Techniques for improving the initial strength of the tibial tray-cement interface bond

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Aims

Loosening of the tibial component after total knee arthroplasty (TKA) is a common indication for revision. Increasing the strength of the initial tibial implant/cement interface is desirable. There is little information about the surgical techniques that lead to the highest strength. We investigated the effects of eight variables on the strength of the initial tibial baseplate/cement interface.

Materials and Methods

A total of 48 tibial trays were cemented into acrylic holders using cement from two manufacturers, at three different times (early, normal, and late) using two techniques: cementing the tibial plateau or the plateau and the keel; and involving two conditions of contamination with marrow fat (at the metal/cement and cement/cement interfaces). Push-out tests were performed with load continuously recorded.

Results

Compared with normal conditions, early cementing increased the mean strength of the interface when using the two cements, Simplex and Palacos, by 48% and 72%, respectively. Late cementing reduced the strength by 47% and 73%, respectively. Cementing the keel increased the mean strength by 153% and 147%, respectively, for the two cements. Contamination of the metal/cement interface with fat reduced the mean strength by 99% and 94% for the two cements but adding cement to the underside of the tibial tray prior to insertion resulted in the mean strength being lowered by only 65% and 43%, respectively.

Conclusion

In order to maximize the strength of the tibial tray/cement interface, cement should be applied to the component soon after mixing, contamination of the interface should be avoided, and the keel and the plateau should be cemented.

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The rate of revision total knee arthroplasty (TKA) has been projected to increase by 600% between 2005 and 2030.[1-3] This is, at least in part, due to undertaking this procedure in younger patients with higher postoperative levels of activity. Aseptic loosening of the tibial component remains a major indication for revision.[4-7] Mikulak et al[8] reported debonding of the tibial baseplate from the cement as the mechanism of failure in 2.9% of TKAs (16 of 557), at a mean follow-up of 56 months (37 to 89). Arsoy et al[9] also reported this as the mechanism of failure in 1.9% of TKAs (25 of 1337), median time of revision of 39 months (13 to 95). The prevalence of this loosening among the seven surgeons in that series varied by 6.4-fold, between 0.7% and 4.5%. This variation suggests an underlying technical component.

Cementation of the keel appears to play a role in survivorship. Silva et al[10] reported that five of 131 TKAs (3.8%) in which cementing had been limited to the tibial baseplate, underwent revision for tibial loosening at a mean of 22 months (2 days to 42 months). In contrast, only five of 1216 TKAs (0.4%) in which the keel was also cemented were revised for tibial loosening ($p < 0.0001$).

Schlegel et al[11] examined the relative advantages of pulsed lavage *versus* syringe lavage on the cement/bone interface. They performed pull-out tests using tibial trays implanted in cadaver knees and found that when pulsed lavage was used to remove marrow from the bone, all of six trays failed at the cement/tray interface. When only syringe lavage was used, five of six failed at the cement/bone interface, highlighting the importance of reducing marrow contamination to strengthen the cement/bone interface.

Evaluation of the initial strength at the cement/metal interface has been assessed using cylindrical

Table I. Experimental conditions

Test condition (temperature, 18ºC)	n	Time at insertion		Keel cemented
Tray Type: TRIATHLON		SIMPLEX (mixing 90 sec)	PALACOS (mixing 30 sec)	
1: Early cementing (low viscosity)	3	3 min*	2 min‡	No
2: Manufacturer recommendation ('normal')	3	7.5 min*	5 min*	No
3: Late cementing (high viscosity)	3	11 min*	9 min*	No
4: Fat contamination of tray/cement interface	3	7.5 min*	5 min‡	No
5: Fat contamination: cement/cement interface	3	7.5 min*	5 min‡	No
6: Early cementing (low viscosity)	3	3 min‡	2 min‡	Yes
7: Manufacturer recommendation	3	7.5 min†	5 min†	Yes
8: Late cementing (high viscosity)	3	11 min†	9 min‡	Yes
Total		24	24	
Grand total		48		

*Date, 21 November 2011; 55% room humidity
†Date, 5 December 2011; 38% room humidity
‡Date, 12 April 2013; 67% room humidity

specimens with surface textures similar to those of cemented tibial baseplates.[12] In general, the strength of the interface increased against both tensile and torsional forces with increasing surface roughness. However, this investigation was limited to the surface finish, did not use actual tibial components, and did not evaluate the type of cement or the cementing technique.

Because of the lack of *in vitro* data on the initial strength of the tibial baseplate/cement interface, we developed an experimental model and investigated the effect of seven different clinically relevant variables (eight conditions, Table I) on the strength of the initial interface. We hypothesized that: 1) the strength of the initial bond was a function of the timing of application of the cement to the baseplate with early application being stronger than later; 2) cementing the keel provides greater initial strength than only cementing the baseplate, and that 3) contamination of the interface with marrow fat would decrease the strength of the bond, but that cementing the underside of the tibial tray might mitigate this. The aim was to provide information that could reduce the occurrence of loosening of the tibial component by providing quantitative data about factors that affect the initial strength of the bond.

Materials and Methods

A total of 48 cylindrical tibial tray supports (diameter 3.5", height 2.125") were machined from 4" diameter acrylic rod (McMaster-Carr, Atlanta, Georgia) (Fig. 1a). A Y-shaped cut was machined onto one surface of the support to accommodate the keel of a Triathlon (Stryker, Mahwah, New Jersey) tibial tray and a 13 mm diameter hole was machined in the opposite surface to allow the insertion of a push rod. Acrylic material was chosen for its chemical affinity to bone cement. Our purpose was only to test the cement/tray interface, not the cement/acrylic interface. The cement/acrylic bond is usually stronger than the cement/tray bond. Thus, the cement/metal bond would usually break first, allowing us to measure the cement/tray bond as affected by different variables without any confounding variables being added. The acrylic support was held in place during the push-out test by custom made holders, with a diameter of 4.0" and a height of 3.0", machined out of acrylic tubes with a diameter of 4.0", whose walls were 3/8" thick (McMaster-Carr). The acrylic support was anchored into the holder by eight stainless steel hex head screws (McMaster-Carr) and by a 3/32" lip machined into the holder (Fig. 1b).

Two different cements, Simplex (Stryker) and Palacos (Heraeus Medical LLC or Zimmer Biomet, Warsaw, Indiana) were tested using the conditions summarized in Table I. In conditions one to five, only the plateau of the tibial tray was cemented (surface cementation). A rigorous, systematic approach was taken by the surgeon and researchers. Only one surgeon (TS) was involved, and the trays were inserted as similarly as possible in both time and technique, as described below, to eliminate confounding factors.

For conditions one to five, a silicone rubber plug was placed in the Y-shaped cut to prevent cement flowing into the keel space of the acrylic support. One 40 g pack of cement powder was added to a MinEvac 3 (Stryker) followed by the liquid monomer. The cement was mixed according to the recommendations of the manufacturer at one revolution per second for 90 seconds (Simplex) or 30 seconds (Palacos). It was then immediately applied to the acrylic support to ensure the highest bonding. After two minutes, the plugs were carefully removed so as not to disrupt the cement or allow it to enter the keel space. The tibial trays were then inserted at three different times: early (low viscosity/still very tacky; this varied between three minutes for Simplex and two minutes for Palacos, due to the faster drying time of Palacos), 'normal' (as recommended by the manufacturer), and late. Conditions four and five were designed to replicate contamination with marrow fat that may occur during surgery. Crisco (Orrville, Ohio) was melted and coloured with Oil Red O (Sigma-Aldrich, St. Louis, Missouri) to enhance the contrast with cement. After the cement was applied to the acrylic support, as in conditions one to three, 13 ml of Crisco, cooled to 37ºC, were injected into the tibial tray cut-out. Thus, when the tray was inserted, the Crisco was displaced onto the plateau. Two conditions were tested. In the first, no cement was applied to the back of the plateau, resulting in direct contamination of the cement/metal interface with fat. In the second, a thin layer of cement was applied to the tray before insertion, resulting in contamination with fat at the cement/cement interface. This test was performed only using the 'normal' insertion time.

In conditions six to eight, both the keel and plateau were cemented. Immediately after mixing, according to the procedure

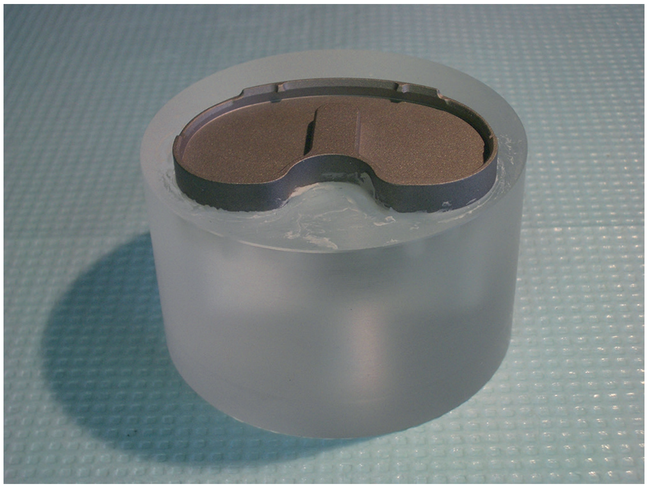

Fig. 1a

Fig. 1b

The tibial tray/acrylic holder system: a) acrylic support with a cemented tray; b) acrylic support (inverted) in a holder with a push rod.

described above, the cement was poured onto the acrylic support previously closed at the bottom with a silicone plug. The cement filled the keel space and the top surface of the support. Trays were inserted at three different times: early, 'normal' (as recommended by the manufacturer), and late. For all conditions, after the insertion, the excess cement was removed with a plastic knife and a 5 lb weight was placed on top of the tray for ten minutes. The temperature and humidity of the environment were recorded using a thermometer/hygrometer (Weatherguide model 1523, Taylor, Oak Brook, Illinois).

A push-out test was performed to evaluate the strength of the interface a minimum of 48 hours after insertion of the tray. For each test, the holder/acrylic support/tray assembly was placed in a universal load tester (INSTRON 8501, Norwood, Massachusetts) with the tray facing downwards (Fig. 1b). The space between the top of the acrylic holder and the tray ensured that it was free to separate from the acrylic support. A 91 mm long, 12 mm diameter stainless steel rod with a 16 mm long, 5 mm diameter hardened, steel tip was inserted into the hole in the acrylic support opposite the tray. This rod, which served as a loading piston for the push-out test, was designed so that its only point of contact was with the keel of the tray. This prevented force from being applied to anything other than the keel of the tray. A constant velocity of 0.05 mm/s was applied to the rod, and the load was recorded continuously throughout the test at a sampling rate of 10 Hz. The test was stopped when the plate debonded from the cement and visibly separated from the acrylic support, and the load dropped substantially.

Statistical analysis. A one-way analysis of variance (ANOVA) for all data ($p = 2.97E\text{-}16$) and two-factor ANOVAs (time and keel cementation) for Simplex and Palacos separately were performed to mitigate type-1 family-wise error. These were followed by two tailed Welch's *t*-tests for the difference of means, with the null hypothesis that there was no difference in the means between conditions. *T*-tests were chosen at the outset of the study without prior knowledge of the results (*a priori*). For these tests, each condition was compared with the manufacturer's recommended or 'normal' condition, within Simplex or Palacos, as this was considered the baseline. In addition, early keel cementing was compared with early plateau-only cementing for Simplex and Palacos separately to assess the effect of cementing the keel better. Late keel cementing, similarly, was compared with late plateau-only cementing. Simplex and Palacos were not compared with each other statistically because the aim of the study was not to provide guidance about choosing a cement, but to provide guidance about their use. The level of significance for all tests was 0.05. Statistical analysis was performed in Microsoft Excel (Microsoft, Redmond, Washington). Power (post hoc: $\alpha = 0.05$, desired power = 0.80) and optimal n/group (*a priori* estimation: $\alpha = 0.05$ and $\beta = 0.20$) were also calculated using G*power (Heinrich-Heine-Universität Düsseldorf, Germany).

Results

The results for both Simplex and Palacos can be seen in Figure 2. Two-factor ANOVA showed statistical significance for both time and cementation of the keel for both cements, in all four cases ($p < 0.001$), implying that both the time of application of the cement and whether the keel was cemented affected the strength of the bond. In general, the values of the force when using Simplex had a small variation within groups. The normal condition had a range for Palacos of 5.95 kN, and for Simplex of 2.15 kN.

The most notable exception to this was Simplex early keel cementing (range 14.788 kN). However, the loads in this case were so high that there can be little doubt of the strength of the bond, up to 37.8 kN load. In fact, the loads were so high that the keel of the tray was damaged by the steel pin pushing on it. This give in the keel may have lowered the load values, and the strength of the bond may be higher than reported. Likewise, our second test for Simplex applied to the keel, at normal timing, cracked off a section of the acrylic tray holder. This test had the highest load in its group, at 31.7 kN. This all suggests that about 30 kN may be the upper limit of this test configuration. Some cracking of the acrylic holder was also seen in the third trial

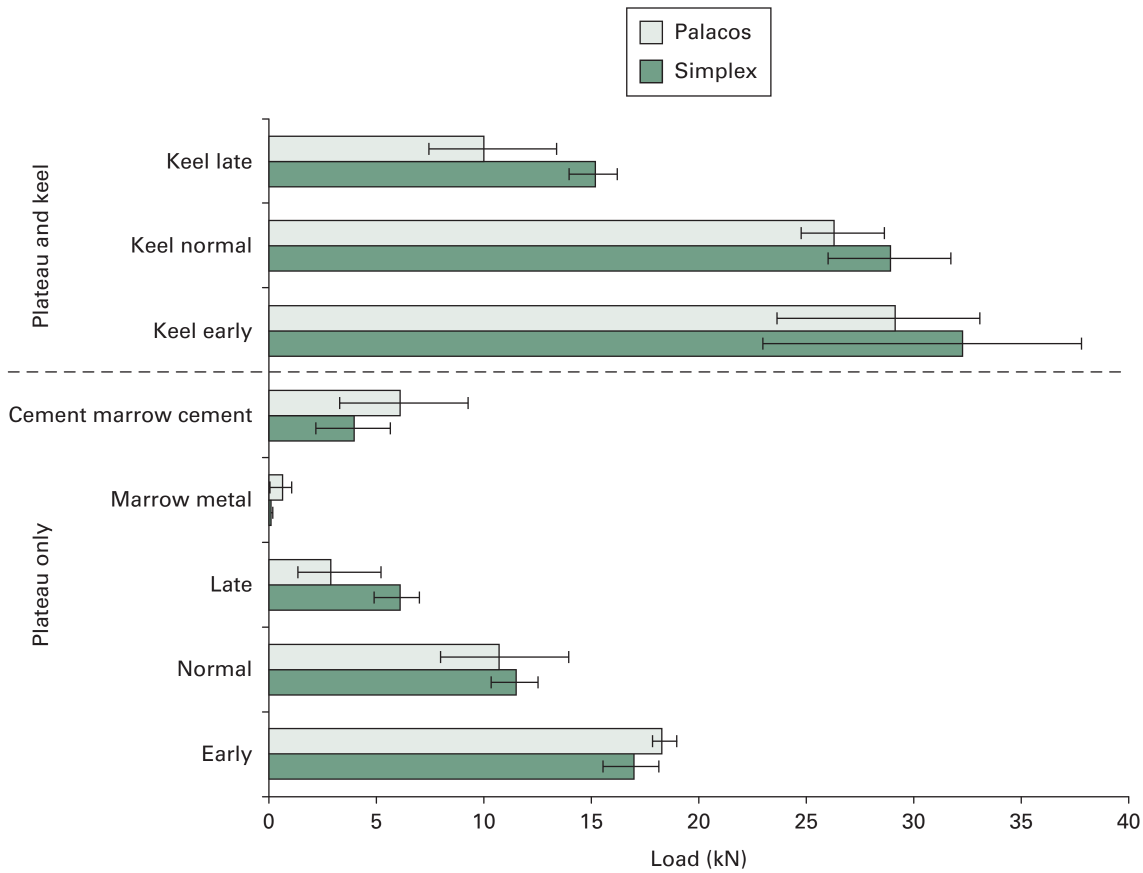

Fig. 2

Graph showing the mean values, with error bars, of the data.

using Simplex at normal timing and the first trial of Simplex keel at late timing. The variation was generally larger for Palacos than for Simplex, both for individual tests and difference of means, the exception being the early condition (Palacos, range 1.13 kN; Simplex, range 2.58 kN).

Compared with cementing under normal conditions, early cementing increased the mean strength of the Simplex interface by 48% (p = 0.011) and of the Palacos interface by 72% (p = 0.049). Late cementing reduced the mean strength of the Simplex interface by 47% (p = 0.004) and the Palacos interface by 73% (p = 0.034). Cementing the keel at the 'normal' time increased the mean strength of the Simplex interface by 153% (p = 0.010) and of the Palacos interface by 147% (p = 0.005) over the respective 'normal' cementing of the plateau only. Likewise, late cementing of the keel increased the mean strength of the Simplex interface by 150% (p = 0.001) and the Palacos interface by 252% (p = 0.043) over late cementing without the keel. Late cementing of the keel gave strengths comparable to that when using normal viscosity cement without the keel (Palacos: late keel, mean 10.03 kN; normal, mean 10.67 kN; Simplex: late keel, 15.20 kNl; normal keel, 11.43 kN). Contamination of the metal/cement interface with fat reduced the mean strength of the interface practically to zero (by 99% (p = 0.003) for Simplex and 94% (p = 0.030) for Palacos). This was reduced by only 65% (p = 0.008) for Simplex and -43% for Palacos by adding cement to the underside of the tibial tray prior to insertion in the presence of contamination with fat. However, this was not statistically significant (p = 0.133) for Palacos. A power analysis showed that all sample sizes were adequate to achieve a power of 0.80 for all comparisons made with Simplex and most comparisons with Palacos, with the exception of late keel *versus* late (Palacos 252%; p = 0.043, achieved power = 0.72), and adding cement to the underside of the tray to mitigate contamination with fat (Palacos -43%; p = 0.133, achieved power = 0.305).

Discussion

Aseptic loosening of the tibial component remains a major indication for revision following TKA.[4-7] Variation in surgical technique probably plays a role. We developed a laboratory model and investigated the effect of several different clinically relevant variables on the strength of the initial baseplate/cement interface as there is no *in vitro* data on this strength. The aim was to provide some information that might reduce the incidence of loosening of the tibial component. Although cement from two different manufacturers was used, our aim was not to recommend one brand over another, and the types of cement were not compared with each other, statistically.

The study has limitations. We only used one type of tibial component, and the results may not translate to other components. The 'heavy-grit' blasted surface finish, the shape of the baseplate and the keel of the Triathlon resembles some other contemporary tibial components. Although many bone cements

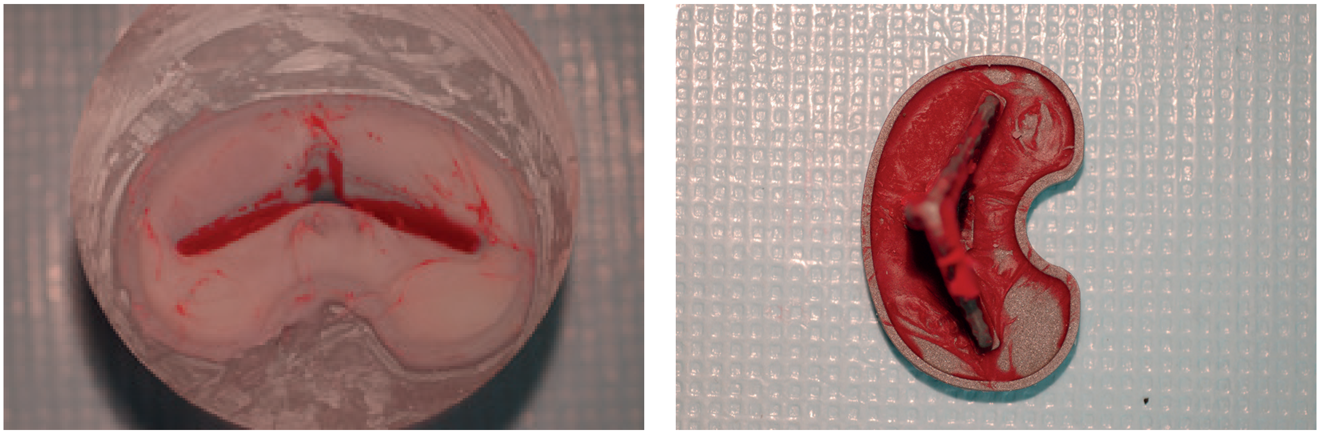

Fig. 3a

Fig. 3b

Photographs showing contamination at the metal-cement interface with marrow fat: a) an intact cement mantle on acrylic support; b) a tray completely lacking cement.

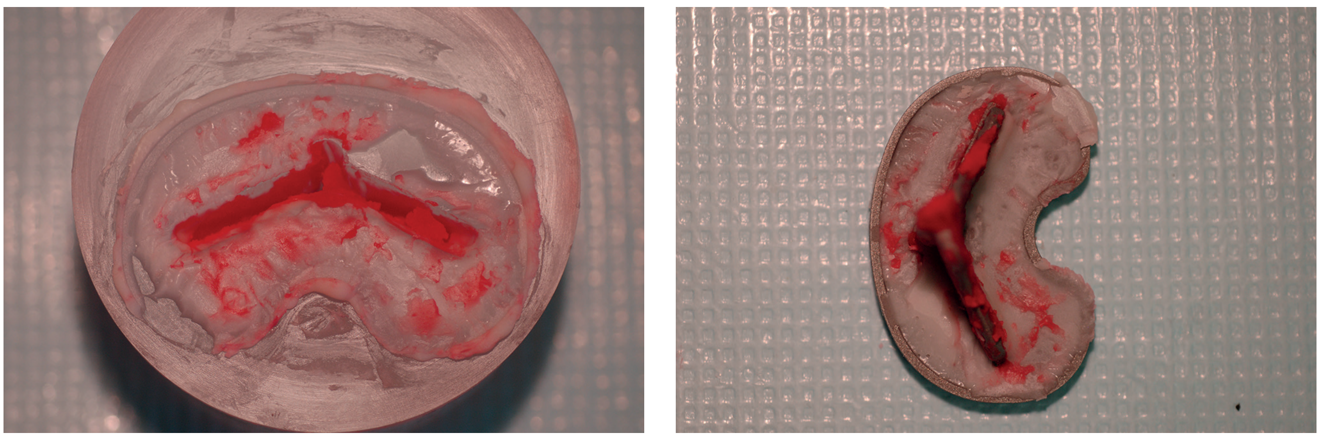

Fig. 4a

Fig. 4b

Photographs showing contamination at the cement/cement interface with marrow fat: a fracture occurred within the cement mantle as shown in a) residual cement on the support and b) a thick layer of cement remaining on the tray.

are commercially available, we only tested two. Simplex and Palacos, however, are the market leaders and the results have implications for most cemented TKAs. We only tested three components for each condition. However, this proved to be adequate for the statistical tests performed on the samples using Simplex. The adequacy of the sample size when testing significance varied for the samples using Palacos. Despite this, significant differences were found between several cementing conditions. We chose a temperature and humidity that were similar to that of many operating rooms. We recognize, however, that these conditions can vary and can affect the characteristics of cement. Having established this *in vitro* model, other components, other cements, and other scenarios relating to contamination at the interface could be similarly tested.

This is the first study, to our knowledge, to use commercially available tibial baseplates in an investigation of the strength of the metal/cement interface. The configuration of the test allowed insertion of the baseplate into a space similar to the one made during surgery, mimicking the displacement of the cement and the influence of potential contaminants such as fat, blood, and saline.

Shephard et al[13] investigated the relationship between surface finish and the time of application of cement to metal using cylindrical sample prostheses in a model of cemented total hip arthroplasty. Their results were similar to ours. Roughened surfaces had significantly greater tensile and shear strengths at early times of cementation with significant decreases in tensile and shear strengths as this time increased.

We also found that the earlier application of cement to the tibial component significantly increased the strength of the interface while later application decreased this strength. For the tests involving both Simplex and Palacos, this significance was clear both practically and statistically. With Simplex, early cementing increased the mean strength of the interface by 48%, and late cementing decreased it by 47%. With Palacos, early cementing increased the mean strength by 72%, and late cementing decreased it by 73%. The handling characteristics of cement perioperatively can vary due to differences in temperature, humidity, and mixing technique. In some cases, the cement may be doughier or 'drier' than intended when the baseplate is inserted, and the initial strength of the interface is reduced. In our experience, Palacos reaches a doughy phase sooner than Simplex, which may explain the greater variation in the initial strength in the normal conditions for Palacos, the lesser variation (range, standard error) in Palacos for the early conditions, the greater mean improvement from cementing early with Palacos, and the greater mean loss of strength from cementing late.

Consistent with clinical experience,[10] cementing the keel provides greater initial strength than cementing only the plateau under normal timing conditions. Because of the increased surface area and perpendicular orientation of the keel, cementing of keel provides relatively high initial bond strength, even with late cementing. Late cementing with the keel gave strengths comparable to normal viscosity cementing without the keel. Thus, cementing the keel may provide a margin of safety against accidentally using cement that is too dry.

Contamination of the interface with marrow fat can substantially decrease the strength, but coating the undersurface of the tibial plateau with cement can mitigate the adverse effect of this contamination. In the contamination trials with Simplex, not coating the underside of the plateau with cement resulted in contamination at the metal/cement interface with fat, and reduced the strength of the interface to essentially zero when complete separation of the tray occurred without any damage to the cement (Fig. 3). However, when the underside of the tray was coated with cement before insertion, contamination with fat occurred at the cement/cement interface. This reduced the mean strength by only 65%, which was similar to cementing late, mitigating the effect of the contamination. The failure occurred within the layer of cement (Fig. 4). In the case of Palacos, contamination of the metal/cement interface with fat similarly reduced the strength by 94% ($p = 0.03$). Contamination of the Palacos cement/cement interface with fat reduced the mean strength by only 43%. However, this was not statistically significant compared with the normal condition ($p = 0.133$). As our null hypothesis was that there would be no difference in strength, this raises the possibility that coating the undersurface of the tibial plateau completely would mitigate the effect of contamination when using Palacos.

We used enough fat to cover the entire interface in an attempt to completely disrupt bonding. This may never occur *in vivo*. However, if fat, blood, or saline in the region of the keel is displaced into the interface, lesser degrees of contamination could decrease the strength of the initial bond to some degree. Contamination may not be seen by the surgeon as the keel and the tibial bone are covered by the plateau portion of the component as it is being inserted. The important point here is that even under the most adverse conditions of contamination, coating the underside of the tibial plateau with cement substantially reduced the effects of contamination for both Simplex and Palacos.

Based on these results, in order to maximize the strength of the initial baseplate/cement interface, the surgeon should cement the keel as well as the plateau of the component. Early application of cement to metal increases the strength of the interface. The surgeon should avoid contamination of the implant and consider applying cement to the undersurface of the component soon after mixing, while it is tacky, apply cement to the prepared bone when it is doughier, and then insert the component.

Take home message

- Apply polymethylmethacrylate (PMMA) cement early to the tibial tray to maximize tray/cement interface strength.
- Cement both the keel and tibial plateau to maximize fixation.
- Avoid contamination of the metal/cement interface. Contamination can reduce the interface strength by as much as 99%.

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H. Schmalzried: Laboratory work, Writing the manuscript.
T. P. Schmalzried: Clinical perspective, Planning the study, Laboratory work, Writing the manuscript.

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