

**Instruments to reduce the risk of tibial fracture
following cementless unicompartmental knee
replacement.**

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Word count: 3228

ABSTRACT

Background: Tibial plateau fracture is an important complication of Cementless Oxford Unicompartamental Knee Replacement. The press fit between the keel and the bone's keel slot is responsible for primary fixation and also contributes to fracture risk. This study investigates whether the fracture risk could be reduced without compromising primary fixation, by using different instruments to widen the keel slot.

Methods: Keel slots were made in polyurethane blocks (n=60) using the standard keel cut saw blade or a new blade that was 0.2mm wider, with adjuvant use of the cemented pick or a prototype rasp. A tibial component was pushed into and pulled out of the slots using a Dartec materials testing machine. It was assumed that the 'push-in' force was related to the risk of fracture and 'pull-out' force was related to fixation. Reproducibility studies with 10 different tibial components were undertaken.

Results: The new blade required significantly lower push-in forces than the standard blade (789N SD130, 1411N SD180; $p<0.001$), but the pull-out forces were not different (240N SD47, 230N SD56; $p>0.999$). With the standard blade the pick decreased the push-in (818N SD318; $p<0.001$) and pull-out (128N SD58; $p<0.001$) forces, but the rasp had no effect. With the new blade the pick had no effect, but the rasp increased the push-in force (1390N SD202; $p<0.001$).

Conclusions: This study suggests the fracture risk will be reduced with the new blades, with no compromise in fixation. If the new blades are used the pick and rasp have no benefit.

Key words: *Fixation, Fracture, Interference, Unicompartamental knee replacement*

Abstract word count: 247 words

1. INTRODUCTION

Unicompartmental Knee Replacement (UKR) is an effective treatment for end stage knee osteoarthritis with advantages over total knee replacement (TKR) including faster recovery, fewer complications, superior patient reported outcomes and reduced mortality [1]. UKR does however have a higher revision rate. This is primarily due to a lower threshold for revision, which may in part relate to misinterpretation of radiolucent lines that are commonly seen around UKR. The cementless Oxford UKR has been shown to have a much lower incidence of radiolucent lines than the cemented, suggestive of improved fixation [2]. In the New Zealand Joint Registry the cementless Oxford UKR has a 96% 10-year survival which is better than that of the cementless Oxford UKR and is similar to that achieved by TKR [3].

The cemented and cementless OUKR components are similar except that the surfaces of cementless components in contact with bone are coated with porous titanium and hydroxyapatite to encourage bony ingrowth [4, 5]. Primary fixation is dependent upon an interference fit between the prosthetic components and bony surfaces. For the tibial component this is achieved by a keel which fits into a keel slot, prepared in the tibia, with a specially designed keel cut saw blade (Fig 1).

Tibial plateau fracture is an important complication of UKR that usually presents in the early post-operative period. Although the published incidence of tibial plateau fracture after cementless OUKR is low (1% or less), we are aware of a number of anecdotal reports of some surgeons having a higher incidence [6-9]. The incidence with cementless fixation is higher than cemented and a cadaveric study has shown that lower loads are required to fracture the tibial plateau with cementless compared to cemented implants [10]. As the preparation of the tibia is the same with cemented and cementless fixation, it is likely that the higher incidence of fracture

with the cementless is due, in part, to the interference fit between the keel and the keel slot. Impaction of the keel within the walls of the slot probably causes a ‘splitting’ force in the tibia which may initiate a crack at the time of surgery. In the early post-operative period this crack may propagate resulting in a fracture.

Campi et al [11] studied, in plastic bones, the relationship between interference, defined as the difference in thickness between the keel and keel slot, and the forces required to “push-in” and “pull-out” the component. It was assumed that the maximum “push-in” force, which causes the ‘splitting’ force in the tibia, was related to the risk of fracture and the maximum “pull-out” force was related to the primary fixation. Although overall both “push-in” and “pull-out” force increased with increasing interference, the relationships were non-linear and there was an optimal window with relatively low “push-in” force and high “pull-out” force. This optimal primary interference was less than that achieved using conventional instrumentation. This suggests that if the slot was widened slightly, thereby decreasing the interference, the fracture risk might be decreased without compromising the primary fixation. Options to slightly widen the slot, which have been used by different surgeons, include the use of a pick, which was originally designed for cemented fixation, a rasp, or a new saw blade (Fig 1). The advantages and disadvantages of these options has not previously been studied.

The aim of this plastic bone study was to determine which of the various instrumentation options for preparing the keel slot for the cementless OUKR tibial component was most effective in reducing the risk of fracture without compromising primary fixation.

2. MATERIALS AND METHODS

The keel slot in the tibia is prepared with a keel cut saw blade, which has two parallel blades (Standard blade, ZimmerBiomet, Fig 1). The slot can be widened by using a pick (ZimmerBiomet), which was originally designed for use with the cemented OUKR. This pick has smooth sides and a sharp end. A prototype rasp has also been developed which has teeth on its side and bottom designed to widen the slot and smooth its bottom. Alternatively, a new wider and deeper saw blade (New Blade, ZimmerBiomet) is available for use.

The dimensions of each instrument type were measured using a digital calliper (Mitutoyo, UK). The new blade was 0.2 mm wider at the tip (most distal point of blade, marked in Fig 1A and B) than the standard blade and was 0.7 mm deeper. The pick and rasp were respectively about 0.5 mm and 0.2 mm wider than the standard blade (Fig 1C and 1D).

2.1 Forces: Push-in & Pull-out

We compared the push-in and pull-out forces associated with the standard and new blades and with the adjunctive use of either the cemented pick or the prototype rasp.

Slots were cut into solid polyurethane foam (20 PCF, Sawbones, Malmö, Sweden), which is widely used as analogue for trabecular bone, using the recommended operating technique [12]. Solid polyurethane foam 20 PCF has similar material properties (density 0.32 g/cm³, compressive modulus 210 MPa) to tibial bone (0.3 g/cm³, range 14-345 MPa) [13-15].

A size C tibial template was clamped to the underlying sawbone blocks and the sawblades were used to cut the slot through the template using the same technique as is used clinically. Afterwards the template was removed and for the groups involving the pick or the rasp these

instruments were subsequently utilised in the slot. There were six groups (i.e. 60 slots in total): Standard Sawblade, Standard Sawblade plus Pick, Standard Sawblade plus Rasp, New Sawblade, New Sawblade plus Pick and New Sawblade plus Rasp. We used a different sawblade for each study group. However, we used one pick and rasp for all groups to minimise any confounding factors. Both instruments are designed for reuse and therefore we did not expect wear to change their dimensions for the number of slots on which they were used.

A custom-made boss was welded to the upper surface of standard cementless size C Oxford UKR components by the company producing the implant (Biomet UK Ltd, Swindon, U.K.), to securely fasten the components to the materials testing machine. A Dartec materials testing machine (HC10) was used to implant and extract one component, at 0.01 mm/s, whilst measuring the push-in and pull-out forces at 250 Hz. Prior to push-in the starting position was determined by measuring the position of the tibial component when the bottom of tibial keel was touching the upper surface of the sawbone block (when offset so the keel was not above the slot). The height at which implantation was halted before the component was withdrawn was determined by bringing the under surface of the tibial tray into contact with the upper surface of the sawbone block. The vertical difference in position was calculated and used to calculate implantation distance.

An increase in the push-in load was noted in all experiments just before implantation was halted. The push-in value we used as our “maximum” was obtained by determining the displacement at which zero load was registered during the pull-out phase of the experiment and finding the push-in load that was recorded at this level of displacement (height). Maximum pull-out forces were also recorded.

2.2 The Effect of Implant Variation

To eliminate the chances that any differences found between the groups were specific to the dimensions of the keel on the tibial component used, 20 additional slots were made; ten with the standard sawblade and ten with the new sawblade. Ten size C tibial components were randomly implanted and withdrawn from a standard sawblade slot or new sawblade slot while the maximum push-in and pull-out forces were recorded.

Slot Measurements

Three further slots were cut with the standard blade and three slots were cut with the new blade. Each of the six slots were cut into 2mm slices. An image of each slice was captured with a digital camera against a dark background with a calibration object to provide scaling. The edge of each slice was detected with a custom routine in Matlab (2017, USA). All slots cut with the same blade were superimposed and the minimum slot width was then calculated for depths of 0.5, 2, 4, 6 and 8 mm.

2.3 Statistical Methods

An online calculator was used to determine the number of specimens we needed to test [16]. The standard deviation of 180 N was estimated from preliminary data and a clinically relevant difference of 250 N was selected as meaningful. Using a power of 0.8 and a significance of 0.05 approximately 9 participants per group were needed.

One-way analysis of variance (ANOVA) with the post hoc Bonferroni procedure was performed to compare the maximum push-in forces and pull-out forces between groups. The paired t-test was used to compare the push-in and pull-out forces to assess for the effect of

implant variation. Statistical significance was defined as $p < 0.05$ for all tests. All statistical analyses were conducted using Stata Version 14.2 (Lakeway Drive, Texas, USA).

2.4 Ethics approval and consent to participate

Not applicable

3. RESULTS

3.1 Forces: Push-in & Pull-out

Figure 2 shows the average forces and standard error during push-in and pull-out for one size C tibial component in 10 standard and 10 new blade slots.

3.2 Push-in Forces

The standard sawblade made slots which had the highest maximum push-in loads averaging 1411 N (SD 180). The new sawblade slots had a lower average maximum push-in load that was almost half that of the standard sawblade ($p < 0.001$) at 789 N (SD 131) (Table 1).

Adjunctive use of the pick with the standard sawblade slots significantly reduced the push-in forces ($p \leq 0.001$) to 818 N (SD 388) compared to the standard sawblade alone. The use of the standard blade with the pick showed no significant difference in push-in force when compared to the slots made with the new sawblade alone. Adjunctive use of the rasp had no significant effect on the push-in forces for the standard sawblade group (Table 1).

Adjunctive use of the pick with slots made with the new sawblade did not significantly affect the push-in forces. Rasp usage created a significant increase in the push-in forces ($p < 0.001$) in the new blade slots to 1390 N (SD 202) (Table 1).

No significant difference in push-in forces was observed between the standard blade with adjunctive pick use and the new blade with adjunctive pick use. Similarly, no differences were observed between the standard blade with rasp and the new blade with rasp groups (Table 1).

Figure 3 illustrates the different push-in forces between the groups.

3.3 Pull-out Forces

There was no significant difference in pull-out forces between the slots made with the standard and new blades. The highest pull-out force was the new saw blade group at 240 N (SD 47) and the second highest was the standard blade group at 230 N (SD 56) (Table 2).

For the standard blade the adjunctive use of the cemented pick significantly reduced the pull-out force to 128 N (SD 58). The rasp had no effect on the pull-out force (Table 2). In the new blade adjunctive use of the cemented pick or rasp had no significant effect on the pull-out forces when compared to the new blade alone (Table 2).

The pull-out forces for slots with the standard blade and pick were significantly lower ($p < 0.001$) 128 N (SD 58) than the new blade and pick 214 N (SD 48). No significant differences in pull-out load existed between the new blade with rasp and the standard blade with rasp (Table 2). See Figure 3 for graphical display of pull-out forces.

3.4 The Effect of Implant Variation

Using 10 different tibial size C components the mean maximum push-in force with the new blade was 905 N (SD 245) and was significantly lower ($p = 0.002$) than the standard blade at 1343 N (SD 219). There were no significant differences ($p = 0.370$) between the pull-out forces of the new blade 168 N (SD 67) and standard blade 195 N (SD 36).

3.5 Slot Measurements

Figure 4 shows the difference between the minimum widths for slots cut with the standard blade and the new blade. At a depth of 0.5 mm the widths are approximately equal but at every

281 subsequent depth (2, 4, 6 & 8 mm) the standard blade width decreased and was smaller than
282 the corresponding width for the new blade. The widths for the new blade were generally more
283 uniform throughout the depth of the slot. The slots were deeper with the new blade than the
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4. DISCUSSION

This study demonstrates that, compared to the standard sawblade, with the new sawblade the push-in force is almost halved while the pull-out force is similar. This suggests that use of the new sawblade should decrease the risk of tibial fracture without compromising fixation. Furthermore no combination of blade, pick or rasp provides a lower push-in force or higher pull-out force than the new sawblade used alone. Therefore, to minimise the risk of fracture without compromising fixation, the new blade should be used instead of the standard and it should routinely be used without any adjuvant instrument. The saw blades are also quick and easy to use as they are guided by the template. Adjuvant use of pick and rasp, as well as taking time, are more susceptible to errors. In part because of these findings the new blade is now the only keel-cut blade available for the Cementless Oxford Knee.

During insertion of the keel into the slot, forces perpendicular to the keel will act on the walls of the bony cavity. Previous biomechanical work by Bishop et al [17] has demonstrated that these normal forces are proportional to the push-in forces. If excessive, these forces can split the bone and lead to fractures [18, 19]. The push-in forces recorded in this study for the standard saw were around 1400 N. In order to generate this sort of load surgeons impact the tibial component with a hammer in order to seat it. Although the typical time for periprosthetic tibial fracture to occur is a few weeks after the operation rather than at the operation itself, we believe that impact loading at the operation might initiate a crack below the keel which, under physiological loading later on, could catastrophically propagate [20].

The graph, Figure 2, gives insights into why the new blade is better than the standard. The load during the push-in phase for the standard and new blade slots remains similar until a depth of

approximately 4 mm whereupon the load required to insert the component into the standard blade slots begins to increase more than the corresponding load for the new blade slots (Figure 2). This trend in the average load displacement curve occurs because the new saw blade is wider at the tip than the standard saw and, as shown by the minimum slot width measurements (Figure 4), produces wider slots that have a more consistent width along their depth.

In addition to slot width (interference) slot depth is likely to have an influence on the risk of fracture. During the last millimetre of insertion the push-in force increased markedly for both the standard blade and new blade slots (Fig 2). This increase was, however, about twice as large with the standard blade slot compared to the new blade slot. This is presumably because the new blade is about half a millimetre deeper than the standard blade and the keel may impact the bottom of the slot. The keel cut saws are deeper than the implant keel, however, as they have two blades, a bit of bone can be left in the centre of the slot (fig 4) against which the keel may impact. The new saw blade, being deeper than the standard blade, may weaken the tibia more but this effect would probably be less than the increased impaction required. Other factors could contribute to the marked increase in force such as the tendency for there to be a build-up of the porous coating at the junction between keel and the underside of the component. This build-up could be coming into contact with the slot edges in the final stage of implantation leading to a sudden increase in load. In some cases this build-up might prevent the implant from seating fully. We have found it is best to leave it slightly proud rather than hitting it hard as it subsequently subsides until it is fully seated.

The results of the study suggest that caution should be used where use of the pick is concerned. While the pick reduced push-in forces when used in conjunction with the standard blade it also significantly reduced the pull-out load when compared to the use of the standard blade alone

or the new blade alone. This suggests that use of the pick for the purposes of widening the slot could potentially compromise fixation. Use of the prototype rasp produced results which are the most difficult to explain. It did not reduce push-in forces when used with the standard blade and in fact increased them when used with the new blade. We suspect that this may have been because it forced debris into the walls or the bottom of the slot thus increasing the push-in force. Usage of the rasp had no significant effect on pull-out loads.

The aetiology of fractures is likely to be multifactorial. During tibial preparation the subchondral bone plate has to be removed which will weaken the tibial plateau. Factors which further weaken it and need to be avoided include a deep resection, deep vertical saw cuts or damage to the posterior cortex during keel preparation [21]. In addition, if the resection is medial the keel will be nearer the cortex. It is also important to ensure that there is no retained bone in the keel slot. After slot preparation a trial tibial component should be inserted. If this cannot easily be inserted it suggests that there is some retained bone. This can be removed by reusing the keel cut blade, pulsatile lavage or possibly by using a pick. All of these factors need to be addressed to help reduce the incidence of tibial plateau fractures.

This study does have some limitations. It was conducted using polyurethane foam which acted as a cancellous bone analogue. The use of polyurethane foam for measuring push-in and pull-out forces is well established in orthopaedic fixation stability studies [22-24]. However, it is unclear how well polyurethane foam can replicate bone during an operation where the presence of blood and fat are likely to affect the friction. It was shown that [25] the friction coefficient for sawbones is significantly less than human bone. Furthermore, bone remodelling cannot be reproduced with an inert testing material. Another limitation is that the tibial components were implanted with a continuous force at 0.01 mm/s, whereas clinically they are impacted with a

hammer. A further limitation is that we only studied the size C component, which is the middle size. Although we repeated the study with ten different size C tibial components we cannot be certain that they are generalizable to all sizes. However for all sizes of tibial component the same instruments are used to prepare the keel slot and the keels have the same width and depth so the interference will be the same. As both push-in and pull-out forces are related to interference [11] the results are likely to be generalizable to all sizes.

5. CONCLUSION

The study suggests that the risk of tibial fracture will be decreased with the new keel cut saw blades compared to the standard blades without affecting fixation. The new blade should therefore be used in preference to the standard blade. With the new blade adjuvant usage of the pick or rasp had no beneficial effect.

6. TABLES

	Standard blade (1441 N, SD 180.1)	Standard blade pick (817.5 N, SD 388.2)	Standard blade rasp (1368 N, SD 309)	New blade (788.8 N, SD 130.5)	New blade pick (1000.8 N, SD 155.7)	New blade rasp (1390.4 N, SD 202.2)
Standard blade		P < 0.001	P > 0.999	P < 0.001	P = 0.004	P > 0.999
Standard blade pick	P < 0.001		P < 0.001	P > 0.999	P > 0.999	P < 0.001
Standard blade rasp	P > 0.999	P < 0.001		P < 0.001	P = 0.017	P > 0.999
New blade	P < 0.001	P > 0.999	P < 0.001		P > 0.999	P < 0.001
New blade pick	P = 0.004	P > 0.999	P = 0.017	P > 0.999		P = 0.009
New blade rasp	P > 0.999	P < 0.001	P > 0.999	P < 0.001	P < 0.050	

Table 1. One-way ANOVA results comparing the mean push-in forces for the 6 slot types produced (n = 60).

	Standard blade (230.2 N, SD 55.8)	Standard blade pick (127.8 N, SD 58)	Standard blade rasp (196.5 N, SD 33.3)	New blade (239.7 N, SD 46.5)	New blade pick (214.4 N, SD 48)	New blade rasp (190 N, SD 38.7)
Standard blade		P < 0.001	P > 0.999	P > 0.999	P > 0.999	P > 0.999
Standard blade pick	P < 0.001		P = 0.040	P < 0.001	P = 0.002	P = 0.100
Standard blade rasp	P > 0.999	P = 0.040		P > 0.999	P > 0.999	P > 0.999
New blade	P > 0.999	P < 0.001	P > 0.999		P > 0.999	P = 0.530
New blade pick	P > 0.999	P = 0.002	P > 0.999	P > 0.999		P > 0.999
New blade rasp	P > 0.999	P = 0.100	P > 0.999	P = 0.530	P > 0.999	

Table 2. One-way ANOVA results comparing the mean pull-out forces for the 6 slot types produced (n = 60).

7. FIGURE LEGENDS

Figure 1. A) Standard keel cut saw blade B) New keel cut saw blade. C) Cemented pick D) Rasp. The new saw blade is slightly deeper than the standard blade and does not have bumpers at either end of the blade. The tip of the blades are shown in A and B.

Figure 2. Average load-displacement curve for push-in/pull-out of size C tibial component into and out of 10 standard blade slots and 10 new blade slots

Figure 3. Bar chart illustrating the push-in and pull-out forces for each group. The error bars represent the standard deviation of each value.

Figure 4. Three standard blade slots and three new blade slots were sectioned into 2 mm slices. The edges of the slots were superimposed and the minimum slot width was determined.

8. DECLARATIONS

8.1 Acknowledgements

None

8.2 Funding statement

This study was funded by a grant from Zimmer Biomet.

8.3 Declaration of interest / ICMJE Conflict of interest

Some of the authors have received or will receive benefits for personal or professional use from a commercial party related directly or indirectly to the subject of this article. In addition, benefits have been or will be directed to a research fund, foundation, educational institution or other non-profit organisation with which one or more authors are associated.

9. AKNOWLEGDEMENTS

Nil

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