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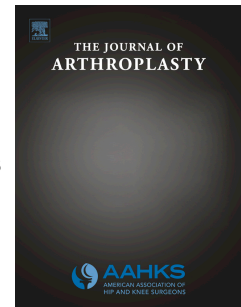
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# Accepted Manuscript

Evaluation of native femoral neck version and final stem version variability in patients with osteoarthritis undergoing robotically implanted THA

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## Evaluation of native femoral neck version and final stem version variability in patients with osteoarthritis undergoing robotically implanted THA

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# Evaluation of native femoral neck version and final stem version variability in patients with osteoarthritis undergoing robotically implanted THA

## *Abstract*

### **Background:**

Combined anteversion in Total Hip Arthroplasty influences both dislocation risk and range of motion.

One of its components, stem version, could be dictated by many factors, from native femoral anatomy to stem geometry and surgeon's choice.

In the current multicenter study, robotic technology was used to assess the influence of native femoral version on final stem version and combined anteversion using a straight uncemented stem.

### **Methods:**

Three hundred and sixty-two patients undergoing total hip arthroplasty were enrolled from 3 different orthopedic centers from 2012 and 2016.

All patients underwent CT planning with measurement of Femoral Neck Version (FNV) and intraoperative measurement of Stem Version (SV), Acetabular component Version (AV) and Combined Version (CV) with robotic instrumentation.

### **Results:**

Mean FNV was  $5.0^{\circ} \pm 9.6^{\circ}$ , SV was  $6.4^{\circ} \pm 9.7^{\circ}$ . The average difference between FNV and SV was  $1.6^{\circ} \pm 9.8^{\circ}$ . A moderate correlation was found between FNV and SV ( $R = 0.48$ ,  $p < 0.001$ ). SV was between  $5^{\circ}$  and  $20^{\circ}$  in 174 patients (48%).

Mean CV was  $28.2^{\circ} \pm 7.9^{\circ}$ . A strong correlation was found between SV and CV ( $R = 0.89$ ,  $p < 0.001$ ).

A significant difference in SV was found between the 3 centers ( $p < 0.001$ ).

CV was  $< 25^{\circ}$  in 109 patients (30.1%). Relative risk of CV  $< 25^{\circ}$  was 8.6 times greater with stem version  $< 5^{\circ}$  ( $p < 0.001$ ).

### **Conclusion:**

With the use of an uncemented single wedge straight stem, SV is highly variable. Despite being moderately correlated with native FNV, SV can be partially influenced by the surgeon. A low SV could be hardly corrected, bringing high risk of low CV.

### **Keywords:**

Anteversion; THA; Combined Version; Robotics; Stem; Total Hip Arthroplasty.

### **Introduction**

Component positioning in Total Hip Arthroplasty (THA) can have a major effect on both clinical outcome and complications rate. Traditionally the recommended positioning for femoral stem is to restore natural offset and anteversion, which can result in great variability of final component placement.[1,2] Various works have in fact shown mean values of native femoral neck version that may range from  $8.84^{\circ} \pm 9.66^{\circ}$  to  $28.1^{\circ} \pm 11.0^{\circ}$ . [3,4]

Following exclusively proximal femoral anatomy could lead to excessive stem anteversion or retroversion, and may result in acetabular impingement and possibly a higher risk of dislocation.

[5,6] In order to avoid such complications and improve the range of motion (ROM) Dorr et al.[7] emphasized the importance of achieving a combined anteversion (the sum of acetabular and stem version) between  $25^{\circ}$  and  $50^{\circ}$ .

Achieving this degree of combined version can be problematic when version choices are limited on the femoral side (related to proximal femoral anatomy). In the situation where the stem is placed in only slight anteversion, adjustments must be done in the acetabular side, creating a risk of cup uncoverage. [8] On the other hand, substantial changes in femoral neck version with stem implantation creates concurrent changes in anterior and lateral femoral offset, potentially resulting in decrements in abductor strength. [9]

The type and geometry of the femoral stem can also affect resultant femoral version. When implanting a straight cementless stem, the final stem anteversion might be influenced by the necessity of placing the component into a best fitting position within the femoral canal. [8]

Several studies reported final stem version in THA after the implantation of an uncemented femoral component. [10,11,12] Two of them also analyzed the relationship between native femoral neck version and stem version using preoperative and postoperative CT measurements. Hirata et al.[13] reported a mean difference of  $9.8^{\circ} \pm 8.8^{\circ}$  in anteversion with a final stem version ranging from  $14^{\circ}$  to  $63.2^{\circ}$ , while Emerson et al.[1] found similar results in the mean difference value with  $8.1^{\circ} \pm 7.4^{\circ}$  but with a final stem version of ranging from  $-11^{\circ}$  to  $22^{\circ}$ .

With the advent of robotically assisted THA, it is now possible to have a direct, real-time knowledge of stem version during surgery. [14] This knowledge enables the surgeon to make intraoperative adjustments to femoral stem version, acetabular component version or both to achieve desired component position goals.

The purpose of this multicenter, retrospective study was to assess the variability of preoperative femoral neck anteversion and final stem and cup version in patients undergoing THA performed with CT based robotic techniques. The hypothesis was that the majority of the implanted stems could be aligned to a physiological range of  $5^{\circ}$ - $20^{\circ}$  of anteversion, regardless of the native femoral anatomy and that an optimal combined version of  $25^{\circ}$ - $50^{\circ}$  could be reached in all patients. The secondary aim of the study was to assess eventual variability in component positioning among different surgeons.

## ***Materials and methods***

Three hundred and sixty-two patients undergoing total hip arthroplasty were enrolled from 3 different orthopedic centers in Italy from 2012 and 2016. Of the 362 patients, 229 came from Center 1, 56 from Center 2 (both located in Northern Italy) and 77 from Center 3 (located in Central Italy). In the considered cohort 173 patients were Females and 189 Males. Diagnoses of congenital hip dysplasia or congenital hip dislocation were considered as exclusion criteria. All patients had Italian citizenship and were characterized by Caucasian ethnicity.

All patients were affected by end-stage hip osteoarthritis and all patients underwent CT scanning as preoperative planning for MAKO Robotically-Assisted THA (Stryker Orthopedics, Kalamazoo, MI, USA).

In all cases THA was performed using a straight, single wedge, uncemented stem (MetaFix™ collarless stem, Corin Group PLC, Cirencester UK), a hemispheric, uncemented, coated cup (Trinity™ Cup, Corin Group PLC, Cirencester UK) and Mako Robotic instrumentation for the implantation of both femoral and acetabular components.

Interventions were performed by 3 different senior surgeons (1 surgeon for each center), a direct lateral approach was used in 259 patients, while a posterior-lateral approach was used in the remaining 103 patients (all 77 patients from center 3 and 16 patients from center 2).

Only CT scans that met the following qualifications were accepted: slices spacing 0.5-1 mm for the pelvis and 2.0-5.0 mm for the knee, kV120-140, mA 200-250.

CT scans were processed with the MAKO Stryker “Crisis” Software to obtain 3D bone models.

Standardized landmarks of proximal femur, distal femur and pelvis were identified by a single observer and then used to determine the Femoral Neck Axis (FNA), the Posterior Condylar Axis (PCA) and the Anterior Pelvic Plane (APP).

The preoperative Femoral Neck Version (FNV) was automatically calculated by the software as the angle formed by the projection of FNA and PCA on the Transverse Plane.

Screw fixation was used for the placement of the femoral and pelvic trackers and morphing acquisitions of the femur and acetabulum were performed to couple CT 3D models and patient's anatomy. The integrated optical guide navigation system was used to measure Stem Version during stem implantation, Cup Version was then intraoperatively planned to achieve a satisfactory

Combined Version and to avoid excessive anterior or posterior acetabular uncoverage with the use of CT based 3D models. Cup was finally implanted in the planned position with the use of Mako Semiautomatic robotic arm. Final Stem Version (SV), final Acetabular component Version (AV)

and final Combined Version (CV) were automatically acquired during the procedure. The reported nominal accuracy of the system is 1 mm or 1°.

During surgery all surgeons tried to obtain adequate press-fit fixation, while aiming to a Stem Version included between 5° and 20° of anteversion; the target for Combined Anteversion was set to 25°-50°, compatibly with acetabular cup coverage by anterior and posterior walls.

Patients were classified depending on FNV, following Paley's criteria[15]: for a FNV value from 5° to 20° version was considered "normal", a FNV < 5° was considered "Decreased" and a FNV > 20° was considered "Increased".

The same classification was applied to the intraoperative values of SV, defining the following groups: "In range" (SV 5°-20°), "Below range" (SV <5°) and "Above range" (SV >20°).

Patients were finally classified in three groups depending on CV according to the combined anteversion parameters dictated by Dorr et al.[7]: "Low CV" (CV<25°), "Desired CV" (CV 25°-50°), "High CV" (CV>50°).

#### *"Statistical Analysis"*

Descriptive data analysis was performed with the use of Microsoft Excel 2016 Data Analysis Tools; Anova Univariate analysis was used to assess differences between mean FNV, mean SV, mean AV and mean CV in patients from the 3 different centers. Means were compared with Student's t-test and associations were evaluated with Pearson's correlation coefficient.

Data was then analyzed through a mixed-effects logistic regression model, where the outcome was SV in the range 5°- 20° and the independent variables was FNV. The mixed-effects model was specified with random intercept and random slope terms, which capture differences between the three hospitals. Linear, quadratic and cubic transformations of FNV were tested. The final model was identified by means of likelihood ratio tests as well as information criteria. Observations having FNV out of the range defined by the first and third quartiles minus / plus two times the interquartile range were excluded from the model. Results were graphically reported as estimated probabilities of FNV in the range 5°;20°, according to FNV and hospital.



The final mixed-effects logistic regression model contained linear, quadratic and cubic terms for FNV. Random intercept and random slope (associated to raw value of FNV) terms were also entered in the model.

Statistical calculation was performed with R 3.3.2 software (The R Foundation for Statistical Computing).

## Results

Mean FNV in the study population was  $5.0^{\circ} \pm 9.6^{\circ}$  (max  $49^{\circ}$  of anteversion, min  $-22^{\circ}$  of retroversion), while SV was  $6.4^{\circ} \pm 9.7^{\circ}$  (max  $40^{\circ}$  of anteversion, min  $-20^{\circ}$  of retroversion) (Figure 1).

The average difference between FNV and SV was  $1.6^{\circ} \pm 9.8^{\circ}$  (max  $34^{\circ}$  in anteversion, min  $-52^{\circ}$  in retroversion). A moderate statistically significant correlation was found between FNV and SV (Pearson correlation  $R = 0.48$ ,  $p < 0.001$ ). Final Stem Version was between  $5^{\circ}$  and  $20^{\circ}$  in 174 patients (48%),  $<5^{\circ}$  in 162 patients (45%), and  $>20^{\circ}$  in 26 patients (7%). (see table 1 and figure 2 for complete data set).

Mean AV in the whole population was  $21.7^{\circ} \pm 4.4^{\circ}$  (max  $35^{\circ}$  in anteversion, min  $7^{\circ}$  in anteversion) and mean CV was  $28.2^{\circ} \pm 7.9^{\circ}$  (max  $57^{\circ}$ , min  $8^{\circ}$ ). A strong statistically significant correlation was found between SV and CV (Pearson correlation  $R = 0.89$ ,  $p < 0.001$ ).

Final Combined Version was between  $25^{\circ}$  and  $50^{\circ}$  in 252 patients (69.6%),  $<25^{\circ}$  in 109 patients (30.1%), and  $>50^{\circ}$  in only 1 patient (0.3%).

Relative risk of “Low Combined Version” was 8.6 times greater in patients with Stem Version “Below Range” ( $p < 0.001$ ).

Each center was then considered separately. The 3 centers had similar values of mean FNV (Center 1:  $5.0^{\circ} \pm 9.4^{\circ}$ , Center 2:  $5.9^{\circ} \pm 8.4^{\circ}$ , Center 3:  $4.4^{\circ} \pm 10.5^{\circ}$ ) with no statistically significant difference. On the contrary SV was characterized by a wide variation between centers (Center 1:

154  $3.4^{\circ} \pm 8.3^{\circ}$ , Center 2  $7.4^{\circ} \pm 9.6^{\circ}$ , Center 3  $15.1^{\circ} \pm 7.7^{\circ}$ ), differences were found statistically  
 155 significant with the ANOVA test.

156 Similar mean values of AV were found in the 3 centers (Center 1:  $21.7^{\circ} \pm 4.6^{\circ}$ , Center 2  $22.3^{\circ} \pm$   
 157  $4.4^{\circ}$ , Center 3  $21.1^{\circ} \pm 3.9^{\circ}$ ) with no statistically significant difference; consequently CV shows the  
 158 same pattern of stem version (Center 1:  $25.1^{\circ} \pm 6.5^{\circ}$ , Center 2  $29.7^{\circ} \pm 7.4^{\circ}$ , Center 3  $36.2^{\circ} \pm 6.1^{\circ}$ )  
 159 with statistically significant difference at the ANOVA test. (Table 2).

160 In Center 1 91 on 229 patients (39.7%) had a “in range” stem version, while in Center 2 27 on 56  
 161 patients (48.2%) had a “in range” stem version and in Center 3 57 on 77 patients (74 %) had a “in  
 162 range” stem version. The difference between centers is particularly significant in patients with a  
 163 reduced FNV since they had an “in range” stem version rate of 22.9% for center 1, 26% for center 2  
 164 and 80% for center 3. (for complete dataset see Table 3 and figure 3).

165 The desired range of Combined Version was obtained in 134 on 229 patients (58.5%) in Center 1,  
 166 in 45 on 56 patients (80.4%) in Center 2 and in 73 on 77 patients (94.8%) in Center 3.

167 When SV was “Below Range” the desired CV was obtained in 37.1%, 56.0% and 50.0% of patients  
 168 in Center 1, Center 2 and Center 3 respectively. When SV was “In Range” the desired CV was  
 169 obtained in 86.8%, 100% and 98.2% of patients in Center 1, Center 2 and Center 3 respectively.  
 170 (Table 3, Figure 4)

171 Given the difference between the 3 centers, and the fact that in center 3 only posterior-lateral  
 172 approach was used, the population of center 2 was divided between Posterior-Lateral approach  
 173 (PLA) (16 patients) and Direct-Lateral approach (DLA) (40 patients); a two-tailed T-Test was used  
 174 to compare SV and FNV-SV difference. SV resulted significantly higher in DLA ( $9.5^{\circ} \pm 9.9^{\circ}$  vs  
 175  $2.0 \pm 6.8^{\circ}$ ;  $p < 0.001$ ), while FNV-SV difference resulted higher in PLA ( $8.3^{\circ} \pm 7.0^{\circ}$  vs  $6.4^{\circ} \pm 4.9^{\circ}$ )  
 176 with no statistically significant difference.

177 A moderate statistically significant correlation between FNV and SV was confirmed also in the  
 178 separate analysis for centers (Center 1  $R=0.61$ ,  $p < 0.001$ ; Center 2  $R=0.54$ ,  $p < 0.001$ ; Center 3  
 179  $R=0.46$ ,  $p < 0.001$ ).

Three hip dislocations were treated with closed reduction and patients had no recurrence of dislocation. Center 1 had 1 post-traumatic dislocation falling descending the stair at 4 months after surgery. Center 2 had 1 dislocation for severe unstable hip dislocated during manual physiotherapy; Center 3 1 post-traumatic dislocation falling from a high step at 3 months after surgery (Table 4).

## Discussion

The present study confirms the great variability of FNV in patients with osteoarthritis and also of final SV when using a straight uncemented stem (mean stem anteversion  $6.4^\circ$  with a standard deviation of  $9.7^\circ$  and ranging from  $-20^\circ$  to  $40^\circ$ ; mean difference between stem version and femoral neck version was  $1.6^\circ \pm 9.8^\circ$  (max  $34^\circ$ , min  $-52^\circ$ ), with femoral stem more anteverted than femoral neck). The ideal version position of the acetabular and femoral components is unknown. [16,17] Traditionally Lewinnek's "safe zone" [18] ( $40^\circ \pm 10^\circ$  of inclination and  $15^\circ \pm 10^\circ$  of anteversion) is considered the gold standard for acetabular cup positioning to avoid dislocation and impingement. [19] Recent literature has emphasized the importance of considering both cup and stem anteversion in order to achieve a combined anteversion in a desired range of  $40^\circ \pm 15^\circ$ . [20,21,22] Current robotic assisted THA gives the surgeon intraoperative knowledge of stem and cup version, which would then allow the surgeon to place both components such that cup position or combined anteversion would fall into the target zone. Despite this intraoperative measurement system, the femoral stem was placed within the targeted range of anteversion ( $5^\circ$ - $20^\circ$ ) in only 48% of patients, while it was implanted below that range in 45% of them. Combined Anteversion was severely affected by such a low rate, falling into the desired range in only 69.6% of patients. These results certainly could have been influenced by low femoral neck version: in the analyzed cohort mean FNV was  $5.0^\circ \pm 9.6^\circ$ , lower than any other analysis in current literature (other studies

on osteoarthritic patients report native femoral neck version ranging from  $13.8^{\circ} \pm 7.9^{\circ}$  to  $28.1^{\circ} \pm 11.0^{\circ}$ . [1,13,23,24]

Furthermore, also the observed discrepancy between FNV and SV was lower than other similar studies: Bargar et al. [23]<sup>Error! Bookmark not defined.</sup> and Hirata et al. [13]<sup>Error! Bookmark not defined.</sup> comparing pre-operative and post-operative CT scans after the implantation of a femoral uncemented stem found a mean prosthetic femoral anteversion of  $22.5^{\circ}$  (range,  $1.0^{\circ}$  to  $39.0^{\circ}$ ; SD,  $8.5^{\circ}$ ) and  $38.0^{\circ}$  (range,  $14.0^{\circ}$  to  $63.0^{\circ}$ ; SD,  $11.2^{\circ}$ ), with a difference of  $8.7^{\circ} \pm 4.8^{\circ}$  and  $9.8^{\circ} \pm 8.8^{\circ}$  respectively.

Emerson et al. [1] with an intraoperative fluoroscopic system also determined a difference of  $8.1^{\circ} \pm 7.4^{\circ}$ . This difference is likely related to the nature of the measurement system, since in the present study stem version was identified intraoperatively with a surgical navigation system, instead of having a post-operative evaluation.

Acetabular component version was intraoperatively planned by the surgeon with the knowledge of prosthetic Stem Version, in order to achieve a satisfactory Combined Version of  $25^{\circ}$ - $50^{\circ}$ ; nevertheless when Stem was positioned with less than  $5^{\circ}$  of anteversion the correct Combined version was obtained only in 40.4% of patients, and relative risk of falling out of the desired range of combined anteversion was 8.4 times higher ( $p < 0.001$ ), even if mean AV was  $24.2^{\circ} \pm 3.5^{\circ}$ , at the higher limit of Lewinnek's safe zone.

The secondary aim of the study was to assess if stem positioning could be operator dependent and if it could variate with gender.

All surgeons targeted the same range of stem version, nevertheless the present data reveal a statistically significant difference between different centers both in mean SV-FNV difference (Center 1:  $-1.5^{\circ} \pm 7.9^{\circ}$ , Center 2:  $1.5^{\circ} \pm 8.7^{\circ}$ , Center 3:  $10.8^{\circ} \pm 9.8^{\circ}$ ) and in stem version behavior in relation to femoral neck version.

Each surgeon acted differently in order change stem version while achieving the best fit into femoral canal. In center 1, slightly anteverted or retroverted femurs were rarely corrected to the

target stem version range and, even in patients with normal femoral neck version, stem was retroverted. On the other hand, in center 3, neck retroversion was more often corrected to target version, but involving a risk of overcorrection. Lastly center 2 showed a correction profile similar to center 1 even if retroverted femurs were more frequently corrected to the normal range (Table 4, figure 3 ).

The reported difference could be explained also by the different surgical approach, since the surgeon in center 3 used only posterior-lateral approach and was probably brought to avoid stem retroversion by the higher dislocation risk. Anyway, in center 2, in which both Direct Lateral and Posterior Lateral approach were used, no statistically significant difference was found in FNV-SV difference.

Emerson et al.[1] suggested that the anatomic shape of the proximal femur determines the anteversion of the stem; the same concept was also supported by Bargar et al.[23], who found a strong correlation between femoral neck version and stem version with a double wedge metaphyseal filling component. Conversely, the present study demonstrated only a moderate correlation, as found by Hirata et al. [13]

The present data also confirm that the extent by which the native anatomy dictates the prosthetic anteversion is affected by the design of the stem. Thinner implants in the sagittal plane, such as single wedge designs like the one analyzed in the present study, are likely to show a lower influence from proximal femoral anatomy. Those characteristics partially allow surgeons to modify stem version to their liking, but create a higher variability of final stem position, especially without an intraoperative knowledge of stem version. [25]

Stem retroversion is often associated to a higher dislocation risk and also advocated to fasten subsidence and eventually component loosening. [26] However in the considered cohort it was not always possible to correct femoral retroversion, leaving 23% (83 patients) of the implanted stems retroverted ( $SV < 0^\circ$ ).

Reduced stem version resulted to be a key factor in determining insufficient combined version; intraoperative planning and robotically guided cup positioning alone were not enough to correct abnormal stem version and to achieve the desired range of combined Version. Positioning the acetabular component with excessive anteversion ( $>25^\circ$ ) could mean landing outside of Lewinnek's safe zone and could expose to risk of impingement, acetabular uncoverage or anterior dislocation. [2,16,18]

When analyzing separately different surgical approaches, we found a 28% of retroverted stems in direct lateral approach surgery (76 retroverted stems on 269 patients) and a 7% of retroverted stems in posterior-lateral approach surgery (7 retroverted stems on 93 patients). The only case of atraumatic hip dislocation in the presented population had a stem version of  $-5^\circ$ , a cup version of  $25^\circ$ , a Combined Version of  $20^\circ$  and occurred in a patient treated with THA with posterior-lateral approach, representing the 1.07% of the patients treated with such approach.

Such results suggest that stem retroversion, and therefore reduced combined version, could be highly tolerated in case of direct lateral approach, while it still represent a risk factor for dislocation in case of posterior-lateral approach.

The present study has several limitations. First of all, the group numbers from each center were different, but since they are homogeneous for gender and age, we feel it is appropriate to combine the patients for analysis. Second, two different surgical approaches were used, possibly influencing stem version. Since there is no literature data supporting stem version difference between different surgical approaches, and also data from our study evidenced no difference when the approaches were used by the same surgeon we treated PLA and DLA the same way.

Third, it was possible to analyze only femoral neck version without taking into account also other factors influencing proximal femur anatomy, such as femoral neck-shaft angle or femoral head offset. Hirata et al. [13] and Imai et al.[27] questioned the relationship between femoral neck version and stem version, suggesting the use of metaphyseal version at the height of lesser

trochanter as a referral, nevertheless femoral neck version was preferred since it remains the most used landmark to assess proximal femur version in conventional THA. Fourth, since only one case of atraumatic dislocation was reported in the present study, a higher amount of data will be required to thoroughly investigate differences in dislocation risk between PL and DL approaches with stem retroversion. Finally, all measurements were performed by the same operator, and it was not possible to assess eventual inter-observer variability. Furthermore, no other report in current Literature had made use of the Crisis Software to measure FNV, so the difference in measurement method could have influenced the comparisons between different works.

## **Conclusion**

The present study confirms the great variability of femoral neck version (FNV) in patients with hip osteoarthritis. We found that with the use of an uncemented single wedge straight stem, final stem version (SV) is highly variable. Despite being moderately correlated with native FNV, SV can be partially influenced by the surgeon, but native femoral retroversion is not always correctable and retroversion of the stem is present in up to 23% of patients. Stem version is a key factor to achieve a satisfactory combined version; in order to correctly follow combined anteversion technique and to avoid excessive or reduced cup version we recommend stem positioning between 5° and 20° in anteversion. Low combined anteversion does not seem to constitute a risk factor for hip dislocation when using a direct lateral approach, while in case of posterior lateral approach it should be avoided. For these reasons, we consider that knowledge of preoperative and intraoperative stem version is fundamental to avoid abnormal combined version and therefore reduce risk of impingement, dislocation or acetabular uncoverage; the use of CT based based planning, CAS or robotic instrumentation could be useful, altogether with stem designs with intrinsic anteversion or cemented fixation.



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ACCEPTED MANUSCRIPT

## Figures

Figure 1: Distribution of Femoral Neck Version (above) and Stem Version (below) in the whole population. In the red area Below Range ( $<5^\circ$ ) and Above Range ( $>20^\circ$ ) results.

Figure 2: Scatter graph of Stem Version in respect to Femoral Neck Version. The stem "safe zone" was highlighted in green. When FNV was  $<5^\circ$  stem version was "increased" 3% of the times, "Normal" 37% of the times and Reduced 60% of the times, meaning that the surgeon was not always able to correct femoral retroversion. Also with a "Normal" FNV stem was positioned with a SV  $<5^\circ$  34% of the times.

Figure 3: Trend of "in range" SV in respect to FNV for surgery center. Center 1 has the lowest rate of "in range" SV for patients with decreased or normal FNV but the highest rate of in range SV for patients with increased FNV.

Figure 4: Scatter graph of Combined Version in respect to Stem Version with each center considered separately. The "Desired combined version" range of  $25^\circ$ - $50^\circ$  was highlighted. The distribution reflects the strong relationship between these two variables. When stem has a "below range" ( $<5^\circ$ ) version there is a high risk of an insufficient Combined Version (59,6% of patients resulted in the "low combined version" group when stem version was  $<5^\circ$ ). All the 3 centers showed the same trend. It is also evident that Center 3, which has the highest rate of "in range" and "above range" stems, also has the highest rate of patients with "Desired" Combined Version.

## Tables

|                                 | <i>Femoral Neck Version &lt;5°</i> | <i>Femoral Neck Version 5°-20°</i> | <i>Femoral Neck Version &gt;20°</i> |
|---------------------------------|------------------------------------|------------------------------------|-------------------------------------|
| <b>Number of patients</b>       | 174 (48%)                          | 168 (46%)                          | 20 (6%)                             |
| <b>StemVersion:</b>             |                                    |                                    |                                     |
| <b>&lt;5°</b>                   | 104 (60%)                          | 57 (34%)                           | 0 (0%)                              |
| <b>5°-20°</b>                   | 64 (37%)                           | 99 (59%)                           | 12 (60%)                            |
| <b>&gt;20°</b>                  | 6 (3%)                             | 12 (7%)                            | 8 (40%)                             |
| <b>Mean Difference (± S.D.)</b> | 5.8°± 9.4°                         | -1.6°± 8.2°                        | -6.8°± 7.2°                         |

Table 1: Femoral Neck Version versus Final Stem Version: Final SV, and mean Version Difference (Stem Version – Femoral Neck Version) in the 3 groups of different FNV from the whole study population. The femoral stem was anteverted with respect to FNV in the group with decreased FNV and retroverted with respect to FNV in Normal and Increased FNV groups. The variation in Mean Difference between the three groups was found to be statistically significant ( $p < 0.001$ ) in the ANOVA test.

|                              | <b>Number of patients</b> | <b>Mean AV</b> | <b>Mean CV</b> | <b>Combined Version Groups</b>    |  |                                    |
|------------------------------|---------------------------|----------------|----------------|-----------------------------------|--|------------------------------------|
|                              |                           |                |                | <i>Low CV</i><br>( $< 25^\circ$ ) | <i>Desired CV</i><br>( $25^\circ$ - $50^\circ$ ) | <i>High CV</i><br>( $> 50^\circ$ ) |
| <b>Whole population</b>      | 362                       | 21.7° ± 4.4°   | 28.2° ± 7.9°   | 109 (30.1%)                       | 252 (60.6%)                                      | 1 (0.3%)                           |
| <b>StemVersion:</b>          |                           |                |                |                                   |  |                                    |
| <b>Below Range (&lt;5°)</b>  | 161                       | 24.2° ± 3.5°   | 22.3° ± 5.2°   | 96 (59.6%)                        | 65 (40.4%)                                       | 0 (0%)                             |
| <b>In Range (5°-20°)</b>     | 175                       | 20.0° ± 3.8°   | 31.4° ± 5.1°   | 13 (7.4%)                         | 162 (92.6%)                                      | 0 (0%)                             |
| <b>Above Range (&gt;20°)</b> | 26                        | 16.8° ± 3.9°   | 43.2° ± 4.4°   | 0 (0%)                            | 25 (96.2%)                                       | 1 (3.8%)                           |
| <b>p-Value (ANOVA)</b>       | -                         | <0.001         | <0.001         | -                                 | -  | -                                  |

Table 2: Combined Version distribution in the 3 groups of Stem Version. When Stem Version is Below Range 59.6% of THAs were positioned in a Combined Version more retroverted then recommended. When the stem was positioned inside or above the target range the desired Combined version was obtained in 92.6% and 96.2% of patients respectively. Only one patient (0.3%) was characterized by an excessive Combined Version.

|                        | <b>NUMBER OF PATIENTS</b> | <b>FEMORAL NECK VERSION (FNV):</b> | <b>STEM VERSION (SV):</b> | <b>MEAN DIFFERENCE (SV-FNV):</b> | <b>ACETABULAR COMPONENT VERSION (AV):</b> | <b>COMBINED VERSION (CV):</b> |
|------------------------|---------------------------|------------------------------------|---------------------------|----------------------------------|---|-------------------------------|
| <b>CENTER 1</b>        | 229                       | 5.0° ± 9.4°                        | 3.4° ± 8.3°               | -1.5° ± 7.9°                     | 21,7° ± 4,6°                              | 25,1° ± 6,5°                  |
| <b>CENTER 2</b>        | 56                        | 5.9° ± 8.4°                        | 7.4° ± 9.6°               | 1.5° ± 8.7°                      | 22,3° ± 4,4°                              | 29,7° ± 7,4°                  |
| <b>CENTER 3</b>        | 77                        | 4.4° ± 10.5°                       | 15.1° ± 7.7°              | 10.8° ± 9.8°                     | 21,1° ± 3,9°                              | 36,2° ± 6,1°                  |
| <b>P-VALUE (ANOVA)</b> | -                         | 0.7                                | < 0.001                   | < 0.001                          | 0.3                                       | < 0.001                       |

Table 3: Mean FNV, mean SV, mean SV-FNV difference, mean AV and mean CV of the population in the 3 study centers. The ANOVA test showed no significant difference in FNV and AV between centers, while a significant difference was present in SV, mean difference and CV.

| Intra-operative Stem Version classification |                       | Pre-operative Femoral Neck Version classification (number of patients) |                     |                      | Intra-operative Combined Version (number of patients) |                      |                | TOTAL |
|---|-----------------------|--|---------------------|----------------------|---|----------------------|----------------|-------|
|   |                       | Decreased FNV (<5°)  | Normal FNV (5°-20°) | Increased FNV (>20°) | Low CV (< 25°)  | Desired CV (25°-50°) | High CV (>50°) |       |
| CENTER 1                                    | SV Below range (<5°)  | 84 (63.6%)   | 48 (36.4%)          | 0 (0%)               | 83 (62.9%)  | 49 (37.1%)           | 0 (0%)         | 132   |
|   | SV In range (5°-20°)  | 25 (22.9%)   | 57 (53.3%)          | 9 (69.2%)            | 12 (13.2%)  | 79 (86.8%)           | 0 (0%)         | 91    |
|   | SV Above range (>20°) | 0 (0%)   | 2 (33.3%)           | 4 (66.7%)            | 0 (0%)  | 6 (100%)             | 0 (0%)         | 6     |
| CENTER 2                                    | SV Below range (<5°)  | 17 (68.0%)   | 8 (32.0%)           | 0 (0%)               | 11 (44.0%)  | 14 (56.0%)           | 0 (0%)         | 25    |
|   | SV In range (5°-20°)  | 7 (26.0%)  | 19 (70.3%)          | 1 (3.7%)             | 0 (0%)  | 27 (100%)            | 0 (0%)         | 27    |
|   | SV Above range (>20°) | 1 (25.0%)  | 2 (50.0%)           | 1 (25.0%)            | 0 (0%)  | 4 (100%)             | 0 (0%)         | 4     |
| CENTER 3                                    | SV Below range (<5°)  | 3 (75.0%)  | 1 (25.0%)           | 0 (0%)               | 2 (50.0%)   | 2 (50.0%)            | 0 (0%)         | 4     |
|   | SV In range (5°-20°)  | 32 (80%)   | 23 (71.9%)          | 2 (40.0%)            | 1 (1.8%)  | 56 (98.2%)           | 0 (0%)         | 57    |
|   | SV Above range (>20°) | 5 (31.3%)  | 8 (50.0%)           | 3 (18.7%)            | 0 (0%)  | 15 (93.8%)           | 1 (6.3%)       | 16    |

Table 4: Patients FNV and CV in relation to SV group in the different centers. In Center 3 stems were more frequently implanted with an "in range" version (74% vs 48.2% of center 2 and 39.7% of center 1), particularly when facing a decreased FNV (80% vs. 28% of center 2 and 22.9% of center 1). Combined Version substantially follows stem version distribution.

|        | Center   | Mechanism  | Gender | Side  | FNV | SV | SV-FNV difference | AV | CV |
|--------|----------|------------|--------|-------|-----|----|-------------------|----|----|
| Case 1 | Center 1 | Traumatic  | F      | Right | 10  | 1  | -9                | 26 | 27 |
| Case 2 | Center 2 | Atraumatic | F      | Left  | 3   | -5 | -8                | 25 | 20 |
| Case 3 | Center 3 | Traumatic  | M      | Left  | 15  | 20 | 5                 | 20 | 40 |

Table 5: Documented cases of dislocation. In the only case of atraumatic dislocation, stem was positioned below range, in a retroverted position; stem version was lower than femoral neck version and, despite the cup was positioned into the safe zone of Lewinnek, Combined Version was lower than the recommended range of 25°-50°.

