Uncompromised quality of the cement mantle in Exeter femoral components implanted through a minimally-invasive direct anterior approach

A PROSPECTIVE, RANDOMISED CADAVER STUDY

E. Mayr,
M. Krismer,
M. Ertl,
O. Kessler,
M. Thaler,
M. Nogler

*From the Medical
University,
Innsbruck, Austria*

A complete cement mantle is important for the longevity of a total hip replacement. In the minimally-invasive direct anterior approach used at the Innsbruck University hospital, the femoral component has to be inserted into the femoral canal by an angulated movement. In a cadaver study, the quality and the extent of the cement mantle surrounding 13 Exeter femoral components implanted straight through a standard anterolateral transgluteal approach were compared with those of 13 similar femoral components implanted in an angulated fashion through a direct anterior approach. A third-generation cementing technique was used. The inner and outer contours of the cement mantles was traced from CT scans and the thickness and cross-sectional area determined.

In no case was the cement mantle incomplete. The total mean thickness of the cement mantle was 3.62 mm (95% confidence interval 3.59 to 3.65). The mean thickness in the group using the minimally-invasive approach was 0.16 mm less than that in the anterolateral group. The distribution of the thickness was similar in the two groups. The mean thickness was less on the anteromedial and anterolateral aspect than on the posterior aspect of the femur.

There is no evidence that the angulated introduction of Exeter femoral components in the direct anterior approach in cadavers compromises the quality, extent or thickness of the cement mantle.

■ E. Mayr, MD, Orthopaedic Surgeon
■ M. Krismer, MD, Professor, Orthopaedic Surgeon
■ M. Ertl, MPh, Statistician
■ M. Thaler, MD, Orthopaedic Surgeon
■ M. Nogler, MD, Associate Professor, Orthopaedic Surgeon
Department of Orthopaedic Surgery
Medical University Innsbruck, Anichstrasse 35, 6020 Innsbruck, Austria.

■ O. Kessler, MD, Orthopaedic Surgeon
Stryker Europe, Scientific & Clinical Affairs, Florastrasse 13, CH-8800 Thalwil, Switzerland.

Correspondence should be sent to Dr E. Mayr; e-mail: eckart.mayr@uibk.ac.at

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The Swedish Arthroplasty Register has shown excellent long-term results for total hip replacement (THR) with the Exeter femoral component (Stryker, Allendale, New Jersey).^{1,2} A number of factors influence the quality of implantation, and consequently survival of the implant. The optimal thickness and extent of the cement mantle are still controversial. There seems to be an association between a thin or incomplete cement mantle and fissures, debonding and loosening.^{3,4} Generally, a thickness of 2 mm is considered to be the minimum permissible.⁴

The final shape of the cement mantle is determined by the geometry of the femoral component, the anatomy of the femur, the broaching of the femoral canal and the cementing technique.⁵⁻⁷ The current method of choice is a third-generation cementing technique with vacuum mixing and the use of a cement gun, lavage of the canal, distal cement restrictors, stem centralisers and pressurisation.^{8,9}

One of the current issues in orthopaedics is the use of minimally-invasive approaches and

the development of new muscle-sparing techniques. The direct anterior approach described by our research group and others,¹⁰⁻¹² is a true muscle-sparing approach exploiting an intermuscular plane between the sartorius and tensor fascia lata muscles. We have developed instruments to facilitate exposure of the medullary cavity by elevating the femur. However, displacement out of the wound is not achieved and therefore the broaches and the femoral component have to be angulated for insertion.

Our aim was to compare the quality and extent of cement mantles surrounding Exeter femoral components implanted through a standard anterolateral transgluteal approach with those of components implanted by a direct anterior approach.

Materials and Methods

We used 13 alcohol-glycerol preserved human cadavers (9 female, 4 male). They were placed in a supine position on a standard operating table. One hip was operated on using the direct anterior approach and the other through a

Figure 1a – CT scans showing the mean areas of the cement mantle in mm² by approach, section and level of the scan. The white cross indicates the four quadrants (1, anteromedial; 2, posteromedial; 3, posterolateral and 4, anterolateral). The horizontal lines indicate the vertical division of the cement mantle into proximal, middle and distal. Figures 1b and 1c – Graphs showing the mean areas of cement in mm² by location in b) the anterolateral and c) the direct anterior approach groups.

conventional anterolateral approach.¹³ The approach used on each side was selected randomly using a computed balanced randomisation list.

In the anterolateral approach group, a longitudinal skin incision of 15 cm to 18 cm was made over the greater trochanter. The capsule of the hip was exposed after cutting the fascia lata, gluteus medius and the vastus lateralis muscles. An osteotomy of the femoral neck was performed to extricate the head and the capsule was completely removed. To obtain direct access to the medullary canal, the common tendon of the external rotators was divided and the leg was placed in a figure-of-four position while the proximal femur was levered over the fascia lata.

In the direct anterior approach group, a skin incision 6 cm to 8 cm long was made two fingerbreadths distal and lateral to the anterior superior iliac spine. After digital exposure of the intermuscular plane between sartorius and tensor fascia lata, the capsule was opened using an H-shaped incision. The femoral head was removed and the posterior capsule in piriformis fossa loosened. In order to lift the femur, a specially-designed double-pronged femoral elevator (Stryker, Allendale, New Jersey) was placed beneath the greater trochanter. The femoral canal was opened by a curved curette and widened with a rongeur.

In both approaches, the medullary canal was prepared using standard Exeter instruments (Stryker) according to the implantation manual. The canal was broached to the largest possible size, but a layer of cancellous bone was retained. Cementing was performed according to third-generation principles using lavage, brushing the cavity and cement restrictors. Palacos cement (Heraeus Medical, Wehrheim, Germany) at room temperature was vacuum-

mixed for 30 seconds, followed by a waiting phase, adjusted in accordance with the manufacturer's instructions, to allow for the ambient temperature. The cement was introduced with a gun with pressurisation achieved through the use of a proximal seal. The Exeter femoral components, with distal centralisers, were introduced into the femoral canal. The cement was allowed to polymerise and cool before the femoral components were removed and the femur was excised. All of the implantations were performed by an experienced hip surgeon (MN).

The cement mantle was evaluated according to the protocol published by Valdivia et al.¹⁴ All specimens were imaged with CT (LightSpeed 16; General Electric, Milwaukee, Wisconsin), using 200 mA and 80 kV. The settings included spacing of 5 mm and a rotation of one second. The slices were 1.25 mm thick, and were sampled over a distance of 20 cm to ensure cover of the entire prosthesis including the cement restrictor. A total of 25 axial images per implant were stored as Dicom files and were imported into Sigma Scan Pro 5 (SPSS Inc., Chicago, Illinois). The inner and outer contours of the cement mantles were traced in all slices. All the measurements were performed by one examiner (EM). The output included data about the perimeter of the implant and the contour of the cement mantle, the cross-sectional area of the implant and the cement mantle, the coordinates of the implant and the contour vertex of the cement mantle. The thickness of the cement mantle was determined at each implant contour vertex as the distance from this point to the closest vertex in the outer cement contour. To assess the thinnest site in the cement mantle at each implant contour vertex, the euclidian distance $d(A, B)$ between the contour vertex A (ax, ay) of each

Table I. Three-way analysis of variance crossed design with regard to the thickness of the cement containing factors, approach, region of the femoral component and cadaver

Source	Type-III sum of squares	Degrees of freedom	Mean square	F-distribution	p value
Approach	8.139	1	8.139	43.656	< 0.001
Stem region	110.048	2	55.024	295.121	< 0.001
Cadaver	168.219	12	14.018	75.187	< 0.001
Approach* stem region	0.049	2	0.025	0.132	0.877
Approach* cadaver	29.658	12	2.471	13.256	< 0.001
Stem region* cadaver	254.265	24	10.594	56.823	< 0.001
Approach* stem region* cadaver	41.690	24	1.737	9.317	< 0.001

* where the two items interact

R-Square (ANOVA) = 0.194 (adjusted R-Square = 0.190)

implant and the contour vertex B (bx, by) of the cement mantle was calculated using a custom-made algorithm. The thickness of the cement mantle was divided into four categories expressed in millimetres (< 1 mm, 1 mm to 1.99 mm, 2 mm to 3.99 mm, ≥ 4 mm) and recorded for each approach.

The scans of the cement mantles were divided into four 90° segments (sections 1 to 4), and the area in mm² within the four sections was calculated (Fig. 1). The alignment of the scan was determined by comparing the axes of the prosthesis and the femur.

Statistical analysis. The SPSS program version 12.0 (SPSS Inc) was used for statistical analysis. Before analysis, the dependent variables were checked for assumption of normality. Since the dependent variables were skewed to the right, a logarithmic transformation was performed which produced a normal distribution. The influence of various factors on the thickness (approach, stem region and cadaver) and on the area (approach, stem region, cadaver and section) of the cement mantle were analysed using a three-way analysis of variance crossed design (ANOVA) and a four-way ANOVA, respectively, followed by the *post-hoc* Bonferroni test. Non-parametric data were evaluated by the Mann-Whitney U test and expressed as the median and interquartile range. Box-and-whisker plots were drawn and 95% confidence intervals (CI) were calculated. The level of statistical significance was set at $p = 0.05$.

Results

The sizes of the femoral components varied between 0 and 3 (0 in four, 1 in 13, 2 in eight, and 3 in one), and those of the cement restrictor ranged between size 10 and 18 (10 in seven, 12 in eight, 14 in eight, 16 in one and 18 in two). In most cadavers the femoral implant was the same size in both hips, but occasionally the size of the femoral cavity differed between sides.

The anatomy of the femur had an important impact on the thickness of the cement mantle (Table I).

The median stem alignment in the anterolateral group was 1° of varus (interquartile range -1° to 1.5°) and in the direct anterior approach group was 0° (interquartile range -1.5° to 0.5°). The difference was not significant ($p = 0.186$). The proximal third of the Exeter femoral component is

Fig. 2

Box-and-whisker plot for thickness of the cement mantle (mm) in relation to the approach and region of the stem. The heavy line is the median, contained in the box defined by the upper and lower quartiles, contained in whiskers within the central 95% of the ordered observations, the dots at the top of the upper whiskers are outliers. The numbers inside the lower boxes indicate the number of cases.

broad and rectangular. This may lead to a thin cement mantle at the edges (Fig. 1a), especially when the component is slightly malrotated within the broached envelope. In the mid sections of the femoral component the shape is rectangular with rounded edges. Distally, the component becomes more circular.

The total mean thickness of the mantle was 3.62 mm (95% CI 3.59 to 3.65). In the anterolateral group it was

Table II. Frequencies of thickness of the cement mantle in categories over the surface area of the femoral component in relation to the approach and the femoral component region

	Cement thickness (mm)	Anterolateral approach (%)	Direct anterior approach (%)	Total (%)
Proximal third	< 1	24 (1.0)	19 (0.8)	43 (0.9)
	1 to 1.99	499 (21.3)	598 (25.2)	1097 (23.3)
	2 to 3.99	957 (40.9)	996 (42.0)	1953 (41.4)
	≥ 4	860 (36.8)	760 (32.0)	1620 (34.4)
	Total proximal	2340 (100.0)	2373 (100.0)	4713 (100.0)
Middle third	< 1	13 (0.5)	12 (0.5)	25 (0.5)
	1 to 1.99	460 (18.5)	600 (24.7)	1060 (21.6)
	2 to 3.99	1288 (51.8)	1124 (46.3)	2412 (49.1)
	≥ 4	724 (29.1)	690 (28.4)	1414 (28.8)
	Total middle	2485 (100.0)	2426 (100.0)	4911 (100.0)
Distal third	< 1	13 (0.7)	7 (0.4)	20 (0.5)
	1 to 1.99	120 (6.3)	113 (5.7)	233 (6.0)
	2 to 3.99	778 (40.5)	994 (50.6)	1772 (45.6)
	≥ 4	1009 (52.6)	852 (43.3)	1861 (47.9)
	Total distal	1920 (100.0)	1966 (100.0)	3886 (100.0)

R-Square = 0.721 (adjustable R-Square = 0.710)

Table III. Four-way analysis of variance (ANOVA) crossed design with regard to areas of cement containing factors, approach, region of the femoral component, cadaver and section

Source	Type-III sum of squares	Degress of freedom	Mean square	F-distribution	p value
Approach	1.959	1	1.959	12.992	< 0.001
Stem region	149.243	2	74.622	494.799	< 0.001
Cadaver	114.386	12	9.532	63.206	< 0.001
Section	299.221	3	99.740	661.356	< 0.001
Approach* stem region	0.013	2	0.007	0.044	0.957
Approach* cadaver	8.270	12	0.689	4.570	< 0.001
Approach* section	2.092	3	0.697	4.624	0.003
Stem region* section	223.558	6	37.260	247.060	< 0.001
Stem region* cadaver	78.943	24	3.289	21.810	< 0.001
Section* cadaver	79.753	36	2.215	14.690	< 0.001

* where the two items interact

R-Square (ANOVA) = 0.721 (adjusted R-Square = 0.710)

3.70 mm (95% CI 3.66 to 3.74) and in the direct anterior approach group 3.54 mm (95% CI 3.50 to 3.58). The mean thickness in the anterolateral group was 0.16 mm greater than that in the direct anterior approach group. The difference was statistically significant ($p < 0.001$; Table I). In the proximal third the difference was 0.1 mm, in the middle third 0.2 mm and in the distal third 0.2 mm, all in favour of the anterolateral group (Fig. 2). To analyse differences in thickness between regions of the femoral component, *post hoc* tests were performed. The thickness of the cement mantle in the proximal third was significantly greater than that in the middle third ($p = 0.002$), and in the distal third it was highly significantly thicker than that in the proximal third ($p < 0.001$).

Areas with a thickness of less than 2 mm were found in the anterolateral group as follows: 21.3% of the proximal third, 18.5% of the middle third and 6.3% of the distal third. In the direct anterior approach the corresponding values were 25.2%, 24.7% and 5.7%, respectively (Table II).

Examination of the axial quadrants revealed areas of thin cement. In the anteromedial and anterolateral quad-

rants (sections 1 and 4), particularly in the middle third of the components, the area of the cement mantle was smaller than that posteriorly (Fig. 1). The interaction between approach and cross-section was significant ($p = 0.003$) (Table III). Compared with the direct anterior approach group, the anterolateral group had larger areas of cement mantle in sections 2, 3 and 4 and a smaller area in section 1. In no case was an incomplete cement mantle found.

Discussion

Recently, minimally-invasive approaches to the hip have been discussed extensively in orthopaedic literature.¹⁵⁻²¹ The direct anterior approach has been used in the University Hospital of Innsbruck since 2003. This approach requires elevation of the femur to facilitate exposure of the femoral canal and it is necessary to introduce the femoral component in an angulated movement.¹² During this manoeuvre the tip of the prosthesis may pass close to the lateral cortex of the femur. For uncemented prostheses this should cause no difficulties. However, in a cemented procedure it was speculated that the distal tip of the femoral component, espe-

cially when equipped with a distal centraliser, could compromise the cement mantle at the cement-bone interface. The risk for implanting the femoral components in a varus position is higher in the direct anterior approach.

One limitation of the study was that the method of preservation of the cadavers tended to partially liquify cancellous bone, thus altering the femoral cavities, compared with living tissue. However, in this investigation any alteration in quality could be ignored as both sides of the cadaver were used.

The appropriate thickness of the cement mantle is still controversial. In general, a thickness of 2 mm to 5 mm is considered to be sufficient.⁴ Valdivia et al¹⁴ reported a mean thickness of 3.4 mm. In their study, Exeter femoral components were introduced straight into the femoral canal. In our study, we found a greater mean thickness in both approaches. Nelissen, Garling and Valstar²² reported that Exeter femoral components implanted with the standard instruments produced a thickness of 2 mm to 9 mm. This was confirmed by our observations.

Cement mantles thinner than 2 mm should be avoided since this may increase the risk of microfractures in the cement.^{3,4} In most instances, an adequate cement mantle could be produced. However, a multitude of variables, such as the anatomy of the femur, and its exposure, resulting in a specific broach envelope, and the cementing technique, influence the final shape of the cement mantle.⁵⁻⁷ It is not always possible to avoid a thickness of less than 2 mm. For Exeter femoral components this is reported to occur in 22% of the mean total surface area of the stem.¹⁴ These data were confirmed by our current observations.

The Exeter femoral component has a straight stem with a broad rectangular cross-section in the proximal aspect. Taking the femoral neck anteversion and the apex-posterior bow into account, it tends to come close to the anterior and anteromedial aspects of the femoral cortex, leaving little space for implantation errors such as malrotation, varus, valgus or flexion malalignment.¹⁴ Our results confirmed these findings with smaller areas of cement mantle in the anterior sections (sections 1 and 4) than in the posterior aspects of the cavity. With the angulated introduction of the femoral components it might have been anticipated that they would have a higher tendency to be placed in a varus position, resulting in less cement on the medial aspect. In our study the medial cement mantles (sections 1 and 2) and alignment of the stem were identical in both groups. Additionally, using an angulated introduction meant there was a risk that the lateral area of the cavity might have deficient cement mantles. However, in no case was an incomplete cement mantle found in this area.

In our cadaver study, Exeter prostheses were implanted using two different approaches. With complete cement mantles and a difference of only 0.16 mm in thickness between both approaches, no evidence was found that the

angulated introduction of the stems in the direct anterior approach compromised the quality, extent or thickness of the cement mantles. We presume that, when minimally-invasive surgery is performed in the same manner in living subjects, the integrity of the cement mantles will not be compromised.

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