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Klinik für Herz-Thorax- und Gefäßchirurgie
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Habilitationsschrift

Endovaskuläre Therapie der thorakalen Aorta: Entwicklung von Implantaten und chirurgischen Techniken

zur Erlangung der Lehrbefähigung
für das Fach Herzchirurgie

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Verwendete Abkürzungen

A.	(anatomisch) Arteria
Aa.	(anatomisch) Arteriae
Abb.	Abbildung im Text
BAA	Bauchaortenaneurysma
com.	(anatomisch) communis
CT	Computertomographie
DHZB	Deutsches Herzzentrum Berlin
Fig.	Figure = Abbildung in Originalarbeit
INSTEAD	INvestigation of STEnt Grafts in Aortic Dissection
IVUS	intravaskulärer Ultraschall
M.	(anatomisch) Musculus
MRT	Magnetresonanztomographie
PAU	Penetrierendes arteriosklerotisches Ulcus
RESTORE	Relay Endovascular Registry for Thoracic Disease
S.	Seite
sin.	(anatomisch) sinistra
Tr.	(anatomisch) Truncus
Tab.	Tabelle
TEE	transösphageale Echokardiographie

1. Einleitung

1.1. Historische Entwicklung

Seit Michael DeBakey 1954 die ersten Gefäßprothesen zu Hause mit der Nähmaschine seiner Frau anfertigte, damit den Ersatz von Aortenabschnitten mit synthetischen Gefäßprothesen aus Polyestergewebe in die Klinik einführte und mit der Hilfe der Industrie zu einer etablierten Methode entwickelte, war das Problem der chirurgischen Behandlung von Aneurysmen grundsätzlich gelöst [1]. In den Jahrzehnten, ja Jahrhunderten zuvor konnten alle Therapieversuche wie Ligatur, Ummantelung, Auffüllung der Aneurysmen mit Fremdkörpern oder aggressiver Kompressionstherapie der in den Zeiten des Aderlasses häufigen falschen Aneurysmen der peripheren Arterien [2] nicht überzeugen, weil sie entweder auf Dauer nicht effektiv waren oder die Gefäßkontinuität nicht wiederherstellen konnten und damit oft zu ischämischen Komplikationen führten. Ein prominenter Patient hat die Entwicklung zur modernen Aneurysmachirurgie beflügelt: Albert Einstein verstarb 5 Jahre nach partieller Ummantelung seines Bauchaortenaneurysmas (BAA) mit Cellophanfolie durch Rudolph Nissen 1955 an einer sekundären Ruptur dieses Aneurysmas, nachdem er den ihm vorgeschlagenen Ersatz des Aneurysmas mit einem Homograft, einen zu diesem Zeitpunkt experimentellen Eingriff, abgelehnt hatte mit den Worten „Ich habe meinen Anteil getan, es ist Zeit zu gehen und ich will es elegant tun“ [3].

Die chirurgische Therapie von Aneurysmen mit Gefäßprothesen hat sich in den folgenden 35 Jahren mit guten Ergebnissen etabliert und wurde an der Bauchaorta zum weitverbreiteten Routine- und Standardeingriff [4]. Die insgesamt sehr viel selteneren Aneurysmen der thorakalen und thorako-abdominellen Aorta wurden durch segmentalen oder kompletten Ersatz weltweit in spezialisierten Zentren behandelt und diese Operation insbesondere durch den Einsatz extrakorporaler Zirkulation mit oder ohne Hypothermie oder regionaler Perfusion ständig verbessert. Dennoch blieb sie mit erheblicher perioperativer Morbidität und Mortalität verbunden [5, 6]. Auf dem Gebiet der Verschlusserkrankungen der Arterien und der Aorta waren als Alternativen zur offenen Chirurgie endovaskuläre Verfahren entwickelt worden, zunächst Bougierung durch Katheter [7], dann Ballondilatation [8] und schließlich Stents zum Offenhalten der wiedereröffneten Gefäßabschnitte [9]. So lag der Gedanke nahe, auch für die Behandlung von Aneurysmen nach einer minimalinvasiven Behandlungsmethode zu suchen, in der Kombination von DeBakey`s Gefäßprothesen und Stents. Volodos berichtete 1991 über die ersten Implantationen von Stentprothesen bei Bauchaortenaneurysmen in der damaligen Sowjetunion, unbeachtet von der medizinischen Weltöffentlichkeit [10]. Erst die Zusammen-

arbeit von Juan Parodi und Julio Palmaz [11], letzterer hatte den Stent erfunden, ergab die Initialzündung einer stürmischen Entwicklung, an der der Autor im Deutschen Herzzentrum teilnehmen konnte.

1.2. Konventionelle Behandlung von Erkrankungen der Aorta thoracica

Während in der infrarenalen Bauchaorta zu über 90 % klassische wahre Aneurysmen vorkommen, sind in der thorakalen Aorta folgende Erkrankungen differenziert zu behandeln: Klassische wahre Aneurysmen, die oft dicht an oder in den Aortenbogen oder in das thorako-abdominelle Segment mit den Abgängen der Viszeralarterien reichen, penetrierende arteriosklerotische Ulcera mit intramuralen Hämatomen oder falschen sacculären Aneurysmen, Aortendissektionen, akute traumatische gedeckte Aortenrupturen und posttraumatische falsche Aneurysmen und Nahtaneurysmen nach vorangegangenen konventionellen Operationen.

1.2.1. Chirurgische Abschnitte der Aorta

Unter chirurgischen Gesichtspunkten, in Hinsicht auf die bei Abklemmung bzw. Landezone für Stentprothesen zu schonenden wichtigen Aortenäste (supraaortale Arterien, Viszeral- und Nierenarterien) und die operativen Zugänge (Sternotomie, laterale Thorakotomie, Thorako-Laparotomie und Laparotomie), wird die Aorta in folgende Abschnitte eingeteilt:

Aortenwurzel	= Aortenklappe und Sinus valsalvae
Aorta ascendens	= vom sinu-tubulären Übergang bis zum Tr. brachiocephalicus
Aortenbogen	= der Abschnitt, der die Abgänge von Tr. brachiocephalicus, A. carotis communis sin. und A. subclavia sin. einschließt
Aorta descendens	= von der A. subclavia sin. bis zum Zwerchfell
Thorako-abdominelle Aorta	= vom Zwerchfell bis zu den Nierenarterien
(Infrarenale) Bauchaorta	= von den Nierenarterien bis zur Bifurkation

Die Segmenteinteilung verwendet die Aortendatenbank des DHZB in Form von nummerierten Abschnitten (Fig. 1, S. 71), wobei die Landezonen des Aortenbogens nach Criado [12] mit identischen Zonen anderer Nummerierung berücksichtigt sind (Fig. 5, S. 24). Diese Einteilung wird in der Habilitationsschrift und den zu Grunde liegenden Publikationen konsequent verwendet, insbesondere die Definition des Aortenbogens. Leider werden diese Definitionen in der Literatur nicht einheitlich verwendet. In vielen Publikationen wird offenbar der gebogene proximale Teil der Aorta descendens (Abschnitt 6 Aortendatenbank) dem Aortenbogen zugerechnet, ohne dass es klar definiert wird.

1.2.2. Chirurgie an Aortenbogen und Aorta descendens

Läsionen der Aorta ascendens und des proximalen Aortenbogens werden über eine mediane Sternotomie in Rückenlage angegangen, Erkrankungen der Aorta descendens und des distalen Aortenbogens über eine linkslaterale Thorakotomie in Rechtsseitenlage. Prozesse, die den Abschnitt zwischen Zwerchfell und Nierenarterien einschließen, erfordern einen thorako-abdominellen Zugang mit linkslateraler Thorakotomie, Durchtrennung des Rippenbogens und des Zwerchfells und Freilegung des linksseitigen retroperitonealen Raumes.

In den überwiegenden Fällen werden die betroffenen Aortenabschnitte durch Gefäßprothesen aus Polyestergewebe (S. 13) ersetzt. Hierzu wird die Aorta abgeklemmt, das Aneurysma eröffnet und die Anastomosen an den Übergängen zu den normalen Aortenabschnitten angelegt. Die Abgänge der Interkostalarterien können in die Prothese reimplantiert werden. Zur Vermeidung ischämischer Schäden der peripheren Organe und des Rückenmarks während der Klemmphase werden die untere Körperhälfte und/oder die Viszeralorgane selektiv perfundiert. Für eine detaillierte Übersicht der verschiedenen Perfusions- und Organprotektionstechniken sei auf eine Übersichtsarbeit des Autors verwiesen [13]. Im DHZB wird die Herz-Lungen-Maschine als femoro-femoraler veno-arterieller Bypass unter Zwischenschaltung eines Oxygenators angewendet. Mit dieser Technik können auch in tiefer Hypothermie und Kreislaufstillstand offenen Anastomosen proximal am Aortenbogen oder distal in der thorako-abdominellen Aorta angelegt werden.

Die eingriffsspezifische Morbidität ist hoch. Im Vordergrund stehen Blutungskomplikationen bei Gerinnungsstörungen durch Heparinisierung und Hypothermie, pulmonale Komplikationen durch die Ein-Lungen-Beatmung und schmerzbedingte Schonatmung, abdominale, renale und neurologische Komplikationen. Als bedeutende präoperative Risiken gelten chronisch obstruktive Lungenerkrankung, fortgeschrittenes Lebensalter, Niereninsuffizienz und Adipositas. Die operativen Ergebnisse sind vornehmlich abhängig von diesen allgemeinen Risiken, der Beteiligung des Aortenbogens und dem Anteil der Notfälle. In hochspezialisierten Zentren mit ausgewähltem Krankengut [5, 14] werden die Mortalität mit 5 bzw. 8 % und die Paraplegierate mit 3,8 bzw. 2,3 % angegeben. In der klinischen Realität können diese Zahlen wesentlich höher liegen [15, 16].

1.2.3. Therapie von Aortendissektionen

Die Dissektion der Aorta muss wegen ihrer pathophysiologischen und anatomischen Besonderheiten von den klassischen Aneurysmen abgegrenzt werden. Der immer wieder verwendete Begriff „Aneurysma dissecans“ verwischt diese Trennung, die mit dem heutigen Stand der bildgebenden Diagnostik immer klar vollzogen werden kann. Es kann wohl im chronischen Verlauf einer Dissektion zur Aneurysmabildung durch Ausweitung des falschen Lumens kommen oder eine Dissektion aus einem klassischen Aneurysma hervorgehen. Im ersten Fall sollte man dann von einer chronischen Dissektion mit Aneurysma des falschen Lumens im zweiten Fall von einem Aneurysma mit Dissektion sprechen. Eine Aortendissektion entsteht immer durch ein akutes Ereignis und trifft wahrscheinlich in den meisten Fällen zuvor makroskopisch unauffällige Aorten. Allerdings gibt es in den wenigsten Fällen eine Bildgebung der Aorta vor der Dissektion zum Vergleich. Der akuten Erkrankung liegen chronische degenerative Veränderungen der Aortenwand im Bereich der Media zugrunde, häufig das histologische Bild einer zystischen Mediadegeneration. Als deren Ursache wird ein chronischer arterieller Hypertonus in Verbindung mit multifaktoriellen genetischen Defekten der elastischen Fasern der Aortenwand und der Metalloproteinasen angesehen. Daneben gibt es eine Reihe von Bindegewebserkrankungen mit klar definierten klinischen Syndromen und in der Genanalyse erkennbaren Defekten, die zur Aortendissektion prädisponieren. Als häufigste Erkrankung gilt das Marfan-Syndrom, seltener sind Ehlers-Danlos-, Loeys-Diez-Syndrom oder andere Bindegewebserkrankungen.

Bei der Dissektion kommt es zu einem Einriss der Intima und der inneren Mediaschichten. Durch diesen strömt das Blut in die Aortenwand, wühlt sich dann im Verlauf der Aorta nach distal vor und bildet so ein zweites, falsches Lumen. Häufig kommt es im Verlauf der Aorta zu einem zweiten Einriss vornehmlich dort, wo große Gefäße abgehen, also an den Viszeral- und Nierenarterien oder an der Aortenbifurkation. Durch dieses Re-Entry kann das Blut aus dem falschen Lumen wieder in das wahre Lumen zurück fließen. Von Größe und Lokalisation dieses Re-Entry hängen der klinische Verlauf und die Ausbildung von Komplikationen ab. Bei ineffektiver Druckentlastung des falschen Lumens über das Re-Entry oder bei fehlendem Re-Entry kann die Dissektionsmembran das Aortenlumen und die Gefäßabgänge verlegen und ischämische Komplikationen auslösen oder es kann zu einer Druckentlastung nach außen, also zu einer Ruptur der Aorta kommen. Das akute Ereignis der Dissektion äußert sich in der Regel durch einen aus heiterem Himmel einsetzenden heftigen thorakalen Schmerz, der als Vernichtungsschmerz dem eines Herzinfarkts ähneln kann. Typisch ist die Schmerz-

lokalisation mehr im Rücken und ein nach kaudal wandernder Schmerz, der offenkundig das Vorwühlen des Blutes in der Aortenwand anzeigt. Das Dissektionsereignis kann aber auch mit nur mäßigen Schmerzen einhergehen oder gar nicht wahrgenommen werden. Es ist nicht ungewöhnlich, dass die Beschwerden als normale Rückenschmerzen, Bandscheibenproblematik oder Schmerzen anderer Ursachen fehlinterpretiert werden und die Diagnose, wenn überhaupt, erst verzögert gestellt wird. Manchmal findet sich auch eine chronische Dissektion als Zufallsbefund bei aktuell beschwerdefreien Patienten. Oft lässt sich durch gezielte Anamnese der Zeitpunkt der akuten Dissektion nachträglich bestimmen, was für die Verfahrenswahl der Behandlung und deren Erfolgsaussichten von Bedeutung ist (S. 91 f).

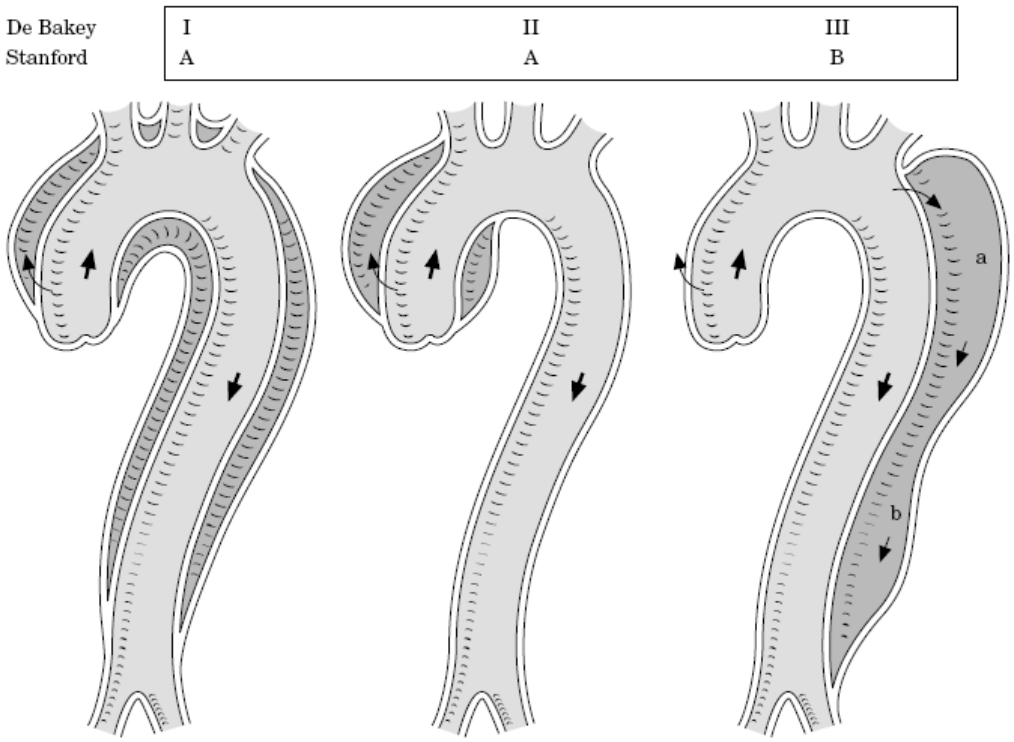

Abb. 1

Zusammenfassendes Schema der beiden Klassifikationen der Aortendissektion Stanford und DeBakey mit der Modifikation nach Reul und Cooley. Erläuterungen im Text. Nach [17] mit freundlicher Genehmigung von Qxford University Press.

Die Aortendissektion wird morphologisch nach alternativ oder ergänzend zu verwendenden Klassifikationen eingeteilt. Die Stanford-Klassifikation [18] unterscheidet, ob die Aorta ascendens betroffen ist (Typ A) oder nicht (Typ B). Die DeBakey-Klassifikation [19] differenziert etwas genauer nach dem Ausgangspunkt, indem der Typ I ausgehend von der Aorta ascendens eine Dissektion der gesamten thorakalen oder auch abdominalen Aorta und der Typ II eine auf die Aorta ascendens und den proximalen Aortenbogen beschränkte Dissektion be-

schreibt. Der DeBakey-Typ III entspricht der Typ-B-Dissektion nach der Stanford-Klassifikation, wobei hier später Reul und Cooley [20] eine Modifikation in die Typen III a (beschränkt auf die Aorta descendens) und III b (Aorta descendens und abdominelle Aorta betreffend) eingeführt haben. Diese letzte Differenzierung wird selten verwendet, bekommt aber in Zeiten der endovaskulären Behandlung wieder Bedeutung [21]. Die Abb. 1 fasst die beiden Klassifikationen schematisch zusammen. In der Klinik hat sich zur Wahl des Therapieverfahrens weitgehend die Stanford-Klassifikation durchgesetzt, da sie ganz einfach unterscheidet zwischen der primär als Notfall operationsbedürftigen Typ-A-Dissektion und der B-Dissektion, die zunächst konservativ abwartend behandelt wird. Die Klassifikation nach DeBakey hat den Vorteil, dass mit der Unterscheidung von Typ I und Typ II eine Differenzierung für die Nachbehandlung getroffen wird, ob zum Zeitpunkt der akuten Dissektion die Aorta descendens und ggf. abdominelle Aorta mit betroffen war oder nicht.

Die oben skizzierten Komplikationsmöglichkeiten, die sich in den einzelnen Aortenabschnitten unterschiedlich auswirken können, bestimmen die Indikation zur akuten Behandlung. Bei Beteiligung der Aorta ascendens, also einer Typ-A-Dissektion kann die Dissektionsmembran die Koronararterien oder die supraaortalen Gefäße verlegen, Austritt von Flüssigkeit aus dem falschen Lumen zu einer akuten Herzbeuteltamponade führen und die Ausdehnung der Dissektion in die Aortenwurzel die Aufhängung der Aortenklappe beeinträchtigen und zu einer akuten Insuffizienz der Aortenklappe führen. Die Letalität der unbehandelten Erkrankung wird auf 40 % sofort und danach auf 1 % pro Stunde geschätzt [22]. Die akute Typ-A-Dissektion ist als ein chirurgischer Notfall anzusehen und sollte umgehend nach Diagnosestellung operiert werden. Die konventionelle Operation mit supracoronarem Ascendens-Ersatz mit oder ohne Aortenwurzelrekonstruktion oder mit klappentragendem Conduit ist Standard und nach einer aktuellen Untersuchung an einem unselektionierten Notfallkollektiv mit einer Letalität von 17 % verbunden [23]. Eine endovaskuläre Alternative ist durch die Nähe zu Koronararterien, Aortenklappe und supraaortalen Gefäßen mit erheblichen Schwierigkeiten und Gefahren belastet und kann daher nur in besonderen Fällen angewendet werden.

1.2.4. Traumatische Aortenrupturen

Die Ruptur der Aorta beim stumpfen Thoraxtrauma ist hierzulande die klinisch bedeutsamste Verletzung der intrathorakalen Gefäße. Die Ausführungen zu anatomischen Charakteristika, Unfallmechanismus und chirurgischer Versorgung vor Einführung der endovaskulären Behandlung sind in stark gekürzter Form und mit wenigen aktuellen Ergänzungen einem Lehrbuchbeitrag entnommen, den der Autor 1999 zusammen mit Prof. Hetzer verfasst hat [24], kurz vor Implantation der ersten Stentprothese in die thorakale im DHZB – bei einem Patienten mit einer gedeckten traumatischen Aortenruptur:

„Die Ruptur der Aorta ist zumeist lokalisiert am Übergang vom Aortenbogen zur Aorta descendens, dort, wo die linke Arteria subclavia abgeht und die bis dahin mobile Aorta durch die Interkostalarterien und die parietale Pleura an der dorsalen Thoraxwand fixiert ist. Dieser Übergang vom mobilen zum fixierten Aortenabschnitt prädisponiert für die Ruptur an typischer Stelle. In diesem Bereich tritt durch eine überstarke Knickung der Aorta eine abnorme Streckung der Intima und der inneren Media ein, welche typischerweise zu einem queren Abriss dieser Strukturen führt. Diese Ruptur entsteht somit bei all jenen Verletzungen, die mit einer starken Deformation des Thorax bei direkter Kompression, kombiniert mit Dezeleration (oder Akzeleration) unterschiedlichen Ausmaßes, einhergehen. Die häufigsten Unfallursachen sind Aufpralltraumen bei Autounfällen mit hoher Geschwindigkeit und Stürze aus großer Höhe.“

„Übereinstimmend zeigen mehrere Beobachtungsserien [25, 26, 27], dass zwischen 80 und 90 % der Verletzten innerhalb der ersten halben Stunde versterben und dass die Verletzten, die lebend das Krankenhaus erreichen, einer stetigen Bedrohung durch eine zweite, dann freie und tödliche Ruptur während der folgenden Stunden und Tage ausgesetzt sind.“ Nur bei einer gedeckten Ruptur kann das unmittelbare Unfallereignis überlebt werden. Hier verhindern die äußere Wand der Media oder auch nur die Adventitia oder die Pleura die freie Ruptur. Es bildet sich also ein falsches Aneurysma aus, das in den axialen Schnitten des CT wie eine lokalisierte Dissektion erscheinen kann. Deswegen wird die Verletzung oft fälschlich als „traumatische Aortendissektion“ bezeichnet.

Die Ausführungen über die diagnostischen Verfahren aus dem Lehrbuchkapitel können 12 Jahre später auf die Computertomographie beschränkt werden, da in der heutigen Praxis der Unfallchirurgie jeder Patient mit Polytrauma oder schwerem Thoraxtrauma einer Ganzkörper-

Computertomographie unterzogen wird und so nur noch wenige Aortenverletzungen unentdeckt bleiben [28]. Die Aortenrupturen wurden chirurgisch durch direkte Naht oder Patchplastik, meistens jedoch durch Interposition einer Aortenprothese geeigneten Kalibers versorgt. Dabei wurden über Jahre zwei Fragen diskutiert:

1. Kann die Aorta einfach abgeklemmt werden oder sollte ein Perfusionsverfahren der unteren Körperhälfte mit dem Ziel der Verhinderung einer Paraplegie eingesetzt werden?
2. Welches ist der optimale Zeitpunkt der Versorgung in Anbetracht der häufig multiplen und schweren Begleitverletzungen?

Die erste Frage wurde durch von Oppell 1994 durch eine Literaturanalyse aller englischsprachigen Publikationen, erschienen von 1972 bis 1992, beantwortet [29]. Eine eigene Metaanalyse der danach erschienenen Publikationen [24] kam zu dem gleichen Ergebnis: Bei einer Mortalität von 20 % in beiden Gruppen, hatten die Patienten ohne distale Perfusion zu 18 % eine Paraplegie, mit Perfusion nur zu 6 %.

Zur zweiten Frage sei das Lehrbuchkapitel zitiert: „Die Handhabung eines Verletzten mit einer nachgewiesenen Aortenruptur und der ideale Operationszeitpunkt werden kontrovers diskutiert. Ein Teil der Autoren vertritt die Auffassung, daß die Ruptur überhaupt nur überlebt werden kann, wenn sie so stabil durch die Umgebungsstrukturen gesichert ist, daß unter blutdrucksenkender Medikation ein Zuwarten zumindest über Stunden aber eventuell auch länger möglich ist, um optimale Bedingungen für den Verletzten und auch für die Logistik der Versorgung zu erreichen. Hier stehen vor allem in der Diskussion die Versorgung von extrathorakalen Verletzungen, die Behandlung eines Schädel-Hirn-Traumas oder einer Lungenkontusion und die Furcht vor möglicher Aggravation von Blutungen intrazerebral, im Bauch und Beckenbereich durch die Heparinisierung während der Versorgung der Aortenruptur. Aus diesen Überlegungen ist dort das Konzept einer früh elektiven Versorgung der Aortenruptur entwickelt worden [30, 31, 32, 33, 34]. Wir vertreten nach wie vor die Meinung, daß die Ruptur sofort nach Diagnosestellung operiert werden sollte, vorausgesetzt, aktiv blutende Verletzungen an anderen, vor allem intraabdominellen Organen sind versorgt. Wir haben beobachtet, daß bei auch nur kurzem Zuwarten eine freie Ruptur das Leben des Patienten beenden kann [35, 36]. Auch kann durch die Pseudokoarktation bei unbehandelter gedeckter Ruptur eine Paraplegie oder schwerwiegende Ischämie abdominaler Organe entstehen [37].

Dieses Konzept der Sofortversorgung wird an anderen Kliniken ebenfalls verfolgt [38, 39, 40, 41, 42]."

Wegen der kurzstreckigen Läsion der Ruptur erschien die Behandlung mit der neuen endovaskulären Methode vielversprechend: „Eine Alternative zu den beschriebenen Operationsverfahren kann in geeigneten Fällen die endovaskuläre Implantation von Stentprothesen darstellen. Bei geeigneter Lokalisation kann damit die Ruptur überbrückt und von innen abgedichtet werden. Der Einsatz der Methode ist an eine exakte Lokalisationsdiagnostik zum Ausschluss weiterer Rupturlokalisationen sowie ein qualitativ hochwertiges Computertomogramm zur Durchmesserbestimmung der Aorta gebunden. Darüber hinaus setzt der Einsatz der Methode beim traumatisierten Patienten eine entsprechende Vorratshaltung der Stentprothesen voraus. Bei bogennaher Ruptur ist diese Methode wegen der Gefahr der Verlegung der supraaortalen Gefäße nicht einsetzbar. Sie bleibt derzeit auf Einzelfälle beschränkt. Erste Erfahrungsberichte liegen bereits vor [43, 44, 45], über Langzeitergebnisse sind noch keine Aussagen zu treffen."

In den folgenden Jahren haben wir die endovaskuläre Behandlung aufgrund ihrer Effektivität und geringen Morbidität in der Akutphase bei schwer traumatisierten Patienten zur Behandlung der ersten Wahl entwickelt. Die eigene Arbeit in 2.4. berichtet darüber.

1.2.5. Das Problem der Rückenmarksischämie bei Aorteneingriffen

Die Ischämie des Rückenmarks mit nachfolgender Querschnittslähmung ist eine bekannte und gefürchtete Komplikation der Chirurgie der thorakalen Aorta. Eine Übersicht der diskutierten pathophysiologischen Mechanismen findet sich bei Gawenda et al. [46]. Als führende Ursache wird die Unterbrechung der Interkostalarterien beim Ersatz der Aorta descendens angesehen. Das Rückenmark wird segmental aus den dorsalen Ästen der Interkostalarterien versorgt. Eine anatomisch definierte Kommunikation zwischen diesen Versorgungsgebieten besteht in den beiden relativ kleinen Aa. communicans anterior und posterior [47]. Diese sind individuell unterschiedlich angelegt und können in ihrem cranio-caudalen Verlauf unterbrochen sein. Unter solchen Umständen könnte der Verschluss einer Interkostalarterie eine Ischämie in dem zugehörigen Segment des Rückenmarkes auslösen, damit die Leitungsbahnen an dieser Stelle zerstören und so zu einer Plegie unterhalb dieses Segmentes führen. Aus dieser Überlegung heraus ist die Reimplantation von Interkostalarterien in die Gefässprothesen entwickelt worden, um die Inzidenz der Paraplegie zu reduzieren [48]. Die Wirk-

samkeit dieser Maßnahme alleine ist in der angeführten Publikation schwer abzuschätzen, da gleichzeitig weitere Maßnahmen, wie die Einführung von distalen Perfusionsverfahren und die Spinalkanaldrainage zur Verbesserung des Gewebsperfusionsdrucks des Rückenmarks eingeführt wurden. Dennoch gilt die Notwendigkeit der Reimplantation von Interkostalarterien als Lehrmeinung für die konventionelle Chirurgie. Abweichend davon hat die Gruppe um Randall Griepp das Konzept eines kollateralen Netzwerkes entwickelt [49] und daraus klinisch einen völlig entgegengesetzten Ansatz mit Erfolg praktiziert: Die Interkostalarterien wurden vor Abklemmung der Aorta systematisch ligiert, um ein Stealphänomen zu vermeiden. Die Paraplegierate war vergleichbar oder niedriger als bei Serien mit Reimplantation [50]. Auf die Theorie des kollateralen Netzwerkes wird im Kapitel 3.4 (S. 93 ff) ausführlich eingegangen.

1.3. Prinzip der endovaskulären Behandlung von Aneurysmen und Dissektionen

1.3.1 Stentprothesen

Die erste selbstgebaute Stentprothese war aus einer herkömmlichen Gefäßprothese aus Polyestergewebe und zwei ballonexpandierenden Palmaz-Stents an beiden Enden zur Verankerung [11] aufgebaut. Dieses Konstruktionsprinzip blieb im Wesentlichen unverändert, aber die Stentprothesen wurden nach den ersten Erfahrungen modifiziert und durch die Entwicklung industriell gefertigter Prothesen in größerem Umfang anwendbar. Sie bestehen aus herkömmlichem Gefäßprothesenmaterial, entweder Polyestergewebe, besser bekannt unter dem Markennamen Dacron® des ersten Herstellers DuPont [51], oder expandiertem Polytetrafluoräthylen (e-PTFE) [52], besser bekannt unter dem Markennamen Gore® des ersten Herstellers W.L. Gore Associates (Flagstaff, AZ; USA) [53], in das Metallfedern (Stents) eingenäht oder eingeklebt sind (Fig. 1 und 2, S. 35). Die Stents sind überwiegend selbstexpandierend und aus Edelstahl oder Nitinol, einer Nickel/Titanverbindung mit superelastischen Eigenschaften [54], gefertigt. Die Stentprothesen sind in Einführungskatheter gepackt, mit denen sie unter Röntgensicht durch die operativ freigelegte A. femoralis oder A. iliaca an den betroffenen Aortenabschnitt vorgeschoben, dort entfaltet werden und sich durch die integrierten Stents in den gesunden Gefäßabschnitten verankern. Aneurysmen werden im Gegensatz zur offenen Operation nicht entfernt, aber die kranke Wand ist nicht mehr dem Blutdruck ausgesetzt (Abb. 2, S. 14). Damit ist die Gefahr des Einreißens der Wand gebannt und die Aneurysmen verschwinden in vielen Fällen im Laufe der Zeit.

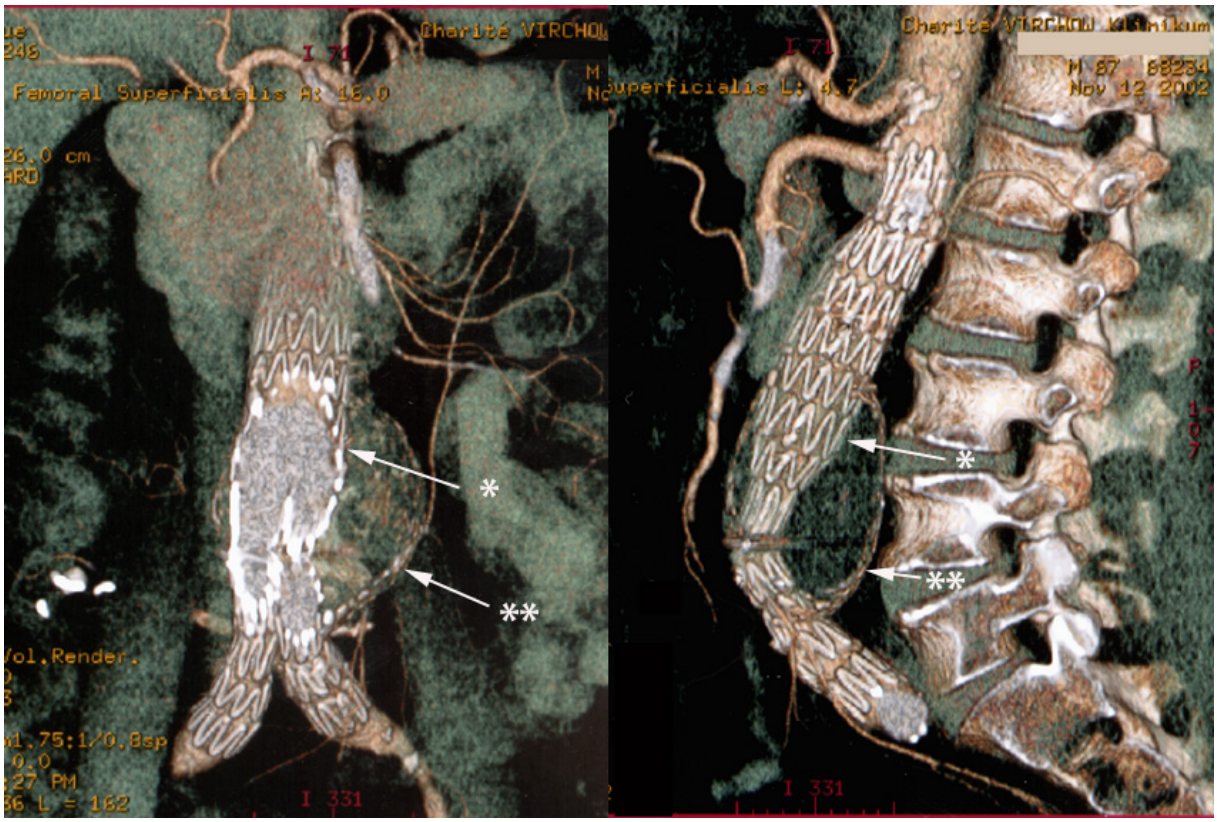

Abb. 2

Aneurysma der Bauchaorta nach Implantation einer Stentprothese: Der Blutstrom läuft durch die Stentprothese (*), die Wand des belassenen Aneurysmas (**) ist deutlich zu erkennen. Der Raum zwischen Stentprothese und Wand ist mit Thrombus ausgefüllt. (Rekonstruktion einer Computertomographie). Nach [55] mit freundlicher Genehmigung des Springer Verlages, Berlin-Heidelberg-NewYork.

Die Durchmesser der Stentprothesen werden nach den Dimensionen der Verankerungszonen der gesunden Aortenabschnitte proximal und distal des Aneurysmas ausgewählt und gegenüber diesen um 10 bis 20 % überdimensioniert. Die Prothesen verankern sich mit der Radialkraft, die aus der Expansionsbestrebung gegenüber der Aortenwand entsteht. Zur zusätzlichen Fixierung werden, bei den einzelnen Modellen unterschiedlich, freie Stentfedern (Fig. 1 und 2, S. 35; Fig. 1A S. 50; Fig. 1 S. 63; Fig. 2BC S. 64), Haken oder Doppelungen der Stentfedern (Fig. 1C S. 35; Fig. 1B S. 50) verwendet. Die Einführungssysteme der Stentprothesen haben Außendurchmesser von 20 bis 26 F. Wegen dieser Größe werden sie über einen kleinen chirurgischen Zugang zu den Femoralarterien implantiert, über den anschließend das Loch in der Arterie mit einer Gefäßnaht sicher verschlossen wird. Nicht selten, nach unserer Erfahrung in ca. 15%, sind enge und verkalkte Beckengefäße für die großen Katheter nicht passierbar oder können durch diese bis hin zur Perforation verletzt werden [56]. In solchen Fällen muss auf einen retro- oder transperitonealen Zugang zu den größeren Gefäßen, der A. iliaca communis oder gar der infrarenalen Aorta ausgewichen werden, bzw. die Gefäßverletzungen akut chirurgisch versorgt werden.

Die Ausmessung der Aorta für die Wahl der Prothesen erfolgt präoperativ mit einer möglichst präzisen Computertomographie (CT) mit dreidimensionaler Rekonstruktion (Angio-CT), ersatzweise auch mit der Magnetresonanztomographie (MRT). Die intraoperative Bildgebung erfolgt mit Röntgendurchleuchtung und Angiographie zur Identifizierung der Landezonen und zur Kontrolle auf Endolecks. Stentprothesen können nur eingesetzt werden, wenn eine Landezone von maximal 40 mm Durchmesser und mindestens 20 mm Länge vorhanden ist, von der keine wichtigen Gefäße abgehen, die durch Stentgrafts verschlossen würden. Somit bestimmt die Nähe zum Aortenbogen bzw. zu den Viszeralarterien im thorako-abdominellen Segment die technischen Grenzen der Stentgraftbehandlung. Weitere Limitationen sind Elongationen und Knickbildungen der thorakalen Aorta, wobei die Weiterentwicklung zu flexibleren und längeren Stentprothesen mit optimierten Einführungssystemen diese technischen Grenzen kontinuierlich verschieben. Endograftimplantationen am oder im Aortenbogen stellen besondere Herausforderungen an die Implantationstechnik und an die mechanischen Eigenschaften von Stentprothesen und ihren Einführungssystemen. Für eine sichere Verankerung im Aortenbogen ist häufig die Implantation des Stentgrafts über die linke A. subclavia hinweg und damit der Verschluss ihres Ostiums durch die Stentprothese erforderlich. Muss der Stentgraft noch weiter proximal im Bogen implantiert werden, sind aufwendige vorherige Bypassoperationen auf die zu verschließenden Aa. carotes communes zwingend erforderlich. Solche Kombinationen von endovaskulären Maßnahmen mit gefäßchirurgischen Operationen werden als Hybridoperationen bezeichnet [57].

1.3.2. Spezielle Aspekte bei Aortendissektionen

Die endovaskuläre Behandlung der Aortendissektion beschränkt sich weitgehend auf die Typ-B-Dissektion. Als Standard der Behandlung hatte sich eine primär konservative Therapie mit Bettruhe, Blutdrucksenkung und Schmerzbehandlung etabliert, da häufig unter der Voraussetzung eines effektiven Re-Entry die Konsolidierung der Erkrankung ohne akut lebensbedrohliche Komplikationen beobachtet wurde und Ergebnisse der akuten chirurgischen Behandlung enttäuschend waren [58]. Allerdings kann auch die Typ-B-Dissektion zu Komplikationen, wie sekundäre Rupturen oder Malperfusionen führen. Dabei ist die Malperfusion tückisch und schwierig zu erkennen. Das Ausmaß der Durchblutungsstörungen ist abhängig von der Verlegung des wahren Lumens und der Gefäßabgänge durch die Dissektionsmembran und von der Beteiligung der abgehenden Gefäße an der Dissektion, wobei diese Verlegungen durch die pulssynchronen Bewegungen der Dissektionsmembran intermittierend erfolgen können und damit die Ausbildung von klassischen Symptomen wie beispielsweise bei einem

Mesenterialinfarkt verschleiert sein kann. Williams und Lee haben 1997 in einer Serie von Publikationen zu pathophysiologischen Experimenten und differenzierter radiologischer Diagnostik der Dissektion einen Schlüssel zum Verständnis der Erkrankung gegeben [59, 60, 61]. Die in Abb. 3 wiedergegebene Schemazeichnung illustriert die Pathophysiologie in prägnanter Weise und zeigt die Ansätze für eine endovaskuläre Therapie.

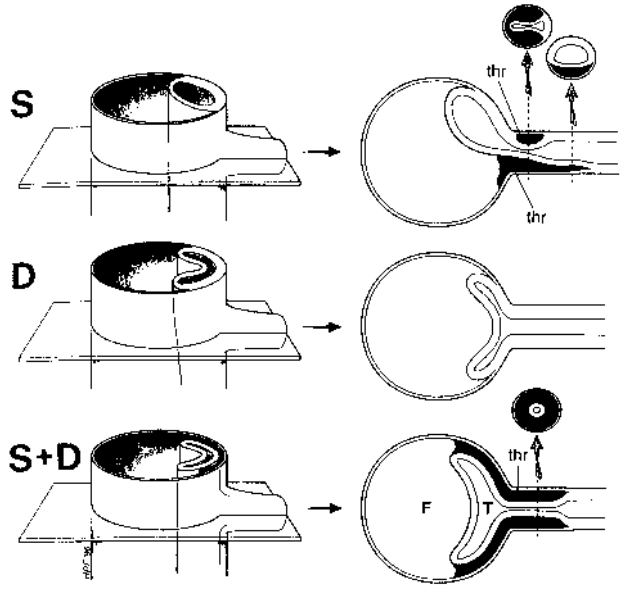

Abb. 3

Zwei Mechanismen der Einengung der Seitenäste durch die Aortendissektion:
Bei der statischen Obstruktion (S) läuft die Dissektionsmembran in den Seitenast hinein und verlegt das wahre Lumen des Gefäßes. Bei der dynamischen Obstruktion (D) ist das Seitengefäß nicht disseziert, aber die Membran der Aortendissektion legt sich wie ein Vorhang über das Ostium. Eine Kombination beider Mechanismen (S+D) kommt ebenfalls vor. Nach [61] mit freundlicher Genehmigung der Radiological Society of North America, Oak Brook, IL.

Die Autoren haben darauf aufbauend das Konzept der endovaskulären Fenestration der Dissektionsmembran zur Dekompression des falschen Lumens entwickelt [62]. Wir haben in schweren Fällen solcher Malperfusionen eine modifizierte Technik [63] angewandt, jedoch mit enttäuschenden klinischen Ergebnissen [64]. Erst die Implantation von Stentprothesen zur Abdichtung des Entry, wie sie zuerst von Dake [65] und Nienaber [66] beschrieben wurde, führt zu einer effektiven Dekompression des falschen Lumens. Diese Technik hat zu einer erheblichen Verbesserung der Ergebnisse geführt [64], sodass wir die Implantation von Stentprothesen jetzt als Standard bei komplizierten Typ-B Dissektionen anwenden ggf. in Kombination mit Implantation von Stents in die Seitenarterien zur Behebung statischer Kompressionen. Die Stentprothese wird in das wahre Lumen implantiert, damit das Entry von innen verschlossen und das falsche Lumen dekomprimiert. Der Selbstexpansion der Stentprothese folgend, erweitert sich das wahre Lumen im Laufe der Zeit und im Idealfall ver-

schwindet das falsche Lumen vollständig (Abb. 4). Mit den positiven klinischen Erfahrungen bildeten sich folgende Indikationen zur Stentgraftbehandlung bei akuten Dissektionen heraus [67, 68]:

1. Malperfusionssyndrom
2. Ruptur oder Zeichen des Flüssigkeitsaustritts aus der Aorta (Pleuraerguß)
3. Progressive Vergrößerung des falschen Lumens im Verlauf
4. Mit konservativen Maßnahmen nicht beherrschbare Schmerzen
5. Schwer einzustellender Hypertonus

Dabei sind die beiden letzten Kriterien als Zeichen eines anhaltend hohen Drucks im falschen Lumen bzw. als Verdacht auf Minderperfusion der Nierenarterien anzusehen.

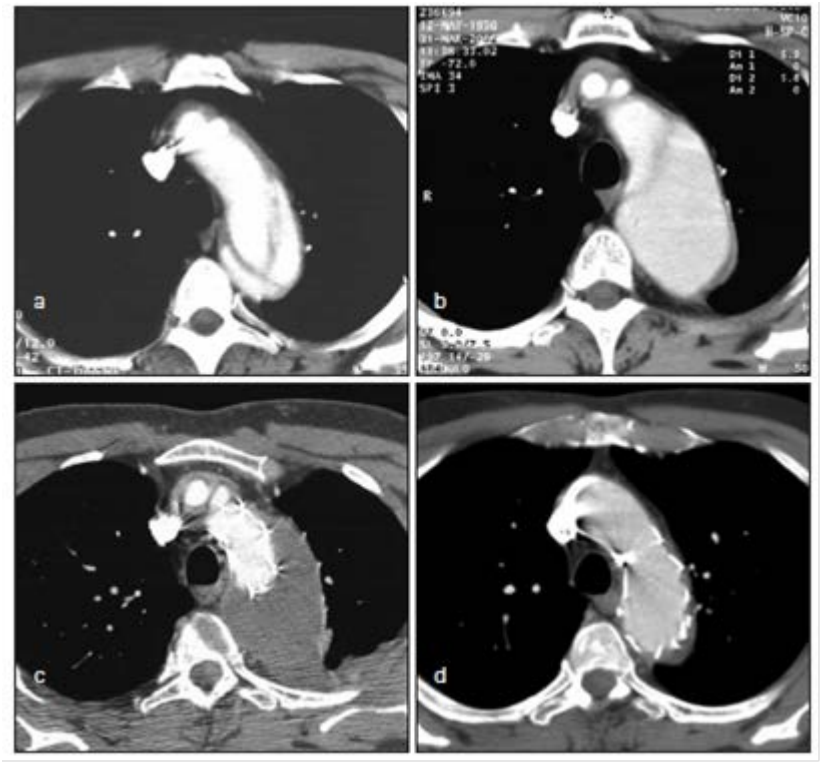

Abb. 4

Stentprothese bei Typ-B-Dissektion (52 jähriger Mann), CT des Aortenbogens im Verlauf:

a. Am Tag der akuten Dissektion;
b. Vier Monate nach der Dissektion progrediente Aneurysmabildung des falschen Lumens;
c. Drei Tage nach Implantation ist die Stentprothese im wahren Lumen noch nicht voll expandiert, das falsche Lumen thrombosiert;
d. Drei Monate nach der Implantation vollständige Remodellierung der Aorta.

Nach [13], mit freundlicher Genehmigung der Mediengruppe Oberfranken – Fachverlage, Kulmbach.

1.4. Ziel

1994 waren die ersten kommerziell hergestellten Stentprothesen in Europa verfügbar. Im DHZB regte Prof. Roland Hetzer früh an, die klinischen Möglichkeiten dieser neuen Therapieform auszuloten. Der Autor erhielt die Gelegenheit, Prof. Wulf Stelter, der als Erster in Deutschland die endovaskuläre Therapie des Bauchaortenaneurysmas in die Klinik einführte, bei seinen ersten Implantationen zu assistieren. Dabei wurde offensichtlich, dass diese innovative Therapieoption am besten von Chirurgen durchgeführt wird, die mit der Anatomie und der Chirurgie der Aneurysmen vertraut sind. Diese spannenden und anregenden Tage in Frankfurt begründeten die Motivation, sich in den folgenden Jahren der endovaskulären Aortenchirurgie zu widmen. Die erste Stentprothese im DHZB wurde am 23.5.1995 in der Bauchaorta implantiert. In den folgenden Jahren wurden ausschließlich BAA endovaskulär versorgt, bis 1999 mit der Talent® Prothese (World Medical, Sunrise FL, USA; ab 2002 Medtronic Vascular, Santa Rosa CA, USA) die erste Stentprothese für die thorakale Aorta verfügbar war. Die erste Stentprothese in der thorakalen Aorta wurde am 9.9.1999 bei einem Patienten mit einer traumatischen Aortenruptur implantiert. Bis September 2013 wurden 450 abdominale und 743 thorakale Stentprothesenimplantationen vorgenommen.

Daraus ergab sich das wissenschaftliche Interesse an der Weiterentwicklung der thorakalen Stentprothesen und Evaluation der endovaskulären Therapie der thorakalen Aorta und ihrer unterschiedlichen Erkrankungen. Mit der Möglichkeit, industriell gefertigte Stentprothesen zur Behandlung thorakaler Aortenerkrankungen einzusetzen, eröffnete sich ein neues Feld mit vielen offenen Fragen. Das Ziel der klinischen Forschung war es, durch systematische Dokumentation solche Fragen zu beantworten und neue Fragestellungen, die sich im Detail aus der Anwendung ergeben würden, zu erkennen und zu bearbeiten, durch Verbesserung technischer Aspekte die Methode zu entwickeln und sinnvolle Kombinationen endovaskulärer und herkömmlicher gefäßchirurgischer Techniken zu erarbeiten.

Als Berater der Firmen World Medical, Medtronic, JOTEC (Hechingen) und Bolton Medical (Sunrise FL, USA) konnte der Autor aus der reichlichen klinisch-praktischen Erfahrung in engem persönlichen Kontakt und Gedankenaustausch mit den Entwicklungsingenieuren Einfluss auf die Weiterentwicklung der Implantate und deren Anpassung an die anatomischen Besonderheiten der thorakalen Aorta nehmen.

2. Eigene Arbeiten

Mit dem ersten endovaskulären Eingriff an der Bauchaorta wurde eine Datenbank angelegt und später für die Besonderheiten der thorakalen Aorta erweitert. In ihr wurden prospektiv klinische und morphologische Daten der Patienten, die Eingriffe und die Nachuntersuchungen mit CT oder MRT erfasst. Alle Daten wurden zeitnah vom Operateur und vom Autor als Betreiber der Datenbank erfasst - mit vielen für die endovaskuläre Versorgung wichtigen Details, die in den Krankenakten nicht dokumentiert sind. Für die Mitarbeit an zwei multizentrischen Studien, der prospektiv randomisierten INSTEAD Studie (INvestigation of STEnt Grafts in Aortic Dissection) und dem prospektiven RESTORE Register (Relay Endovascular Registry for Thoracic Disease), wurden die entsprechenden Daten aus der Datenbank abgeglichen und übermittelt. Daten über konventionelle Vergleichsgruppen wurden der von der Studienzentrale des DHZB geführten Aortendatenbank entnommen, in der alle Aorteneingriffe aus der Klinikdokumentation erfasst werden.

Im Sinne der formulierten Ziele wurden für diese Habilitationsschrift 6 Arbeiten ausgewählt, die als retrospektive Analysen aus prospektiv geführten Datenbanken folgende Fragenkomplexe erforschten:

- Welche umfassenden Erfahrungen mit thorakalen Stentprothesen konnten gewonnen werden?
- Wie sind die Langzeitresultate der endovaskulären Behandlung von Aortendissektionen im Frühstadium und können günstige morphologische Veränderung der Aorta induziert werden?
- Hat die endovaskuläre Behandlung der traumatischen Aortenruptur Vorteile im Vergleich zur konventionellen Operation?
- Gibt es Unterschiede in Inzidenz und Pathophysiologie der Rückenmarksischämie nach Implantation von Stentprothesen im Vergleich zum konventionellen Ersatz der Aorta thoracica?
- Welche Strategie bei Verschluss der A. subclavia durch Stentprothesen ist sinnvoll?

2.1. Klinische Erfahrungen mit thorakalen Stentprothesen

- Zipfel B, Hammerschmidt R, Krabatsch T, Buz S, Weng Y, Hetzer R.
  Stent-grafting of the thoracic aorta by the cardiothoracic surgeon.
  Annals of Thoracic Surgery 2007;83(2):441-9. [56]
  http://dx.doi.org/10.1016/j.athoracsur.2006.09.036
  Abdruck mit freundlicher Genehmigung von Elsevier, Oxford-Amsterdam-Philadelphia.

Die konventionelle Operation der thorakalen Aorta ist wegen des Einsatzes der in der Einleitung beschriebenen Perfusionsverfahren die Aufgabe der Herz-, Thorax- und Gefäßchirurgie. Mit dieser Arbeit gelang der Nachweis, dass die endovaskuläre Technik in das Spektrum der Aortenchirurgie integriert werden kann. Die Veröffentlichung beschreibt die ersten 5 Jahre Erfahrung mit der Implantation thorakaler Stentprothesen. Das eingereichte Abstract wurde von der Society of Thoracic Surgeons in den USA als „Maxwell Chamberlain Memorial Paper“ und damit als Eröffnungsvortrag des Jahreskongresses der Gesellschaft im Januar 2006 in Chicago ausgewählt. Der Vortrag fand große Beachtung.

Es werden 196 Stentgraftimplantationen bei 172 Patienten berichtet. Die im Laufe der Jahre entwickelte Operationstechnik wird kurz beschrieben. Die wichtigste Erfahrung ist die Differenzierung der Patienten in die verschiedenen Formen der Aortenerkrankungen. Dabei fand sich ein relativ geringer Anteil von wahren Aneurysmen und ein mit 60 % sehr hoher Anteil von Notfallpatienten. Die Gesamtmortalität betrug 9,7 % bei einer sehr geringen Paraplegierate von 1 %. Differenziert auf elektive Indikationen und Notfallindikationen zeigt sich ein deutlicher Unterschied in der Mortalität, die bei den elektiven Patienten 0 war (Tab. 3, S. 26).

Stent-Grafting of the Thoracic Aorta by the Cardiothoracic Surgeon

Burkhart Zipfel, MD, Robert Hammerschmidt, MD, Thomas Krabatsch, MD, PhD, Semih Buz, MD, Yuguo Weng, MD, PhD, and Roland Hetzer, MD, PhD

Department of Cardiothoracic and Vascular Surgery, Deutsches Herzzentrum Berlin, Berlin, Germany

Background. **We evaluated endovascular stent-grafting as a new technique in aortic surgery.**

Methods. **One hundred ninety-six stent-grafts were implanted in the thoracic aorta in 172 patients. All procedures but one were performed in the operating room by a team of cardiothoracic surgeons; 112 operations (57%) were emergency procedures. Twenty-four procedures (12%) were reoperations for endoleaks. The left subclavian artery origin was covered in 46 cases and the left common carotid artery in 2 cases. Access was by femoral cut-down in 174 procedures, percutaneous femoral approach in 1, and by conduit to the iliac arteries or infrarenal aorta in 17. Surgical reconstruction of damaged access vessels became necessary in 10 cases.**

Results. **Thirty-day mortality was 9.7% (19 patients). Paraplegia occurred in 1.0% (2 patients). Primary technical success was 85.2%, secondary 91.8%. Six conversions to open repair were necessary, 3 during the procedures and 3 secondarily before discharge. Actuarial survival was 79% at 1 year, 67% at 3 years, and 55% at 5 years.**

Conclusions. **The results are excellent, taking into account the high incidence of emergency procedures and that open surgery is not promising in many patients. The cardiothoracic surgeon can perform the procedure after adequate training in endovascular techniques. Surgical skills are mandatory because of the potential need for extended surgical approach to the access vessels or immediate conversion to open surgery. Therefore, the operating room is the preferred site for this procedure.**

(Ann Thorac Surg 2007;83:441–9)

Since Parodi and colleagues [1] implanted their first homemade endovascular stent-graft, endovascular repair has evolved into a routine procedure for abdominal aortic aneurysms. In thoracic aortic lesions, the potential benefit for the patient is more evident than in abdominal aortic aneurysms because of the more significant mortality and morbidity associated with the conventional procedure. Dake and associates [2] implanted the first stent-graft in the thoracic aorta in 1992, and that series was the stimulus to develop commercial stent-grafts.

As they possessed endovascular skills, vascular surgeons, cardiologists, and radiologists started to treat the thoracic aorta as well as the cardiothoracic surgeons, to whom traditionally patients with thoracic aortic disease were referred. There is growing interest in the whole cardiothoracic community [3] in this new minimally invasive modality. Since we started our endovascular program very early with abdominal aortic aneurysms, experience has accumulated [4], and the technique is now fully integrated into our operative spectrum.

Patients and Methods

Between September 1999 and the end of 2005, we performed 196 thoracic aortic stent-graft procedures in 172 patients (119 male and 53 female), aged 15 to 87 years (mean, 60). Twenty-four implantations were redo operations for secondary graft extension; 22 of these secondary procedures were performed in patients from our own series, 2 were referred from other institutions. Data were collected in a Microsoft Access database from the hospital and office charts, the operative reports, and the preoperative and postoperative measurements. Only stent-grafts approved in the European Community were implanted. Written informed consent for the operation was obtained in all cases according to the rules of regular elective or emergency surgery. This retrospective study was approved by

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Dr Zipfel discloses that he has a financial relationship with Jotec and Medtronic.

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Table 1. Patients' Demographics and Aortic Diseases as Indications for Stent Grafting

Aortic Pathology	n	Male	Age (Years)	Age (Mean)
Traumatic rupture	31	28 (90%)	15–81	37
Posttraumatic aneurysm	4	3 (75%)	37–65	52
Penetrating atherosclerotic ulcer	43	23 (54%)	55–87	70
True aneurysm	26	14 (54%)	57–85	72
Type-B dissection	57	43 (75%)	36–87	62
Suture aneurysm	8	6 (75%)	33–66	54
Others	3	1 (33%)	46–61	55
Total	172	119 (69%)	15–87	60

the Institutional Ethics Committee, which waived the need for additional patient consent to the study.

The indications for primary stent-graft implantation and patient demographics are summarized in Table 1.

One hundred twelve operations (57%) were emergency procedures with these preoperative conditions: active bleeding in 23, contained rupture in 55, malperfusion in type B dissections in 17, symptomatic aneurysm in 12, and 5 urgent procedures because of impending complications.

Diagnostic Evaluation

The elective cases were seen as outpatients, and optimal diagnostic evaluation was performed to plan the procedures and optimize risk factors. That included high-quality spiral computed tomography (CT) and coronarography combined with aortography. In 11 cases of impaired renal function, magnetic resonance imaging replaced CT. The appropriate stent-grafts were chosen in cooperation with the manufacturers; custom-made grafts were ordered if necessary. If coronary artery disease was detected, this was treated by percutaneous intervention or coronary bypass grafting some weeks before the procedure.

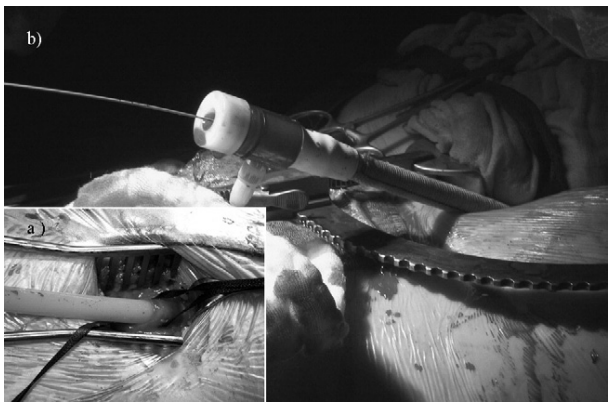

Fig 1. Endovascular access. a) Routine angioaccess consists of exposure of the common femoral artery with a small oblique incision. The delivery system of the stent-graft is advanced directly over the puncture site without arteriotomy guided by the ultrastiff guidewire. b) For the access conduit, a 10-mm Dacron graft has been sutured end to side to the distal abdominal aorta (Fig 3). A 24F sheath is passed through this graft into the suprarenal aorta.

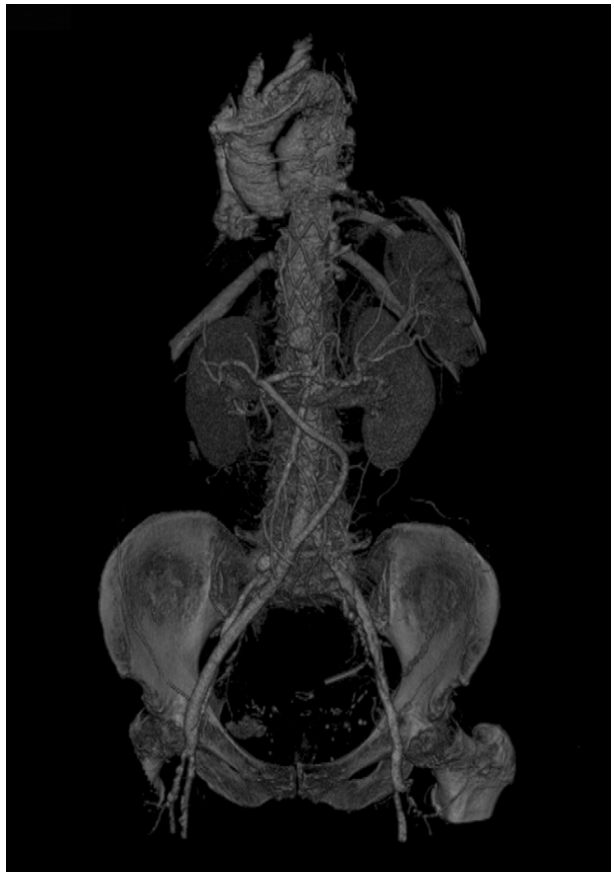

Fig 2. Hybrid procedure for a thoracoabdominal aneurysm in a 72-year-old woman. The celiac axis ostium was covered by the stent-graft (E-vita). The 10-mm Dacron access graft to the distal abdominal aorta was used as a bypass for iliac artery reconstruction after deployment of the endograft. A second bypass (6-mm expanded polytetrafluoroethylene) to the common hepatic artery was anastomosed on top.

In most of the emergency procedures, however, measurements had to rely on the plain axial CT scans performed by the referring hospitals and simple graphical methods. These CT scans were often of inferior quality, with 5- to 10-mm slices. Usually no information concerning the iliac vessels was available from these external emergency evaluations. When in doubt, the correct diameters of the aorta were determined with intraoperative transesophageal echocardiography or intravascular ultrasonography. Stent-grafts were chosen from the in-hospital stock of Talent and, since 2004, E-vita grafts.

Devices and Implantation Technique

We used Talent (Medtronic Vascular, Santa Rosa, California) stent-grafts in 123 procedures, E-vita (Jotec, Hechingen, Germany) in 60, Zenith TX1 (William Cook Europe,

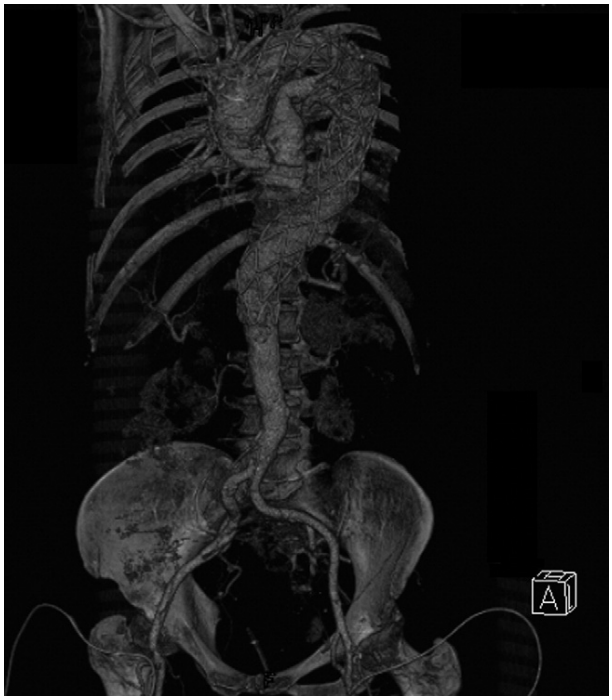

Fig 3. Endograft (E-vita in two long segments) of the entire descending thoracic aorta from the left common carotid artery down to the celiac trunk. The left subclavian artery has been transposed to the left common carotid artery preliminarily and is not excluded by the stent-graft.

Bjaeverskov, Denmark) in 5, Relay (Bolton Medical, Sunrise, Florida) in 4, Endofit (Endomed, Phoenix, Arizona) in 2, Valiant (Medtronic Vascular) in 1, and TAG (W.L. Gore Associates, Flagstaff, Arizona) in 1 procedure. All stent-grafts are self-expanding and are oversized by 10% to 20% related to the outer diameter of the aorta at the landing zone. They are packed in delivery catheters of 22F to 27F. The stent-grafts are described in detail elsewhere [5].

All procedures were performed in a standard operating room, except for one in the cardiology angio-suite. A surgical C-arm with angiography equipment (BV 300; Philips, Eindhoven, Netherlands) was used for intraoperative fluoroscopy and angiography. Additional transesophageal echocardiography was used in 54 procedures and intravascular ultrasonography in 1. General anesthesia was used in all cases, except for 1 in which local anesthesia was used.

The stent-grafts were advanced in retrograde manner from the femoral or iliac vessels and deployed as guided by the landmarks of a target angiogram. Angioaccess is shown in Figure 1. Access conduits were used if the femoral or external iliac arteries were not accessible for the 22F to 27F sheaths (Fig 1b). The conduit is ligated at the end of the procedure or used as an iliofemoral bypass if the artery has been damaged by earlier attempts to advance the stent-graft (Fig 2).

In aneurysm cases, the stent-graft was placed to cover the length of the aneurysm and to extend by a minimum of 20 mm proximally and distally. In many cases, we decided to use extensions ad hoc during the procedure; in longer or tortuous lesions, a modular stent-graft of two or more components was planned from the beginning (Fig 3). Our strategy for type B dissections consisted of endograft placement at least from the origin of the left subclavian artery to cover all entries of the descending thoracic aorta. Currently we use the longest E-vita (230 mm) as standard for type B dissections, and this ends usually just above the diaphragm.

Follow-up was obtained by office visits, hospital reports, telephone interviews with patients, families, and home physicians, and inquiries of local population registries. Actuarial survival was calculated by the Kaplan-Meier method.

Results

In 193 procedures, the stent-graft was successfully placed at the target zone in the thoracic aorta. Three procedures (1.5%) were aborted because of access failure. In 175 procedures, access was from the surgically exposed common femoral artery. Access conduits were necessary in 17 procedures. In an additional 10 patients, arterial reconstruction of the iliac artery had to be performed as the artery had been damaged by the

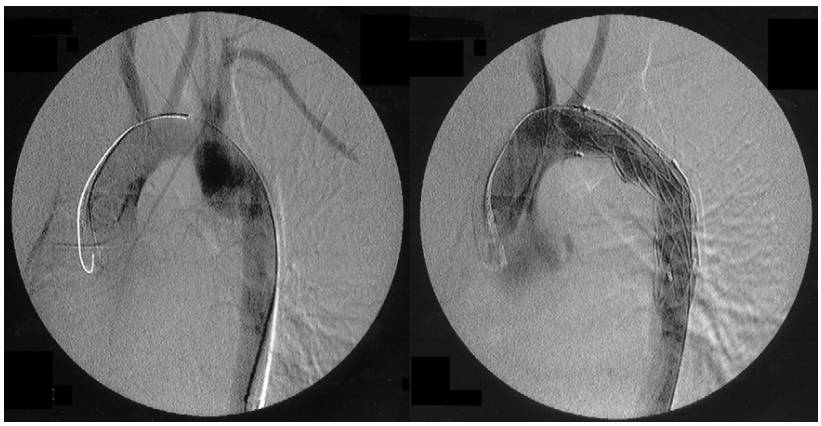

Fig 4. Intraoperative angiograms of a 19-year-old patient with blunt traumatic rupture. (Left) False aneurysm close to the left subclavian artery origin. The endograft delivery catheter is already in park position downstream. (Right) A Talent stent-graft is in place: the Dacron starts immediately downstream of the left common carotid artery; the bare springs are crossing it. The left subclavian artery is occluded. The stent-graft is oversized by 27% and expands to its full diameter at the spot of the rupture.

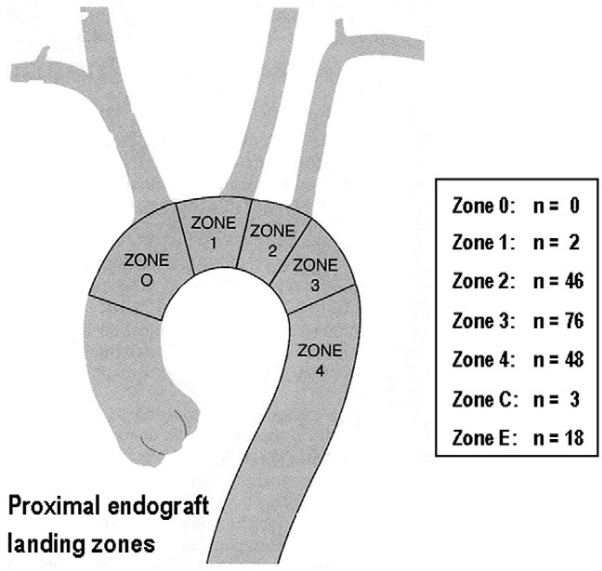

Fig 5. Distribution of proximal endograft attachments (full diameter graft material; bare springs may reach further in proximal direction). Modified from Criado et al [6]: zone C, inside a previously placed conventional surgical graft; zone E, inside a previously placed endograft.

stent-graft delivery system. Therefore, for 30 of 196 procedures (15.3%), access problems made more extensive surgery necessary.

Grafts with diameters of between 20 and 46 mm (average 35.2 mm) were used. The covered length of the segments ranged from 100 to 230 mm. In 150 procedures, one segment was used, in 28 two segments, and in 10 three or more segments. The average number of grafts was 1.26 per procedure (range, 1 to 5). The effective length of covered thoracic aorta per procedure was 155 mm (range, 30 to 394 mm).

Fixation of the stent-graft in the distal aortic arch was required in 122 procedures (63%; Fig 4). The distribution of the proximal landing zones is displayed in Figure 5. Twenty of 48 patients with stent-grafts in landing zone 0 to 2 (41%) had adjunctive extrathoracic transposition or bypass of the left subclavian artery or the left common carotid artery, or both—1 simultaneously, 12 before, and 7 after the endograft procedure.

Distal stent-graft attachment was at the level of the diaphragm or lower in 57 procedures (29.5%). Among these, the celiac trunk origin was crossed with the bare springs in 26 and covered by the endograft in 4. One of these patients required bypass surgery (Fig 2); the remaining 3 had sufficient collaterals verified in selective angiography after deployment. The entire descending aorta from the arch to below the diaphragm was covered in 22 patients, 17 primarily (Fig 3) and 5 step by step with secondary procedures.

The average procedure time was 140 minutes (range, 45 to 445), average fluoroscopy time 15 minutes (range, 4 to 655), and average amount of contrast medium 120 mL (range, 15 to 350 mL). Ninety-five patients (48%) were extubated directly after the procedure, 42 (21%) were ventilated for less than 12 hours, and 59 (31%) required ventilation for between 12 hours and 79 days. After 38 procedures (19%), patients were transferred to the ward directly; 89 (46%) remained in the intensive care unit for less than 24 hours, and 69 (35%) required intensive care for between 1 and 79 days.

Twenty-four procedures were reoperations for secondary graft extensions. Indications were 9 type I endoleaks in aneurysms, 4 type III endoleaks (classification in Chaikof and coworkers [7]), and perforation of the dissection membrane or progression of the disease in type B dissections in 11 cases. Nine redo procedures were performed in the early postoperative period owing to leaks detected in the first postoperative CT.

The Society for Vascular Surgery/American Association for Vascular Surgery 2002 reporting standards for endovascular aortic aneurysm repair [7] define the technical success in terms of (1) successful access, (2) success deployment, (3) absence of type I or III endoleak, (4) patent graft without obstruction, (5) absence of surgical conversion, and (6) absence of 24-hour mortality. According to these definitions, there was 85.7% primary success and 92.4% secondary success after further interventions (9 early secondary stent-graft extensions, 1 Palmaz stent, 1 stent-graft dilatation, 1 surgical endoleak closure) or spontaneous closure of type I endoleak (1 case).

A survey of the 15 technically nonsuccessful cases is given in Table 2. Conversion to open surgical repair was necessary in 6 cases, 3 during the original operation and 3 before discharge. The indications for primary conversion were retrograde type A dissection (patient no. 8, Table 2), access failure (patient no. 11), and rupture after deployment of the stent-graft (patient no. 15).

Patient no. 8 had a proximal type B dissection with a small retrograde intramural hematoma in the aortic arch and malperfusion of renal and visceral vessels, indicating stent-graft therapy. A stent-graft without bare springs (TAG) was chosen. However, opening of the graft caused retrograde dissection reaching into the ascending aorta. Immediate replacement of the ascending aorta was performed with extracorporeal circulation and deep hypothermia (18°C), and the distal anastomosis was performed in circulatory arrest with partial excision of the proximal end of the stent-graft.

In patient no. 11, access through a previously implanted 16/8-mm expanded polytetrafluorethylene (e-PTFE) aortobifemoral graft failed, and conventional throracoabdominal repair was performed during the same operation. The e-PTFE graft—in contrast to Dacron—showed no elastic enlargement when we tried to advance a 22F sheath as a test device.

Patient no. 15 had acute traumatic rupture with extensive mediastinal hematoma associated with multiple injuries after a motor vehicle accident. There was a diameter mismatch between the aortic arch (26 mm) and the descending aorta (20 mm). The 26-mm graft was probably undersized in the proximal portion, which resulted in

Table 2. Survey of Cases With Endograft Failure in Accordance With Reporting Guidelines [7]

No.	Age	Sex	Diagnosis	Localization	Indication	Date	Device	Failure	Intervention	POD	Outcome (30 Days)
1	41	m	Traumatic rupture	Isthmus	Contained rupture	1999-09-09	Talent	Bare spring penetration	Secondary conversion	14	Discharged
2	58	m	Suture aneurysm	Isthmus	Active bleeding	2000-11-15	Talent	Secondary rupture	—	1	Fatal
3	35	m	Suture aneurysm	Ascending	Elective	2002-09-09	Talent	Access failure	Secondary conversion	21	Discharged
4	76	f	PAU	Hiatus	Contained rupture	2003-09-09	Talent	Secondary rupture	—	1	Fatal
5	73	f	PAU	Infradiaphragmal	Symptomatic	2003-12-12	Talent	Secondary rupture	—	1	Fatal
6	80	f	PAU	Infradiaphragmal	Contained rupture	2004-04-23	E-vita	Iliac artery rupture	Iliac artery repair	Intraoperative	Fatal
7	70	f	PAU	Descending	Active bleeding	2004-09-10	Talent	Access failure	Secondary conversion	0	Discharged
8	38	f	Type-B dissection	Distal Arch	Symptomatic	2004-09-24	TAG	Retrograde type-A dissection	Primary conversion	Intraoperative	Further hospitalization Severe neurologic deficit
9	61	m	Type-B dissection Leriche's syndrome	Descending	Malperfusion	2004-11-12	Talent	Failure to restore distal perfusion	—	0	Fatal
10	46	f	Aortopulmonary collaterals (TOF)	Descending	Active bleeding	2005-02-15	Talent	Intraoperative migration Ongoing bleeding	Endograft as rescue procedure after surgery, no further interventions	Intraoperative	Fatal
11	70	m	TAAA	Hiatus	Elective	2005-04-19	Zenith	Access failure	Primary conversion	Intraoperative	Discharged
12	79	f	TAA	Descending	Symptomatic	2005-05-20	E-vita	Endoleak Ia	—	29	Fatal
13	69	m	TAA	Arch/Descending	Elective	2005-07-29	E-vita	Endoleak Ia	—	—	Discharged
14	19	m	Traumatic rupture	Isthmus	Contained rupture	2005-09-18	E-vita	Endoleak Ia	—	—	Further hospitalization
15	39	m	Traumatic rupture	Isthmus	Active bleeding	2005-11-17	E-vita	Endoleak Ia, immediate rupture	Primary conversion	Intraoperative	Fatal

Endoleak Ia = endoleak from proximal attachment site; Endoleak Ib = endoleak from distal attachment site.

f = female; m = male; PAU = penetrating atherosclerotic ulcer; POD = postoperative day; TAA = thoracic aortic aneurysm; TAAA = thoracoabdominal aortic aneurysm; TOF = tetralogy of Fallot.

Table 3. Mortality and Severe Neurologic Complications

	All Procedures n = 196	Elective n = 84	Emergency n = 112
Death	19 (9.7%)	0	19 (16.9%)
Stroke	9 (4.6%)	2 (2.4%)	7 (6.3%)
Paraplegia	2 (1.0%)	0	2 (1.8%)
Combined (Death/ stroke/paraplegia)	27 (13.8%)	2 (2.4%)	25 (22.3%)

a type Ia endoleak leading to immediate free aortic rupture. Immediate sternotomy and graft replacement with extracorporeal circulation was performed. The patient died on the operating table owing to trauma and extracorporeal circulation–related abdominal bleeding.

The indications for secondary conversion to conventional surgery were access failure in 2 cases and bare spring penetration in 1. The latter (patient no. 1) was our very first case. The Talent graft was mishandled in that the partially opened stent-graft was advanced again for about 10 mm after it had slipped downstream during deployment. The false aneurysm was successfully excluded, but postoperative imaging demonstrated one of the bare springs situated in the aortic wall. For safety reasons, after 2 weeks a conventional Dacron graft was implanted with extracorporeal circulation and deep hypothermia. Two more cases required post–stent-graft adjunctive conventional surgery: 1 secondary arch replacement due to a penetrating ulcer remote from the stent-graft [8] and 1 endoleak closure in the aortic arch with beating heart surgery on extracorporeal circulation.

The overall 30-day mortality rate was 9.7% (n = 19); strokes occurred in 6 patients (4.6%). Paraplegia was seen in 2 patients (1.0%). A separate analysis (Table 3) for elective and emergency patients reveals that, except for two strokes, the severe complications occurred in the emergency group.

Actuarial survival is displayed in Figure 6. Cumulative survival was 79% at 1 year, 67% at 3 years, and 55% at 5 years. Mean follow-up was 1.92 years (range, 0 to 6.7), with 324 patient-years.

Comment

Our early results compare favorably with those of other studies on the endovascular treatment of thoracic aortic diseases [6, 9]. Thirty-day mortality of 9.7% is superior to the results of elective conventional surgery, even at a high-volume center [10]. The advantage is even more evident taking into account that, in our series, 60% of the endograft implantations were performed as emergency procedures and that the deaths occurred exclusively in the emergency group (Table 3). Long-term survival of 66.5% at 3 years offers hope to many patients who have previously been denied surgical treatment of thoracic aortic disease because of their advanced age and comorbidity. The 5-year survival rate of 55% is still a preliminary result, with only 11 patients at risk. Ongoing investigation will yield reliable results in the coming years (Fig 6).

The risk of spinal cord ischemia seems to be lower than after conventional surgery (1.0%), despite more extensive covering of the descending thoracic aorta. One of the 2 patients concerned was at extremely high risk for paraplegia, having recovered from paraplegia after previous conventional aortic repair.

Primary and secondary technical success is higher than in previously reported studies with homemade devices [2, 11]. The industrially fabricated grafts have some technical advantages in terms of the fixation mechanism and the delivery systems. The need for secondary graft extensions has been reduced over time owing to growing experience. In the beginning, short stent-grafts were preferred because of the fear of paraplegia. As we learned that covering of longer parts of the aorta or even of the entire descending aorta did not significantly increase the risk of paraplegia, the proximal and distal fixation zones were extended to improve fixation and sealing. The Talent graft, which was our standard graft in stock until 2002, was limited in length to 115 mm in the standard and 150 mm in custom-made configurations. Therefore, more segments had to be used in extensive disease, with connections that may be themselves at risk for secondary endoleak. That has improved with the new stent-grafts that are available in lengths of as long as 200 or 230 mm.

Precise preoperative evaluation for planning and sizing of the endografts and orientation in the three-dimensional space is the key for successful stent-graft therapy. Our method of choice is contrast-enhanced spiral CT with 1.5- to 3-mm slices. The axial CT scans in combination with three-dimensional and multiplane re-

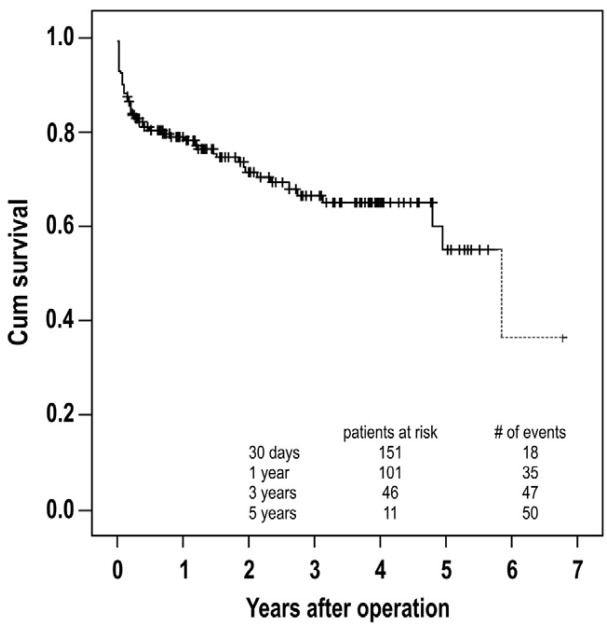

Fig 6. Actuarial survival for all patients.

constructions allow precise measurement of diameters and lengths (aneurysm, proximal and distal landing zone) [12]. In difficult cases with elongated arch or tortuous aorta, the surgeon together with the radiologist reconstruct the landing zones on the workstation of the CT to determine the precise diameter perpendicular to the axis at the landing zones. Moreover, CT provides important information for access of the delivery system on angulation, tortuosity, and calcification of the aorta and iliac vessels. Preoperative angiography is helpful but not absolutely necessary. Magnetic resonance imaging may replace CT if of good quality.

With such preoperative evaluation, intraoperative angiography can be limited to a few shots to identify the target zones and to check the final result. This is provided in sufficient quality by a surgical C-arm with angiography equipment. Endovascular treatment of side branches such as the renal arteries can be done as well. The imaging quality provided by a mobile C-arm has often been criticized versus fixed x-ray machines in the angio-suite [13]. Angiography has limitations in measuring and detecting endoleaks that cannot be overcome even with more sophisticated stationary angiography equipment. Transesophageal echocardiography has proved to be an excellent additional tool. For aneurysms, it is more sensitive in detecting small endoleaks. For dissections, it is essential to identify the endovascular instruments in the true lumen. The entry can be identified by the Doppler flow much more easily than in angiography, and in combination with fluoroscopy of the probe, the entry can be located precisely. The flow dynamic after deployment of the stent graft can be observed under direct echocardiographic vision.

However, with regard to the evolving side-branch technology [14, 15] and more complex aortic arch and throracoabdominal procedures, higher x-ray imaging resolution is desirable. Currently, we are planning a hybrid operating room with fixed high-performance x-ray equipment in our institution. This equipment will allow hybrid cardiac procedures, especially in congenital heart disease, as well as carotid stenting and more complex combined endovascular and surgical procedures. However, as our experience with the C-arm is good, it has to be stressed that this kind of sophisticated equipment is not a sine qua non for starting a thoracic endovascular program. Some authors are still in favor of mobile C-arms, as the imaging quality of the newer models is almost comparable with that of stationary x-ray machines, and this makes the endovascular setting more flexible [16].

This study shows that endovascular repair of the thoracic aorta can be performed by the cardiothoracic surgeon as stent-graft procedures for abdominal aortic aneurysms are performed by vascular surgeons. The procedure can be performed in a standard operating room setting. The same surgeon can carry out the surgical approach and the endovascular procedure. Especially in emergency procedures, the operating room provides a better and safer working environment than the catheterization laboratory or the radiology angio-suite. In every

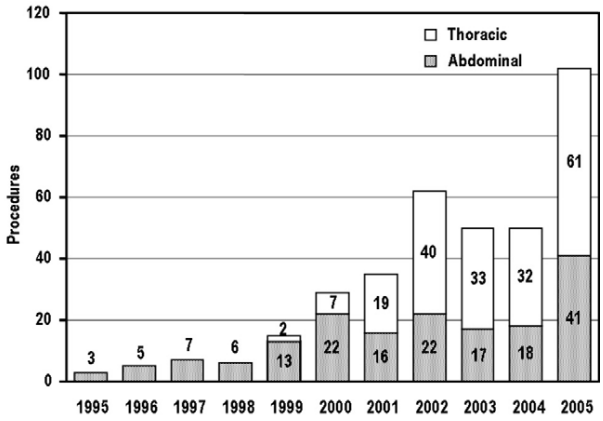

Fig 7. Development of endovascular stent-grafting at the Deutsches Herzzentrum Berlin.

procedure, there may be a need for extended surgery on the access vessels. That was the case for 15.3% of our procedures, and in most of them, the decision was made during the procedures after the simple femoral approach failed. Conversions to open repair are reported rarely, and most of them were performed secondarily [8, 17–20]. Therefore, it has been argued that remote stand-by of cardiovascular surgery might be sufficient back-up for thoracic endovascular procedures. Our experience, however, demonstrates that, albeit rarely, the need for immediate conversion with extracorporeal circulation may arise. Therefore, it is preferable that the procedure is performed by a surgeon who is able to manage all possible complications.

Technical strategies to expand stent-graft applicability in the aortic arch involve the cardiovascular operation field. Recently published techniques of antegrade stent-graft implantation from the ascending aorta may solve some of the technical problems in endografting of the aortic arch [21]. A new hybrid stent-graft can convert the classical staged repair of complex aortic disease into a one-step procedure through a sternotomy with stent-grafting of the descending thoracic aorta and surgical reconstruction of the aortic arch and ascending aorta [22].

For all these reasons, stent-grafting should be integrated into the thoracic surgeon's repertoire. Basic endovascular procedures using the "over the wire" technique are already part of the surgeon's practice for the insertion of intra-aortic balloon pumps and pacemakers, femoral arterial cannulation, and so forth. That will enable the thoracic surgeon to readily adopt the technique. Several opportunities to master endovascular techniques for thoracic surgeons willing to start an endovascular program have been outlined [23]. Surgeons may choose to partner with other endovascular specialists. The industry is offering workshops and small group mentoring arrangements. Proctors are available to assist with cases at the outset.

We gained our initial experience with abdominal aneurysms in 34 procedures starting in 1995 (Fig 7), for the first 2 years in cooperation with two interventional radi-

ologists. From the beginning, we performed the procedures in the operating room. After we took over the program on our own, the first step was to acquire profound systematic knowledge of the interventional instrumentarium and to simplify it to a basic set with a small number of adjunctive wires, catheters, and balloons for troubleshooting and side-branch access. Fellow surgeons and residents have been trained by the first author (B.Z.) since then. The thoracic aortic endovascular program outlined in this paper started in 1999 and has been performed entirely by surgeons. It has grown steadily since then, and currently represents about two thirds of our entire endovascular program.

We thank Anne Gale for editing the manuscript.

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DISCUSSION

DR JOSEPH E. BAVARIA (Philadelphia, PA): Thank you, Mr President. I wish to congratulate Dr Zipfel and his colleagues on their comprehensive single-institution series on thoracic aortic stent grafting. Doctor Zipfel highlights in his manuscript the fact that the procedures were exclusively performed by cardiothoracic surgeons, who also admitted these patients to their service, cared for them, and made decisions about eventual therapeutic options, because they are accomplished open and endovascular CT surgeons. This complete "skill set" paradigm is similar to vascular surgeons performing either open repair or endoabdominal aortic aneurysm (AAA) endografting. The series has reasonable results in a broad spectrum of thoracic aortic diseases, from the technically easier penetrating ulcers and saccular aneurysms to the more difficult "full pavement" extensive atherosclerotic fusiform aneurysms and complicated type B dissections. Additionally, for those surgeons and institutions in the audience without dedicated endovascular operating room suites, Dr Zipfel and colleagues "show us the way" in that all these cases were performed using a mobile C-arm in the operating room.

It should be pointed out that this series represents the early phase of this therapy with relatively early generation devices. More recent device generations, or iterations—especially in the past year with the introduction of the redesigned Gore TAG device, the next generation Medtronic Valiant system, and the Cook Zenith systems—are longer, more flexible at the arch, and simply better than the initial devices. We look forward to industry efforts to design devices specifically for the different thoracic aortic diseases that we confront.

Importantly, this study reinforces yet again that the operating room is the place to perform these procedures, as 17% of the cases required either extensive iliac artery surgery or conversions to open operations.

I have a few questions for Dr Zipfel. First, 25% of your cases covered the left subclavian artery. Approximately half of those had subclavian bypass procedures. Most importantly, 7 had the bypass procedures after the stent operation. Why did these patients need postprocedure restoration of subclavian blood flow, and what were the complications associated with subclavian coverage in your series?

Second, in 17, or approximately 10% of your series, you performed "full coverage or pavement" of the descending thoracic aorta. Additionally, only 26 of the 193 patients were for fusiform, classic atherosclerotic aneurysms. What were your outcomes regarding death, paraplegia, and cerebrovascular accident stroke in this very important subgroup?

Third, importantly, you point out that 23 of the 172 primary procedures, or nearly 13% of patients, needed a reoperation. Can you elaborate on why this reoperation rate was so high? And a follow-up question: Twelve (12) of these reoperations were for type B dissections. Why? Were they acute or chronic type B dissections?

Fourth, how important is it, in your opinion, and this is a bit of an editorial, to have AAA experience in order to perform thoracic aneurysm operations endovascularly, as I know you have significant AAA experience?

I thank The Society for Thoracic Surgeons for the opportunity to comment on this paper. I urge the membership to heed Dr Zipfel's example and acquire endovascular skills. I also urge our leadership and program directors to immediately push for significant endovascular skill sets in our residency programs. Thank you.

DR ZIPFEL: Thank you very much, Dr Bavaria, for your kind remarks. Let me answer the questions. The first question concerns the coverage of the left subclavian artery. The changes in management of the occluded left subclavian artery were a development during our program, because at the beginning we overstented the left subclavian artery quite liberally, as everybody did, and there was a common opinion that this does no harm. We had the experience that 7 of 30 patients, where the left subclavian artery had been covered without preliminary reconstruction, developed ischemia of the arm, 5 exercise induced and 2 at rest. These patients needed postprocedure restoration of subclavian blood flow. We also experienced 3 of the cerebellar strokes which I mentioned. In all, one third of the patients with unprotected coverage of the left subclavian artery experienced complications. This experience changed our policy. For the past year and a half, at least in elective cases, we have performed subclavian reconstruction before we implant the stent graft. In the emergency cases, depending on the situation, we still do the stent graft first and then we look at what has happened. But we are very open to restoring subclavian blood flow after the procedure, even with mild exercise-induced ischemia.

On the second question, in this series altogether, 17 patients had the entire descending thoracic aorta covered from the left subclavian artery or from the common carotid artery down to the celiac trunk. This is also part of the development during the years. First of all, this full coverage of the descending thoracic aorta has become possible only with the new stent grafts with longer segments like E-vita, which we used predominantly. This system allowed us to cover the whole aorta with just two segments and sufficient overlap. In the former Talent era of 10-cm grafts, it would have needed five to six segments to do this, with many connection sites prone to type III endoleaks.

It is astonishing, but we had no paraplegia in this subgroup of patients. The 2 cases of paraplegia I mentioned were the only hint of spinal cord ischemia. We had no reversible spinal cord ischemia. These 2 patients did not have extensive endografts implanted. One of them was at high risk; he had had conventional thoracoabdominal aortic replacement 10 years before he came in with acute bleeding from his proximal anastomosis. He had recovered from paraparesis after the first operation. The other patient was one of the women with a distal perforation of the aorta at the level of the diaphragm from an atherosclerotic ulcer. Remarkably, all intercostal arteries were patent in the intraoperative pre-deployment angiography, and about four pairs were covered by the stent graft. This patient had paraplegia 24 hours after the procedure.

On question number three, there was indeed quite a high incidence of secondary procedures, but this is again due to the first experience with the short stent grafts. At the beginning, everybody was afraid to cover long parts of the aorta, and we had only short stent grafts available. This led to the phenomenon that we had quite a lot of proximal and distal type I endoleaks in the beginning, which we closed with secondary extension grafts. Some of these secondary extension grafts were necessary because of another technical aspect. In the first version, the Talent grafts had bare springs distally and proximally, and we learned early on that these distal bare springs tended to perforate the dissection membrane in type B dissections. This kind of experience was one of the reasons that Medtronic abandoned these distal bare springs. We had 5 cases of this kind, which we managed by extensions with the second version of Talent or the new E-vita grafts without distal bare springs.

The experience in chronic type B dissection is miscellaneous. Some are really reduced in diameter, some stay as they are, but we had also 2 cases where obviously the dissection membrane was so stiff and so rigid that the self-expanding stent graft couldn't do its work. These patients had to be operated on later after a year or so, when we realized that this was unsuccessful.

Let me answer your last question concerning training in AAA. Of course, it is very useful to have training in AAA not only because you can do more cases but also because AAA is an excellent field to train endovascular skills. The endovascular technique itself may be more sophisticated than in thoracic stent grafting, for example, in targeting the contralateral limb or endovascular treatment of important side branches such as the renal arteries. But I think if there is a program that offers many cases for training in thoracic stent grafting, it is definitely not a must to start with AAA procedures before implanting the first thoracic endografts. In terms of setting rules for training programs that qualify for endovascular therapy of the thoracic aorta, there should be a certain number of cases performed as AAA or thoracic cases, with a minimum of, let us say, one third of thoracic cases. Thank you very much.

2.2. Entwicklung einer neuen Stentprothese und klinischer Einsatz

- Zipfel B, Buz S, Hammerschmidt R, Krabatsch T, Duesterhoeft V, Hetzer R.
  Early clinical experience with the E-vita thoracic stent-graft system: A single center study.
  Journal of Cardiovascular Surgery 2008;49(4):417-28. [69]
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Die thorakalen Stentprothesen der 2. Generation zeigten technische Limitationen [70, 71, 72], Daraus ergab sich das Ziel, durch technische Weiterentwicklung der Stentprothesen ihr Anwendungsspektrum zu vergrößern, ihre Sicherheit zu verbessern und dies in der klinischen Anwendung zu belegen.

Als Berater der JOTEC GmbH in Hechingen, Württemberg, hatte der Autor Gelegenheit, an einer solchen Neuentwicklung in enger Kooperation mit den Ingenieuren aktiv mit Ratschlägen aus der Praxis, und mit Modell- und Tierversuchen teilzunehmen. Die neue Stentprothese E-vita thoracic® ist in der Originalarbeit in „Stent-grafts and delivery system“ (S. 35 f) beschrieben. Ergänzend wird hier über die Entwicklung der E-vita® Prothese ausführlicher berichtet:

Die bis dahin verwendeten Talent® Stentprothesen hatten biomechanische Nachteile, insbesondere die steife Verbindung eines Längsdrahtes mit den Bare Stents [73]. Wegen der mechanischen Eigenschaften des Freisetzungskatheters war die Länge der Stentprothesen auf 100 mm bis maximal 150 mm beschränkt. Längere Segmente hätten aufgrund der abknickenden äußeren Plastikhülse in gebogenen Aortensegmenten nicht mehr freigesetzt werden können. Als Nachbar der Textilindustrie fand man in Hechingen die Lösung des Problems in einem Schlauch aus Polyestergewebe, der mit dem hinteren Teil des Hüllkatheters sicher verklebt war. Diese Technologie reduzierte den Reibungswiderstand bei der Freisetzung durch die unvermeidlichen Einfaltungen des Hüllkatheters im stark gebogenen Zustand. So konnten Segmente bis 230 mm Länge sicher freigesetzt werden. Als Konsequenz dieser textilen Lösung musste eine separate Schleuse verwendet werden, um ein Abstreifen des Hüllschlauches während der Passage durch die Beckenarterien zu vermeiden.

Die zweite wesentliche technische Neuerung war der Mechanismus zur separaten Freisetzung der Prothesenspitze, die erlaubt, das Öffnen der Prothese zu beobachten und sie im halbgeöffneten Zustand exakt zu positionieren (Abb. 5).

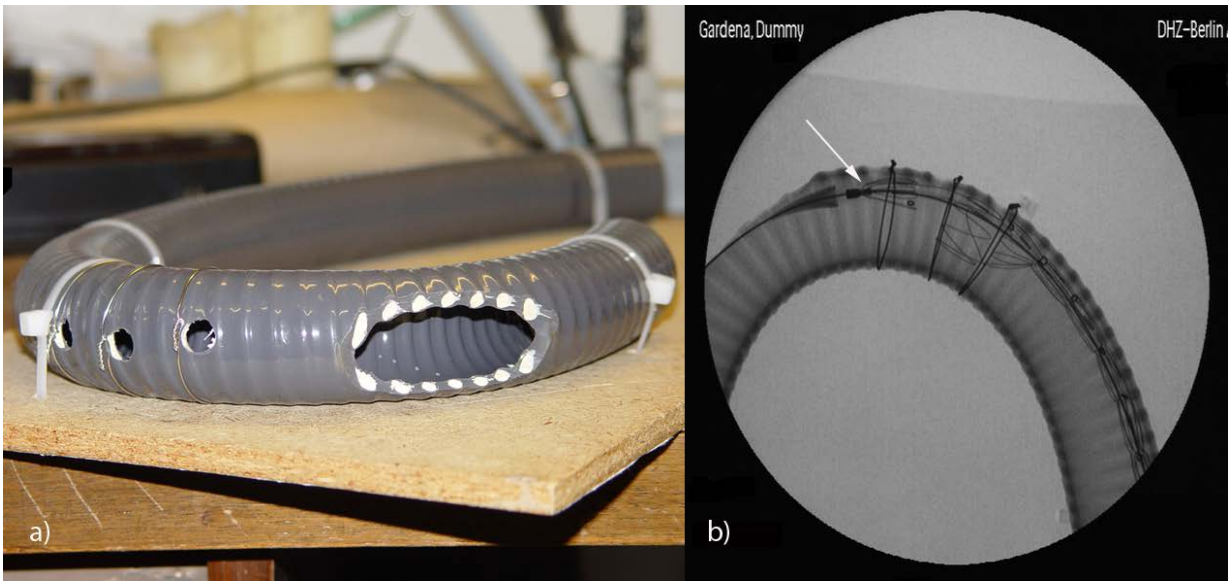

Abb. 5

a) Aortenbogenmodell, gebaut auf der häuslichen Werkbank.
b) Freisetzen eines Prototyps der Evita-Prothese unter Durchleuchtung im Modell. Die separat freizusetzende Spitze des Implantats ist noch geschlossen (Pfeil).

Auf diese Weise konnte das bei den vorhergehenden Prothesenmodellen gelegentlich beobachtete Umklappen der proximalen Prothesenanteile bei der Freisetzung [73] eliminiert werden. Dieses Verhalten der Prothesen in der 2. Generation hatte zu einer Variation der Implantationstechnik geführt, indem die Prothese proximal der eigentlich geplanten Landezone geöffnet und dann in halb geöffnetem Zustand zurückgezogen wurde, allerdings mit der Gefahr von zerebralen Embolien bei Implantation am Aortenbogen. Später haben auch andere Hersteller für ihre Stentprothesen Einführungssysteme mit separater Fixierung des proximalen Prothesenendes entwickelt (Relay®, Bolton Medical, Sunrise, FL, USA und Valiant®, Medtronic). In der ersten Version der E-vita® wurde die proximale Fixierung durch eine Kappe auf dem Zentralkatheter hergestellt, die mit einem Zugdraht gesichert war (Fig. 3 B, S. 36). Dieser Mechanismus entsprach nach unseren klinisch-praktischen Erfahrungen noch nicht den Anforderungen an eine einfache Implantationstechnik, weil der Sicherungsdraht klemmen und dann beim Ziehen die Spitze der Prothese dislozieren konnte. Deswegen wurde der Freisetzungskatheter vollständig umkonstruiert. Nun wird die Fixierung der proximalen Spitze durch einen Schließbolzenmechanismus bewirkt, der sich vom distalen Ende des Freisetzungskatheters leicht bedienen lässt (Fig. 3 S. 36).

Zusätzlich wurde der Freisetzungskatheter mit einer mechanischen Hilfe versehen, deren Wirkprinzip sich an den Hebelspritzen für Silikonkartuschen aus dem Handwerk anlehnte. Bei Freisetzungsversuchen im Labor erwiesen sich die ersten Prototypen in der Hand des

Operateurs als ergonomisch ungünstig und der üblichen Druck-und-Zug-Freisetzung von Hand genau entgegengesetzt gestaltet (Abb. 6). Daraufhin wurde der Mechanismus nochmals komplett neu konstruiert zu der in Fig. 1 (S. 35) abgebildeten endgültigen Form. Diese als „Squeeze-to-release"-Mechanismus bezeichnete mechanische Freisetzungshilfe eliminiert vollständig die Kraftausübung auf die Position der Prothese durch das übliche Zurückziehen der äußeren Hülse von Hand. Damit kann die Prothese exakt auf den Punkt freigesetzt werden.

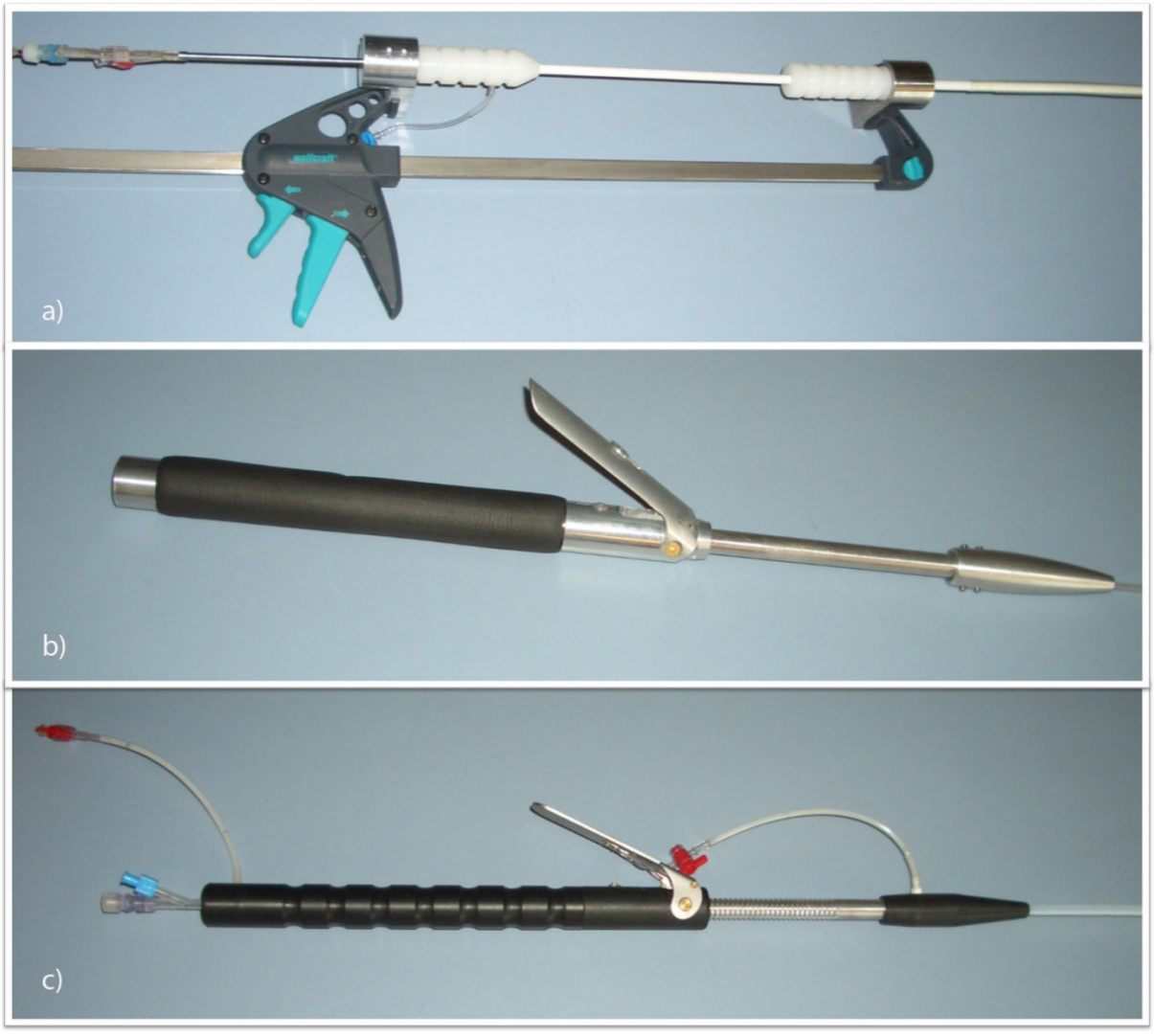

Abb. 6

Prototypen des „squeeze to release" Mechanismus:

a) Alter Freisetzungskatheter eingespannt in ein handelsübliches Werkzeug mit Hebelmechanismus.
b) Erstes Modell des Hebelmechanismus.
c) Vorserienprototyp des Einführungskatheters mit Spülansätzen für Entlüftung.

Mit freundlicher Genehmigung der JOTEC GmbH, Hechingen.

Die Originalarbeit beschreibt die klinischen Erfahrungen an 126 Patienten mit der neuen Stentprothese, die im DHZB erstmals eingesetzt und in einer Serie konsekutiv implantiert wurde. Die inzwischen zum Standard entwickelte Implantationstechnik wird detailliert beschrieben. Die wichtigsten Punkte sind die Auswahl des Arterienzugangs nach dem CT, bei engen und verkalkten Beckenarterien, alternative Zugänge zu mehr proximal gelegenen Arterienabschnitten, die Verwendung eines separaten Katheters für die Zielangiographie in optimaler Durchleuchtungsprojektion bei schon in Position liegendem Freisetzungssystem, bei Dissektionen der Einsatz der TEE und Implantation von langen Stentprothesen, die an der A. subclavia beginnen, auch wenn das Entry weiter distal in der Aorta descendens liegt.

Die klinischen Ergebnisse haben die Erwartungen an die neue Stentprothese erfüllt. Auf den ersten Blick scheinen die Ergebnisse nicht wesentlich besser als die im vorherigen Kapitel berichteten mit Stentprothesen der ersten Generation. Allerdings zeigt sich beim Vergleich, dass mit der neuen Prothese gegenüber der zuvor verwendeten Talent® Prothese bei gleicher Anzahl von Prothesensegmenten pro Implantation signifikant längere Aortenabschnitte behandelt wurden (Tab. 3, S. 43). Der Anteil von Patienten, bei denen die komplette Aorta descendens mit Stentprothesen behandelt wurde, stieg von 2,9 % in der Talent® Gruppe, auf 18,8 % in der E-vita® Gruppe an. Auch der Anteil der Stentprothesenimplantationen im Aortenbogen mit Verschluss der A. subclavia sin. oder weiter proximal gelegener Äste ist deutlich höher. Somit wurden mit der neuen Stentprothese komplexere pathologische Veränderungen der Aorta mit insgesamt gleich guten Ergebnissen operiert. Diese Ergebnisse wurden in der Mehrzahl mit der ersten Version der E-vita® erzielt, die während des Untersuchungszeitraumes eine komplette Überarbeitung erfuhr (s. o.). Die mit der ersten Version beobachteten intraoperativen Migrationen der Prothese, die auf die noch nicht perfekte Konstruktion des Einführungskatheters zurückzuführen waren, sind mit dem neuen Einführungssystem nicht mehr aufgetreten. Mit dem neuen Einführungssystem, das eine präzise und verlässliche Platzierung der Stentprothesen erlaubt, erwiesen sich die von anderen Autoren für die Freisetzung von Stentprothesen empfohlenen, aber potentiell gefährlichen Manöver wie Adenosin induzierter Herzstillstand oder temporärer Herzstillstand durch schnelle Schrittmacherstimulation [74] als nicht erforderlich.

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Early clinical experience with the E-vita thoracic stent-graft system: a single center study

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Aim. **The aim of this study was to evaluate the safety and efficacy of a new endovascular thoracic stent-graft, which was designed to overcome the restrictions of previously used stent-grafts.**

Methods. **Between May 2004 and March 2008 a prospective evaluation was conducted in 126 consecutive patients (71% men; age 64 [19-86] years). A total of 138 implantations were performed. E-vita stent-grafts were implanted for type-B dissection (N.=56), degenerative aneurysm (N.=25), penetrating aortic ulcer (N.=17), blunt traumatic lesions (N.=10), mobile atheroma (N.=1), suture aneurysms (N.=7) and revisionary surgery following previous endograft implantation (N.=22). All patients eligible for stent-grafting were treated with this system regardless of their clinical status and aortic pathology. The percentage of emergency procedures was 52% (N.=72). Per implantation a mean of 1.3 segments was implanted with an effective total covered length of the aorta of mean 204 mm, median 230 mm (0-450 mm). In 32 of 39 cases with more than one segment, the entire descending aorta was included in the procedure.**

Results. **The 30-day mortality rate was 12.3% (17 patients). All deaths but one were in the group of emergency surgery patients. This results in mortality of 1.5% in the elective and 22% in the emergency procedures. Reversible procedure-induced spinal cord ischemia was observed in 2 cases. Stroke occurred in 2.8% (4 patients). Primary technical success was rated at 77 % (106 procedures) and secondary success at 89 % (124 procedures).**

Conclusion. **All forms of thoracic aortic disease can be treated with this new stent-graft. It has proved particularly valuable in cases of difficult conditions in the aortic arch and extended aneurysms. In particular, it is possible to cover the entire thoracic aorta with two or three stent-graft segments, thus considerably reducing the number of connections.**

KEY WORDS: Aorta, thoracic - Stents - Aortic diseases - Aortic aneurysm - Aortic rupture.

Endovascular aneurysm repair (EVAR) has evolved into a routine procedure for abdominal aortic aneurysms (AAA). Numerous devices are on the market, with the first and second generation stent-grafts having already disappeared due to the improvements achieved in the next generation.[1]

In thoracic aortic lesions the potential benefit for the patient is more evident than in AAA because of the more significant mortality and morbidity associated with the conventional procedure. In the thoracic aorta stent-grafting has to handle many more variations of pathology than in the basically uniform AAA.[2] In the beginning the AAA stent-graft technology was transferred to the thoracic aorta. Dake implanted the first homemade stent-graft in the thoracic aorta in 1992 [3] and his series was the stimulus to develop the first commercial stent-grafts.[4, 5] The development is still in progress and redesign became necessary in some devices based on unfavorable clinical experience.[6, 7]

The authors started their thoracic endovascular program in 1999 with the Talent® Stent-Graft (Medtronic Vascular, Santa Rosa CA). A reasonable number of these grafts were implanted.[8] However, the shortcomings of this second-generation device were the

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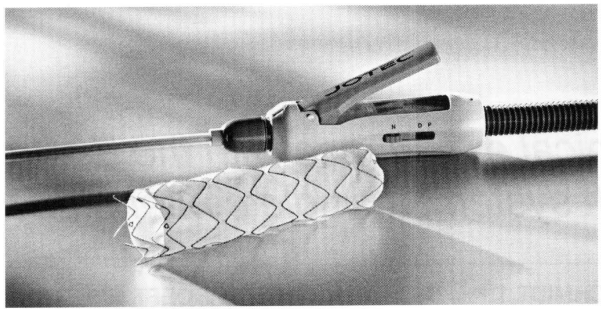

Figure 1.—New version (E-vita thoracic®): Delivery catheter with the Squeeze-to-Release® mechanism and the Dacron/Nitinol self-expanding stent-graft.

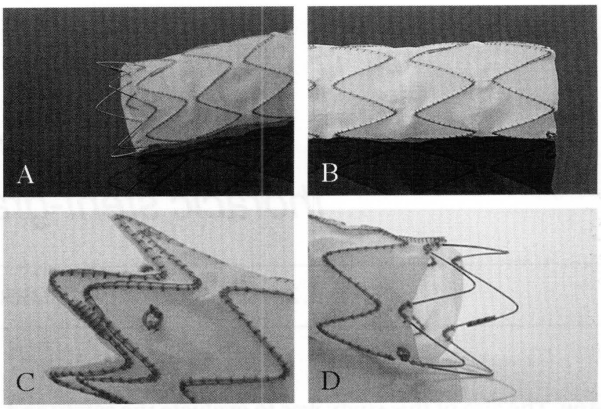

Figure 2.—Configuration of the ends of the E-vita stent-graft: A) Straight Open: bare springs at proximal end of proximal segment; B) Straight Cut at distal end of proximal section, designed for dissections; C) Twin Stent at proximal end of distal section provides additional radial force at fixation; D) Free Spring with bare springs at distal end of distal section for additional transvessel fixation.

stimulus to develop an improved stent-graft with a delivery system that allows the implantation of long grafts even in curved parts of the aorta. The new graft was developed in close cooperation between industry and physicians, based on daily clinical experience.

Materials and methods

Stent-grafts and delivery system

E-vita® (JOTEC GmbH, Hechingen, Germany) has been on the European market since May 2004. The first clinical implantations were performed at our institution.[9] The self-expanding stent-graft consists of a special low porosity woven polyester graft with nitinol springs sutured in the inner side of the stent-graft in a tip-to-tip fashion (Figure 1). The lack of a connecting bar makes the graft flexible. Standard segments with covered lengths of 130, 150, 170 and 230 mm are available. Diameters range between 20 and 44 mm. Four different configurations of the proximal and distal graft ends are produced. In the standard grafts they represent the different ends of two types of stent-grafts designed for the proximal and the distal part of the thoracic aorta (Figure 2). These configurations can be tailored individually in custom-made devices. Custom orders can be manufactured and supplied within one week using only radiosterilizable polymer materials.

The frictional problem when deploying long stent-grafts is solved by use of a textile polyester material in the segment of the outer sheath containing the loaded stent-graft. The stent can therefore be released even if the delivery system is bent at a sharp angle, whereby buckling of a conventional plastic sheath between the stent springs blocks release. In the initial version of the delivery catheter, the stent-graft is released in the conventional way by manual retraction of the outer sheath. The profile was 24 F in all sizes. The proximal end remains closed when the prosthesis is released and can be opened independently in any phase of release (Figure 3A). This enables correction of the position upstream and downstream during deployment and also avoids the windsock effect with the partially opened endograft. This proximal delivery mechanism used to be secured by a wire, which had to be pulled out before the tip was released by pushing the central catheter forward. In clinical practice this mechanism proved to be difficult to manage in tortuous aorta, again a frictional problem.

Based on this clinical experience the delivery catheter was completely redesigned. The new delivery catheter was approved in June 2007 and the stent-graft system is called E-vita thoracic® (Figure 1). The stent-graft itself remained the same. The profile is 20 F, 22 F or 24 F depending on the size of the stent-graft loaded. A mechanical aid has been added to the outer sheath which helps the surgeon to deploy the graft without applying direct force, but if deemed necessary the graft can be released in the conventional pull-back manner at any stage of the delivery. The security wire of the tip has been replaced by a plastic locking ring and the central catheter is attached to

the tip by a metal tube fixed to a button at the end of the delivery catheter (Figure 3C,D)

To protect the textile mantle the graft is implanted through a specially designed separate long 24 F sheath (Easy®; JOTEC GmbH, Hechingen, Germany). The valve of this sheath is soft in order to prevent premature opening of the textile mantle when the delivery catheter is introduced and to eliminate friction between sheath and delivery catheter. Sealing of the valve, when delivery catheters or other endovascular instruments are changed, is achieved by a wire plug, which is applied to the guide-wire from the side directly at the sheath and then pushed into the valve. The wire plug also prevents accidental displacement of the guide-wire. The sheath profile was reduced to 20 F and 22 F in the smaller and medium sizes of the new E-vita thoracic system. According to the manufacturer's recommendations the new delivery catheter can alternatively be advanced without a sheath, because the new tip prevents accidental opening when it is passed through narrow access arteries.

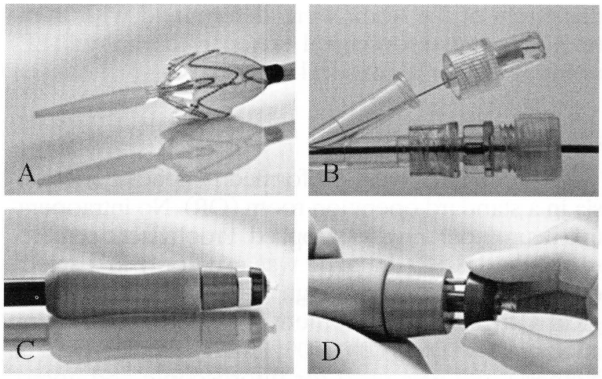

Figure 3.—Separate delivery of the proximal end of the E-vita stent-graft: A) The textile outer sheath is partially opened; the bare springs are still retained in the tip; B) Release mechanism of the tip (old version): the wire is to be pulled out to unlock the graft from the tip. The central catheter is to be pushed forward to release the graft; C) release mechanism of the tip (new version): locking ring in place; D) release mechanism of the tip (new version): The locking ring is removed and the graft is released by pushing the button forward.

Diagnostic evaluation and patient selection

Apart from the emergency conditions listed below, indications for stent-grafting were atherosclerotic aneurysms greater than 55 mm in diameter, penetrating ulcers greater than 20 mm in depth, traumatic rupture, post-traumatic aneurysm and suture aneurysm after previous conventional surgery. In acute or chronic type-B dissections stent-grafting was indicated when patients developed complications, such as aneurysms greater than 55 mm diameter, rapid growth of the false lumen, rupture, malperfusion of side branches even with mild symptoms, for example claudication, and extremely narrow true lumen suggesting malperfusion problems. E-vita has been our graft in stock for emergency procedures since 2004. Therefore virtually all patients eligible for stent-grafting were treated with this device regardless of their clinical status and aortic pathology.

Technical inclusion criteria for the implantation of E-vita grafts were based on the range of sizes available and the recommendation to oversize the stent-graft by 10-20% at the fixation zone: proximal and distal aneurysm neck of minimum 20 mm length and minimum 16 mm maximum 40 mm in diameter. The proximal landing zone in the aortic arch was often extended by generous occlusion of the left subclavian artery (LSA). More extended debranching and hybrid procedures were performed only rarely.

Preoperative aortic measurements were performed mainly with contrast enhanced spiral computed tomography (CT) with 1.5 mm to 3 mm slices. The axial CT scans in combination with 3D and multiplane reconstructions allow precise measurement of diameters and lengths (aneurysm, proximal and distal landing zone).[10] In difficult cases of elongated arch or tortuous distal aorta the surgeon and radiologist together perform the 3D-reconstruction of the CT scan for precise sizing of the landing zones. Moreover, CT provides important information on angulations, tortuousity and calcification of the aorta and iliac vessels. In elective cases coronarography combined with aortography was performed to obtain additional information on aortic morphology and cardiac risk. In cases of impaired renal function magnetic resonance imaging (MRI) replaced CT.

In most of the emergency procedures, however, measurements had to rely on the plain axial CT scans performed by the referring hospitals and simple graphical methods. These CT scans were often of inferior quality, with 5-10 mm slices. Usually no information concerning the iliac vessels was available from these external emergency evaluations. In doubt the correct

diameters of the aorta were determined with intraoperative transesophageal echocardiography (TEE) or intravascular ultrasound (IVUS).

Implantation technique

All procedures were performed in general anesthesia in a standard operation room (OR). No intraoperative neuromontoring was applied. Prophylactic cerebrospinal fluid (CSF) drainage was used only in 2 selected cases deemed to be at high risk for paraplegia. A surgical C-arm with equipment for digital subtraction angiography (DSA) (BV 300®, Philips, Eindhoven, The Netherlands) was used for fluoroscopic and angiographic guidance. Additional TEE was performed in aortic dissection. The authors used a standard operation table with a carbon fiber attachment (Maquet, Rastatt, Germany), which allows circumferential fluoroscopy of the thorax in supine position.

The target and control angiography were usually performed through a 5F or 8F pigtail catheter separate from the access of the stent-graft, which enables repeat angiography during the deployment. This catheter is placed first through an appropriate sheath either from the contralateral femoral artery or from the right or left brachial artery.

Routine access for the stent-graft is achieved with surgical exposure of the common femoral artery using a small oblique incision. The side with less tortuousity and calcification of the iliac arteries is chosen, as identified in preoperative CT-scan. More recently a percutaneous technique was developed for those cases with non-calcified femoral arteries. Directly after puncture and advancing a 0.035" hydrophilic guide-wire (Radiofocus®, Terumo, Tokyo, Japan) two crossed U-sutures are placed around the puncture side with a 10 F percutaneous suture device (Prostar XL®; Abbott Vascular Devices, Redwood City, CA; USA) and the device is replaced by a 12 F sheath (William Cook Europe, Bjaeverskov, Denmark). If the femoral arteries are not accessible, a retroperitoneal or transperitoneal approach is taken and a 10 mm polyester graft is sutured end-to-side to the common iliac artery or the distal abdominal aorta and the stent-graft is implanted over this conduit.[8]

A 0.035" smooth hydrophilic guide-wire (Radiofocus®, Terumo, Tokyo, Japan) followed by a 5 F headhunter catheter (William Cook Europe, Bjaeverskov, Denmark) is positioned in the ascending aorta. The smooth wire is exchanged inside the catheter for an ultra-stiff guide-wire (E-wire®; JOTEC, Hechingen, Germany). In type-B dissection the correct position of the wire in the true lumen is checked with TEE over the entire length of the thoracic aorta. The 20 to 24 F Easy® sheath is advanced over this guide-wire through the iliac arteries and abdominal aorta under fluoroscopy and the end of the sheath is placed at the level of the visceral arteries. This separate sheath was used in all cases, even with the new E-vita thoracic® delivery-system.

The delivery system is advanced retrograde through the sheath and is parked distally to the lesion. The C-arm is then turned to the left anterior oblique projection and the target angiography is performed. The contours of the aorta and the side branches are drawn on the screen with a surgical marker pen. If deemed necessary, blood pressure is lowered to mean 50 mmHg by injection of nitroglycerin. The stent-graft is deployed as described above according to the landmarks on the screen. The delivery system is closed and retracted into the sheath.

An angiography is performed to check the result. Now it is decided whether an extension with a second stent-graft is required or whether ballooning is necessary for better approximation of the stent-graft to the aortic wall. The first version delivery catheter had an integrated compliant balloon, which was removed in the new E-vita thoracic® version. A separate large compliant balloon (Reliant®; Medtronic Vascular, Santa Rosa, CA) is used for this purpose in the later version.

In aneurysm cases, the stent-graft is placed to extend the length of the aneurysm by a minimum of 20 mm proximally and distally. In some cases it is decided to use extensions ad hoc during the procedure; in longer or tortuous lesions a modular stent-graft of two or more components is planned from the beginning. Implantation of additional stent-grafts is facilitated by the E-asy sheath already in place and securing the femoral and iliac pathway. This is especially helpful using the percutaneous technique.

In type-B dissections the longest E-vita (230 mm) is used as the standard, beginning at the origin of the LSA or upstream if necessary. The graft then usually ends just above the diaphragm. It will be extended distally only if additional communications across the membrane above the level of the celiac artery are identified in the angiography check.

After final angiography, catheters and sheaths are removed and the access site is closed with 5-0 Prolene sutures. In percutaneous technique the preemptive

sutures are tied in a technique known from minimally invasive surgery.

Postoperative care and follow-up

Patients without complications were extubated at the end of the procedure or artificially ventilated for a few hours. They were transferred either directly to the normal ward or to the intensive care unit (ICU) for less than 24 hours and were mobilized on the first postoperative day. Longer ventilation and ICU times were seen in emergency patients with severe comorbidity or injuries or sequelae of aortic rupture or malperfusion. Rupture hematoma and hemothoraces were evacuated by chest tube or, if necessary, with a limited surgical approach either at the end of the procedure or with a delay of some days.

Follow-up CT or MRI was performed before discharge or transfer to other hospitals. Assessment of the postoperative result, especially the diagnosis of endoleaks and the assessment of technical success was based on this early follow-up imaging. In only 10 cases did CT or MRI not take place, mainly due to poor clinical status of the patients. In these cases success was evaluated only by the intraoperative completion angiography. Complications, endoleaks and technical success were assessed according to The Society for Vascular Surgery/American Association for Vascular Surgery (SVS/ASVS) 2002 reporting standards for endovascular aortic aneurysm repair,[11] with the modification that retrograde flow into the false lumen distal to the end of the stent-graft in aortic dissection was not considered a type-Ib endoleak.

Data were collected prospectively on an intention-to-treat basis in a Microsoft Access database from the hospital and office charts, the operative reports and the pre- and postoperative measurements. Written informed consent for the operation was obtained in all cases in accordance with the rules for regular elective or emergency surgery. Additional written informed consent was obtained for the study. Follow-up at 1 month was complete for all patients. Further follow-up with CT/MRI and office visits are scheduled for 3 months, 1 year and yearly thereafter. These follow-up-data are as yet incomplete and therefore this report focuses on the early postoperative experience. In all patients in whom secondary closure of endoleak was noted, this was confirmed by follow-up imaging at 3 to 12 months.

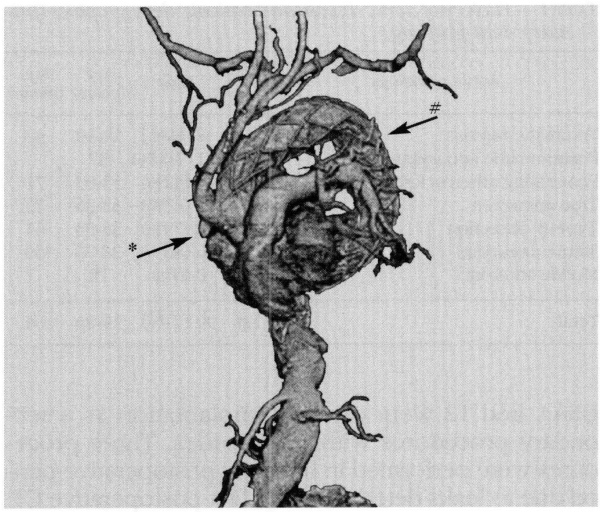

Figure 4.—CT reconstruction of an E-vita thoracic® graft in a 74-year-old man. The stent-graft was implanted in the aortic arch and the proximal descending thoracic aorta as a proximal extension of a two segment Talent graft implanted 4 years before (#: overlap). The E-vita was implanted in antegrade manner with simultaneous total arch debranching and reconstruction with a Y-graft from the ascending aorta (*: stump of the auxiliary access graft for the stent-graft deployment).

Results

Between May 2004 and March 2008 126 patients (71% men; age 64 [19-86] years) were treated with E-vita stent-grafts; 138 consecutive implantations were performed, 116 with the first version delivery catheter and 22 with the new version (E-vita thoracic®). All but one of the implantations were performed in the retrograde manner described above. In one case an antegrade approach through the ascending aorta via median sternotomy was used (Figure 4). Three hybrid stent-graft procedures (E-vita open®, JOTEC, Hechingen, Germany) were excluded from the study, because in these procedures stent-grafting of the descending thoracic aorta from the open aortic arch is part of complex conventional surgery. Indications for stent-grafts were type-B dissection (N.=56), degenerative aneurysm (N.=25), penetrating aortic ulcer (N.=17), blunt traumatic lesions (N.=10), mobile atheroma (N.=1), suture aneurysms (N.=7) and revisionary surgery following previous endograft implantation (N.=22). Ten of these secondary procedures were performed after previous implantation of other stent-grafts (8 Talent®, 2 Relay®; Bolton Medical, Sunrise, FL,

TABLE I.—*Etiology of aortic disease and patients' demographics (primary stent-grafting).*

Aortic pathology	N.	Male	Age (years)	Age (mean)
Traumatic rupture	9	8 (89%)	19-40	32
Posttraumatic aneurysm	1	1 (100%)	37	
Penetrating atherosclerotic ulcer (PAU)	17	7 (42%)	53-83	71
True aneurysm	30	19 (63%)	58-86	72
Type-B dissection	61	48 (79%)	36-83	64
Suture aneurysm	7	6 (86%)	28-76	60
Mobile atheroma	1	0 (0%)	78	
Total	126	90 (71%)	19-86	64

USA), and 12 were cases of implantation as a secondary procedures within this series. Three procedures were performed in the early postoperative period due to leaks detected in the first postoperative CT. The etiology of aortic disease and patient demographics are summarized in Table I.

Seventy-three operations (53%) were emergency procedures with the following preoperative conditions: active bleeding in 8, contained rupture in 26, malperfusion in type-B dissections in 18, and symptomatic aortic disease with impending complications in 21 patients.

One hundred thirty-eight stent-grafts were implanted with an average number of 1.3 segments per procedure. In 99 procedures one segment was used, in 33 two segments and in 6 three segments. In 32 out of the 39 cases with more than one segment, the entire descending aorta was included in the procedure. The covered length of the segments ranged from 80 to 230 mm (mean 175 mm, median 170 mm). Grafts with diameters of between 20 and 44 mm, average 36 mm, median 36, were used. The effective length of covered thoracic aorta per procedure was mean 198 mm, median 225 mm (0-450 mm). The effective cumulative length of covered thoracic aorta after all individual stent-graft procedures was mean 233 mm, median 230 mm (100-450 mm). Custom-made devices were used in 45 implantations.

In all procedures the stent-graft was successfully deployed at the target zone in the thoracic aorta. In 2 procedures (1.4%) immediate conversion to open surgery became necessary. The first patient (a 39-year-old man) had acute traumatic rupture with extensive mediastinal hematoma associated with multiple injuries after a motor vehicle accident. Due to diameter mismatch between the aortic arch and the descending aorta the graft was probably undersized in the proximal portion, which resulted in a type-Ia endoleak leading to immediate free aortic rupture. Immediate sternotomy and graft replacement with extracorporeal circulation (ECC) was performed. The patient died on the operating table from injury and ECC related abdominal bleeding.[8] In the second patient (a 76-year-old man) stent-grafting was a bail-out procedure for a ruptured suture aneurysm at the proximal anastomosis after conventional replacement of the descending thoracic aorta (DTA) 18 months before; there was an aorto-bronchial and an aorto-esophageal fistula and massive bleeding. Despite caliber mismatch between the aortic arch and the conventional graft (40 mm to 28 mm) and a narrow anastomosis it was attempted to close the leak with a 44 mm to 40 mm stent-graft. The graft was deployed but it failed to open completely in the narrow anastomosis, leading to subtotal occlusion of the aorta. An anterolateral thoracotomy was performed, the stent-graft was explanted in deep hypothermia and circulatory arrest and the leak was closed by direct suture. The patient died 2 days later from intractable bleeding from the lung.

Problems in deploying the device from the delivery system occurred in 38 of 116 implantations with the first version (33%). These problems could be solved in all cases by working with the different components of the delivery catheter (pull wire, central catheter and the pusher with the integrated balloon) and all stent-grafts were finally deployed in the desired position. However device migration of 5-20 mm resulted from these problems in 13 cases (11%), making unscheduled graft extensions necessary in 5 cases (4%). With the new version all 22 stent-grafts were placed exactly at the targeted spot without any migration caused by the delivery system. This advance is demonstrated individually by 5 cases where secondary extensions were implanted with the new system without delivery problems while the primary E-vita implantations with the first version had had problems of this kind. Intraoperative migrations not caused by the delivery system occurred in 4 more cases in the whole series. These were surgeon induced in two and caused by final ballooning in two cases. None of them required extension. It was our impression that none of the observed intraoperative migrations were caused by the running bloodstream itself. Relying on avoiding the windsock effect with the retained tip of the stent-graft, the blood pressure was lowered pharmacologically only to a mean of 50-60

mm Hg if deemed necessary. This was the case in 18 implantations (13%). Adenosine induced cardiac arrest or rapid ventricular pacing to stop cardiac output during deployment was never used.

In 101 (73%) procedures routine artery access was through the surgically exposed common femoral artery; 19 procedures (14%) were performed percutaneously. Access from the common iliac artery or the infrarenal aorta by sheath-through-graft technique was necessary in 18 (13%) procedures. In an additional 5 patients arterial reconstruction of the iliac or femoral artery had to be performed after advancing of the stent-grafts had damaged the artery. One patient (an 80-year-old woman) died from unrecognized damage of the iliac artery after successful deployment and finishing the procedure. Therefore in a total of 24 out of 138 procedures (17.4%) access problems made more extensive surgery necessary.

The distribution of proximal and distal landing zones of the stent-grafts is displayed in Figure 5. In 99 (72%) of the 138 procedures the lesions required fixation of the stent-graft in the distal aortic arch. In 46 (33%) the proximal bare springs crossed the left subclavian artery (LSA) with the polyester fabric starting immediately distally from it. In 48 (35%) the LSA was covered by the graft material and the bare springs crossed the left common carotid origin and in 4 patients (3%) the left common carotid artery (LCCA) was covered. Adjunctive extrathoracic surgical reconstruction of the LSA and/or the LCCA were performed in 33 cases to enable more proximal stent-graft attachment within the aortic arch, 9 simultaneous with, 19 before and 5 after the endograft procedure.

Distal stent-graft attachment was below the level of the diaphragm or lower in 59 procedures (44%). Among these, the celiac trunk origin was covered by the endograft in 3. One of these patients required bypass surgery; the remaining two had sufficient collaterals verified in selective post-deployment angiography. The entire descending aorta from the arch up to below the diaphragm was covered with endografts in 35 patients, 33 primarily and 2 step-by-step with secondary procedures.

The median procedure time was 130 minutes (range, 60 to 475), median fluoroscopy time 14 minutes (range, 3 to 61) and median amount of contrast medium 120 ml (range, 30 to 350).

The SVS/ASVS reporting standards for endovascular aortic aneurysm repair [11] define the technical success in terms of successful access, successful deployment, absence of type I or III endoleak, patent graft without obstruction, absence of surgical conversion and absence of 24 h mortality. In accordance with these standards the technical success rate was 77.2% (N=107) primary success and 13.8 % (N.=19) secondary success after further interventions (4 secondary stent-graft extensions, 2 bare stents, 1 stent-graft dilatation, 1 surgical endoleak closure) or spontaneous closure of endoleak (11 cases).

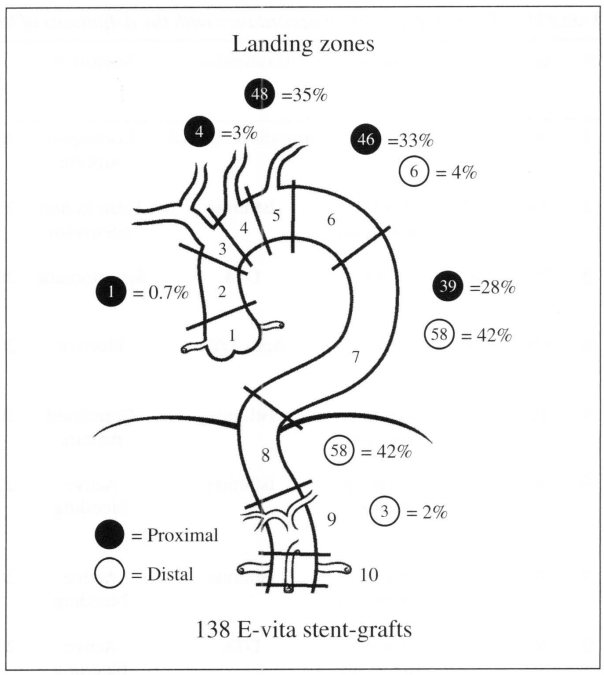

Figure 5.—Distribution of proximal and distal endograft attachments (full diameter graft material; bare springs may reach further in proximal direction); aortic segment specification from the German Heart Institute Berlin aortic database.

A survey of the 12 non-successful cases is given in Table II. The reasons for failure were intraoperative conversion to open surgery (described above) in 2 cases, failure to cover the leak of an infected conventional graft in 1, fatal iliac artery rupture in 1 case, perforation of a dissection membrane in 1 case (followed by emergency AAA repair in combination with bypasses to the visceral arteries to restore the visceral circulation), and endoleak type I in 7 cases. These 7 patients with endoleak were either in poor clinical condition, which prevented further endovascular or surgical treatment, or the endoleaks were deemed to

TABLE II.—*Endograft failure in accordance with the definitions of the SVS/AAVS.*[11]

N.	Age	Gender	Diagnosis	Localization	Indication	Date	Proximal landing zone	Failure	Intervention	POD	Outcome (30 days)
1	80	F	PAU	Infradiaphragmal	Contained rupture	2004-04-23	7	Iliac artery rupture	Iliac artery repair	Intraop.	Fatal
2	54	M	Type-B dissection	Isthmus	False lumen aneurysm	2005-04-25	6	Endoleak Ia	—	—	Discharged
3	79	F	TAA	DTA	Symptomatic	2005-05-20	5	Endoleak Ia	—	29	Fatal
4	69	M	TAA	Arch/DTA	Elective	2005-07-29	4	Endoleak Ia	—	—	Discharged
5	19	M	Traumatic rupture	Isthmus	Contained rupture	2005-09-18	6	Endoleak Ia	—	—	Discharged
6	39	M	Traumatic rupture	Isthmus	Active bleeding	2005-11-17	5	Endoleak Ia, immediate rupture	Primary conversion	Intraop.	Fatal
7	76	M	Suture aneurysm	Ishtmus	Active bleeding	2006-11-22	5	Occlusion stent-graft	Primary conversion	Intraop	Fatal
8	56	M	Suture aneurysm; Infection	DTA	Active bleeding	2007-02-10	7	Leak not covered, continuous aorto-esophageal fistula	—	5	Fatal
9	58	M	Acute type-B dissection; AAA	Isthmus	Malperfusion	2007-05-14	5	Distal perforation of dissection membrane (balloon), ongoing malperfusion	Conventional infrarenal y-graft with side branches to CA and SMA	1	Fatal
10	81	M	TAA	Arch	Symptomatic	2007-08-01	5	Endoleak Ia	—	—	Discharged
11	66	M	TAA	DTA	Elective	2007-09-20	5	Endoleak Ia	—	—	Discharged
12	84	F	TAA, secondary Endoleak Ib	Distal DTA	Contained rupture	2008-03-07	5	Endoleak Ib; secondary rupture	—	1	Fatal

SVS/AAVS: Society for Vascular Surgery/American Association for Vascular Surgery; Endoleak Ia: endoleak from proximal attachment site; Endoleak Ib: endoleak from distal attachment site; AAA: abdominal aortic aneurysms; CA: celiac artery; DTA: descending thoracic aorta; F: female; M: male; LSA: left subclavian artery: PAU: penetrating atherosclerotic ulcer; POD: postoperative day; SMA: superior mesenteric artery; TAA: thoracic aortic aneurysm; TAAA: thoraco-abdominal aortic aneurysm; TOF: tetralogy of Fallot.

be minor with a chance of them closing spontaneously. Five patients were thus discharged with persisting endoleaks.

The overall 30-day-mortality was 12.3% (N.=17); separated for elective and emergency procedures, 30-day-mortality was 1.5% (N.=1) *vs* 21.9% (N.=16).

The cause of the death in the elective group was suicide after a successful procedure and uneventful recovery. Eight patients died from rupture, 1 from access artery bleeding, 2 from sequelae of perioperative ischemia and 6 from deterioration of underlying concomitant diseases. Four ruptures occurred secondarily despite successful stent-graft implantation with a delay of 2 to 10 days. In 2 of them the primary rupture hematoma penetrated the esophagus; in 2 cases of type-B-dissection it was suspected that the false lumen had perforated into the retroperitoneal space.

Stroke or intracranial bleeding occurred in 5 patients (3.6%). Four of these events were disabling or fatal.

Spinal cord ischemia was seen in 2 patients (1.5%), in both cases reversible paraparesis. The first of these patients (female, 79 years) received a stent-graft to exclude an embolizing mobile atheroma at the midportion of the descending thoracic aorta. She developed left-sided paraparesis, which resolved in the first 3 weeks with the patient able to walk. The second patient (a 78-year-old male) experienced complete reversible weakness of his legs in the first days after complete coverage of the descending thoracic aorta for an acute dissection. He reported a similar event after his previous surgical AAA repair. In both cases treatment consisted in elevation of mean blood pressure to 100 mm Hg, assisted by secondary CSF drainage for 32 hours in the first patient.

Discussion

As previously shown by the authors, endovascular repair of the thoracic aorta can be performed in a standard cardiovascular OR setting.[8] The early results compare favorably with those of other studies on the endovascular treatment of thoracic aortic diseases.[12, 13] The authors' experience is characterized by a large proportion of emergency procedures and this E-vita series does not differ very much from the overall experience on first sight. Stent-grafting is especially designed to provide treatment of life-threatening complications of aortic disease in multiply injured [14] or multimorbid and old patients, in whom conventional aortic surgery bears an extremely high risk. For this task a stock of endografts is necessary with options to treat all forms of thoracic aortic disease in any localization amenable for stent-grafting. In order to keep the technique simple and uniform it is reasonable to hold few stent-graft systems in stock. Therefore the procedure can be performed even at night-time by two surgeons and the regular OR staff.

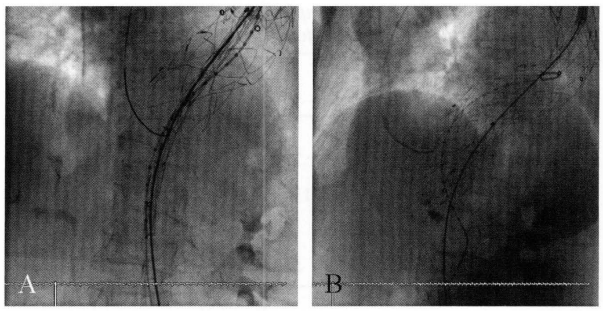

Figure 6.—Delivery of E-vita thoracic stent-graft as a distal extension of a previously implanted E-vita. The proximal and distal end of the Dacron is marked with a pair of ring-markers, the middle of the Dacron with one ring marker. Distal extension graft still closed. Distal extension graft deployed. The distal bare springs provide additional fixation across the celiac artery.

The first system in the stock was the Talent stent-graft, which in clinical practice proved to have some significant shortcomings. It is relatively stiff due to a longitudinal connecting bar and the segments are limited to 110-150 mm in length due to the frictional resistance in the delivery system. The E-vita system retained the advantages of the polyester/nitinol technology and of the proximal bare springs, but promized to overcome the limitations mentioned. It can be adapted, by combinations of the two standard configurations, to the needs of different aortic pathologies such as aortic dissection or aneurysmal disease in close approximation to the supraaortic or visceral vessels. Therefore the authors chose this graft for stock from 2004 onwards. The polyester/nitinol technology is reliable and provides good anchoring of the stent-graft by virtue of the superelastic properties of nitinol. The proximal bare spring adapts the graft better to curved segments of the aorta. Nitinol does not impair MR imaging, which may be a suitable alternative to CT in postoperative follow-up in patients with reduced renal function, which is frequent in patients with thoracic aortic disease. MRI can be used even in early postoperative checks of these polyester nitinol grafts.[15, 16]

In practice the new generation stent-graft met the expectations. More challenging aortic pathology in terms of tortuousity, extension into the aortic arch and length of the thoracic aortic disease was not a

TABLE III.—*Details of primary implantations of second generation (Talent®) and third generation (E-vita®) devices.*

Period	Talent® 1999-2004	E-vita® 2004-2007	
N.	105	117	
Segments per implant	1.29 (1-5)	1.38 (1-3)	NS
Effective length (mm)	134 (97-320)	224 (100-450)	P<0.001
Entire descending aorta covered	3 (2.9%)	22 (18.8%)	P<0.001
Proximal landing zones ≥5	32 (30.5 %)	51 (43.6%)	P=0.004

barrier to treatment. This is illustrated by a comparison of the technical properties of the stent-graft used for primary implantations in our Talent experience and the current E-vita experience (Table III). Although the average number of stent-graft segments per implantation remained nearly the same, the average effective length of descending thoracic aorta (DTA) covered with stent-graft increased significantly. Treatment of complex aortic disease requiring coverage of the entire DTA from the aortic arch or the proximal DTA (zones 4-6) to the level below the diaphragm (zones 8 and 9) was performed only in few special cases with the second generation device. This increased significantly to a percentage of 22% with the E-vita devices. Also, nearly twice as many cases with proximal aortic disease requiring fixation of the stent-graft in the aortic arch were treated with the new device. This difference was highly significant.

The key to success is the capability of the delivery catheter to deploy the device in the desired position with exactitude to the millimeter. The surgeon should be able to control and to correct the deployment at every stage. Therefore the idea of separate release of the tip of the stent-graft was developed. By this mechanism the apposition of the graft to the aortic wall in the landing zone can be watched under fluoroscopy. Adjustments in upstream and downstream direction before final deployment are possible and the windsock effect of the partially opened graft is avoided. This worked quite well in the first version of the delivery system, but the advantage was sometimes compromised in difficult and curved anatomy when the securing wire was pulled. During the study period the delivery catheter was completely redesigned. With the new delivery system these problems have been completely eliminated. The Squeeze-to-Release® mechanism is operated with two fingers even in very curved anatomy and the speed of the delivery can be continually adjusted. Therefore no longitudinal force as in conventional delivery mechanism or rotational momentum as in unscrewing mechanical aids has to be applied to the catheter, which reduces the risk of intraoperative migration caused by the action of the surgeon.

With this delivery catheter the impact of the running bloodstream is controllable, so that potentially dangerous maneuvers of lowering the blood pressure or interrupting cardiac output can be avoided.[17] Recent experimental and clinical findings suggest that hypotensive episodes may be more responsible for spinal cord ischemia induced by aortic surgery or stent-grafting than coverage of the intercostal arteries alone.[18] The incidence of spinal cord ischemia after thoracic aortic stent-grafting shows some variations in the literature. The rate reported here and in the authors' overall experience [8] is reasonably low although no adjuncts such as CSF drainage or intraoperative neuromonitoring were used. It is speculative but this may be due to fact that the authors never used adenosine induced cardiac arrest. Even simple lowering of the blood pressure was used rarely, relying on the controllable deploying mechanism.

The separate sheath has been criticized because it adds about 2 F of profile to the delivery system. The authors found, however, that this sheath with a smooth but trackable dilator passes very well through even narrow excess arteries. It straightens tortuous access vessels and eliminates any friction between the outer sheath of the delivery catheter and the wall of the access artery. This makes deployment easier and more precise. The sheath secures the pathway to the aorta until the end of the procedure. This is especially valuable when several segments are to be implanted. In narrow external iliac arteries the sheath-to-graft technique in the common iliac artery is recommended. In this technique the separate sheath is used through the access 10 mm polyester graft. Bleeding is easily controlled by tying the graft to the sheath. Because of this positive experience we used the sheath as well in all procedures with the new E-vita thoracic delivery system, although this is no longer strictly recommended by the manufacturer.

Stroke is an underestimated complication of stent-grafting and has reached 4% in this series, which is similar to the authors' overall experience. However the figures are too low to find statistically significant risk factors. This reminds that manipulation in the aortic

arch only with catheters and wires may cause ischemic events. The role of covering of the left subclavian artery remains unclear and is currently the subject of further investigation.

The authors' strategy for type-B dissections consisted of endograft placement from the origin of the left subclavian artery (LSA) or just above the origin downwards to cover all entries of the descending thoracic aorta. Usually there is only one proximal entry, which can be adequately closed with a short proximal endograft. However they have learnt that in most cases remodeling of the aorta is limited to that part where the endograft is implanted. Therefore they now use the longest E-vita (230 mm) as standard for type-B dissections and this usually ends just above the diaphragm. This length would have required 3 standard grafts in the Talent era.

The rate of primary technical success is difficult to compare to that of other reports of industrially produced stent-grafts.[5, 12, 13, 19-21] Some of these studies represented highly selected collectives for elective surgery, where anatomical challenges were excluded in order to compare the results with those of open surgery.[19, 21] Others are multicenter registries with the known limitations of registries.[20, 22] Emergency cases were reported to these registries, but in the Talent thoracic registry the relation of elective to emergency implantations was opposite compared to this study [19] and in the Eurostar and United Kingdom registry there were 46% emergencies. Success is further dependent on etiology of aortic disease and the segments affected.[13, 22, 23] Moreover, different criteria to assess technical success were applied. Only the Eurostar and United Kingdom registry refers to the Society for Vascular Surgery/American Association for Vascular Surgery (SVS/AAVS) definitions. In the Talent registry technical failure is defined as failure to complete an intended stent-graft deployment. This was reported with figures of around 2% in the studies. With the E-vita device the bare deployment success was 100%, but the overall technical success in terms of all five criteria was impaired by a relevant number of emergency procedures. In an emergency sophisticated preoperative imaging is sometimes unavailable due to limited time, and compromises in sizing have to made due to the limitations of the in-hospital stock of stent-grafts, which does not cover all potential combinations of sizes. Some of the procedures (cases No. 6, 7, 8, and 12 in Table II) were performed as desperate attempts to save patients' lives beyond the anatomical limitations of stent-grafting, because open surgery was deemed to be lethal. Another case of this kind has been reported earlier.[24]

According to the SVS/AAVS definitions any type-I endoleak has to be considered as technical failure. Some of these leaks are detected because of our policy of performing follow-up CT scans in the very early postoperative period, which is more sensitive than the intraoperative completion angiography. This experience is shared by other authors.[12] Type-I endoleak is a matter of concern in all studies on thoracic endografting and is reported quite frequently.[5, 12, 13, 19-21, 25] Compared to the authors' Talent experience and that of the Talent thoracic registry, with an incidence of 10% persistent endoleaks, the incidence of early proximal endoleaks reported here (N.=25 [18%]: 7 persistent [5%], 7 closed by secondary procedures [5%] and 11 [8%] closed spontaneously) represents technical improvement of the new generation stent-graft especially in the light of the increasing anatomical challenges that have become amenable for treatment with the new flexible device. With short landing zones and a sharp angle from the aortic arch to the DTA the risk of endoleaks increases due to the mechanical and geometrical conditions. Moreover, the orifice of the LSA may interrupt apposition of the graft in the proximal landing zone and cause endoleaks. Error in measurements from the CT films and the learning curve of deploying the stent-graft correctly in difficult arch anatomy play a further role. Some of these leaks seem to seal with the further self-expanding of the stent-graft, especially in aortic dissection. However, the fate of persisting endoleaks and the numbers of spontaneously closing leaks have to be watched carefully in the follow-up period. This is the subject of ongoing investigations. Despite the reasonable advances made, the impression remains that effort is necessary to improve the proximal sealing capacity of the stent-graft in order to better meet the challenges of implantation in the aortic arch.

Conclusions

The E-vita stent-graft has proved in our hands to be a safe and reliable device in the treatment of all forms of aortic disease amenable to stent-grafting. Moreover it offers the possibility of treating technically more complex and anatomically more challenging cases, at least in patients with high risk for open thoracic aortic surgery. The new delivery catheter is unrivalled for precise and easy deployment.

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2.3. Endovaskuläre Behandlung der Aortendissektion

- Zipfel B, Czerny M, Funovics M, Coppi G, Ferro C, Rousseau H, Berti S, Tealdi DG, Riambau V, Mangialardi N, Sassi C.
  Endovascular treatment of patients with types A and B thoracic aortic dissection using relay thoracic stent-grafts: Results from the RESTORE patient registry.
  Journal of Endovascular Therapy 2011; 18(2):131-143. [75]
  http://dx.doi.org/10.1583/10-3233MR.1
  Abdruck mit freundlicher Genehmigung der International Society of Endovascular Specialists, Phoenix, AZ

Die These, dass der Einsatz technisch weiterentwickelter Stentprothesen die Ergebnisse der endovaskulären Therapie verbessert und diese auch bei morphologisch schwierigeren Fällen eingesetzt werden können, wird mit der nächsten Arbeit weiter überprüft. Das Ziel der Arbeit war die Evaluation von Sicherheit und Leistungsfähigkeit der Behandlung von Aortendissektionen mit der neuen Relay® Stentprothese. Diese Stentprothese ist speziell für den Einsatz im Aortenbogen konstruiert. Durch einen spiraligen Längsdraht und ein vorgebogenes Einführungssystem passt sie sich in der Tat sehr gut an die Verhältnisse im Aortenbogen an. Die technischen Details der Prothese sind in der Arbeit kurz beschrieben, eine ausführlichere Darstellung findet sich in der ersten Publikation des RESTORE Registers [76]. An diesem multizentrischen offenen Register nahmen 22 Kliniken in Europa teil, 304 Patienten mit allen Arten von Aortenerkrankungen wurden eingeschlossen [77]. An der Konzeption dieses Registers hat der Autor mitgewirkt, die meisten Patienten in die Studie eingebracht und daher die Erstautorenschaft übernommen. Die Daten und Ausmessungen der Aorta wurden von den teilnehmenden Kliniken an die Studienzentrale gemeldet, dort auf Plausibilität geprüft und ggf. durch Nachfragen korrigiert. Eine Kontrolle der Bildgebung und Ausmessung durch ein unabhängiges Institut (Corelab) wurde nicht durchgeführt.

Die Originalarbeit untersucht die Aortendissektionen als Untergruppe. Aus dem Wesen als offenes Register ergibt sich ein heterogenes Kollektiv, wie es der klinischen Praxis entspricht. Es wurden auch penetrierende Aortenulcera und intramurale Hämatome eingeschlossen, die nach den Empfehlungen der Europäischen Gesellschaft für Kardiologie [17] als Unterformen der Dissektion klassifiziert wurden. Somit lag eine klassische Aortendissektion nur in 54 % der Fälle vor, in 13 % war der Typ der Dissektion nicht gemeldet worden. 3 Patienten (3 %) wurden wegen einer Typ-A-Dissektion behandelt. Die Indikationsstellung zur Stentprothesenimplantation war den behandelnden Ärzten überlassen, abgesehen von den definierten anatomischen Ein- und Ausschlusskriterien. Es wurden also bei 25 % der Patienten die Stent-

prothesen bei unkomplizierten Dissektionen implantiert, die restlichen 75 % wurden als kompliziert klassifiziert. 67 % wurden im chronischen Stadium (älter als 14 Tage nach der klassischen Einteilung; S. 92 ff), 33 % im akuten Stadium implantiert. Wegen der Heterogenität des Kollektivs sind differenzierte Aussagen zur Behandlung von Komplikationen der Dissektion durch die Stentprothese aus dieser Untersuchung schwer zu treffen. Als wichtigstes Ergebnis gilt die morphologische Veränderung der Aorta im Langzeitverlauf von bis zu 2 Jahren: Aufweitung des wahren Lumens bei praktisch gleichbleibendem Aortendurchmesser. Damit wurde durch die Stentprothesen die sekundäre Vergrößerung der dissezierten Aorta verhindert. Die Stentprothesenimplantationen waren zu 95 % technisch erfolgreich. Es sind wenige implantationstechnische Komplikationen beschrieben. Es ereigneten sich 2 retrograde Typ-A-Dissektionen. Insgesamt hat diese Stentprothese bei dem komplizierten Krankengut gute Ergebnisse geliefert und die gute Adaptationsfähigkeit an den Aortenbogen in der Praxis gezeigt.

◆ CLINICAL INVESTIGATION ◆

Endovascular Treatment of Patients With Types A and B Thoracic Aortic Dissection Using Relay Thoracic Stent-Grafts: Results From the RESTORE Patient Registry

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Purpose: To evaluate the safety and performance of Relay stent-grafts in patients with acute or chronic aortic dissections.
Methods: Patients with types A or B aortic dissections suitable for treatment with Relay stent-grafts and followed for 2 years after thoracic endovascular aortic repair (TEVAR) were identified from a company-sponsored registry database established in January 2006. Ninety-one consecutive patients (69 men; mean age 65 years) underwent TEVAR with Relay stent-grafts for dissection. Most patients (76, 84%) had type B dissections; 61 of all patients were classified as chronic and 30 as acute.
Results: The technical success rate was 95% (97% in acute, 95% in chronic, and 93% in type B dissections). The type I endoleak rate was 7% (7% in acute and 8% in chronic dissections); all occurred in patients with type B dissections. Paraplegia, paraparesis, and stroke occurred in 4, 1, and 2 patients, respectively; 2 cases of paraplegia occurred in patients with acute type B dissections. Thirty-day mortality was 8% (13% in acute and 5% in chronic dissections); all deaths occurred in patients with type B dissections. The 2-year survival rate was 82% in the overall population and 84% in patients with type B dissections.
Conclusion: The combination of Relay's features, such as stent conformability, radial force, atraumatic design, and controlled deployment and fixation, may contribute to the safety of the Relay stent-grafts for the treatment of thoracic aortic dissections, including acute and chronic type B dissections.

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Key words: thoracic endovascular aortic repair, stent-graft, aortic dissection, type B aortic dissection, outcome analysis, mortality, endoleak, complications, device design

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Although aortic dissection is a relatively rare condition, it is the most frequently diagnosed lethal condition of the aorta, especially in the setting of acute dissections. Based on the Stanford classification system,[1] ~60% of dissections are classified as type A and the remaining 40% as type B dissections. Immediate surgery is the preferred treatment for both hemodynamically unstable and stable patients with confirmed type A dissections. Uncomplicated type B dissections are usually

See commentary page 144

treated conservatively, while surgery is reserved for complicated dissections, i.e., those accompanied by (imminent) rupture, intractable chest pain, false lumen aneurysm formation, uncontrollable hypertension, and end-organ ischemia.[2] In spite of improvements in surgical techniques, surgery is still associated with high morbidity and mortality. Recent data from the International Registry of Acute Aortic Dissection (IRAD) indicate an in-hospital mortality of 27% in surgically treated patients with type A dissections and 32% in patients with complicated type B dissections.[3]

Since the introduction of thoracic endovascular aortic repair (TEVAR) in 1999,[4,5] this technique is being increasingly used for the treatment of most complications of acute and chronic type B dissections,[3,6] with demonstrated technical feasibility and clinical safety.[7–10] A systematic review of 609 patients with acute or chronic dissections reported a technical success rate of 98%, a 30-day in-hospital mortality of 5%, an overall 2-year survival rate of 89%, a 1% incidence of paraplegia, and a 2% incidence of stroke. Overall complications were significantly higher in patients undergoing stent-graft placement for acute dissection (21.7% versus 9.1% in chronic dissection, $p=0.005$).[11]

TEVAR has also shown encouraging results when compared with surgical treatment. In a recent propensity analysis of patients with acute type B dissections, in-hospital mortality was significantly higher after surgery (33.9%) than after TEVAR (10.6%, $p=0.002$). In-hospital complications occurred in 20% of patients who underwent TEVAR and 40% of surgically treated patients.[10] However, the role of TEVAR in uncomplicated type B dissections is still uncertain. Recently, the randomized INvestigation of STEnt Grafts in Aortic Dissection (INSTEAD) trial failed to demonstrate the benefit of TEVAR with Talent thoracic stent-grafts over medical therapy alone in survivors of uncomplicated chronic type B aortic dissections.[12]

RESTORE (Relay Endovascular Registry for Thoracic Disease) is a European multicenter clinical registry prospectively enrolling patients with thoracic aortic pathologies treated with the Relay and Relay NBS (no bare stent) stent-grafts currently available in Europe. Preliminary results on 150 elective and acute patients followed for 2 years demonstrated an overall 97% technical success rate; 3% of patients developed paraplegia and 9% developed endoleaks.[13] Early mortality was 10%. No stent-graft collapse, rupture, infolding, or migrations were observed.

The objective of this substudy performed on RESTORE registry patients was to evaluate the safety and performance of the Relay thoracic stent-grafts in patients with types A or B acute or chronic aortic dissections.

METHODS

Study Design

The company-sponsored RESTORE registry began in January 2006 to enroll patients with various thoracic aortic pathologies treated with the Relay thoracic stent-graft (Bolton Medical SL, Barcelona, Spain) at 22 centers across Europe. Data obtained during the entire observation period were recorded in the appropriate case report forms, and confidentiality was maintained across the study, which was conducted in accordance with the Declaration of Helsinki.

Eligibility. According to definitions of the European Society of Cardiology task force on aortic dissection,[14] adult patients with aortic dissections, including classical dissections, intramural hematoma, and penetrating ulcers (excluding blunt aortic trauma), were eligible for TEVAR with Relay thoracic stent-grafts if they had (1) proximal and distal aortic necks suitable for stent-graft placement (i.e., diameter ranging between 18 and 42 mm); (2) proximal and distal landing zones suitable for the stent-graft; (3) vascular dimensions, such as aortic diameters and distance from the left

subclavian artery (LSA) to celiac artery, within a range that could be safely treated with a Relay thoracic stent-graft; and (4) adequate vascular access for insertion of the delivery system, i.e., femoral or iliac arteries a minimum 7 mm in diameter to accommodate the 22 to 26-F outer-diameter delivery system and no excessive disease precluding delivery system entry/passage or iliac arteries that could be extended via an access conduit.

Exclusion criteria included pregnant or lactating women, lesion location inaccessible to the delivery system, insufficient arterial access for delivery system entry, insufficient internal diameter of the aorta to accommodate the stent-graft sheath, severe arterial disease, excessive arterial tortuosity, arterial or lesion size incompatible with the stent-graft, congenital connective tissue disease, active systemic infection, mycotic lesions of the aorta, severely compromised left ventricular function, or untreatable allergy to intra-arterial contrast, any of the components of the Relay device, or anticoagulant therapy.

Stent-Grafts

Relay stent-grafts consist of a self-expanding nitinol stent sutured to a polyester vascular graft fabric. In both types, Relay and Relay NBS (Fig. 1), the skeleton of the device is a series of sinusoidal stents with different radial force according to the position along the length of the graft. A curved nitinol wire attached to the graft fabric is attached from the proximal to the distal aspects of the graft with surgical suture, adding column strength while at the same time providing flexibility and torque response to the stent-graft (Fig. 1A). In the Relay NBS, the nitinol stent at the proximal end of the stent-graft is covered with fabric, forming a crown and proximal stent combination (Fig. 1B). Because of this lack of proximal bare stents and the ''crowned'' design of the first proximal stent, Relay NBS is considered particularly suitable for the treatment of acute type B aortic dissections because it avoids potential retrograde dissections that may be promoted by the presence of somewhat more traumatic proximal bare stents or by endografts exhibiting excessive radial force.[6,13]

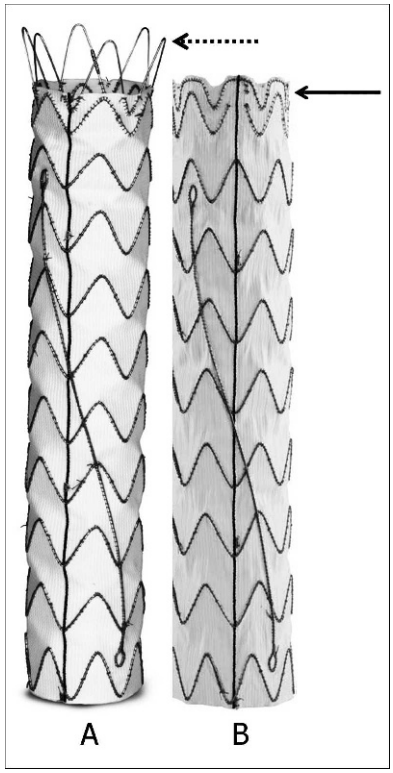

Figure 1 ◆ In the Relay stent-graft, the curved nitinol wire starts below the second row of proximal covered stents and ends close to the distal stent, allowing for sufficient column strength while at the same time providing flexibility and torque response. (**A**) Relay has an alignment zone (dotted arrow) to provide optimal alignment with aortic anatomy and allow proximal capture of the stent-graft for accurate placement. (**B**) In Relay NBS, the proximal end is covered with polyester vascular graft fabric (solid arrow) to optimize apposition of the proximal end of the graft to the lumen wall while minimizing trauma to the intima and risk of fabric infolding.

The Transport Delivery System used by the Relay thoracic stent-grafts consists of a series of coaxially arranged sheaths and catheters (primary introduction sheath and a secondary delivery sheath), a handle, and an apex release mechanism. The stent-graft is constrained within the secondary sheath, which is within the primary sheath. Its novel system of proximal capture of the stent-graft allows a precise and controlled deployment of the endograft within the vessel lumen. A detailed description of the delivery system can be found elsewhere.[13]

Study Protocol

Baseline assessments. Before stent-graft placement, patients underwent a thorough medical history and physical examination, including characterization of vessel access and diagnostic imaging studies [e.g., multidetector computed tomography (CT), magnetic resonance imaging (MRI), or angiography] to assess lesion morphology. Dissections were morphologically classified into type A or B based on the Stanford system[1] and into acute (≤14 days) or chronic (>14 days) depending on the time after the onset of symptoms. If >3 months had elapsed between the screening imaging and the baseline visit, a new imaging study was performed.

Intraprocedural assessments. Procedures were performed under fluoroscopic guidance by cardiothoracic surgeons, vascular surgeons, or interventional radiologists using either a fixed or portable C-arm digital subtraction angiography system. Throughout the procedure, data regarding type of anesthesia; access site; device number, size, and configuration; deployment, migration, patency, and integrity of the device; additional procedures performed prior to or during implantation (such as transposition or bypass); balloon usage; duration of the procedure; estimated blood loss; need for transfusion of blood products; volume of contrast medium; and challenges and complications encountered were recorded in the case report forms. Pre- and periprocedural angiograms were performed for measurement purposes. Postimplantation completion angiography was always carried out to verify immediate results of the procedure.

Postprocedural assessments. Information regarding procedure- or device-related systemic, neurological, and major adverse events (MAEs); duration of intensive care unit (ICU) and hospital stays; need for conversion to open repair; and death within 30 days after the procedure was recorded. Device integrity and lesion status (diameter, length, endoleak rate, and device placement) were evaluated using diagnostic imaging. After discharge, regular follow-up examinations were conducted at 1, 6, 12, and 24 months to assess patient health status, abnormal systemic and neurological findings, and the condition of the incision site. Stent-graft position and condition of the lesion were assessed by means of CT scan, chest radiography, angiography, MRI, and transesophageal ultrasound.

Patient Sample

For this investigation, interrogation of the registry database identified 91 consecutive patients (69 men; mean age 65 years) with aortic dissection enrolled from 17 centers (Appendix) between January 2006 and January 2009 and followed for 2 years after treatment. Written informed consent was obtained from each patient or legal representative. Preliminary midterm results from the RESTORE registry, which included a subset of 29 patients with aortic dissections, were published in 2008.[13] Patients with indications for stent-graft placement included those unfit for surgery (43, 47%) or with a history of previous thoracotomy (13, 14%) or TEVAR (3, 3%).

Comorbidities (Table 1) included hypertension (85%), smoking (43%), cardiac disease (36%), chronic obstructive pulmonary disease (31%), hyperlipidemia (31%), renal disease (15%), diabetes mellitus (10%), carotid artery disease (5%), angina pectoris (6%), and congestive heart failure (3%). A history of acute myocardial infarction was present in 11 patients. Ten patients had undergone percutaneous transluminal coronary angioplasty, while 2 had undergone coronary artery bypass grafting. Overall, 62 (68%) patients were classified as American Society of Anesthesiologists (ASA) class 3 or above.

Of the 91 patients, 61 (67%) presented with chronic dissections (>14 days) and 30 (33%) presented with acute dissections. The majority of patients (76, 83%) had aortic type B dissections (67% chronic and 33% acute), 3 patients had aortic type A dissections (2 chronic and 1 acute), and the remaining 12 cases were unreported. The etiology of the 76 type B dissections was classic aortic dissections in 41 (54%), penetrating ulcers in 17 (22%), intramural hematomas in 9 (12%), and Marfan syndrome in 1 (1%). The remaining 8

TABLE 1
Baseline Data of 91 Patients With Aortic Dissection From the RESTORE Registry

Mean age, y	65 (25–86)
Men	69 (76%)
Comorbidities	
Hypertension	77 (85%)
Smoking	39 (43%)
Cardiac disease	33 (36%)
COPD	28 (31%)
ASA class ≥3	62 (68%)
Dissection characteristics	
Stanford type A	3 (3%)
Stanford type B	76 (84%)
Type not reported	12 (13%)
Acute	30 (33%)
ASA class ≥3	23
Chronic	61 (67%)
ASA class ≥3	39
Complicated	23 (25%)
Uncomplicated	68 (75%)

Continuous data are presented as means (range); categorical data are given as counts (percentages). RESTORE: Relay Endovascular Registry for Thoracic Disease, ASA: American Society of Anesthesiologists, COPD: chronic obstructive pulmonary disease.
* More than one condition per patient.

(11%) patients were classified as having ''other'' etiologies.

A quarter of the patients (n=23) had uncomplicated dissections; the other 68 (75%) patients presented with aneurysm formation (AF, n=32), branch vessel ischemia (BVI, n=5), rupture (n=5), persistent pain (PP, n=6), AF + BVI (n=5), BVI + rupture (n=2), rupture + PP (n=4), BVI + PP (n=6), AF + rupture + PP (n=1), and BVI + rupture + PP (n=2). Sixty-one (80%) of the 76 patients with aortic type B dissections were complicated.

The location of the entry tear was the descending aorta in 54 (59%) patients, the aortic arch in 23 (25%), the abdominal aorta above the celiac axis in 4 (4%), the infrarenal aorta in 4 (4%), and the ascending aorta in 6 (7%) patients. In the latter 6 patients, supra-aortic debranching with rerouting of the upper trunks, an elephant trunk technique, or a similar surgical maneuver was performed before TEVAR.

Definitions and Statistical Analysis

Definitions of neurological adverse events and major adverse events (MAE) were based on International Organization for Standardization definitions for cardiovascular implants/endovascular devices (ISO 25539-1:2003). Deaths included in the analysis were only those resulting from MAEs or device- or procedure-related complications. Technical success was considered when complete covering of entry sites was achieved without endoleak or surgical conversion. Categorical variables are given as counts (percentages), and continuous variables are described using the mean or median, range, and 95% confidence intervals (CI). Survival rates were estimated by the Kaplan-Meier method. Changes in aortic and true lumen diameters between the baseline and serial follow-up images at 1, 6, 12, and 24 months were evaluated for significant differences using Pearson's chi-square test. Significance was set at $p<0.05$. Statistical analyses were performed using SAS statistical software (version 9.1.3; SAS Institute, Inc, Cary, NC, USA).

RESULTS

Intraprocedural Data and Early Outcomes

Femoral access was used in 80 (88%) of the procedures, and the mean access site diameter was 8.5 mm; iliac (n=10) and transconduit (n=1) accesses were used in the remaining patients. A mean of 1.2 stent-grafts were implanted per patient; the majority had bare stents (87%), while only 7% were Relay NBS stent-grafts (6% unreported). The mean stent-graft length was 178.9 mm, and the median proximal and distal diameters were 36 and 34 mm, respectively (Table 2). The landing zone involved aortic arch zones[15] 0 to 2 in 48 (53%) patients and zones 0 to 3 in 77 (85%) procedures (the latter in 83% of patients with acute dissections and 85% in patients with chronic dissections).

Fifteen (17%) procedures were challenging owing to arterial complications, namely occlusion of side branches, including the LSA (most of them intentional). One iatrogenic occlusion of the celiac trunk occurred. Placement of the stent-graft was hampered by

TABLE 2
Intra- and Postprocedural Data From 91 TEVARs Using the Relay Thoracic Stent-Grafts

Intraprocedural Data	
Access site diameter, mm	8.5 (7.0–15.0)
Stent-graft length, mm	178.9 (90.0–250.0)
Landing zone	
0 to 2	48 (53%)
0 to 3	77 (85%)
Additional procedures	47 (52%)
Duration of procedure, h	2.1 (0.7–9.0)
Blood loss, mL	443.0±226
Technical success, %	95 (95% CI 88 to 98)
Type I endoleak rate, %	7 (95% CI 4 to 15)
Complications	
Device-related	8 (9%)
Neurological	
Paraplegia	4 (4%)
Paraparesis	1 (1%)
Stroke	2 (2%)
Postprocedural Data	
ICU stay, d	2.6 (0.1–30.0)
Hospital stay, d	17.8 (1.0–99.0)
Overall 30-day mortality	7 (8%)
In acute dissection patients	4/30 (13%)
In chronic dissection patients	3/61 (5%)
Overall 2-year survival, %*	99 (95% CI 91 to 100)

Continuous data are presented as means ± standard deviation or (range); categorical data are given as counts (percentages).
TEVAR: thoracic endovascular aortic repair, ICU: intensive care unit, CI: confidence interval.
* Kaplan-Meier estimate for freedom from device-related deaths *only*.

failure to deploy the stent-graft at the intended landing zone owing to difficulty in visualizing the radiopaque markers.

Forty-seven (52%) patients required additional procedures, including supra-aortic vessel transposition or bypass (25, 27%), visceral or renal artery bypass (2, 2%), cerebrospinal fluid drainage (3, 3%), dilation ± stenting of visceral or renal arteries (4, 4%; Fig. 2), or other unspecified procedures (13, 14%).

Endografting was technically successful in 95% (95% CI 88 to 98) of the overall study population (in 97% and 95% of patients with acute and chronic dissections, respectively). Type I endoleaks occurred in 6 patients within 30 days of the procedure, all in patients with type B dissections (2 in acute dissections and 4 in chronic dissections). Another patient had a type II endoleak >30 days after the procedure.

Device-related complications occurred in 8 (9%) patients: 6 stent-graft migrations, 1 failure to advance the delivery system, and a partial collapse of the stent-graft (Fig. 3). Neurological complications were observed in 7 (8%) patients: 4 (4%) cases of paraplegia, 1 (1%) paraparesis (1%), and 2 (2%) strokes. All complications occurred in patients with acute aortic dissections except 2 of the paraplegia cases.

None of the patients required conversion to open repair; however, 4 patients had transfemoral (n=2), transthoracic (n=1), and extra-anatomic (n=1) secondary interventions. The transthoracic intervention was a conventional thoracoabdominal aortic replacement in the Marfan patient, who presented a contained rupture in the abdominal aorta. Overall, procedures lasted for a mean of 2.1 hours (2.2 hours in the acute dissections). Mean blood loss was 256.8 mL in patients with acute dissections and 443.0 mL in the overall population. Mean stays in the ICU and hospital were 2.6 and 17.8 days, respectively.

The 30-day mortality was 8% (n=7) in the overall population: 5 in acute dissections and 2 in chronic dissections. All deaths occurred in patients with complicated type B dissections (Table 3). Overall survival rates at 1 and 2 years were 83% (95% CI 71 to 90) and 82% (95% CI 71 to 90), respectively. In the 76 patients with type B dissections, 1- and 2-year survival rates were 85% (95% CI 73 to 92) and 84% (95% CI 73 to 92). When only device-related deaths were considered, the survival rate in the overall population was 99% (95% CI 91 to 100) at both 1 and 2 years; in type B dissections, the rate was 98% (95% CI 89 to 1.0) at both time points.

True and False Lumen Outcomes

The mean follow-up was 10.1±12.0 months. Complete/partial thrombosis of the false lumen was documented in 40%/60%, 63%/37%, 68%/32%, and 100%/0% of patients at 1, 6, 12, and 24 months, respectively. Aortic measurements (Table 4) were obtained for the normal aortic diameters 2 cm proximal to

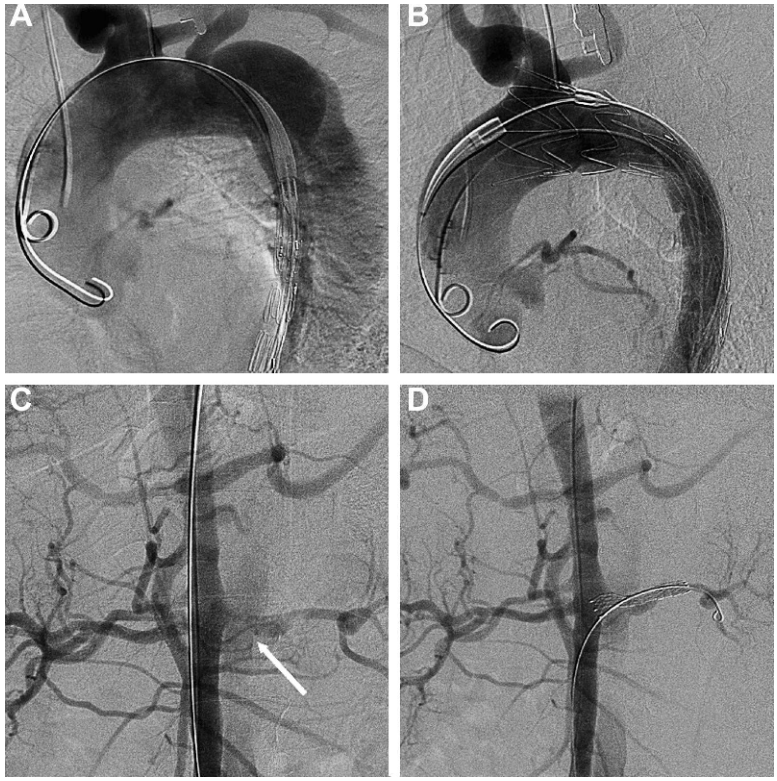

Figure 2 ◆ Intraoperative angiography in a 42-year-old man with an acute type B dissection. (**A**) Typical aortic dissection with an entry tear distal to the left subclavian artery (LSA). The inner sheath of the delivery system is parked underneath the arch. (**B**) Delivery of the Relay stent-graft. The entry tear has been sealed and the LSA occluded. (**C**) Thoracoabdominal angiogram after placement of the stent-graft showing a residual compromise of the left renal artery (white arrow). (**D**) Completion angiogram after placement of a self-expanding nitinol E-njoy peripheral stent in the left renal artery and extending into the true lumen.

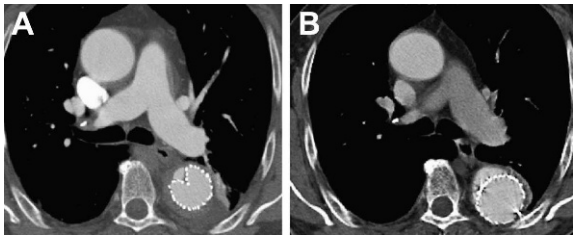

Figure 3 ◆ Computed tomography of the proximal end of a Relay NBS stent-graft used for the treatment of an intramural hematoma in a 74-year-old man. (**A**) On the sixth postoperative day, infolding of the 40-mm stent-graft occurred due to an endograft oversizing of 18%. (**B**) Four months after the procedure, the infolded stent-graft showed spontaneous re-expansion due to dilatation of the aortic segment.

entry tear, the minimum true lumen diameters at mid-level of the dissection, and the normal aortic diameters below the dissection at baseline (in 82, 77, and 62 patients, respectively), 1 month (in 50, 40, and 38 patients, respectively), 6 months (in 39, 31, and 33 patients, respectively), 12 months (in 26, 22, and 20 patients, respectively), and 24 months (in 5 patients for every measurement). Because of the low number of patients at 24 months, these results must be interpreted with caution.

The mean normal aortic diameter 2 cm proximal to entry tear (Fig. 4A) decreased from 30.0 mm (95% CI 28.8 to 31.3) before stent-graft placement to 29.6 (95% CI 24.4 to 34.8) on the last CT image obtained 24 months

TABLE 3
Causes of the 7 Periprocedural Deaths

Type of Dissection	Cause of Death (comment)
Acute B, complicated	Cardiac arrest (double axillary-femoral bypass after TEVAR)
Acute B, complicated	Intracerebral hemorrhage
Acute B, complicated	Not reported (urological and abdominal surgical procedures performed on the same day as TEVAR)
Subacute B, complicated	Retrograde type A dissection
Chronic B, complicated	Mesenteric ischemia, renal failure, and shock
Chronic B, complicated	Abdominal ischemia
Subacute B, complicated	Renal and hepatic failure (transfusion complication)

TEVAR: thoracic endovascular aortic repair.

after the procedure. Overall, differences between pre- and post-procedure diameters were not statistically significant (p=0.15). As shown in Figure 4A, the means and CIs hardly varied during the first year of follow-up. Conversely, the mean minimum true lumen diameter at mid-level increased significantly from 20.8 mm (95% CI 18.1 to 23.5) before stent-graft placement to 32.6 mm (95% CI 0.7 to 64.5) at 24 months post TEVAR (p=0.05; Fig. 4B). Changes in the mean normal aortic diameter below the dissection were less uniform (Fig. 4C). By the end of the follow-up period, the aortic diameter had increased from 27.9 mm (95% CI 26.1 to 29.6) to 31.2 mm (95% CI 27.8 to 34.6). However, differences between these diameters were not statistically significant (p=0.26).

DISCUSSION

This subanalysis of the RESTORE registry data shows that TEVAR with Relay thoracic stent-grafts is a feasible, safe, and effective option for the treatment of patients with aortic dissections, as evidenced by the high rate of technical success, acceptable endoleak and neurological complication rates, and satisfactory 1- and 2-year survival rates.

A diagnosis of type B aortic dissection carries a poor prognosis, even with timely diagnosis and treatment.[3,16] Moreover, a considerable proportion of patients develop dissection-related complications during the chronic phase, requiring interventional treatment or open surgery to prevent aortic rupture.[17,18] Open surgery carries a 4.5% risk of paraplegia and a 9% risk of stroke in patients with acute type B dissections.[19] TEVAR has progressively been gaining acceptance for the treatment of aortic dissections and associated complications since the first successful reports.[4,5,20] Despite these favorable outcomes, TEVAR failed to improve survival in uncomplicated dissections in the first 2 years.[12]

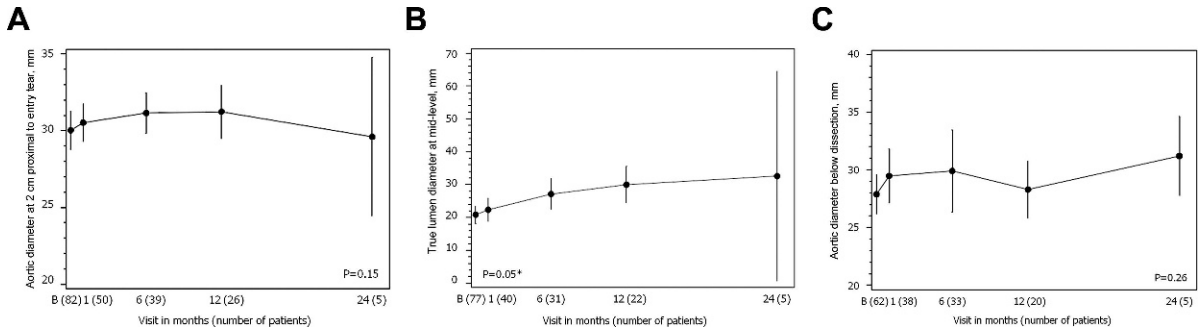

Figure 4 ◆ (**A**) Mean normal aortic diameters 2 cm proximal to entry tear before and after stent-graft placement. (**B**) Mean minimum true lumen diameters at mid-level before and after stent-graft placement. *Statistically significant. (**C**) Mean normal aortic diameters below the dissection before and after stent-graft placement. Bars indicate the 95% confidence interval.

TABLE 4
Mean Aortic Diameters Before and After Stent-Graft Placement in the Overall Population

Measurement	Baseline	1 Month	6 Months	12 Months	24 Months	p
Normal aortic diameter 2 cm proximal to entry tear, mm	30.0 (28.8 to 31.3)	30.5 (29.3 to 31.7)	31.2 (29.8 to 32.5)	31.2 (29.5 to 33.0)	29.6 (24.4 to 34.8)	0.15
Minimum true lumen diameter at mid-level of the dissection, mm	20.8 (18.1 to 23.5)	22.3 (18.6 to 25.8)	27.1 (22.4 to 31.8)	29.9 (24.4 to 35.5)	32.6 (0.7 to 64.5)	0.05
Normal aortic diameter below the dissection, mm	27.9 (26.1 to 29.6)	29.5 (27.1 to 31.8)	29.9 (26.3 to 33.5)	28.3 (25.8 to 30.8)	31.2 (27.8 to 34.6)	0.26

Data are presented as the mean (95% CI).

The rationale behind TEVAR use in aortic dissections is to obliterate the false lumen and restore the normal aortic anatomy in order to prevent aortic expansion and/or rupture. In our study, the 95% technical success rate (98% in acute and 93% in type B dissections) compared well with several studies involving larger populations of patients,[11] including a single-center study that involved first- and second-generation stent-grafts[21] and the more recent Talent Thoracic Retrospective Registry,[22] all of which reported success rates of 92% to 98%. Moreover, our results improve upon the 89% and 78% technical success rates in acute and chronic type B dissections, respectively, reported by Guangqi et al.[23] and also those achieved in EUROSTAR (European Collaborators on Stent-Graft Techniques for Aortic Aneurysm Repair) and the UK Thoracic Endograft Registry,[9] in which technical success was achieved in 89% of patients.

Neurological sequelae are one of the most dreaded complications of TEVAR. Rates of stroke and spinal cord injury (paraplegia/paraparesis) reported in recent studies of TEVAR for aortic dissection range from 0% to 4%.[11,23,24] Similar rates of paraplegia and paraparesis were obtained in this study (4% and 1%, respectively), supporting the safety of TEVAR with Relay devices. Regarding our low 2% stroke rate, this outcome may derive from the unique features of the Relay delivery device, which include a novel proximal tip capture mechanism (present in all Relay stent-grafts since the product was launched in 2005) and a nested double sheath design. Both features add precision, and probably also atraumaticity, during deployment and implantation, because the proximal aspect of the stent-graft is released as the final procedural step. Stroke and spinal cord injury after TEVAR have been associated with obesity, significant intraoperative blood loss ($>$1200 mL), vascular embolization,[25] female gender, LSA occlusion without revascularization, lengthy procedure times ($\geq$160 minutes),[26] and the use of $\geq$3 stent-grafts (i.e., aortic length covered $\geq$205 mm).[27]

Endoleak is the most common complication of TEVAR, with rates ranging from 6% to 22% in patients with aortic dissections.[23,24]

Endoleaks can originate from inadequate fixation to the aortic wall, incompetent overall seal between stent-grafts, or graft defects.[6] In this study, type I endoleaks occurred in 6 patients, a low and acceptable incidence similar to that obtained in other studies.

Long-term survival is a major unsolved challenge in patients with type B dissections. In this study, the 2-year survival rate for patients with type B dissections was 84% (95% CI 73 to 92), very similar to an IRAD follow-up survival study in which the median 2-year procedure- or device-related mortality was 1.3% (95% CI 91 to 100) and the 2-year overall survival rate was 83%.[16] Guangqi et al.[23] reported 2-year survival rates after TEVAR of 88% and 75% in patients with acute and chronic dissections, respectively. In their meta-analysis, Eggebrecht et al.[11] reported a survival rate of 89%. Without being optimal, survival rates obtained with Relay devices exceeded those achieved with surgical repair (78%) or medical treatment (76%) reported by the IRAD.[16]

Independent predictors of follow-up mortality include female sex, in-hospital renal failure or hypotension/shock, pleural effusion on chest radiography, and a history of prior aortic aneurysm or atherosclerosis.[16] Although these factors cannot be controlled by further improvements in endograft devices, they strongly suggest that strict monitoring is essential to improve mid- and long-term survival after an effective repair of the aortic dissection. Any side branch occlusion that does not resolve with placement of a stent-graft alone needs to be diagnosed and treated with additional endovascular procedures (Fig. 3).

Avoidance of malperfusion syndromes is critical to survival. However, during early stages, their diagnosis is frequently missed, thus requiring the use of advanced diagnostic imaging techniques to identify them.[14] Compared with results from IRAD,[16] the INSTEAD trial[12] (INvestigation of STEnt Grafts in Aortic Dissection) showed an improvement in the outcome of patients with acute type B dissections treated with medical therapy, which could be partly attributed to advances in imaging techniques and increased expertise. When a malperfusion syndrome is identified in time, decompression of the false lumen by implantation of a stent-graft is the most successful therapy,[28] yielding far better results than conventional surgery.[29]

Several studies have shown that TEVAR yields better short-term outcomes in terms of mortality and associated complications than open repair of type B aortic dissections.[3,10] In our study, the 30-day mortality was 8%. The EUROSTAR and IRAD studies both reported mortality rates of 6.5%,[3,9] and mortality in the meta-analysis[11] was 5.3%. We observed higher 30-day mortality in patients with acute rather than chronic dissections (13% versus 5%, respectively). Our results agree with those of Eggebrecht et al.[11] (9.8% versus 3.2% for acute and chronic dissections, respectively; $p=0.015$) but differ from the results obtained by Guangqi et al.,[23] who reported a 30-day mortality of 1.4% in acute dissections and of 8.2% in chronic dissections. Patients with acute dissections may present with complications such as malperfusion syndromes and hemodynamic instability,[3] and overall they have poorer preoperative health status than chronic patients. Therefore, higher in-hospital mortality is expected in acute patients, in agreement with our findings.

Finally, the significant increase in the minimum true lumen diameter ($p=0.05$), together with the absence of significant progression in the proximal and below-dissection aortic diameters ($p=0.15$ and $p=0.26$, respectively) observed in our study at 12 and 24 months post procedure could be considered a sign of favorable aortic remodeling and aortic stability. Continued false lumen patency, as opposed to aortic remodeling, is among the strongest predictors of secondary aneurysm formation over time.[30,31] TEVAR has been shown to induce aortic remodeling in patients with type B aortic dissections,[12,32,33] thus representing a potential advantage of this technique over medical therapy for the treatment of these patients.

Retrograde type A dissections are a rare but serious complication that may be associated with stent-graft placement, but controversy persists regarding whether stent-grafts with proximal bare stents have a higher risk for this complication.[34,35] However, the fact

that retrograde type A dissections are not limited to a specific stent-graft may also suggest that it is the semi-rigid design of the device rather than the proximal bare spring that may be responsible for the aortic tear.[34] In RESTORE, we have documented 2 retrograde dissections, one of them in the present study and the other was described in Zipfel et al.[34] Both tears occurred while using the standard configuration of Relay stent-grafts. Although Relay NBS was developed to avoid the influence of bare springs, this device was available only at the end of the study period and thus only 7% of NBS configurations where used. Because of this, available information is limited, and follow-up data are not mature enough to draw conclusions. In the near future, it will be interesting to compare outcomes of the 2 different proximal configurations in an otherwise identical stent-graft design, which is the one of the objectives of the currently ongoing RESTORE II registry.

Conclusion

The results obtained from this subanalysis of the RESTORE registry patients are encouraging and provide additional support for TEVAR using Relay stent-grafts for acute and chronic aortic dissections. The combination of Relay's features, such as high stent conformability, low stent radial force, smooth and atraumatic design, controlled deployment, and fixation by its proximal capture mechanism, suggest that TEVAR using Relay devices is a feasible and safe procedure for the endovascular treatment of aortic dissections, including acute and chronic type B dissections.

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APPENDIX

Centers enrolling the 91 RESTORE registry patients with aortic dissections: Deutsches Herzzentrum Berlin, Germany (Burkhart Zipfel and Roland Hetzer, n=23); Allgemeines Krankenhaus Wien, Austria (Martin Czerny and Martin Funovics, n=17); Nuovo Ospedale Sant'Agostino Estense, Modena, Italy (Gioacchino Coppi, n=9); Azienda Ospedaliera Universitaria San Martino, Genova, Italy (Carlo Ferro, n=8); Hôpital de Rangueil, Toulouse, France (Herve Rousseau, n=8); Ospedale del Cuore, Fondazione G. Monasterio, Massa, Italy (Sergio Berti, n=5); IRCCS Policlinico San Donato Milanese, Milano, Italy (Domenico G. Tealdi, n=4); Hospital Clinic Provincial, Barcelona, Spain (Vincent Riambau, n=3); Ospedale San Filippo Neri, Roma, Italy (Nicola Mangialardi and Pierluigi Costa, n=3); Policlinico Santa Maria Le Scotte, Siena, Italy (Carlo Sassi, n=3); HRU Carlos Haya (Alfonso Muñoz, n=2) and Hospital Clinico Universitario De Malaga, Málaga, Spain (Alberto M. Palanca, n=1); IRCSS Ospedale San Raffaele, Milan, Italy (Roberto Chiesa and Enrico Maria Marone, n=1); Hospital Virgen De La Salud, Toledo, Spain (M. Doblas, n=1); Hospital Universitari Germans Trias I Pujol, Badalona, Spain (Carlos Esteban, n=1); Hospital Universitario Marques De Valdecilla, Santander, Spain (Ivan García, n=1); Evangelismos Hospital, Athens, Greece (Ioannis Kaskarelis, n=1).

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2.4. Stentprothesen bei traumatischer Aortenruptur

Zipfel B, Chiesa R, Kahlberg A, Marone EM, Rousseau H, Kaskarelis I, Riambau V, Coppi G, Ferro C, Sassi, Esteban C, Mangialardi C, Tealdi DG, Nano G, Schoder M, Funovics M, Buz S, Hetzer R.
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Nach dem die Vorteile der endovaskulären Behandlung bei akuten traumatischen Aortenrupturen im Vergleich zur konventionellen Operation am eigenen Klinikkollektiv gezeigt werden konnten [79], untersucht diese Arbeit die Effektivität der Relay® Prothese an der Untergruppe des RESTORE Registers von 40 Patienten mit einer Nachbeobachtung von 2 Jahren. Es zeigten sich exzellente Frühergebnisse ohne durch die Implantate bedingte Komplikationen, obwohl die Analyse der Fälle im Detail ergab, das in 30 % von den Empfehlungen des Herstellers zur Dimensionierung der Stentprothese abgewichen wurde. Es ist die bislang einzige Publikation, in der dieser praktisch wichtige Aspekt untersucht wurde. Im Kontrast zu Berichten kollabierter Stentprothesen anderer Typen, bei denen einer exzessiven Überdimensionierung die wesentliche Rolle bei dieser schwerwiegenden Komplikation zugeschrieben wurde, scheint diese Stentprothese, wahrscheinlich wegen ihrer speziell an den Aortenbogen angepassten Konstruktion, solche in Notfallsituationen häufig unvermeidbaren Fehler eher zu verzeihen und die Therapie sicherer zu machen. Auch die mittelfristigen Ergebnisse bis zu 2 Jahren sind exzellent, wobei einschränkend die Schwierigkeit von kompletten Nachuntersuchung gerade bei dem Kollektiv der Traumapatienten zu berücksichtigen ist.

Endovascular Repair of Traumatic Thoracic Aortic Injury: Final Results From the Relay Endovascular Registry for Thoracic Disease

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Background. **In blunt thoracic aortic injury, thoracic endovascular aortic repair (TEVAR) offers a less invasive alternative to open chest surgery. New reliable and accurate stent grafts have widened the endovascular treatment options. We report our experience with the Relay stent graft Bolton Medical, Sunrise, FL; Barcelona, Spain) for treatment of this injury.**

Methods. **Relay Endovascular Registry for Thoracic Disease (RESTORE) is a multicenter, prospective European registry, which enrolled patients treated with the Relay stent graft for thoracic aortic diseases from April 2005 to January 2009. Regular follow-up examinations were conducted for up to 24 months. This paper analyzes the cohort of patients treated for traumatic aortic injury.**

Results. **Forty adult trauma patients from 12 European centers underwent TEVAR. Mean age was 40 years and 34 patients were male. The proximal landing zone involved aortic arch zones 1 to 2 in 40% and zone 3 in 55% of procedures. Technical success was achieved in all cases. One (2.5%) patient suffered a rupture of the iliac artery. No patient developed procedure-related paraplegia or required conversion to open surgery. Follow-up imaging demonstrated complete exclusion of the traumatic tear and regression of the false aneurysms without endoleak or graft infolding. One late device-related complication was reported; penetration of the distal end of the stent graft treated by stent-graft extension. Thirty-day mortality was 2.5 % (n = 1), and late mortality 2.5% due to a secondary accident. Actuarial 2-year survival was 93.7%.**

Conclusions. **Thoracic endovascular aortic repair with the Relay stent graft is a safe and effective treatment for patients with traumatic aortic injury.**

(Ann Thorac Surg 2014;97:774–81)

One of the most life-threatening consequences of blunt chest trauma is rupture of the thoracic aorta. An estimated 80% to 90% of all victims die at the scene of the accident. In survivors a thin layer of adventitia that covers a transverse tear in the intima and media prevents complete rupture and thus produces a traumatic pseudoaneurysm. If untreated, approximately 30% of surviving patients admitted to a hospital will die within the first 24 hours [1, 2]. Most injuries occur in the proximal descending thoracic aorta or, less commonly, at the arch or ascending aorta, just distal to the aortic valve [2, 3].

In addition to traumatic aortic injury, most patients presenting with blunt chest trauma sustain multiple open and closed extrathoracic lesions [2, 4, 5], which may

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prompt the development of shock and coma more likely than the aortic pseudoaneurysm. In order to minimize morbidity and mortality in the multiply traumatized patient, the choice of treatment for aortic injury repair is critical.

The past decade has witnessed an important shift in the management of selected traumatic aortic injuries from open surgical repair to thoracic endovascular aortic repair (TEVAR) with stent grafts [3, 4]. In comparison with open surgery, endovascular repair is less invasive, does not require single lung ventilation, cardiopulmonary bypass, systemic anticoagulation, or aortic cross-clamping and produces less blood loss [4, 5]. In multiply traumatized patients, these features translate into lower intraoperative and postoperative mortality and paraplegia rates [4–7].

Although endovascular repair was associated with significantly lower mortality than open repair, a considerable risk for serious device-related complications was observed and a major and urgent need for improvement in the available endograft devices was stated [6].

A novel endovascular stent graft was designed specifically for the thoracic aorta and the aortic arch. This stent graft is more flexible, has a less traumatic proximal bare stent configuration, and exerts a gentler radial force. To evaluate whether these improved technical features translate into better patient outcome we analyzed the data from a multicenter registry in the trauma subgroup.

Material and Methods

Study Design

Relay Endovascular Registry for Thoracic Disease (RESTORE) is a European, prospective, monitored, clinical registry of consecutively enrolled patients treated with the Relay thoracic stent graft (Bolton Medical, Sunrise, FL; Barcelona, Spain) for various thoracic aortic pathologies. A total of 304 patients were included by 22 centers between April 2005 and January 2009. The follow-up period was limited to 2 years. The study design in detail and final operative and mid-term results of the entire cohort were published in 2010 by Riambau and colleagues [8]. Results of a subgroup of 91 patients treated for aortic dissection were reported in 2011 [9]. The Institutional Review Board or local ethics committee of each center approved participation in the registry. Written informed consent for the operation was obtained in all cases according to the rules of regular elective or emergency surgery. Patients gave additional consent for collection of the data. From this registry 40 patients having the stent graft implanted for blunt traumatic thoracic aortic injury were identified. The analysis of this subgroup is the object of this paper.

Selection Criteria

Thoracic endovascular aortic repair was considered for adult patients with traumatic aortic injury and with the following anatomic characteristics: (1) a proximal and distal aortic neck suitable for stent-graft placement; (2) vascular dimensions, such as aortic diameters and distance from left subclavian artery (LSA) to celiac artery, within a range that could be safely treated with a stent graft; and (3) adequate vascular access for insertion of the delivery system sized from 22 to 26 F (7.4 to 8.7 mm). Patients were excluded from TEVAR on grounds other than access site issues if there was (1) genetic connective tissue disorders, such as Marfan syndrome; (2) history of allergy to intra-arterial contrast medium, to any of the components of the device or to anticoagulant therapy; (3) active systemic infection; or (4) severely compromised left ventricular function. The TEVAR was performed within 24 hours after the trauma or with a delay according to the treatment strategy of the physician performing the stent-graft implantation [5, 10].

Stent-Graft Description and Implantation Technique

The Relay stent graft consists of self-expanding sinusoidal nitinol stents and a curved nitinol wire sutured to a polyester fabric. The curved wire starting below the second row of covered stents and ending close to the distal stent, allows sufficient column strength and provides flexibility and torque response for the stent graft (Fig 1). Two different standard configurations, 1 with a proximal bare stent and 1 with a non-bare stent (RELAY-NBS), are available for use according to the operator's preference. The delivery system consists of a primary introduction sheath, a secondary delivery sheath, a handle, and an apex release mechanism. Its pioneering system of proximal clasping of the stent graft allows precise and controlled deployment (Fig 2A-C). The device, the delivery catheter, and the deployment procedure have been described in detail previously [8]. First results on challenging arch anatomy were published in 2009 [11]. The device has been approved in Europe since 2005 and in the US since September 2012, and has been used in over 7,000 patients worldwide.

Study Procedures

Selected patients underwent a preoperative evaluation consisting of medical history taking, physical examination, and thoracic computed tomography (CT) scan. Magnetic resonance imaging, angiography, or transthoracic echocardiography were also carried out in some patients. This evaluation provided baseline information regarding localization and morphology of the rupture indicated by acute traumatic pseudoaneurysms and aortic measurements of proximal and distal landing zones. Based on these data, treating physicians selected the appropriate stent graft and designed the treatment plan. The measurement technique used in the CT scans was left to the discretion of the implanting physician and varied throughout the study period with the evolving Digital Imaging and Communications in Medicine standards and reconstruction tools. Depending on the medical institution, procedures were performed by cardiothoracic surgeons, vascular surgeons, or interventional radiologists under fluoroscopic and angiographic guidance. During the stent-graft procedure the following data were recorded: type of anesthesia; access site; device size and configuration; additional procedures related to the endovascular procedure; balloon

Fig 1. Relay stent graft in the short version (100 mm), which was used in 65% of the trauma cases.

usage; duration of the procedure; estimated blood loss; need for transfusion of blood products; volume of contrast medium administered; and challenges and complications encountered. Technical success was defined as complete exclusion of the aortic lesion, absence of endoleak and complete covering of ruptures and entry sites. During the early postoperative period (ie, less than 30 days after the procedure), procedure or device-related systemic and neurologic complications, duration of intensive care unit and hospital stay, need for conversion to open repair, or death were recorded. After discharge, regular follow-up examinations were scheduled at 1, 6, 12, and 24 month intervals to assess the patient's health status, including abnormal systemic and neurologic findings. Device integrity and lesion status (diameter, length, presence of endoleak) were evaluated with CT scan or one of the alternative imaging methods mentioned above. Follow-up data were obtained by telephone interview when examinations were lacking.

Statistical Analysis

Categoric variables are given as counts (percentages), and continuous variables are described using the mean and range. Cumulative survival rates were estimated by the Kaplan-Meier method. Statistical analyses were performed using SAS statistical software (version 9.1.3; SAS Institute, Inc, Cary, NC). The RESTORE registry results were submitted to a quality control analysis by an independent external institution (Trial Form Support Co, Barcelona, Spain) using a random sample of 61 cases representing 20% of the entire series.

Results

Between January 2006 and January 2009, 40 patients with traumatic injury of the thoracic aorta from 12 hospitals underwent TEVAR with Relay stent grafts. Mean age of patients was 40 years (range, 18 to 74) and 34 (85%) patients were male. Baseline patient characteristics are summarized in Table 1. All patients had contained aortic pseudoaneurysms (blunt aortic injury grade III). Three patients (7.5%) had trauma-induced paraplegia prior to stent-graft placement; 1 of them has been described in detail elsewhere [12].

Intraoperative and postoperative outcomes are summarized in Table 2. The data refer solely to the endovascular procedure itself; concomitant orthopedic and trauma procedures were not reported. In-hospital data are influenced by differing policies of the reporting hospitals on transferring traumatized patients to trauma centers for further treatment. A total of 40 stent grafts were used, meaning that only 1 unit per patient was required. Proximal endograft attachments in the aortic arch landing zones [13] are displayed in Figure 3. The technical details of the implanted stent grafts and their oversizing in relation to the aortic diameter are given in Table 3. No customized stent grafts were used in this sub-cohort of the registry. Hypotension was induced pharmacologically for the moment of deployment in 18 (45%) patients; adenosine-induced cardiac arrest or rapid ventricular pacing was not applied. During stent-graft placement 3 (7.5%) patients required additional surgical procedures related to the aortic injury. All endovascular stent grafts were delivered successfully. Ballooning of the stent graft with compliant aortic balloons was performed in 4 cases; in 2 for suspicion of a proximal endoleak with orthograde perfusion of the fully covered LSA and in 2 for better alignment of the stent graft. No endoleak was noted at the end of the procedures.

One (2.5%) patient suffered a device-related complication that consisted in rupture of the external iliac artery during removal of the delivery device. No other procedure-related complications occurred and no patient required conversion to open repair at any point during the study. No patient developed new onset paraplegia related to the aortic procedure. One multiply traumatized patient died due to cardiac arrest 19 days after TEVAR in the acute trauma phase, resulting in a 30-day mortality of 2.5%.

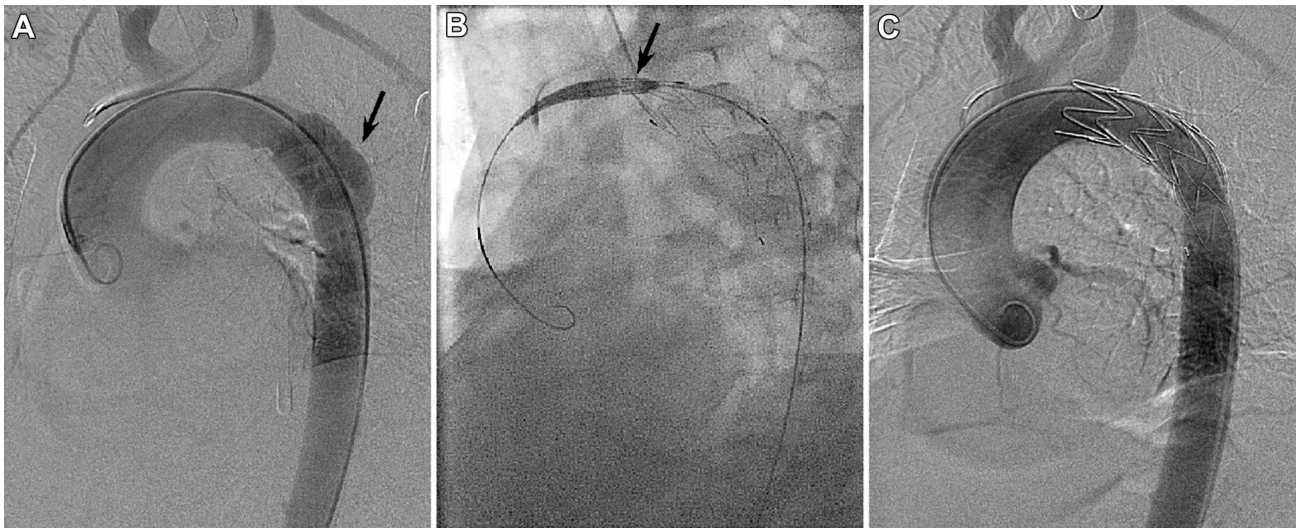

Fig 2. (A) Thoracic aortic angiography showing a traumatic pseudoaneurysm located at the aortic isthmus (arrow). (B) Intraoperative angiography showing the Relay stent graft partially delivered. After positioning, the stent graft is deployed and released from the capturing system (arrow). (C) Follow-up angiography showing how the stent graft adapts to the aortic anatomy.

Follow-Up

Follow-up visits were reported at 1, 6, 12, and 24 months with imaging available in parentheses for 40 (35), 38 (26), 36 (19), and 33 (20) patients, respectively. Imaging showed sustained remodeling of the traumatic lesions. One device-related complication was reported; penetration of the aortic wall at the distal end of the stent graft, which had been oversized by 41%, was found at the 12-month visit and was repaired 4 months later by extending the stent graft distally with a second stent graft. One patient died 260 days after the procedure from a secondary accident (carbon monoxide intoxication). The actuarial survival was 97.5% at 12 and 93.7% at 24 months (Table 2; Fig 4).

Table 1. Demographic and Preoperative Patient Data (n = 40)

Characteristic	No.	%
Age (years)		
Mean (range)	40 ± 15.9 (18–74)	
Gender		
Male	34	85
Female	6	15
ASA class (3 or above)	25	63
Pseudoaneurysm morphology		
Saccular	36	90
Fusiform	4	10
Mean pseudoaneurysm diameter (mm)	34.3 ± 12.6 (7–70)	
Timing of TEVAR after injury		
<24 hours	20	50
1 – 14 days	15	38
14 days – 6 months	3	8
Late chronic	2[a]	5

[a] Both 27 years after injury.

ASA = American Society of Anesthesiologists; TEVAR = thoracic endovascular aortic repair.

Comment

The present report on 40 patients with traumatic thoracic aortic injury shows that TEVAR with the Relay is a safe and effective procedure, as evidenced by 100% technical success and the low intraoperative and postoperative mortality and morbidity related to the endovascular procedure itself.

Traditionally, patients with traumatic thoracic aortic injury have been treated with open repair with either primary anastomosis or an interposition graft [3, 4]. Timing of conventional surgery after the trauma, immediate versus delayed, has been discussed for many years [4, 14, 15]. Both approaches [5, 10] have been transferred to the endovascular repair of blunt thoracic aortic injury and have been brought together in this international multicenter study cohort. In this study, 50% underwent endovascular repair of the aortic trauma in the early phase of trauma management within 24 hours. The overall results of this study are excellent and no differences were identified between immediate and delayed endovascular treatment. Thus, it can be concluded that TEVAR performed during the early phase of a multiple trauma has less concerns regarding procedure-induced mortality and morbidity compared with open repair, and it has become a part of early multiple trauma management in some institutions [5, 16].

In recent years TEVAR with stent grafts has been adopted as the preferred treatment for traumatic thoracic aortic injury in many high-volume centers, largely due to the significant decrease in perioperative mortality and neurologic complication rates observed in clinical trials

Table 2. Intraoperative, Postoperative, and Follow-Up Patient Data (n = 40)

Variable	No.	%
Intraoperative data		
Type of anesthesia		
General	37	93
Local or loco-regional	3	7
Access site		
Femoral	37	93
Iliac	3	7
Access site diameter (mm)		
Mean (range)	8.3 ± 1.5 (6.0–12.0)	
Additional procedures		
Complete transposition of supraaortic vessels	1	2.5
LCCA to LSA bypass	2	5
Duration of procedure (hours)		
Mean (range)	1.6 ± 0.8 (0.4–4.0)	
Postoperative data		
Technical success	40	100
Device-related complications	1	2.5
Mean ICU stay (days)	6.4 ± 295 (0–60)	
Mean hospital stay (days)	32.9 ± 58 (1–370)	
30-day and in-hospital mortality	1[a]	2.5
Procedure or device-related deaths	0	0
Follow-up data		
Late deaths	1[b]	
Procedure or device-related deaths	0	0
Actuarial survival rate		
12 months		97.5
24 months		93.7

[a] Related to concomitant trauma. [b] Secondary accident on day 260 (carbon monoxide intoxication).

LCCA = left common carotid artery; ICU = intensive care unit; LSA = left subclavian artery.

[4–7, 16]. However, so far none of the commercially available endovascular devices has proven to be completely effective for the treatment of thoracic aortic injuries, and short-term complications such as stroke, puncture-site complications, or device collapse may cause morbidity rates varying between 3% and 36%. In our registry, only 1 patient (2.5%) suffered a rupture of the external iliac artery, which was repaired surgically. No patient developed an endoleak and no patient required conversion to open surgery. In comparison with other studies using different endovascular devices the incidence of these complications is acceptable [6, 17, 18]. Also, the actuarial survival of 93.7% with 2 deaths unrelated to the aortic procedure highlights the safety of the stent graft implanted.

The most common location for traumatic aortic injuries is the aortic isthmus, very close to the origin of the LSA [2, 3, 18]. Anatomically, this region poses several technical challenges related to the aortic arch diameter and angulation. This is an issue of special concern in trauma patients, who are mostly young and, consequently, have shorter proximal landing zones, smaller arch radius of the curvature, and smaller aortic diameter [3]. Implantation at this site may result in poor apposition of the stent graft to the aortic wall and may lead to infolding, endoleak, or even complete collapse of the stent graft [6, 19–21].

The Relay stent graft has been specifically designed for the thoracic aorta. This stent graft has greater spacing between stent zones for added conformability and a unique spiral support strut for longitudinal support at the outer curvature leading to better adaptability to the inner curvature of the aortic arch. This strut is not directly connected to the bare springs, rendering the proximal graft-end flexible. Because of this unique construction the stent graft adapts better to the aortic wall, even in the steeply curved aortic arch of the young trauma patient [3]. Therefore the bare-stent configuration was chosen by the implanting physicians in 95% of the cases. The proximal landing zone involved aortic arch zones 1 to 2 in 40% of the procedures, reflecting an aggressive policy to cover the LSA if the aortic tear is located close to it. This may be 1 explanation for the low incidence of proximal endoleak compared with that of other series [18]. In only 3 cases was protective revascularization of the LSA performed, in one case simultaneously with the mandatory aortic arch rerouting for implantation in zone 1. No complications

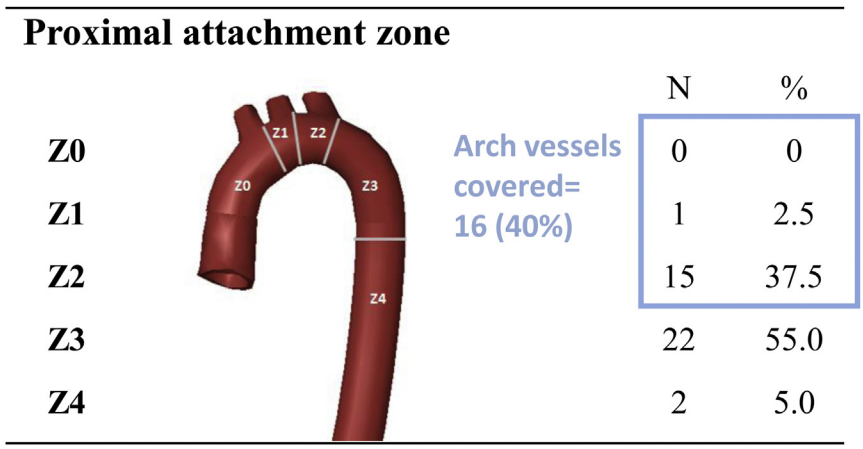

Fig 3. Proximal endograft attachments distributed in aortic arch landing zones according to Criado and colleagues [13].

Table 3. Aortic Diameters, Technical Details, and Oversizing of the Stent Grafts

Variable	Proximal End	Distal End
Aortic diameter	24.7 ± 4.9 mm	22.9 ± 4.6 mm
Range	16–34 mm	16–32 mm
<20 mm (n)	5	10
20–30 mm (n)	29	28
>30 mm (n)	6	2
Stent-graft diameter	28.9 ± 5.2 mm	28.7 ± 5.2 mm
Range	22–38 mm	22–38 mm
22 mm (n)	6	6
24–30 mm (n)	19	20
>30 mm (n)	15	14
Oversizing	18.0 ± 11.7 %	26.3 ± 11.7%
Range (%)	0-47.4%	6.7–55.6%
<10 % (n)	9	3
10–20 % (n)	19	12
>20 % (n)	12	25
Stent-graft end		
Bare stent (n)	38	–
Non bare stent (n)	2	40
Stent-graft length	116.2 ± 27.6 mm	
100 mm[a] (n)	26	
150 mm[a] (n)	13	
172 mm (n)	1	

[a] Nominal lengths; actual lengths vary by ±10 mm dependent on diameter.

related to LSA occlusion were observed. This practice in emergencies is consistent with recently published guidelines [22] but protective revascularization should be considered individually [23].

One main concern regarding endograft devices is sizing. Traumatic injuries usually involve a transverse tear in the intimal and medial layers. Therefore, short stent grafts are sufficient to cover the defect and avoid unnecessary coverage of intercostal arteries. In addition, stent grafts of small diameters may be appropriate in small-diameter aortas of adolescents. The Relay stent graft is available in lengths from 100 to 250 mm and diameters from 22 to 46 mm, making it suitable for the treatment of a wide range of patients and aortic anatomies. All manufacturers of stent grafts recommend oversizing by 10% to 20% in relation to the aortic diameter at the attachment site. In the clinical setting of acute repair of traumatic injuries this recommendation can be difficult to meet due to the need for short-term availability and small aortic diameter. This is highlighted by our experience that at the proximal end only 48% of the stent grafts were sized within the recommended range, and at the distal end only 30% (Table 3). Excessive oversizing of the distal end was identified as the most probable cause of the only observed late device-related complication. The double-sheath delivery system has proven especially valuable in TEVAR for aortic trauma because it eliminates friction during deployment between the inner sheath and the often narrow and spastic iliac arteries. It has been improved since the registry period by hydrophilic coating of the outer sheath, which should further reduce complications of the iliac access arteries as experienced in 1 case.

In our cohort, technical success was achieved in all 40 patients. Stent-graft collapse as a complication with sometimes devastating consequences has been reported in case reports [19–21] and cohorts of similar size [6, 16, 24, 25] in which stent grafts without additional proximal bare-spring fixation have been used. Misalignment at the inner curve [16] and excessive oversizing have been suspected as causes of device collapse [19, 24, 25]. No case of stent-graft collapse was recorded in our study, although oversizing beyond the

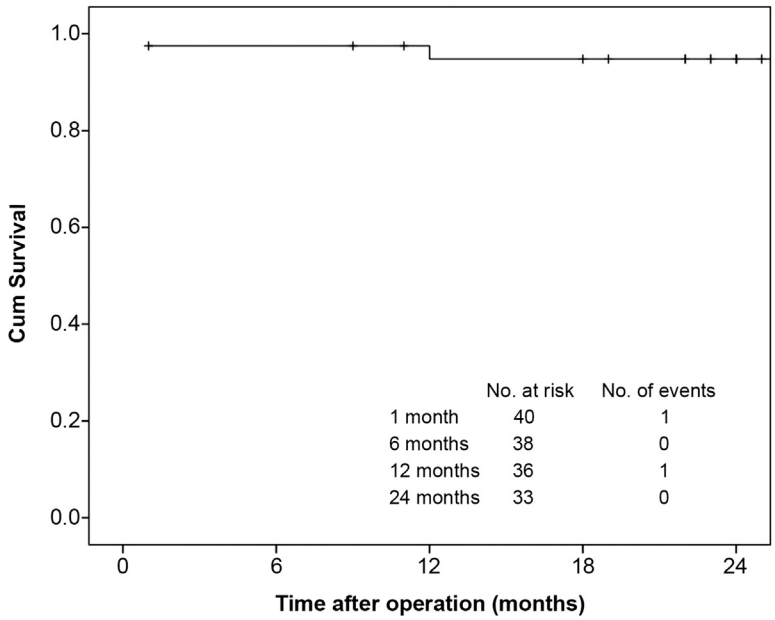

Fig 4. Actuarial 2-year survival of 40 patients after endovascular repair of thoracic aortic injury. (cum = cumulative.)

recommendation occurred in 30% of the cases by up to 47%. It seems that the Relay stent graft is more forgiving these unavoidable faults and thus adds more safety to the procedure.

Limitations

Relay Endovascular Registry for Thoracic Disease is an open nonrandomized registry to observe TEVAR with a specific stent graft. The use of this stent graft was left at the discretion of the treating physician and was limited by the availability of stent grafts in stock in emergency cases. No information was collected on the use of other stent grafts or conventional surgery during the inclusion period. No core lab control was performed for imaging-based data. For the subgroup of traumatic aortic injury no data are available on the extent, severity, and treatment of concomitant trauma. Due to practical problems in following trauma patients, loss to follow-up incidence was high and therefore only actuarial survival data could be calculated by the Kaplan-Meier method.

Conclusions

The combination of the features of the Relay stent graft and its delivery system makes it effective and safe for the treatment of patients with traumatic aortic thoracic injury with a low proportion of device-related complications. The new device seems to represent a step forward in the improvement of endograft technology for this special indication [6]. Our results provide additional support for TEVAR with stent grafts as the preferred treatment of traumatic thoracic aortic injury. The long-term behavior of aortic stent grafts in mainly young trauma patients remains unclear. So far, in all follow-up examinations we saw remodeling of the aorta at the rupture site. Whether the early benefits of stent grafting in acute trauma will be sustained in the long term needs to be examined in further studies.

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2.5. Rückenmarksischämie nach Stentprothesen

- Zipfel B, Buz S, Redlin M, Hullmeine D, Hammerschmidt R, Hetzer R.
  Spinal cord ischemia after thoracic stent-grafting: Causes apart from intercostal artery coverage.
  Annals of Thoracic Surgery 2013;96(1):31-8. [80]
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Die Frage nach der Inzidenz und möglichen Ursachen von Rückenmarksischämien und bleibenden Querschnittslähmungen wurde an 406 konsekutiv operierten Patienten untersucht und dabei alle sequentiellen Eingriffe auf den Patienten bezogen ausgewertet. Prospektiv wurden alle, auch die vorübergehenden, auf Ischämie verdächtigen Ereignisse registriert und mit univariater logistischer Regression der Einfluss aller in der Literatur diskutierten Faktoren geprüft. Für eine multivariate Statistik waren die Fallzahlen mit Ischämie zu klein. Dazu ist eine detaillierte individuelle Auswertung der 11 betroffenen Patienten angegeben. Die Inzidenz war für Rückenmarksischämien mit gesamt 2,7%, davon 1,5% bleibende Paraplegien sehr niedrig, auch ohne prophylaktische spinale Flüssigkeitsdrainage, die in der konventionellen Aortenchirurgie zur Bekämpfung der perioperativen Paraplegie eingesetzt wird und von vielen Autoren auch für die endovaskuläre Behandlung gefordert wird. Das Für und Wider dieser Zusatzmaßnahme wird in der Arbeit ausführlich diskutiert.

Eine kritische Länge der mit Stentprothesen abgedeckten Aorta für das Auftreten von Rückenmarksischämien konnte trotz des großen Kollektivs nicht errechnet werden. Es fanden sich schwache Korrelationen für vorhergegangenen konventionellen oder endovaskulären Ersatz der abdominellen Aorta, Bedeckung der gesamten Aorta descendens vom Bogen bis zum Tr. coeliacus und die thorako-abdominelle Implantation mit Stentprothesen mit Seitenarmen oder Fenstern für Viszeral- und Nierenarterien, letzteres bei noch geringer Fallzahl. Die individuelle Analyse förderte andere mögliche Mechanismen zu Tage, wie Embolisation von Debris in die Interkostalarterien, schwere Darmischämie, prologierten hämorrhagischen Schock und Heparin induzierte Thrombopenie, die an der Kausalität der gefundenen statistischen Korrelationen zweifeln lassen.

Spinal Cord Ischemia After Thoracic Stent-Grafting: Causes Apart From Intercostal Artery Coverage

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Background. **Examination of a large collective combined with individual case analyses may give new insights into mechanisms and prevention of spinal cord ischemia (SCI) after thoracic endovascular repair.**

Methods. **In an 11-year period, stent-grafts were implanted in 406 patients for various aortic pathologic conditions. The mean age was 63 years (15–91 years) and 300 (74%) patients were men; 58 patients underwent staged thoracic stent-graft procedures. The length of aorta covered was between 75 and 584 mm (mean, 204 mm). Thoracoabdominal branched or fenestrated stent-grafts were implanted in 11 patients. The left subclavian artery was occluded in 161 patients (39%); this occurred in half of them (n = 78) after protective revascularization. Prophylactic cerebrospinal fluid (CSF) drainage was used selectively in 4 cases; no neuromonitoring was used.**

Results. **The incidence of SCI was 2.7% (n = 11); 6 patients (1.5%) had major permanent deficits. Conditions that had a potential influence on SCI were analyzed. Statistical correlation was found for previous conventional or endovascular abdominal aortic aneurysm repair (odds ratio [OR], 4.8), coverage of the entire descending thoracic aorta (OR, 3.6), and implantation of thoracoabdominal branched and fenestrated stent-grafts (OR, 9.5). Individual analyses revealed other conditions that might have played a role, such as embolization into the segmental arteries, severe visceral ischemia, profound hemorrhagic shock, and heparin-induced thrombocytopenia.**

Conclusions. **The incidence of SCI is unexpectedly low despite extensive sacrifice of intercostal arteries. Extended coverage of the thoracic and thoracoabdominal aorta seems to have a higher risk, but other factors may contribute to the individual disaster.**

(Ann Thorac Surg 2013;96:31–8)

Spinal cord ischemia (SCI) with subsequent paraplegia has been recognized as a dreaded complication after surgical procedures on the thoracic aorta, with incidences reported up to 6.8% in centers of excellence. Impairment of segmental spinal cord perfusion by intercostal arteries is considered the major mechanism. Therefore, reimplantation of the intercostal arteries during conventional repair has been used to avoid this complication [1], which is impossible in endovascular repair. Despite sometimes extensive sacrifice of segmental arteries, the incidence of SCI in stent-grafting has been unexpectedly low in the worldwide experience. Examination of a large single-center collective combined with individual case analyses may give new insights into mechanisms and prevention of SCI after stent-grafting.

Patients and Methods

In an 11-year period (until December 2010), thoracic stent-grafts were implanted in a total of 423 patients for various aortic pathologic conditions. For this study, only patients with completed pure endovascular stent-graft procedures were selected. Ten patients who had uncompleted implantations and 7 patients with hybrid stent-graft procedures with antegrade implantation from the open aortic arch in circulatory arrest were excluded. Demographics and indications for primary stent-graft implantation in the remaining 406 patients are summarized in Table 1. To identify all events of SCI, all stent-graft procedures in each patient were observed. Thus, 67 secondary stent-graft procedures in 58 patients were included, performed 16 months (2 days–8 years) after the initial procedure and resulting in 473 procedures in total.

We performed 313 procedures in a standard operating room with a mobile angiography C-arm (BV 300 and BV Pulsera, Philips, Eindhoven, Netherlands) and 160 procedures since 2008 in a hybrid operating room

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*Drs Zipfel and Buz contributed equally to this work.

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Table 1. Patient Demographics and Aortic Diseases as Indications for Stent-Grafting

Aortic Pathologic Condition	n	Male Patients (%)	Age (y)	Age (mean)
Aneurysm	103	73 (71)	28–91	69
Penetrating atherosclerotic ulcer	70	43 (61)	49–87	72
Type B dissection	164	128 (78)	36–89	64
Trauma	66	55 (84)	15–82	41
Mobile atheroma	2	0	61–78	69
Infection	1	1	59	
Total	406	300 (74)	15–91	63

(Artis zee ceiling-mounted system; Siemens, Erlangen, Germany).

We implanted E-vita stent-grafts (Jotec, Hechingen, Germany) in 214 procedures; Talent stent-grafts (Medtronic Vascular, Santa Rosa, CA) in 121 procedures; Relay stent-grafts (Bolton Medical, Sunrise, FL) in 107 procedures; Zenith stent-grafts (William Cook Europe, Bjaeverskov, Denmark) in 24 procedures; EndoFit stent-grafts (Endomed Inc, Phoenix, AZ) in 2 procedures; TAG stent-grafts (WL Gore Associates, Flagstaff, AZ) in 2 procedures, and Valiant stent-grafts (Medtronic Vascular, Santa Rosa, CA) in 3 procedures. We have described the stent-grafts and the implantation technique in detail previously [2]. General anesthesia was given in all cases, except for 3 patients who received local anesthesia. No adenosine-induced cardiac arrest or rapid ventricular pacing was used for the moment of deployment; the mean arterial pressure was adjusted to 60 mm Hg if necessary. Prophylactic cerebrospinal fluid (CSF) drainage was performed selectively in 4 patients; no neuromonitoring was used. Patients were transferred to the normal ward directly after 106 (22.4%) procedures and remained in the intensive care unit (ICU) for up to 8 hours after 103 (21.8%) procedures, between 8 and 24 hours after 104 (22.0%) procedures, and for more than 24 hours after 154 (32.6%) procedures.

The length of aorta covered was 204 mm (75–584 mm) and was calculated per patient as the length of all implanted segments minus overlap in primary and secondary procedures. The extent of stent-grafting is displayed in Figure 1. In 80 patients (14.7%), the entire descending thoracic aorta (DTA) was covered from the aortic arch (Fig 1, segments 2–6) to the infradiaphragmal portion (segment 8 or beyond). In 161 (39.4%) patients, the left subclavian artery (LSA) was covered with the stent-graft; in 78 (19.2%) patients, protective revascularization of the LSA [3] was performed preliminarily or simultaneously with the procedure. In 15 patients, more proximal arch vessels were covered, with previous revascularization of these vessels and the LSA. Thus, the LSA was definitively occluded in 68 patients (16.9%). The thoracoabdominal segment (8 and beyond; Fig 1) was covered in 147 (36.2%) cases. The celiac trunk was covered in 12 patients, 1 with simultaneous bypass and 1 with a chimney stent. Eleven patients had branched or fenestrated stent-grafts extending into the infrarenal aorta [4].

Data were collected in a prospectively maintained database. This study was approved by the institutional ethics committee, which waived the need for additional patient consent. All patients with postoperative neurologic abnormalities were seen by the neurologist (DH). SCI outcome was graded according to the Society for Vascular Surgery reporting standards [5]. Follow-up was obtained through office visits, hospital reports, and telephone interviews with patients, families, and home physicians.

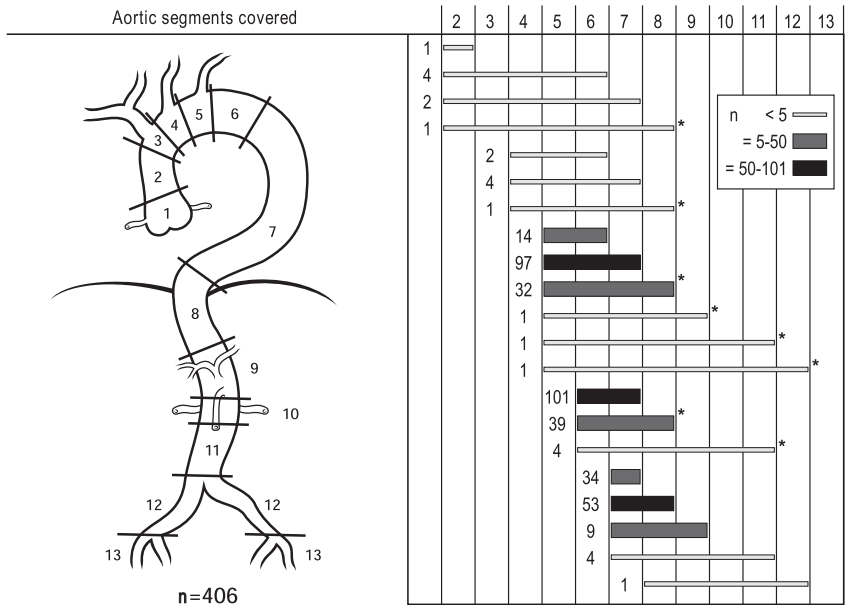

*Fig 1. Aortic segment specification from the Deutsches Herzzentrum Berlin aortic database (left). Segments 2 to 6 are equivalent to proximal endograft attachments zones 0 to 4 in the endovascular classification [19]. The bar chart (right) displays the extent of individual stent-graft coverage of the aorta with the number of patients displayed left of the bars. Bars marked with * depict coverage of the entire descending thoracic aorta (segments 6 to 8 or more).*

Univariate logistic regression was performed to identify predictors of SCI reported as the odds ratio (OR) with 95% confidence interval (CI). p less than 0.05 was considered to indicate a significant association. The risk of SCI for the length of aorta covered was assessed using the area under the receiver operating characteristic (ROC) curve. Statistical analyses were performed using PASW Statistics, version 18.0 (SPSS Inc, Chicago, IL).

Results

Overall 30-day mortality was calculated from the last individual procedure and was 10.3% (n = 42) overall, 2.8% (n = 5) in elective cases and 16.2% (n = 37) in emergencies. Eleven patients were identified as having new onset of spinal cord events (paraplegia, paraparesis, mild anterior spinal artery syndrome). Twelve events in patients with sustained paraplegia before stent-graft implantation induced by trauma or dissection were not considered stent-graft related.

The incidence of SCI was 2.7% (n = 11); 6 patients (1.5%) had major permanent deficits (grade 3). All events occurred during hospitalization at 5 hours to 19 days after the procedure. In 3 patients, early postoperative onset was assumed because paraplegia was noted immediately at the end of prolonged postoperative sedation. Two SCI events occurred after secondary procedures.

Table 2 shows the statistical analysis for factors potentially associated with SCI. Receiver operating characteristic curve analysis for length of aorta covered demonstrated no correlation, with the area under the curve equal to 0.65 (95% CI, 0.48–0.81). A critical length of aortic coverage for SCI could not be determined.

A survey of the 11 patients with SCI related to clinical and morphologic features, procedural details, and individual analysis of SCI events is given in Tables 3 to 5 in chronologic order. Hypotensive episodes have been registered by chart review and observation by the surgeon and the nursing staff. Correct correlations of mean arterial pressure at baseline before the procedure and mean arterial pressure after the procedure and preceding the SCI event could not be evaluated because 6 of 11 events occurred with delay on the normal ward, where continuous invasive blood pressure monitoring was not available. Two events early in our experience (patients 2 and 3) occurred after pharmacologic treatment of postoperative hypertension. Secondary CSF drainage was performed in both cases without effect.

Special features that may have played a role in the individual SCI event were observed:

Patients 1 and 7 received the stent-grafts as bailout procedures in desperate rupture situations and the paraplegia was part of the overall disaster. Both patients died in the ICU, patient 7 from a secondary rupture. A mobile atheroma in a normally calibrated DTA (Fig 2) was covered with the shortest available stent-graft in patient 3. Thrombus at the landing site of the stent-graft was identified in patients 6 and 8 (Fig 3). Visceral ischemia and acute abdomen in patient 10 was caused by type B dissection with complete true lumen collapse. The perfusion was restored with 2 overlapping stent-grafts occluding the LSA plus a bare metal aortic stent (E-xl, Jotec, Hechingen Germany) across the visceral arteries and 2 self-expanding stents implanted into the superior mesenteric artery. The patient was hypotensive for a long

Table 2. Factors Potentially Associated With Spinal Cord Ischemia

Variable	N (%)	No. SCI (%)	Odds Ratio (95% CI)	*P* Value
Etiology				
Aneurysm	103 (25.4)	7 (6.8)	4.9 (1.4–17.3)	0.012
Penetrating aortic ulcer	70 (17.2)	1 (1.4)	0.5 (0.1–3.8)	0.468
Type B dissection	164 (40.4)	2 (1.2)	0.3 (0.7–1.5)	0.141
Trauma	66 (16.3)	0	0.2 (0.00–2.9)	0.228
Mobile atheroma	2 (0.5)	1 (50)	[c]	[c]
Infection	1 (0.2)	0	[c]	[c]
Emergency	228 (56.2)	5 (2.2)	1.6. (0.5–5.2)	0.545
Hemorrhagic shock	29 (7.1)	2 (6.9)	3.0 (0.6–14.7)	0.182
Extent of stent-grafting				
Entire DTA covered[a]	79 (19.5)	5 (6.3)	3.6 (1.1–12.3)	0.038
Thoracoabdominal aorta[b]	147 (36.2)	7 (4.8)	3.2 (0.9–11.1)	0.107
Branched/fenestrated stent-grafts	11 (2.7)	2 (18.2)	9.5 (1.2–50.6)	0.032
LSA occluded	68 (16.9)	1 (1.5)	2.0 (0.3–16.2)	0.499
Previous operation				
AAA repair	46 (11.3)	4 (8.7)	4.8 (1.4–17.2)	0.026
Thoracic aorta repair	39 (9.6)	2 (5.1)	2.2. (0.5–10.3)	0.286
Paraplegia at previous operation	2 (0.5)	2 (100)	[c]	[c]
Overall	406 (100.0)	11 (2.7)	…	…

[a] Segments 6–8 or more; [b] segment 8+; [c] no statistics because of small sample.

AAA = abdominal aortic aneurysm; CI = confidence interval; DTA = descending thoracic aorta; LSA = left subclavian artery; SCI = spinal cord ischemia.

Table 3. Characteristics of Patients With Spinal Cord Ischemia

Patient No.	Age (y)	Sex	Diagnosis	Indication	Previous Repair	Remarks
1	66	M	Aneurysm	Hemorrhagic shock	TAA	Ruptured proximal anastomotic aneurysm; SCI at first operation
2	69	F	PAU	Contained rupture	...	Poor general condition; liver cirrhosis
3	78	F	Mobile atheroma	Elective	AAA (Y)	...
4	78	M	Type B dissection	Symptomatic	AAA (T)	Secondary TEVAR 21d later
5	76	M	Aneurysm	Elective	AAA (Y)	SCI grade 1 at AAA repair
6	74	M	Aneurysm	Elective	...	AAA planned for second-stage EVAR
7	77	M	Aneurysm	Hemorrhagic shock	AAA (Y)	Ruptured 103 mm TAAA type I; bailout procedure
8	74	M	Aneurysm	Elective	...	AAA, EVAR 39 mo later
9	60	F	Aneurysm	Elective	TAA	Extension of ascending, arch, elephant trunk repair
10	36	M	Type B dissection	Malperfusion	...	Visceral ischemia
11	68	F	Aneurysm	Elective	...	Secondary TEVAR 27 mo later

See Figure 1 for landing zones.

AAA = abdominal aortic aneurysm; EVAR = endovascular aneurysm repair; PAU = penetrating atherosclerotic ulcer; SCI = spinal cord ischemia, T = tube graft; TAA = thoracic aortic aneurysm; TAAA = thoracoabdominal aortic aneurysm; TEVAR = thoracic endovascular aneurysm repair; Y = bifurcated graft.

period with mean arterial pressure of 55 to 60 mm Hg until the stent-graft was implanted. The creatine kinase level was elevated up to 2,970 U/L as an effect of reperfusion. Postoperative delirium developed in patient 1, resulting in long-term respirator therapy. With this status he was hypertensive without receiving medication except careful sedation. He moved all extremities vigorously until day 19, when paraplegia was noted. Heparin-induced thrombocytopenia type II was detected and was considered the most probable cause of this late paraplegia.

Comment

The incidence of SCI was remarkably low, although two thirds of the patients were treated in emergency conditions and the extent of stent-grafting has moved to more lengthy coverage of the aorta with growing experience and advances in stent-graft technology [2]. Five of 11 patients regained motor function and were ambulatory at follow-up. The incidence of 1.5% permanent paraplegia compares favorably with that of other studies on endovascular treatment of diseases of the thoracic aorta, being at the lower end of reported incidences of between 1.5 and 9% [6].

Griepp and Griepp [7] developed the collateral network concept, which may explain these findings: Preformed collaterals in the erector spinae muscles maintain the collateral circulation to the spinal cord when origins of intercostal arteries are occluded. This network has 25-fold the capacity of the anterior and posterior spinal arteries and is able to remodel within a vulnerable period of 24 to 48 hours toward longitudinal perfusion and expansion of its capacity [8]. The collateral network

Table 4. Procedure Details of Spinal Cord Ischemia

Patient No.	Device	Length (mm)	Landing Zone		LSA	Ballooning	Thrombus Distal Neck
			Proximal	Distal			
1	Talent	155	6	6	Patent[a]	+	+
2	Zenith	124	7	8	Patent[a]	+	+
3	E-vita	150	7	7	Patent[a]	+[b]	–
4	E-vita	340	6	8	Patent[a]	+	–
5	Relay	145	7	7	Patent[a]	–	–
6	E-vita	230	5	7	Patent[a]	+	+
7	Relay	315	6	8	Patent[a]	–	+
8	Relay	200	7	8	Patent[a]	–	+
9	Zenith	531	6	11	Patent[a]	+	–
10	Relay	260	5	8	Occluded	–	–
11	Zenith	562	5	12	Patent[a]	+	–

[a] Applies also to LSA coverage with prophylactic reconstruction; [b] only proximal attachment.

See Figure 1 for landing zones.

LSA = left subclavian artery.

Table 5. Analysis of Spinal Cord Ischemia Events

	Ischemia Onset		Plegia/Paresis								
Patient No.	Time	Location	Level	Side	Hypotension	Anemia	CSF Drainage	Suspected Cause	Recovery Grade	Outcome	Remarks
1	< 16 h	ICU	?	Bilateral	+	+	...	Shock	3	Died 27 d	Left cerebral infarction Unconscious until death in MOF
2	9 h	ICU	T8	Bilateral	+	–	Secondary	Hypotension	3	Died 32 d	Meningitis after CSF drain; sepsis; MOF
3	22 h	Ward	T8	Left	–	–	Secondary	Debris	2	Died 47 mo	CSF drain without effect
4	22 h	Ward	T11	Bilateral	+	+	...	Hypotension/ anemia	1	Alive 61 mo	...
5	36 h	Ward	?	Bilateral	–	–	...	?	2	Alive 48 mo	...
6	8 h	Ward	T9	Right	–	–	...	Debris	2	Died 21 mo	...
7	< 20 d	ICU	?	Bilateral	+	+	...	Shock; CPR	3	Died 32 d	Secondary rupture of esophagus
8	5 h	Ward	T8/9	Bilateral	–	–	...	Debris	3	Alive 39 mo	...
9	54 h	Ward	?	Bilateral	–	+	...	Anemia	1	Died 12 mo	...
10	< 15 h	ICU	T5/7	Bilateral	+	+	...	Visceral ischemia	3	Alive 25 mo	Maximum CK 2,970 U/L Laparotomy POD 2: vital organs
11	19 d	ICU	T10	Bilateral	–	–	...	HIT	3	Alive 13 mo	Delirium; moved all extremities vigorously until d 19

Ischemia onset time less than or equal to that detected with end of postoperative sedation. Hypotension = documented episodes of mean arterial pressure < 80 mm Hg preceding the event. Recovery grading according to Society for Vascular Surgery Ad Hoc Committee: 1= resolved with minimal sensory deficit, able to walk independently; 2 = minor motor deficit, able to walk with assistance or independently; 3 = nonambulatory (wheelchair bound).

CK = creatine kinase; CSF = cerebrospinal fluid; CPR = cardiopulmonary resuscitation; HIT = heparin-induced thrombocytopenia; ICU = intensive care unit; MOF = multiorgan failure; POD = postoperative day.

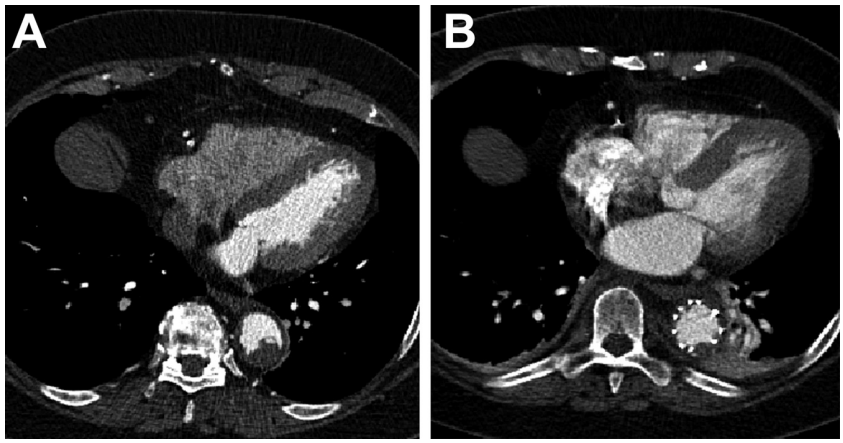

Fig 2. Patient 3. (A) 10 × 40 mm mobile atheroma in mid-descending thoracic aorta (preoperative computed tomographic scan). (B) Atheroma is pressed against the aortic wall after placement of the stent-graft.

is fed by branches of the subclavian and hypogastric arteries. Protective revascularization of these arteries can reduce paraplegia [9]. Based on these considerations, we developed a policy of prophylactic LSA reconstruction during the study period. Because of the low SCI incidence and generous nonrandomized application, we could not demonstrate a benefit [3]. However, such a policy has been recommended on level C evidence in the recent guidelines [10].

We tried to identify factors associated with SCI by statistical analysis and found correlations to coverage of the entire DTA, previous abdominal aortic aneurysm (AAA) repair, and thoracoabdominal fenestrated and branched stent-grafts. The clinical relevance of these statistical correlations has to be viewed with caution because individual case analysis revealed other suspected mechanisms, especially in the 4 patients with previous AAA repair and the 2 patients with thoracoabdominal branched grafts out of a small sample. Coverage of thoracoabdominal segment 8, in isolation or in combination with extended coverage, showed no correlation. No correlation was found to the cause of aortic disease; a negative correlation to type B dissection was marginal and not significant. No critical length of coverage could be determined. This is in contrast to another report on a smaller sample size [11]. Previous AAA repair is considered a risk for SCI, but a recent report found no SCI at all, even with 24% of the thoracic and abdominal procedures performed simultaneously [12].

In patients 3, 6, and 8, paraplegia occurred in opposition to discussed risk factor concepts. Individual case analysis gave rise to the suspicion that other conditions might have played a role: Embolization of thrombus or debris into the segmental arteries was described in theory as a "unique threat" of endovascular treatment to spinal cord perfusion [7]. In patient 3, the suspicion naturally suggested that this happened with fragments of the mobile atheroma (Fig 2). In patients 6 and 8, retrospective analysis of the computed tomographic scan found circular thrombus at the distal landing site, which had been undergone balloon dilation (Fig 3). The unilateral occurrence of paraplegia in both patients supports this theory, which is illustrated in Fig 4. From this experience, we are reluctant to exclude mobile atheroma or thrombus with stent-grafts. Further we check landing sites very carefully for thrombus or

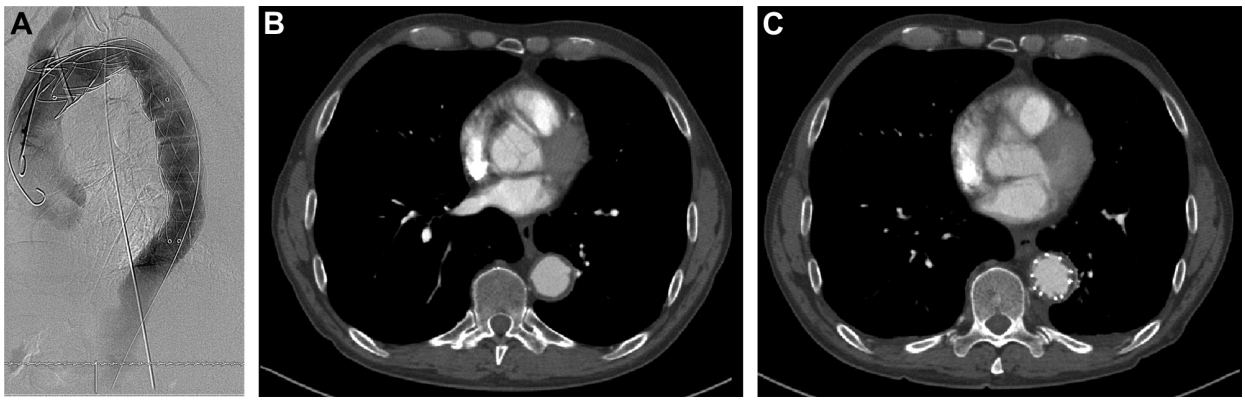

Fig 3. Patient 6. (A) Stent-graft ends in descending thorac aorta above diaphragm; left subclavian artery (LSA) is covered after preliminary left common carotid to LSA bypass (intraoperative completion angiogram). (B) Wall-adherent thrombus of 2- to 5-mm thickness at distal landing site (preoperative computed tomographic scan). (C) Distal landing site after placement of stent-graft, which was oversized at that spot by 33%; thrombus is compressed between aortic wall and stent-graft.

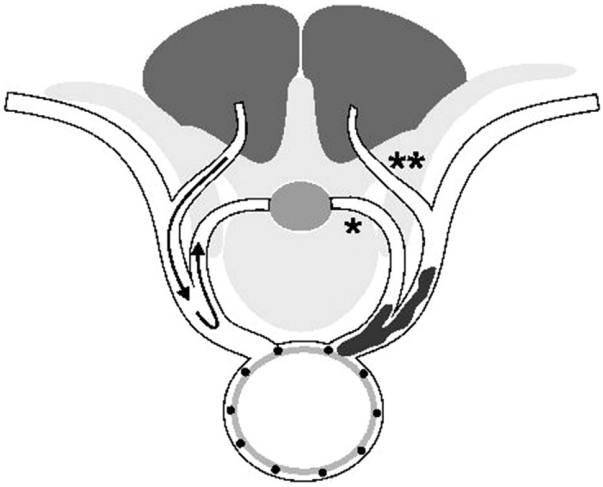

Fig 4. Intercostal artery coverage versus embolization (anatomical sketch). First dorsal branch (*) supplies corresponding segment of spinal cord, and second dorsal branch (**) connects to collateral network in erector spinae muscles. Perfusion is maintained if ostium of intercostal artery is simply covered by stent-graft (left side of figure); collateral perfusion is blocked if thrombus or debris is pushed beyond the first branch (right side of figure).

"shaggy aorta" and try to avoid excessive oversizing and unnecessary balloon dilation.

Visceral ischemia-reperfusion injury may contribute to spinal cord injury mediated by proinflammatory cytokines. This has been suspected clinically in conventional surgery [13] and demonstrated in a rabbit model [14]. In patient 10, dissection-induced severe visceral ischemia may have added additional damage to extensive coverage of the aorta and unprotected occlusion of the LSA.

In 5 of 11 cases, SCI was associated with hypotensive episodes, and postoperative anemia was noted in 3 patients. We recognized from 2 early adverse experiences that maintenance of a robust mean arterial blood pressure is important as a protective adjunct for SCI. In most instances this is achieved simply by discontinuation of antihypertensive medication and early mobilization. When needed, volume, transfusion, or noradrenaline is administered. Heparin-induced thrombocytopenia type II was another factor suspected.

A benefit of CSF drainage has been shown only in conventional aortic surgery by 1 randomized study exclusively in repairs of type I and type II thoracoabdominal aneurysms [15]. Prophylactic CSF drainage has also been proposed in endovascular repair, but there is a lack of evidence that this adjunct is effective, and it may have intrinsic complications even in experienced hands [16]. We used primary CSF drainage in the first 2 patients in whom we implanted lengthy stent-grafts (200 mm), with distal landing in zone 8, and in the first 2 patients with thoracoabdominal branched stent-grafts. In half of these patients, the CSF drainage did not work properly for technical reasons, but no SCI occurred. This experience revealed relevant clinical disadvantages of CSF drainage: it prevents early mobilization, requires trained staff, and confines the patient to the ICU for at least 48 hours (the recommended period for postoperative drainage), whereas 66% of our patients required no care in the ICU or care for less than 24 hours. From the 1.5% permanent paraplegia rate virtually without prophylactic CSF drainage, we conclude that in thoracic endovascular repair, liberal use of this adjunct cannot be recommended. Its theoretical benefit has to be weighed against the potential complications of spinal canal puncture [17]. Also, the secondary use of CSF drainage once SCI has occurred is ambiguous in effect despite anecdotal reports [18]. We saw no immediate effect in 2 patients but complete or nearly complete recovery in 4 patients with the conservative adjuncts.

Our current strategy to prevent SCI consists of (1) generous prophylactic LSA reconstruction in patients receiving lengthy thoracic stent grafting or those with previous repair of thoracic or abdominal aorta [3], (2) correction of postoperative anemia, (3) maintaining the mean arterial pressure at 80 to 100 mm Hg for the vulnerable period, and (4) prophylactic CSF drainage in patients deemed to be at an exceptionally high risk (history of SCI, lengthy DTA coverage in combination with previous AAA repair, occluded hypogastric arteries, thoracoabdominal branched stent-grafts).

Limitations

Because of the small sample of SCI cases, only univariate statistical analyses were performed. Conclusions about the clinical relevance of correlations have to be drawn with caution. This observational study is considered to be of only a hypothesis-generating nature. Identification of causes apart from intercostal artery coverage is based solely on clinical observations and retrospective analysis of the available imaging scans.

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INVITED COMMENTARY

Spinal cord injury leading to paraplegia remains a dreaded complication after surgical intervention for descending and thoracoabdominal aortic pathology, and it has a reported incidence as high as 6% to 7% in high-volume centers of excellence. Paraplegia is caused by a multitude of factors in the setting of open repair and includes loss of segmental spinal cord perfusion by intercostal arteries, ischemia during aortic cross clamping, and relative postoperative hypotension leading to decreased collateral flow. Numerous protective adjuncts have been developed for the perioperative and postoperative period in an effort to reduce the incidence of temporary and permanent paraplegia. Factors leading to spinal cord injury in the setting of thoracic endovascular repair have not been studied as extensively as with open repair. Sacrifice of segmental intercostal artery perfusion remains the primary cause of spinal cord ischemia, but the incidence of permanent injury remains low. In this study by Zipfel and colleagues [1], the authors examined their experience with more than 400 stent graft procedures performed over an 11-year period. The results were outstanding, with a 2.7% overall incidence of spinal cord injury and a 1.5% incidence of permanent deficit. Thoracic endovascular repair was performed in both elective and emergent clinical settings with numerous surgical techniques being used. Furthermore, individual case analysis was performed for 11 patients who developed postprocedure paraplegia.

Zipfel and colleagues [1] touch on an important issue that we recognize at our institution with these procedures. Maintenance of a robust mean arterial blood pressure is an extremely important protective adjunct for preventing spinal cord injury and is one of the few protective variables that can be controlled postoperatively. In a significant percentage of their individual cases that developed paraplegia, hypotension was clearly documented, whether because of hypovolemia, medication, or systemic inflammation. There is further evidence that correction of the low blood pressure resulted in significant recovery of function in several of these patients. The current study also demonstrates that extensive coverage of the descending aorta and a history of previous abdominal aortic aneurysm repair represent risk factors for potential spinal cord ischemia. Maintaining a mean blood pressure of 80 to 100 mm Hg would be particularly important in these subgroups of patients because of the increased risk of injury. Although the use of cerebrospinal fluid drainage is used commonly in the setting of open surgery, its benefit in endovascular repair, including the present series, is not so evident.

The authors should be congratulated for providing a critical analysis and further insight into the causes behind spinal cord injury following thoracic endovascular repair.

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2.6. Chirurgische Strategie bei Verschluss der A. subclavia

Zipfel B, Buz S, Hammerschmidt R, Hetzer R.
Occlusion of the left subclavian artery with stent grafts is safer with protective surgical reconstruction.
Annals of Thoracic Surgery 2009;88:498-505. [81]
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Die A. subclavia sin. muss bei ca. 40 % der thoraklen Implantationen zur sicheren Verankerung des Implantates im Aortenbogen durch die Stentprothese an ihrem Abgang verschlossen werden [56]. Anfangs wurde das ausgehend von Erfahrungen mit früheren Operationsmethoden [82, 83] als weitgehend folgenlos betrachtet und keine Rekonstruktion der Arterie durchgeführt [84, 85, 86]. Die Beschäftigung mit der Pathophysiologie der Durchblutung des Rückenmarkes (Kapitel 3.4.) und der möglichen Beeinträchtigung der Durchblutung des hinteren Hirnbasiskreislaufs bewirkte jedoch eine andere Sichtweise zu diesem Thema. So wurde, zumindest vor geplanten langstreckigen Stentprothesenimplantationen, prophylaktisch ein Carotis-subclavia-Bypass oder ein Subclavia-Carotis-Transposition angelegt [87], entweder einzeitig mit der Implantation der Stentprothese oder bei planbaren Fällen vorher im Abstand von 2 bis 3 Wochen.

In der Originalarbeit wird die Hypothese geprüft, ob diese prophylaktische Rekonstruktion der A. subclavia sin. klinisch von Vorteil sei. Retrospektiv wurde mit den prospektiv erhobenen Daten ein Vergleich zwischen 2 Gruppen von Patienten angestellt, bei denen die A. subclavia sin. durch den Stentgraft verschlossen wurde mit oder ohne vorherige Gefäßrekonstruktion. Hinsichtlich der schwerwiegenden neurologischen Komplikationen von links hemisphärischen Schlaganfällen oder Paraplegien konnten keine signifikanten Unterschiede gefunden werden. Dabei zeigte sich in Bezug auf Schlaganfälle ein Vorteil der geschützten Gruppe, der knapp nicht signifikant war (Tab. 2, S. 81). Außerdem hatten die beiden betroffenen Patienten in dieser Gruppe noch zusätzliche Gefäßrekonstruktionen der A. carotis com. sin. Hinsichtlich der spinalen Durchblutungsstörung waren wegen der geringen Inzidenz (nur ein Fall einer reversiblen Spinalischämie in beiden Gruppen) keine signifikanten Unterschiede feststellbar. Jedoch war in der Gruppe mit vorheriger Revaskularisation die Länge der mit Stentprothesen abgedeckten Aorta von median 230 mm signifikant länger als bei der ungeschützten Gruppe mit median 130 mm. So blieb die Schlussfolgerung spekulativ, dass durch die vorherige protektive Rekonstruktion der A. subclavia sin. die gefürchtete Paraplegie nach Implantationen langer Stentprothesen verhindert wurde.

Occlusion of the Left Subclavian Artery With Stent Grafts Is Safer With Protective Reconstruction

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Background. **Safe fixation of endovascular stent grafts in thoracic aortic disease often requires covering of the left subclavian artery (LSA) with the stent graft. It is controversial whether this occlusion can be done without additional risk of ischemic complications.**

Methods. **In 102 patients treated with endovascular stent grafts, the LSA was covered. In a nonrandomized clinical practice, unprotected occlusion of the LSA was performed in 63 patients (61%), whereas 39 patients underwent extrathoracic subclavian to carotid artery revascularization before (n = 28) or concomitantly with (n = 11) the endovascular procedure.**

Results. **Left cerebral ischemia occurred in 11% of the unprotected group and in 5% of the protected group. The difference was not statistically significant. The difference in spinal cord ischemia was insignificant owing to the low incidence in general, but the covered length of the aorta was significantly longer in the protected group. Arm ischemia after unprotected LSA occlusion occurred in 25%.**

Conclusions. **The interpretation of the results remains speculative because many factors contribute to left cerebral ischemia. However, in terms of overall complications, there is a significant difference in favor of the group protected by revascularization of the LSA either before or simultaneously with stent grafting. Arm ischemia is mostly mild and can be managed secondarily. Subclavian revascularization is associated with relatively low risk and should be considered in advance, at least when extended covering of the thoracic aorta is intended.**

(Ann Thorac Surg 2009;88:498–505)

For safe fixation of stent grafts in the distal aortic arch, it is often necessary to use the segment between the left common carotid artery (LCCA) and the left subclavian artery (LSA) as the proximal landing zone [1] with subsequent occlusion of the LSA. Liberal use of this technique is recommended in all cases with short distance between the LSA and the aortic lesion or in elongated aortic arches to avoid migration of the stent graft and subsequent type I endoleak, or in traumatic transsection to achieve safe exclusion of the contained rupture [2]. Based on the experience of sacrificing the LSA in coarctation repair [3, 4], LSA occlusion was initially deemed to carry a low risk, and clinical experience seemed to confirm that [5, 6]. When more experience was gained, some cases were noted with ischemic complications to which LSA occlusion may have contributed. Therefore, we changed our policy toward more liberal prophylactic LSA reconstruction. This retrospective study evaluates whether this prophylactic procedure may benefit the patient.

Patients and Methods

Between September 1999 and June 2008, endovascular stent grafts were successfully implanted in 274 patients for various thoracic aortic pathologies. In 102 (37%) of these patients the LSA was covered with the stent graft, 98 (96%) during the initial procedure and 4 (4%) as a secondary procedure. This subgroup of 102 patients was analyzed. In 3 of these patients, more proximal arch vessels were also covered, with mandatory previous revascularization of these vessels.

Data were gathered retrospectively from a Microsoft Access prospective database of all patients undergoing endovascular aneurysm or dissection repair. Stent grafts were only implanted when they were approved in the European Union. The prospective database was approved by the Institutional Ethics Committee. Written informed consent to data collection was obtained. This retrospective study was approved by the Institutional Ethics Committee, which waived the need for additional patient consent to the study.

Ninety-two procedures were performed in a standard operating room, and a surgical C-arm with angiography equipment (BV 300; Philips, Eindhoven, Netherlands) was used for intraoperative imaging. One procedure was

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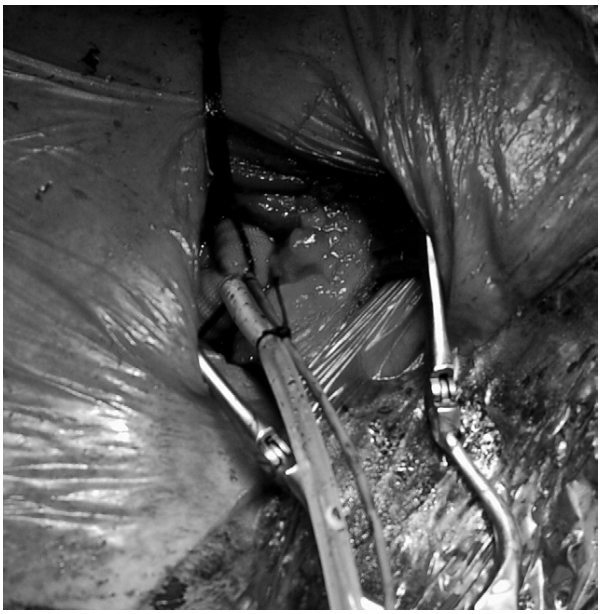

Fig 1. Hybrid procedure of simultaneous left subclavian artery (LSA) bypass and stent grafting: intraoperative situs showing the left common carotid artery to LSA bypass with a pigtail catheter inserted for target angiography.

performed in the cardiology angiography suite. Since March 2008, 9 procedures have been performed in a new hybrid operating room equipped with a fixed angiography unit with integrated angiography table (Artis Zee ceiling-mounted; Siemens, Erlangen, Germany). General anesthesia was used in all cases.

We used E-vita stent grafts (Jotec, Hechingen, Germany) in 52 procedures; Relay (Bolton Medical, Sunrise, FL) in 26; Talent (Medtronic Vascular, Santa Rosa, CA) in 23 procedures; and TAG (W. L. Gore Associates, Flagstaff, AZ) in 1 procedure. All stent grafts are self-expanding and are oversized by 10% to 20% in relation to the outer diameter of the aorta at the landing zone determined by preoperative computed tomography or magnetic resonance imaging. They are packed in delivery catheters of 22F to 27F. The stent grafts were advanced in retrograde manner from the femoral or iliac vessels and deployed as guided by the landmarks of a target angiogram. We have described the stent grafts and the implantation technique previously in detail [7].

Table 1. Patients' Demographics and Aortic Diseases as Indications for Stent Grafting

Aortic Pathology	Number	Male	Age, Years (range)	Age, Years (median)
Traumatic rupture	23	17 (74%)	18–81	37
Posttraumatic aneurysm	3	1 (33%)	37–72	65
Penetrating atherosclerotic ulcer	13	7 (54%)	54–81	71
True aneurysm	19	10 (53%)	57–85	72
Type B dissection	39	31 (80%)	38–83	60
Suture aneurysm	5	4 (80%)	28–56	34
Total	102	70 (69%)	18–85	59

Extrathoracic LSA revascularization was performed through a standard horizontal supraclavicular incision. The LCCA was exposed after mobilization of the internal jugular vein; then the fat tissue of the supraclavicular fossa was divided, and the phrenic nerve identified. To expose the LSA, the anterior scalenus muscle was partially or completely divided. When LSA to LCCA transposition was performed, the LSA was exposed further proximally to the origin of the left vertebral artery, as close to the aortic arch as possible. The LSA was then clamped and divided, and the stump was closed with a double 4-0 polypropylene mattress and running suture. The LSA was then moved to the LCCA and implanted with a rectangular end-to-side anastomosis with a 4-0 polypropylene running suture. In LCCA-LSA bypass procedures, this proximal dissection of the LSA was avoided, and an 8-mm collagen sealed polyester graft (FlowNit Bioseal; Jotec, Hechingen, Germany; or Hemashield Gold; Maquet, Rastatt, Germany) was im-

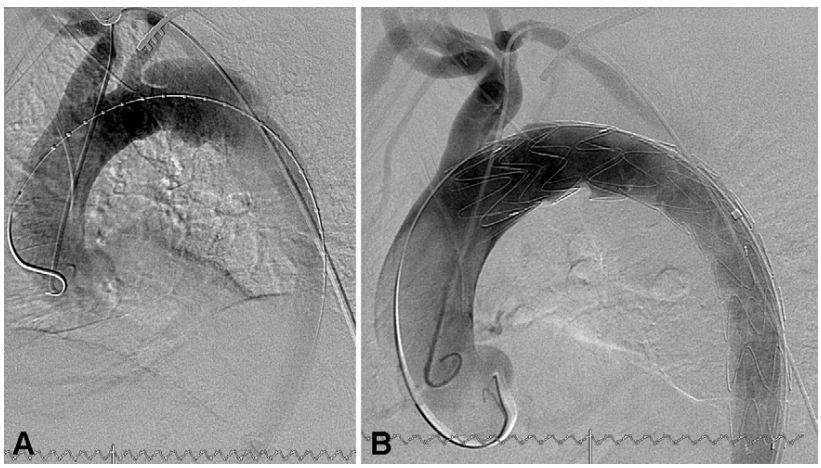

Fig 2. Hybrid procedure of simultaneous left subclavian artery (LSA) bypass and stent grafting: intraoperative angiograms from a 79-year-old man with type-B dissection. (A) The pigtail catheter through the bypass marks the origin of the left common carotid artery (LCCA). (B) The covered part of the Relay stent graft has been placed exactly behind the LCCA origin.

Table 2. Ischemic Complications With Possible Relationship to Left Subclavian Artery (LSA) Occlusion

Complications	Unprotected LSA Occlusion (n = 63)	Previous LSA Reconstruction (n = 39)	*p* Value
Left hemispheric ischemia or stroke	7 (11%)[a]	2 (5%)[b]	0.477
Spinal cord ischemia (reversible)	1 (2%)	0	NS
Left arm ischemia	16 (25%)	0	<0.001
Secondary LSA reconstruction	15 (24%)	0	<0.001
Emergency procedures	55 (87%)	10 (26%)	<0.001
Effective length of stent graft (median/mm)	130 (90–395)	230 (100–390)	<0.001
Entire DTA covered	7 (11%)	9 (23%)	0.123

[a] One multiple trauma patient with severe cerebral edema and final brain death after severe head injury was not considered as having ischemic neurologic complications. [b] Both patients had more proximal coverage of the aortic arch and extensive revascularization (see text): one right common carotid artery to left common carotid artery to LSA bypass and one complete debranching of the aortic arch.

DTA = descending thoracic aorta; NS = not significant.

planted between the most cranial section of the LSA and the LCCA with two end-to-side anastomoses with 4-0 polypropylene running sutures, the LCCA anastomosis rectangular to the lateral aspect of the LCCA. Thirty bypasses were performed, with ligation of the proximal LSA in 6 cases and 9 transpositions. In simultaneous procedures, the LSA reconstruction was performed as the first step before stent graft implantation. The bypass or the transposed LSA was used as the approach for a separate catheter for target angiography (Figs 1 and 2) [7, 8].

Left arm ischemia was determined by clinical examination by the surgeon if one of these criteria was fulfilled: cold, perspiring, cyanotic extremity, and numbness or compromise of motor function at rest or during exercise.

All ischemic neurologic events with a potential relationship to impairment of the LSA circulation are reported in this retrospective review, namely, any left cerebral reversible ischemia or stroke and any not clearly trauma-induced clinical spinal cord compromise.

Results

Seventy patients (69%) were male; mean age was 59 years (range, 18 to 85). The indications for the stent graft implantation and patient demographics are summarized in Table 1. Sixty-five operations (64%) were emergency procedures with these preoperative conditions: active bleeding in 9, contained rupture in 23, malperfusion in type-B dissections in 20, symptomatic aneurysm in 10, and 3 urgent procedures because of impending compli-

Table 3. Details of Neurologic Events

No.[a]	Sex	Age (Years)	Aortic Pathology	Indication/Comorbidity	Neurologic Event
Unprotected LSA occlusion					
1	M	73	Type B dissection	Rupture	Brain stem infarction; reversible hemiplegia
2	M	75	Saccular arch aneurysm	Contained rupture	Left hemispheric stroke; fatal outcome
3	M	42	Traumatic rupture	Contained rupture; severe head injury, subdural hematoma; Huntington chorea	Left cerebellar infarction; fatal outcome
4	M	68	Saccular arch aneurysm	Elective; surgical closure of endoleak POD 3	Left hemispheric infarction after second operation; disabling stroke
5	M	57	Traumatic rupture	Contained rupture; moderate head injury; spinal fracture, traumatic paraplegia T5	Cerebellar/brainstem infarction; spinal cord injury progression to C4/5
6	M	42	Type B dissection	False lumen expansion; uncontrolled hypertension	Left posterior infarction; disabling stroke
8	M	22	Traumatic rupture	Contained rupture; no head injury	TIA during recovery
9	M	59	Type B dissection	Malperfusion with paraplegia	Paraparesis reversible within 24 hours
10	M	77	Traumatic rupture	Contained rupture; stable spinal fracture	Tetraplegia reversible; trauma related?
Previous LSA reconstruction					
7	M	72	Saccular arch aneurysm	Elective	Embolic left hemispheric stroke after RCCA-LCCA-LSA bypass; disabling; fatal outcome
11	M	74	Extended arch and DTA aneurysm	Elective	Left hemispheric TIA after total arch debranching

[a] Patients numbered consecutively after date of operation.

C = cervical segment; DTA = descending thoracic aorta; LSA = left subclavian artery; LCCA = left common carotid artery; M = male; POD = postoperative day; RCCA = right common carotid artery; T = thoracic segment; TIA = transient ischemic attack.

cations. No patient had previous coronary bypass grafting using the internal thoracic artery.

Stent grafts with diameters of between 20 mm and 46 mm (median 36 mm) were used. In 77 procedures, 1 segment was used; in 19 procedures, 2 segments were used; and in 6 procedures, 3 segments were used. The average number of grafts per procedure was 1.3. The effective length of covered thoracic aorta per procedure was 190 mm (range, 90 to 395 mm). In 16 cases (16%), the complete thoracic aorta with a distal landing zone caudal of the diaphragm was covered.

In nonrandomized clinical practice, unprotected occlusion of the LSA was performed in 63 patients (61%), whereas 39 patients underwent extrathoracic subclavian to carotid artery reconstruction before (n = 28) or concomitantly with (n = 11) the endovascular procedure (protected group).

Implant details of the two groups with protected or unprotected coverage of the LSA and ischemic complications to which the occlusion of the LSA may have contributed are given in Table 2. There was a 25% incidence of left arm ischemia in the unprotected group. A more detailed description of the neurologic events is given in Table 3. Overall incidence of left cerebral events was 9% (n = 9), with insignificant differences between the two groups (11% versus 5%). Incidence was 12% among trauma patients (n = 3 of 26), 11% (n = 4 of 37) among those with aneurysms and 5% (n = 2 of 39) among those with dissections. Two spinal cord events are reported although they were most likely related to the underlying disease or trauma. One case of spinal cord ischemia was induced by the acute dissection with malperfusion and was reversible within 24 hours after implantation of the stent graft with unprotected LSA occlusion (patient 9). In the second case (patient 10), the patient had posttraumatic reversible tetraplegia after stable cervical spine fracture without displacement, which was deemed spinal contusion by the orthopedic surgeons, but the contribution of LSA coverage by the stent graft remains unclear. Two cases of clearly trauma-related paraplegia in severely dislocated spinal fractures were excluded. One case was a patient (patient 5) who later had cerebellar and brainstem infarction and a progression of the spinal cord injury to the level C4/5. The other case was a 17-year-old boy, who was the only trauma patient with simultaneous LSA reconstruction, which was performed with the intent of preserving the arm circulation for pushing the wheelchair; interestingly, this patient did not experience any deterioration of his initial neurologic status. One multiple trauma patient with severe cerebral edema and final brain death after severe head injury was not considered as having an ischemic neurologic complication because it was obviously trauma induced.

Arm ischemia occurred at rest in 2 cases and during exercise in 14 cases after simple coverage of the LSA. In 1 case, unexplained segmental neurologic disorder was discussed, and it resolved immediately after secondary LCCA to LSA bypass. Incidence of arm ischemia was 28% (n = 7 of 25) for trauma, 31% (n = 8 of 26) for dissections, and 8% (n = 1 of 12) for aneurysms. Thirteen patients

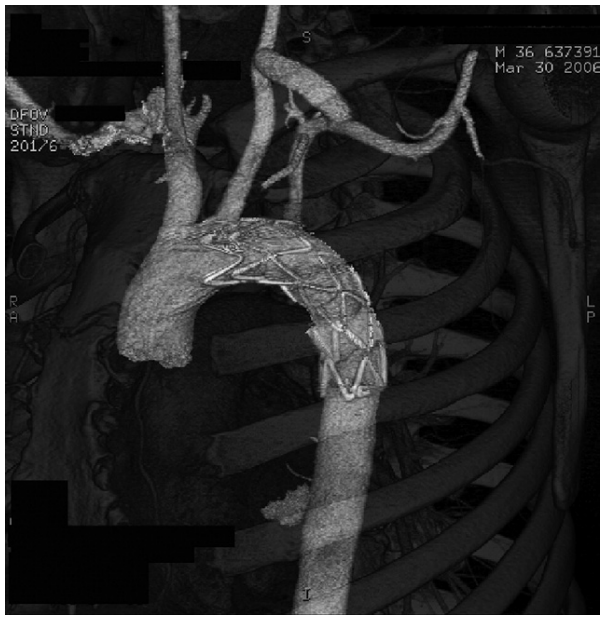

Fig 3. Secondary left subclavian artery (LSA) bypass: computed tomography reconstruction from a 36-year-old-man with blunt traumatic rupture. The left common carotid artery to LSA bypass was implanted 16 days after the stent graft procedure. The rupture is completely excluded by the E-vita stent graft.

received secondary revascularization of the LSA with immediate resolution of the symptoms (Fig 3); 3 patients declined the secondary operation because the symptoms were tolerable. In 1 case, the symptoms disappeared completely after 2 years. Complications in association with the LSA revascularization, including the secondary procedures, were noted in 22%: 1 embolic stroke (patient 7), 10 phrenic nerve palsies, 8 of them reversible, and 1 lymph fistula requiring intervention.

Other Outcomes

The median length of hospital stay was 20 days (mean, 28.1 ± 26.7; range, 2 to 162). Length of hospital stay was 7 days or less for 14%, 14 days or less for 29%, and 30 days or less for 71% of all patients. Overall 30-day mortality was 10.8% (n = 11).

Comment

Several limitations hamper the interpretation of the results. As a retrospective review of prospectively maintained data, our analysis was limited to the variables that were collected during clinical care. The practice of revascularization of the LSA has changed during the study period. This change was initiated by the experience of two cerebellar infarctions in 2 multiple trauma patients (patients 3 and 5; Table 3), in whom the coverage of the LSA was suspected to have caused additional ischemic damage to the severe injury of brain and spinal cord. The concept of liberal revascularization was guided by the intention to prevent possible severe complications with

the adjunctive procedure. The two groups of protected and nonprotected LSA occlusion are not randomized and are divided by clinical practice and individual decisions. As a result, both are inhomogeneous in terms of underlying diseases. Emergency procedures are significantly more frequent in the unprotected group. The anatomical and pathophysiologic considerations concerning prophylactic LSA reconstruction will be discussed in detail to establish whether the retrospective results may have matched these ideas.

Impairment of the Left Arm Circulation

Because of preformed collaterals, occlusion of the LSA orifice remains asymptomatic in many cases. Arm ischemia is mostly mild. Clinical problems have been reported to be infrequent in the literature. Many authors claim that if weakness or numbness of the arm occurs, that may disappear with time [6, 9]. In a recently published meta-analysis [10], left arm claudication was reported in 23 of 29 articles cited, with an incidence of 0% in 15 papers and an incidence between 2% and 14% in eight papers. We observed an incidence of 25% (n = 16) in the unprotected group. This obvious difference may be explained by a straightforward surgical approach to manage postoperative exercise-induced left arm weakness or pain after occlusion of the LSA. If the patients experience symptoms, we offer them secondary revascularization. Therefore, the majority were managed by secondary revascularization, with immediate resolution of the symptoms. Arm ischemia is less frequent in patients with thoracic aneurysms compared with dissection and trauma, probably owing to the higher age in this group that limits activity and thus exercise-induced symptoms.

Cerebral Ischemia

Many factors apart from LSA occlusion, such as extended atherosclerotic aortic arch disease, emergency procedures and trauma, may contribute to left cerebral ischemia. Stroke occurring after stent grafting may be caused as well by occlusion of the supra-aortic vessels or by emboli arising from manipulation of the aortic arch [11]. Therefore, in no case of this clinical study can LSA occlusion be proven as the single cause for cerebral ischemia. Three cases of left posterior cerebral infarctions were probably related to impairment of the perfusion of the vertebral artery. They were verified by cerebral computed tomography scans and differentiated from additional sequelae of head injury in 2 patients. In the remaining 6 cases (Table 3), the contribution to LSA occlusion is speculative. The two type-B dissection cases (patients 1 and 6) had no involvement of the arch vessels. A correlation to the underlying disease cannot be found, probably because of the small number and the various mechanisms. Also, the difference in the rate of cerebral ischemia with potential contribution to LSA occlusion of 11% of the patients with simple LSA coverage compared with 5% of patients with previous revascularization is insignificant, but ischemic complications in the protected group occurred in those patients with extensive coverage and revascularization of supra-aortic arteries. The stroke in 1 patient (patient 7) was caused by the revascularization procedure itself (plaque embolization from the LCCA anastomosis). Therefore, it is supposed that unprotected LSA occlusion by a stent graft may bear a higher risk of left cerebral ischemic complications. Peterson and colleagues [12] found similar results, with a 50% cerebral complication rate in 8 unprotected LSA occlusions in a study comparable to this one. Data from the open Eurostar registry of 606 patients revealed significantly different postprocedural stroke rates of 8% in the unprotected group and 0% in the protected group [13].

We did not see symptomatic subclavian steal syndrome with dizziness on exertion of the arm. Follow-up duplex sonography revealed reversal of flow in the vertebral artery in most cases [14], which seems to be normal after occlusion of the LSA, but symptoms requiring surgical intervention were not reported.

Diagnostic evaluation of the cerebral perfusion with extra- and intracranial Doppler sonography is recommended by several authors before occluding the LSA with a stent graft [9]. This evaluation is complex, time-consuming, and examiner-dependent. Therefore, when in doubt or without these diagnostic tools, protective revascularization is reasonable. Atherosclerotic disease of the common carotid artery at the site of the anastomosis should be ruled out by simple duplex ultrasound.

Spinal Cord Ischemia

The collateral perfusion of the spinal cord is fed by branches of the subclavian artery. In normal anatomy, the anterior and posterior spinal arteries arise from the vertebral arteries, but variations of direct origin of the spinal cord artery from the LSA have been described [15]. In these instances, the spinal cord perfusion is directly dependent on the LSA. Also, experimental findings support the theory that the LSA contributes to spinal cord perfusion. In a pig model, fewer intercostal arteries had to be occluded to induce paraplegia if in addition the subclavian arteries were occluded [16]. Experimental and clinical findings stress the importance of collateral blood flow to the spinal cord when intercostal arteries are sacrificed in conventional thoracoabdominal surgery [17, 18] and challenge the concept of reimplantation of intercostal arteries in conventional thoracic surgery [19]. Long stent grafts cause unavoidable extensive segmental artery sacrifice, and the incidence of spinal cord ischemia is unexpectedly low in our own and all other published series [8, 20–23]. Maintaining the collateral blood flow by avoiding cross-clamping and hypoperfusion in the endovascular technique is the most probable explanation. The first clinical evidence that LSA occlusion may be a risk for spinal cord ischemia in thoracic stent grafting was published by the Eurostar registry in 2007 [13]: in 606 patients, LSA occlusion was found to be an independent risk factor for spinal cord ischemia (odds ratio 3.9, $p = 0.027$).

Guided by these considerations, we practiced prophylactic revascularization at least in all patients in whom the placement of long stent grafts covering the entire descending thoracic aorta was planned and in all patients

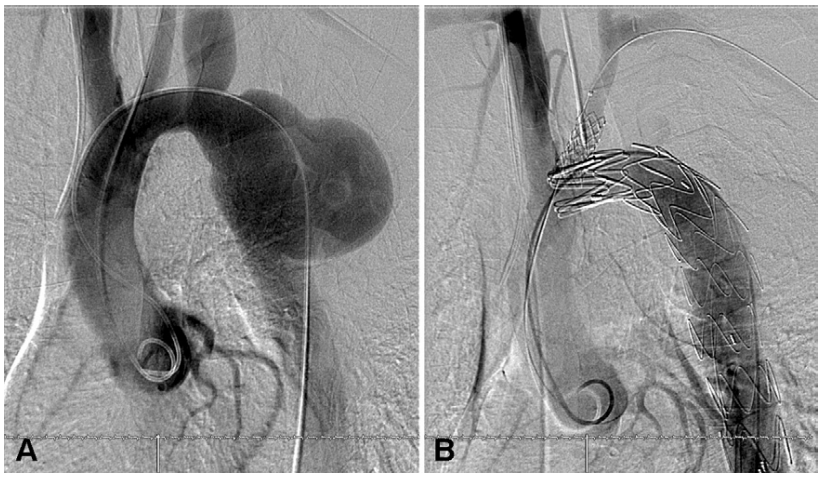

Fig 4. Left subclavian artery (LSA) transposition to prevent type II endoleak through the LSA. Intraoperative angiograms from a 28-year-old man with patch aneurysm after coarctation repair in childhood: (A) target angiography shows the stump of the huge LSA after preliminary transposition; (B) completion angiogram demonstrates complete exclusion of the aneurysms, a minimal blush of dye in the LSA stump, and the rectangular anastomosis of the LSA to left common carotid artery transposition.

with previous replacement of the abdominal or thoracic aorta. Fortunately, we were not able to test the validity of this practice, because the rate of paraplegia is so low that subgroup analysis is statistically insignificant. Moreover, in both registered cases of spinal cord ischemia, it remains questionable whether the neurologic damage was caused by implantation of the stent graft.

Although, as a result of our policy, the coverage of the thoracic aorta was significantly longer in the protected group, with 23% coverage of the entire descending aorta from the LSA to the celiac artery, no spinal cord ischemia occurred. One remarkable case with additional abdominal aneurysm repair has been described earlier [24]. In conclusion, maintaining the collateral perfusion fed by the LSA seemed to prevent spinal cord ischemia.

Type II Endoleak

If the LSA origin is situated very close to the aortic aneurysm retrograde, endoleak [25] is anticipated. A typical situation is illustrated in Figure 4. The safest method to prevent that is extrathoracic ligation or disconnection of the LSA, which is then easily combined with revascularization [26]. Therefore, in these special cases, prevention of a type II endoleak is an additional indication for prophylactic LSA revascularization. Then, LSA transposition is the most reliable method because the proximal LSA is definitely disconnected. Bypass can be combined with ligation of the LSA proximal to the vertebral and mammarian artery. This procedure requires the same extent of surgical dissection as transposition. When retrograde leak is unlikely or probably minor, we prefer simple LCCA to LSA bypass. If an endoleak occurs, this can be closed with coils or occluders during the stent graft procedure.

Endovascular Approach to LCCA Through Bypass or Transposition

The carotid-subclavian bypass or transposition opens an easy access point to place a catheter in the left carotid artery. The crossing of catheter and guidewire marks the spot at the origin of the LCCA where the proximal end of the stent graft has to be placed. The technique is used in simultaneous procedures (Fig 1) and also in stent grafting after preliminary revascularization with an approach through the left brachial artery (Fig 4). The endovascular access through the bypass has two additional technical options. If the stent graft has been placed too far upstream, the LCCA orifice can be easily opened with a bare metal stent (Fig 4). This technique can also be applied intentionally as the "chimney" technique [27]. In the case of a type II endoleak, the catheter can be placed simply into the proximal LSA to deposit coils or occluders close to the stent graft. Our experience with this technique is so satisfactory that this is another argument for considering preemptive LSA revascularization.

Conclusion

Occlusion of the LSA with the stent graft may be safe if a short stent graft is implanted in the proximal aorta, and if stenoses and abnormalities of the supra-aortic and intracranial arteries supplying the brain can be ruled out. Arm ischemia can be handled safely after the procedure. We recommend prophylactic revascularization for all patients in whom the placement of long stent grafts covering the entire descending thoracic aorta is planned and for all patients with previous replacement of the abdominal or thoracic aorta. Protective LCCA to LSA bypass is mandatory in patients with previous coronary bypass grafting using the internal thoracic artery to prevent coronary ischemia. Moreover, the carotid to subclavian bypass or transposition enables easy access to place a catheter in the left carotid artery for more precise placement of the stent graft in the aortic arch. In doubt, we therefore regard LSA revascularization as indicated.

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INVITED COMMENTARY

We very much appreciate the opportunity to analyze the manuscript by Zipfel and colleagues [1]. They have stated that prophylactic subclavian artery revascularization may reduce significant neurologic complications. They concluded that prophylactic reconstruction of subclavian artery is safer than later elective reconstruction after stent graft repair of thoracic aorta disease. However, the authors demonstrated no statistical difference in neurologic complications between the patients in the protected and unprotected series.

When one reviews the major neurologic complications in the unprotected series, they all occurred in patients undergoing urgent procedures for type B dissections or traumatic injuries. Moreover, because many of these events occurred in patients with traumatic brain injury, it is difficult to conclude that preoperative subclavian artery revascularization would have altered the incidence of neurologic events.

We agree entirely with the concept that left arm ischemia is not the main indication for doing such prophylactic revascularization. In our series, approximately 40% of the patients undergoing stent graft coverage of the subclavian artery required subclavian artery revascularization [2], similar to the present study.

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We believe that preoperative subclavian artery reconstruction should be performed in high-risk patients, including those with dominant left vertebral artery, an incomplete circle of Willis, or a patent left internal thoracic artery graft. In addition, based on the experience presented by Zipfel and colleagues [1], it may be appropriate to consider revascularization in urgent cases and patients with traumatic aortic injury or dissection.

Although the authors suggest that prophylactic subclavian revascularization should be done when long areas of the thoracic aorta are covered, they have no data to support this. The paraplegia rate was low in both groups. With this approach, the need for postoperative subclavian artery revascularization has been less than 15% in our experience [2]. We also agree that carotid subclavian bypass is a safe and simple procedure to perform either before or concomitant with stent graft repair of aneurysms, although we note that the authors had a 2.6% stroke rate with this procedure [1].

In summary, we do not agree that left subclavian artery revascularization needs to be performed in all cases of stent graft repair of thoracic aneurysms, even when long areas needed to covered. We believe in a selective approach based on a preoperative anatomic assessment.

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3. Diskussion

3.1. Entwicklung der endovaskulären Behandlung und der Implantate

Mit der ersten Implantation einer Stentprothese in die thorakale Aorta im DHZB wurde 1999 klinisches Neuland betreten. Es waren zwar schon bescheidene Erfahrungen mit selbst hergestellten Stentprothesen veröffentlicht worden [88], aber mit den ersten industriell hergestellten Prothesen eröffnete sich ein großes Anwendungsfeld und ein Feld der klinischen Forschung [71]. Diese Stentprothesen der 2. Generation waren von den Implantaten für das infrarenale BAA modifiziert. Die besonderen Bedingungen der thorakalen Aorta insbesondere des Aortenbogens machten neue Konstruktionen erforderlich [70].

Kapitel 2.1. beschreibt die Erfahrungen der Lern- und Entwicklungsphase der ersten Jahre [56]. Eine wichtige Erkenntnis aus dieser Arbeit war die Heterogenität des Kollektivs der mit thorakalen Stentprothesen behandelten Patienten im Gegensatz zu dem homogenen Kollektiv der BAA, mit denen die ersten Erfahrungen mit Stentprothesen gesammelt wurden [89, 90]. Die Heterogenität machte es sinnvoll, in weiteren Untersuchungen diese Untergruppen separat zu betrachten und auszuwerten. Daher wurde in den folgenden Jahren keine Nachfolgeuntersuchung für das Gesamtkollektiv veröffentlicht. Mit zunehmender Erfahrung und der Verfügbarkeit neuer längerer Prothesenmodelle nahm die Länge der abgedeckten Aorta stetig zu, ohne dass es zu vermehrtem Auftreten von Paraplegien kam. Die intraoperative Bildgebung erfolgte zu dieser Zeit mit einem mobilen chirurgischen Bildverstärker, dessen Vor- und Nachteile ausführlich diskutiert wurden. Die Möglichkeit, im Operationssaal zu arbeiten, rechtfertigte die Limitierungen der intraoperativen Bildgebung, vor dem Hintergrund, dass bei 17 % der Patienten umfangreichere chirurgische Maßnahmen erforderlich waren als die bloße Freilegung der Femoralarterie. Die transösophageale Echokardiographie (TEE) wird als unentbehrliches Hilfsmittel bei Aortendissektionen beschrieben. Die TEE dient zur sicheren Identifizierung des wahren Lumens und ist zu diesem Zweck besser geeignet als die Angiographie [91]. Sie wird seitdem routinemäßig verwendet und von den Anästhesisten durchgeführt. Die TEE hat aus diesen praktischen Vorteilen den auch im DHZB versuchsweise eingesetzten intravaskulären Ultraschall (IVUS) völlig verdrängt, der von einigen Chirurgen, vor allem in den USA, gerne benutzt wird [66, 92]. In der Diskussion ist bereits die konkrete Planung eines Hybridoperationssaales erwähnt. In Kapitel 2.6. wird der Fortschritt beschrieben (S. 79 f): Seit März 2008 werden die Stentprothesen in einem mit einer fest installierten Angiographieanlage ausgerüsteten Hybridoperationssaal implantiert. Das hat zu einer wesentlichen Verbesserung der intraoperativen

Bildgebung ohne Verzicht auf die Standards des Operationssaals geführt und mit der besseren Bildgebung in der Folgezeit auch weitere Ausweitungen der endovaskulären Therapie über bisher vorhandene anatomische Grenzen hinweg möglich gemacht (Abb. 7).

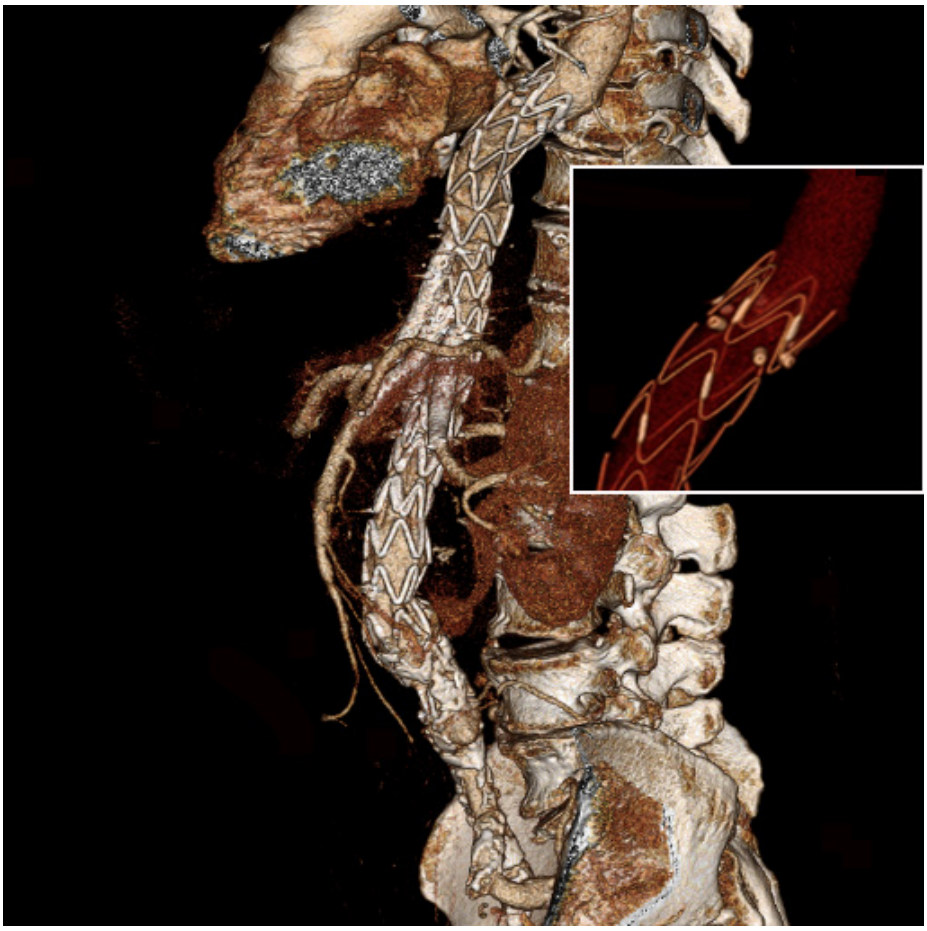

Abb. 7

Postoperative CT Rekonstruktion einer Stentprothese mit Seitenarmen zu Tr. coeliacus, A. mesenterica sup. und beiden Nierenarterien und zusätzlicher Fixierung der Prothese proximal mit Endostaples (Insert) zur Behandlung eines thorako-abdominellen Aneurysmas Typ Crawford IV.

Die technische Entwicklung der Stentprothesen, von der kurzen relativ steifen Talent® mit einem einfachen Druck und Zug Einführungssystem hin zu den modernen Systemen mit reibungsarmem, mechanisch unterstützten Einführungssystemen und langen Segmenten, konnte der Autor durch die Mitarbeit an der Entwicklung der E-vita thoracic® mitgestalten. Die Auswahl der Stentprothesen für das eigene endovaskuläre Programm wird bestimmt durch solche Einblicke in die Technologie und von den praktischen klinischen Erfahrungen. In Sinne der Übersichtlichkeit für auszubildende Assistenten und Operationsschwestern ist eine Beschränkung auf wenige Systeme geboten. Folgende Forderungen sind an eine Stentprothese für die thorakale Aorta zu stellen:

1. Flexible Stentprothese
2. Auswahlmöglichkeit kurzer und langer Segmente bis 250 mm Länge
3. Präzise durch den Operateur kontrollierbare Freisetzung
4. Wahlmöglichkeit von an die Aortendissektion angepasste Konfigurationen
5. Wahlmöglichkeit von proximalen atraumatischen freien Federn
6. Option individuell gefertigter Prothesen
7. Metallkomponenten ohne Artefakte im MRT

Derzeit werden im DHZB E-vita thoracic®, Relay® und Zenith® (Cook Medical Europe, Bjaeverskov, Dänemark) implantiert. Von allen 3 Systemen können auch Sonderanfertigungen hergestellt werden, Prothesen mit Seitenarmen oder Fenestrationen eingeschlossen. Diese Weiterentwicklung der Technologie wird in zunehmendem Umfang eingesetzt [93]. Die Abb. 7 zeigt ein Beispiel.

3.2. Vorteile und Chancen der Stentprothesen bei Aortendissektionen

Für die Aortendissektion bedeutet die endovaskuläre Operation mit Stentprothesen nicht nur eine minimal-invasive Alternative, sondern eine qualitativ neue Behandlung gegenüber der konventionellen Chirurgie, da sie in der Lage ist, den Blutfluss in das wahre Lumen zurückzuleiten und dadurch in günstigen Fällen eine komplette oder partielle Ausheilung der Dissektion auch distal der Gefäßprothese zu bewirken.

Die Behandlung der akuten komplizierten Typ-B-Dissektion mit Stentprothesen rasch zu einem überzeugenden Konzept entwickelt. Die Nachbeobachtung dieser Notfallpatienten [94, 95, 96] zeigte das Potential der Stentprothesen, die Dissektion im Sinne einer Remodellierung zum Verschwinden zu bringen, zumindest längs der Strecke, wo sie implantiert sind (Abb. 4). Bestätigt hat sich das auch in größeren systematisch untersuchten Kollektiven wie in Kapitel 2.3 beschrieben [75]. Aus der Beobachtung dieser günstigen morphologischen Veränderungen stellte sich die Frage, ob auch Patienten mit unkomplizierten Typ-B-Dissektionen, die bislang konservativ behandelt wurden, langfristig von Stentprothesen profitieren könnten. Dafür sprechen die günstigen morphologischen Veränderungen, dagegen mögliche durch Stentprothesen induzierte Komplikationen, zum Beispiel mit dem Stentgraft assoziierte Typ-A Dissektionen, die das erreichte gute Ergebnis zunichtemachen können [97, 98, 99, 100, 101]. Zur Prüfung dieser Hypothese wurde die multizentrische randomisierte INSTEAD-Studie durchgeführt, an der der Autor in Konzeption und Planung und mit Einschluss und

Nachbeobachtung von 13 Patienten beteiligt war. Eingeschlossen wurden nur Patienten, die in der akuten Phase der ersten 14 Tage nach der Dissektion keine der eingangs definierten Komplikationen erlitten hatten. Zur endovaskulären Behandlung war nach dem Studienprotokoll einheitlich die Talent® Stentprothese vorgeschrieben. Das Ergebnis über zwei Jahre ergab keine signifikanten Unterschiede zwischen den beiden Gruppen bezüglich kumulativen Überlebens, aortenbedingten Todesfällen und dem Fortschreiten der Aortenerkrankung, obwohl die durch die Stentprothesen induzierten günstigen morphologischen Veränderungen mit hoher Signifikanz bestätigt wurden [102].

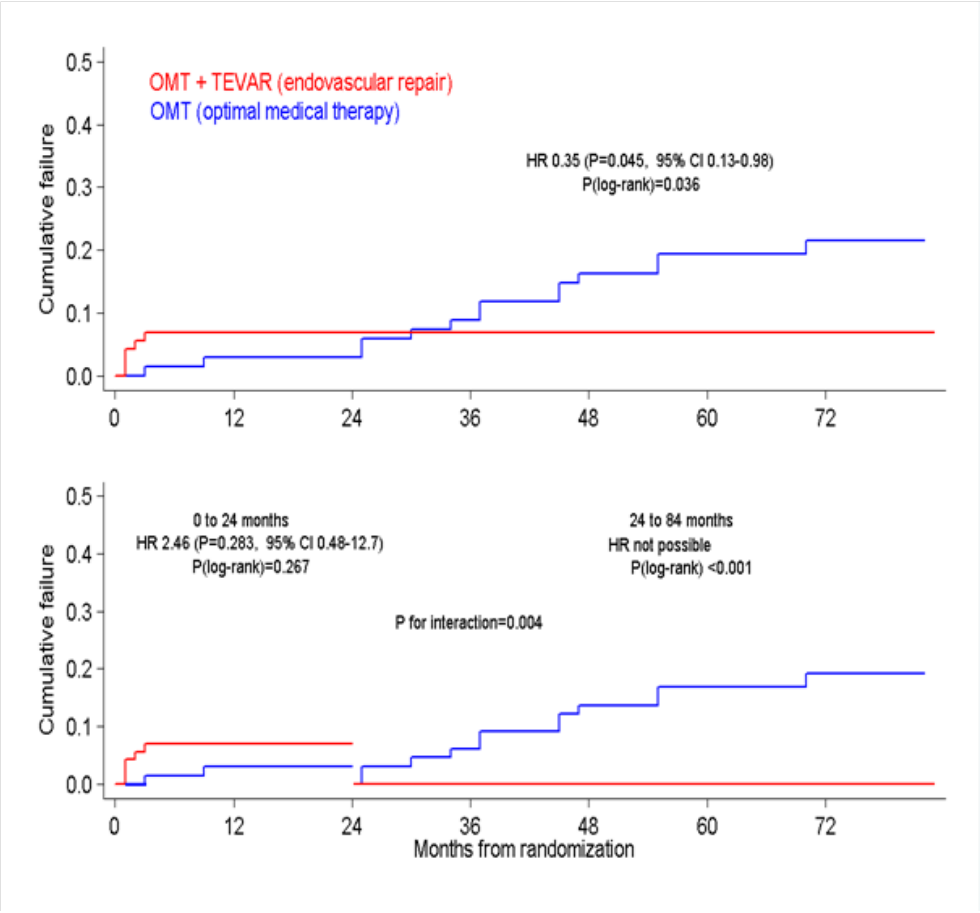

Abb. 8

Aortaspezifische Mortalität der beiden Gruppen der INSTEAD Studie nach 5 Jahren. Es zeigt sich eine signifikant niedrigere Mortalität in der Stentgraftgruppe im Vergleich zur konservativen Therapie [103]

Die Studie fand große Beachtung. Als mögliche Gründe für das überraschend neutrale Ergebnis wurden diskutiert: die bessere Qualität der konservativen Behandlung unter Studienbedingungen und die technischen Nachteile der Talent® Stentprothese aus der 2. Generation (S. 30 f). Unter diesen Umständen war die Nachbeobachtungszeit zu kurz, um Unterschiede zu zeigen. Eine Nachuntersuchung der ursprünglich randomisierten Patienten nach 5 Jahren

wurde kürzlich publiziert [103]. Nun konnte ein signifikanter Vorteil der Stentprothesengruppe bezüglich Gesamtmortalität und aortenbedingter Todesfälle gezeigt werden (Abb. 8, S. 90). Vor dem Hintergrund des Ergebnisses der einzigen randomisierten Studie zu Stentprothesen in der thorakalen Aorta und der inzwischen deutliche verbesserten Technologie wird sich der Therapiealgorithmus auch der primär unkomplizierten Typ-B-Dissektion hin zur endovaskulären Therapie verschieben. Sie kann dabei mit einem gewissen Zeitabstand zum akuten Ereignis durchgeführt werden.

Die Beschränkung der INSTEAD-Studie auf „chronische“ Dissektionen über 14 Tage wurde zwar kritisiert [104], hat aber das Ergebnis nicht ungünstig beeinflusst, denn alle Patienten, inklusive der Crossover-Fälle innerhalb des ersten Jahres reagierten mit einer vollständigen Remodellierung der Aorta im Bereich der Stentprothese. Für die Randomisierung wurde ein Zeitraum von 14 Tagen bis zu einem Jahr definiert, um komplizierte von unkomplizierten Dissektionen aus dem Verlauf sicher zu unterscheiden [105]. Die in Lehrbüchern festgelegten Einteilung der Dissektion in ein akutes und chronisches Stadium mit der Grenze von 14 Tagen [106] resultiert aus der frühen chirurgischen Erfahrung, dass die Dissektionsmembran im akuten Stadium fragil und damit eine Operation mit höheren Komplikationen behaftet sei. Eine wissenschaftliche Evidenz für die Grenze von 14 Tagen gibt es nicht. Bereits Borst ergänzte 1991 in seinem Betrag zum deutschsprachigen Standardlehrbuch der Herzchirurgie [107] ein subakutes Stadium: „Eine Dissektion wird als akut definiert, wenn sie innerhalb von 14 Tagen nach dem plötzlichen Schmerzereignis zur Operation kommt; als subakut, wenn das Ereignis nicht mehr als 2 Monate zurückliegt; als chronisch bei Verstreichen eines noch längeren Zeitraumes. Vom Standpunkt des Operateurs aus gesehen erscheint eine Trennung von akuter und subakuter Dissektion allerdings weitgehend irrelevant, da in beiden Fällen die Aortenwandungen zart und brüchig sind und eine narbige Stabilisierung der äußeren Wandschicht erst im späteren Verlauf zustande kommt“. Der letzte Satz, aus Sicht der konventionellen Operation geschrieben, ist für den heutigen endovaskulären Ansatz aktuell: Auch die Erfahrung mit den Stentgrafts erfordert eine Modifikation der etablierten chirurgischen Stadieneinteilung, da offenkundig die Elastizität der Dissektionsmembran und damit die Fähigkeit zur Remodellierung der Aorta durch die Stentprothese auch noch weit über die Grenze von 14 Tagen hinaus gegeben ist. Es bleibt unklar wie weit Stentprothesen bei Patienten mit wirklich chronischen Dissektionen eine effektive Alternative zur konventionellen chirurgischen Behandlung darstellen können. Die eigenen noch unveröffentlichten Erfahrungen sind ambivalent. Es ist durch weitere Forschungen zu klären, bis zu welchem Zeitpunkt nach der Dissektion man noch mit einer effektiven Erweiterung des wahren Lu-

mens durch die Stentprothesen rechnen kann. Die in der Literatur angegebenen Grenze von 2 oder 3 Monaten basieren auf Schätzungen [107] oder Gruppeneinteilungen bei Datenanalysen [108] und nicht auf mathematischen Modellen, für die viel größere Stichproben erforderlich wären. Vermutlich liegt die Grenze noch später, etwa bei den im Design der INSTEAD Studie angenommenen 12 Monaten.

Während nach effektivem Verschluss des Entry abhängig vom Alter der Dissektion eine vollständige Remodellierung der Aorta in der Länge zu beobachten ist, über die der Stentgraft implantiert ist, bleibt das Schicksal der distal davon gelegenen Aortenabschnitte insbesondere der abdominellen Aorta unklar. Die Verlängerung der Stentprothesen mit großlumigen Aortenstents (ohne Prothesen) nach distal in die thorako-abdominelle Aorta [109, 110] wäre ein Ansatz, auch hier die Remodellierung zu erreichen und einer erfolgreichen endovaskulären Behandlung der gesamten dissezierten Aorta nahe zu kommen. Die zu diesem Thema bereits veröffentlichten Studien [111, 112] verwenden einen Stent, der noch aus der Pionierzeit der endovaskulären Therapie stammt und wegen seiner geringen Expansionskraft Probleme bereiten kann [113]. Im DHZB wird bei Notfällen mit im thorako-abdominellen Abschnitt kollabiertem wahren Lumen ein neu konstruierter Stent mit klinisch gutem Erfolg einsetzt [114, 115]. Die Evaluierung dieser Strategie in einer prospektiven Studie [116] ist ein aktuelles klinisches Forschungsprojekt.

3.3. Traumatische Aortenruptur: „Endovascular is the winner“

Die endovaskuläre Methode wurde kurz nach Einreichen des Manuskripts des oben zitierten Lehrbuchbeitrages [24] im DHZB eingeführt und erwies sich als so überzeugend, dass die letzte konventionelle Operation der traumatischen Aortenruptur im Jahr 2004 durchgeführt wurde. Die Studie von 39 endovaskulär versorgten traumatischen Aortenrupturen im Vergleich zu den bis dahin konventionell operierten Patienten repräsentierte zum Zeitpunkt ihrer Veröffentlichung die größte Erfahrung in einem einzelnen Zentrum [79]. Eine Untersuchung vergleichbarer Größe war eine multizentrische Studie an 28 Patienten [117]. Trotzdem erreichten die festgestellten Unterschiede zwischen den beiden Gruppen aufgrund immer noch zu kleiner Fallzahlen keine statistische Signifikanz. Unter diesem Vorbehalt zeigte sich doch ein Vorteil der endovaskulären Behandlung bezüglich der postoperativen Mortalität, insbesondere auch unter dem Aspekt, dass in der endovaskulären Gruppe ein Trend zu schwereren Verletzungen feststellbar war.

Der Kommentar des Herausgebers des European Journal of Cardiothoracic Surgery zu dieser Originalarbeit fasst den durch die endovaskuläre Behandlung erzielten Fortschritt in 4 Worten zusammen: „Endovascular is the winner“ [118]. Die endovaskuläre Therapie ist inzwischen zur allgemein akzeptierten Methode der Wahl für die akute traumatische Aortenruptur geworden [22]. Auch die im Lehrbuchbeitrag [24] diskutierte Frage hinsichtlich der Versorgung der Verletzung im Früh- oder Spätstadium des Polytraumamanagements ist mit der endovaskulären Therapie zugunsten der Frühversorgung entschieden. Im DHZB werden inzwischen die Stentprothesen in Zusammenarbeit mit den zuweisenden Traumazentren in der Operationsphase II des Polytraumamanagements [119, 120] nach Versorgung von akut lebensbedrohlichen Verletzungen wie intraabdomineller Organruptur, schwer blutenden Hüft- und Oberschenkelfrakturen und operationsbedürftigen Schädel-Hirn-Traumen implantiert und die Patienten ggf. zur Operation der Verletzungen der nächsten Priorität direkt weiter verlegt.

Das dauerhafte Verhalten der Stentprothesen, die bei meist jungen Menschen implantiert werden, ist noch unerforscht. Die Nachverfolgung gerade bei diesen Patienten, die nach überstandenem Polytrauma häufig keine Notwendigkeit für kontinuierliche Nachkontrollen sehen, ist ausgesprochen schwierig. Kapitel 2.4. liefert hier mit Nachbeobachtungen über 2 Jahre einen ersten Beitrag. Ein klinisches Forschungsprojekt in Zusammenarbeit mit der Unfallchirurgie der Charité hat eine möglichst lückenlose bildgebende Dokumentation des Langzeitverlaufes zum Ziel.

Die biomechanischen Überlegungen, für die Versorgung traumatischer Aortenrupturen Stentprothesen mit über das proximale Prothesenende herausragenden Stents („Bare-Stents“) auszuwählen, welche sich an ihrem proximalen Ende besser an die Aortenwand anlegen, waren offenkundig richtig. Wir haben keinen Fall von Kollaps des proximalen Stentgrafts im Aortenbogen beobachtet. Dieses Problem wird bereits in der ersten Arbeit [79] diskutiert. In den folgenden Jahren erschienen etliche weitere Berichte über den Kollaps von Stentprothesen anderer Typen an ihrem proximalen Ende [121, 122, 123, 124, 125, 126]. Auch in der multizentrischen Studie mit der Relay® Prothese sind solche Probleme nicht aufgetreten [78].

3.4. Stentprothesen, Paraplegie und die Bedeutung der A. subclavia sinistra

In der konventionellen Aortenchirurgie galt 1999 die Reimplantation von Interkostalarterien als Standardverfahren, um die Inzidenz der postoperativen Paraplegie zu vermindern. Bei der endovaskulären Behandlung der Aorta descendens und der thorako-abdominellen Aorta ist der Verschluss von Interkostalarterien unvermeidlich und eine Reimplantation technisch nicht durchführbar. Das Risiko für eine Ischämie des Rückenmarks müsste also größer sein als bei konventioneller Chirurgie mit Reimplantation der Interkostalarterien, und zwar umso höher, je länger die mit der Stentprothese überdeckte Strecke der Aorta descendens und damit die Zahl der verschlossenen Interkostalarterien wird.

Die Ergebnisse aus der eigenen Praxis entsprachen aber nicht diesen Befürchtungen, auch als mit Fortschreiten der Technologie die Implantation von langen Stentprothesen möglich wurde [56, 69]. In der Analyse in Kapitel 2.5 an 406 Patienten war die Inzidenz von spinalen Ischämien 2,7 %, die von permanenten Paraplegien 1,5 % [80]. Auch aus der Literatur wurden deutlich niedrigere Inzidenzen von Paraplegie nach endovaskulärer Therapie berichtet als nach konventioneller Operation (Übersicht in [127]).

So liegt der Schluss nahe, dass andere Gefäßgebiete die Durchblutung des Rückenmarks aufrechterhalten können, wenn die segmentalen Arterien unterbunden sind. Aus der Anatomie ist bekannt, dass die präformierten Längskollateralen des Rückenmarks (Aa. communicans anterior und posterior) zusätzlich proximal aus dem Versorgungsgebiet der A. subclavia und distal aus dem Versorgungsgebiet der A. iliaca interna gespeist werden [47]. Allerdings sind beide anatomisch präformierten Kollateralen im Spinalkanal sehr dünn. Dies gilt auch für die A. radicularis magna Adamkiewicz, der bei der Rückenmarksperfusion ein besonderes Gewicht beigemessen wurde [128, 129]. Es ergibt sich die Frage, ob nicht eine effektivere kollaterale Durchblutung existiert. Über den 2. Dorsalast der Interkostalarterie steht jede segmentale Arterie des Rückenmarks mit dem Netz kleiner Arterien in der dorsalen Rückenmuskulatur (M. erector spinae) in Verbindung (Fig. 4, S. 76). Dieses arterielle Netzwerk käme für eine unterstützende kollaterale Perfusion des Rückenmarkes infrage. Die Arbeitsgruppe um Randolph Griepp hat die Hypothese in einer Reihe von Tierexperimenten untersucht Der Autor hatte Gelegenheit, vor ihrer Veröffentlichung die Experimente im Labor in New York zu sehen, die die scheinbar widersprüchlich niedrige Inzidenz von spinalen Ischämien nach endovaskulärer Therapie erklären können. Am Schwein konnte mit Ausgusspräparaten der Arterien nachgewiesen werden, dass das kollaterale Netzwerk im

M. erector spinae, gemessen an den aufsummierten Gefäßquerschnitten, eine mehrfache Kapazität im Vergleich zu den bekannten kleinen Arterien längs der Vorder- und Hinterkante des Rückenmarks aufweist [130], und dass sich dieses zuvor ungerichtete arterielle Netzwerk nach experimentellem Verschluss der Interkostalarterien innerhalb von wenigen Tagen in eine longitudinale Richtung ausrichtet, offenbar in Anforderung der longitudinalen Perfusion des Rückenmarkes [131]. Aus der Summe der experimentellen Ergebnisse hat Griepp das Konzept des kollateralen Netzwerkes der Rückenmarksperfusion entwickelt [49] und in der konventionellen Aortenchirurgie danach gehandelt (S. 12f).

In einem früheren Experiment an Schweinen waren zur Induktion einer Paraplegie Ligaturen von im Mittel 12,8 segmentalen Arterien in cranio-caudaler Richtung erforderlich. Dies entspricht der Ligatur aller thorakalen interkostalen Arterien. Wenn die Arteria subclavia zusätzlich verschlossen wurde, war nur noch die Ligatur von 9 Interkostalarterienpaaren notwendig. [132]. Das Experiment ist ein Hinweis auf die Bedeutung der A. subclavia für die Kollateralperfusion des Rückenmarkes. Das Ostium der A. subclavia sin. muss häufig bei der endovaskulären Versorgung der Aorta descendens verschlossen werden, um eine suffiziente Verankerung des Stentgrafts weiter proximal im Aortenbogen zu erreichen [12, 56]. Anfangs wurde dieser iatrogene Verschluss als weitgehend gefahrlos betrachtet, da das Netz von Kollateralarterien in der Muskulatur des Schultergürtels meistens eine ausreichende Durchblutung des linken Armes in Ruhe sicherstellt. Wenn es trotzdem zu ischämischen Symptomen kommt, können diese sekundär durch eine Revaskularisation der Arteria subclavia behoben werden [84]. Das war in der eigenen Erfahrung in immerhin 25 % der Fälle erforderlich [81]. Gegen den iatrogenen Verschluss der A. subclavia sprach die Möglichkeit von zerebralen Ischämien im Versorgungsgebiet der A. vertebralis und die Beeinträchtigung der Kollaterialperfusion des Rückenmarkes, die erst später in die Überlegungen einbezogen wurde. Das Risiko cerebraler Ischämien kann man durch aufwendige bildgebende Diagnostik (CT, MRT, transcranieller Doppler) zur Kollateralperfusion über den Circulus arteriosus Willisii eingrenzen [133], aber für die Rückenmarkperfusion gibt es keinen präoperativen Test. Die extrathorakale Rekonstruktion der A. subclavia mit Carotis-subclavia-Bypass oder Subclavia-carotis-Transposition ist in der Hand des Chirurgen ein Eingriff mit geringem Risiko und geringem Zeitaufwand [57, 87]. Die durch tierexperimentelle Daten gestützten Überlegungen zur Bedeutung der A. subclavia für die kollaterale Rückenmarksperfusion mündeten in dem Konzept, bei geplanten Stentprothesenimplantationen über 20 cm Länge eine Subclavia-Rekonstruktion vorweg durchzuführen. Die Originalarbeit im Kapitel 2.6 [81] untersuchte

zwei Gruppen von Stentprothesenimplantationen mit Verschluss der A. subclavia sin. mit und ohne vorherige chirurgische Revaskularisation. Hinsichtlich der spinalen Ischämie war wegen der geringen Inzidenz kein statistisch signifikanter Nachweis eines Vorteils für die prophylaktische Rekonstruktion zu führen, jedoch waren in der Gruppe mit vorheriger Revaskularisation die Strecken der mit Stentprothesen abgedeckten Aorta signifikant länger als bei der anderen Gruppe. So blieb die Schlussfolgerung spekulativ, ob durch vorherige protektive Rekonstruktion der A. subclavia sin. die Paraplegie bei langen Stentgraftimplantationen vermieden wurde. Daten aus dem Eurostar-Register an 606 Patienten stützten unsere Schlussfolgerung: der Verschluss der A. subclavia sin. ohne protektive Maßnahmen wurde als ein unabhängiger Risikofaktor für eine Paraplegie gefunden [134]. Nach diesen Ergebnissen wurde das Konzept der prophylaktischen Rekonstruktion der A. subclavia sin. beibehalten. Im begründeten Vertrauen auf diese absichernde Maßnahme wird die Indikation zum Verschluss der A. subclavia sin. im Sinne einer sicheren Verankerung der Stentprothese großzügig gestellt. Im Laufe der Zeit hat diese Meinung immer mehr Anhänger gefunden [135, 136, 137]. In den kürzlich veröffentlichten Richtlinien der Society for Vascular Surgery [138] wird eine prophylaktische Rekonstruktion der A. subclavia sin. grundsätzlich für alle elektiven Stentgraftimplantationen empfohlen, bei denen die Arteria subclavia verschlossen werden soll. Das Evidenzniveau für diese Empfehlungen wird als niedrig eingestuft. Das entspricht den letzlich spekulativen Schlussfolgerungen unserer Untersuchungen. Kontrollierte Studien zu diesem Thema sind aus praktischen Schwierigkeiten nirgendwo durchgeführt worden.

Die aktuell praktizierte Strategie zur Vermeidung der Paraplegie ist am Schluss des Kapitels 2.5. zusammengefasst: (1) großzügige prophylaktische Rekonstruktion der A. subclavia sinistra, (2) Ausgleich postoperativer Anämie, (3) Anheben oder Halten des arteriellen Mitteldrucks bei 80 – 100 mm Hg in der vulnerable Phase der ersten 48 Stunden und (4) prophylaktische spinale Flüssigkeitsdrainage nur bei Patienten, bei denen ein besonders hohes Risiko einer Paraplegie angenommen wird [129].

4. Zusammenfassung

Im Laufe von 12 Jahren wurde die endovaskuläre Therapie von Erkrankungen der thorakalen Aorta durch kontinuierliche Verbesserung im Detail und begleitende klinische Forschung zu einem Standardverfahren in der Herz-, Thorax und Gefäßchirurgie entwickelt. Die Mitarbeit an der Neuentwicklung einer Stentprothese hat zum Fortschritt der Technologie beigetragen. Es wurde eine chirurgische Strategie entwickelt zur Erweiterung der Landezone im Aortenbogen durch Umsetzen der A. subclavia sin. und weiter proximal liegender Aortenbogengefäße. Mit Hilfe dieser Zusatzmaßnahme erwies sich das Risiko einer Paraplegie als gering, auch bei langstreckigen Stentprothesen und ohne Spinalkanaldrainage. Für die Aortendissektion wurde die Erkenntnis gewonnen, dass die endovaskuläre Therapie gegenüber der konventionellen Operation nicht nur eine minimal-invasive Alternative, sondern eine qualitativ neue Behandlung bedeutet. Durch die wissenschaftliche Beschäftigung mit der innovativen Operationsmethode wurden neue pathophysiologische Einsichten zu dieser komplexen Erkrankung gewonnen. Für die Behandlung von akuten Komplikationen der Dissektion wie Malperfusion und drohender Ruptur wurde die endovaskuläre Implantation von Stentprothesen zur Therapieoption der 1. Wahl. Die Forschungsergebnisse werden dazu beitragen, dass die Stentprothese auch für unkomplizierte Typ-B-Dissektionen zu einer wissenschaftlich fundierten Therapieoption wird. Für die akute traumatische Aortenruptur wurde nicht zuletzt durch die zitierten Arbeiten die Stentprothese zum Standard der Behandlung. Für degenerative Aortenaneurysmen und chronische Dissektionen sind die frühen Ergebnisse erfolgversprechend. Die Ermittlung von Langzeitergebnissen wird die Aufgabe der nächsten Jahre sein.

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Erklärung

§ 4 Abs. 3 (k) der HabOMed der Charité

Hiermit erkläre ich, daß

weder früher noch gleichzeitig ein Habilitationsverfahren durchgeführt oder angemeldet wird bzw. wurde,

die vorgelegte Habilitationsschrift ohne fremde Hilfe verfaßt, die beschriebenen Ergebnisse selbst gewonnen sowie die verwendeten Hilfsmittel, die Zusammenarbeit mit anderen Wissenschaftlern/Wissenschaftlerinnen und mit technischen Hilfskräften sowie die verwendete Literatur vollständig in der Habilitationsschrift angegeben wurden,

mir die geltende Habilitationsordnung bekannt ist.

Berlin, den 2. Oktober 2013 Dr. med. Burkhart Zipfel