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KNEE REVISION SURGERY

Sagittal profile has a significant impact on the explantability of well-fixed cemented stems in revision knee arthroplasty: a biomechanical comparison study of five established knee implant models

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Abstract

Background Easy revisability is gaining increasingly in importance. The removal of well-fixed cemented stems is very demanding and is often associated with increased operative morbidity. Implant design may be here a decisive impact factor, and the best way to ascertain it is experimentally. Aim of this study is to assess different cemented stems of established knee revision implants in regard to their removal capability.

Methods Based on their sagittal profile, five stem extensions from known manufacturers were divided in conical, conical–cylindrical and cylindrical designs. The pedicles were also characterized in respect to their cross section, diameter and surface roughness. The cemented stems were dismounted six times each in a reproducible biomechanical setup. The explantation energy required was determined and statistical analyzed.

Results The conical shaft needed significantly the slightest explantation energy with 19.2 joules ($p=0.004$). There was a strong negative linear correlation between conicity proportion and explantation energy of the cemented stems ($R^2=0.983$). The removal of the three purely cylindrical shafts—regardless of their differences in diameter, cross-sectional design and surface– was the most demanding (98.3, 105, and 116.7 joules) with only secondary differences between them.

Conclusion The longitudinal stem profile may have a primary impact on the explantability of well-fixed cemented shafts with conical designs showing superiority. Cross-sectional profile and surface roughness had here a less decisive influence on the explantability. Surgeons can choose proper implants and removal techniques depending on potential implant-associated revision risks and re-revisions to be expected.

Keywords Total knee arthroplasty · Revision · Explantation · Implant removal · Cemented stems · Stem design · Conical stems · Stem conicity · Complications

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Introduction

While the primary knee arthroplasty (PKA) together with its increasing demands still remains the gold standard of the surgical treatment of the gonarthrosis [1], literature and register data have definitely shown that the revision knee arthroplasty (RKA) is over the last few years on the march [2–7].

Although new generation implants, optimized surgical approaches and perioperative management in the endoprosthetics have improved the treatment status, the results of RKA are, moreover, limited [8], as the complication rates compared to PKA are still very high [9–15].

In spite of all efforts made, the rate of periprosthetic infections (PPI) lies around 17–19% showing increasing tendency [4, 16]. The overall re-revision rates after septic or aseptic primary revision stand approximately at 30% [17–20] with arthrofibrosis (23%) and PPI (21%) being the most frequent causes after a first aseptic revision [21]. These conditions are often associated with well-fixed joint prostheses. Consequently more and more freshly cemented and possibly non-loosened prosthesis must be removed.

Interestingly, intraoperative fracture risk in RKA is about six- to tenfold higher than in PKA, while 17% occur during implant explantation [9, 12–14].

Evidence suggests that cemented stems offer a more harmonic stress distribution along the stem, and therefore, less micromotions metaphyseal and lower peak pressure values at the stem tip compared to cementless fixation techniques [22–27]. In addition, the use of antibiotic-loaded bone cements in aseptic RKA lowers the risk of re-revision by half, according to recent literature [28]. Therefore, due also to satisfying long-term clinical outcomes, cemented stems are favoured by a variety of authors [29–34].

In front of such considerations, it is essential that a careful and bone sparing treatment during exchange arthroplasty is ensured. Hence, implants with comparable durability and an easier revisability are preferable. That is why long-stem cemented endoprostheses in spite of their outstanding survivor rates are seen critical by some authors [24, 35–40].

There is, however, hardly up to now in the literature any data available involving implant-associated factors in relation with revisability in RKA, although practical experience does show that there are here in fact various product-specific differences in it. Micro- and macrostructural properties of successful implants noted in the registers can considerably differ depending on the manufacturer (Table 1). Nonetheless, concerning particularly the biomechanical role of stem design in the explantability of well-fixed cemented implants little information exist. In a recent preliminary examination that used the same biomechanical setup as the current study, cemented conical stems with a cone angle of at least 0.5° proved to be significant easier to remove ($p < 0.001$) compared to cylindrical ones [41]. However, comparative data

Table 1 Implant characteristics of the original shaft components of different revision knee systems tested

No.	Model	Material	Surface roughness (Ra)[a] (μm)	Surface appearance[b]	Macro design
1	Endo-Model SL, LINK	CoCrMo	1.6	Matte	Straight, 2° conical shaft (100% conicity), cross section: round with 3 plane surfaces each offset 120°, L 130 mm, Ø 14/10 mm
2	MUTARS®, Implantcast	CoCrMo	1.45[c]	Matte	Straight, 2° conical 1/3 proximal and cylindrical 2/3 distal, cross section: round, 2 longitudinal grooves in the cylindrical portion each offset 180°, size: L 160 mm, Ø 13 mm
3	NexGen, LCCK, Zimmer	Titanium (TiAi6V4)	1.6	Matte	Straight, cylindrical shaft, cross section: round, 9 longitudinal fins (sharp fluted stem), size: L 130 mm, Ø 14 mm
4	P.F.C. SIGMA, TC3, DePuy/Synthes	Titanium (TiAi6V)	0.45	Satin	Straight, cylindrical shaft, cross section: round, 8 longitudinal fins, size: L115 mm, Ø12 mm
5	NexGen, RH, Zimmer	Titanium (TiAi6V4)	0.25	Smooth	Straight, cylindrical shaft, cross section: round, 4 longitudinal, semi-circular grooves each offset 90° (straight stem-smooth), size: L 100 mm, Ø 15 mm

L length; *Ø* diameter; *Ra* average surface roughness

[a]Ra values according to manufacture

[b]According to classification by Crowninshield et al. [43]

[c]With possible roughness variations depending on the final blast process during implant manufacturing

involving analysis of different original implants appear to be missing.

Aim of the current study was, therefore, to compare the explantability of five well-fixed cemented renowned revision knee prostheses available on the market and to analyze the influence of some main implant design properties they have, such as the sagittal profile (conicity), the cross-sectional design as well as the surface roughness on the debonding process of implant–cement interface (ICI).

Materials and methods

Five shaft extensions of established RKA models taken from four different manufacturers were included in the current study (shaft 1: *Endo-Model SL, LINK;* shaft 2: *MUTARS® Revision Knee System, ImplantCast;* shaft 3: *NexGen LCCK Revision Knee System, Zimmer;* shaft 4: *P.F.C. SIGMA TC3 Revision Knee System, DePuy;* and shaft 5: *NexGen RH Revision Knee System, Zimmer*). The implant design characteristics of each RKA model are presented in a tabular overview below (Table 1). Aim of the study was on above original components to biomechanically analyze the impact of three design properties: (1) sagittal profile (conicity), (2) cross-sectional design (geometry and diameter) and (3) the surface roughness (Ra in µm) on the stem explantation, after these have been well-fixed cemented. Each sagittal profile was defined in terms of percentage proportion of conicity in relation to the entire stem length. Shaft 1 had a pure conical profile with 100% conicity, shaft 2 a conical–cylindrical profile with 25% conicity proximal and shaft 3 a pure cylindrical profile with 0% conicity. These three stems had otherwise equal diameter (range ø 13–14 mm) and surface roughness (Ra range 1.45–1.6 µm). Shafts 3, 4, and 5 were pure cylindrical implants that possessed obvious differences in surface roughness and cross-sectional design (geometry and diameter). All five stems had a straight sagittal axis. The material of stems 1 and 2 was CoCrMo and of 3, 4, and 5 was titanium (Fig. 1).

The explantability of each stem tested was evaluated in terms of explantation energy (EE) required until implants were completely removed.

To determine the sample size for this biomechanical study power analysis (g*power 3.1.) was performed. For an effect size of 2.0, an alpha error of 0.05 and a power of 0.85 a number of $n = 6$ test replications for each stem design was sufficient to achieve statistical significance.

The explantation test was performed for each cemented stem 6 times in a reproducible biomechanical setup, which has been described in detail in a preliminary investigation [41]. Each stem was brought into a metal tube and was cemented at a same depth of exact 100 mm. Three screws were introduced as barbs along the side in the metal tube

Fig. 1 Sagittal profile and cross section of the five stem extensions enclosed in this study: Stems 1, 2, and 3 possess different sagittal profile (conicity proportion); Stems 3, 4, and 5 are pure cylindrical shafts with differences in diameter, cross section and surface roughness. The transparent green space framed by dashed lines corresponds to the cemented depth of 100 mm that was maintained the same in all cases. The red dashed line depicts the level of cross-sectional images. Shaft 2 has a steel cylinder welded onto it, which was used for the fixation of the extraction instrument

into the hardening cement to prevent any failure of the cement–metal tube interface, as main focus of the study was given on the ICI reactions only.

The metal tube consisted of steel, was 190 mm long and exhibited an outside diameter of 25 mm, and an inside diameter of 21 mm. As extraction instrument, a 150 cm long and 2 kg (2.060 g) heavy metal rod with a 2 kg (1.930 g) heavy slot weight of steel was used. The metal rod of the extraction instrument could be screwed tightly via a 1 cm-long M8 thread onto the backside of the shaft component to be tested (Fig. 2a–c).

For each explantation test, a set of 80 g PMMA bone cement (*PALACOS® Heraeus Medical*) and a Vacuum Mixing system (*PALAMIX® Heraeus Medical)* were used. The process of mixing and application of the cement was carried out strictly according to the manufacturer's directions. The filling of each tube with cement was performed by *"gun pressurization*" in retrograde technique. The metal tube was clamped vertically to the worktable by a rigid fixation device

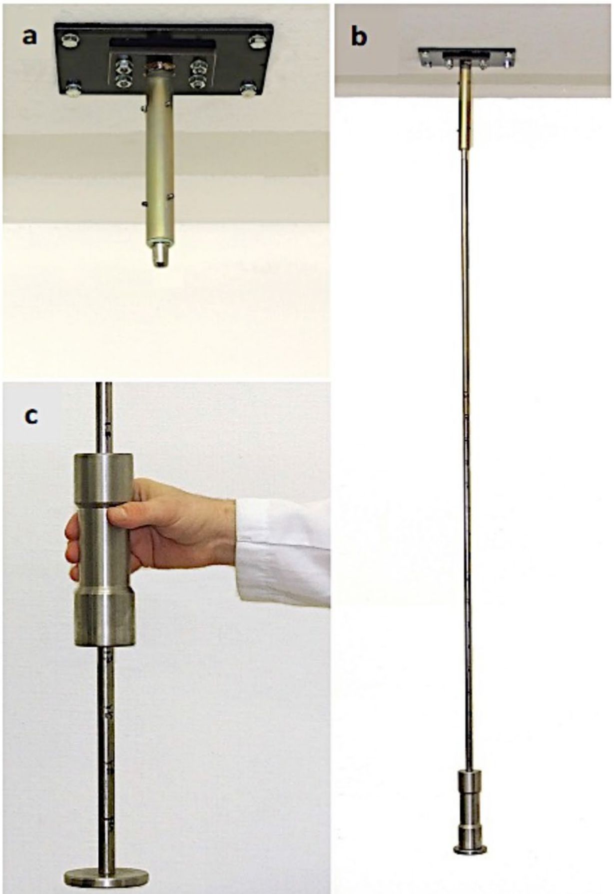

Fig. 2 **a** Vertical fixation of the metal tube to the ceiling of the investigation room in an inverted direction pointing towards the floor. **b** Collinear order of the whole biomechanical apparatus, with the extraction instrument fixed onto the base of the cemented stem pointing vertically towards the floor as an extension of the stem axis. **c** Slotted weight was dropped in the axial direction from the specified height marked on the side of the bar, before descending to the impact point

forming an abutment system. This way no cement leakage and a backpressure effect could occur while forcing cement inside the tube. After placing the stem centrally in the tube superfluous cement was cut away via scalpel.

Using an integrated metal screw plate as basis, the metal tube with the shaft cemented in it, was first inverted and then fixed to the ceiling, pointing vertically towards the floor. The extraction instrument was screwed onto the cemented shaft that was well-fixed in the metal tube, so that the slotted weight could drop by gravity in the same vertical axis with that of the stem being examined (Fig. 2a, b).

During the explantation phase, the investigator let the 2 kg slotted weight drop down to the impact point of the bar from a given height, which was marked on the side of the rod (Fig. 2c). The interval between each of the marks comprised 5 cm. Thus, beginning with a 5 cm height, the slotted

Table 2 Explantation energy of the five shafts tested in joule

Shaft no.	*N*	Maximum	Minimum	Mean	Standard deviation
Shaft 1	6	10.0	35.0	19.2	9.2
Shaft 2	6	45.0	105.0	80.8	26.9
Shaft 3	6	105.0	130.0	116.7	11.3
Shaft 4	6	75.0	135.0	105.0	26.8
Shaft 5	6	75.0	115.0	98.3	14.0

weight was dropped axially and parallel to the shaft axis. If that did not result in any implant loosening, the height of drop was then increased by another 5 cm. This process was repeated so often, until it gave way to an entire detachment of the stem from the cement coat. The highest and last drop, which did lead to a complete shaft explantation was then noted and used later for the calculation of the EE (*potential energy* $= m\ g\ h$).

The results of these experiments were analyzed by means of the statistics software package *IBM SPSS Statistics version 19*. All results were expressed as average values ± SD. For evaluating any significant differences ($p < 0.05$) seen in the EE among the five tested shafts—and therefore, any comparisons of the independent groups here—the non-parametric Mann–Whitney *U* test was employed, as a non-normal distribution of the collective could be identified by the Shapiro–Wilk test. Regression analysis was performed to analyze potential correlations between conicity of sagittal profile and EE of the cemented stems tested.

Results

The results of required EE after all tests for each stem are summarized in Table 2. The EE of shaft 1 with purely conical profile (19.17 ± 9.2 joules) was significantly less than of all other stem designs ($p = 0.004$). The three purely cylindrical stems (shafts 3, 4, and 5) had to do with the highest energy levels (106.7 ± 17.4 joules) independent from other implant characteristics, while the stem with the conical–cylindrical profile lay between those two implant designs (80.8 ± 26.9 joules).

Comparing the first three stems 1, 2, and 3 (Fig. 1) that had different sagittal conicity profiles (100%, 25%, and 0%, respectively) but otherwise equal surface roughness and diameter the regression analysis revealed a strong negative linear correlation between conicity proportion of sagittal stem profile and explantation energy ($R^2 = 0.983$), as depicted in diagram (Fig. 3).

The pure cylindrical stems 3, 4, and 5 (Fig. 1) presented only small EE differences between them, as depicted in bar diagram (Fig. 4). A solely significance ($p = 0.04$) found

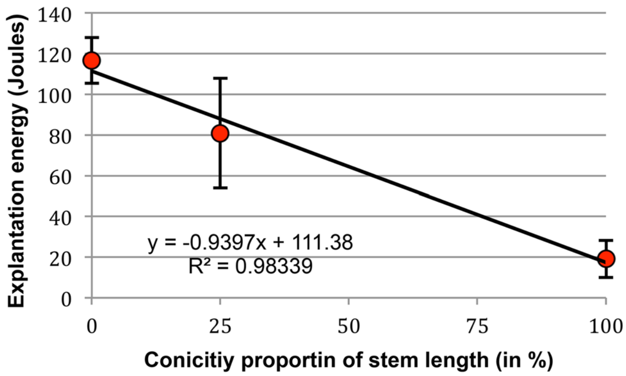

Fig. 3 Correlation chart between explantation energy and percentage conicity proportion of the entire stem length of the cemented stems tested. A strong linear correlation with less energy demands towards increasing conicity of sagittal stem profile is here illustrated ($R^2 = 0.983$)

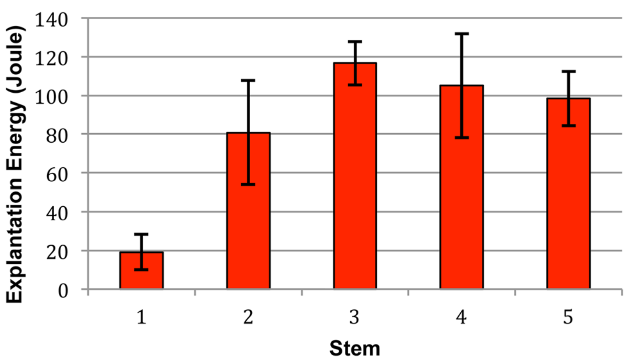

Fig. 4 Bar chart: distribution of the explantation energy for each of the five implants tested

between the matte shaft 3 with the highest EE of all implants tested (116.7 joules) and the smooth shaft 5 with EE 98.3 joules may be explained by their great differences in surface roughness (Ra 1.6 µm–0.25 µm, respectively), as their cemented surfaces in length and diameter were similar (ø 14 mm, L 100 mm and ø15 mm, L 100 mm respectively). Further pairwise comparisons of the other implant features (cross-sectional design or diameter) within the three pure cylindrical stems did not reveal any significant differences in terms of EE (Fig. 4).

Discussion

Main result of the current study is that the 2° pure conical stem 1 (Endo-Model SL, LINK) could be significantly easier removed from the surrounding cement coat than all other stems tested ($p = 0.004$). Furthermore, there was a strong negative linear correlation ($R^2 = 0.983$) between the conicity proportion of the entire stem length and the required EE of the first three well-fixed cemented stems here tested. The other implant properties tested such as the cross-sectional diameter and geometry and the surface roughness had in comparison with conical profile only a secondary and immeasurable effect on the EE of these cemented stems. Hence, based on the results illustrated in this study, it can be postulated that the sagittal stem profile seems to have proportional to its ratio of conicity a primary impact on the detachment of the ICI during explantation procedures of well-fixed cemented RKA long stems.

We could evidence that the pure conical stem 1 was associated with significantly less EE than all other stem designs included (19.17 ± 9.2 joules, $p = 0.004$), while all cylindrical stems here revealed the highest EE levels (Table 2).

According to our knowledge and clinical experience, although there is no evidence suggesting the superiority of a certain sagittal stem profile (conical vs. cylindrical) in terms of improved implant functioning and survival rates, we have often experienced an easier and tissue-friendlier revisability of well-fixed cemented stems that have conical designs. Many cylindrical cemented shafts that are still well-fixed during revision, cannot be removed without major bone loss or selective cortical fenestration. Against this backdrop, implants with comparable durability and less invasiveness during revisions have a decisive advantage.

It is only recently that data have been collected for the first time on the superiority of a certain stem design involving cemented explantation. In a recent preliminary investigation that used the same biomechanical setup as the current study, aim was given to test the effect of different conical angles of cemented smooth shafts on the debonding process of ICI. It could be shown that conical shafts with a profile angle of at least 0.5° can be explanted significantly easier than cylindrical ones [41]. However, up to now, no comparative data existed concerning the explantability of different original RKA stems in relation with their design.

The findings of our study agree not only to the results of the mentioned publication [41], but could further determine a significant impact of the conicity proportion of stem length on the explantability of cemented RKA stems by revealing a negative linear correlation between them ($R^2 = 0.983$). Whereas for the loosening of a conical stem at ICI only few millimeters implant displacement are sufficient, for the explantation of a well-fixed cemented cylindrical stem more detaching loads are required, until the implant to its full length is loosen from the cement coat. Therefore, the bigger the contact and friction area of a cylindrical stem on the cement the higher the EE needed to completely remove the implant.

Although the results of this study regarding the sagittal profile were significant, this could not be confirmed for the other tested implant properties, as they were not very conclusive. The contact area size (diameter and cross-sectional design) and surface roughness showed here only a minor impact compared to stem conicity on the ICI detachment and the required EE.

Comparing the cylindrical shafts, stem 5 possessed the biggest diameter of all with 3 mm and 1 mm differences to shafts 4 and 3, respectively. However, its polished-smooth surface hat also the lowest Ra value with 0.20 µm and 1.35 µm differences to the satin and matte surfaces of shafts 4 and 3, respectively. Shaft 5 revealed the lowest EE compared to the other cylindrical stems (Table 2), which depicts the impact of surface roughness on the EE of cemented stems. Our results correspond to the literature as cement adhesion and abrasion properties can defer between various surface roughness values of cemented implants and the forces required to induce micromotions within the ICI are greater of a rough than a smooth stem surface [42, 43].

Cross-sectional design is an important implant characteristic especially in cases of press-fit fixation that contribute to improve stability against increasing bending and rotational moments associated with daily activities such as walking, climbing stairs, or standing-ups [44, 45]. In the current study, cross section of the cemented stems tested here reveled no significant resistance against axial loads like the ones usually induced intraoperatively during implant removal procedures. Therefore, we assume that transverse geometry by equal contact surface has only a minor influence on the detachment of ICI through axial pull loads. Concerning the impact of stem diameter on EE, it was difficult to define, as there was no matching pair of stems with otherwise similar sagittal profile and roughness to compare. In our idealized biomechanical setup, the integrated extraction system induced axial pull forces that were in a collinear order with the stem axis. This reflects to commonly used surgical approaches during implant removal, where in an equal manner axial pull loads via extraction instruments (e.g., slap hammer) are used to remove implants. However, there are still some differences in design or fixation mechanisms of extraction instruments and thus, in load transfer between femoral and tibial stem removal. Considering this fact, possible deviations or offsets between pull-out forces and stem axis can cause in clinical praxis a momentum that may have an additional effect on the EE.

Although loosening of RKA implants commonly occurs at the cement–bone interface (CBI), main focus of the study was to analyze the impact of implant design on the failure of ICI and not that of CBI during removal of well-fixed cemented RKA stems. As praxis shows that high extraction manoeuvre can endanger the surrounding bone integrity during removal of well-fixed implants, CBI should be treated with specialized tools in a separate step after extraction of the stem, to avoid unnecessary bone losses [46, 47]. The discrepancy between the cement–metal tube interface of the experimental environment and the cement–bone interface of the reality faced intraoperatively may be a further variation factor of the overall EE needed.

Three failure patterns of the cement coat during explantation of cemented shafts have been described in a preliminary investigation using the same biomechanical setup as here [41]. In the present study, only two failure patterns could be observed: Either the stems loosened themselves from an intact and firmly attached on metal tube cement coat ($n = 23$), or they became loosened from a broken cement coat on the level of crew insertions, which remained proportionately in both the stem and the metal tube ($n = 7$). The 6 out of 7 malfunctioning probes occurred explicit during the explantation of the 3th ($n = 3$) and 4th cylindrical stem ($n = 3$), which reflects the high demands of explanation energy needed. Since, however, our intent was to strictly test only the implant explantability (loosening of the stem from the well-fixed cement coat) and not any debonding effects of the cement–metal tube interface, all of the 7 cases described above were repeated, until here the first failure pattern appeared.

A further goal of this study was to represent results that reflect to reality by comparing original components from different manufactures that are commonly used in RKA. A drawback here was the inclusion of various implant properties to analyze the differences of EE, as they may present possible biases. However, to improve sample homogeneity two test groups were created to compare similar implant properties: The stems 1, 2, and 3 of the first group possessed different sagittal profiles with otherwise equal surface roughness and diameter (ø 13–14 mm). According to a classification of surface roughness based on Ra values in µm [43], all stems of the first group were characterized as equal with a matte surface (Ra range 1.45–1.6 µm). In the second group, only pure cylindrical stems (shafts 3, 4, and 5) were included to test their differences in diameter and surface roughness.

Another limitation could be the small sample size and number of test replications for each stem, whereby power analysis could characterize both of them as sufficient enough for achieving statistical significance.

Conclusion

The 2° conical shaft 1 induces a significantly and reproducible better explantation than the other models tested (19.17 ± 9.2 joules, $p = 0.004$). Conical profile may thus have a higher impact on the ICI detachment of well-fixed stems during removal procedures than other implant properties, such as diameter, cross-sectional design, or surface roughness.

Hence, not only the cone angle, but also the conicity proportion of stem length have a significant influence on the explantability of cemented RKA stems that are still not loosen during surgery.

The data presented in this work enable attending physicians to estimate the potential ease of well-fixed cemented stem explantation and the associated morbidity in RKA. While conical cemented shafts can be in most cases easily removed, an early decision for a cortical fenestration may be the best solution when dealing with the removal of well-fixed cylindrical stems. Surgeons can now choose proper implants and removal techniques depending on potential implant-associated risks and the possibility of expected re-revisions.

Clinical trials could provide important information for further understanding the impact of sagittal stem profile on the revision morbidity and the overall survivorship of the RKA implants.

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Compliance with ethical standards

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