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Short Communication

The effect of polyethylene creep on tibial insert locking screw loosening and back-out in prosthetic knee joints

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ABSTRACT

A prosthetic knee joint typically comprises a cobalt–chromium femoral component that articulates with a polyethylene tibial insert. A locking screw may be used to prevent micromotion and dislodgement of the tibial insert from the tibial tray. Screw loosening and back-out have been reported, but the mechanism that causes screw loosening is currently not well understood. In this paper, we experimentally evaluate the effect of polyethylene creep on the preload of the locking screw. We find that the preload decreases significantly as a result of polyethylene creep, which reduces the torque required to loosen the locking screw. The torque applied to the tibial insert due to internal/external rotation within the knee joint during gait could thus drive locking screw loosening and back-out. The results are very similar for different types of polyethylene.

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1. Introduction

A prosthetic knee joint consists of a distal femoral component that articulates with a polyethylene tibial insert, secured in a tibial tray that is anchored in the tibia. Dislodgement of the tibial insert from the tibial tray may be caused by trauma, or non-traumatic events such as locking mechanism defect, improper surgical placement, or physiological forces applied to the joint, e.g., during deep flexion (Poulter and Ashworth, 2005; Hedlundh et al., 2000; Park et al., 2007). Several reports in the literature describe specific cases of patients experiencing non-traumatic dislodgement of the tibial insert resulting from locking mechanism disengagement (Wright et al., 2011; Rutten and Janssen, 2009; Anderson et al., 2007; Davis et al., 1991; Ries, 2004; Chen et al., 2011; In et al., 2011; Lachiewicz and Geyer, 2011), attributed to unusual knee loading conditions and kinematics (Davis et al., 1991; Ries, 2004; Chen et al., 2011; In et al., 2011), or even the use of highly crosslinked polyethylene (Lachiewicz and Geyer, 2011).

Three types of locking mechanisms are regularly used to secure the polyethylene tibial insert in the metal tibial tray in total knee arthroplasty (TKA). They can be categorized as linear, peripheral, or central capture mechanisms (Thienpont, 2013). Linear locking mechanisms are based on a tongue and

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groove structure that runs anterior to posterior and/or medial to lateral. Peripheral capture mechanisms use a snap-fit with beveled edges along a portion or the entire perimeter of the tibial insert. Either mechanism may be augmented with a locking pin to reduce micromotion between the tibial insert and tibial tray. Central locking mechanisms use a pin with a peripheral flange for rotational stability or a central locking screw.

In this paper, we focus on failure of the central locking screw mechanism by loosening and back-out. While this is a rare complication (Wright et al., 2011), it has major consequences that lead to surgical re-intervention (Thienpont, 2013). Thus, it is a significant problem, and an understanding of the physical mechanism that drives locking screw loosening is needed to enable designing the next generation locking screws that do not exhibit this failure mode. Several cases of locking screw failure have been discussed in the literature. Shah et al. (2002) reported two cases of locking screw disengagement and subsequent migration. Cho and Youm (2009) investigated 13 cases of locking screw migration resulting from approximately 250–300 surgeries performed at their institution. These prosthetic knee joints used a combined snap-fit and locking screw mechanism. Screw migration was detected on average 27 months after implantation, and in all cases the screw had completely loosened and migrated into the joint. Rapuri et al. (2011) studied five cases of TKA failure due to disengagement of the locking screw. Loosening of the screw is believed to occur because of a counter-clockwise torque created by the axial rotation of the femur on the tibia that occurs as the knee extends during gait. This torque is transmitted via the highly rotationally constrained femoral component and tibial post to the locking screw. Over many cycles, this may lead to screw loosening. In the left knee, this mechanism generates a clockwise torque that may actually prevent loosening. However, analysis has shown that one third of all knees exhibit reverse axial rotation with gait. Therefore, failures of this locking mechanism may still occur in the left knee Dennis et al., 2004.

Although clinical observations of locking screw loosening and back-out in TKA have been documented in the literature, the physical mechanism that drives this phenomenon is not yet fully-understood. Torque created during gait (Rapuri et al., 2011) and micromotion between the tibial insert and tibial tray are believed to contribute to locking screw loosening (Anderson et al., 2007). In addition, we hypothesize that the viscoelastic character of the tibial insert, which leads to creep under sustained load (Lee and Pienkowski, 1998), reduces the preload of the locking screw and, thus, the corresponding torque required to loosen the locking screw. Hence, the objective of this paper is to quantify the reduction of the preload of the locking screw as a function of polyethylene creep, for different types of polyethylene used in contemporary prosthetic knee joints.

2. Materials and methods

We experimentally evaluate the effect of creep of four different polyethylene types on locking screw loosening. The polyethylene types are: (a) ultra-high molecular weight polyethylene (UHMWPE) GUR 1020 blended with vitamin E, (b) UHMWPE GUR 1020, (c) GUR 1020 blended with vitamin E, cross-linked with 75 kGy gamma radiation, and (d) GUR 1020 cross-linked with 75 kGy gamma radiation and remelted. Fig. 1(a)–(d) shows $40 \times 40 \times 20\ mm^3$ polyethylene specimens of each type, each with a 6 mm metric screw clearance hole in its center. We use block-shaped specimens rather than actual tibial inserts to focus the study on the relationship between creep and the resulting torque needed for screw loosening, apart from a specific insert design. Notwithstanding, the block thickness of 20 mm is relevant to revision tibial inserts, which often are thicker than primary inserts. Fig. 2 shows the experimental setup. The polyethylene specimens are affixed to an aluminum base with a 6 mm stainless steel metric screw, similar to a typical locking screw used in commercial implants (Fig. 2(b)). We use a digital torque wrench (AC Delco ARM601-3, accuracy $\pm 2\%$) to fasten the

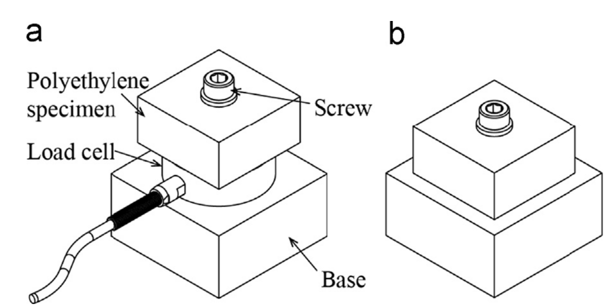

Fig. 2 – Schematic of the experimental setup (a) measuring the bolt preload with a load cell (one specimen), and (b) without load cell (remainder of specimens).

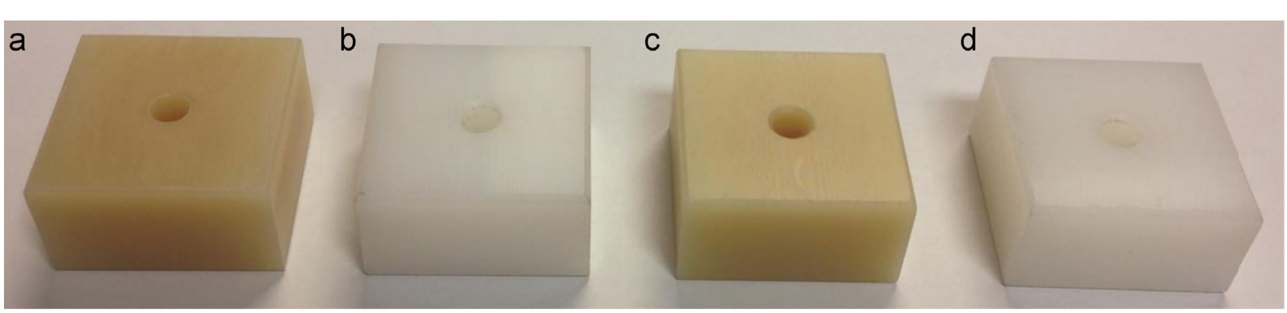

Fig. 1 – Different types of polyethylene used in this study (a) ultra-high molecular weight polyethylene (UHMWPE) GUR 1020 blended with vitamin E, (b) UHMWPE GUR 1020, (c) Vitamin E-blended cross-linked polyethylene (XLPE) GUR 1020 (75 kGy gamma radiation), and (d) XLPE GUR 1020 (75 kGy gamma radiation, remelted).

locking screw with a torque of 9 Nm, similar to the prescribed torque for locking screws in commercial implants (Cho and Youm, 2009). We have placed five specimens of each polyethylene type, fixed to an aluminum base with a preloaded locking screw, for four months (180,000 minutes) in a temperature-controlled chamber at $37\pm1\,^{\circ}$C. One control specimen of each polyethylene type is placed in the same environment but is not subject to loading by a locking screw. Additionally, one specimen of polyethylene type (b) is equipped with a donut load cell (Futek LTH350, 5000lbs) as shown in Fig. 2(a), which enables monitoring the locking screw preload as a function of time. After the four-month experiment, the torque to loosen the bolts is measured with a torque wrench and compared to the torque applied to fasten them. The thickness of the specimens before and after the experiment is compared as well.

3. Results and discussion

Fig. 3 shows the preload of the locking screw as a function of time, normalized with the initial preload immediately after fastening (t=0), for the single specimen of type (b) equipped with a load cell. We observe that the preload initially decreases very fast, reaching 50% of its initial value after only 20 min as a result of primary creep of the polyethylene (Meyers and Chawla, 2002). After approximately 100 min, the decrease of the normalized preload becomes approximately constant, which is typically referred to as secondary creep (Meyers and Chawla, 2002). After four months (180,000 min), the locking screw has almost lost 70% of its initial preload.

Table 1 lists the experimental results of all polyethylene specimens used, showing the torque used to fasten the locking screw at the beginning of the experiment and the torque needed to loosen the locking screw at the end of the experiment, after 180,000 min. We observe that for all four polymer types, the torque needed to loosen the screw is almost three times smaller than the torque used to tighten the screw. We observe severe plastic deformation underneath the screw head, but it is a local phenomenon, and the thickness of the specimens remains unchanged across most of the proximal surface. Fig. 4 shows the ratio of final to initial torque used to loosen and fasten the screw, for each of the

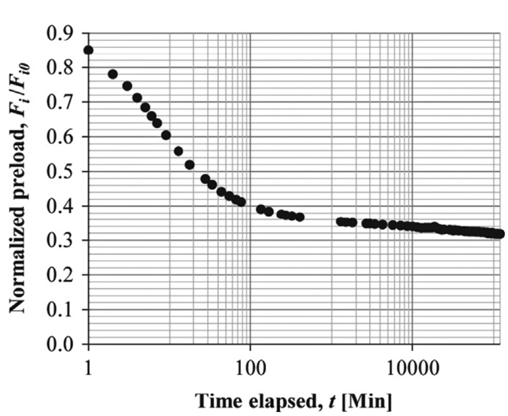

Fig. 3 – Preload of the locking screw F_i normalized with the initial preload F_{i0}, versus time.

four polyethylene types evaluated in this study. The average value is reported, calculated from five identical specimens. The error bars indicate ±1 standard deviation. Since the error bars overlap, the four polyethylene types appear to exhibit nearly equivalent propensities for screw loosening.

The reduction of locking screw preload is important because it relates to the torque needed to loosen the locking screw. The relationship between the torque requirement T and preload F_i is given as (Budynas and Nisbett, 2011)

$$T = KF_i d, \tag{1}$$

where d is the major diameter of the screw thread, and K is a coefficient that can be calculated as

$$K = \left(\frac{d_m}{2d}\right)\left(\frac{\tan\lambda + f\sec\alpha}{1 - f\tan\lambda\sec\alpha}\right) + 0.625 f_c \tag{2}$$

with d_m the mean screw thread diameter, f the friction coefficient between the screw and the threaded hole, f_c the friction coefficient between the screw head/collar and the proximal surface of the polyethylene specimen, λ is the screw thread helix angle and α is the screw thread angle (60° for metric thread). Typical values of K range between 0.1 and 0.5, mainly dependent on the friction coefficient f between the screw and the threaded hole, which is determined by the surface finish of the screw thread. From the torque to fasten and loosen the screw in combination with the preload measurement using the load cell, K is experimentally determined to be approximately 0.5 (using Eq. (1)). Although Eq. (1) shows that the torque needed to fasten and loosen a screw is independent of the length of the screw, empirical evidence suggests a higher likelihood of screw loosening of shorter screws (Chen et al., 2011). In fact, implant manufacturers only offer tibial inserts with locking screw mechanisms for tibial insert sizes thicker than a certain threshold.

Since polyethylene has viscoelastic properties and since the screw loosening torque diminishes under no other driving force than compression of the polyethylene and tension in the screw, we conclude that polyethylene creep caused the screw loosening observed in our experiment. This is confirmed by the diminished preload observed over the course of the experiment in the instrumented screw-block assembly. Polyethylene is subject to creep under loading and, thus, the locking screw preload inevitably decreases with time, reducing the torque needed to loosen the locking screw. Torque moments of approximately 10 Nm have been reported during gait (Andriacchi et al., 1986), and within the tibial implant assembly, this torque must be persistently resisted by all the features of the insert-tray locking mechanism to maintain the integrity of the assembly. Our experiment demonstrates that the locking screw is an impersistent locking feature due to polyethylene creep, and the nearly constant-rate secondary creep suggests that its loosening torque could diminish to practically nil in the long term. Consequently, the screw could be loosened by torsional strain within the insert itself (elastic deformations), or by micro-motion at the insert-tray junction, both resulting from normal gait (Rapuri et al., 2011). Repetitious occurrence of this micromotion could result in locking screw back-out as has been clinically observed (Cho and Youm, 2009; Rapuri et al., 2011).

Table 1 – Experimental results showing the different materials and the respective torque of the locking screw at the beginning and the end of the experiment.

ID	Material	Additive	Cross-link	Initial thickness [mm]	Final thickness [mm]	Initial torque [Nm]	Final torque [Nm]
a1	GUR 1020	Vitamin E	None	20.07	20.04	9.30	3.50
a2	GUR 1020	Vitamin E	None	20.02	20.02	9.00	3.20
a3	GUR 1020	Vitamin E	None	19.95	19.94	9.10	3.50
a4	GUR 1020	Vitamin E	None	19.97	19.97	9.30	3.60
a5	GUR 1020	Vitamin E	None	19.99	19.94	9.50	2.80
a6	GUR 1020	Vitamin E	None	20.04	20.06	0.00	0.00
b1	GUR 1020	None	None	19.97	19.97	9.20	3.20
b2	GUR 1020	None	None	20.02	20.01	9.00	2.90
b3	GUR 1020	None	None	19.99	20.00	8.90	3.10
b4	GUR 1020	None	None	20.00	20.00	9.00	3.20
b5	GUR 1020	None	None	20.05	20.03	9.10	3.60
b6	GUR 1020	None	None	20.03	20.03	0.00	0.00
c1	GUR 1020	Vitamin E	75 kGy gamma	19.99	19.97	8.90	4.00
c2	GUR 1020	Vitamin E	75 kGy gamma	19.89	19.89	9.00	3.00
c3	GUR 1020	Vitamin E	75 kGy gamma	19.87	19.87	9.10	4.00
c4	GUR 1020	Vitamin E	75 kGy gamma	19.98	19.98	9.00	2.80
c5	GUR 1020	Vitamin E	75 kGy gamma	20.05	19.97	9.20	3.50
c6	GUR 1020	Vitamin E	75 kGy gamma	20.02	20.06	0.00	0.00
d1	GUR 1020	None	75 kGy gamma	20.05	20.01	9.10	3.50
d2	GUR 1020	None	75 kGy gamma	20.03	20.01	9.30	3.00
d3	GUR 1020	None	75 kGy gamma	20.02	19.96	9.20	3.90
d4	GUR 1020	None	75 kGy gamma	20.03	20.00	9.40	2.70
d5	GUR 1020	None	75 kGy gamma	20.04	19.99	8.90	3.10
d6	GUR 1020	None	75 kGy gamma	20.07	10.04	0.00	0.00

Features to mitigate locking screw loosening include the use of a metal insert assembled with the polyethylene insert, as shown in one design example depicted in Fig. 5. For long-term efficacy, the metal insert should bear practically all of the compressive load under the screw cap and share practically none of it with the polyethylene insert. In addition, using a reverse threaded screw in the right knee, and/or using a threaded locking cap to secure the screw in place could be viable options. Surgeons selecting any such design should ascertain its rationale for avoiding screw loosening, mindful of the inherent creep behavior of polyethylene under sustained load.

4. Summary

Using a simple model representing a thick tibial insert, we have experimentally measured the reduction of locking screw preload resulting from polyethylene creep, along with the corresponding reduction of the loosening torque of the

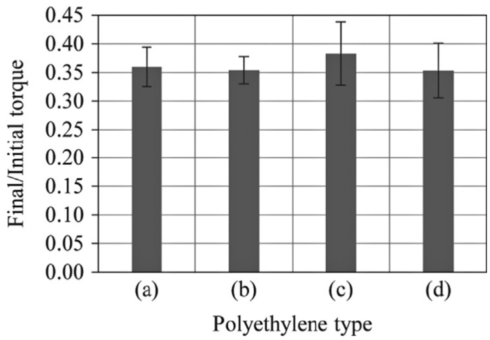

Fig. 4 – Average ratio of final and initial torque of the locking screw, showing the reduction in torque required to loosen the screw as a result of polyethylene creep. The error bars indicate ± one standard deviation.

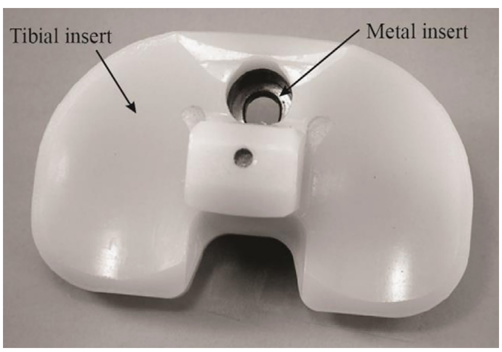

Fig. 5 – Tibial insert designed with a metal insert in the locking screw hole, which is a means to reduce the risk of locking screw loosening and back-out.

locking screw. The preload of the locking screw decreases significantly immediately after fastening the locking screw due to primary creep, and then decreases further at a reduced rate due to secondary creep. Consequently, the torque required to loosen the locking screw decreases with time. As a result, the torque applied to the tibial insert due to internal/external rotation within the knee joint during gait could drive locking screw loosening and back-out as postulated by others. The results are similar for four different types of polyethylene used in contemporary prosthetic knee joints, and have implications for the design of future locking screw mechanisms.

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