J.M. Andreoli, R.J. Lewandowski, R. Ryu; Radiology, Northwestern Memorial Hospital, Chicago, IL

**Purpose:** We aimed to compare the safety of permanent (pIVC) and potentially retrievable (rIVC) inferior vena cava filters by reviewing the U.S. Food and Drug Administration Manufacturer and User Facility Device Experience (MAUDE) database. We hypothesize that self-reported complication rates respectively associated with rIVC and pIVC filters are equivalent.

**Materials and Methods:** The MAUDE database was reviewed from January 1, 2009 to December 31, 2012. Product class search criteria were “filter, intravascular, cardiovascular.” The total number of complications per year and complication type/rates were recorded for pIVC and rIVC devices. Binomial test was used for statistical analysis with rejection of the null hypothesis at p<0.05.

**Results:** 1,606 reported adverse events (AE) involving 1,057 IVC filters were identified. 1,394 (86.8%) AE involved rIVC and 212 (13.2%) involved pIVC (p<0.0001). The number and percentage of each specific AE was higher in rIVC compared to pIVC (see table). The most commonly reported AE varied depending on filter brand: fracture (27.1%) for Bard (Bard Peripheral Vascular, Tempe, AZ) devices, IVC penetration (29.9%) for Celect (Cook Medical, Bloomington, IN), placement difficulties for Optease (Cordis Endovascular, Warren, NJ) (30.8%) and Gunther Tulip (Cook Medical, Bloomington, IN) (45%).

**Conclusion:** MAUDE database review reveals statistically significantly higher complication rate associated with rIVC compared to pIVC filters. Among rIVC filters prevalence of each specific complication varied widely among brands. This study suggests that optional filters are inferior to permanent devices in terms of self-reported, device-associated complications.

### Table: Total, Permanente and Retrieval

<table>
<thead>
<tr>
<th>Type of Complication</th>
<th>Total</th>
<th>Permanent</th>
<th>Retrieval</th>
</tr>
</thead>
<tbody>
<tr>
<td>All complications</td>
<td>1606</td>
<td>212 (13.2%)</td>
<td>1394 (86.8%)</td>
</tr>
<tr>
<td>Fracture</td>
<td>350</td>
<td>16 (4.6%)</td>
<td>334 (95.4%)</td>
</tr>
<tr>
<td>Migration</td>
<td>215</td>
<td>46 (21.4%)</td>
<td>169 (78.6%)</td>
</tr>
<tr>
<td>Limb Embolization</td>
<td>154</td>
<td>4 (2.6%)</td>
<td>150 (97.4%)</td>
</tr>
<tr>
<td>Tilt</td>
<td>197</td>
<td>3 (1.5%)</td>
<td>194 (98.5%)</td>
</tr>
<tr>
<td>IVC Penetration</td>
<td>228</td>
<td>14 (6.1%)</td>
<td>214 (93.9%)</td>
</tr>
<tr>
<td>VTE/PE</td>
<td>30</td>
<td>8 (26.7%)</td>
<td>22 (73.3%)</td>
</tr>
<tr>
<td>IVC Thrombus</td>
<td>41</td>
<td>8 (19.5%)</td>
<td>33 (80.5%)</td>
</tr>
<tr>
<td>Placement Issue</td>
<td>318</td>
<td>99 (31.1%)</td>
<td>219 (68.9%)</td>
</tr>
<tr>
<td>Other</td>
<td>73</td>
<td>14 (19.2%)</td>
<td>59 (80.8%)</td>
</tr>
</tbody>
</table>

1:39 PM Abstract No. 176

Optional vena cava filter placement and 3 months retrievability: results of the PREPIC 2 randomized multicenter trial

O. Pellerin1,2, F. Barral3, O. Sanchez3,4, M. Midulla4, G. Meyer5,6, P. Mismetti4, M. Sapoval1,2; 1Interventional Radiology Dpt., Georges Pompidou European Hospital Assistance Public – Hôpitaux de Paris, Paris, France; 2Medical University, René Descartes Sorbonne Paris Cite, Paris, France; 3Neuroradiology Dpt., Université Jean Monet Saint Etienne, Faculté de Médecine. Centre hospitalier Universitaire de Sainte Etienne., Saint Etienne, France; 4Medicine & Therapeutic Dpt., Université Jean Monet Saint Etienne, Faculté de Médecine. Centre hospitalier Universitaire de Sainte Etienne., Saint Etienne, France; 5Pneumology Dpt., Georges Pompidou European Hospital Assistance Public – Hôpitaux de Paris, Paris, France; 6Cardiovascular Radiology Dpt., Université de Lille Centre Hospitalier Régional Universitaire de Lille., Lille, France

**Purpose:** To report the implantation and retrieval vena cava filter success rate of the ALN filter in a the setting of a prospective randomized trial (PREPIC 2) trial filter subgroup.

**Materials and Methods:** Prep2 is a prospective open randomized study with a blind evaluation that compared retrievable ALN vena cava filter (ALN Implant Chirurgicaux) maintained for 3 months with no filter insertion in patients receiving anticoagulant therapy for acute symptomatic pulmonary embolism (PE) associated to deep vein thrombosis. The filter retrieval was systematically scheduled at 3 months. The primary goal of this ancillary study is to report the technical success rate of filter implantation and removal. The secondary goal is to report filter related complications.

**Results:** Between 08-2006 and 07-2012; 399 patients (median 76 years) with acute PE and no contradiction to anticoagulation therapy were enrolled. 193 patients received an ALN filter after randomization in the filter arm in addition to anticoagulation therapy, using femoral (162) basilic (15) or jugular vein (16), access. Filter wasn’t implanted because of 2 (1%) technical failure; 3 (1.5%) non confirmation of PE diagnosis after randomization; and 2 (1%) patients’ death before implantation. post implantation cavogram showed >15° tilting in 19 (9.8%) cases. Minor complications were observed in 20 cases (11.9%): 4 (2%) <20 mm migration; 10 (5.2%) >3 mm filters struts penetration outside the cava and 3 (1.6%) puncture site hematoma; 5 (2.6%) tilt increase were reported. Among the 166 (92.2%) patients who were referred for extraction after 3 months (93 days [89-98]), retrieval was successfully performed in 92.2% (153). 3 (1.8%) asymptomatic filter thrombosis were observed. Failure of extraction was observed in 13 (7.8%) case, because of >15° tilt (n=9, 5.4%) or non removable fibrotic bridge to IVC n=4/2.4%. Filter removal was successfully performed in an median of 20 min [15-40].

**Conclusion:** The ALN filter was successfully extracted in 92.2% in this multicenter experience with a little complication rate.

1:48 PM Abstract No. 177

Development of radiopaque resorbable medical device

B. Singhana1,2, A. Chen3, P. Slattery4, I.K. Yazdi5, K. Maldonado1, E. Tasciotti6, M.J. Wallace1, M. Eggers7, S.Y. Huang1, M.P. Melancon1,8, 1Interventional Radiology, The University of Texas MD Anderson Cancer Center, Houston, TX; 2The Faculty of Liberal Arts and Sciences, Nakhon Phanom University, Nakhon Phanom,
Thailand; 3Medical School, The University of Texas - Houston, TX; 4College of Medicine, Northeast Ohio Medical University, Youngstown, OH; 5The Methodist Hospital Research Institute, Houston, TX; 6Imaging Physics, The University of Texas MD Anderson Cancer Center, Houston, TX; 7Adient Medical Device, Houston, TX; 8Graduate School of Biomedical Science, The University of Texas – Health, Houston, TX

Purpose: Resorbable filter device could provide the critical protection against pulmonary embolism through the period of highest risk after major surgery or trauma, while avoiding the long-term disadvantages of currently available filtration devices. However, monitoring the integrity of these absorbable devices poses a challenge because of their inability to image using conventional imaging techniques, such as computed tomography (CT) and x-ray. Therefore, in this study, poly(p-dioxanone) [PPDO], a biodegradable polymer used as a filter device, is made radiopaque by coating with iodine-based contrast agents, 4-iodobenzoyl chloride (IBC) and 2,3,5-triiodobenzoxyacid (TIBA).

Materials and Methods: Coated PPDO was obtained by incubating PPDO in different concentrations of IBC and TIBA using 100% dichloromethane (DCM) and 5-10% (v/v) DMSO (dimethyl sulfoxide)–DCM solvents at room temperature. After 24 h, PPDO was dried, washed with ethyl acetate, and dried under vacuum. Characterization was done using CT, X-ray, scanning electron microscopy (SEM), and differential scanning calorimetry (DSC). Phantom CT imaging was also performed by incorporating the PPDO with and without coating on chicken breast.

Results: Results show that 5-10% (v/v) of DMSO-DCM is the best solvent system to completely dissolve the iodine-based agents compared to 100% DCM. CT and X-ray images of the coated PPDO clearly showed signal enhancement compared to uncoated PPDO. Calculation of the CT Hounsfield unit (HU) gave 290 ± H11006 for IBC and 313 ± 2 for TIBA. Coated PPDO with IBC and TIBA showed higher HU values than bone (115 ± 2). Phantom imaging validated the signal enhancement with coated PDO as compared to bare PPDO. Furthermore, SEM analysis depicted that the morphology of the PPDO surface does not change after coating.

Conclusion: The significant increase in signal intensity with coated PDO as compared to bare PDO using x-ray and CT imaging shows its major advantage as a radiopaque resorbable filter. The radiopacity allows for monitoring the position and integrity of the filter while in place, therefore increasing its safety and efficacy as a medical device.

Purpose: To investigate complications and effectiveness of routine and advanced inferior vena cava (IVC) filter retrieval techniques.

Materials and Methods: A retrospective review was performed of patients who underwent IVC filter placement and/or retrieval attempt over a 10 year period. Patient demographics, retrieval technique(s), pre-retrieval computed tomography, pre-retrieval venography, and clinical/imaging follow-up for 30 days post-retrieval were analyzed.

Results: A total of 1060 retrievable IVC filter placements were reviewed. There were 231 filter retrieval attempts included in our analysis, with success rates of 73.2% (169/231) and 94.7% (54/57) for routine and advanced filter retrieval techniques, respectively. In 227 cases with routine and advanced techniques utilized sequentially, the success rate of filter retrieval was 98.2% (223/227). Overall filter retrieval complication rate was 1.7% (4/231); complications in 4 patients (with multiple complications in some cases) included IVC dissection, IVC intussusception, IVC thrombus/stenosis, filter fracture with embedded strut, IVC injury with hemorrhage, and vascular injury from complicated venous access. The rate of complication associated with advanced technique was significantly higher compared to routine technique (5.3% vs. 0.4%). Longer dwell time, more transverse tilt, and presence of embedded hook were associated with significantly increased rates of failed routine retrieval technique. There was no significant difference in success or complication rates associated with various utilized advanced retrieval techniques including wire loop and snare, endobronchial/endomyocardial forces, balloon displacement, loop snare, and tilted-filter straightening techniques. The Gunther Tulip filter (Cook Inc, Bloomington, In) was associated with significantly lower rates of failed routine technique and embedded hook compared to other retrievable filter types.

Conclusion: IVC filter retrieval techniques are highly effective with a low complication rate; however, advanced filter retrieval techniques are associated with a significantly higher complication rate compared to routine technique.

Strut perforation over time for the celect vena cava filter

J. Castle, K. Andersson, X. Yang, G. Guy, J.D. Dowell; The Ohio State University Wexner Medical Center, Columbus, OH

Purpose: Evaluate the perforation rate for the Celect IVC filter in our study population and its relationship to progressive strut perforation.

Materials and Methods: Retrospective, IRB-approved review of 91 patients with at least 3 computed tomography (CT) studies after infrarenal placement of a Celect IVC filter at our institution between 1/1/2007 and 6/1/2013. Filter strut perforation and the number of struts (primary and secondary) perforating the IVC (strut > 3 mm outside caval wall) were evaluated on each of the 3 follow-up CT studies by two independent radiologists (Kappa statistics). The patients were then split into three groups based on the presence of strut perforation and if additional struts perforated over time. Perforation rates in different gender and malignancy status groups were compared (Z-test).