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ORIGINAL STUDY

Impact of stem-broach sizing on the cement mantle of Lubinus SP II stems. A CT scan analysis

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Lubinus SP II stems are cemented either line-to-line with the largest broach or one-size undersized. The purpose of this study was to compare both implantation techniques. We used 18 polymeric stem replicas cemented line-to-line and undersized in paired cadaveric femora and analyzed them with CT scan images. Cementing Lubinus stems line-to-line resulted in higher medullary canal-filling indices (28.26 ± 4.10%), thinner cement mantles (3.29 ± 0.40 mm), more cement defects (5.12 ± 1.69%) and more areas of thin cement (23.81 ± 7.13%) than undersizing (respectively : 23.61 ± 4.24%, 3.62 ± 0.43 mm, 1.48 ± 2.04%, 15.11 ± 5.93%). In both settings, over 80% of areas of thin or deficient cement were supported by cortex. Using a line-to-line technique, adequate stem alignment was achieved without distal centralizer. Undersizing the stem and using a distal centralizer reduced the incidence of distal cement defects by a factor 10. While stems cemented line-to-line might have mechanical advantages, undersizing and using distal centralizers reduced potential pathways for debris migration to the bone-cement interface.

Keywords : hip arthroplasty ; femoral stem ; cement mantle ; Lubinus SP2 ; computed tomography ; cementing technique.

INTRODUCTION

The cement mantle surrounding femoral hip implants acts as a mechanical interface between stem and bone (*2,14*) and limits the possibilities of debris migration to the femoral canal (*1,8*). As such, a uniform and substantial cement mantle without defects, that is well anchored into cancellous bone and well supported by cortical bone, should be adequate. In order to avoid areas of thin or deficient cement, some manufacturers have developed implants which try to match the inner proximal femoral anatomy (*3,17*). The Lubinus SP II stem (Status Physiologus, Waldemar Link GmbH, Hamburg, Germany) is one of these "anatomic" cemented stems. It is asymmetric, and has a left and a right version with a characteristic S-shaped curvature in the lateral view, a large collar and a femoral neck with 19° of anteversion (fig 1). It is made of

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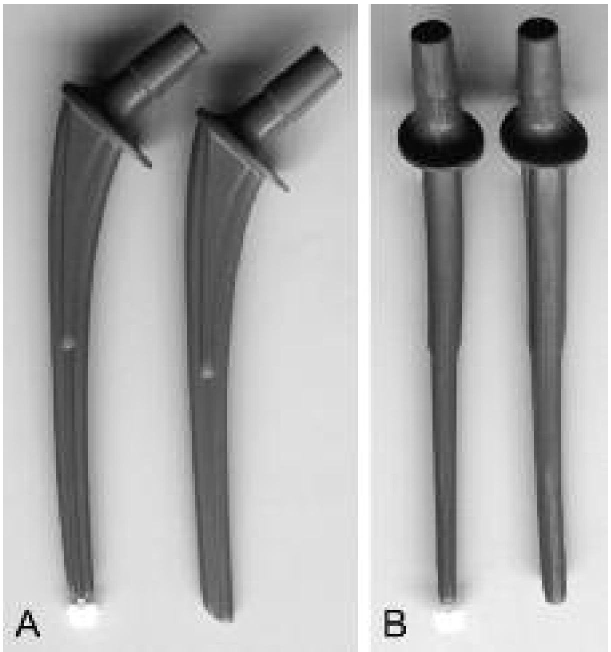

Fig. 1. — Anteroposterior (A) and lateral (B) view of polymeric replicas of the Lubinus SP II stem. The undersized stem was instrumented with a distal centralizer (left) ; the line-to-line stem was implanted without distal centralizer (right).

cobalt-chrome with a satin to matte surface finish (Ra = 0.39 to 1.4 µm) *(4,5)*. The Lubinus stem is widely used throughout Europe *(16)*. Overall, clinical and experimental results have been favourable *(6,10,11,13,15,21)*.

To further "optimize" the cement mantle, manufacturers proposed to undersize (US) the stem compared to the broach. However, many implants that are cemented line-to-line (LL) with the largest broach have been very successful *(9,17,20)*. The surgical technique of the Lubinus SP II stem allows both implantation philosophies. According to the manufacturer, both techniques are widely used, but it is unknown, which is superior and what the implications are for the stem-cement-bone composite.

We used a validated CT scan based measurement tool *(18)* to analyze the effect of the line-to-line and undersized implantation of an "anatomic" Lubinus SP II stem on the cement mantle quality. We compared both implantation techniques, focusing on mechanically and/or biologically relevant parameters. When differences were found, their potential implications were evaluated.

MATERIALS AND METHODS

Stem implantation technique

Eighteen polymeric replicas of the Lubinus SP II stem (fig 1), provided by the manufacturer, were implanted in nine pairs of embalmed cadaver femora. An experienced hip surgeon (T.S.) and an experienced theatre nurse (C.V.P.) performed all implantations with original instruments, according to the recommended surgical technique and simulating a realistic intra-operative setting. Radiographic templating was performed on anteroposterior and lateral views and nine pairs of femora suitable for a stem size 2 or 3 were selected. The femoral neck was cut according to templating. Flexible reamers were used to open the medullary canal until cortical contact was achieved. Subsequently, broaches of increasing size were used to prepare the femoral canal according to templating and until the largest possible broach was inserted. Both femora from the same donor were reamed and broached to the same size and a calcar planer was used in all cases. Four pairs of small femora were reamed to 12 mm and broached with a size 2 broach. Five pairs of larger femora were reamed to 14 mm and broached with a size 3 broach. At one side, we implanted a stem replica with the same size as the broach (line-to-line technique). At the other side, a one-size undersized replica was used. Undersized replicas were instrumented with an in-stem distal centralizer (PMMA Invis™ distal post centralizer, Smith & Nephew, Memphis, Tennessee, USA) of 10 mm for stems size 1 and of 11 mm for stems size 2. Sides were allocated randomly.

We applied a third generation cementing technique including the use of a distal cement plug and cleansing of the femoral canal with 2 l of water at 37°C with a pressure lavage system (Stryker, Mahwah, New Jersey, USA). Eighty gram of polymethylmethacrylate cement (Palamed, Biomet, Warsaw, Indiana, USA) was vacuum mixed (30 s, 0.1 bar) at 18°C with a mixing/pressurizing system (Optivac, ScandiMed, Biomet, Warsaw, Indiana, USA) and injected into the femoral canal, 3 minutes after starting the mixing. Cement was pressurized with a proximal seal during 1 minute. At 4 minutes, the stem replica was inserted manually until the collar contacted the calcar cut. Pressure was maintained during stem insertion and until complete setting of the cement.

Data analysis

All specimens were scanned with a Somaton Sensation 16 CT scanner (Siemens AG, Erlangen, Germany) using the following settings : adjacent slices ; collimation : 6 × 0.75 mm ; slice thickness : 1.0 mm ; reconstructed slice interval : 0.5 mm and reconstruction kernel : 80U very sharp. Specimens were positioned based on the CT laser beam and scanned along their longitudinal axis. In total 4978 images (LL : 2483, US : 2495) were reconstructed from the medial calcar cut to the distal stem tip.

Validated custom segmentation software *(18)* identified the contours of the cement mantle, the outer and the inner cortex, according to their gray values in the CT image. Differences in gray values between the polymeric stem replica and the cement could be distinguished visually but were too small for easy automated segmentation. For this, implants were CT scanned and segmented separately, and the contours were fitted to the stem in corresponding CT images of the specimens.

Based on their contours, the volumes of the four elements (cortical and cancellous bone, cement and prosthesis) were calculated by multiplying the cross-sectional area of an element by the slice interval and by integrating these volumes over consecutive CT images. The mean degree of centralization of two elements within one specimen was calculated by averaging the distances between their centroids over consecutive images. The "canal-filling index" of an element was defined as : (volume of an element) / (volume of medullary canal)× 100. Global stem alignment with respect to the medullary canal was evaluated by calculating the angle between the line of best fit to the centroids of the medullary canal and the line of best fit to the centroids of the stem *(19)*. Both lines were calculated in a region starting 1 cm above the stem tip and extending for 8 cm proximally. The varus-valgus tilt and anteroposterior tilt were defined as the angles between both lines, after projection onto the frontal and sagittal plane respectively.

The cancellous bone thickness was calculated in the CT scan plane, while the cement mantle thickness was calculated in 3D *(18,19)*. For each CT image, the cement mantle thickness (including cement pressurized into cancellous bone) and the cancellous bone thickness were averaged in 72 segments of 5° around the prosthesis centroid. In total, both parameters were analyzed in 358,416 (LL : 178,776 ; US : 179,640) segments. Segments with a mean cement thickness < 1 mm were defined as "cement mantle defects", segments with a mean thickness < 2 mm as "areas of thin cement". Within each CT image, twenty-eight segments were considered as "corner" regions of the stem's cross-section, the remaining forty-four segments were considered as "flat" regions (fig 2).

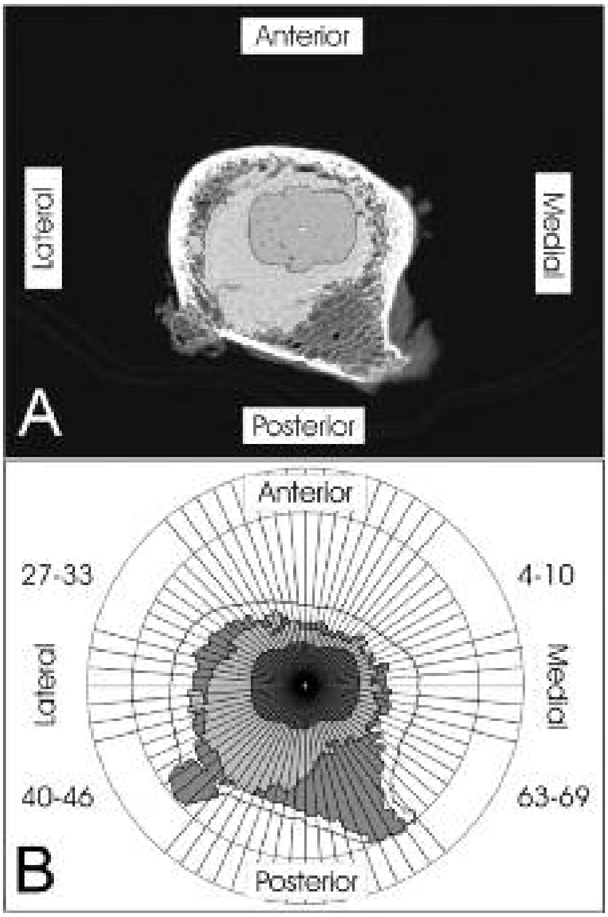

Fig. 2. — Segmented CT scan image of a Lubinus SP II replica cemented in a donor femur (A). Reconstructed image based on the segmentation procedure (B). The image was divided in 72 segments of 5° around the prosthesis centroid. Segments 4 to 10, 27 to 33, 40 to 46 and 63 to 69 represent corner regions ; the remaining segments represent flat regions of the stem.

Statistical methods

We compared results of stems cemented LL and US in paired femora with a two-tailed paired samples Student's t-test. The effect size (d = Mean[differences between pairs] / SD[differences between pairs] × √2) was calculated for each parameter *(23)*. In contradiction to "statistical significance", the "effect size" is independent from sample size and reflects the magnitude of the difference between the line-to-line and undersized technique. An effect size > 0.8 can be considered as "large". Setting the significance criterion (p-value) to 0.05 and using nine pairs of femora, the power was 80% when the effect size of the paired t-test reached 1.5. However, when the effect size of the paired t-test decreased to 1.0, the power dropped to 43%. Frequencies were compared with a Chi^2-test. Statistical analysis was conducted with Excel 2000 (Microsoft Inc., Redmond, USA) and SPSS 13.0 (SPSS Inc., Chicago, USA). P-values < 0.05 were considered statistically significant.

RESULTS

The average radius of undersized stems was 0.55 ± 0.11 mm smaller ($p < 0.001$) than that of line-to-line stems (sizes 1-2 : 0.64 ± 0.04 mm [$p < 0.001$] ; sizes 2-3 : 0.47 ± 0.08 mm [$p < 0.001$]). Overall, the Lubinus SPII stem filled 25.94 ± 4.70% of the medullary canal. The volume and medullary canal-filling index of stems implanted line-to-line were larger than those of undersized stems. The amount of cement was similar in both settings (table I).

Stem centralization within the cement mantle and the medullary canal was similar in both groups (table II). In the distal 1/3, undersized stems instrumented with a distal centralizer were better centred, than line-to-line stems without centralizer. Overall, stem alignment within the distal femoral canal did not differ significantly between groups (table II). The maximal global misalignment was 3.68°. Only one stem was misaligned more than 3° and this was an undersized stem. In the frontal plane, half the stems were in neutral position (< 1° of varus or valgus). The remaining 9 stems (LL : 5, US : 4) were in varus between 1.13° and 2.57°. In the sagittal plane, 11/18 stems were in neutral position (< 1° of anterior or posterior tilt). The remaining 7 stems (LL : 2, US : 5) presented an anterior tilt between 1.06° and 2.70°. All maximal values were found in the undersized group.

Stems inserted line-to-line had a thinner cement mantle than undersized stems, but differences were small (0.33 ± 0.21 mm) and were not significant in the proximal 1/3 of the specimens (table III). In both settings, the mean cement thickness in the proximal 1/3 (4.08 ± 0.61 mm) was larger than in the middle (3.11 ± 0.45 mm ; $p < 0.001$) and the distal 1/3 (3.15 ± 0.42 mm ; $p < 0.001$). The average cement thickness below the medial femoral neck cut was 3.78 ± 0.78 mm and was similar in both settings (table III). Cement defects and areas of thin cement were more numerous after line-to-line implantation than in the undersized group, especially in the distal 1/3 (table III). However, even in the line-to-line setting, the amount of cement defects was limited (5.12 ± 1.69%). In both settings, areas of thin or deficient cement were more frequent at the corners of the stem (defects LL : 8.33%, US : 2.69% ; thin cement LL : 32.93%, US : 21.93%) than in the flat regions (defects LL

Table I. — Average volume and average medullary canal-filling index ([volume of an element] / [volume of medullary canal] × 100) after "line-to-line" and "undersized" stem cementation

	Line-to-Line	Undersized	Diff. between pairs (LL-US)		p-values	ES**
	Mean (SD)	Mean (SD)	Mean (SD)	95% CI		
Total volume (cm^3)	112 (14.33)	113 (14.42)	-1.05 (2.58)	-3.03 / 0.94	0.259	0.57
Volume of cortical bone (cm^3)	51.7 (11.92)	51.5 (11.58)	0.25 (3.51)	-2.46 / 2.95	0.839	0.10
Volume of medullary canal (cm^3)	59.9 (8.11)	61.2 (11.08)	-1.29 (4.64)	-4.86 / 2.27	0.427	0.39
Volume of stem (cm^3)	16.7 (1.13)	14.1 (1.31)	2.57 (0.31)	2.33 / 2.81	< 0.001*	11.71
Volume of cement (cm^3)	25.3 (4.05)	26.4 (4.30)	-1.13 (2.52)	-3.07 / 0.80	0.214	0.64
Volume of remaining cancellous bone (cm^3)	17.9 (4.82)	20.6 (7.86)	-2.73 (3.92)	-5.75 / 0.28	0.070	0.99
Canal-filling index of the stem (%)	28.26 (4.10)	23.61 (4.24)	4.65 (1.59)	3.43 / 5.87	< 0.001*	4.14
Canal-filling index of the cement (%)	42.24 (2.94)	43.55 (4.51)	-1.31 (3.91)	-4.32 / 1.69	0.343	0.47
Canal-filling index of the cancellous bone (%)	29.50 (5.15)	32.83 (8.01)	-3.34 (4.19)	-6.55 / -0.12	0.044*	1.13

* Paired t-test : $p < 0.05$ is statistically significant. ** ES : Effect size for a paired t-test.

Table II. — Stem centralization within the cement mantle and medullary canal and stem alignment in the medullary canal

	Line-to-Line	Undersized	Diff. between pairs (LL-US)		p-values	ES**
	Mean (SD)	Mean (SD)	Mean (SD)	95% CI		
Overall stem / cement centralization (mm)	1.36 (0.74)	1.37 (0.92)	0.00 (0.54)	-0.41 / 0.42	0.947	0.01
Stem-cement proximal 1/3 (mm)	1.79 (0.48)	1.91 (0.74)	-0.12 (0.82)	-0.75 / 0.51	0.678	0.20
Stem-cement middle 1/3 (mm)	1.02 (0.62)	1.28 (0.66)	-0.27 (0.95)	-1.00 / 0.47	0.428	0.39
Stem-cement distal 1/3 (mm)	1.56 (0.57)	1.16 (0.30)	0.40 (0.47)	0.03 / 0.76	0.035*	1.19
Overall stem / medullary canal centralization (mm)	2.53 (0.55)	2.60 (0.91)	-0.07 (0.93)	-0.79 / 0.65	0.823	0.11
Stem-medullary canal proximal 1/3 (mm)	4.86 (0.85)	5.05 (1.28)	-0.19 (1.11)	-1.04 / 0.66	0.619	0.24
Stem-medullary canal middle 1/3 (mm)	1.10 (0.30)	1.51 (0.80)	-0.41 (0.91)	-1.11 / 0.29	0.216	0.63
Stem- medullary canal distal 1/3 (mm)	1.62 (0.37)	1.23 (0.28)	0.38 (0.34)	0.12 / 0.64	0.009*	1.60
Global tilt of the stem in the medullary canal (°)	1.52 (0.87)	1.79 (0.98)	-0.27 (0.90)	-0.96 / 0.43	0.395	0.42
Stem alignment in frontal plane (°)	1.16 (0.75)	1.31 (0.90)	-0.15 (0.70)	-0.68 / 0.39	0.551	0.29
Stem alignment in sagittal plane (°)	0.82 (0.71)	1.07 (0.74)	-0.24 (1.26)	-1.21 / 0.72	0.579	0.27

* Paired t-test : $p < 0.05$ is statistically significant. ** ES : Effect size for a paired t-test.

Table III. — Mean cement mantle and cancellous bone thickness after "line-to-line" and "undersized" stem cementation in three areas along the stem. Cement mantle "defects" and "areas of thin" cement as a percentage of 5° segments around the prosthesis centroid

	Line-to-Line	Undersized	Diff. between pairs (LL-US)		p-values	ES**
	Mean (SD)	Mean (SD)	Mean (SD)	95% CI		
Overall cement mantle thickness (mm)	3.29 (0.40)	3.62 (0.43)	-0.33 (0.21)	-0.49 / -0.17	0.001*	2.26
Proximal 1/3 of stem (mm)	4.04 (0.69)	4.13 (0.54)	-0.09 (0.50)	-0.47 / 0.30	0.608	0.25
Middle 1/3 of stem (mm)	2.91 (0.32)	3.32 (0.48)	-0.41 (0.20)	-0.56 / -0.25	< 0.001*	2.89
Distal 1/3 of stem (mm)	2.89 (0.30)	3.41 (0.36)	-0.51 (0.13)	-0.61 / -0.41	< 0.001*	5.55
Cement thickness in calcar region (mm)	3.69 (1.07)	3.86 (0.89)	-0.17 (1.00)	-0.95 / 0.60	0.616	0.25
Overall prevalence of cement defects (< 1 mm) (%)	5.12 (1.69)	1.48 (2.04)	3.63 (2.34)	1.84 / 5.43	0.002*	2.20
Cement defects in proximal 1/3 (%)	2.16 (2.03)	1.19 (2.57)	0.97 (2.23)	-0.75 / 2.69	0.229	0.61
Cement defects in middle 1/3 (%)	4.54 (3.26)	2.45 (3.93)	2.09 (5.57)	-2.19 / 6.37	0.293	0.53
Cement defects in distal 1/3 (%)	8.80 (3.87)	0.83 (1.22)	7.97 (4.31)	4.66 / 11.29	0.001*	2.62
Overall prevalence of areas of thin cement (< 2 mm) (%)	23.81 (7.13)	15.11 (5.93)	8.70 (4.64)	5.13 / 12.27	< 0.001*	2.65
Thin cement in proximal 1/3 (%)	11.47 (7.50)	10.49 (8.07)	0.98 (6.06)	-3.66 / 5.62	0.640	0.23
Thin cement in middle 1/3 (%)	26.60 (11.07)	19.78 (7.79)	6.82 (10.71)	-1.41 / 15.05	0.092	0.90
Thin cement in distal 1/3 (%)	33.93 (6.78)	15.27 (8.54)	18.66 (7.32)	13.03 / 24.29	< 0.001*	3.60
Overall cancellous bone thickness (mm)	1.17 (0.33)	1.37 (0.57)	-0.20 (0.30)	-0.43 / 0.02	0.070	0.98
Proximal 1/3 of stem (mm)	2.91 (0.64)	3.39 (1.06)	-0.49 (0.55)	-0.91 / -0.06	0.030*	1.25
Middle 1/3 of stem (mm)	0.25 (0.20)	0.32 (0.31)	-0.07 (0.15)	-0.18 / 0.04	0.189	0.67
Distal 1/3 of stem (mm)	0.22 (0.23)	0.30 (0.34)	-0.07 (0.24)	-0.25 / 0.11	0.388	0.43
Cancellous bone thickness in calcar region (mm)	1.71 (1.39)	2.12 (1.23)	-0.41 (1.43)	-1.51 / 0.69	0.419	0.40
Cancellous bone thickness in areas of cement defects (mm)	0.47 (0.87)	1.59 (1.37)	-1.12 (1.27)	-2.09 / -0.14	0.029*	1.25
Cancellous bone thickness in areas of thin cement (mm)	0.46 (0.55)	1.00 (0.66)	-0.53 (0.46)	-0.89 / -0.18	0.009*	1.62

* Paired t-test : $p < 0.05$ is statistically significant. ** ES : Effect size for a paired t-test.

3.08%, US : 0.72% ; thin cement LL 18.01%, US 10.78%, Chi^2-test : p all < 0.001).

Whatever implantation technique was used, cancellous bone between cortex and cement was found almost exclusively in the proximal 1/3 of the specimens. Differences in cancellous bone thickness between line-to-line and undersized stems were small (< 0.5 mm) and were only significant in the

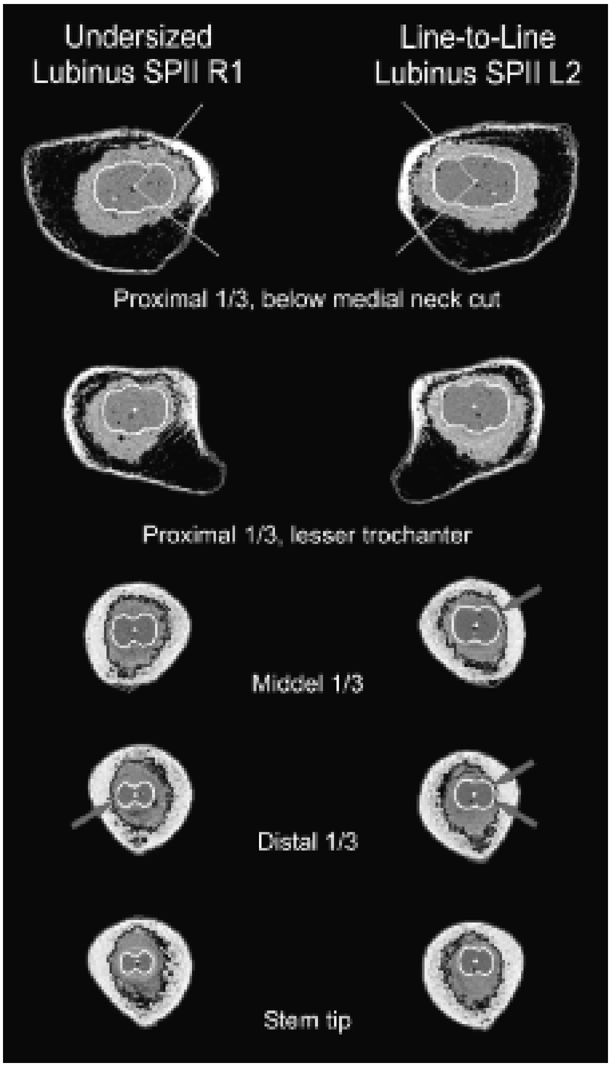

Fig. 3. — Segmented CT images of an undersized and a line-to-line Lubinus SP II replica implanted in both femora of the same donor. Proximally, below the medial femoral neck cut, large quantities of cement and cancellous bone were found in both cases. The stem implanted line-to-line presents more cement defects and areas of thin cement than the undersized stem (arrows). These areas were located mainly at the stem corners and were mostly supported by cortical bone. The tip of the undersized stem instrumented with a distal centralizer was better centred than the tip of the line-to-line stem implanted without centralizer.

proximal 1/3 (table III). The cancellous bone layer below the medial femoral neck cut was 1.92 ± 1.29 mm thick and was independent from the implantation technique (table III). In areas of thin or deficient cement, line-to-line stems contained less cancellous bone than undersized stems (table III). In both settings, over 80% of areas of thin or deficient cement were supported by cortex or < 1 mm of cancellous bone.

DISCUSSION

Currently, the Lubinus SP II stem is cemented either using an implant with similar dimensions as the largest possible broach (line-to-line technique) or using an undersized stem. Based on a validated CT scan evaluation technique *(18)*, we compared morphometrical measurements of the stem-cement-bone composite resulting from both implantation philosophies (fig 3). Undersizing the stem and using a distal centralizer, produced a thicker cement mantle, less cement defects and less areas of thin cement compared to a stem cemented line-to-line without centralizer. As described previously *(19,20)*, a third generation cementation technique can generate cement mantles over 3 mm thick, even after line-to-line implantation. Due to the small radial difference between stem sizes (0.55 mm) and to cement pressurization into cancellous bone, the impact of the surgical technique on the overall cement thickness was limited (0.33 mm). In the proximal 1/3 of the stem, where more cancellous bone was available, the cement mantle was thicker (> 4 mm) and was independent from the implantation technique. However, more distally, cement pressurization was limited by cortical bone and differences were more marked.

The low canal-filling index of the Lubinus stem and the cement pressurization into retained cancellous bone can explain the low number of cement defects (5%) even after line-to-line implantation. In general, defects were associated with corner regions of the stem and were mostly supported by cortex. These regions corresponded to "point contacts" between stem and cortex in places where lack of cancellous bone limited cement interdigitation. Compared to a line-to-line implantation without distal centralizer, undersizing and using a distal centralizer, reduced the overall incidence of cement defects by at least a factor three but reduced the incidence of distal defects by a factor ten. That reduction might be important because cement defects are potential pathways for particle migration and could be a source of distal osteolysis.

Stem alignment and stem centralization within the cement mantle and the femoral canal were similar in both groups. However, all "extreme" misalignments were found in the undersized group although these stems were better centred distally. This apparent contradiction resulted from the use of distal centralizers in the undersized group but not in the line-to-line group. They reduced the eccentricity of the small tip of undersized stems (canal-filling index < 25%), but could not always prevent global stem misalignment. Line-to-line stems without centralizer were guided by bony contacts in the proximal and middle third of the medullary canal. This provided an adequate alignment but could not prevent the eccentric location of the relative small stem tip (canal-filling index < 30%). As such a distal centralizer for the Lubinus SPII stem could be considered even in the line-to-line scenario.

In the region below the medial femoral neck cut and despite a tendency to varus stem positioning, the implant and the cortex were separated by 3.8 mm of cement and almost 2 mm of cancellous bone. This was independent from the implantation technique and was attributed to the straight proximal part of the medial border of the Lubinus stem. As the region below the medial femoral neck cut is subjected to high stresses, providing a thick cement layer in that region could be favourable (*2,12,14*). However, the presence of weak cancellous bone is detrimental (*2,22*). As such, it is advisable to curette superfluous cancellous bone, preserving a well-fixed layer of 2 or 3 mm for cement-bone interlock.

Although our CT scan based evaluation tool allows accurate *in vitro* measurements of the stem-cement-bone complex (*18*), it can be criticized. We assumed the left and right femur of a single donor to be "identical" and that is not always the case. However, in our study, the total volume, the amount of cortex and the volume of the medullary canal of paired specimens were all similar (table I). Moreover, we do not see an alternative way to compare two cementing techniques using human femora. Blood contamination and access impairment to the proximal femur caused by soft tissues, were not reproduced. This might result in a better cement mantle than could be achieved in clinical practice. However, as the implantation circumstances were standardized, this does not impair the direct comparison of both surgical techniques. To avoid metal scatter artefacts, we used moulded polymeric stem replicas provided by the manufacturer. These replicas had different surface and heat capacity characteristics than metal implants and could have presented small size and shape mismatches. We only investigated the Lubinus SP II stem with Palamed cement in a standardized setting. As such the conclusions drown cannot be extrapolated to other stem types, other cement brands or other implantation modalities. Finally, only nine pairs of femora were analyzed. As such, and despite the large number of CT images, the study lacks power when the effect size is smaller than one and only "major" differences were statistically significant. On the other hand, some differences were small in absolute terms (< 0.5 mm) even if they were statistically significant and had a large effect size.

The exact clinical, mechanical and biological consequences of the stem implantation technique remain unclear. FEA models (*7,12*) suggest that the medullary canal-filling capacity of the stem and direct cortical bone support to the cement, improve mechanical implant stability despite larger areas of thin cement. On the other hand, larger line-to-line implants, result in more cement defects and could favour particle-induced osteolysis (*1,8*). For the Lubinus stem, this could be particularly detrimental because the highest incidence of such defects was found distally. Yet, it is unknown if in clinical practice, improved mechanical stem stability compensates for that potential "biological" drawback. Nevertheless, it is clear that excellent long-term results have been reported using both implantation philosophies (*9,17,20*). Further clinical and mechanical studies are needed to investigate the exact impact of stem-broach sizing on the long-term implant survival.

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