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Technical note

Fixation strength of a polyetheretherketone femoral component in total knee arthroplasty☆

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ABSTRACT

Introduction: Introducing polyetheretherketone (PEEK) polymer as a material for femoral components in total knee arthroplasty (TKA) could potentially lead to a reduction of the cemented fixation strength. A PEEK implant is more likely to deform under high loads, rendering geometrical locking features less effective. Fixation strength may be enhanced by adding more undercuts or specific surface treatments. The aim of this study is to measure the initial fixation strength and investigate the associated failure patterns of three different iterations of PEEK-OPTIMA® implants compared with a Cobalt–Chromium (CoCr) component.
Methods: Femoral components were cemented onto trabecular bone analogue foam blocks and preconditioned with 86,400 cycles of compressive loading (2600 N–260 N at 1 Hz). They were then extracted while the force was measured and the initial failure mechanism was recorded. Four groups were compared: CoCr, regular PEEK, PEEK with an enhanced cement-bonding surface and the latter with additional surface primer.
Results: The mean pull-off forces for the four groups were 3814 N, 688 N, 2525 N and 2552 N, respectively. The initial failure patterns for groups 1, 3 and 4 were the same; posterior condylar foam fracture and cement–bone debonding. Implants from group 2 failed at the cement–implant interface.
Conclusions: This study has shown that a PEEK-OPTIMA® femoral TKA component with enhanced macro- and microtexture is able to replicate the main failure mechanism of a conventional CoCr femoral implant. The fixation strength is lower than for a CoCr implant, but substantially higher than loads occurring under in-vivo conditions.

1. Introduction

The initial fixation of the femoral component after total knee arthroplasty (TKA) is an important outcome measure for the success of the procedure. The research and development in cementless TKA is focused on primary stability through mechanical fixation (e.g. press-fit or pin/screw fixation) to allow the biological process of bone ingrowth to provide long-term fixation [1–5]. In cemented fixation there are two interfaces at which failure can occur; the cement–bone and cement–implant interface. Studies that focused on the integrity of the cement–bone interface concluded that of the two this one was the most vulnerable, especially when the counterface was cortical bone [6,7]. The interdigitation of bone cement (PMMA) with trabecular bone provides the strength through mechanical interlock. However, in time the strength of this interface decreases as a result of bone resorption caused by stress shielding, wear particle induced osteolysis or thermal necrosis [8–10].

The fixation of the cement–implant interface relies on the implant bonding surface geometry (recesses and undercuts; i.e. cement pockets) to obtain long-term mechanical interlock with the cement. Additional efforts have been made to improve cement-to-implant adhesion to further improve fixation. This led to the enhancement of the cement-bonding interfaces from the early metal components to the current designs [11–14]. Studies showed that smooth implant surfaces had low interface adhesive strength, whereas a roughened interface appeared significantly stronger by adding a level of micro-mechanical interlock

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[15,16]. Chemical agents have also been studied, including the use polymethylmethylacrylate (PMMA) pre-coatings or primers known from applications in hip arthroplasty and dentistry [5,17].

The fact that implant fixation is primarily a consequence of macro- and/or micro-mechanical interlock means that the cemented femoral component is inherently well fixated directly post-operative if adequate surface roughness and undercuts (or cement pockets) are available. This was also shown for polyethylene acetabular liners that clearly benefitted from the addition of profiles on the cement–implant interface since the interface had negligible strength without profiles [18].

Early TKA failures with a mechanical cause are usually related to implant sizing and positioning rather than suboptimal fixation [19]. The apparent absence of early clinical problems related to the cement mantle has probably led to only a short list of studies focusing on initial fixation issues of cemented femoral knee implants. Those that did evaluate the strength of the bone-implant or cement–implant interface used pull-out or push-off experiments. Most studies used coupon samples [5,11,12,14–16] and surprisingly few have studied the effect of the entire femoral implant geometry [20,21]. Bergschmidt et al. performed high-flex pull-out tests on synthetic femurs and reported an average pull-out force of 2322 N for ceramic implants compared to 4769 N for metallic ones. This reduction in fixation strength may not be problematic as a 5-year clinical follow-up study of the component showed outcomes similar to CoCr devices [22]. Hence, it seems that cemented fixation of a standard CoCr femoral component has a considerable factor of safety against mechanical debonding and that components with a 49% (2322 N/4769 N) lower fixation strength perform adequately under in-vivo conditions.

The studies above all make use of stiff metal or ceramic implants [11,21] and thus share the fact that the material hardly deforms under the loading conditions. The object of the current study is a polyetheretherketone (PEEK) femoral TKA component. It is a polymer known for its wear resistance, strength and biocompatibility [23], but is weaker and substantially more compliant compared to metals and ceramics. These features may have potential benefits for application in TKA [24], but could also jeopardize the fixation strength and failure mechanisms of the femoral implant.

Prior experiments on the fixation of PEEK to PMMA have been conducted in-house to assess the influence of cement-bonding surface finish on the bond strength. These tests were performed on coupon specimens under tensile and under shear loads. A smooth PEEK coupon was easily debonded and did not provide any noteworthy strength. Based on these findings surface features were added, comprising of a large rib macrotexture and laser etched microtexture. This greatly improved the fixation strength, but those data were difficult to relate to either pure tensile of shear strengths as the multidimensional interface features provided interlock between the coupon and cement layer. Therefore, we decided to perform strength tests with the entire implant geometry to be able to relate findings of one implant to the other.

The current study was designed to assess the primary fixation strength and failure mechanisms of a cemented TKA femoral component made of PEEK and compare that with the same design made of CoCr. Three designs of the PEEK implant were considered; a smooth cement pocket design, a design with enhanced cement bonding features, and the latter with additional primer.

2. Materials and methods

2.1. Study design

The present study was set up as a controlled experimental design with four groups. Group 1 consisted of CoCr (N = 4) implants (Maxx Orthopedics Inc., US), which served as a control for the other three groups because of its present clinical applications (Fig. 1A). Group 2 was a regular PEEK implant (N = 5) with the exact same geometry as the CoCr component and identical cement pockets, yet lacking the surface roughness of CoCr (Fig. 1B). They were machined from a block of annealed PEEK-OPTIMA® (Invibio Ltd, Thornton-Cleveleys, UK). Group 3 was the injection molded PEEK-OPTIMA® (N = 5) with enhanced cement-bonding features (ribs and laser-etching, Fig. 1C). Group 4 was added which were the same implants as group 3 but included a primer on the PEEK surface prior to implantation (N = 4). This primer (Scotchbond Universal, 3M ESPE, Neuss, Germany) is commonly used in dental applications with positive results when tested with PEEK [25].

2.2. Experimental set-up

All groups were cemented onto biomechanical testing foam blocks, analogue to trabecular bone (Sawbones Europe AB, Malmo, Sweden). A cellular foam block was chosen (0.32 g/cm^3) as the mechanical properties are similar to healthy trabecular bone with regard to stiffness (137 MPa) and strength (5.4 MPa) and allowed cement penetration [26]. To minimize differences between samples the foam blocks were machined to geometrical cutting specifications. Milling residue was removed with vacuum suction and any remaining particles were cleaned off with pressurized air. Heraeus Palacos-R bone cement was used in combination with the Palamix vacuum mixing system (Heraeus Medical, Wehrheim, Germany). The implants were cemented according to the protocol described by Vaninbroukx to achieve maximum fixation [27]. Prior to cementation group 4 received the adhesive primer. A fine brush was used to apply the adhesive to the implant surface. Subsequently, the adhesive (in liquid state) was distributed with pressurized air to form a constant thin film after which it was left under a UV light source for 10 min.

The reconstructions were pre-conditioned by subjecting them to 24 h of 1 Hz cyclic compressive, slightly medially biased loading on a hydraulic uni-axial testing rig, between 2600 N–260 N. The maximum load of 2600 N was based on the ISO-14243 standard for knee replacement [28]. The cyclic loading was applied in extension through a modified matching tibial component (Fig. 2A). After preconditioning the foam blocks were firmly clamped onto a platform. A customized surgical extractor was placed over the medial and lateral recesses in the distal flange of the femoral component to apply the tensile load from the hydraulic testing rig (Fig. 2B). The machine was set to displacement control at a rate of 0.5 mm/min. This resulted in a pure axial tensile load with respect to the implant alignment. During preconditioning and the pull-off test a planar *xy*-bearing was mounted to maintain axial alignment.

2.3. Outcome measures

During the pull-off phase observations of debonding, cracking, deformations and total failure were recorded. Displacements and loads were recorded throughout the test. The outcome measures were the maximum pull-off load and failure patterns. The main failure mode was defined as the damage corresponding to the greatest loss of strength after the peak force, i.e. cement–foam debonding, cement–implant debonding or foam fracture.

2.4. Statistics

Results were described with the mean and standard deviation for each group. A one-way ANOVA with post-hoc Bonferroni correction was employed to calculate the two-sided statistical significance of differences between groups ($\alpha = 0.01$).