We carried out a prospective randomised study to evaluate the blood loss in 60 patients having a total knee arthroplasty and divided randomly into two equal groups, one having a computer-assisted procedure and the other a standard operation. The surgery was carried out by a single surgeon at one institution using a uniform approach. The only variable in the groups was the use of intramedullary femoral and tibial alignment jigs in the standard group and single tracker pins of the imageless navigation system in the navigated group.

The mean drainage of blood was 1351 ml (715 to 2890; 95% confidence interval (CI) 1183 to 1518) in the computer-aided group and 1747 ml (1100 to 3030; CI 1581 to 1912) in the conventional group. This difference was statistically significant (p = 0.001). The mean calculated loss of haemoglobin was 36 g/dl in the navigated group versus 53 g/dl in the conventional group; this was significant at p < 0.00001.

There was a highly significant reduction in blood drainage and the calculated Hb loss between the computer-assisted and the conventional techniques. This allows the ordering of less blood before the operation, reduces risks at transfusion and gives financial saving. Computer-assisted surgery may also be useful for patients in whom blood products are not acceptable.

Total knee arthroplasty (TKA) results in considerable blood loss.1,2 The safest and most effective method of reducing the requirement for blood transfusion is to minimise intra-operative bleeding by the use of a tourniquet,3 minimally-invasive surgery,4 diathermy coagulation, sealing of the intramedullary femoral canal,5 the position of the knee6 and the use of antifibrinolytic agents.7

Computer navigation has been developed to allow accurate intra-operative positioning of the components without breaching the intramedullary cavities8 and may provide an opportunity for reducing blood loss. However, prolongation of the operating time, as currently occurs in computer-assisted surgery, may negate this benefit.

We have carried out a prospective, randomised study to evaluate the blood loss in computer-assisted navigated TKA and compared this with the loss using a standard conventional surgical technique with intramedullary alignment guides.

Patients and Methods
Between July 2001 and July 2003, all patients requiring a unilateral primary TKA for osteoarthritis were considered for inclusion in the study. Those with a history of a bleeding diathesis, those in whom non-steroid anti-inflammatory medication was contraindicated and those taking warfarin were excluded.

The patients were randomly allocated to one of two groups by sealed envelopes. There were 30 in each group and the patients were well-matched for age, gender, weight, height, comorbidities, type of anaesthesia and the pre-operative level of haemoglobin (Hb) (Table I). The patient, anaesthetist (before the onset of the procedure) and ward staff did not know which procedure had been undertaken. The approval of the institutional review board was obtained and all patients fully consented to their inclusion in the study.

Patients who were taking non-steroidal anti-inflammatory drugs were advised to abstain from using them one week before surgery. All patients had predonated autologous blood for transfusion according to a pre-ordained schedule.

Operative technique and prosthesis. The operations were performed by a single surgeon (AJS) in one hospital using a uniform surgical approach, instrumentation, technique and release.

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Y. Kalairajah, MA, MPhil, FRCS(Tr & Orth)
Orthopaedic Arthroplasty and Sports Surgery Fellow
Y. Kalairajah, MA, MPhil,
FRCS(Tr & Orth),
Orthopaedic Arthroplasty and Sports Surgery Fellow
From Sportsmed SA,
Adelaide, South Australia
Correspondence should be sent to Mr Y. Kalairajah;
e-mail: yega@orthospecialist.net

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Y. Kalairajah, MA, MPhil, FRCS(Tr & Orth)
Orthopaedic Arthroplasty and Sports Surgery Fellow
Y. Kalairajah, MA, MPhil,
FRCS(Tr & Orth),
Orthopaedic Arthroplasty and Sports Surgery Fellow
From Sportsmed SA,
Adelaide, South Australia
Correspondence should be sent to Mr Y. Kalairajah;
e-mail: yega@orthospecialist.net
sequence. The operations were carried out in a bloodless field using a pneumatic tourniquet at a pressure of 350 mmHg after exsanguination. A medial parapatellar approach was used through a midline skin incision. The length of the incision was identical in all cases with no attempt to perform minimally-invasive surgery. Bone cuts and soft-tissue balancing were done in the same sequence. Three standard calibrated suction Redivac bottles (Biomet TM, Warsaw, Indiana) were used, two as deep drains and the third superficially. The wound was closed in layers and a Velband (Johnson & Johnson, Braintree, Massachusetts) and a crepe bandage dressing was applied from the ankle to the proximal portion of the thigh before the tourniquet was released. The only variable in the two groups was the use of intramedullary femoral and tibial alignment jigs in the standard group, while single bicortical tracker pins (4 mm in diameter) of the Stryker Imageless Knee Navigation System (Stryker-Leibinger, Freiburg, Germany) were inserted into the tibia and femur in the navigated group. In the standard group a bone plug was used to seal the defect created by the intramedullary rod in the femur before closure of the wound.

All patients had a unilateral primary TKA using an uncemented hydroxyapatite-coated press-fit Scorpio TM knee (Stryker Howmedica Osteonics, Allendale, New Jersey) with a cemented patellar button.

**Method of anaesthesia and thromboprophylaxis.** All patients received spinal or general anaesthesia and a femoral nerve block from one of two anaesthetists (RC, PD). In all patients thromboprophylaxis consisted of 300 mg of aspirin once daily post-operatively and the wearing of thromboembolic stockings.

**Blood transfusions and post-operative management.** All patients were routinely transfused with between one and two units on the anaesthetist’s assessment of each patient’s haemodynamic parameters. Further units were given as necessary according to the volume in the drains and the clinical status.

Both groups followed a standard post-operative rehabilitation including immediate post-operative continuous passive movement and physiotherapy.

The volume in the drains was recorded and the drains were removed on the second day after surgery. This was the primary outcome measure.

The Hb level was measured in all patients in the week preceding surgery and on the second post-operative day. Calculation of the loss of Hb level was carried out, as a secondary outcome measure, by subtracting the post-operative from the pre-operative Hb level and adding the number of units transfused as follows:

\[
\text{Total Hb loss} = \text{Pre-Hb} - \text{Post-Hb} + \text{units transfused}
\]

(assuming 1 unit of blood = 1 g/dl)

**Statistical analysis.** Estimations of sample size were carried out with alpha and beta fixed at 5% and 20%, respectively, for an unpaired \(t\)-test. A clinically significant level of blood loss was thought to be 300 ml and studies of previous blood loss in drains in TKA suggested a SD of approximately 400 ml. The required sample size per group was thus determined to be 28. In order to allow for undetermined problems a further two patients were added, giving a total of 30 in each group.

The data were tested for normality using normal quantile plots which suggested that the normality assumption was justified. The data were further plotted to visualise the distribution and the two groups demonstrated some right skew in the analysed data. The normality assumption was still considered to be valid in view of the large sample size of 60. When an F (variance ratio) test confirmed that the two groups had equal variance the results were analysed by a two-tailed \(t\)-test with equal variance. When this assumption was not valid a \(t\)-test with unequal variances was used. A \(z\)-test was carried out to compare proportions in the two groups when necessary. A two-tailed \(p\) value of 0.05 or less was considered to be significant for all analyses performed. All data were provided with their 95% confidence interval (CI) when appropriate.

**Results**

The mean tourniquet time was 89 minutes (55 to 125; 95% CI 84 to 94) in the computer-assisted surgery group and 74 (40 to 132; 95% CI 66 to 82) in the standard group. This increase of 15 minutes (95% CI 5 to 24) in the mean operating time was significant \((p = 0.002)\).

The mean total blood loss in the drainage bottles was 1351 ml (715 to 2890; 95% CI 1183 to 1518) in the computer-assisted surgery group and 1747 ml (1100 to 3030; 95% CI 1581 to 1912) in the standard group. This difference of 396 ml (95% CI 158 to 633 ml) was statistically significant \((p = 0.001); \text{Fig. 1})\. There was negligible blood loss during the operation. The mean calculated Hb loss for the computer-assisted surgery group was 36.5 g/dl (95% CI

<table>
<thead>
<tr>
<th>Table I. Details (mean; SD; range) in both groups</th>
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<tbody>
<tr>
<td><strong>Computer-assisted surgery group</strong></td>
</tr>
<tr>
<td>Mean age in yrs</td>
</tr>
<tr>
<td>Female (%)</td>
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<tr>
<td>Mean height in cm</td>
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<tr>
<td>Mean weight in kg</td>
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<tr>
<td>ASA grade I or II (%)</td>
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<tr>
<td>Patients received spinal anaesthesia (%)</td>
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<tr>
<td>Mean pre-operative Hb* (g/dl)</td>
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</tbody>
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*Hb, haemoglobin level
33.2 to 39.8) versus 52.6 g/dl (95% CI 46.4 to 58.7) in the standard group; the difference (16.1 g/dl; 95% CI 8 to 24) was significant ($p < 0.00001$).

The mean reduction in blood loss in the drainage bottles in the computer-assisted surgery group in relation to the control group was 23% (CI 9 to 36) and in the calculated Hb loss 31% (95% CI 16 to 46).

Discussion
This study has shown that there is a highly significant reduction in blood drainage and in the calculated Hb loss in computer-assisted surgery compared with the conventional procedure when using an uncemented implant, three suction drains for 48 hours and immediate continuous passive movement.

The mean blood loss in the drains in the standard patients was higher than those in previous reports (1500 ml), while the mean calculated Hb loss was towards the upper end of the levels in such studies (30 to 50 g/dl).

The transfusion requirements in our patients could not be analysed since all were transfused in the early post-operative period. If a conventional transfusion threshold of 8 g/dl would require computer-assisted surgery patients to have only grouping and saving rather than cross-matching blood with the potential to make financial saving.

The computer-assisted operation saves blood, lessens the risks of transfusion and may be useful in patients for whom blood products are not acceptable.

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