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**Commentary**

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# Thrombosis Prevention After Total Hip Arthroplasty

## A Prospective, Randomized Trial Comparing a Mobile Compression Device with Low-Molecular-Weight Heparin

By Clifford W. Colwell Jr., MD, Mark I. Froimson, MD, MBA, Michael A. Mont, MD, Merrill A. Ritter, MD, Robert T. Trousdale, MD, Knute C. Buehler, MD, Andrew Spitzer, MD, Thomas K. Donaldson, MD, and Douglas E. Padgett, MD

**Background:** Thromboembolic disease is a common complication of total hip arthroplasty. The purpose of this study was to compare a new mobile compression device with low-molecular-weight heparin with regard to their safety and effectiveness for the prevention of venous thromboembolic disease.

**Methods:** Patients who had a total hip arthroplasty were randomized to receive prophylaxis with a mobile compression device or low-molecular-weight heparin for ten days. Use of the compression device began intraoperatively, and the patients in this group could receive 81 mg of aspirin daily after the surgery. The first injection of the low-molecular-weight heparin began between twelve and twenty-four hours after the surgery. After ten to twelve days, all patients underwent bilateral lower-extremity duplex ultrasonography to screen for deep venous thrombi in the calf and thigh. Any clinical symptoms of pulmonary embolism were evaluated with spiral computed tomography lung scans. Bleeding events and utilization of (i.e., compliance with) prophylactic treatment in both groups were documented. Clinical evaluation to look for evidence of deep venous thrombi and pulmonary emboli was performed at twelve weeks postoperatively.

**Results:** Four hundred and ten patients (414 hips) were randomized; 392 of these patients (395 of the hips) were evaluable with regard to the safety of the intervention and 386 patients (389 hips) were evaluable with regard to its efficacy. Demographics were similar clinically between the groups. The rate of major bleeding events was 0% in the compression group and 6% in the low-molecular-weight heparin group. The rates of distal and proximal deep venous thrombosis were 3% and 2%, respectively, in the compression group compared with 3% and 1% in the heparin group. The rates of pulmonary embolism were 1% in the compression group and 1% in the heparin group, and there were no fatal pulmonary emboli. Within the twelve-week follow-up period, two events (one deep venous thrombosis and one pulmonary embolus) occurred in one patient in the compression group following negative findings on duplex ultrasonography on the twelfth postoperative day. There was no difference between the groups with regard to the prevalence of venous thromboembolism.

**Conclusions:** When compared with low-molecular-weight heparin, use of the mobile compression device for prophylaxis against venous thromboembolic events following total hip arthroplasty resulted in a significant decrease in major bleeding events.

**Level of Evidence:** Therapeutic Level II. See Instructions to Authors for a complete description of levels of evidence.

Thromboembolic disease is a common complication following total joint arthroplasty that has been recognized since the National Institutes of Health Consensus Development Conference in 1986<sup>1</sup>. Without prophylaxis,

the rate of deep venous thrombosis after total hip arthroplasty is as high as 50%<sup>2</sup>. Since it has been estimated that 90% of symptomatic pulmonary emboli originate from lower-extremity deep venous thrombi<sup>3</sup>, prevention of these

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A video supplement to this article will be available from the *Video Journal of Orthopaedics*. A video clip will be available at the JBJS web site, [www.jbjs.org](http://www.jbjs.org). The *Video Journal of Orthopaedics* can be contacted at (805) 962-3410, web site: [www.vjortho.com](http://www.vjortho.com).

thrombi has become the standard of care after total hip arthroplasty. On the basis of the evidence in the literature, chemoprophylaxis with warfarin, low-molecular-weight heparin, or fondaparinux sodium is recommended after total hip arthroplasty to prevent venous thromboembolic disease. Chemoprophylaxis with agents designed to impact the clotting cascade, however, carries a bleeding risk with associated complications of blood loss, transfusion, transfusion-related transmission of disease, wound-healing problems, hematoma, slowed rehabilitation, wound drainage, and infection. Mechanical methods of prophylaxis are often used for patients with a higher bleeding risk or as an adjunct to chemoprophylaxis.

The use of mechanical compression devices for prophylaxis against deep venous thrombosis is an attractive option because it has minimal impact on postoperative hemostasis. Few complications associated with the use of these devices have been identified. Mechanical compression devices have been theorized to prevent clot formation by increasing venous blood flow from the legs<sup>4</sup>, causing the release of endothelial-derived relaxing factors<sup>5</sup> and causing release of urokinase<sup>6,7</sup>. The relaxing factors and the urokinase prevent or impede the development of thrombosis and help to break down clots while they are forming. Mechanical compression has been associated with rare reports of compartment syndrome and peroneal nerve palsy<sup>8,9</sup>. Bleeding rates with intermittent pneumatic compression devices are considered to be similar to those with placebos: about 4% after total hip arthroplasty<sup>10</sup>.

Two potential problems associated with compression devices—poor patient utilization<sup>11</sup> and the peak venous velocity generated<sup>12</sup>—are often the source of criticism leveled against their routine use. Widely available hospital-based compression devices prevent walking, are often difficult to apply, are quite challenging for the elderly to use, and tend to be bulky and uncomfortable. Devices that deliver higher peak venous velocity achieve it through rapid inflation of the compression sleeve by utilizing an air compression chamber in the pump unit. The rapid inflation often creates an annoying impact sensation on the patient's leg, further decreasing usage of the device. To overcome the problems of poor inpatient utilization and a lack of adaptability for home use and to achieve a high peak venous velocity without compromising patient utilization, a portable, battery-operated Continuous Enhanced Circulation Therapy plus Synchronized Flow Technology (CECT+SFT) compression device (Active Care + SFT; Medical Compression Systems, Or Akiva, Israel) was developed. This compression device can be worn while the patient is in or out of bed with minimal inconvenience, can be applied easily by the patient, and can be sent home or to an extended-care facility with the patient for continuous use with compliance documented on a liquid crystal display screen in the device.

The hypothesis tested in this prospective, randomized, multicenter, controlled trial was that this portable compression device (CECT+SFT) would be safer than low-molecular-weight heparin with respect to major bleeding after total hip arthroplasty without a negative impact on efficacy.

## Materials and Methods

Four hundred and ten nonconsecutive patients (414 hips) provided consent to participate in the study between June 2006 and June 2008, after the study was approved by the institutional review board at each of nine participating sites. This trial was registered (NCT00358735) on the ClinicalTrials.gov web site. Of the patients who provided consent, 392 (395 hips) were evaluable with regard to the safety of the intervention and 386 patients (389 hips) were evaluable as participants in an intent-to-treat trial for determination of efficacy (Fig. 1). Inclusion criteria included an age of eighteen years or older and being scheduled for a primary unilateral total hip arthroplasty. Exclusion criteria included a history of venous thromboembolism, a coagulation disorder including the known presence of factor V Leiden, a solid malignant tumor, peptic ulcer disease, and major surgery in the prior three months.

A computer-generated randomization schedule utilizing a blocking sequence of ten was created at a central coordinating center that also served to collect, store, and analyze data from each of the nine sites. The randomization schedule was not concealed from the study coordinators at each site before group allocation was assigned, and the coordinators, the surgeons, and the patients enrolled in the study were not blinded to the type of intervention. Patients were randomized to either use a portable, battery-powered CECT+SFT compression device or receive low-molecular-weight heparin (enoxaparin sodium [Lovenox]) in a dosage of 30 mg every twelve hours until discharge and then 40 mg once daily. The compression device was placed on both of the patient's calves immediately after the induction of anesthesia. Patients in the compression-device arm of the trial were allowed to receive 81 mg of aspirin daily after the operation at the discretion of the treating surgeon. The low-molecular-weight heparin was started the morning after the surgery. Treatment with the mobile compression device or low-molecular-weight heparin was continued for ten days.

The compression device applies intermittent, sequential pressure to the leg in correlation with the patient's respiratory-related venous phasic flow in a systematic pattern, increasing the peak venous velocity of venous blood flow to reduce the risk of clot formation. The disposable limb sleeves fit over the patient's calves in a form-fitting manner and are secured with hook-and-loop (Velcro) fasteners. The sleeves are then connected to the pump with plastic hoses. The 1.65-lb (0.74-kg) pump can function for up to six hours on battery power, the pump and battery pack can be easily carried with a shoulder strap, and the battery pack can be recharged when plugged into an electrical outlet. The compression device monitors the respiratory-related venous phasic flow and generates the compression in synchronization with this flow. Synchronization with venous phasic flow increases the peak venous velocity by 66% with a gentle compression. This device provides a maximum pressure during inflation of 50 mm Hg and uses eight seconds of compression followed by thirty-six to fifty-six seconds of decompression in synchronization with the respiratory-related venous phasic flow. Compliance with

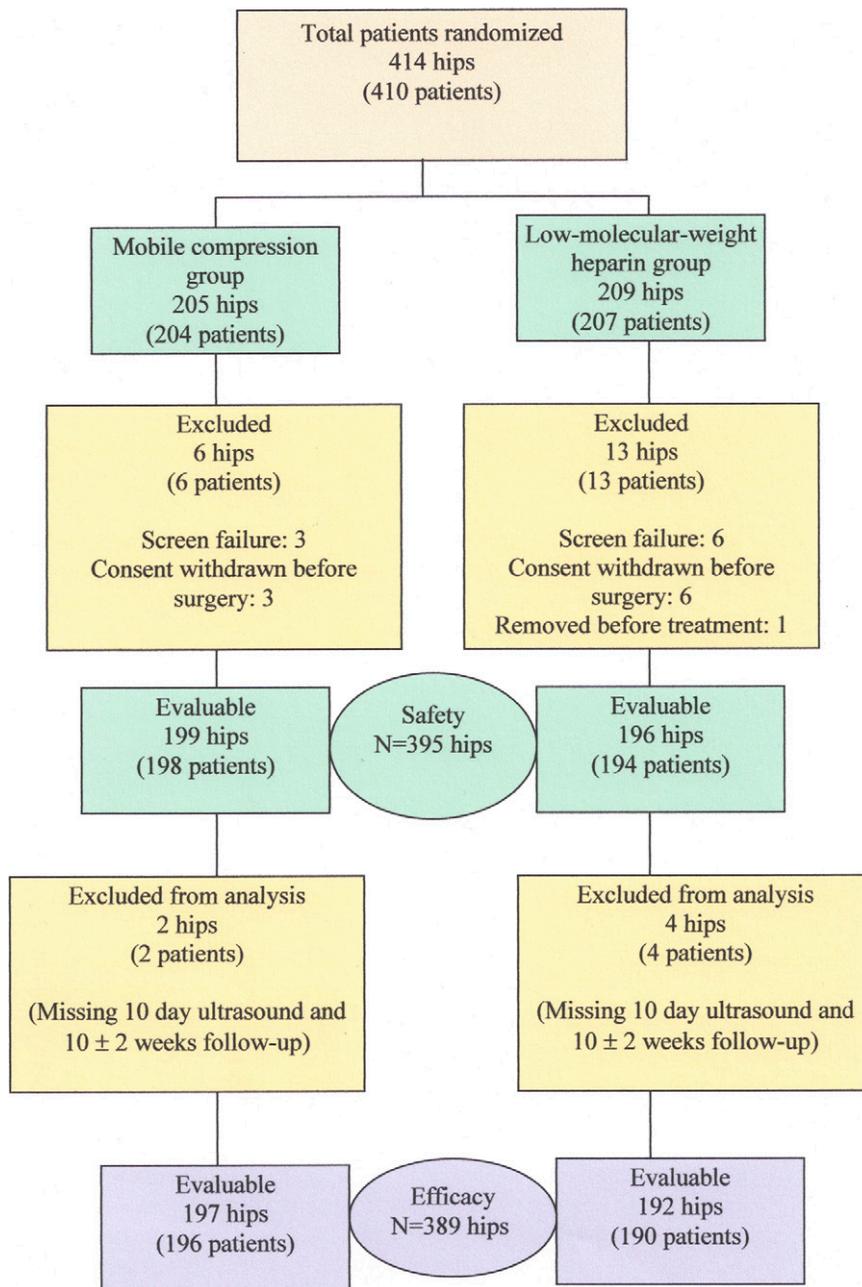


Fig. 1  
Schematic showing enrollment of the patients for the safety and efficacy analyses. (One patient with a staged bilateral procedure was randomized to both groups.)

utilization of the compression device was measured by an internal timer in the pump unit. This timer detects the amount of time that the device is properly functioning and is actually being worn by the patient; the total time is displayed on the device screen. Compliance in the low-molecular-weight heparin group was determined from hospital records and from a patient diary of the dates and times of injections at home.

Patients in both groups were closely monitored throughout their hospitalization for any potential bleeding complications and for clinical signs and symptoms of deep venous

thrombosis or pulmonary embolus. Major bleeding was defined as bleeding that required rehospitalization or prolonged hospitalization, required any intervention such as surgery or hematoma aspiration to prevent permanent impairment or damage, endangered critical organs (intracerebral, intraocular, intraspinal, pericardial, or retroperitoneal), was life threatening, or caused death. Minor bleeding was any bleeding that was not major bleeding (e.g., increased wound drainage reported by the surgeon or a drop in the hemoglobin level not requiring transfusion or prolonged hospitalization).

The bleeding index (defined as the number of units of whole blood or packed red blood cells transfused plus the difference between the first hemoglobin value after surgery and the value prior to discharge), a decrease in the hemoglobin level of  $\geq 20$  g/L, and the number of units of blood transfused were reported. All nine investigators participated in the development of the study protocol and approved the definition of bleeding events before the study commenced.

Both groups continued their assigned treatment at home or at an extended-care facility and returned ten to twelve days after the surgery for bilateral duplex ultrasonography of the lower extremities performed to detect occult deep venous thrombosis. Duplex ultrasonography was used as the definitive test for diagnosis of deep venous thromboembolism because essentially all hospitals in the United States are presently using this modality, which has replaced venography, for the diagnosis of deep venous thrombi. There is ample evidence<sup>13-16</sup> that the accuracy, sensitivity, and specificity of duplex ultrasonography are equivalent to those of venography for the diagnosis of proximal deep venous thrombi, which are more likely to result in a pulmonary embolus following total hip arthroplasty. Every positive scan was adjudicated by an independent neurologist who has been interpreting vascular duplex ultrasound studies since 1976. This reviewer had no knowledge of the interpretation of the investigator at the study site or of the treatment to which the patient had been randomized. All patients with a negative scan were followed clinically, for a mean (and standard deviation) of  $10 \pm 2$  weeks, for signs or symptoms of deep venous thrombi, pulmonary emboli, or rehospitalization because of a complication related to the method of prophylaxis, a bleeding complication, or a wound problem. Patients with a positive scan were treated and followed according to each institution's protocol.

### Statistical Analysis

A power analysis showed that 196 patients in each group were needed in order to detect a significant difference in the frequencies of major bleeding events between groups with 80% power and a confidence level of 95%. The Fisher exact test was used for the sample-size calculation with an estimated effect size of 4%. The study was not powered for efficacy, as explained in more detail in the Discussion section.

Demographics were compared to ensure that the randomization process had resulted in similar patient characteristics between groups. Chi-square tests were used to assess group differences in categorical variables, and independent t tests were used to compare continuous variables.

The Fisher exact test was used to compare the primary variable of safety, the frequency of major bleeding events, between the groups as well. Other bleeding data were compared between the groups as well. Categorical variables (the proportion of patients with a drop in the hemoglobin level of  $\geq 20$  g/L and the proportion of those who had a bleeding index of  $\geq 2$ ) were examined with use of the chi-square test. Continuous variables (the mean number of units of blood transfused and the mean bleeding index) were analyzed with use of independent t tests or the Mann-Whitney U test when appropriate. Frequencies were used to summarize the anesthesia types in both groups as well as the numbers of venous thromboembolic events and bleeding events for each anesthesia type.

The secondary variable of efficacy, the frequency of venous thromboembolic events, was compared between groups by using a chi-square test. A subgroup analysis comparing venous thromboembolism rates between aspirin users and those who did not use aspirin in the compression group was also performed. Analyses of efficacy were performed with use of the intent-to-treat method (an analysis based on the initial treatment intent, not on the treatment actually administered). The intent-to-treat analysis was utilized in order to capture a practical estimate of venous thromboembolic events in each group as they would occur in clinical practice, rather than in a group of highly compliant patients. All tests were two-tailed, and the alpha level was set at 0.05.

### Source of Funding

Medical Compression Systems (Or Akiva, Israel) provided the funding to carry out the study. They had no input in the study design, data retrieval or analysis, or manuscript preparation.

### Results

Of the 392 patients (395 hips) who were evaluable with regard to the safety of the intervention, 198 (199 hips) were in the compression group and 194 (196 hips) were in the

**TABLE I** Demographics of Participants

|                                     | Mobile Compression Group<br>(N = 199 Hips) | Low-Molecular-Weight Heparin<br>Group (N = 196 Hips) | Range  | P Value |
|-------------------------------------|--|--|--------|---------|
| Mean age (yr)                       | 63   | 62   | 20-88  | 0.394   |
| Mean body-mass index ( $kg/m^2$ )   | 28   | 29   | 16-49  | 0.020   |
| Female sex (%)                      | 55   | 54   |        | 0.811   |
| Diagnosis of osteoarthritis (%)     | 94   | 95   |        | 0.400   |
| Mean duration of surgery (min)      | 91   | 96   | 41-190 | 0.056   |
| Mean length of hospital stay (days) | 3.2  | 3.2  | 2-10   | 0.606   |

low-molecular-weight heparin group (Fig. 1). Demographics were similar clinically in the two groups (Table I). Major bleeding occurred in eleven of the 395 cases. All eleven bleeding events occurred in the heparin group, and the difference between the rate in that group (eleven of 196) and the rate in the compression group (zero of 199) was significant ( $p = 0.0004$ ) (Table II). The bleeding complications included two hematomas, which resolved spontaneously and did not require drainage or surgical exploration. Data regarding blood transfusions, the mean difference in the hemoglobin level between the immediate postoperative measurement and discharge, and the bleeding index are presented in Table II.

Minor bleeding occurred in seventy-four (37%) of the 199 cases in the compression group and seventy-eight (42%) of the 185 cases in the heparin group ( $p = 0.319$ ). The eleven patients who experienced a major bleeding event were excluded from the analysis of minor bleeding.

The types of anesthesia used in each group are presented in Table III, as are the numbers of venous thromboembolic and major bleeding events occurring in association with each anesthesia type.

Of the 386 patients (389 hips) who were evaluable with regard to the efficacy of the intervention, 196 (197 hips) were in the compression group and 190 (192 hips) were in the heparin group (Fig. 1). Aspirin was used in addition to the compression device in 125 (63%) of the 197 cases in the compression group.

A total of sixteen deep venous thrombi were detected by bilateral duplex ultrasonography examinations, and four pulmonary emboli were diagnosed by spiral computed tomography scans in the two cohorts. All four pulmonary emboli were symptomatic, but no deaths occurred. The patients in the compression group had a total of ten venous thromboembolic events (a rate of 5%), including eight deep venous

**TABLE II Major Bleeding Events, Units Transfused, Bleeding Index, and Change in Hemoglobin Level**

|  | Mobile Compression Group (N = 199 Hips) | Low-Molecular-Weight Heparin Group (N = 196 Hips) | P Value |
|--|---|---|---------|
| Major bleeding   | 0                                       | 11 (6%)   | 0.0004  |
| Anemia (requiring prolonged hospitalization)                           |   | 5   |         |
| Anemia with hypotension (requiring intervention to prevent impairment) |   | 2   |         |
| Hematoma (requiring prolonged hospitalization)                         |   | 1   |         |
| Hematoma (requiring rehospitalization)                                 |   | 1   |         |
| Urinary bleeding (requiring rehospitalization)                         |   | 1   |         |
| Increased wound drainage (requiring rehospitalization)                 |   | 1   |         |
| Blood transfusions   | 59 (30%)                                | 74 (38%)  | 0.088   |
| Total no. of blood units used  | 82                                      | 122   |         |
| Autologous units   | 56                                      | 59  |         |
| Allogeneic units   | 26                                      | 63  |         |
| Mean no. of units transfused per patient                               | 1.4                                     | 1.6   | 0.141*  |
| Mean no. of units transfused per group                                 | 0.4                                     | 0.6   | 0.050*  |
| Bleeding index†‡   |   |   |         |
| No. of patients with an index of $\geq 2$                              | 44 (23%)                                | 61 (32%)  | 0.055   |
| Mean bleeding index  | 1.3                                     | 1.5   | 0.052   |
| Change in hemoglobin level‡§   |   |   |         |
| No. of patients with a change of $\geq 20$ g/L                         | 31 (16%)                                | 37 (19%)  | 0.436   |
| Mean change (g/L)  | 8                                       | 9   | 0.798   |

\*Derived with use of the Mann-Whitney U test. †Bleeding index = number of units of whole blood or packed red blood cells transfused + (first hemoglobin value after surgery – hemoglobin value at discharge). ‡The analysis excludes sixteen hips (ten in the mobile compression group and six in the low-molecular-weight heparin group) for whom the first hemoglobin value after surgery and/or the value at discharge was either not measured or missing. §The change from the first measurement of the hemoglobin level after surgery to the measurement at the time of discharge.

**TABLE III Number of Venous Thromboembolic Events and Major Bleeding Events Associated with Each Type of Anesthesia in Each Group**

| Anesthesia                     | All Hips (N = 395 Hips) |                                 | Mobile Compression Group (N = 199 Hips) |                                 | Low-Molecular-Weight Heparin Group (N = 196 Hips) |                                 |                                |
|--------------------------------|-------------------------|---------------------------------|---|---------------------------------|---|---------------------------------|--------------------------------|
|                                | Total No. (%)           | No. with Venous Thromboembolism | Total No. (%)                           | No. with Venous Thromboembolism | Total No. (%)                                     | No. with Venous Thromboembolism | No. with Major Bleeding Event* |
| General                        | 167 (42)                | 8                               | 84 (42)                                 | 4                               | 83 (42)   | 4                               | 3                              |
| General + spinal               | 33 (8)                  | 4                               | 20 (10)                                 | 2                               | 13 (7)  | 2                               | 0                              |
| General + local block          | 10 (3)                  | 1                               | 8 (4)                                   | 1                               | 2 (1)   | 0                               | 0                              |
| General + spinal + local block | 9 (2)                   | 0                               | 4 (2)                                   | 0                               | 5 (3)   | 0                               | 0                              |
| Spinal                         | 94 (24)                 | 5                               | 41 (21)                                 | 1                               | 53 (27)   | 4                               | 6                              |
| Spinal + local block           | 3 (1)                   | 0                               | 1 (1)                                   | 0                               | 2 (1)   | 0                               | 1                              |
| Spinal + epidural              | 78 (20)                 | 2                               | 41 (21)                                 | 2                               | 37 (19)   | 0                               | 1                              |
| Epidural                       | 1 (0.3)                 | 0                               | 0                                       | 0                               | 1 (1)   | 0                               | 0                              |
| All hips                       | 395                     | 20                              | 199                                     | 10                              | 196   | 10                              | 11                             |

\*All major bleeding events occurred in the low-molecular-weight heparin group.

thrombi (five distal thrombi [3%] and three proximal thrombi [2%]) and two pulmonary emboli (1%). One pulmonary embolus was detected on the second postoperative day and one, on the seventeenth postoperative day. The pulmonary embolus that was identified on the seventeenth day was in a patient who had that complication as well as a deep venous thrombosis following negative findings on duplex ultrasonography on the twelfth postoperative day. Of the eight patients in the compression group who had deep venous thrombosis, four were receiving aspirin. One of the two patients who had a pulmonary embolism in that group was receiving aspirin as well.

In the heparin group, there were ten venous thrombi (a rate of 5%), with six distal thrombi (3%) (bilateral in two patients), two proximal thrombi (1%), and two pulmonary emboli (1%). One pulmonary embolus was detected on the third postoperative day, and the other was detected on the fifth postoperative day.

The difference in the rate of venous thromboembolic disease between the compression group (5%; ten of 197 hips) and the heparin group (5%; ten of 192 hips) was not significant ( $p = 0.953$ ). All venous thromboembolic events were reported to have been successfully treated and to have resolved without short-term (three-month) sequelae.

The patients in the compression group used the device for a mean of eleven days (range, one to fifteen days), a mean of 221 hours (range, twenty-four to 321 hours) in total, and a mean of twenty hours per day. Reasons for removal of the mobile compression device included intolerance of the motor noise, a mild skin rash, and warmth of the device on the legs. The heparin group used a mean of twelve doses (range, two to seventeen doses) during a mean of ten days of prophylaxis.

## Discussion

Our hypothesis that this portable compression device (CECT+SFT) would prove to be safer than low-molecular-weight heparin with respect to major bleeding after total hip arthroplasty was verified. Major bleeding occurred in 6% (eleven) of the patients in the heparin group and in none of the patients in the compression group ( $p = 0.0004$ ). This rate of major bleeding is similar to the 5.3% rate reported after the pooling of the results of five studies in which a total of 1741 patients utilized low-molecular-weight heparin after total hip arthroplasty<sup>17</sup>. No patient with a major bleeding event in our study had additional surgery or specific treatment within the three months of clinical follow-up. We powered the study for an evaluation of safety instead of an assessment of efficacy for two reasons. First, practicing orthopaedic surgeons are deeply concerned about bleeding issues associated with any of the utilized prophylactic drugs. This is demonstrated in the recent American Academy of Orthopaedic Surgeons guidelines for prophylaxis against symptomatic pulmonary embolism following total hip arthroplasty<sup>18</sup>. Second, because of the low rates of venous thromboembolic events associated with low-molecular-weight heparin (based on well-known and widely reported data)<sup>17,19</sup>, a study to demonstrate equivalency, non-inferiority, or superiority in efficacy would require a minimum of 1480 patients per group.

Our findings with regard to venous thromboembolic events support those in a previously reported study comparing a similar compression device with low-molecular-weight heparin<sup>20</sup>. In that study, which included both total hip and total knee arthroplasties, Gelfer et al. compared prophylaxis with an earlier version of this portable compression device as well as aspirin with administration of 40 mg of enoxaparin daily. Using

a venographic end point, they found compression to be associated with a significant reduction in the frequency of deep venous thrombi after total hip arthroplasty, with the complication being detected in zero of thirty-three patients in the compression group compared with thirteen of forty patients in the enoxaparin group. The rates of bleeding events were reported to be similar between the groups. Since aspirin was used in the study by Gelfer et al. and there was a difference of opinion among our investigators about the use of aspirin, we allowed daily use of 81 mg of aspirin as an option in the compression group in our study. The decision to use or not use aspirin as an adjunct to the compression device was based on surgeon preference and on the standard of care in the respective hospitals. Although more than half (63%) of the patients in the compression group used aspirin, the rates of deep venous thrombosis and pulmonary embolism were the same as those for the patients who did not use aspirin. Since this study was not powered to determine the effect of the use of aspirin, we are unable to reach any conclusion regarding the benefits of the use or nonuse of aspirin with the mobile compression device.

The utility of pneumatic compression devices for prophylaxis against venous thromboembolism has been the subject of considerable study, and the risk reduction has been found to be generally comparable with that provided by pharmacologic methods. In a cohort of patients treated with total hip arthroplasty, Paiement et al. found the rates of deep venous thrombi and bleeding events to be similar between those who received low-dose warfarin and those who used a pneumatic compression foot-pump device<sup>21</sup>. They reported deep venous thrombosis in 17% (twelve) of seventy-two patients in the warfarin group and 17% (eleven) of sixty-six patients in the pneumatic compression group, with no major bleeding occurring in either group. In contrast, Bailey et al. found that use of a thigh-high pneumatic compression device after total hip arthroplasty was associated with a rate of deep venous thrombosis (three events in fifty patients) that was significantly better than the rate in a group that used low-dose warfarin (twelve events in forty-five patients); no clinically important bleeding occurred in either group<sup>22</sup>. In a cohort of patients treated with total hip arthroplasty, Warwick et al. demonstrated that the prevention of deep venous thrombosis was equivalent between a group treated with low-molecular-weight heparin (enoxaparin) (eighteen events in 138 patients) and one treated with a foot pneumatic compression device (twenty-four events in 136 patients); there was increased wound drainage but no increased bleeding with the enoxaparin<sup>23</sup>. In a study of patients treated with total hip arthroplasty, Pitto et al. found that prophylaxis with an intermittent foot pneumatic compression device resulted in a rate of deep venous thrombosis (three of 100 patients) that was half the rate in a group that received enoxaparin (six of 100 patients); they reported increased drainage and minor bleeding with enoxaparin<sup>24</sup>.

The need for extended thromboprophylaxis beyond the current routine three to four-day hospital stay following total

hip arthroplasty has been well documented in the literature<sup>25-28</sup>. The portable device evaluated in this study enables seamless continuation of in-hospital use with extended outpatient protection without the associated risks of bleeding or thrombocytopenia. Previously, no portable external device that could be used by the patient for ten days or longer was available, and the literature clearly demonstrates that this is a minimum time frame for prophylaxis following total hip arthroplasty<sup>17</sup>. This is one of the first studies comparing an intermittent compression device with low-molecular-weight heparin in which both treatment arms were carried through the recommended ten days of treatment.

Despite the consistent success of pneumatic compression devices, patient compliance and utilization remain a concern. The device in this study detects if the sleeves are being worn and records the number of hours of utilization. The display of the time for which the device is used can be visualized by the patient and medical staff in the hospital, by the patient during home use, and when the device is returned after use. Whether direct monitoring by the patient of the amount of time for which the device is used influences patient compliance would be a topic for future research, with the hypothesis that knowing the amount of usage would be a benefit. A direct correlation has been reported between the amount of time for which a pneumatic compression device is worn and its effectiveness<sup>29</sup>. The mobile compression device has been studied relative to other pneumatic compression devices<sup>30-32</sup>. In a study of patients treated with total joint arthroplasty who received low-molecular-weight heparin, Froimson et al. reported a rate of venous thromboembolism of 1.3% in a group that used a Continuous Enhanced Circulation Therapy (CECT) device compared with 4.3% in a group that used a different intermittent compression device<sup>31</sup>. No pulmonary emboli were reported in the CECT group. The greater success seen in the CECT group could be attributed at least partially to the increased time of use, as the CECT device was worn 83% of the time whereas the other device was worn 49% of the time<sup>31</sup>. In a study of trauma patients, the portable compression device was worn 78% of the time whereas a traditional leg compression device was worn 59% of the time ( $p = 0.004$ )<sup>32</sup>. No device increases blood flow or causes the release of intrinsic anticoagulants if the patient removes it because of discomfort or activity. In a study by Edwards et al., patients treated with total hip arthroplasty as well as prophylaxis with low-molecular-weight heparin and a portable compression device who had negative findings for deep venous thrombosis wore the device for an average of 20.9 hours per day, or 87% of the maximum usable hours<sup>33</sup>. Another study in which patients treated with total hip arthroplasty received low-molecular-weight heparin and wore intermittent compression stockings revealed no instances of deep venous thrombi when the patient had worn the stockings for six hours or more<sup>34</sup>. On the average, our patients, who were treated with total hip arthroplasty, used the mobile compression device for twenty of twenty-four hours, or 83% of the time, for the mean of eleven days, which is longer than the duration of use reported in studies of other compression devices<sup>11,24</sup>.

Our study was limited because the number of patients was not adequate to delineate the difference in efficacy between the two methods of prophylaxis, although our results did support our hypothesis regarding safety and there were no worrisome findings related to efficacy. The lack of blinding in this study is also a limitation, although compression-device studies are difficult to blind. The use of ultrasound may have also limited our findings because positive venographic findings have been used as an end point in large randomized, prospective studies<sup>35-37</sup>. However, duplex ultrasonography has become the diagnostic standard in most U.S. hospitals, making it more representative of real-time medical management.

In conclusion, this prospective study comparing a mobile compression device with low-molecular-weight heparin for prophylaxis in patients treated with total hip arthroplasty demonstrated significantly less major bleeding, with similar rates of venous thromboembolic events, in the patients who used the mobile compression device. ■

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