REPORT

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Effect of cement fill ratio in loosening of hip implants

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Femoral loosening is one of the most prevalent causes of revision orthopedic surgeries. Cement mantle thickness has been directly correlated with femoral loosening. If the mantle is too thick, there is an increased risk of radiolucent lines and inconsistent densities. Also, the more bone that is reamed out during the procedure can lead to instability, especially if the quality of the bone is compromised due to osteoporosis. Too thin of a mantle can lead to a higher probability for cement fracture, loosening the prosthetic even further. This study has shown that there is an ideal thickness range between 2 to 5 mm that should be kept. From radiographic images one can measure the thickness of the cement mantle showing the loosening characteristics.

Introduction

The cement-stem interface is the most prevalent location where femoral loosening occurs. This is due to the material and mechanical properties mismatch that exists at the interface, which is affected by the oscillatory forces during the activities of daily life. It is here, where fretting occurs, that the repeated relative motions accrue deformation on the surface of both the stem as well as the more fragile cement. Fatigue striations on the fracture surfaces establish that fractures in cement mantle were due to fatigue loading over long time period.[1] Circumferential factors and radially oriented factors are usually associated with debonding of cement from stem.[1] Factors like cementing technique and stem size also affect loosening of femoral component. Advances in cementing technique and better stem design reduced loosening rate.[2] Most cracks in cement mantle were originated from pores in bone cement, which results in loosening of prosthesis. Cementing technique, like vacuum mixing, reduces 70–80% pore area compared with non-vacuum mixing.[3] It was observed that with increase in the penetration depth the stresses at bone/bone cement also increased. A penetration depth of 2.2–2.9 mm is sufficient for achieving initial stability and huge loss of bone can be avoided.[4]

Thin specimens showed loosening due to increase in inducible motions over time, whereas in thick specimens inducible motions tend to decrease over time. Although the average crack length is comparable in both the cases, thin specimen surface showed sudden crack growth whereas thick specimen surface showed stable crack growth.[5] Thus, cement mantle thickness plays an effective role in affecting hip prosthesis by loosening. Occurrence of thin mantles can be reduced by anatomic stem design and low canal flare index. Use of centralizers showed risk of thin cement mantle in Gruen zone 8 and 9 (see **Table 1**, where worn areas were identified) by pushing the stem anteriorly.[6] Thickness of the cement affects not only stress but also micromovement. Cement thickness of 2 mm increased shear stress proximally and showed micromovement over cement-bone interface. Increase in thickness greater than 7 mm showed slipping at cement-bone interface. Maximum values of microdebonding and compressive stress at various interfaces related to the cement mantle thickness are shown in **Figures 1 and 2**. It is observed that optimum cement thickness was in the range of 3 to 5 mm.[7] When cement mantle thickness was increased from 2.4 to 3.7 mm the axial strains reduced by 40% in the distal lateral cement and by 49% in the distal medial cement along the femoral stem under axial load of 1,400 N.[8] By measuring the cement thickness and radiolucent lines on X-rays, information can be gathered about the bone resorption after implantation. By collecting this data across many different patients, quantification and analysis may be conducted on what cement mantle ratio provides the best fit.

Results

Given that the ideal thickness of the cement surrounding the femoral stem to be between 2–5 mm, and assuming that the femoral stem has a diameter of 12.7 mm, the following ratios would be calculated: $T_m = \frac{T_s}{R_a}$, R_a was the total reamed surface which equals: $R_a = 2{*}\mathit{Cement\ Thickness} + T_s$

$$F.R. = \frac{12.7}{(2*2)+12.7} = 0.76\,;\; F.R. = \frac{12.7}{(2*3)+12.7} = 0.68$$

$$F.R. = \frac{12.7}{(2*4)+12.7} = 0.61\,;\; F.R. = \frac{12.7}{(2*5)+12.7} = 0.56$$

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Table 1. Coverage of fretting wear area in each Gruen zone of stem surface

	Fretting Wear Area (%)			
Stem Surface	**Anterior**	**Posterior**	**Medial**	**Lateral**
Zone 1	0	60		10
Zone 2	20	20		90
Zone 3	30	0		10
Zone 4	0	0	0	0
Zone 5	10	10	0	
Zone 6	30	80	10	
Zone 7	10	90	80	

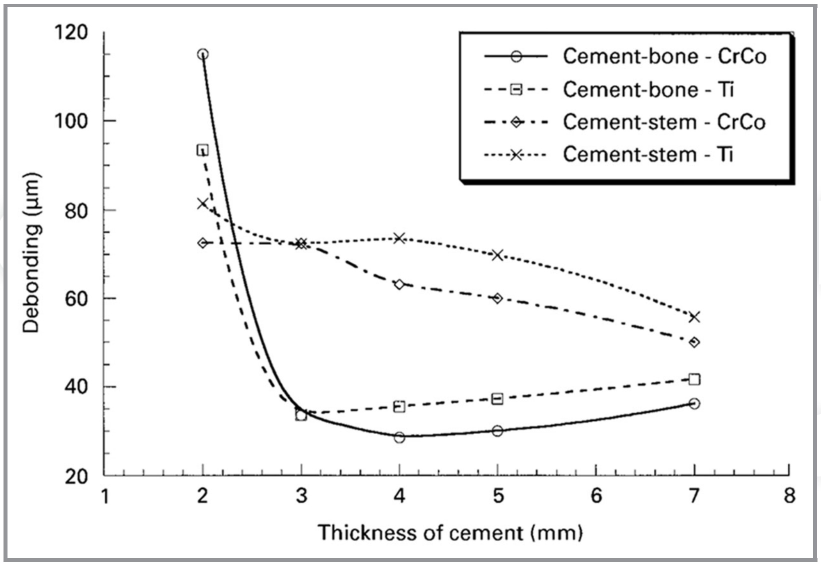

Figure 1. Figure showing debonding at various interfaces w.r.t cement mantle thickness.[7]

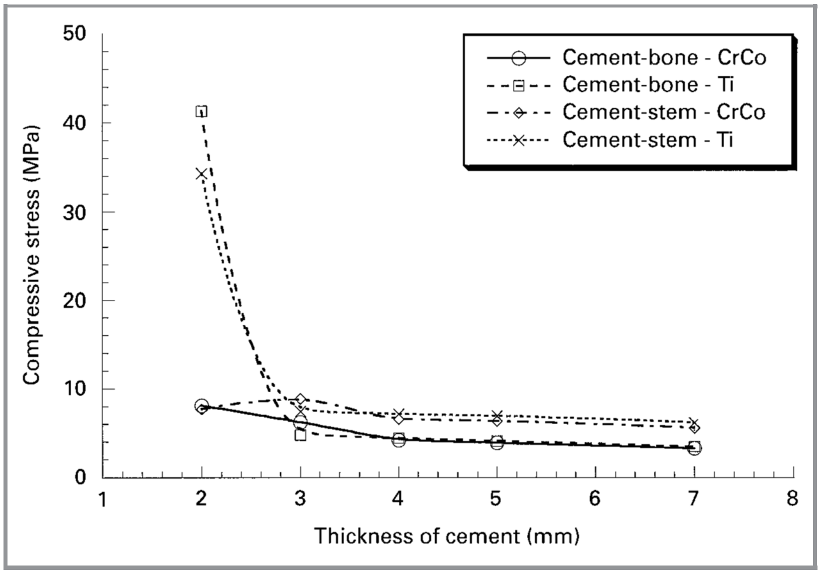

Figure 2. Figure showing Compressive stress at various interfaces w.r.t cement mantle thickness.[7]

This procedure was repeated for the range of cement thickness from 1 to 7 mm, in increments of a tenth of a millimeter. The corresponding decrease can be seen in **Figure 3**, which shows as the thickness increases, the cement fill ratio decreases in an exponential manner following the equation: $y = 0.92e^{-.098x}$. For the ideal case of a mantle thickness between 2–5mm, the fill ratio should be within the range of 0.56–0.76.

Three cases were analyzed using the finite element suite ANSYS V11 sp1 x64. The first used a setup including the minimum fill ratio of 0.86, which equals a mantle thickness of 1 mm. The other tests were run on ratios of 0.68 and 0.48, respectively. The problem was simplified by omitting the femoral head and neck components and static analysis was performed by applying an equivalent load to the femoral stem. This load had two components, a vertical force of -2,500 N as well as a moment of 62,500 N·mm to replicate the behavior of an offset vertical load. By meshing the stem and the cement interface in a hexagonal brick pattern, a more accurate finite element analysis was accomplished.[9] The simplified force analyses are shown in **Figure 4** (left). This was found to be directly correlated with the amount of deflection seen by the mantle while under stress, shown on the right column of **Figure 4** (right).

Further investigation of the stresses shown in the cement material can be seen in the left column of **Figure 4**. With the 1 mm thick mantle, the stresses are seen around 9 MPa where the bone and cement interface exists. It must be noted that the deflections being portrayed on the right hand column of the figure are shown visually amplified 15-fold, but the deflections shown in the cement are directly correlated with the amount of deflection shown in the stem, due to the softer material characteristics of the cement.

Radiographic analysis. One of the most common methods for measuring cement mantle thickness in vivo is through radiographic imaging of the implant from the different perspectives.[10] It is important to make sure both magnifications on radiographs are the same, to ensure a correct reading. If they are not the same magnifications, it can be fixed using a correction factor. In this case, the lateral view of the implant was a different magnification than the anterior view. By measuring the length of the femoral stem, it was concluded that the lengths differed from 21.5 to 20.0 cm. By taking the ratio of the two lengths, the correction factor of 1.075 was found.

$$X = \frac{L1}{L2} = \frac{21.5}{20} = 1.075$$

The thicknesses were then measured from proximal end to distal end on the radiographs of each of the striations apparent, which corresponded

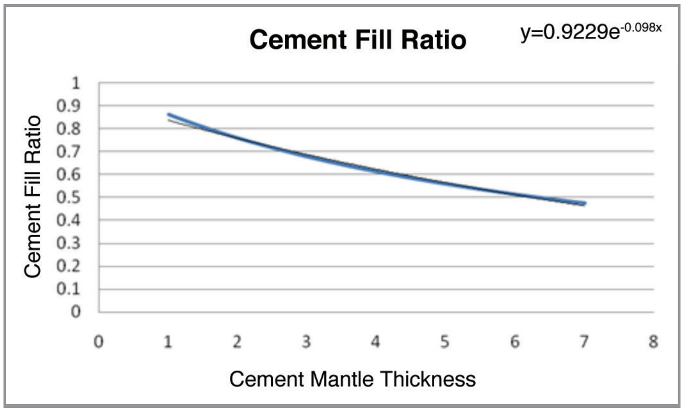

Figure 3. Cement fill ratio with respect to the mantle thickness assuming a 12.7 mm diameter femoral stem.

to the bone, cement thickness, implant, cement thickness, and bone from a cross sectional view as seen in **Figure 5**. The first few measurements were discarded due to an inability to determine where the material interfaces were located. Each of the measurements from the lateral view then had to be adjusted by the correction factor, so it would be more congruent when comparing the two films. Radiographic measurements from lateral view and anterior view were recorded in **Tables 2 and 3**. FG is the femoral stem diameter, and EH corresponds to the diameter of the reamed canal. From the calculations previously discussed, the ideal femoral implant cement fill ratio needs to be between 0.56 and 0.76.

The anterior view from **Table 3** shows the majority of the values fall within that range, except for the far distal end of the implant. However, the lateral view of the implant shows a significantly lower than ideal fill ratio, except for being in the minimum of the range toward the top of the implant. This also correlates to **Figure 6A and B** which is the cement mantle thickness of the anterior and posterior side of the lateral view where the cement on the anterior side of the implant was significantly thinner than desired.

Each of the fill ratios were then calculated from the radiographic data following the equation:

$$\frac{T_s}{2*CementThickness+T_s}$$

The data was then plotted in **Figures 7 and 8**. Since the thickness of the stem is not consistent throughout the implant, as it was assumed in the previous investigation, it is expected that the fill ratio to decrease as the stem thickness also decreased. This can be seen in **Figure 8** where an assumed 3 mm thick mantle was surrounding the actual femoral stem concurring with the previously mentioned fill ratio limits of 0.56–0.76, falling just below the range at the end. **Figure 9** shows that the stem diameter is linearly correlated with the cement fill ratio. So as the diameter of the stem increased cement fill ratio decreases, assuming a cement mantle thickness of 3 mm on each side, would decrease by the following equation: fill ratio (F.R.) = -0.0146(T_s) + 0.7697

Also, by comparing the mantle thickness to the fill ratio, the following equation can be derived, where T_m is the mantle thickness: fill ratio (F.R.) = $0.92e^{-0.098*Tm}$

Discussion

Experiments[5,8] demonstrated that thin cement mantle is one of the most important causes for implant failure. Three different cement mantle thickness scenarios were investigated in this study with mantle of 1, 3 and 5 mm thickness, with the researched value of an ideal cement mantle thickness needing to be between 2 to 5 mm. The fill ratio was found to be between 0.56–0.76, which was affected directly by both the reamed area as well as the femoral stem diameter. Cement fill ratio with respect to mantle thickness is shown in **Figure 3** which shows an exponential relationship $y = 0.92e^{-0.098x}$. From **Figure 3** it is observed that with increase in cement mantle thickness the fill ratio decreases. From the radiographic analysis, the calculated fill ratio from the given acceptable cement thickness range was on par with that seen in the film from one view. However, from **Tables 2 and 3** the fill ratios were too low toward the distal measurements with decrement in femoral stem diameter from lateral view. This shows that the cement mantle thickness is high toward the distal region. The same trend of decrement in fill ratio is observed from anterior view. **Figure 4** shows the stresses applied to cement mantle which shows increase of stress distribution with increase in thickness and reduction of strains. Equivalent von Mises stress varied from 24.6 MPa for 1 mm mantle thickness to 17.9 MPa for 5 mm mantle thickness. The maximum deformation varied from 0.03 to 0.06 mm for 1 and 5 mm mantle thickness, respectively. This is shown in **Figure 6A and B** as the C1 is much larger than C2, yet significant thinner than the corresponding measurements in **Figure 5**.

Materials and Methods

A test method was reported in ISO Standard 7206–4:2002 which describes how a cyclic load should be applied to the head of a stem that is embedded in a solid medium as shown in **Figure 10**. The specimen should also be closely inspected for any defects caused by loading it onto the test machine. The test machine should be able to have an applied error no greater than ± 2% from the maximum applied load. The femoral stem itself should be set at an angle of 9° ± 1 in flexion, which correlates to angle β in **Figure 11**. Angle α would need to be 10° ± 1 in adduction, also shown in **Figure 11**. These angles place implant in a more ergonomic position which allows correlation between in vitro testing and in vivo results. The load should be between 300 to 2,300 N in the form of a sine wave to approximate three times of the average body mass.

Experimental design. Three different cement mantle thickness scenarios were created. The thin mantle had a constant thickness of 1 mm, also one with a 3 mm cement mantle, which correlated with the desired thickness stated in several laboratory studies.[7] A thicker design was created with a 5 mm thick mantle. For simplicity, each model was designed as a column of PMMA cement mantle which was inserted into a corresponding stainless steel holder. The implant was then placed in the mantle, reaching

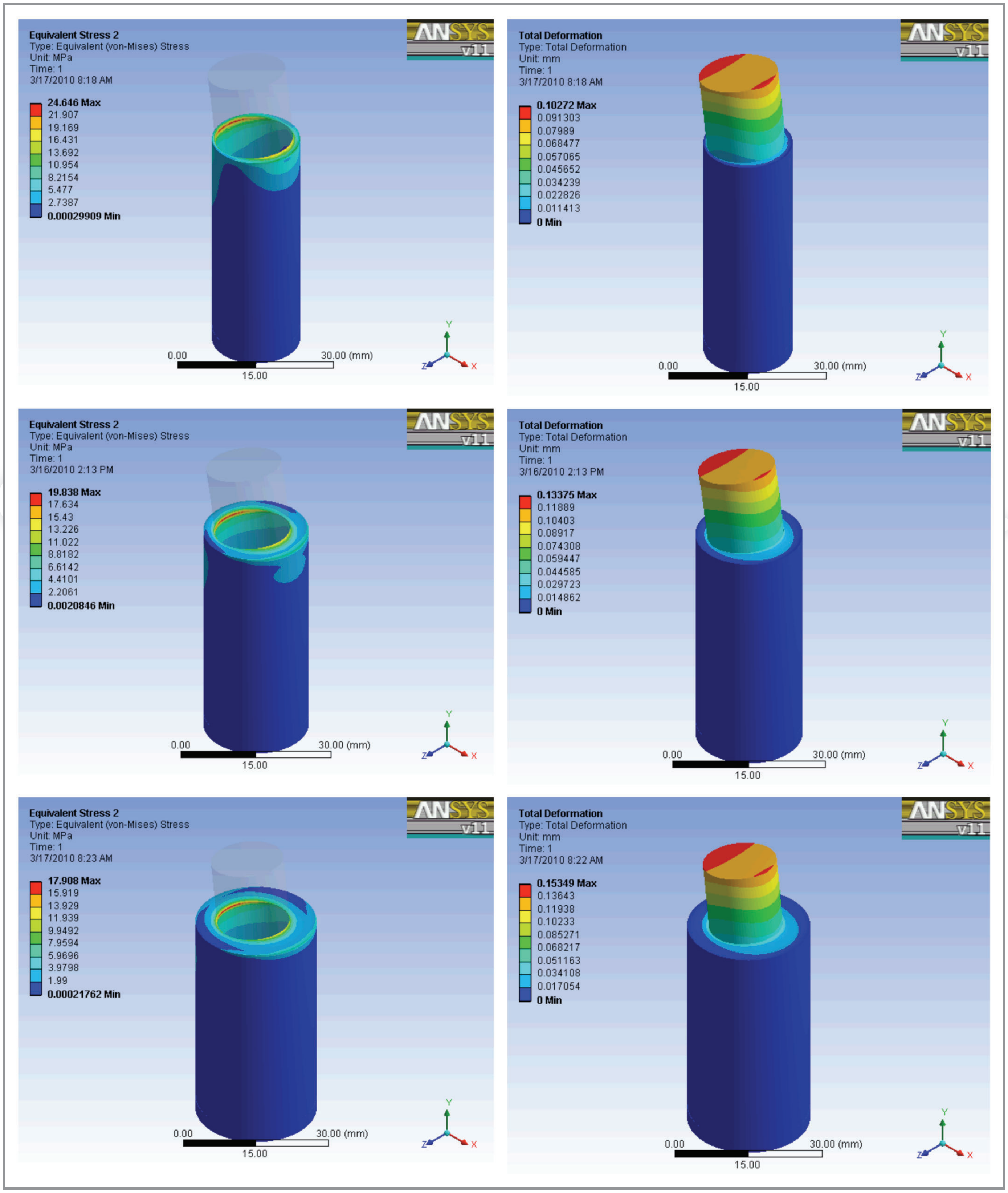

Figure 4. From top left going down are the equivalent stresses applied to just the cement mantle, while on the right going down are the deflections placed on both the mantle as well as the femoral stem. Top row of pictures correspond to 1 mm thick mantle, below that is the 3 mm, and below that is the 5 mm.

Figure 5. X-ray image of a hip implant, used to determine the fill ratio.

Table 2. Radiographic measurements from lateral view

Radiograph 2 Lateral View		
FG	**EH**	**Fill Ratio**
17.2	26.9	0.640
16.1	25.8	0.625
15.1	25.8	0.583
12.9	24.2	0.533
12.9	25.8	0.500
12.4	22.6	0.548
11.8	22.0	0.537
10.8	21.5	0.500
10.2	21.0	0.487
9.7	21.0	0.462
8.6	18.8	0.457
8.6	19.4	0.444
7.5	18.3	0.412
7.5	19.4	0.389
6.5	19.9	0.324
6.5	20.4	0.316

FG is the femoral stem diameter, and EH corresponds to the diameter of the reamed canal.

Table 3. Radiographic measurements from anterior view

Radiograph 1 Front View		
FG	**EH**	**Fill Ratio**
18.0	24.0	0.750
16.0	22.5	0.711
15.0	20.5	0.732
15.0	21.0	0.714
13.0	18.0	0.722
13.0	18.0	0.722
12.0	17.5	0.686
12.0	19.0	0.632
12.0	18.0	0.667
11.5	17.5	0.657
11.0	16.5	0.667
11.0	18.0	0.611
10.5	18.5	0.568
10.0	18.0	0.556
10.0	17.0	0.588
9.5	19.0	0.500
7.0	16.0	0.438

FG is the femoral stem diameter, and EH corresponds to the diameter of the reamed canal.

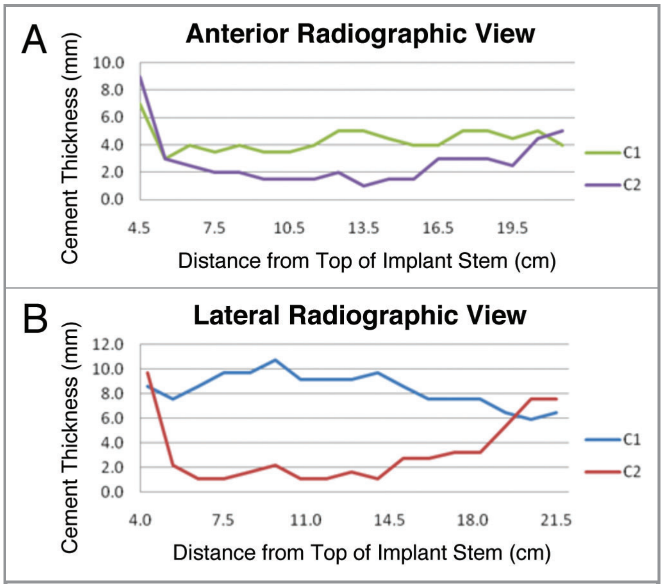

Figure 6. (A) Anterior radiographic data where cement thickness were recorded vs. position for both lateral and medial sides. (B) Lateral radiographic data where cement thickness were recorded vs. position for both posterior and anterior sides.

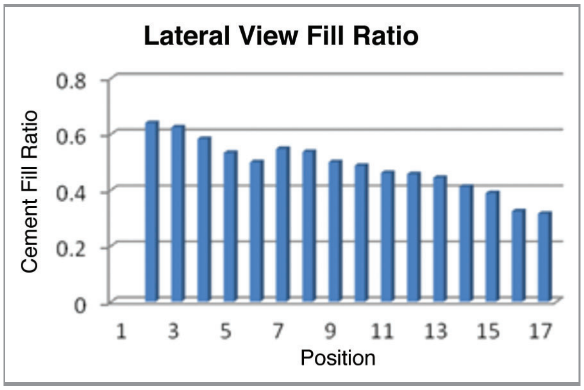

Figure 7. Fill ratio plotted vs. position of lateral fill ratio.

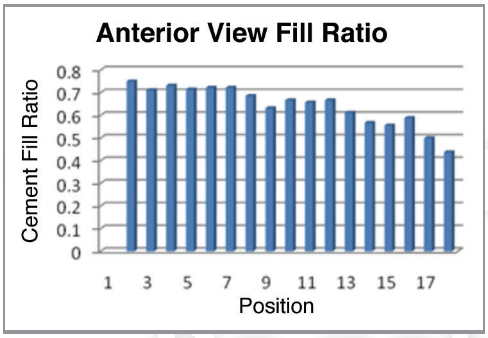

Figure 8. Fill ratio plotted vs. position of anterior fill ratio.

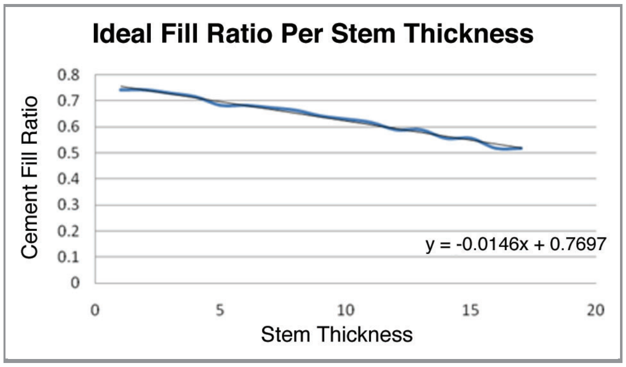

Figure 9. Ideal Fill ratio plotted vs. stem thicknesses.

half way up the femoral stem. Each of these cases is shown in **Figure 12**. By assuming that the implant diameter, as well as the reamed femoral cavity was consistent throughout each experiment, the variance in the cement mantle thickness would cause an increase in the cement mantle ratio. Given that the stem thickness is T_s and the reamed area has a diameter of R_a it can be concluded that if T_s stays constant through all cases, the R_a must be reamed more to accommodate stem. If the ratio of T_s/R_a gives the cement mantle thickness T_m and R_a is the increasing variable, the fill ratio (F.R.) will decrease.

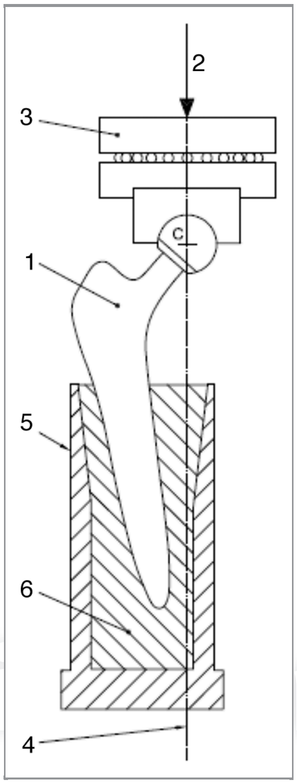

Figure 10. General orientation of specimen under test according to ISO 7206–4:2002 (E).

Conclusion

Cement mantle thickness has been directly correlated with femoral loosening. Cement fill ratio is calculated by considering stem thickness (T_s) and reamed area (R_a) parameters. It can be concluded that there is a middle region for an ideal cement mantle ratio. From several laboratory studies it was observed that optimal cement mantle thickness was in the range of 3 to 5 mm. X-rays provide qualitative indication on the measure of fill ratio. For optimal cement mantle thickness we obtained ideal femoral implant cement fill ratio between 0.56–0.76 and we observed the cement fill ratio decreases in an exponential manner with increase in cement mantle thickness. FEM models are able to predict the stress and deformation at the stem/cement and bone/cement interface.

By looking at the material characteristic properties, a thicker mantle would offer low stress at the bone cement interface, which can loosen as well. The increased loss of bone mass due to the reaming process can lead to instability and increased risk of bone fracture. If the mantle is too thick, there is an increased risk of radiolucent lines and inconsistent densities. This was further investigated and found to be majorly caused by the implant being placed further toward the anterior side of the femoral cavity and other factors like bleeding, back pressure, differential cure rate, etc. Alternatively, if the mantle is too thin, it can lead to a higher probability for cement fracture which loosens the prosthetic even further. Also, having a hip stem that is more of an oval cross

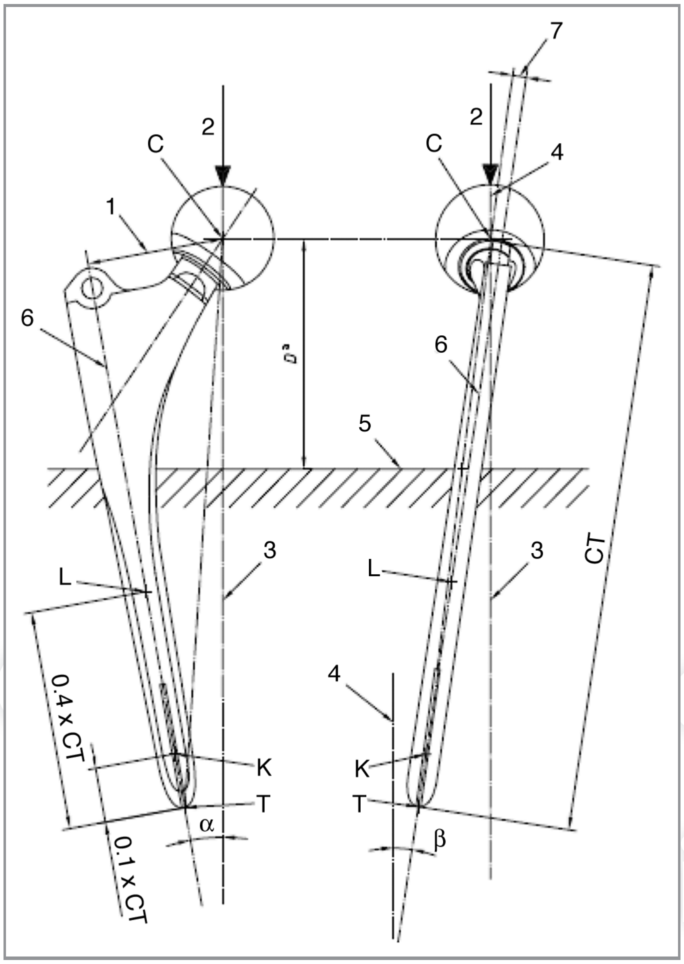

Figure 11. Orientation of specimen for test under ISO 7206–4:2002 (E).

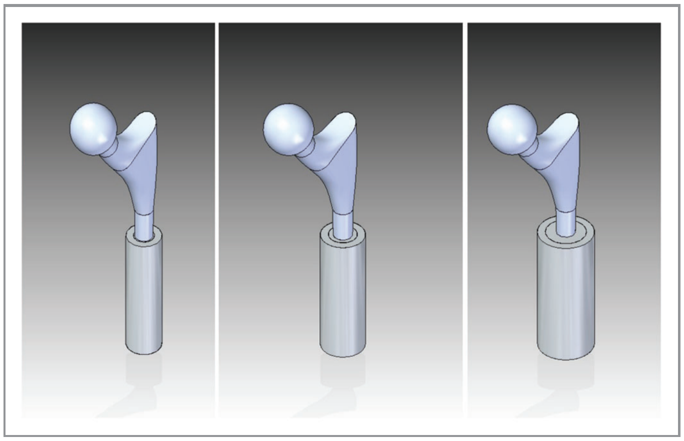

Figure 12. Design of the cement mantle around the femoral stem, and encased in the stainless steel enclosure. The 1 mm thick mantle is shown on the far left, the 3 mm is in the middle and the 7 mm is shown on the right.

section allows for a thinner mantle in one direction, when a round cross-sectioned area is reamed out of the bone. This would cause a correct thickness medially and laterally, and a thinner one in the other directions. The higher stresses observed in the proximal end suggest that cement failure is due to thin cement mantle and poor mechanical properties in the distal region is due to thick cement mantle where stress levels are low. From this study it is observed that for improving the stability of hip prosthesis considered in this study, a cement fill ratio between 0.56–0.76 eliminates the risk of hip prosthesis loosening.

Disclosure of Potential Conflicts of Interest

No potential conflicts of interest were disclosed.

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