Accuracy and Repeatability of CT-Scan Evaluating the Polyethylene Wear in Hip Arthroplasty

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ABSTRACT

Background: Polyethylene wear in hip arthroplasty is an early indicator of potential implant failure, with the wear rate directly associated with the probability of requiring a revision surgery highlighting the vital need for precise patient follow-up method. In our study, we assessed the accuracy and repeatability of CT scans in measuring polyethylene wear. Our goal was to validate the effectiveness of a newly developed custom software designed to automate and improve precision.

Materials and Methods: We conducted a comparative analysis between modified implants intentionally subjected to wear by the manufacturer and the estimates generated by the software method. To evaluate repeatability, each implant underwent two CT scans using various combinations of irradiation dose protocols, bone or tissue filter reconstructions, and metallic artifacts correction techniques.

Results: The accuracy and the repeatability coefficient were 0.03 mm and 0.04 mm respectively. All measurement differences for all combinations of protocols, filters and correctors lied within the agreement limit under 0.1 mm set as clinical acceptance threshold. The average time for analysis was 15 seconds per scan. No difference on accuracy was found between routine low dose and high dose protocol according to Kruskal-Wallis test.

Conclusion: This approach is highly clinically applicable in routine use with a single CT method. This tool offers simplicity, inter-rater reliability, high reproducibility, and is aptly useful for monitoring wear rate regardless of acquisition protocol and high accuracy level.

Keywords: Hip Arthroplasty, CT Scan, Femoral Head Penetration, Polyethylene Wear

Cite this article: *DUTREY T et al.*, Accuracy and Repeatability of CT-Scan Evaluating the Polyethylene Wear in Hip Arthroplasty. *Front Med Case Rep* 2023; 4(5): 1-10.

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Introduction

Polyethylene wear is an early indicator of the potential for implant failure in hip arthroplasty, with its rate of wear directly linked to the risk of requiring a revision procedure (Sochart, 1999). A significant rise in the demand for primary hip replacements is anticipated (Erivan *et al.*, 2019), particularly due to aseptic loosening, osteolysis, and wear that collectively contribute to a substantial 53% of all cases requiring revision (Delaunay and Hamadouche, 2012). If the wear rate stays below 0.1 mm per year, there are seldom indications of osteolysis, and the prosthetic implant demonstrates a remarkable survival rate of over 90% even after 25 years. However, when the wear rate escalates to 0.2 mm per year, the survival rate sharply declines, falling to less than 30% after 20 years and virtually disappearing by the 25-year mark (Dumbleton *et al.*, 2002; Sochart, 1999). This underscores the vital need for meticulous and precise patient follow-up method.

Currently, all measurement methods used the penetration of the femoral head into the acetabulum (FHP) to monitor the polyethylene wear *in vivo* (Grillini and Affatato, 2013; Mccalden *et al.*, 2005). This assessment is based on the premise that the displacement of the femoral head within the acetabulum is a consequence of the loss of polyethylene material. Two-dimensional radiographic techniques can determine *in vivo* cup centers but struggle to assess anteroposterior wear with a limited reproducibility attributed to the suboptimal quality of the lateral angle images (Grillini and Affatato, 2013; Mccalden *et al.*, 2005). In an effort to overcome these challenges, the computerization of X-ray equipment and the utilization of contour detection software tools have been employed to assist clinicians (Devane *et al.*, 1995; Hardinge *et al.*, 1991; Ilchmann *et al.*, 1995; Martell *et al.*, 2003), however, these methods are associated with a time-consuming process, often requiring at least 15 minutes per image. A recent study highlighted the impressive precision of the radiostereometry analysis (RSA) technique considered as the gold standard to monitor the FHP (Callary *et al.*, 2017). However, RSA does come with a set of drawbacks: it involves the insertion of tantalum (Ta73) beads into the patient's bone which renders it an invasive and impractical method for routine application, or stay universally inaccessible, requiring trained technicians and specialized laboratory equipment.

Consequently, CT scans have gradually supplanted RSA. Variations in patient positioning and errors related to acetabulum orientation can be rectified through image transformation within a 3D coordinate system (Olivecrona *et al.*, 2004; The *et al.*, 2006). The incorporation of the 3D rendering feature empowers users to directly position visual markers on the three-dimensional surface of the implant and extract a collection of points along its periphery. This method substantially improves the precision of contour

detection, although it should be noted that the process may take several minutes per scan up to 20 (Jedenmalm *et al.*, 2008, 2011).

Subsequently, this study assessed the precision and accuracy of CT scans using a custom-made software which facilitates the segmentation of prosthesis images from 3D CT datasets without requiring anatomical references or prior knowledge of the implant's shape.

Materials and Methods

The software-based method was used to estimate the FHP with different polyethylene inserts on a total of 128 scanners, and this estimation was then compared to the given wear produced directly by the manufacturer.

We used a set of 8 implants with 3 new and 5 modified ultra-high molecular weight (UHMWPE) polyethylenes. For modified inserts, the polyethylene thickness was reduced to simulate wear by increasing the inner diameter from 1 to 5 mm with a precision tolerance of 0.01 mm (Fig. 1). All inserts were placed in a water-filled pelvic phantom with an acetabular cup size 51 and a cementless stem. A compression system simulated patient loading. To calibrate the prosthesis, we determined the mechanical clearance by measuring the initial FHP of the three non-modified implants and then subtracted it from the FHP of the modified ones.
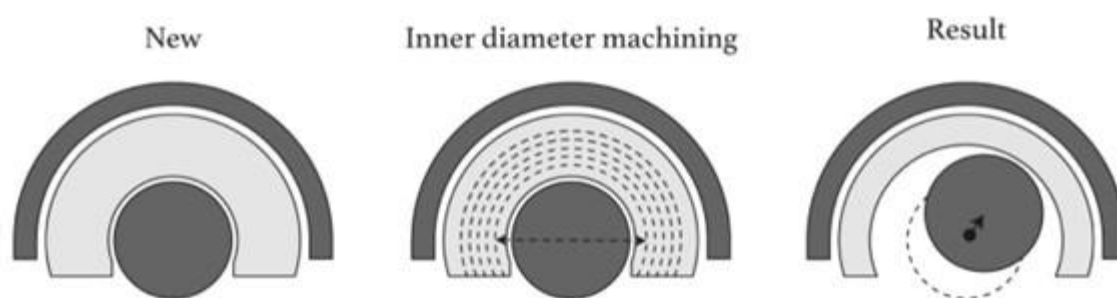
Figure 1: Drawing showing how to reduce polyethylene thickness machining the inner diameter to simulate femoral head penetration into the cup.

Acquisitions

Each insert in the pelvic phantom underwent two CT scans within a short time interval of 5 minutes to ensure repeatability examinations. Each scan involved two successive acquisitions: the first with a lower

radiation dose (LD) proposed by the manufacturer and the second with the high radiation dose (HD) to enhance spatial resolution. Delivered doses given by the device were recorded. From each acquisition, multiple image reconstructions were generated using combinations of filters (bone or tissue) and a metallic artifact corrector (Semar).

Software

We created a custom application titled "Tomography Automatic Analysis System" (TOMAAS), which operates as an extension of the open source 3DSlicer software (Fedorov *et al.*, 2012). This application comprises several components, with the first being an image segmentation solution using Hounsfield unit scale from DICOM data, and the second calculating the femoral head penetration as the distance between the cup and the head centers (Fig. 2). In this study we executed the application with a computer MacBook Pro 2018.
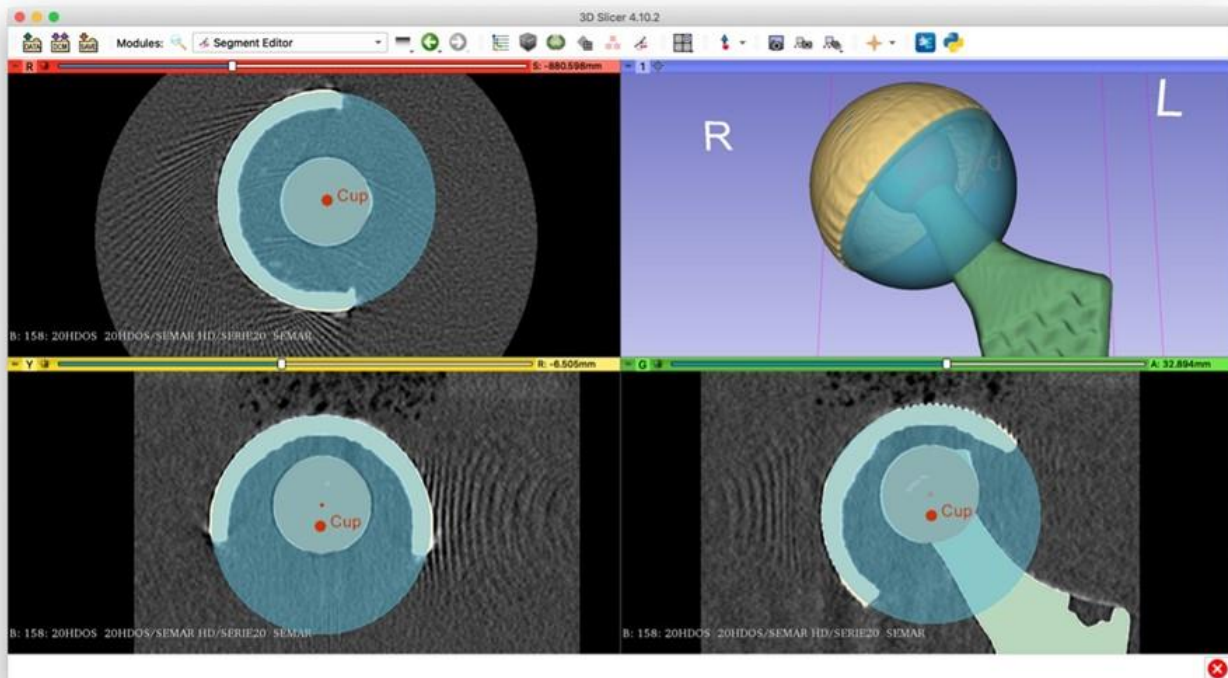
Figure 2: Visual supervision of the estimated centers of rotation and penetration of the femoral head.

Comparison Between Measured and True Wear

The software method was considered as an instrument with both systematic and random errors and the modified polyethylene wear as the reference wear. Accuracy and repeatability were assessed based on ISO definitions (ISO 3534-2:2006). Accuracy was determined as the closeness of agreement between

the software result and the reference value of each modified polyethylene, evaluated by the Pearson correlation coefficient and the Bland Altman method. Repeatability was assessed by evaluating the agreement among repeated measures obtained from the measurement process. The accuracy and the repeatability coefficient were calculated according to Ranstam, *et al.* (2000).

Statistical Evaluation of Errors

Normal distribution was assessed using the Shapiro-Wilk normality test. Quantitative variables were expressed as means with standard deviation (SD) or 95% confidence interval (IC 95). To assess the accuracy and repeatability, the Standard Error of measurement (SEM) was calculated as the mean difference between these measurements and the true value with a 95% confidence interval. 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. All statistics were performed with RStudio v1.2.5042 and R v4.0.0 package.

Results

Accuracy and Repeatability

A very strong correlation of 0.99 ($p < 2-16$) was found using the Pearson correlation method between the software estimation and the true wear, with differences distributed normally according to a Shapiro-Wilk test ($p = 0.106$).

The Bland Altman Plot was used to assess the bias as the mean difference of -0.012 mm (IC95% +/- 0.013) between the two methods with the agreement limits ranging from -0.093 (bias – 1.96 SD) to 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 (Fig. 3).

The accuracy coefficient was 0.027 mm assuming there is no bias according to Ranstam *et al.* (Ranstam *et al.*, 2000), and the repeatability coefficient was calculated as 0.038 mm with differences distributed normally according to a Shapiro-Wilk test ($p = 0.631$).
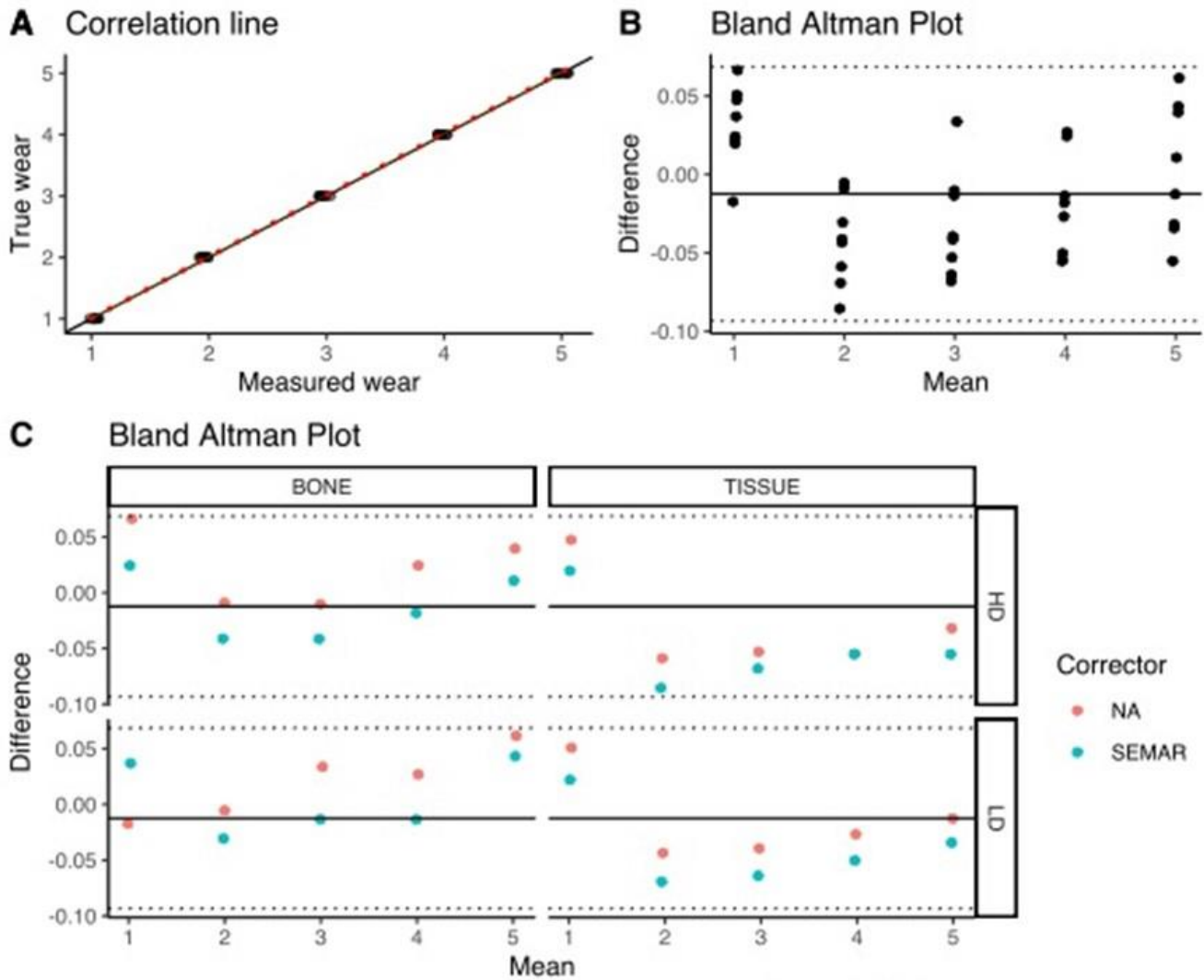
Figure 3: Accuracy of the software measurement method.

Differences Between Groups

No difference was found between HD and LD protocol according to Kruskal-Wallis test (p = 0.36) and boxplot but a difference was statistically significant between FILTER groups (p = 0.001). Pairwise Wilcoxon test between groups showed that only the difference between BONE and TISSUE-SEMAR group was significant (adjusted p = 0.004). We also identified 4 outliers in TISSUE group with overestimation due to significant artefact presence causing implant shape distortion (Fig. 4).

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 that is estimated to a hip region delivered dose of 3,2 mSv (SD 0,1) for LD and 5,2 mSv (SD 0,2) for HD protocol.

The average time required for measurements including image segmentation and femoral head penetration measurement is 15.1 (SD 0.57) seconds.
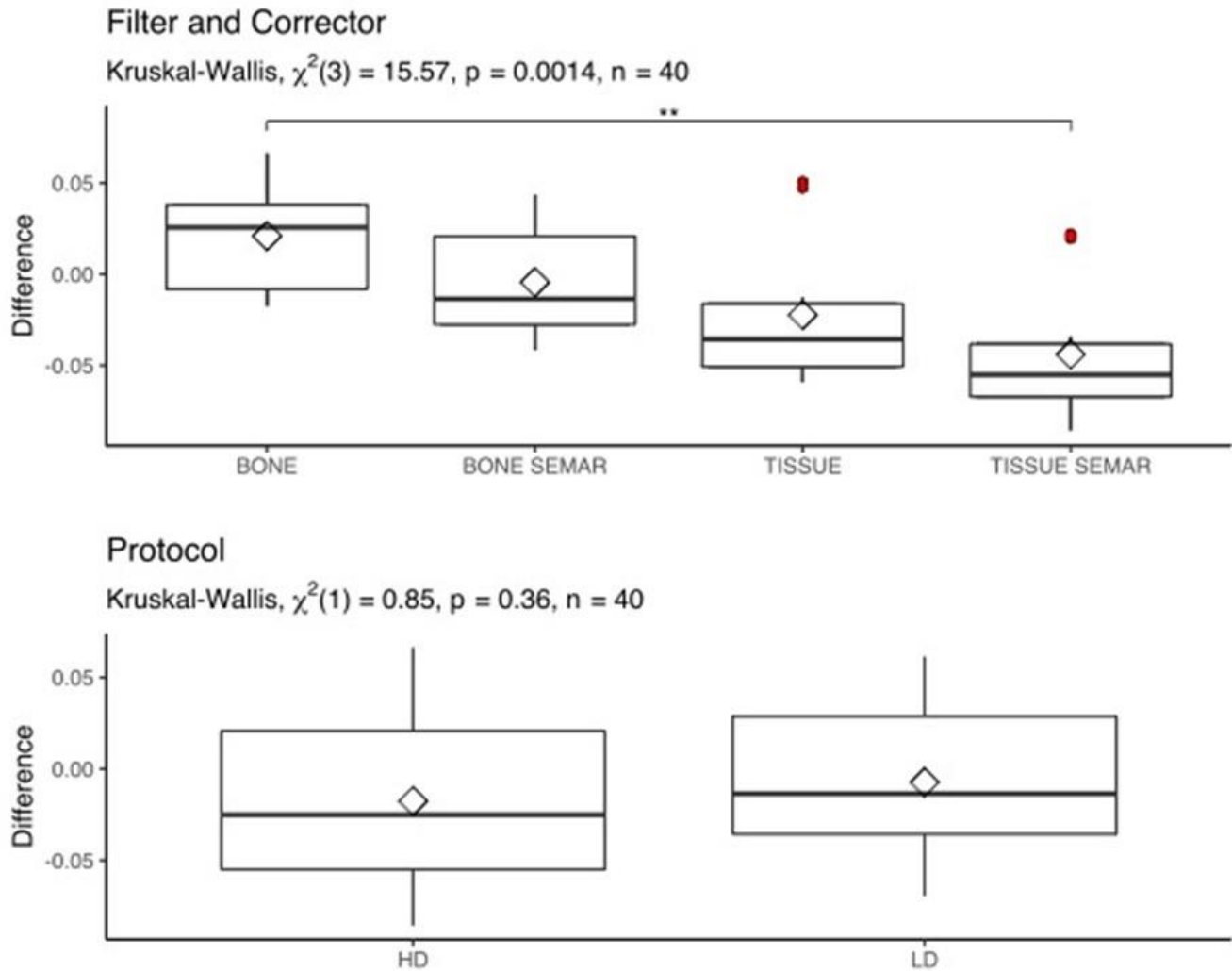
Figure 4: Influence of the filter, corrector and protocol on accuracy.

Discussion

CT imaging plays an essential role in a comprehensive implant follow-up strategy, as highlighted by Roth, *et al*. (2012). This imaging technique serves a multifaceted purpose, including monitoring polyethylene wear and assisting in the detection of various conditions such as osteolysis, peri-prosthetic fractures, loosening, and migration, as exposed by Kitamura, *et al*. (2005).

Our approach offers highly precise and reliable measurements of polyethylene wear, consistently under the relevant threshold of 0.1 mm. This level of precision is particularly significant, considering the

typical polyethylene wear rates encountered in clinical practice and the associated risk of implant failure, as noted by Dumbleton, *et al.* (2002).

Recent investigations into radiation doses reveal that low-dose protocols can achieve imaging quality and accuracy comparable to RSA, even as low as 0.70 mSv (Eriksson *et al.*, 2019). This suggests that the use of the scanner is no longer a limiting factor, considering low-dose protocols yielding acceptable accuracy and image quality, as corroborated by previous research (Boettner *et al.*, 2016; Brodén *et al.*, 2020; Eriksson *et al.*, 2019).

Importantly, no substantial differences were observed between high-dose and low-dose protocols in our study, combined with the precision offered by our software, this robustly endorses the recommendation for clinical use of the low-dose protocol, in harmony with previous research on CT and dose protocols (Brodén *et al.*, 2020; Eriksson *et al.*, 2019).

In addition, our method minimizes the need for human intervention, saving valuable time and providing a solution to the image processing difficulties encountered in previous research studies (Boettner *et al.*, 2016). We also anticipate potential applications of our method, with an integration into CT scan hardware during image reconstruction or operated in the background on the Picture Archiving and Communication System (PACS), generating a diagnostic report when implants are detected.

However, it's also essential to acknowledge the challenges that may arise, particularly in the presence of unexpected anomalies in the images, a phenomenon observed in earlier studies (Goldvasser *et al.*, 2014; Jedenmalm *et al.*, 2008, 2011). These anomalies introduce complexities that necessitate careful consideration. To prevent these findings, we ensured a visual supervision of the implant positioning and femoral head penetration.

Finally, our method has the potential to identify the initial stages of implant wear during regular patient follow-up, preempting the onset of osteolysis and the subsequent risk of complete implant loosening. This proactive strategy empowers the surgeon to recommend early therapeutic interventions, thereby preventing the progression to complete implant loosening.

Conclusion

Our study demonstrated that a single CT method can achieve a level of accuracy and repeatability that is highly relevant for assessing wear rates, which can lead to osteolysis earlier than previous methods.

Consequently, the capability to track polyethylene wear with an accuracy of approximately 0.03 mm, regardless of the acquisition protocol, should be of considerable interest for future in-vivo studies.

Credit Author Statement

Thomas DUTREY: conceptualization, investigation, formal analysis, methodology, writing – Original draft, Writing – Review & editing.

Eloi VIGNON: supervision, validation, investigation, methodology, Writing – Review & editing.

All authors reviewed and edited the manuscript and approved the final version of the manuscript.

Conflicting Interests: The authors declare no potential conflicts of interest with respect to the research, authorship, and/or publication of this article.

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