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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

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Marcovigi Andrea email: <u>dott.marcovigi@gmail.com</u> Address: via del Pozzo 71, 41124 Modena, Italy Phone number: +39 059 422 4309 Fax number: +39 059 422 4313 1 Evaluation of native femoral neck version and final stem version

2 variability in patients with osteoarthritis undergoing robotically

- 3 implanted THA
- 4

5 Abstract

6 Background:

- 7 Combined anteversion in Total Hip Arthroplasty influences both dislocation risk and range of motion.
- 8 One of its components, stem version, could be dictated by many factors, from native femoral anatomy to
- 9 stem geometry and surgeon's choice.
- 10 In the current multicenter study, robotic technology was used to assess the influence of native femoral
- 11 version on final stem version and combined anteversion using a straight uncemented stem.

12 Methods:

- 13 Three hundred and sixty-two patients undergoing total hip arthroplasty were enrolled from 3 different
- 14 orthopedic centers from 2012 and 2016.
- 15 All patients underwent CT planning with measurement of Femoral Neck Version (FNV) and intraoperative
- 16 measurement of Stem Version (SV), Acetabular component Version (AV) and Combined Version (CV) with
- 17 robotic instrumentation.
- 18 Results:
- 19 Mean FNV was 5.0°±9.6°, SV was 6.4°±9.7°. The average difference between FNV and SV was 1.6°±9.8°. A
- 20 moderate correlation was found between FNV and SV (R = 0.48, p < 0.001). SV was between 5° and 20° in
- 21 174 patients (48%).
- 22 Mean CV was 28.2°±7.9°. A strong correlation was found between SV and CV (R = 0.89, p < 0.001).
- 23 A significant difference in SV was found between the 3 centers (p<0.001).
- 24 CV was <25° in 109 patients (30.1%). Relative risk of CV <25° was 8.6 times greater with stem version <5°
- 25 (p<0.001).
- 26 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.

30 *Keywords*:

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

32

33 Introduction

Component positioning in Total Hip Arthroplasty (THA) can have a major effect on both clinical

35 outcome and complications rate. Traditionally the recommended positioning for femoral stem is to

36 restore natural offset and anteversion, which can result in great variability of final component

37 placement.[1,2] Various works have in fact shown mean values of native femoral neck version that

38 may range from $8.84^{\circ} \pm 9.66^{\circ}$ to $28.1^{\circ} \pm 11.0^{\circ}$.[3,4]

39 Following exclusively proximal femoral anatomy could lead to excessive stem anteversion or

40 retroversion, and may result in acetabular impingement and possibly a higher risk of dislocation.

41 [5,6] In order to avoid such complications and improve the range of motion (ROM) Dorr et al.[7]

42 emphasized the importance of achieving a combined anteversion (the sum of acetabular and stem

43 version) between 25° and 50° .

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]

50 The type and geometry of the femoral stem can also affect resultant femoral version. When

51 implanting a straight cementless stem, the final stem anteversion might be influenced by the

52 necessity of placing the component into a best fitting position within the femoral canal. [8]

53	Several studies reported final stem version in THA after the implantation of an uncemented femoral
54	component. [10,11,12] Two of them also analyzed the relationship between native femoral neck
55	version and stem version using preoperative and postoperative CT measurements. Hirata et al.[13]
56	reported a mean difference of $9.8^{\circ} \pm 8.8^{\circ}$ in anteversion with a final stem version ranging from 14°
57	to 63.2°, while Emerson et al.[1] found similar results in the mean difference value with $8.1^{\circ} \pm 7.4^{\circ}$
58	but with a final stem version of ranging from -11° to 22°.
59	With the advent of robotically assisted THA, it is now possible to have a direct, real-time
60	knowledge of stem version during surgery. [14] This knowledge enables the surgeon to make
61	intraoperative adjustments to femoral stem version, acetabular component version or both to
62	achieve desired component position goals.
63	The purpose of this multicenter, retrospective study was to assess the variability of preoperative
64	femoral neck anteversion and final stem and cup version in patients undergoing THA performed
65	with CT based robotic techniques. The hypothesis was that the majority of the implanted stems
66	could be aligned to a physiological range of 5° -20° of anteversion, regardless of the native femoral
67	anatomy and that an optimal combined version of 25°-50° could be reached in all patients. The
68	secondary aim of the study was to assess eventual variability in component positioning among
69	different surgeons.

70

71 *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.

78	All patients were affected by end-stage hip osteoarthritis and all patients underwent CT scanning as
79	preoperative planning for MAKO Robotically-Assisted THA (Stryker Orthopedics, Kalamazoo, MI,
80	USA).
81	In all cases THA was performed using a straight, single wedge, uncemented stem (MetaFix TM
82	collarless stem, Corin Group PLC, Cirencester UK), a hemispheric, uncemented, coated cup
83	(Trinity TM Cup, Corin Group PLC, Cirencester UK) and Mako Robotic instrumentation for the
84	implantation of both femoral and acetabular components.
85	Interventions were performed by 3 different senior surgeons (1 surgeon for each center), a direct
86	lateral approach was used in 259 patients, while a posterior-lateral approach was used in the
87	remaining 103 patients (all 77 patients from center 3 and 16 patients from center 2).
88	Only CT scans that met the following qualifications were accepted: slices spacing 0.5-1 mm for the
89	pelvis and 2.0-5.0 mm for the knee, kV120-140, mA 200-250.
90	CT scans were processed with the MAKO Stryker "Crisis" Software to obtain 3D bone models.
91	Standardized landmarks of proximal femur, distal femur and pelvis were identified by a single
92	observer and then used to determine the Femoral Neck Axis (FNA), the Posterior Condylar Axis
93	(PCA) and the Anterior Pelvic Plane (APP).
94	The preoperative Femoral Neck Version (FNV) was automatically calculated by the software as the
95	angle formed by the projection of FNA and PCA on the Transverse Plane.
96	Screw fixation was used for the placement of the femoral and pelvic trackers and morphing
97	acquisitions of the femur and acetabulum were performed to couple CT 3D models and patient's
98	anatomy. The integrated optical guide navigation system was used to measure Stem Version during
99	stem implantation, Cup Version was then intraoperatively planned to achieve a satisfactory
100	Combined Version and to avoid excessive anterior or posterior acetabular uncoverage with the use
101	of CT based 3D models. Cup was finally implanted in the planned position with the use of Mako
102	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°.
- 105 During surgery all surgeons tried to obtain adequate press-fit fixation, while aiming to a Stem
- 106 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.
- 108 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 $< 5^{\circ}$ was considered "Decreased" and a FNV $> 20^{\circ}$
- 110 was considered "Increased".
- 111 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°).
- 113 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°-
- 115 50°), "High CV" (CV>50°).

116 "Statistical Analysis"

117 Descriptive data analysis was performed with the use of Microsoft Excel 2016 Data Analysis Tools;

118 Anova Univariated analysis was used to assess differences between mean FNV, mean SV, mean

119 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 121 122 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 123 three hospitals. Linear, quadratic and cubic transformations of FNV were tested. The final model 124 was identified by means of likelihood ratio tests as well as information criteria. Observations having 125 FNV out of the range defined by the first and third quartiles minus / plus two times the interquartile 126 range were excluded from the model. Results were graphically reported as estimated probabilities of 127 FNV in the range 5° ;20°, according to FNV and hospital. 128

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 StatisticalComputing).

134

135 **Results**

136 Mean FNV in the study population was $5.0^{\circ} \pm 9.6^{\circ}$ (max 49° of anteversion, min -22° of

retroversion), while SV was $6.4^{\circ} \pm 9.7^{\circ}$ (max 40° of anteversion, min -20° of retroversion) (Figure

138 1).

139 The average difference between FNV and SV was $1.6^{\circ} \pm 9.8^{\circ}$ (max 34° in anteversion, min -52° in

140 retroversion). A moderate statistically significant correlation was found between FNV and SV

141 (Pearson correlation R = 0.48, p < 0.001). Final Stem Version was between 5° and 20° in 174

patients (48%), $<5^{\circ}$ in 162 patients (45%), and $>20^{\circ}$ in 26 patients (7%). (see table 1 and figure 2

- 143 for complete data set).
- Mean AV in the whole population was $21.7^{\circ} \pm 4.4^{\circ}$ (max 35° in anteversion, min 7° in anteversion)
- and mean CV was $28.2^{\circ} \pm 7.9^{\circ}$ (max 57°, min 8°). 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° and 50° in 252 patients (69.6%), <25° in 109 patients (30.1%), and >50° in only 1 patient (0.3%).
- 149 Relative risk of "Low Combined Version" was 8.6 times greater in patients with Stem Version
 150 "Below Range" (p<0.001).
- 151 Each center was then considered separately. The 3 centers had similar values of mean FNV (Center
- 152 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° \pm 9.6°, Center 3 15.1° \pm 7.7°), 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 $22,3^{\circ} \pm$
- 4,4°, Center 3 21,1° \pm 3,9°) with no statistically significant difference; consequently CV shows the
- 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
- 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
- reduced FNV since they had an "in range" stem version rate of 22.9% for center 1, 26% for center 2
- 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,
- 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
- in Center 1, Center 2 and Center 3 respectively. When SV was "In Range" the desired CV was
- 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
- 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
- to compare SV and FNV-SV difference. SV resulted significantly higher in DLA $(9.5^{\circ} \pm 9.9^{\circ} \text{ vs})$
- 175 2.0 \pm 6.8°; p<0.001), while FNV-SV difference resulted higher in PLA (8,3° \pm 7.0° vs 6,4° \pm 4.9°)
- 176 with no statistically significant difference.
- 177 A moderate statistically significant correlation between FNV and SV was confirmed also in the
- 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).

185 **Discussion**

- 186 The present study confirms the great variability of FNV in patients with osteoarthritis and also of
- 187 final SV when using a straight uncemented stem (mean stem anteversion 6.4° with a standard
- deviation of 9.7° and ranging from -20° to 40° ; mean difference between stem version and femoral
- 189 neck version was $1.6^{\circ} \pm 9.8^{\circ}$ (max 34°, min -52°), with femoral stem more anteverted than femoral
- neck). The ideal version position of the acetabular and femoral components is unknown. [16,17]
- 191 Traditionally Lewinnek's "safe zone" [18] $(40^\circ \pm 10^\circ \text{ of inclination and } 15^\circ \pm 10^\circ \text{ of anteversion})$ is
- 192 considered the gold standard for acetabular cup positioning to avoid dislocation and impingement.
- 193 [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

- 204 on osteoarthritic patients report native femoral neck version ranging from $13.8^{\circ} \pm 7.9^{\circ}$ to $28.1^{\circ} \pm$
- 205 11.0°).[1,13,23,24]
- 206 Furthermore, also the observed discrepancy between FNV and SV was lower than other similar
- studies: Bargar et al.[23]^{Error! Bookmark not defined.} and Hirata et al.[13]^{Error! Bookmark not defined.} comparing
- 208 pre-operative and post-operative CT scans after the implantation of a femoral uncemented stem
- found a mean prosthetic femoral anteversion of 22.5° (range, 1.0° to 39.0° ; SD, 8.5°) and 38.0°
- (range, 14.0° to 63.0°; SD, 11.2°), 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 $8.1^{\circ}\pm$

212 7.4°. 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
- 214 having a post-operative evaluation.
- 215 Acetabular component version was intraoperatively planned by the surgeon with the knowledge of
- prosthetical Stem Version, in order to achieve a satisfactory Combined Version of $25^{\circ}-50^{\circ}$;
- 217 nevertheless when Stem was positioned with less than 5° 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
- 220 higher limit of Lewinnek's safe zone.
- The secondary aim of the study was to assess if stem positioning could be operator dependent and ifit 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]

250 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

253 retroverted (SV<0°).

Reduced stem version resulted to be a key factor in determining insufficient combined version; 254 intraoperative planning and robotically guided cup positioning alone were not enough to correct 255 abnormal stem version and to achieve the desired range of combined Version. Positioning the 256 acetabular component with excessive anteversion (> 25°) could mean landing outside of 257 Lewinnek's safe zone and could expose to risk of impingement, acetabular uncoverage or anterior 258 dislocation. [2,16,18] 259 260 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 261 262 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°, a cup version of 263 25°, a Combined Version of 20° and occurred in a patient treated with THA with posterior-lateral 264 approach, representing the 1.07% of the patients treated with such approach. 265 Such results suggest that stem retroversion, and therefore reduced combined version, could be 266 highly tolerated in case of direct lateral approach, while it still represent a risk factor for dislocation 267 in case of posterior-lateral approach. 268 The present study has several limitations. First of all, the group numbers from each center were 269 different, but since they are homogeneous for gender and age, we feel it is appropriate to combine 270 the patients for analysis. Second, two different surgical approaches were used, possibly influencing 271 stem version. Since there is no literature data supporting stem version difference between different 272 surgical approaches, and also data from our study evidenced no difference when the approaches 273 were used by the same surgeon we treated PLA and DLA the same way. 274 Third, it was possible to analyze only femoral neck version without taking into account also other 275 factors influencing proximal femur anatomy, such as femoral neck-shaft angle or femoral head 276 offset. Hirata et al. [13] and Imai et al. [27] questioned the relationship between femoral neck 277

version and stem version, suggesting the use of metaphyseal version at the height of lesser

11

trochanter as a referral, nevertheless femoral neck version was preferred since it remains the mostused 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

287 influenced the comparisons between different works.

288

289 *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 adirect lateral approach, while in case of posterior lateral approach it should be avoided.

300 For these reasons, we consider that knowledge of preoperative and intraoperative stem version is

301 fundamental to avoid abnormal combined version and therefore reduce risk of impingement,

302 dislocation or acetabular uncoverage; the use of CT based based planning, CAS or robotic

303 instrumentation could be useful, altogether with stem designs with intrinsic anteversion or cemented

304 fixation.

		ACCEPTED MANUSCRIPT
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305	110/07	
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370 371

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1 Figures

2

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

5

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° 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° 34%
of the times.

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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.

13

- 14 Figure 4: Scatter graph of Combined Version in respect to Stem Version with each center considered separately. The "Desired
- 15 combined version" range of 25°-50° was highlighted. The distribution reflects the strong relationship between these two variables.
- 16 When stem has a "below range" (<5°) version there is a high risk of an insufficient Combined Version (59,6% of patients resulted in
- 17 the "low combined version" group when stem verson was<5°). 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.

20

Tables

	Femoral Neck Version <5•	Femoral Neck Version 5*-20*	Femoral Neck Version >20•
Number of patients	174 (48%)	168 (46%)	20 (6%)
StemVersion:			
< 5 °	104 (60%)	57 (34%)	0 (0%)
5°-20°	64 (37%)	99 (59%)	12 (60%)
> 20 °	6 (3%)	12 (7%)	8 (40%)
Mean Difference (± S.D.)	$5.8^{\circ} \pm 9.4^{\circ}$	$-1.6^{\circ} \pm 8.2^{\circ}$	$-6.8^{\circ} \pm 7.2^{\circ}$

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.

	Number of patients	Mean AV	Mean CV	Com	Froups	
				Low CV	Desired CV	High CV
				(< 25°)	(25°-50°)	(>50°)
Whole population	362	$21.7^\circ\pm4.4^\circ$	28.2° ± 7.9°	109 (30.1%)	252 (60.6%)	1 (0.3%)
StemVersion:						
Below Range (<5°)	161	$24.2^\circ \pm 3.5^\circ$	$22.3^\circ \pm 5.2^\circ$	96 (59.6%)	65 (40.4%)	0 (0%)
In Range (5°-20°)	175	$20.0^\circ \pm 3.8^\circ$	$31.4^\circ \pm 5.1^\circ$	13 (7.4%)	162 (92.6%)	0 (0%)
Above Range (>20°)	26	$16.8^\circ \pm 3.9^\circ$	$43.2^\circ \pm 4.4^\circ$	0 (0%)	25 (96.2%)	1 (3.8%)
p-Value (ANOVA)	-	< 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.

	NUMBER OF PATIENTS	FEMORAL NECK VERSION (FNV):	STEM VERSION (SV):	MEAN DIFFERENCE (SV-FNV):	ACETABULAR COMPONENT VERSION (AV):	COMBINED VERSION (CV):
CENTER 1	229	$5.0^\circ \pm 9.4^\circ$	$3.4^\circ\pm8.3^\circ$	$-1.5^\circ \pm 7.9^\circ$	$21,7^\circ\pm4,6^\circ$	$25,1^\circ\pm 6,5^\circ$
CENTER 2	56	$5.9^\circ\pm8.4^\circ$	$7.4^\circ\pm9.6^\circ$	$1.5^\circ\pm 8.7^\circ$	$22,3^{\circ}\pm4,4^{\circ}$	$29,7^{\circ}\pm7,4^{\circ}$
CENTER 3	77	$4.4^{\circ} \pm 10.5^{\circ}$	$15.1^\circ \pm 7.7^\circ$	$10.8^\circ \pm 9.8^\circ$	$21,1^{\circ}\pm3,9^{\circ}$	36,2° ± 6,1°
P-VALUE (ANOVA)	-	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	-	ive Femoral Ne classification umber of patien		Intra-operative Combined Version (number of patients)			
		Decreased FNV (<5°)	Normal FNV (5°-20°)	Increased FNV (>20°)	Low CV (< 25°)	Desired CV (25°-50°)	High CV (>50°)	TOTAL
C E N T E	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
R 1	SV Above range (>20°)	0 (0%)	2 (33.3%)	4 (66.7%)	0 (0%)	6 (100%)	0 (0%)	6
C E N	SV Below range (<5°)	17 (68.0%)	8 (32.0%)	0 (0%)	11 (44.0%)	14 (56.0%)	0 (0%)	25
T E	SV In range (5°-20°)	7 (26.0%)	19 (70.3%)	1 (3.7%)	0 (0%)	27 (100%)	0 (0%)	27
R 2	SV Above range (>20°)	1 (25.0%)	2 (50.0%)	1 (25.0%)	0 (0%)	4 (100%)	0 (0%)	4
C E N	SV Below range (<5°)	3 (75.0%)	1 (25.0%)	0 (0%)	2 (50.0%)	2 (50.0%)	0 (0%)	4
T E	SV In range (5°-20°)	32 (80%)	23 (71.9%)	2 (40.0%)	1 (1.8%)	56 (98.2%)	0 (0%)	57
R 3	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	М	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°.

Native Version 40 35 30 25 25 20 15 15 10 5 0 13/22 - 121-20 271:26 251-24 9/20 21/22 17/128 19120 2122 21/20 19/28 15/26 23/24 13/14 +12 212 2913 3113 3313 3513 3513 3113 3914 WA 91^{,8} <u>م</u>ارد 31.2 210 22 310 516 118 51 Femoral Neck Version [°] **Stem Version** 40 35 30 25 25 20 15 15 10 5 0 Stem version [°]

ACCEPTED MANUSCRIPT







