

# Cementing of the hip arthroplasty stem increases load-to-failure force: a cadaveric study

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**Background and purpose** — To date, there is not a single clinical or mechanical study directly comparing a cemented and a cementless version of the same stem. We investigated the load-to-failure force of a cementless and a cemented version of a double tapered stem.

**Material and methods** — 10 femurs from 5 human cadaveric specimens, mean age 74 years (68–79) were extracted. Bone mineral density (BMD) was measured using peripheral quantitative computed tomography. None of the specimens had a compromised quality (average T value 0.0, –1.0 to 1.4). Each specimen from a pair randomly received a cemented or a cementless version of the same stem. A material testing machine was used for lateral load-to-failure test of up to a maximal load of 5.0 kN.

**Results** — Average load-to-failure of the cemented stem was 2.8 kN (2.3–3.2) and 2.2 kN (1.8–2.8) for the cementless stem ( $p = 0.002$ ). The cemented version of the stem sustained a higher load than its cementless counterpart in all cases. Failure force was not statistically significantly correlated to BMD ( $p = 0.07$ ).

**Interpretation** — Implanting a cemented version of the stem increases the load-to-failure force by 25%.

It has been shown that cementless hip arthroplasty components have a higher incidence of periprosthetic femoral fractures (PFFs), with type 2 stems the most susceptible (Carli et al. 2017). The type 2 stem is calcar loading and the most commonly used (Khanuja et al. 2011). Cemented stems are primarily classified as loaded-taper or composite-beam (Scheerlinck and Casteleyn 2006) with the former having a reported higher PFF incidence rate (Carli et al. 2017).

Mechanically, only loaded-taper designs have been investigated for load-to-failure. Ginsel et al. (2015) found that an Exeter stem (Stryker Orthopaedics, Mahwah, NJ, USA) with a larger cross-section tolerates more torque until failure, Morishima et al. (2014) found that an Exeter stem (Stryker) with increased length tolerates more torque and energy until failure. Erhardt et al. (2013) compared the double taper CPT stem (Zimmer, Warsaw, IN, USA) with the triple taper C-Stem (DePuy, Raynham, MA, USA) and found no difference in torque or energy, but only in fracture patterns. Clinically, both in electively implanted setting and in fracture treatment settings, cemented stems have a substantially lower incidence of PFF (Carli et al. 2017).

Due to different classifications of cementless and cemented stem designs, different availability of each stem in different countries as well as the fact that not all stem designs have a cemented and a cementless version, we were unable to identify a mechanical comparison of a cemented and cementless version of the same stem (Carli et al. 2017).

We investigated and quantified the direct load-to-failure force of a cementless and a cemented version of a double tapered stem. Based on current literature evidence, our hypothesis was that the cementless version would have lower load-to-failure.



Figure 1. Cemented and cementless Polarstem with the original instruments.

## Material and methods

### Specimen preparation

The femurs were donated by the authors' anatomical institute. The specimens originated from 4 male and 1 female adults with an average age of 74 years (68–79). After obtaining the paired femurs they were embalmed with a solution consisting of 96% ethanol and 2% formaldehyde. During perfusion, approximately 15 L of the solution was passed through the femoral artery. All specimens were thawed at thermostat temperature of 19°C and the implantation and testing were performed at that same ambient temperature.

To exclude damage related to preexisting fractures or tumors, all specimens were clinically and radiographically examined for integrity. The surrounding soft tissue was stripped from the specimens. Bones were then wrapped in moist towels using the aforementioned embalming solution and stored in a cooling chamber at 4°C to avoid drying artifacts until testing, which occurred after 6–12 months.

### Bone mineral density assessment

In order to exclude osteoporotic specimens and to do a comparison of load-to-failure and bone density, a bone

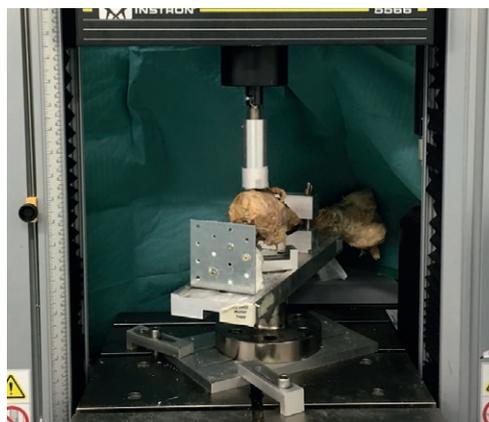


Figure 2. The mechanical setup.

mineral density (BMD) analysis was performed. Peripheral quantitative computed tomography (pQCT) measurements were used to analyze BMD. For the pQCT measurements, a Stratec XCT Research SA instrument was used (Stratec Medizintechnik GmbH, Pforzheim, Germany). Measurements of BMD were performed at the neck region after obtaining specimens from the cadavers.

### Femoral stem tested

The implants we compared were the cementless Polarstem and the cemented Polarstem (Smith & Nephew, Baar, Switzerland). Cementless Polarstem is a titanium alloy (Ti-6Al-4V ISO 5832-3) double tapered femoral stem with 180 µm of Ti-plasma spray combined with 50 µm of hydroxyapatite coating with fixation occurring on the calcar and metaphysis. Cemented Polarstem is a stainless-steel ISO 5832-9 double tapered femoral stem. We used standard stems with CCD 135°, with each specimen in a pair randomly receiving either a cemented or a cementless stem (Figure 1).

The implantation was performed according to the manufacturer's operating manual and using the original instruments. The trials were implanted until a secure press-fit was obtained. The trials were controlled radiologically for size and fracture. For the cemented version, we used 40 mL of Palacos R+G (Heraeus, Hanau, Germany) in a third-generation technique, with a Buck cement restrictor (Smith & Nephew, Baar, Switzerland). A minimum of 20 minutes was allowed for the cement to set. A polyethylene cup with an inner diameter of 32 mm was used as the acetabulum (Reflection Smith & Nephew, Baar, Switzerland). It was fixed with cement and screws in 45° inclination and 10° of anteversion. A 32 mm ceramic head (BioloX, Ceramtec, Plochingen, Germany) was implanted on the femoral component. The distal femoral fixation was placed at 40 cm distal from the resection using a screw clamp to prevent axial rotation of the specimen. Proximally, a joint was created by inserting the ceramic head into the created acetabulum. The femoral mechanical axis was set parallel to the ground (Figure 2).

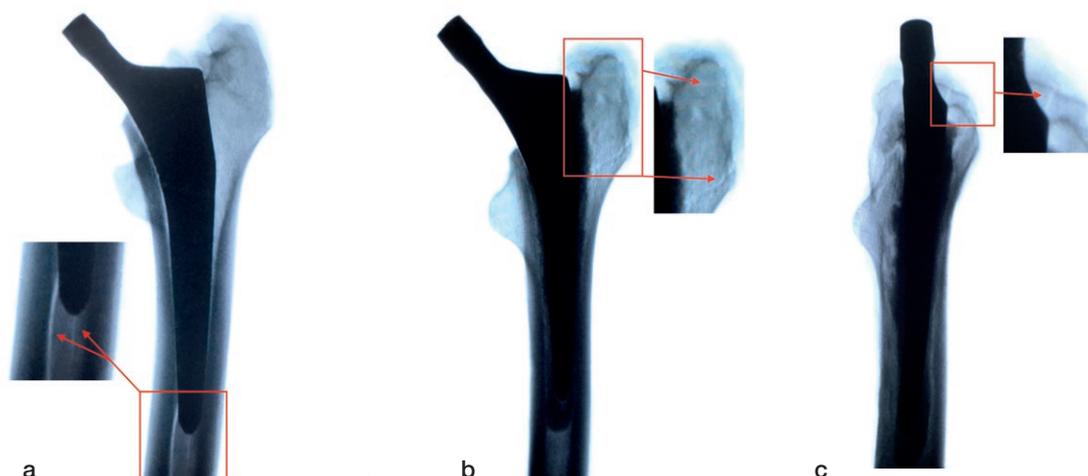


Figure 3. (a) Radiograph of the fracture of the femur with a cementless stem, anteroposterior view. (b) Radiograph of the fracture of the femur with a cemented stem, anteroposterior view. (c) Radiograph of the fracture of the femur with a cemented stem, lateral view.

### Load to failure assessment

Each specimen was tested with load-to-failure on an Instron 5566 universal testing machine (Instron Corp., Darmstadt, Germany) (Figure 2). A 3 cm diameter cylinder was attached to the testing machine and used to apply compression force axially. The test sequence started at 5 N force with the cylinder positioned directly over the greater trochanter. The load was continuously raised at a velocity of 3 N/s. Criteria for discontinuation of testing were premature rotation of the femur (fixation failure) or occurrence of a fracture (final result).

### Power analysis and statistics

First, a trial run with 4th-generation composite femurs (Sawbones, Pacific Research Laboratories, Inc., Vashon, WA, USA) was performed in the same manner as described above for the purpose of power analysis. Based on the differences in forces observed, to reach an alpha of 0.05 and a power of 0.8 the number of cadaveric pairs necessary was 5.

The data were collected at 100 ms intervals using the instrument-specific Bluehill Software (Instron, Norwood, MA, USA).

Load at failure (kN), and time (s) were recorded. The difference in force between implants was statistically analyzed using a paired t-test and the correlation of force and BMD was analyzed using Pearson's correlation. Statistical significance was set at  $p < 0.05$ .

### Ethics, funding and potential conflicts of interest

All donors provided written consent by their own free will for the use of their body for research purposes. The study was approved by our institution's ethics board (164/17, 02 November 2017). This study received no external funding.

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## Results

### Bone mineral density

Bone mineral density of the tested femurs was 0.9 g/cm<sup>2</sup> (0.8–1.1). There was no statistically significant difference in BMD between the specimens receiving cemented and cementless components ( $p = 0.8$ ). None of the specimens were of compromised bone quality compared with the corresponding reference value (T-value range –1.0 to 1.4).

### Implants and load-to-failure

Implant sizes were the same in each pair with 1 pair size 1, 2 size 3, 1 size 4, and 1 size 5. A fracture was produced consistently in all specimens. Average load-to-failure of the cemented stem was 2.8 kN (2.3–3.2). Average load-to-failure of the cementless stem was 2.2 kN (1.8–2.8). Cementless stems suffered a fracture of the medial wall on the level of the fracture, extending distally. Cemented stems fractured primarily on the greater trochanter, extending onto the lateral wall, which ultimately caused a dislocation of the stem (Figure 3). The cemented stems sustained a higher load than the cementless stems in all pairs. The mean estimated difference in force between the 2 stems was 0.6 kN (95% CI 0.3–0.8), which corresponds to a force produced by 57 kg. This difference was statistically significant ( $p = 0.002$ ). There was no statistically significant correlation between fracture force and BMD ( $p = 0.07$ ).

## Discussion

This study demonstrates on average 25% increased load-to-failure force of a cemented version compared with a cementless version of the same femoral stem.

There are a number of studies comparing PFF rates in cemented and cementless stems after both elective total arthroplasty and hemiarthroplasty due to femoral neck fracture, but of different designs. After elective arthroplasty, an increased PFF incidence in cementless compared with cemented stems, with a 3- to 14-fold difference in incidence, was found in a number of studies (Cook et al. 2008, Sheth et al. 2013, Thien et al. 2014, Abdel et al. 2016). The highest reported incidence is nevertheless only 0.45% after 2 years (Thien et al. 2014) and 3.5% after 20 years (Abdel et al. 2016) for uncemented stems. After hemiarthroplasty due to femoral neck fracture, the differences are even more extreme and – for some cementless stems – concerning. The differences occur mainly due to poorer bone quality observed in hemiarthroplasty patients (Langslet et al. 2014). In their respective studies, Langslet et al. (2014), Inngul et al. (2015), Phillips et al. (2013), Foster et al. (2005) all uniformly report a higher incidence of PFF in cementless stems, with incidence of PFF with a cementless stem as high as 12% after 12 months (Inngul et al. 2015). Even young patients have been reported to have excellent outcomes after cemented stems (Kiran et al. 2018).

Mechanically, it has been shown that larger stems can improve primary stability of both cemented (Ginsel et al. 2015) and cementless (Fottner et al. 2017) stems due to a better bone load. Increasing the length of the cemented stem has also been shown to increase primary stability (Morishima et al. 2014). Both of these aspects increase the surface contact area between the implant and the bone and have been utilized in designing the stem used in this study (Klasan et al. 2018), when compared with the implant it was based on, the Corail stem (DePuy, Raynham, MA, USA). These 2 stems have not been tested against each other. Furthermore, Carli et al. (2017) report a lack of comparison between a cemented and a cementless version of the same stem with regards to PFF rate or load-to-failure. Data suggest that bone mineral density around the stem decreases more with a cemented stem (Li et al. 2007) than with a cementless stem (Flatøy et al. 2016, Aro et al. 2018), without a correlation to subsidence. Again, a direct comparison like that in this study is yet to be performed.

In clinical settings, the evidence suggests a higher risk of PFF (Hailer et al. 2010, Sidler-Maier and Waddell 2015, Carli et al. 2017) and a higher revision rate (McMinn et al. 2012) for cementless stems. Yet, the evidence suggests cementless stems are used more often (Lehil and Bozic 2014). According to some researchers, a clear consensus on when to use cemented stems is missing (Moskal et al. 2016).

This lack of consensus and data was one of the reasons to perform this study. Due to a higher risk of revision in older patients with cementless stems (Jämsen et al. 2014), studies set different thresholds for “older age” patients (Moskal et al. 2016), which affects the results depending on the study population. Since the definition of “elderly” is also unclear in the orthopedic literature (Sabharwal et al. 2015), these thresholds are even more difficult to define. There is also an expectation of older patients having lower bone quality (Wright et al. 2014) where a combination of a higher risk of falling, soft bone, and slower osseointegration make the surgeon incline toward cementing the stem. This provides immediate osseointegration and protects the implant at the same time, as was shown in our study. In this study, where non-osteoporotic bones were used, the difference in force-to-failure corresponds to 80% of the weight of an average European adult (Walpole et al. 2012).

Stem design has also been shown to influence the PFF and revision rate for both cemented (Palan et al. 2016, Kazi et al. 2019) and cementless stems (Carlson et al. 2017). Also, cemented and cementless versions of the same stem do not exist as often or do not have worldwide distribution. For instance, the cemented version of the stem used in our study is not available in the United States despite showing excellent clinical results (Klasan et al. 2018). Further studies with other stems available in both versions in a clinical and a mechanical setting are needed to provide this information.

Several limitations need to be noted for our study. Cemented fixation occurs within 10 minutes at room temperature, whereas cementless stems were press-fitted. The direct implications of our study can therefore only be observed in the postoperative phase, prior to bone in-growth *in vivo*; this, however, remains a clinically relevant period with registry data showing a PFF rate of  $2.1\% \leq 90$  days postoperatively (Lindberg-Larsen et al. 2017). Second, unidirectional compression force was used to produce a fracture, whereas fractures are always a result of a combination of forces. Our study also does not account for soft tissue contributions due to stripping of soft tissue and it therefore cannot precisely determine the mechanical effect of the implant in a patient where soft tissue is present. Finally, we used embalmed and not fresh frozen specimens. It has been shown, however, that the mechanical characteristics of fresh frozen specimens and embalmed cadaveric specimens are similar (Topp et al. 2012). A polyethylene-ceramic bearing has been used, as this is the standard bearing used in our institution. Even though the revision rate for this bearing is lower (Peters et al. 2018), we do not believe it affected the outcome of this particular study.

In summary, implanting a cemented version of the stem increases the load-to-failure force by 25%. We recommend using a cemented stem in older patients and patients who are at risk of falling.

AK and MB conducted the experiments. AK, SP, and TN wrote the manuscript. CB and TH devised the study and reviewed the manuscript together with MS, who did the statistical analysis.

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