DEBATE: FEVAR is the best option for aortic neck length < 9mm
FOR the motion

CX @ LINC 2016
Management of short infrarenal aortic necks
Thursday, January 28, 2016

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Within the past 12 months, the presenter or their spouse/partner have had a financial interest/arrangement or affiliation with the organization listed below.

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The Case in Favor of the Proposal

- Framing the issue – what’s important
- Anatomic considerations and real world experience with traditional stent-graft devices in “short” necks.
- The importance of IFUs and what can happen when we go beyond the limits of testing and regulatory recommendations.
- What do we do when juxta becomes para and existing chimneys become problematic?
- What about new opportunities with EVAS plus chimneys...is this the answer?
What have we learned from older generation of endografts?

1. *Durability Matters!*
50-60% of patients are still Alive at TEN YEARS

What Determines IFU?
(and why is it important?)

- Rigorous pre-clinical animal and in vitro testing to simulate specific parameters: neck length, angulation etc...
- Hundreds or thousands of devices tested to failure

- Clinical evidence collected based on tested parameters
- Structured monitoring to ensure credibility of data

- After years of testing and millions of $$, approvals and labeling (IFU) based on evidence from in vitro, animal and clinical testing

When we treat patients on label, we have the weight of years of testing behind us.
The Importance of Instructions for Use (IFU)

“In this multicenter patient population, compliance with published EVAR device IFU guidelines was low, and post-EVAR aneurysm sac enlargement was high…”
Predictors of Abdominal Aortic Aneurysm Sac Enlargement After Endovascular Repair

Andres Schanzer, MD; Roy K. Greenberg, MD; Nathanael Hevelone, MPH; William P. Robinson, MD; Mohammad H. Eslami, MD; Robert J. Goldberg, PhD; Louis Messina, MD

10228 patients (1999-2008)
59% < 5.5 cm

✓ Compliance with EVAR device guidelines was low
✓ Post EVAR sac enlargement was high

❖ 41% had Sac enlargement @ 5 years
❖ ONLY 42% of EVAR’s had anatomy that fit guidelines
Beyond IFU: Challenging Neck Anatomy

Some devices can work outside the IFU in selected cases.
Results Not Always Acceptable in Hostile Anatomy

3 years later

Migration

Occlusion of The right limb

Emergency Fem fem

Late conversion
Standard EVAR for the 10-mm Neck

A comprehensive strategy composed of the essential experience and technology needed to achieve satisfactory outcomes when treating short-necked aneurysms.

BY AMIR H. MALKAWI, MD, FRCS; MATT M. THOMPSON, MD, FRCS;
AND IAN M. LOFTUS, MD, FRCS

The preferred therapeutic options for infrarenal abdominal aortic aneurysms (AAA) with short proximal landing zones are open surgical repair or endovascular treatment with custom-made fenestrated stent grafts (Figure 1). However, significant comorbidities frequently limit the role of open surgical repair, and the use of custom-made fenestrated devices is restricted by morphological criteria and delays in availability related to the complexity of manufacturing. “Off-the-shelf” fenestrated and branched solutions are still under development, and evidence on their long-term durability is lacking.

Standard endovascular aneurysm repair (EVAR) is sometimes the only option for patients deemed unfit for open repair and when custom-made fenestrated devices are not feasible. EVAR should only be performed after robust consideration of the pros and cons of using a device outside of the manufacturer’s instructions for use (IFU). The incidence of type IA endoleak, migration, and reintervention are higher when EVAR is extended beyond the IFU. Despite this, immediate recognition and intervention can result in short- and midterm outcomes not dissimilar to EVAR with favorable morphology. However, long-term outcomes remain undefined.
Standard EVAR for the 10-mm Neck

A comprehensive strategy composed of the essential experience and technology needed to achieve satisfactory outcomes when treating short-necked aneurysms.

BY AMIR H. MALKAWI, MD, FRCS; MATT M. THOMPSON, MD, FRCS; AND IAN M. LOFTUS, MD, FRCS

The preferred therapeutic options for infrarenal abdominal aortic aneurysms (AAAs) with short proximal landing zones are open surgical repair or endovascular treatment with custom-made fenestrated stent grafts (Figure 1). However, significant comorbidities frequently limit the role of open surgical repair, and the use of custom-made fenestrated devices is restricted by morphological criteria and delays in availability related to the complexity of manufacturing. “Off-the-shelf” fenestrated and branched solutions are still under development, and evidence on their long-term durability is lacking.
outside the IFU has increased but may have a detrimental effect on long-term outcomes.

In experienced, high-volume units, standard EVAR for treating aneurysms with short proximal necks can be performed with acceptable results. Careful planning, appropriate device selection, high-quality intraoperative imaging, and advanced endovascular skills are essential for a successful primary outcome. Despite this, there will be a higher incidence of endoleak, migration, and sac expansion. An intensive postprocedure surveillance strategy is needed to enable early detection and timely reintervention to maintain a low incidence of post-EVAR rupture.
Chimney/Snorkel grafts

Malina M, et al
Guiding catheter or sheath positioned just above gutter; micro-catheter advanced into sac via gutter; coils introduced
Injection of glue or Onyx via microcatheter during its withdrawal out of gutter
The chimney graft technique for preserving visceral vessels during endovascular treatment of aortic pathologies.

Moulakakis KG¹, Mylonas SN, Avgerinos E, Papapetrou A, Kakisis JD, Brountzos EN, Liapis CD.

Abstract

OBJECTIVE: Patients with juxtarenal, pararenal, or thoracoabdominal aneurysms require complex surgical open repair, which is associated with increased mortality and morbidity. The "chimney graft" or "snorkel" technique has evolved as a potential alternative to fenestrated and side-branched endografts. The purpose of this study is to review all published reports on chimney graft (CG) technique involving visceral vessels and investigate the safety and efficacy of the technique.

METHODS: Studies were included in the present review if visceral revascularization during endovascular treatment of aortic pathologies was achieved via a CG implantation. Reports on the chimney technique for aortic arch branches revascularization were excluded. A multiple electronic health database search was performed on all articles published until April 2011.

RESULTS: The electronic literature search yielded 15 reports that fulfilled the inclusion criteria. A total of 93 patients (81.3% male; mean age, 71.9 ± 0.9 years) were analyzed. In 77.4% of the patients, the CG procedure was applied for the treatment of abdominal aortic aneurysms. Out of the 93 patients, 24.7% were operated on in an urgent setting (symptomatic or ruptured aneurysm). A total of 134 CGs were implanted: 108 to the renal arteries, 20 to the superior mesenteric artery, five to the celiac trunk, and one to the inferior mesenteric artery. In 57 patients, a single CG was deployed; in 32 patients, two CGs; in three patients, three CGs; and in one patient, four CGs were deployed. Ninety-four percent of CGs were directed proximally, whereas 6.0% were directed caudally. Primary technical success was achieved in all patients.

A total of 13 patients (14.0%) developed a type I endoleak. Three were detected and treated intraoperatively. Postoperatively, 10 type I endoleaks were revealed, four of which required secondary intervention. During a mean follow-up period of 9.0 ± 1.0 months, 131 of 134 (97.8%) CGs remained patent. Two CGs to the renal arteries and one to the superior mesenteric artery occluded. Postoperatively, 11.8% of patients suffered renal function impairment and 2.1% a myocardial infarction. Ischemic stroke presented in 3.2% of patients. The 30-day in-hospital mortality was 4.3%.

CONCLUSIONS: The role of the chimney technique in the management of complex abdominal aortic aneurysms is still unclear. This technique has relatively good results, considering the anatomic limitations of the aortic neck. However, long-term endograft durability and proximal fixation remains a significant concern. Thus, there is a reasonable hesitation to embrace the method for widespread use in the absence of long-term data.
## Systematic review of chimney and periscope grafts for endovascular aneurysm repair

A. Wilson, S. Zhou, P. Bachoo and A. L. Tambyraja

Aberdeen Vascular Surgical Service, Aberdeen Royal Infirmary, Foresterhill, Aberdeen AB25 2ZD, UK

Correspondence to: Mr A. L. Tambyraja (e-mail: andrew.tambyraja@nhs.net)

<table>
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<tr>
<th>Reference</th>
<th>No. of patients</th>
<th>Sex ratio (M : F)</th>
<th>No. of vessels</th>
<th>Elective : urgent repair</th>
<th>Mean TAA size (mm)</th>
<th>Mean follow-up (months)*</th>
<th>Immediate patency†</th>
<th>Early (&lt; 30 days) type I leak†</th>
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Overall: 58 patients (47:7 M:F), 74 vessels studied, 13:45 repair type, mean TAA size 68.4 mm, mean follow-up 13.3 months, 74% immediate patency, 9% early type I leaks.
Caution

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<td>Overall</td>
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Strokes?
Strokes?

4% to 5% in published meta-analyses
Why New Devices?

1. Commercial Interest: Attempt to gain competitive edge
2. Drive for Lower Complications
3. Improved Performance and Longer Durability
4. Expanding the Applicability of EVAR to challenging anatomies and New Aortic Segments
Allows Extension over Renal Arteries

The Zenith Fenestrated Graft
Custom Made
85-year-old woman: Very Short Neck

Type II endoleak treated at 3 years / well at 6 years (92y)

Greenberg RK, Sternbergh WC 3rd, Makaroun M, Ohki T, Chuter T, Bharadwaj P, Saunders A; Fenestrated Investigators.

Abstract

OBJECTIVE: This article reports the intermediate-term (24-month) outcomes of a prospective multicenter trial designed to evaluate the Zenith Fenestrated AAA Endovascular Graft (Cook Medical, Bloomington, Ind) for treating juxtarenal abdominal aortic aneurysms with short proximal necks. The study goals were to evaluate the safety and preliminary effectiveness of the device and refine patient selection criteria.

METHODS: Five centers in the United States enrolled 30 patients with juxtarenal aortic aneurysms with \( \geq 50\) mm diameter and short proximal necks. Devices were custom-designed for each patient based on measurements from reconstructed computed tomography (CT) data. Follow-up studies included physical examinations, laboratory studies, CT imaging, mesenteric-renal duplex ultrasound imaging, and abdominal flat plate radiographs at hospital discharge, at 1, 6, and 12 months, and yearly thereafter up to 5 years.

RESULTS: During a 1-year period, 30 patients (80% men; mean age, 75 years) with a mean aneurysm size of 61.4 mm were enrolled. In these 30 patients, 77 visceral vessels were accommodated by fenestrations located within the sealing segment of the grafts. The most common design accommodated two renal arteries and the superior mesenteric artery (66.7%). All prostheses were implanted successfully. No visceral arteries were lost. Of the 30 patients treated, 27 were available for 12-month follow-up and 23 were available for 24-month follow-up. No aneurysm-related deaths, aneurysm ruptures, or conversions were observed through 24 months of follow-up. No type I or type III endoleaks were observed. Type II endoleaks were noted in six (26.1%) at 12 months and four (20.0%) at 24 months. No patients had aneurysm growth \( > 5 \) mm. Aneurysm size decreased in 16 of 23 (69.6%) and was stable in the remaining patients at 24 months. Eight patients experienced a renal event (4 renal artery stenoses, 2 renal artery occlusions, and 2 renal infarcts). Five underwent secondary interventions. No renal failure developed requiring dialysis.

CONCLUSIONS: The intermediate-term (24-month) results of the 30 patients in this multicenter study are concordant with previous single-center studies and support the concept that placement of fenestrated endovascular grafts is safe and effective at centers with experience in endovascular repair and renal/mesenteric stent placement.
Results of the United States multicenter prospective study evaluating the Zenith fenestrated endovascular graft for treatment of juxtarenal abdominal aortic aneurysms.

Oderich GS¹, Greenberg RK², Farber M³, Lyden S², Sanchez I⁴, Fairman R⁵, Jia F⁶, Bharadwaj P⁶; Zenith Fenestrated Study Investigators.

Abstract

OBJECTIVE: This study reports the results of a prospective, multicenter trial designed to evaluate the safety and effectiveness of the Zenith fenestrated endovascular graft (Cook Medical, Bloomington, Ind) for treatment of juxtarenal abdominal aortic aneurysms (AAAs).

METHODS: Sixty-seven patients with juxtarenal AAAs were prospectively enrolled in 14 centers in the United States from 2005 to 2012. Custom-made fenestrated stent grafts were designed with one to three fenestrations on the basis of analysis of computed tomography data sets. Renal alignment was performed with balloon-expandable stents. Follow-up included clinical examination, laboratory studies, mesenteric-renal duplex ultrasound, abdominal radiography, and computed tomography imaging at hospital discharge and at 1 month, 6 months, and 12 months and yearly thereafter up to 5 years.

RESULTS: There were 54 male and 13 female patients with a mean age of 74 ± 8 years enrolled. Mean aneurysm diameter was 60 ± 10 mm. A total of 178 visceral arteries required incorporation with small fenestrations in 118, scallops in 51, and large fenestrations in nine. Of these, all 118 small fenestrations (100%), eight of the scallops (16%), and one of the large fenestrations (11%) were aligned by stents. Technical success was 100%. There was one postoperative death within 30 days (1.5%). Mean length of hospital stay was 3.3 ± 2.1 days. No aneurysm ruptures or conversions were noted during a mean follow-up of 37 ± 17 months (range, 3-65 months). Two patients (3%) had migration ≥ 10 mm with no endoleak, both due to cranial progression of aortic disease. Of a total of 129 renal arteries targeted by a fenestration, there were four (3%) renal artery occlusions and 12 (9%) stenoses. Fifteen patients (22%) required secondary interventions for renal artery stenosis/occlusion in 11 patients, type II endoleak in three patients, and type I endoleak in one patient. At 5 years, patient survival was 91% ± 4%, and freedom from major adverse events was 79% ± 6%; primary and secondary patency of targeted renal arteries was 81% ± 5% and 97% ± 2%, freedom from renal function deterioration was 91% ± 5%, and freedom from secondary interventions was 63% ± 9%.

CONCLUSIONS: This prospective study demonstrates that endovascular repair of juxtarenal AAAs with the Zenith fenestrated AAA stent graft is safe and effective. Mortality and morbidity are low in properly selected patients treated in centers with experience in these procedures.

Gallitto E¹, Gargiulo M, Freyrie A, Mascoli C, Massoni Bianchini C, Ancetti S, Faggioni G, Stella A.

Abstract

AIM: To evaluate the early and mid term results of the endovascular treatment of juxta-renal abdominal aortic aneurysms (j-AAA) using fenestrated endograft (FEVAR).

METHODS: Between 2008 to 2013 all consecutive patients underwent FEVAR using Cook-Zenith fenestrated endograft for treating j-AAA (proximal neck length <5mm) with renal aortic α/β angle < 60°, were prospectively collected in a database. Cardiovascular risk factors, co-morbidities, aortic-iliac morphological features, intra and post-procedural data were analyzed. Pre-operative FEVAR planning was performed by a thoraco-abdominal computer tomography angiography (CTA) and the 3D/Center Lumen Line reconstructions (3Mensio). Follow-up was conducted by duplex ultrasound (DUS)/ contrast enhancement DUS (CEUS) and/or CTA at 1,6,12-month and yearly thereafter. Early endpoints were: technical (TS) / clinical (CS) success, renal function worsening (≥ 30% of pre-operative creatinine value) and type I/III endoleak. Mid term endpoints were: type I/III endoleak, target visceral vessels patency, j-AAA shrinkage, freedom from re-intervention and survival.

RESULTS: Twenty patients (M: 94.7%; mean age: 73.4±5.9 years; ASA ≥3: 100%) were enrolled. The mean neck length and j-AAA diameter were 2 ± 1.4mm (range: 0-4mm) and 54.9 ±5mm respectively. Eleven (55%) endograft with 2 fenestrations and a scallop, 8 (45%) with 3 fenestrations and a scallop and 1 (5%) with 1 fenestration and a scallop were implanted. Sixty-seven visceral vessels were re-vascularized. TS and CS were 100% and 95% respectively (1/20 30-day mortality). Peri-operative renal function worsening was observed in 15% of cases. The mean follow-up was 25±20 months (range: 2-72months). [No type I/III endoleak or occlusion of target visceral vessels occurred.] There was j-AAA shrinkage in 65% of patients and no cases of j-AAA enlargement were observed. There were no FEVAR-related re-interventions. Survival at 12, 24 and 36 months were 89.4%, 80.5% e 80.5% respectively.

CONCLUSION: According to our results, the endovascular treatment for j-AAA, with α/β angle < 60°, is safe and effective.
Times have changed
Abdominal Aortic Endografting Beyond the Trials: A 15-Year Single-Center Experience Comparing Newer to Older Generation Stent-Grafts

Fabio Verzini, MD, PhD, FEBVS¹; Giacomo Isernia, MD¹; Paola De Rango, MD, PhD, FEBVS¹; Gioele Simonte, MD¹; Gianbattista Parlani, MD¹; Diletta Loschi, MD¹; and Piergiorgio Cao, MD, FRCS²

¹Vascular and Endovascular Surgery Unit, Hospital S. Maria della Misericordia, University of Perugia, Italy. ²Vascular Surgery Unit, Department of Cardiosciences, Hospital S. Camillo–Forlanini, Rome, Italy.

New Generation Stent Grafts better than old grafts @ 7 Yr for Reinterventions          Conversions          AAA Growth

Nellix Endobag System (EVAS)

Department of Cardiothoracic Surgery, Stanford University School of Medicine
The Morphological Applicability of a Novel Endovascular Aneurysm Sealing (EVAS) System (Nellix) in Patients with Abdominal Aortic Aneurysms

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WHAT THIS PAPER ADDS
A novel endovascular technique for the management of abdominal aortic aneurysm (AAA) is assessed. Morphological applicability is assessed in a range of patients who have undergone traditional infrarenal endovascular aortic repair (EVR), open repair (OR), fenestrated endovascular repair (FEVR) or non-operative management. The anatomical applicability of this new technology in these patients is assessed and compared with other endograft devices currently in use. It is concluded that EVAS (Nellix) technology appears to be widely applicable to contemporary infrarenal AAA practice, and provides an additional solution for patients currently being treated by EVR outside current devices’ instructions for use.

Table 1. Instructions for use for Nellix and contemporary endovascular aortic repair devices.

<table>
<thead>
<tr>
<th>Instruction</th>
<th>Nellix</th>
<th>Cook Zenith</th>
<th>Medtronic</th>
<th>Gore</th>
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</thead>
<tbody>
<tr>
<td>Non-aneurysmal AN length</td>
<td>≥10 mm</td>
<td>≥15 mm</td>
<td>≥10 mm</td>
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<tr>
<td>Non-aneurysmal AN diameter</td>
<td>18–32 mm</td>
<td>18–32 mm</td>
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<td>19–29 mm</td>
</tr>
<tr>
<td>Maximum aortic blood flow lumen diameter</td>
<td>≤60 mm</td>
<td>–</td>
<td>–</td>
<td>–</td>
</tr>
<tr>
<td>Maximum common iliac artery diameter</td>
<td>8–35 mm</td>
<td>7.5–20 mm</td>
<td>8–25 mm</td>
<td>8–18.5 mm</td>
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<tr>
<td>Angle from neck to sac</td>
<td>&lt;60</td>
<td>&lt;45</td>
<td>If AN length 10–15 mm, then ≤45</td>
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<tr>
<td>Angle from suprarenal aorta to neck</td>
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AN = aortic neck.
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CASE REPORT

Treatment of a Juxtarenal Aneurysm With the Nellix Endovascular Aneurysm Sealing System and Chimney Stent

Amir H. Malkawi, MD, FRCS; Jorg L. de Bruin, MD; Ian M. Loftus, MD, FRCS; and Matt M. Thompson, MD, FRCS

St George’s Vascular Institute, St George’s Healthcare NHS Trust, London, UK.

Purpose: To present treatment of a juxtarenal aneurysm using the Nellix endovascular aneurysm sealing system (EVAS) and a chimney stent.

Case Report: A 79-year-old woman was diagnosed with a 6-cm juxtarenal aneurysm. Standard endovascular aneurysm repair was not possible due to lack of an adequate infrarenal landing zone, and poor iliac access and angulated visceral aortic branches precluded a custom-made fenestrated solution. The patient was not a suitable candidate for open surgery due to significant comorbidity, so she underwent successful endovascular aneurysm repair with the Nellix EVAS system and a renal chimney stent. Follow-up imaging at 6 months showed a sealed aneurysm sac and patent renal chimney stent.

Conclusion: The Nellix EVAS system obliterates the aneurysm sac using polymer-filled balloons. The ability of the balloons to compress and seal the aneurysm off

Nellix Endobag System (EVAS)
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Conclusion: The Nellix EVAS system obliterates the aneurysm sac using polymer-filled endobags. The ability of the modular system of customizing stent placement offers...
grafts. The Nellix EVAS system with chimney stent offers an alternative to patients unsuitable for a fenestrated device or open surgery. However, this early result should be interpreted with caution until longer term data are available to define whether this technique has widespread applicability and long-term durability. The current policy in our institution is to offer patients this endovascular solution only when they are considered too high risk (predicted mortality >20%) for conventional surgery and are morphologically unsuitable for a fenestrated endograft.
Yes, times have changed
But Durability Matters

1. Endoleaks
2. Branch occlusion chimneys > fenestrated
3. Extension of disease – when juxta morphs into para after initial treatment with standard EVAR/chimney or EVAS/chimney
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4. Strakes
Standard EVAR for the 10-mm Neck

A comprehensive strategy composed of the essential experience and technology needed to achieve satisfactory outcomes when treating short-necked aneurysms.

BY AMIR H. MALKAWI, MD, FRCS; MATT M. THOMPSON, MD, FRCS; AND IAN M. LOFTUS, MD, FRCS

The preferred therapeutic options for infrarenal abdominal aortic aneurysms (AAAs) with short proximal landing zones are open surgical repair or endovascular treatment with custom-made fenestrated stent grafts (Figure 1). However, significant comorbidities frequently limit the role of open surgical repair, and the use of custom-made fenestrated devices is restricted by morphological criteria and delays in availability related to the complexity of manufacturing. “Off-the-shelf” fenestrated and branched solutions are still under development, and evidence on their long-term durability is lacking.
Standard EVAR for the 10-mm Neck

The use of chimney grafts in combination with conventional endografts to treat short or no-neck aneurysms has been previously described.\textsuperscript{1–3} Despite reported high initial technical success rates in experienced centers, long-term outcomes are variable with a significant rate of early and late adverse events that include endoleak, component failure, and target vessel loss. The formation beyond the IFU.\textsuperscript{3} Despite this, immediate recognition and intervention can result in short- and midterm outcomes not dissimilar to EVAR with favorable morphology.\textsuperscript{4,5} However, long-term outcomes remain undefined. A
Period.
End.
Thank You