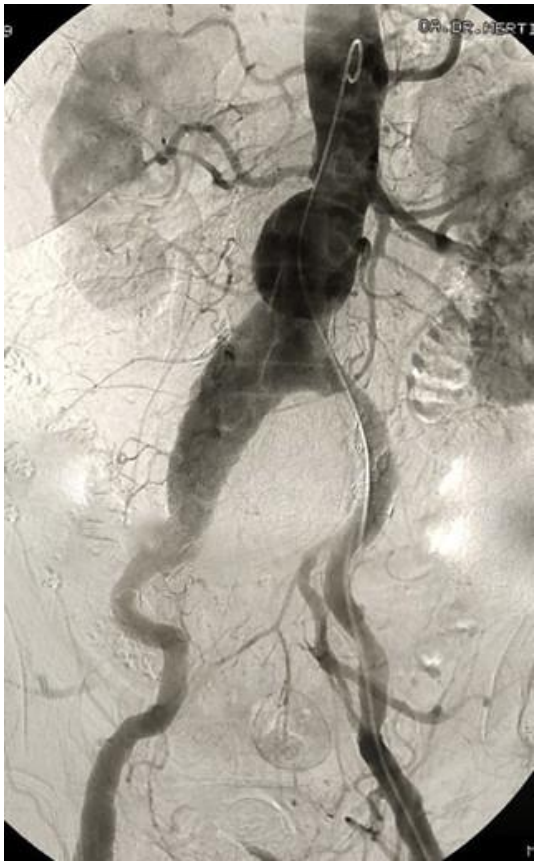
Evangelisches Amalie Sieveking-Krankenhaus

albertinen
in besten Händen

24. Norddeutsche Gefäßtage
Aorta endovaskulär: gibt's was Neues?

Neue IFU bei kurzem Hals



“Hostile Neck”

1. Halslänge </=10 mm
2. Fokale Ektasie innerhalb des Halses über 3mm
3. >2 mm “reverse taper” bis 1 cm unterhalb der Nierenarterien
4. Halsthrombus >/=50% der Circumfirenz
5. Angulation >/=60 Grad innerhalb 3cm unterhalb der Nierenarterien

- Wer liest Gebrauchsanweisungen?

Welchen Einfluss hat die Therapie innerhalb und außerhalb der IFU für das Outcome von EVAR`s

Circulation. 2011 Jun 21;123(24):2848-55. doi: 10.1161/CIRCULATIONAHA.110.014902. Epub 2011 Apr 10.

Predictors of abdominal aortic aneurysm sac enlargement after endovascular repair.

Schanzer A[1], Greenberg RK, Hevelone N, Robinson WP, Eslami MH, Goldberg RJ, Messina L.

Author information

Open/close author information list

Erratum in
Circulation. 2012 Jan 17;125(2):e266.

Abstract

BACKGROUND: The majority of infrarenal abdominal aortic aneurysm (AAA) repairs in the United States are performed with endovascular methods. Baseline aortoiliac arterial anatomic characteristics are fundamental criteria for appropriate patient selection for endovascular aortic repair (EVAR) and key determinants of long-term success. We evaluated compliance with anatomic guidelines for EVAR and the relationship between baseline aortoiliac arterial anatomy and post-EVAR AAA sac enlargement.

METHODS AND RESULTS: Patients with pre-EVAR and at least 1 post-EVAR computed tomography scan were identified from the M2S, Inc. imaging database (1999 to 2008). Preoperative baseline aortoiliac anatomic characteristics were reviewed for each patient. Data relating to the specific AAA endovascular device implanted were not available. Therefore, morphological measurements were compared with the most liberal and the most conservative published anatomic guidelines as stated in each manufacturer's instructions for use. The primary study outcome was post-EVAR AAA sac enlargement (>5-mm diameter increase). In 10 228 patients undergoing EVAR, 59% had a maximum AAA diameter below the 55-mm threshold at which intervention is recommended over surveillance. Only 42% of patients had anatomy that met the most conservative definition of device instructions for use; 69% met the most liberal definition of device instructions for use. The 5-year post-EVAR rate of AAA sac enlargement was 41%. Independent predictors of AAA sac enlargement included endoleak, age ≥ 80 years, aortic neck diameter ≥ 28 mm, aortic neck angle >60°, and common iliac artery diameter >20 mm.

CONCLUSION: In this multicenter observational study, compliance with EVAR device guidelines was low and post-EVAR aneurysm sac enlargement was high, raising concern for long-term risk of aneurysm rupture.

Schanzer et. al Circulation 2011

Evangelisches Amalie Sieveking-Krankenhaus
albertinen
in besten Händen

- Schanzer et. al Circulation 2011

- Patienten n = 10,228
- Außerhalb strikter IFU 5983 (58.5%)

- Primärer Endpunkt Größenwachstum
- 41% der Patienten zeigten nach 5 Jahren ein Aneurysmawachstum
- Unabhängige Prediktoren – Endoleak Typ I, Alter >80 Jahre, Aortenhalsdurchmeser >28mm, Aortenhalswinkel >60°, A. iliaca commnis >20mm
- Zusammenhang zwischen Abweichung von der IFU und Rate der Zunahme des Aneurysmasackes.
- Sorge des Autors um Langzeitergebnisse

J Vasc Surg. 2006 Nov;44(5):932-7; discussion 937.

Effect of challenging neck anatomy on mid-term migration rates in AneuRx endografts.

Fulton JJ[1], Farber MA, Sanchez LA, Godshall CJ, Marston WA, Mendes R, Rubin BG, Sicard GA, Keagy BA.

Author information

Abstract

OBJECTIVE: To establish the effect of challenging neck anatomy on the mid- and long-term incidence of migration with the AneuRx bifurcated device in patients treated after Food and Drug Administration approval and to identify the predictive factors for device migration.

METHODS: Prospectively maintained databases at the University of North Carolina (UNC) and Washington University (WU) were used to identify 595 patients (UNC, n = 230; WU, n = 365) who underwent endovascular repair of an infrarenal abdominal aortic aneurysm with the AneuRx bifurcated stent graft. Those patients with at least 30 months of follow-up were identified and underwent further assessment of migration (UNC, n = 25; WU, n = 59) by use of multiplanar reconstructed computed tomographic scans.

Effect of challenging neck anatomy on mid-term migration rates in AneuRx endografts. Fulton et. al ; J Vasc Surg. 2006 Nov

84 Patienten – außerhalb der IFU 30%

Signifikant höhere Migration und sekundäre Interventionsrate

graft-related complications occurred in 38% of patients (FNA, 27%; UFNA, 64%; P = .003; relative risk, 1.7). There was no incidence of late rupture or open conversion. The relative risk of migration for UFNA patients was 2.5 compared with FNA patients (P = .0003). A larger neck angle and a longer initial graft to renal artery distance were predictors of migration, whereas shorter neck length approached but did not reach statistical significance.

CONCLUSIONS: Patients who have unfavorable aneurysm neck anatomy experience significantly higher migration, device-related complication, and secondary intervention rates. However, there was no incidence of open conversion, rupture, or abdominal aortic aneurysm-related death, thereby supporting the AneuRx device as a feasible alternative to open repair even in patients with challenging neck characteristics. Enhanced surveillance should be used in these high-risk patients.

J Vasc Surg. 2008 Jul;48(1):19-28. doi: 10.1016/j.jvs.2008.02.003. Epub 2008 Apr 28.

Outcomes following endovascular abdominal aortic aneurysm repair (EVAR): an anatomic and device-specific analysis.

Abbruzzese TA[1], Kwolek CJ, Brewster DC, Chung TK, Kang J, Conrad MF, LaMuraglia GM, Cambria RP.

Author information

Open/close author information list

Abstract

OBJECTIVE: We performed a device-specific comparison of long-term outcomes following endovascular abdominal aortic aneurysm repair (EVAR) to determine the effect(s) of device type on early and late clinical outcomes. In addition, the impact of performing EVAR both within a [illegible] of specific instructions for use (IFU) for each device was examined.

Outcomes following endovascular abdominal aortic aneurysm repair (EVAR): an anatomic and device-specific analysis. Abbruzzese et. al ; J Vasc Surg 2008 Jul

565 Patienten außerhalb der IFU 39%

Signifikant höhere Rate an EVAR bezogene adverse events

[illegible] and December 31, 2005, 565 patients underwent EVAR utilizing one of three commercially available [illegible]rative (< or =30 days) mortality, intraoperative technical complications and need for [illegible]ity conversion to open repair, reintervention, development and/or [illegible]king), and a combined endpoint of any graft-related [illegible] outside of the recommended device [illegible]. 39.3% of grafts we[illegible] CZ vs 35 and 31 months for GE a[illegible] reintervention, and GRAE was similar among devi[illegible] there was no difference between devices on actuarial analysis. Com[illegible] .01). Graft placement outside of IFU was associated with similar 5-year freedom fro[illegible] (P > .05), but a lower freedom from GRAE (74% outside IFU vs 86% within IFU; P = .021), likely relat[illegible] thrombosis (2.3% outside IFU vs 0.3% within IFU; P = .026). The differences in outcome for grafts placed within vs out[illegible] device-specific.

CONCLUSION: EVAR performed with three commercially available devices provided similar clinically relevant outcomes at 5 years, although no graft migration occurred with a suprarenal fixation device. As anticipated, application outside of anatomically specific IFU variables had an incremental negative effect on late results, indicating that adherence to such IFU guidelines is appropriate clinical practice.

J Vasc Surg. 2009 Oct;50(4):738-48. doi: 10.1016/j.jvs.2009.04.061.

The correlation of aortic neck length to early and late outcomes in endovascular aneurysm repair patients.

AbuRahma AF[1], Campbell J, Stone PA, Nanjundappa A, Jain A, Dean LS, Habib J, Keiffer T, Emmett M.

Author information

Abstract

BACKGROUND: Initially, patients with a short angulated aortic neck were consider
Recently, however, more liberal use of EVAR has
outcomes.

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RESU
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late reintervention was comparable in all groups. Postoperatively, the size of the abdominal
decreased or remained unchanged in 95%, 94%, and 88% in L1, L2, and L3, respectively (P = .660). Rates of freedom from late type I endoleak at 1, 2, and 3 years were 84%, 82%, and 80% for L1; 68%, 54%, and 54% for L2; and 71%, 71%, and 53% for L3 (P = .0263). Rates of freedom from late intervention at 1, 2, and 3 years were 96%, 94%, and 92% for L1; and 94%, 83%, and 83% for L2; and 93%, 93%, and 93% for L3 (P = .5334).

CONCLUSIONS: EVAR can be used for patients with a short aortic neck; however, it was associated with a significantly higher rate of early and late type I endoleaks, resulting in an increased use of proximal aortic cuffs for sealing the endoleaks.

The correlation of aortic neck length to early and late outcomes in endovascular aneurysm repair patients.

Aburhama et. al ; J Vasc Surg. 2009 Oct;50(4):738-48

238 patients klassifiziert bezüglich der Halslänge (>15, 10-15, <10mm).

Typ I Endoleakraten erhöht früh (12%, 42%, 53%) – erhöhter Einsatz eines CUFF

Rate der Spätinterventionen nicht erhöht

- Therapiere nicht außerhalb der IFU!?

- In den Studien bis zu 40% außerhalb der devicespezifischen IFU!

Format: Abstract

Send to

J Vasc Surg. 2016 Jul;64(1):63-74.e2. doi: 10.1016/j.jvs.2016.01.034. Epub 2016 Mar 23.

No major difference in outcomes for endovascular aneurysm repair stent grafts placed outside of instructions for use.

Beckerman WE[1]. Tadros RO[2]. Faries PL[1]. Torres M[1]. Wengerter SP[1]. Vouvouka AG[1]. Lookstein RA[3]. Marin ML[1].

No major difference in outcomes for endovascular aneurysm repair stent grafts placed outside of instructions for use.

Beckerman WE : J Vasc Surg 2016 Jul

566 Patienten - außerhalb der IFU 69%

2003 – 2014

Kein Unterschied bezüglich Mortalität und Aneurysma bezogener Mortalität

Kein Unterschied bezüglich der Typ I Endoleakraten und Aneurysmawachstum

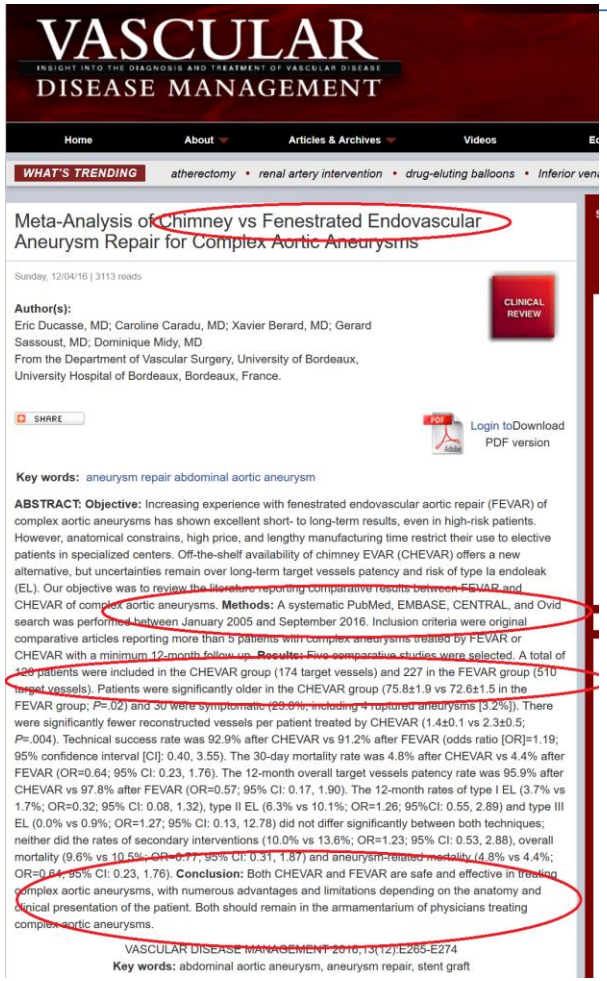
CONCLUSIONS: Despite most EVAR patients being treated outside of IFU, there was no difference in outcomes with respect to all-cause mortality or aneurysm-related mortality. In addition, with the exception of perioperative blood transfusions, there was no association between IFU adherence and late-onset rupture, need for reintervention, rates of endoleak, aneurysm sac enlargement, or most other major complications.

- Auf Grund **k**urzer (<10 mm) , **w**eiter (> 29 mm), **a**ngulierter (> 75°), oder **k**onischer infrarenaler Hälse (KWAK) kommt derzeit eine signifikante Patientenpopulation für EVAR nicht in Frage

FEVAR vs. CHEVAR

Patency

Endoleak Typ I



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Meta-Analysis of Chimney vs Fenestrated Endovascular Aneurysm Repair for Complex Aortic Aneurysms

Sunday, 12/04/16 | 3113 reads

CLINICAL REVIEW

Author(s):
Eric Ducasse, MD; Caroline Caradu, MD; Xavier Berard, MD; Gerard Sassoust, MD; Dominique Midy, MD
From the Department of Vascular Surgery, University of Bordeaux, University Hospital of Bordeaux, Bordeaux, France.

SHARE

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Key words: aneurysm repair abdominal aortic aneurysm

ABSTRACT: Objective: Increasing experience with fenestrated endovascular aortic repair (FEVAR) of complex aortic aneurysms has shown excellent short- to long-term results, even in high-risk patients. However, anatomical constrains, high price, and lengthy manufacturing time restrict their use to elective patients in specialized centers. Off-the-shelf availability of chimney EVAR (CHEVAR) offers a new alternative, but uncertainties remain over long-term target vessels patency and risk of type Ia endoleak (EL). Our objective was to review the literature reporting comparative results between FEVAR and CHEVAR of complex aortic aneurysms. **Methods:** A systematic PubMed, EMBASE, CENTRAL, and Ovid search was performed between January 2005 and September 2016. Inclusion criteria were original comparative articles reporting more than 5 patients with complex aneurysms treated by FEVAR or CHEVAR with a minimum 12-month follow-up. **Results:** Five comparative studies were selected. A total of 126 patients were included in the CHEVAR group (174 target vessels) and 227 in the FEVAR group (510 target vessels). Patients were significantly older in the CHEVAR group (75.8±1.9 vs 72.6±1.5 in the FEVAR group; *P*=.02) and 30 were symptomatic (23.8%, including 4 ruptured aneurysms [3.2%]). There were significantly fewer reconstructed vessels per patient treated by CHEVAR (1.4±0.1 vs 2.3±0.5; *P*=.004). Technical success rate was 92.9% after CHEVAR vs 91.2% after FEVAR (odds ratio [OR]=1.19; 95% confidence interval [CI]: 0.40, 3.55). The 30-day mortality rate was 4.8% after CHEVAR vs 4.4% after FEVAR (OR=0.64; 95% CI: 0.23, 1.76). The 12-month overall target vessels patency rate was 95.9% after CHEVAR vs 97.8% after FEVAR (OR=0.57; 95% CI: 0.17, 1.90). The 12-month rates of type I EL (3.7% vs 1.7%; OR=0.32; 95% CI: 0.08, 1.32), type II EL (6.3% vs 10.1%; OR=1.26; 95%CI: 0.55, 2.89) and type III EL (0.0% vs 0.9%; OR=1.27; 95% CI: 0.13, 12.78) did not differ significantly between both techniques; neither did the rates of secondary interventions (10.0% vs 13.6%; OR=1.23; 95% CI: 0.53, 2.88), overall mortality (9.6% vs 10.5%; OR=0.77; 95% CI: 0.31, 1.87) and aneurysm-related mortality (4.8% vs 4.4%; OR=0.64; 95% CI: 0.23, 1.76). **Conclusion:** Both CHEVAR and FEVAR are safe and effective in treating complex aortic aneurysms, with numerous advantages and limitations depending on the anatomy and clinical presentation of the patient. Both should remain in the armamentarium of physicians treating complex aortic aneurysms.

VASCULAR DISEASE MANAGEMENT 2016;13(12):E265-E274
Key words: abdominal aortic aneurysm, aneurysm repair, stent graft

Meta-Analysis of Chimney vs Fenestrated Endovascular Aneurysm Repair for Complex Aortic Aneurysms

Ducasse et al. ; VASCULAR DISEASE MANAGEMENT 2016;13

Five comparative studies were selected. A total of 126 patients were included in the CHEVAR group (174 target vessels) and 227 in the FEVAR group (510 target vessels)

The 12-month overall target vessels patency rate was 95.9% after CHEVAR vs 97.8% after FEVAR

The 12-month rates of type I EL 3.7% vs 1.7%

overall mortality 9.6% vs 10.5%;

aneurysm-related mortality 4.8% vs 4.4%

Vascular. 2017 Feb;25(1):92-100. doi: 10.1177/1708538115627718. Epub 2016 Jul 10.

Treatment of complex aortic aneurysms with fenestrated endografts and chimney stent repair: Systematic review and meta-analysis.

Yaoguo Y[1,2], Zhong C[1,2], Lei K[1,2], Yaowen X[1,2].

Author information

Yang Yaoguo et al ; Vascular February 3, 2016

- 42 relevant studies and 2264 patients with aortic aneurysm undergoing fenestrated endovascular aneurysm repair and chimney stent repair
- The follow-up aneurysm-related mortality was 1.4% and 3.2% ($p = 0.018$)
- A total of 156 vessels showed restenosis or occlusion after primary intervention (3.6% and 3.4%)
- The cumulative type I endoleak was 2.0% after fenestrated endovascular aneurysm repair compared with 3.4%

Abstrac

Objectiv … English, compara … hed until related t … neurysm January … e 30-day repair ar … n mortality … tal of 156 dysfunct … chimney vessels … epair stent rep … 0), compare … urysm respecti …

repair and chimney stent repair, respectively (p = 0.437). The re-intervention frequency was 205 and 19 cases after fenestrated endovascular aneurysm repair and chimney stent repair, respectively (11.7%, 5.6%, p = 0.001). Conclusions Fenestrated endovascular aneurysm repair and chimney stent repair are safe and effective in treating patients with complex aortic aneurysm. A higher aneurysm-related mortality was observed in chimney stent repair while fenestrated endovascular aneurysm repair was associated with a higher re-intervention rate.

Ann Surg. 2015 Sep;262(3):546-53; discussion 552-3. doi: 10.1097/SLA.0000000000001405.

Collected world experience about the performance of the snorkel/chimney endovascular technique in the treatment of complex aortic pathologies: the PERICLES registry.

Donas KP[1], Lee JT, Lachat M, Torsello G, Veith FJ; PERICLES investigators.

Collaborators (23)

Author information

Abstract

OBJECTIVES: We sought to analyze the collected worldwide experience with use of snorkel/chimney endovascular aneurysm repair (EVAR) for complex abdominal aneurysm treatment.

BACKGROUND: EVAR has largely replaced open surgery worldwide for anatomically suitable aortic aneurysms. Lack of availability of fenestrated and branched devices has encouraged an alternative strategy utilizing parallel or snorkel/chimney grafts (ch-EVAR).

METHODS: Clinical and radiographic information was retrospectively reviewed and analyzed on 517 patients treated by ch-EVAR from 2008 from 2014 by prearranged defined and documented protocols.

RESULTS: A total of 119 patients in US centers and 398 in European centers were treated during the study period. US centers preferentially used Zenith stent-grafts (54.2%) and European centers Endurant stent-grafts (62.2%) for the main body component. Overall 898 chimney grafts (49.2% balloon expandable, 39.6% self-expanding covered stents, and 11.2% balloon expandable bare metal stents) were placed in 692 renal arteries, 156 superior mesenteric arteries (SMA), and 50 celiac arteries. At a mean follow-up of 17.1 months (range: 1-70 months), primary patency was 94%, with secondary patency of 95.3%. Overall survival of patients in this high-risk cohort for open repair at latest follow-up was 79%.

CONCLUSIONS: This global experience represents the largest series in the ch-EVAR literature and demonstrates comparable outcomes to those in published reports of branched/fenestrated devices, suggesting the appropriateness of broader applicability and the need for continued careful surveillance. These results support ch-EVAR as a valid off-the-shelf and immediately available alternative in the treatment of complex abdominal EVAR and provide impetus for the standardization of these techniques in the future.

The Pericles Registry

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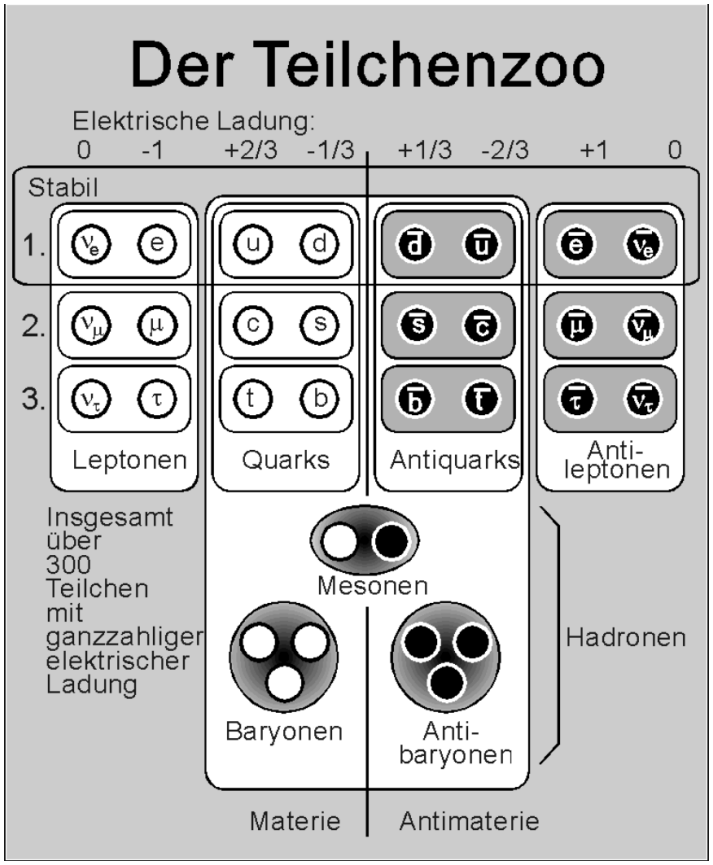
- Retrospektive Registerstudie
- K. Donas et. al; Ann Surg. 2015 Sep
- 517 Patienten CHEVAR von 2008 – 2014
- 119 US und 398 Europäische Zentren
- Mean follow up 17,1 months
- US zu 54,2% Zenith (Cook) Europa 62,2 Endurant II (Medtronic)
- 898 Chimeygrafts
- 49,2% ballon expandable covered
- 39,6% self-expanding covered
- 11,2 balloon expandable bare metal stents
- Primary Patency 94%
- Secondary Patency 95,3%
- Vergleichbare Ergebnisse zu FEVAR


Der Teilchenzoo
Elektrische Ladung:
0 -1 +2/3 -1/3 +1/3 -2/3 +1 0
Stabil
1.
2.
3.
Leptonen
Quarks
Antiquarks
Anti-leptonen
Insgesamt über 300 Teilchen mit ganzzahliger elektrischer Ladung
Mesonen
Baryonen
Anti-baryonen
Hadronen
Materie
Antimaterie


OVATION PRIME
ABDOMINAL STENT GRAFT SYSTEM
AORFIX
Endovascular Stent Graft
Medtronic
Endurant II
AAA STENT GRAFT SYSTEM
anaconda™
AAA Stent Graft System
COOK
MEDICAL
Bolton Medical
A WerfenLife Company
Cordis
GORE
EXCLUDER
AAA ENDOPROSTHESIS

6. Dezember 2016 CE-Kennzeichnung für Endurant II/IIs Stentgraft in Kombination mit einem Ballonexpandierbaren gecoverten Stent

Endurant™ II
Endurant™ IIs

Gefäßprothesensystem

INHALT

1. Produktbeschreibung

Das Endurant™ II/Endurant™ IIs Gefäßprothesensystem ist zur endovaskulären Behandlung von Aneurysmen vorgesehen. Nach Platzierung innerhalb der Zielläsion exkludiert die Gefäßprothese die Läsion von der Blutbahn, mindert so den auf die Aneurysmawand wirkenden Blutdruck und schafft dadurch eine dauerhafte Ausweichblutbahn innerhalb des körpereigenen Gefäßsystems des Patienten.

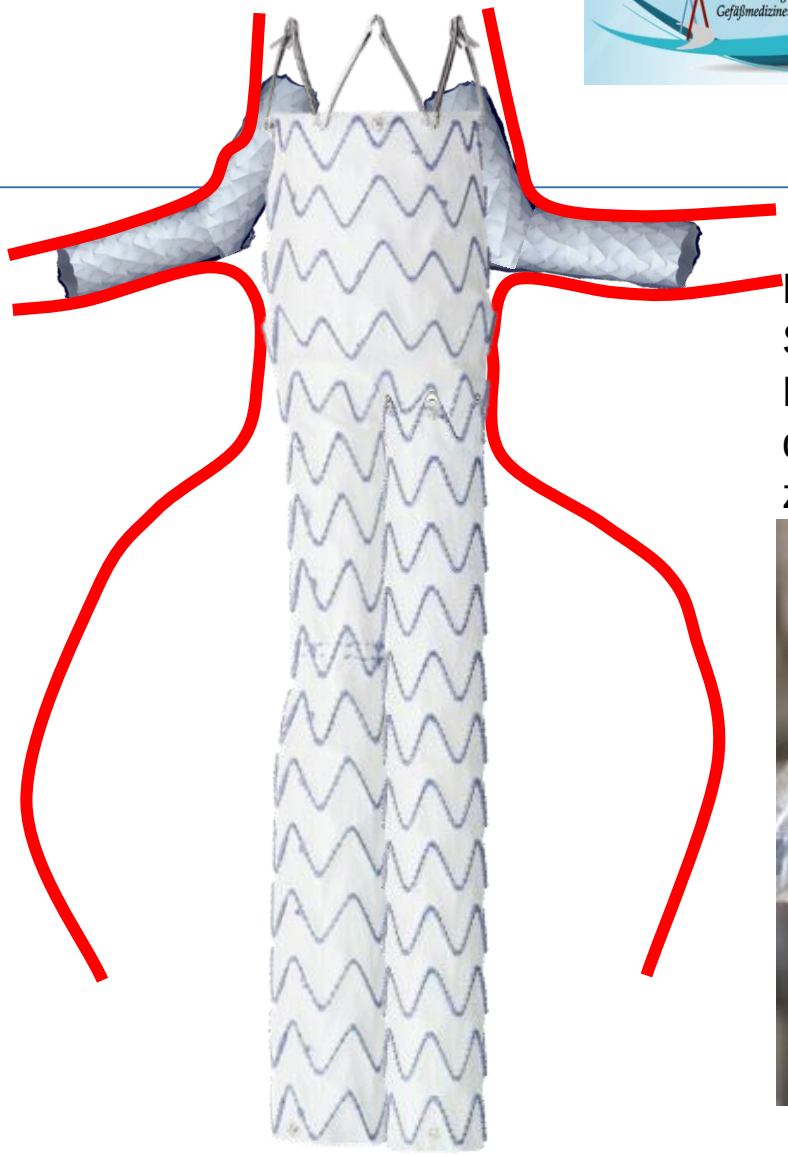
Das Gefäßprothesensystem umfasst zwei Hauptkomponenten: die implantierbare Gefäßprothese und das Einwegträgersystem. Das Trägersystem wird mit der Gefäßprothese vorbestückt und unter Durchleuchtungskontrolle zum Aneurysma vorgeschoben. Bei Freisetzung expandiert die Gefäßprothese, um der Form und Größe der Dichtungszonen ober- und unterhalb des Aneurysmas zu entsprechen.

1.1. Gefäßprothese

Die Endurant II/Endurant IIs Gefäßprothese (Abbildung 1) verfügt über zwei grundlegende Konfigurationen: eine Y-Prothesenkonfiguration und eine Schenkelkonfiguration. Zusätzliche Konfigurationen umfassen die iliakale Verlängerung, die aortale Verlängerung, die abdominale Rohrprothese und die aorto-uni-iliakale (AUI-)Gefäßprothese. Nach der Platzierung der Y- oder AUI-Einheit werden Prothesenschenkel und zusätzliche Gefäßprothesen nacheinander in das Gefäß eingeführt und mit den bereits implantierten Komponenten verbunden.

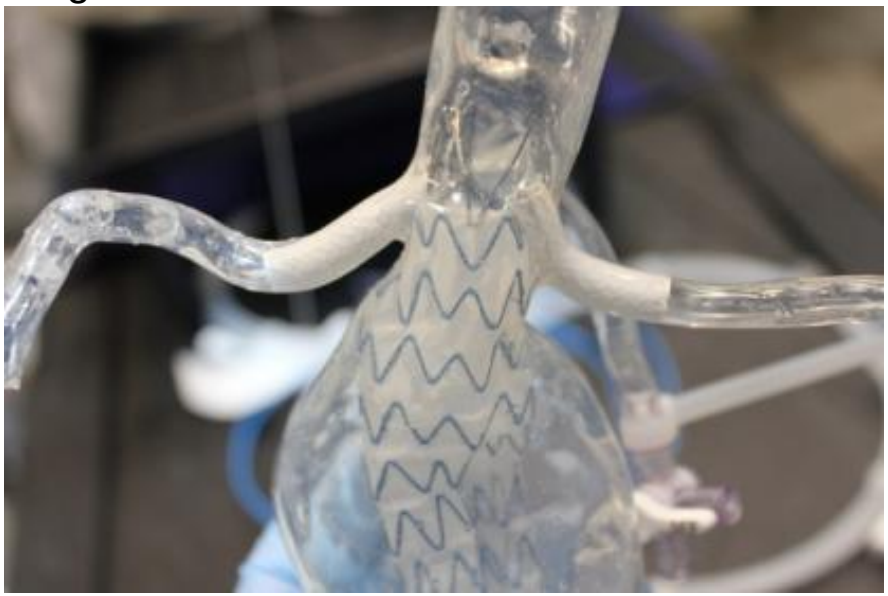
Alle Endurant II/Endurant IIs Gefäßprothesenkonfigurationen bestehen aus Nitinolstents, die mit nicht resorbierbaren Nähten auf das Prothesengewebe aufgenäht werden. Zur besseren Darstellung des Systems und zur einfacheren und genaueren Platzierung der Gefäßprothese ist diese mit röntgendichten Markierungen gekennzeichnet. Die Darstellung der Nitinolstents kann auch unter Durchleuchtung erfolgen.

Die Komponenten der Gefäßprothese sollten größer als der gemessene Innendurchmesser des Gefäßes sein (Abschnitt 9.2). Tabelle 1 enthält eine Zusammenfassung der Gefäßprothesenmaterialien.

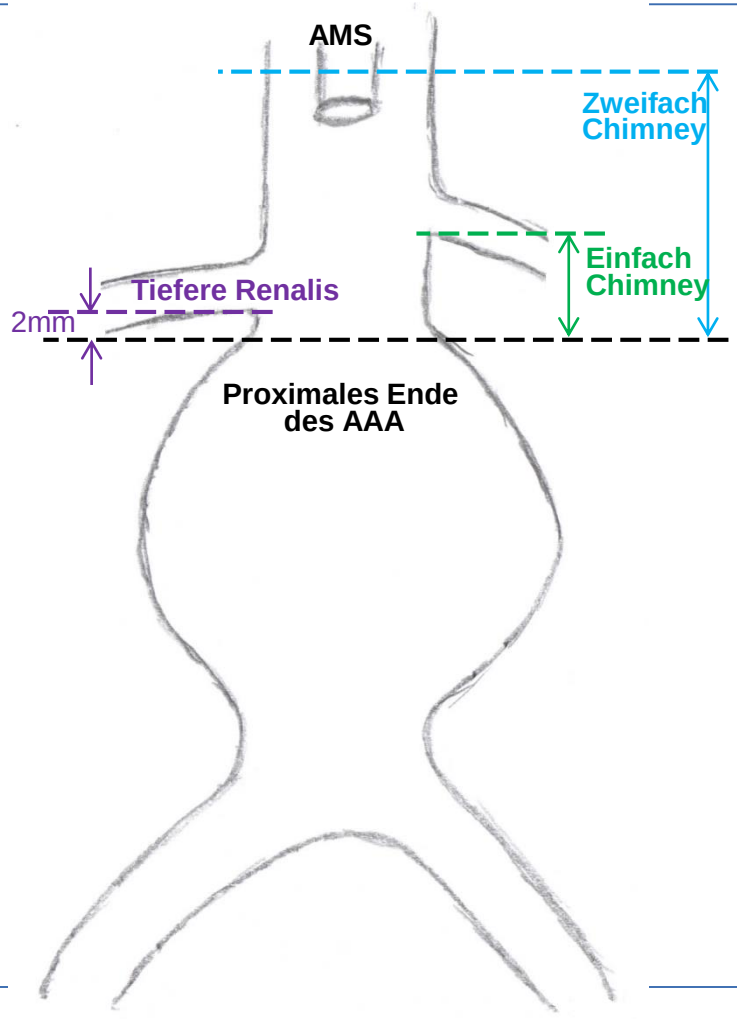


ChEVAR = Chimney-EVAR

Platzierung eines oder mehrfacher gecoverter Stents parallel zum Stentgraft, um die Landezone nach proximal zu verlängern und dabei die Perfusion der überdeckten Abgänge zu gewährleisten

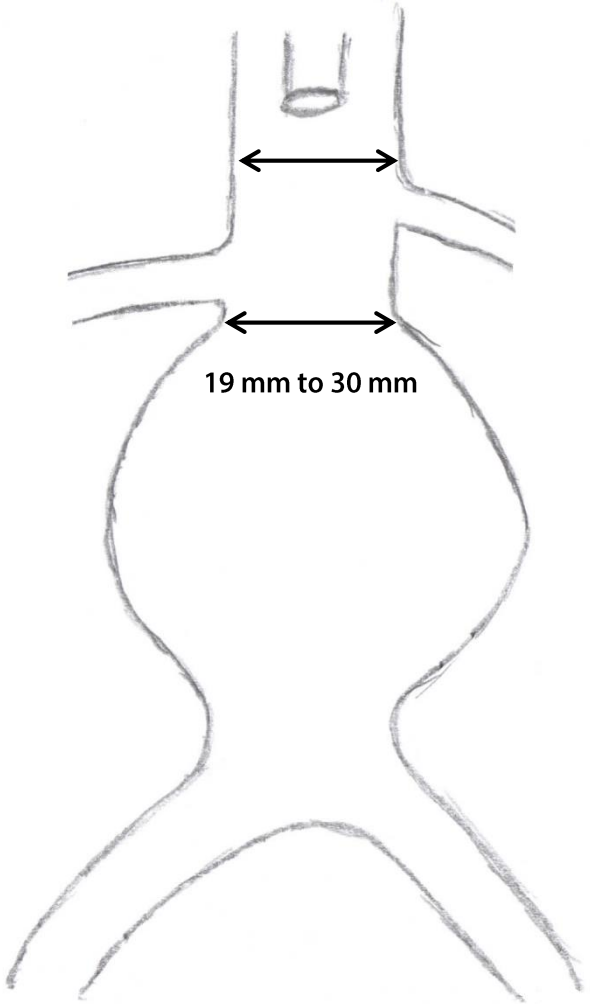


Medtronic Indikation
JUXTARENALE AAA - ABDICHTUNG



- CE-Zulassung **NUR** für primäre Einsätze, nicht für Revisionen
- **MINIMALE** Abdichtung
  - Für einfach Chimney: **15 mm** ab proximalem Ende des AAA bis zur höcheren Renalis
  - Für zweifach Chimney: **15 mm** ab proximalem Ende des AAA bis zur AMS
- Voraussetzung: Ein **MINIMALER** infrarenaler Hals von **2 mm** (2 mm bis 9 mm)

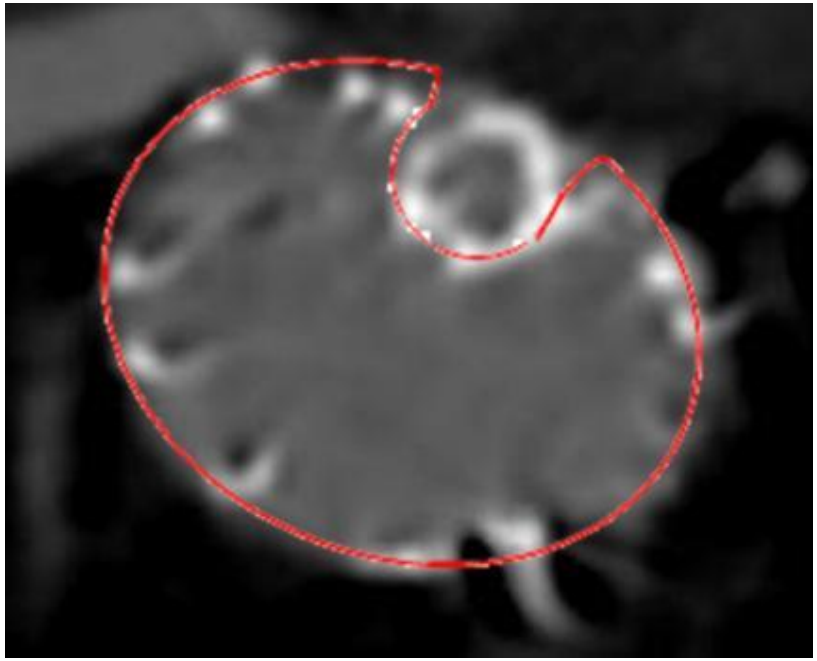
Medtronic Indikation
JUXTARENALE AAA - DIAMETER



- Behandlung von Aortendiametern
  - **19 mm bis 30 mm**
- Empfehlung bei Überdimensionierung
  - **20 to 30%**

Graft diameter (proximal; mm)	Gefäßdurchmesser (mm)	
	Standard EVAR	ChEVAR
23	19 -20	N/A
25	21-22	19-20
28	23-25	21-23
32	26-28	24-26
36	29-32	27-30

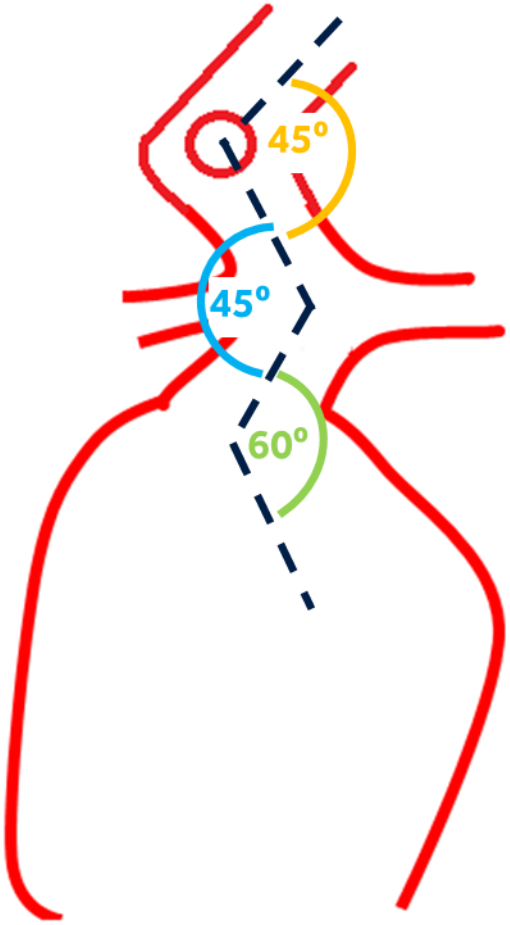
Medtronic Indikation
JUXTARENALE AAA - DIAMETER



- entsprechende Überdimensionierung ermöglicht optimale Anpassung des Stentgrafts um den Renalisstent

- Empfehlungen zur Überdimensionierung sind sowohl bei einfach als auch zweifach Chimney gleich

JUXTARENALE AAA - AORTEN ANGULATION
Medtronic Indikation



- Maximum supra AMS* Winkel

45°

- Maximum suprarenaler Winkel

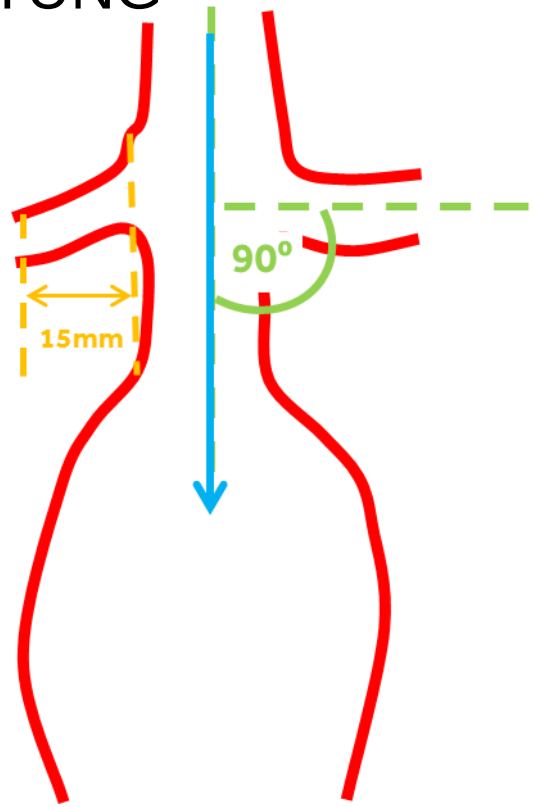
45°

- Maximum infrarenaler Winkel

60°

Für weitere Details bitte auf die IFU beziehen; M059210T001 [global]; * = Ateria Mesenterica Superior

Medtronic Indikation
JUXTARENALE AAA - RENALE ANGULATION AND ABDICHTUNG



- A. renalis Abdichtungszone

  15 mm

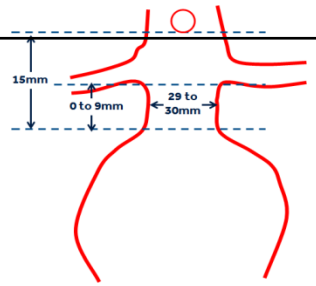
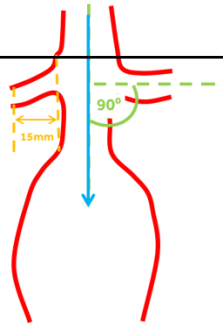
- Maximale renale Angulation max. im rechten Winkel zur Aorta

  90□

- *Winkel darf nur aus der Zugangsrichtung des renalis Stents bemessen werden*

JUXTARENALE AAA
Indikation Zusammenfassung

Geringfügige Kalzifizierung und Thrombus auf Höhe des proximalen Halses
Adäquater A. axillaris oder A. brachialis Zugang
Wenig Thrombus oder Kalzifizierung im Bogen oder Aorta descendens

Halslänge	Angulation	Renalis
• *Neue Halslänge* 15 mm • Infrarenale Halslänge ≥ 2 mm bis 9 mm • • Neuer Halsdurchmesser von 19 bis 30 mm • Ein- oder zweifach Chimney möglich	• Supra AMS Angulation von 0° - 45° • Suprarenale Halsangulation 0° - 45° • Infrarenale Halsangulation 0° - 60°	• Maximale A. renalis Angulation 0° - 90° (basierend auf renaler Aorten Centre line) • Renale Abdichtungszone von 15 mm
		

Für weitere Details bitte auf die IFU beziehen; M059210T001 [global]

Zusätzlich benötigtes MAterial
HINWEIS: PRODUKTSELEKTION IST IN VERANTWORTUNG DES BEHANDELNDEN ARZTES

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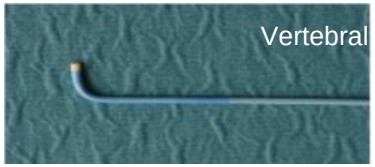
- **Weicher Draht** für einen einfachen A. renalis Zugang
  - **Empfehlung**:
    Soft GLIDEWIRE® Hydrophil beschichteter Führungsdraht[1]
- **Renalis Draht**
  - **Empfehlung:** Rosen Führungsdraht[2]
    Gutes Kompromiss zwischen Steifigkeit und Flexibilität, atraumatisch und mit kurzer Spitze

- **7F Schleuse, 90 cm Länge**
  - **Empfehlung:** Flexor® Shuttle® Führungsschleuse[2]
    Atraumatische Spitze für A. renalis Zugang

- **Katheter - 5F minimale Länge von 110 cm – 125 cm**
  - **Empfehlung:** Vertebral, Multipurpose.
    Man muss in der Lage sein damit durch die 90 cm lange Schleuse zu arbeiten. Auswahl von verschiedenen Konfigurationen zur Kannulierung der Renalis wäre ideal.



- **Gecoverter Ballonexpandierbarer Stent**
  - **Empfehlung:** Advanta™ V12[3]
    Jeder für die A. renalis zugelassene Stent kann verwendet werden*

- **Ballon - Anwendung**
  - Reliant™ Ballon zur optimalen Anpassung des Endurant™ Stentgrafts mit der Aortenwand und den A. renalis Stents
  - Zusätzliche Aufdehnung des Renalis Stents kann mit dem mitgelieferten Ballon erzielt werden. Dabei muss die IFU befolgt werden. Bei Bedarf kann ein größerer Ballon gewählt werden, um den Diameter des Stents anzupassen.
  - **Empfehlung:** Admiral Xtreme™ PTA Ballonkatheter OTW 0.035" Unterstützung für das Renalis Zugangsmanöver (4 mm x 40 mm)

- **Inflationssysteme**
  - 20 CC Spritze
  - 20 CC inflationsystem mit einem Manometer

[1] = Terumo Medical Corporation; [2] = Cook Medical; [3] = MAQUET Cardiovascular, LLC;
* = Medtronic R & D Testung fand unter Nutzung des Advanta™ V12 Stents von Maquet

ChEVAR mit dem Endurant™ StentGraft

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The PROTAGORAS study to evaluate the performance of the Endurant stent graft for patients with pararenal pathologic processes treated by the chimney/snorkel endovascular technique

Konstantinos P. Donas, MD,[a,b] Giovanni B. Torsello, MD,[a,b] Gianluca Piccoli, MD,[c] Georgios A. Pitoulias, MD,[a,b,d] Giovanni Federico Torsello, MD,[c] Theodosios Bisdas, MD,[a,b] Martin Austermann, MD,[a,b] and Daniele Gasparini, MD,[c] *Münster, Germany; Udine, Italy; and Thessaloniki, Greece*

- **128** Patienten mit pararenalen Pathologien und der Indikation in Chimney Technik mit **Endurant™** und Atrium **Advanta™ V12**[1] Stents behandelt zu werden
- Follow up: 3 Jahr in einer Kaplan Mayer Analyse

K. Donas et. al, J Vasc Surg. 2016 Jan;63(1):1-7; [1] =MAQUET Cardiovascular, LLC

PROTAGORAS Studie
STUDIEN ERGEBNISSE

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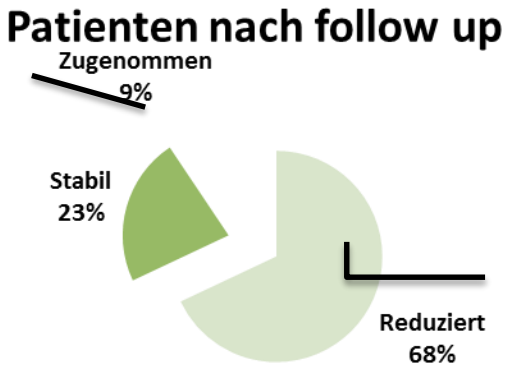
- Primäre Endpunkte:
  - Aneurysma Sackdurchmesser Rückbildung
  - Chimney Graft Offenheit
- Aneurysma Sackrückbildung: **64.8**+/-14.6 mm → **60.1**+/-16.3 mm, **p <0.001**
- NeunTyp Ia Endoleak benötigten einen sekundären Eingriff: **1.6 %**

90,6 % Patienten mit reduzierten oder stabilen AAA Diametern



K. Donas et. al, J Vasc Surg. 2016 Jan;63(1):1-7

PROTAGORAS Studie
PRIMÄRE CHIMNEY GRAFT OFFENHEIT

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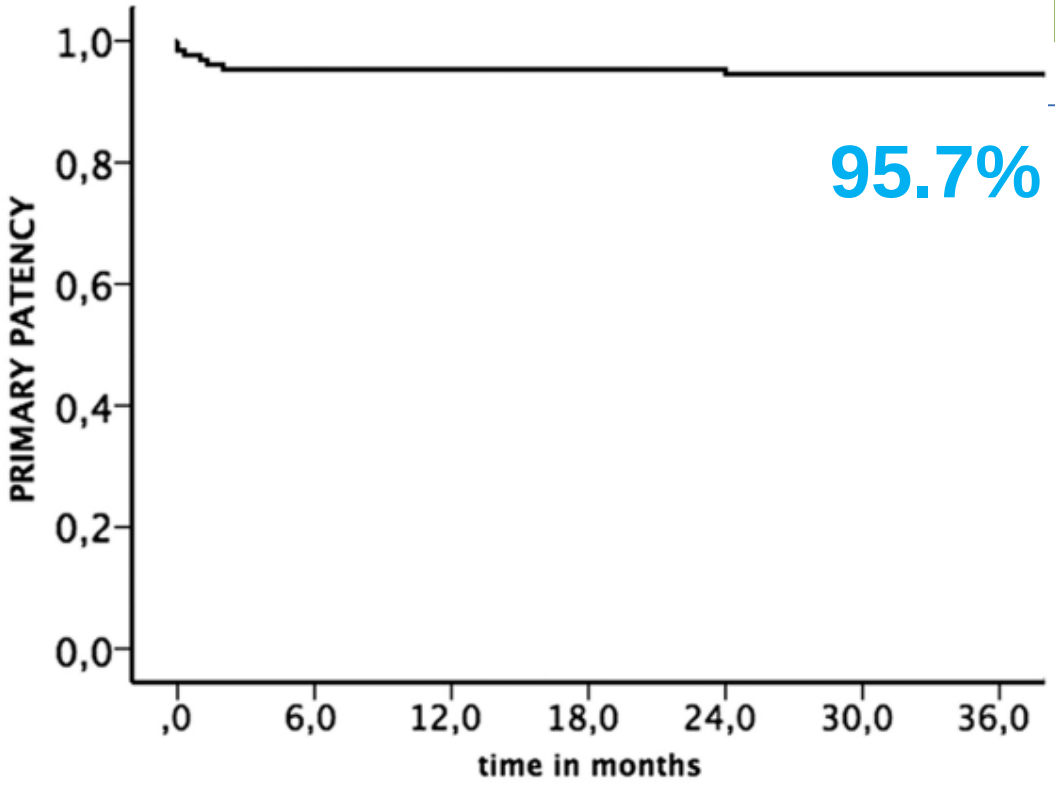

patients at risk:	128	105	92	84	64	52	38
chimney's at risk:	187	152	138	125	93	75	52
standard errors:	0,04	0,04	0,04	0,04	0,04	0,04	0,03

K. Donas et. al, J Vasc Surg. 2016 Jan;63(1):1-7

PROTAGORAS studie
REINTERVENTIONEN

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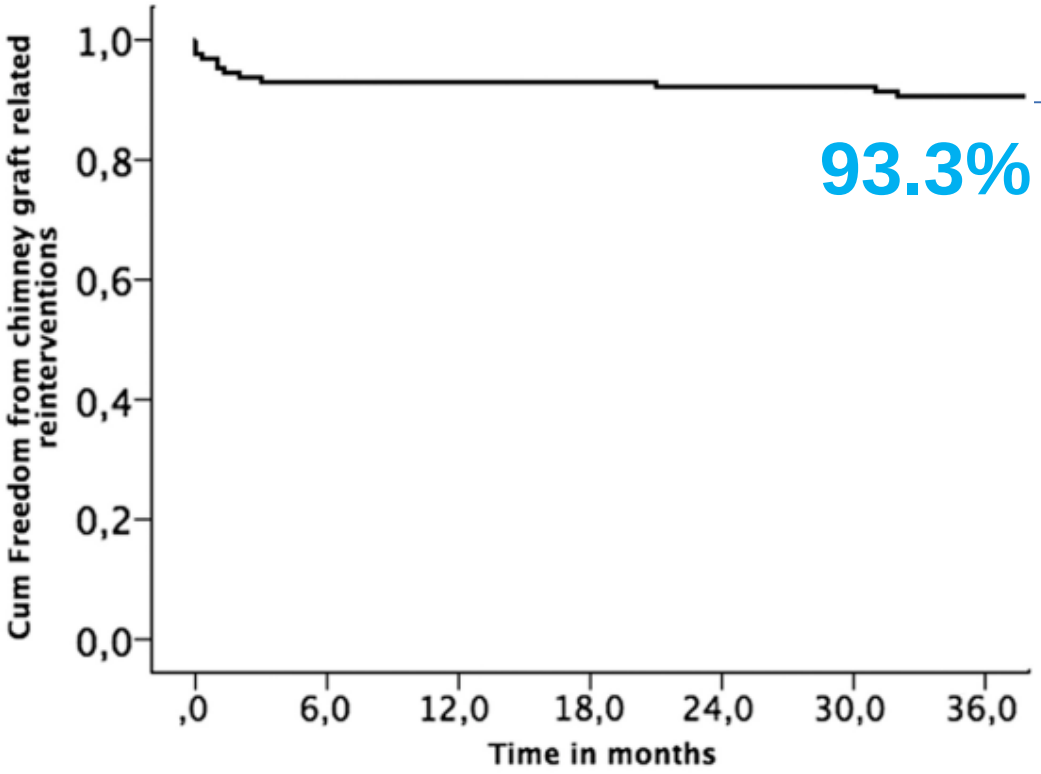

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K. Donas et. al, J Vasc Surg. 2016 Jan;63(1):1-7

PROTAGORAS Studie
SCHLUSSFOLGERUNG DES AUTORS

Evangelisches Amalie Sieveking-Krankenhaus
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- Standardisierung bei Behandlung mit ChEVAR Technik unter Verwendung von Endurant™ in Kombination mit Advanta™ V12[1] bei **128 Patienten** ermöglicht eine hohe **technische Erfolgsrate**, signifikante **Aneurysmasack Rückbildung** und eine niedrige **sekundäre Prozedurrate**.
- Standardiserierung der Therapie, vernünftige Systemauswahl und Kreierung einer neuen proximalen Landezone von >15 mm scheinen der Schlüssel für eine verantwortungsbewusste Behandlung von Patienten mit pararenalen Aneurysmen mit der ChEVAR Technik .
- Dennoch: Es sind weitere Erfahrungen von anderen Zentren notwendig, um diese Therapie als vollständige und sichere alternative zu etablieren.

K. Donas et. al, J Vasc Surg. 2016 Jan;63(1):1-7; [1] =MAQUET Cardiovascular, LLC

- Zusammenfassung

- Ein großer Teil von EVAR wird international außerhalb der IFU implantiert
- Frühere Studien zeigten eine Unterlegenheit der Therapie mittels EVAR außerhalb der IFU
- Neuere Studien lassen hoffen
- CHEVAR hat vergleichbare Resultate zur FEVAR hinsichtlich Größenprogredienz und Offenheitsraten der Seitenarme
- CHEVAR bietet im Notfall die Möglichkeit off the shelf juxtarenale BAA´s zu therapieren
- CHEVAR ist eine etablierte Therapieform bei juxtarenalen BAA´s,
- Die Endurant II hat die Zulassung für die Parallel-Stenttechnik