)	3.27 (2.94 to 3.61)
F ₂ (/ BW)	1.7	1.33 (1.24 to 1.42)	1.62 (1.47 to 1.77)
F ₃ (/ BW)	3.4	3.67 (3.46 to 3.89)	2.37 (2.11 to 2.63)
Moment at F ₁ (/ BW×Ht)	N/A	0.0612 (0.0584 to 0.0641)	0.0646 (0.0569 to 0.0724)
Moment at F ₂ (/ BW×Ht)	N/A	0.0201 (0.0183 to 0.0218)	0.0282 (0.0245 to 0.0318)
Moment at F ₃ (/ BW×Ht)	N/A	0.0525 (0.0500 to 0.0550)	0.0379 (0.0344 to 0.0415)
Flexion/extension (°)	43	48.6 (47.1 to 50.2)	41.2 (37.52 to 44.9)
Abduction/adduction (°)	12	15.7 (14.4 to 17.0)	10.5 (8.9 to 12.1)
Internal/external rotation (°)	11	17.1 (15.4 to 18.8)	19.5 (15.0 to 24.0)

Note: Peak contact forces occur at slightly different times in the cycle for different individuals and hence the average normalised data in the Figures (averaged at the same time interval) is subtly different in magnitude to the average peak force in Table 3 that were taken at the time point of maximum force.