
# VISCERAL ARTERIES AND AORTOILIAC ARTERIES

## *THE USE OF COVERED STENT IN VISCERAL AND AORTOILIAC INJURIES*

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**Disclosure**

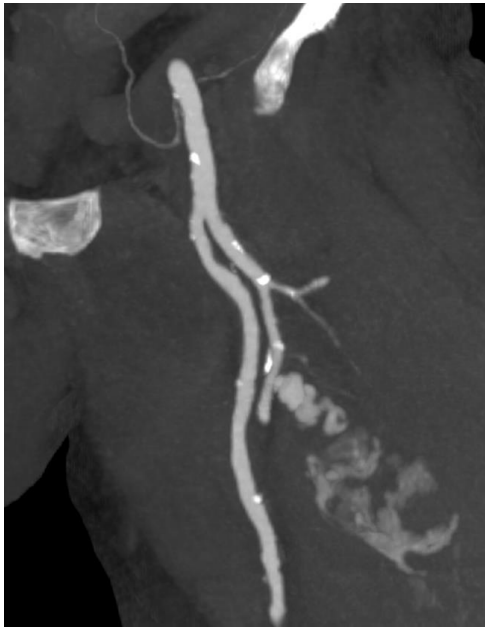
Speaker name:

Maria Antonella Ruffino

I have the following potential conflicts of interest to report:

- ☐ Consulting
- ☐ Employment in industry
- ☐ Shareholder in a healthcare company
- ☐ Owner of a healthcare company
- ☐ Other(s)
- ☒ I do not have any potential conflict of interest

Vessel injuries (spontaneous bleeding, inflammatory vessel erosion and pseudoaneurysm, iatrogenic or post-traumatic rupture, perforation and dissection) can occur in a vast array of arterial and venous  beds and represent life-threating conditions



Endovascular therapy (embolization with coils, plugs, liquid embolic agents and implantation of covered stent) has become a therapeutic option for treating arterial injuries providing a minimally invasive and effective alternative to surgery

In the last decades, stent grafts have been increasingly used in vessel injuries

*ADVANTAGES OVER COIL EMBOLIZATION*

- Low morbidity compared to embolization or surgery in appropriate candidates, mainly thank to preserved perfusion
- Rapid and effective exclusion of the lesion/defect avoiding the risk of re-bleeding
- No risk of non-target embolization

*LIMITS*

- Large sheath
- Poor trackability and conformability
- The implantation of a covered stent usually is limited by anatomic suitability

# COVERED STENT FOR VASCULAR INJURIES

Cardiovasc Intervent Radiol (2012) 35:472–482
DOI 10.1007/s00270-012-0339-7

INVITED SUBMISSION: CIRSE STANDARDS OF PRACTICE GUIDELINES

## CIRSE Guidelines: Quality Improvement Guidelines for Endovascular Treatment of Traumatic Hemorrhage

**Sam Chakraverty · Karen Flood · David Kessel · Simon McPherson · Tony Nicholson · Charles E. Ray Jr. · Iain Robertson · Otto M. van Delden**

**Appendix 2**

Outline indicating how decision making might be influenced by nature of injuries

| Site | Nonoperative management | Interventional radiology | Damage control surgery |
|---|---|---|---|
| Thoracic aorta | No role except in small partial thickness tears (4, C) | Stent graft for suitable lesions (2, B) | Ascending aortic injury or arch injury involving great vessels (4, C) |
| Abdominal aorta | No role | Occlusion balloon, stent graft for suitable lesions (4, C) | Injury requiring visceral revascularization or untreatable by endovascular therapy (4, C) |
| Peripheral or branch artery | No role | Occlusion balloon, stent, stent graft or embolization (4, C) | Any lesion that cannot rapidly be controlled or that will require other revascularization (4, C) |
| Kidney | Subcapsular or retroperitoneal hematoma without active arterial bleeding (3, C) | Active arterial bleeding, embolization or stent graft (4, C); arterial occlusion < 6 h, stent/stent graft | Renal injury in association with multiple other bleeding sites, or other injuries requiring urgent surgical repair |
| Spleen | Lacerations, hematoma without active bleeding, evidence of false aneurysm (3, C) | Active arterial bleeding or false aneurysm; focal embolization for focal lesion; proximal embolization for diffuse injury (3, C) | Packing or splenectomy for active bleeding in association with multiple other bleeding sites |
| Liver | Subcapsular or intraperitoneal hematoma, lacerations without active arterial bleeding (3, C) | Active focal arterial bleeding; focal embolization if possible; nonselective embolization if multiple bleeding sites as long as portal vein patent (3, C) | Packing if emergency laparotomy is needed, with subsequent repeat CT and embolization if required |
| Pelvis | Minor injury with no active bleeding | Focal embolization for arterial injury (bleeding, false aneurysm or cutoff) (3, C) | External compression and subsequent fixation if bleeding from veins or bones |
| Intestine | Focal contusion with no evidence of ischemia, perforation, or hemorrhage (3, C) | Focal bleeding with no evidence of ischemia or perforation, or to stabilize the patient, allowing interval laparotomy pending treatment of other injuries (4, D) | Ischemia or perforation requiring laparotomy with or without bowel resection |

The patient's clinical condition will also affect decision making. Level of evidence: 1, 2, 3, 4, 5; grade of recommendation: A, B, C, D

## ANATOMIC SUITABILITY:

- Proximal artery lesions
- Adequate proximal and distal neck
- 5- to 10-mm length of artery before and after the lesion without arterial division
- Adequate caliber
- Vessel path allowing for safe catheter navigation

Data reported in literature about their employment in the treatment of arterial injuries are limited to small series or case reports

CLINICAL STUDY

# The Use of Balloon-expandable Stent Grafts for the Management of Acute Arterial Bleeding

Ulrike Stampfl, MD, Christof-Matthias Sommer, MD, Nadine Bellemann, MD, Jürgen Weitz, MD, PhD, Dittmar Böckler, MD, PhD, Götz Martin Richter, MD, PhD, Hans-Ulrich Kauczor, MD, PhD, and Boris Radeleff, MD, PhD

*J Vasc Interv Radiol 2012; 23:331–337*

Injury, Int. J. Care Injured (2008) **39**, 1295–1303

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INJURY

INTERNATIONAL JOURNAL OF THE CARE OF THE INJURED

www.elsevier.com/locate/injury

# Emergency stent graft implantation for ruptured visceral artery pseudoaneurysm

Mourad Boufi, MD,[a] Hicham Belmir, MD,[a] Olivier Hartung, MD,[a] Olivier Ramis, MD,[b] Laura Beyer, MD,[c] and Yves S. Alimi, PhD,[a] *Marseille, France*

(J Vasc Surg 2011;53:1625-31.)

# Extremities—Indications and techniques for treatment of extremity vascular injuries

**O. Doody*, M.F. Given, S.M. Lyon**

*Department of Radiology, The Alfred Hospital, Commercial Road, Melbourne 3004, Australia*

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Cardiovasc Intervent Radiol (2007) 30:523–525
DOI: 10.1007/s00270-006-0089-5

# Treatment of a Hepatic Artery Aneurysm by Endovascular Stent-Grafting

Guttorm L. Jenssen,[1] Jan Wirsching,[1] Gustav Pedersen,[2] Svein Roar Amundsen,[2] Steinar Aune,[2] Einar Dregelid,[2] Torbjørn Jonung,[2] Alireza Daryapeyma,[2] Elin Laxdal[2]

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[3]Institute of Surgical Sciences, University of Bergen, Bergen, Norway

Cardiovascular Revascularization Medicine 16 (2015) 156–162

Contents lists available at ScienceDirect

Cardiovascular Revascularization Medicine

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# Covered stents for endovascular repair of iatrogenic injuries of iliac and femoral arteries☆

Sebastian Kufner [a,*], Salvatore Cassese [a], Philipp Groha [a], Robert A. Byrne [a], Heribert Schunkert [a,b], Adnan Kastrati [a,b], Ilka Ott [a], Massimiliano Fusaro [a]

[a] *Deutsches Herzzentrum München, Technische Universität München, Munich, Germany*
[b] *DZHK (German Centre for Cardiovascular Research), Partner Site Munich Heart Alliance, Munich, Germany*

ELMER PRESS

Case Report

Cardiol Res. 2017;8(5):246-253

# Successful Treatment of Iatrogenic External Iliac Artery Perforation With Covered Stent: Case Report and Review of the Literature

Muhammad Umer Awan[a], Bassam Omar[a, b], Ghazanfar Qureshi[a], Ghulam Mustafa Awan[a]

# CURRENT AVAILABLE COVERED STENTS

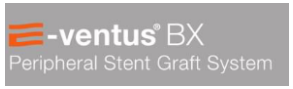
## Self-expandable stent grafts





## Balloon-expandable stent grafts








LIFESTREAM™
Balloon Expandable Vascular Covered Stent

BARD PERIPHERAL VASCULAR


## COMPARISON OF ATTRIBUTES

| Attribute | SX | BX |
|---|---|---|
| Radial strength / recoil resistance | - | + |
| Conformability / flexibility | + | - |
| Diameter adjustment | - | + |
| Deployment accuracy | - | + |
| Compression recovery | + | - |

***The ideal peripheral stent-graft does not exist***
(and probably will never come)
but **the needs for the most perfect one:**

- Low profile device (all sizes in 6 Fr sheath)
- Good flexibility
- High radial force
- High conformability after deployment
- Easy navigation
- Good stent retention during navigation/stenosis negotiation
- No need of protected (by the vascular sheath) deployment
- Precise deployment
- Possible tapering
- Good overdistension with minimal foreshortening

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# *PERSONAL EXPERIENCE*

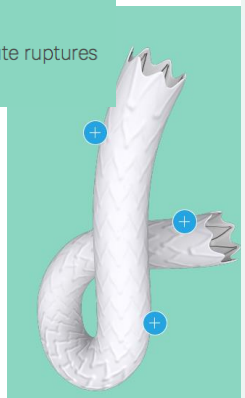
In June 2015 we started to implant the BeGraft Peripheral Stent Graft System, Bentley, Hechingen, Germany, (and the BeGraft Coronary Stent Graft in case of small vessel size (<5 mm) in patients with visceral and peripheral vessels injuries.

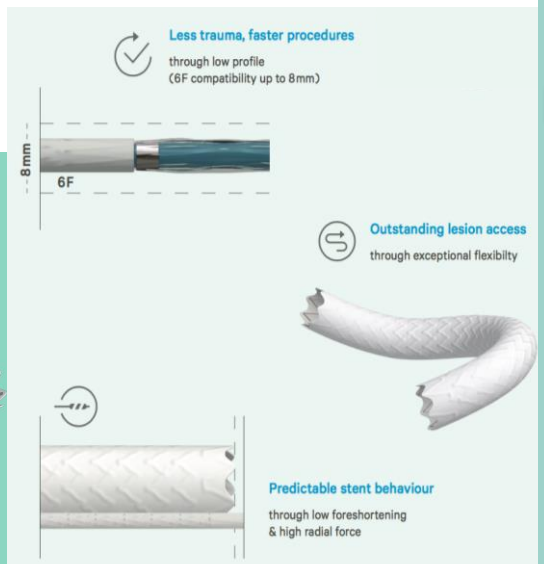
Bentley

**BeGraft**
peripheral

The BeGraft Peripheral Stent Graft System is indicated for intraluminal chronic placement in iliac and renal arteries for:

- Restoring and improving the patency
- Treating aneurysms, acute perforations, acute ruptures and fistulas






| | |
|---|---|
| Graft Material | Micro-porous ePTFE tubing (203 ± 25µm) |
| Stent Material (Composition) | CoCr (L605) |
| Stent Graft Design | Single Stent |
| Strut Dimensions (Width x Thickness) | 0.135 x 0.145 mm (SV)<br>0.145 x 0.145 mm (MV)<br>0.165 x 0.145 mm (LV) |
| Delivery System | OTW |
| Introducer Sheath Compatibility | 6F up to Ø 8 x 57 mm<br>7F |
| Guide Wire | 0.035" |
| Shaft Size | 5F |
| Balloon Marker Material | Platinum / Iridium |
| Nominal Pressure | 9 bar Ø 5.0 - 7.0 mm<br>8 bar Ø 8.0 - 10.0 mm |
| Rated Burst Pressure | 13 bar Ø 5.0 - 7.0 mm<br>12 bar Ø 8.0 - 10.0 mm |
| Catheter Shaft Length | 75 cm and 120 cm |
| Expanded Stent Graft Diameter | 5.0, 6.0 mm (SV)<br>7.0, 8.0 mm (MV)<br>9.0, 10.0 mm (LV) |
| Nominal Stent Graft Length | 18, 22, 28, 38, 58 mm (SV)<br>18, 23, 27, 37, 57 mm (MV)<br>27, 37, 57 mm (LV) |
| Shelf Life | up to 3 years |

Peripheral Stent Graft System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# *DEVICE OVERVIEW*

| Expanded Stent Graft Diameter | Nominal Stent Graft Length | Introducer Sheath Size | Catalogue Number for Catheter Length | |
|---|---|---|---|---|
| | | | 75 cm | 120 cm |
| 5 mm | 18 mm | 6 F | BGP1805_1 | BGP1805_2 |
| | 22 mm | | BGP2205_1 | BGP2205_2 |
| | 28 mm | | BGP2805_1 | BGP2805_2 |
| | 38 mm | | BGP3805_1 | BGP3805_2 |
| | 58 mm | | BGP5805_1 | BGP5805_2 |
| 6 mm | 18 mm | 6 F | BGP1806_1 | BGP1806_2 |
| | 22 mm | | BGP2206_1 | BGP2206_2 |
| | 28 mm | | BGP2806_1 | BGP2806_2 |
| | 38 mm | | BGP3806_1 | BGP3806_2 |
| | 58 mm | | BGP5806_1 | BGP5806_2 |
| 7 mm | 18 mm | 6 F | BGP1807_1 | BGP1807_2 |
| | 23 mm | | BGP2307_1 | BGP2307_2 |
| | 27 mm | | BGP2707_1 | BGP2707_2 |
| | 37 mm | | BGP3707_1 | BGP3707_2 |
| | 57 mm | | BGP5707_1 | BGP5707_2 |
| 8 mm | 27 mm | 6 F | BGP2708_1 | BGP2708_2 |
| | 37 mm | | BGP3708_1 | BGP3708_2 |
| | 57 mm | | BGP5708_1 | BGP5708_2 |
| 9 mm | 27 mm | 7 F | BGP2709_1 | BGP2709_2 |
| | 37 mm | | BGP3709_1 | BGP3709_2 |
| | 57 mm | | BGP5709_1 | BGP5709_2 |
| 10 mm | 27 mm | 7 F | BGP2710_1 | BGP2710_2 |
| | 37 mm | | BGP3710_1 | BGP3710_2 |
| | 57 mm | | BGP5710_1 | BGP5710_2 |

**6 Fr up to 8 mm ⊘**

Bentley

BeGraft peripheral

## Compliance Chart

| Inflation Pressure [bar] | Stent Outer Diameter [mm] | | | | | |
|---|---|---|---|---|---|---|
| | Ø 5.0 | Ø 6.0 | Ø 7.0 | Ø 8.0 | Ø 9.0 | Ø 10.0 |
| 8 | | | | 8.0 | 9.0 | 10.0 |
| 9 | 5.0 | 6.0 | 7.0 | 8.3 | 9.2 | 10.2 |
| 10 | 5.2 | 6.2 | 7.2 | 8.5 | 9.4 | 10.4 |
| 11 | 5.3 | 6.4 | 7.3 | 8.7 | 9.6 | 10.6 |
| 12 | 54 | 6.5 | 7.5 | 8.8 | 9.7 | 10.7 |
| 13 | 5.5 | 6.6 | 7.6 | | | |

**Almost 10% overdistention close to RBP**

NP Nominal Pressure

RBP Rated Burst Pressure

# *RETROSPECTIVE ANALYSIS*

A retrospective analysis of all the data of the treated patients was performed.

Informed consent was obtained from patients who were deemed to be able to provide consent at the time of the procedure

## *PRIMARY ENDPOINTS*

- To evaluate the efficacy of the Begraft peripheral stent-graft intended as technical success in excluding the vessel lesion/defect
- To evaluate the safety of the device in terms of peri-procedural (minor and major) complications related to the device, 30-day clinical success, recurrence of the lesion

## *SECONDARY ENDPOINT*

- To determine the patency of the device during the follow up

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**June 2015 and September 2017**

**41 patients** (age 66.14±14 y, 24 males)

15/41 (36.6%) patients were haemodinamically unstable

*LESIONS*

| | | |
|---|---|---|
| - Active bleeding | 17 pts. | (41.5%) |
| - Dissection | 16 pts. | (39%) |
| - Pseudonaeurysm | 6 pts. | (14.6%) |
| - AVF | 1 pt. | (2.4%) |
| - Enteric-iliac fistula | 1 pt. | (2.4%) |

All patients, except for unstable or bleeding patients with coagulation disorder, received anticoagulation protocol of a bolus of 2500 <UI of heparin at the beginning of the procedure

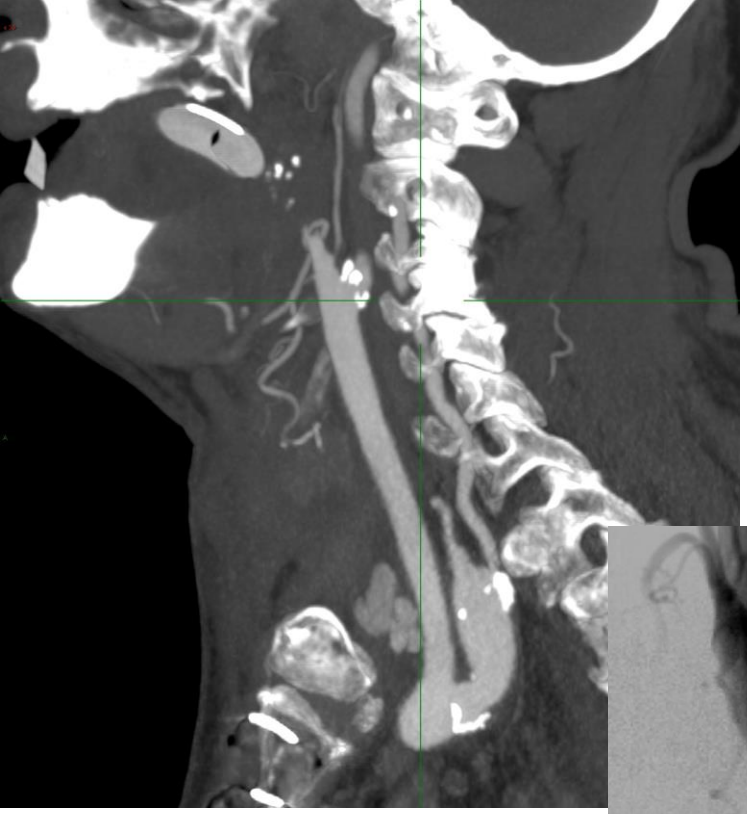
ACT was kept within the 275-300 sec range with folowing injection of 1000 UI of heparin/hour with anticoagulation time control

A broad-spectrum antibiotic therapy was administered only in case of suspected infection

*LESION LOCATION*

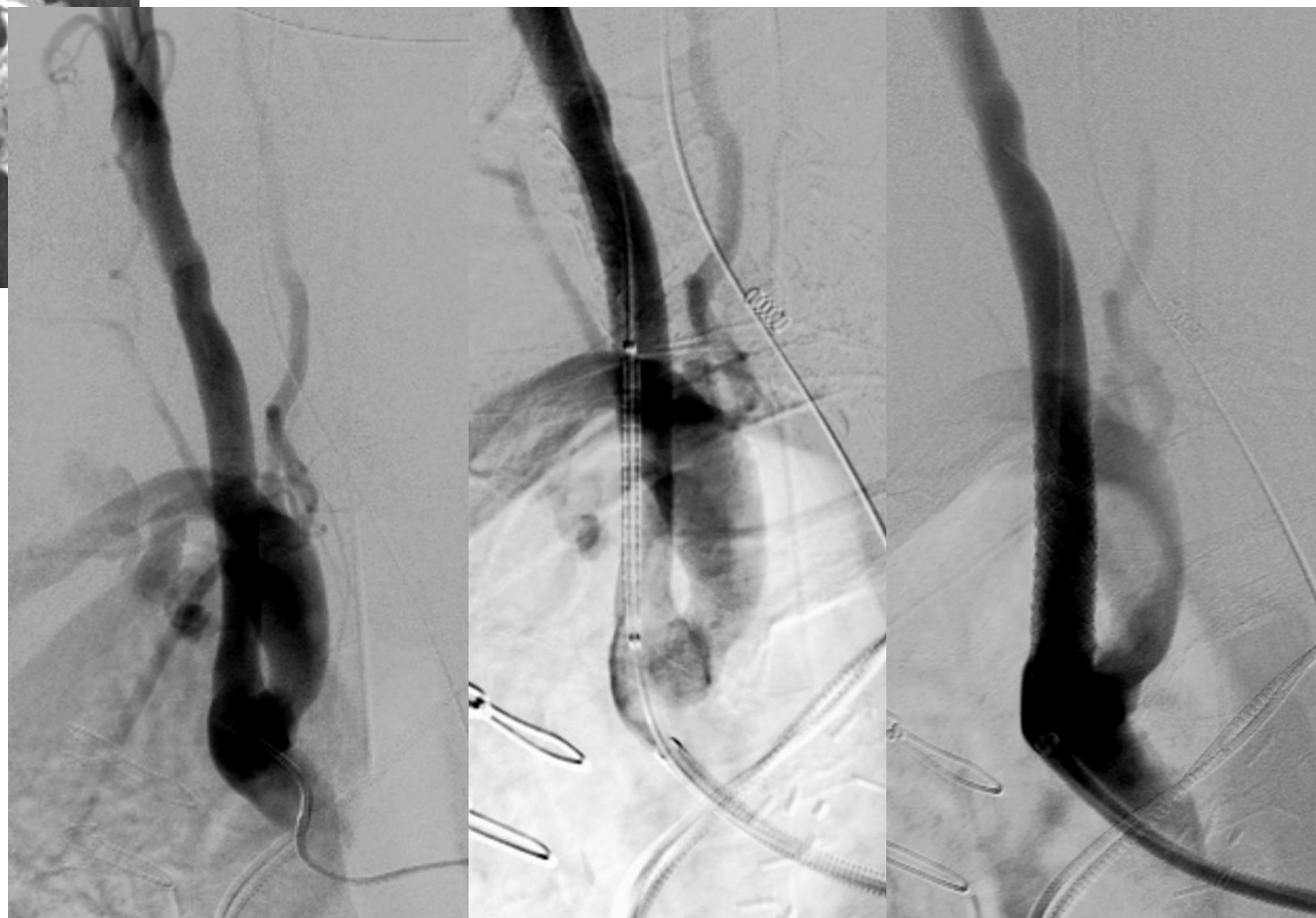
| | |
|---|---|
| - brachiocephalic a. | 1 |
| - common carotid a. | 2 |
| - common iliac a. | 19 |
| - external iliac a. | 6 |
| - superficial femoral a. | 4 |
| - tibial a. | 1 |
| - aorto-renal bypass | 1 |
| - fem-fem left-to-right bypass | 1 |
| - celiac trunk | 2 |
| - hepatic a. | 3 |
| - innominate vein | 1 |

After the procedure, a DAT was administred (clopidogrel 75 mg and aspirin 100 mg daily) for 3 months followed by aspirin (100 mg daily) to be used for the lifetime thereafter

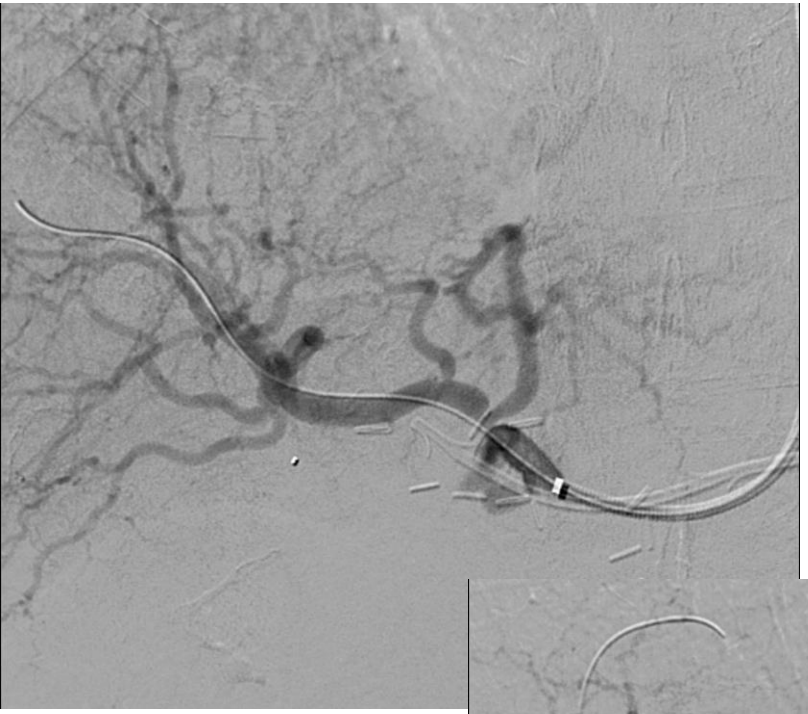


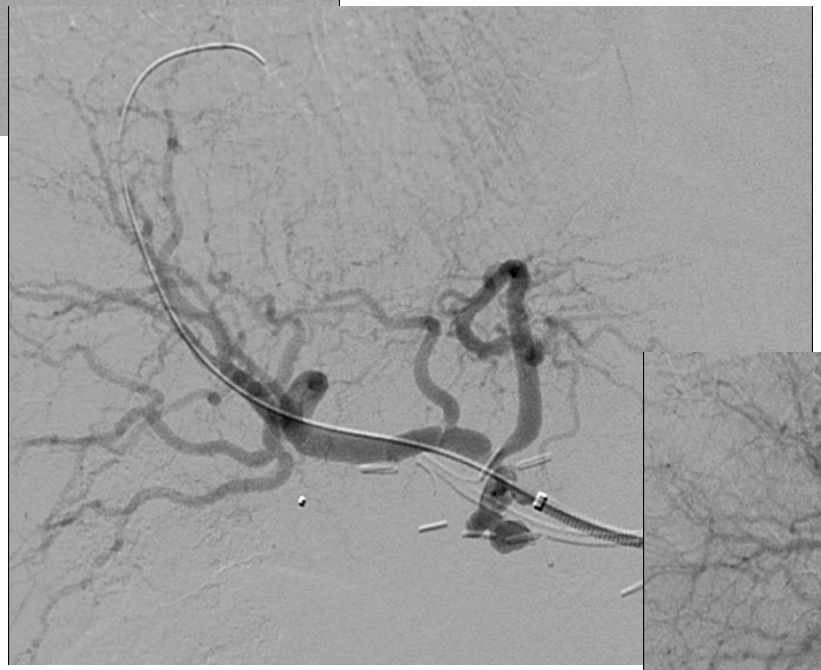
RIGHT FEMORAL ARTERY ACCESS

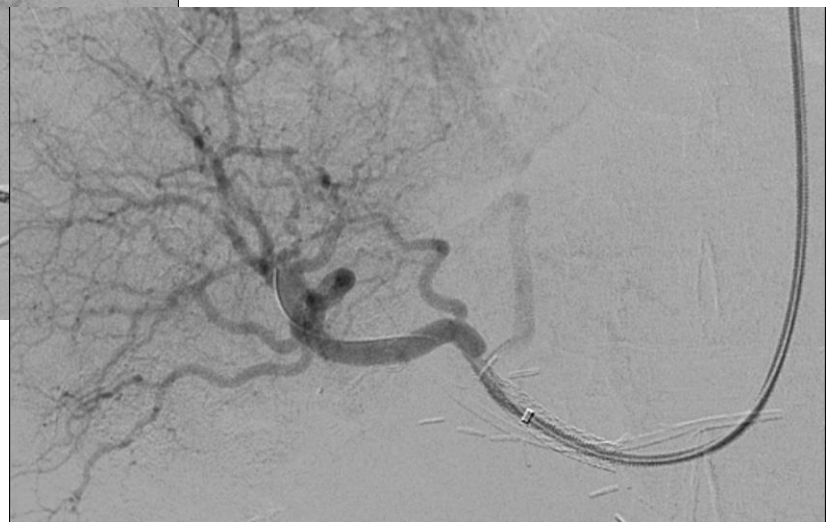
- 6-F, 90 cm sheath (Neuron™ MAX088, Penumbra)
- 6F Select™ Catheter, 125 SIM, Penumbra
- Radifocus® Guidewire M Standard Type, Terumo
- **BeGraft Peripheral, Bentley, 10-mm x 37 mm/120 cm length**



POST- TRAUMATIC COMMON CAROTID A. RUPTURE





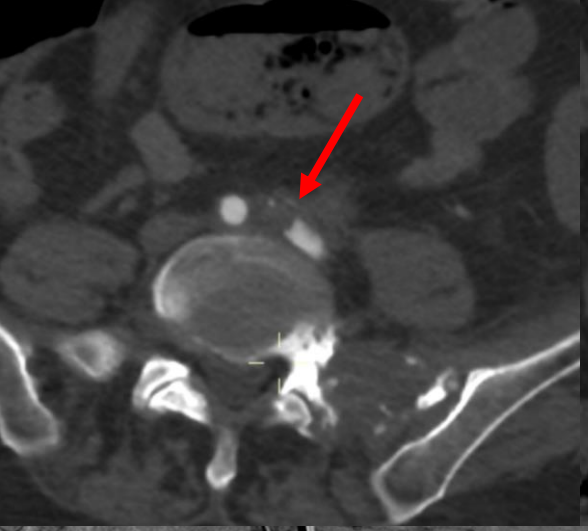


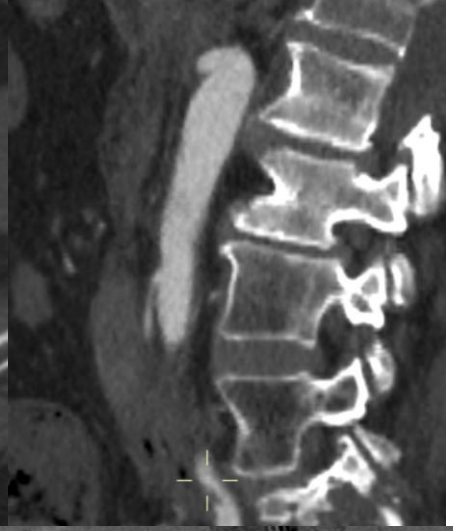
LEFT BRACHIAL ARTERY ACCESS

- Radifocus® Introducer Sheath 5-F, 11 cm, Terumo
- Radifocus® Guidewire M Standard Type, Terumo
- Tempo® Multipurpose 5-F, 100 cm, Cordis

- 6-F, 80 cm sheath (Flexor® Shuttle® Guiding Sheath, Cook Medical)
- Radifocus® Guidewire M Standard Type, Terumo
- **BeGraft Peripheral, Bentley, 7-mm x 57-mm/120 cm length**

# HEPATIC ARTERY BLEEDING AFTER PANCREATIC SURGERY

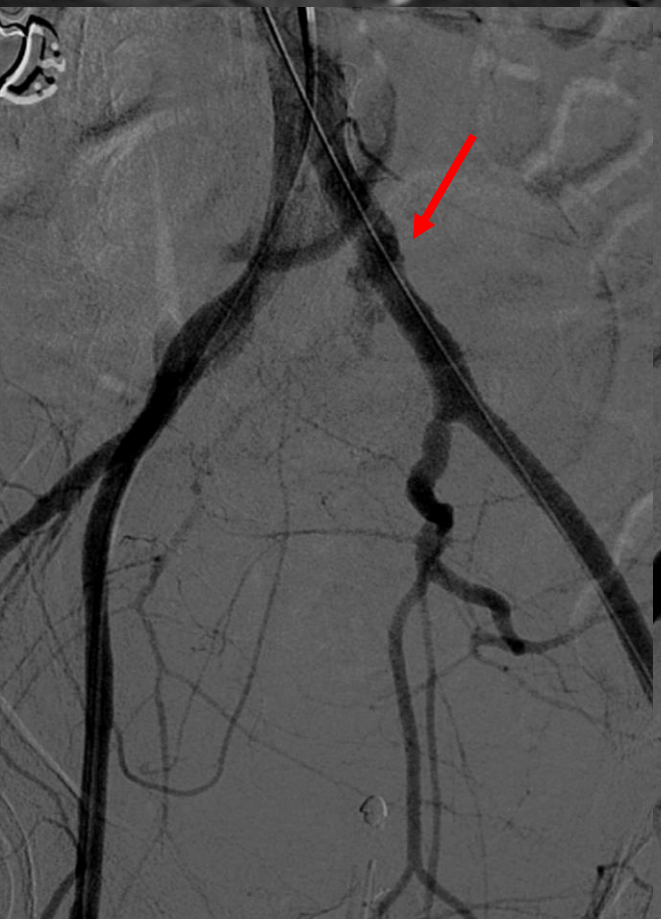


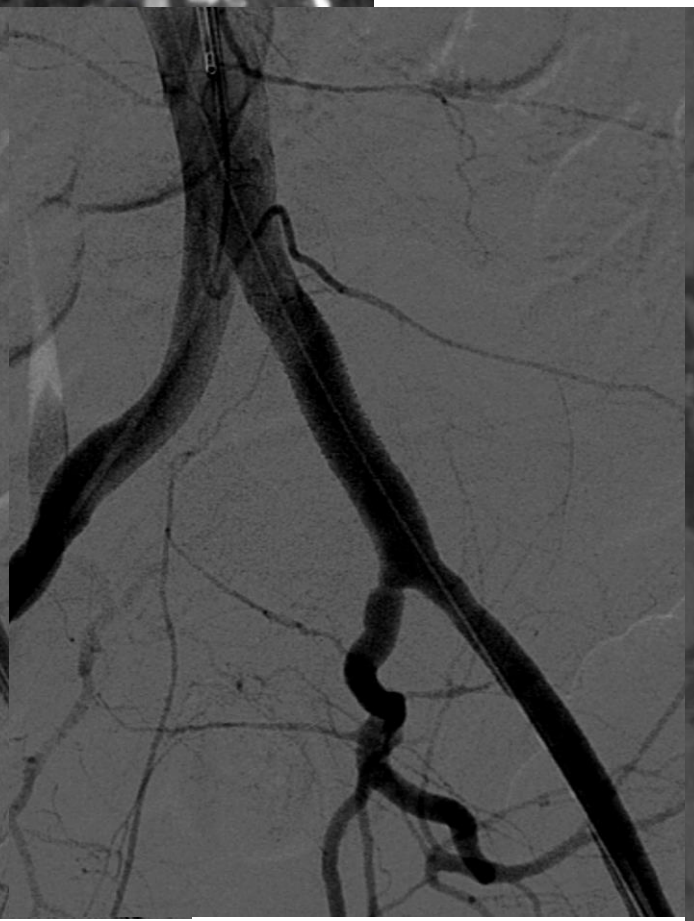


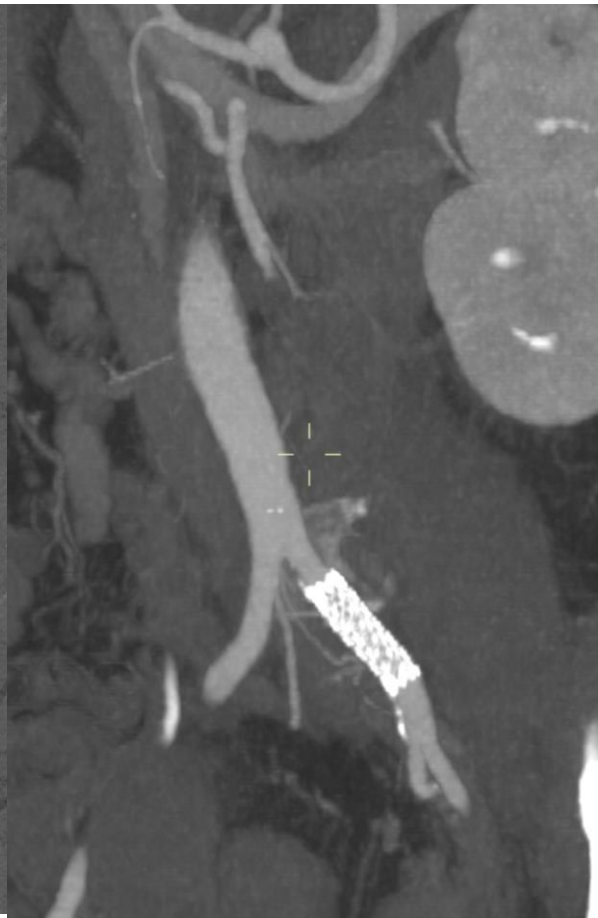
# ENTERIC-ILIAC FISTULA

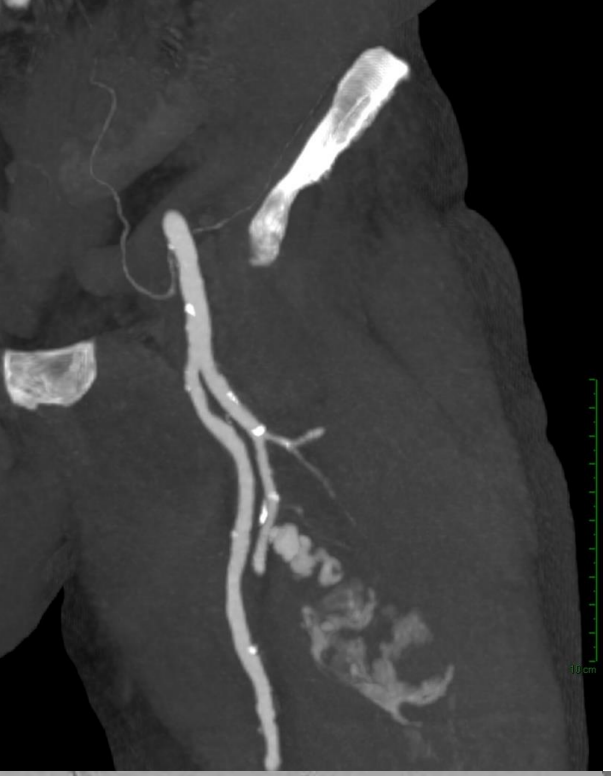
LEFT FEMORAL ARTERY ACCESS

- Radifocus® Introducer Sheath 7-F, 11 cm, Terumo
- Radifocus® Guidewire M Standard Type, Terumo
- **BeGraft Peripheral, Bentley, 10-mm x 37-mm/75 cm length**





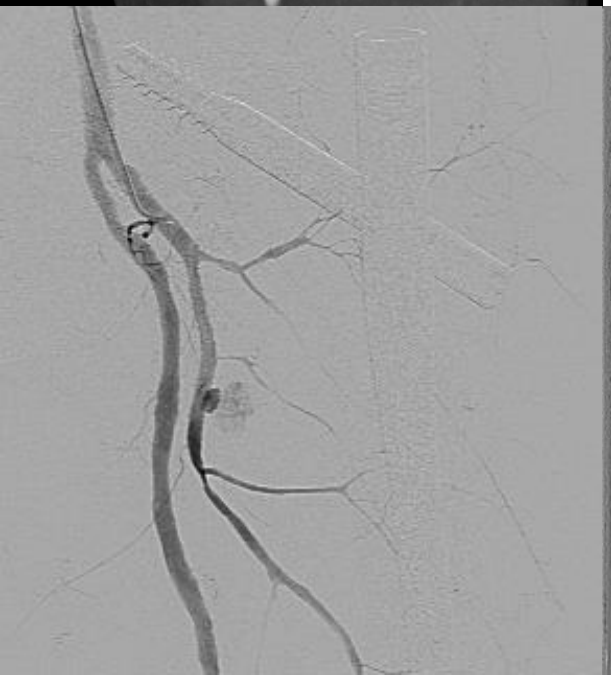


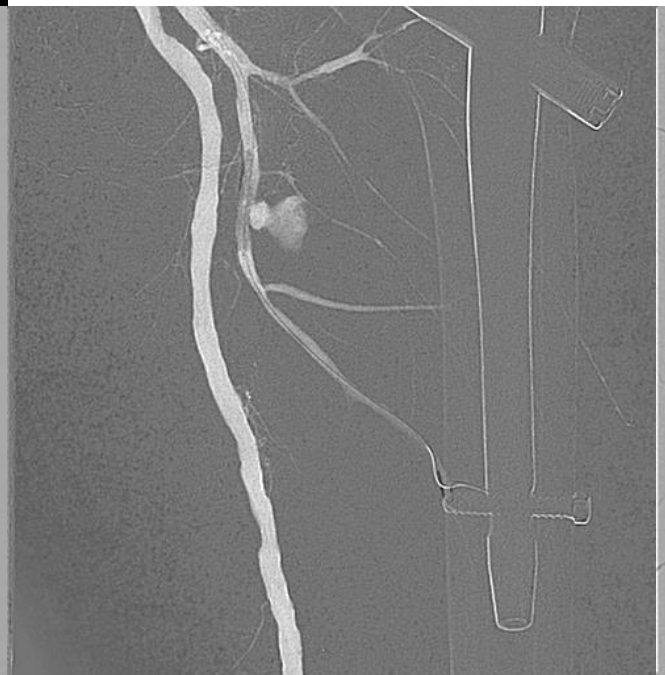


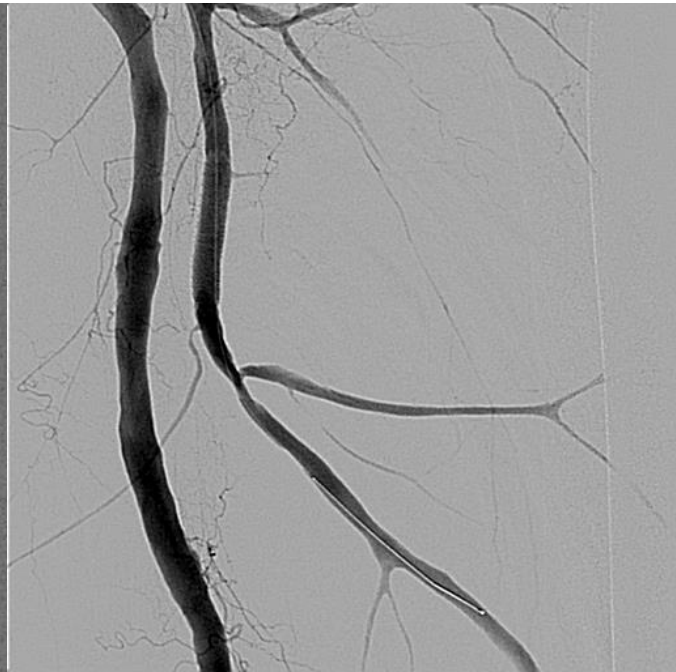
# PROFUNDA FEMORAL ARTERY BLEEDING AFTER TOTAL HIP REPLACEMENT

RIGHT FEMORAL ARTERY ACCESS

- 6-F, 45 cm sheath (Flexor® Shuttle® Guiding Sheath, Cook Medical)
- V-14™ Controlwire™ guidewire, Boston Scientific
- **BeGraft Coronary, Bentley, 3.5-mm x 21-mm inflated up to 4.5 mm**







# *RESULTS*

TECHNICAL SUCCESS: 41/41 patients (46 stent-grafts)

- 5 pts. required 2 overlapped stent-grafts either positioned during the same procedure
- in 2 cases due to the small diameter of the vessels (a tib. a. and an hepatic a.), a BeGraft Coronary stent-graft was implanted

CLINICAL SUCCESS: 40/41 patients (97.6%)

- one new bleeding form another branch of an hepatic a. was observed 36 days after the first treatment, due to the progression of acute pancreatitis (embolization with coils)

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# *RESULTS*

| | | |
|---|---|---|
| MAJOR COMPLICATIONS: | 1 exitus (not related to the procedure) | (2.4%) |
| MINOR COMPLICATIONS: | 1 CFA pseudoaneurysm | (2.4%) |
| | 1 closure device failure | (2.4%) |

We did not notice any stent fracture or migration so far

After a mean FU of 405±262 days all the implanted devices are patent, corresponding to a rate of no patency $\leq 2 \times 10^{-2}$ events per person-years (EPPY)

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# *BeGRAFT PROPERTIES vs IDEAL PERIPHERAL STENTGRAFT*

| | |
|---|---|
| ▪ Low profile device (all sizes in 6 Fr sheath) | 6 F up to 8 mm |
| ▪ Good flexibility | ✓ |
| ▪ High radial force | ✓ |
| ▪ High conformability after deployment | ✓ |
| ▪ Easy navigation | ✓ |
| ▪ Good stent retention during navigation/stenosis negotiation | ✓ |
| ▪ No need of protected (by the vascular sheath) deployment | ✓ |
| ▪ Precise deployment | ✓ |
| ▪ Possible tapering | - |
| ▪ Good overdistension with minimal foreshortening | ✓ |

## *LIMITS OF THE STUDY*

- Single centre study
- Limited number of the patients
- Single arms study without comparison to other devices, embolizations with coils or surgery
- Retrospective study with possible selection bias

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# *CONCLUSION*

Endovascular treatment of vessels injuries by the implantation of the BeGraft Bentley Peripheral (and Coronary in case of small size vessel) Stent-Graft System with exclusion of the lesion/defect and preservation of flow along the target vessel, is minimally invasive, safe and effective, with high patency rate during follow up

The good trackability of its delivery system, the small profile of the stent-graft, its flexibility and conformability allow for the rapid treatment of the lesion even in case of tortuous anatomy

Long term follow up are needed to confirm our findings

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