FEMORAL CANAL OCCLUSION IN TOTAL HIP REPLACEMENT USING A RESORBABLE AND FLEXIBLE CEMENT RESTRICTOR


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We have investigated the use of a conically-shaped cement plug made of Polyactive (PA), a biodegradable copolymer. The flexibility and hydrogel properties were thought to facilitate occlusion of the femoral canal even when it was oval or irregular in shape. The function of the plug was first compared with that of the Thackray polyethylene model in 16 artificial plastic femora.

The maximum intramedullary pressure achieved during cementing was ten times higher with the biodegradable model. Migration or leakage of cement did not occur when the diameter of the femoral canal was equal to or smaller than the diameter of the plug. We also showed that the biodegradable properties of this implant were such that it did not require removal during revision.

The new plug was tested in a pilot clinical trial. At two years only two out of 21 patients had evidence of migration or leakage of cement, probably due to a mismatch in the size of plug and femoral canal. There were no local changes in the femur.

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Adequate fixation of cemented total hip prostheses in the medullary canal requires pressurised cementing which implies effective sealing of the distal femoral canal (Amstutz et al 1976; Osborn and Newesely 1980; Harris, McCarthy and O’Neill 1982; Oh et al 1987). Improved distribution of the cement in the medullary canal ensures better interdigitation with cancellous bone, thereby increasing the strength of the cement-bone and the cement-prosthesis interfaces. Effective removal of the bone marrow by conical reamers has been shown to reduce the loosening rate of hip prostheses (Harris et al 1982) and the vascular problems encountered during cementing (Wenda et al 1993; Wheelwright, Byrick and Wigglesworth 1993). We have shown that the Thackray polyethylene plug (Fig. 1) has a failure rate of at least 25%, and this

Fig. 1
The Thackray polyethylene cement plug.

has been confirmed by others (Bakker et al 1988; Northmore-Ball, Narang and Vergroesen 1991; Thomsen et al 1992). Cement leakage and migration of the plug were observed frequently and osteolysis of the bone around the plug was seen in 5% of firmly fixed prostheses by five
years. Parts of the polyethylene plug have been seen to break off during insertion and although vigorous flushing was immediately performed detached pieces have been observed in the cement on radiographs taken after the operation (Fig. 2). At revision the plug could not be retrieved through the femoral canal in 15% of patients, thus requiring opening of the distal femur, with the consequent hazard of potential fracture through the window.

We have previously analysed the reasons for cement leakage or plug migration in a series of 100 patients after primary hip replacement. We measured the anteroposterior (AP) and lateromedial (LM) diameters of the femoral canal on radiographs. The size of the femoral implant was used to assess the enlargement of the radiograph. Leakage or migration occurred in 20% of the patients in whom the AP diameter of the femoral canal proved to be considerably larger than the LM diameter (LM/AP < 0.75); we believe that the reason lay in the mismatch of the round plug in an oval femoral canal.

A family of bioerodible copolymers containing polyethyleneoxide terephthalate (PEO) and polybutylene terephthalate (PBT), Polyactive (PA), has recently been introduced (Bakker et al 1988, 1990a; Grote et al 1991; Sakkers, de Wijn and van Blitterswijk 1992; Van Blitterswijk et al 1993; Bulstra et al 1994; van Loon 1994; Radder, Leenders and van Blitterswijk 1994; Radder 1995) which is biocompatible with soft (Grote et al 1991; Van Blitterswijk et al 1993; Beumer, van Blitterswijk and Ponec 1994a,b) and hard tissue (Bakker et al 1988, 1990; Bulstra et al 1994; Radder et al 1994; Radder 1995). We selected a compound containing 70% of PEO and 30% of PBT (PA 70/30) because of its flexibility (Sakkers et al 1992; Beumer et al 1994a,b), biodegradability (Bakker et al 1990; van Blitterswijk et al 1993; Bulstra et al 1994; van Loon 1994) and hydrophilic properties (Sakkers et al 1992; Beumer et al 1994a,b; Radder et al 1994) which allow the plug to swell to the elliptical form of the femoral canal. We have now studied the properties of a restrictor made from this material in vitro and in a trial on 21 patients.

**PATIENTS AND METHODS**

The cement plug was made from Polyactive (PA), a compound of polyethyleneoxide terephthalate and polybutylene terephthalate (PEO/PBT) with a PEO/PBT ratio of 70/30 (HC Implants BV, Leiden, The Netherlands). There were three different sizes (10, 12, 15 mm), based on the dimensions of the femoral canal found in a previous study, and the plug has a conical shape with three indentations.
(Fig. 3). The diameter, the thickness of the restrictor and the size of the indentations were chosen so that the flexibility and swelling of the plug inside the femoral canal would give a tight fit in a wide range of canal diameters.

In clinical use, the plug must be placed at least 1.5 cm distal to the tip of the prosthesis. We use a conical reamer to remove medullary bone from the femoral canal, followed by calcar broaches. The conical shape and the length of the wall of the plug ensured primary contact with the reamed inner wall of the femur.

**Experimental study.** We assessed the swelling properties of the PA plugs by soaking them in Ringer lactate solution for 5 to 30 minutes. The dimension of the bottom of the plugs was recorded for each size at five-minute intervals. We used 16 trial plastic femora (Sawbones Eurge, Malmö, Sweden) eight of which were reamed to a diameter of 13 mm and eight to 15 mm. Polyethylene plugs (Thackray, DePuy, Leeds, UK) comparable to other conically-shaped, non-bioresorbable plugs served as a control group (Fig. 1).

All plugs were placed at a depth of 10 cm from the medial calcar. The femoral canal was then irrigated with Ringer’s solution for ten minutes. An intracompartamental pressure system (Stryker, Kalamazoo, Michigan) was placed inside the femoral canal through a bore hole which was securely locked with glue to allow accurate measurement of the intramedullary pressure. A cement gauge (Howmedica, New York) was fixed inside the proximal femur using high-viscosity Palacos cement with gentamicin (Merk, Darmstadt, Germany) (Fig. 4). Cement was applied with a cement gun and the intramedullary pressure was recorded during the introduction and hardening. After setting, the femora were sectioned sagittally and the position of the cement plugs assessed. Leakage of cement or fragmentation of the plug were recorded.

**Degradation study.** Injection-moulded samples of the Polyactive plug approximately 1 mm thick with a surface area of 60 cm² were placed in 20 ml of physiological saline and kept at 37°C in the dark for up to 52 weeks. Reduction of the original mass was noted after 2, 4, 6, 8, 10 and 12 months and the molecular weight determined using gel-permeation chromatography.

**Clinical study.** After approval of the ethical committee we used the PA plug in 21 patients to examine the handling characteristics, safety, leakage and migration of the cement. All patients gave their informed consent. Radiographs were studied to assess local changes in the bone around the plug. Before and during the operation we measured the AP and LM diameters of the femoral canal to select the right size of plug. At operation the femoral canal was reamed using conical reamers, followed by calcar broaches. Using the final size of the femoral implant, we defined the depth of placement of the plug and placed it at least 1.5 cm deeper than the projected tip of the femoral stem. The medullary canal was irrigated.
The increase in size of 12, 15 and 20 mm Polyactive cement restrictors soaked in Ringer lactate solution for 0 to 45 minutes.

Table II. Details of 21 patients in whom the PA plug was inserted (LM = lateromedial diameter (mm); AP, anteroposterior diameter (mm))

<table>
<thead>
<tr>
<th>Case</th>
<th>LM</th>
<th>AP</th>
<th>AP-LM</th>
<th>LM/AP</th>
<th>Leakage*</th>
<th>Migration*</th>
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* + = <1 cm; ++ = >2 cm on radiograph

Aqueous hydrolysis of the cement plug in vitro showing the percentage of the molecular weight and that of the original mass as a function of the immersion time (log(months + 1)).
with Ringer lactate solution. The acetabular cup was then prepared and placed. After trial reduction the femoral stem was cemented into the canal.

Patients were reviewed at 6 weeks and at 3, 6, 12 and 24 months after operation.

RESULTS

Experimental study. We recorded the size of the three different PA plugs every five minutes while soaking in the Ringer lactate solution. The bottom diameter of the plug increased by 5% after five minutes and by 10% after ten minutes reaching a plateau after 30 minutes with an increase in the original bottom diameter of 20% (Fig. 5).

Table I gives the results of measurement of the intramedullary pressure and migration and leakage in trial femora compared with the Polyactive cement plug.

With the Thackray polyethylene cement plug (8 femora) the maximum intramedullary pressure recorded during cementing was 2 kPa. All plugs showed considerable migration and one plug placed in a 13 mm reamed femoral canal had fragmented during insertion.

All the PA plugs withstood pressures of at least 9.3 kPa, but when the 10 mm plug had been placed in a large femoral canal of 15 mm in diameter migration of between 1 and 3 cm occurred. If plugs of a larger size were inserted, such as a 15 mm restrictor in a 13 mm or a 15 mm reamed femoral canal, there was no significant migration of the plug. Intramedullary pressures of up to 21.3 kPa were recorded with the larger plugs due to their tighter fit. Fragmentation was not seen with the biodegradable restrictor.

Degradation study. All samples showed a marked decrease in molecular weight to about 25% after four months, indicating breakdown of the polymer chain. There was a significant loss of mass to 80% of the original by six months (Fig. 6).

Clinical study. At operation the PA plug proved easy to insert. The mean time between placement of the plug and cementing was 30 minutes. Postoperative radiographs showed that in one patient the PA plug had migrated 2 cm distally during the procedure. In this case the ratio of the LM and AP diameters was <0.75. Leakage of cement was seen in one patient in whom the diameter of the canal was more than 2 cm in the preoperative films (Table II).

At a mean follow-up of one year no local or systemic side-effects of the plug were observed. The Harris hip score was similar to that of a random control group. No local osteolysis or other changes were seen in the femora (Fig. 7).
DISCUSSION

There are many factors which determine the long-term survival of a cemented hip prosthesis (Johnson et al 1995). The use of a plug allows a higher pressure when cementing, better canal filling and a stronger cement-prosthesis and cement-bone interface, significantly reducing the rate of loosening (Harris et al 1982). We have found a total complication rate of 25% using the Thackray polyethylene cement restrictor due to leakage, migration or fragmentation of the plug. Other studies have shown that many types of synthetic plug were deficient in achieving adequate and consistent occlusion of the femoral canal (Johnson et al 1995). Leakage of cement and migration of the plug may cause a reduction in pressurisation, thereby reducing the strength of fixation of the prosthesis (Lindberg and Carlsson 1983; Kristiansen and Jensen 1985) and an enhanced pressure in the distal bone-marrow which must increase the risk of embolus formation. In many of our patients fragmentation of the polyethylene plug had occurred, leaving fragments behind within the cement.

A plastic model was chosen for the experimental study to allow a more uniform spectrum of diameters of the femoral canal than would have been possible with cadaver specimens. These tests in vitro showed that when a Thackray plug was used only a low pressure was obtained due to leakage of cement and migration of the plug. Similar findings have been reported for other experiments in vitro (Mallory 1981; Lindberg and Carlsson 1983; Johnson et al 1995).

At revision operations we always remove all remaining cement including the plug because of the possibility of a low-grade infection which may lead to loosening. In many cases it has been very difficult to remove the plug through the medullary canal and this has necessitated a distal cortical hole which severely reduces the strength of the femur (Northmore-Ball et al 1991). A degradable plug avoids this problem.

The newly designed plug proved easy to insert and its flexibility ensured tight closure of the distal femoral canal. The hydrogel properties of the copolymer Polyactive allows considerable swelling of the biomaterial in the presence of fluid giving a significant but safe swelling pressure (Sakkerset al 1992) and ensuring intimate contact between cement and bone (Radder et al 1994). In the experimental study the new plug was shown to fit tightly inside the femoral canal and allow a high cementing pressure without leakage of cement, plug fracture or migration of the plug (Mallory 1981; Paul and Hodgkinson 1992).

The cement plug degraded in vitro as has previously been shown in vivo (Beumer et al 1994a,b; Radder et al 1994; Radder 1995). A decrease in molecular weight leads to a decrease in mass and then disappearance of the degraded products, as for other polymers.

The elliptical shape of the femoral canal probably accounts for the failure of the Thackray and other plugs. The ability of the PA plug to swell and adjust its shape allows proper occlusion of the canal.

The PA plug does not induce the formation of bone within its substance and no formation of a pedestal was seen. In our 21 patients there was no evidence of bony change around the plug on radiographs.

The biodegradable plug is easy to insert and ensures tight cement packing. At operation, sizing of the plug is by measuring the AP and LM diameters of the femoral canal on the radiographs. We are currently performing a prospective randomised study using the Thackray restrictor and the PA plug.

We wish to thank Miss A. Meertens for her valuable help with the feasibility study.

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REFERENCES


