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Can version of the proximal femur be used for CT planning uncemented femoral stems?

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Highlights

- PFV is highly variable, when using an uncemented, single-wedge, straight femoral stem.
- Native version of the proximal femur (NFV) is not a useable guide for planning the achieved version of an uncemented straight-tapered femoral stem (PFV).
- Further work should focus on using the internal bony anatomy and the influence of stem design when planning uncemented femoral stems.

Abstract

Three-Dimensional Computed Tomography (3D-CT) planning can predict the prosthetic femoral size in uncemented primary Total Hip Arthroplasty (THA). Correct sizing usually results in optimal varus/valgus femoral alignment; however, its effect on the Prosthetic Femoral Version (PFV) is poorly understood. Most 3D-CT planning systems use Native Femoral Version (NFV) to plan PFV. We aimed to assess the relationship between PFV and NFV in primary uncemented THA using 3D-CT analysis. Pre- and post-operative CT data were retrospectively collected from 73 patients (81 hips) undergoing primary uncemented THA with a straight-tapered stem. 3D-CT models were used to measure PFV and NFV. The clinical outcomes were evaluated. The discrepancy between PFV and NFV was low (<5°) in 43%, moderate (5-10°) in 40%, high (10-15°) in 11% and very high (>15°) in 6% of the cases. We found that NFV is not a useable guide for planning PFV. The 95% limits of agreement were both high at 17° and 15°, respectively. Satisfactory clinical outcomes were recorded. The discrepancy was large enough to recommend against the use of NFV for planning PFV when using straight-tapered uncemented stems. Further work should focus on the internal bony anatomy and the influence of stem design when planning uncemented femoral stems.

Keywords: Total Hip Arthroplasty, 3D-CT Planning, Prosthetic Femoral Version, Uncemented Fixation

1. Introduction

Achieving adequate Prosthetic Femoral Version (PFV) is critical for the biomechanical stability of a Total Hip Arthroplasty (THA) [1,2]. A low PFV is associated with an increased dislocation rate via the posterior approach [3,4], elevated torsional moments [5], and posterior head migration [2]. Previous studies have highlighted that delivering a PFV of less than 10° is detrimental to the rotational stability of the reconstructed hip joint [1]. In addition, impingement is common in uncemented femoral stems with a PFV of less than 5° [6].

Native Femoral Version (NFV) is commonly used to plan PFV [7–11]. The rationale is based on the fact that uncemented femoral stems, designed for a tight press-fit into the bone, tend to follow the shape of the internal femoral canal, implying that this position restores NFV [8].

Adults with normal hip anatomy have an NFV that ranges from -15° to 34° [12]. PFV follows a similar spread, ranging from -23° to 39° [10,11,13,14]. In this regard, following merely NFV may lead to suboptimal PFV and post-operative complications [7]. Furthermore, there is limited intra-operative control of the PFV, which is dictated by the internal morphology of the proximal femur, for conventional uncemented straight-tapered femoral stems [15,16].

Previous studies using robotic tools or Two-Dimensional (2D) imaging techniques have highlighted an important difference between PFV and NFV in primary THA using conventional femoral stem designs [7,17]. Different methods have been used to measure version angles, but Three-Dimensional Computed Tomography (3D-CT)-based measurements have been reported as the virtual equivalent to the reference standard (dry bone measurement) [18–20].

We aimed to assess, using 3D-CT image analysis techniques, if NFV is useful for planning and delivering PFV in primary uncemented THA in a series of 81 cases. Our primary objective was to quantify the difference between PFV and NFV. Our secondary objective was to evaluate the clinical outcomes, including the dislocation rate. Our hypothesis was that PFV was not similar to NFV.

2. Materials and Methods

2.1 Study design

This study was a retrospective case series of 73 patients (81 hips) undergoing primary uncemented THA between February 2017 and May 2021. Pre- and post-operative CT scans of the patients were used to perform 3D-CT analysis of PFV and NFV (Figure 1). The inclusion criteria were: Osteoarthritis (OA) of the hip and no prior surgery. Demographics included 49% female gender, 52% a right-operated side, and a median (Range) age of 62 (32-86) years (Table 1).

2.2 Pre-operative imaging and surgical planning

All patients had pre-operative low-dose CT scans optimised for surgical planning. The implant manufacturer produced a pre-operative plan using proprietary software (MyHip Planner, Medacta International SA, Castel San Pietro, Switzerland) to define the optimal size, position and orientation of the femoral prosthesis, according to the surgeon's preferences.

In detail, the femoral component size was selected to plan the optimal fit-fill in the femoral canal and Femoral Offsets (FO) [21], including the head's neck length. During 3D-CT planning, the patient's NFV was measured, but the surgical target was a PFV of 20°. In addition, the plan was to restore the native horizontal and vertical FO and leg length with reference to the contralateral side. Regarding the acetabular component, the plan aimed for an inclination of 40° and an anteversion of 20°. With regard to the level of the femoral neck osteotomy, the aim was to restore the leg length. The femoral neck osteotomy plane was defined as a plane inclined 45° to the long axis of the proximal femur.

2.3 Surgical approach, implants and Patient-Specific Instrumentation (PSI)

The surgery was performed through a posterior approach by a single consultant orthopaedic surgeon who specialises in hip arthroplasty and has done more than 1000 primary and revision hip arthroplasties. An uncemented straight, single-wedged, tapered stem (Quadra-H System; Medacta International SA, Castel San Pietro, Switzerland) was used. On the acetabular side, a hemispheric press-fit Hydroxyapatite (HA) coated cup (Mpact System; Medacta International SA, Castel San Pietro, Switzerland) was used.

Intra-operatively a Patient-Specific (PS) femoral neck osteotomy guide was used to perform the osteotomy. The guide was 3D-printed to fit the contours of the femoral head-neck junction. The sterilised PS cutting jig was positioned on the femoral head-neck junction and two pins secured its position. The surgeon then performed the osteotomy with an oscillating saw blade flush on the surface of the guide.

The canal was opened using a starter reamer and femoral stem rasps, with sequentially increasing sizes, so that the etched stem marker was level with the cut surface of the femur, and the rasp was secure when tested by twisting. The stem was then press-fitted and tested by twisting the implant within the femur and confirming that this did not cause movement between the stem and the bone.

2.4 Post-operative imaging

The post-operative CT scans were low-dose and had a slice thickness of 0.75 mm and a spatial resolution of 0.6 mm. These scans were corrected for metal artefacts; a Normalised Metal-Artefact Reduction (NMAR) algorithm was implemented, using the post-operative CT scans, to eliminate the metal artefact and generate the 3D models of the femurs and the prosthetic components [10,22].

2.5 3D-CT assessment of NFV and PFV

A comparison between NFV and PFV was carried out using Simpleware ScanIP software (Version 2021.03; Synopsys, Inc., Mountain View, USA). NFV and PFV were measured based on the pre- and post-operative 3D-CT reconstructed models, respectively. In this comparison, the discrepancy between PFV and NFV was quantified.

The NFV is defined as the angle between the femoral neck axis and the posterior condylar axis, measured on the transverse plane of the femoral coordinate system [23]. The femoral neck axis is assumed to pass through the centre of the most distal cross-section of the femoral neck (Point A) and the centre of the femoral head [20]. Therefore, the NFV was defined from bony landmarks on the external surface of the femur (Figure 1).

The PFV is defined as the angle between the axis of the reconstructed femoral neck and the posterior condylar axis, projected on a plane perpendicular to the mechanical axis of the reconstructed femur [13]. We computed the axis of the reconstructed femoral neck as the line connecting the centre of the reconstructed femoral head with a clearly defined landmark at the top of the femoral stem [10] (Figure 1).

The post-operative cup version was measured in the Anterior Pelvic Plane (APP) [24]; a radiographic definition was used [25]. The cup plane was defined as the best-fitted plane based on 10 points taken on the cup rim. A Combined Version (CV) between 25° and 50° was considered as the optimal range [16].

2.6 Repeatability and reproducibility analysis of the CT measurement method

We measured the repeatability and reproducibility of our CT measurement method using intra- and inter-observer analyses, respectively. For the intra-observer analysis, the same user measured PFV twice for 30 randomly selected cases, while for the inter-observer analysis, a second user ran the test twice for 20 randomly selected cases.

Measurements of PFV were also obtained using an independent, commercially available software (ZedHip, LEXI Co, Ltd, Tokyo, Japan).

2.7 Statistical analysis

The median, Interquartile Range (IQR), minimum and maximum values were estimated for the data of the whole population of cases. The normality of data was tested using the Kolmogorov-Smirnov test (n>50).

We compared the PFV and NFV for each case and used a Bland-Altman (BA) plot to show the discrepancy and measured the limits of agreement. A linear regression model was fit to the data to look for a linear relationship between PFV and NFV. The coefficient of determination (R^2) was used to indicate the level of correlation.

In addition, we compared the version angles (PFV and NFV) between the female and male groups using the unpaired Mann-Whitney test. The significance level was set at P = 0.05.

For the intra-observer variability, we quantified the mean and Standard Deviation (SD) of the difference between the two measurements performed by the same operator. For the inter-observer variability, we used the difference between the first measurement of the main observer and the only measurement of the second user. A one-way analysis of variance (ANOVA) was used to obtain the Intra-Class Correlation (ICC) for the intra- and inter-observer measurements.

3. Results

3.1 NFV and PFV measurements

For all patients, the median NFV (minimum; IQR; maximum) was 14° (-13°; 7 to 20°, 36°) and the median PFV (minimum; IQR; maximum) was 13° (-18°; 8 to 17°; 33°) (Figure 2). NFV was higher in the female group (median of 17° (IQR 11 to 24°)) than in the male group (median of 11° (IQR 4 to 17°)) (P = 0.009). There was no statistically significant difference between the PFV of the female (median of 14° (IQR 8 to 20°)) and male (median of 11° (IQR 6 to 16°)) groups (P = 0.25).

The median discrepancy between PFV and NFV (minimum; IQR; maximum) was -0.4° (-23°; -6 to 4°, 14°). The discrepancy between PFV and NFV was low (<5°) in 43% of patients, moderate (5-10°) in 40%, high (10-15°) in 11% and very high (>15°) in 6%. Compared to NFV, PFV was increased by 0-5° in 25% of patients, by 5-10° in 18.5%, by 10-15° in 6%, and by 15° or more in 0%. In comparison with NFV, PFV was decreased by 0-5° in 18.5% of patients, by 5-10° in 21%, by 10-15° in 5%, and by 15° or more in 6% (Figure 3).

A linear regression analysis showed a moderate positive correlation of R^2=0.36 (P<.001) between PFV and NFV, with 69% of the cases lying outside the confidence interval range (Figure 4). A BA plot of the discrepancy between PFV and NFV showed that the 95% limits of agreements (Mean ± 1.96 SD) were -17° and 15° respectively (Figure 5).

An NFV between 15° and 20° (optimal version according to Tönnis [26]) was reported in 23% of the patients. Twenty-three per cent (23%) of the patients had an NFV outside the range of 5 to 30° (optimal version ± 10°). One female patient (1%) had retroversion of their native femur (Figure 6).

Regarding the distribution of PFV in all patients, a PFV of between 15° and 20° (optimal version according to Tönnis [26]) was reported in 21% of the femoral stems. Twenty-one per cent (21%) of the femoral stems had a PFV outside the range of 5 to 30° (optimal version ± 10°). Five patients (6%) had retroverted PFV (Figure 6).

The median CV (minimum; IQR; maximum) was 37° (7°; 28 to 45°, 56°). A CV within the optimal range (25° to 50°) [16] was obtained for 69% of the femoral stems (Figure 7).

3.2 Repeatability and reproducibility analysis of the CT measurement method

We achieved excellent intra-observer repeatability and inter-observer reproducibility for the PFV measurements. In both analyses, the ICC was more than 0.99, while the mean (± SD) difference between the same and different raters was 0.01 ± 1° and -0.4 ± 2°, respectively. The mean (± SD) difference between the PFV measured by the external software (ZedHip, LEXI Co, Ltd, Tokyo, Japan) and our method was -1 ± 2°.

3.3 Clinical outcomes

The median (minimum; IQR; maximum) follow-up time for the entire cohort was 45 months (15; 37 to 54; 66). There were no unexpected intra-operative complications, such as a femoral fracture. None of the patients were lost to follow-up or deceased. At the most recent follow-up, none of the hips have been revised for any cause. Post-operative evaluation revealed adequate fixation with no loosening one year after the surgery. There were two dislocations, which were reported five weeks and one year post-operatively; these were successfully treated with one closed reduction procedure. There was no recurrence of the dislocation, and the OHS was 48/48 for both cases one year post-operatively.

4. Discussion

It has been widely proven that 3D-CT pre-operative planning is accurate in terms of component sizing [11,27–35]. Limited studies have documented its accuracy in terms of prosthetic component version, particularly for the femoral stem, which is under-investigated compared to the acetabular cup [10,11,29,30,36,37]. Evaluating the accuracy of 3D-CT planning of implant orientation is challenging; acquiring an adequate sample size of post-operative CT scans is not straightforward due to barriers such as the radiation dose and the complexity of the scanning protocols.

This was the first study to assess the relationship between the PFV (the achieved version of the femoral stem) and the NFV (the version of the bony femoral neck and head before the neck osteotomy is performed), using 3D-CT image analysis in 81 cases, to assess the real-world useability of NFV as a planning guide for uncemented THA. We found that NFV is not a useable guide for planning the achieved version of the femoral stem. The discrepancy between PFV and NFV was low (<5°) in only 43% of the cases, and the lower and upper 95% limits of agreement were both high at 17° and 15° respectively.

Previous studies have reported not only a high variability of PFV (-23° to 39°) [10,11,13,14] but also an important average difference between PFV and NFV (1.6° to 9.8°) [7,8,15,17]. These used different imaging modalities [8], measurement methods [17] and robotic or navigating tools [7,15] to assess the relationship between PFV and NFV. We measured both PFV and NFV based on models reconstructed from 3D-CT using a standard coordinate system that is not affected by the patient’s position within the scanner; this procedure is considered the virtual equivalent of the reference standard [20].

The difference between PFV and NFV in our study is comparable to previous studies using navigating tools; Marcovigi et al. (2018) reported a mean (SD) difference of 1.6° (9.8°), and Worlicek et al. (2016) reported a mean (SD) discrepancy of 1.9° (9.5°) [7,15].

This information is consistent with previous studies that found the PFV measurement between navigation tools and CT to be the same [16].

Contrastingly, our results highlight a difference with studies using other imaging modalities and 2D measurement methods. The median discrepancy between PFV and NFV (minimum; IQR; maximum) found in our study was -0.4° (-23°; -6 to 4°; 14°). Emerson et al. (2012), using a combination of fluoroscopic and 2D MRI-based methods, found a mean (SD) difference of 8.1° (7.4°), while Hirata et al. (2014), using a 2D CT-based measurement method, reported a mean difference of 9.8° [8,17].

In our study, there was a correlation between PFV and NFV, but this was only moderate (R^2=0.36). Our findings did not indicate a strong correlation that would suggest the potential clinical use of NFV for CT planning. Similar results were reported by previous studies that included robotic instrumentation or an imageless navigation device; Marcovigi et al. (2018) have reported a moderate correlation of 0.48 (P<.001), Worlicek et al. (2016) have reported a Spearman's correlation coefficient of 0.39 (P<.003) and Park et al. (2015) have reported a correlation of 0.61 (P=0.005) [7,15,20].

Currently, commercially available software cannot predict the final version of a conventional uncemented femoral stem. The patient's NFV may constitute the only available pre-operative variable related to the PFV, potentially explaining its common use as a guide to planning PFV. The measurement of either an excessive or retroverted NFV pre-operatively can raise concerns about delivering a suboptimal PFV, and surgeons may consider alternative designs or approaches to achieve a more optimal PFV. In this regard, matching or optimising PFV based on NFV may be helpful.

However, NFV, as currently measured, is not representative of the complex femoral internal shape. Commonly used pre-operative femoral variables characterise the external femoral shape, which is the part of the femur that is removed during neck osteotomy. During implantation, conventional femoral stem designs tend to follow the metaphyseal twist of the internal femoral morphology to eventually acquire the so-called “best-fit” position [7,15,38]. There is a need to study the relationship between the internal morphology of the proximal femur and PFV.

In this regard, the final position of the femoral stem may be dictated by the level of the femoral neck osteotomy since this constitutes the entry point of the femoral stem into the intramedullary canal. Consequently, the resection height may cause a PFV significantly varying from the patient’s NFV. In this study, the osteotomy level was defined using a PS cutting guide, which has been proven to deliver the femoral neck osteotomy with high accuracy to the surgical plan [39]. Future research could examine whether the accuracy of this PS guide is related to the discrepancy between PFV and NFV.

Shorter metaphyseal femoral stems may be a targeted approach to reconstructing the natural twist of the proximal femur by loading the metaphyseal calcar region, which is the entry point during implantation. A recent cadaveric study comparing PFV in calcar-guided and conventional femoral components reported a mean (SD) difference (NFV-PFV) of 1.8° (3.2°) and 10.3° (5.8°), respectively [40].

Additionally, surgeons should consider femoral components that allow sufficient intra-operative adjustability of PFV to achieve the target. Femoral stems featuring modular necks have been proposed to effectively restore hip biomechanics [41]. However, these components have been proven to perform poorly in material and design combinations [42,43]. In contrast, the malleable nature of the cement mantle in cemented fixation can offer greater control of the PFV [6,8,16], while the cemented femoral stem designs have reported excellent survivorship [44]. However, the intra-operative adjustability of the PFV using the cement mantle would be subjected to individual differences among surgeons in achieving the target position. Previous studies comparing PFV in uncemented and cemented THA have reported a significantly lower variability of PFV and a lower rate of retroversion in the cemented THA [45].

Based on the results of the current study, 79% of the femoral stems reported a PFV of 5-30° (optimal version ± 10° [26]). Intra-operative measurement of the final version of the broach, using either robotic tools or 3D-printed anteversion guides, may inform the surgeon about the final PFV. This information may be valuable in distinguishing the cases which significantly vary from the patient's NFV or the surgical target. The surgeon can then consider the above-mentioned approaches to deliver the intended PFV.

According to the findings of this study, 20% of the femoral stems reported a PFV of less than 5°. Given the importance of an adequate PFV to avoid dislocation or impingement [3,4,6], special consideration should be given when using an uncemented stem. For this reason, Dorr et al. (2009) [16] have emphasised the importance of delivering a CV between 25° and 50° to avoid dislocation in primary uncemented THA.

The present study confirms the high variability in NFV in patients with hip OA. Therefore, following NFV exclusively may lead to a suboptimal PFV, potentially impacting the clinical outcomes [7]. For this reason, NFV was measured pre-operatively, but the surgical target was a PFV of 20°. Independently of the surgical plan, however, the surgeon has limited control to change the PFV of a straight uncemented femoral stem that is dictated by the endosteal canal; the final PFV significantly varies from the NFV and the surgical target.

These findings highlight no relevance to using NFV as a guide for PFV and suggest the need to improve current planning approaches and target philosophies regarding the PFV in primary, uncemented THA. NFV only partly dictates the position of the femoral component. The final position of the "best-fit" stem (the PFV) is a consequence of fitting a straight stem down the canal of a twisted and bowed proximal femur, resulting in high variability of PFV. This understanding could equip surgeons with the knowledge that commercially available software cannot predict the PFV. Instead, they may consider intra-operative anteversion guides and cemented stems to deliver the intended PFV.

We acknowledge limitations. First, a single femoral stem design was adopted. Therefore, our findings might not be transferred to other stem designs. Second, all surgeries were performed through a posterior approach. Different surgical techniques may have an impact on the PFV. In addition, 3D-CT analysis may be influenced by factors contributing to errors in the outcome measures, such as the manual selection of anatomical landmarks, the scanning procedure and metal artefacts. We addressed this by utilising an established methodology and by performing repeatability and reproducibility analysis tests. Our method proved to be reliable as in both analyses the ICC was more than 0.99. Furthermore, the CT scans were corrected for metal artefacts to optimise the 3D-CT reconstruction. This step could have introduced subtle changes in generating the 3D models representing the prosthetic components. However, we measured the PFV based on clearly identifiable landmarks, and subtle changes would have a negligible effect on the outcomes' variability.

5. Conclusion

Planning and delivering PFV is challenging. The patient's NFV cannot be reliably used to predict the version of a straight, single-wedged, tapered, uncemented femoral stem, known as PFV. Surgeons should be aware of this and consider intra-operative anteversion guides and cemented stems to deliver the target version.

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Table 1: Characteristics of the study group

	Study Group (n=81 Hips)
Gender (Females) (%)	40 (49)
Age (Years) (Median, Range)	62 (32-86)
Treatment Side (Right) (%)	42 (52)
Component Size (Median, Range)	3 (0-9)

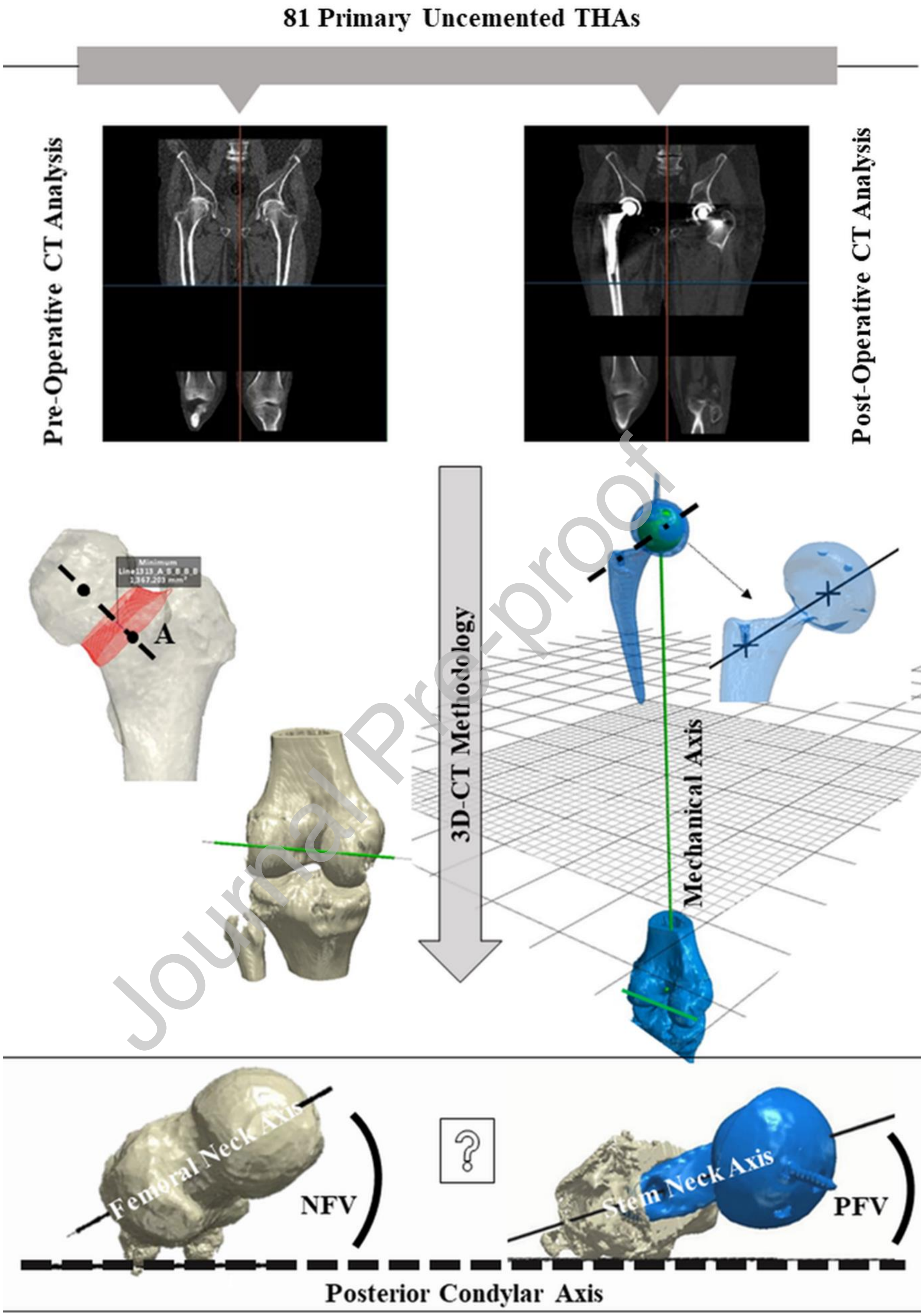

Figure 1: Flow Chart illustrating the study design and the methodology adopted to determine NFV and PFV. [colour]

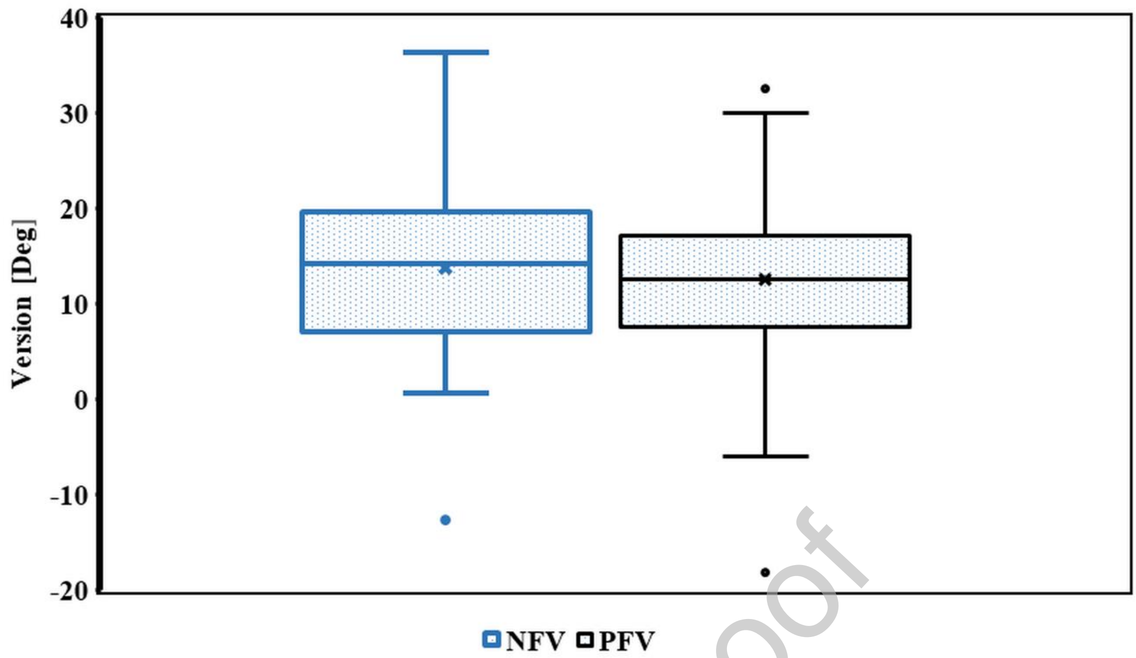

Figure 2: Box Plot illustrating NFV and PFV for all patients. [colour]

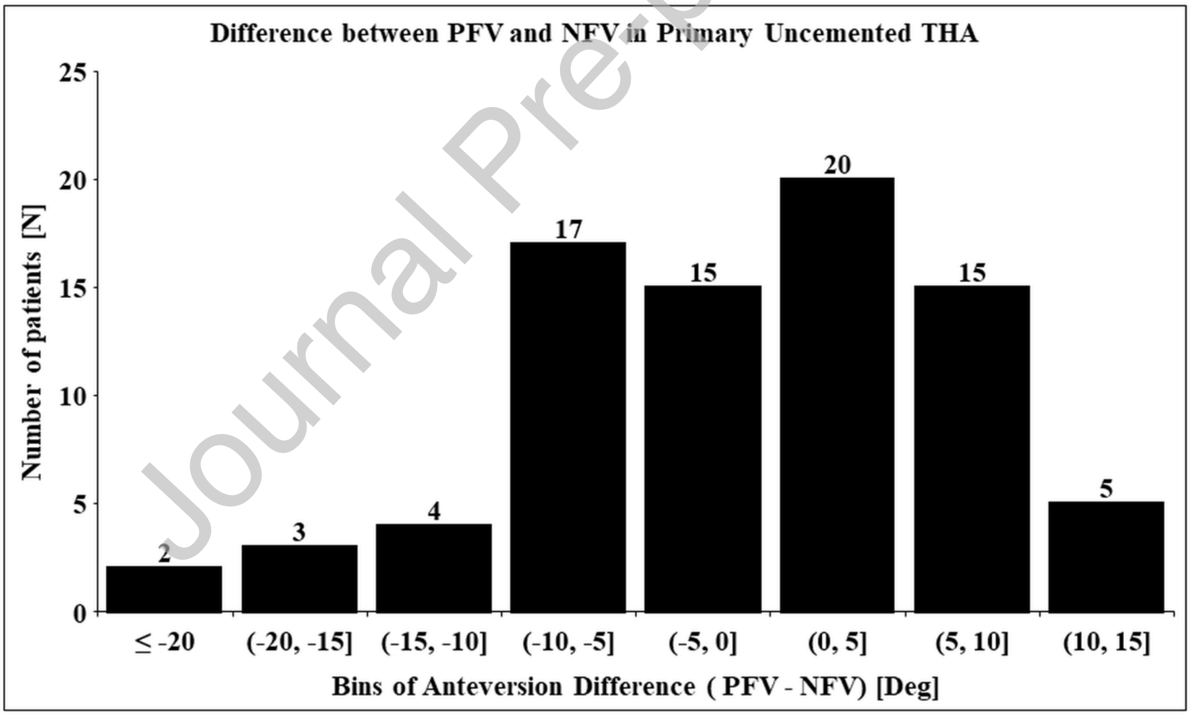

Figure 3: Histogram illustrating the frequency of the discrepancy between PFV and NFV.

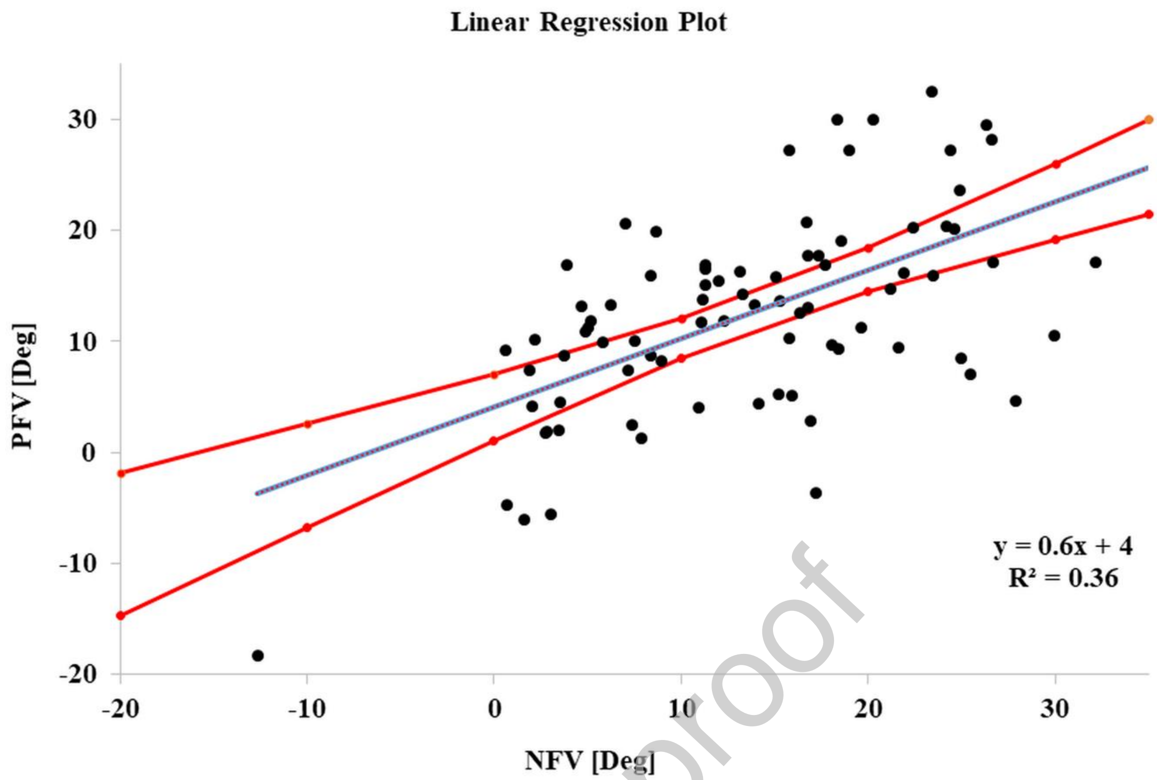

Figure 4: A linear regression analysis plot illustrating PFV as a function of NFV. A moderate positive correlation (R^2=0.36, P<.001) was found between PFV and NFV, with 69% of the cases lying outside the confidence interval range (Red lines). [colour]

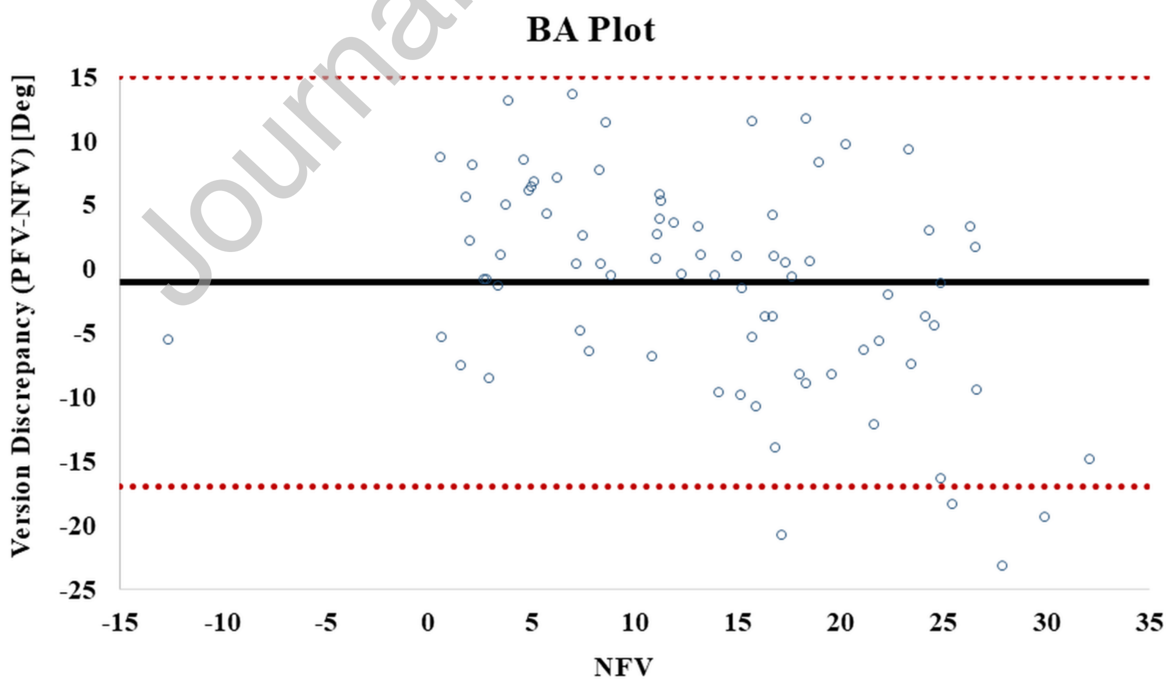

Figure 5: Bland-Altman plot of the comparison between PFV and NFV. [colour]

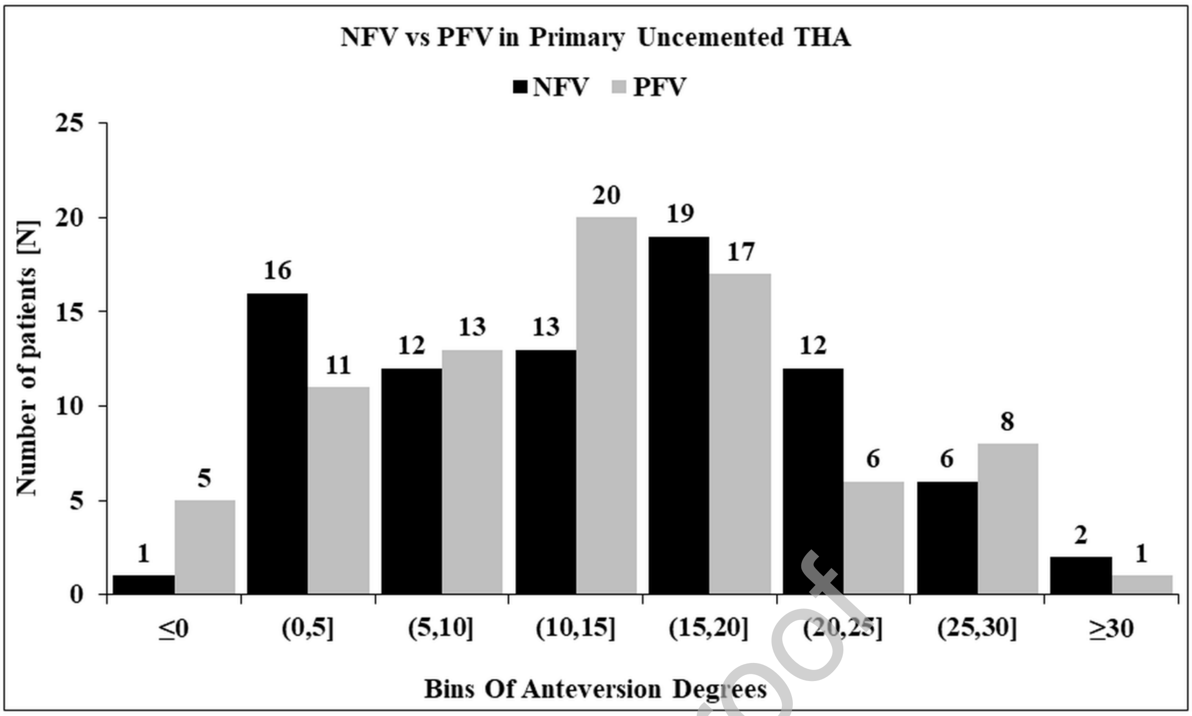

Figure 6: Histogram depicting the distribution of NFV and PFV in 81 patients.

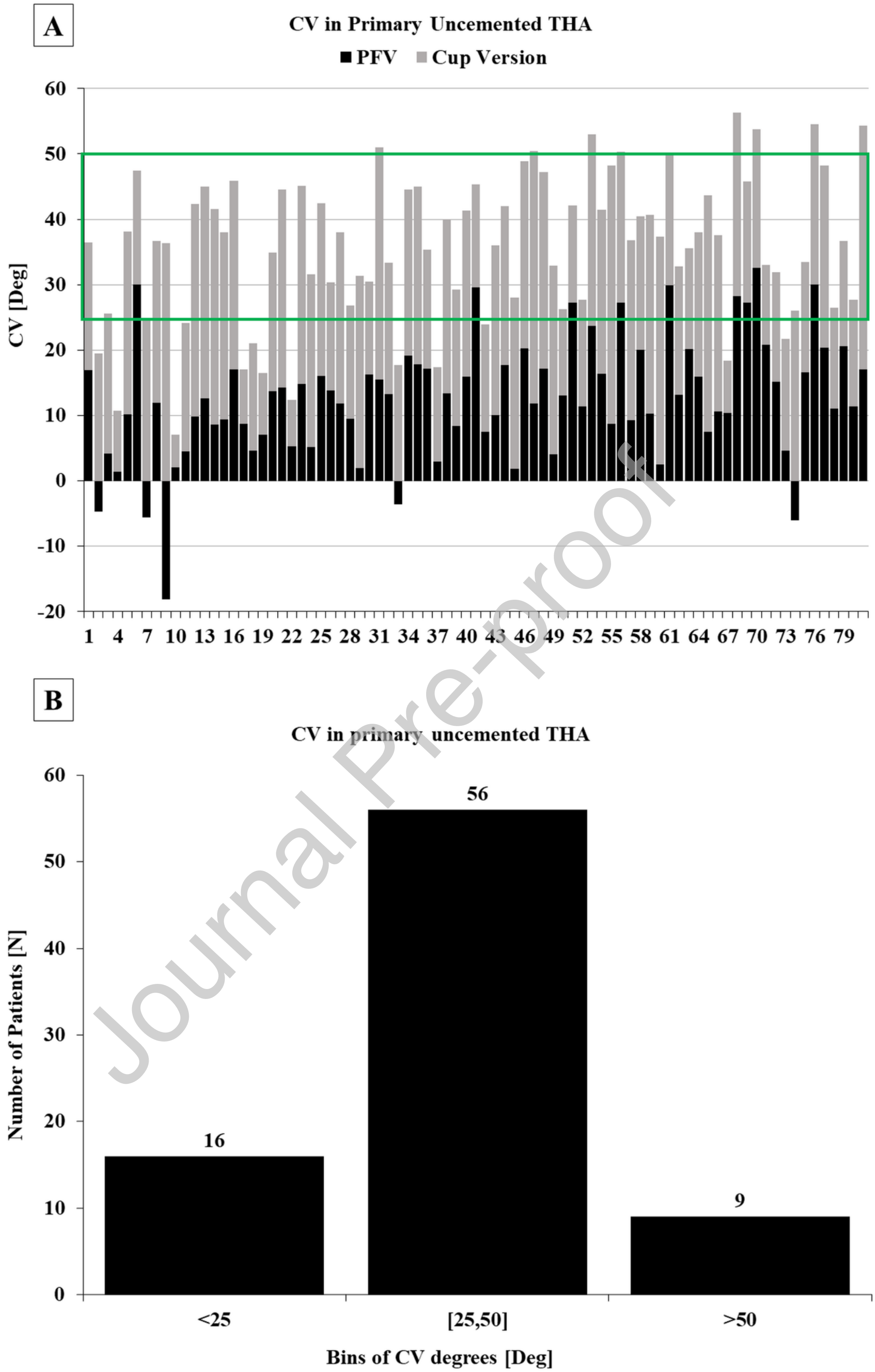

Figure 7: Bar graph illustrating CV (A) and its distribution (B) in 81 patients undergoing

primary uncemented THA.

Conflicts of Interest:

One author declares institutional funding not directly related to this work. The remaining authors declare no conflict of interest relevant to this work.

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Ethical Approval:

Institutional review board approval NHS RNOH R&D Service Evaluation (SE16.020-11/08/2016).

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Table 2: Characteristics of the study group

	Study Group (n=81 Hips)
Gender (Females) (%)	40 (49)
Age (Years) (Median, Range)	62 (32-86)
Treatment Side (Right) (%)	42 (52)
Component Size (Median, Range)	3 (0-9)

Journal: MEDICAL ENGINEERING & PHYSICS

Title of Paper: **Can version of the proximal femur be used for CT planning uncemented femoral stems?**

Declarations

The following additional information is required for submission. Please note that failure to respond to these questions/statements will mean your submission will be returned to you. If you have nothing to declare in any of these categories then this should be stated.

Conflict of interest
All authors must disclose any financial and personal relationships with other people or organisations that could inappropriately influence (bias) their work. Examples of potential conflicts of interest include employment, consultancies, stock ownership, honoraria, paid expert testimony, patent applications/registrations, and grants or other funding.

Ethical Approval

Work on human beings that is submitted to *Medical Engineering & Physics* should comply with the principles laid down in the Declaration of Helsinki; Recommendations guiding physicians in biomedical research involving human subjects. Adopted by the 18th World Medical Assembly, Helsinki, Finland, June 1964, amended by the 29th World Medical Assembly, Tokyo, Japan, October 1975, the 35th World Medical Assembly, Venice, Italy, October 1983, and the 41st World Medical Assembly, Hong Kong, September 1989. You should include information as to whether the work has been approved by the appropriate ethical committees related to the institution(s) in which it was performed and that subjects gave informed consent to the work.

Competing Interests

One author declares institutional funding not directly related to this work. The remaining authors declare no conflict of interest relevant to this work.

Please state any sources of funding for your research

This research received no external funding.

DOES YOUR STUDY INVOLVE HUMAN SUBJECTS? Please cross out whichever is not applicable.

Yes

~~**No**~~

If your study involves human subjects, you MUST have obtained ethical approval.

Please state whether Ethical Approval was given, by whom and the relevant Judgement's reference number

Institutional review board approval NHS RNOH R&D Service Evaluation (SE16.020-11/08/2016).

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