Does Increased Cement Pressure Produce Superior Femoral Component Fixation?

John K. Dozier, MD,* Tim Harrigan, ScD† William H. Kurtz, MD,‡
Christopher Hawkins, PhD,§ and Robert Hill**

Abstract: A new system of femoral cement pressurization is presented that attempts to produce sustained and elevated cement pressure. Five paired cadaver femora were pressurized with Simplex cement, and PFC femoral components were inserted. One of each pair was pressurized with the new system, and 1 was pressurized with an existing device. Pressure was recorded at the proximal and distal levels. After curing, all 10 specimens were sectioned at similar levels and subjected to push-out testing to failure. Specimens that achieved higher pressures and longer duration of pressures tended to show higher levels of failure (not statistically proven on 10 specimens). Cementing techniques that use higher pressurization of cement are recommended. It is mandatory, however, that the femur be thoroughly cleaned of fat before the application of these techniques to avoid a fat embolism syndrome. **Key words:** total hip, femur, cement pressurization.

Failure of fixation of the femoral component has been a prominent cause of failure of total hip arthroplasty. Cementing techniques have gone through first-generation and second-generation levels and now into third-generation techniques, including distal plugging, thorough lavage, drying, pore reduction, and pressurization. The focus of this article is the area of pressurization of bone cement. Is there a threshold of what may be considered optimal cement pressure?

Material and Methods

Embalmed femora from 6 cadavers were harvested. One side was done with a PFC femoral cement pressurization system (Johnson & Johnson Professional, Raynham, Massachusetts) and the contralateral side with a Zimmer bone cement injector (Zimmer, Warsaw, IN). One pair of femora was discarded because of improper placement of a distal plug proven on x-rays of all specimens. This left 5 pairs for the present study.

Procedure in Detail

The PFC device (Fig. 1) is an off-the-shelf fitted plug made to be occlusive proximally. Various sizes are available to fit a range of femoral sizes. The two components are a molded silastic plug and an associated Teflon funnel. Preparation of the femur proceeds normally except that reaming is kept to a minimum and during broaching care is taken to leave some cancellous bone. An occlusive distal plug is placed at the proper level. The inner walls of the femoral cavity are thoroughly cleaned of all fat and reaming debris with a powerful, radially directed spray during an extended period of time. Three liters of irrigant is considered optimal. The femur is then kept dry by using a suction tampon (Smith and Nephew Richards, Memphis, Tennessee) and

*From *Orthopaedic Surgery, Houston, Texas, the †Department of Orthopaedic Surgery, University of Texas Medical School, Houston, Texas; ‡the University of Texas Southwestern, Dallas, Texas; the §Department of Statistics, Rice University, Houston, Texas; and the **University of Houston, Houston, Texas.*

Submitted March 9, 1999; accepted July 13, 1999.
Funds were received from Johnson & Johnson Orthopaedics in support of the research material described in this article.
Reprint requests: John K. Dozier, MD, 8830 Long Point, Suite 106, Houston, Texas 77055

doi:10.1054/arth.2000.2967
0883-5403/00/1504-0014$10.00/0

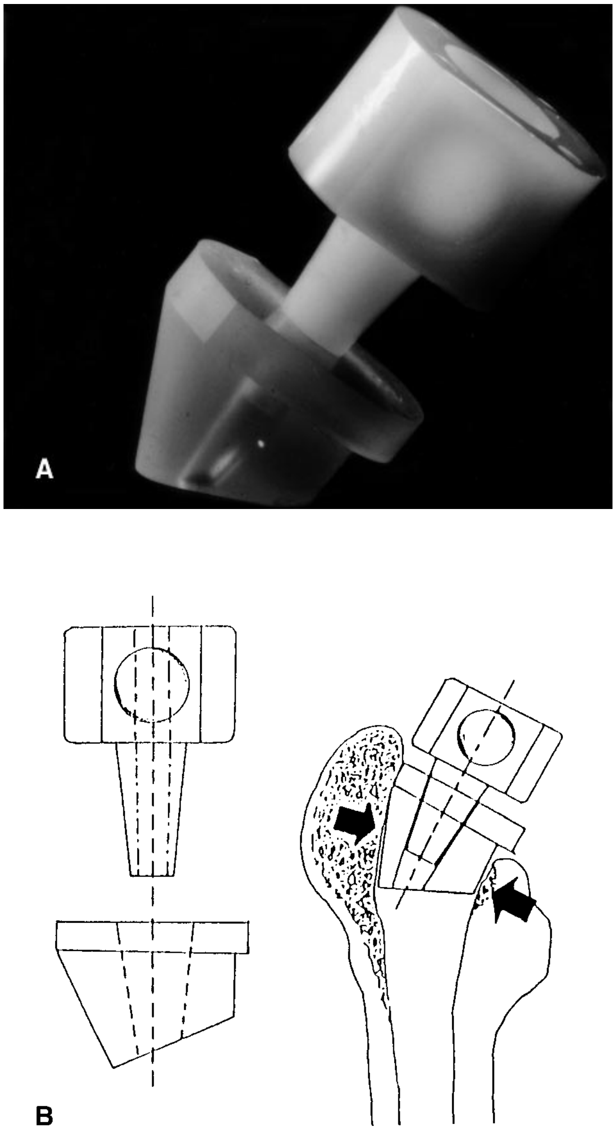

Fig. 1. (A) Molded silastic plug and Teflon (DuPont, Wilmington, DE) funnel. (B) Insertion method. As the funnel is fully seated, the plug expands to occlude the femur proximally.

H_2O_2–soaked sponges (Fig. 2). Cement is mixed, centrifuged (International Equipment Company Needham Heights, MA), and the femoral cavity is filled from below to just below the cut femoral neck. The properly fitted proximal plug is fully seated and held forcefully by an assistant. The funnel is then inserted fully, thereby expanding the soft silastic proximal plug into the walls of the femoral cavity. The nozzle of the cement gun is placed into the funnel mouth, and repeated clicks of the trigger are accomplished in approximately 20 seconds. The nozzle is kept in place, the cement gun is removed, and continued cement pressurization is gained by manually inserting the stylus into the cement nozzle (Fig. 3). The femoral component is then inserted. The cement mass experiences 3 periods of pressurization with this system. In this study, 5-mm holes were drilled through the cortical walls to accept pressure transducers. These holes were placed laterally over the proximal one third and the distal one third of the cement mass. Piezo (Entran Devices, Inc., Fairfield, NJ) electric pressure transducers were threaded into the holes. Cement pressures were recorded digitally on a personal computer, and pressure graphs were produced.

The Zimmer specimens were treated similarly with placement of the harder rubber nozzle into the femoral neck. An effort was made to position the nozzle so that maximal pressure was obtained and the cement flashback was avoided. With this system, the cement mass experiences 2 periods of pressurization. Figure 4 shows graphs for the fourth pair of specimens and is typical for the group. After curing, a diamond-edged Marks laboratory saw was used to cut 4 1-cm-thick disks from similar levels of each of the 10 femora.

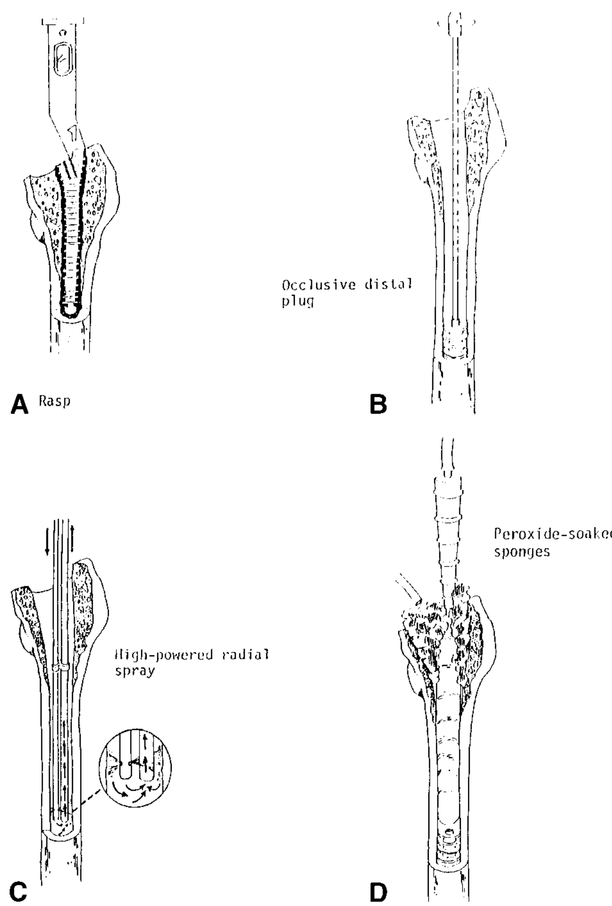

Fig. 2. (A) Sequential rasping, (B) distal occlusion, (C) high-powered radial spray, and (D) drying of the femur.

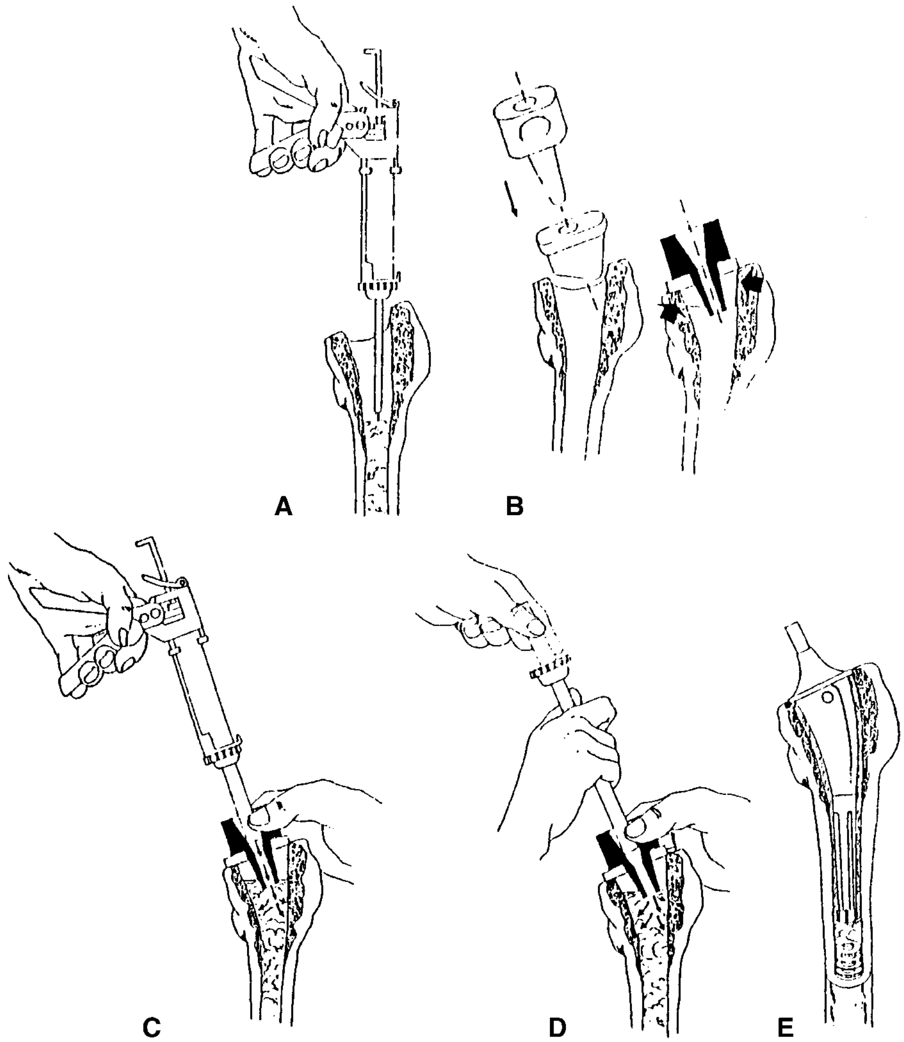

Fig. 3. Sequence of cement placement, proximal plugging, and cement pressurization. (A) Centrifuge cement. The femur is filled from below. (B) The Silastic plug is inserted and expanded with the funnel. (C) Cement is pressurized with the gun. (D) Cement is pressurized with the stylus. (E) Insertion of the component.

Each disk was subjected to failure in a distal-to-proximal orientation on a specially designed jig that could be adjusted to support the cortical bone of each disk (Fig. 5). Lexan disks were ground to fit 1 to 2 mm within the outline of the cement mantle. The Actuator of a servohydraulic test frame (MTS 810, MTS Systems Corp., Minneapolis, MN) was then centered over the Lexan, and pressure was applied to failure. *Failure* was defined as push-out of the metal cement composite with secondary fractures of the cortical rim or sudden burst fracture of the rim usually in 2 to 3 places.

Results

Graph Appearance

The cement pressurization/time curve is different for the 2 devices. The PFC femoral cement pressurizing device produces curves that have 3 areas of increased pressure. The first area occurs during the use of the gun, the second and highest during the use of the manual stylus, and third during insertion of the component. The Zimmer device has 2 areas of increased pressure: 1 during the use of the gun and 1 during component insertion. Fig. 4 shows a typical comparison.

Time of Pressurization: PFC Versus Zimmer

Referring to the 10 pressurization graphs, a determination can be made of the total time of pressurization above the 0 psi pressure line (Fig. 4). Total pressurization includes gun, stylus, and component insertion. The 5 PFC femora experienced a total pressurization time of 226.5 seconds and a mean pressurization time of 45.3 seconds. The 5 Zimmer femora experienced a total pressurization time of 137.0 seconds and a mean pressurization time of 27.4 seconds.

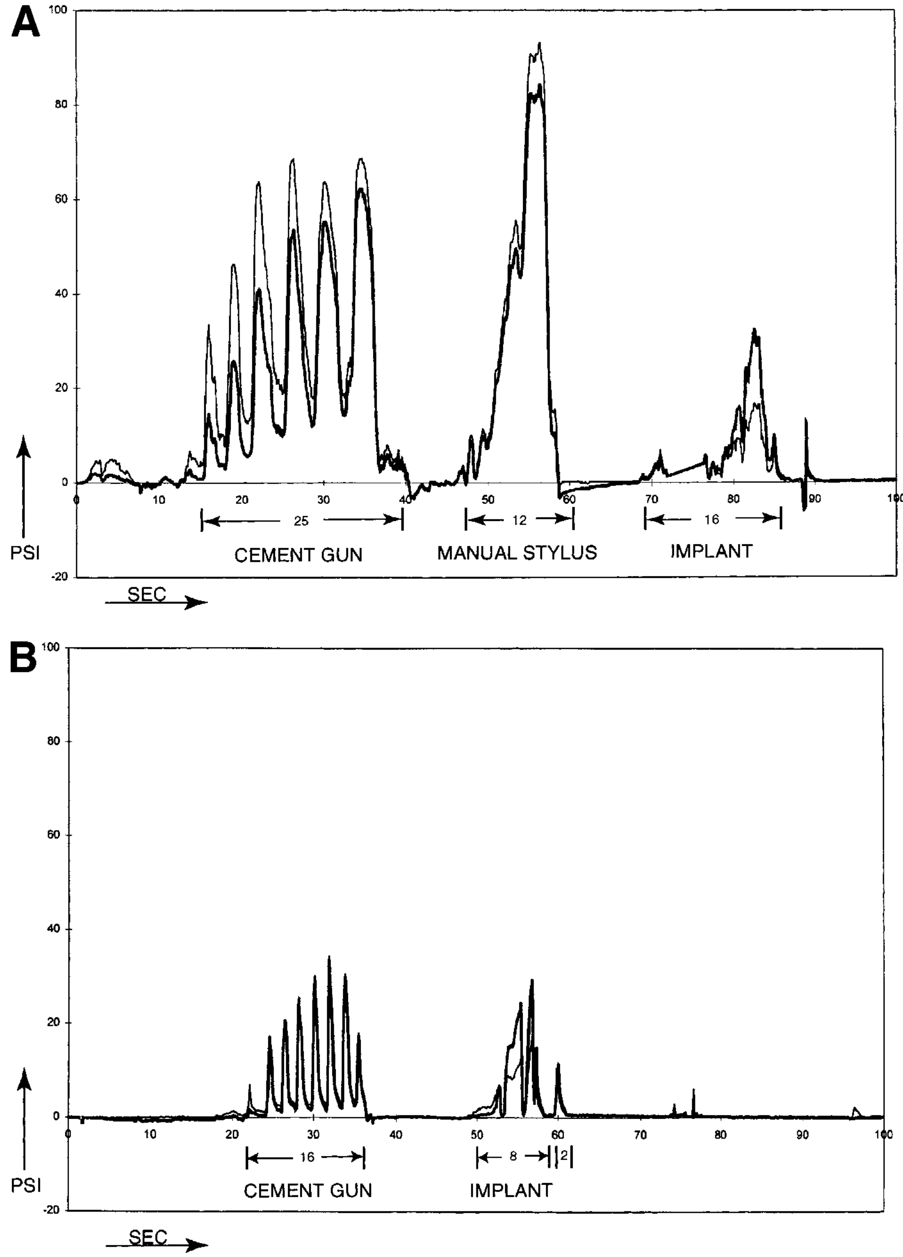

Fig. 4. (A, B) Cement pressurization curves with PFC plug versus Zimmer plug. (—), upper pressure transducer; (**—**), lower pressure transducer.

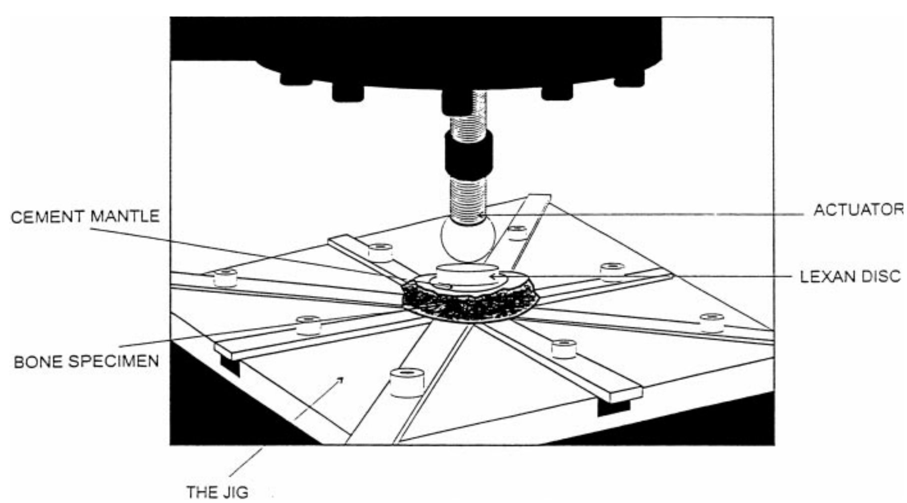

Fig. 5. The servo hydraulic text frame lexan disk and specimen push-out testing.

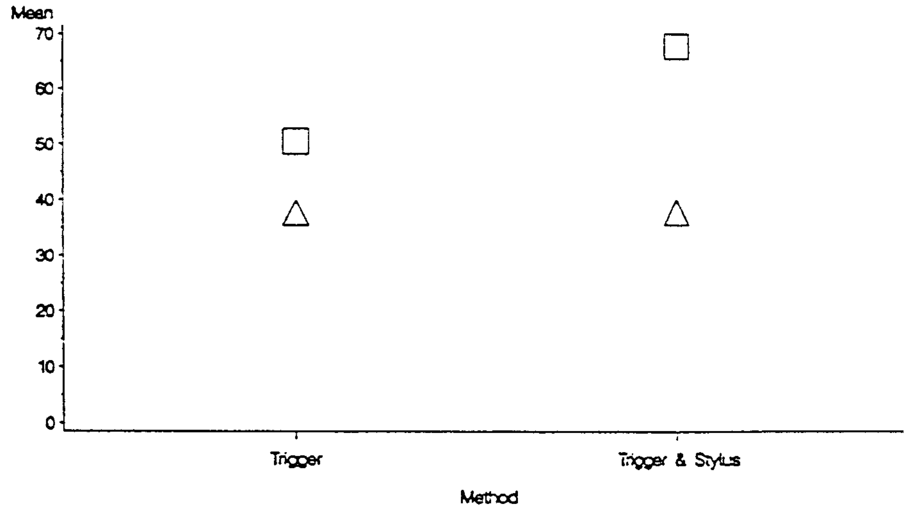

Fig. 6. Comparison of mean cement peak pressures: PFC versus Zimmer. (△), Miller; (□), PFC.

A paired-sample *t*-test revealed significantly greater mean pressurization time for the PFC femora ($P = .01$). Because the validity of the *t*-test is qualified by the small sample size, a nonparametric test based on median pressurization time was also conducted. The median pressurization time was also found to be significantly greater for the 5 PFC femora ($P = .03$).

Peak Cement Pressure Means: PFC Versus Zimmer

Figure 6 plots the mean peak pressure by device. The mean peak pressure with the trigger was higher with the PFC device than with the Zimmer device. The difference, however, was not statistically different ($P = .33$). There was a significant difference ($P = .02$) between the mean cement pressure produced by the Zimmer trigger and the PFC stylus methods (Table 1).

Area Under the Pressure Profile: PFC Versus Zimmer

Excel software (Microsoft, Redmond, WA) and the trapezoidal method ($\frac{1}{2}[h1 + h2][t2 - t1]$) were used to quantitate the area under the pressure profile of the 5 PFC and 5 Zimmer femora. The trapezoidal method is a computer-generated method to determine the area under a curving graph line. This determination is done by creating a series of trapezoidal shapes, then adding them together to determine the total area under a graph.

The area under the pressure profile curve is believed to be representative of the duration of time of cement pressurization. Using the trapezoidal method of analysis, it is shown that the trigger portion of the Johnson & Johnson device produced a mean of 4.9 and the Zimmer device 1.8 P.S.I./sec. The difference is statistically significant psi/s ($P = .0029$). Similarly, under the total curve from 0 to 90 seconds, it is shown that the J&J device produced a mean of 9.8 psi/s and the Zimmer device a mean of 3.0 psi/s. This difference is statistically significant ($P = .0039$).

Table 1. Summary Statistics

Data Set	Mean	Variance	Standard Deviation	Standard Error of Mean
PFC trigger peak	50.2	625.7	25.01	11.18
PFC stylus	68.2	389.2	19.73	8.82
Miller trigger peak	37.6	121.3	11.01	4.92

Mean Load to Push-Out Failure: PFC Versus Zimmer

Push-out loads at failure were collected from 17 of a possible 20 PFC sections and from 19 of a possible 20 Zimmer sections (Fig. 7). The mean push-out strength of the 17 PFC sections was 581.48 psi and of the 19 Zimmer sections was 507.78 psi (ie, the PFC sections resisted push-out an average of 72.7 psi over the Zimmer sections (not statistically significant, $P = .1239$) (Table 2).

Discussion

It is believed that the poor results reported with first-generation cemented femoral components reflect suboptimal cement techniques at that time.

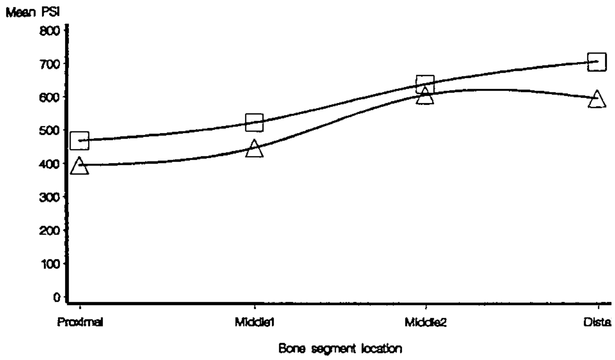

Fig. 7. Mean push-out load to failure: PFC group versus Zimmer group. Mean push-out strength: Miller device, 508.78 PSI; PFC device, 581.48 PSI. (△), Miller; (□), PFC.

The two critical features that determine the intrusion of cement into bone are the viscosity of the cement and the pressure used to deliver the cement. This pressurization is best done with a cement gun and an adequate femoral seal [1].

Rey et al. [2] studied the intrusion characteristics of bone–cement into bovine cancellous specimens. He found that chilled monomer simplex cement increased the depth of intrusion to 5.8, 8.2, and 12.7 mm at 20, 40, and 60 lb. psi. Hawala et al. [3] studied factors that contribute to the shear strength of the cement–bone interface. The major feature to emerge was a consistently higher shear strength if the cement reached within 3 mm of the corticocancellous junction. Failure to do so resulted in decreased shear strength. These authors believed that this phenomena reflected an increasing density of each trabecula as it approaches the endosteal surface. We believe that the present study demonstrates this phenomenon (ie, specimens with increased cement pressure tended to show higher average push-out loads [not proven statistically]).

Askew et al. [4] believed that pressure magnitude is the most influential of the factors of cement penetration behavior and in the development of failure load capacity but that a duration of cement pressure was not a significant factor. In the present study, the duration of pressure as reflected by a comparison of the area under the pressure curves was 3.06 times greater with the PFC device than with the Zimmer device. We believe that this was a significant factor in obtaining higher capacities to failure.

Bean et al. [5] concluded that sustained pressure of 60 psi would engage the important medial and posterior compression trabeculae and that the result was a 30% increase in shear strength in these areas. Following Wolf's law, medial and posterior are the locations of the strongest compression trabeculae. This concept of medial/posterior strength was verified by Bugbee et al. [6]. In a study of 12 fresh clean plugged femora, cement was pressurized. An average of 28 psi was recorded. A total of 236 bone–cement sections were isolated and tested on a servohydraulic testing machine. The strongest interface was proximal medial, and the weakest was distal lateral.

Push-out tests suffer from several problems. Dhert et al. [7] state that the size of the hole through which pressure is experienced in the support jig and Young's modulus of the implant are parameters that are most strongly influenced by the interference stress distribution, and lack of standardization with regard to these parameters can lead to uninterpretable test results. A clearance of more than 0.7 mm leads to inaccurate results. Being aware of these

Table 2. Comparison Load to Failure: PFC versus Zimmer Femoral Specimens

Load to Failure for PFC Femurs (lbs)							
Section	Femur 1	Femur 2	Femur 3	Femur 4	Femur 5	Mean	Standard Error
Proximal	406.0	566.5	247.6	593.3	525.9	467.86	63.71
Middle 1	*	543.5	420.9	578.6	537.6	520.15	34.30
Middle 2	*	966.8	681.2	315.9	578.1	635.50	134.56
Distal	808.6	944.3	606.5	*	450.2	702.40	109.01
Load to Failure for Miller Femurs (lbs)							
Section	Femur 1	Femur 2	Femur 3	Femur 4	Femur 5	Mean	Standard Error
Proximal	273.93	364.3	304.2	481.5	549.8	394.75	52.58
Middle 1	351.56	510.7	388.2	585.9	390.4	445.35	44.22
Middle 2	482.90	741.7	575.2	*	610.4	602.55	53.61
Distal	729.90	789.5	717.3	214.8	510.7	592.44	105.50

*Unrecorded data.

limitations, we customized Lexan disks as closely as possible to contour just inside the cement mantle outline.

In a series of 97 consecutive hybrid hips using third-generation cementing techniques that included pressurization, Schmalyzried and Harris [8] reported 91% good or excellent results with 1 revision because of femoral loosening and 1 hip with radiographic loosening of the femoral component and thigh pain. In a similar series of 100 consecutive hybrid total hip arthroplasties also using third-generation cementing techniques that included pressurization, Oishi et al. [9] reported grade A cement mantles in 81% and grade B in 19% of patients. There were no grade Cs or Ds. In this group of 100 patients, 3 patients reported thigh pain, and there was 1 failure at 7 years leading to revision [9].

As is shown in Fig. 6, the highest mean cement pressure with the PFC device is 50.2 psi with the gun and 68.2 psi with the stylus. With the Zimmer device, 37.6 psi is established. A proper goal of pressurization is 60 psi in the clinical setting.

We believe that the greater area under the PFC pressure profile reflects the more occlusive nature of the device. Cement flashback and resultant pressure drops to low levels are avoided, and sustained levels of pressure occur. The sustained levels of pressure produce more area under the pressure profile.

Clinical loosening of femoral implants over time involves biologic events. In laboratory push-out tests, only mechanical events are addressed.

The importance of a totally occlusive distal plug cannot be emphasized enough. If the distal plug allows cement escape distally down the femur, inadequate proximal pressures follow, as seen in femur no. 5 of the PFC series. For this reason, this specimen and its mate were not included in this study. In addition, distal escape of cement under high pressure exposes the unwashed portion of the femur with an attendant increased chance of fat embolization. Currently, we use a PFC multiple flanged distal plug.

Patients undergoing cemented arthroplasty of the hip frequently show moderate embolic phenomena as seen with transesophageal echocardiographic studies [10]. These events may be well tolerated but can be catastrophic and fatal. A documented fatal marrow embolism case after the use of a porous-coated noncemented bipolar hip endoprosthesis was reported by Arroyo et al. [11]. In this case, the femur was reamed to 14 mm and rasped to 14 mm, and a no. 14 femoral stem was inserted. No description of irrigating the femoral canal was provided.

Four cases of a fat embolism syndrome after the use of cementless acetabular press-fit components and cemented press-fit femoral components were reported by Watson and Stuhlberg [12]. The authors postulated that intramedullary debris was generated by instrumentation designed to accomplish a press-fit implant. Substantial detritus was created and was not adequately removed by standard cleaning and drying techniques. The use of a press-fit femoral stem with polymethyl methacrylate resulted in additional femoral pressurization, which forced remaining intramedullary fatty debris into the venous circulation with resultant fat embolism syndromes.

Thorough lavage using 1 L of unpressurized fluid has been shown by transesophageal echocardiogram to reduce statistically the number and size of fat embol generated during pressurized cement application in a group of hemiarthroplasties. In addition, hypotensive episodes were seen only in the portion of the study of patients receiving only minimal lavage [13].

High-volume, high-pressure pulsatile lavage with a Simpulse device (CR Bard, Cranston, RI) resulted in a 75% reduction in the number of fat emboli after bilateral cemented arthroplasty in dogs [14]. It is considered dangerous and contraindicated to use this device without thorough lavage of the femoral canal. The use of 3 L of lavage delivered by means of a powerful radial spray such as the Simpulse plus system, Davol (CR Bard, Cranston, RI), is optimal. We have experienced no clinical cases of fat embolism since following this procedure.

Conclusion

The PFC device and Zimmer device have been compared regarding cement pressurization and failure loads with push-out studies. We believe that because of the occlusive nature of the PFC device, higher cement pressures are produced over longer periods of time, which, in turn, create a tendency to produce improved push-out load evaluations (not statistically proven). Since 1989, the device has been used in cemented endoprostheses and hybrid total hip arthroplasties employing the techniques previously described. It is, however, mandatory that all fat and loose fragments of bone marrow be thoroughly cleaned from the femur with a high-powered spray. Otherwise, as with any other high-pressure system, a fat embolism syndrome can be easily produced. If the fat is thoroughly cleaned, the chance of a fat embolism syndrome is minimal [15].

References

1. Jasty M: Cemented fixation of the femur. Instr Course Lect 43:373, 1994
2. Rey R, Paiement G, McGann W, et al: A study of intrusion characteristics of low viscosity cement sim-

plex P and palacos cement in a bovine cancellous bone model. Clin Orthop 215:272, 1987
3. Hawala M, Lee AJD, Ling RSM, Vangala SS: The shear strength of trabecular bone from the femur, and some factors affecting the shear strength of the cement bone interface. Arch Orthop Trauma Surg 92:19, 1978
4. Askew MJ, Steege JW, Lewis JL, et al: Effect of cement pressure in bone strength on polymethylmethacrylate fixation. J Orthop Res 1:412, 1984
5. Bean DJ, Hollis M, Woo SL-Y, Convery, FR: Sustained pressurization of polymethylmethacrylate: a comparison of low and moderate viscosity bone cements. J Orthop Res 6:580, 1988
6. Bugbee WD, Barrera DL, Lee AC, Conery FR: Variations in shear strength of the bone cement interface in the proximal femur. Trans Orthop Res Soc 17:22, 1992
7. Dhert WJA, Verheyen CEPM, Braak LH, et al: A finite element analysis of the push-out test: influence of test conditions. J Biomech Mater Res 26:119, 1992
8. Schmalzried T, Harris W: Hybrid total hip replacement. J Bone Joint Surg Br 75:608, 1993
9. Oishi CS, Walker R, Colwell Jr C: The femoral component in total hip arthroplasty: six to eight year follow up in one hundred consecutive patients after VSE of a third generation cementing technique. J Bone Joint Surg Am 76:1130, 1994
10. Christie J: The coagulative effects of fat embolization during intramedullary manipulative procedures. Tech Orthop 11:1, 1996
11. Arroyo JS, Garvia KL, McGuire MH: Fatal marrow embolization following porous coated bipolar hip endoprosthesis. J Arthroplasty 9:449, 1994
12. Watson JT, Stuhlberg B: Fat embolism associated with cementing of femoral stems designed for press-fit application. J Arthroplasty 4:133, 1989
13. Christie J, Robinson CM, Singer B, Ray DC: Medullary lavage reduces embolic phenomena and cardiopulmonary changes during cemented hemi-arthroplasty. J Bone Joint Surg Br 77B:456, 1995
14. Byrick RJ, Bell RS, Colin KJ, Waddell J: High-volume, high pressure pulsatile lavage during cemented arthroplasty. J Bone Joint Surg Am 71A:1331, 1989
15. Sherman RMP, Byrick RJ, Kay JC, et al: The role of lavage in preventing hemodynamic and blood-gas changes during cemented arthroplasty. J Bone Joint Surg Am 65:500, 1983