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Influence of Implant Design and Individual Joint Laxity on *In Vivo* Medio-Lateral Stability of the Knee

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Abstract

Background: There are different factors that influence medio-lateral joint stability; implant design and individual joint laxity being two of them. In this study, we assessed the *in vivo* effect (1) of implant conformity and (2) of individual patient laxity on medio-lateral stability by comparing 2 implants in different flexion angles.

Methods: 129 patients were treated with TKA between May to August 2014; 67 in Group A (Attune, DePuy-Synthes) and 62 in Group B (P.F.C. DePuy-Synthes). Dynamic stability testing was performed with navigation (Knee3, Brainlab). Medial and lateral gap values were recorded and compared statistically in 5-degree steps of flexion, starting at extension to maximum flexion. Subgroup analysis of individual laxity was performed in the different implant groups. Patients were divided in 3 subgroups (1=tight: <2 mm; 2= medium: 2 mm to 5 mm; 3lax: >5 mm) based on individual pre-OP laxity.

Results: Group A showed a reduced gap opening on the medial side in all flexion angles, the difference being significant between 5° to 85° and at 135°. For the lateral gap there were no significant differences. Subgroup analysis showed an increased medial stability in all flexion angles for tight knees (subgroup 1). In contrast to that, subgroup 3 showed no significant difference between implants.

Conclusion: In this study we could quantify for the first time *in vivo*, that implant conformity and individual laxity are relevant factors for ml stability in TKA. While in tight knees both factors work additive, in lax knees the effect of implant design is dominated by laxity.

Keywords: Total Knee Arthroplasty; *In vivo* stability; Navigation; Dynamic stress testing; Conformity; Laxity

Introduction

Reestablishing joint stability throughout the entire Range of Motion (ROM) is one of the most important factors in successful Total Knee Arthroplasty (TKA) [1,2]. This stability is the sum of a number of different passive and active factors, such as the individual tension of the collateral ligaments itself or the muscle activity. However, medio-lateral (ml) stability is an individual parameter. While some knees are very lax and physiologically open more than 3 mm to 5 mm, others are tighter and open only 1 mm to 2 mm. Due to that fact no absolute value for perfect joint stability exists [3].

Besides those individual factors, implant position is another important factor for ml stability. Every change in position can directly affect the tension of the ligaments and by that the stability. A raised joint line, for example can cause midrange instability, while a reduced posterior offset can be a reason for flexion instability [4,5]. Therefore, the aim of TKA surgery is an individual implant position that results in balanced gaps. Insall defined a balanced TKA as one having equal gap sizes medial-lateral for extension as well as for flexion gaps [6].

In addition to the factor of implant position, implant related design factors also have a major influence on joint stability [7]. Constrained knees are developed to take over the function of compromised ligaments. Depending on the amount and type of insufficiency, different types of implant constraints exist. Unconstrained knees are designed to allow the medial and lateral collateral ligament to function without structural support. Only the shapes of the femoral component and its congruence in relation to the insert have a supporting effect on the medio-lateral (ml) and anterior-

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posterior (ap) stability. This effect of congruency is described to be higher in extension than in flexion [8,9].

The geometry of implants, in particular the shape of the condyles is varying between implants. While some companies recommend a single radius design, others have multiple varying radii of the femoral component [10-12]. To analyze the effect of these different designs on ml stability throughout ROM, multiple *in vitro* techniques are used [10,13,14]. Based on those *in vitro* results, companies describe the effect of implant design on stability and use the differences as an argument for superiority against older models or competitor models [13,15], whether this *in vitro* effect can also be proven *in vivo*, however until now remains unclear. Subjective clinical examination for example does not provide quantitative data. Applying standardized stress tests, performed under fluoroscopy or with ultrasound can deliver quantitative data but only in static positions [16-18]. With newer navigation systems it is possible to perform standardized stress tests throughout ROM at different phases of surgery. Based on initial stress testing, the individual joint laxity can be quantified. The effect of implant design on ml stability can be quantified at the end of surgery with the implant in place by applying the same stress tests. The high inter- and intra individual reliability of this testing has been proven recently [19]; both being in a range of maximum 2 mm.

Our first hypothesis in this study was that different TKA designs with the same amount of constraint provide different dynamic ml stability, due to their different conformity. The second hypothesis was that the effect of individual joint laxity has an additional effect on the implant related results of hypothesis 1. The objectives of this study were therefore (1) to assess the quantitative differences between two implants, by analyzing the opening of medial and lateral gaps from extension to full flexion under dynamic stress testing using a modern navigation system, and (2) to analyze the effect of individual patient laxity on these results.

Material and Methods

129 knee patients were treated with TKA between May and August 2014, all surgeries being performed by the same, experienced surgeon (H.G.). 67 patients were summarized as Group A, all treated with Attune (Depuy-Synthes) CR, fixed bearing implant. The other 62 patients summarized as Group B treated with P.F.C. Sigma (Depuy-Synthes), CR fixed bearing. The Attune implant is suggested to be a higher conforming implant due to its geometry of the femoral condyles and the matching insert surface based on *in vitro* studies [20].

For each patient, we recorded demographic data as gender, age, BMI, and pre-operative Hip-Knee-Ankle (HKA) angle. Only varus type osteoarthritis knee patients were included in this study in order to reduce the influence of deformity on the results. The decision which implant type was used was made randomly, not based on activity levels, age or other factors. We excluded patients with previous infection, fracture or dislocation of the knee. Patients with history of femoral and/or tibial osteotomy and patients with extra articular deformity or severe bone loss were also excluded.

In all patients a standardized, tibia-first, gap balanced, navigation work flow (Knee3, Brainlab) was used. To determine the individual pre-op status of the knee a first dynamic stress testing was performed before any ligament release or bony resection was made. Based on the amount of lateral gap opening in extension, the patients were divided in 3 subgroups of laxity. Subgroup 1 showed less than 2 mm lateral opening, demonstrating a tight joint without any laxity. In this subgroup, 9 patients of Group A and 22 of group B were summarized. In subgroup 2, patients were summarized with a lateral opening between 3 mm to 5 mm, demonstrating a medium amount of laxity. In this subgroup 41 patients of Group A and 29 of Group B were summarized. All knees showing an increased opening of the lateral extension gap of more than 5 mm demonstrating increased laxity were summarized as subgroup 3. This group consisted of 18 patients of Group A and 11 of Group B. For each group the mean and Standard Deviation (SD) was calculated and the differences between Group A and B were analyzed.

Based on gap differences, leg axis and degree of knee extension, the decision for tibial bone cut and soft tissue release was made. After that dynamic stability testing was again performed with trial spacer in place. Based on the individual ligament situation, sizing and positioning of the femoral component was made in an adjusted mechanical alignment technique. The aim at that point was to achieve HKA within a 3° corridor, a full extending but not hyperextending knee and a balanced extension and flexion gap, being equal in gap size. Femoral bone cut was performed according to that plan and after that, dynamic stability testing was again performed with the trial implant *in situ*. The gap values were obtained in 5-degree steps of flexion, starting from full extension up to maximum flexion. The stability data was first analyzed for the different implant groups and second for subgroup analysis regarding individual laxity.

Patient written consent for data collection was given in a blinded way. As the treatment of patients was performed according to the defined standards of the hospital, no additional ethic approval was required.

To assure that the pre-OP function did not affect the outcome we measured Knee Society and Knee Functional score in all patients and compared them statistically using student t-test.

To exclude that change in joint line position would affect the results of this study; we measured the thickness of distal femoral bone cuts intra-operatively with the navigation software. Mean and standard deviation was calculated and compared between both groups.

Unpaired student t-test was also used for comparing post-operative HKA and dynamic stability data between the different implants. We analyzed medial and lateral gap sizes from extension to full flexion in 5-degree steps and compared the difference between Group A and B with the student t-test. The same tests were used for the subgroup analysis of joint laxity. To analyze whether potential changes of ml stability in the different groups and subgroups might affect the clinical outcome we additionally obtained the post-OP Knee Score and functional Knee score 2-year post-OP. The difference in comparison to the pre-OP scores and between groups was statistically analyzed by using paired and unpaired t-tests.

Results

Both groups had equivalent demographics as they showed no significant differences for sex, age, BMI and pre-operative HKA (p-value: 0.998, 0.092, 0.138, 0.167) (Table 1).

Comparison of Group A and B showed reduced opening of the medial gap in Group A at all flexion angles; the difference being significant between 5° to 85° knee flexion and at 135°. This is demonstrating an increased medial stability of this implant. For the

Table 1: Demographic data of Group A and B.

Parameter			**p-value**
Gender	Group A n(%)	Group B n(%)	
Male	30 (44.78)	30 (48.39)	0.998
Female	37 (55.22)	32 (51.61)	
Parameter	**Mean**	**±SD**	**p-value**
Age (years)	66.02 ± 8.60	73.87 ± 9.85	0.992
BMI (kg/m²)	29.59 ± 5.51	30.98 ± 5.66	0.138
Pre-op HKA (degrees varus)	5.30 ± 2.56	4.61 ± 322	0.167

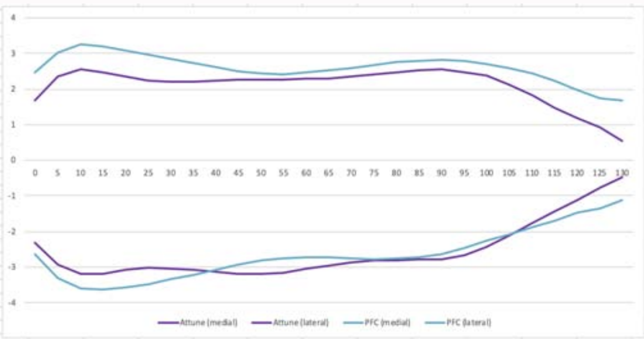

Figure 1: Comparison of Group A and B shows less opening of the medial gap in Group A at all flexion angles, being significant between 5° to 85° and at 135°. For the lateral gap it shows more inconsistent gap opening between groups.

lateral gap, a more inconsistent gap opening between groups was found; the differences being non-significant in all positions (Figure 1).

Results for subgroup laxity analysis showed in subgroup 1 (<2 mm) in all flexion angles significantly smaller medial gap sizes for implant A compared to B (Figure 2a). On the lateral side, Group A showed also significantly smaller gap sizes between 60° to 125° of flexion. In subgroup 2 (2 mm to 5 mm), smaller gap opening was found on the medial side in all flexion angles being significant only between 55° to 90° of flexion (Figure 2b). For subgroup 3 (>5 mm), no significant differences between the two groups were found, neither on the medial nor on the lateral side (Figure 2c).

Any effect of alignment on ml stability could be ruled out as the post-operative HKA angle was almost similar for both groups (Group A: 1.0° ± 0.8° varus; Group B 0.8° ± 1.1° varus, p=0.069). The difference and the standard deviation were being very small and statistically non-significant. Comparing pre- to post-operative HKA angle we found a change from 5.3° ± 6.7° to 1.0° ± 0.6° varus in Group A and from 4.6° ± 10.7° to 0.7° ± 1.4° varus in Group B.

The effect of changing the joint line on the ml stability was also ruled out by measuring mean distal femoral cutting thickness. It was 8.0 mm ± 1.6 mm for the medial and 7.8 mm ± 3.2 mm for the lateral condyle in group A, 7.8 mm ± 2.1 mm and 7.4 mm ± 2.8 mm for group B. The difference between groups again was very small and not significant neither for the medial (p=0.307) nor for the lateral condyle (p=0.171).

No post-Op complications occurred in either of the groups.

The pre-OP Knee Score showed no significant difference between group A and B (p=0.523). The two-year post-OP follow-up showed

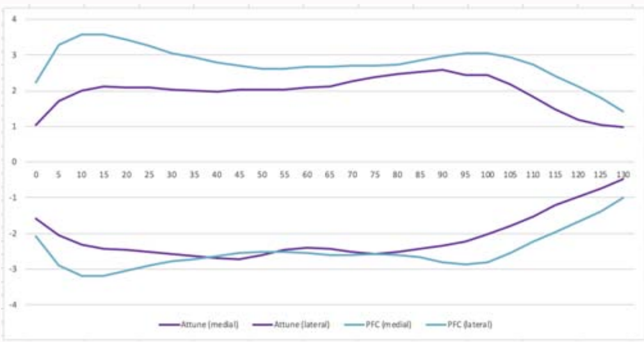

Figure 2A: Results of subgroup laxity analysis; subgroup 1 (< 2 mm) shows significantly smaller medial gap size in all flexion degree and between 60° to 125° on lateral side for implant A compared with B.

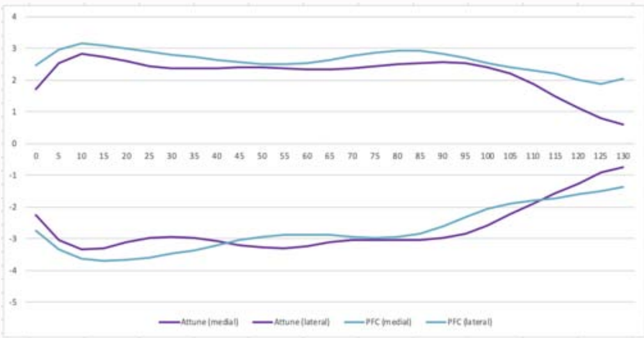

Figure 2B: Results of subgroup laxity analysis; subgroup 2 (2 mm to 5 mm) shows significantly smaller medial gap size between 55° to 90°, but neither at other flexion angles nor for the lateral gap.

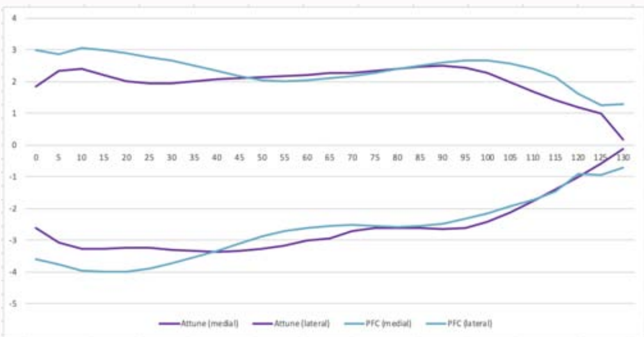

Figure 2C: Results of subgroup laxity analysis; subgroup 3 (>5 mm), no significant differences are shown between the two groups.

significantly increased average knee scores (p<0.0001) in both groups (Group A: 89.3 ± 12.3; Group B: 93.3 ± 8.6). Comparison between groups showed no significant (p=0.104) difference. For the functional score, Group A showed improved scores (92.7 ± 10.6) compared to group B (91.6 ± 10.3), however the difference again being non-significant (p=0.657).

The subgroup analysis again showed small, non-significant differences between implants (subgroup 1: p=0.95, subgroup 2: p=0.60, and subgroup 3: p=0.06 for knee score and p=0.55, 0.99, 0.85 for functional score). The two-year post-OP follow-up showed in all subgroups a significantly increase of the knee score and the functional score (subgroup 1-3: p<0.0001 for knee scores; subgroup 1 p=0.019, 0.008, subgroup 2: p<0.0001, <0.0001, subgroup 3: p<0.0001, p=0.003

for functional scores in Group A and B, respectively). Between groups we also did not find a significant difference.

Discussion

In this study, we have analyzed the influence of implant design and individual laxity on ml stability in TKA. We hypothesized that higher implant conformity will lead to improved ml stability and found that to be true for the medial compartment but not for the lateral one. We further hypothesized that individual laxity will additionally affect the ml stability of implants. This hypothesis was only true for patients with tight joints. In those the effect of increased ml stability of more conforming implants was even more pronounced. It could be assessed in all joint positions and additionally in the lateral compartment, too. In lax joints, on the other hand, the hypothesis was found to be false. In those lax knees, there is no difference between implants could be measured neither in a single position nor in one joint compartment. This is demonstrating that individual joint laxity is an additional, relevant factor for ml stability. This factor is working in addition to implant conformity in tighter joints. In lax joints, on the other hand it is dominating the effect implant conformity, and therefore in those patients more relevant.

To our knowledge this is the first *in vivo* study that has analyzed the quantitative effect of implant design on ml stability. The effect that higher conforming implants provide significantly higher ml stability in the medial compartment is in accordance to the described subjective impression of surgeons [21]. This improved ml stability, however is not automatically leading to better knee scores [22]. In contrast to other studies [23], we have not measured significantly improved scores for the higher conforming implants in this study. We found the functional knee score to be higher; the difference however was not significant. As results of outcome scores are described to be multifactorial [24,25], we believe that implant design is only one small factor. Implant position and demographic factors also influence score results and ml stability. To eliminate those factors, we have carefully selected the patient groups and assured *via* navigation that implant position was comparable in both groups. For example, distal joint line shift known to be a relevant factor could be excluded. While in Group A, the medial distal cut was 8.0 mm ± 1.3 mm and it was 7.8 mm ± 1.4 mm in group B.

In the subgroup analysis, we looked at the effect of joint laxity on ml stability in different implant designs and additionally compared the different subgroups to find out whether laxity might affect the outcome itself. In tighter joints the effect of implant conformity and ligament tension work additive, demonstrating increased ml stability in all joint positions and also in both compartments of the femoro-tibial joint. In lax joints, on the other hand, both factors work subtractive. Meaning that laxity is dominating the increased conformity of the implant. Both ways of collaboration however do not affect the functional outcome significantly. Functional Knee score in Subgroup 1 was higher than in Subgroup 2 or 3, the difference, however, was not significant.

Clary et al. [13] used an *in vitro* knee simulator and compared the same two implant-types we tested *in vivo*. They found a more stable medial condyle in the more conforming implants in particular in early flexion. This is in accordance to our findings. However, they only analyzed one stability scenario so they have not analyzed whether this effect of increased ml stability is more prominent in tighter or in laxer knees. We found the effect to be most prominent in very stable/tight knees, while the effect of conformity was significantly reduced in very lax knees. In their *in vitro* model Clary et al. [13] have looked more closely at the effect of conformity on anterior-posterior (ap) translation and femoro-tibial rotation and found the more conforming design to simulate a more natural knee kinematic. Unfortunately, we cannot compare our *in vivo* data with their results because the navigation system we used is providing data only ml gap size but not on ap translation.

In this study we have used a navigation-based technique in order to measure ml stability. This is done under standardized stress testing. As this testing was performed by a single surgeon, the potential of intra- and interindividual variations exist. However, in a previous study we could show that the reliability of this navigation technique is very high; for intra- as well as for interindividual testing [19]. The confidence interval showed a deviation of less than 2 mm in 95% of cases. These results were obtained in all different flexion angles, too. As a weakness of the navigation technique in general it has to be mentioned that a learning curve of 30 to 50 cases exists [26]. However, this study was performed by a single surgeon with more than 10 years of experience in navigation.

One limitation of this study is sample size. While a power analysis was performed for the overall group analysis between implants, the numbers for subgroup analysis on laxity became smaller. This might influence this part of the study. Another limitation is that we have analyzed only 2 implants. As there are other designs like single radius knees or medial pivoting knees, it would have been very interesting to see the effect of those implant designs on ml stability, too. However, as the Knee 3 system from Brainlab is a closed platform we could not test other implant designs in this set-up.

In conclusion, we have quantified the effect of implant conformity and individual joint laxity on ml joint stability for the first time *in vivo*. The more conforming implant lead to a significantly reduced gap opening on the medial side. This effect was even more pronounced in tighter joints. In very lax joints the effect of implant conformity could not be measured, demonstrating that joint laxity is more important than implant conformity. In the future, we plan to analyze the effect of different implant designs on ml and ap stability. Therefore, more advanced analyzing techniques for open CAS machines need to be developed.

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