

◆ **TABLE OF CONTENTS** ◆

The following abstracts (arranged alphabetically by first author) were presented during **International Congress XIX on Endovascular Interventions**. The Congress, under the direction of Edward B. Diethrich, Nabil Dib, and Robert Strumpf, was presented February 12–16, 2006, by the Arizona Heart Institute Foundation and endorsed by the INTERNATIONAL SOCIETY OF ENDOVASCULAR SPECIALISTS.

P19 Progenitor Cells Progress to Organized Contracting Myocytes after Chemical and Electrical Stimulation: Implications for Vascular Tissue Engineering O Abilez, P Benharash, E Miyamoto, A Gale, C Xu, C Zarins <i>Stanford, California, USA</i>	I-1
Carotid Duplex Velocity Criteria Revisited for the Diagnosis of Carotid In-Stent Restenosis AF AbuRahma <i>Charleston, West Virginia, USA</i>	I-1
Endoluminal AAA Repair Causes More Perioperative Renal Dysfunction Than Open Repair but No Long-term Deterioration (1–3 y) M Adiseshiah <i>London, UK</i>	I-2
TRT in CIN, PVD, AAA, TAA, CABG, and Beyond! Targeted Renal Therapy in Chronic Renal Insufficiency and Contrast Induced Nephropathy (CIN) DE Allie, CJ Hebert, MD Lirtzman, CH Wyatt, VA Keller, AA Allie, CM Walker <i>Lafayette, Louisiana, USA</i>	I-3
Stent-Grafting of Non-Atherosclerotic Internal Carotid Artery Lesions A Assadian, C Senekowitsch, J Strassegger, GW Haggmüller <i>Vienna, Austria</i>	I-3
Transradial Approach for Cardiovascular Interventions: Why, How, and When! A Benassi, G D’Anniballe, L Steffanon <i>Modena, Italy</i>	I-4
Fenestrated and Branched Aortic Endografts: Are We Ready for the Aortic Arch? M Berce, D Hartley, J Anderson <i>Adelaide, Perth, and Ashford, Australia</i> ..	I-4
Experiences With Foam Sclerotherapy J Bergan <i>La Jolla, California, USA</i>	I-5

Continued

◆ TABLE OF CONTENTS ◆

New Approach for Type A Aortic Dissection With Combined Ascending Aortic Repair and Supra-Aortic Vessel Transposition	
P Bergeron, T de Chaumaray, P Coulon, M Ruiz-Patino, F Mariotti, A Shah, J Gay <i>Marseille, France</i>	I-6
PRIAMUS (Proximal Flow Blockage Cerebral Protection During Carotid Stenting)	
G Biamino <i>Modena, Mercogliano, Cortignola, and Mirano, Italy</i>	I-6
Molecular Therapy as a New Strategy in the Prevention of Restenosis. Role of NO/iNOS and CO/HO-1 in Inhibition of Intimal Hyperplasia in a Rodent Model of Balloon Injury	
GM Biasi, A Froio, MG Cerrito, A Scagliarini, S Turolo, A Liloia, G Deleo, ML Lavitrano <i>Milan, Italy</i>	I-7
The Orqis Cancion Endovascular System for Refractory CHF	
SF Bolling, B Czerska, RM Oren, MR Zile, MA Konstam, and the MOMENTUM investigators <i>Ann Arbor and Detroit, Michigan; Iowa City, Iowa; Charleston, South Carolina; Boston, Massachusetts, USA</i>	I-8
Spinal Cord Ischemia and Endovascular Treatment of Thoracic Aneurysm: Prediction or Prevention?	
J Busquet <i>Paris, France</i>	I-8
Branched Stent-Grafts for Thoracoabdominal and Pararenal Aortic Aneurysms	
TAM Chuter <i>San Francisco, California, USA</i>	I-9
Preliminary Results of the Medtronic Vascular Thoracic Stent-Graft System for Patients With Thoracic Aortic Disease. The Valor Trial: High-Risk, Nonsurgical Arm	
RM Fairman, MA Farber, RA White, JM Tucheck, FJ Criado <i>Philadelphia, Pennsylvania; Chapel Hill, North Carolina; Torrance, California; Maywood, Illinois; Baltimore, Maryland, USA</i>	I-10
DVT: When to Treat, When Not to Treat, Uses of Lysis and Mechanical Thrombectomy	
ZJ Haskal <i>New York, New York, USA</i>	I-11
Role of Adhesion Molecules in the Induction of Restenosis After Angioplasty in the Lower Limb	
P Heider, M Wildgruber, O Wolf, W Weiss, H Berger, M Hanke, H-H Eckstein <i>Munich, Germany</i>	I-11
New Concept of Stenting for the Treatment of Peripheral Arterial Aneurysm: First in Vitro and Animal Studies With the Multilayer Stent	
M Henry, N Frid, P Gruffaz, I Henry, M Hugel <i>Nancy, France; Hyderabad, India</i>	I-12
Stent-Graft Repair of Complicated Acute Type B Dissections: An 8-Year Experience	
K Ivancev, N Dias, B Sonesson, B Koul, M Malina <i>Malmö, Sweden</i>	I-12

Continued

◆ TABLE OF CONTENTS ◆

Aortic Debranching to Facilitate Endograft Repair of Complex Thoracoabdominal Aneurysms	
K Kasirajan, R Milner, E Chaikof <i>Atlanta, Georgia, USA</i>	I-13
Cryoplasty Therapy for Critical Limb Ischemia and Claudication	
G Kasper, PM Clark <i>Toledo, Ohio, USA</i>	I-13
Respect, Don't Fear, the Short Proximal Aortic Neck: Analysis of the BCVI AAA 10-Year EVAR Experience	
BT Katzen, A Maclean, J Benenati, G Zemel, A Powell, S Samuels, H Katzman <i>Miami, Florida, USA</i>	I-14
Autologous Peripheral Blood Stem Cell Transplantation in Patients With Peripheral Critical Ischemia	
R Kolvenbach, E Schwierz <i>Düsseldorf, Germany</i>	I-14
Complications of Vascular Surgery After Treatment With Endovascular Intervention	
Z Krajcer, N Strickman, A Mortazavi, K Dougherty <i>Houston, Texas, USA</i>	I-15
An Engineered VEGF-Activating Zinc Finger Transcription Factor Induces Angiogenesis and Bone Marrow Endothelial Progenitor Cell Production	
GK Lam, RG Mitchell, BH Annex, CD Kontos <i>Durham, North Carolina, USA</i>	I-16
Fascia Suture of Large Access Sites After Percutaneous Endovascular Treatment of Aortic Aneurysms and Dissections	
T Larzon, H Geijer, G Gruber, R Popek, L Norgren <i>Örebro, Sweden</i>	I-16
Outcomes and Lessons Learned From Fenestrated Grafting in Western Australia: Review of 58 Cases	
MMD Lawrence-Brown, JB Semmens, D Hartley, E Allen <i>Nedlands and Perth, Western Australia</i>	I-17
Clinical Outcome of Combined Surgical and Endovascular Treatment of Complex Thoracic Aortic Aneurysms	
PH Lin, W Zhou, M Reardon, RL Bush, EK Peden, AB Lumsden <i>Houston, Texas, USA</i>	I-17
EVAR for rAAA With Shock: Implantation of Bifurcated Stent-Grafts During Continuous Transfemoral Balloon Occlusion of the Aorta	
M Malina, F Veith, K Ivancev, B Sonesson <i>Malmö, Sweden; New York, New York, USA</i>	I-18
Previously Underestimated Incidence of Subclinical Myocardial Damage: A Prospective Concurrent Comparison of Endovascular Versus Open Repair of Infrarenal AAA	
J May, N Abraham, D Sullivan, GH White, JP Harris <i>Sydney, Australia</i> ...	I-19
Results of Treatment of Infrapopliteal Arterial Occlusive Disease Using the SilverHawk Plaque Excision Device	
JF McKinsey <i>New York, New York, USA</i>	I-19

Continued

◆ TABLE OF CONTENTS ◆

Anatomical Suitability for Endovascular Treatment of Ruptured Abdominal Aortic Aneurysms	
M Mehta, RC Darling III, SP Roddy, Y Sternbach, KJ Ozsvath, PB Kreienberg, PSK Paty, BB Chang, M Dhiraj, DM Shah <i>Albany, New York, USA</i>	I-20
Absence of Buttock Claudication Following Stent-Graft Coverage of the Hypogastric Artery Without Coil Embolization in Endovascular Aneurysm Repair	
M Mell, G Tefera, M Schwarze, S Carr, C Archer, J Hoch, W Turnipseed <i>Madison, Wisconsin, USA</i>	I-21
Initial Experience With a Remote Pressure Sensor During Endovascular TAA Repair	
R Milner, PG Silveira <i>Atlanta, Georgia, USA; Florianopolis, Brazil</i>	I-21
Ultrasound-Assisted Thrombolysis: A New Concept for an Old Treatment	
A Motarjeme <i>Downers Grove, Illinois, USA</i>	I-22
Dynamic Cine CTA Imaging Discovers Renal Artery Conformational Change Secondary to EVAR: Implications for a Fenestrated Future	
BE Muhs, A Teutelink, M Prokop, KL Vincken, ELG Verhoeven, FL Moll, HJM Verhagen <i>Utrecht and Groningen, The Netherlands</i>	I-22
Is Percutaneous Aortic Valve Replacement Just an Unrealistic Dream?	
S Müller-Hülsbeck, T Attmann, T Jahnke, G Lutter <i>Kiel, Germany</i>	I-23
In Vivo Attenuation of Myointimal Hyperplasia Using Transforming Growth Factor Beta 3 in an Interposition Graft Model	
MO Murphy, J Ghosh, AT Halka, A Carter, NJ Turner, MW Ferguson, CM Kielty, MG Walker <i>Manchester, UK</i>	I-24
Endovascular Aneurysm Repair With Suprarenal Versus Infrarenal Fixation: A Controlled Study of Renal Effects	
S Parmer, JP Carpenter <i>Philadelphia, Pennsylvania, USA</i>	I-24
Biological Treatment for Aneurysms: Is It the Third Wave After Resection and EVAR?	
JC Parodi, FE Parodi <i>St. Louis, Missouri, USA</i>	I-25
Cerebral Protection Devices Should Be Used Routinely in Carotid Artery Stenting	
JC Parodi, FE Parodi <i>St. Louis, Missouri, USA</i>	I-25
Does Carotid Stenting Work in the Long Run? 5-Year Results of CAS in Major European Centers	
P Peeters, M Bosiers, J Verbist, K Deloose, H Sievert, J Sugita, F Castriota, A Cremonesi <i>Bonheiden and Dendermonde, Belgium; Frankfurt, Germany; Ravenna, Italy</i>	I-26
Comparison of Endovascular and Standard Open Surgical Repair of Abdominal Aortic Aneurysms: 5-Year Follow-up Using the Excluder Bifurcated Endoprosthesis	
BG Peterson, JS Matsumura, MS Makaroun, DC Brewster, for the Excluder Bifurcated Endoprosthesis Investigators <i>Chicago, Illinois, USA</i>	I-26

Continued

◆ TABLE OF CONTENTS ◆

Italian Excluder Registry: Preliminary Results	
C Pratesi, F Benedetti Valentini, E Vecchiati, PG Cao, P Castelli, R Chiesa, G Coppi, G De Blasis, L Ganassin, P Mancinelli, G Passalacqua, P Passariello, GR Pistolese, G Simonetti, D Tealdi <i>Florence, Rome, Perugia, Reggio Emilia, Varese, Milan, Modena, Avezzano, and Treviso, Italy</i>	I-27
Different Therapeutic Strategies for Multilevel Aortic Disease	
G Pratesi, N Troisi, L Azas, A Fargion, R Pulli, W Dorigo, A Alessi Innocenti, C Pratesi <i>Florence Italy</i>	I-28
Endovascular Approaches for Complex Forms of Recurrent Aortic Coarctation	
O Preventza, GH Wheatley III, J Williams, VG Ramaiah, J Rodriguez-Lopez, EB Diethrich <i>Phoenix, Arizona, USA</i>	I-28
Four-Year Results of the Pivotal U.S. Multicenter Trial of the Powerlink Endograft for EVAR	
V Ramaiah for the Endologix Investigators <i>Phoenix, Arizona, USA</i>	I-29
The Role of Carotid Imaging in the Selection of Patients for Endovascular Treatment	
AW Reid <i>Glasgow, Scotland, UK</i>	I-29
Early Clinical Experience With Virtual Histology Intravascular Ultrasound	
D Reid <i>Wishaw, Scotland, UK</i>	I-31
Early Experience of a New Stent-Graft and Delivery System for Arch Applications: Worldwide and Single-Center Updates	
V Rimbau <i>Barcelona, Spain</i>	I-31
Preventive Treatment of Type II Endoleaks Using Fibrin Glue: A 2-Year Experience	
S Ronsivalle, F Faresin, F Pettenuzzo, M Riggi, R Lipari, C Rettore, L Pedon, M Zanchetta <i>Padua, Italy</i>	I-32
Remote SFA Endarterectomy and Distal aSpire Stenting: Multinational Results at 3-Year Follow-up	
D Rosenthal <i>Atlanta, Georgia, USA</i>	I-32
Is Carotid Artery Stenting Really Dangerous in Octogenarians?	
C Setacci, A Cremonesi, F Castriota, G de Donato, F Setacci, E Chisci, M Pieraccini, A Cappelli <i>Siena, Italy</i>	I-33
Inferior Vena Cava Syndrome: Recognition and Management	
P Thorpe <i>Iowa City, Iowa, USA</i>	I-33
Impact of Venous Hemodynamics on Development of Endovascular Stent-Vein Valves	
R Tripathy, F Osse <i>Wellington, New Zealand; Sao Paulo, Brazil</i>	I-34
Abdominal Aortic Aneurysm in Women: Should They Be Screened?	
SM Trocciola, EJ Ryer, SC Lin, RA Chaer, B DeRubertis, M Pierce, P Christos, L Mureebe, PL Faries, KC Kent <i>New York, New York, USA</i>	I-35

Continued

◆ TABLE OF CONTENTS ◆

Endofixer Endosuturing Device: Experimental Tests	
G Tuscano, C Adami, R Calvi, L Patorno <i>Modena and Verona, Italy</i>	I-35
Effect of Endoleak and Stent-Graft Design on Aortic Properties Following EVAR:	
Determination Using a Novel Dynamic Cine MRA Imaging Modality	
JA van Herwaarden, BE Muhs, KL Vincken, J van Prehn, A Teutelink, LW Bartels, FL Moll, HJM Verhagen <i>Utrecht, The Netherlands</i>	I-36
Protection and Management of Visceral Artery and Hypogastric Artery Disease in Patients With AAAs That Are Treated by EVAR	
FJ Veith, M Mehta <i>Bronx and Albany, New York, USA</i>	I-36
Vertebral Angioplasty and Stenting: True Indications	
GH Wheatley III, K Halow, J Rodriguez-Lopez, V Ramaiah, R Ravi, EB Diethrich <i>Phoenix, AZ, USA</i>	I-36
Does Preop AAA Size Influence Sac Regression and Classical Remodeling With the Powerlink System?	
JB Williams <i>Peoria, Illinois, USA</i>	I-37
Greater “Oversizing” of Aortic Endografts Is Required for Shorter Aneurysm Necks in Endovascular Aortic Aneurysm Repair (EVAR)	
SS Zhou, J Brennan, TV How, GL Gilling-Smith, PL Harris <i>Liverpool, UK</i>	I-39
The E-Vita Stent-Graft in Endovascular Thoracic Aortic Procedures: First Clinical Experience	
B Zipfel, R Hammerschmidt, T Krabatsch, S Buz, R Hetzer <i>Berlin, Germany</i>	I-39

◆ ABSTRACTS

P19 Progenitor Cells Progress to Organized Contracting Myocytes after Chemical and Electrical Stimulation: Implications for Vascular Tissue Engineering

O Abilez, P Benharash, E Miyamoto, A Gale, C Xu, C Zarins
Stanford University, Stanford, California, USA

Purpose: To test the hypothesis that a level of chemical and electrical stimulation exists that allows differentiation of progenitor cells into organized contracting myocytes so that they can serve as components for tissue engineered vascular grafts.

Methods: A custom-made bioreactor was constructed with the capability of delivering electrical pulses of varying field strengths, widths, and frequencies. Individual chambers of the bioreactor allowed us to continuously electrically stimulate cultured cells under microscopic observation. On day 0, 1% dimethyl sulfoxide (DMSO), known to differentiate cells into myocytes, was added to P19 progenitor cells. Immediately after, electrical pulses of varying field strengths (0–3 V/cm), widths (2–40 ms), and frequencies (10–25 Hz) were applied continuously for 22 days. On day 5, the media containing DMSO was exchanged with regular media and the electrical stimulation continued. From days 6–22, the cells were visually assessed for signs of viability, contractility, and organization.

Results: P19 cells remained viable, with pulsed electrical fields <3 V/cm, pulse widths <40 ms, and pulse frequencies from 10 to 25 Hz. On Day 11, the first spontaneous contractions were observed. For individual colonies, local synchronization and organization were seen. We were also able to synchronize multiple colonies with externally applied electrical fields.

Conclusion: P19 progenitor cells progress to organized contracting myocytes after chemical and electrical stimulation. We will use the results from this study to help us differentiate other progenitor cells into organized smooth muscle cells. Incorporation of such cells into

existing methods of producing endothelial cells, fibroblasts, and scaffolds may allow production of improved tissue engineered traditional and endovascular grafts.

Carotid Duplex Velocity Criteria Revisited for the Diagnosis of Carotid In-Stent Restenosis

AF AbuRahma

Robert C. Byrd Health Sciences Center
of West Virginia University, Charleston,
West Virginia, USA

In the past decade, percutaneous carotid angioplasty/stenting has become a widely accepted treatment modality for significant carotid artery stenosis in high-risk patients. However, there has been an ongoing debate regarding which duplex ultrasound criteria to use to determine the rate of restenosis after carotid stenting. Presently, standard duplex ultrasound velocity criteria have not been established for patients undergoing carotid stenting.

Early studies have reported the incidence of carotid in-stent restenosis to range between 1% and 50%. These reported rates varied depending on the definition of restenosis used, the method of stenosis calculations, and the duration of follow-up. We previously reported a higher rate of $\geq 50\%$ carotid in-stent restenosis (32%) when applying the standard carotid duplex ultrasound velocity criteria for non-stented carotid arteries (peak systolic velocity [PSV] ≥ 140 cm/s). Few other published studies have reported the potential source for errors when using the standard ultrasound criteria after carotid stenting, since the reduced compliance of stented carotid arteries may produce falsely elevated velocities relative to the native non-stented carotid artery. Therefore, we conducted a prospective study to revisit duplex ultrasound criteria for determining the rate of significant ($\geq 50\%$) in-stent carotid restenosis.

In analyzing a subset of 12 patients who had both completion carotid angiography and carotid duplex ultrasound within 30 days after

stenting, 10 patients with normal post-stenting carotid angiograms (<30% residual stenosis) had PSVs of the stented internal carotid artery (ICA) ≤ 150 cm/s; 2 patients with $\geq 30\%$ residual stenosis had ICA PSVs > 150 cm/s.

Eighty patients who underwent carotid stenting as a part of clinical trials (Maverick 1 and 2, Capture, Crest, and Shelter trials) will be analyzed. All patients underwent post-stenting carotid duplex ultrasound scanning at 1 month and then every 6 months thereafter. PSVs and end-diastolic velocities of the ICA and common carotid artery (CCA) and the ICA/CCA PSV ratios were recorded. Patients with PSVs of the stented artery > 150 cm/s underwent carotid computed tomographic angiography and/or conventional carotid arteriography to verify the presence of $\geq 50\%$ in-stent restenosis. Receiver operator curve analyses will be conducted to determine the sensitivity, specificity, positive predictive value, and negative predictive value of the threshold of PSV of > 150 cm/s for detecting $\geq 50\%$ in-stent restenosis.

Endoluminal AAA Repair Causes More Perioperative Renal Dysfunction Than Open Repair But No Long-term Deterioration (1–3 y)

M Adiseshiah

University College Hospital London, UK

Purpose: To compare (1) perioperative renal function in well-matched patients undergoing

OR (Group A) or ER (Group B) and (2) preoperative renal function in other ER patients (Group C) with function 1 to 3 years after surgery.

Methods: Of 73 patients undergoing AAA repair, 45 were recruited to this prospective case-control study as follows: Group A: 14 patients (12 men; median age 77 years), Group B: 14 patients (11 men; median age 76 years), and Group C: 17 patients (14 men; median age 76 years). Serum creatinine (Cr), Cr clearance, and/or glomerular filtration rate (GFR) estimates were carried out with MAG3 renal studies. From the MAG3 renal scans, the perfusion, split renal function, mean parenchymal transit time (MPTTI), and outflow pattern were assessed. Groups A and B underwent scintigraphic evaluation preop and at 8 days postop. Group C were assessed preop and at 1 to 3 years postop.

Results: Fifteen (48%) of 31 patients undergoing ER had preop renal dysfunction (GFR < 50 mL/min) compared with OR (2/14, 14%; Table). Ten patients from Groups B and C developed severe renal dysfunction. Two of these died, 1 required hemodialysis (graft deployed over the renal arteries), 2 were dialysis-free but developed worsening renal function, and 5 regained their previous renal function. In 4 ER cases, differential function improved, in 1 with RPF it deteriorated, and in 9 it was unchanged.

Conclusion: ER inflicts a greater degree of perioperative renal dysfunction than OR. In the absence of technical problems with en-

TABLE
Comparative Renal Function Parameters in Matched Patients Undergoing Open or Endovascular AAA Repair

	Group A (OR) (n=14)		Group B (ER) (n=14)		Group C (ER) (n=17)	
	Pre	Post	Pre	Post	Pre	Post
Serum Cr, mmol/L	122 (82–210)	161 (90–260)	130 (81–200)	181 (80–341)	124 (68–256)	146 (68–491)
		p<0.008		p<0.01		NS
GFR, mL/min	52 (30–110)	47 (23–108)	51 (29–84)	39 (8–97)	49 (20–90)	43 (0–114)
		p<0.01		p<0.008		NS
MPTTI, s*	190	270	172	267	195	210
		p<0.02		p<0.002		NS
Post GFR						
Post MPTTI		p<0.03				
		p<0.01				

Continuous data presented as mean (range).

Cr: creatinine, GFR: glomerular filtration rate, MPTTI: mean parenchymal transit time, NS: not significant.

* Normal < 240 s.

dograft deployment, renal function in ER in the long term is not adversely affected.

◆ ————— ◆

TRT in CIN, PVD, AAA, TAA, CABG, and Beyond! Targeted Renal Therapy in Chronic Renal Insufficiency and Contrast Induced Nephropathy (CIN)

DE Allie, CJ Hebert, MD Lirtzman, CH Wyatt, VA Keller, AA Allie, CM Walker
Cardiovascular Institute of the South,
Lafayette, Louisiana, USA

The mortality and morbidity of the chronic renal insufficiency (CRI) patient undergoing non-percutaneous coronary intervention (PCI) endovascular and open cardiovascular procedures is significantly increased without contrast-induced nephropathy (CIN), and sparse data exists if CIN becomes involved. The incidence of CIN in PCI is 14% to 37%, with in-hospital mortalities of 7.1% to 35.7% if dialysis is required with a 2 to 3 times higher 1-year mortality. Pre-existing CRI and diabetes (DM) are major predictors for CIN in PCI, and if they occur simultaneously will increase the CIN incidence to 50% in PCI. The role of CIN in percutaneous peripheral interventions (PPI), AAA and TAA EVAR is unknown but likely more significant than PCI as the incidence of DM and CRI is significantly higher in PPI. Little is known about CIN in open vascular or cardiac surgery (CS), but in CS, even mild degrees of CRI (creatinine 1.5–1.8 mg/dL) have associated increased in-hospital, 30-day, and 1-year mortalities. Clearly, any treatment strategy designed to target the CRI or at-risk-for-CIN patient could have profound clinical impact. Targeted renal therapy (TRT) is one such novel therapy where direct high-dose intrarenal infusion of fenoldopam, a short-acting selective dopamine-1 agonist and vasodilator, is infused into both renal arteries by the recently FDA-approved Benephit PV Infusion System.

TRT with fenoldopam 0.2 to 0.4 mcg/kg/min via the 5-Fr Benephit bifurcating catheter was utilized in a variety of high-risk PPI (n=24), EVAR (n=5), and CS (n=7) patients with treatment durations of 1 (periprocedural) to 48

hours via both femoral and brachial access. No patient developed CIN or >25% rise in creatinine in this small 1-month initial experience.

Conclusion: TRT via the Benephit Infusion System is a novel therapy in treating the high-risk CRI patient. This technique has potential widespread clinical use in treating many of our cardiovascular patients even beyond CIN.

◆ ————— ◆

Stent-Grafting of Non-Atherosclerotic Internal Carotid Artery Lesions

A Assadian, C Senekowitsch, J Strassegger, GW Hagmüller
Wilhelminenspital Vienna, Austria

Purpose: To report our experience with combined conventional and endovascular covered stent treatment of nonatherosclerotic internal carotid artery (ICA) lesions under reversed flow.

Methods: From February 1999 to June 2005, 16 ICAs in 13 symptomatic patients (mean age 48 years, range 30–78) were revascularized using a hybrid conventional/endovascular technique. All patients were treated with a covered stent introduced via a cervical approach.

Results: Two patients suffered a perioperative transient neurological deficit. Duplex scans revealed ideally patent prostheses; both patients fully recovered without any changes on repeat computed tomography. One patient developed perioperatively a recurrent laryngeal nerve weakness. No perioperative strokes or deaths were observed. The follow-up ranged from 1 to 68 months (mean 43). No thromboembolic neurological events, graft occlusions, or hemodynamically significant stenosis were seen during the observation period.

Conclusion: Stent-grafting of nonatherosclerotic ICA lesions is safe, with low perioperative morbidity and very good long-term patency.

◆ ————— ◆

Transradial Approach for Cardiovascular Interventions: Why, How, and When!

A Benassi, G D'Anniballe, L Steffanon
Hesperia Hospital, Modena, Italy

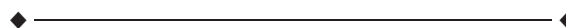
Purpose: To report the technique for and our results with the transradial approach for percutaneous transluminal angioplasty (PTA).

Technique: An Allen test was performed to verify ulnar collateral flow in the hand. The arm is abducted 45%, immobilized with a rigid system (Radistop), and after local anesthesia, the radial artery is punctured with a 19-G needle. The artery is catheterized with a 0.032-inch guide on which is inserted an introducer sheath. To avoid induced spasm, a mixture of heparin (5000 units), verapamil (1 mg), and nitroglycerin (0.4 mg) was infused through the introducer sheath.

In the last 2 years, we performed 35 renal PTAs (75% of all cases), 4 vertebral PTAs, and 5 PTAs of the abdominal trunks. All these procedures were performed using the "coronary technique," with a 6-F guiding catheter and 0.014-inch guidewire. We also performed 8 PTAs of the subclavian artery and 11 cases of iliac PTA mixing the traditional technique with 0.035-inch guidewire and 6 or 7-F sheath with the "coronary technique" by means of guide catheters or long sheath and 0.014-inch guides. Finally, we performed 24 cases of carotid PTA (11% of all cases) always using NeuroShield filter protection and a 7-F guiding catheter or 6-F long sheath. We used 2 techniques in consideration of the different anatomic structure: in 12 cases we cannulated the common carotid artery with a diagnostic catheter, then after having positioned an exchange wire in the external carotid artery, we deeply cannulated the common carotid artery with a guiding catheter or long sheath. In 12 cases, we cannulated the common carotid ostium with a guiding catheter (generally of the inner mammary artery) and completed the procedure from this position. In this case, generally we placed an extra-stiff 0.014-inch support guide in the external carotid to offer more stability to the whole system. On the pre-discharge control, all the radial arteries remained open; in our global coronary expe-

rience with 6,000 cases, the percentage of vessel occlusion is <2% and local complications 0.001%.

Conclusion: The radial approach can be used in many patients for different procedures. The advantages are mainly related to patient comfort and to a quicker discharge with an evident reduction in assistance costs. However, dedicated devices are required for routine use of this approach in peripheral procedures.



Fenestrated and Branched Aortic Endografts: Are We Ready for the Aortic Arch?

M Berce, D Hartley, J Anderson
Royal Adelaide Hospital, Adelaide; Cook Research (Australia), Perth; and Ashford Hospital, Ashford, Australia

Fenestrated endoluminal grafting is a procedure whose initial purpose was to deal with an unsuitable proximal aortic neck during implantation of an endograft in those patients deemed to be at high risk of open surgical repair. The principle was to utilize the juxtarenal segment of the aorta in order to achieve a durable seal while allowing continued renal and visceral perfusion via accurately placed fenestrations in the proximal graft segment. Initially, this required fenestration to aortic wall contact in order to create a durable seal. In some high risk patients, this was not always possible due to significant dilatation of the visceral aortic segment. To overcome this problem it became necessary to bridge the gap between the graft and the target vessel(s) ostium to produce a durable seal. This has been achieved in a variety of ways, the most simple of which was to breach the gap with a covered balloon-expandable stent. Success in this area encouraged us to expand such an approach to the treatment of suitable thoracoabdominal aneurysms.

A necessary prerequisite common to all forms of fenestrated and branch grafting is the ability to maintain rotational control of the device during delivery. In this way, alignment of all target vessels becomes possible. Rotational ability is dependent on factors such as

iliac artery anatomy, aortic angulations, aortic unfolding (especially in thoracic implants), and the proximity of the device to the site of entry. The aortic arch in general does not allow current devices to be rotated to any degree. Fixed curvatures of arch delivery systems have allowed easier and more accurate graft placement.

The presence of previously implanted branch vessel stents may prohibit both wall contact and device rotation, particularly if these stents sit proud in the lumen. Should the aortic lumen be significantly narrowed by mural thrombus, then rotation in the presence of a fixed graft side branch may not be possible; in such circumstances, alignment is not achieved. In those circumstances where the branch is forced against mural thrombus, there may be a failure of the branch to completely deploy, resulting in both the loss of the target vessel and continued perfusion of the aortic sac via the partially compressed side branch. Problems with unfavorable luminal anatomy have been largely overcome either with internal branches, internal hinged branches, or the use of reinforced fenestrations, which improve the ability of balloon-expandable stent-grafts to bridge the graft-vessel ostium gap.

Placement of indwelling guidewires in the branches at the time of graft loading can significantly simplify the procedure. To date, all methods have been employed to achieve a satisfactory seal; in some patients, a combination of more than one technique has been employed. These techniques have been used to successfully treat thoracoabdominal aneurysms by a groin approach; in most cases this has been achieved by a percutaneous approach. All cases required the use of custom-built grafts, and all to date have aimed at "anatomical" reconstruction. Targeted vessels to date have included carotid, left subclavian, celiac, superior mesenteric and renal vessels, with high success rates being achieved.

Conclusion: Experience gained in the treatment of juxtarenal aneurysms has allowed us to deal with thoracoabdominal aneurysms using similar methods. Progress in device use and design suggests that such procedures can be increasingly applied to the treatment suitable aortic arch aneurysms. A significant

proportion of our treatments have been carried out for late failure of open aortic repair.

Experiences With Foam Sclerotherapy

J Bergan

La Jolla, California, USA

Foam sclerotherapy must be looked upon as an entirely new method of treatment for venous insufficiency. We find it is useful in all types of varices and believe it is proven to be safe, simple, cheap, reliable, and repeatable. Making the foam uses two 5-mL syringes and a 2-way stopcock. The mixture is one part sclerosant and 4 parts room air. Only detergent sclerosing agents, such as Sotradecol and Polidocanol, at any concentration from 0.25% to 3% can be used.

In treating varicose veins, all published reports describe efficacy >80% in terms of immediate and primary venous occlusion. Repetition of injections in cases of initial failure allows the results to approach 95% efficacy with 3 sessions. Early and midterm results to >5 years demonstrate a recurrence rate of about 20%. Treating recurrences by injections is as simple as primary treatment and is at least as effective.

Severe complications of foam sclerotherapy are rare. In our experience, most DVTs are gastrocnemius veins or 1 of 2 posterior tibial vein thromboses sometimes after telangiectasia or reticular vein sclerotherapy. The incidence of deep and/or muscular venous thrombosis after sclerotherapy can be estimated around 3 per 10,000 sclerotherapy sessions. The more frequent complications are visual disorders, such as hemianopsia with a moiré effect. These adverse reactions have been observed with liquid sclerosing agents, but their incidence estimated at 0.5–1.0 per 100 foam sessions is much higher with foam. They are also observed in patients suffering from migraine and sometimes reproduce the typical aura. A dry cough is sometimes encountered. Finally, the usual sclerotherapy side effects of matting, superficial thrombi, and residual pigmentation are observed.

Conclusion: The question arises of why foam sclerosant treatment of varices succeeds when liquid sclerotherapy has made little impact. The answer lies in the nature of successful sclerotherapy, the endpoint of which is irreversible venous vascular fibrosis. This only occurs in response to endothelial cell destruction with exposure of the subendothelial layer of cells. This is accomplished by detergent sclerosants that work by the mechanism of protein theft denaturation, in which an aggregate of detergent molecules forms a lipid bilayer in the form of a cylinder, a sheet, or micelle. This disrupts the endothelial cell surface by stealing away the essential proteins from the cell membrane surface and producing delayed cell death. Foam is retained in the treated vein; liquid washes out quickly.



New Approach for Type A Aortic Dissection With Combined Ascending Aortic Repair and Supra-Aortic Vessel Transposition

P Bergeron, T de Chaumaray, P Coulon, M Ruiz-Patino, F Mariotti, A Shah, J Gay
Saint-Joseph Hospital, Marseille, France

Purpose: To describe a new less invasive approach for treating acute type A dissections involving the aortic arch in high-risk patients (HRP) unfit for aortic arch replacement.

Method: From January to October 2005, we treated 4 HRPs (2 women 48 and 68 years old and 2 57-year-old men) who were admitted in emergency for acute type A dissection involving the aortic arch. All presented with circulatory shock and were unfit for aortic arch surgery. In all patients, the innominate artery was debranched and bypassed end-to-end to the ascending aortic graft. We found this approach justified in 1 patient in whom no entry tear was seen in the ascending aorta or when the intimal flap originating from the ascending aorta extended to the arch, as seen in the other 3 patients. We performed adjunctive procedures to the aortic valve in 3 cases (1 valve replacement and 2 valvuloplasties) and a coronary bypass in 1 case. In a second step after complementary imaging, a carotid-ca-

rotid bypass was associated with aortic arch stent-graft exclusion. In 1 patient, the false channel completely thrombosed after the first step and the endovascular step had not been performed. We used TAG and EndoFit devices 20 cm long that covered the aortic arch and proximal descending aorta.

Results: During a mean follow-up of 8 months (range 4.6–10.6), there was no death or neurological complication. All patients showed a thrombosed thoracic aortic false channel, which remained patent at the abdominal level.

Conclusion: The staged closed hybrid procedure we describe allows all cardiac surgeons to avoid aortic arch replacement for type A dissections in HRP. This procedure is feasible and appears safe. The evolution of the design of industrial devices toward increased flexibility and length would certainly bring further security and efficacy.



PRIAMUS (Proximal Flow Blockage Cerebral Protection During Carotid Stenting)

G Biamino

Modena-Reggio Emilia S. Agostino Hospital,
Modena; Casa di Cura Montevergine,
Mercogliano; Casa di Cura Villa Maria
Cecillia, Cortignola; General Hospital,
Milano, Italy

Purpose: To evaluate the applicability and efficacy of the Mo.Ma device for prevention of cerebral embolization during carotid artery stenting (CAS) in a real world population.

Methods: In 4 centers in this Italian prospective registry, 416 patients (300 men; mean age 72 ± 9 years) were enrolled between October 2001 and March 2005. Of these, 264 (64%) were symptomatic with $>50\%$ diameter stenosis and 152 (36%) were asymptomatic with $>70\%$ diameter stenosis. The Mo.Ma Proximal Flow Blockage Embolic Protection System was used to perform protected CAS, achieving cerebral protection by endovascular clamping of the common carotid artery (CCA) and of the external carotid artery (ECA).

Results: Technical success, defined as the ability to establish protection with the Mo.Ma

device and to deploy the stent, was achieved in 412 (99%) cases. The mean duration of flow blockage was 4.9 ± 1.1 minutes. Transient intolerances to flow blockage were observed in 24 (5.8%) patients, but in all cases the procedure was successfully completed. No periprocedural strokes or deaths were observed. Complications during hospitalization included 16 (3.8%) minor strokes, 3 (0.7%) transient ischemic attacks, 2 (0.5%) deaths, and 1 (0.2%) major stroke. This resulted in cumulative rates at discharge of 4.6% for all strokes and deaths and 0.7% for major strokes and deaths. All the patients underwent 30-day follow-up, at which time there were no deaths or strokes, confirming the overall cumulative 4.6% all strokes and deaths rate, 0.7% rate of major stroke and death and 0.7% rate of major strokes and deaths at follow-up. In 245 (58.9%) cases, there was macroscopic evidence of debris after filtration of the aspirated blood.

Conclusion: This Italian multicenter registry confirms and further supports the efficacy and applicability of the endovascular clamping concept with proximal flow blockage in a broad patient series. Results match favorably with current available studies on carotid stenting with cerebral protection.

◆ ————— ◆

Molecular Therapy as a New Strategy in the Prevention of Restenosis. Role of NO/iNOS and CO/HO-1 in Inhibition of Intimal Hyperplasia in a Rodent Model of Balloon Injury

GM Biasi, A Froio, MG Cerrito, A Scagliarini, S Turolo, A Liloia, G Deleo, ML Lavitrano
University of Milan-Bicocca, Milan, Italy

Purpose: To identify new strategies for the prevention of restenosis based on the therapeutic effect of the protective molecules L-arginine by nitric oxide synthases (NO/iNOS) and carbon monoxide/heme oxygenase-1 (CO/HO-1) involved in the pathogenetic events of vascular injury.

Methods: In this study, a rat carotid balloon injury (BI) model was used as the gold stan-

dard for the study of intimal hyperplasia and restenosis. Sprague Dowley rats ($n=40$) were randomly assigned to 8 experimental groups ($n=5$ each) and treated with L-Arg (2.25%) as a NO donor, CO (250 ppm) zinc protoporphyrin IX (ZnPPiX) ($50 \mu\text{mol/kg}$) as an HO-1 and iNOS inhibitor, Sn protoporphyrin (SnPP) ($50 \mu\text{mol/kg}$) as an HO-1 inhibitor, and L-NAME (10 mg/kg) as an iNOS inhibitor. The treatment groups were A: carotid subjected to BI; B: rats w/o BI, w CO; C: rats w/o BI, w L-Arg; D: rats w BI, w L-Arg; E: rats w BI, w L-Arg + ZnPP 5 days before BI; F: rats w BI, w L-Arg, w SnPP 5 days before BI; G: rats w BI, w CO; and H: rats w BI, w CO, w L-NAME 5 days before BI.

Rats were anesthetized with isoflurane, and balloon injury was performed in the left carotid artery using a 2-F Fogarty catheter. Rats were sacrificed 14 days after the procedure, and the carotid arteries (left and right) were collected. Cross sections of carotid arteries were stained with hematoxylin-eosin. I/M area, I/M thickness, and % stenosis are summarized as the mean \pm SEM of rats that received the different treatments.

Results: Treatment with L-Arg as a NO donor or with CO resulted in a protective effect with prevention of intimal hyperplasia. The percentage of stenosis in the groups treated with L-Arg or CO (D,G) was significantly reduced versus group A, which was subjected to BI without treatment ($p<0.05$). Treatment with ZnPP, which inhibits HO-1, abolished the protective effect due to NO. The percentage of stenosis in rats treated with L-Arg in combination with ZnPP (E) was similar to the non-treated BI (A). Treatment with SnPP, which inhibits HO-1 but does not inhibit iNOS, did not abrogate the effect of L-Arg. The percentage of stenosis in group SnPP treated (F) was significantly reduced versus group A (non-treated BI) and group E (ZnPP treated) ($p<0.05$). Treatment with L-NAME, which inhibits iNOS, did not abrogate the effect of CO.

Conclusion: The results suggest that both HO-1/CO and iNOS/NO inhibit intimal proliferation in our model of balloon injury in rats. There is evidence that there is a functional relationship between CO and NO; nevertheless, we demonstrated for the first time that iNOS/NO exerts a beneficial effect without direct involvement of

HO-1 and that CO does not require iNOS/NO for its protective effect. CO and NO might be used clinically as therapeutic molecules in the prevention of restenosis following vascular injury and more in general in the treatment of arteriosclerotic vascular diseases.

The Orqis Cancion Endovascular System for Refractory CHF

SF Bolling, B Czerska, RM Oren,
MR Zile, MA Konstam, and
the MOMENTUM Investigators

University of Michigan, Ann Arbor, and
Henry Ford Hospital, Detroit, Michigan;
University of Iowa, Iowa City, Iowa; Medical
University of South Carolina, Charleston,
South Carolina; Tufts-New England Medical
Center, Boston, Massachusetts, USA

Purpose: To present results with the Cancion system, a small novel endovascular circuit that produces continuous (nonpulsatile) aortic flow augmentation (CAFA) for refractory decompensated congestive heart failure (CHF).

Methods: CHF patients (21 men; mean age 53 ± 12 years) with exacerbated CHF and elevated PCWP (despite inotropes) and reduced renal function and/or diuretic resistance were studied. Cancion pump inflow was via a femoral artery catheter and outflow via a percutaneous aortic catheter (20) or axillary cannula (4). Hemodynamics were measured at baseline, during, and after device therapy.

Results: The cath lab insertion time for the Cancion system was <30 minutes. Total Cancion CAFA duration was 73 hours (range 24–112), with a mean pump flow of 1.33 L/min. During pump flow, mean PCWP decreased from 28 ± 5 to 22 ± 9 mmHg, then to 20 ± 7 mmHg at 24 and 72 hours, respectively ($p < 0.0001$). In these patients, baseline cardiac index was 1.97 ± 0.46 L/min/m², which increased to 2.24 ± 0.45 L/min/m² at 72 hours ($p < 0.005$). This beneficial effect was sustained as noted by a PCWP of 21 ± 7 L/min/m² and CI of 2.32 ± 0.47 ($p < 0.0001$) at 24 hours post pump removal. Furthermore, the Cancion-treated patients had a fluid balance (I/O) of -3.5 L, weight loss averaged 2.2 kg, and creatinine trended downward ($p = 0.095$). Finally, left ven-

ticular unloading was evident by left atrial reduction on echo, from 5.1 ± 0.6 to 4.4 ± 0.5 cm ($p < 0.01$) and diminishing LVidD/S dimensions. Clinically, there was improvement in KCCQ health status, which continued at 14 and 30 days post treatment with the Cancion system.

Conclusion: CAFA induced progressive improvement in hemodynamics, with improved cardiac performance, geometry, and negative fluid balance in exacerbated CHF. The Cancion system represents a promising endovascular therapy for refractory CHF patients.

Spinal Cord Ischemia and Endovascular Treatment of Thoracic Aneurysm: Prediction or Prevention?

J Busquet

Clinique Chirurgicale Val d'Or, Saint Cloud;
The Rothschild Foundation Group,
Paris, France

Paraplegia and paraparesis complicate surgical repair of thoracic aneurysms in 6% to 40% of patients, associated with a 20% increase in mortality rate. The mechanism of spinal cord ischemic injury is multifactorial, including interruption of blood flow, inadequate pre-existing vascularization of the spinal cord, spasm of the microcirculation, and increased spinal fluid pressure. Several isolated or combined techniques have been used during open repair to minimize cord ischemia, including reduction of aortic cross clamping time, revascularization of intercostal arteries, intrathecal papaverine injection, intraoperative administration of naloxone, steroids or barbiturate agents, distal perfusion, pump bypass, regional cooling of the spinal cord, systemic cooling and drainage of the cerebrospinal fluid (CSF).

The use of endovascular stent-grafts for exclusion of descending thoracic aneurysm of the aorta is a real "surgical revolution." Despite a lack of large series analysis, this type of procedure brings great expectations, but implantation of stent-grafts in this specific location carries the same risk of spinal cord ischemia, although it appears to occur with a lower incidence from 0% to 6%. The symp-

toms appear either immediately or most of the time with delayed onset. During the natural history of thoracic aneurysms, many intercostal branches are already occluded due to the progression of wall thrombosis. The sudden deployment of the stent-graft does not produce steal syndrome in the perfusion of the spinal cord. The use of short stent-grafts and the avoidance of covering the T8 to L2 level minimize the risk of paraplegia. Endovascular procedure time is shorter than surgery without aortic cross-clamping and reperfusion injury. Previous abdominal aortic aneurysm open repair is a risk factor of paraplegia due to absence of lumbar and hypogastric collateral circulation going to the spinal cord.

The visualization of the artery of Adamkiewicz and the anterior spinal artery is important to aid in surgical planning and to prevent postoperative ischemic complications after stent-graft implantation in the descending thoracic aorta. The origin of Adamkiewicz artery is variable but usually arises from a left intercostal or lumbar artery (77%) and from the T8 to L1 level (86%). Anatomical assessment of spinal cord blood flow is feasible either by selective intercostal angiography or, more recently, by noninvasive computed tomographic (CT) and magnetic resonance (MR) angiography. The endovascular strategy can be influenced by the preoperative identification of the main spinal arterial supply, preventing the coverage of the aortic zone predicted at risk of spinal ischemia. Raising the systemic blood pressure and reducing cerebrospinal fluid pressure are usually helpful to maintain sufficient collateral blood flow in spinal circulation, especially in case of delayed onset paraplegia or paraparesis.

Conclusion: Careful case selection and prudent decision making are necessary when a patient is evaluated for endovascular exclusion of thoracic aortic aneurysm, taking into account the risk of neurological complications directly related to spinal cord ischemia. Assessment of spinal arterial blood supply is an efficient adjunct to preoperative screening to improve outcome of the endovascular procedure. Written informed consent from all patients eligible for aortic stent-grafting is fundamental due to the high variability of spinal arterial circulation.

◆ ————— ◆

Branched Stent-Grafts for Thoracoabdominal and Pararenal Aortic Aneurysms

TAM Chuter

University of Southern California—
San Francisco, California, USA

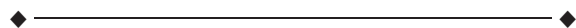
The substitution of a covered stent for an uncovered stent converts a fenestrated stent-graft into a form of branched stent-graft suitable for use in selected cases of pararenal and thoracoabdominal aneurysm. The intercomponent connection may be enhanced by the addition of internal, external, upgoing, downgoing, transaxial, and partial cuffs. The distinctions between these may seem trivial, but they have important consequences for stent-graft insertion, the likelihood of endoleak, and long-term stability.

When the connection point is a simple fenestration, the rules of fenestrated stent-graft insertion apply. Stent-graft design has to mirror aortic anatomy precisely, and each fenestration has to line up exactly with each branch artery orifice. A common variant of the fenestrated approach involves the use of a "hinged fenestration," in which a small inner fenestration is connected to a larger outer fenestration by a short, curved polyester cap. The inner fenestration, which opens distally to the lumen of the stent-graft, is the real site of intercomponent connection. The outer fenestration opens laterally to the aneurysm outside the stent-graft; in theory, its greater diameter affords a small degree of latitude in the relative positions of the fenestration and the target artery. A transversely oriented cuff on the outer surface of a fenestration may have a limited role in improving the intercomponent seal. However, there is a risk that the presence of such a cuff may complicate target artery catheterization, especially when the position is not quite right and the wall of the stent-graft close to the wall of the aorta.

Longitudinal cuffs orient the line of insertion with the long axis of the stent-graft and the aorta. In many cases, the cuff is only accessible through its proximal end, which necessitates prior release of the top cap and

transbrachial insertion of the covered stent. The former eliminates any possibility of repositioning the stent-graft to facilitate target artery catheterization. However, precise position is less important when the line of insertion follows the long axis of the aorta; the catheter can be directed to the target artery, even when the outer orifice of the cuff is not quite at the intended location. The additional overlap afforded by the longitudinally oriented cuff enhances intercomponent sealing and attachment, even with self-expanding covered stents. This is a particular advantage for visceral arteries, such as the celiac, in which a balloon-expanded stent might be crushed by diaphragmatic excursion. The low pullout resistance and low kink resistance of the Fluency covered stent are both addressed by the insertion of an additional stent, such as a Wallstent. This does little to increase the frictional forces between components, but it stabilizes the connection by stiffening the covered stent and restricting the range of possible movements. The resulting conduit is so stiff that there is little possibility of disconnection, unless the graft is being used to bridge a very long gap between the primary stent-graft and the target artery.

Conclusion: Multibranched stent-grafts with short axial cuffs are easier to catheterize, more stable, more versatile, and less susceptible to errors in stent-graft design or insertion than those with simple fenestrations.



Preliminary Results of the Medtronic Vascular Thoracic Stent-Graft System for Patients With Thoracic Aortic Disease. The Valor Trial: High-Risk, Nonsurgical Arm

**RM Fairman, MA Farber, RA White,
JM Tucheck, FJ Criado**

University of Pennsylvania, Philadelphia, Pennsylvania; University of North Carolina, Chapel Hill, North Carolina; Harbor-UCLA Medical Center, Torrance, California; Loyola University Medical Center, Maywood, Illinois; Union Memorial Hospital, Baltimore, Maryland, USA

Purpose: To evaluate the safety and efficacy of the Talent Thoracic Stent Graft System (TTSG)

for patients with thoracic aortic disease who were high risk for open surgery (SVS 3) and/or nonsurgical candidates not associated with SVS scoring.

Methods: The study was a prospective, non-randomized, multicenter, consecutive, observational trial with descriptive components. The proximal and distal nonaneurysmal aortic neck diameter requirement was within the range of 18 to 42 mm. The study enrolled 137 patients (81 men; mean age 75 years) with thoracic aortic pathologies that included TAA (75%), dissection (12%), pseudoaneurysm (7%), and traumatic injury (6%). Median maximum aneurysm diameter at treatment was 64 mm, and the median aneurysm length was 108 mm. The safety primary endpoint was all cause mortality and the efficacy primary endpoint was the proportion of patients with successful aneurysm treatment. The secondary 30-day endpoints evaluated the percentage of patients who experienced successful deployment and delivery of the stent-graft, death, paraplegia/paraparesis, secondary procedures due to endoleak, and one or more major adverse clinical events (MACE). Endpoints beyond 30 days included secondary procedures, open conversion, device migration, loss of patency, rupture, endoleaks, and one or more MACE. Supplementary clinical utility measures were also recorded. Standard follow-up interval examinations were prescribed at 1 month, 6 months, 1 year, and annually thereafter. There were no external controls.

Results: Procedural success was 98%. The 30-day all cause mortality was 7.3%, with a paraplegia/paraparesis rate <1% at 1 month. Fourteen percent of the procedures required a conduit for access. The 1 and 8-month endoleak rates were 9% and 6%, respectively. The 30-day stroke incidence was 7.3%. There were no cases of aneurysm rupture, loss of stent-graft patency, or open conversions at 8 months; however, 7% required secondary procedures during this interval. Clinical utility measures included mean duration of procedure (2.9 hours), volume of contrast used (166 mL), estimated blood loss (363 mL), and hospital length of stay (9.9 days).

Conclusion: These results demonstrate highly favorable preliminary outcomes in a high risk, nonsurgical population of patients with het-

erogeneous thoracic aortic pathology who would have been historically managed with "watchful waiting." Procedural success was high, while operative mortality, stroke incidence, and paraplegia/paraparesis rates were particularly low. Long-term follow-up will be required to demonstrate durability and prevention of aneurysm-related mortality.

DVT: When to Treat, When Not to Treat, Uses of Lysis and Mechanical Thrombectomy

ZJ Haskal

New York Presbyterian Hospital, Columbia University College of Physicians and Surgeons, New York, New York, USA

It has been more than 20 years since a National Institutes of Health (NIH) Consensus Conference concluded that anticoagulation therapy was an incomplete therapy for deep vein thrombosis (DVT) because of its inadequate impact on subsequent post-thrombotic syndrome (PTS). Anticoagulation does not eliminate the source of subsequent embolization nor does it prevent endothelial and valve damage, development of venous hypertension, or permanent impairment to the pulmonary vascular bed. It has been reported that only 4% of patients given anticoagulants resolve their DVT completely.

In contrast to the prophylactic effects of anticoagulation, catheter-directed therapy (i.e., clot dissolution, fragmentation, and removal) should be viewed as a therapeutic approach. Evidence suggests that early, complete DVT lysis can preserve valve function, thereby reducing the risk of PTS. Systemic fibrinolytic therapy has been shown to be more effective than conventional treatment with full heparin anticoagulation. However, catheter-directed fibrinolytic therapy can reduce the risks by improving the efficiency of drug delivery and concomitantly reducing drug doses.

Current treatment involves prophylactic anticoagulation with intravenous low-molecular-weight heparin or subcutaneous unfractionated heparin followed by oral warfarin sodium, bed rest, and elevation of the affected limb. The duration of symptoms at the on-

set of treatment is predictive of fibrinolytic therapy outcome; thrombolysis is more effective in acute DVT (≤ 10 days) than in chronic DVT (> 10 days) regardless of the location of the thrombus. Patients with no prior history of DVT have a greater incidence of complete lysis than those with a history of DVT. Patency is more likely to be maintained in patients with iliofemoral DVT than in those with femoropopliteal DVT. After lysis, patients with venographically documented complete lysis have substantial long-term patency benefits. Thus, the best outcomes of catheter-directed fibrinolytic therapy are achieved in patients with acute DVT, no history of DVT in the affected limb (i.e., previously undamaged valves and venous endothelium), and complete lysis by catheter-directed thrombolysis. Stated another way, a limb without prior DVT, treated acutely, had the highest chance of complete clot lysis, restoration of valve (and limb) function, and durable patency.

Clearly, rapid, safe, and efficacious therapies for DVT will be necessary for expanding their adoption. This author's longstanding approach to treating acute and chronic symptomatic DVT always involves a combination of mechanical thrombectomy and lytic drugs, delivered together to accelerate clot removal with target procedure lengths of less than 1 day. In cases of long-standing, chronic DVT with continued venous obstruction, there is often little role for lytic use. More liberal use of stents has been anecdotally essential for achieving therapeutic improvements.

Role of Adhesion Molecules in the Induction of Restenosis After Angioplasty in the Lower Limb

P Heider, M Wildgruber, O Wolf, W Weiss, H Berger, M Hanke, H-H Eckstein
Rechts der Isar Medical Center, Technical University Munich, Germany

Purpose: To investigate the performance of the soluble forms of the adhesion molecules p- and e-Selectin, VCAM, ICAM, and MCP-1 in patients in the early course after angioplasty to focus on the answer to endothelial injury.

Methods: We investigated 44 patients (25 men;

mean age 68 ± 8 years) with peripheral arterial occlusive disease (PAOD). Twelve (27%) patients received angiography, 22 (69%) had balloon angioplasty, and 10 (31%) had stent implantation. Patients were examined before therapy, on discharge, and at 2, 4, and 24 weeks after the procedure. Follow-up included clinical examination and ankle-brachial index measurement. Blood samples for ELISA testing were taken before intervention, at 15 and 60 minutes after balloon inflation or stent placement, at 24 hours, and at 2 and 4 weeks after therapy.

Results: Ten (31%) patients developed restenosis 6 months after intervention. These patients had elevated levels of e-Selectin ($p=0.011$). P-Selectin levels were high after balloon angioplasty and had maximal levels after stent angioplasty, yet without significant difference between restenotic group ($p=0.62$). ICAM serum levels were significantly increased at 24 hours and remained elevated at 2 and 4 weeks ($p=0.002$) in all patients. VCAM serum levels were elevated over the entire time course in the restenotic group, but only 15 minutes after intervention did the difference reached borderline significance ($p=0.080$). MCP-1 levels in patients with restenosis were lower than in patients without ($p=0.059$).

Conclusion: Our study shows that circulating adhesion molecules in the early course after angioplasty can be positively associated with restenosis development. Stent angioplasty leads to a more severe irritation of the endothelium. Angiographic procedure itself leads to activation of inflammation and rise of pro-inflammatory pathways, especially in the selectins.

New Concept of Stenting for the Treatment of Peripheral Arterial Aneurysm: First in Vitro and Animal Studies With the Multilayer Stent

M Henry, N Frid, P Gruffaz, I Henry, M Hugel
Nancy, France; Global Research Institute
Hyderabad, India

Purpose: To evaluate a spatial 3-dimensional braided stent structure made using new multilayer braiding technology.

Methods: This multilayer stent has multiple

interconnected layers, thus allowing it to adapt the number of layers of the structure to the nature of the artery, to its morphology, to its size, and to the area where it is located. Stents can be designed to whatever the size of the artery, i.e., from 5 to 50 mm. The design features a robust and integrated flexible structure to treat aneurysms instead of using modules as is the case for many existing devices.

Results: Through the study of finite components and through in vitro and in vivo tests, we have found that the multiplicity of layers and the denseness of the meshing (without any Dacron or PTFE covering) reduces the pressure in the aneurysm sac by modifying the hemodynamic conditions, e.g., by eliminating the weak vibrations in the arterial wall generated by the slowing of the turbulent flow and increasing the flow shearing stress in the mainstream flow.

Conclusion: A new concept, the multilayer stent (without any covering), has been developed to treat aneurysm. It opens a new approach to treating aneurysms.

Stent-Graft Repair of Complicated Acute Type B Dissections: An 8-Year Experience

K Ivancev, N Dias, B Sonesson, B Koul, M Malina

Malmö University Hospital, Malmö, Sweden

Purpose: To analyze a single-center experience with endovascular repair of complicated acute type B dissections (EVR-ABD).

Methods: A retrospective analysis was performed of patients undergoing EVR-ABD between January 1997 and December 2004. During that time, 31 patients (20 men; mean age 74 years (IQR 64–79) underwent EVR-ABD. Severe comorbidities were encountered in the majority of patients contributing to classifying 17 (55%) patients in ASA III group, 8 (26%) patients in ASA IV group, and 1 (3%) patient in ASA V group. Indications for treatment were contained rupture (22 patients), intractable pain and hypertension (6 patients), acute bowel ischemia (2 patients), and 1 pa-

tient with transient paraplegia and lower limb and renal ischemia. Until January 2001, homemade stent-grafts were used in 4 patients; thereafter, commercially available stent-grafts were utilized.

Results: Five (16%) patients died within 30 days of EVR-ABD (including 1 before 2001). Postoperative complications occurred in 15 (48%) patients, including 1 paraplegia converted into paraparesis after cerebrospinal fluid drainage, 5 strokes, 3 lower limb ischemia, 3 myocardial infarctions, 2 pulmonary infections, and 1 gastrointestinal infection. During a median 19-month follow-up (IQR 14–31), 6 more deaths occurred: 2 due to stent-graft-related causes and 4 due to cardiac disease.

Conclusion: Stent-graft repair of complicated acute type B dissections appears to provide results justifying their use as an alternative to open surgical treatment.



Aortic Debranching to Facilitate Endograft Repair of Complex Thoracoabdominal Aneurysms

K Kasirajan, R Milner, E Chaikof

Emory University School of Medicine,
Atlanta, Georgia, USA

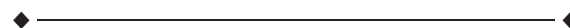
Purpose: To evaluate the benefits of extra-anatomical bypass procedures in creating an adequate landing zone in patients at high risk for open surgery and not anatomically suitable for standard endograft procedures.

Methods: Over a period of 5 years, 22 extra-anatomical bypasses were done to facilitate endograft placement in 22 patients (mean age 77 ± 8 years). Ascending aorta to innominate/left common carotid bypass procedures were done in 4 patients (chronic dissection 3, true aortic arch aneurysm 1). Left carotid to subclavian bypass was done in 6 patients, left axillary to celiac and superior mesenteric artery bypass in 1, splenorenal bypass in 2, right renal to hepatic in 1, iliorenal in 2, common iliac to bilateral renal in 1, ilio-superior mesenteric artery (SMA) in 2, and iliac to SMA and renals in 3. All patients had prohibitive cardiac risk factors, 11 had chronic obstructive pulmonary

disease; end-stage renal disease was present in 2 patients.

Results: All but 1 patient had the endograft placement done concomitantly. Mean operative time was 5.7 ± 1.4 hours. Grafts used include the Gore thoracic excluder in 13, Talent thoracic stent-graft in 7, a custom device in 1, and Zenith in 1. Average length of hospital stay was 12 ± 7 days. No intent-to-treat failure was noted. Three patients had a type I endoleak on completion. Perioperative complications included stroke in 1 patient and an upper gastrointestinal bleed in 1 requiring operative intervention. Perioperative mortality was observed in 2 patients. The first patient developed a bare spring perforation of an aortic dissection resulting in paraplegia and death secondary to a myocardial infarction; the other patient died secondary to a pulmonary embolism on the 12th day after surgery. During follow-up (mean 17 ± 11 months), 2 patients needed reintervention for a type I and a type III endoleak, and 4 patients died secondary to underlying medical comorbidities.

Conclusion: Patients who are not ideal candidates for traditional open surgical repair or endograft placement may be offered hybrid open/endograft procedures as a possible treatment option with acceptable early and late morbidity.



Cryoplasty Therapy for Critical Limb Ischemia and Claudication

G Kasper, PM Clark

St. Vincent's Mercy and Medical Center,
Toledo, Ohio, USA

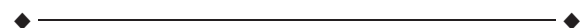
Purpose: To report our experience in treating primary stenotic lesions in the lower extremities using cryoplasty therapy.

Methods: We used cryoplasty to treat 81 atherosclerotic lesions in 77 patients (49 men, mean age 73 ± 8 years). The lesions were located in the iliac (4, 5%), CFA (7, 9%), SFA (47, 58%), popliteal (14, 17%), and tibial/peroneal (9, 11%) arteries. Comorbidities included tobacco use (54, 73%), documented coronary artery disease (50, 65%), diabetes (26, 32%), hypertension (65, 83%), and end-stage renal

disease (13, 16%). Indications for treatment were claudication (26, 32%), ischemic ulceration (47, 58%), and ischemic rest pain (8, 10%). Ankle-brachial indices were used to assess peripheral perfusion.

Results: Follow-up ranged to 18 months (mean 10.8). The ABI at baseline was 0.55 ± 0.18 and was 0.78 ± 0.23 at follow-up. Primary patency was achieved in 69 (85%) limbs. Secondary patency was achieved in 72 (89%) limbs. During the original procedure, 4 (5%) stents were placed to address vascular recoil and 6 (7%) were placed to address flow-limiting dissections. At follow-up, 1 stent was placed, and restenosis developed in 15 (18%) limbs, requiring repeat intervention.

Conclusion: We have had good overall success with cryoplasty therapy, with findings similar to those in the IDE study. In particular, we have had good success in patients with critical limb ischemia, for whom options are limited. Because it involves a minimally invasively non-implantable device, cryoplasty does not preclude future interventions in the same vessel should restenosis occur.



Respect, Don't Fear, the Short Proximal Aortic Neck: Analysis of the BCVI AAA 10-Year EVAR Experience

BT Katzen, A Maclean, J Benenati, G Zemel, A Powell, S Samuels, H Katzman
Baptist Cardiac and Vascular Institute,
Miami, Florida, USA

Purpose: To compare endovascular aneurysm repair (EVAR) outcomes of patients with short proximal aortic necks to those with >15-mm necks.

Methods: Between 1994 and 2004, we treated 584 AAA patients with EVAR. There were 400 patients with neck measurements from helical CT scans (3-mm slices) used for this analysis. The cohort was divided into 3 groups according to the length of the proximal aortic neck: 5 to 9 mm (group I, 41 patients), 10 to 14 mm (group II, 50 patients), and ≥ 15 mm (group III, 309 patients). Primary endpoints were mortality, type Ia endoleak, conversion, and delayed

rupture rates. We also examined age, sex, survival (early and late), and renal function.

Results: Mean age did not differ significantly. Mean proximal neck lengths for the groups were I: 7 mm, II: 11 mm, and III: 25 mm. This analysis included Talent (n=166 via research protocol), Ancure (n=138), Excluder (n=39), AneuRx (n=21), Vanguard (n=20), Zenith (n=14), and Trivascular (n=2) endografts. The Talent and Zenith permit transrenal fixation. The dominant device used by group was I: Talent (78%), II: Talent (66%), and III: Ancure (39%), but the Ancure, AneuRx, and Excluder were also used successfully in all groups. Type Ia endoleak rates varied among the groups: I: 19.5%, II: 2%, and III: 4.2% ($p=0.0001$). Group I was also statistically more likely ($p=0.0001$) to have both early and late type Ia endoleaks, which were managed by balloon angioplasty, balloon-expandable stents, and the use of additional sealing cuffs. A greater neck angulation did not contribute to an increased type Ia endoleak rate. There was no statistical difference in procedural success, postprocedural creatinine clearance, conversion to open surgery, delayed rupture rate, and overall survival.

Conclusion: Type Ia endoleak rate is significantly higher in the group with the shortest neck; however, it was managed almost entirely with endovascular techniques and did not affect the long-term durability or comparative success of EVAR in the 3 groups of patients. Patients with proximal necks >10 mm fared as well as those in the standard >15-mm group. Endovascular repair of abdominal aortic aneurysms with proximal necks <10 mm can be accomplished but may require additional procedures to acquire a proximal seal.



Autologous Peripheral Blood Stem Cell Transplantation in Patients With Peripheral Critical Ischemia

R Kolvenbach, E Schwierz
Augusta Hospital, Düsseldorf, and
Red Cross Blood Transfusion and
Cell Therapy Centre, Germany

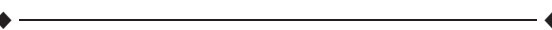
Purpose: To test the hypothesis that stem cells can be used to improve the outcome in patients with end-stage peripheral ischemia.

Methods: In a tertiary vascular surgery center, we conducted a prospective safety and feasibility study involving patients with critical ischemia with rest pain or ischemic tissue loss who had a minimum of 2 failed endovascular procedures and/or bypass operations and faced limb loss without successful therapy. All patients had to undergo digital subtraction angiography and an additional magnetic resonance imaging (MRI) study before stem cell therapy. Duplex and ankle-brachial index (ABI) evaluations were performed before and after injections. Postoperatively, clinical, ultrasound, and MRI examinations were performed after 4 weeks and every 6 months. Adult peripheral stem cells were mobilized from the bone marrow after injection with granulocyte colony stimulating factor (G-CSF). Peripheral stem cells were collected by means of apheresis and processed in order to obtain CD 34 cells, which were cryopreserved and stored. CD 34 cells were either injected directly into the muscle of the lower leg at 4 preset injection sites or, if possible, into a patent vessel in addition to the intramuscular injection. Injection was performed within 3 weeks after stem cell mobilization. Simultaneously cell seeding controls were performed.

Results: Cell injection was well tolerated in all cases without side effects. At a mean 11-month follow-up, 2 patients required major amputations because of gangrene and MRSA infections with septic syndrome 3 and 5 weeks, respectively, after CD 34 injections. In 2 patients, minor amputations were performed. In the remaining patients, healing of ischemic ulcers and reduced rest pain were observed compared to preoperative clinical symptoms. All patients experienced a swelling of their leg for 2 to 3 weeks after injection. There were no thrombotic complications. In all cases, the MRI scan showed a significantly increased cross-sectional number of blood vessels after independent evaluation, even in cases without a detectable improvement of the ABI. We observed a clear reduction in the amount of pain medication required. It seems that the results in younger patients (<70 years) were better compared to elderly patients.

Conclusion: This patient cohort presented a worst case scenario referred to us for amputation after multiple failed reconstructive pro-

cedures. The main reason for major amputation in 2 cases was progressive infection in spite of surgical and antibiotic therapy. The cohort is too small to draw any conclusive evidence from of it. We cannot say yet whether a combination of intra-arterial and intramuscular injection is superior to intramuscular cell injection only, although it seems that the combined approach yields better results. Peripheral stem cell mobilization was well tolerated. This is the first time that a larger number of patients with end-stage peripheral ischemia were treated with stem cells as a final option before amputation. Our results justify continuation of this safety study as a first step before initiating a randomized study.



Complications of Vascular Surgery After Treatment With Endovascular Intervention

Z Krajcer, N Strickman, A Mortazavi,
K Dougherty

St. Luke's Episcopal Hospital, Texas Heart
Institute, Houston, Texas, USA

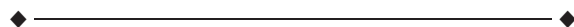
Purpose: To examine the morbidity and mortality after surgical abdominal aortic aneurysm (AAA) repair in patients who underwent endovascular AAA repair and who developed late stent-graft failure.

Methods: A total of 465 consecutive patients (409 men; mean age 71 ± 8 years) with infrarenal AAA were treated with the AneuRx stent-graft from November 1998 through December 2004. Follow-up evaluation included serial duplex ultrasound and CT imaging.

Results: On follow-up (mean 48 ± 11 months), 126 (27%) patients had died secondary to non-aneurysm-related causes. Of the remaining 339 patients, follow-up at 2 years illustrated AAA reduction from 54 ± 11 to 45 ± 12 mm ($p < 0.001$). At 3, 4, and 5-year follow-up, stent-graft migration (> 1.5 cm) and/or modular component separation occurred in 73 (21.5%) patients; 2 (0.6%) patients suffered aortoenteric fistula, and AAA rupture was seen in 4 (1.1%) patients. Surgical treatment for late stent-graft complications included device removal with surgical AAA repair in 14

(18%) patients. There was no operative mortality in the surgical group; however, 1 patient died late after surgery due to septicemia. There were 35 patients who underwent endoluminal repair: suprarenal aortic endograft placement in 10 (28.5%) patients, infrarenal placement of aortic and/or iliac components in 22 (62.8%) patients, and aortomonoiliac endograft placement in 3 (8.5%) patients. One patient with aortoenteric fistula and 1 patient with rupture died (3.8%) before treatment could be administered; the other 26 (33.3%) patients are under close observation.

Conclusion: Endovascular AAA repair is an attractive alternative to an open surgical approach. Late complications, however, continue to plague patients and physicians. Endograft migration and component separation are not an unknown occurrence after stent-graft procedures. Surgical mortality and morbidity after failure of endoluminal repair is low and can be performed safely when other alternatives are not available.



An Engineered VEGF-Activating Zinc Finger Transcription Factor Induces Angiogenesis and Bone Marrow Endothelial Progenitor Cell Production

GK Lam, RG Mitchell, BH Annex, CD Kontos
Duke University Medical Center, Durham,
North Carolina, USA

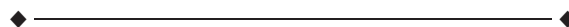
Purpose: To determine the effects of engineered vascular endothelial growth factor zinc finger protein (VEGF-ZFP) in normal skeletal muscle and on the bone marrow reservoir of endothelial progenitor cells (EPC).

Methods: WT C57BL/6 mice were divided into 3 groups: (1) sham saline intramuscular (IM) injection, (2) single VEGF-ZFP IM injection, or (3) 4 repeated VEGF-ZFP IM injections (days 0, 3, 6, and 9). After 28 days, the mice were sacrificed, and the tibialis anterior and gastrocnemius muscles were analyzed for capillary density and VEGF mRNA expression. Bone marrow harvested from the tibiae and fibulae was analyzed for EPC content by depleting cells containing the lineage (lin) mark-

ers CD3, CD5, CD8, B220/CD45RA, Mac1/CD11b, Gr1, Ter119, and thy-1. The lin⁻ population was analyzed for expression of c-kit, sca-1, and VEGFR2 by flow cytometry to determine EPC content.

Results: Compared to sham-treated mice, treatment with the VEGF-ZFP increased VEGF mRNA levels. A single injection of VEGF-ZFP resulted in no difference in capillary density or EPC content compared to sham-infected mice. Repeated injections of the VEGF-ZFP led to short term and sustained increases in capillary density ($p < 0.05$ versus sham). Flow analysis of bone marrow EPC content in this subgroup revealed >4-fold increase in the number of lin⁻ c-kit⁻ sca-1⁻ VEGFR2⁺ cells compared to the sham-treated group.

Conclusion: Treatment of non-ischemic skeletal muscle with the VEGF-ZFP plasmid induces VEGF expression, angiogenesis, and increased bone marrow EPC content. This may provide a novel treatment for patients with atherosclerotic vascular disease.



Fascia Suture of Large Access Sites After Percutaneous Endovascular Treatment of Aortic Aneurysms and Dissections

**T Larzon, H Geijer, G Gruber, R Popek,
L Norgren**
Örebro University Hospital, Örebro, Sweden

Purpose: To describe a novel technique in which the cribriform fascia covering the common femoral artery in the groin is tied.

Methods: Between August 2001 and September 2004, a consecutive series of 127 patients with aortic disease had endovascular treatment in which 251 femoral arteries were used for access. Twelve patients had a secondary intervention, and 44% were acute operations. A fascia suture was performed in 131 (52%) of the femoral arteries. Data for analysis of access-related complications were collected prospectively in this nonrandomized study. Endpoints were bleeding, thrombosis, pseudoaneurysm, stenosis, and other access-related complications. Ankle-brachial index (ABI) was recorded prospectively. Duplex ultraso-

nography (US) of both common femoral arteries was performed postoperatively in a subgroup of patients.

Results: Fascia suture was primarily successful in 123 (94%) of the 131 femoral arteries. Perioperative bleeding (n=5) or thrombosis (n=3) was solved by a surgical cutdown. Eight femoral arteries were reoperated within 24 hours because of bleeding (n=4), thrombosis (n=3), and intimal dissection (n=1). Two patients had late complications; one of them had acute surgery 28 months postoperatively because of bleeding from a pseudoaneurysm. There was no difference in ABI during the study period in the accessed vessel after closure with fascia suture. In 55 US observations corresponding to 50 patients, 3 minor pseudoaneurysms were detected. Four of 5 patients with stenoses were monitored by ABI, and none of them had a significant decrease in ABI during a median 15-month follow-up.

Conclusion: The fascia suture technique is feasible for closure of the femoral artery access after percutaneous repair of aortic diseases, even in acute situations. Failures can be easily managed. Late complications requiring additional procedures are rare. A randomized study comparing fascia suture with a percutaneous suture-mediated closure device is underway.

**Outcomes and Lessons Learned
From Fenestrated Grafting
in Western Australia:
Review of 58 Cases**

**MMD Lawrence-Brown, JB Semmens,
D Hartley, E Allen**

Centre for Health Services Research, The
University of Western Australia, Nedlands;
Royal Perth Hospital, Cook R & D, Perth,
Western Australia

Purpose: To describe the outcomes of 58 patients with an aneurysm of the abdominal aorta who were treated with a fenestrated Zenith stent-graft in Perth (Western Australia) between October 1997 and September 2004.

Methods: Six endovascular surgeons contributed data to this longitudinal, retrospective, multicenter study involving 58 patients (mean

age 75.5 ± 8.5 years) treated with fenestrated stent-grafts. The data for all cases were collected from the medical records, company supply records, and planning charts. Patient deaths were ascertained from the medical records and the State Death Registry. The results of the endovascular aneurysm repair was determined on the basis of procedural, technical, and treatment success.

Results: Fenestrated stent-grafts were used in 116 target vessels: 56.8% of patients had 2 or more target vessels. Technical success was 82.8% for patients (and 90.5% for target vessels treated); procedural success was 74.1%, and treatment success was 86.2%. There were no cases of conversion or rupture. The 30-day mortality rate was 3.4% (2 patients). Loss of target vessels occurred in 19.0% of patients (9.5% of target vessels). Factors associated with loss of target vessel were unstented vessel, $>60^\circ$ angulation of the aneurysm neck, multiple renal vessels, and vessels ≤ 4 mm in diameter. Over a 1.4 ± 1.2 -year follow-up, 4 (6.9%) patients developed renal impairment, but none required dialysis. Fourteen (24.1%) patients had a secondary intervention. Unresolved endoleaks persisted in 1 (1.7%) patient.

Conclusion: The use of the fenestrated stent-graft extends the options for patients with infrarenal aortic aneurysm that have necks unsuitable for standard endovascular repair. It carries higher risks of mortality than for standard endovascular repair. The mortality of selected patients with fenestrated stent-grafts is comparable to the mortality for open repair. Target vessel occlusion predominantly results from pre-existing disease or the lack of a stent. The lessons learned contribute toward the guidelines for users of fenestrated stent-grafts.

**Clinical Outcome of Combined
Surgical and Endovascular Treatment
of Complex Thoracic
Aortic Aneurysms**

**PH Lin, W Zhou, M Reardon, RL Bush,
EK Peden, AB Lumsden**
Baylor College of Medicine,
Houston, Texas, USA

Purpose: To describe the utility of a hybrid treatment strategy incorporating surgical and

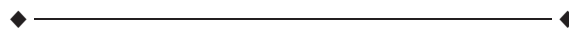
endovascular approaches in patients with complex thoracic aortic aneurysms, who were either poor candidates for open aneurysm repair or unsuitable for endovascular treatment alone.

Methods: During a recent 12-month period, all patients with complex thoracic aortic aneurysms who underwent a hybrid treatment approach including surgical and endovascular repair were reviewed. Treatment strategy and clinical outcome were analyzed. A total of 13 patients (9 men; mean age 68 years, range 52–82 years) underwent the hybrid surgical and endovascular treatment for complex thoracic aortic aneurysm. Aneurysm pathologies included arch aneurysms (n=4), ascending aortic pseudoaneurysm (n=1), descending aneurysms (n=3), total aortic aneurysms involving both descending and ascending components (n=3), and type III thoracoabdominal aneurysm (n=2). Five (38%) patients had histories of prior aortic aneurysm repairs. The presenting symptoms were pain (n=7, 54%) and dyspnea (n=2, 15%), while the remaining 4 (31%) patients were asymptomatic. Anatomical constraints that precluded endovascular repair included aneurysm involving the supra-aortic trunk (n = 8), short distance between the aneurysm and the aortic valve (n=1), close proximity to the mesenteric vessels (n=2), and inadequate access (n=3).

Results: To overcome these challenges, various adjunctive open approaches were utilized that rendered endovascular repair a feasible option. Six (46%) patients underwent surgical debranching procedures of the supra-aortic trunks, which included carotid-carotid bypass, carotid-subclavian bypass, aorto-innominate bypass, or aorto-carotid bypass. Among these patients, 5 received thoracic endograft implantation via an iliac or femoral approach, while 1 patient received antegrade deployment of the stent-graft via the ascending aorta. Three (23%) patients underwent ascending aortic aneurysm repairs with elephant trunks and supra-aortic vessel debranching followed by descending aortic stent-grafting. Additionally, 4 (31%) patients received aorto-visceral bypass to lengthen the landing zone for endograft implantation. Other surgical adjunctive maneuvers included carotid artery access (n=1) and iliac artery conduit creation (n=3)

to facilitate the delivery of the stent-graft. Technique success was achieved in all patients, and there was no perioperative mortality. Two (15%) patients had immediate endoleak, which was resolved by 1 month. Procedural-related complications included 1 retroperitoneal hematoma at the site of the iliac conduit, which was treated nonoperatively. During a mean 5-month follow-up, 2 patients died due to unrelated causes. All remaining patients had stabilization of their aneurysm without evidence of enlargement or symptoms.

Conclusion: Our study illustrates a hybrid treatment approach combining adjunctive surgical bypass and thoracic aortic endograft procedures that can be utilized successfully in the treatment of complex thoracic aortic aneurysms. This combined strategy represents an attractive solution for patients with poor cardiopulmonary reserve and potentially reduces cardiac stress, which remains the predominant cause of morbidity and mortality associated with the traditional open treatment.



EVAR for rAAA With Shock: Implantation of Bifurcated Stent- Grafts During Continuous Transfemoral Balloon Occlusion of the Aorta

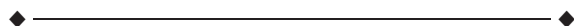
M Malina, F Veith, K Ivancev, B Sonesson
Malmö University Hospital, Malmö, Sweden;
Montefiore Medical Center,
New York, New York, USA

Purpose: To present a novel technique of aortic clamping during endovascular aneurysm repair (EVAR) in patients with ruptured abdominal aortic aneurysms (AAA) and circulatory collapse.

Technique: A balloon catheter is inserted percutaneously from the femoral artery and inflated in the suprarenal aorta. An introducer sheath must support the balloon. A bifurcated stent-graft is passed from the contralateral groin and deployed beneath the balloon. Carbon dioxide facilitates angiography while the aortic blood flow is arrested. The sheath makes it possible to retrieve the balloon after

the endograft has been deployed. A second balloon is inflated inside the bifurcated stent-graft until the limb extensions have been inserted and the aneurysm is fully excluded. The second balloon allows aortic cross-clamping without obstructing visceral perfusion during limb deployment.

Conclusion: Bifurcated aortic stent-grafts can be deployed while the aorta is continuously "clamped" from a transfemoral approach. This may allow EVAR in patients with circulatory collapse due to aneurysm rupture.



Previously Underestimated Incidence of Subclinical Myocardial Damage: A Prospective Concurrent Comparison of Endovascular Versus Open Repair of Infrarenal AAA

J May, N Abraham, D Sullivan, GH White, JP Harris

Royal Prince Alfred Hospital and University of Sydney, Australia

Purpose: To assess the true incidence of perioperative myocardial damage associated with endovascular versus open infrarenal abdominal aortic aneurysm (AAA) repair.

Methods: Between July 1999 and June 2001, preoperative and postoperative serum troponin T (TnT) levels were measured in all patients presenting for elective AAA repair at Royal Prince Alfred Hospital. A total of 35 open and 112 endovascular AAA repairs were included in the study. The incidence of myocardial damage was recorded on the basis of standard clinical, biochemical, and electrocardiographic changes or a subclinical increase of $\geq 50\%$ in serum TnT. Patients were excluded if the TnT increase was associated with a significant increase of serum creatinine ($>50\%$) with no other evidence of myocardial ischemia. The differences between the groups were analyzed with the chi-square test and odds ratios.

Results: There was no significant difference in age, sex, preoperative serum creatinine, or preoperative serum TnT between the 2 treatment groups. Seventeen patients had biochemical evidence of myocardial damage, which was clinically obvious in only 1 patient.

Even though the incidence of previous myocardial infarction was significantly higher in patients undergoing endovascular repair (41%) than open repair (22%; $p < 0.05$), the overall incidence of myocardial damage (clinical or subclinical) was significantly higher in the open group compared with the endovascular group (8 [25%] of 32 versus 9 [8%] of 109, respectively; odds ratio, 3.7; 95% confidence interval 1.28 to 10.49; $p < 0.02$).

Conclusion: Since there was only 1 patient with clinical myocardial ischemia in the open group and none in the endovascular group, our major clinical finding from the study was that there is biochemical evidence of previously underestimated myocardial damage associated with elective AAA repair regardless of the type of repair. This subclinical damage is significantly less with endovascular than with open repair. The finding, we believe, is relevant when deciding on the method of AAA repair, even when the patient is considered low risk.



Results of Treatment of Infrapopliteal Arterial Occlusive Disease Using the SilverHawk Plaque Excision Device

JF McKinsey

Columbia University,
New York, New York, USA

Purpose: To determine the initial technical success and 1-year clinical outcomes for patients undergoing revascularization of infrapopliteal arterial segments with minimally invasive catheter-based plaque excision using the SilverHawk catheter.

Method: Patients undergoing plaque excision treatment of arterial occlusive disease were enrolled in the TALON Registry (Treating PeripherAls with SiLverHawk: Outcomes Collection), which is an observational, consecutive, nonrandomized, multicenter registry. There have been 981 patients enrolled in the trial to date. As of 2/28/05, 601 patients were enrolled in the TALON registry, of which 167 (57% men) had 317 treated lesions in 240 infrapopliteal regions. The cardiovascular risk factors included diabetes (74.5%), coronary history (56%), and a history of previous pe-

ripheral interventions (63%). The Rutherford classification was >3 in 79% of the cases. The lesions were located in the tibioperoneal (27%), peroneal (21.5%), posterior tibial (19.6%), anterior tibial (28.7%), dorsalis pedis (2.5%), and calcaneal (0.6%) arteries. Lesion characteristics included 96% primary lesions, 69% moderate to severe calcification, and 34.4% total occlusions. The patients underwent clinical examination and noninvasive hemodynamic evaluations to determine technical success and 6 and 12-month freedom from re-intervention.

Results: Predilation was required in 10.4% of cases, and post plaque excision adjunctive therapy was required in 20%, with 0.3% (n=1) requiring a stent. The mean lesion length was 33.4±42.7 mm. Preprocedural mean diameter stenosis was 90.4% versus 8.3% after plaque excision alone. In those patients who required adjunctive therapy, the post plaque excision residual stenosis was 34.5%, which was reduced to 13.2% after adjunctive therapy. The procedural complications included perforation (1.9%) and dissection (1.9%). There were no reports of distal embolization. Follow-up hemodynamic measurements were available for 33% of the patients; the average ankle-brachial index was 0.86±0.2. Freedom from reintervention was 84% at 6 months and 77% at 12 months. The limb loss rate at 1 year was 9.8%. The below-the-ankle amputation rate was 4% at 1 year.

Conclusion: Patients with severe arterial occlusive disease involving the infrapopliteal region can be effectively and safely treated with the SilverHawk plaque excision system, with a low complication rate and favorable freedom from reintervention rates at 6 and 12 months.



Anatomical Suitability for Endovascular Treatment of Ruptured Abdominal Aortic Aneurysms

M Mehta, RC Darling III, SP Roddy,
Y Sternbach, KJ Ozsvath, PB Kreienberg,
PSK Paty, BB Chang, M Dhiraj, DM Shah
The Vascular Group, PLLC, Albany Medical
Center Hospital, Albany, New York, USA

Purpose: To retrospectively analyze the preoperative computed tomographic (CT) scans

of patients who presented for repair of ruptured abdominal aortic aneurysm (r-AAA) to determine their anatomical suitability for endovascular repair.

Methods: From 2002 to 2005, 64 (64%) of 99 patients presenting with r-AAA had preoperative CT imaging for review. Those scans were compared to 50 consecutive patients who presented for elective AAA repair. CT scans were analyzed for (1) aneurysm neck length, diameter, calcifications, angulations, and thrombus; (2) iliac artery stenosis, tortuosity, calcifications; and (3) aneurysm size. All patients were evaluated for the possibility of being candidates for aneurysm treatment with any of the FDA-approved stent-grafts.

Results: There were no significant differences between the groups in the variables examined (Table). Only 7 (11%) patients with r-AAA had aortoiliac anatomy prohibitive for endovascular repair. Of the remaining 57 (89%) patients, 43 (75%) had anatomy suitable for bifurcated modular devices, and the remaining 14 (25%) could be suitable for aortomonoiliac stent-grafts due to tortuous anatomy.

Conclusion: Similar to elective aneurysm repair, a vast majority of patients with r-AAA are anatomically suitable for endovascular repair using currently available stent-grafts. Unsuit-



TABLE

Demographics and AAA Morphology in Patients With Ruptured Versus Non-Ruptured Abdominal Aortic Aneurysms

	Ruptured	Non-Ruptured
N	64	50
Male/female	49/15	41/9
Mean aneurysm size, cm	6.2	5.6
Para-renal aneurysms	7 (11%)	9 (18%)
Mean aortic neck length, mm	18	19
Mean aortic neck diameter, mm	24	24
Aortic neck angulation >60°	9 (14%)	8 (16%)
Mean CIA diameter, mm	14	15
Severe CIA tortuosity		
calcifications	10 (16%)	11 (22%)
Mean EIA diameter, mm	8	9
Severe EIA tortuosity/		
calcifications	7 (11%)	8 (16%)



CIA: common iliac artery, EIA: external iliac artery, NS: not significant.

able neck anatomy is the primary reason for exclusion. Endovascular repair can be offered to most patients presenting with AAA rupture.



Absence of Buttock Claudication Following Stent-Graft Coverage of the Hypogastric Artery Without Coil Embolization in Endovascular Aneurysm Repair

M Mell, G Tefera, M Schwarze, S Carr, C Archer, J Hoch, W Turnipseed
University of Wisconsin,
Madison, Wisconsin, USA

Purpose: To evaluate the safety and efficacy of stent-graft coverage of the hypogastric artery origin without coil embolization during endovascular treatment of aortoiliac or iliac aneurysms.

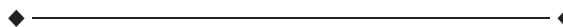
Methods: We conducted a retrospective chart review of 21 patients (10 men; mean age 76.5 years, range 67–86) who underwent endovascular aneurysm repair with hypogastric artery coverage without coil embolization at the University of Wisconsin from September 2001 to September 2005. The aneurysm location included 12 aortoiliac, 7 isolated common iliac artery, and 2 isolated hypogastric artery aneurysms. The mean iliac aneurysm diameter was 3.4 cm (range 1.7–5.0).

Data collected for analysis included demographics, operative reports, serial computed tomographic angiograms (CTA), and clinical outcome. Successful aneurysm exclusion was defined as the absence of an endoleak from the hypogastric artery origin. Clinical outcomes evaluation included morbidity and mortality, as well as the occurrence and duration of new onset buttock claudication. Buttock claudication was further correlated with patency of the superior gluteal artery. All aneurysms were treated with commercially available endograft systems. The iliac extension cuffs were generally extended up to 2 cm into the corresponding external iliac artery. The amount of stent-graft diameter oversize was also evaluated.

Results: All covered hypogastric arteries were patent prior to the procedure. The en-

dovascular devices used were the Excluder in 10 patients, the AneuRx in 2 patients, and a Zenith in 1 patient. The iliac limb extension into the external iliac artery was oversized an average of 33% (range 9%–60%). Immediate seal was achieved in all patients. Mean follow-up was 7 months (range 1–34). No type I endoleaks developed from the aortic or external iliac artery. No type II endoleaks developed from the origin of the hypogastric artery. New-onset buttock claudication occurred in 2/22 (9.5%) patients, but resolved in both patients. No additional secondary procedures, aneurysm rupture, or aneurysm-related death occurred.

Conclusion: Stent-graft coverage of the orifice of the hypogastric artery without coil embolization is a safe and effective adjunct during the treatment of aortoiliac or iliac aneurysm, with a low incidence of buttock claudication.



Initial Experience With a Remote Pressure Sensor During Endovascular TAA Repair

R Milner, PG Silveira
Emory University School of Medicine,
Atlanta, Georgia, USA; University Hospital,
Florianopolis, Brazil

Purpose: To report an initial experience with a remote pressure sensor (RPS) to document successful aneurysm exclusion and assist with identification of endoleaks during thoracic endografting.

Methods: Institutional review board approval was obtained. The pressure sensor was inserted through the same access site used for thoracic endograft insertion. The sensor was interrogated initially to confirm its function. Pre and post-exclusion pressures were measured. The intraoperative measurements were correlated with an intrasac catheter, radial artery line, and completion arteriogram. Additional remote pressure measurements were taken at postoperative days 1 and 30.

Results: The sensor was successfully placed into the descending thoracic aneurysm. Pre-exclusion measurement revealed a mean

pressure of 97 mmHg and a pulse pressure of 58 mmHg. Post-exclusion measurement revealed a mean pressure of 95 mmHg but a decrease in pulse pressure to 39 mmHg. A completion arteriogram confirmed the pressure measurement's finding of aneurysm exclusion. Postoperative day 1 measurements revealed a mean pressure of 55 mmHg and pulse pressure that decreased to 16 mmHg. Postoperative day 30 measurements revealed a mean pressure of 49 mmHg and a stable pulse pressure of 16 mmHg.

Conclusion: This is the first report of the successful insertion and interrogation of a remote pressure sensor in the thoracic aorta. The sensor confirmed periprocedural aneurysm exclusion. Further studies are planned to substantiate these findings.

Ultrasound-Assisted Thrombolysis: A New Concept for an Old Treatment

A Motarjeme

Midwest Vascular Institute of Illinois,
Downers Grove, Illinois, USA

Purpose: To report one center's clinical experience with ultrasound-enhanced thrombolysis in the treatment of peripheral arterial occlusion and deep venous thrombosis.

Methods: Between January and July 2005, 17 patients (13 men; mean age 71.5 years, range 39–88) with 19 occlusions were treated with combined ultrasound/lytic therapy for acute and chronic occlusions of the peripheral vasculature. Twelve occlusions in 12 patents with peripheral arterial occlusion and 7 occlusions in 5 patients with deep venous thrombosis were treated.

Results: Technical success was achieved in all 17 patients, and no device failures or adverse events were reported. Complete lysis was achieved in 11 (92%) cases of peripheral arterial occlusion and 7 (100%) cases of deep vein thrombosis. One patient with a chronic occlusion of the common femoral artery–superficial femoral artery was refractory to lysis after 7 hours of thrombolysis. Average times to achieve complete lysis were 17.4 hours (range 8–25) in peripheral arterial occlusions

and 35.2 (range 20–48) in patients with deep vein thrombosis.

Conclusion: Complete lysis of acute and chronic occlusions of the peripheral vasculature can be achieved using combined ultrasound/lytic therapy with reduced duration of lytic infusion compared to historical controls.

Dynamic Cine CTA Imaging Discovers Renal Artery Conformational Change Secondary to EVAR: Implications for a Fenestrated Future

**BE Muhs, A Teutelink, M Prokop,
KL Vincken, ELG Verhoeven, FL Moll,
HJM Verhagen**

University Medical Center, Utrecht and
Groningen, The Netherlands

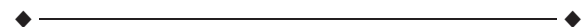
Purpose: To study the effect of an endograft on the natural renal artery motion per cardiac cycle using electrocardiographically (ECG)-gated 40/64-slice computed tomographic angiography (CTA).

Methods: Thirty-seven renal arteries were studied, 12 before and 25 after endovascular repair (EVAR) using the Talent, Excluder, or Cook fenestrated devices. The pre-EVAR scans were considered to represent normal renal artery motion in patients with aneurysms. The post-EVAR scan was used to study the effect of endografts. Data was acquired using a novel ECG-gated dynamic 40/64-slice CT scanner during a single breath hold with a standard dose of 17.5–21 mGy, 1.25-mm collimation, and a pitch of 0.2 to 0.3. Eight gated datasets covering the cardiac cycle were reconstructed perpendicular to the center flow lumen of each renal artery at 1.2 cm and 2.4 cm from aortic attachment. Center of mass (COM) was plotted on a Cartesian coordinate system and maximal COM displacement determined per cardiac cycle for pre and post-EVAR renal arteries. The direction of the movement was also recorded. Both normal and post-EVAR renal movement was determined and compared using Student *t* tests, with $p \leq 0.05$ considered significant.

Results: Normal renal artery motion is im-

pressive, with up to 3-mm movement both near and distant from the aorta (range 1.1–3.0, mean 2.0 ± 0.57). EVAR significantly inhibits proximal physiological renal motion, resulting in a 30% decrease in maximal movement (range 0.2–2.8 mm, mean 1.4 ± 0.7 ; $p \leq 0.05$). Distal renal artery motion is unaffected by EVAR, with motion similar to the pre-EVAR state. Both pre and post-EVAR renal arteries typically exhibit a “figure of eight” direction of movement.

Conclusion: ECG-gated dynamic CTA is feasible on a 40/64-slice scanner with standard radiation dose and can detect potentially serious consequences of emerging endovascular technology. EVAR appears to change renal artery conformation by limiting proximal cardiac cycle renal artery motion while leaving distal motion unaffected, possibly resulting in long-term ill consequences. Furthermore, the motion of the renal arteries in relation to fixed endograft fenestrations may explain occluded side branches, rising creatinine, and reported stent fractures following fenestrated endograft implantation.



Is Percutaneous Aortic Valve Replacement Just an Unrealistic Dream?

S Müller-Hülsbeck, T Attmann, T Jahnke,
G Lutter

University Hospital Schleswig-Holstein,
Campus Kiel, Germany

Results indicate that minimally invasive heart valve operations were able to reduce surgical trauma but could not generally improve post-operative outcome because they are still open heart procedures and depend on cardiopulmonary bypass. Therefore, they are associated with a multitude of risks. A further reduction of the invasiveness is being considered to counteract these problems.

Percutaneous treatment of valvular heart disease remains a final frontier of interventional cardiovascular medicine. It has been proven conclusively that percutaneous balloon aortic valvuloplasty does not change the natural history of the disease and is as-

sociated with near universal restenosis at 6 to 12 months. Percutaneous transfemoral orthotopic aortic valve implantation in humans is reality and not an unrealistic dream any longer.

In August 2004, German newspapers reported about Grube and coworkers from Siegburg, Germany, who percutaneously implanted an aortic valve in India. Back in 2002, Cribier et al. had already published the first human case description and subsequently initialized the I-REVIVE study: patients with end-stage aortic valve stenosis who are not candidates for surgery are treated by percutaneous aortic valve implantation through an antegrade transeptal or a retrograde approach. These patients receive percutaneous aortic predilation, thus the native valve is not ablated. Unfortunately, only 6 of the 11 patients in the series are alive in short-term follow-up, with no signs of heart failure at 18 days to 3.5 months. These preliminary studies demonstrate that percutaneous implantation of the valved stent in the aortic position can be achieved in patients with end-stage calcific aortic stenosis.

Pulmonary valve implantation already has proved to be a promising complementary approach to surgical programs. Bonhoeffer's group performed 35 procedures with no early death and only 3 procedural complications. Early and late outcome was comparable to 94 surgically-treated patients in the control group and aortic position, as well as current latest experimental data dealing with this topic.

Current limitations and so far unsolved problems have to be taken into account when considering a patient for percutaneous aortic valve placement: migration of a valved stent, paravalvular leakage, rhythm disturbance, hemodynamic instability, small aortic valve area, valve dysfunction after compression and re-expansion, impairment of coronary flow and mitral function, and finally missing data about in vivo durability of such a new valve. In spite of this, some physicians have made aortic valve placement reality.



In Vivo Attenuation of Myointimal Hyperplasia Using Transforming Growth Factor Beta 3 in an Interposition Graft Model

**MO Murphy, J Ghosh, AT Halka, A Carter,
NJ Turner, MW Ferguson, CM Kielty,
MG Walker**

Manchester Royal Infirmary,
Manchester, UK

Purpose: To assess the use of transforming growth factor (TGF)-beta 3 in attenuating the development of para-anastomotic myointimal hyperplasia in an animal model of small diameter vascular graft failure.

Methods: Under general anesthesia, 10 adult goats underwent bilateral polyurethane interposition graft insertion in the carotid position. Following completion of the anastomosis, each artery received adventitial infiltration of 50 ng of TGFbeta 3 around the anastomosis, the other side a placebo. Postoperatively, each animal received 150 mg of aspirin daily. The arteries were explanted, half at 6 weeks and the remaining 5 at 3 months for histological examination.

Results: Vessel wall thickness surrounding the anastomosis was reduced by 37% in TGFbeta 3-treated arteries compared to placebo at 6 weeks and 3 months, principally due to reduced smooth muscle cell (SMC) proliferation. There was decreased overall luminal loss on angiography. Total collagen content was not significantly different between TGFbeta 3 and placebo sides. Further analysis for the subendothelial matrix component collagen type VIII showed decreased levels on the treated side. Total elastin content was reduced on the TGFbeta 3-treated side.

Conclusion: Direct, single-dose, subadventitial infiltration of TGFbeta 3 following insertion of an interposition graft reduces SMC proliferation and elastin content. It would appear that TGFbeta 3 holds promise as a prophylaxis against the development of myointimal hyperplasia, the predominant cause of graft failure in peripheral bypass surgery.

Endovascular Aneurysm Repair With Suprarenal Versus Infrarenal Fixation: A Controlled Study of Renal Effects

S Parmer, JP Carpenter

University of Pennsylvania School of
Medicine, Philadelphia, Pennsylvania, USA

Purpose: To evaluate the effect of suprarenal fixation on renal function by comparing homogeneous patient populations receiving EVAR grafts that are identical in design, delivery method, and manufacturer, except for utilizing either suprarenal or infrarenal fixation.

Methods: In the setting of 2 pivotal FDA trials, 283 patients underwent EVAR with the Powerlink bifurcated graft. The trials' inclusion and exclusion criteria and grafts were identical except for fixation scheme: either suprarenal (SR) or infrarenal (IR). Clinical, laboratory, and computed tomographic (CT) data were retrospectively reviewed. Comparison of preoperative, perioperative (1-7 days), and postoperative (>7 days) alterations in serum creatinine (SCr), creatinine clearance (CrCl), and blood pressure was performed. Renal adverse events were determined by CT and clinical chart review and included renal infarction, renal artery stenosis (either progressive or requiring renal stent placement), and renal artery occlusion.

Results: Patient characteristics for both groups were well matched. Both SR and IR groups demonstrated a significant increase in SCr and a decrease in CrCl over time. Comparing SR and IR cohorts, however, showed no significant difference in SCr or CrCl between groups during any time period. There were no differences in postoperative renal impairment (IR 10.2% and SR 7.6%, $p=0.634$) or the need for hemodialysis (IR 0.7% and SR 0%, $p=1.00$). Although both groups had significant improvements in systolic and diastolic blood pressure during the initial hospitalization, blood pressure returned to preoperative baseline levels during follow-up. No difference was detected between the SR and IR cohorts in systolic or diastolic blood pressure at any time period studied. There was no significant difference in the number of renal adverse events detected by CT between the



IR (10) and SR (3) groups (6.8% and 3.8%, respectively, $p=0.550$).

Conclusion: Suprarenal fixation does not lead to a significant increase in acute renal events, renal impairment, or alteration in blood pressure in comparison to infrarenal fixation. Patients undergoing aneurysm repair with devices utilizing either suprarenal or infrarenal fixation develop progressive renal dysfunction over time. Further studies are needed to determine the long-term effects of SR fixation on renal function and progression of renal artery stenosis.



Biological Treatment for Aneurysms: Is It the Third Wave After Resection and EVAR?

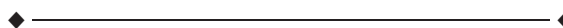
JC Parodi, FE Parodi
Washington University,
St. Louis, Missouri, USA

Mechanisms of aneurysm formation and growth have been extensively studied in the last decade. Aneurysms develop as a result of chronic inflammation of the aortic wall, a decrease in aortic medial smooth muscle cells, and progressive destruction of structural connective tissue proteins, particularly elastin and collagen. Key aspects of this process include atherosclerosis, oxidative and mechanical stress, increased local production of proinflammatory cytokines, and increased expression of matrix metalloproteinases (MMPs) that degrade structural proteins. In the near future, a pharmacological approach might suppress ongoing aneurysmal degeneration in individuals with small aneurysms.

At Washington University, Robert Thompson demonstrated in animal models of aortic aneurysms that genetic and pharmacological inhibition of MMPs, especially MMP-2 and MMP-9, can suppress development of aneurysms. Several substances have been tested in animals and indicate that they are effective in preventing the formation of aneurysms: doxycycline, curcumin, PDTC, statins, rapamycin, and ACE inhibitors among others. Early clinical studies using doxycycline as an inhibitor of MMPs showed promise. All drug

therapies proposed for aneurysms directly or indirectly inhibit MMPs and decrease degradation of connective tissue.

In a recent article published online on November 27, 2005, in *Nature Medline*, Koichi Yoshimura from Yamaguchi University School of Medicine described that selective inhibition of c-Jun N-terminal kinase in vivo not only prevented the development of AAA but also caused regression of established AAA in 2 mice models. Biological treatment of aneurysms could represent a new alternative, as it was with gastroduodenal ulcers in the past that transformed the medical treatment into the first and best option for most of the cases of gastroduodenal ulcers.



Cerebral Protection Devices Should Be Used Routinely in Carotid Artery Stenting

JC Parodi, FE Parodi
Washington University,
St. Louis, Missouri, USA

Embolization was shown to be universal during carotid artery stenting (CAS). Evidence came from 3 different in vitro studies and from the use of transcranial Doppler monitoring. Both methods disclosed that in every single case particle formation and embolization takes place during the CAS procedure. The impact of embolization on the patient will depend on the size, number, and composition of particles; where the particles lodge in the brain; and the functional vascular reserve of the brain among other variables. Most of the cases don't show any major clinical consequence of proven microemboli to the brain, although diffusion-weighted magnetic resonance imaging (MRI) studies showed new lesions in between 10% to 40% of the cases.

Silent infarcts are not benign since cognitive changes and the incidence of dementia are significantly increased in those patients. It is obvious that the goal to prevent all emboli is going to be hard to achieve since instrumentation in the arch and cannulation of supra-aortic trunks produce particles that cannot be trapped. Minimal instrumentation

planned with the help of 3D reconstructed MR angiographic images will reduce embolization in this initial stage of the procedure.

Miniaturization of systems, as well as their improved flexibility, will also lessen the creation of particles during the procedure. There is a compromise between the porous size of the filters and flow resistance. Particles <100 microns will continue to cross filters through the pores. The importance of microemboli is still a matter of debate.

Proximal protection devices are showing promising results since the lesion does not need to be crossed to establish cerebral protection. Flow reversal appears as a viable solution to embolization. Flow reversal has its own problems though, including large profile and potential intolerance. The product is now being improved to decrease its profile. Intolerance, which occurs in about 5% of the cases, is being addressed by 3 means: first, by discontinuing the antihypertensive medication 24 hours prior to the procedure; second, by using ischemic preconditioning; and third, by combining flow reversal with a filter (air bag-seat belt technique) if needed.

Conclusion: No one can affirm that emboli to the brain are beneficial, and most of the interventionists would not elect to allow emboli to go to their own brains if they had the choice.

Does Carotid Stenting Work in the Long Run? 5-Year Results of CAS in Major European Centers

P Peeters, M Bosiers, J Verbist, K Deloose, H Sievert, J Sugita, F Castriota, A Cremonesi

Imelda Hospital, Bonheiden, and AZ St-Blasius, Dendermonde, Belgium; CardioVascular Center Frankfurt, Germany; Villa Maria Cecelia Hospital, Ravenna, Italy

Purpose: To report the late stroke and patency rates after carotid artery stenting (CAS) from 4 high-volume European centers over a 5-year period.

Methods: Between February 1, 1993 and December 31, 2004, 2172 patients were selected

at the 4 participating centers with the intention to treat carotid stenosis endovascularly. Conscientious follow-up was done according to the in-hospital stipulations of each center and was entered into a database both retrospectively and prospectively. Long-term restenosis and stroke-death rates were investigated, statistically analyzed, and stratified using the Kaplan-Meier method.

Results: Of the 2172 patients analyzed on an intention-to-treat basis, 2165 (99.7%) were technically successful. Of these, 306 (14.1%) were performed without and 1859 (85.9%) with embolic protection device (EPD); 96 (4.4%) patients received balloon dilation only, and stenting was performed in 2069 (95.6%) cases. Kaplan-Meier analysis of major stroke/all death and of significant restenosis (>50%) found stroke/death rates at 1, 3, and 5 years, respectively, of 4.1% (n=1356), 10.1% (n=476), and 15.5% (n=138). The restenosis rates were 1.0% (n=1363), 2.0% (n=480), and 3.4% (n=139) at the same intervals.

Conclusion: The patency and stroke/death rates resulting from our database analysis are pleasing and indicate that CAS is a valuable treatment method for carotid artery disease in the longer term.



Comparison of Endovascular and Standard Open Surgical Repair of Abdominal Aortic Aneurysms: 5-Year Follow-up Using the Excluder Bifurcated Endoprosthesis

BG Peterson, JS Matsumura, MS Makaroun, DC Brewster, for the Excluder Bifurcated Endoprosthesis Investigators
Chicago, Illinois, USA

Purpose: To analyze the 5-year long-term outcomes comparing endovascular abdominal aortic aneurysm repair (EVAR) to open surgical repair using the Excluder Bifurcated Endoprosthesis.

Methods: From December 1998 to January 2000, 334 patients underwent either standard open repair (n=99; control group) or EVAR (n=235; test) at 19 institutions. Core lab radio-

graphic data and clinical results were evaluated after 5 years of follow-up.

Results: At 5-year follow-up, overall (test 71.7%, control 78.5%, $p=0.17$) and aneurysm-related survival (test 97.9%, control 96.6%, $p=NS$) were similar between the two groups. There have been 10 open conversions in the test group, most commonly for aneurysm growth without demonstrable endoleak, and 2 deaths after conversion. Freedom from major adverse events was significantly lower in the test group (20.2% versus 28.9%, $p<0.0001$). At 5 years, the test group had 0% limb narrowing, 0% component migration, 0% stent fracture, 3% trunk migration (1/34), 3% endoleak (1 type II/33), and 42% aneurysm growth (14/33) ≥ 5 mm compared to baseline. Mean aneurysm size in these latter 14 patients was 6.8 cm (range 5.3–8.7). Throughout follow-up, there were no aneurysm ruptures in either group.

Conclusion: EVAR is safer than standard open repair in suitable patients at 5 years' follow-up. In terms of freedom from MAE, there is a significant advantage for EVAR despite the need for reintervention. While aneurysm growth is seen in 42% of patients in the test group at 5 years, expansion is not associated with endoleak or aneurysm rupture. The device has been modified to address aneurysm sac expansion after EVAR, and subsequent clinical trials are underway.



Italian Excluder Registry: Preliminary Results

**C Pratesi, F Benedetti Valentini, E Vecchiati,
PG Cao, P Castelli, R Chiesa, G Coppi,
G De Blasis, L Ganassin, P Mancinelli,
G Passalacqua, P Passariello, GR Pistolesse,
G Simonetti, D Tealdi**

University of Florence, University La Sapienza, and University of Tor Vergata, Rome; Hospital of Reggio Emilia; Policlinico Monteluce, Perugia; University Dell'Insubria, Varese; Hospital S. Raffaele and Hospital Policlinico S. Donato, Milan; Hospital S. Agostino, Modena; Hospital of Avezano; Hospital of Treviso, Italy

Purpose: To retrospectively analyze the Italian experience with the Excluder Bifurcated Endoprosthesis in endovascular aortic repair.

Methods: Between October 1998 and July 2005, 783 patients (711 men; median age 72 years, range 44–93) underwent EVAR with the Excluder Bifurcated Endoprosthesis. Each participating center in this study had at least 40 EVAR using this commercially available endoprosthesis. After device implantation, data from the follow-up examinations at 1, 3, 6, 12, 18, and 24 months, and yearly thereafter were collected from each center and entered into a specific database. Distant monitoring of the database entries evaluated the percentage of missing data per center. We performed a retrospective review of the clinical cases (direct monitoring) at each center to evaluate the quality and precision of actual patient data. Early and long-term results were analyzed by chi-square test and Kaplan-Meier curves (log-rank test).

Results: The mean aneurysm diameter was 53.29 ± 9.9 mm. The mean proximal neck diameter was 22.52 ± 2.2 mm, and the mean length was 28.26 ± 8.8 mm; 392 (50.1%) patients were ASA III or IV, and 477 (61%) patients underwent peripheral anesthesia. Mean operation time was 126.6 ± 44.6 minutes. Technical success was achieved in 780 (99.6%) patients. Three patients underwent surgical conversion, in 2 cases due to iliac artery rupture and in the remaining one for the inability to advance the device. Thirty-seven (4.8%) endoleaks were observed on completion angiography. Intraoperative mortality was 0.5%. Median follow-up was 37.4 months (range 1–60). Type II endoleaks were observed in 47 patients, whereas 5 had a type I, with an estimated freedom from endoleak at 48 months of 80.6%. There were no type III or type IV endoleaks and no migration. The aneurysm sac was stable in 64.8%, reduced (>5 mm) in 27.4%, and increased (>5 mm) in 7.8%. Thirty-eight (4.9%) patients required reinterventions, with an estimated freedom from reintervention at 48 months of 87.3%. Four patients underwent conversion to open repair. One aneurysm rupture was observed and no AAA-related death.

Conclusion: Our results demonstrate that endovascular aortic repair using the Excluder Bifurcated Endoprosthesis is successful in the exclusion of abdominal aortic aneurysms,

with low morbidity and mortality at short and medium-term follow-up.

Different Therapeutic Strategies for Multilevel Aortic Disease

**G Pratesi, N Troisi, L Azas, A Fargion,
R Pulli, W Dorigo, A Alessi Innocenti,
C Pratesi**
University of Florence, Italy

Purpose: To retrospectively analyze our experience in the treatment of patients with concomitant abdominal aortic aneurysm (AAA) and thoracic aortic disease.

Methods: From January 2000 and December 2004, 776 patients underwent AAA repair (571 open surgery and 205 endovascular repair) at our department. In 6 of these patients, thoracic aortic involvement was present: descending thoracic aortic aneurysm in 4 cases and type B dissection and penetrating aortic ulcer in the remaining 2 cases. Five patients had a simultaneous hybrid treatment (open abdominal aortic aneurysm repair and endovascular thoracic aortic exclusion), while the remaining one was entirely treated endovascularly.

Results: Technical success was obtained in all the patients. No intraoperative mortality or complications occurred, and no patient developed temporary or permanent neurological deficits. In the postoperative period, 1 patient required an adjunctive stent-graft placement for the treatment of a type III endoleak. The mean follow-up was 11.2 ± 4.5 months (range 1–24). No death, endoleak, or reintervention occurred.

Conclusion: Our results suggest simultaneous treatment of patients with concomitant AAA and thoracic aortic disease to be feasible and safe; it is associated with low perioperative morbidity and mortality rates and encouraging midterm results. However, larger studies with longer term results are expected.

Endovascular Approaches for Complex Forms of Recurrent Aortic Coarctation

**O Preventza, GH Wheatley III, J Williams,
VG Ramaiah, J Rodriguez-Lopez,
EB Diethrich**

Arizona Heart Institute and Arizona Heart Hospital, Phoenix, Arizona, USA

Purpose: To review our complete endovascular experience with recurrent aortic coarctation in adults.

Methods: Since 1998, 10 patients (8 men; median age 48 years, range 16–63) with recurrent aortic coarctation were referred to our institution for treatment. Nine of 10 patients had recurrent coarctation. Clinical presentations included: pseudoaneurysm (n=2), restenosis (n=3), pseudoaneurysm accompanied by restenosis (n=4), and 1 rupture of a post-coarctation pseudoaneurysm. All but one of the patients had a prior coarctation repair. All patients were treated using an endovascular approach as part of a single-center investigational device exemption protocol.

Results: Nine patients were eligible for endovascular repair, with 1 open repair done due to rupture. In the endovascular patients, 3 patients underwent pre-intervention balloon angioplasty in preparation for stenting or implantation of an endoluminal graft. Endovascular interventions included stenting of the aorta with a Palmaz stent (n=3), implantation of an endoluminal graft (n=2), and a combination of both treatments in 4 patients. For the lone open repair, a chronic dissection was identified 1 year after the index procedure, and an endovascular repair was conducted 5 years later. In preparation for the endovascular repair, 2 patients underwent a carotid-subclavian bypass, and 2 patients required a carotid-subclavian bypass post-intervention due to left upper extremity claudication. Two patients required reintervention: one repair was done due to the migration of the stent and the other due to the formation of an intimal tear with pseudoaneurysm. The median length of stay after repair was 2.0 ± 2.3 days.

Conclusion: Endovascular approaches to adult coarctation appear to be safe and effective. With the emergence of endoluminal graft

repair and the widespread availability of the Palmaz stent, endovascular repair offers an excellent alternative to open surgery for complex cases of recurrent coarctation. Additional studies are indicated to assess the long-term outcomes of these patients.

Four-Year Results of the Pivotal U.S. Multicenter Trial of the Powerlink Endograft for EVAR

V Ramaiah for the Endologix Investigators
Arizona Heart Institute and Arizona Heart Hospital, Phoenix, Arizona, USA

Purpose: To review the continued surveillance in patients treated with the unibody Powerlink bifurcated stent-graft to assess the longer term durability and efficacy of the device.

Method: The controlled FDA trial involved 15 centers that prospectively enrolled 258 patients (192 test subjects and 66 controls) between July 2000 and March 2003 for endovascular aneurysm repair using the Powerlink system. Results were assessed with contrast-enhanced computed tomography (CT) and 3D reconstructions produced by the core lab pre-operatively and at all subsequent follow-up points (1, 6, and 12 months and annually).

Results: Kaplan-Meier freedom from AAA-related mortality at 4 years was 97.9%, and there have been no aneurysm ruptures. There have been 4 surgical conversions in the trial: 3 intraoperatively and 1 at 12 months to treat a type I endoleak. Through 48 months, 29 secondary procedures have been performed in 24 patients. The most common has been for treatment of type II endoleak (14 procedures). There were 6 procedures to treat type I endoleak, 6 procedures to treat graft limb occlusion, and 3 native artery procedures. There were 4 patients with migration >10 mm, with none leading to a secondary procedure. There have been no types III or IV endoleaks through 48 months. Sac diameter and volume demonstrated mean decreases at all follow-up time points (Table). Retrospective review of sac morphology in patients with paired results showed 70% experienced a mean of 12.7° of straightening of sac angulation be-

TABLE
Sac Diameters and Volumes Over Time in Patients Treated with the Powerlink Bifurcated Stent-Graft

	Mean Volume, mL	Mean Diameter, mm
Preop	135.5	50.4
12 mo	124.6	45.8
24 mo	118.9	42.9
36 mo	113.6	40.9
48 mo	112.2	39.8

tween 1 and 48 months. There have been no graft fabric defects or wire fractures in the follow-up of all patients through 48 months.

Conclusion: The Powerlink system continues to demonstrate safety and efficacy in protecting patients from AAA rupture and AAA-related mortality through 4 years of patient follow-up. The secondary procedure rate has remained low, and there has been only 1 late conversion at 12 months. Mean aneurysm sac diameters and volumes have continued to regress at all follow-up time points, and there is evidence of classical remodeling of the aorta in a majority of patients. Durability of the system appears to be very robust, with no graft material failures or stent fractures through 4 years. The long main segment of the unibody bifurcated Powerlink stent-graft allows placement at or near the aortic bifurcation, providing anatomical fixation that appears to contribute to its significant resistance to migration. Continued follow-up of patients enrolled in the trial is ongoing.

The Role of Carotid Imaging in the Selection of Patients for Endovascular Treatment

AW Reid

Glasgow Royal Infirmary,
Glasgow, Scotland, UK

Noninvasive vascular imaging continues to advance rapidly with new technology, providing essential information for the planning of endovascular intervention. The alternative, invasive arteriography, carries a small but def-

inite morbidity, with potential for transient or permanent ischemic events, complications that are added to the institutional 'stroke rate' for subsequent endovascular stenting or operative repair. For these reasons and for optimum patient care, it is important that non-invasive techniques are maximally utilized when assessing the suitability of patients for supra-aortic intervention.

Being simple to use, readily available, accurate, and safe, color flow Doppler ultrasound remains our initial line of investigation, demonstrating stenosis, flow disturbance, flow reversal, and plaque burden. Duplex ultrasound has been shown to be accurate in diagnosis of the 'surgical grade' narrowing of 70% to 99% stenosis using peak systolic velocity measurements and velocity ratios. Ultrasound technology now boasts 'triplex' imaging—live and simultaneous real-time image, color flow, and pulse waveform displays. Plaque morphology is readily identified by ultrasound and an important predictor of periprocedural complications. Ultrasound can also be utilized as a screening test, allowing the commencement of disease modifying drugs, and to provide follow-up imaging to assess their effect.

If there is a problem with ultrasound or if intervention (surgical or endovascular) is to be considered, the patient should undergo magnetic resonance angiography (MRA). With modern machines, MRA rivals the quality of invasive angiography and is superior to noninvasive ultrasound assessment of the carotid territories, as it will show the full length of the artery from the aortic arch up to the circle of Willis.

Of the different types of MRA available, our practice relies upon time-of-flight (TOF) MRA and contrast-enhanced (CE) MRA. TOF MRA is entirely a flow-based technique where flowing blood creates the imaging signal without the need for contrast medium. While it can offer high spatial resolution, TOF MRA is direction dependent and can lead to problems when imaging tortuous vessels and tight stenoses with turbulent flow. CE MRA involves an intravenous injection of gadolinium to shorten profoundly the T_1 value of the flowing blood and give an anatomical display of the

lumen, but without flow directional information.

In the identification of surgical grade carotid stenoses, both TOF and CE MRA have been shown to be highly sensitive and specific. In the planning of endovascular treatment at the carotid bifurcation, knowledge of the proximal anatomy is important: extreme tortuosity, a bovine configuration, or proximal atheromatous plaque all have implications for catheter access that may influence the choice between surgery and stenting. MRI can also give the carotid endovascular interventionist detail of plaque morphology. Although still innovative, using surface microcoils and motion compensatory software, this technique is capable of high-quality images of the plaque, outlining calcium, fibrous cap, lipid, thrombus, and hemorrhage.

CT angiography (CTA) has similar strengths and advantages to MRA in the detection of occlusive carotid disease. Indeed, being a relatively small field with rapid and usually predictable flow in medium sized vessels, carotid imaging is ideal for CTA. However, it has the drawbacks of radiation dose and overlying bone, which can obscure the arteries. As a result, we reserve it for patients in whom MRA is contraindicated (pacemakers, aneurysm clips, metal heart valves, etc.). It is only the advent of multislice technology that has made CTA fast enough to image the carotid arterial flow from the great vessel origins to circle of Willis in the purely arterial phase, within the 8 seconds prior to venous return. High definition brings detail equivalent to conventional arteriography, but plaque morphological detail is poor and limited to the presence or absence of calcification.

Follow-up imaging after intervention is problematic. Metallic stents can partially obscure the vessels from ultrasound and can cause a local magnetic field artifact in MRA. As a result, we utilize CTA as the main follow-up mode in carotid stenting, both at the bifurcation and especially in common carotid origin lesions.

All 3 main noninvasive techniques have great advantages, but also a number of limitations. It is an understanding of the balance of these that allows a local imaging protocol to develop. Local expertise, experience, and

access to appropriate modern machinery will also factor in. However, it is important that each modality is used maximally by appropriately trained staff in the context of a clinical protocol. Close collaboration between the interventionist and the imager, with appropriate feedback, is essential to ensure the correct and most appropriate imaging information is supplied for each carotid intervention.

Early Clinical Experience With Virtual Histology Intravascular Ultrasound

D Reid

Wishaw Hospital, Wishaw, Scotland, UK

Virtual histology intravascular ultrasound (VH IVUS) is the latest advance in IVUS imaging. It provides a color-coded map of arterial wall plaque and distinguishes between different plaque types. The frequency spectrum of ultrasound reflected from different plaque types is collated by computer software and assigned different colors (fibrous: dark green, fibro-fatty: light green, calcified: white, and necrotic lipid core: red). This provides a color-coded map that is superimposed on the original IVUS image, providing great detail of plaque morphology. VH IVUS has been validated against true histological sections of the arterial wall with extremely close correlation.

Recent investigation into the nature and composition of arteriosclerotic plaque has been possible because of this new development. VH IVUS has highlighted the concept of "vulnerable" plaque, color coding it red. While this development is especially likely to influence coronary interventions (where vulnerable plaque is associated with plaque rupture and sudden death), the role of VH IVUS is also likely to impact peripheral cases, particularly carotid artery interventions. This is because it would be extremely helpful for the interventionist to be able to anticipate how the plaque will behave at the moment of treatment. Will the plaque embolize? Will it resist complete stent deployment? Carotid angioplasty and stenting procedures could thus be tailored during the procedure around

the plaque type which is identified by VH IVUS.

Early Experience of a New Stent-Graft and Delivery System for Arch Applications: Worldwide and Single-Center Updates

V Riambau

Hospital Clinic of Barcelona, Spain

Purpose: To present the first experience with the Relay Thoracic Stent-Graft and its delivery system, Transport, specifically designed for aortic arch applications.

Methods: Relay received CE approval in April 2005. In the US, it is currently under PMA investigation in a Phase I multicenter, prospective, nonrandomized trial. As of the end of July, 52 elective patients have been treated with 80 endografts at 25 centers worldwide. Thoracic aortic aneurysm and/or penetrating atherosclerotic ulcer were the most common diagnoses. All lesions were located in zone 0 to 3 of the arch. The Transport delivery system is a catheter-based, 2-stage delivery device with controlled release of the most proximal stent.

Results: All of the implant procedures have been technical successes (100%) in that devices were deployed with accuracy and without evidence of endoleak. Furthermore, there have been no reported incidences of surgical conversion, lesion rupture, migration, or required secondary intervention. One (1.9%) in-hospital death was registered. One (1.9%) delayed paraplegia was observed 24 hours after the procedure and was fully resolved 4 months later.

Conclusion: The Relay thoracic endograft represents a new, effective, and accurate alternative to aortic arch endografting. Some limitations observed in previous designs have been overcome. Further technical improvements for specific thoracic lesions, like dissections, are ongoing.

Preventive Treatment of Type II Endoleaks Using Fibrin Glue: A 2-Year Experience

S Ronsivalle, F Faresin, F Pettenuzzo, M Riggi, R Lipari, C Rettore, L Pedon, M Zanchetta

Ospedale di Cittadella, Padua, Italy

Purpose: To describe our experience of 2 years in the use of fibrin glue (Tissucol) for the preventive treatment of type II endoleaks during endovascular procedures for abdominal aortic aneurysms.

Methods: From June 2003 to July 2005, we treated 84 patients (77 men; mean age 73.3 years, range 61–86) with fibrin glue to prevent the appearance of type II endoleaks. During the procedure, pressure of the aneurysm sac was monitored using a BriteTip 5-F catheter, which was positioned through the femoral artery. We also used the AcuNav Diagnostic Ultrasound Catheter, which we believe can provide useful ultrasound information regarding the morphology and physiology of the aneurysm sac before and after endovascular treatment. Follow-up provides for echo color Doppler examination prior to discharge and at 1, 3, 6, and 12 months and then every 6 months, together with direct abdominal radiography prior to discharge and computed tomography (CT) at 6 months.

Results: Intraoperative angiography and echo color Doppler examination evidenced no type II endoleaks in any of the patients. Only 2 patients exhibited a type II endoleak at 1-month follow-up.

Conclusion: The experience of these 2 years leads us to confirm that this new intraoperative technique appears to be a suitable procedure; this preventive “ad hoc” strategy provides easier aortic side branch occlusion than transarterial and translumbar embolotherapy, and the results represent an improvement compared to historical data. However, these promising early results still need to be matched by long-term follow-up.

Remote SFA Endarterectomy and Distal aSpire Stenting: Multinational Results at 3-Year Follow-up

D Rosenthal

Medical College of Georgia,
Atlanta, Georgia, USA

Purpose: To examine the results of remote SFA endarterectomy (RSFAE) in conjunction with distal aSpire stenting in a multinational study.

Methods: RSFAE is a minimally invasive procedure performed through a limited groin incision. Two hundred thirty-five patients were included in this study. The indications for the procedure were claudication in 188 patients and limb salvage in 47. After RSFAE, the outflow tract atheromatous plaque was “tacked” with the aSpire stent, which is a polytetrafluoroethylene-covered nitinol stent with high radial strength yet flexible enough to withstand the compressive forces at the knee joint. Prior to stent deployment, if the stent is not in optimal position, it can be “wrapped down,” repositioned, and re-expanded. Therefore, not only is the plaque endpoint tacked, but the collaterals are preserved as well. All patients underwent follow-up examination with serial color-flow duplex ultrasound scanning.

Results: The mean length of endarterectomized SFA was 28.4 ± 6.2 cm (range 20–37). The primary cumulative patency rate by means of life-table analysis was $61.4\% \pm 13.5\%$ at 36 months (mean 19.2, range 2–36). During follow-up, percutaneous transluminal balloon and/or stent angioplasty was necessary in 24 patients for a primary assisted patency of $71.8\% \pm 8.5\%$ at 36 months. The locations of the restenoses after RSFAE were evenly distributed along the endarterectomized artery. There was 1 death (myocardial infarction), 5 (2%) wound complications (3 hematomas, 2 seromas), and the mean hospital LOS was only 1.3 ± 0.4 days.

Conclusion: RSFAE with distal a Spire stenting is a minimally invasive, safe, durable procedure for the treatment of long-segment SFA occlusive disease.



Is Carotid Artery Stenting Really Dangerous in Octogenarians?

C Setacci, A Cremonesi, F Castriota,
G de Donato, F Setacci, E Chisci,
M Pieraccini, A Cappelli
University of Siena, Italy

Purpose: To evaluate whether carotid artery stenting (CAS) performed in octogenarians increases the procedure-related risk.

Methods: In 2 centers, 1219 successful stent procedures (of 1222 attempted, 99.75%) were performed in 1199 patients (903 men; median age 71 years, range 46–89). The 23 bilateral cases were treated in staged procedures. A large number of patients were symptomatic (798, 66.5%). Cerebral protection involved distal filter devices (1123, 92%), occlusive distal balloons (12, 1%), or proximal balloon protection (84, 7%). The majority of the procedures (1206, 99%) were elective, and 13 were emergent/urgent (1%) for amaurosis fugax (2), crescendo TIA (3) and minor stroke (8). Patients were separated into 2 age categories: <80 (1078, 88.4%) and ≥80 (141, 11.6%). The occurrence of stroke and death was reviewed by an independent clinical events committee.

Results: Three lesions in octogenarians could not be treated because of failure of vessel access (1) and extremely tortuous arteries (2). The mean intervention time was 21±7 minutes and was similar in both patients group. The major complication rate in octogenarians was 2.1% (2 fatal strokes, 1 minor stroke) compared with 0.6% in younger patients (1 minor stroke, 4 minor strokes). All octogenarians who had a complication were neurologically symptomatic before CAS.

Conclusion: CAS is safe and effective in elderly patients only if protected. The indication has to take into account not only lesion severity and neurological symptoms, but also comorbidities. The preprocedural evaluation has to be very careful and must include clinical, neurological, and peripheral vascular risk stratification. In elderly patients, an objective risk/benefit evaluation should be always the leading factor for decision making.



Inferior Vena Cava Syndrome: Recognition and Management

P Thorpe
University of Iowa Healthcare,
Iowa City, Iowa, USA

Purpose: To evaluate the results of endovascular repair for chronic, benign inferior vena cava (IVC) and ilio caval obstruction to see if endovenous reconstruction is a safe, effective, and durable treatment option.

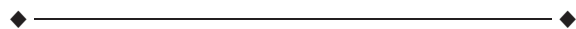
Methods: Between October 1995 June 2005, 26 patients (20 men; mean age 41 years, range 17–73) underwent endovascular repair for IVC occlusion. Twenty-one patients had benign, chronic total infrarenal IVC obstruction, and 3 had acute thrombotic occlusion of a partial, chronic caval stenosis. Mean duration of symptoms was 12.1 years (range 1–25 years). Symptomatic post-thrombotic syndrome patients underwent baseline pelvic/lower extremity duplex and phlebography to determine the pattern of venous flow and location of venous occlusion. When inferior vena cava occlusion was identified, cross-sectional imaging studies (computed tomography or MRV) were performed to exclude malignancy. Patients were screened for hypercoagulability status and baseline labs established. Serial calf measurements and lab values were obtained at 6-hour intervals while patients underwent catheter-directed thrombolysis followed by angioplasty. Axial vein reconstruction was guided with intravascular ultrasound. Self-expanding metallic stents were placed in overlapping, tandem fashion. In cases of bilateral iliac involvement, the crisscross caval stent configuration was used. Patients were anticoagulated during thrombolysis and then converted to warfarin for long-term therapy. Completion duplex studies were obtained. Patients were followed at 1 month and at 6 to 12-month intervals thereafter. Clinical and disability scores were recorded.

Results: Two patients with malignancy-related caval obstruction were successfully treated with relief of venous hypertension, but both died of their malignancy. Six filters were occluded: Greenfield (3), Simon Nitinol (1), and

TrapEase (1). Three chronically occluded filters were successfully stented open. All patients had bilateral lower limb venous hypertension with the exception of 2 individuals aged 17 (left only) and 26 (right only). Thirteen (54%) of 24 had a history of pulmonary embolus, and 14/24 (58%) had caval interruption with a filter (12) or surgery (2). The 48 limbs included 2 prior below-knee amputations for venous disease. The following classifications were recorded: CEAP 1 (2), CEAP 3 (11), CEAP 4 (19), CEAP 5 (9), and CEAP 6 (5). The entire IVC was occluded in 7/24 (29%) and infrarenal in 16/24 (67%).

Mean follow-up is currently 4 years (range 8 months to 10 years). Primary patency among 22 surviving patients is 71%; 7 patients have been re-dilated. Assisted patency is 23/24 (96%) and secondary patency is 100%.

Conclusion: Endovenous reconstruction of the chronically occluded IVC can be accomplished with low morbidity and excellent long-term technical and clinical results.



Impact of Venous Hemodynamics on Development of Endovascular Stent-Vein Valves

R Tripathy, F Osse

Wellington Hospital, Wellington,
New Zealand; Venaclinic,
Sao Paulo, Brazil

Purpose: To describe the hemodynamics of venous blood flow across deep vein valve stations in normal, refluxing, surgically corrected, valve-stented, and stent supported vein valve transplanted veins and how bio-mechanical factors impact stent-vein valve design.

Methods: Using computational fluid dynamics with zero dimensional, lumped-parameter network models combined with 3D finite element meshed models of sheep internal jugular vein, the blood flow across the valve station was mapped in experimental (a) normal, (b) refluxing, (c) surgically corrected vein valve (trapdoor valvuloplasty), (d) valve stented (externally nitinol supported valve

stations), and (e) stent-supported valve transplanted (vein valve segment without nitinol stents at ends) veins. Flow rates (antegrade and refluxed), shear stress distribution, and changes in geometric and fluid dynamics parameters, e.g., velocities, stagnation, and boundary layering effects, were recorded, analyzed, and compared among the 5 groups using nonlinear (FEA) and CAD motion and structural (MAYA) software. Valve leaflet integrity was assessed by histopathological examination at 6 months postimplantation.

Results: Normal valves show 4 phases of the valve cycle that represent the "forward-flow loop" propulsion. Incompetent valves have loss of valve equilibrium or "holding" phase before the valves attempt to close, leading to reflux. Their cusps and vein walls below the valve station also have areas of low shear that may predispose to thrombosis and inability for antegrade propulsion. These areas were seen to develop excessive thickening of vein wall adjacent to the valve station, with valve stiffening. Surgically corrected refluxing valves behave hemodynamically like normal valves but have stagnation and secondary vortical turbulence loops that increase the propensity for eventual valve station dilatation and reflux. Valve stented veins show loss of complete valvular opening phase, resulting in altered geometry and boundary layering at the valve stent level. This results in severe pressure differential, possibly leading to observed microfractures of valve leaflets. Stent-supported vein wall transplants closely modeling among normal flow hemodynamics, with the least stagnation, boundary effects, valve immobility, vein wall thickening, and valve leaflet fractures. Low shear areas were transferred to present locations and did not affect vein valve leaflet function.

Conclusion: Development of vein valve stents is in its infancy. Lessons learned from our study are in favor of stent-supported vein valve transplantation. Further research is needed to clarify the future role of endovascular valves in the treatment of deep venous valvular insufficiency.



Abdominal Aortic Aneurysm in Women: Should They Be Screened?

SM Trocciola, EJ Ryer, SC Lin, RA Chaer,
B DeRubertis, M Pierce, P Christos,
L Mureebe, PL Faries, KC Kent

New York Presbyterian Hospital, Weill
Medical College of Cornell University,
Columbia College of Physicians and
Surgeons, New York, New York, USA

Purpose: To examine risk factors for abdominal aortic aneurysm (AAA) in a large cohort of women.

Methods: Adults (men > 60, women > 65 years old) without a previous history of AAA underwent ultrasound screening for AAA at 100 US hospitals through the SAVE program. Patients completed a questionnaire of demographics and potential risk factors.

Results: 10,382 adults (5907 women; mean age 69 years) were screened during the first year of this program. Prevalence of AAA ≥ 3.0 cm in diameter was 3.9% (174/4475) in men and 0.7% (40/5907) in women ($p < 0.0001$). Univariate models demonstrated that AAAs in women were significantly associated with age, with the highest prevalence in those 75 to 84 years old ($p < 0.0001$). Heart disease (myocardial infarction or coronary revascularization) was significantly associated with AAA in women, with an odds ratio (OR) of 3.9 (95% confidence interval [CI] of 2.0 to 7.5, $p < 0.0001$). Smoking (OR 2.2, 95% CI 1.1 to 4.4, $p = 0.02$) and Native American background (versus Caucasian, OR 3.7, 95% CI 1.3 to 10.6, $p = 0.01$) were also significantly associated with AAA in women. Smoking, heart disease, and age remained independent predictors of AAA in women on logistic regression analysis. There was no association seen between AAA and high blood pressure or family history of AAA.

Conclusion: These results represent the largest cohort of women evaluated for risk factors for AAA. Although the prevalence of AAA among women is low, the elevated rates of AAA found among older women with a history of smoking or heart disease support screening of these high-risk women. Further investigation of elevated rates of AAA among

Native American women is needed to clarify implications for this subgroup.

Endofixer Endosuturing Device: Experimental Tests

G Tuscano, C Adami, R Calvi, L Patorno
University of Modena and University of
Verona, Italy

Purpose: To evaluate the technical possibilities of the Endofixer and its ability to ensure the fixation of an endovascular graft to prevent any kind of migration or endoleaks, without increasing anchoring systems (hooks and barbs) and with minimum radial force.

Methods: The experimental tests were performed through different steps. First, mechanical tests were done to monitor the sewing procedure to accomplish endograft fixation without any surrounding aortic lesion. Second, Endofixer material durability was tested. Third, the device was tested using a simulating in vitro network system (network, pulsatile pump, flow and strength measuring device) to evaluate the maximum allowable parameters connected to blood flow. Fourth, a test was done using porcine aorta ($n = 15$) and cadaveric aortas ($n = 10$) to compare the difference between the tensile strength supported by a typical endograft stent (bare and barbs and hook equipped) to the one afforded by Endofixer.

Conclusion: Stent-graft migration is an important complication of endovascular abdominal aortic aneurysm repair. New aortic stent-grafts use new designs and material, but still rely on radial force, hooks and barbs, or fenestrated grafts to improve the anchoring area. The Endofixer uses a transmural surgical suture to create the best incorporation of the graft in the aortic wall, with a result that will withstand the maximum aortic pulsatile forces.

Effect of Endoleak and Stent-Graft Design on Aortic Properties Following EVAR: Determination Using a Novel Dynamic Cine MRA Imaging Modality

JA van Herwaarden, BE Muhs, KL Vincken, J van Prehn, A Teutelink, LW Bartels, FL Moll, HJM Verhagen
University Medical Center, Utrecht,
The Netherlands

Purpose: To utilize novel cine magnetic resonance angiography (MRA) to characterize aortic stiffness ($\hat{\alpha}$) and elastic modulus (Ep) as indexes of wall compliance during the cardiac cycle. Furthermore, we sought to determine if different endograft designs or the presence of endoleaks affected these indexes.

Methods: Eleven patients were scanned pre and postoperatively. Aortic area and diameter during the cardiac cycle were determined using dynamic MRA at 4 levels: 3 cm above the renal arteries, between the renal arteries, 1 cm below the renal arteries, and at the level of maximum diameter of aneurysm sac. Ep and $\hat{\alpha}$ were calculated. Data are presented as median (range); $p < 0.05$ was considered significant.

Results: Preoperatively, Ep and $\hat{\alpha}$ were significantly higher within the aneurysm sac compared to all other levels ($p < 0.05$). Stiffness within the aneurysm sac increased following EVAR ($p < 0.05$). After implantation, patients with Excluder demonstrated Ep and $\hat{\alpha}$ within the aneurysm neck that was 94% and 60% higher, respectively, compared to those with Talent ($p < 0.05$). The presence of endoleak had no effect on Ep and $\hat{\alpha}$, with values indistinguishable between those with and without endoleak.

Conclusion: This study introduces the feasibility of cine MRA imaging-based calculations of elastic modulus and stiffness. AAA patients demonstrate increased Ep and $\hat{\alpha}$ within the aneurysm sac. EVAR results in increased aneurysm sac Ep and $\hat{\alpha}$ and may potentially be used as a marker of successful aneurysm exclusion. Stent-graft design alters Ep and $\hat{\alpha}$ within the aneurysm neck, which may have consequences for endograft durability. The

presence of endoleak has no effect on Ep and $\hat{\alpha}$.

Protection and Management of Visceral Artery and Hypogastric Artery Disease in Patients With AAAs That Are Treated by EVAR

FJ Veith, M Mehta
Montefiore Medical Center, Bronx, and
Vascular Institute, Albany, New York, USA

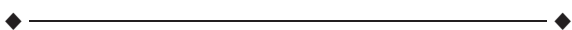
Purpose: To analyze the consequences of interrupting one or both hypogastric arteries (HA) in the standard surgical or endovascular treatment of aortoiliac aneurysms (AIAs).

Methods: From 1992 to 2004, 218 patients with abdominal aortic aneurysms ($n=92$), iliac aneurysms ($n=42$), or AIAs ($n=84$) required interruption of one ($n=166$) or both ($n=52$) HAs as part of their endovascular ($n=159$) or open repair ($n=59$). Endovascular treatment was performed with a variety of industry or surgeon-made grafts in combination with coil embolization of the HAs. The standard surgical techniques included oversewing or excluding the origins of the HAs and extending the prosthetic graft to the external iliac or femoral artery. Twelve patients treated by open repair underwent preoperative coil embolization of one or both HAs.

Results: There were no cases of buttock necrosis, ischemic colitis requiring laparotomy, or death when one or both HAs were interrupted. Persistent buttock claudication occurred after 20 (12%) of the unilateral and 6 (12%) of the bilateral HA interruptions. New onset impotence occurred in 11 (7%) of the unilateral and 6 (12%) of the bilateral HA interruptions. Minor neurological deficits of the lower extremity were observed in 3 (2%) of the patients with unilateral HA interruption, but in no patient undergoing bilateral HA interruption.

Conclusion: Although HA flow should be preserved if possible, selective interruption of one or both HAs can usually be accomplished safely during endovascular and open repair of anatomically challenging AIAs. We believe other comorbid factors, such as shock, distal

embolization, or the failure to preserve collateral branches from the external iliac, common femoral, and deep femoral arteries, may have contributed to the morbidity in other reports of HA interruption.



Vertebral Angioplasty and Stenting: True Indications

GH Wheatley III, K Halow, J Rodriguez-Lopez, V Ramaiah, R Ravi, EB Diethrich
Arizona Heart Institute and Arizona Heart Hospital, Phoenix, Arizona, USA

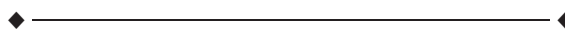
Purpose: To review our cumulative percutaneous experience for vertebral artery lesions with regards to indications, treatment, and outcome.

Methods: We retrospectively reviewed our clinical experience with patients who underwent percutaneous interventions for vertebral artery disease between 1998 and 2005. Charts were reviewed with respect to preoperative symptoms and indications, type of intervention, perioperative events, resolution of symptoms, and follow-up imaging studies. Fifteen interventions were performed on 12 patients. All patients had symptoms of vertebrobasilar insufficiency, including vertigo, diplopia, dysarthria, and gait ataxia, and were receiving medical therapy.

Results: Three (25%) patients had a history of a prior transient ischemic attack (TIA), 1 (8.3%) patient had a prior cerebrovascular accident (CVA), and 2 (16.7%) patients had both a prior TIA and CVA. Preoperatively, focal neurological deficits were present in 3 (25%) patients, while 7 (58.3%) patients had concomitant carotid artery disease that was corrected prior to the vertebral artery intervention. Four (33.3%) patients had a contralateral vertebral artery occlusion, and 3 (25%) patients suffered from bilateral vertebral artery disease. Technical success was achieved in all 12 (100%) patients. Balloon-expandable stents were used in 11 (91.7%) patients, and 2 (16.7%) patients had the procedures performed in association with a cerebral protection device. Thirty-day mortality was 8.3% (1/12); the single death was a cardiac-related

event on postoperative day 14. Mean hospital stay was 1.75 days. There were no postoperative CVAs (0/12, 0%), and 1 patient (1/12, 8.3%) experienced a TIA. Follow-up (average 8.6 months) was available in 6 (54.5%) patients who received 8 vertebral interventions. All patients were asymptomatic (6/6, 100%), and all vertebral arteries (8/8, 100%) were patent by duplex examination with associated antegrade flow.

Conclusion: Vertebral artery interventions are safe and effective for patients with vertebrobasilar insufficiency refractory to medical management. Early to midterm follow-up suggests that treated lesions remain patent and contribute to complete resolution of symptoms. Percutaneous interventions for vertebral artery lesions may be a useful treatment modality in symptomatic patients with vertebrobasilar insufficiency; additional studies are warranted.



Does Preop AAA Size Influence Sac Regression and Classical Remodeling With the Powerlink System?

JB Williams
Cardiac, Thoracic, and Endovascular Therapies, Peoria, Illinois, USA

Purpose: To test the theory that treating aneurysms <50 mm in diameter with the Powerlink device may provide more complete sac regression and classical remodeling of the aorta.

Methods: This investigation utilized the database from the Powerlink endoluminal graft PMA pivotal trial on patients enrolled between July 2000 and March 2003 to detect and characterize changes in aneurysm morphology in relation to aneurysm size treated. All patients included in the analysis had 3D reconstructions performed by the study core lab. Patients were divided into cohorts based on preop aneurysm size (>50 and ≤50 mm), then analyzed for maximum sac diameter, change in sac angulation, change in neck angulation, change in aortic length from distal renal artery to bifurcation, and % sac regression by diameter. Maximum sac angle was

TABLE
Summary Statistics for Selected Aneurysm Measures by Follow-up Time and Baseline Aneurysm Diameter

	Follow-up Time				
	1 Mo	6 Mo	12 Mo	24 Mo	36 Mo
Baseline Diameter >50 mm					
Diameter, mm	n=52, 57.0 (49.0, 76.8)	n=52, 53.8 (31.4, 76.5)	n=65, 50.6 (33.8, 64.7)	n=57, 46.3 (30.4, 69.7)	n=35, 46.0 (26.8, 72.1)
Neck angle, °	n=52, 30.8 (12.7, 61.7)	n=52, 29.9 (9.8, 72.2)	n=64, 29.2 (9.0, 70.8)	n=57, 29.0 (11.4, 70.7)	n=35, 28.3 (11.5, 56.8)
Sac angle, °	n=41, 139.3 (87.6, 75.0)	—†	—†	n=52, 148.2 (110.4, 78.4)	n=28, 146.8 (113.7, 174.4)
Length, mm*	n=51, 121.6 (90.9, 159.1)	n=52, 125.5 (91.9, 157.5)	n=64, 125.9 (94.3, 157.2)	n=56, 125.7 (99.0, 163.9)	n=35, 127.4 (100.1, 166.0)
Baseline Diameter ≤50 mm					
Diameter, mm	n=69, 45.6 (38.5, 55.4)	n=67, 43.8 (29.7, 53.3)	n=81, 41.9 (30.2, 54.7)	n=62, 39.7 (27.8, 53.5)	n=41, 37.8 (28.6, 52.1)
Neck angle, °	n=66, 23.0 (7.4, 53.4)	n=65, 24.7 (8.3, 71.7)	n=80, 23.4 (7.1, 75.9)	n=62, 22.9 (8.8, 48.8)	n=41, 24.3 (7.4, 53.9)
Sac angle, °	n=52, 148.0 (107.9, 178.3)	—†	—†	n=57, 155.6 (111.6, 179.3)	n=35, 159.3 (132.7, 177.1)
Length, mm*	n=64, 115.6 (89.0, 145.4)	n=63, 116.9 (91.9, 151.4)	n=80, 116.1 (91.6, 155.6)	n=64, 118.0 (92.0, 155.6)	n=41, 120.1 (97.0, 158.1)

Data are given as the number (n), mean (minimum, maximum).

* Length of aorta from distal renal artery to bifurcation.

† Measurement not done.

defined as the angle from the distal proximal neck to the maximum inflection point in the sac to the aortic bifurcation (180° being a straight line).

Results: Patients in both cohorts experienced significant reduction in mean sac diameter at all follow-up time points (6, 12, 24, and 36 months; Table). The sacs regressed in the >50-mm group from a mean of 57.0 mm at 1 month to 46.0 mm at 36 months, representing a mean decrease of 26.1% (p<0.0001) in diameter (29.9% in volume). The sacs regressed in the ≤50-mm group from a mean of 45.6 mm at 1 month to 37.8 mm at 36 months representing a mean decrease of 23.9% (p<0.0001) in diameter (18.8% in volume). The patients in the >50-mm cohort experienced significant reduction of mean neck and sac angulation at all follow-up time points. The neck angle decreased by a mean of 3° (p=0.0394) from 1 to 36 months, and the sac angulation straightened by a mean of 7.8° (p=0.0009) over this same time period. Patients in the ≤50-mm cohort had significant

reductions only in mean sac angle (7.6°, p=0.0005; straighter at 36 months), but not neck angle (p=0.9128). The change in distance from distal renal artery to bifurcation was statistically significant, but minimal in both cohorts: 3 mm (p=0.0022) in the >50-mm cohort and 1.9 mm (p=0.0113) in the ≤50-mm cohort at 36 months.

Conclusion: Preop AAA size does appear to influence sac regression based on the findings of this analysis. Endovascular treatment of smaller AAAs (≤50 mm) with the Powerlink device provides nearly complete sac regression and classical remodeling to near normal aortic measurements within the first 3 years post treatment. However, patients with larger aneurysms (>50 mm) experienced a larger percentage reduction in mean sac diameter and greater straightening of sac angulation over 36 months than patients with smaller aneurysms. Both cohorts tended to regress faster in the first year of follow-up than at later time points; however, significant decreases continued through 36 months. Patients in the

smaller aneurysm cohort exhibited no significant change in neck angulation over the follow-up period; this may demonstrate the ability of the Powerlink to prevent worsening aneurysm morphology. Treatment with the Powerlink endoluminal stent-graft appears to be beneficial in terms of aneurysm remodeling through 36 months for all patients. The long main body and column strength of the Powerlink may uniquely influence the remodeling of the aneurysmal aorta as evidenced by these results.

Greater "Oversizing" of Aortic Endografts Is Required for Shorter Aneurysm Necks in Endovascular Aortic Aneurysm Repair (EVAR)

SS Zhou, J Brennan, TV How,
GL Gilling-Smith, PL Harris
Royal Liverpool University Hospital,
Liverpool, UK

Purpose: To examine the effectiveness of the proximal seal in relation to aneurysm neck length and oversizing.

Methods: An in vitro model of the proximal seal of an infrarenal aortic endograft was constructed with pulsatile flow. Aortic sections of bovine aorta with compliance matching that of the abdominal aorta of humans aged 60 to 70 years were selected. A truncated body of a Zenith endograft was deployed into this model. The length of the "neck" into which the graft was deployed was 10, 15, 20, 30, and 40 mm. For each of the neck lengths, "oversizing" of a device was varied by increasing or decreasing pressure within the flow circuit to vary the distension of the "neck." Any leak of fluid from the seal zone was referred to as an "endoleak."

Results: A change of mean pressure from 60 to 160 mmHg resulted in an increase in the diameter of the neck from 26 to 32 mm. The minimal percentage of oversizing above which no endoleak decreased with increasing length of the neck as follows: 10 mm: 20%, 15 mm: 16%, 20 mm: 10%, 30 mm: 7%, and 40 mm: 4%.

Conclusion: In a healthy bovine aorta, the lu-

minimal diameter, the degree of oversizing of an endograft, and the security of the seal are pressure dependent. There is a reverse relationship between the length of the neck and the minimal degree of oversizing to prevent endoleak. Greater oversizing may be required for shorter aneurysm necks in EVAR.

The E-Vita Stent-Graft in Endovascular Thoracic Aortic Procedures: First Clinical Experience

B Zipfel, R Hammerschmidt, T Krabatsch,
S Buz, R Hetzer
Deutsches Herzzentrum Berlin, Germany

Purpose: To evaluate the E-vita stent-graft after 1.5 years of clinical application.

Methods: The E-vita stent-graft is more flexible, with longer segments than other available endografts, and the ends can be freely configured by the physician. In 42 patients (22 women; mean age 67 years, range 45–86), E-vita stent-grafts were implanted into the thoracic aorta. The indications for implantation were type B dissection (n=12), degenerative aneurysm (n=9), penetrating aortic ulcer (n=11), revisionary surgery following previous endograft implantation (n=7), and anastomotic aneurysms (n=3). With an effective total length of the endografts of 210 mm (110–394), a mean of 1.3 segments were implanted per implantation. In 32 cases, 1 segment was implanted, in 6 cases 2 segments, and in 4 cases 3 segments. In all 10 cases with >1 segment, the entire descending aorta was included in the procedure.

Results: The 30-day mortality rate was 12% (5 patients). All deaths were in the group of emergency surgery patients. No cases of paraplegia or stroke were observed. Primary technical success was rated at 88% (36 patients) and secondary success at 97% (45 patients). In 1 case, a proximal leak was closed in a secondary procedure with a Palmaz stent; a further proximal endoleak in an arch aneurysm was closed from the exterior with the beating heart attached to the heart-lung machine.

Conclusion: Initial clinical results are very promising. All forms of thoracic aortic diseases can be treated. The new system has proved particularly valuable in cases of difficult conditions in the aortic arch and extend-

ed aneurysms. In particular, it is possible to cover the entire thoracic aorta with 1 or 2 stent-graft segments, thus reducing the number of connections by a considerable margin.

◆—————◆