# Effectiveness of the ROBODOC System during Total Hip Arthroplasty in Preventing Intraoperative Pulmonary Embolism

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**Abstract.** Intraoperative pulmonary embolism can occur not only during cemented total hip arthroplasty (THA) but also during cementless THA. In the present study, we demonstrated the usefulness of the ROBODOC femoral milling system in reducing intraoperative pulmonary embolism, as indicated by results of transesophageal echocardiography and hemodynamic monitoring. A prospective clinical trial was conducted with 58 patients (60 hips) who were randomly divided into 2 groups: group 1, 38 patients (40 hips) who underwent cementless THA with preparation of the femoral canal using ROBODOC; group 2, 20 patients (20 hips) who underwent conventional manual cementless THA surgery. During femoral preparation, severe embolic events were observed at a significantly lower frequency in group 1 (0%) than in group 2 (30%) (p<0.0001). During stem insertion, incidence of severe embolic events was significantly lower in group 1 (0%) than in group 2 (20%) (p<0.0001). Moreover, during hip relocation, incidence of severe embolic events was significantly lower in group 1 (8%) than in group 2 (45%) (p<0.0001). The ROBODOC system decreased the incidence of severe embolic events during femoral preparation, resulting in low incidence of severe events during stem insertion and hip relocation. The present results suggest that the ROBODOC femoral milling system may reduce the risk of pulmonary embolism during cementless THA.

## 1  Introduction

Hypotension, hypoxemia, cardiopulmonary dysfunction and death are well-known complications of cemented total hip arthroplasty (THA) (1-3). These complications can be caused by increased intramedullary pressure of the femur as a result of cement infusion or stem insertion, and by introduction of fat and bone marrow cells into the venous system. These causes can activate the blood coagulation system. Formation of thrombi and migration of fat and bone marrow cells to the lungs produce pulmonary embolism (4-6). There have been reports that decompression in the medullary space

of the femur can have a prophylactic effect against pulmonary embolism (7-11). However, there have even been reports of death from intraoperative pulmonary embolism in cases of cementless THA (12); risk of pulmonary embolism is thus not limited to cemented THA. Increases in intrafemoral pressure can be caused not only by application of cement and insertion of the femoral stem but also by preparation of the femoral canal (13)(14). Rasping the intramedullary canal of the femur can increase intrafemoral pressure, causing intravasation of fat and bone marrow. It is reasonable to hypothesize that the ROBODOC system (15), which precisely excavates the femoral canal automatically using a milling system that does not increase intrafemoral pressure, can reduce the risk of pulmonary embolism during cementless THA.

The purpose of this study was to estimate the effectiveness of the ROBODOC femoral milling system, compared with manual surgery, in preventing pulmonary embolism during cementless THA.

## 2    Materials and Methods

Between September 2000 and February 2002, we performed a prospective study of 58 patients (60 hips) with osteoarthritis of the hip joint who underwent cementless THA with or without the ROBODOC femoral milling system. The patients were randomly divided into 2 groups: group 1, 38 patients (40 hips) who underwent preparation of the femoral canal with ROBODOC; group 2, 20 patients (20 hips) who underwent manual surgery. Patients were matched for gender, age, height, weight at surgery, and preoperative physical status. Preoperative physical status was assessed according to the criteria of the American Society of Anesthesiologists (16).

Each patient was placed in the lateral decubitus position, and the hip joint was exposed through the postero-lateral approach. A press-fit acetabular component was inserted without cement in all cases.

In group 2, the femur was prepared with standard broaches and washed with pressurized lavage, followed by insertion of a tapered stem (VerSys Fiber Metal Taper, Zimmer, Warsaw, IN) in the largest size 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, followed by insertion of a tapered stem (VerSys Fiber Metal Taper, Zimmer, Warsaw, IN) scheduled preoperatively.

In all cases, surgery was performed under general anesthesia with epidural anesthesia. Endotracheal intubation was performed, and mechanical ventilation was used for airway management. In all cases, inspired O2 concentration remained at a constant level (0.33%). After induction of anesthesia, a 5-MHz echocardiographic probe (Hewlett-Packard; Andover, MA) was inserted into the esophagus of each patient, and the heart was visualized. The frequency and grade of embolic events at each stage of the operation were assessed. Echocardiographic findings were classified into 4 grades, according to the classification system of Pitto et al (8), as follows: grade 0, no emboli; grade 1, a few fine emboli; grade 2, a cascade of fine emboli or embolic masses with a diameter <5 mm; grade 3, fine emboli mixed with embolic masses with a diameter $\geq$ 5 mm (Fig. 1 (a)-(d)).
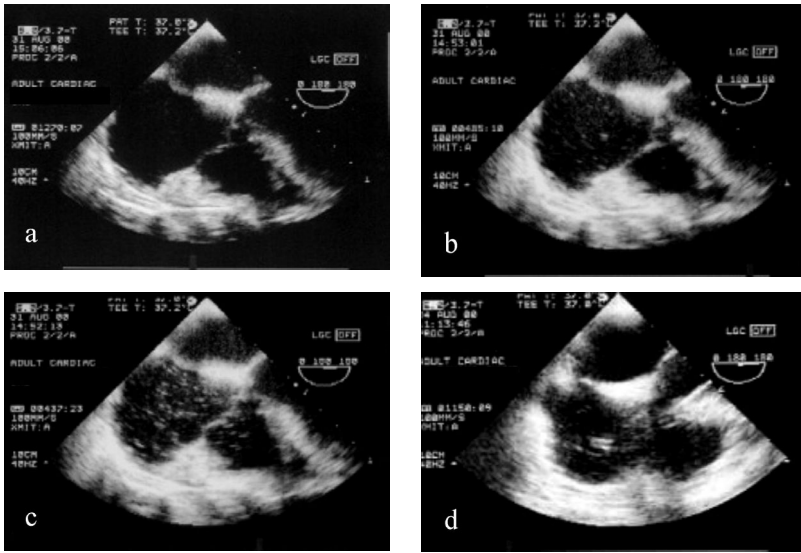
**Fig. 1. (a)-(d)**: Right atrium during echocardiography
(a) Grade 0:No emboli. (b) Grade 1:A few fine emboli. (c) Grade 2:A cascade of fine emboli or embolic masses less than 5mm in diameter. (d) Grade 3:Large embolic masses more than 5mm in diameter.

Echocardiographic findings, blood gas (PaO2), arterial oxygen saturation (Sat), systolic blood pressure (SBP) and heart rate (HR) were recorded at the time of surgical incision, femoral preparation, stem insertion, hip relocation and the end of the operation. All data was expressed as percentage of the value at the time of skin incision. At each stage, the relationship between echocardiographic findings and change in measured data was evaluated, and the effectiveness of the ROBODOC femoral milling system in preventing pulmonary embolism during THA was estimated.

Statistical analysis was performed using the Mann-Whitney U test; and a P value of less than 0.05 was considered to indicate statistical significance.

## 3    Results

Mean age at surgery was higher in group 2 than in group 1, and average height and weight were lower in group 2 than in group 1. No patients in either group had severe systemic disease (class 3 or 4, according to the system of the American Society of Anesthesiologists (16)). There was no significant difference in gender, age, weight, height or preoperative physical status between the groups (Table 1).

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

In group 2, 6 hips (30%) had an embolic event of grade 2 or greater during preparation of the femur, but no patients in group 1 had an embolic event of grade 2 or greater during femoral preparation. The differences in frequency and intensity of

embolic events during preparation of the femur between the 2 groups were significant (p<0.0001) (Table 2). During stem insertion, the incidence of events of grade 2 or greater was significantly lower in group 1 (0%) than in group 2 (20%) (p<0.0001). Moreover, during hip relocation, 3 hips (8%) in group 1 and 8 hips (40%) in group 2 had a grade-2 embolic event, and 1 hip (5%) in group 2 had a grade-3 embolic event. The incidence of events of grade 2 or greater was lower with ROBODOC (8%) than with manual surgery (45%).

**Table 1. Data on the patients**

|  | Group 1[a] | Guroup 2[b] | P-value[d] |
|---|---|---|---|
| Number of hips | 40 | 20 |  |
| Gender (male/female) | 7/33 | 3/17 | 0.808 |
| Age (yrs.) | 57.9±10.5[c] | 61.0±8.0[c] | 0.209 |
| Weight (kg) | 58.3±12.1[c] | 55.5±10.0[c] | 0.515 |
| Height (cm) | 155.9±6.5[c] | 154.0±8.4[c] | 0.380 |
| Physical status (no. of patients)[e] |  |  |  |
| class 1/2/3/4 | 25/15/0/0 | 14/6/0/0 | 0.851 |

[a]Patients had THAs with ROBODOC system.

[b]Patients had THAs with manual surgery.

[c]The values are given as the mean and the standard deviation.

[d]Mann-Whitney U test

[e]Physical status was assesed according to the system of American Society of Anesthesiologists

To evaluate changes in measured data at each stage, the data from the 2 groups were combined and then divided into 2 groups based on grade of embolic events: grade 1 or lower, and grade 2 or higher on echocardiography. At all stages, in the grade 2 or higher group, PaO2 and Sat values were significantly lower (p<0.05), and SBP values tended to be lower than in the grade 1 or lower group, but HR values showed no distinct tendency (Table 3).

**Table 2.The frequency and grade of embolic events in each manipulation of the operation**

|  | Group 1[a] | | | Guroup 2[b] | | | P-value[c] |
|---|---|---|---|---|---|---|---|
|  | Grade 1 | Grade 2 | Grade 3 | Grade 1 | Grade 2 | Grade 3 |  |
| Preparation of the femur |  |  |  |  |  |  |  |
| No.(%) of hips | 4(10) |  |  | 14(70) | 5(25) | 1(5) | p<.0001 |
| Implantation of stem |  |  |  |  |  |  |  |
| No.(%) of hips | 12(30) |  |  | 14(70) | 3(15) | 1(5) | p<.0001 |
| Relocation of hip joint |  |  |  |  |  |  |  |
| No.(%) of hips | 22(55) | 3(8) |  | 11(55) | 8(40) | 1(5) | p<.0001 |

[a]Patients had THAs with ROBODOC system.

[b]Patients had THAs with manual surgery.

[c]Mann-Whitney U test

# 4    Discussion

Intraoperative sudden death is the severest complication of THA. For cemented THA, intraoperative mortality reportedly ranges from 0.02 to 0.5%, and frequency of cardiac arrest reportedly ranges from 0.6 to 10% (17-20). The principal cause of these complications in cemented THA appears to be pulmonary embolism caused by femoral bone manipulation using cement, and prophylactic methods such as decompression of the femoral canal with venting holes (7-9, 10,11) or jet lavage (21) have also been reported. Death from intraoperative pulmonary embolism has even been reported in cases of cementless THA (12), and it is unclear what prophylactic methods can best prevent intraoperative pulmonary embolism during cementless THA.

**Table 3.Hemodynamic change**

|  |  | Preparation of the femur | Implantation of stem | Relocation of hip joint |
|---|---|---|---|---|
| **PaO2** | Grade 0 or 1 | 106.1±11.9 | 101.4±12.3 | 103.3±11.4 |
|  | Grade 2 or 3 | 87.5±9.1 | 87.1±8.0 | 92.0±9.0 |
|  | P-value[a] | 0.0011 | 0.026 | 0.003 |
| **SBP** | Grade 0 or 1 | 98.2±11.6 | 97.1±11.8 | 99.2±14.0 |
|  | Grade 2 or 3 | 90.7±11.7 | 90.6±5.9 | 91.9±5.6 |
|  | P-value[a] | 0.273 | 0.211 | 0.046 |
| **Sat** | Grade 0 or 1 | 100.4±0.9 | 100.2±0.8 | 100.4±0.8 |
|  | Grade 2 or 3 | 99.1±0.4 | 99.0±0.7 | 99.6±0.6 |
|  | P-value[a] | 0.0004 | 0.0072 | 0.0013 |
| **HR** | Grade 0 or 1 | 100.9±10.2 | 102.4±13.8 | 104.7±16.4 |
|  | Grade 2 or 3 | 98.3±5.1 | 98.0±11.2 | 102.2±8.2 |
|  | P-value[a] | 0.488 | 0.442 | 0.747 |

The values are given as the mean and the standard deviation. Each data was expressed in percentage with the value at skin incision as reference.
[a]Mann-Whitney U test

Evaluation of embolic events using transesophageal echocardiography allows detection of passage of fat or bone marrow through the heart, which has been reported in a number of cases of orthopedic surgery (8,10,22-27). However, it is difficult to directly and clearly define the essential nature of echogenic particles. Pitto et al. (8) reported that grade-1 events also occurred when infusion of the central venous catheter was at maximum flow, and, in the present study, grade-1 events were observed when infusion of the peripheral venous catheter was at maximum flow. Also in the present study, events of grade 2 or greater were associated with a significant decrease in PaO2 and Sat and a tendency toward lower SBP, whereas grade-1 events were not associated with conspicuous differences in these values. This suggests that detection of events of grade 2 or higher by echocardiography is cause for concern. The association between severe embolic events (grade 2 or 3) and changes in hemodynamic and cardiorespiratory indicators observed in the present study is consistent with the findings of previous studies (8, 10, 23, 27,28).

Pitto et al. (8) used transesophageal echocardiography to study patients with osteo-arthrosis 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 group 2 of the present study, severe embolic events were found in 30% during femoral preparation, 20% during stem insertion, and 45% during hip relocation. Pitto et al. found a very low rate of embolic events in cases of cementless THA, but the stem design they used (CLS; Sultzer Medica) was different from the one used in the present study (VerSys Fiber Metal Taper; Zimmer, Warsaw, IN). Stem design and/or instruments used in femoral preparation may greatly affect generation of embolic particles.

Pitto et al. 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, and they emphasized this finding despite the low frequency with which these events occurred. Schmidt et al. (29) also reported embolic events during preparation of the femur, and reported that embolic events could be reduced by using a cannulated awl and a cannulated rasp. In the present study, in group 2 (manual surgery), grade 1 events were found in 70% of hips, grade 2 in 25%, and grade 3 in 5% during femoral preparation, but severe embolic events (grade 2 or higher) were not found in group 1 (ROBODOC). This suggests that the ROBODOC femoral milling system is more effective than manual surgery in preventing pulmonary embolism during femoral preparation.

In the present study, in group 2, embolic events of grade 2 or higher occurred at higher frequency during hip relocation (45%) than during femoral preparation (30%) or stem insertion (20%). During femoral bone manipulation, the hip joint was maintained at a flexion-adduction-internal rotation position until insertion of the stem. 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 flow of fat and bone marrow into the stagnated venous system as a result of femoral bone manipulation before reduction of the hip. This induces formation of thrombi. These embolic particles migrate to the lungs and pulmonary embolism then occurs when venous blood flow is resumed due to reduction (4-6). Apparently, it is important to avoid introducing fat and bone marrow into the venous system as a result of femoral bone manipulation. In contrast to our results for group 2, incidence of embolic events of grade 2 or higher in group 1 was 0% during femoral bone manipulation and 8% during hip relocation. The ROBODOC milling system decreased the amount of fat and bone marrow introduced into the venous system during femoral preparation, resulting in low incidence of severe events during stem insertion and hip relocation.

In the present study, severe embolic events were observed in patients who underwent cementless THA, but they occurred at a lower frequency than those reported for cemented THA in the literature. Despite this difference in frequency, it is clear that development of fatal embolic events during THA is an important concern whether or not cement is used. In order to prevent embolic events, it is important to avoid introducing fat and bone marrow into the venous system during surgical manipulation. The present results indicate that the ROBODOC femoral milling system decreased the incidence of severe embolic events during femoral preparation, resulting in low inci-

dence of severe events during stem insertion and hip relocation. This finding suggests that the ROBODOC femoral milling system may reduce the risk of pulmonary embolism during cementless THA.

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