

## Poor results with the Shuttle Stop

### Resorbable versus nonresorbable intramedullar cement restrictor in a prospective and randomized study with a 2-year follow-up

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**ABSTRACT** – In a randomized prospective study we compared 2 femoral plugs as regards probable migration of the restrictor, cement leakage and possible early aseptic loosening.

In group I, the femoral canal was plugged with a resorbable Shuttle Stop (HC Implants, BV, Leiden, The Netherlands). In group II, a nonresorbable restrictor of polyethylene was used (De Puy, UK). Both groups were identical as regards age, gender and primary disease. All patients were followed for at least 2 years after surgery. Postoperatively, we found more failures with displacement of the femoral plug and cement leakage in group I than in group II. At the 2-year follow-up, we found no differences in stem loosening or grade of radiolucent lines in the cement-bone interface. We can not recommend the Shuttle Stop for femoral canal sealing in total hip replacement.

Modern cementing technique is based on pressurization to improve cement-bone interface. Unless the femoral canal is sufficiently sealed with some type of restrictor, this basic requirement will not be fulfilled and prosthetic loosening may be expected at an early stage (Oh et al. 1978, Jeffery 1997).

Several materials and designs have been used for femoral canal closure (Jeffery 1997, Harris and McGann 1986, Bulstra et al. 1996). Most of these are nonresorbable and difficulties in removing the restrictor in revision cases have been reported (Northmore-Ball et al. 1991). This problem may be solved by introducing biodegradable plugs.

Recently, a biodegradable restrictor has become available that has an effective sealing capacity

(Shuttle Stop). In this randomized prospective study, we compared the restrictor to a nonresorbable polyethylene restrictor, as regards probable migration of the restrictor, cement leakage and early aseptic loosening.

#### Patients and methods

During the period November 1995 to June 1996, 70 patients admitted for a primary cemented THR were randomized to 2 comparable groups with 35 patients in each. The randomization was done just before surgery with sealed envelopes. The trial was approved by the local ethics committee and written consent was obtained from all patients after oral and written information. Equal numbers of operations were done via a posterior approach by the senior staff, which included registrars in training, and 7 surgeons who were very experienced in hip surgery.

1 patient was excluded from the study because of other complications peroperatively; therefore 29 women and 40 men were included. Their median age was 67 (39–85) years. The distributions of age and gender were similar in the groups. 54 cases had primary arthrosis, 11 sequelae from femoral neck fractures and 3 rheumatoid arthritis, but there were no real differences between the groups (Table).

In group I, the femoral canal was plugged with the Shuttle Stop (HC Implants BV, Leiden, The Netherlands), a fully biodegradable cement restrictor made of a compound of polyethylene oxide terephthalate and polybutylene terephthalate. In group II, the femoral canal was closed with a non-



Figure 1. The polyethylene plug (De Puy) is shown on the left, and the Shuttle Stop on the right.

degradable polyethylene restrictor (De Puy, UK) (Figure). The biodegradable restrictor needs time to absorb fluid and swell, which should improve its fixation (Bulstra et al. 1996). In group I, the femur was therefore prepared before the acetabulum and the restrictor in place at least 15 min before cementing. The biodegradable restrictors come in 4 sizes and the nondegradable in 3. They were inserted, in accord with the instructions, at least 1.5 cm distal to the tip of the prosthesis. Their size was determined with a special instrument which measured the diameter of the femoral canal in two directions. In case of doubt, the larger restrictor was chosen.

After the reaming of the femur, fat and bone fragments were removed from it with pulsatile high pressure lavage before introducing the cement gun containing vacuum-mixed Palacos high-viscosity cement. Pressurization was done digitally after complete filling of the femoral canal and insertion of a titanium rough-surfaced Bimetric stem. After surgery, all patients were allowed full weight bearing. Radiographs were taken after 3 months and at least 2 years postoperatively.

We tried to use the same magnification, but postoperative measurements were based on the magnification factor calculated from the 28 mm caput size. These radiographs were evaluated according to probable migration or tilting of the plug and cement leakage and those at the latest follow-up were evaluated for signs of loosening using Gruen et al.'s method (1979) (Table).

The data were analyzed with the chi-square test with *p*-values of 0.05 considered as significant.

## Results

All patients were assessed 3 months after surgery. In group I, we found 8 distortions or displacements of the plug and 13 cases of cement leakage on the radiographs. 3 of the displaced plugs also showed cement leakage. In group II, no distortions or displacements were seen, but 3 patients had cement leakage ( $p < 0.01$ ) (Table).

During the follow-up, 10 patients died of causes unrelated to the THR, 2 were too sick to undergo a radiographic evaluation and in 1, the hip later disarticulated because of severe gangrenae. 2 years after surgery, 56 patients could be evaluated, 30 from group I and 25 from group II.

In group I, definite failures defined as stem loosening and revision THR, occurred in 2 cases and 1 had probable loosening, with a fracture of the cement just above the stem tip. 1 of these had cement leakage, but none had plug failure. All 3 had clearly visible radiolucent zones on the postoperative radiographs which gradually increased during the observation period (Table). In 2 cases, minor radiolucency was seen initially but it did not increase during the follow-up.

In group II, 1 stem loosened in a patient with marked radiolucent zones postoperatively. No statistically significant difference was found between the groups as regards the rate of loosening or grade of radiolucent lines at the cement-bone interface.

In group I, 1 patient had displacement and tilting of the resorbable plug which left a gap of 2 cm below the stem tip without any cement on the first postoperative radiographs. At the 2-year follow-up, the gap was unchanged but osteolysis had gradually become severer (Figures 2 and 3). At present, the patient refuses to undergo excocleation of the cyst and bone transplantation because he has no pain and there are no signs of loosening.

## Discussion

An important issue in modern cementing technique in THR is cement pressurization (Harris and McGann 1986, Schmalzried and Harris 1993, Oishi et al. 1994), which requires firm sealing of the distal femoral canal. Several devices have been used to deal with this problem.

Patient data in groups 1 and 2. The zones of Gruen et al. (1979) are used to define osteolysis. The findings concerning stem loosening are based on the examination 2 years after surgery.

Group 1 – Biodegradable cement restrictor						Group 2 – Non-degradable cement restrictor					
Case	Etiology	Osteolysis (Gruen zone)	Leakage	Failure	Stem loosening	Case	Etiology	Osteolysis (Gruen zone)	Leakage	Failure	Stem loos.
1	A	1,2,4,5,6,7	-	-	+	35	A	1	-	-	-
2	A		-	-	-	36	A	1,3,4	-	-	+
3	RA		+	-	-	37	A		-	-	-
4	A		+	-	-	38	A		-	-	-
5	SFNF		-	-	-	39	Perthes		-	-	-
6	A		-	+	-	40	A		-	-	-
7	A		+	-	-	41	SFNF		-	-	-
8	SFNF		-	-	-	42	A		-	-	-
9	A		+	+	-	43	SFNF		-	-	-
10	SFNF		-	-	-	44	SFNF		-	-	-
11	A		-	+	-	45	A		-	-	-
12	A		-	+	-	46	A		-	-	-
13	A	1,2	+	-	-	47	A	1	-	-	-
14	SFNF	1,7	-	-	+	48	A		-	-	-
15	A		-	-	-	49	SFNF		+	-	-
16	A		-	-	-	50	A		-	-	-
17	A	2,3,5,6	+	-	+	51	A		-	-	-
18	A		-	-	-	52	A		-	-	-
19	A		-	-	-	53	A		-	-	-
20	A		+	-	-	54	A		-	-	-
21	A		-	-	-	55	A		-	-	-
22	A		+	-	-	56	A		-	-	-
23	A		-	-	-	57	A		-	-	-
24	RA		-	-	-	58	SFNF		-	-	-
25	A		-	+	-	59	A		-	-	-
26	A		+	+	-	60	A		-	-	-
27	A	3,5	+	-	-	61	A		-	-	-
28	A		-	-	-	62	A		-	-	-
29	A		+	+	-	63	A		-	-	-
30	A		-	+	-	64	SFNF		+	-	-
31	A		-	-	-	65	A		-	-	-
32	SFNF		-	-	-	66	A		+	-	-
33	A		+	-	-	67	A		-	-	-
34	A		+	-	-	68	RA		-	-	-
						69	A		-	-	-

A = primary arthrosis, RA = rheumatoid arthritis, SFNF = sequelae from femoral neck fracture

Bulstra et al. (1996) introduced a conically-shaped biodegradable copolymer plug made of Polyactive, which is flexible and may facilitate closure even in patients with an irregular femoral canal. In revision cases, we agree with Bulstra et al. (1996) that all cement and foreign material, such as a plastic plug must be removed because low-grade infections may gradually induce loosening. This procedure is facilitated by a degradable plug. A fenestration in the femoral bone, which weakens the bone can then be avoided. To avert distal disappearance of any foreign material in the shaft during revision, we use the procedure

described by Northmore-Ball et al. (1991) with a K-wire through the femoral bone just below the cement-plug sealing. This procedure can reduce the need for fenestration.

Bulstra et al. (1996) evaluated the Shuttle Stop in 21 patients and had 1 case of severe migration and leakage and 1 with minor leakage. This was ascribed to a mismatch between the size of the plug and femoral canal. It does not accord with our findings—i.e., 8/30 plug migrations of 1/2 cm or more and 13/30 cement leakages. This high failure rate occurred despite careful explanation about the proper use of the plug by the company and



Figure 2. 2 weeks postoperatively.



Figure 3. 2 years after surgery, the osteolysis has increased around the stem tip.

awareness of the mismatch problems and time for swelling to ensure a correct closure. It could be due to the fact that we intended to perform the study in an orthopedic department with many operations carried out by several surgeons at all levels of experience and not by a single surgeon with a special interest in sealing the femoral canal. In an experimental study with several synthetic plugs, cement leakage and plug migration were evaluated (Johnson et al. 1995). The plug from De Puy, which we used (group II), had the best stability, as in our patients with no migration and only 3 cases of cement passing beyond the plug.

Our series is small since the main aim was to evaluate the sealing capacity of the 2 plugs. Cement leakage reduces the pressure, which can be transferred to interdigitating the cement into bone and might be expected to weaken the fixation of a prosthesis with early aseptic loosening as a result (Lindberg and Carlsson 1983, Kristiansen and Jensen 1985, Dozier et al. 2000). 3 cases of

aseptic loosening and revision THR together with 1 case of cement fracture were observed during a short period of observation, 3 of them in group I. This loosening rate is higher than expected.

In 8 cases, the cement-bone interface was insufficient, 5 of these were among the biodegradable plug. The findings were not statistically significant and may have been due to insufficient pressurization of the cement, which was performed digitally during the study. We believe that modern pressurization techniques can reduce this phenomenon. Only 4 of these patients had no symptoms and we detected no progression of the osteolytic zone. We believe that the cyst seen at the stem tip in 1 case was caused by marked migration of the plug and not by degradation products because some cement is placed below this process. This has been shown in an experimental study (van Blitterswijk et al. 1992, Beumer et al. 1994).

We could not reproduce the positive results reported by Bulstra et al. (1996). Although our

series is small, we are concerned about the radiographic findings, which may lead to a higher rate of loosening than average. Therefore we can not recommend the Shuttle Stop for femoral canal sealing in THR.

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