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RESEARCH

Survival of primary total knee arthroplasty in a modern anatomic implant with and without a short stem extension

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Abstract

Introduction In primary conventional TKA, the tibial fixation is achieved by the epiphyseal and metaphyseal zone. One of those two zones of fixation, can be compromised by the local bone quality (bone micro-architecture and resistance), previous surgery or decreased surface of contact, leading to micro-mobility of the implant and potentially leading to aseptic loosening (AL). It was our hypothesis that the addition of a short fully cemented stem would improve the metaphyseal and epiphyseal fixation of the implant. To verify this hypothesis, the goals of this retrospective study were therefore to compare if (1) The presence of a short, stubby stem will dissipate stress and decrease micro-mobility at the epiphyseal level resulting in less radiolucent lines around the tibial component. (2) Short stem primary TKA may improve survivorship of the implant in patients potentially at risk for aseptic loosening.
Materials and methods Retrospective cohort study of 326 patients operated with a morphometric implant between 2013 and 2018. A short stubby stem was added to the tibial implant, if at the time of the tibial cut, the surgeon judged the epiphyseal bone quality to be poor or a smaller tibial size was necessary. All primary TKA were radiographically evaluated. RLLs were recorded and described according to their radiological aspect, localization, time of appearance and their progression over time. Survivorship was compared in the 2 groups using the national joint registry.
Results 71 TKAs out of 326 (22%) were stemmed. Of the 255 TKAs without stem, 53 (21%) showed RLLs under the tibial base plate and 1 case (0.4%) was revised for potential AL of the tibial implant. No RLLs were observed in the group of stemmed implants and no revisions for aseptic loosening were needed. Patients with stubby stems were elderly women with risk factors for osteoporosis or young men in need for correction of big coronal deformities.
Conclusion A short stubby stem extension can reduce the rate of RLLs and AL in primary TKA, probably by adding metaphyseal fixation to the classic epiphyseal fixation of the tibia and by a reduction in micro- and macro-motion of the tibial component. Based on the results of our study, the addition of a short cemented stubby stem decreased the rate of RLL with no revision observed in the stemmed group during the study period. The used knee system allows this option. Intra-operative decision can be made easily when risk factors such as osteoporosis, female gender, big deformities, obesity can be identified.
Level of evidence III

Keywords Zone of fixation · Stemmed primary TKA · Aseptic loosening · Revision

Introduction

In primary conventional TKA, the tibial fixation is achieved by the epiphyseal and metaphyseal zone. One of those two zones of fixation, can be compromised by the local bone quality (bone micro-architecture and resistance), previous surgery or decreased surface of contact [1–3].

Depending of the design of the implant, the surface of contact can be optimized using a more anatomical implant for the epiphyseal zone and more robust keel for the metaphyseal level [4].

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This difference in primary fixation could potentially explain why some knee designs present with early failure, because of aseptic loosening, more often than other designs [5–8].

Bone graft can be used for cysts and cement can be used for weak microarchitecture. But in case of combined factors, adding a third zone of fixation with a stubby stem in primary TKA, will increase the surface of contact, the resistance to compression and distraction forces as observed in revision TKA [4].

Concepts of fixation can be tested under laboratory conditions with mechanical testing [9, 10] or in observational studies looking at survivorship of different implant designs [4, 11].

Identifying potential risk factors preoperatively as a proxy for clinical osteoporosis could be considered an important part of the surgical planning [12]. The same can be said for coronal deformity analysis and the potential for correction of the total deformity with an intra-articular osteotomy, called total knee arthroplasty. The resulting post-operative mechanical axis can predict the area of the tibial epiphysis that will be undergoing compression or distraction forces, resulting into micromotion. Also, for patients with reduced epiphyseal areas of contact surface (small size tibia or metaphyseal wear extension resulting in a lower tibial cut), metaphyseal zone fixation with a short stubby stem for better primary fixation might be key. If the implant design offers the flexibility of adding a stem extension during surgery, where the conditions of epi- and metaphysis can be evaluated, the final decision can be taken by the surgeon to optimize the options for fixation.

To the best of our knowledge, there are no studies yet, comparing the survival of Persona Total Knee Arthroplasty (Zimmer Biomet, Warsaw, Indiana, US) with or without short stem extension in conventional primary TKA.

The purpose of this study was to understand the influence of a tibial stem extension in primary TKA on the micro - and macro-motion of the implant, observed as Radiolucent lines (RLL) on postoperative radiographs, as a proxy for micromotion.To verify this hypothesis, the goals of this retrospective study were therefore to compare if (1) The presence of a short, stubby stem will dissipate stress and decrease micromobility at the epiphyseal level resulting in less radiolucent lines around the tibial component.

(2) Short stem primary TKA may improve survivorship of the implant in patients potentially at risk for aseptic loosening.

Materials and methods

The authors retrospectively reviewed 328 TKAs operated between 2013 and 2018, for primary osteoarthritis (OA) using the same surgical technique and one type of arthroplasty (Persona, Postero-Stabilized (PS) cemented device (Zimmer Biomet, Warsaw, Indiana, US)). All patients underwent routine post-operative clinical and radiological controls at 3, 6, 12, 24 weeks, as well as 1, 2 and 5 year(s) postoperative, if it was possible.

Were excluded from this study, 2 patients with a history of infection. Finally, 326 TKAs were retrospectively reviewed. 255 TKAs (78%) were without a stubby stem, and 71 TKAs (22%) with a stubby stem and both groups were studied comparatively. The surgeon, with his own experience, decided during surgery to add a stubby stem, depending of the observed epiphyseal bone quality. When it was estimated osteoporotic, a short stubby stem was added to improve the metaphyseal and proximal diaphyseal fixation (high zone 3). All implants were cemented in one session including the keel and stem, when it was added, with a high-viscosity, antibiotic-loaded cement (Refobacin Bone Cement, Zimmer Biomet, Warsaw, US).

To answer the study hypotheses, the authors retrospectively compared the clinical and radiological outcome of the Persona implant, with and without short stem

One author (DW), reviewed all the post-operative X-ray's (AP, lateral, 30° axial patellar view and standing full leg) up to a minimum of 4 years postoperative. The measurement system utilized for this study was the Carestream PACS software (Rochester, NY, US), which gives a high degree of accuracy, with a tolerance of 0.1 mm (mm) for RLLs size measurements and 0.1 degree for the angle measurements.

Firstly, radiolucent lines were detected by reviewing post-operative X-rays. The number of RLLs observed in each group was noted. Localization of RLLs (area under the tibial baseplate) was classified in zones according to the Knee Society Scoring System (Knee Society Total Knee Arthroplasty Roentgenographic Evaluation and Scoring System (KSRES)) by Ewald [13]. RLLs can be osteolytic or osteosclerotic. They can appear early or late and can be isolated (one side of the tray) or combined (both sides). The sequence of appearance on both sides of the implant can be simultaneously (both present from the start) versus sequentially (first one side and then on the other side). In case of sequential appearance of RLLs, the authors identified the time of appearance of the first RLL as Time 1. For the appearance of the second side RLL, Time 2 was used. The size in mm and the evolution (still visible or disappeared) was noted according to guidelines [14]. Based on the radiological follow-up, three types of RLLs were defined based on localization (medial, lateral or both sides), the sequence of appearance; simultaneously or sequentially: Isolated RLLs (appearance on one side only), Combined RLLs (appearance on both sides simultaneously) and Sequential RLLs (appearance on both sides sequentially).

Secondly, All these radiographs analyzed for the presence of RLLs were also evaluated for signs of macro-mobility and aseptic loosening. Such post-operative changes around the tibial component that qualify as signs of macro-mobility are: progressive radiolucent lines around the keel, epiphyseal bone apposition on the compression side of the tilted implant and progressive tilting of the implant with distraction on the opposite side of the tibial implant on successive post-operative radiographs. Radiological signs of macro-mobility combined with pain and reduced functional outcome can be considered aseptic loosening [3, 15]. Alignment was collected for all study patients as mean pre-operative and post-operative Hip Knee Ankle (HKA) angles (varus < 178° or valgus > 182°). All TKAs with RLLs were collected in a database, including date of surgery, last follow-up in our center and whether the TKA was revised or not, revision in- or out-house, time to revision (from index surgery) and the reason for revision, as noted in the register.

Finally, the authors reviewed for both groups, demographic data, such as the age at time of surgery, gender and BMI. Furthermore, clinical data about diseases with a risk for poor bone quality (endocrinological pathologies, rheumatologic pathologies, renal disease, positive history of alcohol or smoking and medication or treatments with a potential bone remodeling impact (steroids)), were retrieved from the hospital medical records system. The level of tibial resection, polyethylene thickness, tibial base plate size and potential complications, such as per-operative fractures, was also collected from the surgical notes and included in the data base.

Descriptive statistics were used for demographic, surgical and mechanical data and sample characteristics are presented as numbers, means and standard deviations; categorical variables are presented as percentages. For continuous variables, violations of the normality assumption were tested using the Shapiro-Wilk test. The intra-observer difference was reconciliated by reading the same radiographs more than 5 times. The Cohen's Kappa was almost perfect agreement with an intra-observer agreement score of 0.82.Between-group differences were tested using unpaired T-tests. GraphPad Prism software 9.0 (Graphpad, La Jolla, CA, US) was used for statistical analyses, and a p-value < 0,05 was considered as statistically significant.

Results

The radiological characteristics of Persona implant with and without a short, stubby stem are represented in Fig. 1.

The authors didn't observe any differences between the study groups for the size of the tibial implant or the covered surface area (Table 1), Stem length was significantly ($p < 0.0001$) longer in the group with stubby stem extension (Table 1).

71 knees (22% of procedures) needed a stubby stem according the senior surgeon, due to poor local bone quality at the tibial epiphyseal level (Table 2). The authors observed a significant ($p < 0.0001$) difference in the rate of RLLs with 53RLLs/255 TKAs (21%) for the Persona group without stem (Figs. 2) and 0 RLLs /71 TKAs (0%) for the Persona group with stubby stem (Table 2).

The pre and post operative HKA angle values were similar between Persona with RLLs and Persona with stubby stem, with mean pre-operative deformities within 10 degrees both for varus (64%) and valgus (36%). Postoperatively, while aiming for adjusted mechanical alignment, 77% obtained this for the varus group and 23% remained in functional valgus alignment (HKA 182°) (Table 3).

No cases of aseptic loosening were observed in both groups. However, based on National Registry data, for the Persona study group without stem, 1/255 TKAs was revised (survivorship of 99.6%). The patient presented with an Isolated RLL and no radiological signs of aseptic loosening, but was considered loose by a surgeon in another center and therefore revised. None of the patients in the Persona group with short, stubby stem (survivorship of 100%) were revised, demonstrating excellent survivorship for both study groups.

Demographic data showed that the patients in the group with stem were significantly ($p = 0.052$) older (73 +/- 9 years versus 68 +/- 11 years) and female gender was significantly ($p = 0.0084$) more represented (5/1 versus 3/1) in this group. BMI was not significantly different in between both groups (Table 3).

The proportion of clinical risk factors for osteoporosis per patient was the same in both groups of implants with a proportion of 0.62 clinical risk factors per patient in the Persona group without stem compared to a proportion of 0.62 clinical risk factor per patient in the stubby stem group (Table 3).

When comparing women to men in the short stem study group, we obtained two profiles of patients. The female gender group was significantly older ($p = 0.004$), than the male group. Clinical risk factors for osteoporosis were high in both gender groups with a proportion of 0.75 clinical risk factor per patient in the male group with short, stubby stem, compared to a proportion of 0.86 clinical risk factor

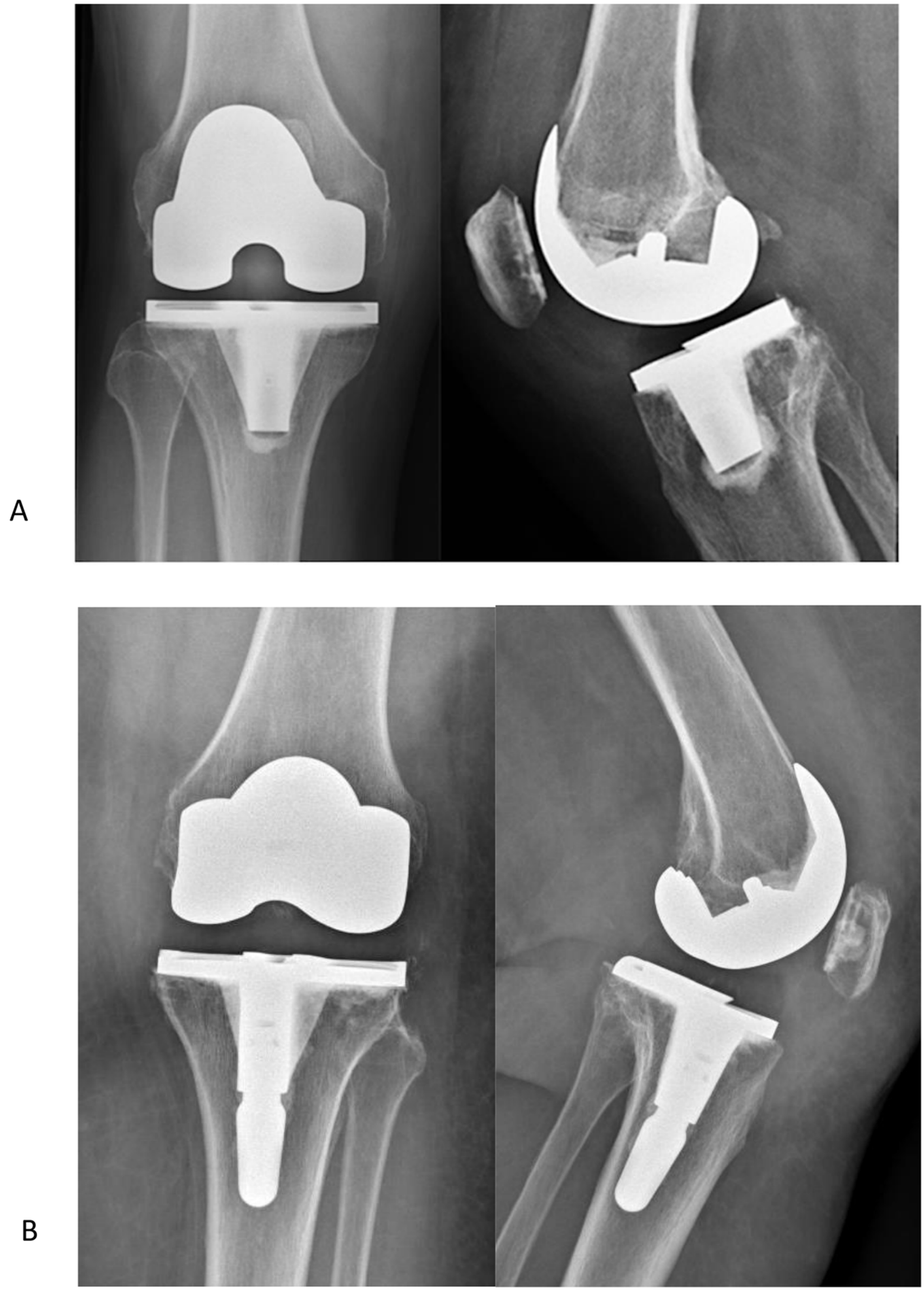

Fig. 1 Post-operative X-rays of both implants with same mediolateral size showing the differences between the keel (shape and length) with and without stubby stem. ***a*** Persona implant without stem ***b*** Persona implant with short, stubby stem

per patient in the women group with short, stubby stem (Table 4). The male group of patients with a stem showed the use of a thicker polyethylene ($p = 0.0058$) and a larger tibial base plate size ($p < 0,0001$), than in the female group (Table 4).

Discussion

Survival of TKA will depend of multiple factors. As all factors can't be perfectly controlled and planned, the improvements in surgery and implant design in recent years permit to increase the success rate of this procedure. As all patients are different, all procedures need to be adapted and planned

Table 1 Implant size characteristics in Persona study groups with and without stubby stem

Variables	Persona	Persona with stem	*P*
Tibial base plate			
ML size (mm)	73 ± 5	71 ± 4	
Antero posterior medial size (mm)	52 ± 4	51 ± 3	
Antero posterior lateral size (mm)	46 ± 4	45 ± 3	
Keel length (mm)	35 ± 3	66 ± 8	< 0.0001
Medialization (mm)	2 ± 1	2 ± 1	
Polyethylene			
Thickness (mm)	11 ± 1	11 ± 2	0.028

Table 2 Number of patients with RLLs, aseptic loosening and revision in both groups of implants

Number of patients	Without stubby stem	With stubby stem	*p*
Total	255	71	
With radiolucent lines	53	0	< 0.0001
With signs of aseptic loosening	1	0	0.5985
Revised for loosening of implant	1	0	

pre operatively to reach as close as possible the longest survival of the implant. But in some cases, the planification can be sufficient, and the local bone quality may be softer than expected [16]. This observation is found in our daily practice at the time of the proximal tibial cut or during the preparation of the tibial base plate. This condition, may appear without preoperative diagnosis of clinical risk factors or osteoporosis. Primary implant fixation to avoid aseptic loosening can be crucial for good outcome in total knee arthroplasty [17]. Despite of potentially being the same intervention, patient's surgical and mechanical factors can be very different. These parameters can change the outcome for patient, surgeon and implant.

Is this study, the authors used an anatomical implant known to be an implant with an optimal epiphyseal coverage and a greater metaphyseal surface of contact by the squared keel. This implant compared to a conventional design, offers a better survival rate, reducing the rate of ALL [15].

Despite this improvement, previous studies, do not show a decrease of RLLs, being present in approximatively 20% of the prosthetic population [15].

Previous studies, have described types of RLLs depending of the time of apparition, localization, aspect, evolution, etc. and have found that RLLs are different from AL [3]. Authors have demonstrated that RLLs are due to micromotion at the epiphyseal level, as observed in RSA studies [18]. Moreover, in case of poor bone quality or big correction, micromotion can evolve to macromotion of the implant, with apparition of predictive sign of loosening [3].

In this study, the senior surgeon found 71 knees (22% of patients) with a proximal softer epiphyseal bone during the surgery, and decided to add a stubby stem in those patients, in order to increase the surface of contact between the implant and the bone. The results show that the group of patients with a stubby stem, show no case of RLLs testifying of the absence of micromotion at the epiphyseal level.

Radiolucent lines have often been considered as a proxy for aseptic loosening. In previous studies, authors have described the frequency of RLLs (23%) and the different types of RLLs, as well as the radiological signs of aseptic loosening [3]. They described isolated RLLs that can be seen either at the medial (70%) or lateral (30%) side of the tibial implant, mostly corresponding to the concave side of the deformity. The authors also described combined RLLs that would be present on both sides of the implant from the start (9%) and sequential RLLs that would start on one side of the implant and progressively develop on the other side (4%). These type of RLLs could behave badly and should be followed-up. Moreover, they described radiological signs of aseptic loosening as RLLs around the keel of the tibial implant, as metaphyseal densification and epiphyseal bone apposition and finally by progressive increases in deformity as measured by postoperative HKA-angle increases. In the present study, the implant without stem presented with the same occurrence of RLLs (21%) as previously described, however the study group with stem presented no RLLs. This finding suggests that RLLs observed on radiographs could be a proxy for micro-motion of the implant, without necessarily being a sign of aseptic loosening. This micromotion at the epiphyseal level and therefore also the RLL observation can be reduced by the introduction of a two-zone fixation with a metaphyseal short stem extension.

In the present study, adding a short stem extension also confirmed the absence of radiological signs of aseptic loosening and the need for revision, but more interestingly lead also to a reduction of the RLLs to 0%. In the absence of RLLs none of the study patients were revised in- or out-house, this in contrast to the group without stem where one patient was revised in the presence of an isolated medial RLL.

This finding suggests that the "bone-implant" surface of contact, increased by the stem at the metaphyseal level will impact micromotion observed at the epiphyseal level. This aligns with previous studies about the same anatomical implant [19–25].

In this study, the choice to add a stubby stem or not was made by the senior surgeon depending on the local bone quality. This was evaluated during surgery by the "thumb resistance test" of the bone exposed after the proximal tibial cut.

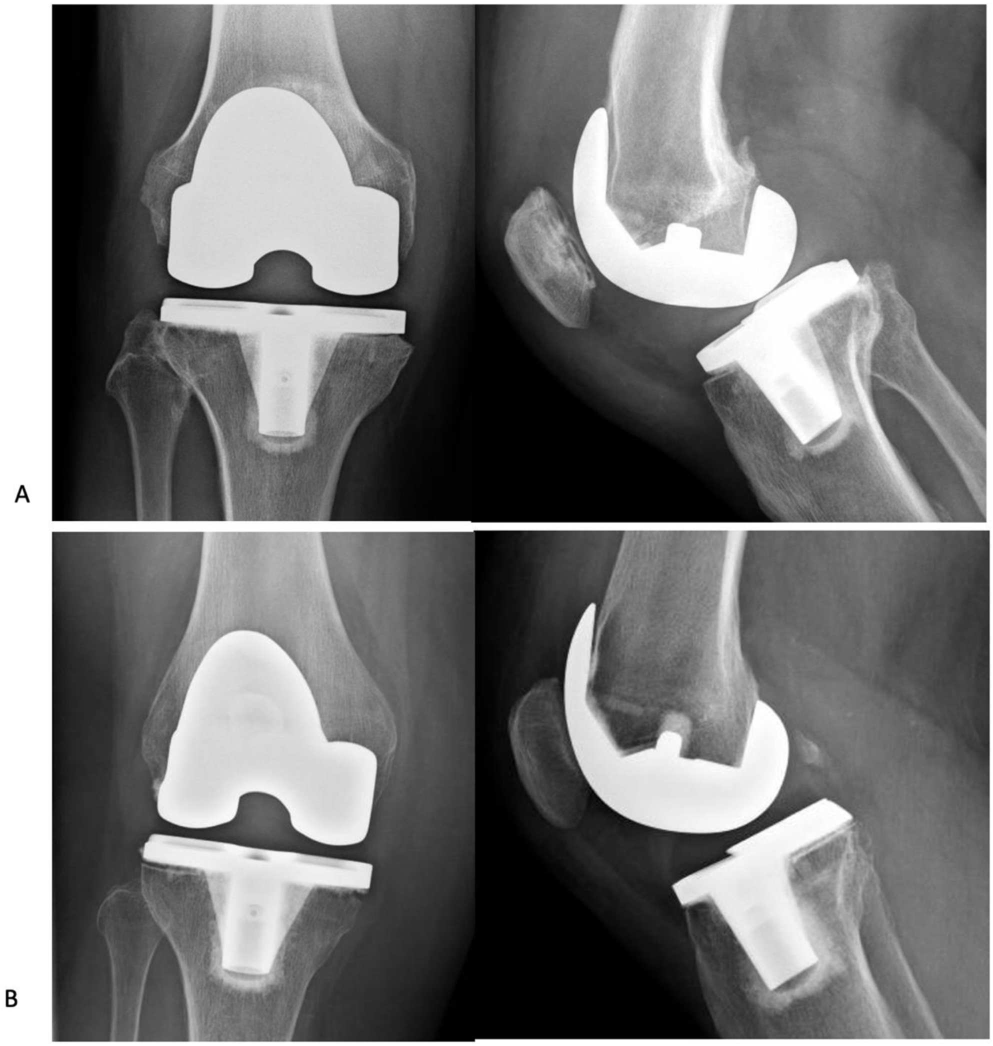

Fig. 2 Post-operative X-rays of Persona implant without stubby stem ***a*** Persona implant with Isolated RLL ***b*** Persona implant with Combined RLLs

Table 3 Demographics and mechanical data of patients in the group of Persona with RLLs and the group of Persona with stubby stem

Variables	Persona with RLLs	Persona with stem	*P*
Number of patients with RLLs	53/255	0/71*	<0.0001*
Demographic data			
Age (years)	68 ± 11	73 ± 9 *	0.052*
Gender female/male ratio	2/1	5/1*	0.0084*
BMI (kg/m2)	31 ± 7	29 ± 5	0.1761
Clinical risk factors for osteoporosis per patient (proportion)	32/53 (0.60)	44/71 (0.62)	0.8583
Mechanical data (degrees)			
Pre-operative angle			
Varus (64%)	174 ± 4	173 ± 4	0.5424
Valgus (36%)	188 ± 5	188 ± 5	0.7445
Post-operative angle			
Varus (77%)	179 ± 2	178 ± 2	0.9457
Valgus (23%)	183 ± 2	182 ± 1	0.2404

Values expressed as Means ± SD; * significant value

Table 4 Demographics, mechanical and implant size characteristics in Persona group with stubby stem

Variables	Male	Female	*P* value
Number of patients	12	59	< 0.0001*
Demographic data			
Age (years)	68 ± 11	75 ± 9*	0.0040*
BMI (kg/m2)	31 ± 7	29 ± 5	0.1559
Amount of clinical risk factors per patient (proportion)	9/12 (0.75)	51/59 (0.86)	0.2280
Mechanical data (degrees)			
Pre-operative angle			
Varus (64%)	171 ± 5	173 ± 4	0.2728
Valgus (36%)	188 ± 1	185 ± 1	0.1766
Post-operative angle			
Varus (77%)	178 ± 1	178 ± 2	0.5427
Valgus (23%)	183 ± 2	182 ± 1	0.1127
Implant size			
Polyethylene (mm)	12 ± 1	10 ± 1*	0.0058*
Tibial base plate (mm)	75 ± 3	70 ± 4*	< 0.0001*

RSA studies? biological bone markers or BMD analysis could be influenced by the stage of OA, BMI, global bone resorption (including bone metastasis), hip or vertebral pathologies and don't necessarily reflect the local bone quality, because of the intrinsic multiple factors between the global bone architecture and predisposing factors (diseases, BMI, surgery, etc.) [24].

Jin et al. had however shown that an additional stem did not show any difference compared to standard implants, in an in vitro study [6]. The limitation of an in vitro study is that it cannot consider the impact of the quality of the bone under the implant and the evolution of the quality of this bone over time, especially in elderly women [26]. Gallo et al. described in a study about osteolysis in knee arthroplasty the combination of biological (bone modification after surgery and reaction to wear particles) and mechanical factors (alignment and stress resistance), both contributing to late loosening. He described the importance of the design of the implant, the quality of the polyethylene, the overall alignment of the limb and the activity levels of the patient [27].

In the present study, the authors confirm by their results that a morphometric implant without a stem leads rarely to aseptic loosening and that adding a short stem extension reduces RLLs to 0%, even in patients with biological and mechanical risk factors for optimal tibial fixation [28]. The biomechanical explanation, is that stemmed tibial components increase the mechanical stability and allow for a more physiological load distribution with a reduction of 60% of strain in the proximal tibia [26]. It decreases stresses at the cement mantle (compressive stress) by 136% and shear force by 92%, as the stem transfer loads more distally, hence decreases the stress on the proximal metaphyseal region [26, 28, 29]. A stubby stem is therefore key, to obtain a better strain repartition by augmenting the bone contact of the implant and reduce tibial toggling [17].

Retrospectively, the authors identified two different demographic profiles of patients in the group of Persona TKA with a short stem: young men with important preoperative deformities and elderly women with clinical risk factors for osteoporosis. This observation shows the bias of the surgeon who decided to stem or not, because these conditions are well documented in the literature as being major risk factors for loosening of the implant. Radiographical studies of the coronal alignment and surgical planning of the different osteotomy levels during TKA was always done in the department. Therefore, the knowledge about the need for a stem in case some extra-articular deformity would not be corrected or the level of resection would be low on the tibia was available. However, the retrospective observation of the presence of several clinical risk factors for osteoporosis, not individually known to the surgeon during the procedure, shows well that the quality of the epiphyseal bone observed during surgery, corresponds to the overall bone quality and the risk for osteoporosis. BMI didn't appear to be different in between both groups in the present study. Stemmed implants have already shown their efficacy in obese patients, in the presence of high pre-operative deformities [17, 28–30] and for elderly women with osteoporosis [26]. The same efficacy was observed in this study with 100% survivorship at short-term follow-up (5 years). In this study, the authors found a significant difference in PE size in the group with a short stem between men and women. In the case of an important pre-operative deformity, the need for a lower tibial cut can lead to the use of a thicker PE, which is a well-known risk factor to increase revision rates in TKA [31, 32]. Rajamaki et al. suggested therefore to use constrained knee designs in order to decrease the failure rate [31]. In the present study, there were no implant failures nor revisions, suggesting that a morphometric knee design in the presence of a stubby stem can decrease the risk of failure without increased constraint. This statement is only true if the knee is well balanced by an experienced knee surgeon.

Literature reports that the ideal size for a stem extension, is between 30 and 50 mm maximum, to prevent impingement with the tibial cortical bone. This corresponds to the stem length used in the studied implant since fixation in primary knee remains usually limited to the metaphyseal area of the proximal tibia, without diaphyseal engagement [17, 30, 33]. Surgeons aiming for kinematic alignment will have to plan their surgeries to avoid lateral cortical impingement when correcting bigger deformities needing lower tibial cuts or higher varus medial proximal tibia (MPT)-angles asking for more joint line obliquity.

This study has several limitations. Firstly, it is a retrospective study without the possibility to randomize usage of the short, stubby stem and observe the rate of RLL or aseptic loosening in two comparable patient groups. Secondly, the choice to add a stem was based on the surgeon's peroperative evaluation of the epiphyseal bone quality and not on a clinical pre-operative diagnosis. It will be interesting for further studies to prospectively identify patients preoperatively who might be in need for a stubby stem extension. According to this study and with survivorship as proxy for the right peroperative choices made, elderly osteoporotic women and younger males with big deformity correction could benefit from stubby stem usage. It might also be interesting to develop a device that measures the epiphyseal bone quality during surgery, helping the decision to use a stem or not. Thirdly, the total number of patients with a stubby stem included in this study was clearly smaller, but a substantial difference in the rate of tibial RLLs was observed (21% vs. 0%), leading to a statistical difference. Finally, this study is about only one implant design. It will be interesting to study the recent findings of these authors for other morphometric or symmetrical knee designs.

Conclusion

Local bone quality during TKA may be of lower quality than expected in some patients, despite a well-planned surgery, due to multiple factors, leading to a higher risk of poor bone-implant fixation.

The usage of a short, stubby stem extension in primary TKA seems to reduce micro- and macro-motion of an implant observed radiologically as a reduced occurrence of radiolucent lines.

Improved fixation in at least two zones of the proximal tibia reduces the rate of aseptic loosening in patients at risk with correction of important deformities or severe osteoporosis leading to excellent survivorship.

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Declarations

Ethical approval All investigations are conformed to the Declaration of Helsinki and are approved by the ethical committee of Comité Ethique Hospitalo-Facultaire Saint-Luc-UCL: 2017/10MAI/262.

Conflict of interest One Author (DW) declares no conflict of interest in regard to this work. One Author (ET) reports conflicts of interest according to his ICMJE declaration.

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