Intra-operative digital imaging

ASSURING THE ALIGNMENT OF COMPONENTS WHEN UNDERTAKING TOTAL HIP ARTHROPLASTY

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Aims

The aims of this study were to examine the rate at which the positioning of the acetabular component, leg length discrepancy and femoral offset are outside an acceptable range in total hip arthroplasties (THAs) which either do or do not involve the use of intra-operative digital imaging.

Patients and Methods

A retrospective case-control study was undertaken with 50 patients before and 50 patients after the integration of an intra-operative digital imaging system in THA. The demographics of the two groups were comparable for body mass index, age, laterality and the indication for surgery. The digital imaging group had more men than the group without. Surgical data and radiographic parameters, including the inclination and anteversion of the acetabular component, leg length discrepancy, and the difference in femoral offset compared with the contralateral hip were collected and compared, as well as the incidence of altering the position of a component based on the intra-operative image.

Results

Digital imaging took a mean of five minutes (2.3 to 14.6) to perform. Intra-operative changes with the use of digital imaging were made for 43 patients (86%), most commonly to adjust leg length and femoral offset. There was a decrease in the incidence of outliers when using intra-operative imaging compared with not using it in regard to leg length discrepancy (20% *versus* 52%, p = 0.001) and femoral offset inequality (18% *versus* 44%, p = 0.004). There was also a difference in the incidence of outliers in acetabular inclination (0% *versus* 7%, p = 0.023) and version (0% *versus* 4%, p = 0.114) compared with historical results of a high-volume surgeon at the same centre.

Conclusion

The use of intra-operative digital imaging in THA improves the accuracy of the positioning of the components at THA without adding a substantial amount of time to the operation.

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The demand for primary total hip arthroplasty (THA) in the United States is projected to increase by 174% between 2005 and 2030.[1] Data from the National Inpatient Sample in 2012 showed that 34.5% of arthroplasties are performed at institutions where less than 400 THAs are performed per year.[2] It has been reported that malalignment of components is more likely when the operation is undertaken by a low volume surgeon and that low volume hospitals are more likely to have higher complication rates.[2,3] It is therefore important to continue to implement strategies to help decrease both malalignment of components and the complications associated with malalignment.

The outcomes of THA, including post-operative pain, function, range of movement, instability, the incidence of complications, and the survival of the components are affected by both surgeon and patient-dependent factors. Factors controlled by the surgeon include: previous experience and volume, surgical approach and technique, operating time, the type of components, their positioning and the method of fixation. The optimal positioning of components has been shown to have a major impact on outcome.[4-12]

The optimal positioning of the acetabular component has been guided by studies showing the effects of malalignment on the rate of dislocation, acetabular polyethylene wear,

Table I. Demographic and surgical details of cohorts with and without digital imaging

Factor	Control group (without digital imaging)	Case group (with digital imaging)	p-value
Patients, n	50	50	
Gender (male:female)	18:32	30:20	0.03*
Mean age in yrs, n (SD; range)	63.00 (10.63; 42 to 89)	59.68 (10.48; 32 to 85)	0.119†
Mean body mass index in kg/m^2, n (SD; range)	30.21 (5.73; 19.29 to 43.32)	30.97 (4.80; 20.98 to 39.53)	0.470†
Laterality (left:right)	26:24	19:31	0.228*
Primary diagnosis			0.331*
Osteoarthritis	40	46	
Osteonecrosis	6	3	
Rheumatoid arthritis	3	1	
Fracture	1	0	
Head size, mm			0.361*
< 36	3	7	
36	45	42	
> 36	2	1	
Intra-operative digital imaging time in mins, n (SD; range)	N/A	5:00 (2:30; 2:27 to 14:57)	N/A

*chi-squared test for categorial variables
†unpaired *t*-test for continuous variables
N/A, not applicable

limb length discrepancy (LLD), abductor weakness and limp, pelvic osteolysis and the need for re-operation.[4,5,7,8,12] In 1978, Lewinnek et al[7] described the "safe zone" of positioning of the acetabular component at 40º (SD 10º) of inclination and 15º (SD 10º) of anteversion. These ranges remain the ideal targets. More recent studies have reported similar findings, with some suggesting that a narrower range can further decrease the risk of dislocation.[12]

Additionally, the restoration of leg length and femoral offset significantly affects the outcome after THA, including post-operative pain, function, the survival of the components, the incidence of complications and polyethylene wear.[6,8-10,13] LLD after THA also has serious consequences and can be associated with nerve injury, low back pain, abnormal gait, dissatisfaction, and litigation.[14-17] Femoral offset has a direct effect on the stability of the hip, strength (absence of limp) and range of movement.[10,13]

Many ways of optimising the position of the acetabular component and minimising leg length and femoral offset inequalities have been described with a range of acceptance by arthroplasty surgeons. Intra-operative guides, computer navigation, robotic assistance, intra-operative radiographs, and intra-operative digital imaging with digital measurement tools all have been studied.[3,18-22] Computer navigation significantly increases the accuracy of positioning of the acetabular component and decreases LLDs.[19,23] Leg length equality and the orientation of the femoral stem can both be improved significantly using robot-assisted THA, compared with manual positioning.[22] Similarly, both fluoroscopy and plain radiographs may be used intra-operatively to aid the accurate positioning of components.[20,21,24,25] Digital imaging also allows the rapid measurement of positioning using digital tools intra-operatively. Ezzet and McCauley[20] showed that it could be used to decrease the incidence of malpositioning and leg length inequality to 1.5%.

The current study expands previous research on intra-operative digital imaging and the positioning of components.[20,26] The primary aim was to examine the frequency in which the positioning of the acetabular component, LLD and femoral offset are placed outside a determined target range in cohorts using and not using intra-operative digital imaging and compared with historical controls recently published from the same institution.[3] Our hypothesis was that use of digital imaging would significantly reduce the number of radiographic outliers.

Patients and Methods

We performed a retrospective case-control study comparing THA with the use of an intra-operative digital imaging system (case group) to THA previously undertaken without the use of this imaging system (control group). Inclusion criteria, similar to those set out by Callanan et al[18] and Barrack et al[3] required patients to have a post-operative digital anteroposterior (AP) pelvic radiograph of acceptable quality (acceptable pelvic tilt, rotation, and position of the leg), a cross-table lateral radiograph of acceptable quality, and an intra-operative image saved in our picture archiving and communication system (PACS) (Merge RadSuite, Chicago, Illinois) confirming the use of digital imaging for the case group. A power analysis indicated that, with a goal of reducing outliers by 30%, a total of 50 THAs were required in each group to obtain a power of 0.80.

All patients were selected from a single surgeon's caseload (RB). The Radlink digital imaging system (Radlink Inc., Los Angeles, California) was integrated into their workflow in July 2013. We obtained the control group by reviewing all patients who underwent THA between January 2012 and July 2013. A total of 72 consecutive patients were reviewed before we found 50 who met the inclusion criteria. The case group were obtained by reviewing those

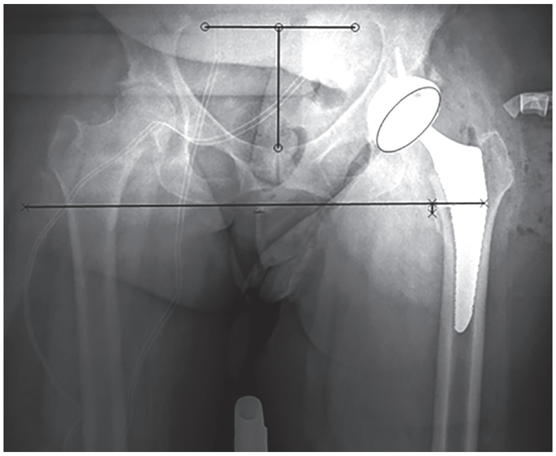

Fig. 1

Screenshot of intra-operative digital radiograph demonstrating the tools used to measure inclination angle, anteversion angle, femoral offset, and leg lengths. Note that final acetabular component is in place and trial femoral stem, head, and neck are in place for the trial reduction to allow for adjustments prior to all final components.

who underwent THA after routine digital imaging was introduced and the most recent software upgrades were installed, between August 2016 and April 2017. A total of 57 consecutive patients were reviewed before we found 50 who met the inclusion criteria. The demographic details of the patients are shown in Table I.

All THAs were performed through a posterolateral approach with the patient in a lateral position. For the control group, the THAs were routinely undertaken and post-operative supine AP pelvic radiographs were taken in the post-anaesthesia care unit (PACU). For the case group, the operation was undertaken in the same way; however, after the trial reduction using both the permanent acetabular component and liner and the trial femoral broach, head, and neck, an AP cross-table pelvic radiograph was taken with a sterilely draped mobile x-ray cassette stand adjacent to the patient's pelvis on one side and the x-ray machine on the other. Based on the quality of the radiograph in regard to pelvic tilt and rotation, the position of the operating table and/or x-ray machine were adjusted to obtain the optimum quality of image. This radiograph was transferred to the digital imaging software system in the operating theatre. The surgeon then using the system's goniometers, rulers, and ellipses, which measured the inclination and anteversion of the acetabular component, the leg lengths and the femoral offset (Fig. 1). The author (RB) made adjustments to the components based on this assessment, as were deemed necessary, and the final femoral stem and head were introduced. A supine AP pelvic radiograph was then obtained in the PACU.

The medical records and radiographs of each patient were reviewed. Surgical details which were noted included the laterality, the size of the femoral head, the operating time and changes made using the digital imaging system (Tables I and II). Radiographic measurements, including the inclination and anteversion of the acetabular component, leg length, and femoral offset were recorded from the radiographs obtained in the PACU uploaded to the Radlink system. Pre-operative templating and intra-operative measurements of the position of the components can be made using this system. The reliability of this software has been previously validated and shown to be accurate within 5º on post-operative radiographs.[26] All measurements of leg length and femoral offset were made adjusting for magnification using the diameter of the femoral head as a reference.

The inclination and anteversion of the acetabular component was measured using the transischial line as a reference and with the best fit ellipse at the face of the component. LLD was measured in millimeters as in previous studies, using the transischial line intersecting each femur and recording the distance to the most medial portion of each lesser trochanter.[20] Femoral offset was recorded as the measurement in millimetres from the centerline of the femur to the centre of rotation of the femoral head.[10] Two reviewers (DH, MH) performed all radiographic measurements. Inter-observer reliability was tested by having them compare the measurements from 15 randomly selected radiographs.

The acceptable ranges for inclination and anteversion of the acetabular component were defined as between 30º and 55º, and between 5º and 35º, respectively, as previously reported from our institution and similar to other studies.[3-5,7,12,18] LLD[15,16,20,27] and femoral offset were considered acceptable if within 5 mm of the contralateral limb.[6] Any measurement outside this range was recorded as an outlier. We used a previously published cohort including 1292 THAs from high volume surgeons at our institution to compare the accuracy of the position of the acetabular component prior to using digital intra-operative imaging in the case group.[3] This study had ethical approval.

Statistical analysis. Demographic data and outcomes were compared between groups using an unpaired *t*-test for continuous variables and a chi-squared test for categorical variables. Inter-observer reliability was calculated with the intraclass correlation coefficient. A $\kappa > 0.60$ was defined as showing substantial agreement between reviewers. A p-value ≤ 0.05 was considered significant. All statistical tests were performed using SPSS Statistics for Windows, version 23 (IBM, Armonk, New York).

Results

Digital imaging was noted to take a mean of five minutes (2.27 to 14.57) (Table I). Intra-operative changes were made for 43 patients (86%) following the use of intra-operative digital imaging, most commonly to adjust leg length and femoral offset (Table II). There was a significant difference in the mean inclination of the acetabular component, LLD and femoral offset when comparing the two groups. There was no difference in the mean anteversion of

Table II. Intra-operative changes based on intra-operative digital imaging

Intra-operative change	Frequency, n (%)
Yes	43 (*86*)
No	7 (*14*)
Type of intra-operative change	
Acetabular component inclination	2 (*4*)
Acetabular component anteversion	2 (*4*)
Leg length	39 (*78*)
Femoral offset	25 (*50*)
Femoral stem size	8 (*16*)

Table III. Component placement details

Factor	Control group (without digital imaging)	Case group (with digital imaging)	p-value*
Mean acetabular inclination (°), n (SD; range)	48.02 (6.34; 32 to 65)	44.86 (5.01; 33 to 55)	0.007
Mean acetabular anteversion (°), n (SD; range)	19.88 (5.45; 7 to 35)	21.48 (5.64; 8 to 35)	0.152
Mean absolute leg length discrepancy (mm), n (SD; range)	6.11 (4.88; 0 to 21)	3.44 (2.85; 0 to 14.6)	0.001
Mean absolute femoral offset inequality (mm), n (SD; range)	4.64 (3.32; 0.1 to 15.9)	3.35 (2.08; 0.1 to 7.6)	0.021

*unpaired *t*-test

Table IV. Incidence of malpositioned component 'outliers'

Factor	Acceptable range	Control group outliers (without digital imaging), n (%)	Case group outliers (with digital imaging, n (%)	p-value*
Patients		n = 50	n = 50	
Acetabular inclination, °	30 to 55	4 (*8*)	0 (*0*)	0.059
Acetabular anteversion, °	5 to 35	0 (*0*)	0 (*0*)	N/A
At least one out of range (inclination or anteversion)		4 (*8*)	0 (*0*)	0.059
Absolute leg length inequality, mm	< 5	26 (*52*)	10 (*20*)	0.001
Absolute femoral offset inequality, mm	< 5	22 (*44*)	9 (*18*)	0.004

*chi-squared test
N/A, not applicable

the acetabular component between the two groups (p = 0.152; Table III). The use of the digital imaging system significantly reduced the number of outliers for LLD and inequality of femoral offset (Table IV) (Fig. 2). There was a strong trend towards reduced outliers for inclination of the acetabular component (0% *versus* 8%, p = 0.059), but this did not reach statistical significance. There was a significant reduction in outliers for acetabular inclination when comparing the case group with the historical control group (Table V) (Fig. 3).[3]

Discussion

The orientation of the acetabular component and the restoration of leg lengths and femoral offset all contribute to the success of THA.[4-12]

The optimal position of an acetabular component has been guided by many studies since Lewinnek et al[7] demonstrated a significantly lower rate of posterior dislocation in components within a "safe" range. Biederman et al[12] reported that patients with anteversion of < 10º had a six-fold higher relative risk of posterior dislocation than those with anteversion of 15º (SD 5º). Computer kinematic models by D'Lima et al[28] showed that inclination between 45º and 55º resulted in the maximum range of movement and stability with respect to impingement when combined with appropriate acetabular and femoral anteversion. More vertically inclined acetabular components (range 55º to 69º) are associated with an increased vertical and horizontal migration of the component and increased polyethylene wear, osteolysis and complications.[4] It has previously been suggested that a more vertical inclination angle increases the load per unit area in the superior aspect of the polyethylene liner, with increased polyethylene wear and wear debris production when using conventional polyethylene.[29] However, with the advent of highly crosslinked polyethylene, higher inclination angles, up to 55°, may have little to no impact on wear.[30] Moreover, there is some evidence that there is no link between edge wear in metal-on-polyethylene THA and wear across the overall articulation. Therefore, there is less concern about the impact of higher angles of inclination and edge wear in these types of articulation.[31,32] As suggested by Harris[31] this is a "privileged" position of metal-on- polyethylene articulations given that edge wear has significant impact on metal-on-metal and ceramic-on-ceramic bearings.[33,34] The ranges for hard-on-hard bearings are probably narrower. De Haan et al[35] have suggested acetabular inclination of < 45º given the correlation between inclination and metal ion levels in

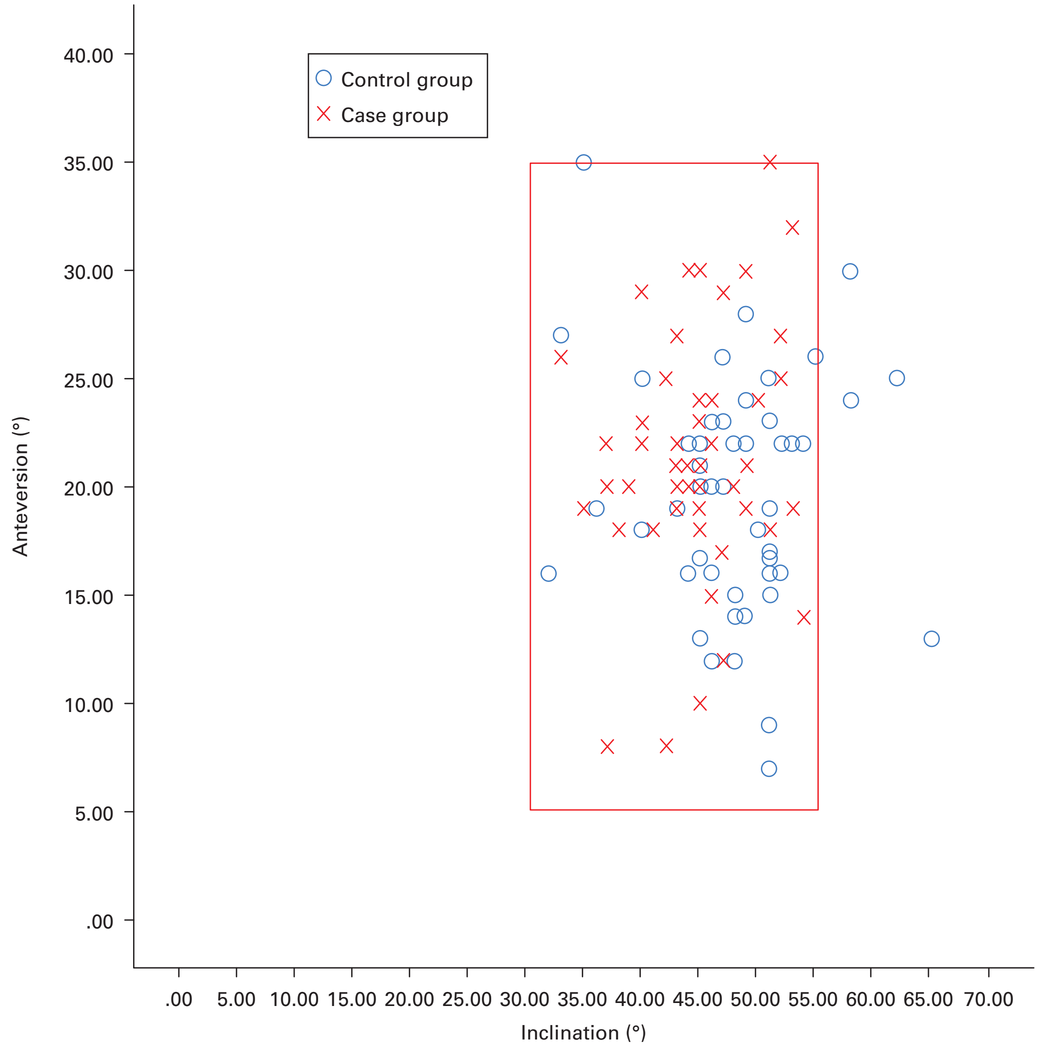

Fig. 2

Scatterplot demonstrating the distribution of acetabular component inclination and anteversion for the group not using (control) and the group using (case) intra-operative digital imaging. The components lying within the solid box represent components positioned in acceptable range (inclination 30° to 55°, anteversion 5° to 35°).

metal-on-metal resurfacing arthroplasty, and Langton et al[36] reported that patients with adverse reactions to metal debris had significantly greater acetabular anteversion compared with asymptomatic patients (mean 27.4° *versus* 19.7°, $p < 0.001$), suggesting that anteversion should be < 20° for hard-on-hard bearings.

Based on these studies and our experience, our goals were 45° for inclination and 20° for anteversion with acceptable ranges of between 30° and 55° for inclination and 5° and 35° for anteversion. These ranges are similar to those selected by Barrack et al[3] and Callanan et al,[18] as well as to the classic Lewinnek et al[7] "safe" ranges. Both Barrack et al[3] and Callanan et al[18] also separately detail the potential risk factors linked to malalignment and conclude that minimally invasive surgical approaches, low volume surgeons, and obese patients are potential risk factors for malalignment. However, even in a high volume surgeon group, an incidence of outliers with 11% of acetabular components having angles of either inclination and/or anteversion outside the acceptable ranges has been reported.[3]

Our study details how the introduction of intra-operative digital imaging into a high volume surgeon's practice can significantly decrease and/or eliminate the incidence of malaligned acetabular components, significantly decrease the incidence of LLD (> 5 mm) and more accurately restore femoral offset. Ezzet and McCauley[20] demonstrated the impact of intra-operative digital measurements and found that unexpected acetabular malalignment occurred in only 0.5% of cases where intra-operative digital imaging was used. Furthermore, Beamer et al[21] had previously shown significant improvement of acetabular alignment using intra-operative fluoroscopy. We found additional potential for improved accuracy of digital imaging compared with fluoroscopy alone.

Table V. Incidence of malpositioned component 'outliers'

Factor	Acceptable range	Historical high volume surgeons control group outliers (without digital imaging), n (%)	Case group outliers (with digital imaging), n (%)	p-value*
Patients		n = 1292	n = 50	
Acetabular inclination, °	30 to 55	96 (*7*)	0 (*0*)	0.023
Acetabular anteversion, °	5 to 35	56 (*4*)	0 (*0*)	0.114
At least one out of range (inclination or anteversion)		161 (*12*)	0 (*0*)	0.001

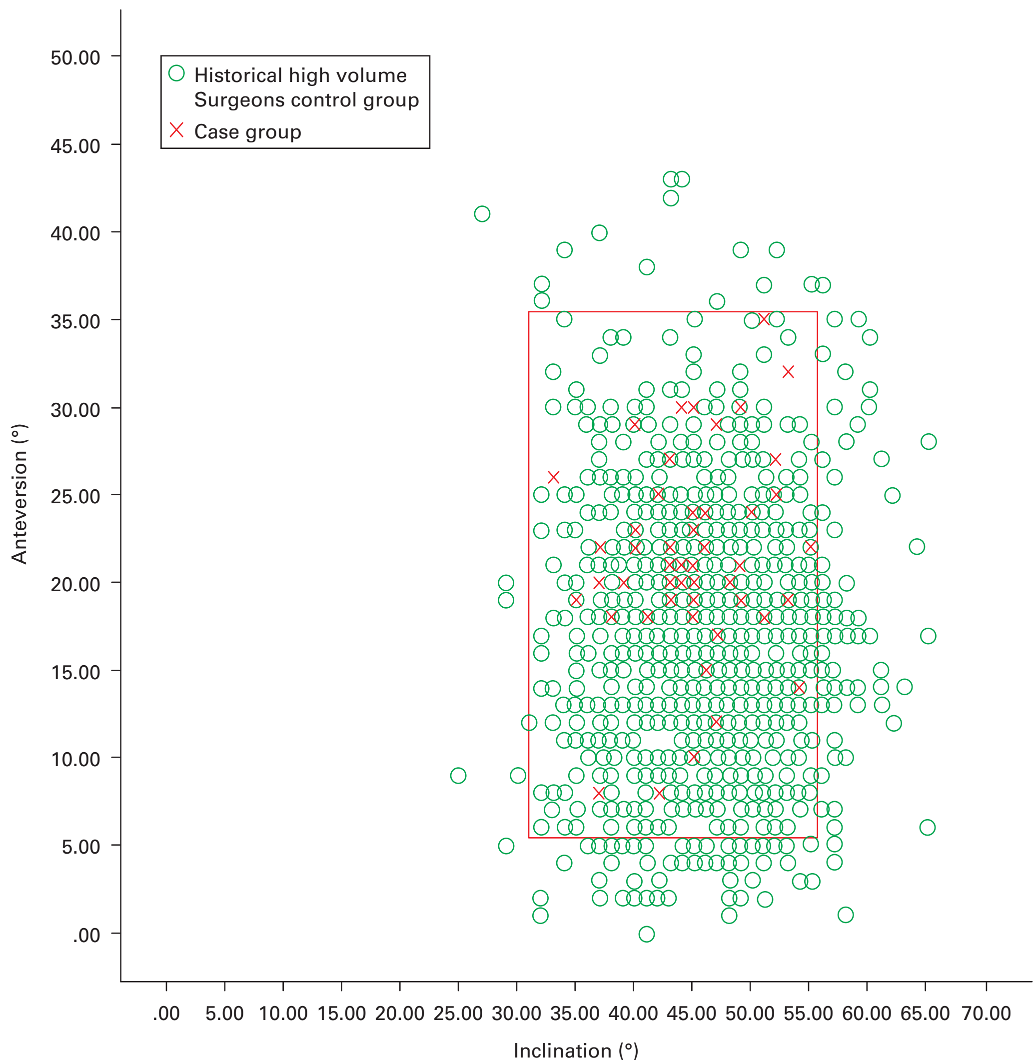

Fig. 3

Scatterplot demonstrating the distribution of acetabular component inclination and anteversion for the historical high volume surgeon group (control) and the group using intra-operative digital imaging (case). The components lying within the solid box represent components positioned in acceptable range (inclination 30° to 55°, anteversion 5° to 35°).

The optimal positioning of components reduces the incidence of leg length inequality. Gurney et al[16] have shown significantly increased oxygen consumption, heart rates, and disparities in muscle activity between limbs with an increased leg length inequality and concluded that a LLD of between 2 cm and 3 cm is the critical point with regard to effects on most physiological parameters. Bhave et al[27] additionally reported that LLD creates an asymmetry in the ground reaction force and that surgical lengthening of a short limb to within 1 cm of the contralateral limb reduced the asymmetry to less than a significant level. Previous studies assessing the use of intra-operative digital imaging have either set a target range of within 5 mm of the contralateral limb or have attained this target with all of their THAs using digital imaging.[20,26] Thus, our goal was also to correct any LLD with an acceptable range being within 5 mm of the contralateral leg. Prior to the use of intra-operative digital imaging, LLD of > 5 mm occurred in 52% of our cases. Most of the outliers (18 of 26) were within between 5 mm and 10 mm of the contralateral limb. With the use of digital imaging, a LLD of > 5 mm was only seen in 20% of patients. Ezzet and McCauley[20] reported similar findings with use of digital imaging; 1% of THAs were outside the 5 mm target range. Lim et al[25] using an intra-operative radiographic PACS-based method, reported increased accuracy in restoring leg lengths with outliers of > 6 mm decreasing from 32% without imaging to 19% with imaging. Our results show that the number of outliers in LLD can be significantly decreased using intra-operative imaging.

Fackler and Poss[13] have shown that femoral offset correlates with the stability of the hip when comparing distances between the femoral head and the tip of the greater trochanter between their group with a dislocation of the hip and those without a dislocation (p < 0.025). Jinno et al[37] also suggested that higher offsets provided greater range of internal rotation to subluxation, and McGrory et al[10] showed that femoral offset correlates positively with the range of abduction, and the strength of abduction correlates positively with both femoral offset and the length of the abductor lever arm. Little et al[6] found that reproduction of femoral offset to within 5mm of the native offset was associated with a reduction in polyethylene wear, suggesting that minimising the difference between the femoral offset and that of the contralateral hip will improve the outcome after THA. Our goal was to restore the offset to be equal to that of the contralateral hip with an acceptable range being within 5 mm. We found a significant improvement in the ability to restore femoral offset using intra-operative digital imaging. Prior to implementation, the offset of 44% of hips was > 5 mm outside the range of the offset of the contralateral hip. Most of the outliers (19 of 22) were within 5 mm to 10 mm of the contralateral hip. When using intra-operative digital imaging, there was a significant improvement in restoration of offset with only 18% having an offset of > 5 mm outside the range of the contralateral hip. This large decrease shows the ability of the imaging system to identify inequality that may have previously been indiscernible.

The limitations of the study are mostly due to it being retrospective. First, the groups were not matched with regards to gender, which may lead to a selection bias. Secondly, the results may be unique to a single surgeon and not reproducible to all surgeons. The results in the control group, however, were similar to large recently published studies involving > 1000 THAs by several surgeons.[3,18] Thirdly, given that radiographs were assessed retrospectively, many patients with inadequate radiographs were excluded from the study, which may also contribute to selection bias. Fourthly, radiological analysis suffers from interobserver variations. Although our κ was > 0.6, this limitation remains. A future prospective randomised controlled study with strict radiographic protocols would remedy most of these limitations.

In conclusion, these results show that the use of intra-operative digital imaging as a supplement to good surgical technique can significantly improve the positioning of the acetabular component and the restoration of leg lengths and femoral offset in THA.

Take home message:

- Intra-operative digital imaging decreases the incidence of outliers in LLD, femoral offset inequality and acetabular component positioning in both inclination and anteversion.
- The incidence of intra-operative changes made when using digital imaging is substantial and, on average, takes a limited amount of intra-operative time.
- The use of intra-operative digital imaging in THA improves the accuracy of component positioning without adding a substantial amount of time to the case.

Author contributions:

D. Hambright: Data collection, Radiographic measurements, Analysis, Writing manuscript.

M. Hellman: Data collection, Radiographic measurements, Statistical analysis, Writing manuscript.

R. Barrack: Principal Investigator, Operating surgeon, Analysis, Manuscript editing.

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