The cement-canal prosthesis

A new cementation technique studied in cadaver femora

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This report presents the cement-canal prosthesis. Acrylic cement is injected through the prosthesis by means of an integrated drill hole system. A second canal system within the prosthesis allows suction from the cavities, which could form in the mantle during cement injection. In an experimental study using 36 human cadaveric femora, 3 cement implantation pressures (0.5 bar, 1.0 bar and 1.5 bar) were used. A conventional cementing technique served as a control. Compared to the controls, a deeper penetration of bone cement into cancellous bone was found. Increasing cement pressure led to deeper cement penetration. The average depths of the cement layer were 2.2 mm at 0.5 bar implantation pressure, 2.9 mm at 1.0 bar and 3.9 mm at 1.5 bar. A cement mantle without voids was achieved by this technique, whereas control specimens showed a wide variability in cement defects.

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To improve the filling of the medullary canal by bone cement, Draenert (1988) developed an implantation device. When the cement was injected using a pressure of approximately 4 bar, complete cement filling of the medullary canal was reported (Draenert 1988). As the risk of embolism is correlated to implantation pressure (Wenda et al. 1990), distal and proximal venting of the femur should be provided by means of canalized screws.

The aims of my study were to examine the quality of the cementation, using a new implantation system, and to evaluate the penetration depths into cancellous bone according to the various pressures used during implantation. The results were compared to a conventional cementing technique.

Device and methods

In preliminary tests, a 11 cm long cylindrical hollow tube of stainless steel (the prosthesis) was implanted into transparent acrylic tubes to permit a visual assessment of the cement flow (Figure 1). The cement was injected through a drill hole system within the prosthesis. A second drill hole system within the prosthesis was connected to vacuum suction. The outlets of the suction and the cement canal systems are located in a staggered arrangement in order to permit immediate evacuation of trapped air and liquids, such as blood within the cement mantle. Because of the canal system, the device is called the cement-canal prosthesis.

The shape of the prosthesis had to allow easy extraction out of the cement mantle. Therefore, a straight stem design was chosen. Complete cement filling with no visible macroscopic defects was found over the whole length of the prosthesis (Figure 1). The distal femoral plug and the proximal seal are part of the prosthesis and fulfil two functions: to fix the prosthesis within the cement mantle and to provide proximal and distal sealing.

Implantation technique in cadaver femora

A tapered reamer with a radius exceeding that of the prosthesis by 1 mm was used for standardized preparation of 36 cadaveric human femora. Precooled 0–4 °C acrylic cement (Palacos R, Fa. Merch, Darmstadt, Germany) was used in all experiments. It was hand-mixed and filled into a cement injector. Due to previous cooling, the cement has a low viscosity (Draenert 1988, Merck 1989) when it is injected.

A specially designed cement injector was constructed which allowed application of a defined cement pressure during implantation. This injector includes a spring which exerts a force onto the syringe. By calibration of the system, a relation between compression of the spring and cement pressure was achieved. The dead space volume of the cement-canal system in the prosthesis was filled at a pressure of 2 bar. The medullary cavity itself was filled with reduced cement pressure (0.5, 1.0, 1.5 bar, respec-

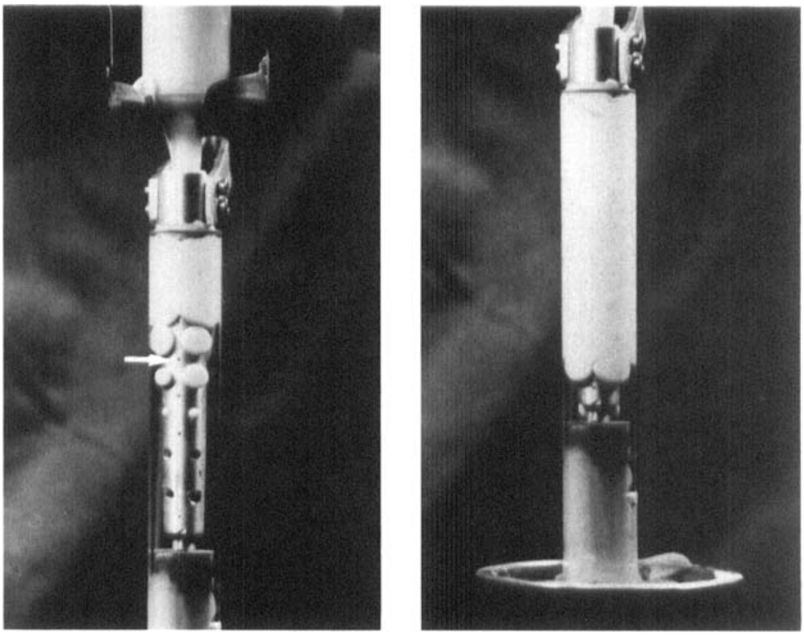

Figure 1. Two stages of cement injection in acrylic tubes at an interval of about 3 s. Uniform formation of the cement layer without visible voids is demonstrated. Arrow points at a suction outlet hole.

tively), which was kept constant over the entire period for cement curing.

Three cement-curing pressures were investigated (0.5, 1.0, and 1.5 bar). One series for a given cement-pressure comprised 6 femora with cement-canal technique and 6 controls using conventional cementing technique in the contralateral femur.

For implantation by cement-canal technique, the prosthesis was inserted into the medullary canal and connected to the vacuum system of the operation room (0.2 bar). The level of osteotomy was 1 cm proximal to the trochanter minor. Since cancellous bone is present only in the proximal intertrochanteric area of the femur, a short prosthesis of 4.5 cm length was used in the experiments for measuring the cement penetration depths. Thanks to this short design, it was easier to extract the prosthesis from the cement layer, which itself had to stay intact for further evaluation. Before implantation, the prosthesis had been waxed with stearin and the distal plug was only glued on, to allow easy extraction from the cement mantle.

All tests with cadaveric specimens were carried out in blood flow-simulating conditions. Therefore, according to Benjamin et al. (1987) and following the recommendations given by Draenert (1988), 4 holes of 1 mm diameter were drilled into the femur along the linea aspera at equal distances over the length of the prosthesis and a further 4 holes laterally and another 4 holes medially. Afterwards, the specimen was tied up in a plastic bag, which was infused with a water column of 20 cm height.

A conventional cementation technique served as control. After mixing, the cement was filled into a syringe. A suction tube was inserted into the femur down to the predicted end of the prosthesis and connected to the operating room's suction system. By means of injection with a syringe, the cement was then placed at the plane of osteotomy and sucked in the anterograde direction into the medullary canal to the predicted end of the prosthesis. After careful removal of the suction tube, the prosthesis was slowly inserted into the femur. In these experiments the same prosthesis was used. All cement and suction outlets were sealed with glue and a separate distal plug was used. No proximal seal was used in this technique, and thus no additional pressure was exerted onto the cement when the prosthesis was inserted.

Evaluation

A universal testing machine (Fa. Zwick, Typ 7025-3, 7900 Ulm/Donau, Germany) was employed to pull the prostheses out of the intact cement mantle. Using a grinding disk-cutting device, the bone specimens were each cut into 10 slices, beginning at the plane of osteotomy spaced 5 mm apart and documented photographically together with a ruler (Figure 2).

Figure 2. Cross-sections of femora after implantation, using cement-canal injection technique (left) at a pressure of 1.5 bar and control specimen (right). There are visible voids in cementation of the control femur, whereas no voids are seen in the femur with cement-canal technique.

Visible cement defects were measured in relation to the ruler on the photographs, and thus the size of the corresponding defect area was calculated. The cement penetration depths were measured at 16 circular and regularly distributed points separated from each other by an angle of 22.5°. Only the actual penetration of the acrylic cement into the cancellous bone was measured. A computer Fortran program developed especially for this purpose was used to store the 5,760 single measurements and to make a statistical evaluation. Average values, median values and standard deviations of the different sections and locations were calculated. For statistical evaluation, the Wilcoxon method (Sachs 1980) of matched pair testing (cement-canal injection versus control) was performed. The test of Wilcoxon, Mann and Whitney (Sachs 1980) for random samples was used for comparison of penetration depths between the 3 different implantation cement pressures.

Results

Figure 2 presents the cross-sections of the femur after implantation, using the cement-canal technique (left) at a pressure of 1.0 bar. No cement defects can be seen. The corresponding control shows several cement

Table 1. Cement penetration depths (mm) into cancellous bone, mean *SD*

Level of femur	Cement-canal prosthesis						Control prosthesis	
	0.5 bar		1.0 bar		1.5 bar			
Osteotomy	2.44	*0.41*	3.39	*0.79*	4.39	*0.91*	1.18	*0.23*
5 mm	2.47	*0.40*	3.51	*0.97*	4.38	*0.71*	1.18	*0.23*
10 mm	2.25	*0.38*	3.11	*0.56*	4.20	*0.71*	0.93	*0.20*
15 mm	2.21	*0.38*	2.75	*0.55*	3.90	*0.56*	0.95	*0.18*
20 mm	2.11	*0.38*	2.36	*0.27*	3.16	*0.36*	0.88	*0.15*
25 mm	1.91	*0.31*	2.23	*0.27*	3.16	*0.36*	0.83	*0.13*
30 mm	2.10	*0.48*	2.02	*0.45*	2.98	*0.41*	0.79	*0.16*
35 mm	1.86	*0.35*	1.89	*0.41*	2.93	*0.53*	0.63	*0.09*
40 mm	1.67	*0.30*	1.34	*0.17*	3.33	*0.39*	0.56	*0.06*
45 mm	1.42	*0.26*	1.22	*0.19*	2.69	*0.37*	0.55	*0.07*

defects. Quantitative assessment showed large differences in cementation defects of the control specimens with a mean 4 (0–18) percent defect area, which was greater than in the contralateral femora ($P < 0.05$). None of the specimens implanted by the cement-canal technique showed any macroscopically visible defects in the cement.

The cement-canal technique involved deeper cement penetration into cancellous bone than the conventional cementation technique did (Table 1). The average depths of the cement layer were 2.2 mm at 0.5 bar cement implantation pressure, 2.9 mm at 1.0 bar, and 3.9 mm at 1.5 bar. Increasing cement injection pressure resulted in deeper cement penetration. However, the cement penetration was not homogeneous and reflected the varying trabecular structure of the cancellous bone at the proximal femur.

Discussion

The cement-canal prosthesis provides the opportunity to achieve an exact positioning of the prosthesis within a homogeneous cement layer, which is virtually free of voids. The length of the cement layer is determined by the femoral plug, which is connected to the distal end of the prosthesis. Except for a specially designed cement injector, no other implantation tools are needed.

The increased intramedullary pressure during implantation represents a critical factor in all cementing techniques. As shown by various authors (Bednarz and Roewer 1989, Watson and Stulberg 1989, Henn-Beilharz et al. 1990), pulmonary embolism may rsult from this elevated pressure. Pressures as low as 0.8 bar lead to embolism in sheep (Wenda et al. 1990). It seems beneficial to use a cementing technique with the lowest possible pressure.

By conventional cementing technique, pressures ranging up to 2 bar (conventional hand-injection technique), 4 bar (finger-packing), 5 bar during prosthetic insertion and 4 bar in the final hammering of the prosthesis have been reported (Schlag et al. 1976). Since time is limited in conventional cementing techniques, it seems almost impossible to avoid such high pressures, if secure penetration into the cancellous bone is to be achieved.

However, with the cement-canal prosthesis it is possible to sustain the cement pressure for the whole period of cement curing.

Local differences in trabecular bone structure (Knauss 1981) influence the flow pattern of acrylic cement into cancellous bone. However, the resulting cement mantle was homogeneous in all cases. Jansson et al. (1993) showed that an adequate interlock with the femoral bone can be provided by the cement-canal technique, even at low cement injection pressures.

This study indicates that the combination of cement injection and suction of the femoral canal leads to a homogeneous cement mantle without voids. The implantation procedure proved easy to accomplish. The magnitude of the cement pressure is automatically controlled by the cement injector. The prosthesis is inserted into the femur before the cement is applied, thus defining its position within the cement mantle.

Further development of this prosthesis aims at a more practical implantable design with respect to structural stability of the implant and optimization of the cement flow.

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