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Optimal interference of the tibial component of the cementless Oxford Unicompartmental Knee Replacement

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Objectives

The primary stability of the cementless Oxford Unicompartmental Knee Replacement (OUKR) relies on interference fit (or press fit). Insufficient interference may cause implant loosening, whilst excessive interference could cause bone damage and fracture.

The aim of this study was to identify the optimal interference fit by measuring the force required to seat the tibial component of the cementless OUKR (push-in force) and the force required to remove the component (pull-out force).

Materials and Methods

Six cementless OUKR tibial components were implanted in 12 new slots prepared on blocks of solid polyurethane foam (20 pounds per cubic foot (PCF), Sawbones, Malmo, Sweden) with a range of interference of 0.1 mm to 1.9 mm using a Dartec materials testing machine HC10 (Zwick Ltd, Herefordshire, United Kingdom) . The experiment was repeated with cellular polyurethane foam (15 PCF), which is a more porous analogue for trabecular bone.

Results

The push-in force progressively increased with increasing interference. The pull-out force was related in a non-linear fashion to interference, decreasing with higher interference. Compared with the current nominal interference, a lower interference would reduce the push-in forces by up to 45% ($p < 0.001$ One way ANOVA) ensuring comparable (or improved) pull-out forces ($p > 0.05$ Bonferroni *post hoc* test). With the more porous bone analogue, although the forces were lower, the relationship between interference and push-in and pull-out force were similar.

Conclusions

This study suggests that decreasing the interference fit of the tibial component of the cementless OUKR reduces the push-in force and can increase the pull-out force. An optimal interference fit may both improve primary fixation and decrease the risk of fracture.

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Keywords: Interference fit, Cementless implants, Push-in force, Pull-out force

Article focus

- To identify the optimal interference fit of the tibial component of the cementless Oxford Unicompartmental Knee replacement;
- To assess the relationship between the push-in force (the force required to seat the implant) and the pull-out force (the force required to remove the component) of a cementless implant.

Key messages

- The push-in force progressively increases with increasing interference, while the pull-out force was related in a non-linear fashion to interference;
- A reduced interference fit may both improve primary fixation and decrease the risk of fracture.

Strengths and limitations

- First study measuring the relationship between interference and the push-in and pull-out forces of the tibial component of the cementless OUKR;
- This is a plastic bone study and the results need to be confirmed on cadaveric studies or animal models.

Introduction

Interference fit (or press fit) is the fixation between two parts that is generated by friction after they have been pushed together. For orthopaedic implants, interference is defined as the difference between the size of the implant and the size of the bone cavity into which the implant is pressed, and is measured in millimetres. The optimal interference fit for orthopaedic implants is uncertain, however, a previous biomechanical study has suggested that the optimal interference for a peg in cancellous bone should range between 0.65 mm and 0.8 mm.[1] The optimal interference is likely to be influenced by implant design, friction coefficient of the surfaces, and the skeletal segment in which the implant is used. Insufficient interference would compromise the primary stability of the implant and might cause implant migration, loosening and failure. In contrast, excessive interference increases the assembly load required to implant the component which in turn generates stress in the bone, trabecular damage and increases the risk of fractures.[2,3]

In 2004, a cementless version of the Oxford Unicompartmental Knee Replacement (OUKR, Zimmer Biomet, Swindon, UK) was introduced with the aim of reducing the incidence of radiolucent lines and improving the survival of the implant.[4,5] This aim has been achieved with the New Zealand Joint Registry having a ten-year survival of about 96%, which is similar to that of total knee arthroplasty.[6] The primary stability of the cementless OUKR relies on interference fit. The optimal interference for this specific implant is still unclear. While a radiostereometric analysis study has confirmed the reliability of cementless fixation of the OUKR,[7] a cadaver study has suggested that lower loads are required to cause a fracture in bone implanted with cementless compared with cemented OUKR tibial components.[8] As fractures are usually internally fixed and the components are not revised National Registries do not provide useful information on fracture rates. However, anecdotally, some surgeons have suggested that there is a higher incidence of perioperative tibial plateau fractures with cementless fixation. While the current interference of the cementless tibial component is sufficient to ensure reliable stability, it may be unnecessarily high and increase the risk of perioperative tibial plateau fracture.

The aim of this plastic bone study was to identify the optimal interference fit of the cementless tibial component of the OUKR. The force required to seat the component (push-in force), which is related to the risk of fracture, and the force required to remove the component (pull-out force), which is related to primary stability, were measured.

Materials and Methods

A computer numerical control (CNC) machine (Hurco VM1 High Wycombe, United Kingdom) was used to cut slots in blocks of solid polyurethane foam (20 pounds per cubic foot (PCF), (Sawbones, Malmo Sweden), which is the most widely used analogue for trabecular bone.[9,10] A custom-made boss was welded to the upper surface of 12 standard cementless size C Oxford UKR components by the company producing the implant (Zimmer Biomet UK Ltd, Swindon, United Kingdom), to securely fasten the components to the materials testing machine. A Dartec materials testing machine HC10 (Zwick Ltd, Herefordshire, United Kingdom) was used to implant and extract the tibial components, at 0.01 mm/s, whilst measuring the push-in and pull-out forces.

Six components were used and each was implanted in 12 new slots with a range of interference of 0.1 mm to 1.9 mm (slot width ranging from 3.8 mm to 2.0 mm). The length and depth of the slots were constant (39 mm and 14 mm, respectively) and exceeded the dimensions of the keel, to exclude the influence of the impingement on the bottom or with the anterior or posterior ends of the slot. Each component was tested starting from the minimal interference to the maximal interference, to reduce the risk of damaging the porous coating on the components. The experiment was repeated with six further tibial components on a cellular polyurethane foam block (15 PCF, Sawbones, Malmo Sweden), which is a more porous analogue for trabecular bone.

The thickness of the keel of 12 standard, size ‘C’ cementless tibial components was measured by two independent observers (SC and SM) with a digital calliper (Sealey, Bury St. Edmunds, United Kingdom). Ten measurements were performed in ten different positions on the keel following a standardized sequence (Fig. 1), to consider the irregularity and non-homogeneous distribution of the coating. The thickness of each keel was estimated by the mean of the ten measurements.

Interference was defined as the difference in millimetres between the mean width of the keel and the nominal width of the tibial slot (Fig. 1).

Statistical analysis. Study data were reported using means, ranges and standard deviations (SD). One-way analysis of variance (ANOVA) tests were performed to compare the push-in and pull-out forces for different values of interference. The *post hoc* analysis was carried out with the Bonferroni procedure. A paired *t*-test was used to compare the repeated measurements of the keel width. Statistical significance was set at $p < 0.01$. Pearson’s correlation test was performed to measure the inter-observer variability. All analyses were carried out using SPSS version 22.0 for Windows (SPSS Inc., Chicago, Illinois).

Results

Measurement of the keel of the cementless OUKR. The mean thickness of the keel of the tibial components was 3.87 mm (range 3.83 to 3.92) (Table I). The intra-observer correlation was 0.82 (95% CI 0.44 to 0.94),

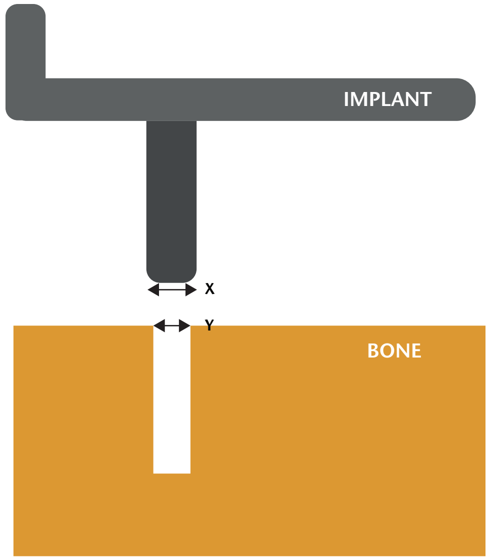

Fig. 1

The interference is calculated as the difference between the size of the implant (x) and the size of the bone cavity into which it is pressed (y) (interference = x–y).

indicating an almost perfect agreement according to the Landis and Koch criteria. There was no significant difference between the measurements performed by the two observers ($p = 0.31$ Student's *t*-test).

Push-in and pull-out measurement. In the solid polyurethane blocks (20 PCF), the push-in force progressively increased with increasing interference (Fig. 2). With the maximum interference tested (1.9 mm) the push in force was 1852 N (Standard deviation (SD) 106). The pull-out force was related in a non-linear fashion to interference. The highest pull-out force (380 N, SD 24) was obtained with an interference of 0.7 mm, which required a push-in force of 925 N (SD 65). The pull-out force decreased with higher interference.

For an interference ranging from 0.9 mm and 1.3 mm, which is the current clinical range based on the design of the implant and surgical instruments, the push-in force varied between 1254 N and 1456 N and the pull-out force between 167 N and 317 N. In comparison, interferences of 0.7 mm, 0.6 mm or 0.5 mm had push-in forces that were reduced by up to 45% ($p < 0.001$) and comparable or superior pull-out forces ($p > 0.05$). The pull-out force progressively decreased with interference of 0.4 mm and less.

The one-way ANOVA revealed a significant difference for different values of interference both for the push-in and the pull-out measurements ($p < 0.001$). The results of the *post hoc* analysis are reported in Table II.

With the more porous bone analogue, although the forces were lower, the relationship between interference and push in and pull out force were similar (Fig. 3). Again, the pull-out force decreased with higher interference.

Table I. Mean thickness of the keel of each tibial component

Component	Mean thickness (mm)	Range (mm)
A	3.88	3.73 to 4.02
B	3.83	3.73 to 3.93
C	3.88	3.83 to 3.94
D	3.83	3.75 to 3.91
E	3.92	3.80 to 4.08
F	3.92	3.81 to 4.06
G	3.87	3.77 to 4.02
H	3.85	3.79 to 3.97
I	3.84	3.73 to 3.92
L	3.85	3.72 to 3.93
M	3.92	3.81 to 4.09
N	3.83	3.74 to 3.96
Overall mean	**3.87**	**3.76 to 3.99**

The pull-out force presented almost constant values for an interference ranging from 0.5 mm to 1.9 mm.

With the maximum interference tested (1.9 mm) the push in force was 1123 N (SD 242). The highest pull-out force was around 200 N, obtained with for all the value of interference ranging from 0.7 mm to 1.3 mm.

For the current range of interference, the push-in force varied between 595 N and 835 N and the pull-out force between 196 and 199 N. Compared with this, interferences of 0.7 mm, 0.6 mm or 0.5 mm had push-in forces that were reduced by up to 47% ($p < 0.001$) and comparable pull-out forces ($p > 0.05$). Also in the cellular block, the pull-out force progressively decreased with interference of 0.4 mm and less. The results of the *post hoc* analysis are reported in Table III.

Discussion

This study suggests that decreasing the interference fit of the keel of the cementless OUKR would significantly decrease the push-in force required to seat the component, without diminishing the pull-out force and therefore ensuring the same level of primary stability.

There was an almost linear correlation between the nominal interference and the push-in force; the higher the interference the higher the push-in force. In contrast, there was a non-linear correlation between interference and the pull-out force. On the 20 PCF solid polyurethane blocks, the pull-out force was approximately constant for interference ranging from 1.1 mm to 1.9 mm, with a median value of 167 N. It increased for values of interference ranging from 0.5 mm to 0.9 mm, reaching the peak value of 380 N for a nominal interference of 0.7 mm, and then progressively decreased for values of interference below 0.4 mm.

The interference that is achieved with the current implant design ranges from 0.9 mm to 1.3 mm. The variability in interference is caused by the irregularity in the geometries of both the porous coating and the bone slot. According to the results of this study, the optimal nominal interference should be between 0.5 mm and 0.7 mm. Compared with the current range (0.9 mm to 1.3 mm),

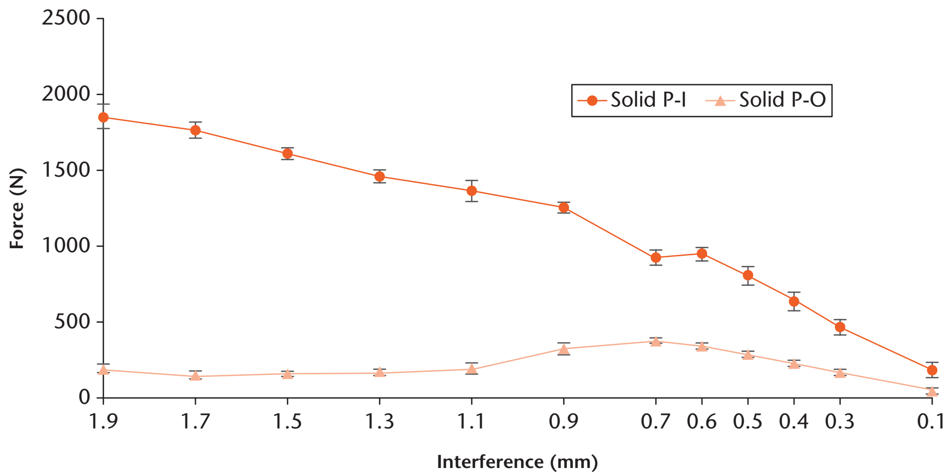

Fig. 2

Mean push-in (PI) and pull-out (PO) value with varying interference for the solid testing material (20 PCF) (95% confidence intervals).

Table II. Results of the Bonferroni *post hoc* analysis. Significance was set as < 0.01. There was a significant difference in push-in force between the current interference and what we are investigating to be the optimal range of interference. There was no difference in the pull-out between the 0.5, 0.6 and 0.7 slot. In contrast, the interference values in the 'optimal range' showed a superior pull-out force compared with an interference of 1.1 mm and 1.3 mm

Push-in force				
			Current range	
	Interference	**0.9 mm**	**1.1 mm**	**1.3 mm**
	0.5 mm	< 0.01	< 0.01	< 0.01
Optimal range	**0.6 mm**	< 0.01	< 0.01	< 0.01
	0.7 mm	< 0.01	< 0.01	< 0.01
Pull-out force				
			Current range	
	Interference	**0.9 mm**	**1.1 mm**	**1.3 mm**
	0.5 mm	1	< 0.01	< 0.01
Optimal range	**0.6 mm**	1	< 0.01	< 0.01
	0.7 mm	0.1	< 0.01	< 0.01

this 'Optimal range' produces an equal or superior pull-out force, with a reduction in the push in force up to 45%. A very similar pattern of results was obtained using the cellular polyurethane blocks, which has different mechanical properties and friction coefficient.

The results are consistent with those reported by Berahamani et al[1] who demonstrated, in a cadaveric study assessing the initial stability of pegs, that beyond a certain interference the fixation strength does not increase. These findings were explained by excessive stresses during insertion that would cause damage and permanent deformation to the bone and limit additional stability.[1,11] The permanent deformation leads to an actual interference fit that is less than the nominal interference.[2,12] The permanent deformation was higher for higher nominal interference. The difference between the nominal interference and the effective interference that resulted was minimal for an interference of 0.3 mm, and increased with increased interference. The actual interference was around 30% of nominal interference for an interference of 0.9 mm.[2]

During the insertion of an implant with an interference fit into bone, forces normal to the bone surfaces are generated. These forces will tend to split the bone and can cause fractures.[2,13] A biomechanical study by Bishop et al[12] demonstrated that whilst the push-in force is significantly higher than the pull-out force, the normal forces on the bone are roughly equivalent to the push-in force.

The results of this study show that a reduced nominal interference would require a lower push-in force to seat the tibial component of the cementless OUKR, yet would achieve a similar or higher pull-out force. Potentially the push-in force could be nearly halved so the normal forces that would tend to split the bone would be nearly halved. In addition, there would be less damage to trabecular bone and the impaction required to implant the component would be reduced. By limiting these problems, a lower nominal interference could reduce the risk of

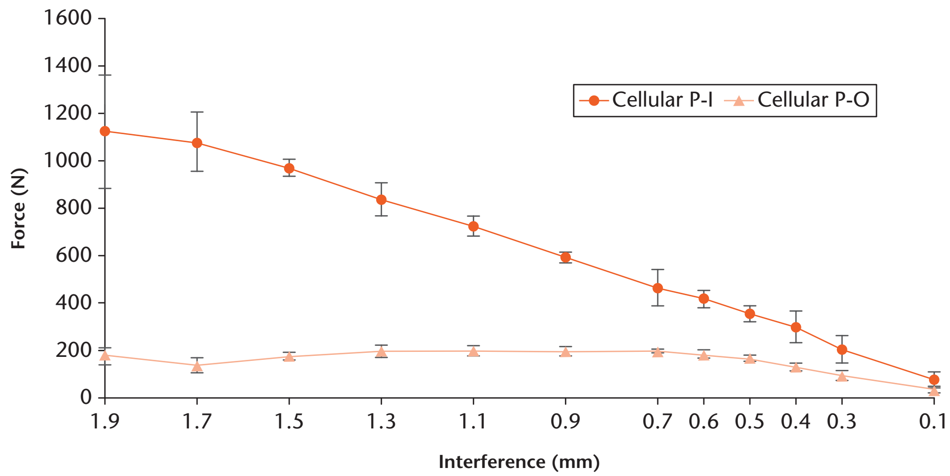

Fig. 3

Mean push-in (PI) and pull-out (PO) value with varying interference for the cellular testing material (15 PCF) (95% confidence intervals).

Table III. Results of the Bonferroni *post hoc* analysis. Significance was set as < 0.01. There was a significant difference in push-in force between the current interference and the 'optimal' range of interference. In contrast, there was no difference in the pull-out forces

Push-in force				
			Current range	
	Interference	**0.9 mm**	**1.1 mm**	**1.3 mm**
	0.5 mm	< 0.01	< 0.01	< 0.01
Optimal range	**0.6 mm**	0.11	< 0.01	< 0.01
	0.7 mm	1	< 0.01	< 0.01
Pull-out force				
			Current range	
	Interference	**0.9 mm**	**1.1 mm**	**1.3 mm**
	0.5 mm	1	0.96	1
Optimal range	**0.6 mm**	1	1	1
	0.7 mm	1	1	1

perioperative tibial condyle fracture, without compromising primary fixation.[14,15]

This is the first study to identify the current and the optimal range of interference for the tibial component of cementless OUKR and assess its correlation with push-in and pull-out forces. Despite its clinical relevance, there is a lack of published data on this topic. The study has some limitations. First, tests were carried out on artificial bone. Even though the Sawbones blocks used are meant to have properties similar to that of cancellous bone, their friction coefficient will inevitably be different from human bone. However, a second testing material, having a different modulus and structure were tested and found to have similar results. Future research could compare the optimal interference with current interference in animal or cadaveric bone, although neither of these provides a good representation of osteoarthritic bone.

The implants were tested in dry conditions, while bone is covered by fluid and blood. However, a previous study comparing dry and wet Sawbones blocks as experimental models for the testing of press-fit implants has reported that the dry or wet condition has limited effect on the dynamic friction coefficient of plasma sprayed surfaces.[16]

In a full assessment of primary stability, micromotion at the bone-implant interface must be assessed. This was not carried out and represents another limitation of the current study. This aspect could be investigated in future studies. Finally, we could not formally correlate the risk of fracture with the nominal interference.

In conclusion, this study suggests that decreasing the interference fit of the keel of the cementless OUKR reduces the push-in force without decreasing the pull-out force. A lower interference fit should therefore decrease the risk of tibial plateau fracture without compromising fixation.

References

1. **Berahmani S, Janssen D, van Kessel S, et al.** An experimental study to investigate biomechanical aspects of the initial stability of press-fit implants. *J Mech Behav Biomed Mater* 2015;42:177-185.
2. **Damm NB, Morlock MM, Bishop NE.** Friction coefficient and effective interference at the implant-bone interface. *J Biomech* 2015;12:3517-3521.
3. **Scott CE, Eaton MJ, Nutton RW, et al.** Metal-backed versus all-polyethylene unicompartmental knee arthroplasty: Proximal tibial strain in an experimentally validated finite element model. *Bone Joint Res* 2017;6:22-30.

4. **Murray DW, Liddle AD, Judge A, Pandit H.** Bias and unicompartmental knee arthroplasty. *Bone Joint J* 2017;99-B-1:12-5.
5. **Blaney J, Harty H, Doran E, et al.** Five-year clinical and radiological outcomes in 257 consecutive cementless Oxford medial unicompartmental knee arthroplasties. *Bone Joint J* 2017;99-B-5:623-631.
6. **No authors listed.** Association NZO. The New Zealand Joint Registry Seventeen Year Report. 2016. https://nzoa.org.nz/system/files/NZJR%2017%20year%20Report.pdf
7. **Kendrick BJ, Kaptein BL, Valstar ER, et al.** Cemented versus cementless Oxford unicompartmental knee arthroplasty using radiostereometric analysis: a randomised controlled trial. *Bone Joint J* 2015;97-B:185-191.
8. **Seeger JB, Haas D, Jager S, et al.** Extended sagittal saw cut significantly reduces fracture load in cementless unicompartmental knee arthroplasty compared to cemented tibia plateaus: an experimental cadaver study. *Knee Surg Sports Traumatol Arthrosc* 2012;20:1087-1091.
9. **Kelly N, McGarry JP.** Experimental and numerical characterisation of the elasto-plastic properties of bovine trabecular bone and a trabecular bone analogue. *J Mech Behav Biomed Mater* 2012;9:184-197.
10. **Szivek JA, Thompson JD, Benjamin JB.** Characterization of three formulations of a synthetic foam as models for a range of human cancellous bone types. *J Appl Biomater* 1995;6:125-128.
11. **Gebert A, Peters J, Bishop NE, Westphal F, Morlock MM.** Influence of press-fit parameters on the primary stability of uncemented femoral resurfacing implants. *Med Eng Phys* 2009;31:160-164.
12. **Bishop NE, Hohn JC, Rothstock S, Damm NB, Morlock MM.** The influence of bone damage on press-fit mechanics. *J Biomech* 2014;47:1472-1478.
13. **Nowak M, Kusz D, Wojciechowski P, Wilk R.** Risk factors for intraoperative periprosthetic femoral fractures during the total hip arthroplasty. *Pol Orthop Traumatol* 2012;77:59-64.
14. **Rudol G, Jackson MP, James SE.** Medial tibial plateau fracture complicating unicompartmental knee arthroplasty. *J Arthroplasty* 2007;22:148-150.
15. **Van Loon P, de Munnynck B, Bellemans J.** Periprosthetic fracture of the tibial plateau after unicompartmental knee arthroplasty. *Acta Orthop Belg.* 2006;72:369-374.
16. **Grant JA, Bishop NE, Götzen N, et al.** Artificial composite bone as a model of human trabecular bone: the implant-bone interface. *J Biomech* 2007;40:1158-64.

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Author Contributions
- S. Campi: Contributed to the conception and design of the study, performed testing, data analysis and interpretation, wrote the manuscript.
- S. J. Mellon: Contributed to study design, performed testing and data interpretation, reviewed the manuscript.
- D. Ridley: Contributed to study set-up and design and data intrepretation.
- B. Foulke: Performed testing, reviewed the manuscript.
- C. A. F. Dodd: Contributed to the conception and design of the study and data interpretation, reviewed the manuscript.
- H. G. Pandit: Contributed to the conception and design of the study, revised the manuscript.
- D. W. Murray: Conceived original idea, contributed to data interpretation, critical revision and final approval of the manuscript.

Conflicts of Interest Statement
- D. Ridley is an employee at Zimmer Biomet.