Pulsed lavage improves fixation strength of cemented tibial components

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Abstract Pulsatile lavage is purported to improve radiographic survival in cemented total knee arthroplasty (TKA). Similarly, a potential improvement of fixation strength of the tibial tray has been assumed based on the increased cement penetration. In this study, the influence of pulsed lavage on fixation strength of the tibial component and bone cement penetration was evaluated in six pairs of cadaveric specimens. Following surgical preparation, the tibial surface was irrigated using pulsatile lavage on one side of a pair, while on the other side syringe lavage was applied. All tibial components were implanted using the same cementing technique. Cement penetration and bone mineral density was assessed based on computed tomography data. Fixation strength of the tibial trays was determined by a pull-out test with a material testing machine. Median pull-out forces and cement penetration were significantly ($p=0.031$) improved in the pulsed lavage

group as compared to the syringe lavage group. Enhanced fixation strength is suggested as being a key to improved survival of the implant. Consequently, pulsatile lavage should be considered as a mandatory preparation step when cementing tibial components in TKA.

Introduction

Survival rates of 90–95% at ten to 15 years achieved with contemporary total knee arthroplasty (TKA) designs prove the viability of the operative treatment of end-stage degenerative joint disease [6–8, 13, 23]. However, aseptic loosening of the cemented tibial component remains problematic, as this complication remains the main reason for failure [23]. The bone–cement interface seems to be especially critical in terms of implant survival [16, 27]. This can be partially explained by increased micromotion at this interface due to high shear forces and by bone resorption due to the presence of polyethylene wear particles (“back-side-wear”) [4, 22, 28]. Mobile bearing knees, high flexion knees or other modern designs may alter loading of the tibial implant and possibly increase strains at the bone–cement interface. Thus, maximum primary stability and a reduction of local micromotion between implant and bone should be achieved at the time of surgery to improve long-term survival. Apart from factors like surgical preparation and implantation technique, irrigation of the osseous surface and the application of bone cement are crucial steps for the initial stability of the component [5, 24, 25]. High-pressure lavage, combined with a modern cementing technique, has the potential to reduce failures in cemented revision total hip arthroplasty (THA) due to aseptic loosening [2, 3]. Especially the interdigitation of cement into the cancellous bone may be important in enhancing

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shear strength at the corresponding interface [1, 19, 21]. The incidence of radiolucent lines in TKA was reduced significantly when pulsatile lavage was routinely used [3, 27]. Although radiographic findings are not necessarily indicators of clinical failure, progressive radiolucencies are commonly associated with implant loosening and hence their reduction would appear to be favourable [9, 26].

The particular benefit of pulsed lavage in improving tibial implant stability in TKA has not been proven to date. The aim of this study was to investigate whether the amount of cement penetration into trabecular bone increases in pressure-irrigated specimens and whether the cement penetration depth influences fixation strength in cemented tibial components.

Materials and methods

Twelve paired, proximal thirds of fresh-frozen cadaveric tibiae, which were stored at -27°C , were used for analysis. Median age of the donors (four male, two female) was 71.5 years (range 48–90). Specimens were thawed for 24 hours to ambient temperature prior to the experiments. Computer tomography (CT) scans were performed for all tibiae to determine bone mineral density (BMD) and to rule out osseous irregularities (Philips M 8000 Brilliance 4, Best, The Netherlands; resolution $0.4 \times 0.4 \times 0.6 \text{ mm}^3$). BMD was determined from the mean Hounsfield unit (HU) value within a cylindrical volume of $4,000 \text{ mm}^3$ near the tibial surface using a calibration phantom (Avizo 5.0, VSG, Burlington, MA, USA). Surgical preparation and implantation of the tibial plateau was performed according to manufacturer's specifications (PFC Sigma Knee System, DePuy Orthopaedics, Warsaw, Indiana, USA). A screw thread (8 mm) was cut into the upper, central hole of the components to facilitate later testing. Horizontal resection was performed with neutral slope (0°) cutting guides and the corresponding drills and keel punches were used for final preparation. Following randomisation, the cut surface of one side of a pair underwent pulsatile lavage using 1800 ml of normal saline (Simpulse SOLO Irrigation System, Bard Davol, Warwick, RI, USA), while the contralateral side was irrigated with the identical volume of fluid using a bladder syringe.

A high viscosity bone cement was chosen for fixation of the components (SmartSet HV, DePuy Orthopaedics, Warsaw, Indiana, USA). According to the manufacturer, the prepared bone cement allows a working time of eight minutes, while final set is reached at 12.5 minutes at 18°C . After careful drying of the bone surfaces, bone cement was vacuum mixed (SmartMix Cemvac 60 g, DePuy Orthopaedics, Warsaw, Indiana, USA) for 60 seconds and application to the bone was started 180 seconds later. An appropriate

amount of bone cement was hand-pressurised on the tibial surface while the stem channel was left cementless (surface cementation technique). Each tibial tray was carefully inserted and impacted with ten mallet blows. After curing of the cement, specimens underwent CT scans for assessment of bone cement penetration (Philipps Brilliance 40 CT, Best, The Netherlands; resolution $0.15 \text{ mm} \times 0.15 \text{ mm} \times 0.40 \text{ mm}$). Artefacts in the CT images caused by the metallic implant were reduced by a smoothing kernel filter. Bone, cement and implant were segmented based on an automatic thresholding algorithm (Avizo 5.0, VSG, Burlington, MA, USA). Based on the known volume of each implant, threshold between bone and cement was set to 800 HU, which showed the most accurate results in a previous validation study. For three specimens with high BMD, automatic segmentation of cement and trabecular bone was error-prone requiring manual adjustments to separate the corresponding volumes. Segmented volumes were then reconstructed. Cement penetration was sampled perpendicular to the tibial surface for a maximum depth of 20 mm (Matlab 14, Mathworks, Natick, MA, USA; resolution $0.5 \text{ mm} \times 0.5 \text{ mm}^3$). Ten landmarks were positioned manually on the cut bone surface to define the tibial plateau plane using a least square best-fit algorithm. Median cement penetration depth and range were calculated for the entire cemented area.

Specimens were then embedded in metal cylinders 8 cm below the tibial tray with the surface being level with the testing table (RenCast FC 53 Polyol/FC 53 Isocyanate; Huntsman, Salt Lake City, UT, USA). For assessment of

Fig. 1 Set-up for mechanical testing (adapter detached from material testing machine)

Table 1 Specimen characteristics and results

Specimen	Sex	Age (years)	Pulsatile lavage	BMD (mg/cm ³)	Tray size	Pull-out force (N)	Cement penetration (mm)
1R	F	90	Yes	31	3	1377	1.94
1L			No	41	3	615	0.62
2R	M	66	No	57	5	242	1.17
2L			Yes	90	5	864	1.35
3R	F	48	No	63	3	465	0.78
3L			Yes	78	3	1287	1.29
4R	M	70	Yes	69	3	1142	0.86
4L			No	68	4	683	0.80
5R	M	74	Yes	110	4	1391	1.74
5L			No	97	4	574	1.66
6R	M	73	No	86	3	562	0.51
6L			Yes	93	3	1263	1.18

R right, L left, F female, M male, BMD bone mineral density

fixation strength, specimens were mounted on a material testing machine (MTS 858, MTS Systems, Eden Prairie, MN, USA). A custom-made adapter was screwed to the tibial tray, attached to a kardan coupling and connected to the servohydraulic machine (Fig. 1). A XY-table was used to prevent shear forces. Pull-out testing was performed under displacement control at a rate of 0.5 mm/sec until interface failure. Sampling frequency was 50 Hz. Maximum force to failure was recorded. The failure pattern was photographed to allow later analysis. A Wilcoxon matched pairs signed rank test with a type 1 error probability of 5% was calculated to compare pull-out forces, cement penetration and BMD between the pulsed and the syringe lavage group. Statistical analysis was carried out using GraphPad Prism 5 for OS X (GraphPad Software, Inc., La Jolla, CA, USA).

Results

Median BMD of all specimens was 74 mg/cm³ (range 31–110; Table 1). No difference in BMD between the pulse lavage and syringe lavage groups was present ($p=0.312$). Cement penetration was significantly ($p=0.031$) increased

in the pulsed lavage group compared to the syringe lavage group (1.32 mm, range 0.86–1.94 vs. 0.79 mm, range 0.51–1.66). Median pull-out forces were 1,275 N (range 864–1391) and 568 N (range 243–683) in the pulsed lavage group and the syringe lavage group, respectively (Fig. 2). The force to failure was similar to the penetration depth higher in the pulse lavage group ($p=0.031$). In all pulsed lavage specimens failure was induced at the cement–implant interface, while in the syringe lavage group, five of the six failures occurred at the cement–bone interface (Fig. 3). In one specimen (5L, syringe lavage) a mixed failure mode was observed, as half of the cement mantle remained on the tibial surface, while the other part was bonded to the implant. Figure 4 shows an example for the cement penetration analysis for one specimen.

Discussion

Various studies have demonstrated the efficacy of pulsed lavage in enhancing cement penetration into cancellous bone [2, 3, 12, 20]. As greater cement penetration allows increased contact area with trabeculae in the cancellous

Fig. 2 Cement penetration depths (*left*) and pull-out forces (*right*) for the six tibial pairs

Fig. 3 Characteristic failure pattern for one specimen pair: syringe lavage (*left*), pulsed lavage (*right*)

bone, improved strength at the interfaces and hence increased stability of the implant may be expected [18]. Although improvements in clinical survival were demonstrated for cemented THA when pulsatile lavage was routinely used, comparable evidence for TKA is missing [2, 10]. An Australian survey of cementing techniques in TKA stated that only 68% of the respondents used pulsed lavage on a routine basis [17]. Given the increasing economic pressure on hospitals, there is concern that this number might further decrease.

This study demonstrates that cement penetration and likewise fixation strength improved significantly when pulsed lavage was used. In the syringe lavage specimens, failure occurred at the cement–bone interface, which is a sign for the low interface strength. This is critical, as fixation in this area has been shown to be crucial for the outcome in TKA [16, 25, 27]. It should be noted that the pull-out testing performed in this study represents a non-physiological loading condition, as the tibial tray is loaded under shear and compression *in vivo*. The testing setup used was a simplification of the *in vivo* loading to estimate overall interface strength, as shown in a comparable setting for patellar components [32].

In our study, a surface cementing technique was used. This could be questioned regarding the ongoing debate, whether the stem should be cemented or left cementless. A cementing technique involving the stem of the implant would probably show an increase in overall pull-out forces. However, access of pulsatile lavage to the stem channel is limited, and thus a surface cementing approach was chosen to isolate the influence of the irrigation technique.

From a clinical point of view, the penetration achieved might be insufficient as cement intrusion below 1.5 mm has been shown to be associated with early development of radiolucent lines [31]. However, similar cement penetrations were shown before in a cadaveric study [20]. Furthermore, definition of the “ideal cement penetration” in TKA is still controversial, e.g. while some studies recommended a minimal interdigitation depth of 4 mm, others deemed a range from 3–5 mm as acceptable [18, 29–31]. Generally, a minimum penetration of 2–3 mm has been suggested to engage at least one layer of transverse trabeculae and thus improve resistance to shear and tensile forces [31]. Care should be taken when interpreting these recommendations, as they are partially based on sawbone models or radiographically determined data. In plain radiographs, accuracy of discrimination between cement layer above the bone surface and actual cement interdigitation is difficult, possibly leading to an overestimation of the actual cement penetration. The cement was applied manually to the prepared specimens in this study. This method was shown to achieve less cement penetration in comparison to pressurisation techniques using a syringe or gun [15, 18]. However, other investigations described either only minor improvement of intrusion depths or overpenetration (> 5 mm) when using cement pressurisation [14, 30]. Though, penetration depths exceeding 5 mm might lead to thermal necrosis and thus early weakening of the resulting interface [11].

Despite proven advantages, pulsatile lavage seems to be used infrequently during preparation in TKA. The results of this study provide evidence that the use of pulsed lavage improves fixation strength and bone cement penetration considerably when compared to syringe lavage. Since

Fig. 4 *Left*: 3D reconstruction of bone and cement mantle. *Right*: Anterior-posterior projection of the cement penetration depth (mm)

initial fixation strength is considered a key to long-term survival of the implant, the use of pulsed lavage should be regarded as a mandatory preparation step when cementing tibial components.

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