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Accuracy and Repeatability of CT Scan in Hip Surgery (SARAH Study)

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Summary

Introduction

In 2018 in France, 183,139 surgical hip procedures were recorded (1), among them, hip arthroplasty was the most frequent with 148,965 primary hip replacements and 19,304 revision procedures. Between 2018 and 2050, primary hip replacement should increase by 41.9% to 114.3% (1).

Seven causes of first revision have been identified (2); aseptic loosening, peri-prosthetic fracture, infection, osteolysis and wear, dislocation, technical error and implant fracture (2). Aseptic loosening, osteolysis and wear represented on their own 53% of all causes of revision.

Polyethylene wear is an early indicator of the risk of implant failure with a wear rate directly correlated to the risk of revision (3). When the wear rate is less than 0.1 mm/year, rare signs of osteolysis are detected and prosthesis survival at 25 years is greater than 90%, but with a wear rate of 0.2 mm/year, survival at 20 years is less than 30% and non-existent at 25 years (3,4). To sum up, each 1 mm increasing leads to an increase of the revision risk per year of 45% for the acetabulum and 32% for the femur (3).

Currently, all in vivo methods for polyethylene wear monitoring assess penetration of the femoral head into the acetabulum (FHP) (5,6), considering that the displacement of the femoral head within the acetabulum is due to the loss of polyethylene substance. This migration can be studied in a two-dimensional or three-dimensional coordinate system.

Two-dimensional uni or duoradiographic methods can detect in vivo cup centers but do not allow measurement of anteroposterior wear (5–7). To overcome this problem, a lateral incidence is added to take into account three-dimensional wear, but this method suffers from 4 times less reproducibility due to the poor quality of this incidence (8,9).

To overcome these limits, computerization of X-ray equipment and contour detection software such as Manchester X-ray Image Analysis (MAXIMA) (10), Ein Bild Roentgen Analyse (EBRA) (7,11), Martell's Hip Analyse Suite (HAS) (9,12) or PolyWare (Draftware Inc.) (8,13) assist the clinician but are associated with a time-consuming process up to 15 minutes at least per image (7,8,8–12). A recent study demonstrated the superiority of radiostereometry analysis (RSA) in terms of accuracy to measure femoral head penetration (FHP) (14). RSA is now considered as the gold standard for the monitoring of early migration and a valuable tool to ensure revision but has many limitations (15); (1) the methods requires implantation of tantalum (Ta73) beads in the patient bone to define a constant reference maker and is therefore invasive and not suitable for routine use. (2) the method is not available everywhere, requires trained technician and dedicated materials in laboratory conditions.

Therefore, RSA has been gradually overcome by CT scan. Patient positioning variations and errors depending on the orientation of the acetabulum can be fixed with image transformation in the 3D coordinate system, using for example the McKibbin plane (16,17). The introduction of the 3D rendering function allows the users to directly position visual landmarks on the 3D surface of the implant and extract a set of points on the edge. This technique significantly improves the accuracy of contour detection, but the procedure can take up to 20 minutes per scanner (18,19). To reduce image post-treatment time, some authors have proposed different algorithms or external software such as Osirix, 3D Reshaper or Geomagic Studio (20,21), but these tools remain user-dependent (22,23).

Then this study evaluated accuracy and precision of CT scan with an open-source software (3DSlicer) providing image segmentation of the prosthesis from 3D CT data set, neither need for anatomic reference or knowledge of the implant's shape. The method was tested on calibrated polyethylene cup to evaluate penetration of the femoral head (FHP) into the acetabulum.

Materials and Methods

Hip implant

We used a total hip prosthesis from Serf company (Décines-Charpieu, Rhône Alpes, France). The acetabular cup of the Novae® series is based on the concept of double mobility, consisting of a SunFit TH cup size 51 and a mobile insert made of ultra-high molecular weight polyethylene (UHMWPE). The acetabulum cup is not perfectly spherical and equipped with a cylindrical collar. The femoral component is composed of a 22.2 mm size head and a cementless Libra® stem. Eight polyethylene inserts were used, 3 new and 5 modified. For modified inserts, the polyethylene thickness was reduced to simulate wear by increasing the inner diameter (Figure 1).

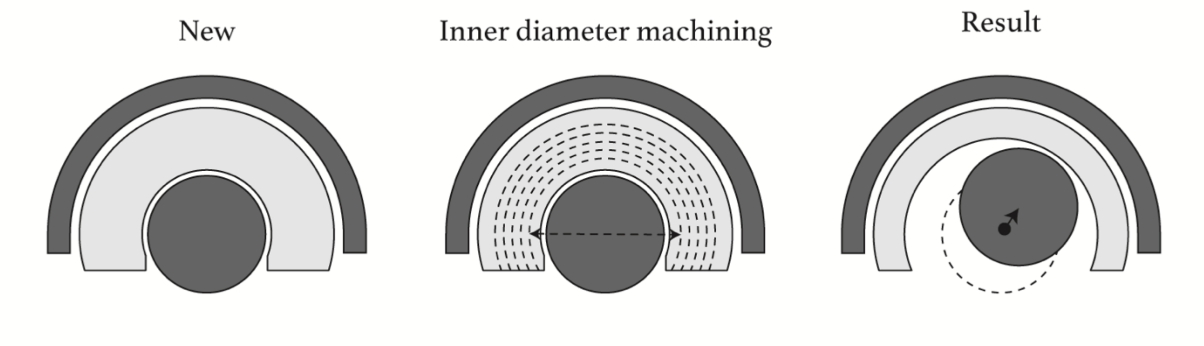

Figure 1 : Drawing showing how to reduce polyethylene thickness machining the inner diameter to simulate femoral head migration into the cup.

Expected wear after machining is summarized in Table 1. Machining was carried out by Serf with a tolerance of 0.01 mm on the inner diameter. In our prosthesis, there is a mechanical clearance resulting in a displacement of the femoral head towards the acetabulum of 0.45 mm. The prosthesis is then embedded in a pelvic phantom with a compression system to simulate patient loading (Figure 2).

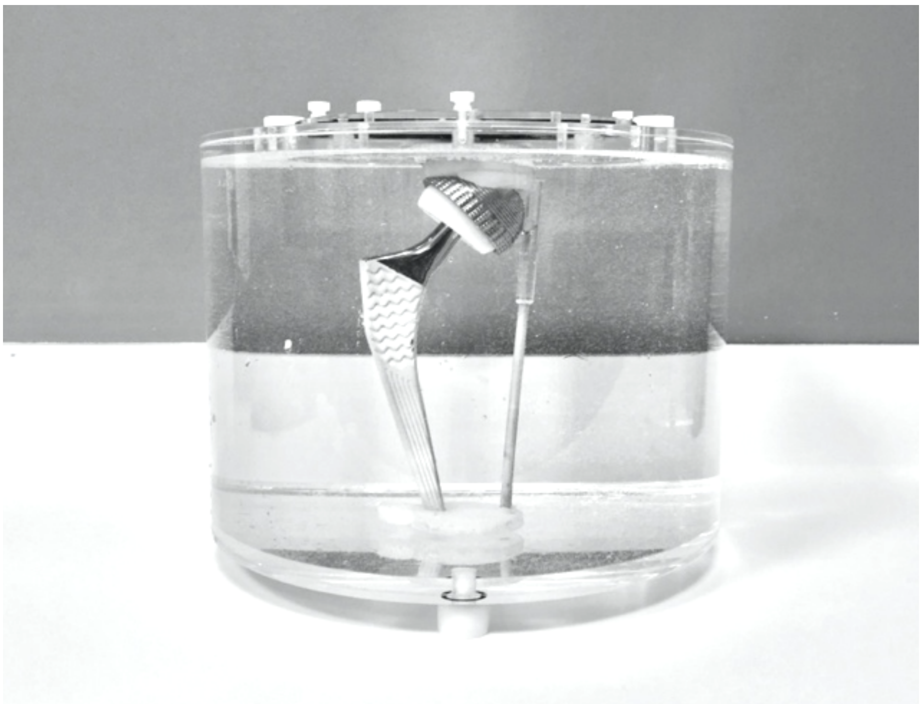

Figure 2 : Pelvic phantom filled with water embedding hip implant with compression system.

Software

The dedicated open-source software called 3DSlicer was used to open DICOM data set. All functions of the radiology software can be controlled with command lines to avoid the human factor. It integrates VTK library (Visualization Toolkit, Kitware) based on OpenGL standard for 3D visualization functions. 3DSlicer v.4.10.2 (https://www.slicer.org) runs on Windows, MacOSX, or various Linux distributions.

CT acquisition

A Canon Aquilion One Genesis CT device was used to obtain 3D data set of the phantoms. Two protocols were used, the first routinely used with a low radiation dose (LD) and another including a set of adjustments to improve the spatial resolution (HD). The parameters for volumetric acquisition are the following: 135kV, 0.75 rotation time with 250 mA and 400 mA for LD and HD, with AIDR3D enabled for adaptative delivered dose. From each acquisition, several image reconstructions were generated with reconstruction interval of 0.25 mm and different combinations of filters (bone or tissue) and with or without metallic artefact corrector (Semar) for a total of 64 volumes (8 inserts * 2 protocols * 2 filters * 2 corrector).

Femoral head penetration measurement

For each imaging data set, image segmentation was performed applying automatic threshold on Hounsfield units. The segmented volume was then visible by superimposition. 3D rendering of the external surface was then displayed. Two additional spheres were automatically fitted to the femoral head and cup shape (Figure 3). Distance between centers were calculated. Correct positioning of the two spheres were visually checked by scrolling through the sections or rotating the 3D object to ensure that there are no obvious errors.

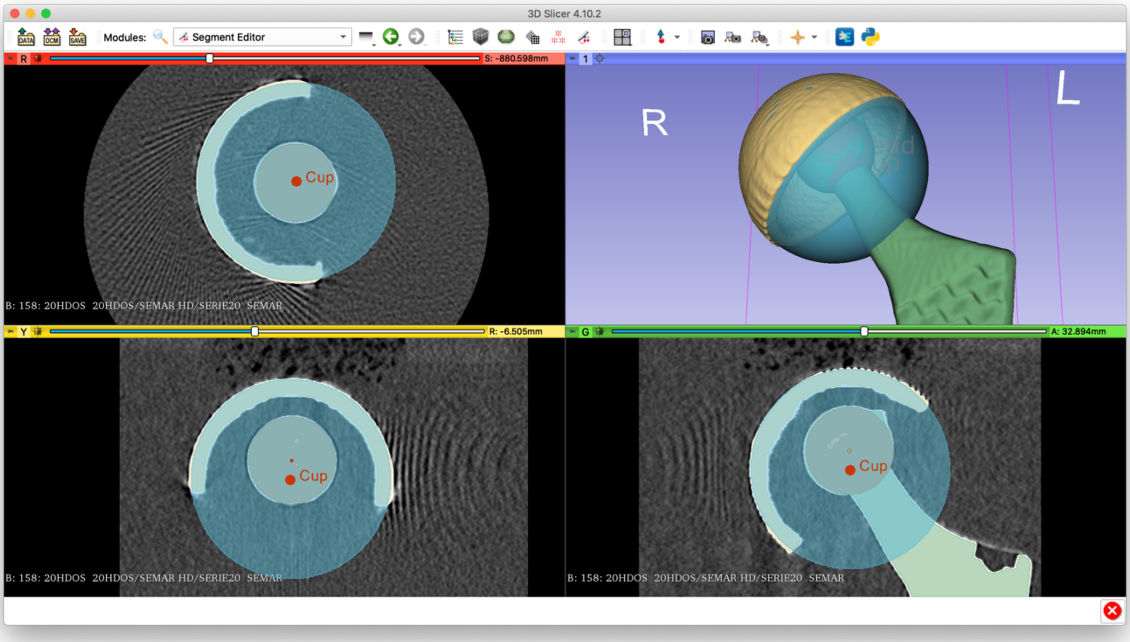

Figure 3 : Viewing 3DSlicer with 3D rendering of the segmentation and 3D spheres fitted to the cup and the femoral shape.

Comparison between measured and true wear

To calibrate exact diameters of the prosthesis including mechanical clearance, 3 new implants without any modifications were studied to obtain average measures of the femoral head penetration. The mean value of these 3 measures was subtracted from measures obtained on the 5 modified implants to have real wear measurements. This measurement is compared to true wear due to machining to assess the method systematic measurement error called bias.

To ensure repeatability, acquisition of each prosthesis was repeated within a short time interval of 5 minutes. The femoral head penetration of the 8 implants was directly compared between the two series.

Statistical evaluation of errors

All statistics were performed with RStudio v1.2.5042 and R v4.0.0 package. Quantitative variables were expressed as means or medians, standard deviation [SD] and range. Normality distribution was assessed using the Shapiro-Wilk test. The method was tested for systematic errors by computing an interval estimate of the bias (the mean error and the 95% confidence interval for the mean) and accuracy and repeatability were calculated according to ISO definitions (ISO 3534:3,11 and 3,14) at the 95% confidence level obtained from the Student's t-test distribution. Nonparametric Kruskal-Wallis or Wilcoxon's test were used to calculate pairwise comparisons between groups as residue normality or variance homogeneity assumptions were not verified. Statistical significance was set at $P < 0.05$ or adjusted when necessary for multiple tests according to Bonferroni.

Results

The average time required for measurements including image segmentation and femoral head penetration measurement is 15.1 (13,78 – 17,04) seconds [SD 0.57].

Mean measurement error

When comparing measured and true wear, the mean difference was -0.012 mm (IC95% 0.013). Results are summarized in Table 2 grouped by protocol, filter and artefact corrector. Differences were distributed normally according to a Shapiro-Wilk test ($p = 0.106$). There was a strong correlation with the measurement method ($R = 0.99$; $p < 2^{-16}$). To evaluate reproducibility, a Bland Altman graph plotting the difference for each measure is given as Figure 4. Limits of agreement were calculated with lower limit as -0.093 (bias – 1.96 SD) and upper limit as 0.069 (bias + 1.96 SD). Statistically all measurement differences are between the upper and lower limits corresponding to the agreement limits, and below the threshold of +/- 0.1 mm set as clinically significant.

Superimposed spheres confirmed each image segmentation provided error-free implant extraction.

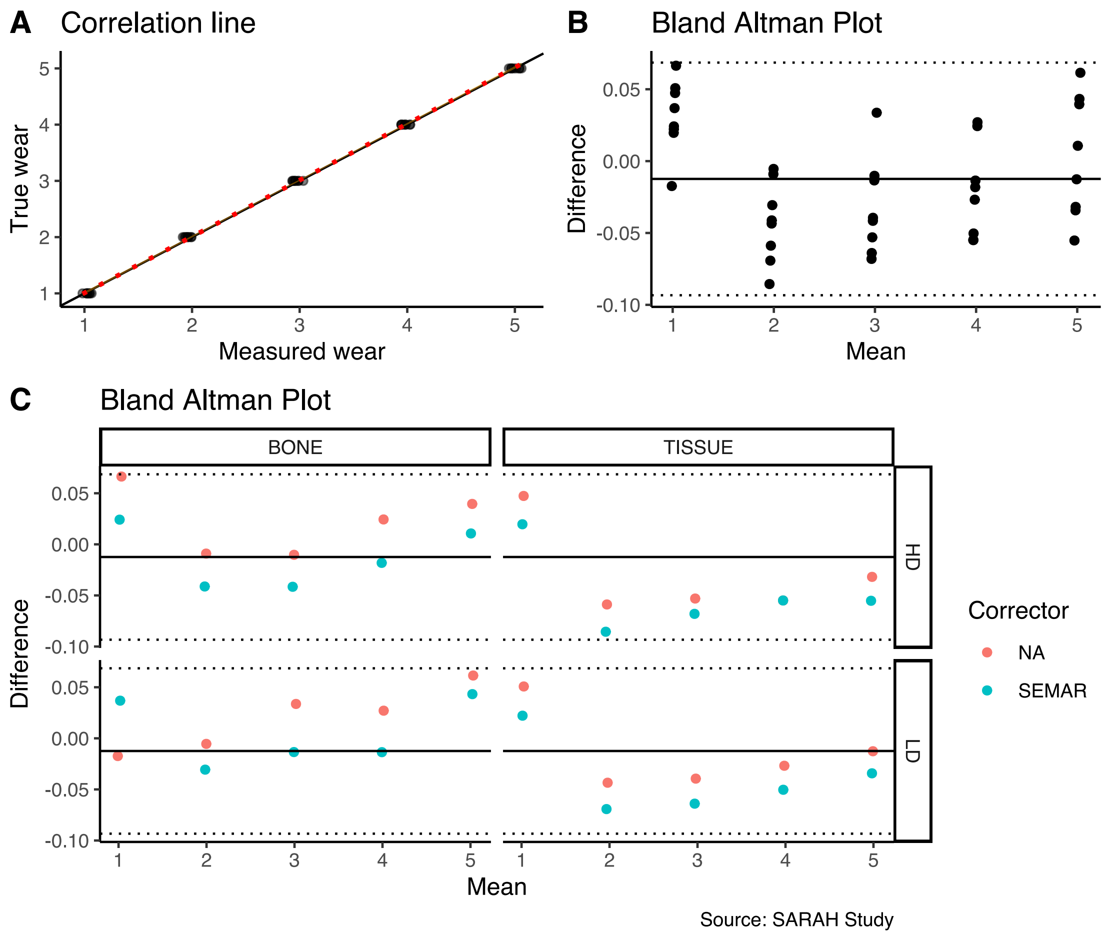

Figure 4 : Results between measured and true wear due to machining. (A) showing the correlation line (dotted red line) with the solid line if values were equal. (B,C) showing a Bland Altman Plot with agreement limits (dotted line) from -0.093 (bias – 1.96 SD) to 0.069 (bias + 1.96 SD) and solid line corresponding to the mean difference -0.012 mm (IC95% 0.013) between measured and real wear. “NA” in red dots when no corrector is used.

Repeatability and Accuracy

Repeatability was 0.038 mm and accuracy was 0.027 mm assuming there is no bias comparing the two repeated measurements according to Ranstam et al. (24). Differences were distributed normally according to a Shapiro-Wilk test (p = 0.631).

Differences between groups

No difference was found between HD (-0.018 mm [SD 0.044]) and LD (-0.007 mm [SD 0.039]) protocol according to Kruskal-Wallis test (p = 0.36) and boxplot (Figure 5). There was a statistically significant difference between filter groups as assessed using the Kruskal-Wallis test (p = 0.001). Pairwise Wilcoxon test between groups showed that only the difference between BONE and TISSUE-SEMAR group was significant (Wilcoxon's test, adjusted p = 0.004). We identified 4 outliers in TISSUE group (red points) with overestimation (Figure 5) due to significant artefact presence causing implant shape distortion.

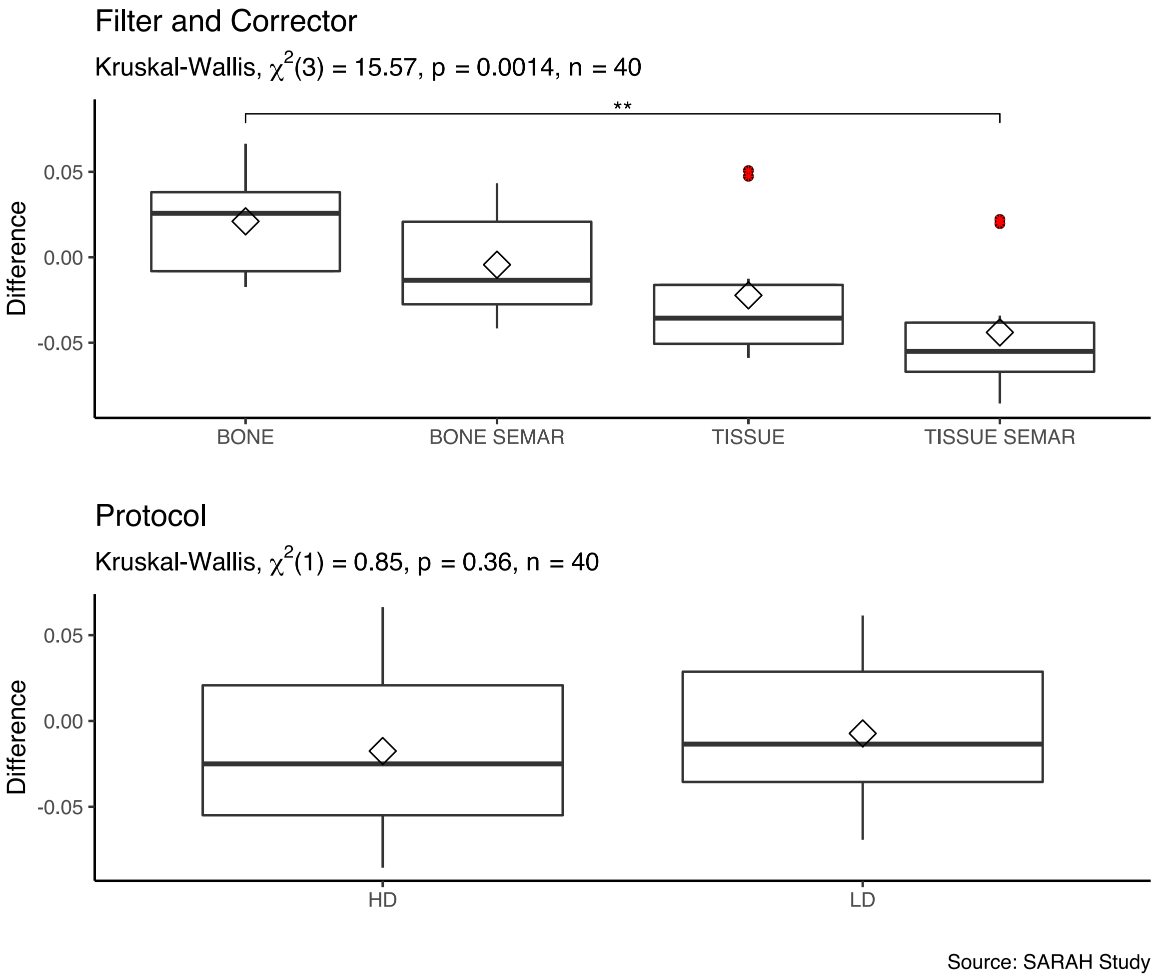

Figure 5 : Boxplots showing the influence of Filter and Corrector (upper) and Protocol (lower) factors on accuracy. Comparison between groups with Kruskal-Wallis and pairwise Wilcoxon's test showing only significant difference (** adjusted p = 0.004) between BONE and TISSUE-SEMAR group. Red dots for the 4 outliers.

Irradiation dose

The delivered dose by each scanner was recorded according to the Product Dose Length (PDL). The mean PDL was 213 mGy.cm (199 – 224,6) for LD and 345 mGy.cm (322,4 – 363,9) for HD protocol. The PDL is then multiplied by a conversion factor (25) k = 0.015 adapted to the relevant hip region to obtain a result in mSv corresponding to the Effective Dose (E). The mean delivered dose was 3,2 mSv (3 – 3,4) for LD and 5,2 mSv (4,8 – 5,5) for HD protocol.

Discussion

We have detailed in Table 4 previous results from different methods of femoral head penetration measurement. There is a progressive improvement in precision and fidelity according time to reach a maximum in our study with a repeatability coefficient and an accuracy being up to 0.038 mm and 0.027 mm respectively (18–20,22,23,26,27). Our method provided highly accurate and reliable measurements of femoral head penetration. All the differences for software measurements lied within the 95% limits of agreement, below the threshold of +/- 0.1 mm that was designated as clinically relevant. The presence of tolerance in the machining of the internal diameter of the inserts (0.01 mm) may be an explanation for the measurement fluctuations that cause the mean systematic error (or bias) of -0.013 mm.

Previous studies (20) have already pointed the need to reduce time consumption for a routine use that have been achieved in this study with the removal of human interaction (about 15 seconds [13,78 – 17,04]). To our knowledge, this is the first study using a fully automated method.

We believe that CT imaging is part of a global approach for patient follow-up, for monitoring polyethylene wear as we have shown, but also for differential diagnosis (osteolysis, peri-prosthetic fracture, loosening, migration). We know that RSA is still prized and described as gold standard by some authors, but these studies are only available under laboratory conditions (5,28). Recently a study with 40 dose reduction protocols reported that the quality was enough to achieve accuracy generally obtained in RSA with low dose protocols, which one was until 0.70 mSv (29). The use of the scanner is no longer a limit knowing that RSA generally achieves a dose of 1 mSv and low dose protocols are fully compatible with acceptable accuracy and image quality (21,28–31).

Our mean delivered dose (3,2 mSv) with our routinely used low-dose protocol is quite similar to the doses given in typical pelvis CT (3 – 4 mSv) (25). No difference was found between HD and LD protocol (p = 0.36), in addition to the high degree of precision achievable with this software (accuracy 0.027 mm), low dose protocol is highly recommendable for clinical use in accordance with previous CT and low dose studies (29,30). We think the co-morbidities related to wear and loosening in the elderly leading to revision procedures are such that it is perfectly conceivable with low dose protocols to imagine a dose of diagnostic CT to prevent complications.

Only 1 scanner was tested, so we were able to find different results, but the spatial resolution of the devices is close or even equivalent and depends mainly on the acquisition and reconstruction parameters. We can imagine an increase in performance in the coming years with the improvement of CT hardware and software (spatial resolution, reconstructions, filters, algorithms). Some conditions have been foreseen, but our method could encounter difficulties in case of unexpected presence of anomalies on the image as found in other studies (18,19,27). All in all, we recommend the use of BONE or BONE SEMAR filter, however the presence of specific artefacts (contralateral prosthesis) or more difficult examination conditions (obese patient for example) has not been tested.

This method raises the problem of reliance on artificial intelligence for the diagnosis of anomalies. In our study, user control is preserved with a 3D display of sphere positioning around implants, but we can discuss the problem of blind confidence in the interpretation of the image. For example, we think this automated method could be executed by the CT scan hardware during image reconstruction or in background on the PACS system.

For a technical approach, our method cannot distinguish the plastic deformation cause (creep) and true wear in charge of FHP. Chronologically, there is an early stage during that creep occurs within polyethylene (32) and true wear is distinguished when the rate stabilizes over time (5,33,34). This widely accepted issue in in-vivo measurements explains the dispersion of rates observed in the literature according to the time between primary and revision surgery (from 0.005 to 0.6 mm/year) (35). To solve this problem, the authors consider that the migration of the femoral head is mainly due to creep during the first year (5).

Furthermore, it is common to find an initial displacement of the head into the polyethylene explained by a diameter tolerance between the parts to reduce friction forces. This can be as low as 0 to 0.5 mm although this is not systematically specified by the manufacturer (36) or reach up to 1.1 mm on two postoperative radiographs spaced 3 weeks apart (33).

In conclusion, our study showed a single CT method achieving relevant accuracy and reproducibility to assess wear rate that causes osteolysis earlier than previous methods. Thus, the ability to follow polyethylene wear with an accuracy about 0.03 mm regardless of acquisition protocol in further in-vivo studies should be of some interest.

Tables

Table 1 : Insert population with 3 new and 5 modified inserts with inner diameter machined to reduce the polyethylene thickness and simulate femoral head penetration (FHP).

Insert	Inner diameter (mm)	FHP simulated (mm)
1 (new)	22.4	0
2 (new)	22.4	0
3 (new)	22,4	0
4	24.4	+ 1
5	26.4	+ 2
6	28.4	+ 3
7	30.4	+ 4
8	32.4	+ 5

Table 2 : Mean error between software measurement and true wear (machining).

Protocol	Filter and Corrector	N for each series	Mean difference (mm)	SD
HD	TISSUE	5	-0.03	0.045
HD	TISSUE SEMAR	5	-0.049	0.040
HD	BONE	5	0.022	0.033
HD	BONE SEMAR	5	-0.013	0.030
LD	TTISSUE	5	-0.014	0.038
LD	TISSUE SEMAR	5	-0.039	0.037
LD	BONE	5	0.020	0.032
LD	BONE SEMAR	5	0.005	0.033
All groups		40	-0.012	0.041

Results summarized by protocol, filter and corrector. Mean difference in millimetre (mm) and standard deviation (SD).

Table 3 : Mean error between two series (Series 1 – Series 2)

Protocol	Filter and Corrector	N for each series	Mean difference (mm)	SD
HD	TISSUE	8	-0.004	0.018
HD	TISSUE SEMAR	8	0.001	0.018
HD	BONE	8	0	0.023
HD	BONE SEMAR	8	-0.009	0.023
LD	TTISSUE	8	0.002	0.014
LD	TISSUE SEMAR	8	0.009	0.020
LD	BONE	8	0.003	0.018
LD	BONE SEMAR	8	0.011	0.023
All groups		64	0.002	0.020

Results summarized by protocol, filter and corrector. Mean difference in millimetre (mm) and standard deviation (SD).

Table 4 : Results reported by previous studies about femoral head penetration measurement with bias, accuracy and repeatability.

Studies	Bias	Accuracy (mm)	Repeatability (mm)
Olivecrona *et al*.2005 *(26)*	-0.07	0.6 - 1.04	0.53 - 1
Jedenmalm *et al*. 2008 (18)	-0.15	0.55	0.4
Vandenbussche *et al*. 2010 (23)	0.08 **		
Jedenmalm *et al*. 2011 (19)	-0.12	0.51	0.39
Goldvasser *et al*. 2014 (27)	-0.09	0.17 **	-0.15 à -0.02 **
Maguire *et al*. 2014 (22)	+/- 0.1		0.077
Boettner *et al*. 2016 (21)	0.08	0.13 à 0.16	0.18 à 0.22
Boettner *et al*. 2016 (20)		0.11	0.13
Current study	-0.01	0.03	0.03

All these studies except (**) marked calculate precision according to the Ranstam et al. recommendations (24).

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Abstract

Background

In cases of hip prothesis, acetabular cup wear remains a clinical challenge and current methods are associated with relative accuracy and weak reproducibility. In this study, we evaluated 3DSlicer open-source software providing image segmentation and CT-scan femoral head penetration (FHP) measurements. All 3DSlicer functions were executed in command line to avoid human interaction.

Methods

To simulate in-vitro FHP, polyethylene cups were modified to obtain given wear. Cups were then placed in a pelvic phantom and images acquired with a high and low dose protocol. Cup thicknesses measured by CT were compared to real values using Bland Altman method. Accuracy, repeatability, and bias of the CT method according to ISO definitions were calculated with the 95% confidence level. Kruskal-Wallis and pairwise Wilcoxon test were performed to compare the effects of the acquisition protocol, the reconstruction filter and the artefact corrector on accuracy. A p value under 0.05 was considered as significative or adjusted according to Bonferroni for multiple tests.

Results

The systematic error of the 3D fully automated method was -0.012 mm (CI 95% 0.013), the repeatability coefficient and the accuracy were 0.038 mm and 0.027 mm respectively. All measurement errors for all combinations of protocols, filters and corrector lied within the agreement limit under +/- 0.1 mm set as clinical acceptance threshold. The average time for analysis was 15 seconds (13,78 – 17,04). No difference on accuracy was found between routine low dose (3 – 3,4 mSv) and high-resolution (4,8 – 5,5 mSv) protocol ($p = 0.36$). TISSUE filter group was sensitive to artefacts with 4 outliers.

Conclusion

This approach is highly clinically applicable in routine use with a single CT method that requires only 15 seconds. The possibility of monitoring wear rate regardless of acquisition protocol and high accuracy level about 0.03 mm should be of interest in further in-vivo prospective studies.

Keywords

Hip arthroplasty, CT scan, Femoral head penetration, Polyethylene wear, Implant follow-up