

# Tempofilter II implantation in patients with lower extremity fractures and proximal deep vein thrombosis

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## PURPOSE

We aimed to examine the efficacy and safety of Tempofilter II (B. Braun, Melsungen, Germany) implantation to prevent pulmonary embolism in patients with lower-extremity fractures and proximal deep vein thrombosis (DVT).

## MATERIALS AND METHODS

The records of patients with lower limb fractures and proximal DVT who were implanted with Tempofilter II devices from May 2004 to August 2009 were reviewed. Data collected included success rate, occurrence of pulmonary embolism, retrieval rate, and complications.

## RESULTS

A total of 176 eligible patients, including 129 males (73.3%) and 47 females (26.7%) with a median age of 42.0 years (interquartile range [IQR], 34.0–52.0 years) were included in the study. Filters were successfully implanted in 174 patients (98.9%). One patient experienced a pulmonary embolism after implantation and died. Filters were removed without complications in all other patients. Median filter implantation time was 27 days (IQR, 25.0–29.0 days). Visible organized thrombi were present on the surface of 144 (82.8%) of filters after removal, and the diameter of most thrombi (n=124) ranged from 0.5 to 1.0 cm. Filters migrated <2 cm in 104 patients (59.8%) and ≥2 cm in five patients (2.9%). In these five cases, three filters migrated into the right atrium and two migrated to the orifice of the renal veins.

## CONCLUSION

Tempofilter II is safe and may be useful in cases of lower extremity fracture with proximal DVT for the prevention of pulmonary embolism. The filter is easily placed and retrieved, and associated with minimal complications.

**A**cute pulmonary embolism (PE) is one of the most common causes of death in hospitalized patients (1, 2). The mortality rate of PEs is especially high in trauma patients, as these tend to develop latent PEs. Although the mortality associated with PEs has been greatly reduced by the application of inferior vena cava filters (VCFs) (3, 4), permanent VCF implantation is associated with long-term complications such as recurrent deep vein thrombosis (DVT), filter dislocation, migration, and rupture (5–8). Thus, for patients with a long life expectancy and transient risk for venous thromboembolism, nonpermanent VCF placement is preferred (6). Currently, two types of nonpermanent filters are available: temporary and retrievable filters. Retrievable filters can be used to prevent PE in trauma patients during the high-risk period while avoiding the complications associated with long-term placement (9, 10). If a thrombus is trapped by the filter, the filter can be maintained at the original position and removed after thrombus resolution (5). However, because the recommended usage time of this type of filter is relatively short (usually 12 days), the extraction rate is low and many are left in place permanently (11).

The Tempofilter II (B. Braun, Melsungen, Germany) is a second-generation temporary caval filter with an indwelling time of up to six weeks (12). The filter is placed and retrieved by means of a tethered cable fixed to a subcutaneous anchoring device. There is only one prior large-scale study, including placement of 104 Tempofilter II filters in 103 patients with PE, DVT, or both (12). They reported only one case of PE after filter placement, no mechanical complications related to the filter, and successful retrieval in all but one case regardless of thrombus entrapment (12).

The purpose of this study was to examine the efficacy and safety of the Tempofilter II in Chinese patients with lower extremity fractures and proximal DVT.

## Materials and methods

This was a single-center, retrospective study investigating the Tempofilter II in patients with lower limb fractures admitted to our hospital from May 2004 to August 2009. Once admitted, all patients were administered low-molecular-weight heparin (enoxaparin sodium [Clexane, Sanofi Winthrop Industrie, Maisons-Alfort, France] 100 IU/kg, subcutaneously, every 12 hours) to prevent venous thromboembolism unless contraindicated, based on the American College of Chest Physicians guidelines (2). Anticoagulation was temporarily discontinued 12 hours prior to open reduction and internal fixation surgery, and resumed 12 hours after the procedure. Patients who developed a DVT before surgery, as confirmed by deep venous ultrasonography or venog-

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raphy, were implanted with a Tempofilter II inferior VCF.

Temporary VCF implantation was considered appropriate for this group of patients because they had a high but transient risk of PE as indicated by inferior vena cava occlusion of more than 50% of the vessel lumen, or floating thrombi, as demonstrated on the imaging study. VCF implantation was not attempted if patients had severe heart disease, such as arrhythmia, or were diagnosed with a PE. This study was approved by the Institutional Review Board of Jishuitan Hospital, and because the study was retrospective, the requirement for informed consent was waived.

#### Filter implantation

The Tempofilter II is a cone-shaped, eight-legged, hookless filter introduced and retrieved by means of a tethering catheter that reaches a final length of 35–45 cm (12). The manufacturer indicates that filters should only be de-

ployed if the vena cava is 28 mm or less and should be explanted within 12 weeks of placement. In this study, all filters were inserted via the right internal jugular vein as directed by the manufacturer. Filters were deployed at the initial segment (confluence of the iliac veins) if the inferior vena cava was unobstructed and its diameter was <3 cm, as demonstrated on inferior vena cavography. The silicone olive was fixed subcutaneously at the neck.

#### Post-filter-implantation management

Patients were treated with prophylactic anticoagulants (enoxaparin via subcutaneous injection every 12 hours) and closely monitored for signs of PE throughout the period between filter implantation and removal. Catheter-directed thrombolytic treatment was initiated one week following orthopedic surgery, which we consider safer and more effective than initiating two weeks after surgery as recommended (2). After filter placement, patients

remained on bed rest for 24 hours. Computed tomography pulmonary angiography (CTPA; GE LightSpeed® VCT XT, GE Healthcare, Waukesha, Wisconsin, USA) was performed if a symptomatic PE (chest pain, dyspnea, low oxygen saturation) was suspected. To detect filter migration, abdominal X-rays were performed on the first, fourth, and seventh day, and then every week until filter explantation.

#### Filter removal

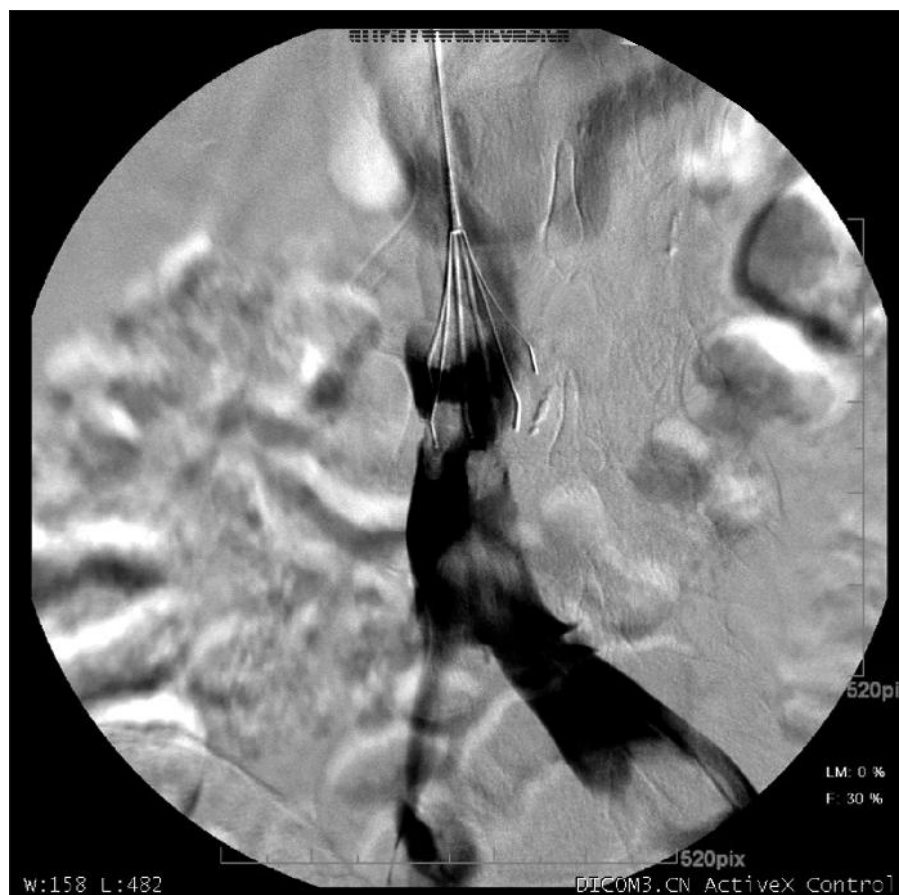
Filters were removed when blood D-dimer levels returned to normal; D-dimer levels were tested every three days. To identify large thrombi trapped within the filter, inferior vena cava ultrasonography and cavography (AXIOM Artis U, Siemens AG, Munich, Germany) were performed immediately before filter retrieval. If a large thrombus (>10 mm in diameter) was trapped by the filter (Fig. 1), urokinase (Nanjing Nanda Pharmaceuticals, Nanjing, China) 500 000 IU were administered through the indwelling catheter in the femoral vein until the thrombus was no longer visible and D-dimer value returned to the normal range, which usually required 7–12 days.

#### Follow-up

After filter explantation, heparin was discontinued, and patients were switched to warfarin (Marevan, Orion Corporation, Espoo, Finland) for a period of 3–6 months. The warfarin dose was adjusted to achieve an international normalized ratio (INR) prothrombin time of 1.8–2.5, as determined by weekly blood tests; following coagulation stabilization, prothrombin time was measured every three weeks. Patients wore stretch socks to prevent sequelae of DVT during the follow-up period.

#### Statistical analysis

Continuous variables were presented as medians and interquartile ranges (IQR, the range between the 25th and 75th percentiles) due to the non-normal distribution, and categorical variables were expressed as count and percentage. Descriptive statistics were performed using the SAS software, version 9.2 (SAS Institute Inc., Cary, North Carolina, USA).



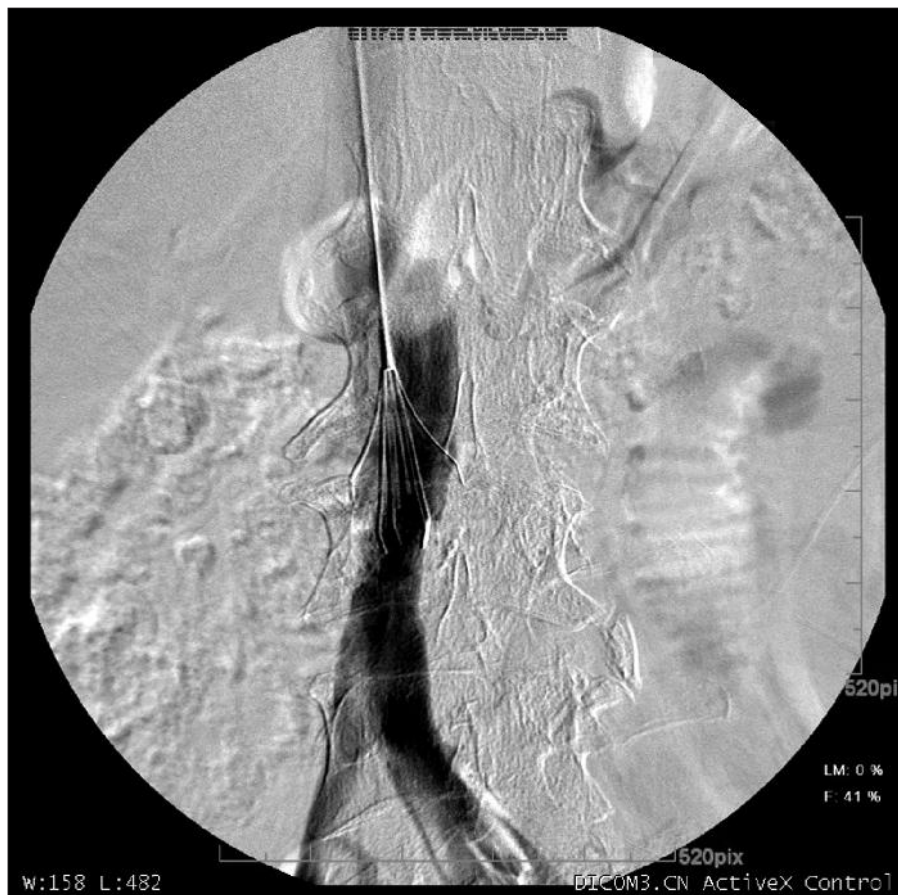
**Figure 1.** Digital subtraction angiography showing a large thrombus trapped by a temporary vena cava filter.

**Table 1.** Demographic and clinical characteristics of patients with deep vein thrombosis (n=176)

Age (years)	42.0 (34.0–52.0)
Male gender	129 (73.3)
DVT location	
Left lower extremity proximal DVT	83 (47.4)
Right lower extremity proximal DVT	66 (37.7)
Proximal DVT in both lower extremities	26 (14.9)
Temporary filters successfully implanted	174 (98.9)

DVT, deep vein thrombosis.

Data are presented as median (interquartile range) or n (%).

**Figure 2.** Digital subtraction angiography after filter removal; no thrombi are visible.

## Results

A total of 176 patients, including 129 males (73.3%) and 47 females (26.7%) with a median age of 42.0 years (IQR, 34.0–52.0 years), implanted with Tempofilter II devices following postsurgical DVTs were included in the study. Demographic data are summarized in Table 1. The average duration from injury to orthopedic surgery was 5–7 days. Of these patients, 174 (98.9%) were successfully implanted with tem-

porary filters. In one case, the guide-wire coiled in the cardiac atrium and failed to travel to the inferior vena cava and the procedure was stopped due to the development of an arrhythmia. The other implantation failure was due to suspected thoracic outlet syndrome, which crushed the outer sheath of the filter and resulted in failure of passage. No visible vascular malformation was identified in this patient during the implantation procedure.

The characteristics of the 174 patients who were successfully implanted with filters are summarized in Table 2. One patient experienced a PE and died during the treatment. Thus, a total of 173 patients (99.4%) completed anticoagulation and thrombolytic treatment. The patient who experienced the PE was a 42-year-old male admitted for a left femoral neck fracture due to a motor vehicle collision. Ultrasonography revealed acute thrombosis of the left femoral and popliteal veins. Four days later, a temporary filter was placed, and orthopedic surgery was performed two days after filter placement, following X-ray confirmation of retention at the original site, without complication. One week after surgery, the patient suddenly developed chest tightness and respiratory distress during physical therapy. Blood gas analysis demonstrated a low  $PO_2$  of 43.9 mmHg, electrocardiography showed no evidence of acute myocardial infarction, and chest X-ray revealed displacement of the filter to the right atrium and large bilateral patchy shadows. Acute massive PE was diagnosed, and the patient died despite emergency treatment.

The median length of filter residence in the remaining 173 patients was 27 days (IQR, 25.0–29.0 days). The filter was successfully removed in 154 patients (88.5%); filter removal was delayed by the need to dissolve filter-trapped thrombi in the 19 remaining patients (10.9%), but all were ultimately successful (Fig. 2). Twelve filters (6.9%) were mildly deformed or tilted, which did not affect removal.

Organized thrombi were visible on the surface of 144 (82.8%) of the filters following removal, and 124 of the thrombi had a diameter of 0.5 to 1.0 cm, too small for visualization on ultrasonography, computed tomographic vena cavography, or inferior vena cavography. The largest thrombus extracted along with the filter was 2.0 cm in length and 0.8 cm in diameter (Fig. 3). Filters migrated <2 cm in 104 patients (59.8%), and severely ( $\geq 2$  cm) in five patients (2.9%). In these five cases, three filters migrated into the right atrium and two migrated to the orifice of the renal veins; all were retrieved without complications. The



**Figure 3.** Explanted filter with trapped thrombus.

**Table 2.** Clinical characteristics and outcomes of patients with successful filter implantation (n=174)

Age (years)	42.0 (34.0–52.0)
Male gender	127 (73.0)
Duration of filter implantation time (days)	27.0 (25.0–29.0)
Follow-up period (months)	4.0 (3.0–6.0)
Treatment outcome	
Completion	173 (99.4)
Pulmonary embolism during treatment	1 (0.6)
Filter removal	
Removed at first scheduled attempt	154 (88.5)
Large thrombus at first attempt	19 (10.9)
Died	1 (0.6)
Filter migration	
No	65 (37.4)
Mild (< 2 cm)	104 (59.8)
Severe (≥ 2 cm)	5 (2.9)
D-dimer (mg/L)	11.0 (6.7–19.0)

Data are presented as median (interquartile range) or n (%).

most common complication was mild bruising at the surgical site, which resolved after discontinuation of thrombolysis.

The median follow-up period was four months (IQR, 3.0–6.0 months). During follow-up, 52 patients (30.1%) had signs and symptoms suggestive of a PE; however, CTPA was negative in

all cases. One patient experienced a recurrent lower limb DVT and another experienced a symptomatic PE during follow-up. The patient with recurrent DVT was a 28-year-old male whose original DVT was caused by a leg fracture. Following temporary filter placement, orthopedic surgery, and three weeks of postoperative anticoagula-

tion and thrombolytic therapies, the patient's D-dimer level was normal, and repeated ultrasonography revealed no acute thrombus. The filter was removed as scheduled as no large thrombi were detected by lower extremity venogram. The patient was given warfarin prior to discharge, but during the prolonged car ride back home without limb movement for more than 5 hours, he developed swelling of the lower extremities. He returned to the hospital and was diagnosed with a recurrent thrombus accompanied by elevated D-dimer levels. He was instructed to elevate his legs and continue taking warfarin to lower the INR to 2.5. One week later, the swelling had subsided and the D-dimer level had normalized, and no recurrent thrombi were detected at follow-up six months later. Thus, the recurrent DVT was suspected to be due to prolonged lack of movement/activity.

The patient with symptomatic PE was a 32-year-old male who developed an acute DVT after a femoral shaft fracture. The patient's temporary filter placement, orthopedic surgery, and three weeks of postoperative monitoring on anticoagulation and thrombolytic therapies proceeded without incident. The D-dimer level was normal, and lower extremity venogram did not demonstrate trapping of large thrombi. He was discharged after filter retrieval and prescribed warfarin. One week after discharge he suddenly developed chest tightness and respiratory distress. His D-dimer level was elevated (13.44 mg/L), INR was 1.2, and PO<sub>2</sub> was low (60.1 mmHg). CTPA demonstrated a PE, and anticoagulation therapy was administered. Respiratory symptoms resolved, and the warfarin dose was increased until the INR reached 2.5–3. As no symptoms of a recurrent PE had occurred at the one-year follow-up, the PE was suspected to be due to insufficient warfarin, resulting in maintenance INR <2.5.

## Discussion

In this study, the Tempofilter II was successfully implanted in 174 of 176 patients with lower extremity fractures and proximal DVT. In the 174 patients with successful implantation, only one experienced a PE, all filters

were removed successfully regardless of thrombus entrapment, and no filter-related complications occurred. These results suggest that the Tempofilter II is safe and effective in preventing PE in high-risk patients.

The incidence of acute DVT in patients with lower extremity fractures can be as high as 65%, with a mortality of 4%–7% (1, 13, 14). Although VCFs have significantly decreased the occurrence of fatal PE (2, 15, 16), permanent filter insertion is associated with long-term complications such as delayed filter migration, filter fracture, and arteriovenous fistula (7, 8). Becker et al. (7) reported that without anticoagulant treatment, up to 15.3% patients implanted with a filter developed inferior vena cava obstruction, and even with anticoagulation the occlusion rate was 1.7%. Thus, to prevent PE while minimizing risks associated with filter implantation, temporary, selective VCFs are generally recommended in patients with a high, transient risk of PE (4, 7).

While there remains debate regarding the indications for permanent inferior VCF implantation, the introduction of temporary and retrievable filters, and percutaneous implantation techniques has extended the indications for filter implantation. These nonpermanent filters are recommended not only for patients with contraindications to anticoagulation but also patients with iliofemoral venous thrombosis and inferior vena cava thrombosis as well as patients with a high risk of developing a DVT (4, 5). The Eastern Association for the Surgery of Trauma (EAST) guidelines for preventative cava filter implantation indicate that VCFs may be used prophylactically in patients with contraindications to anticoagulation, paraplegia, complicated pelvic fractures, multiple long bone fractures, and those over 45 years of age (17).

Retrievable filters have been shown to reduce the risk of a PE (3), and have a number of advantages over other types of filters. They can be used to prevent a PE in trauma patients during the high-risk period while avoiding the complications of long-term placement (9, 10). If the filter entraps a thrombus, it can be left in place until it resolves (5). Placement and retrieval is generally simpler than with other types of

filters (3, 12). However, the indwelling time for most retrievable filters is relatively short (most recommendations are to remove them within 12 days); thus, the explantation rate is low and many of them become permanent (11). The Tempofilter II is usually left in place for up to six weeks, with a longest reported indwelling time of 80 days (12). The manufacturer indicates that the filter can be left in place for up to three months, and removed without any additional equipment. In most reports, the Tempofilter II is used in trauma patients with a high thrombosis risk and in a prothrombotic state (5).

In the current study, organized thrombi were trapped by the filter in 144 cases (82.8%). This is greater than the rate of 23.5% reported by Bovyn et al. (12). A possible reason for this difference is patient selection; patients in our study were all relatively young with lower limb fractures, whereas the population in their study was more heterogeneous.

Physiologically, a thrombus may organize two to three weeks after formation, at which point the likelihood of a PE due to thrombus embolism while removing the filter is low. Thus, in our study, if the thrombus trapped by the filter was small (<1.5 cm in diameter), it was extracted with the filter at the first retrieval attempt. In the 19 cases (10.9%) in which large filter-associated thrombi partially obstructed the inferior vena cava at the scheduled filter removal time, the filter dwelling times were extended for one to two weeks with supplemental anticoagulant and thrombolytic treatment to allow the thrombus to totally organize and attach to the venous wall. This lowers the possibility of PE resulting from thrombus detachment during the filter removal process. Filters were subsequently successfully removed, and permanent filters were not placed, as no organized thrombi were revealed by venography. Computed tomographic vena cavography indicated that the inferior vena cava was unobstructed in these patients three months later.

Filter migration is one of the most severe complications of VCFs, and migration to the heart or lung, which is sometimes fatal, has been reported (18–20). The reported migration rate

of the VenaTech filter is 7%–19% (21–23), and that of the Greenfield filter is 8%–15% (8, 24). In this study, we monitored filter position by radiography at regular intervals, and 104 (59.8%) of the filters were found to have migrated <2 cm and five (2.9%) migrated  $\geq$  2 cm, including three that migrated into the right atrium and two that migrated to the orifice of the renal veins. These displacement rates are greater than those reported by Bovyn et al. (12), who observed, among a total of 104 inserted filters, upward displacement <6 cm in eight cases, and one case of migration to the right atrium. Given the risk of migration to the orifice of the renal veins, we recommend that VCFs should be deployed at the initial segment of the inferior vena cava to minimize this risk, as a trapped thrombus obstructing the renal veins could cause renal insufficiency. The risk of migration to the right atrium is difficult to reduce, as the indwelling catheter of the Tempofilter II traverses the right atrium, and may move along with the heartbeat.

In our study, we had to stop one filter implantation due to an evoked arrhythmia. Since elderly patients often have cardiac diseases, every precaution should be taken in filter placement because an arrhythmia or other cardiac problem might be triggered by the procedure.

There are some limitations to this study that should be considered. In addition to the retrospective study design, our patient population was homogeneous, so our results may not be generalizable. In addition, given the lack of a control group not implanted with a temporary VCF, we cannot draw conclusions regarding whether filter placement decreases risk of PE. Lastly, the delay in this study of five to seven days from the time of injury to surgery is not common in many countries, though it is not unusual in ours.

In conclusion, the Tempofilter II is safe and may be useful in cases of lower extremity fracture with proximal DVT for the prevention of PE. The filter is easily placed and retrieved, and associated with minimal complications.

#### **Conflict of interest disclosure**

The authors declared no conflicts of interest.

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