Effectiveness of the ROBODOC system in preventing intraoperative pulmonary embolism

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ABSTRACT **Intraoperative pulmonary embolism occurs not only during cemented but also during cementless total hip arthroplasty (THA). We determined whether the ROBODOC femoral milling system can reduce intraoperative pulmonary embolism, by using of transesophageal echocardiography and hemodynamic monitoring.**

We did a prospective clinical trial with 71 patients (75 hips) who were divided into 2 groups: group 1, 46 patients (50 hips) who underwent cementless THA with preparation of the femoral canal using ROBODOC; group 2, 25 patients (25 hips) who underwent conventional cementless THA surgery in whom separate measurements were made during preparation of the femur, insertion of the stem and relocation of the hip. The incidence of severe embolic events was lower in group 1 than in group 2.

Our findings suggest that the ROBODOC femoral milling system may reduce the risk of clinically significant pulmonary embolism during cementless THA

Hypotension, hypoxemia, cardiopulmonary dysfunction and death are well-known, but rare complications of cemented total hip arthroplasty (THA) (Burgess 1970, Jones 1975, Kallos 1975). These complications can be caused by an increase in intramedullary pressure in the femur as a result of cement infusion or stem insertion. Introduction of fat and bone marrow cells into the venous system can activate the blood coagulation system. Formation of thrombi and migration of fat and bone marrow cells to the lungs produce pulmonary embolism (Saldeen 1969, Modig et al. 1975, Sharrock et al. 1995). Some authors suggest that decompression in the medullary space of the femur can have a prophylactic effect against pulmonary embolism (Herndon et al. 1974, Kallos et al. 1974, Tronzo et al. 1974, Wenda et al. 1993, Pitto et al. 1999). There have also been reports of death from intraoperative pulmonary embolism in cases of cementless THA (Arroyo et al. 1994). The risk of pulmonary embolism is therefore not limited to cemented THA. An increase in intrafemoral pressure can be caused not only by the application of cement and insertion of the femoral stem, but also during preparation of the femoral canal (Modig et al. 1974, Wenda et al. 1990). Rasping the intramedullary canal of the femur increases intrafemoral pressure, by causing intravasation of fat and bone marrow. We hypothesized that robotic milling (Bargar et al. 1998), which excavates the femoral canal precisely, should reduce the risk of pulmonary embolism during cementless THA.

We determined whether the incidence of peroperative pulmonary embolism during cementless THA differed between the ROBODOC femoral milling system, and manual surgery.

Patients and methods

Between 2000 and 2002, we performed a prospective study of 71 patients (75 hips) with osteoarthrosis of the hip who underwent cementless THA, with (September 2000–August 2001) or without (September 2001–February 2002) the

Table 1. Patient data

	Group 1 ROBODOC system	Group 2 Manual surgery
Number of hips	50	25
Gender (male/female)	10/40	5/20
Age [a]	58 (9.8)	60 (9.9)
Weight (kg) [a]	58 (12)	57 (11)
Height (cm) [a]	156 (9.6)	154 (9.4)
Physical status [b] class 1/2/3/4	33/17/0/0	14/6/0/0

[a] Mean (SD)
[b] Number of patients with physical status was assessed according to the system of the American Society of Anesthesiologists

ROBODOC femoral milling system. Group 1 (ROBODOC) consisted of 46 patients (50 hips), and group 2 (manual) of 25 patients (25 hips). The preoperative physical status was assessed, using the criteria of the American Society of Anesthesiologists (1963). Gender distribution, age, weight, height and preoperative physical status were similar in both groups (Table 1).

Each patient was placed in the lateral decubitus position, and the hip joint was exposed through the posterolateral approach. In all cases, a press-fit acetabular component was inserted without cement. In group 2, the femur was prepared with standard broaches and washed with pressurized lavage. We then inserted the largest tapered stem (VerSys Fiber Metal Taper, Zimmer, Warsaw, IN) that provided a stable press-fit. In group 1, the femur was prepared using the milling tools of the ROBODOC system, which prepares the femoral canal by milling and lavaging the intramedullary space simultaneously. This was followed by insertion of a tapered stem (VerSys Fiber Metal Taper, Zimmer, Warsaw, IN), selected preoperatively. No pharmacological prophylaxis was given. However, in both groups, during surgery, a bandage was tightly wrapped around the lower extremity of the operated side, as prophylaxis against thromboembolism.

Surgery was performed under combined general and epidural anesthesia. Endotracheal intubation, and mechanical ventilation were used for airway management. In all cases, the inspired O_2 concentration remained at a constant level (33%). After induction of anesthesia, a 5-MHz echocardiographic probe (Hewlett-Packard; Andover, MA) was inserted into the esophagus, and the heart was visualized. The frequency and grade of embolic events at each stage of the operation were assessed. Intraoperative echocardiographic monitoring was recorded on video. The video images were analyzed by an anesthesiologist unaware of the surgical method used. The echocardiographic findings were divided into 4 grades, according to Pitto et al. (1999): grade 0, no emboli; grade 1, a few fine emboli; grade 2, a cascade of small emboli or embolic masses with a diameter < 5 mm; grade 3, small emboli mixed with embolic masses having a diameter ≥ 5 mm (Figure).

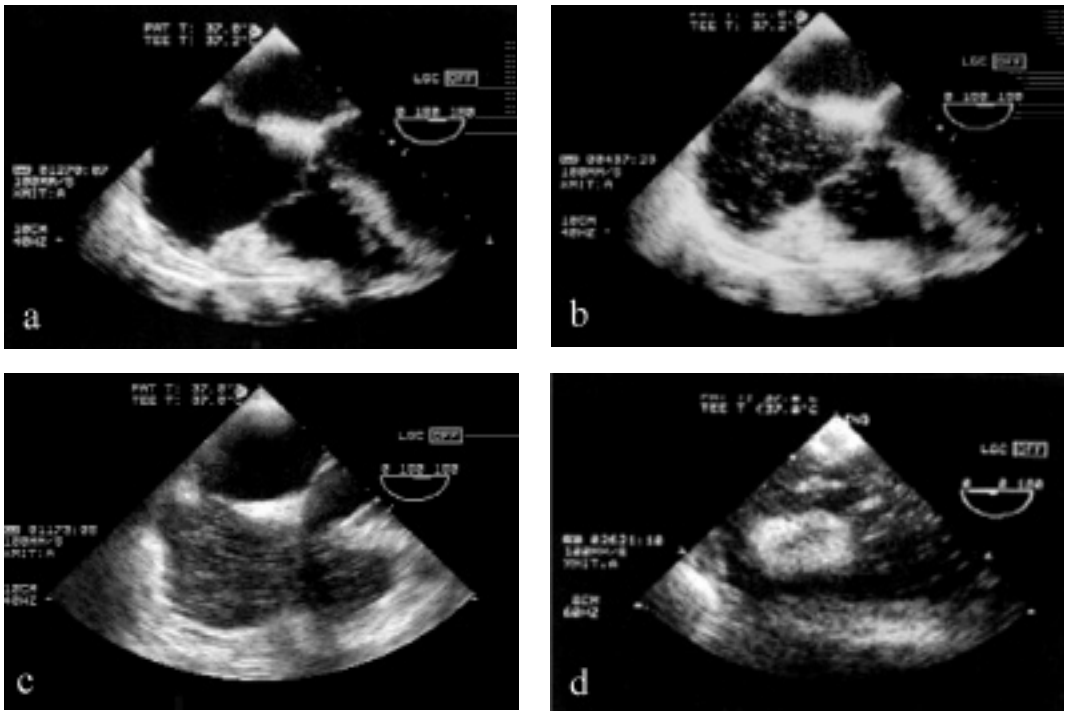
The echocardiographic findings, blood gas (PaO_2), arterial oxygen saturation (Sat), systolic blood pressure (SBP) and heart rate (HR) were recorded at the time of the surgical incision, femoral preparation, stem insertion, hip relocation and at the end of the operation. All data were expressed as a percentage of the value at the time of the skin incision.

The statistical analysis was done, using the Mann-Whitney U-test; a p-value less than 0.05 was considered to indicate statistical significance.

Results

In both groups, no embolic events were detected by transesophageal echocardiography during incision of the hip, dislocation of the joint or osteotomy of the femoral neck, or at the end of the operation.

In group 2, 9/25 hips had a grade 2 or greater embolic event during preparation of the femur, but no patient in group 1 had a similar event. The frequency and severity of embolic events during preparation of the femur between the 2 groups differed significantly ($p < 0.001$; Table 2). During insertion of the stem, the incidence of events of grade 2 or greater was lower in group 1 (0/50) than in group 2 (5/25) ($p < 0.001$). During hip relocation, 4 hips in group 1 and 11/25 hips in group 2 had a grade 2 embolic event, and 1 hip in group 2 had a grade 3 embolic event. Overall the incidence of events of grade 2 or greater during hip relocation was lower with ROBODOC (4/50) than with manual surgery (12/25).



Right atrium during echocardiography.
a) Grade 0: No emboli.
b) Grade 1: A few small emboli.
c) Grade 2: A cascade of small emboli or embolic masses less than 5 mm in diameter.
d) Grade 3: Large embolic masses more than 5 mm in diameter.

Table 2. The frequency and grade of embolic events during various stages of the operation. No. (%) of hips

	Group 1 – ROBODOC			Group 2 – Manual surgery			P-value [a]
	Grade 1	Grade 2	Grade 3	Grade 1	Grade 2	Grade 3	
Preparation of the femur	4 (8)			16 (64)	8 (32)	1 (4)	<0.001
Implantation of stem	18 (36)			17 (68)	4 (16)	1 (4)	<0.001
Relocation of hip joint	29 (58)	4(8)		13 (52)	11(44)	1 (4)	<0.001

[a] Mann-Whitney U-test

To evaluate changes at each stage, the data from the 2 groups were combined and then divided into 2 groups based on the grade of embolic events: grade 1 or lower, and grade 2 or higher on echocardiography. At all stages, in grade 2 or the higher group, PaO_2 and Sat values were lower, and SBP values tended to be lower than grade 1 or the lower group, but HR values showed no definite tendency (Table 3).

Discussion

Evaluation of embolic events using transesophageal echocardiography permits detection of passage of fat or bone marrow through the heart, which has been reported in several cases of orthopedic surgery (Heinrich et al. 1988, Wenda et al. 1993, Christie et al. 1994, 1995, Woo et al. 1995, Pitto et al. 1998, Pitto et al. 1999, 2000). However, it is difficult to define clearly the essential nature

Table 3. Hemodynamic changes. Values are mean (SD). All data are expressed as a percentage of the value at the time of the skin incision.

	PaO_2			SBP			Sat			HR		
Grade	0 or 1	2 or 3	P [a]	0 or 1	2 or 3	P [a]	0 or 1	2 or 3	P [a]	0 or 1	2 or 3	P [a]
Preparation of the femur	106 (12)	88 (9.1)	0.001	98 (12)	91 (11)	0.3	100 (0.9)	99 (0.4)	0.0004	101 (10)	98 (5.1)	0.5
Implantation of stem	101 (12)	87 (8.0)	0.03	97 (12)	91 (5.9)	0.2	100 (0.8)	99 (0.7)	0.007	102 (14)	98 (11)	0.4
Relocation of hip joint	103 (11)	92 (9.0)	0.003	99 (14)	92 (5.6)	0.05	100 (0.8)	100 (0.6)	0.001	105 (16)	102 (8.2)	0.7

[a] Mann-Whitney U-test

of echogenic particles. Pitto et al. (1999) reported that grade 1 events also occurred when the infusion via the central venous catheter was at maximum flow. In our study, we observed grade 1 events when infusion via the peripheral venous catheter was at maximum flow. We also found that grade 2 or greater events were associated with significant reduction in PaO_2 and Sat and a tendency towards a lower SBP, but grade 1 events were not. This suggests that the detection of grade 2 or higher events by echocardiography is a cause of concern. The association between severe embolic events (grade 2 or 3) and changes in hemodynamic and cardiorespiratory indicators in our study accords with the findings of others (Ries et al. 1993, Wenda et al. 1993, Christie et al. 1994, Pitto et al. 1998, 1999). Although events of grade 2 or greater were associated with a significant reduction in PaO_2 and Sat, the change in PaO_2 was greater than that in Sat, because PaO_2 is more sensitive to cardiorespiratory change than Sat (Table 3).

Pitto et al. (1999) used transesophageal echocardiography to study patients with osteoarthrosis of the hip who underwent THA. Among their subjects who underwent cemented THA, they found severe embolic events (grade 2 or higher) in 10% during preparation of the femoral canal, 85% during stem insertion and 75% during reduction. Among those who underwent cementless THA, they found severe embolic events in 15% during femoral preparation and 0% during stem insertion and reduction. However, in our patients operated on with manual technique, severe embolic events occurred in one third during femoral preparation, one fifth during stem insertion, and one half during hip relocation. Pitto et al. (1999) found a very low rate of embolic events in cases of cementless THA, but the stem design they used (CLS; Sultzer Medica) differed from the one used by us. Thus, stem design and/or instruments used in femoral preparation may affect the generation of embolic particles.

Pitto et al. (1999) also found, among patients who underwent cementless THA, grade 1 embolic events in 10% and grade 2 embolic events in 15% during preparation of the femur. They were concerned about this finding despite the low frequency with which these events occurred. Schmidt et al. (2000) also reported embolic events during preparation of the femur, and reported that these events could be reduced by using a cannulated awl and a cannulated rasp. In our study, severe embolic events (grade 2 or higher) were not found in group 1 (ROBODOC) during preparation of the femur.

In group 2, embolic events of grade 2 or higher occurred at higher frequency during hip relocation than during femoral preparation or stem insertion. During femoral bone manipulation, the hip joint was kept in a flexion-adduction-internal rotation position until the stem was inserted. As a result, venous stasis occurred, and this may have interfered with observation of embolic events by echocardiography during preparation of the femur or stem insertion. Embolic events during reduction of the hip may be due to a flow of fat and bone marrow into the stagnated venous system as a result of femoral bone manipulation before reduction of the hip. These embolic particles can cause pulmonary embolism when venous blood flow is resumed due to reduction (Saldeen 1969, Modig et al. 1975, Sharrock et al. 1995). The ROBODOC milling system reduced the amount of fat and bone

marrow introduced into the venous system during femoral preparation, resulting in a low incidence of severe events during stem insertion and hip relocation.

Some authors have reported problems with the ROBODOC system. Nogler et al. (2001a,b) noted postoperative knee pain in the medial femoral condyle after a 2-pin-based ROBODOC hip arthroplasty procedure, and a risk of heat injury during cutting of cement in the ROBODOC revision procedure. In our series, no severe problems were associated with the ROBODOC system. All our patients underwent primary hip arthroplasty via a posterolateral approach, using a 2-pin-based ROBODOC procedure. The distal pin was implanted in the lateral condyle, and only a few patients complained of postoperative knee pain.

None competing interests declared.

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