

THE INFLUENCE OF FEMORAL STEM THICKNESS AND IMPLANTATION TECHNIQUE ON THE STRENGTH OF THE BONE CEMENT BOND

A. W. SAVINO¹, G. B. J. ANDERSSON², T. P. ANDRIACCHI¹, S. HAMPTON¹ & J. O. GALANTE¹

¹Department of Orthopaedic Surgery, Rush-Presbyterian-St. Lukes Medical Center, Chicago, USA, and

²Department of Orthopaedic Surgery, Sahlgren Hospital, Göteborg, Sweden

The influence of stem thickness, stem orientation, and insertion pressure on the strength of a prosthesis-cement-bone system was studied *in vitro*. Three types of prostheses were used with thick and thin stems, allowing for thick or thin cement envelopes. They were implanted with different stem orientations, and with and without a distal femoral cement plug. They were then loaded in a testing machine until a discontinuity of the load deflection curve occurred. The main factor determining the failure load was the presence of the distal plug. In specimens with plugs the main load at failure was 6.5 N, in specimens without a plug it was 4.8 N ($P > 0.05$). The most stable combination was the thick stem with a thin cement envelope placed in valgus or neutral orientation, and implanted with a distal cement plug. It was concluded that when no plug was present failure occurred at the bone-cement interface; when a plug was present it occurred at the prosthesis-cement interface.

Key words: biomechanics; bone cement; endoprosthesis; hip prosthesis; loosening

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Loosening of the femoral prosthesis in total hip replacements represents a mechanical failure of the system. In addition to the clinical problems associated with this failure, fatigue fractures of the femoral stem are usually preceded by loosening. While failure due to loosening has been well documented (Amstutz et al. 1976, Beckenbaugh & Ilstrup 1978, Carlsson & Gentz 1980, Coventry et al. 1972, Gruen et al. 1979, McBeath & Foltz 1979, Pellicci et al. 1979) there is insufficient information relating mechanical factors to loosening. It seems generally accepted, however, that inadequate fixation at surgery and breakdown of the mechanical bond between the stem and the cement, as well as failure at the cement-bone interface, are important sources.

Improvements in the cementing techniques have been suggested. These include vigorous finger packing, insertion of a plug distally in the femoral canal to increase insertion pressure, and positioning the prosthetic stem in valgus to reduce stress at the interfaces. Another parameter which could influence the mechanical strength of the system is the amount of cement placed around the femoral stem. The amount of cement is dependent on the thickness of the prosthetic stem, and to a lesser degree on the size of the medullary canal.

The purpose of the present work was to study the influence of stem thickness, stem orientation and insertion pressure on the strength of a prosthesis-cement-bone system *in vitro*.

MATERIALS AND METHODS

The proximal 25 cm of 30 human femora were obtained at necropsy within 10 hours of death from subjects dying from diseases not known to affect the quality of bone. The age range of the subjects was from 28 to 84 years, with a mean age of 62 years. Eighteen specimens were from males and 12 from females. After removal, antero-posterior and lateral radiographs were obtained of each specimen to determine the presence of disease or abnormalities. The specimens were then placed in sealed polyethylene bags and stored at minus 20 degrees C. During preparation and testing, the specimens were maintained at 100 per cent humidity at room temperature in a predetermined and consistent location within the laboratory.

All femoral shafts were transected distally 17 cm below the base of the neck perpendicular to the long axis of the bone. The neck was cut at an angle of 40–45 degrees, about 2 cm above the minor trochanter. Care was taken to preserve the calcar femoris. The medullary canal was reamed to accept the individual prosthesis with the appropriate reamers.

Three types of prostheses of different design were used. They were standard Charnley prostheses, Müller prostheses and CAD prostheses. The Charnley prosthesis in this system constitutes a thin stem prosthesis, the Müller prosthesis a thin but intermediate stem and the CAD a thick stem prosthesis. No prosthesis was used more than once. The differences in stem sizes permitted different size cement envelopes to be studied.

Fixation was obtained with Zimmer bone cement (Radio-opaque) Poly Methyl Methacrylate. Standard powder-liquid packets were used containing 40/0 g/mg powder polymer and 20 cm³ liquid monomer. The entire powder-liquid packets were mixed yielding 10–15 g of acrylic cement. As cement mass, thickness, powder-to-liquid ratio, mixing temperature and chemical modifications influence the resulting mechanical strength, the same batch of Bone Cement Polymer Mixture was used throughout (Charnley 1970, Lazansky 1974, Meyer et al. 1973). Ambient temperature was maintained throughout with curing at room temperature.

The mixing and insertion procedures were done by the same person.

The cement was inserted while in the dough stage using a cement syringe (Oh et al. 1975). The dough time in our laboratory was 2.5–3 minutes. In the tests, setting time was approximately 8.5 minutes. In some of the tests a distal cement plug was used, which was then inserted from the distal end.

The prostheses were inserted using a standard technique. In nine experiments they were placed in varus, in thirteen in valgus and in eight in a neutral position (Table 1). After the prosthesis had been implanted, x-rays were taken of the pre-tested specimen to assure the orientation of the component. The orientation was considered neutral when the axis of the prosthesis shaft was parallel with the axis of the femoral shaft, and valgus or varus when the axis deviated from the axis of the shaft of the femur in the appropriate direction; in the valgus position the tip of the prosthesis was at the medial cortex of the femur, in the varus position at the lateral cortex.

The cemented specimen was placed in a fixation device in which the shaft was supported distally by a metal plate and held firmly with 16 threaded screws placed at 90 degrees circumferentially in the steel test fixture (Figure 1). The fixation device was then placed in a floor model Instron testing machine with a predesigned anterior displacement block simulating the acetabulum.

The testing technique used was similar to that used by Martz (1956), Hirsh & Frankel (1960) and Charnley (1965). The prosthesis was incrementally loaded at a cross head speed of 5.08 cm/min with load cell calibrated to 10,000 N full scale. In every case the loads were applied until a discontinuity in the load deformation curve occurred. This discontinuity was assumed to indicate a failure somewhere in the bone-cement-implant system. After failure, the prostheses were unloaded and removed for macroscopic and radiographic (antero-posterior and lateral) examination. The bone was then dissolved from the cement envelope using nitric acid and the cement again inspected to determine the location of the failure.

Table 1. Mean load at deflection. The number of specimens in each group are given in parentheses. Values are in Newtons

Make of prosthesis	Surgical procedure	Stem orientation			Overall mean
		Neutral	Varus	Valgus	
CAD	Plug	8.900(1)	5.000(2)	8.900(3)	7.600
	No plug	4.750(1)	5.000(4)	4.250(3)	4.833
Charnley	Plug	4.450(1)	—	—	4.450
	No plug	5.000(3)	4.300(2)	—	4.720
Müller	Plug	5.450(2)	900(1)	7.050(5)	5.881
	No plug	—	—	4.900(4)	4.900

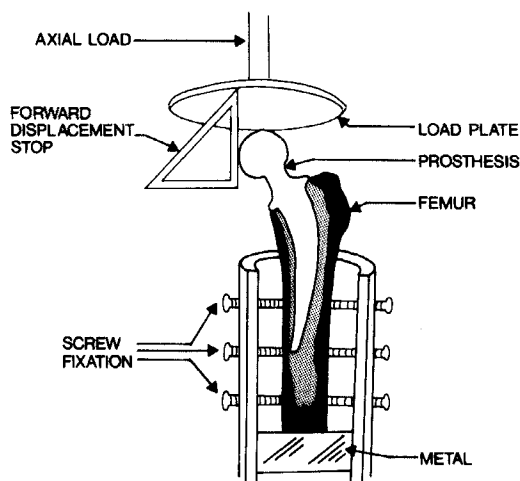


Figure 1. The specimen was mounted in a fixation device which was placed in an Instron materials testing machine. Axial load was applied to the femoral head until a discontinuity occurred in the load displacement curve.

In 4 of the 30 specimens, the sequence was halted by gross changes in the load deflection curve and audible cracking of the bone/bone-cement envelope. When these specimens were examined, cement fractures were found on the lateral aspects of the femoral prosthesis shaft with gross loosening of the prosthesis.

Statistical tests were made on the 5 percent level using chi square analysis.

RESULTS

Mechanical tests

The overriding factor influencing the strength of the system was the use of the distal plug. In 15 specimens with plugs the mean ultimate load at failure was 6.473 N, in specimens without plug 4.813 N (Table 1). The difference is statistically significant ($P > 0.05$). Statistically significant differences were also found between specimens with narrow stem prostheses and thick cement envelopes (Charnley and Müller prostheses), and specimens with thick stem prostheses and thin cement envelopes (CAD prostheses) but only when a plug was present ($P > 0.05$). The main failure loads for the three prosthesis designs were 4.450 N for Charnley, 5.88 N for Müller, and

7.60 N for CAD. When no distal plug was present there was no difference in failure loads between the larger stems with thin cement envelopes and the smaller stems with the thick cement envelopes.

The stem orientation influenced the magnitude of the failure load also. The mean failure load for prostheses inserted in varus was 4.389 N, for the prostheses inserted in a neutral position 5.550 N, and for the valgus stem 6.600 N. The difference is statistically significant ($P > 0.05$). When considering the plug - no plug influence on the results with respect to the stem orientation only the CAD experiments are complete. Again the results indicate that the plug was the main factor determining the failure load.

The mechanical test data were consistent from specimen to specimen. Statistical analysis showed the general behavior trends to be meaningful ($P > 0.05$).

Gross examination

The cement-prosthesis interface was intact, even after bone removal, except in four specimens. These specimens were two Charnley prostheses, and two Müller prostheses. The failure loads of these specimens are given in Table 2. Three of the specimens had bone and cement fractures, one (a Charnley prosthesis) a fracture in the upper lateral part of the cement envelope.

DISCUSSION

Before the implications of the results of this study are discussed, it is important to consider the fundamental assumptions of the study and the influ-

Table 2. Load at deflection in specimens with macroscopic bone-cement failure

Make of prosthesis	Orientation	Load (N)
Charnley	Varus	4.700
Charnley	Neutral	5.000
Müller	Neutral	4.450
Müller	Valgus	5.500

ence they may have on the results. The first assumption is that the *in vitro* model reflects *in vivo* conditions. As the conditions simulated *in vitro* are quite different from the actual *in vivo* situations, the results presented are assumed to be valid for purely comparative analysis. Thus, the actual magnitude of the failure loads are probably not as important as the relative values among the different conditions simulated. The reproducibility of the results and the statistically significant data tend to support this hypothesis.

The second assumption concerns the prediction of the failure load based on a discontinuity in the load displacement. We have assumed that some type of failure has been initiated when a discontinuity in the load displacement curve is first encountered, although the failure could not always be demonstrated at examination.

Care was taken to ensure that the discontinuities were not merely artifacts of the experimental set-up such as failure of the external fixation of the femur or slippage in the loading system. If we were successful in our attempts the discontinuity is reflective of a failure somewhere within the system.

Since the prosthesis-cement and cement-bone interfaces are the weakest links in systems such as these, it was felt that the first failure would occur at one of these locations. Thus, it seems appropriate to assume that the first failure, reflected by a change in the load deflection behavior of this system, would occur at one of the interfaces.

It seems these failures are quite small since post-failure analysis was able to produce obvious evidence of gross failure in only 4 specimens out of 30. We think that the failure mode reflects a slight slippage of either the cement envelope or the prosthesis within the cement envelope into a new stable position. This may constitute the onset of some type of loosening process.

If the results of the study can be assumed to reflect the *in vivo* situation, it appears that factors such as stem orientation, stem stiffness, cement envelope thickness and the presence or lack of a distal cement plug are all important factors in maintaining a stable cement fixation. A thick stem with a thin cement envelope placed in a valgus or neutral orientation implanted with a distal cement plug is the most stable combination. It

appears that the overriding factor in determining the failure load was the presence of the distal plug. Without the cement plug, results indicate no statistical difference in failure loads between the thinner stems and the thicker stems. While the lack of data for some test conditions in various orientations makes it impossible to draw more definite conclusions, the results indicate that the presence of the plug is the most important factor in determining where the initial failure will occur. This study would support the theory that two interface failure modes are possible; one at the bone-cement interface, and the other at the prosthesis-cement interface. The failure when no plug was present was assumed to occur at the bone cement interface. This failure mode was found to be independent of the stiffness (size) of the stem and the thickness of the cement envelope. This situation seems to reflect the clinically observed phenomenon of subsidence in which the entire system sinks distally in the intramedullary canal. It seems reasonable that this failure mode would not depend on the stiffness of the stem, since it is primarily a piston type movement. The bending stiffness of the stem does not play a role in a subsidence type failure.

The failure in the presence of the plug appears to occur at the prosthesis-cement interface. In this case the stem stiffness plays an important role. When the stem is loaded it bends away from the cement envelope along the lateral surface. A more flexible stem will bend more and put a greater strain on the proximal lateral stem-cement interface than will a stiffer stem. The plug enhances the cement-bone bond to such an extent that the next weakest link in the chain fails: the cement-stem interface.

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Correspondence to: Gunnar Andersson, M.D., Department of Orthopaedic Surgery I, Sahlgren Hospital, S-413 45 Gothenburg, Sweden.